ORGANIZING RESPONSIBILITIES FOR NOVELTIES IN MEDICAL GENETICS

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ORGANIZING RESPONSIBILITIES FOR NOVELTIES IN MEDICAL GENETICS

DYNAMICS AND PRODUCTIVITY OF MUTUAL POSITIONING IN HYBRID FORUMS

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en de assistent-promotor
Dr. B.J.R. van der Meulen

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1.1 Introduction

"New knowledge brings along new possibilities and new responsibilities" reads the opening sentence from an article on the use of genetic information within the life insurance business (Soeteman, 1988, p.193, translated from Dutch).

While this quote is from one specific case that I have studied in this thesis, it neatly introduces the overall theme as well: the changes and shifts in responsibilities which occur when new knowledge or new technologies get introduced into society. The nature of such changes in responsibilities is diverse. Entirely new types of responsibilities can emerge. For example, knowledge about the long-term negative effects of introducing certain man-made substances in the environment evokes a responsibility of present generations towards future generations. In other cases new knowledge shifts responsibilities from one actor to another. For example, if obesity is thought to be caused by personal diet choices, it is the individual's responsibility to prevent or fight it. If obesity is found to have genetic causes, then individual responsibility diminishes and clinical geneticists take over responsibility to prevent or fight what is now seen as a disease. From the point of view of shifts in bearing responsibility, it is clear that responsibility can also be delegated to material artefacts. A door groom takes over the responsibility to close the door from people who pass through. Speed ramps take over the responsibility to keep traffic speed in check from policemen.[1] When considering changes in responsibilities we need to consider both human and non-human actors.[2]

Shifts and changes in responsibilities occur generally, for all sorts of new knowledge and technology. It is clear that we can consider these shifting and emerging responsibilities and sometimes new responsibilities are explicitly discussed and form part of the introduction trajectory of a novelty. This is what happened in the case of genetics and insurance in the Netherlands. I will briefly present the genetics and insurance case as an example, which I will further elaborate on when developing my theme and articulating the goals of my research.

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[1] The examples are taken from (Latour, 1997).

[2] To take a symmetric approach on the role of humans and non-humans in the constitution of the social – or indeed – the sociomaterial or sociotechnical is central to many of the approaches in Science and Technology Studies (STS), and in particular in Actor-Network Theory (ANT).

In the late nineteen eighties the development of predictive DNA diagnostic testing opened up a debate on the potential effects of the availability of genetic knowledge regarding the life insurance business.[3] There was some anecdotal evidence that insurers would use genetic knowledge in the selection of insurance candidates, and amongst genetic researchers and patient groups there was a concern that a genetic underclass might emerge for whom it would be difficult or impossible to obtain insurance products. It was feared that these negative social consequences would overshadow the potential benefits, notably preventive medical options. In an early stage of the development, patients, genetic researchers, medical professionals and their representative organizations called upon the insurance industry to change their underwriting practice so as to prevent genetic selection and to enable the establishment of preventive medical options. Insurance companies were not readily inclined to take up this newly attributed social responsibility. A debate arose on the issue of genetics & insurance which, in various modalities, continues today.

Already in 1990, the Association of Insurance Companies established a moratorium on genetic testing. Insurance industry agreed not to require insurance candidates to undergo a genetic test before accepting them for insurance. And when insurance candidates had already been tested elsewhere, they were not obliged to mention the test results, provided that the insured sum did not exceed 150,000 Euro. With this moratorium on genetic testing, insurance industry accepted a new social responsibility. In their own account, they took up responsibility not to hinder further development of medical technology: *"The assumption that the negative impact of genetic testing on access to insurance could result in an important hindrance to participate in such tests forms the background of the moratorium. Thus the advance of medical technology could be threatened"* (Welwezen, 1997, p.34-36, translated from Dutch). The moratorium did not settle the debate. There was widespread mistrust of the good intentions of insurance industry and legal regulation was called for. Members of Dutch Parliament used their legislative responsibility and formulated a Private Members' Bill. In 1998 the moratorium on genetic testing was supplemented by the Medical Examinations Act.

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[3] In the Netherlands much of the debate on genetics & insurance concerns in particular the impact of genetic knowledge on the private life insurance business. The impact on health insurance is thought to be less of a problem, since there is a collective health insurance system.

The case of genetics and insurance shows that the introduction and development of predictive genetic testing and predictive genetic information involves changes in the responsibilities of a number of social actors. A genetic test that predicts future health problems can be used as an indication for preventive medical treatment so as to prevent disease. But the test does not stand by itself. It is accompanied by a number of new responsibilities, both within and outside the medical context. If we focus – as above – on the context of life insurance, we see how insurance companies are held responsible to keep genetic selection to a minimum so as to allow the development and application of genetic testing. Parliamentarians take up responsibility to develop the legislative terms for the use of genetic information by insurance companies. In those cases where legislation does not protect people against genetic selection by insurance companies, responsibility to cover against certain risks shifts to the individual.

The aim of this thesis is twofold. First, I aim to contribute to a better understanding of the process by which responsibilities change when novelties are introduced into society. More in particular I will analyze organizing responsibilities as a governance process. Second I aim to explore means by which it is possible to improve the process of organizing responsibilities, focusing specifically on the role of so-called hybrid forums, deliberative settings in which a heterogeneous set of actors and heterogeneous type of arguments co-exist and co-evolve.

1.2 Why focus on organizing responsibilities?

A number of authors have addressed the overall theme of novelty and responsibility. Ulrich Beck is probably the best-known author on this theme. In 1986 he introduced the term World Risk Society, claiming that many of the technologies that are introduced in modern technological society bear risks, which are characteristically different from the dangers of the past (Beck, 1986, p.503). [4] Parallel to his diagnosis of the World Risk Society, Beck diagnosed contemporary society as showing 'organized irresponsibility': modern technological society

[4] These new risks are risks that bear the following characteristics. They can no longer be perceived by human senses and for their determination, society depends on scientists and their scientific methods. Potential damage is irreversible, and transgresses over longer time periods and distance. Finally, because of the large scale of damage, traditional answers such as insurance and liability fall short.

allows scientists, engineers and industry to develop and introduce all sorts of new technologies – nuclear energy, genetically modified organisms, new chemical substances, etc. – while it simultaneously lacks the means to hold anyone accountable and liable for the side effects and potential harm that accompany these novelties (Beck, 1988, 1995).

Beck has been criticized for taking a realist approach to risk and for neglecting the social construction of what in our society is deemed risky (Adam et al., 2000; Healy, 2001).[5] Regardless of that critique, Beck's Risk Society thesis was widely followed. Not for its apocalyptic message though, but for characterizing contemporary society as a society preoccupied with risk and with the distribution of risk. From that point of view, it is possible to turn around Beck's diagnosis and ask the question whether the increased risk awareness is changing the way modern technological societies deal with the introduction of new technologies. That is the way in which this study relates to the Risk Society thesis. Instead of regarding Risk Society as a reflection of organized irresponsibility, as Beck does, I consider the increased risk awareness to be a development that changes the way in which novelties are introduced in society and which might contribute positively to the organization of responsibilities.

Others likewise addressed the positive challenge of organizing responsibilities. De Vroom et al. (1998) for example reflected on the challenge to organize responsibilities, so as to change a situation of organized irresponsibility into one of organized responsibility. Whereas for the early Beck 'organization of responsibilities' amounts to a strict application of the precautionary principle, stringently restricting the introduction of novelties with unknown risks in our society, De Vroom et al. on the other hand, take seriously the institutional dimension of organized irresponsibility. The main problem of risk society, they argue, is not as such an increase of risk, but rather the shifts in, or disappearance of, responsibilities. In this thesis, I similarly address the challenge to organize responsibilities.

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[5] In his later work, Beck acknowledges that a change in risk perception is one of the elements that make contemporary technological society a Risk Society. But he does not give up on realism: "I am both a realist and a constructivist, using realism and constructivism as far as those meta-narratives are useful for the purpose of understanding the complex and ambivalent 'nature' of risk in the world risk society we live in" (Beck, 2000, p.212).

As is the case in the work of Beck and De Vroom, the challenge of organizing responsibilities is often linked to the specific context of Risk Society. The starting point of this study however, is that the process of organizing responsibilities can and should be studied as such, independent of the Risk Society diagnosis and its related question of technological risk and the specific responsibility to prevent physical harm or the responsibility to compensate for that harm. In other words, whether or not novelties are perceived as risky or harmful, it is important anyhow to understand the processes by which responsibilities change as novelties are introduced in society.

There are two main arguments why this is important. The first argument is that the success of the introduction of a novelty depends on the appropriate changes in the related responsibilities. In the case of genetics & insurance for example, the role that insurers had to play in order for genetic testing to become a success was recognized at an early stage of the development and a moratorium on genetic testing was declared. If insurers' responsibility had not been recognized at this early stage, the introduction of genetic testing in medical practice might have failed, as genetic selection by insurers would have led to negative reactions.

Of course one might question the assumption here, of the necessity and desirability of introducing a novelty. My second argument for focusing analysis on the process of organizing responsibilities relates to this question and the associated normative discussion. Over the past few years, a number of authors within Science & Technology Studies (STS) and pragmatic ethics have advocated the analysis and assessment of shifting responsibilities as a way to assess the introduction of new technologies. Rappert (2001) for example, advocates an analytical focus on the distribution of responsibilities as a remedy against the limited practical value of radically constructivist and post-essentialist approaches in STS.[6] In a paper that discusses the controversy between proponents and opponents of the use of non-lethal weapons, Rappert shows that any attempt to assess the risks and benefits of a certain technology bears with it an inherent tension between generalization and

[6] For an example of a radically constructivist and post-essentialist approach see Grint & Woolgar (1992, 1997). There is a longstanding debate in STS, expressing uneasiness with the constructivist approach for its failure to develop narratives on technology to engage in and contribute to the social debate on the pros and cons of new technologies. See for example Kling (1992a, 1992b), Winner (1993) and Hutchby (2001) who advocate a middle ground between realism and relativism.

contextualization. It is from this tension that ambiguities in the assessment of technologies arise.[7] 'One way of usefully working with [FM: these] ambiguities without trying to settle them is to consider their distribution, and where responsibility for their resolution is located', so argues Rappert (2001, p.572).

De Vries et al. (2002; 2004) argue that normative debates on technologies should be evaluated in terms of the new roles, competencies, responsibilities and power relations which the newly articulated norms perform. And pragmatic ethicists, observing the limitations of traditional ethics for judging the introduction of new technologies in society, have also proposed an analytical focus on shifting responsibilities. Keulartz et al. (2004, p.10) for example criticize traditional ethics because "the idea of change plays no significant role in ethical theory building". That leaves only two options open for the outcome of traditional ethical debate: admission or prohibition of developments. In other words, traditional ethics has no repertoire or conceptual tools to contribute to the development of normatively better innovations. As an alternative, Keulartz et al. developed four tasks for a pragmatist ethics in a technological culture. One of these tasks, 'dramatic rehearsal', explicitly takes into account the shifts in moral responsibilities and social roles: 'A pragmatic ethics would emphasize the emergence of a new practice and explore possible arrangements for the new rules, relations and responsibilities to go with that new practice.' (Keulartz et al., 2004, p.21)

The authors discussed above have convincingly argued that in order to assess the introduction of novelties we need to assess the changes in the related sociotechnical configurations of responsibilities. I argue that we need to go one step further and address the question of whether we can do something to actually achieve a preferred configuration of responsibilities. So, besides the normative question about the desirability of one configuration of responsibilities over the other, there is a more general question of whether it is possible to make change in the configuration of responsibilities the outcome of a process of deliberate organization. For it is one

[7] 'At the heart of the problem in any sort of evaluation is that actors are trying to find an appropriate meeting point between making generalizable claims that give some policy, or other practical, guidance, and wanting to be responsive to the context-specific justifications for particular deployments. Any attempt to establish a definitive assessment of non-lethals is thus open to alternative criticisms that crucial but contingent variables have been suppressed (as in the case of general claims), or that nothing of much applicability or generalizability is being offered (as in the case of specific claims).' (Rappert, 2001, p.570).

thing ‘to explore possible arrangements’ for new responsibilities, as Keulartz et al. advocate, but it is something else to *influence* the actual outcome of the process in which configurations of responsibilities change.[8]

Before we can address this question of how we can make change in configurations of responsibilities the outcome of a deliberate process of organizing, we first need a better understanding of the de facto processes by which configurations of responsibilities change. Changes in responsibilities are often not primarily, and certainly not exclusively the result of deliberate attempts to organize responsibilities. Changes in responsibilities can emerge behind the back of the actors that are consciously trying to improve the configurations of responsibilities. Deliberate attempts to organize responsibilities have to take these emergent patterns into account. If one wants the changes in responsibilities to be the outcome of more conscious and deliberate attempts to organize responsibilities, so as to be able to discuss and achieve social desirability, the dual dynamics of emergent and deliberate organization have to be understood. Thus the aim of this thesis is to better understand the process of organizing responsibilities.

1.3 Sociotechnical configurations of responsibilities

Thus far I have talked about responsibility as if it is clear what responsibility means. But the meaning of responsibility is far from clear-cut. The notion of responsibility generally refers to a variety of meanings and connotations. Based on an extensive analysis of responsibility discourse, Harmon (1995) makes a distinction between three related meanings of responsibility: agency, accountability and obligation:

> *“Agency. To qualify for status as an agent, one is first assumed to possess the power to cause events to happen through the voluntary exercise of one’s will. (…) The second aspect of agency, symbolized by what Niebuhr calls the image of “man the answerer”(p.56), holds that agents are accountable for their actions to other members of their communities (…) It is this second aspect that transforms agency from a merely descriptive concept into an explicitly moral one.”(…)*

[8] The shift in objective and analysis that is advocated here is similar to the shift that is implicated when moving from Technology Assessment (TA) to Constructive Technology Assessment (CTA) (Rip et al., 1995).

> *"Accountability. In its simplest form, accountability refers to an authoritative relationship in which one person is formally entitled to demand that another answer for – that is, provide an account of – his or her actions; rewards or punishments may be meted out to the latter depending on whether those actions conform to the former's wishes. To say that someone is accountable, in other words, is to say that he or she is liable for sanctions according to an authoritative rule, decision, or criterion enforceable by someone else (Kelman & Hamilton, 1989, p.195)."*
>
> *"Obligation introduces an explicitly moral meaning of responsibility by suggesting that one should, or should not, perform a particular action. (...) Obligation has what Baier (1986), in discussing the idea of agent-responsibility, terms a forward-looking dimension, in addition to the backward-looking dimension implied by ascriptions of responsibility to an agent for having already caused an event to happen. It is this forward-looking sense of responsibility that enables us to speak of a duty or obligation to bring about a desired future state of affairs."* (Harmon, 1995, p.25,26)

Agency, accountability and obligation, the three modes of meaning of responsibility are quite strongly related within the overall responsibility discourse. One mode of meaning invokes the other modes of meaning, and from the negation of one mode easily follows the negation of the other modes. Responsibility as (moral) obligation for example is usually not attributed to those that are thought to lack the agency to deal with the matter under consideration. Van Gunsteren (1989) draws attention to the way in which accountability, the retrospective mode of responsibility is related to the prospective mode of responsibility-as-obligation. From decisions on accountability we derive future obligations and role responsibilities. The three modes of meanings, though related, are certainly not interchangeable. People are sometimes held retrospectively accountable for failing to fulfill their obligations, even in circumstances in which it is hard to sustain that they had agency to prevent failure. Ministerial responsibility is a case in point. The other way around, parents are attributed with the moral obligation to bring up their children, but that is not to say that they are necessarily held accountable for their children's misbehavior.

The analytical distinction between the three modes of meaning of responsibility makes clear how my approach to organization of responsibilities is different from

some of the other authors that I discussed here. When Beck characterizes modern technological society as expressing organized irresponsibility, he uses the term responsibility predominantly in its retrospective meaning, referring to the question who is accountable or liable when things go wrong. The same holds for De Vroom and Rappert. In this study, on the other hand, I use the term responsibility in its prospective meaning, referring to the duty to 'take responsibility', in which case responsibility is forward-looking and refers to an obligation to do something.

In a stable situation, the term responsibility in this prospective meaning refers to what Hart termed "role-responsibility":

> '*Whenever a person occupies a distinctive place or office in a social organization, to which specific duties are attached to provide for the welfare of others or to advance in some specific way the aims or purposes of the organization, he is properly said to be responsible for the performance of these duties, or for doing what is necessary to fulfill them. Such duties are a person's responsibilities.*' (Hart, 1968, p. 212)

Now that I have introduced an analytical distinction between the three modes of meaning of responsibility, I can be more specific regarding my claim that non-human actors need to be taken into account when considering shifting responsibilities. It is clear that non-human actors cannot be held accountable in the literal sense of the word and it is clear that we do not impose on non-human actors the moral obligation to take responsibility. But, we can easily think of non-human actors as bearers of agency[9] in the sense that non-human actors enable and constrain the sort of agency that human actors have. In fact we should not consider agency as an attribute of a single actor alone – whether that actor is human or non-human. Rather, agency is an attribute of a heterogeneous network of human and non-human actors.[10] Or following Callon and Law (1995) agency is an emergent property of a 'hybrid collectif'.

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[9] Here I use agency in its descriptive non-moral meaning.

[10] Triggered by Latour's symmetrical approach to humans and non-humans (1988, 1992) a philosophical debate arose which addressed the question if and how humans are morally different from non-humans and the implications for human moral responsibility in taking a symmetrical approach to humans and non-humans (Verbeek, 2000) (Swierstra, 1999) (De Vries, 2001) (Akkerman, 2001). The debate is rooted in the paradoxes within responsibility discourse that arise from the two connotations of the term agency, the one descriptive, the other moral (ref. Harmon).

In other words, with the introduction of novelties new affordances are introduced, new "functional and relational aspects which frame, while not determining, the possibilities for agentic action in relation to an object" (Hutchby, 2001, p.444) [11] and which open up existing configurations of responsibilities. The example of the door groom and the speed ramp were mentioned before to illustrate how responsibility can become delegated to artefacts. The door groom takes over from humans the obligation to close the door, even making it difficult to keep the door open if so desired. In the words of Vos:'(T)here is a continuous spectrum between rules of conduct and material objects through which the 'be obliged' is transformed into the 'be able to' (Vos, 2003, p.94). [12]

The example of the door groom and the speed ramp concern rather simple cases in which there is an almost one to one transfer of responsibility from humans to non-humans. The transfer is however never perfect. Take the example of a speed ramp. The French jokingly call it a 'gendarme couché', which translates into English as 'sleeping policeman'. The term concisely denotes how responsibilities can shift from human to non-human actors. But it is not a perfect transfer. Instead the situation is transformed, or, in Latour's terms, the situation is 'translated'. In certain circumstances the differences become apparent, for example when an ambulance passes the street in which human policemen have been replaced by sleeping policemen. Whereas human policemen can make way for an ambulance, sleeping policemen won't wake up, confronting the ambulance personnel with the responsibility to know where the speed bumps are and to avoid them as best as they can when choosing directions. Thus, "there is not a simple transfer of morality to things, morality is transformed, it is translated, whence a new spectrum of responsibilities, tasks and duties emerges" (Vos, 2003, p.94).

When taking into account the role of non-humans, the notion of individual human agency becomes problematic. Agency in its descriptive meaning is not a property of individual human beings, but agency is distributed over a heterogeneous network, which consists of both humans and non-humans. Paradoxes arise as agency in its descriptive meaning is distributed over a network, whereas agency in its moral meaning is a property of human actors alone. Human actors can be held accountable, but it is difficult to hold accountable a heterogeneous network. In this thesis I do not consider responsibility from a moral perspective.

[11] I here refer to Hutchby to define the notion of a novelty's affordances. In an earlier publication, Norman (1990) used the concept of affordances in the context of design, arguing that in 'good' design the affordances of an artefact are readily perceivable by the intended users.

[12] Following Latour, Achterhuis (1995), Verbeek (2000) and Jelsma (2003) have pleaded for moralizing artefacts for the better. For example to mediate desirable consumer behaviour in such a way as to improve sustainability.

I will use the term configuration of responsibilities to refer to the network of interrelated human role responsibilities and technological affordances. As an example figure 1.1 depicts the network that is involved in the configuration of responsibilities for car safety. Car safety is realized in a network that contains seatbelts, air bags, road infrastructures and road users as well as a number of actors – government, police, schools, parents, automobile industry – that take responsibility for safe cars, safe infrastructures and the safe behavior of road users.

After such a configuration of responsibilities has stabilized, we tend to take it for granted, but Wetmore (2004) has shown how car safety once was the subject of intensive and sometimes fierce debate, in which mutual responsibilities were contested. In the 1960s, proponents of the so-called "crash avoidance" approach argued that car injuries could best be prevented by preventing collisions; they emphasized the car drivers' responsibility to drive safely. Proponents of the "crash worthiness" approach on the other hand argued that cars should be designed in such a way as to minimize injury in case of collision. These "auto safety advocates promoted the development of technologies designed to circumvent, replace, or compensate for "irresponsible" human actions because they believed that devices and techniques would be considerably more obedient and reliable than the American public. Other organizations, however, contested such reallocations because they also involved a shift in responsibilities throughout the rest of the sociotechnical network of auto safety." (Wetmore, 2004, p.377) The "crash worthiness" approach was initially resisted by automobile industry, as they feared to be held accountable and liable for those situations in which the delegation to prevent injury to the car would fail. The intervention of government was needed to stimulate and support the new approach and to urge automobile industry to take up responsibility to build safer cars. Legislation was developed and a new federal agency was set up as a new layer of responsibility. This case in which a novelty (a seatbelt) is introduced to take over from human car drivers some responsibility for safety illustrates how such an apparently simple transfer involved changes in a much wider configuration of responsibilities.

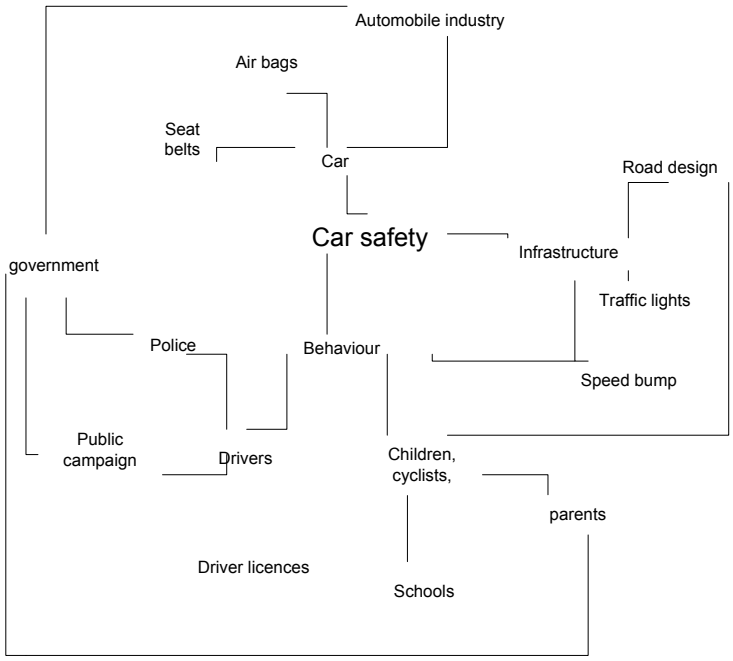

Fig. 1.1: The network of human and non-human actors that is involved in car safety.

In a second episode in the history of automobile safety, which was analyzed by Wetmore ‘‘manufacturers’ fears about the burden of responsibility for such an artefact became a reality, when air bags were blamed for a handful of catastrophic failures.’ (Wetmore, 2004, p.399) Again mutual responsibilities became contested, as now car drivers were claiming their right to de-install the air bags in their own cars, thus claiming back their personal responsibility for car safety. This second episode illustrates that stability in a configuration of responsibilities is only temporary and that organizing responsibilities is an ongoing process of finding mutual alignment in a configuration of responsibilities.

1.4 Organizing responsibilities and hybrid forums

Configurations of responsibilities are sociotechnical configurations, configurations which include human as well as non-human actors. By implication, when novelties induce change in existing configurations of responsibilities, the role and position of a number of actors, human as well as non-human, is at stake. In conscious and deliberate attempts to (re)organize responsibilities the role of all human and non-

human actors needs to be taken into account. Conscious deliberation on shifting configurations of responsibilities involves the definition of scientific facts and technological properties besides a discussion on what responsibilities different human actors are able to bear, and besides a discussion on the balancing of different interests. It involves different types of assessment that are typically organized within domains of society that normally stand apart (science vs. politics for example). Because of the broad range of actors, potentially involved in and affected by changing configurations of responsibilities, and because of the relevance of knowledge and expertise on the properties of the novelties that are part of the sociotechnical configurations of responsibilities, the quality[13] of deliberation will improve through the involvement of a wide range of different actors, who bring in a wide range of different expertises and a wide range of different considerations. Hence, I focus in this thesis on hybrid forums as arrangements that may contribute productively to the process of organizing responsibilities for novelties.[14] I use the term hybrid forum as it was introduced by Callon and Rip (1992) for deliberative settings in which a heterogeneous set of actors is simultaneously involved and in which a heterogeneous set of questions, problems and arguments co-exist and co-evolve:

> *"It is a forum because we find actors debating and, in principle at every moment, new actors can enter the debate. It is hybrid, because the actors, the problems that they define and the resources that they mobilize are heterogeneous. In these hybrid forums the three poles, distinguished earlier: the pole of techno-science, that of law and regulation and, that of the sociopolitical and economic world are present. But, they are not (relatively) distinct spaces/universes between which the (several independent) experts are searching for adjustments. In (the hybrid forum) the poles are characterised by a strong interpretation of actors and debate"* (Callon & Rip, 1992, p.148).

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[13] 'Quality of deliberation' here refers to quality of the social learning process – the articulation of the situation - and to moral quality of the deliberation, meaning that all interests are taken into account.

[14] Rip et al. (2000) proposed interactions in hybrid forums as productive tools in situations of high uncertainty and Kirejczyk et al. (2003) proposed hybrid forums to be productive to open up room for arguments of justice. Callon, in his later work on economic framing, 'promote(s) the constitution of hybrid forums capable of holding debates on the organization of markets'. (Callon et al., 2002, p.213)

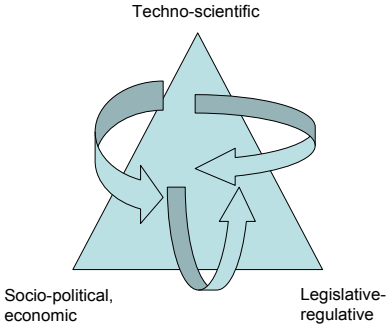

Figure 1.2 Intermingling poles in a hybrid forum

Figure 1.2 visualizes the hybrid forum concept. Whereas the domains of the sociopolitical-economic, the techno-scientific and the legislative-regulative in many cases remain fairly separated, with distinctive ways of argumentation, distinctive settings for debate and distinctive spokespersons, in hybrid forums these domains intermingle. The debate on genetics and insurance exemplifies the heterogeneity of actors and considerations that are involved in and play a role in a debate on shifting responsibilities and novelty. A wide range of different considerations and arguments intermingle in this debate: expectations on developments in human genetics, sociopolitical values such as privacy and solidarity, the interest of insurance companies on a private market, the medical promises of human genetic population research, treatment options, the interpretation of existing legislation, etc. And the actors involved in the debate also vary widely: ranging from geneticists to politicians, insurance companies, doctors, patients, STS scholars, and experts in medical law.

1.5 Proliferation of hybrid forums

The concept of the hybrid forum represents a broad category. In chapter 2 I will discuss different types of hybrid forums, which can be distinguished. Here I will list a variety of examples of hybrid forums and show that hybrid forums are not just a proposed form of interaction, which occurs occasionally, but actually proliferate in contemporary society. The proliferation of hybrid forums relates to an overall change in the interaction structures between the domains of science and technology on the one hand and the domains of politics and civil society on the other hand.

These changing interaction structures are the result of a number of related developments, which will be discussed in this section.

A first development that contributed to the proliferation of hybrid forums is the increasing social concern with the unintended consequences and risks of new technological developments, as implicated in the rise of Risk Society. Interaction structures between the domains of science and technology development and the domains of politics and civil society started to change when Western societies in the nineteen sixties and seventies were increasingly presented with the negative side effects of scientific and technological developments, notably in the form of environmental degradation and nuclear threat. In the US as well as in Europe bodies for risk assessment and technology assessment were established to assess the potential risks and side effects of new technologies prior to their wide-scale introduction. These risk assessment bodies were not necessarily hybrid in composition.[15] But over time recognition grew, that scientific judgment could not always reduce uncertainties and that scientific experts sometimes lacked the authority to resolve controversies over risks and side effects. As a result, the idea took root that in order for technology assessment and risk assessment to take normative judgment into account, there was a need for broader stakeholder involvement and wider public dialogue.[16] Technology assessment evolved from an analytical activity to inform politics and policy into a broader range of activities that included supporting public dialogue and stakeholder participation.

Nowadays, public and stakeholder participation and consultation in decision-making on scientific and technological matters have become common practice. To

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[15] In the Netherlands for example, decision making on the introduction of GMO's (Genetically Modified Organisms) was deliberately split up in two separate trajectories. One in which scientific experts were to assess the technological risks of introducing GMO's in the environment and another trajectory in which broader, ethical aspects were to be discussed by a wide range of social actors and stakeholder groups (Jelsma, 1999).

[16] Underlying the increase in participation and consultation practices there are different perspectives on what constitutes the problem. On the one hand there is a widespread concern with the decline in public trust in the institutions of science. From that perspective, public participation and transparency in scientific decision making are seen as ways to re-establish public trust and to improve the public understanding of science. Increasingly these initiatives are informed by scholars in Science and Technology Studies and Sociology of Scientific Knowledge who have criticized the deficit model (Wynne, 1991, 1996) and the public education model (Callon, 1999) that underlie the many initiatives that are meant to improve the science-public relation. As an alternative scholars in STS propagate a dialogue model: the co-production of knowledge model in which the cognitive value of non-scientific expertise is acknowledged (Callon, 1999).

mention a few examples: broad public debates on genetic modification have been organized, such as GM Nation? in the UK and the Food & Genes debate[17] in the Netherlands. In Canada, the Canadian Royal Commission on New Reproductive Technologies conducted a public inquiry, consulting the Canadian public on an unprecedented scale (Strathern, 2002). In the UK, the Human Genetics Commission – itself an example of a commission that represents heterogeneous actors and expertises – routinely consults a wide range of social and stakeholder groups to inform their advisory reports to government.

Increasingly hybrid forum types of interaction shift to earlier phases of technological development. As Rip & Kemp state: "the key problem [FM: of technology assessment] is that impacts [FM: of technology] are co-produced by the several actors involved. So, any impact assessment depends on the nature, and the trace-ability, of the co-production processes. For this reason, technology assessment, especially in Europe has evolved from a policy analysis tool into support for dialogue and interaction among actors actually and potentially involved in co-production processes." (Rip & Kemp, 1998, p.365) In France for example, the National Institute for Agricultural Research (INRA) established a hybrid forum to address the question whether or not INRA should pursue field trials with genetically modified grapevines (Marris et al., 2008). In the Netherlands the Ministry of Health established a hybrid steering committee to stimulate the development of drugs for rare genetic and other orphan diseases, composed of representatives from industry, patient groups, medical professionals, scientists and advisory bodies. With regard to their internal policy making, the Dutch Ministry of Health also adopted an anticipatory approach in which hybrid stakeholder participation was a key element. In the 'Biotechnology as Open Policy Process' project[18] hybrid consultations took place to inform the Ministry's policy agenda on medical biotechnology. Furthermore, as part of a wider anticipatory policy on the implications of genetic research for health care, the Ministry commissioned an advisory report to assess the quality of existing legislation and regulation in light of expected future developments in human genetic research and technology (Ministry of Health

[17] In Dutch: 'Eten en Genen' debat.
[18] In Dutch: 'Project Biotechnologie als Open Beleidsproces'.

Welfare and Sports, 2000; ZonMw, 2003). In the advisory trajectory that followed, a heterogeneous set of actors, experts and considerations were brought together.[19]

These are just a few examples of the recent proliferation of hybrid forums. Clearly, interaction between the domains of science and society is not only confined to the production or application stages of development. Interaction between the domains of science & society is gradually moving further upstream from the application stage, to the stage of co-production (CTA) up to the stages of early scientific development and setting of the research agenda. This upstream engagement is most apparent in science policy. Backed up by the Lisbon agenda[20], which aims to make the European Union the most competitive and knowledge-driven economy world-wide, governments throughout the European Union are trying to strengthen their grip on the science system. And increasingly the financing of public research is steered by considerations of economic as well as public value. The engagement of citizens and stakeholders with science is also gradually moving upstream (Wilsdon & Willis, 2004). It is now widely recognized that public involvement in the GMO[21] debate came too late to be of significant influence on the decision making – by governments as well as by the biotech industry – which steered the development. As a result public dialogue initiatives struggled with a lack of credibility. Critics could easily argue that the public dialogues were mere public campaigns to mitigate public concerns and mistrust. With respect to recent developments in nanotechnology and nanoscience the lessons from the GMO debate are taken to heart. In the UK the Royal Society and the Royal Academy of Engineering recommended the chief scientific adviser to 'establish a group that brings together representatives of a wide range of stakeholders to look at new and emerging technologies and identify at the earliest possible stage areas where potential health, safety, environmental, social, ethical and regulatory issues may arise and advise on how these might be addressed' (The Royal Society and Royal Academy of Engineering, 2004, p.87). In NanoNed – a Dutch research consortium within

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[19] ZonMw (the Netherlands Organization for Health Research and Development) was commissioned to write an advice on these matters. For this purpose the ZonMw Genetics Committee was established. In chapter 6 I will analyze a hybrid consultation meeting that was organized by this committee.

[20] In March 2000, the EU Heads of States and Governments agreed to make the EU "the most competitive and dynamic knowledge-based economy in the world" (Source: http://www.europarl.europa.eu/ summits/lis1_en.htm).

[21] Genetically Modified Organism.

nanotechnology – research on constructive technology assessment for nanotechnology is an integral part of the program.

To conclude, social concern with the unintended consequences and risks of new techno-scientific developments has lead to an increase in hybrid forum type interactions. Hybrid forums proliferate, because certain social actors are concerned about modernity's unintended consequences and because there are (other) social actors who are concerned about these concerned social actors. Furthermore hybrid forums proliferate as interaction is no longer confined to discussing the risks and side effects of the end products of scientific and technological research. Increasingly, such engagement also addresses the co-production processes and early stages of techno-scientific developments.[22]

1.6 Hybrid forums as forums for prospective responsibility positioning

In the preceding two sections I claimed that hybrid forums can be productive arrangements for organizing responsibilities and I argued that hybrid forums and hybrid forum types of interactions actually proliferate in contemporary technological society. Both are good reasons to focus empirical analysis on hybrid forum interactions. It should be noted however that organization of responsibilities hardly ever is a formal or informal objective of the hybrid forums that can be found in contemporary technological societies. In this section I will develop the claim that even if organization of responsibilities is not an explicit or implicit objective, hybrid forums are interesting research sites to analyze the process of organizing responsibilities. First, because the interactions of hybrid forums may be indicative

[22] According to Callon (1998) growing societal concern with the risks and side effects of new scientific and technological developments is not the only reason for hybrid forums to proliferate. Callon points out that there are also epistemological reasons for the proliferation of hybrid forums. Callon emphasizes that the specific nature of the risks and side effects that seem to proliferate in modern technological societies has implications for the process and methods of knowledge production that are necessary to contain and manage these risks. The growing influence of the techno-sciences in modern society leads to a proliferation of connections and interdependencies, resulting in an overall increase in complexity and uncertainty. According to Callon this is already leading to a change in the conditions of knowledge production, more in particular to the methods of experimentation. In complex and uncertain situations, such as exemplified by the BSE ('mad cow disease') controversy, "experts or scientists on their own, working in their usual way – i.e., shut away in their laboratories – can do nothing. In order to trace links, correlate findings, produce and test hypotheses, they will always be forced to deal with non-specialists." (Callon, 1998, p.261-262)

of the ongoing organization of responsibilities, second because hybrid forum interactions may de facto contribute to the process of organizing responsibilities.

As far as the ongoing organization of responsibilities is concerned, Van Gunsteren (1989) pointed out that public accountability forums – such as parliamentary inquiries – play an important role. In such accountability forums, after something has gone wrong 'what occurred as a blind event is related to human actions and decisions.' Agency appears, and may be debated. 'The blind event receives a human point of address.' (Van Gunsteren, 1989, p.110, translated from Dutch) Moral judgment is involved in this process and from decisions on accountability we derive future obligations and role responsibilities. Van Gunsteren's accountability forums are retrospective and come into play after something has gone wrong; after the existing configuration of role responsibilities proved inadequate and the overall situation can no longer be assessed as responsible.

With the introduction of novelties, agency structures change and so reorganization of responsibilities might be in order, even before things go wrong. In addition to the *retrospective* accountability forums discussed by Van Gunsteren, there can be *prospective* responsibility forums, which play a role in prospective organization of responsibilities. With respect to modern biotechnology and human genetics for example, there is a wide range of different forums in which the impact – both positive and negative – of these developments is discussed prospectively: public media, academic conferences, parliamentary debate, government advisory committees, public funding boards, ethical committees, court cases, stakeholder conferences, expert consultations, citizen panels etc.

How does this happen? Engaging in discussion and debate over the impact of new knowledge and new technologies, forum participants articulate and anticipate changes in the configuration of responsibilities. This is particularly clear in how people in interactions on technology, not only discursively position or assess the technology, but also position themselves and others in a specific role responsibility in relation to this technology. Harré and Van Langenhove (1999) have developed a framework – positioning theory – for analyzing this dynamic process of mutual positioning in interpersonal discursive interactions. Through discursive interaction

people negotiate and communicate their relative positions, and thus their relative responsibilities.[23]

Responsibility positioning in hybrid forums has added value compared to the responsibility positioning which occurs in local contexts. Within hybrid forums, because of the broad composition, actors are brought together that may not normally interact within the confines of the local contexts in which roles and responsibilities are embedded. Interactions in hybrid forums can thus improve social learning processes between the actors that are involved in a changing configuration of responsibilities, but who do not normally interact. Furthermore, within hybrid forums responsibility positioning is not confined to the present state of affairs, but can also take place prospectively. In that respect, hybrid forums can be regarded as a kind of playground, in which prospective configurations of responsibilities can be put to the test discursively.

My conceptualization of a hybrid forum as a playground resembles the conceptualization of Rip et al. (2000), who suggested regarding a hybrid forum "as a 'microcosm' in which the surrounding composition and structure are re-presented". Note the use of the hyphen in the word 're-presented' in the definition above. A hybrid forum as a microcosm does not merely represent the surrounding world, but it presents it anew. That raises the question how in different types of hybrid forums the wider world is re-presented and to what effect. A hybrid forum may have features of a playground, but that does not mean that mutual positioning within a hybrid forum is without consequences. How the interactions in a hybrid forum – the microcosm – relate to what is going on in the wider world and how the interactions in the hybrid forum have impact upon that wider world depends on the nature of the forum. When a hybrid forum is formally established with a specific mandate, it produces different types of interactions and different kinds of outcomes than a hybrid forum which is more of an ad hoc nature or which does not have a specific mandate. How the nature of a hybrid forum relates to its role within the process of organizing responsibilities is one of the questions to be addressed in my empirical analysis.

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[23] In chapter 2, where I develop a conceptual framework for organizing responsibilities and hybrid forum interactions, I present a more elaborate discussion of positioning theory.

In the next chapter where I develop a conceptual framework I will further elaborate on prospective responsibility positioning and the role of hybrid forums. Here, I conclude with briefly introducing the two research questions that will be addressed in this thesis. My first research question concerns the nature of the process of organizing responsibilities:

1. What does the process of organizing responsibilities – the ongoing mutual adjustment in a configuration of responsibilities – look like?

The answer to that question can form a starting point for thinking about how to improve processes of organizing responsibilities. One way of doing so is already suggested in this introduction. I expect that hybrid forums can contribute to the process of organizing responsibilities. Empirical research is needed to support that claim. Thus my second research question reads:

2. How can hybrid forums contribute to the process of organizing responsibilities?

2
Conceptual framework

2.1 Introduction

The introduction of novelties in our society, whether these novelties take the form of new artefacts, new organisms, new technologies or new knowledge, will always to some extent change pre-existing role responsibilities. Novelties can take over from humans certain responsibilities. Novelties can also confront humans with new responsibilities to take up. In many cases changes in role responsibilities take place within the local context of the introduction site of a novelty without much interference or involvement from actors outside of this local context. This applies, for example, to professionals who need to develop new skills for working with a new technology. It also applies to people who are diagnosed with Familial Hypercholesterolemia[24] and who need to comply with medical treatment schemes and dietary requirements in order to reduce the risk of a heart attack. There are also cases in which the introduction of novelty involves changes in role responsibilities of a much wider range of actors in a much larger network. In such cases, a disorganized situation can easily arise due to indistinctness and disagreement between different actors about their mutual responsibilities.

The issue of genetics and insurance is a case in point. The development of predictive genetic testing linked the sociotechnical practice of medical genetics with the sociotechnical practice of private insurance. Clinical geneticists have argued that the successful development and introduction of medical genetics depends on insurance companies taking up a social responsibility and changing their selection methods. Whether insurance companies can do so without other public goods being sacrificed is still up for discussion. The insurance sector has argued that some of the proposed changes may well undermine the entire sector. The introduction of novelty – in this case medical genetic knowledge – led to disagreement between different social actors and actor groups regarding their mutual responsibilities. Thus the introduction of novelty induced dealignment in a configuration of responsibilities.[25]

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[24] Familial Hypercholesterolemia (FH) is a hereditary condition. People with FH suffer from high blood cholesterol levels and have an increased risk of developing coronary heart disease. See further chapter 4.

[25] Following (Rip, 1995, p.424) 'alignment' is used as a "concept that indicates the mutual and well-functioning adjustment at the collective level". Novelties will never completely fit into existing alignment, so there will be some dealignment, and subsequent re-alignment.

In a technological society novelties are introduced all the time. Whether on a small or on a large scale, novelties induce changes in social role responsibilities. In some cases realignment is reached easily in other cases realignment is hard to achieve. I will use the term **organizing responsibilities** to refer to the ongoing process of finding mutual adjustment of responsibilities. A **configuration of responsibilities** is defined as a network of interrelated role responsibilities and technological affordances.

In this chapter I develop a framework that conceptualizes the process of 'organizing responsibilities' as well as the relation between 'organizing responsibilities' and 'hybrid forum interactions'. This conceptualization provides a first order answer to the research questions which I will then study empirically:

1. What does the process of organizing responsibilities – the ongoing finding of mutual adjustment in a configuration of responsibilities – look like?
2. How can hybrid forums contribute to the process of organizing responsibilities?

2.2 Responsibility positioning in local sociotechnical practices

Responsibility is a relational and dynamic concept (Rip, 1981). Actors take up responsibility in relation to other actors. Responsibility can also be attributed to actors by other actors so as to hold them accountable in a moral, political or legal sense. The process of 'organizing responsibilities' is first of all situated in the social and discursive interactions between the actors of local sociotechnical practices. I will use positioning theory, as it was developed by Harré and Van Langenhove (1999) as a first order conceptualization of 'organizing responsibilities' on the local level. In section 2.2.2 I will extend positioning theory to include non-human actors.

2.2.1 The basics of positioning theory

Positioning theory builds on the academic tradition that studies the performativity of speech (Austin, 1962; Searle, 1969). Statements that 'do' things are called performative. Congratulating and apologizing are examples of performative speech. Positioning falls within the same category. The concept of positioning is derived from the discursive study of the social-psychology of interpersonal relations. It is

best understood as the dynamic and discursive version of the social concept of role or identity.

To explain the conceptual framework of positioning theory I will introduce an example, taken from Harré and Van Langenhove (1999). If Jones says to Smith: "Please iron my shirt", then both Jones and Smith are positioned in that one sentence. Jones positions himself as someone who has the right to command Smith. Smith is being positioned as someone who can be commanded by Jones. This is what Harré and Van Langenhove call first order positioning. I note that the sentence is not a simple command; it anticipates on possible roles, which might be negated. **First order positioning** refers to how people position themselves and others in an essentially **moral space or order**.

The conversation can develop in a number of ways. Smith could reply: "Well sure, Mr. Jones, your shirt will be ready in an hour." Smith takes up the position attributed to her by Jones. Jones may be a hotel guest and Smith may be a chambermaid. Smith's reply confirms the moral order set out by Jones. It is now clear that a **storyline** was drawn upon (and is further developing) that manifests a customer-servant relation. Not least important, the ironing gets done.

Now imagine that Smith replies: "Why should I? I am not your maid, am I?" Such a reply is an example of **second order positioning**. "Second order positioning occurs when the first order positioning is not taken for granted by one of the persons involved in the discussion" (Harré & Van Langenhove, 1999, p.20). Smith may be Mr. Jones' wife, who is fed up with being treated as his housekeeper. When second order positioning occurs, positions have to be negotiated. Second order positioning is also called accountive positioning. Jones may reiterate his request, but now providing additional arguments, for example him having a very busy schedule. The conversation shifts from the ironing request to the storyline itself. In renegotiating the storyline, the moral order changes along with the conversation. The conversation may end in disagreement or a new moral order may be agreed upon. Such a new moral order may for example imply that Jones can ask Smith to iron his shirt, but only under specific circumstances.

Finally the conversation can also give rise to **third-order positioning**, accountive positioning – in which the moral order is discussed – outside the initial discussion. That occurs for example when Jones and Smith on a later occasion discuss what

happened. Or if Jones discusses with a friend what happened between him and Smith. First, second and third-order positioning can occur together. In the example of Jones discussing with a friend, there is first order positioning of the friend as someone Jones can confide in. And there is third-order accountive positioning of Jones and Smith. The basic claim of positioning theory is that discursive interaction makes people understand and negotiate their relative positions. Such positions include mutual responsibilities. I will speak of **responsibility positioning** to refer in particular to the discursive interaction from which people understand and negotiate their mutual role responsibilities.

The conceptual framework of basic positioning theory can be captured in the **position-storyline-(speech)action triad**, in which position, storyline and (speech)-action mutually shape each other (see figure 2.1). While speech acts refer to the utterances within a discursive interaction, the dynamics are not limited to explicit utterances. Thus, 'speech' is bracketed, because acts more generally can and should be taken into account when analyzing mutual positioning. Not going to a meeting to which one has been invited is an action, not a speech action, but it will equally be interpreted as a way of positioning oneself and might also influence the continuation of the ongoing storyline. Speech acts that build up a conversation unfold along storylines in which the different participants of the conversation take a specific position or temporary role. And the other way around, a storyline within a conversation opens up particular positions for the participants in the interaction to take up. "Conversations have story lines and the positions people take in a conversation will be linked to these story lines" (Harré & Van Langenhove, 1999, p.17).

Positioning theory is both a theory and a method. As a theory it describes how actors communicate their relative positions, and it also proposes a discursive mode of ordering (Law, 1994), ordering by the ongoing story line. Positioning theory assumes a disciplining force of discourse. People relate to the speech acts of a conversation as it is ordered by the relation between the position of the speaker and the ongoing storyline. And while people can reject the positions available to them within a specific storyline, they cannot avoid referring to the storyline. Even to reject the position attributed by the storyline, the storyline has to be invoked. As is depicted by the double-headed arrows in fig 2.1, storyline, speech act and position mutually shape each other. It is a dynamic order.

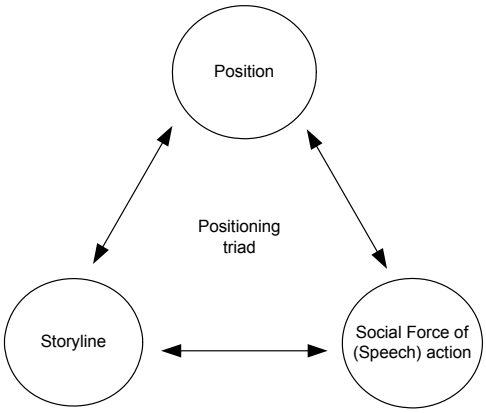

Figure 2.1: Mutually determining position/act-action/storyline triad (adapted from (Harré & Van Langenhove, 1999, p.18))

The conceptual framework of the position-action-storyline triad can be used as a method to empirically analyze the attribution and rejection of certain social positions or – in the context of this thesis – of role responsibilities. One example is the discursive interaction between a doctor and a patient in a consulting room. From the empirical analysis of the storylines that structure the interactions between doctor and patient, everyday medical practice can be evaluated, for example in terms of patient autonomy, one of the central values in medical ethics.[26] Also in empirical analyses one may find cases in which new storylines emerge along with new or shifted positions, in which certain storylines dominate or gain dominance over others or in which a clash of storylines may indicate moral disorder or just dealignment in a configuration of responsibilities.

The example of patient autonomy fits well within positioning theory as developed by Harré and Van Langenhove, because it is situated in a local practice. In the processes of organizing responsibilities that are analyzed in this thesis, a supra-local level of governance practices and hybrid forums is involved, where responsibility positioning is a third-order phenomenon. But it is different from how I introduced third-order positioning here. In the exchange between Jones and his friend that was used as an example, there was reference back to the specific conversation between Jones and Smith. In processes of organizing responsibilities, a lot of third-order positioning occurs in more general terms. People act as spokespersons for a range

[26] Schermer (2002) provides an example, even if she did not explicitly use positioning theory.

of examples, which they need not have experienced themselves. To capture the phenomena that occur, I will extend basic positioning theory in section 2.3.3.

2.2.2 Broadening positioning theory to non-humans: script theory

As novelties induce shifts or changes in configurations of responsibilities, a conceptualization of 'organizing responsibilities' needs to take the role of these novelties in responsibility positioning into account. This section introduces the notion of a technological or material **script** to understand that role. The role of artefacts and materiality in configurations of responsibilities was considered by Latour (1992) and Akrich (1992b). Akrich introduced the notion of script to refer to the specific sociotechnical configuration presupposed in and prescribed by technological artefacts and design. "Like a film script, technical objects define a framework of action together with the actors and the space in which they are supposed to act" (Akrich, 1992b, p.208).

Take electronic consumer products. Nowadays, many companies selling these products do not want consumers to tinker with them. Neither in order to change the technological configuration and characteristics of the device, nor in order to fix it when it is broken. The warranty often states that guarantee will be voided if the device has been tinkered with. Often the force of such prescriptions is further strengthened by the material design, which makes it impossible to reach the functional components of a device without breaking a seal, or by making it impossible to open a device without damaging it. Thus, the script of the artefact prohibits a role for the consumers in changing the functionality of a device, or in repairing it when it is broken. Either consumers are expected to have a professional technician do the repairing, or they are encouraged to throw away a broken product and replace it with a new one. In the latter scenario, the script of the artefact now also restricts the user in taking up the role of environmentally conscious consumer who tries to diminish the production of waste.

The semiotic concept of a material script can easily be integrated in positioning theory, so as to broaden the theory and to include both human and non-human actors as engaging in mutual positioning. An artefact enters the conversation by its material script. Just like Jones says: "Iron my shirt" the script of an artefact can be

read as “push this button” or in case of a speed ramp “slow your speed”. [27] Thus the script of a novelty positions human actors in new role responsibilities. Whether these responsibilities will be taken up, or whether the script of a novelty will be neglected or transformed depends on the situation (Akrich, 1992a). In any case interaction starts and accountive or second order positioning may follow. And while in the course of an ongoing interaction, a novelty may not literally talk back, it certainly acts. In that respect some material scripts are more difficult to neglect than others. It is possible to neglect the script of a speed bump, but only at the cost of damaging your car.

Like a speech act of a human actor, the script of a non-human actor can challenge existing moral orders. That is most apparent when a material script positions people in new role responsibilities which conflict with older, pre-existing responsibilities. In such cases there can be a need for developing a new moral order in which new responsibilities can be weighed against old responsibilities. For example, the ongoing development of new medical technologies has called into question doctors’ responsibility to extend life. A new moral order developed in which responsibility to extend life is weighed against the expected quality of the extended life. Thus new artefacts – or more broadly novelties – can call existing moral orders into question and may induce a change of moral order.

2.3 Organizing responsibilities as a governance process

In section 2.2 I introduced positioning theory to conceptualize the process of organizing responsibilities at the level of local sociotechnical practice. In this section I will further broaden the conceptualization of organizing responsibilities and include a supra-local level of formal and informal governance arrangements and practices. As is the case for the local level, responsibility positioning takes place at the supra-local level, but in addition configurations of responsibilities become visible and can be discussed. Furthermore responsibility positioning at the supra-local level will include a prospective element: what could be a good (useful, productive) configuration of responsibilities? I will extend basic positioning theory to cover the more complex situation of organizing responsibilities as a multi-level

[27] Van Lente (1993, p.193) proposed a similar extension of positioning theory.

process. Before developing these points, I will briefly discuss the notion of 'governance', following Van Kersbergen and Van Waarden (2001) for the basics.

Over the last decades, 'governance' has become a popular research topic in a number of disciplines, such as sociology, political science, public administration, law and economics. Many different forms of governance are distinguished in the literature. In the broad definition that is used in the NWO Shifts in Governance research program: *"Governance* refers to the phenomenon that many public functions increasingly seem to be assumed and carried out by actors other than the classical government institutions of the nation-state (and its subdivisions). Public administration is thus increasingly becoming 'unbounded', involving various public, non-governmental and private actors in various ways in the process of decision making over public goods" (NWO, 2004, p.4). The widespread interest for the topic can be attributed to the perceived shifts in structures and arrangements that provide for the capability to govern. Research in governance studies deals with the nature, the causes and consequences of these changes.[28]

According to Van Kersbergen and Van Waarden governance studies from various disciplinary backgrounds share as basic issue that societal policy making and decision making require some minimal degree of centralization and concentration on the one hand and that on the other hand centralization and concentration of power require checks and balances (Van Kersbergen & Van Waarden, 2001, p.7). This then leads to further questions discussed in the literature, for example whether traditional arrangements and de facto mechanisms for control of power (voice, exit, accountability)[29] are still effective and whether governance arrangements and

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[28] Van Kersbergen en Van Waarden (2001) mention four general trends affecting the level and location of governance: the increased importance of knowledge in our technological society; internationalization; economization and individualization. The corresponding changes in governance are numerous. The governing capacities of national governments give way to governance arrangements on a European or international level; the role of experts and technocracy increases as "more knowledge goes into decision making processes, as policy makers try to increase the 'rationality' of their decisions"; privatization of public services strengthens the importance of the market as a mode of governance over hierarchical forms of governance by state institutions, etc., etc.

[29] The concepts of voice and exit were first introduced by (Hirschman, 1970) in his classic study of organizational decline and recovery. The exit option is essential in economic competition: it refers to customers' option to switch from one organization to another and provides an incentive for those in charge to keep their members or clients satisfied. The option of voice then is the logical and complementary counterpart of the exit option. It is an essential element of political systems and refers to "any attempt at all to change, rather than escape [exit] from an objectionable

practices 'produce' legitimate outcomes. Different types of governance studies focus on different aspects of these broad questions. Some focus on legitimacy in terms of output (good policy), others link effectiveness more explicitly to democratic legitimacy (deliberative governance) and there are governance studies that are concerned with creating framework conditions, such as optimizing market mechanisms (economic governance) or improving transparency and accountability in the private sector (corporate governance) (Hajer et al., 2004). My research does not belong to any of these specific strands within governance studies. In this thesis 'organizing responsibilities' in circumstances of considerable configurational change is the object and objective of governance. The core idea of governance studies – that is that governance is unbounded, involving various public, non-governmental and private actors – still applies.

2.3.1 Governance arrangements and governance practices

Shifts and changes in configurations of responsibilities in local sociotechnical practices can be observed through, and are partly constituted by, the discursive interactions within these practices.[30] The analysis of responsibility positioning can be used to trace dealignment and realignment in configurations of responsibilities. However, to study dealignment and realignment in a configuration of responsibilities as a process of organizing, a focus on local sociotechnical practice is not sufficient, because responsibility positioning does not freely take all directions and is not merely discursive. There is a backdrop to the discursive interactions in local sociotechnical practices which accounts for a degree of social ordering. Story lines can draw on this backdrop. Responsibility positioning is enabled and constrained by elements outside local sociotechnical practices. These elements have stability, relatively independent from these local sociotechnical practices. They should be conceptualized and studied in their own right. I will use the term **governance arrangements** to refer to the supra-local level of these elements outside the immediate context of local sociotechnical practices which structure responsibility positioning in these local practices. The constitutive elements of governance arrangements include legislation and regulation,

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state of affairs" (Hirschman, 1970, p.30) The threat of exit is an incentive for those in charge to listen to their members or customers and to take their preferences seriously.

[30] In line with the previous conceptualization, I use the term discursive interaction in a broad sense, including the semiotic reading of material scripts and social acts.

institutionalized discourse, financing arrangements, etc. Formal as well as de facto governance arrangements occur and it is a question for empirical research what kind of governance arrangements structure responsibility positioning in a specific case.

Thus, there are two ideal-typical paths for organizing responsibilities. The process in which realignment of responsibilities results from mutual responsibility positioning in local sociotechnical practices forms a first ideal-typical path for organizing responsibilities (path (1) in fig. 2.2). In many cases – especially if a novelty radically challenges existing configurations of responsibilities – change in a configuration of responsibilities will be contested or deemed impossible because of constraints which are rooted outside the local sociotechnical practices. In those cases mutual responsibility positioning in local practices will at best only partly resolve dealignment. Elements of governance arrangements – for example existing legislative, regulative or public financing arrangements – may need to be changed in order to enable or enforce certain changes in configurations of responsibilities. Such a supra-local process in which realignments are enforced or enabled by a change in governance arrangements forms the second ideal-typical path for organizing responsibilities (path (2) in fig. 2.2).

There are various ways in which governance arrangements can be changed. Legislative change for example takes place through the formal political process and requires political decision-making. But change in moral order or dominant discourse involves other types of change processes. What characterizes all governance arrangements, is that they form a backdrop to local sociotechnical practices and that as a backdrop they cannot be changed directly by the first and second order positioning processes that take place in local sociotechnical practices. There are other practices, however, in which governance arrangements are debated and established. I will use the term **governance practice** to refer to the practices in which governance arrangements are set and changed.

Note that the governance practice should itself be conceptualized as a sociotechnical practice in which configurations of responsibilities may shift due to the introduction of novelty. Internet technology for example is often brought up as a technology with far-reaching implications for the functioning of governance, with both potential positive – e.g. democratizing – and negative – e.g. diminished governability – consequences. The focus of this thesis however is on change in configurations of responsibilities brought about by the introduction of novelty

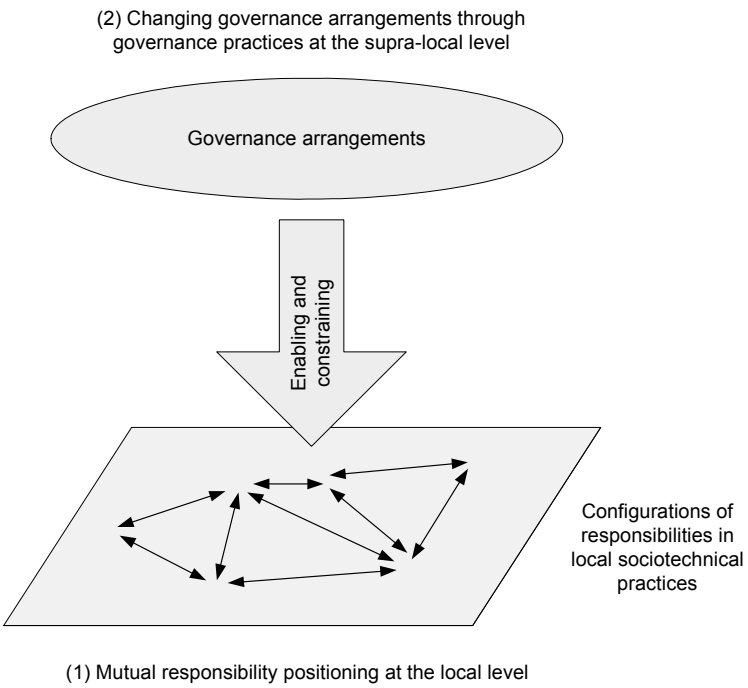

Figure 2.2: Two levels and ideal-typical paths for organizing responsibilities

outside the sociotechnical practices of governance. I will not empirically study the governance practice as itself a sociotechnical practice. Also from here on I will confine the use of the term sociotechnical practices to refer to local sociotechnical practices, whereas I will use the term governance practices to refer to the sociotechnical practices of governance arrangements.

Governance practices can be more or less formal and more or less institutionalized. As noted, it is increasingly recognized that governing capabilities do not rest with formal governmental institutions alone, but are distributed over a wider network of actors and institutions. In order to develop policies which address societal problems and political objectives, governmental actors need the expertise, the knowledge and often also the cooperation and support of a range of societal actors and stakeholders. One way in which formal governmental actors respond to this situation is by involving these societal actors in policy development and implementation, often through engaging representative intermediary organizations such as sector organizations, societal groups, professional associations, trade

unions, patient organizations, employers' organizations, branch organizations etc. It also works in the other direction: these representative intermediary organizations also actively approach governmental actors to address their issues of concern. Through these multilateral and bilateral interactions between governmental actors and intermediary actors, policy networks are formed which have a role in policy articulation and preparation. These policy networks also create *de facto* linkages between those controlling formal governance arrangements and the actors in local sociotechnical practices.[31] When these policy networks concern the governance of novel technologies and knowledge they will often be hybrid in composition, bringing into contact the poles of the sociopolitical and economic, with that of the techno-scientific and that of the legislative-regulative.

2.3.2 Hybrid forums as intermediate settings for third-order responsibility positioning

Hybrid forums are settings outside of local sociotechnical practices, in which actors *from* these sociotechnical practices come together and interact. In terms of positioning theory, hybrid forums are **settings for third-order positioning**; that is, settings where accountive as well as prospective positioning outside the primary interaction context of local sociotechnical practices can take place. As settings for third-order positioning, hybrid forums differ in an important way from the primary interaction contexts which are represented. In local sociotechnical practices interaction is limited to those actors that engage in joint practices (e.g. doctors with their patients, or insurers with their clients). Direct interactions between actors that do not engage in joint practices, but who nonetheless are constituents of the same sociotechnical configuration – and who are therefore mutually dependent – are absent. Within hybrid forums, interaction is possible between actors that do not normally interact in everyday local practice. As settings for third-order positioning hybrid forums enable the concurrent positioning of all actors (human as well as non-human) that play a role in a configuration of responsibilities. This includes actors from governance practices.

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[31] The concept of 'policy network' has become common in studies of governing and governance, cf. (Mayntz, 1999) My use of the concept is substantially the same as in these literatures, but I emphasize how these policy networks create *de facto* linkages between supra-local government actors and local level sociotechnical practices.

Storylines and moral orders that do not normally co-appear at the local level can come together in hybrid forums. All involved actors will be confronted with dealignment, which can form a starting point for joint articulation of new storylines and new moral orders reflecting realignment between responsibility positions in the overall configuration of responsibilities. Thus, hybrid forums enable modes of social learning that are not similarly possible at the local level of sociotechnical practices nor at the supra-local level of governance practices and arrangements.[32] Hybrid forums occupy an intermediate position between local sociotechnical practices and governance arrangements (See fig. 2.3).

In my conceptualization of a hybrid forum I have highlighted those characteristics which can make a hybrid forum productive in organizing responsibilities for novelties. But it should be noted that in hybrid forums much more will be going on

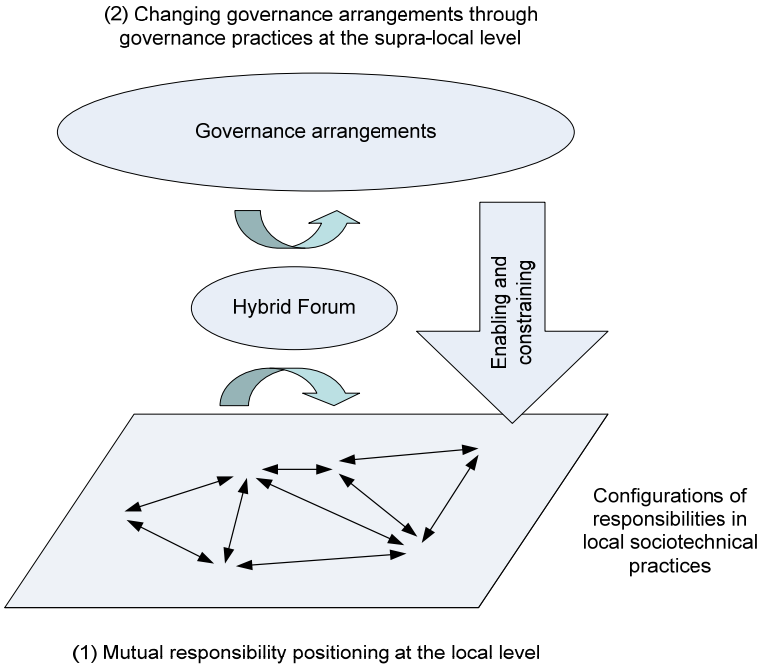

Figure 2.3: Hybrid forum as governance practice for organizing responsibilities

[32] Hybrid forums are like alignment macro-actors (Rip, 1995, p. 426), but not to introduce new technology, but to address the opening up of existing configurations of responsibilities.

than third-order responsibility positioning. Organizing responsibilities is my focus as an analyst, but forum participants will define what they are doing in other terms. And it is not only a matter of definition, forum participants will actually do other things, which may interfere with third-order responsibility positioning. Therefore we need to conceptualize and study hybrid forums not merely as settings for third-order responsibility positioning, but also as governance practices with forum participants as governance actors.

2.3.3 Responsibility positioning at the supra-local level

At the supra-local level of hybrid forums and other governance practices responsibility positioning takes place outside the context of local sociotechnical practice and is thus by definition third-order positioning. As local actors are often not directly represented, but are represented by people who can speak for their position, accountive positioning does not directly relate back to positioning in local sociotechnical practices. Furthermore, third-order positioning at the supra-local level does not necessarily refer back to earlier acts of positioning, but may also prospectively anticipate future responsibility positions and moral orders. Eventual effects of third-order positioning in hybrid forums on local actors' first order responsibility positioning are indirect.

In first and second order positioning participants engaged in a discussion position themselves directly and the analysis of responsibility positions is straightforward. The storylines on the other hand need not be articulated as such, but are to be inferred by the analyst from the way the conversation develops. This is often the other way around for third-order responsibility positioning at the supra-local level. There, it is less likely that participants in the discussion position themselves directly and it is more likely that particular storylines and implicated moral orders will be discussed. The discussion develops on the level of storylines, and responsibility positions are to be inferred by the analyst from the storylines that are articulated.[33] Analysis of responsibility positioning on the supra-local level should focus on how

[33] Though there are also occasions in which third order responsibility positioning is quite similar to first and second order positioning. In those cases forum participants position themselves directly. For example, when -in a discussion on prenatal screening - someone says: 'It is my responsibility as a doctor to inform pregnant women about the possibilities of prenatal Down syndrome screening.'

storylines and argumentative scenarios develop and change, rather than on a direct inquiry whether positions shift.[34]

The central role of storylines at the level of governance practices and hybrid forums leads to a further extension of my conceptual framework. Third-order responsibility positioning at the supra-local level is about the interaction between storylines rather than the direct interaction between positions. Such interactions are similar to what Hajer (1995) calls inter-discursive interaction. In hybrid forums issues are discussed by a diverse group of actors who do not share the same discursive practice. Ideas, terminology, phrases, considerations and knowledge that are used by actors in one discursive practice may be incomprehensible to, or interpreted differently by, actors from other discursive practices. Hajer encountered this in his study of acid rain controversies, and his analysis of inter-discursive dynamics can be applied to hybrid forums.[35]

Hajer takes over from social-interactive discourse theory, as developed by Billig, Davies and Harré, the idea that social interaction should be understood from a dynamic and discursive perspective. Discourse or more specifically the storylines in discursive interactions provide people with subject positions. This also holds at the more aggregate level on which Hajer focuses. Hajer adds that the mere idea of storylines and subject positions falls short as an explanatory framework since these concepts do not explain why some storylines have more force than others, how new

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[34] In 'Organizing modernity' John Law describes organizational ordering within a large research laboratory. My study resembles his study, because we partly use the same sort of empirical data - ethnographic observations made during (committee) meetings and because both studies look at ordering, although on a different level. There is also a similarity in the way he analyzes his data, using the concept of a story: "Stories are often more than stories: they are clues to patterns that may be imputed to the recursive sociotechnical networks." (p.19) "And in practice it, for me, it's an attempt to find some kind of common space or area of overlap, between first, symbolic interactionism (whose patterns tend to be rather local); second, post-structuralist discourse analysis, whose patterns in some cases seem to be strangely hegemonic; and a third theoretical tradition, that of the actor-network analysis (…)." (Law, 1994, p. 19,20)

[35] Theoretically Hajer draws on the work of Foucault, Billig, Davies, and Harré. As Hajer notes, Foucault strongly argued to take discourse seriously as an element of the social with a constitutive role of its own. It is not merely a medium. Foucault sees discourse as an element of the social that both enables and constrains ongoing interactions; discourse governs. Although theoretically Foucault argued to take micro level discursive interactions seriously, much of his empirical work presents a strangely hegemonic role for discourse. In Foucault's work the role of the discoursing subject remains ambivalent. Billig, Davies and Harré on the other hand focused explicitly on the role of individual actors and developed a 'social-interactive' discourse theory. Positioning theory as it was discussed in section 2.1 of this chapter is an example of this approach. In Hajer's approach these macro level and micro level approaches are linked to one another.

storylines emerge or how consensus is reached. Discourse analysis, so argues Hajer "is not only essential for the analysis of subject positions but also [FM: for the analysis] of 'structure positionings' (referring to which structural elements can be changed, and what institutions remain seen as fixed or permanent)." (Hajer, 1995, p.55,56) This is a necessary addition because social-interactive discourse theory spends 'relatively little attention to the degree to which discourse can become structured in institutional arrangements' (Hajer, 1995, p.57). Hajer introduces two concepts '**discourse structuration'** and '**discourse institutionalization'** to explain and describe the fact that some story lines are more difficult to change then others:

> *'We will speak of the condition of discourse structuration if the credibility of actors in a given domain requires them to draw on the ideas, concepts and categories of a given discourse (...) We will speak of discourse institutionalization if a given discourse is translated into institutional arrangements, i.e. if the theoretical concepts of [FM: in Hajer's case] ecological modernization are translated into concrete policies (...) and institutional arrangements.'* (Hajer, 1995, p. 60,61)

Hajer analyses discourse as it plays an important, but often underexposed role in policy and politics. It is Hajer's aim to reveal the sub-political elements within politics, as produced by discourse. He focuses on the processes in which '**discourse coalitions**'[36] are formed. Hajer perceives political struggle as a struggle for discursive hegemony. Following this perspective and in opposition to mainstream political theory, coalitions are then formed not between people that perceive their positions and interests as similar or shared, but rather by people that are attracted to a similar set of storylines. "Discourse-coalitions are defined as the ensemble of (1) a set of story-lines; (2) the actors who utter these story-lines; and (3) the practices in which this discursive activity is based. Storylines are here seen as the discursive cement that keeps a discourse-coalition together." (Hajer, 1995, p. 65)

Important for the study of my cases is Hajer's insistence that a text – whether written or spoken – in general derives its political force from its multi-

[36] The 'discourse coalition' concept builds on Sabatier's 'advocacy coalition' concept (Sabatier & Jenkins-Smith, 1993), but differs because it emphasizes the constitutive role of language in policy coalitions and policy change.

interpretability. Hajer uses the term '**discursive affinities'** to explain multi-interpretability:

> *"Separate elements might have a similar cognitive or discursive structure which suggests that they belong together. In that case actors may not understand the detail of the argument but will typically argue that 'it sounds right'. This element of the explanation of a discursive order thus does not primarily refer to the actors and their intention but explicitly operationalizes the influence of discursive formats on the construction of problems."* (Hajer, 1995, p.66,67)

By focusing on the structuring aspects of discourse, the impression may be created that discourse alone determines the outcome of hybrid forum interactions. It should be stressed though that Hajer's theory of inter-discursive interaction does not neglect or deny the importance of non-discursive elements in the struggle for discursive hegemony. Hajer distinguishes three non-discursive factors that influence the dynamics of the struggle for discursive hegemony: credibility, acceptability, and trust. Whether or not a specific storyline is accepted depends on these three factors. "Credibility is required to make actors believe in the subject-positioning that a given discourse implies for them and to live by the structure positionings it implies; acceptability requires that position to appear attractive or necessary; trust refers to the fact that doubt might be suppressed and inherent uncertainties might be taken for granted if actors manage to secure confidence (…)." (Hajer, 1995, p.59)

To conclude, Hajer's theory on the discursive dynamics of inter-discursive issues can be used to analyze responsibility positioning at the supra-local level of hybrid forums and other governance practices. The non-discursive factors credibility, acceptability and trust link third-order responsibility positioning at the supra-local level with responsibility positioning in local sociotechnical practices, while the concepts of discourse structuration and institutionalization indicate the link between responsibility positioning and the backdrop of governance arrangements.

2.4 The hybrid forum setting

The hybrid forum concept is not a dichotomous concept, which means that there is not a clear analytical distinction between forums that are hybrid and forums that are

non-hybrid. Rather forums and arenas differ from each other in the degree of hybridity. Some forums and arenas have as a main characteristic that they are hybrid. Other forums and arenas have as a main characteristic that they are non-hybrid, but still these forums can exhibit hybrid facets on specific occasions, in particular when discussing hybrid issues. Parliament counts as an example. And there is a third category of intermediate cases where a forum or arena combines a non-hybrid front stage with a clearly hybrid backstage. The Health Council, a Dutch scientific advisory council that advises the government and Parliament on health issues, counts as an example. Differences between hybrid forum settings have impact on how hybrid forums can be productive. I will discuss the variety of hybrid forum settings. The aim is not to give an extensive overview but to discuss the kind of phenomena and dynamics that play a role in how hybrid forums are productive in organizing responsibilities.

2.4.1 Variety of hybrid forum settings

A first hybrid forum to be discussed is the diffuse hybrid forum. It is the hybrid forum par excellence, in the sense that it provides in principle for a maximum scope of different kinds of actors and different kinds of considerations. The diffuse hybrid forum is not bounded, not with respect to the kind of actors that are allowed to participate and not with respect to the kind of issues and arguments that are allowed to be debated. Discussion and interaction in the diffuse hybrid forum is dispersed over a variety of public spaces, such as the forum pages of national newspapers; a discussion forum on radio or television; the 'letters to the editor' section of professional journals; public meetings; etc. Debate in the diffuse hybrid forum does not lead to concrete results in the form of an advice or a clear recommendation (Kirejczyk et al., 2003). The diffuse hybrid forum comes closest to the concept of hybrid forum as it was first introduced by Callon and Rip (1992): a deliberative setting in which a heterogeneous set of actors is simultaneously involved and in which a heterogeneous set of questions, problems and arguments co-exist and co-evolve.

When a forum is set up with a specific objective in mind and when the hybrid composition of a forum forms a main characteristic which is thought to contribute to achieving the aims of that forum, I will call it a purposively hybrid forum. When such a forum has a linkage to formal governance practices, we can speak of a commissioned hybrid forum. A hybrid governmental advisory committee, installed

to formulate advice on a specific issue is an example. Commissioned hybrid forums are always bounded in one or more ways. Often, commissioned hybrid forums have a specific mandate which puts restrictions on the kinds of questions to be answered, and the kinds of answers to be given. In general commissioned hybrid forums are also bounded in terms of membership. And, as there is the expectation that a commissioned hybrid forum will come to some sort of a conclusion – preferably a consensual one - a commissioned hybrid forum is often also bounded in time. Whereas deliberation in the diffuse hybrid forum can go on and on and on, deliberation in a commissioned hybrid forum comes to an end and to some sort of a conclusion.

Although the forum notion suggests that there are recurring interactions, a non-recurring hybrid meeting can be productive in organizing responsibilities in ways similar to hybrid forums. It is therefore interesting to take such meetings into account, especially because these types of meetings occur frequently, like when commissioned forums organize consultation meetings with a hybrid group of people, such as stakeholders, experts or members of the wider public.

Among the variety of hybrid forum settings, scientific advisory councils which operate on the boundary between science and politics, form a special category as they combine a non-hybrid front stage with a hybrid backstage. Miller (2001) and Bal, Bijker and Hendriks (2002) have shown that scientific advisory councils are actively engaged in establishing and maintaining productive, but not necessarily stable boundaries between science and politics. Miller has termed this work 'hybrid management': "To maintain these productive and dynamic relationships, boundary organizations need to be able to manage hybrids – that is, to put scientific and political elements together, take them apart, establish and maintain boundaries between different forms of life, and coordinate activities taking place in multiple domains" (Miller, 2001, p.487).[37]

[37] Miller (2001) developed his ideas on the basis of an analysis of the SBSTA, the Subsidiary Body for Scientific and Technological Advice, which was created in 1992 by the U.N. Framework Convention on Climate Change (UNFCCC) "for the explicit purpose of establishing new expert advisory arrangements" (p.479).

In an extensive and detailed empirical study of the Dutch Health Council Bal, Bijker and Hendriks (2002; 2004; 2004) made similar observations.[38] They characterize the position of the Health Council as 'The Paradox of Scientific Authority'. Whereas the Council's authority rests on their position as an objective and independent scientific advisory council, science only rarely produces knowledge that is immediately relevant for policy. Bal et al. (2002) describe how the Council lives with that paradox, or better how it solves that paradox and makes it productive. They describe the coordination mechanisms that are used to alternately adjust science to policy and to purify science from policy. The creation and maintenance of a productive boundary between what happens front stage in the advisory process and what happens back stage is a crucial part of that coordination work. Front stage – that is publicly visible – the Health Council maintains the 'illusion' that their advisory work is purely scientific, while backstage political and societal elements play a role in a carefully orchestrated process of mixing and purifying science, policy and society in order to create productive advice. Bal et al. (2002; 2004) use the metaphor of the laboratory and workbench to describe this process of trying out productive alignments between science, policy and society.

2.4.2 Hybrid forum productivity

In section 2.3.2 I introduced mutual responsibility positioning as a dynamic and discursive process, facilitated through hybrid forums, and contributing to organizing responsibilities. Actors that are engaged in a discussion about novelties not only position or assess a novelty, but they also position themselves and others in a specific role responsibility in relation to this technology. Such mutual positioning

[38] "Boundary organizations, in our terms, are hybrid forums in which science and non-science can be aligned with each other. Though the word 'boundary organization' indicates that such organizations are actually located on a frontier - "they exist on the frontier of two relatively distinctive social worlds" – what matters to us is that they co-produce boundaries through their activities. Furthermore, the term boundary organization suggests a more or less neutral mouthpiece from scientific knowledge to policy, reifying the boundaries between science and politics rather than problematizing them. In addition, the notion tends to weaken the differences between the sciences and society: as if only two distinctive social worlds are at issue in stead of many. The term 'hybrid forum' does not harbor such drawbacks, although it is not necessary to emphasize the differences: whereas the concept of 'boundary organization' calls attention to the position of such organizations in between different social worlds (or, in Wittgenstein's words: life forms), the term 'hybrid forum' emphasizes the heterogeneous work that is done within such organizations." (Bal et al., 2002, p.310, translated from Dutch)

between people, organizations, or constituencies may improve understanding of each other's position and as such can help to achieve realignment in a configuration of responsibilities. Shared narratives or storylines can develop, which structure ongoing interaction and positioning.

Mutual responsibility positioning in hybrid forums does not necessarily lead to closure of a discussion. That is especially the case when there are different interests at stake. In the diffuse hybrid forum discussions may not come to a conclusion because "Le forum hybride n'en appelle à aucune souverain". Deliberation in a commissioned hybrid forum is different from deliberation in the diffuse hybrid forum because at some stage an outcome is expected, which enforces a reduction of complexity and which may conclude the discussion. Furthermore if there is a mandate it creates legitimacy for the outcome and the linkage with other governance practices increases the likelihood that the outcome has an impact in the wider world. But success is not guaranteed. When the agreement that is reached within the confines of a commissioned hybrid forum travels to the diffuse hybrid forum it can still become contested by outsiders who feel that their position or interests have not been properly represented.

Although a scientific advisory council is not a hybrid forum in the strong sense, a scientific advisory council may play an important role in organizing responsibilities. One of the means by which the Health Council for example can contribute to organizing responsibilities is through the text of the advisory report. Bal et al. have shown that in the Council's advisory work the performative strength of the advisory text is given elaborate consideration and that attempts are made to make the text into a kind of blueprint for a coordinated operation of involved societal actors (Bal et al., 2002, p.188,189; Hendriks et al., 2004, p.282-286). I expect though that the need to maintain a front stage position as an independent, objective and apolitical scientific advisory council impacts the way in which a scientific advisory council can operate. In that respect a scientific advisory council is different from other types of hybrid forums.

Several authors have noticed that for purposively hybrid forums to be productive conflicting design requirements apply. There are two characteristics of a hybrid forum that are important to take into account. First of all, as I argued in chapter 1, the hybrid composition of a forum contributes to the quality of responsibility positioning, in the sense that all actors involved in a configuration of

responsibilities should be represented, including the non-human actors.[39] This poses specific requirements for the composition of a hybrid forum. Ideally one would want all the actors that are potentially involved in the changing configuration of responsibilities to be represented. But, as shifts in one part of the configuration of responsibilities can have unforeseen repercussions on another part of the configuration it is not always possible to conceive of a blueprint of the ideal hybrid forum composition beforehand. As an alternative to the ideal composition one could aim for a procedural guarantee for hybridity. Such a procedural guarantee could contain the requirement of a forum to function publicly and to allow new participants to engage in the discussions.

A second important characteristic of a hybrid forum relates to the question how a hybrid forum contributes to realignment of responsibilities, how it contributes to stabilizing a new configuration of responsibilities when novelty has opened up and made obsolete the pre-existing configuration. Here the position and the boundary of a hybrid forum are crucial aspects. A forum's position is important for it influences to what extent the products of a forum have authority and impact outside the forum. The forum's boundary is important for reaching closure of the discussion. When a hybrid forum is not bounded, but open to many different perspectives it can be difficult to re-align mutual responsibilities, especially in those cases where there is a conflict of interest.

When taken as design criteria, the two forum characteristics discussed above, that of openness and that of boundedness, impose conflicting requirements on a hybrid forum. Paraphrasing Strathern (2002, p.254), hybrid forums are somewhat curious attempts to frame and contain hybridity through creating hybridity. Likewise, Callon et al. (2001) and Kirejczyk et al. (2003) pointed at the conflicting requirements for hybrid forum productivity. They argued that the relationship between on the one hand 'productivity' of commissioned hybrid forum interactions, which they define as the ability to reach a robust outcome, and on the other hand the degree of hybridity, which is defined as the broadness of arguments and considerations that can be brought into the forum discussions takes the shape of an inverted u-curve. When the degree of hybridity is too high, it will be difficult or

[39] Democratic quality can also be an argument for hybridity, in the sense that all involved actors should have the opportunity to represent their interest. While it is an important issue, in this thesis the focus lies on organizing responsibilities and not on democratic quality.

impossible to reach closure of the discussion. When the degree of hybridity is too low, there is a substantial chance that the closure that is reached will be contested by those excluded from the forum, once the product of the forum interactions re-enters the diffuse hybrid forum. Kirejczyk et al. argue that "the optimum [FM: of the inverted u-curve of hybrid forum productivity] is case dependent and cannot be determined a priori" (Kirejczyk et al., 2003, p.252-253, translated from Dutch).

In discussing the limitations of hybrid forum productivity both Kirejczyk and Rip considered the productivity of interactions in isolated hybrid forums and both suggested to shift the analysis and evaluation of individual forums, to an analysis of overlap and linkages between different hybrid forums: *"*In addition to tracing and evaluating the hybrid forums themselves, one should therefore also study the overall pattern of linkages between hybrid forums, what these add up to, and how they perform." (Rip et al., 2000, p.16) (Kirejczyk et al., 2003, p. 264). I add that I need to extend the analysis even further and include in my study the non-hybrid forums as well. Firstly, because I am interested in the overall process of organizing responsibilities. Governance practices in general, whether these are hybrid or non-hybrid can play a role in that process. Further, as was already noted forums for which hybridity is not a main attribute can still exhibit hybrid characteristics on specific occasions. So in addition to focusing on the role of individual forums I will focus on the linkages between different forums and arenas.

The focus on linkages between forums is one more reason to focus the empirical analysis on storylines instead of positions. Analyzing positions could be relevant when the main linkages between forums were embodied linkages, formed by forum participants who travel between forums. But I expect that the products of forum discussions travel mainly as texts and that it is thus more relevant to focus the analysis on storylines.

2.5 Research questions and introduction to the next chapters

Now that I have conceptualized organizing responsibilities as a multi-level process and elaborated on the role of hybrid forums within this process, I can further specify my research questions and account for the choice of empirical cases. In section 2.4, I argued that the conflicting productivity requirements on hybrid forums imply that it is more interesting to focus on the productivity of overlap and linkages between different arenas and forums, rather than restricting the analysis and focusing it on

individual hybrid forums. Thus the focus of analysis comes to lie on my first research question: What does the process of organizing responsibilities – the ongoing mutual adjustment in a configuration of responsibilities – look like? Furthermore, a focus on the entire process of organizing responsibilities makes it possible to broaden the empirical scope of my analysis from purposively hybrid forums to forums and arenas that primarily feature a non-hybrid character, yet – on occasion - can still exhibit hybrid forum types of productivity. That includes the intermediate cases which combine a non-hybrid front stage with a hybrid backstage. I will deal with this variety of hybrid forum settings by focusing on those elements and dynamics that seem particularly relevant for understanding how hybrid forums can and cannot be productive. These elements/dynamics serve as foci of attention in my analysis. Thus in a way my second research question on the contribution of hybrid forums to the process of organizing responsibilities, becomes integrated within my first research question.

Based on the discussion in this chapter, I can already identify a number of relevant elements/dynamics: Mutual responsibility positioning; Representation of a novelty's affordances and; Concluding or resolving normative conflict. The first dynamic of mutual responsibility positioning has been extensively discussed and needs no further explanation here. The second one, the proper representation of a novelty, is important in order to achieve a robust alignment in a configuration of responsibilities. This is not always easy. The properties of many novelties are ambiguous and because of their novelty often uncertain. Also, in many cases there are complex interdependencies between the properties of a novelty (or non-human actor) and the attributed roles of the human actors in a configuration of responsibilities. Thus, actors engaged in a discussion over responsibilities may differ in their opinion on the correct representation of a novelty. The third element, concluding and resolving normative conflict, is relevant, because there can be conflicting interests at stake - which means that discussions on novelties and responsibilities can easily evolve into controversy. Further, I expect that more productive elements/dynamics will be found, when reflecting on the empirical material.

When focusing on the overlap and linkages between different hybrid forums and arenas, as suggested above, the contribution of hybrid forum interactions for organizing responsibilities concerns how the interactions in a hybrid forum or arena

influence the dynamics of the overall process. The productive role of a hybrid forum is assessed in terms of external effect. However, when there are many actors, forums, and arenas involved, the situation becomes complex and the productive role of a hybrid forum becomes partly contingent upon the specific situation. For those who are interested in an evaluative perspective – like policy makers who need to decide whether or not to facilitate or promote hybrid forums as governance practices - such contingencies complicate the assessment of a hybrid forum. As an alternative to assessing external effect, I also assessed hybrid forums in terms of the productivity of internal processes. Ideally, I would have wanted to combine the analysis of internal and external hybrid forum productivity in one and the same case. In practice this was not always possible, because I was not in all cases allowed to observe hybrid forum discussions, and for those I was allowed to study, I could not always easily assess external effects. Therefore, in this thesis I will address the role of hybrid forums in organizing responsibilities, including both internal and external productivity, but in a mosaic way.

To answer my research questions I first chose a domain of innovation. A main selection criterion was that a variety of hybrid forum types of interactions would be present and that there would be a culture of assessing and anticipating new developments. The domain of clinical genetics and medical biotechnology met these requirements. There were several interesting hybrid forums that could be studied. First of all there was an initiative to establish a multi-party hybrid forum to discuss new developments in the domain of clinical genetics and medical biotechnology. This was the Forum Genetics, Health and Healthcare, which later was renamed as the Forum Biotechnology and Genetics. In chapter three I will analyze how this forum emerged and evolved into a particular type of governance practice. The analysis produces relevant lessons on the types of interactions that are at work in a hybrid forum, thus providing empirical ground to elaborate in more detail on the idea that hybrid forums can be productive in organizing responsibilities.

Secondly, the domain of clinical genetics was interesting because the Netherlands Organization for Health Research and Development (ZonMw) was commissioned to write an advice in which they were asked to reflect on the consequences of future applications of genetic knowledge in healthcare for the legal position of patients and citizens. As part of this advisory trajectory, hybrid consultation meetings were

organized, which could be studied. Chapter 6 presents an analysis of one of these meetings in which the use of genetic data by insurers and employers is discussed. Thirdly, I felt clinical genetics and medical biotechnology to be an interesting domain of study, because the Health Council is known to have an important role as a scientific advisory council within this domain.[40] Thus the domain of clinical genetics and medical biotechnology enabled me to study the role of purposively hybrid forums, including the special case of the Health Council, which combines a non-hybrid front stage with a hybrid backstage.

Besides analyzing the two purposively hybrid forums introduced above, I selected two cases where the introduction of a novelty opened up a public and political debate in which responsibilities were disputed. In both cases I analyzed the overall process of organizing responsibilities by following the development of and interaction between various responsibility storylines, as the discussion travelled from one forum or arena to the next. The first case concerns the introduction of prenatal screening on Down syndrome in Dutch healthcare and will be discussed in chapter 4. The second case concerns the debate on insurance selection that started when the introduction of a wide scale genetic screening program on Familial Hypercholesterolemia was proposed. This case will be presented in chapter 5.

The reason for choosing my first case was partly pragmatic. The issue of prenatal screening was discussed in the Forum Biotechnology and Genetics, to which I had access. Choosing this case enabled me to combine the analysis of the internal and

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[40] At different stages in the development of clinical genetics, the Health Council played an important role in translating locally achieved alignments and rules to the level of governmental policy (Nelis, 1998). Bal, Bijker et al. (2002) confirm the influential role of the Health Council in the domain of medical genetics. At the start of their research project Bal et al. asked members of Health Council staff to list the most and least successful Health Council advisory reports. Four advisory reports within the domain of medical genetics were labeled most successful: Heredity: science and society (Gezondheidsraad, 1989), Genetic Screening (Gezondheidsraad, 1994), Population Screening Act (Gezondheidsraad: Commissie WBO, 1996) and Gene Therapy (Gezondheidsraad, 1997a). None of the advisory reports on issues of genetics and medical biotechnology were listed as 'failed' advisory reports. Furthermore, when asked to account for their policy on developments in genetics, both the Dutch Association for Human Genetics (NAV) as well as the Dutch Association for Clinical Genetics (VKGN) refer to Health Council advice: 'NAV's policy regarding running business and legislation is to a large extent recorded in the reports of the Health Council and in existing laws. (…) Representatives of NAV participate in the Health Council's committees. (...) 'The members of the VKGN are often asked for advice on new development in genetics. Various Health Council advisory reports came about with the aid of VKGN members.' (VSOP, 2000, p.26,27).

external productive role of a purposively hybrid forum. The second case was chosen, because the issue transcends the boundaries of two societal domains – collective healthcare and the private insurance market - which normally remain separate and in which very different governance arrangements and practices are involved. I expected that organizing responsibilities would be particularly challenging in this case and that the purposively hybrid forums would potentially have a large role to play. A further reason to select these two cases is that in both cases the role of the Health Council could be studied.

3
The Forum Biotechnology and Genetics

3.1 Introduction

On the 12th of December 2000, the Dutch Minister of Health installed the Forum Genetics, Health and Healthcare ('Forum Genetica, Gezondheid en Gezondheidszorg', FGHH). Two years later, on the 1st of January 2003[41] this Forum merged with the Platform Medical Biotechnology ('Platform Medische Biotechnologie') to form the Forum Biotechnology and Genetics ('Forum Biotechnologie en Genetica', FBG). The Forum[42] brings together a broad range of organizations that are involved in and affected by the developments in medical genetics and medical biotechnology, such as organizations that represent patients, medical professionals, clinical geneticists, government advisory bodies, insurance companies, bio-pharmaceutical industry and ministries. In other words, the Forum Biotechnology and Genetics has got a hybrid constitution.

In this chapter and in chapter 4, I will present observations and analyses concerning this Forum. Chapter 4 discusses the Forum in relation to a specific case: organizing responsibilities for prenatal screening on Down Syndrome. In this chapter, I will focus on the Forum itself and address the question how the Forum came into being and how it evolved. The Forum Biotechnology and Genetics was not established with a shared idea on how it could be productive, neither was there a sole actor who could strongly frame the nature of the forum and its activities. The FBG was created as a multi-party initiative without a shared vision on the role and position of the Forum and without a shared problem framing. Over time, Forum participants learned what they could do. The types of interactions and their effect varied from occasion to occasion and over time. As far as ideas on productivity played a role, these ideas did not relate to the governance challenge of organizing responsibilities.

The analysis in this chapter accordingly does not take the form of a formal evaluation on how best to construct a hybrid forum to contribute to the process of organizing responsibilities. Rather I will present how the Forum evolved over time into a particular kind of governance practice and I will reflect on the lessons that can be learned. In particular the analysis will situate the FBG as a governance

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[41] 1st of January 2003 was the date of formal establishment. But, as the FBG was retroactively established, the FBG only functioned according to the new structure from April 2003 onwards.

[42] I use the word 'Forum' with a capital F to refer to the Forum Genetics, Health and Healthcare or to its successor the Forum, Biotechnology and Genetics.

practice, competitive and interdependent in relation to other governance practices, showing how this context enabled and constrained the development of the Forum from a loosely structured meeting place into a more structured arrangement for hybrid interaction.

3.2 The Forum Biotechnology and Genetics – an evolving governance practice

The Forum Biotechnology and Genetics (FBG) was formally established by the Minister of Health on January 1st, 2003. Within the FBG the former Platform Medical Biotechnology and the former Forum Genetics, Health and Healthcare (FGHH) were merged. The observations and analysis presented in this chapter concern the Forum Genetics, Health and Healthcare (from the start in December 2000 until December 2002) and the first 21 months of the FBG (from January 2003 until September 2004).[43] In this first section the history and development of the Forum Genetics, Health and Healthcare and the Forum Biotechnology and Genetics are presented. An overview of the history and development of the Forum is given in table 3.1.

3.2.1 The pre-history (1994-2000)

In the years preceding the formal establishment of the Forum Genetics, Health and Healthcare organizations involved in and affected by developments in medical genetics met on several occasions to discuss the implications of these developments. In retrospect these meetings prepared the ground for establishment of a multi-party forum. In February 1995 the Platform for Science and Ethics organized a 'public' debate under the title 'Predictive Genetic Research, where are we going?' The main event was set up in the style of a Danish consensus conference. During a three day conference a lay panel heard experts and at the end of the conference they presented a final declaration on predictive genetic research. Media coverage of the event was low and the aim of the organizers to trigger a broader public debate failed (Aarts et al., 2001; Van Oest et al., 1995). In another respect however the project did have considerable impact. Preceding the 'consensus conference' five thematic workshops were organized. Especially in this preparation

[43] Appendix 1 gives a complete overview of all the meetings that I observed and analyzed.

Period	Characterization	Details
1994-2000	On a variety of occasions, a hybrid group of stakeholders involved in and affected by developments in medical genetics meets to discuss these developments. Gradually the idea to establish a more permanent platform/forum takes root.	• Consensus conference 'Predictive Genetic Research, where are we going?' (February 1995) • Invitational conference on 'Genetic Research and Chronic Diseases in the Next Century' (1997) • Workshop at the Ministry of Health in the context of preparation for the policy document 'The Application of Genetics in Healthcare' (Feb.1999) • Second Invitational Conference 'A Joint Policy on Genetic Research' (20th of January 2000)
Feb. 2000 – Dec. 2000	Negotiation on the design of the FGHH by the core group	
Dec. 2000 – June 2003	First establishment period of Forum Genetics, Health and Healthcare	• December 12, formal establishment FGHH • The Forum Genetics, Health and Healthcare meets twice a year. • The Forum's preparation group meets six times a year. • Secretarial support is limited to organizational matters only • May 2002, Internal evaluation of the FGHH • 5th of June 2003, last meeting of the FGHH preparation group
April 2003 – January 2006	Forum Genetics and Healthcare and the Platform Medical Biotechnology merge and continue under the new name of Forum Biotechnology and Genetics.	• Formal establishment of the Forum Biotechnology and Genetics (1st of January 2003). • Initially the former Forum Genetics, Health and Healthcare and the former Platform Medical Biotechnology continued their existence as separate Committees functioning under the overarching structure of the Forum Biotechnology and Genetics. As of March 2004 these Committees are abolished. • First plenary meeting of platform and forum (7th of April 2003). • FGHH Preparation group is abolished (June 2003) • Two part-time secretaries support the FBG with the preparation and formulation of discussion papers and statements. • An agenda committee is formed by the chair, the vice-chair and the three secretaries. • Temporary working groups are set up to formulate discussion papers and statements. • The agenda committee meets with representatives from the Ministry of Health to discuss evaluation criteria (27th of November 2003) • Interim evaluation by the Ministry of Health (23rd of March, 2004)
January 2006 – December, 2007	2nd FBG establishment period	• Renewed establishment of the Forum Biotechnology and Genetics for a period of 2 years • The Forum sub committees are formally abolished
January 2008 – Dec. 2011	3rd FBG establishment period	• Renewed establishment of the Forum Biotechnology and Genetics for a period of four years

Table 3.1: An overview of the history and development of the Forum Genetics, Health and Healthcare and its successor the Forum Biotechnology and Genetics

phase a large number of organizations and stakeholders were brought together as organizers and participants of these workshops. During these events most of the organizations and stakeholders met for the first time. An important network effect had been created and from this time onwards more interactions between these parties were organized (Aarts et al., 2001, p.85).

The idea to establish a platform in which representatives from science, patient organizations, government, medical professionals, employer organizations and insurance companies would come together on a more regular basis and in order to reach a joint policy was first discussed in 1997, during an invitational conference on 'Genetic Research and Chronic Diseases in the Next Century', organized by the VSOP, the Dutch umbrella organization for parents and patient organizations for hereditary diseases, and the NCCZ, the National Committee for Chronic Diseases. The conference focused on developments in predictive genetic research. Panel discussions were held on three issues: 'Social responsibility of insurers and industry'; 'Genetic research and the consequences for health care'; and 'The establishment of a platform on predictive genetic research'. The Dutch term 'platform' was used in a figurative meaning, referring to a forum for deliberation.

At the end of this conference twelve organizations signed a 'declaration of intent', a list of basic principles and recommendations to arrive at a joint policy on genetic research. The declaration points out that a joint policy and vision concerning the correct application of genetic research was lacking. Genetic research and knowledge offers new opportunities for patients with hereditary and congenital diseases. However, that same knowledge raises questions and causes uncertainties for which healthcare, society and politics have not yet found answers. The last statement of the declaration reads that:

> *'It is advisable that a platform is established where science, industry, professional associations and patients associations communicate about developments in genetic research and about everyone's responsibility in the context of these developments'* (VSOP/NCCZ, 1997, p.40).[44]

[44] 'Speakers from a variety of areas emphasized the developments in genetic research and the related consequences. They also pointed out that to date there was a lack of collective policy or vision concerning the correct way to apply the possibilities of genetic research. The developments in the area of genetic research move rapidly. The newly acquired knowledge offers many

Over the following years the idea to establish such a platform was repeated on several occasions.

In 1998, at the time when the coalition agreements for a new government were discussed, a group of 18 organizations advocated the formation of a National Committee on Heredity and HealthCare.[45] In February 1999 the Ministry of Health organized a workshop on heredity to consult involved parties in preparation of a policy document entitled 'The application of genetics in health care' (Ministry of Health Welfare and Sports, 2000). On that occasion consulted parties again made the plea for a national forum or committee. This began the involvement of the Ministry of Health in the initiative to establish a forum on genetics and healthcare.

In 1999 the VSOP, in collaboration with the Foundation for Future HealthCare Scenarios (STG)[46] started to formulate a Joint Policy on Genetic Research (VSOP, 2000). Input for that policy document was given by a wide range of organizations. During a second invitational conference in January 2000 the document was discussed and - with some changes – 18 different organizations subscribed to the Joint Policy Genetic Research, also referred to as the 'Soestduinen objectives'. Later on these objectives came to weakly structure the Forum's agenda and they were also referred to in the Forum Genetics, Health and Healthcare's 'plan of action' (FGHH, 2000). A framework for the establishment of this Forum was presented during the January conference. This framework had been jointly prepared by the VSOP, STG and the Ministry of Health. It was proposed that representatives from nine organizations would form the core group of this Forum and that a wider group of organizations would participate when relevant for the issue at stake (VSOP, 2000, p.32). At the end of that conference day, representatives of these nine

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possibilities and therefore perspective to many patients suffering from hereditary and/or congenital defects. However, that same knowledge evokes questions and creates uncertainties that are yet to be answered by the health care sector, society at large, and the political arena. A collaborative effort by all the involved parties can create the conditions needed to enable the search for answers and solutions. (...) The propositions were met with wide approval from the participants. The participants assign priority to the development of concerted policy concerning genetic research.' (VSOP/NCCZ, 1997, p.39, translated from Dutch)

[45] In Dutch: 'Nationale Commissie Erfelijkheid en Gezondheidszorg'

[46] The Foundation for Future HealthCare Scenarios (STG) had a role in consulting organizations and preparing the joint policy document. Later the STG would take up preparative work in the first period of the trajectory in which the formal establishment of the Forum was prepared.

Patients:
– Umbrella organization of parents and patients organizations for hereditary diseases, (in Dutch: Vereniging Samenwerkende Ouder- en Patiëntenorganisaties (VSOP))
Government:
– The Ministry of Health, Social Welfare and Sports, (in Dutch; Ministerie van Volksgezondheid, Welzijn en Sport (VWS))
Healthcare providers:
– Association of University Hospitals (in Dutch: Vereniging van Academische Ziekenhuizen (VAZ))
– Umbrella organization of the Foundations for Clinical Genetics (Vereniging Stichtingen Klinische Genetica) (VSKG)
Medical professionals:
– Royal Dutch Medical Association (in Dutch: Koninklijke Nederlandsche Maatschappij tot bevordering der Geneeskunst (KNMG))
– Dutch Society for Clinical Genetics (Vereniging Klinische Genetica Nederland (VKGN))
Medical Scientists:
– Dutch Association for Human Genetics (Nederlandse Antropogenetische Vereniging (NAV))
Private sector / Industry:
– Association of Insurance Companies (Verbond van Verzekeraars (VvV))
– Working Group Pharmaceutical Genetics (Werkgroep Farmaceutische Genetica)

Table 3.2: Organizations represented in the FGHH preparation group

organizations came together for the first time.[47] These organizations are listed in table 3.2.[48]

So, from the mid-nineties onwards, there was a movement towards more communication and coordination between the different stakeholders involved with, and affected by, developments in medical genetics. Initially some form of communication and coordination was established through one-off events and conferences initiated by different parties, and through the formulation of a Joint Policy on Genetic Research. But it was stated that a more permanent means for communication and coordination was needed. Apparently there was a broad

[47] Interview J. v/d Wijngaard, 11-09-02, The Hague.
[48] The nine organizations are represented by eight people. The VKGN and VSKG are represented by one and the same person.

demand for communication and coordination to respond to the uncertainties and complexities related to the swift developments in medical genetics.

3.2.2 The Platform Medical Biotechnology - A parallel initiative

A movement towards communication was also visible in relation to developments in medical biotechnology. Here the bio-pharmaceutical industry took the initiative to strengthen communication and coordination. From 1997 onwards the involvement of bio-pharmaceutical industry in public debate on genetics had gradually increased. The public response to the birth of cloned sheep Dolly in 1997 and the hostile public and political response to genetically modified crops (GMOs) made the industry recognize the importance of social acceptance. The negative public image of agricultural biotechnology was perceived as a threat to developments in medical biotechnology. There was a question whether Nefarma, the branch organization for the research-oriented pharmaceutical industry, would cooperate with Niaba, the branch organization for biotechnology. Because of Niaba's involvement in the public debate on GMOs and agricultural biotechnology, Nefarma decided that it was better not to establish formal cooperation. They did not want medical biotechnology to be associated with agricultural biotechnology. Instead, in 1999, three pharmaceutical companies and Biofarmind established a working group on bio-pharmaceutical genetics.[49] Biofarmind, the branch organization for biotechnological pharmaceutical industry had been established two years earlier.

Parallel to the initiative to establish a forum on genetics and healthcare, Biofarmind had been working on the establishment of a multi-party platform, which at the end of 1999 resulted in the establishment of an independent Platform Medical Biotechnology, financially supported by the Ministry of Health. From the start some people involved in both the Platform Medical Biotechnology and the Forum Genetics, Health and Healthcare were unhappy about the two initiatives running parallel. In fact there was some overlap in the agendas of both Forum and Platform as well as overlap in the organizations represented (Aarts et al., 2001, p.90). There was discussion whether or not the two should merge. In the period 2000-2003, adjustment and exchange between the Platform Medical Biotechnology and the Forum Genetics and Healthcare occurred through participants with double

[49] Interview Van Schagen, 16-02-2000.

membership and because Platform and Forum came to share a secretariat. Platform and Forum eventually merged into one Forum, the Forum Biotechnology and Genetics, but that did not happen until January 1st 2003.

As in all communicative interactions, mutual positioning occurred in the meetings between the stakeholders involved in the development and societal embedding of medical genetic innovations.[50] These acts of mutual positioning can reduce some of the uncertainties in the development and societal embedding of medical genetic innovations and can also lead to some coordination between the different organizations involved. It is because of the need for reducing uncertainties and complexities that organizations have an interest in establishing and formalizing settings for deliberation such as the Platform Medical Biotechnology and the Forum Biotechnology and Genetics. But becoming involved in such dedicated settings for communication and coordination can also have unwelcome positioning effects. Parties can become positioned by others as a 'Forum–party', with unwanted consequences such as being associated with other stakeholders that participate in the Forum or becoming seen as co-responsible for Forum statements. We saw how Nefarma did not want to be associated with Niaba because they did not want to be associated with the developments in agricultural biotechnology, because of the negative public image.

3.2.3 The Forum-in-the-making

After the second invitational conference of January 2000, the core group of eight[51] and the STG started a trajectory to prepare for the formal establishment of the Forum Genetics, Health and Healthcare. From the start, there was discussion about the Forum's shape and objective; whether or not the Forum would meet behind closed doors or whether it would serve to facilitate and stimulate public discussion; whether members participated in a personal capacity or on behalf of their organization; whether the Forum would represent a broad or a small range of actors; and whether the forum would serve an explorative and anticipatory role or be more executive. The Ministry of Health had a strong preference for the Forum to play a role in the public debate: a broad range of relevant organizations had to be

[50] More detailed examples of these will be shown later on in this chapter as well as in chapter 4.
[51] Although there were nine parties represented, the core group consisted of eight members. The Dutch Society for Clinical Genetics and the Dutch Association for Human Genetics were represented by the same person.

represented and the Forum had to be active, up to taking a position on governmental policy papers.[52] Other participants argued for a more restricted membership. They argued that a public and broadly representative forum would impede open and free discussion among participating members in a personal capacity. Being able to talk in a personal capacity is important as it enables participants to communicate freely without the risk that the organizations they represent become committed (see section 3.3.1). A small forum was furthermore thought to be more operative. So, in negotiating the shape of the Forum, participants tried to balance the need for communication and coordination with participants' fear to become committed. There were different ideas on how to best strike this balance. The Ministry of Health valued communication among a broad range of different parties, whereas other stakeholders preferred more open communication within a selected group of parties.

It took almost a year before the preparational stage was finished and the Forum Genetics, Health and Healthcare could formally be established. Discussions during this period often wandered from procedural to more substantial issues, which indicates the immediate communicative needs of the organizations involved. The organizations' reluctance to become committed to the Forum became clearly visible during the preparations as some members of the core group reconsidered their Forum membership. The Association of Insurance Companies thought that many of the issues on the proposed forum agenda were not their business. With respect to other issues they thought it be better not to be involved in too early a stage, because of the political connotation and their position as a stakeholder. The Association of Academic Hospitals expressed problems with being formally represented. Eventually, both the Association of Insurance Companies and the Association of Academic Hospitals maintained their membership.[53]

On the 22nd of March 2001 the Minister of Health formally decided to establish the Forum Genetics, Health and Healthcare retroactively as of the 12th of December 2000. The choice for a formal establishment by the Ministry of Health was pragmatic. It was the easiest way of formalizing the Forum. The choice for formal establishment did have consequences though for the further evolution of the Forum,

[52] Interview A. Kruijff, 2000.
[53] Ibid; interview M. Gerritsen, 18-09-2000.

especially concerning the role of the Ministry of Health. The Forum was established for a period of two years. Continuation of the Forum after the initial two years was to be decided by the Ministry of Health, on the basis of an evaluation (FGHH, 2000, p.6). The Forum GHH came to be positioned as a governance instrument and part of the Ministry's policy about which it was answerable to Parliament. The Ministry's representative thus came to have a double role. Apart from being a member of the Forum's preparation group, he also formed a liaison with the Ministry in its role as financer and principal.

Differences of opinion with respect to the position and role of the Forum did not disappear with the formal establishment of the Forum. It is true that in line with the preferences of the Ministry of Health, the establishment decree (in Dutch: 'instellingsbeschikking') consistently speaks of participating organizations. Members of the Forum are appointed by the Minister on the recommendation of these participating organizations. Furthermore it is said in the decree that decision making in the Forum takes place with a majority of present votes and that the Forum functions publicly and broadly. That is to say that the results of the Forum are accessible to third parties and that a large number of organizations is involved (Staatscourant, 2001). The establishment decree thus appears to say that the Forum GHH is a representative forum which is able to take majority decisions and formulate public Forum viewpoints. But it is clear from the presentation of the preparatory stage that that would be at odds with parties' reluctance to become committed. The threat that parties could leave the Forum, which had been very tangible in the preparative stage, remained, and influenced the way in which the Forum operated. During the period of my observations an actual vote on decisions never took place. As far as the Forum made some viewpoints public, it was either on the basis of overall consensus[54] or - if overall consensus was lacking – an overview of different viewpoints and arguments was given.[55] The chance that a situation would occur in which represented organizations might feel bound – even in a loose way - to Forum viewpoints was minimized. That is to say that, situations

[54] That concerns for example the letter that was sent to Members of European Parliament on the "Report on the ethical, legal, economic and social implications of human genetics", composed by the temporary committee on Human Genetics of the European Parliament, also known as the Fiori report.
[55] That concerns for example the first standpoint on prenatal screening (see chapter 4).

in which organizations could be called to account for their position being different from the Forum's position had to be avoided. As the Forum's chair puts it:

> *'And from the beginning we emphasized that the goal of the Forum is to exchange and discuss viewpoints and that it is not a committee in which positions have to be taken, to which the various represented organizations would have to conform. Because that would not have worked.'*[56]

As to the principle of the Forum functioning publicly and broadly, the actual practice was a bit different from what was suggested in the establishment decree. For example, there was initial reluctance to let me observe the Forum meetings. Only after an agreement on publication of my data was signed, I was allowed to be present in the Forum meetings.[57] With respect to the Forum being broadly representative the story is twofold. A two-layered structure was chosen, which consisted of the continuation of the core group of eight and a broad group of participants that formed the actual Forum.[58]

The core group was eventually called the preparation group. It formed the agenda committee for the broader Forum. Furthermore the preparation group prepared draft standpoints for the broader Forum to discuss and compensated for the lack of substantial secretarial support at that time. As was stated in the establishment decree, the preparation group was formed in order to "enhance the operativeness"[59]. Besides these practical advantages, the two-layered structure also formed a de facto compromise between those participants arguing for the benefits of a small and semi-closed forum and those participants who opted for a broad and publicly functioning forum. The Forum functioned in this constellation for about two and

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[56] Interview Lanphen and Gerritsen, 23-05-2002, The Hague, translated from Dutch.

[57] My observations and analysis concentrate on the interactions in the broader forum. Initially I was not allowed to attend the preparation group meetings and I was not able to analyze the interactions and effects. Only in a later stage I observed some of the preparation group meetings. In that later stage the preparation group primarily discussed and evaluated the functioning and positioning of the Forum.

[58] In this broad Forum new members are admitted if they represent a party that is not yet represented in the Forum. The Forum's chair also actively tried to attract new members. That happened for example during a symposium organized on the occasion of the 10th anniversary of the Dutch branch of the medical biotech company Genzyme. On that occasion the chair publicly invited parties to participate in the FGHH (The Hague, 10th of April 2002).

[59] "To enhance the Forum's operativeness, it has been determined to put together from the ranks of the Forum a preparation group consisting of most highly involved participants." (Staatscourant, 2001, translated from Dutch)

half years, from December 2000 until June 2003, when the preparation group was abolished. With the preparation group meeting six times a year, as opposed to the broader Forum meeting only twice a year, it can be expected that the activities of the preparation group had effects of its own. These are not reported in this chapter, since my analysis is mainly based on observations made during the broad Forum meetings.[60]

3.2.4 The Forum Genetics, Health and Healthcare, a multiple knot in a sociotechnical policy network

Basically the Forum GHH was a meeting place for parties who represented a wide variety of actors involved in the development or application of genetics in health and healthcare. In general Forum members shared what they themselves sometimes called a 'positive disposition' (in Dutch: 'positieve grondhouding') regarding developments in medical genetics and medical biotechnology. To further characterize the Forum we need to look at what actually happened during Forum meetings and at what happened as a result of Forum meetings. Information exchange was the main activity during Forum meetings. It was seen as an important function of the Forum and was an important reason for Forum members to participate. Information was exchanged concerning ongoing governmental policy developments such as the formulation of an integrated ethical assessment framework on biotechnology, advisory trajectories such as the one on gene patents and processes of self-regulation such as the one concerning genetics and insurance. The Forum was well suited to this activity, because many Forum members, in particular the members of the preparation group were important spokespersons within the domain of genetics and healthcare. Individually, these members were often invited to participate in public discussions or they were consulted in policy and advisory trajectories. By sharing their knowledge and experience, the Forum was relatively well-informed on what was going on within policy and advisory circles. Information exchange concerned not only factual information, but also entailed the exchange of personal judgments on how policy issues would develop.

The time spent on substantive discussions among Forum members was fairly low, especially in the beginning. On one occasion this was signaled and the preparation

[60] See footnote 57.

group decided to change the format of the meeting in order to stimulate more discussion. Chair:

> *"Previously, in the preparation committee (...) we asked whether they [FM: the Ministry of Health] could arrange a presentation about the way they are presently dealing with those topics, what they are doing at the moment. Of course the Ministry can easily organize this, but such a presentation is of course bound to be very boring. So [FM: we said] let's just, since the Forum is actually meant to be a place for discussion, let's just prepare a couple of propositions."*[61]

Discussion indeed followed, although there was much time spent on clarifying the propositions. At nearly each meeting one or more presentations were scheduled, in which Forum members as well as external guests would inform the members of the Forum on a variety of issues such as the problems experienced with the Population Screening Act, the activities of other organizations such as the Orphan Drugs Platform[62], and the Netherlands Genomics Initiative[63] or the results of advisory trajectories, such as the Bioscience and Policy advisory report, issued by the Council for Public Health and Healthcare.[64] Such presentations were meant to inform the members and somewhat provided the Forum with the character of a study club. In addition, these presentations often formed occasion for some discussion and the exchange of viewpoints.

On some occasions, the Forum GHH functioned as a sounding board or collective for policy consultation. At the very first Forum meeting, for example, the recent Governmental policy paper on the Application of Genetics in Healthcare was discussed (Ministry of Health Welfare and Sports, 2000). Based on this discussion a Forum response to this policy paper was composed. It was intended as input for a round table meeting that was organized by the temporary Parliamentary Committee Terpstra (June 2001). This Committee was preparing the Parliamentary debate on this policy paper. But when the draft response was discussed during the second FGHH plenary meeting, some members argued that they first needed to consult

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[61] Interview Lanphen and Gerritsen, 23-05-2002, The Hague, translated from Dutch.
[62] In Dutch: 'Stuurgroep weesgeneesmiddelen'.
[63] In Dutch: 'Regieorgaan Genomics'.
[64] In Dutch 'Raad voor de Volksgezondheid en Zorg' (RVZ).

with their organization before they could support the Forum's response. Since there was no time to do so, a formal Forum response was not sent. And the Forum's chair who had suggested taking along some Forum members to the roundtable meeting was asked to go there alone to represent the Forum.

From the start there were Forum participants who thought that the Forum should be more than just an informal meeting place, free of commitment. They thought that the Forum should outwardly act as a collective. Occasionally this was tried, such as with the Forum's response to the governmental policy paper on the application of genetics in healthcare. Such attempts were never easy though, and not always successful. One successful example is the way the existence of the Forum served as a lobby group to convince Members of European Parliament against certain amendments that were made to the "Report on the ethical, legal, economic and social implications of human genetics", composed by the temporary committee on Human Genetics of the European Parliament, also known as the Fiori report. The challenged amendments contained a ban on the use of human embryos for stem cell research. An attempt at collective action was also made when the initiative was taken to write a position letter on the need to extend the legal term for keeping medical records, which was considered important for the progress of genetic research.

Apart from these examples of (attempts at) occasional collective action, there were more examples of Forum interactions resulting in concrete actions. The Forum formed a channel through which individual organizations came to engage in bilateral and multilateral activities, external to the Forum:

Forum secretary:

> *If you ask me, it has anyway become a much more intimate group. If you compare to that first meeting, that really was a lot more static. I don't think that there is anyone at the table now who hasn't in some way spoken with the other parties.*

Forum chair:

> *And they also do lots of stuff outside, you know.*

Forum secretary:

> *Yes, lots…*

Femke Merkx:

What kind of things?

Forum chair:

You know, things outside of the Forum...

Forum secretary:

Initiatives outside of the Forum, but initiated by it, thanks to the Forum...

Forum chair:

Yes, because they meet each other here, you can see it happening.

Forum secretary:

Yes, a whole lot coming from industry and the patient organizations, but also a whole lot together with the VAZ[65], a lot's being done with them, and people such as X and Y, who you now can often find within the industry. Well, that wasn't happening at all just 3 or 4 years ago.[66]

To characterize the Forum, the metaphor of a knot within a sociotechnical policy network is helpful. The Forum formed a knot where actors, but also policy documents, information on policy trajectories and visions on future developments were brought together. The effect of this bringing together varied from occasion to occasion and so there are various ways to characterize the Forum. One moment the Forum was an informal meeting place for information exchange, the other moment it was a study club; a forum for discussion; a collective stakeholder; or a sounding board for policy consultation. While what was brought together in the Forum as well as the effect of this bringing together varied, it is the bringing together that is essential. Hence the Forum GHH formed a multiple knot in a sociotechnical policy network.

3.2.5 Changes in the Forum's constellation

Parallel to the different things that are visible in what happened during and in relation to Forum meetings, the projections of Forum members' of what the Forum

[65] The Association of University Hospitals.
[66] Interview Lanphen and Gerritsen, 23-05-2002, The Hague, translated from Dutch.

is also differed. These differences reflect the actual variety of what happened in the Forum, but also reflect differences in the expectations and wishes of what the Forum's role should be. While in many respects the Forum maintained its multiple roles, over time changes took place which strengthened some Forum characteristics while weakening others. The projections of both insiders and outsiders on what the Forum was or should be played a role in this process of change.

A noticeable difference existed in the way in which government initially perceived the Forum's role and how some Forum members as well as the secretary and chair perceived the Forum's role. In the Integral biotechnology report[67] (Ministry of Economic Affairs et al., 2000, p.29) for example, the Forum is discussed under the heading of 'public debate'. But some Forum members as well as the chair and secretary did not position the Forum as an instrument for public debate, but as an instrument for policy consultation. They expressed their discontent with the Ministry not actively using the Forum for policy consultation and as sounding board. That happened for example when the representative from the Ministry reported on the policy initiative to develop an integrated ethical assessment framework for developments in biotechnology and genetics, a policy initiative in which the FGHH had not been involved.[68] More generally, at that time it was not standard practice for the Ministry of Health to proactively inform the FGHH about their policy activities.

Forum secretary:

> *'Beforehand, I had also thought that it would be much more matter of course that we would also receive documents from the Ministry of Health too.'*

Forum chair:

> *'Yes'*

Forum secretary:

> *'And in practice we only get documents from the Ministry after explicitly and persistently asking for them. And that's practice both within the Forum and within the Platform just the same.'*

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[67] In Dutch: 'Integrale nota biotechnologie'.
[68] FGHH plenary meeting, 23rd of May 2002.

Forum chair:

'Yeah, we aren't actively used.

Forum secretary:

[FM: *It's*] *not matter of course.*[69]

While Forum participants expressed their disappointment that the FGHH was not used more actively in policy development, outsiders, perceived the Forum as a privileged and influential group, which they would gladly join.[70] [71] The Forum's chair confirmed this picture of a group of privileged people, in the sense that it is

"of course a very pleasant opportunity to hear exceptional things or meet exceptional people."

But she puts into perspective the idea that the Forum itself is very influential:

"The picture people have of us, is that it's… people of course quickly get the feeling it's a sort of inner circle, you know. That it's just a very small,

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[69] Interview Lanphen and Gerritsen, 23-05-2002, The Hague, translated from Dutch.

[70] Forum secretary: *Although X did mention in the preparation group last time, that when he's in meetings, somehow parties he talks to do look up at the forum, people who would all love to join the forum. Now we don't know who those people are, but he maintained that there is a large group of parties who would really love to….who in some way look up to the forum.*
Femke Merkx: *So what kind of organizations are those, which would like to join?*
Forum chair: *Probably other clinical genetic centers or something comparable. And also more individual parties and private parties, I think. There are of course many private enterprises who are very interested in the things we discuss here.*
(Interview Lanphen and Gerritsen, 23-05-2002, The Hague, translated from Dutch).

[71] The Forum is open to people from "organizations active within or otherwise connected to, the domain of genetics in relation to health and/or healthcare." (Staatscourant, 2001, p.22, translated from Dutch). But, in order to maintain a workable size, people that represent constituencies that are already represented by someone else, weren't admitted.
Femke Merkx: *(…) so are there also people who actually apply and submit a request to be included?*
Forum chair: *All the people who have so far submitted a request, you know, organizations, so far we have accepted them all and we have been able to accept them. For instance recently that National initiative [FM: Netherlands Genomics Initiative], your own [FM: request] as well, that of the clinical chemists, that was it, right? you know, that of [FM: the organization for] health care law. But we did state at the very beginning that if someone is already represented, or somehow there already is a certain representative, then we won't add a second party to the table, since this already is a large assembly, you really can't be much larger. And eh, so if another patient organization wants to join, an individual one such as the Heart Foundation or some such, then we'll say, yes, well the NPCF is already at the table. So, doubling is not the intention.*
(Interview Lanphen and Gerritsen, 23-05-2002, The Hague, translated from Dutch)

influential little club. We're a very small club. Taken together, you can say, we're very influential, but that is mostly due to influence that each party individually wields and not so much the influence that we have as a forum per definition."

On the other hand, the combination of the different influential organizations did have certain effects, exactly because of the public image that was created of being an influential group. The Forum's chair puts it like this:

"But we do of course have a common denominator which allows us to speak on behalf of a large number of parties, and that really is very convenient. And the Forum as such does have its own place. Such as when we are invited to come talk about… with that temporary committee in de the Second Chamber… that says enough of course. That the people we invite to come speak here usually all come, also says enough, in my opinion."[72]

The perception of an inner circle also existed among members of the broader Forum but then it concerned the Forum's preparation group. During the first internal evaluation, which was carried out in May 2002, it appeared that members of the preparation group were more positive about the Forum than the other members (Gerritsen, 2002). This is not surprising, since information exchange was the most important reason for members to participate in the Forum. And because the preparation group met more frequently, there was more extensive information exchange within the preparation group than there was throughout the Forum as a whole. Forum members had the feeling that they missed out on things. When the FGHH's secretary accidentally sent all Forum members an e-mail, which had been meant for the preparation group alone, there were four members who responded that if the e-mail was meant to be an invitation to participate in the preparation group, they would gladly accept that invitation. When discussing the results of the evaluation with the preparation group, the Forum's chair argued to take the Forum members' feelings seriously:

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[72] Interview Lanphen and Gerritsen, 23-05-2002, The Hague, translated from Dutch.

> *"the question lives 'what's happening in that preparation committee? We should be concerned about that, that wasn't our intention. The broad forum should receive our documents and a short account of the meetings."*[73]

Indeed it was decided that all public documents, discussed in the preparation group, would be sent to all Forum members; Forum members would be informed about the agenda, and concise minutes of the preparation group meetings would be circulated. Furthermore it was decided to increase the frequency of Forum meetings. On the other hand, members of the preparation group were of the opinion that, for the preparation group to be productive, it had to remain semi-closed. The arguments used were similar to those that were used in earlier stages when the Forum's form and structure were discussed: in public and open meetings, organizations and their spokespersons will sit back and only voice party lines. It was argued that semi-closed meetings are needed to contribute to policy preparation.

As a result of the evaluation it was furthermore concluded that more secretarial support was needed to be able to prepare the contents of Forum meetings and discussion papers. Extension of the secretariat required extra financial means. In the meantime the end of the formal term of the FGHH had come closer and over the next few months more discussion followed on how to continue the FGHH. The Ministry of Health wanted to combine the FGHH with the Platform Medical Biotechnology under one designation and secretariat, because it was thought there were already too many of these forums.[74] Most Forum and Platform members however did not want to merge, because they thought this would make the agenda too broad. The Ministry's representative further proposed that in time a third branch could be added to discuss developments in agricultural and industrial biotechnology.[75] Such would fit within the governmental ambition towards more integrative policy making. While at some points the relevance of integration was recognized by preparation group members, they were also worried that the negative image of agricultural biotechnology would come to influence the wider developments.

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[73] Preparation group meeting 4th of September 2002, translated from Dutch.
[74] Preparation group meeting, 04-09-02.
[75] Preparation group meeting, 12-12-02.

Preparation group member:

> *We need to be careful that discussions don't become mingled in improper ways. We saw how that worked in the debate concerning the Integral Biotechnology Report.*

Chair:

> *That is an important comment. Scary images can determine public opinion.*

The Ministry's representative also suggested that in the future the Forum could play a role in providing Forum members as well as citizens with information.[76] As secretarial support was already insufficient, preparation group members did not consider this a realistic option.

The future of the Forum was also discussed during the FBG plenary meeting of Nov. 7th 2002. At that time it had become clear that the Ministry's plan to bring together Forum and Platform would include an overall budget cut. The budget cut was part of general economy measures at the Ministry. It was decided to send the State Secretary a pressing letter, explaining the need for more budget. And it was decided that other options for funding should be explored. In January 2003 the Forum chair and secretary together with the chair of the Platform Medical Biotechnology met with the State Secretary to discuss the budgetary problems. The outcome of the meeting was that the State Secretary promised to look into the problem and to investigate how the Ministry could contribute to a solution. As a condition it was stated that Forum and Platform should also look for additional funding opportunities. An e-mail was sent out to all Forum and Platform members requesting support from their organizations. A number of organizations responded positively and promised different forms of support, ranging from financial support to making meeting facilities available. Furthermore it was investigated whether there were funding opportunities through the National Genomics Initiative (NGI), in which nine and a half million Euros would be invested in research and communication on the societal and ethical aspects of genomics research. This attempt to increase the Forum's budget was unsuccessful. Eventually the lack of secretarial support was resolved as both the Ministry and Nefarma - the Dutch Branch Organization for the Research-oriented Pharmaceutical Industry - decided to

[76] Preparation group meeting, 04-09-02.

second one of their employees as parttime secretary working for the Forum/Platform.[77] [78]

More structural changes in the Forum's and Platform's constellation followed. The Forum and the Platform came to reside under one name: the Forum Biotechnology and Genetics. A structure was set up in which the former Forum and the Platform continued their existence as separate Committees (the Genetics, Health and Healthcare Committee and the Medical Biotechnology Committee). On top of the two committees the new Forum Biotechnology and Genetics (FBG) was established. The FBG was made up of members from both committees. The former Platform chair took up the position as chair of the FBG. The former Forum chair got the position of vice-chair. The role of the secretariat also changed. Formerly, only organizational matters were dealt with by the secretary. The expansion of the secretariat with two part-time secretaries made it possible for the secretariat to take up work regarding the preparation of discussion papers and statements. The preparation group of the Forum was abolished.[79] The discontinuation of the preparation group followed from the expansion of the secretariat. Besides, it also met objections which had been raised earlier in an evaluation of the forum GHH, by members of the broader forum. The function of the preparation group was taken over by an agenda committee formed by the three secretaries and the two chairs. Temporary working groups were envisioned for in-depth discussion and for formulating draft papers, something that before had been a task for the preparation group.

Concerning the Forum's formal (or legal) position the Ministry and the Forum's chairs had different preferences. The Ministry wanted the Forum to become a foundation, but the chairs did not think that that was a good idea, as – so they argued - for the long-term continuity was not guaranteed. Also in an earlier stage the FGHH's chair had argued that if the Forum were to be positioned at a distance from the Ministry, it would be more difficult to prioritize general public interest.

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[77] This was announced on February 19th 2003, a day before the Forum's plenary meeting.
[78] In order to support the independent position of the Forum the secretariat would not come to be housed at the Ministry but at the Netherlands' organization for Health Research and development (ZonMw).
[79] The last preparation group meeting was held on June 5th 2003.

Eventually it was decided to install the Forum for a period of three years retroactively as of the 1st of January 2003 (Staatscourant, 2004b).

3.2.6 Ongoing changes: constellation, focus and external influences

On the 7th of April 2003 the former Platform and Forum had their first plenary meeting. From this time onwards, things functioned according to the new structure of the Forum Biotechnology and Genetics. With the new structure and the new secretaries in place, discussion in the Forum became more extensive. A period began in which prioritizing the agenda and developing a focus were main objectives. A work plan, the establishment decree, a long-range policy plan and an activity plan were successively developed and discussed. As a result the Forum's activities became more focused. In particular the Forum strengthened its role as a forum for policy consultation.

Changes became first visible in the way the work plan and the establishment decree were phrased. A draft work plan, addressing objectives, activities, organization form and procedures of the FBG and a draft establishment decree were discussed during the FBG plenary meeting of June 5th 2003. At the meeting someone observed that there were inconsistencies both within the draft work plan and between the draft work plan and the draft establishment decree. In the work plan it was stated that

> *"In principal, no votes will be cast concerning decisions. If a decision is not taken unanimously, as a rule it will be noted that there is also a minority position"* (FBG, 2003c, p.2).

This was considered inconsistent with another part of the work plan that read

> *"The FBG will make its existence widely known by publicly presenting opinions concerning relevant topics. These opinions must be accepted by a majority within the FBG or the Committees"* (FBG, 2003c, p.2).

And in the draft establishment decree it was stated that

> *"Decisions within the FBG and the Committees will be taken based on a majority of present votes"* (FBG, 2003a).

It was decided to remove this last sentence from the establishment decree. Furthermore the phrasing of the work plan was changed so that it became more consistent. The above quotes were changed as follows:

> *"We will not vote about signals to be sent to the ministry of Health or to other involved parties. In case of plural opinions about a topic, as a rule a description of these thoughts will be printed, or the opinions of the participants who form the minority can be mentioned."*

and:

> *"The FBG will make its existence widely known by publicly presenting articles, press releases and documents concerning relevant topics. In these publications, it will be described how the thoughts concerning the topic at hand were weighed against each other"* (FBG, 2003f, p.2).

Thus the aim of making the Forum's deliberations more publicly visible and turning these deliberations into input for the policy process had been made more realistic as it was not required that the Forum would speak with one voice. This was an important step which paved the way for a bigger role for the Forum in terms of policy consultation. The Forum's role change was also reflected in a change of the formal position of the representatives from the Ministries.[80] In the FGHH, the representative of the Ministry of Health had been one of the members. In the establishment decree of the FBG this was changed so that representatives of the Ministries became observers.

It was acknowledged that a plurality of opinions was represented in the Forum and that achieving consensus would not always be possible and would not always be needed. Yet an attempt at finding some common ground among the Forum members was made, in order to enable the secretaries to prioritize the Forum's agenda and activities and because there was a strong wish to act as a collective and to develop shared opinions.[81] As a first step a long-term policy plan 2004-2005 was

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[80] As a result of the merging of the FGHH and the PMB, more Ministries became involved with the Forum. Besides the Ministry of Health, the Ministry of Economic Affairs, the Ministry of Agriculture, Nature Conservation and Fishery, the Ministry of Education, Culture and Science and the Ministry of Finance were represented as observers during Forum meetings.

[81] *"Originally, the contributions of the individual members were as a rule strongly connected to the opinions they brought with them based on their backgrounds and the parties they represented.*

made, which was meant to offer a *"framework to further prioritize activities"* (FBG, 2003b, p.1). A series of meetings that were meant to get the new secretary acquainted with the Forum members resulted in an evaluation of prior Forum and Platform activities. This evaluation formed input for the policy plan. It appeared that Forum members' priorities and preferences of issues to be taken up on the agenda diverged widely.[82] To come to a prioritization of themes, a working group was established which came together once on the 6th of October 2003. The working group formulated five core themes for the next three years. The themes all have in common that they specify aspects of the broader Forum's positive disposition regarding developments in medical genetics and medical biotechnology. But all remain quite abstract. The following themes were formulated:

1. *"To offer a sound contribution to the ethical debate, based on the question 'what should we feel bound to do in the patient's interest?*
2. *To promote more consistent application of current genetic knowledge in health care, to stimulate that patients can profit from scientific advances as soon as possible.*
3. *To facilitate the role of genetics and life sciences in the knowledge economy.*
4. *To boost the debate regarding differences and similarities of European and national legislation, and to point out the consequences for patients, for knowledge acquisition and economy.*
5. *To point out the importance of breaking new ground in research and to promote such research whenever possible"* (FBG, 2003b, p.3)

During the working group meeting, the Forum's secretary who acted as chair, repeatedly came back at the 2005 Forum evaluation, which would form the basis for decision making on extending the subsidy after 2005. He argued that in 2005 things

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This produced a pluralistic approach regarding the various matters people commented on. Although the importance of a multi-faceted opinion shouldn't be underestimated, by now one realizes that it is important to come to more univocal opinions." (FBG, 2003b, p.1).

[82] 'For the prioritization of topics/activities, the following was included in the consideration: The diversity of topics to which FBG-members award priority. The diverging preferences became even clearer during the second series of introductory conversations. Every one mentions a different topic. The only issue mentioned four times is "Integral legislation Biotechnology". "Community Genetics", in the sense of family screening and self-testing, and the topic "Insurability in the standard health care package, mortgages and life insurances" were mentioned twice.' (FBG, 2004b).

needed to be achieved that would justify further funding by the Ministry or that would open other funding opportunities, such as for example the EU 7th framework program. Or else the Forum should make itself indispensable to Parliament. The Forum's secretary spoke in terms of "survival strategies". The draft long-term policy plan 2004-2005 conveyed a similar message[83] and concluded that external communication was crucial:

> *'In conclusion:*
>
> *1) Communication is the primary factor which will have to make third parties aware of the FBG as a relevant party, whose opinions should be taken into account. This is also a prerequisite to be able to enforce commitment for continuing this structure at the end of the subsidy period'* (FBG, 2003b, p.3,4).

The plan was discussed during the FBG plenary meeting of October 2003. As said, the plan proposed five core themes which were still quite abstract. It gave a framework for prioritizing but did not set concrete priorities. Besides it was overly ambitious and further choices were needed. That concerned in particular the four main objectives that had been taken over from the decree of establishment and from the work plan:

- *"Exchange of information, insights and viewpoints concerning new developments;*
- *Assessment of new developments regarding their contribution to health care and public health;*
- *Stimulation of and contribution to balanced communication, opinion forming and decision making by national government, politicians and other involved organizations.*
- *Stimulation of opinion forming in the public domain"*(FBG, 2003b, p.2).

During the FBG plenary meeting it was decided to focus on the first three of the objectives and not to take up a role in stimulating a broader public debate. The main

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[83] *'The FBG has been active since the middle of 2003. For a period of three years, VWS offers a subsidy of 33.860, 36 euro excluding VAT. What will happen after this period is not clear yet. The FBG must prove its right to exist in those three years and will have to look for ways to continue its activities.'* (FBG, 2003b, p.1)

argument was that there are other organizations that already take up that role, such as the Rathenau Institute and the National Dialogue Genetics (also known as the 'Bilderbergconferences'). While this choice was quite easily made, it appeared more difficult to further prioritize the Forum's activities. Both the vice-chair and the Ministry's representative repeatedly tried to draw out a shared Forum ambition:

Representative from the Ministry:

> *I miss enthusiasm. What is it we all feel passionate about, what moves us?* (…)

Vice-chair:

> *We should concretely ask ourselves when we want to have things realized. For example, in 2006 we want to have realized a preconceptional advice for everyone. I also want to say something positive. Talking in itself has added value. We know how to find each other.* (…)

Vice-chair:

> *I'm rather interested, what is it that we would have liked to realize?* (…)

Representative from the Ministry:

> *We can achieve much more than we think. If we work together and come up with a good strategy, then the departments and the politicians can't ignore us.* (…)

Vice-chair:

> *I still miss enthusiasm and heartfelt feelings. I heard one.*

Forum member:

> *We may all harbor our personal heartfelt feelings, what we need is shared heartfelt feelings.*

Vice-chair:

> *"This is what we want to achieve' that's what's lacking.*

Forum secretary:

> *I strongly agree with that. If there are any proposals, the secretariat will take them further.* (…)

Vice-chair:

We need focus, what is it we want to achieve, just like X is saying.

As the attempts to draw out concrete shared Forum ambitions were not very successful, other kinds of considerations were put forward to help prioritize the Forum's activities and agenda. These considerations did not concern the contents of developments in medical biotechnology and genetics, but concerned external conditions which were considered important for the continuation of the Forum's existence, such as evaluation criteria put by the Ministry and the need to become more visible to Forum outsiders. Also the need to align the Forum's agenda with the governmental policy agenda was put forward as an external criterion for prioritizing

Forum member:

Will we be held accountable for goals set in the establishment decree? If so, we need to adjust the policy plan accordingly. (…)

Vice-chair:

It is important to have an issue focus. A position on issues is also necessary when turning to the public at large. (…)

Representative from the Ministry:

We need to consider strategy. What will the Ministry of Health hold us accountable for? That is important too. After all, the Ministry funds us. There is an agreement now up until March. But we don't know what the Ministry expects from us. We need to find out.(…)

Forum member:

When we prioritize things, we need to consider whether the time is right for it.

Chair:

We need to address issues that are on the policy agenda.

The trend that expectations, preferences and opinions of actors outside the Forum were taken into consideration when trying to prioritize the Forum's agenda and activities, continued over the next period. Take for example the meeting of the Medical Biotechnology Committee on November 6th 2003. The day before, Forum

secretary and some Forum members had been present – as public - at a consultation meeting on biotechnology[84] between Members of Parliament and Members of government. The Forum was one of the topics that were discussed. The Forum secretary reported that some of the Parliamentarians had a wrong picture of the Forum and that the State Secretary had difficulties convincing these MPs that the Forum was a good club. A Christian Democratic MP for example, wondered whether the Forum's positive disposition towards developments in medical biotechnology and medical genetics would also imply a positive disposition towards developments such as 'designer babies'.[85] The chair concluded that *"The internal function is very valuable, but now we have to drive towards products and impact, some members of Parliament now harbor an incorrect view of the Forum."* Later, during that same meeting, someone else suggested to strengthen the role of the Forum in anticipating new developments, because Members of Parliament had indicated that new developments had taken them by surprise. Another member suggested taking to heart the State Secretary's suggestion not to get going on the most controversial issues.

So Forum members had started articulating the importance of outsider perceptions for the future continuation of the Forum. To become visible and to become seen to have a positive impact became an important Forum objective. The preferences of the Ministry in particular came to influence the Forum's agenda. On November 27th 2003 the Forum chairs and one of the secretaries met with three representatives from the Ministry to discuss the Ministry's evaluation criteria and to collect input for the Forum's draft activity plan. The outcome of this meeting was broadly consistent with what had been discussed in the Forum's meeting on the long-term policy plan. The forum would focus on the first three main objectives (information exchange; anticipating and assessing new developments; and contributing to the process of opinion formation and decision making) (FBG, 2003e). In order to enable the Forum to take up a role in policy consultation, the Ministry promised to better use the Forum as a channel to explain and communicate governmental policy.[86] It was further announced that concrete subjects or issues for the Forum to

[84] In Dutch: 'Algemeen Overleg Biotechnologie'
[85] The term 'designer baby' refers to the possibility of human genetic enhancement by the combined methods of genetic engineering and in vitro fertilization.
[86] "The Ministry of Health will increase its use of the FBG as a medium to explain the ministry's policy in the area of medical biotechnology" (FBG, 2003e).

take up would be agreed on and that these would form the basis for evaluating the Forum. The Ministry suggested the issue of human tissue engineered products, because in due time decisions were to be made on this issue. Although the Forum secretaries were of the opinion that this issue had no priority among members of the FBG, the issue was indeed taken up and a working group was established. At the FBG plenary meeting of January 22nd 2004 some Forum members expressed their doubts about this topic. One remarked that the Ministry's questions were very complicated and complex. Some one else made critical remarks about the way this topic had been put on the Forum's agenda:

Forum member:

> *I have a procedural question, in what role does the Ministry of Health ask this, as Ministry or as a [Forum] member?*

Chair:

> *As Ministry.*

Forum member:

> *So as an external member, then it is an external request.*

Chair:

> *That fits the model, doesn't it?*

Forum member:

> *This is a test case, I felt that was ambiguous.*

Representative from the Ministry:

> *The background is… In the past, we have agreed on things, we're working on the policy agenda, what role do we project for the Forum? It is important that we can see that the Forum is able to live up to that role. Talking to the secretary and the chair, we said: let's agree on priorities and couple these to measurement moments. Whether you call it a request, or the result of negotiation, does not matter that much to me.'*

Forum member:

> *It's not so much a request. A request would be legitimate. But the motivation must be that it is in the interest of the Forum, or whether the Forum considers*

it of interest. Now, what's labeled the motivation does not primarily follow the interest of the Forum, but the chance to score with the Ministry. I feel that's a weak argument. (…)

Chair:

So do you feel we should not provide technically executive advice?

Forum member:

My remark was procedural, not concerning content.

As the issue of human tissue engineered products was indeed very complex, experts external to the Forum were asked to participate in this working group. Out of thirteen people participating, seven were external experts working for example at the National Institute for Public Health and the Environment (RIVM), the Leiden University Medical Center, Erasmus Medical Center and Isotis, an orthobiology company. Involving external experts was something that now occurred more frequently. In two other working groups that were established at that time, one working on the EU-directive Tissues and Cells[87] and another one working on Biobanks, people from outside the Forum participated. Many of these external participants were researchers who brought in specific techno-scientific expertise. But the working groups were also open to other types of expertise and included for example a member of the Institute for Health Ethics, a Member of Parliament, a representative of an advisory council of the Royal Dutch Academy of Sciences and an expert in medical law. Involving external experts in the Forum's work entailed a change that was recognized and positively evaluated by Forum chairs, secretaries and the Ministry of Health. In a letter that formed the Forum's contribution to the interim evaluation of March 2004 it is said that:

'Increasingly, issue experts are joining in on the working groups, appointed by FBG members to participate with them or representing them in the working groups. This way the content of the issue papers is tested by direct practical experience, aside from the check against the opinions of the umbrella

[87] The working group did not discuss the directive as such, as it was considered too complicated. Rather the working group elaborated on the directive's concrete consequences for research practice. (FBG plenary meeting 23-10-03)

organizations represented by the members of the FBG in the working group' (FBG, 2004a, p.4).

And in a memorandum on "Points for improvement for the Forum Biotechnology and Genetics" written by the Ministry of Health at the occasion of the interim evaluation it is suggested to:

> *"Continue the establishment of so-called expert groups. Explanation: Participation by issue experts in working groups on the recommendation of members is increasing. As such, so-called expert groups are developing. The practical experience that is put forward in the working groups this way is of great value. The content of the issue papers is checked against direct practical experience"* (Ministry of Health Welfare and Sports, 2004, p.1).

Overall the FBG interim evaluation by the Ministry of Health was positive. It also led to another change in the Forum's structure. Abolishment of the separate committees was suggested. This suggestion was adopted. Though for the time being, until the new structure had proven itself, the committees would be kept alive but dormant. Eventually, the evaluation by the Ministry turned out positive and the Forum was to be established anew, first for a period of two years until December 2007 and after that for a period of four years until December 2011. Table 3.3 presents an overview of letters, issue papers and notice papers ('signalementen') that were issued by the FBG in the period from January 2003 until September 2004.

Date	Subject	Form	Addressee	Initiative	Method
23/06/2003	WRR advisory report 'Decision making on Biotechnology'	Notice paper	Ministry of Health, Welfare and Sports	FBG initiative	Based on a forum plenary discussion on the WRR advisory report
14/08/2003	Integrated Ethical Assessment Framework	Letter	Rathenau Institute	FBG/ FGHH (discussion started in FGHH)	FBG working group
14/11/2003	EU-directive Human Tissues and Cells	Letter	European Parliament	FBG initiative	FBG working group with external members
22/01/2004	'Societal agenda Medical Biotechnology'	Report of the group discussions	Project leader BOB project ('Biotechnology as Open Policy process') Ministry of Health	Consultation by Ministry of Health, Welfare and Sports	Group discussions during FBG plenary meeting
09/02/2004	Prenatal Screening and neonatal mortality (I)	Notice paper	Permanent Parliamentary Committee on Health, Welfare and Sports	FBG initiative	FBG working group
08/04/2004	Innovation	Invitational Conference	Ministry of Health and Innovation Platform	FBG in collaboration with Council for Health Research (RGO)	Prepared by FBG working group with external members
26/04/2004	Human Tissue engineered Products	Issue paper	Ministry of Health, Welfare and Sports	Request by the Ministry of Health, Welfare and Sports	FBG working group with external members
29/04/2004	EU-consultation document 'Proposal for a harmonized framework on human tissue engineered products'	This is a modified version of the Issue paper on Human Tissue engineered products	European Commission	-	FBG working group with external members
16/09/2004	Prenatal Screening (II)	Notice paper	Ministry of Health, Welfare and Sports - Permanent Parliamentary Committee on Health, Welfare and Sports	FBG initiative	FBG working group
16/09/2004	Biobanks	Issue paper	Ministry of Health, Welfare and Sports - Permanent Parliamentary Committee on Health, Welfare and Sports	Suggested by the Ministry of Health, Welfare and Sports	FBG working group with external members

Table 3.3: FBG output from January 2003 until September 2004

3.2.7 The Forum Biotechnology and Genetics, on the conception of a hybrid forum

Within a wider policy network which is concerned with the governance of innovations in medical biotechnology and medical genetics, the Forum Biotechnology and Genetics forms a new and a unique arrangement in which the pole of the sociopolitical and economic, the pole of the techno-scientific and the pole of the legislative-regulative are brought together. At the same time the FBG is as a forum in which actors are represented that play a role in the configurations of responsibilities in which novelties in medical genetics and in medical biotechnology become embedded. In both respects the Forum Biotechnology and Genetics forms a hybrid forum. As the FBG represented a new and unique arrangement there were no similar arrangements that could serve as a role model.[88] This explains why much time was spent discussing and negotiating the Forum's role, the organizational structure and the rules of engagement.

Initially, there existed different views on the role of the FBG, both among Forum members themselves as well as among Forum outsiders. As a result – and especially in the early phase of the Forum's existence (FGHH) - the Forum took on multiple roles: ranging from an informal meeting place for information exchange, to study club, a discussion forum, a collective stakeholder and a sounding board for policy consultation. In the early stage the Forum is best characterized as a multiple knot in a sociotechnical policy network. It started as a bottom-up initiative of a collective of actors, who were all somehow involved in the development of medical genetics and medical biotechnology.

Over time the Forum gradually evolved from a loosely structured meeting place where members' need for communication, information exchange and alignment formed the main driver, into a more structured arrangement for hybrid policy consultation, where the wish to preserve the Forum became leading in determining the activities of the Forum. As a result the Forum became more strongly directed to meet the projections and objectives of Forum outsiders whose support was thought

[88] Sometimes Forum members referred to the British Human Genetics Commission (HGC) as a role model for the FBG, though it was recognized that the HGC's position is very different from that of the FBG. The HGC is "the UK Government's advisory body on new developments in human genetics and how they impact on individual lives." (Source:http://www.hgc.gov.uk/Client/index.asp?ContentId=1). The HGC is much better facilitated than the FBG and it is also more focused on discussing social, ethical and legal issues and on promoting public debate.

to be crucial for the continued existence of the Forum. This process can be characterized as a process of reversal, because the Forum of which the establishment was initially driven by the communicative needs of its members, now turned itself into the main driving force (Disco & Van der Meulen, 1998a, 1998b; Van den Ende, 1994).

Reversal started off when the Forum came to be seen as an entity acting on its own accord and was no longer considered primarily as a meeting place. In the notion of the Forum-as-a-meeting-place, the initiative for, and control of what happens, lies with the individual members who choose to meet and to exchange information. When conceiving the Forum-as-an-entity, expectations, perceptions and ideas on what the Forum is or should be, influence what is and can be done in the Forum. It is not just the perceptions or the role expectations that matter. What matters is a combination of role expectations on the one hand and decisions that are made to enable these roles on the other hand. Or to put it differently, because of role expectations, concrete decisions are made to enable these roles, which then further influence what the Forum can do and how the Forum is perceived. In that respect, the notion of the Forum as an entity that is acting on its own accord already began when an independent chair was appointed. Even though the Forum at that time was still primarily a meeting place, the presence of an independent chair who could speak on behalf of the Forum created the possibility for the Forum to be represented as an entity. That happened for example during the round table meeting which was organized by the temporary Parliamentary Committee Terpstra; some Forum members represented their own organization, whereas the Forum's chair represented the Forum.

At a later stage, when the FGHH and the PMB were brought together and secretarial support increased, the Forum-as-an-entity gained further momentum, as now there was not only the chair, but also two Forum secretaries who acted in the service of the collective of actors represented in the Forum. To enable the secretaries' work there was a need for prioritizing the agenda. Because it appeared hard for the secretaries to find shared priorities to work on, actors external to the Forum increasingly determined the Forum's agenda. That was the case for some of the issues that had been proposed by the Ministry of Health in the context of the agreements on the Forum's evaluation. But it also applied to the issue of biobanks, for which the enthusiasm to participate in a working group appeared to be high, but

only after the issue had raised the interest of a politician: the issue had not come up in the earlier inventory of issues to be discussed in the Forum. Maybe Forum members had just not thought about it at that time, but it seems that the fact that a Member of Parliament was interested in the issue was important to raise Forum members' interest. External actors also became involved in the Forum's discussions: external experts were invited to participate in the working groups, because working groups were established regarding issues in which the Forum did not have enough expertise.

3.3 Multiple representations, multiple effects

Hybrid forums such as the FBG may play a productive role in processes of organizing responsibilities as they form a microcosm of the wider world in which the wider world is presented anew. This second part of this chapter addresses the question which aspects of the wider world are represented in the FBG in what way and with what potential effect. As was shown above, the FBG forms a multiple knot in a sociotechnical policy network and there is no one single answer to the question what is represented and how the FBG may contribute to organizing responsibilities. Yet it is possible to distinguish between different modes in which the wider world is represented in the FBG. I will present four vignettes that provide main examples of these different modes. At the end of this chapter I will reflect on the effect of these representations and how these may contribute to processes of organizing responsibilities.

In the first vignette I will show how FBG members ambiguously represent wider world parties and constituencies. On the one hand they speak in a personal capacity, on the other hand they are important spokespersons representing a specific organization. In the second vignette I will show that many Forum members were strongly motivated to realize the application of genetic and biotechnological innovations in Dutch healthcare. This vignette draws attention to an important aspect of the wider world, which I did not explicitly theorize in my conceptual framework. Novel developments do not simply emerge. Rather many novel developments start off as expectations and promises, which are propagated by actors who want to see these expectations and promises materialize (Van Lente, 1993). It appeared that many of such actors were represented in the FBG. I will argue that with their attempts to enroll the Forum in fostering new developments, a

bridging setting (Garud & Ahlstrom, 1997) was created. In chapter two I developed the idea that hybrid forums can be productive in organizing responsibilities, because they form settings for accountive prospective responsibility positioning outside the immediate context of local practices. The third vignette shows examples of such third-order prospective accountive responsibility positioning. Finally in the fourth vignette I will show how the FBG sometimes is expected to represent the diffuse hybrid forum and functions as a sounding board.

3.3.1 'Speaking in a personal capacity': ambiguity of forum membership

How a Forum member relates to the group or organization he or she represents, was an important and ongoing point of discussion among Forum members. According to the establishment decree Forum members were represented on recommendation of a particular organization. That does not imply that Forum members formally represent these organizations. During meetings it was repeatedly stated that Forum members speak in a personal capacity, without a mandate from the organization they represent and without requirement of consultation. Also it was repeatedly stated that people participated in the Forum because of their expertise in or involvement with the developments of medical genetics and medical biotechnology and not as formal representatives of organizations and stakeholders.

So Forum members spoke in a personal capacity. The curious thing is that this was emphasized again and again in nearly each meeting. Why was it felt necessary to do so? First of all because it was not so obvious that Forum members spoke in a personal capacity. Not only because they were represented on recommendation of a specific party, but also because many of them happened to be one of the main spokespersons of the organization by which they were recommended. I argue that the repeated statement that members speak in a personal capacity is a rhetorical device with which Forum members and facilitators tried to create a productive boundary between the Forum and the wider world. The statement reminded the Forum that its members *are* indeed important spokespersons in the wider world and that it is good to have them in the Forum for that reason, while simultaneously it was used to create an atmosphere within the confines of the Forum in which Forum members could speak freely. Thus, the representative status of Forum members was ambiguous. They did not formally represent an organization or party, nor did they merely speak on a personal title. Their representational position was somewhere in

between these two extremes and varied somewhat between occasions and also between people.

This ambiguous representational status needed continuous construction. In part it was discursively constructed. For example in phrasing the formal FBG establishment decree. While the establishment decree of the FGHH only mentioned the organizations that recommend the Forum members, the establishment decree of the FBG on the other hand, mentioned both Forum members and organizations by name. The phrasing of the establishment decree was discussed in the Forum. At the request of one of the Forum members, the order of the wording was changed, so that persons were mentioned first, followed by the organization by which they were recommended. This order was chosen to reflect that Forum members participate in the Forum in a personal capacity.

Discussions about representational status typically arose at those occasions where it was suggested that the FBG should formulate standpoints. On those occasions the ambiguous representational status of Forum members created particularly tense situations. Because the Forum lacked a strong mandate, there was a propensity to strengthen the authority of the Forum's standpoints by pointing out that Forum members are appointed on the recommendation of a specific organization so that the Forum in this regard is broadly representative. Individual organizations on the other hand feared to become bound to Forum viewpoints that they did not share. This fear needed to be dispelled. For example, in the case of the Forum's position letter regarding the WRR advisory report, a footnote was added, which read as a disclaimer:

> *"the opinion of the FBG describes the possible implications of a matter discussed by the FBG, seen through the eyes of a wide variety of experts. Individual members of the FBG do not act as representative or spokesperson for their faction or employer. As a consequence, no formal position is assumed"* (FBG, 2003d).

This disclaimer construction did not in all cases resolve the tensions of ambiguous representation. Two Forum members in particular expressed problems. One of them stated that she was not able to speak in a personal capacity. The other argued that she had problems with the Forum issuing standpoint letters, because members are represented in a personal capacity. Interestingly, outside of the Forum, both these

members participated in formal negotiations to lay down the Protocol Insurance Examinations. This Protocol formed a self-regulatory measure providing representative organizations of insurers, patients and medical professionals with the opportunity to fill in the details of the Medical Examinations Act, an Act which regulates the use of genetic data by insurers.[89] While the issue of genetics and insurance selection was a main concern for many people involved in the Forum and an issue which had been on the agenda since the first VSOP invitational conference in 1997, there had never been any attempts to formulate a Forum standpoint on the issue of genetics and insurance. Instead the progress and outcome of the self regulatory process were regularly reported on in Forum meetings. The example of the genetics and insurance issue shows that speaking in a personal capacity is avoided between Forum members who are also engaged in formal negotiations.

The construction of ambiguous representational status also influenced organizational choices that were made. When discussing how the FGHH should proceed after its initial two years of existence, someone suggested allowing participating organizations to make financial contributions to the Forum. Initially this suggestion was not followed, as someone else argued that "*that conflicts with the idea that we are here in a personal capacity.*"[90] A little while later though, when it appeared that the Ministry would cut down the Platform and Forum budget, Forum members proved not to be rigid on this point. The previous argumentation was abandoned as at that time participating organizations were asked for financial contributions.

The ambiguous representation that we find in the FBG needed permanent and careful construction. As a result there was a lot of talk on representational status and related issues such as the objective of the Forum. These discussions came at the expense of more substantive type of interactions and discussions. Especially in the start-up phases of the Forum, this kind of discussion could dominate.[91] Forum members perceived the added value of their ambiguous representational status and

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[89] The Medical Examinations Act regulates the use of genetic data and medical (genetic) examinations by insurers and employers. In chapter 5 and chapter 6 I will discuss the issue of genetics and insurance selection in more detail.

[90] Preparation group meeting, 04-09-02.

[91] As a Forum observant I was initially greatly disappointed by what I encountered in the forum's meetings. There was endless talk about what the forum could or should be and about what could or should be done, but it seemed that hardly anything was actually 'going on'. I had to adjust many of my prior expectations about the kind of analyses that I could make.

they consciously constructed the setting of their interactions so as to achieve that added value. The quotes below illustrate this. The setting was a preparation group meeting, where one of the preparation group members, who represented organization X proposed to involve Forum and Platform in a meeting of his organization. The occasion was that organization X was facing major budget cuts. To safeguard the organization's future, a business plan had been written with which the organization tried to raise support from public and private bodies. A meeting was planned to present and discuss this business plan. The Forum member representing organization X wanted to involve the Forum and Platform in this meeting. When he brought up this idea in the preparation group meeting, a discussion ensued which started by emphasizing that Forum members are represented in a personal capacity and do not formally represent their organization:

Forum member representing organization X:

(...) Organization X invites the platform and the forum.

Forum member A:

They are invited as organs?

Forum member representing organization X:

Not just as organs, definitely also as parties.

Chair:

You know that the people here represent their organizations without the requirement of consultation.

Forum member B:

Necessarily so.

Chair:

That is the golden formula of this Forum.

Forum member B:

They are individuals with a certain position within the debate, not isolated from the world at large, yet the people here do not formally speak on behalf of organization Y. That complicates internal tuning too [FM: he's talking about

tuning in to the opinions of the organization they 'represent']. I don't have to explain that to you. It is less of an issue in our case, but still.

The added value – or golden formula – of ambiguous representation as it is perceived and articulated by one of the Forum members consists of the fact that Forum members have a position in the debate (as would be the case when organizations were formally represented) and yet there is no need for consultation with other members of one's organization, which means that instant discussion is possible. Then the setting of the meeting was discussed. The Forum member representing organization X announced that he wanted to invite other organizations that were not participating in the Forum:

Aside from this, we would like to invite other parties, representatives of trusts for instance. I have to think about that some more.

Forum member A:

All at the same time?

Forum member representing organization X:

Considering the time, it will be hard not to do this at the same time. (...)

Forum member B:

Then the Forum will first have to debate this itself. Apparently, there is sufficient cause for discussion: 9,5 million [FM: will be spent on the Centre for Society and Genomics], the invitation by organization X. This is of importance for the Forum itself anyway. (...) Then you have something to refer to. The Forum can't take up a position itself together with others.

Forum member representing organization X:

The Forum is a sounding board, people attend in a personal capacity.

Chair:

That's different from what you said before.

Forum member representing organization X:

That's correct, I am also still exploring.

Chair:

The idea of consultation is quite clear. That's possible without prior analysis [FM: regarding the opinions gathered in the Forum]. Analysis requires substantive [FM:secretarial] support. That is lacking. (…)

Chair:

I suggest joint consultation of the Forum and the Platform. As a representative organ, it is possible to take up a position without pinning down the individual parties. As such, there is rather little compunction to say something. I don't think we should take it any further than that, or you make things really difficult. We don't necessarily all have to be present.

The suggestion to invite other than Forum members to the meeting was not welcomed by the preparation group members: the Forum cannot take a position together with other parties, it was claimed. Instead it was suggested that organization X would consult the Forum and Platform and so use them as a sounding board. But, the Forum member representing organization X still wanted to involve other organizations and suggested that they could be invited as audience.

Chair (addressing representative of organization X):

Are you satisfied?

Forum member representing organization X:

Yes, but at least possibly invite people as non-participant observers.

Chair:

No, let's not. That's asking for lids.

Forum member B:

Who would you want to invite?

Forum member representing organization X:

External financiers.

Chair:

It should be possible [FM: to deal with them] with written advice.

Forum member A:

I agree with the chair

Forum member C:

Yes, me too.

Forum member A:

We don't know what will come to the fore, we must have the possibility to talk openly. If financiers attend, I would feel inhibited.

The Forum members' reluctance to let external parties listen in to their meeting illustrates how Forum members want to be somewhat shielded off from the wider world, so as to be able to speak in a personal capacity and to discuss things openly. Inviting external parties would be asking for lids.[92]

Interestingly, and in contrast with the claim made above that the Forum cannot take a position together with other parties, at some later occasions external experts were invited to participate in working groups and shared positions have actually been issued. For example, a letter to Dutch Members of European Parliament about the EU-directive "Tissues and Cells" was composed by the FBG in collaboration with the Netherlands' organization for Health Research and Development (ZonMw) and co-signed by a number of organizations, part of which were represented in the Forum and part of which were not represented in the Forum (FBG, 2004a). Apparently, the specific context of an issue or a discussion influences whether members prefer to construct a shielded setting to enable free discussion with participants speaking in a personal capacity or whether they allow a more open setting so as to enable external organizations to participate. To conclude, the FBG's members' ambiguous representative status is productive because it provides room for maneuver in which the drawbacks of formal representation on the one hand and of contributing in a personal capacity on the other hand can be mitigated.

[92] Eventually the Forum member who represented organization X decided not to invite the Forum, but to organize a meeting to which he invited a variety of organizations, including some of the organizations that were represented in the Forum.

3.3.2 The Forum as a bridging setting in a sociotechnical policy network

The Forum formed a knot in a sociotechnical policy network, where intermediary organizations, policy documents, information on policy trajectories and visions on future developments were brought together. Initially it was foremost a meeting place where information and visions were exchanged, but from the beginning there were also members who wanted the Forum to achieve more concrete results. Forum members shared a positive disposition towards the application of genetics and biotechnology for healthcare purposes and many were strongly motivated to realize the application of genetic and biotechnological innovations in Dutch healthcare. Some individual Forum members had strong and concrete ideas about what was needed and they actively tried to convince others to adopt these ideas. Those others typically included parliamentarians and policy makers, but could also be other actors that needed to be enrolled. Examples of what some Forum members thought was needed are listed below:

- The development and implementation of preconception healthcare;
- The implementation of prenatal Down syndrome screening;
- Changing the reimbursement structure for orphan drugs so as to enable their development;
- Increasing the use of genetic testing in the diagnosis of children with rare diseases in order to shorten the long periods that are often needed to diagnose rare diseases when using regular clinical techniques;
- An extension of the legal term for keeping medical records, which was considered important for the progress of genetic research.

For those Forum members who had strong ideas on what is needed to realize the application of genetics and biotechnology in healthcare, one way of achieving concrete results through the Forum was to use the Forum as an ambassador for their own ideas. When they tried to do so, they were confronted with interests, opinions and knowledge other than their own. Take for example the draft position letter on the need to extend the legal term for keeping medical records, which had been prepared by the FGHH's preparation group. When the letter was discussed in the FGHH plenary meeting two Forum members argued that a debate was needed, because they thought that their organization might have interests that were not yet

taken into account in the draft position letter. Eventually such a debate did not take place because there were other reasons[93] not to send out this position letter. Yet, the example makes clear that within the Forum, actors who promote a specific scenario – in this case the development and application of genetic research by making long-term medical records available – are confronted with the possible conflicting interests of other actors involved in the scenario. Thus, Forum interactions generated events where those who try to enact certain techno-scientific scenarios and those who need to be involved to make these scenario's come true, probe each others' "realities". Garud and Ahlstrom (1997) have used the term 'bridging events' for occasions like these.[94]

My claim that Forum interactions generated bridging events should not be misinterpreted. I do not imply that bridges between different positions are necessarily built or that consensus develops on what scenario to follow. The primary effect of these bridging events is rather a learning effect, in which it becomes clear that positions and views differ between Forum members. That in itself is important, as it can form a starting point for developing innovation scenarios that are shared among a broader range of actors, enhancing the possibility that "appropriate technology evolves over time" (Garud & Ahlstrom, 1997, p.46). Some Forum members were indeed of the opinion that the development of shared ambitions and viewpoints should be an important Forum objective. In particular, this concerned the representative from the Ministry and the Forum's chair. At the last meeting of the FGHH preparation group, members reflected on the Forum's objective and function. The Minister's representative said what he envisioned:

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[93] One reason was that in the mean time a number of advisory councils had taken up the issue. One of these was the Health Council. It was argued that the Forum's position letter would never be as profound as the Health Council's advisory report and that the Forum should not sit on the Council's chair.

[94] Garud and Ahlstrom (1997) have shown how the co-evolution of medical technology involves different types of assessment approaches, which are employed by different constituencies and in different stages of technology development. The main difference in assessment approach is that between the insiders and the outsiders of technology development. The insiders of technology development are typically engaged in bringing a particular type of technology development to fruition and tend to frame the assessment in terms that suit the strong aspects of that particular technology. The outsiders of technology development on the other hand take up a comparative perspective in assessing a technology, which enables them to select between different technological options. Thus insiders and outsiders of technology development perform different roles in technological change. Insiders perform enactment cycles which result in a proliferation of different innovative paths, while outsiders perform selection cycles which result in a focusing of efforts.

We have to see where the [diverse] viewpoints [within the Forum] overlap, where we meet. For us, it is important to develop a vision on large themes such as innovation. That way it becomes possible to walk the same path and join forces. The strategy should be to develop shared goals.[95]

The Forum GHH's chair sided with him and stated that she considered it her task to stimulate the Forum to come up with such an overall vision. It was also one of the reasons she wanted to expand secretarial support:

"*We need a substantive secretariat, not just input coming from the members. I've noticed that people do not sufficiently offer input that goes beyond the separate party views."*[96]

Not everyone wholeheartedly embraced the ideal of developing shared ambitions, as had been propagated by the Minister's representative. One of the preparation group members interpreted this ideal as an undesired attempt to steer developments:

"It sounds to me like wanting to turn the steering wheel. Myself, I am the kind of person who prefers to say 'provide people with the means, let things happen.' Then you'll automatically find out what works and what doesn't. That's another way to perceive your role. Let the free market and the user say what should and what should not be used. Let the ministry facilitate and make sure things do not get out of hand."[97]

Some one else articulated a more modest way in which the Forum should aim to be a bridging setting: in issuing viewpoints the Forum should represent the collective opinion that comes out of the interaction between Forum members' different view points. This Forum member referred to a situation in which one of the preparation group members had taken the lead in writing a position letter on a policy initiative; a route which he thought had not produced the sought-after result:

I felt rather at a loss in the determination of our position regarding [policy initiative A]. (...) I tried to come up with something better myself, but I

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[95] Preparation group meeting, June 5, 2003.
[96] Preparation group meeting, January 30, 2003
[97] Preparation group meeting, June 5, 2003.

eventually ended up in an organizational knot. It's not about my personal opinion nor about the position of my organization. With just one hour of joint discussion about this topic, we should be able to get much further than the memo we have now. (...) While the Parliamentary question underlying all this is of importance. (...) In our reaction we need to represent what we, as a collective in interaction, feel about this topic.[98]

The secretary responded that this route had been followed because of time constraints. In a later stage a working group on this issue was still established.

So, since medical-genetic and medical-biotech future scenarios were represented in the Forum, almost by definition Forum interactions generated bridging events. While initially these bridging events formed the unplanned products of Forum interactions, once they occurred and once they had demonstrated the gaps between different actors' views, bridging itself became to be seen as an important Forum objective and Forum facilitators and some of its members started to consciously enact and to construct the Forum as a bridging setting. That development was further strengthened as it was realized that the Forum had to become externally visible in order to gain support from Forum outsiders, on which the future of the Forum depended, e.g. Members of Parliament and the Ministry of Health. Working groups were established in which issues were discussed with the aim of composing Forum viewpoints.

3.3.3 Third-order prospective accountive responsibility positioning

In chapter two I developed the idea that hybrid forums can be productive in organizing responsibilities because hybrid forums function as settings in which third-order prospective accountive responsibility positioning take place, which then feed back into local sociotechnical practices. A first finding is that explicit third-order prospective accountive positioning occurred only infrequently in the meetings that I observed. I present and analyze a clear example here.[99] I examined the entire Forum meeting in detail, but in my presentation of the data I focus on those parts of

[98] Ibid.
[99] Another example will be presented in chapter 4 where I will analyze the FBG's contribution to the discussion on the introduction of prenatal screening in Dutch health care.

the interaction in which third-order prospective accountive responsibility positioning occurred.

The issue that was discussed in the meeting of the Genetics, Health and Healthcare Committee (CGHH) of 26 August 2003, is the Baby Kelly Case. It concerns a court case in which the parents of the multiply handicapped baby Kelly held a hospital liable for the wrongful life of their child, because the hospital had not offered prenatal diagnostics to Kelly's parents. In March 2003, the Court of Justice of The Hague judged the wrongful-life claim of the multiply handicapped baby Kelly as legitimate. It was the first time a Dutch court allowed this claim. The wrongful-life claim is related but principally different from the wrongful-birth claim. A wrongful-birth claim is made on behalf of the parents and refers to wrongdoing and harm to the parents as a result of the birth of a handicapped child. The wrongful-life claim is made on behalf of the child and refers to the wrongdoing and harm inflicted on the child itself for being born handicapped. The hospital that was held liable appealed to the Supreme Court of the Netherlands.

The meeting of the Genetics, Health and Healthcare Committee of the FBG started with a presentation by an invited speaker – a legal scholar – who informed the members of the CGHH about this case. The speaker presented various legal aspects of the case and offered a legal argument in favor of the wrongful-life claim. His presentation and the discussion that followed represent an instance of how the FBG formed a 'platform' for information exchange.[100]

There is more to the meeting than just an exchange of information and legal argumentation. At various moments participants in the meeting engage in third-order accountive responsibility positioning. The invited speaker did so a number of times. One example is how he referred to Dittrich, a liberal Member of Parliament, jumping on to this case: "*As usual, Dittrich wanted to be the first to get into an issue*". In a more neutral reporting style he continued to describe how Dittrich had pleaded for legislation to prohibit wrongful life claims. Another example of third-order accountive responsibility positioning occurred when he reported that the

[100] One of the committee members who was not present at the meeting, but who had received the speaker's article, noted on a later occasion that: "This fits well within the Forums' function. X sent me the article. Unfortunately I couldn't attend the meeting. But, on the basis of that information, our organization determined its viewpoint."

medical professions, midwives and obstetricians are still considering what their view is, and commented:

> *"I think that that is good. One should not rush into adopting a viewpoint in matters like these."*

Such accountive positioning of actors that are not present at the meeting can still have effects. One effect is that such positioning is accepted and used on other occasions. Another effect is that Forum members present, who are in a similar situation as the actors positioned by the speaker, are indirectly positioned in these speaking acts. The speaker also positioned the Forum members directly. After listing the viewpoints various societal actors had taken on this case, he continued:

> *'These are extremely diverse viewpoints. Which is good for the debate. Eventually, the legal experts will decide. It is a good thing that this position has been taken. As long as it is before the Supreme Court, a moratorium is in place.'*

He then invited Forum members to voice their opinion on this case:

> *'You can now voice your opinion, now the time has come for a societal debate.'*

This is first order positioning of Forum members in their role as spokespersons for viewpoints on the case.

Subsequently, he made his invitation to voice opinions more specific, after presenting an overview of what he called 'slippery slope arguments', i.e. arguments claiming that while adjudging this wrongful life claim may be acceptable it could (and would) lead to future developments and situations deemed undesirable. The speaker presented six such arguments. Adjudging the wrongful life claim can eventually lead to:

1) a duty to carry out prenatal diagnosis;
2) claims from children against their parents;
3) a rise in the number of abortions;
4) eugenetics;

5) a claim culture;
6) claims for less serious injury.

After the presentation the Committee's chair opened the floor for discussion, inviting Forum members to voice their opinion. The discussion focused on the slippery slope arguments and third-order prospective accountive responsibility positioning occurred. That is to say that Forum members accounted for their prospective responsibility position in relation to cases similar to the one in the court case. Both the speaker and the Committee's chair explicitly invited the Forum members to position themselves in that way.

Speaker:

> *'I am trying to gauge the sentiments (here) how society is predisposed towards prenatal diagnostic tests. Are they a right or an obligation? Lawyers can incorporate such societal feelings in their judgment.'*

The chair then explicitly addressed the geneticists represented in the Forum and asked them to bring forward their viewpoint. The response of both geneticists confirmed that adjudging the wrongful life claim would have an effect on geneticists' prospective behavior.

Geneticist A:

> *'It increases the incentive to inform people.'*

Geneticist B:

> '*You can't make any mistakes, it offers a strong incentive toward that direction.'*

The geneticists' self positioning then gave occasion to prospective accountive responsibility positioning of geneticists - or medical professionals in general - by a representative of the Ministry of Health, who said*:*

> *'One should only provide information when this makes sense based on medical insights. As a care provider, one should continually ask oneself: 'Is there a point to this?'*

The emphasis on 'continually' implies, first that there will not be a general rule, the medical professional has to judge each case on its own terms; and second, a suspicion that eventually, medical professionals might prefer to inform their patients on medical options, even when they think that from a medical perspective informing does not make sense.

The second slippery slope argument, about children holding their parents liable for their wrongful life, was discussed briefly.[101] Again third-order accountive responsibility positioning occurred. One of the geneticists argued that children claiming against their parents went too far as parents have a freedom of choice in these matters.[102] According to him prospective parents do not have an obligation to prevent the birth of a handicapped child. This positioning act was accepted by the other participants. It also gave occasion to further reflections on the wider moral order that structures responsibility positioning vis-à-vis handicapped children. One of the patient representatives spoke up for the prospective handicapped child and articulated the child's prospective rights:

> *"I am trying to accommodate the claim of a child. You have a right to adequate medical care. Rightful claims are at issue here."*

The issue implied here is: who is responsible for the medical care for handicapped children. Raising this issue suggested that future developments might change the current situation in which medical care for handicapped children is provided as part of social security arrangements. As prenatal diagnostic opportunities increase and parents come to decide whether or not they choose to prevent the birth of a handicapped child, one argument can be that the responsibility to provide for medical care should then shift from the collective towards individual parents. That is definitely not the direction that was propagated by the participants. The immediate response of the Chair to the patient's representative claiming the child's right to medical care, was:

> *"That is a claim directed to society as a whole"*

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[101] The other slippery slope arguments did not get discussed as time was too short.

[102] *"In our society, freedom of choice is of major importance. Others should not lay claims in these matters. Wrongful life claims by children against their parents move beyond what is acceptable."*

and the patient representative elaborated:

> '*Yes, if society professes, that decision [FM: whether to enable diagnostics or not] was taken 18 years previously, then that claim should be directed to society. That is a different kind of claim. Children who lay claim against their parents, this is conceivable, yet not desirable. To prevent this, health care must be of good quality.'*

Interestingly, towards the end of the meeting the chair asked whether developments like the ones discussed in this meeting can actually be predicted. This question reflects an instrumental way of looking at the debate. I have shown that in addition to the attempts to predict developments, future responsibilities were anticipated and discussed. In my analysis this is more important than predictability. The added value of the discussion in this meeting lies in the contributions that were made (– however small –) in negotiating and co-constructing the future developments. While there are no data about the effect of the third-order responsibility positionings in this meeting on the actually enacted responsibilities in the local sociotechnical contexts, the possibility of a linkage between local setting and forum setting was recognized by the speaker. At the end of the meeting he once again called on the participants to bring forward their viewpoints in the public debate and he specifically called on insurers and the medical professions to bring clarity in the criteria for offering prenatal diagnostics:

> *"If that clarity is lacking, than you make yourself very vulnerable for 'personal damage suits'"*

In other words, he built on the ability of the medical professions and insurers to draw up (medical) guidelines as a means to govern the professionals' role responsibilities locally.

While these examples show interesting features, third-order prospective accountive responsibility positioning did not occur very often in Forum meetings. What was different in this Forum meeting compared with other Forum meetings? First of all, a legal court case was discussed, which in itself is a strong case of retrospective accountability positioning. Then, slippery slope arguments were presented which relate acts of retrospective accountability positioning to acts of prospective

responsibility positioning. Also because some of the positioned actors were present there was occasion for third-order prospective accountive responsibility positioning. Because slippery slope arguments reflect prospective storylines third-order prospective accountive responsibility positioning was induced.

A second noticeable difference between this Forum meeting and other Forum meetings is that both the chair and the speaker explicitly invited Forum members to position themselves, in particular with respect to the storylines behind the slippery slope arguments.[103] Third-order responsibility positioning was thus evoked by acts of first order positioning. The speaker supported these acts of first order positioning by self-positioning his own profession, saying that:

> '*Legal professionals are troubled by slippery slope arguments. They are speculative, we do not know what the future will be like'* and also that *'Legal professionals can weigh such societal feelings in their judgment.'*

In other words – according to the speaker - it is societal actors' responsibility to articulate and negotiate what a desired future would look like and it is the responsibility of legal professionals to take these societal feelings into account when formulating a judgment on the legal case.

Third-order prospective accountive responsibility positioning occurred also at a plenary Forum discussion on the advisory report on 'Decision making on Biotechnology' from the Scientific Council for Government Policy (WRR, 2003). Interestingly the circumstances during this meeting resembled those of the Baby Kelly case meeting. Again there was an external speaker – in this case one of the authors of the report – who introduced a prospective storyline in which new responsibilities were articulated.[104] And again the chair played an important role by

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[103] In a later stage, the speaker would reiterate this request to bring forward opinions on this case. Some of the organizations represented in the FBG answered this request. The FBG itself did not issue a standpoint on this case.

[104] This prospective storyline concerned the responsibilities for dealing with the risks involved in the introduction of novel applications of biotechnology. It was suggested that *'risk liability'* (risicoaansprakelijkheid') should be the leading principle in attributing responsibility and accountability and not *'culpability'* ('schuldaansprakelijkheid'). This new principle entails that in deciding whether someone can be held liable, the question whether a risk was known is replaced by the question whether a risk could have been known. Government was positioned as being the party responsible for creating the circumstances in which these private and public responsibilities are attributed and carried.

asking Forum members to position themselves with regard to this storyline.[105] In Forum plenary meetings, third-order prospective accountive responsibility positioning occurred only incidentally.[106] The combination of an external speaker introducing a prospective responsibility storyline and a chair who actively invited Forum members to position themselves appears to be an important condition fostering third-order prospective accountive responsibility positioning.

3.3.4 The forum as a sounding board

In the first three vignettes the focus was on modes of representation that are at play in the interactions between Forum members internally. But Forum meetings did not only comprise internal Forum interactions, as external speakers were often invited to give a presentation. These external presentations formed an important source of information for Forum members. Also these presentations gave occasion to discussion amongst Forum members or - as was discussed in the third vignette - to third-order accountive prospective responsibility positioning.

The Forum was also of use for the external speakers. For them, the Forum functioned as a sounding board where they could hear the opinion and expertise of a wide range of organizations. Such was the case with the presentation on the baby Kelly court case, where the speaker explicitly and repeatedly asked the organizations and constituencies represented in the Forum to voice their opinion, as he thought it was important for him as a legal professional to take into account broader societal feelings. And there were other examples in which the Forum was positioned as a sounding board. During the FBG plenary meeting of Feb. 20th 2003, two external speakers presented previews of an advisory report that was to be published in due time. One concerned a Health Council advisory report 'Public awareness about genetics' (Gezondheidsraad, 2003). The other concerned an advisory report on the effects of gene patenting on healthcare and innovation, written by an organization and policy consultancy (Van de Bunt Adviseurs voor Organisatie en Beleid, 2003). That advisory report was commissioned by the

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[105] Chair: *'Lets discuss among ourselves. X, as a policy advisor, does not have to defend himself. (...) are you in favor of this proposition or do you oppose it? (...) Is that good or bad?'*

[106] Third order prospective accountive responsibility positioning may occur more frequently during working group meetings. In chapter 4 I will analyze in detail the interactions of the FBG working group on prenatal screening.

Ministry of Economic Affairs and the Ministry of Health, Welfare and Sports on the request of Parliament.

After the presentations there was occasion for questions, remarks and discussions and in both cases the Forum was positioned as a sounding board. In the case of the Health Council advisory report, the Forum's chair concluded the discussion by telling the Health Council secretary to take to heart the remarks that had been made in writing the presentation letter to the Minister ('aanbiedingsbrief') and in writing the press release. In the case of the advisory report on gene patents, the consultancy's managing director explicitly positioned the Forum as a sounding board:

> *"We have reached the very last phase, if anybody at this moment has any remarks to make, we can still incorporate them. So this is a last check for us, what does this evoke?'*

The Health Council also maintained a more permanent relation with the Forum, as the secretary of the Council's standing committee on genetics attended the Forum's meetings as an observer. For the Health Council it is important to know the sentiments, the interests and the positions that exist among societal actors. As a scientific advisory council they need to shield their advisory work from interference with political and societal interests, but at the same time – in order to produce advice that is relevant to the policy process– they need to create productive alignments between science, policy and society (Bal et al., 2002). In order to be able to do so, they need to be tuned into what is going on inside society. Having an observer position in the Forum Biotechnology and Genetics is one of the means to achieve that.[107] Furthermore attendance of Forum meetings by the Council's secretary also created what Bal et al. following Giddens (1990) and Shapin (1994), called an access point. A contact by which the Council – normally operating behind closed doors and as an impersonal institute – creates a more personal appearance. As far as trust is thus created in the Council's work, it increases the support for the Council's work. This is important as the Forum tends to address issues that are also taken up by the Health Council.

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[107] The organization of hearings and the publication of draft reports are other means by which the Health Council anticipates the reception of their advisory reports. (Bal et al., 2002)

To conclude, the fourth vignette of the Forum as a sounding board, concerns how the Forum can improve the work of other actors that are involved in the governance of genetics, biotechnology and healthcare, as it provides efficient entrance into (or representation of) the diffuse hybrid forum. Such can be relevant – as we saw – for legal professions, as well as for policy advisors.

3.4 How hybrid forums can be (made) productive in organizing responsibilities – some lessons learned

In this chapter I have gathered insights on how a forum like the FBG emerges and evolves as a hybrid forum and on the different modes in which the wider world is represented in this hybrid forum. In this concluding section I will present these insights as four lessons to keep in mind when a hybrid forum is set up with a view to contribute to organizing responsibilities.

3.4.1 Lesson 1

> *A hybrid forum as a governance practice is not isolated from other governance practices. When constructing or developing a hybrid forum, one should take into account how other types of governance practices will influence what is done, what can be done and what needs to be done in a hybrid forum.*

The FBG emerged from a bottom-up need of societal actors and stakeholders to communicate and exchange information on novel developments in medical biotechnology and medical genetics. The FBG was thus rooted in a sociotechnical policy network, initially starting off as a knot within this policy network. As a result of this specific history, many intermediary actors, some of which have strong enactment positions, are represented in the Forum. This has consequences for the type of activities and interactions characteristic for the Forum (see further Lesson 4). There will always be a history, and thus - depending on the objectives of a hybrid forum - it may be needed to counter or adjust such historically shaped characteristics. A simple example of such adjustments was how experts external to the Forum were asked to participate in the Forum's temporary working groups.

What a hybrid forum *can* do is shaped by what other actors and governance practices are doing already. The activities of other governance practices influenced

the Forum's agenda. In particular, this concerned the advisory work of the Health Council and the negotiations that took place between organizations representing insurers, patients and medical practitioners to lay down the Protocol Insurance Examinations. For the Health Council, Forum members were of the opinion that they should not compete with the Council as they would not be able to match the thoroughness of their advisory reports. Forum members involved in the formal negotiations on the Insurance Examinations Protocol expressed having difficulties with their ambiguous position as Forum members (cf. Vignette 1). This effectively implied that the option to advance the genetics and insurance debate through the FBG was not pursued.

Finally, what *needs* to be done in a hybrid forum in order to contribute to the distributed process of organizing responsibilities also depends on the role that other governance practices play in that process. Further conclusions on this point require analysis of the process of organizing responsibilities which will be taken up in the following empirical chapters. I will come back to this point in the final conclusions. A point that can be made here, is how a hybrid forum can be productive for other governance actors as it functions as a sounding board in which the diffuse hybrid forum is represented (see fourth vignette).

3.4.2 Lesson 2

> *Forum members' ambiguous representative status is productive because it provides room for maneuver in which the drawbacks of formal representation can be mitigated while there is still a link between the positions taken inside a forum and those taken by organizations or groups from which the forum members come.*

In order for forum negotiations to have an impact on the wider world, one might think that it is best to establish a forum in which forum members formally represent their constituency. However, my analysis of the FBG has shown that participating organizations are wary of formal representation, and for good reasons. They don't want to be accountable for a forum majority position with which they disagree as an individual organization. Pushing formal representation increases the risk that organizations withdraw from participation in a forum, or else that forum participants refrain from any attempts to produce forum positions. Both are

problematic if a hybrid forum aims to be productive in organizing responsibilities. First because, in order to be able to reach robust mutual adjustments between the role responsibilities of the actors involved in a configuration of responsibilities, it is important that all these actors are represented and able to position themselves. In the case of the FBG for example, healthcare insurers never attended Forum meetings. This was regretted by other Forum members, who wanted to discuss the issue of healthcare access in relation to the coverage offered by health care insurance packages. Second, formal representation can be unproductive because it may constrain the forum's attempts at reaching shared forum positions. In chapter 4 I will show that such attempts are important, because they force forum members to position themselves and to search for adjustment. Furthermore formal representation can also severely limit a forum's ability to quickly come to decisions, as forum members need to consult with the organizations that they represent.

As we saw in the FBG case, the drawbacks of formal representation can be mitigated by using the discursive device of 'speaking in a personal capacity'. Even though Forum members were often important spokespersons, 'speaking in a personal capacity' enabled them to engage in discussions and even to make these public, while at the same time the formal position of the organization they represented was left to the organization's own discretion.

3.4.3 Lesson 3

> *Hybrid forums can be productive as settings for third-order (prospective) responsibility positioning, but third-order responsibility positioning does not occur spontaneously. Third-order responsibility positioning must be induced by the presence of storylines that entice forum members to position themselves and/or by facilitators or others actors pushing forum members to position themselves.*

A main idea developed in chapter 2 was that hybrid forums can be productive in organizing responsibilities as they form settings for third-order responsibility positioning. That is to say that hybrid forums are settings in which actors *involved in* local sociotechnical practices come together and interact, and in which accountive and prospective positioning outside the primary interaction context of local sociotechnical practices takes place. The analysis of the FBG has shown that

this form of positioning indeed occurred, although other forms of positioning were more dominant, in particular first and second order positioning, e.g. as innovation enactment actors. For example, a patient representative would position him/herself predominantly as pushing for innovation desired by patients, but only rarely as questioning the role of patients in the configurations of responsibilities.

The relative lack of third-order responsibility positioning can be related to the fact that a hybrid forum does not primarily work as a microcosm of the wider world, where participants play out their roles again. Rather, it is a governance practice, and forum members position themselves accordingly in their role as governance actor/forum member, and less so in relation to the constituency they represent. In other words, while hybrid forums have the potential to contribute to organizing responsibilities because third-order responsibility positioning can occur, this is not automatic. Specific incentives are needed to evoke third-order responsibility positioning.

3.4.4 Lesson 4

Hybrid forums can be productive as bridging settings.

My last lesson is of a different nature than the first three. It includes a reflexive lesson regarding my definition of the process of organizing responsibilities and formulates a new hypothesis on hybrid forum productivity. In the second vignette I showed that many Forum members were strongly motivated to realize the application of genetic and biotechnological innovations in Dutch healthcare. In terms of my conceptualization of responsibility positions, these enactment actors take up what we could call a meta-responsibility to create novelties and to enable innovative developments. This is actually how one of the Forum participants, in a discussion of the FBG's long-term policy plan, described one of the roles of the Forum. In this discussion, ethics was suggested as one of the themes for the FBG to focus on.[108] Initially, the Forum participant was reluctant to include ethics as a Forum theme. At a later stage he wanted to keep ethics on the agenda, though with

[108] FBG working group on the long term policy plan, October 6, 2003.

a specific meaning attached, namely ethics as the responsibility to fulfill the potential of novelties in medical genetics and medical biotechnology.[109]

The second vignette draws attention to an important aspect of the wider world, which I did not explicitly theorize in my conceptual framework. In my conceptual framework I focused on the process in which a novelty becomes embedded in a configuration of responsibilities. I did not consider the preceding stages in which research is done, knowledge is developed and promises and expectations are communicated to create support. Support is needed to raise funding, but support is also needed to generate conditions that are beneficial to the development and research process. In the case of the FBG, we saw for example how Forum members advocated an extension of the legally required term for keeping medical records, which was considered an important condition for the further development of medical genetic research.

The stage of research and innovation development and the stage of societal embedding are strongly interwoven, because the promises and expectations that act to create support, anticipate on, and thus prepare for, societal embedding. The attractiveness and credibility of these promises and expectations may ease or hinder the creation of support that is needed for the developmental stage. The interweaving between the stages of innovation development and that of societal embedding forms an argument to extend the concept of organizing responsibilities from one that concerns the stage of societal embedding towards a concept that also includes the stage of research and innovation development. When using this broader interpretation of organizing responsibilities, a form of hybrid forum productivity becomes relevant which I did not anticipate in my conceptual framework and which was revealed by my observations of FBG meetings: hybrid forums can be productive as bridging settings, where those who try to develop certain techno-scientific novelties and those who need to be involved to enable these developments, "probe each others' realities" (Garud & Ahlstrom, 1997). Productivity includes that innovation paths are looked for that are most promising, in terms of development as well as in terms of societal embedding.

[109] He referred to this particular understanding of the term ethics as 'new ethics'.

4

Organizing responsibilities for prenatal Down syndrome screening

4.1 Introduction

In chapter 3 I described how the Forum Biotechnology and Genetics emerged and how it evolved into a particular type of hybrid forum. In this chapter I will again analyze the FBG, but here I will focus the analysis on a specific topic that was discussed; the issue of prenatal Down syndrome screening. It was one of the first topics for which the FBG established a working group. I chose this topic for further analysis, because it concerns the introduction of a novelty for which mutual responsibilities were contested and which was extensively debated, involving various arenas, organizations and governance practices – including the purposively hybrid forum FBG. Therefore it seems a good case for learning about the process of organizing responsibilities and for studying how a purposively hybrid forum contributed to that process.

In sections 4.2 and 4.3 the overall debate on prenatal Down syndrome screening in the period between May 1998 and autumn 2004 will be analyzed. Section 4.2 presents a chronology of the debate and introduces the institutionalized discourses, the arguments, and the storylines that played a role. In section 4.3 the nature and course of the debate is characterized, focusing in particular on three critical periods: the controversy surrounding the first Health Council advisory report; the State Secretary's policy decision on the first Health Council advisory report; and the State Secretary's policy decision regarding the second Health Council advisory report. Section 4.4 focuses on the discussions on prenatal Down syndrome screening which took place in the Forum Biotechnology and Genetics. I distinguish three episodes in the FBG discussion, which overlap with the three critical periods that I analyzed for the overall debate.[110] As I will show, the way in which interactions in the FBG contributed to the process of organizing responsibilities differed between these episodes.

[110] Actually the first episode concerns an analysis of the Forum Genetics, Health and Healthcare, the Forum that preceded the Forum Biotechnology and Genetics (see chapter 3).

4.2 Maternal Serum Screening: a novelty to-be-realized?

The discussion and debate on wide scale prenatal Down syndrome screening in the Netherlands started in the late 1980s.[111] The development and introduction of a new type of test, the maternal serum screening test, opened up the existing configuration of responsibilities for prenatal diagnosis of Down syndrome. Before the development of maternal serum screening, wide scale screening on Down syndrome had not been discussed. The prenatal diagnostic tests on Down syndrome that existed at that time – amniocentesis and chorion villus sampling - were expensive and risky. As these are invasive tests, there is a 1% risk of miscarriage, i.e. spontaneous abortion of a healthy fetus. Prenatal Down syndrome diagnostics was offered only to pregnant women who were known to have a high risk of carrying a child with Down syndrome. The risk of carrying a child with Down syndrome increases with the mother's age. Since 1985 prenatal Down syndrome diagnostics was actively offered to all pregnant women above the age of 36. In practice approximately 50% of these women actually decide to take this test (Kirejczyk et al., 2003). In case the test result is positive, parents can decide to abort the unborn child with Down syndrome.

Popkema et al. (1997) described the development of maternal serum screening in the laboratory and analyzed its script (Akrich, 1992b); how the test challenged the existing configuration of responsibilities for prenatal diagnostics. Maternal serum screening is a blood test, which can be used to predict the chance that a pregnant woman carries a child with Down syndrome. It is not a diagnostic test that predicts with certainty, but rather one that indicates the relative risk of Down syndrome. The test does not involve any risks for the unborn fetus. Researchers suggested using maternal serum screening as an indication for subsequent invasive diagnostics by means of amniocentesis or chorion villus sampling. A positive result of a maternal serum screening test can be used as an indication to offer invasive prenatal

[111] Maternal serum screening was first developed as prenatal screening for Neural Tube Defects (NTD). The debate on prenatal Down syndrome screening was preceded by and is rooted in the debate on NTD screening. The analysis in this chapter focuses on Down syndrome screening and will only discuss Neural Tube Defects as far as it is important to understand the discussion on prenatal Down syndrome screening. For a more elaborate account of the early development of maternal screening and the Triple test as well as the public and political debate see (Popkema et al., 1997), (Stemerding & Van Berkel, 2001) and (Kirejczyk et al., 2003)

diagnostics. The test result gives a more accurate indication of the relative risk of Down syndrome than the mother's age alone.

As maternal serum screening is relatively cheap and does not involve any physical risks for the mother or for the unborn child, the test created the possibility of wide scale prenatal screening. The existence of this new test opportunity entailed choices: the choice whether or not to further develop the test, the choice whether or not to take the test and subsequently a choice on whether or not to abort a child with Down syndrome. The development of maternal serum screening thus opened up the existing configuration of responsibilities that surrounded pregnancy and Down syndrome. Whereas in earlier times the birth of a child with Down syndrome was just bad luck, the development of maternal serum screening has made Down syndrome into something that *could* have been prevented. Whether it *should* be prevented and how responsibilities for prevention should be distributed became the subject of a long and intensive debate.[112]

In the period analyzed (1998-2004) the configuration of responsibilities for prenatal Down syndrome screening was fragmented. There was legislation that made prenatal screening subject to license requirement. So far a license had not been issued. Nonetheless, a number of prenatal Down syndrome screening practices had evolved, which differed regionally, even locally. It was unclear what the formal duties, rights and responsibilities of pregnant women, medical practitioners and government were and there was a related controversy concerning the quality of the prenatal screening tests. This section presents a chronology of the discussion and decision making on prenatal Down syndrome screening and identifies the responsibilities that are implicated in the discussion. Table 4.1 summarizes the chronology and location of the debate.

[112] Different types of maternal serum screening tests exist with different characteristics. In the course of the debate on prenatal Down syndrome screening, the introduction of different types of tests (double test, Triple test, ultrasound, combination test) were proposed. In the latest stage of the debate, the range of different testing opportunities broadened even further, when the use of neck fold measurement by means of ultrasound was proposed as a screening technique.

	Period / date	Health Council	Diffuse Forum	Political Arena	Forum Biotechnology and Genetics
First stage of the debate on prenatal screening	May 1998	Advisory Request			
	December 12 2000				Foundation of the Forum Genetics, Health and Health Care
	May 2001	Publication of first Advice about prenatal screening	Critique of the first Health Council advice on prenatal screening		
	October 2001		Consultation meeting organized by Ministry of Health		
	April-October 2003				PMB and FGHH merge into FBG
Second stage of the debate on prenatal screening	21 November 2003			State Secretary's policy response to 1st HC advice	
	Jan/Feb 2004				E-mail discussion on first FBG notice letter
	12 February 2004			Round Table meeting with Parliamentarians	
	April 2004	Publication of second advice on prenatal screening			
	June 7th 2004			State Secretary's policy response to 2nd HC advice	
	June 8th 2004			Parliamentary Meeting (AO)	
	June 29th 2004			Continued Parliamentary Meeting (VAO)	
	July 7th 2004				1st FBG working group meeting on Down syndrome screening
	August 11th 2004				2nd FBG working group meeting on Down syndrome screening
	September 9th 2004				The FBG plenary meeting approves the second notice letter

Table 4.1 Chronology and location of the debate on prenatal Down syndrome screening (1998-2004)

4.2.1 The governance arrangement and divergent local and regional practices for prenatal screening

The development of prenatal Down syndrome screening was preceded by two related developments: maternal serum screening for neural tube defects (NTD) and prenatal diagnostics concerning Down syndrome for pregnant women above the age of 36. In 1990 the State Secretary of Health decided not to make prenatal screening on NTD a collective healthcare provision. The low quality of the test as well as the small risk of abortion of a healthy fetus formed arguments against wide scale screening. In the early 1990s with the development of the Triple Test it became possible to use maternal serum in prenatal screening for Down syndrome. The development of the Triple Test reopened the debate on maternal serum screening as it was claimed that maternal serum screening could improve the existing clinical practice of prenatal diagnostics on Down syndrome. However, for reasons of low test quality, the government again decided against wide scale prenatal screening.

While the government on different occasions had decided not to make prenatal screening a collective provision for all pregnant women, a variety of regional prenatal screening practices had meanwhile developed. The University Hospitals of Utrecht and Groningen for example had offered maternal serum screening for Neural Tube Defects since the early 1980s and they started offering the Triple Test in the early 1990s. While government through the collective financing arrangements of the Dutch healthcare system could control the collective provision of prenatal screening, they could not prevent certain regions using alternative financing arrangements, such as hospital or research budgets, to provide and develop prenatal screening.[113]

The situation changed when in 1996 new legislation - the Population Screening Act[114] - came into force (Zorg Onderzoek Nederland, 2000a). The Population Screening Act had been developed to make certain forms of population screening subject to license requirement:

> *'"The main reason for governmental regulation in this area is the wish to ensure that the population or groups within the population will only be*

[113] In the North-East region of the Netherlands maternal serum screening was financed with a special budget from the Foundation for Heredity Education ('Stichting Erfelijkheidsvoorlichting') (Kirejczyk et al., 2003, p.91).
[114] In Dutch: 'Wet Bevolkingsonderzoek' (WBO).

confronted with screening programs of good quality. Because of the legitimizing effect and the pressure that these screening programs embody, government has formulated qualitative demands concerning such things as the testing method, the nature of the diseases and disorders to be traced and the organization of the program." (KEMO, 1992)' quoted in (Kirejczyk et al., 2003, p.105, translated from Dutch).

In the years preceding the introduction of the Population Screening Act there had been discussion regarding its scope. There was some disagreement whether prenatal screening and prenatal diagnostics should fall under the Population Screening Act. Disagreement concerned two issues in particular: whether or not pregnancy forms an indication for medical care and whether or not the provision ('aanbod' in Dutch legal terms) of information about prenatal screening is subject to license requirement, or if rather license requirement should only concern the actual provision of the test.[115] The Health Council in its advisory report on Genetic Screening (Gezondheidsraad, 1994) recommended making the provision of information about prenatal screening subject to license requirement. This interpretation was adopted by the Ministry of Health, who stated that:

[115] The Dutch term 'aanbod' (offer or provision) is a central category within the Population Screening Act. The term is used for medical provisions that are pro-actively offered to the population as a whole or to specific groups within that population. The license requirement is a means to protect people against screening programs of low quality. To decide whether or not something counts as a proactive offer or 'aanbod', the attribution of the initiative of the encounter between client and medical professional is of central concern. If the client takes the initiative to consult a doctor for some medical problem, the Medical Treatment Agreement Act applies (In Dutch: 'Wet op de geneeskundige behandelingsovereenkomst' WGBO). If the doctor or another care provider takes the initiative to offer medical examination, then the population screening act applies.
In the case of pregnancy, it is difficult to distinguish between the two. On the one hand the pregnant woman herself takes the initiative to consult a doctor. In that respect it can be argued that the Medical Treatment Agreement act applies and not the Population Screening Act. On the other hand – and especially in the Netherlands where a discourse and practice exists which considers pregnancy to be a life event that should not be unnecessarily medicalized - pregnancy is not perceived as a medical condition. In that respect it can be argued that informing women about prenatal screening does indeed count as a proactive offer, as many women might not expect to be offered these kinds of information and choices when they consult a doctor about their pregnancy. It is clear that there is a grey area in which it is difficult to decide whether or not the Population Screening Act applies. This grey area accounts for some of the controversy and discussion on the legal interpretation.

'"*When for instance a brochure in the waiting room or a sign on the door calls attention to the possibility to undergo the test, then this is considered an offer in the sense of the WBO* [FM: Population Screening Act]" (brief VWS, 1996)' quoted in (Kirejczyk et al., 2003, p.104).

In 1996 it was furthermore decided that the standard practice in which prenatal diagnostic testing was provided to women above the age of 36, would become subject to license requirement under the legislative framework of the Population Screening Act (Kamerstukken II, 1995-1996). In 1998 a provisional license was issued.

A special Health Council Committee ('Commissie WBO') advises the Minister whether and under what conditions permission for population screening is to be given. In 1998 two applications of maternal serum screening for Down syndrome and Neural Tube Defects were rejected (Gezondheidsraad: Commissie WBO, 1998). The Committee, at that time, made the reservation that a definite judgment on prenatal Down syndrome screening could not be given. A definitive judgment required a more extensive assessment of all types of newly developed prenatal Down syndrome screening tests. Such an advice was thought to be too complex for this committee and it was recommended that a special Health Council committee should be established. In May 1998 the Ministry of Health followed that advice and commissioned the Health Council to write an advice on prenatal screening. (Gezondheidsraad, 2001c, p.211)

With the introduction of the Population Screening Act the clinical practices of prenatal screening that already existed had not altogether become illegal. In the Population Screening Act a distinction was made between situations in which the initiative to offer medical diagnostics or treatment lies on the side of the medical practitioner or healthcare system, and situations in which the client or patient takes the initiative to approach a medical practitioner with a specific health care request. The first is regarded as 'provision' ('aanbod') and is subject to license requirement. But a license is not required if the patient or client takes the initiative herself. In the case of prenatal screening that means that pregnant women, who ask to be tested, can have a test. The professional association of gynecologists developed a provisional guideline that women under the age of 36 can have a Triple test if they

ask for it and if they pay for the test themselves.[116] Many medical professionals working in prenatal care considered this situation to be unworkable.[117] On the one hand the Medical Treatment Agreement Act[118] requires them to inform their patients concerning relevant medical information, on the other hand they are not allowed to inform their patients about the option of prenatal screening on Down syndrome and NTD (Gezondheidsraad, 2001c, p.36).

4.2.2 The Health Council advisory report on prenatal screening

In May 1998 the Minister of Health requested the Health Council to advise her about prenatal screening on Down syndrome and Neural Tube Defects. The Health Council was asked to assess the relative value of different types of prenatal tests that had been or were being developed. Furthermore the Council was asked to reflect on the ethical, legal and social aspects: 'Which moral issues arise if prenatal screening were to be offered to all pregnant women?' (Gezondheidsraad, 2001c, p.212, translated from Dutch) And they were asked to address the question whether task distribution or rather concentration of screening was more suitable from a perspective of quality. In May 2001, after an advisory trajectory of three years, the Health Council published its advisory report.

It was concluded that 'Predictive screening based on a Triple test offered to all pregnant women is more effective than the existing screening based on age' (Gezondheidsraad, 2001c, p.65) and it was recommended that pregnant women of all ages should be provided with the option of prenatal screening by means of the Triple test under the condition that the detailed recommendations on how best to organize such a provision of prenatal screening would be followed. These recommendations concerned in particular the availability of enough counseling time and trained counselors in order to guarantee 'informed consent'. Furthermore, in order to obtain reliable test results concentration of the testing practice within a limited number of laboratories was required.[119]

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[116] A special agreement with health insurers was made. In case the Triple test would show an increased risk on Down syndrome, the follow-up invasive diagnostic test would be paid for by health insurance.
[117] See footnote 115.
[118] In Dutch: 'Wet op de geneeskundige behandelingsovereenkomst' (WGBO).
[119] " - the involved laboratories must work according to an accredited quality system based on international standards, for instance ISO 15189; the laboratory must perform a sufficient number of measurements in order to compose reliable median values; one can think of five to eight

The Health Council committee emphasized that the prevention of children with Down syndrome did not form the objective and moral legitimization of prenatal screening. Rather, the objective and moral legitimization of prenatal screening was formed by offering future parents different options for action ('handelingsopties' in Dutch). This argument strongly reflected the discourses of patient autonomy, right of self-determination and of the Population Screening Act. Two generally accepted and widely shared conditions followed which strongly framed the advice: non-directive counseling and the provision of high quality screening.

Patient autonomy and non-directive counseling had for long been strong norms within clinical genetic practice (Nelis, 1998). Pregnant couples should be provided with the opportunity to make a well-informed and truly autonomous choice whether or not to opt for prenatal screening. In terms of responsibility, pregnant couples have an *individual responsibility* for making a decision whether or not to have a Triple test, in virtue of their own normative conviction . Whereas patient autonomy as a norm is shared throughout clinical practice, in the specific case of prenatal screening, a strong version of patient autonomy is required. It is recognized that actively approaching pregnant women with an offer for prenatal screening, carries the implicit norm that prenatal screening is a sensible choice. It is realized that patient autonomy can easily dissolve in local clinical practice. In order to avoid the implicit normativity of offering prenatal screening, the strong norm of patient autonomy requires other ways of informing pregnant couples about testing options and requires a specific organization of the screening practice. It is emphasized in the advisory report that:

> *'When the screening options discussed in this advisory report are implemented, the greatest challenge will be to present the options in such a way that one can actually speak of informed consent. If screening practice does not live up to this requirement, this not only means that an important ethical and legal precondition is not met, but also that the moral justification*

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laboratories that each perform ten to twenty thousand measurements a year, depending on the level of participation."(Gezondheidsraad, 2001c, p.20, translated from Dutch).

of the offer as such is compromised."[120] (Gezondheidsraad, 2001c, p.135, translated from Dutch)

In order to assess the quality of different prenatal screening options, the Health Council committee compared prenatal screening for pregnant women of all ages to the pre-existing clinical practice in which invasive prenatal diagnostics is only offered to pregnant women over 36. They considered pre-existing practice to be a yardstick for quality as it had been standard practice for years.[121] The advice presented a number of different criteria for quality: the annual number of invasive diagnostic procedures, the overall detection percentage, the percentage of false-positive test results, the cost/detection ratio and the detection/miscarriage ratio. On all these variables the Triple test scored better than the pre-existing practice of prenatal diagnostics (Gezondheidsraad, 2001c, p.63) and it was therefore concluded that 'Predictive screening based on a Triple test offered to all pregnant women is more effective than the existing screening based on age.' (Gezondheidsraad, 2001c, p.65, translated from Dutch).

Whereas on other subjects and on other occasions the Health Council is often capable of writing authoritative and undisputed advice that contributes to mutual adjustment in configurations of responsibilities (Bal et al., 2002), the advisory report on prenatal screening gave rise to a lot of controversy and critique. The Council was mainly challenged on two points. The Council's judgment of the quality of the Triple test was disputed and it was argued that the report implied that it is good to reduce the birth rate of children with Down syndrome. Gynecologists Hamerlyncnk & Knuist and Kleiverda & Vervest were the most influential critics of the Health Council advisory report. The main point of critique concerned the low test-sensitivity for women at a younger age. Furthermore, younger women have a lower relative risk to carry a fetus with Down syndrome. The critics of the Health Council advisory report argued that both were arguments to maintain an age limit

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[120] The advisory report does not draw any conclusions concerning the amount of counseling time that is needed. But in an illustrative example an average counseling time of twenty minutes is used. (Gezondheidsraad, 2001c, p.158)

[121] 'It must be acknowledged that prenatal screening for Down syndrome has been available in this country for a long time now. Through the acceptance of that practice (the offer to all pregnant women aged 36 and above to undergo an amniocentesis or chorion villus sampling) the question has also been answered, albeit implicitly, whether prenatal screening for disorders such as Down syndrome and neural tube defects serve a morally acceptable purpose.' (Gezondheidsraad, 2001c, p. 119, translated from Dutch)

for offering prenatal screening (Kirejczyk et al., 2003). The low test-sensitivity at a younger age implies that under 36 the test shows a false-negative test result more often, meaning that the Triple test does not indicate a high risk of Down syndrome, whereas the pregnant woman - in fact - does carry a fetus with Down syndrome. Under the age of 36, almost as many fetuses with Down syndrome are missed with this test as are found.[122] The critics of the Health Council advisory report argued that offering prenatal screening to younger women provides them with an unjustified reassurance and that therefore the age limit for offering prenatal screening should be maintained (Kleiverda & Vervest, 2001).

The Health Council advice had not completely neglected the fact that younger women run a lower risk of carrying a fetus with Down syndrome, nor had they completely neglected the fact that the number of false negative test results increased at younger age. It was recognized that both the detection/miscarriage ratio and the cost/detection ratio would further improve if Triple test screening was restricted to an older age group. On the other hand, it was argued that restricting prenatal screening to older age groups, the overall sensitivity of the test, that is the ratio between the number of detected fetuses with Down syndrome and the total number of fetuses with Down syndrome would be considerably worse. In addition, it was argued that the value of information regarding the test is equal for pregnant women of all age and that the occurrence of NTD is equal for women of all age (Gezondheidsraad, 2001c, p.165,166). Apparently for the Health Council these arguments outweighed a higher detection/miscarriage ratio and a lower cost/detection ratio.

The second main criticism was that the Health Council advisory report implied that prevention of the birth of children with Down syndrome formed the objective of prenatal screening. This criticism was voiced among others by the Minister of Health, Borst, who had requested the advice. The critique was strongly rejected by the Health Council's Chair, Knottnerus. 1,5 year after publication of the advice,

[122] The ratio between false-positive test results and false-negative test results is not a given, but depends on the chosen margin of acceptable false-positive or false-negative test results. It is possible to decrease the number of false-positive test results, but in that case the number of false-negative test results will increase. A high number of false-negative test results is undesirable since it leads to false reassurance. A high number of false-positive test results, on the other hand, is also undesirable since it increases the number of miscarriages of healthy fetuses, induced by invasive DNA diagnostic testing.

Borst and Knottnerus discussed the issue in the journal 'Medisch Contact'.[123] Borst – during her ministry - never came with a formal policy response to the Health Council's advice:

> *'First, I wanted the societal sensibilities to be tracked.'* And: *'With such an advisory report, I feel it is useful to let the discussion flourish in society, in order to observe which arguments are employed before taking a decision as Minister.'* (Visser & Maassen, 2002, translated from Dutch)

She characterized the Health Council advice as 'overly rational':

> *"She knows that an advice such as this one implicitly assumes that it is a good thing to actively limit the number of Mongoloid children born. 'However, such a view is not uncontested in the Netherlands and as Minister one has to take this into consideration.'"* (ibid.)

The former Minister's statements formed the occasion for a strong response by the Health Council's chair. Knottnerus said he was '*shocked*' by Borst's opinion that the Health Council advice on prenatal screening implicitly assumed that it is good that a minimum of children with Down syndrome are born. He strongly rejected this statement:

> *'To actively limit the number of children with Down syndrome to be born 'is a completely objectionable aim, which, as was also stated in the advice, is not compatible with the moral foundation of our society'* (Knottnerus & Borst-Eilers, 2002, translated from Dutch).

He further said he was amazed to receive this criticism from the former Minister, who as a Minister had been responsible for the formulation of the advisory request. The Minister had wanted to know how new forms of prenatal screening related to the existing clinical practice of prenatal testing. Again reference was made to the already existing practice of prenatal diagnostics for women over 36:

> *'In answering this question, the Health Council was not only guided by scientific evidence, but also – as a starting point for its ethical reflection – by*

[123] A weekly journal by the Royal Dutch Society for Medicine (KNMG).

the given that screening for Down syndrome has been an accepted practice since the 1970s, in order to (exactly as worded above): provide expectant parents with an option to act which they otherwise would have lacked. (...) If the Minister had desired public discussion of the acceptability of screening for Down syndrome as such, it would have been more logical to organize such a debate rather than requesting advice concerning the best way to organize screening' (Knottnerus & Borst-Eilers, 2002, translated from Dutch).

Eventually, such a broad debate on the acceptability of Down syndrome screening was organized anyway, after the publication of the Health Council advisory report. In October 2001, the Ministry of Health organized a broad consultation meeting and participants were asked to write a position letter. 'The various organizations that communicated their position in a letter addressed to the minister, did not utilize new problem definitions. Rather, they used the same ones as the Health Council and the opponents had' (Kirejczyk et al., 2003, p.137, translated from Dutch). A number of parties, such as the Royal Dutch Medical Society, the Federation of Parent Organizations, the Association for Perinatal Care and Consumers and the National Health Insurance Board opposed the Health Council's Advice and argued that the age limit for prenatal screening should not be abolished.[124] At the consultation meeting the frequently used argument against the introduction of the Triple test for all pregnant women was that it would lead to undesirable medicalization of pregnancy. On the other hand many parties also supported the Council's argument that pregnant women of all ages had the right to self-determination. Finally, medical professionals expressed their concern that the pressure/strain on medical practice would be too high if they would have to follow the Council's recommendations on non-directive counseling. This forms a very practical argument against abolishment of the age limit, saying that in practice medical professionals will not be able to bear the role responsibility that is attributed to them (Kirejczyk et al., 2003, p.124-126).

4.2.3 The State Secretary's policy decision – November 2003

Eventually it took 2.5 years until the State Secretary of Health, in November 2003, finally took a policy decision on the Health Council's advisory report on prenatal

[124] Some suggested lowering the age limit from 36 to 30 years.

screening.[125] She decided not to follow the Council's recommendation to offer all pregnant women the Triple test. The lower incidence of Down syndrome and the lower test-sensitivity for younger women formed the main reasons to maintain the age limit of 36. For women under the age of 36 the provisional guideline as had been developed by the gynecologists was made permanent:

> *'Pregnant women under the age of 36 who themselves request predictive prenatal testing can be accommodated at their own expense. In case the test suggests an elevated risk, this serves as an indication for invasive diagnostics'* (Kamerstukken II, 2003-2004c, p.7).

With her policy decision the State Secretary made a clear statement that the provision of prenatal screening for women under the age of 36 was not a state responsibility. According to some of the advocates of prenatal screening this was an example of Christian moral politics. With her decision not to make prenatal screening a collective provision, the eventual responsibility for the prevention of the birth of children with Down syndrome became more expressly an individual matter: pregnant women had to take the initiative to ask for the test and they had to pay for the test themselves.

For two reasons the discussion did not come to an end here. First of all, it was uncertain whether parliament would support the State Secretary's proposed policy. The policy decision was discussed in parliament during the annual budget debates. Two parliamentary motions were brought forward. An objection that was often raised against the then existing clinical practice in which pregnant women could have a test at their own initiative, was that in practice this would lead to inequality between those women who are well-informed and often better educated and those women who are not well-informed. The first motion reflected that objection. With reference to the Medical Treatment Agreement Act ('WGBO') the motion stated that all pregnant women should be provided with information about prenatal screening.[126] Although the policy decision very clearly stated that informing

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[125] Formally, a policy position is required within three months after publication. The delay was partly caused by the public controversy and partly because of the resignations of two successive cabinets.

[126] 'The Chamber, Having heard the deliberations, considering that at present different methods are available that can reveal serious disorders in an early stage of pregnancy; considering that based on the Population Screening Act (WBO) pregnant women do not automatically receive

pregnant women on prenatal screening counted as a provision which was subject to license requirement, the State Secretary was amenable to the suggestion of changing this legal interpretation. During the parliamentary debate, she proposed to make a distinction between actively offering the test to pregnant women ('aanbod' or provision) on the one hand, and offering information about the test on the other hand. The provision would be restricted to pregnant women over 36; offering information about the test would apply to all pregnant women. The compromise also implied a change in responsibilities for prenatal screening. With her initial policy decision the State Secretary had made the prevention of children with Down syndrome the express responsibility of individual pregnant couples/women. Inequality is the inevitable consequence of such a strong individual responsibility. The ability after all to take individual responsibility requires that individual pregnant women are well-informed. Such inequality was thought undesirable and a (new) responsibility was articulated during the parliamentary debate: medical practitioners should provide all their patients with information concerning prenatal testing. A second motion was more critical about the State Secretary's proposed policy. This motion stated that the Health Council advisory report should be followed and that all pregnant women should be offered a Triple test (Kamerstukken II, 2003-2004b). A vote on both motions was postponed as it was agreed upon that the issue deserved a more extensive debate at a later moment.

The State Secretary had chosen a clear position: according to her prenatal screening was not a state responsibility. But it was uncertain whether the State Secretary's proposed policy would pass through parliament. Uncertainty also concerned the compromise – as was supported by the State Secretary - that providing information about prenatal screening was not subject to license requirement. That policy implied a change in the then prevalent interpretation of the Population Screening Act. It

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information from their doctor or midwife about the existing prenatal tests and the associated advantages and disadvantages; considering that it is of the utmost importance that patients/consumers are sufficiently informed in order to take a well-considered decision; considering that the Medical Treatment Agreement Act (WGBO) stipulates that the care provider must fully inform the care receiver about the medical possibilities; requests the government to see to it that professionals responsible for medical care during pregnancy inform all pregnant women about the various methods that can reveal serious disorders in the child, including possibilities, constraints, risks and consequences of these methods, and proceeds to the order of the day' (Kamerstukken II, 2003-2004a).

raised a discussion whether or not the State Secretary's position was legally tenable.[127] [128]

The ongoing development of new and better tests for prenatal screening formed a third reason for the debate on prenatal screening not yet to be concluded. In light of new developments the Health Council was preparing a second advisory report that could potentially shift the prior positions. The policy decision regarding the first Health Council advisory report mentioned these technical developments and announced an update of the first Health Council advice, expected to be published at the end of 2003. The State Secretary had decided not to await this new advice, arguing that:

> *'As medical developments move along quickly, it is to be expected that other and better (combinations) of testing will become available shortly. Most importantly, medical practitioners are urgently waiting for a clear frame work for handling prenatal screening*.' (Kamerstukken II, 2003-2004c, p.2,3)

In the winter of 2004, the configuration of responsibilities for prenatal screening was still fragmented. Differences between local and regional medical practices had proliferated. The late political decision concerning the Health Council advisory report had provided room for these different practices to develop.[129] [130]

Discussion in parliament resumed when figures were published which suggested that the baby mortality rate in the Netherlands was among the highest in Europe. These figures were linked up with Dutch prenatal screening policy. On the 12th of February 2004 the permanent parliamentary commission on health issues organized a round table meeting with a range of experts and stakeholders to inform themselves

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[127] The suggestion not to make a provision of information subject to license requirement had been raised before in the first half of the 1990s (by BOSK and KEMA).
[128] See for example (De Wert, 2004; Kleiverda, 2004).
[129] In 2002 approximately 40.000 pregnant women (out of a total population of 200.000) chose to have a non-invasive prenatal screening test (10.000 Triple tests, 20.000 ultra sounds, and 10.000 combination tests) (Gezondheidsraad, 2004, p.40).
[130] ''In some clinics it is offered, in others pregnant women get a test if they ask for it (and not if they don't). This leads to uncertainty among pregnant women and inequality in access. Care providers find themselves placed in the dilemma that according to the obligation to inform as stipulated in the WGBO [FM: Medical Treatment Agreement Act] they are required to inform the pregnant women about the maternal serum test if they ask about it, but they are not formally allowed to offer this test.'(ZonMw, 2003, p.63, translated from Dutch).

about the issue of baby mortality and prenatal screening. This round table meeting would form the primary occasion for the Forum Biotechnology and Genetics to try to formulate a Forum position on prenatal screening (to be discussed in section 4.4).

4.2.4 New technological developments - The State Secretary's policy decision concerning the second Health Council advisory report

A second Health Council advisory report regarding prenatal screening was published at the end of April 2004. It concluded that a combination of neck fold measurement by means of ultrasound and the so-called double test (a maternal serum screening test) was qualitatively better than the Triple test, which had been recommended in the first advisory report. In a number of respects, the quality of prenatal screening could be improved by introducing this so-called combination test. This included an improvement of the sensitivity of the test. In an earlier stage of the debate, low test-sensitivity - especially for younger women – had been used as an argument against the abolishment of the age limit. A further advantage of the combination test over the Triple test is that it is possible to have the test in an earlier stage of pregnancy. The second Health Council advisory report recommended making prenatal screening with the combination test available to all pregnant women.[131]

On June 7th 2004, the State Secretary published her policy decision concerning this second Health Council advice.[132] Despite the fact that in a number of respects the quality of prenatal screening had improved, the State Secretary maintained the age limit for prenatal screening. Women under the age of 36 should be provided with information about prenatal testing, and would have to pay for the test themselves. Under the age of 36, prenatal screening is not a provision of collective health care. The low incidence of Down syndrome in younger women formed the main argument to maintain the age limit. In a letter to Parliament the State Secretary further explained her decision as follows:

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[131] Although it had meanwhile become clear that opinions on acceptability of Down syndrome screening itself varied widely in society, the Health Council chose not to engage in that discussion. The committee was not asked to judge acceptability of prenatal Down syndrome screening as such. Similar to the first Health Council advisory report, the existing formal practice of offering pregnant women over 36 invasive diagnostic testing was used as a normative yardstick to assess alternative screening and testing arrangements.

[132] The early moment of that decision came as a surprise. On the 3rd of May 2004, the State Secretary sent the Health Council advisory report to parliament. In the cover letter she announced that the political decision regarding the advice would be made in September 2004.

> *'Pregnancy is first and foremost a very personal and individual matter. In contrast, prenatal screening, when offered to the whole population, is a mass affair: by preference such screening is offered in a manner that is as uniform and predetermined as possible. Policy will have to steer a middle course between these two extremes. As far as I am concerned - and this follows naturally from the cabinet's position - this mean is to be sought through responsible care for pregnant women, including adequate provision of information. Furthermore, each pregnant woman must know that she has a free choice; both the freedom to request the test, and the freedom to refuse it'* (Kamerstukken II, 2003-2004e, p.2).

She further stated:

> *'The central aim therefore never is: to find as many potential defects as is possible, but: to offer the kind of care that leads to the best possible guidance of pregnancy.'* (Kamerstukken II, 2003-2004e, p.5)

In this justification, the tension between a discourse of patient autonomy, self-determination and free choice and the requirement of high quality screening comes to the fore. These discourses imply that government's interference with pregnancy ought to be limited: *'A pregnancy is first and foremost a very personal and individual matter'* and *'Furthermore, pregnant women should know that they have freedom of choice; both the freedom to request the test, and the freedom to refuse it.'* On the other hand, quality requirements call for a large scale, standardized and closely directed practice of prenatal screening. Whereas, in a number of respects the combination test had brought an improvement compared to the Triple test, the tension between strong patient autonomy and the need to organize clinical practice on a collective level, had remained undiminished. Under the chapter heading 'Quality and Organization', the Health Council advisory report sketched how to achieve a high quality screening practice. The quality of a test or screening practice is not a given, but needs to be organized. Take for example the neck fold measurement. In the Netherlands, at that time, ultrasound testing during pregnancy was not a standard provision, although in practice ultra sound testing was widespread. About 80-90 % of all pregnant women received an ultra sound test. The test is used primarily to determine duration of pregnancy and multiple births. Integration of the neck fold measurement within this existing clinical practice

would be the most obvious route for implementation. The Health Council however expected that high quality screening could not be reached within this existing clinical practice. It argued that qualified and experienced ultra sound operators are needed in order to guarantee the quality of neck fold measurement. Concentration of neck fold measurement within regional centers was recommended.

Other organizational requirements apply: the determination of reference values for the blood test requires concentration, standardization and control of laboratory diagnostics; pregnant couples need to receive adequate, balanced and up-to-date information on both the test and on Down syndrome in order to be able to make a well-informed and autonomous choice; medical practitioners involved in counseling need to be trained for the job; In order for the advantage of first trimester testing to be effective, pregnant women have to consult a doctor in an early stage of pregnancy; public information is needed. Overall, the organization of quality, as proposed in the second Health Council advisory report, requires national steering and control and considerable collective effort. Furthermore, a certain scale is needed in order to achieve an acceptable quality of laboratory measurements and sufficient practical experience of medical practitioners. Assuming a participation degree of 60%, the Health Council had recommended concentration within a maximum of eight regional centers (Gezondheidsraad, 2004, p.60).[133]

Regarding the discussion on the delineation between the Population Screening Act and the Medical Treatment Agreement Act, the State Secretary also maintained her earlier policy: the provision of information about prenatal screening does not require permission within the legal framework of the Population Screening Act. Pregnant women's right to be informed on available diagnostic options is regulated in the legal framework of the Medical Treatment Agreement Act. She further stated that in the context of the evaluation of the Population Screening Act, she was examining the need to clarify possible inconsistencies between the two legislative frameworks.[134] The State Secretary's policy implied that pregnant women can take

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[133] 'The quality of risk assessments based on blood tests strongly depends on reliable normal values for the substances to be measured. This reliability increases with the number of measurements per laboratory. Because of this, on a yearly basis per laboratory ten to twenty thousand measurements are needed' (Gezondheidsraad, 2004, p.60).

[134] 'Surrounding this point of information provision, a discussion has emerged whether informing pregnant women outside of the high-risk group basically isn't the same as offering population wide screening. In that case, only those pregnant women, belonging to the group for whom a

individual responsibility to construct themselves as being 'at risk'. It is a collective and medical responsibility to provide all pregnant women with adequate information on the possibilities of risk determination. Yet it is not a state responsibility to actively improve or organize high quality prenatal screening for women under the age of 36.

In the parliamentary debates that followed the State Secretary's policy position, opinions were divided (Kamerhandelingen II, 2003-2004; Kamerstukken II, 2003-2004e). Proponents and opponents of the State Secretary's policy roughly earned an equal amount of votes.

4.3 Inconclusive discourses, and storylines in the debate

In the period between 1998 and 2004 discussion and debate on prenatal screening focused on the question whether or not the age limit for the provision of prenatal screening should be abolished and how to organize prenatal screening in order to optimize the quality of the screening practice. In the case description of the preceding section I described the different arguments, storylines and institutionalized discourses that played a role in this debate. In this section I will characterize the debate by analyzing its discursive structure. The analysis will be focused on three important episodes within the debate: the controversy surrounding the first Health Council advisory report, the State Secretary's policy decision concerning the first Health Council advisory report and the State Secretary's policy decision concerning the second Health Council advisory report.

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permit is given on the basis of the Population Screening Act (WBO) should be informed. Concretely, at this moment the Population Screening Act only permits offering prenatal screening of Down and NBD [FM: Neural Tube Defect] to pregnant women aged 36 and over. It may not be offered to younger pregnant women, nor may they be informed by their care professional. My reasoning is different. Care professionals must offer good information to their patients with regard to their health care issues. In this case that would mean information on the course of pregnancy, rules of life, risks. A patient actually is entitled to receive information; this is stipulated in the Medical Treatment Agreement Act (WGBO). But there are of course limits to this information provision (…) Only that which is truly relevant, of immediate consequence to the patient, can and must be included. And what is relevant, changes over time. (…) At this time, giving information on risk determining tests for Down and NBD is actually obvious. An advisory report from the Health Council on the scope of the Population Screening Act (WBO) offers arguments that support this position. For that matter, I am presently looking into the question whether the evaluation of the WBO gives cause to clarify possible contradictions between the WGBO and WBO' (Kamerstukken II, 2003-2004e, p.2,3).

4.3.1 Controversy concerning the Health Council advisory report

In this section I will analyze both the discursive structure of the main arguments in the Health Council advice as well as the discursive structure of the main critique on the Health Council advice and conclude on the nature of the controversy.[135] Three 'institutionalized'[136] discourses strongly structured the Health Council advisory report on prenatal screening: a discourse of ethical liberalism[137], the discourse of the Population Screening Act and a discourse of the Health Council as an independent and apolitical scientific advisory council, the Health Council's mandate. Figure 4.1 presents the institutionalized discourses (beams), main arguments (rectangles) and storylines (ellipses) of the first Health Council advisory report on prenatal screening and how these arguments and storylines relate to each other and to these institutionalized discourses (arrows).

A specific challenge for the Health Council was to advise on the quality of different types of screening tests, while simultaneously refraining from taking a position on the value of prenatal screening as such. This last point was vested on two reasons. First, the institutionalized discourse on ethical liberalism implied that individual parents were the only ones in the legitimate position to decide about the value of prenatal screening. Neither explicitly nor implicitly was the Health Council 'allowed' to take a position on the value of prenatal screening.[138] The challenge to advise on quality, while refraining from taking a position on the value of prenatal

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[135] The analysis of the Health Council argument is based on what Bal et al. (2002) call the front stage of advice: the text of the advisory report and public statements of Health Council (committee) members. I did not study or analyze the back stage of the advice: that is the non-public interactions in the Health Council committee meetings and the non-public interactions between Health Council staff and the Ministry of Health. Back stage, additional arguments and storylines may have featured in the discussion and may have influenced or contributed to the outcome of the advice. For the purpose of my analysis however, studying the discursive linkages between different arenas, a focus on the front stage of the advice is needed. It is the argumentation of the advisory report that travels to other arenas, not the arguments that played a role during committee meetings. And when critics argue their alternative points of view, they relate to the arguments and storylines of the text of the advisory report.

[136] I put 'institutionalized' between inverted commas because strictly speaking ethical liberalism is not an institutionalized discourse, but a structuring discourse.

[137] I use the term ethical liberalism to refer to the related discourses of patient autonomy, freedom of choice and the right of self-determination.

138 The Health Council's advisory report on prenatal screening on Neural Tube Defects (Gezondheidsraad, 1988) had been criticized by members of parliament for it explicitly mentioned the prevention of handicapped life as an argument for offering prenatal screening (Kirejczyk et al., 2003).

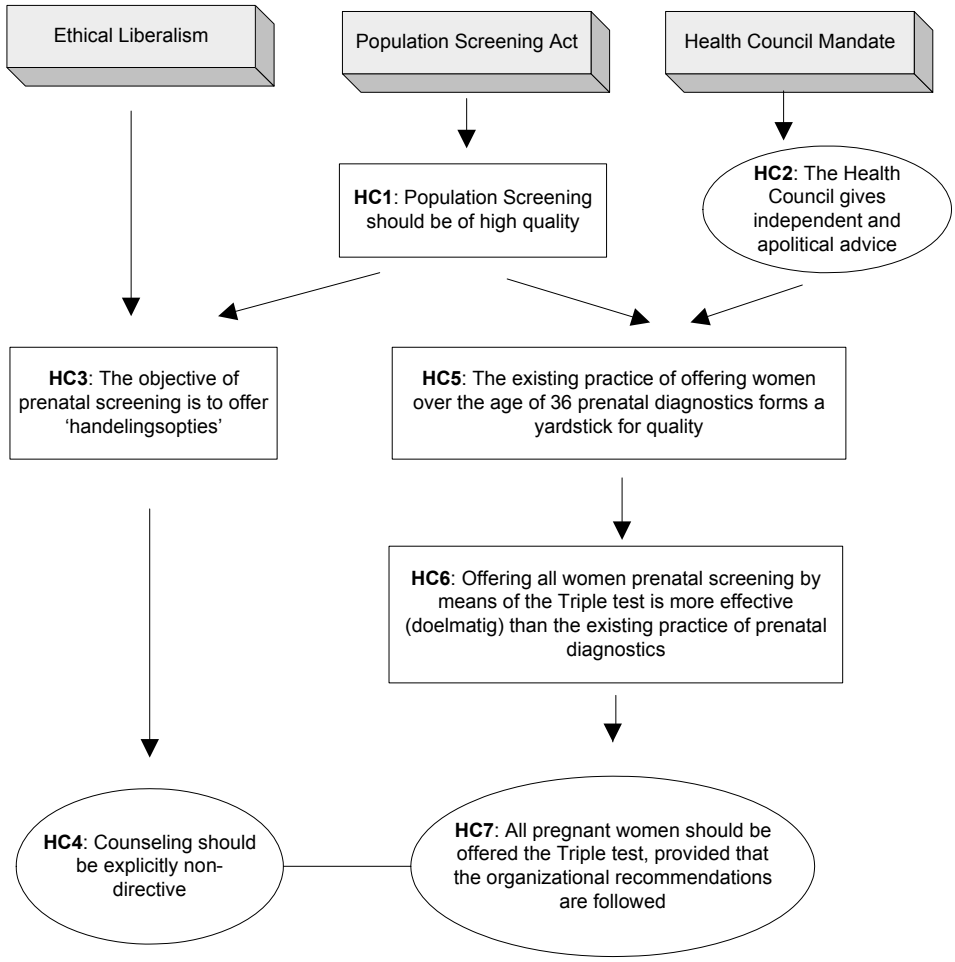

Figure 4.1: Institutionalized discourses, arguments and main storylines of the first Health Council advisory report on prenatal screening

screening, was further enhanced by the position of the Health Council as a boundary organization between science and politics. The Council owes its authority to its position as a scientific, objective and apolitical advisory council. At the same time they are expected to give politically useful advice. In doing so, they cannot avoid taking a normative position. Implicitly or explicitly the assessment of the quality of different screening options always carries norms. The normative position

concerns both the quality standard as well as the kind of quality criteria that are taken into account.

The Health Council's approach for dealing with this intricate position was taking the implicit norms of the existing practice of prenatal diagnostics for women over 36 as a starting point for the quality assessment of prenatal screening (argument HC5). Different quality measures were determined and were judged relative to this existing practice. The existing practice of prenatal diagnostics was thus used as a base on which a conclusion on the quality of prenatal screening could be built, without the need to argue explicitly how the side effects of screening (viz. miscarriages induced by invasive diagnostics, false positive and false negative test results, medicalization of pregnancy) balance with the benefits of providing parents options of choice ('handelingsopties'). Using a metaphor, the existing practice of prenatal diagnostics functioned as a bridge over marshland (or a pontoon) on which the conflicting requirements on the Health Council advice could be combined, without subsiding in the swamp of open-ended arguments. The Council concluded that offering all pregnant women prenatal screening by means of the Triple test is more effective than the existing practice of prenatal diagnostics (argument HC6) and that all pregnant women should be offered the Triple test provided that the organizational recommendations are followed (storyline HC7). An important recommendation was that counseling should be explicitly non-directive (storyline HC4).

The controversy that followed the publication of the advisory report showed that many of the involved actors were not convinced that the configuration of responsibilities that had been proposed by the Health Council was the right way to proceed. In particular there was disagreement on the mutual responsibilities between the government on the one hand and pregnant couples on the other hand. Whereas the Council had argued that government should provide pregnant women of all ages with the opportunity to decide for themselves whether or not to have the test, critics argued that for younger women the low sensitivity of the test and the low risk of Down syndrome formed reasons for government to take responsibility not to offer them the option of choice. The critics supported their position by pointing out that in the conclusion of the Health Council advice the fact that the quality of the Triple test decreases at younger age had been neglected. For younger women the sensitivity of the Triple test is low, meaning that the number of false

negative test and/or false positive test results is high (HC8 in figure 4.2).[139] The critics did not bring in new scientific data about the test quality. The lower test-sensitivity had also been reported in the Health Council advisory report. But, whereas for the critics it was a reason to maintain an age limit for prenatal screening (CRITICS2), arguing that it would lead to unwarranted medicalization of pregnancy and unjustified feelings of reassurance (CRITICS1), the Health Council argued differently.[140] The Health Council felt the overall detection percentage would decrease when restricting the test to an older age group (HC10) and that the value of information on prenatal testing is equal for pregnant women of all age groups (HC11).[141] The Council felt these arguments were more important than the argument of low test-sensitivity for younger women.

The Health Council committee had chosen the existing practice of prenatal diagnostics as a yardstick for quality and in that way tried to refrain from taking an explicit normative position on the value of prenatal screening.[142] The critique of the advice showed that the implicit quality norm of the existing practice of prenatal diagnostics did not provide an unequivocal guideline to assess the relative quality of prenatal screening. There were different aspects of quality, and the critics of the Health Council advisory report assigned a different weight to the relative

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[139] The quality norm of the existing practice of prenatal diagnostics (HC5) did not provide a conclusive argument to settle the difference of opinion between the Health Council and its critics. Regarding the sensitivity of the test, the existing practice of prenatal diagnostics and the proposed practice of prenatal screening were incommensurable. Whereas prenatal *diagnostics* provides a certain diagnosis with no false positive or false negative test results, prenatal *screening* provides an estimation of relative risk. When the relative risk exceeds a certain value, pregnant women are offered prenatal diagnostics. Below this value, women are not offered prenatal diagnostics, though they still run a small risk of carrying a child with Down syndrome. This remaining risk accounts for the false negative test results.

[140] Related to the argument of low test-sensitivity and medicalization of pregnancy, was the argument that cost effectiveness of screening younger women was low and that the provision of non-directive counselling – an important condition for achieving autonomous decision making - would be difficult as obstetricians already experienced time constraints in providing good quality healthcare. The Health Council had also observed this bottleneck, but they considered this not as a principle argument against screening, but as something to be resolved.

[141] "Although the average chance of a child with Down syndrome is smallest for young pregnant women, individual chances can be just as high as in any other age category. The value of information regarding this chance is equal for pregnant women of all ages. Because of this, the committee feels that prenatal screening for Down syndrome should be offered to all pregnant women" (Gezondheidsraad, 2001c, p.166, translated from Dutch).

[142] The Health Council committee on prenatal screening had deliberately decided not to discuss the introduction of a new age limit for prenatal screening. It was argued that there were no objective criteria to decide on a new age limit. (Kirejczyk et al., 2003, p.132)

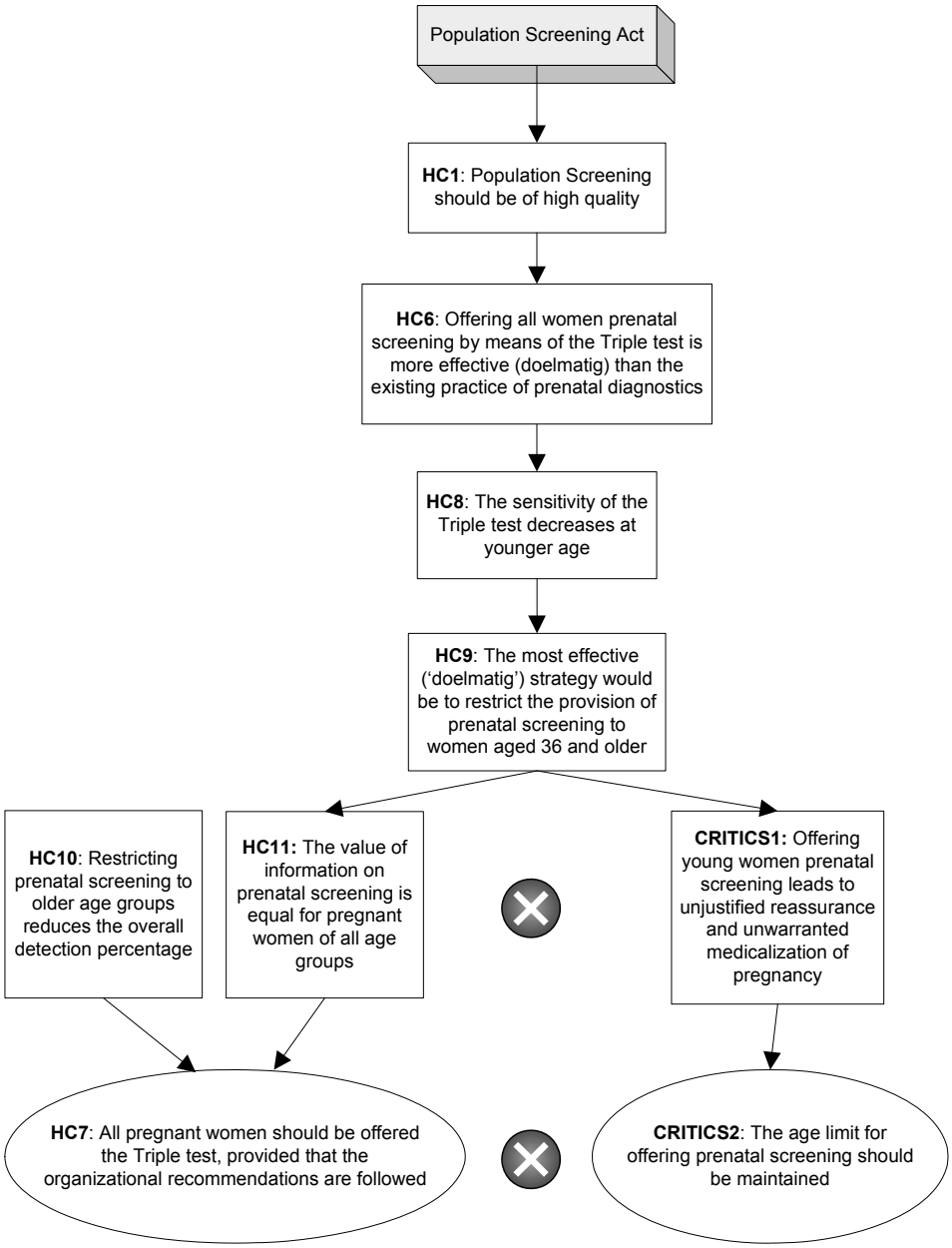

Fig. 4.2: Conflicting paths of argumentation on the quality of prenatal screening and abolishing the age limit

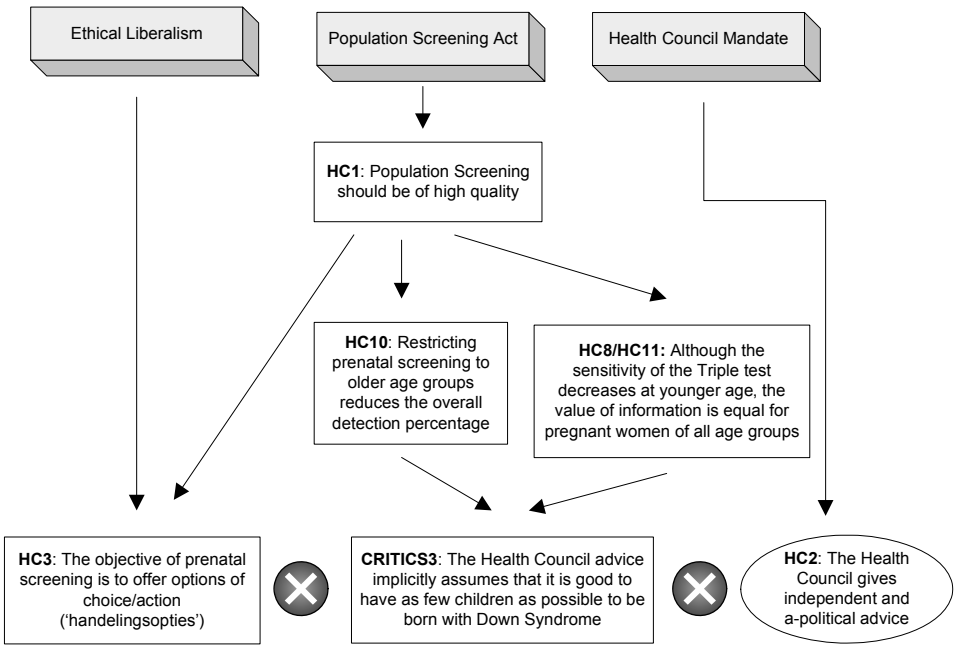

Fig. 4.3: Critique of the Health Council's implicit normative position

importance of these different quality aspects than the Health Council committee had done.[143]

It is explicitly and repeatedly stated in the Health Council advisory report that the objective of prenatal screening is to offer pregnant women and their partners options of choice and not to explicitly limit the number of children born with Down syndrome. Despite this explicit positioning, the Health Council committee was criticized for implicitly assuming that it is good to have as few as possible children born with Down syndrome (CRITICS3 in figure 4.3). That is a criticism which not only conflicts with the aim of prenatal screening, but also with the objective and apolitical position of the Council (HC3 en HC2). The criticism can be understood through the arguments that were offered by the Council to abolish the age limit, in

[143] Besides by using existing diagnostic practice as a yardstick for quality it is taken for granted that this practice represents a broadly accepted quality norm.

particular the argument that restriction of prenatal screening to older age groups reduces the overall detection percentage (HC10).

The Health Council advisory report and the discussion which followed in the diffuse hybrid forum did not result in conclusive argumentation in favor or against abolishing the age limit. Analysis of the argumentative structure of the debate – as presented in this section – shows that critics of the Health Council advisory report drew on similar institutionalized discourses, arguments and technological scripts, as the Council did, but ended up with a different conclusion. Thus, the difference of opinion can not be explained from differences in starting points or arguments. That implies that further exchange of these arguments will not resolve the controversy on abolishing the age limit. The debate as it is structured by the institutionalized discourses of the Prenatal Screening Act and ethical liberalism is structurally inconclusive.

4.3.2 Parliamentary response to the State Secretary's policy decision on the first Health Council advisory report

Above I have shown how the Health Council was reproached for writing an implicitly normative advice suggesting that all pregnant women should be offered prenatal screening not matter what age they are. When the State Secretary decided not to follow the Health Council's advice and to maintain the age limit for prenatal screening, she faced a similar critique. Advocates of prenatal screening blamed her for pushing Christian moral politics. This shows that, whether one is arguing against or in favor of maintaining the age limit, the institutionalized discourse of ethical liberalism is easily mobilized to discredit the owner of the argument for imposing norms on other people in matters that should be individual moral decisions. So, while the widely shared discourse of ethical liberalism seems highly attractive as a governance principle that can preserve normative plurality, the analysis of this case shows that it does not provide a moral order that can resolve responsibility conflicts in the configuration of responsibilities for prenatal screening.[144]

Unlike the Health Council, the State Secretary had a legitimate position to take explicit political and normative decisions. But the State Secretary's decision to

[144] I will come back to this in chapter 7 where I reflect on the dominancy of the ethical liberalism discourse in relation to the aim of organizing responsibilities.

maintain the age limit for prenatal screening did not end the debate on prenatal screening. When the State Secretary's policy was discussed in Parliament, new storylines were introduced in the discussion. The acceptance of these new storylines would involve a change of institutionalized discourse and the debate shifted to a discussion of an eventual change in institutionalized discourse (see fig 4.4). The State Secretary proposed not to follow the Health Council's recommendations, but instead to maintain the status quo. Prenatal screening is not actively offered to women under the age of 36 (SS1). Under the age of 36, women who ask for the test can have one, if they pay for the test themselves (SS2). Members of Parliament criticized her policy as it would lead to inequality between women who are well-informed about the options of prenatal screening and who can ask for a test and those women who are not well-informed (P1). As an additional policy measure Members of Parliament suggested that all pregnant women should be informed concerning the options of prenatal screening (P2). The State Secretary was amenable to accept this policy suggestion (SS3). The policy implied a change in the then prevalent interpretation of the sphere of action of the legal framework provided by the Population Screening Act and of that of the Medical Treatment Agreement Act.

The Medical Treatment Agreement Act deals with rights and responsibilities in the context of the individual doctor-patient relationship and the Act attributes medical practitioners with the obligation to inform their patients about relevant treatment and diagnostic options. The Medical Treatment Agreement Act was used to argue that medical practitioners have the legal obligation to inform pregnant women about the opportunities of prenatal screening. In contrast, the Population Screening Act makes the provision of information about prenatal screening subject to license requirement.[145] According to the legal framework of the Population Screening Act, the Minister of Health - not the individual medical practitioner - is accountable for the decision whether or not – and under what conditions - to inform pregnant women about prenatal screening.

[145] That is, in the then usual interpretation of the Population Screening Act.

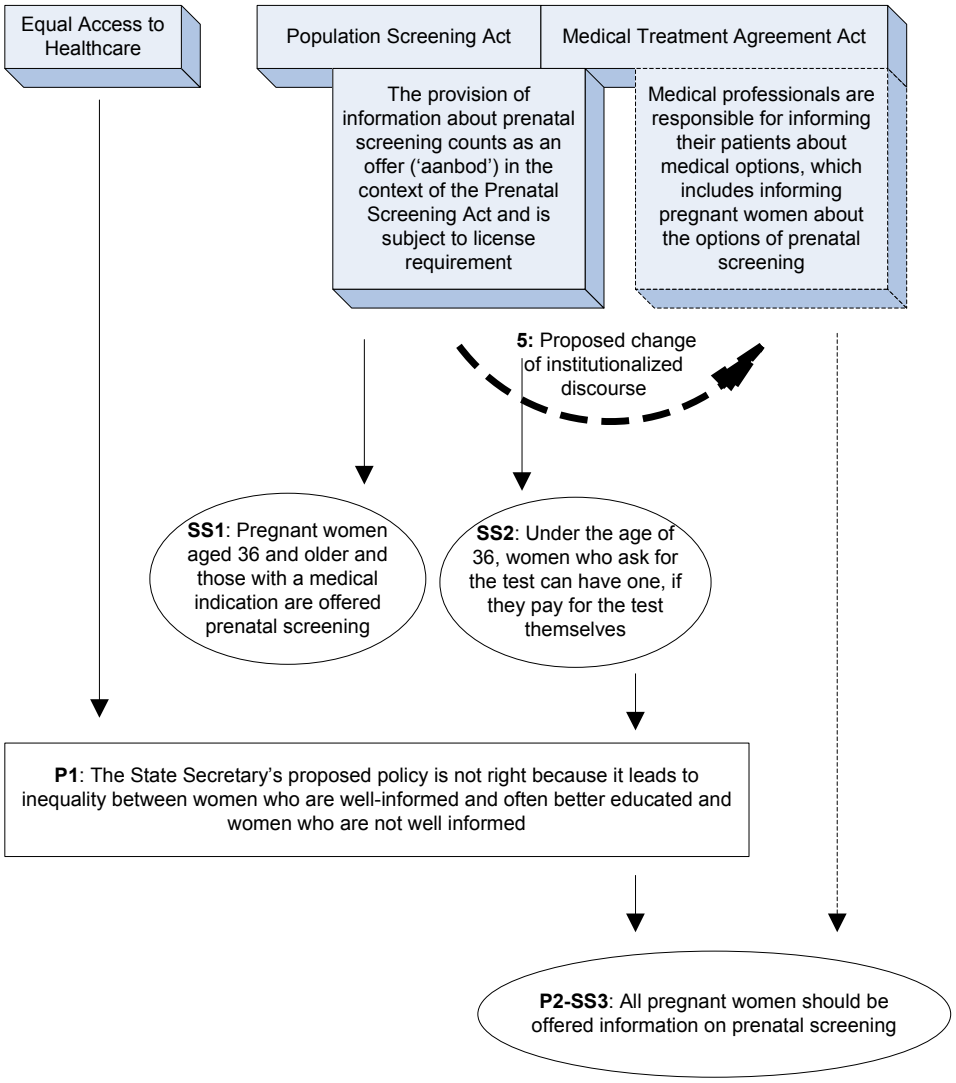

Fig 4.4: A new story line and the implicated change of institutionalized discourse in the Parliamentary debate on prenatal screening (November 2003)

The proposed policy change suggested that the provision of information about prenatal screening is a responsibility of medical practitioners, regulated by the legislative framework of the Medical Treatment Agreement Act. This proposed change in institutionalized discourse is visualized in figure 4.4 by the dotted arrow. Figure 4.5 depicts the shift in governance arrangement and the change in the configuration of responsibilities that is implicated with this adjustment.

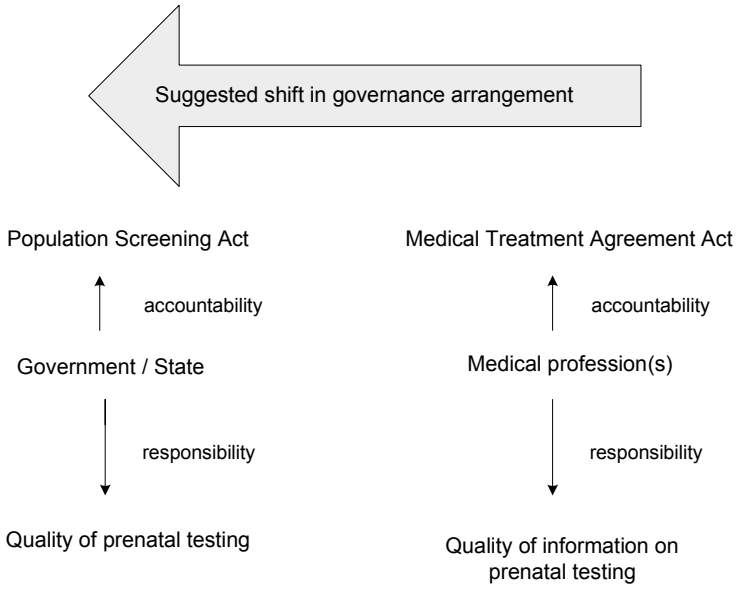

Figure 4.5: Suggested shift in governance arrangement and related change in role responsibilities.

The introduction of the equality argument in the Parliamentary discussion of November 2003 entailed a change in the overall main structure of the debate. The discourse on equality provided an argument for changing the then prevalent institutionalized discourse on the demarcation between the Population Screening Act and the Medical Treatment Agreement Act. A new policy was suggested in which a distinction is made between the provision of prenatal screening and the provision of information about prenatal screening, which provides a compromise between those arguing in favor of abolishing the age limit and those arguing against it. The proposed compromise did not immediately lead to agreement. Rather, it introduced a new focus in the discussion: the demarcation between Population Screening Act and Medical Treatment Agreement Act.

4.3.3 The State Secretary's policy decision on the second Health Council advisory report

In April 2004 the Health Council published a second advisory report on prenatal screening. The advice presented new technological options and the latest scientific knowledge on prenatal screening. A new storyline was introduced which read that the so-called combination test was qualitatively better than the Triple test, also

regarding the sensitivity of the test (HC15 in fig. 4.6). It was recommended that prenatal screening by means of the combination test should be made available to all pregnant women (HC18 in fig. 4.6). Like the first advisory report, the second advisory report stated that a coordinated program within a single organizational structure and with national management was needed to guarantee quality of the screening.[146] Additional arguments were given stating that the recommended organizational structure would enable a restructuring of the present situation of unbridled growth (HC14 in fig. 4.6) and that within such a structure new scientific developments could be steered in the right direction (HC13 in fig. 4.6). The Health Council committee advised to implement the recommended organizational structure irrespective of the outcome of decision making on prenatal screening (HC16 in fig. 4.6).[147] And it stated that "in order to enable a strong control it is crucial that the screening program is linked to the funding of medical practice" (Gezondheidsraad, 2004, p.56) (HC17 in fig. 4.6). Furthermore, the Health Council did not accept the change of institutionalized discourse as was implicated in the State Secretary's policy compromise. It was argued that systematically informing pregnant women about testing opportunities calls for ex ante quality assessment and that the licensing system of the Population Screening Act provides the legal instrument for that (HC12 in fig. 4.6).

For the State Secretary the new technological scripts as presented in the second Health Council advice, which entailed an improvement in the sensitivity of the test, did not lead to a change in her prenatal screening policy (SS1, SS2, SS3 in fig. 4.7). It became clear that the low test-sensitivity was not the main reason for the State Secretary to maintain the age limit. Rather, the low incidence of Down syndrome in younger aged women formed the main reason (SS6 in fig. 4.7). Furthermore, the State Secretary offered additional arguments for her policy. She argued that the script of the test itself, in particular the organizational requirements which are

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[146] "The committee recommends making screening for Down's syndrome and neural tube defects available to all pregnant women, using the combination test (1:175) or else second-trimester ultrasound scan. It believes that the high quality required for implementation is feasible, on condition that there is a coordinated program within a single organizational structure and with national management." (Gezondheidsraad, 2004, p.11,12).

[147] "Central control is necessary for the restructuring of the present situation of unbridled growth and for quality control, registration and evaluation of the screening program. Control of this kind is also needed to steer new developments in the right direction" (Gezondheidsraad, 2004, p.17,18). The committee advises (...) to implement this organizational structure regardless of the results of the decision making process concerning screening" (Gezondheidsraad, 2004, p.56).

implied when organizing the quality of the screening, come to the fore as conflicting with pregnancy in terms of something of personal and individual concern (SS4, SS5 in fig. 4.7). Policy needs to find a middle course in between these two requirements (SS7 in fig. 4.7).

The change of institutionalized discourse which had been suggested during the parliamentary debate regarding the first Health Council advisory report was now formally stated in the policy letter about the second Heath Council advisory report. It argues that pregnant women ask for medical counseling during their pregnancy.[148] It follows that the provision of information about prenatal screening does not count as an offer in the context of the Population Screening Act, but rather that the Medical Treatment Agreement Act applies and that medical professionals are responsible for informing pregnant women about the options of prenatal screening.

[148] "In the event of a pregnancy there is a demand for care, namely that of a pregnant women wanting guidance in her pregnancy, and who also runs certain risks due to her pregnancy" (Kamerstukken II, 2003-2004e, p.2).

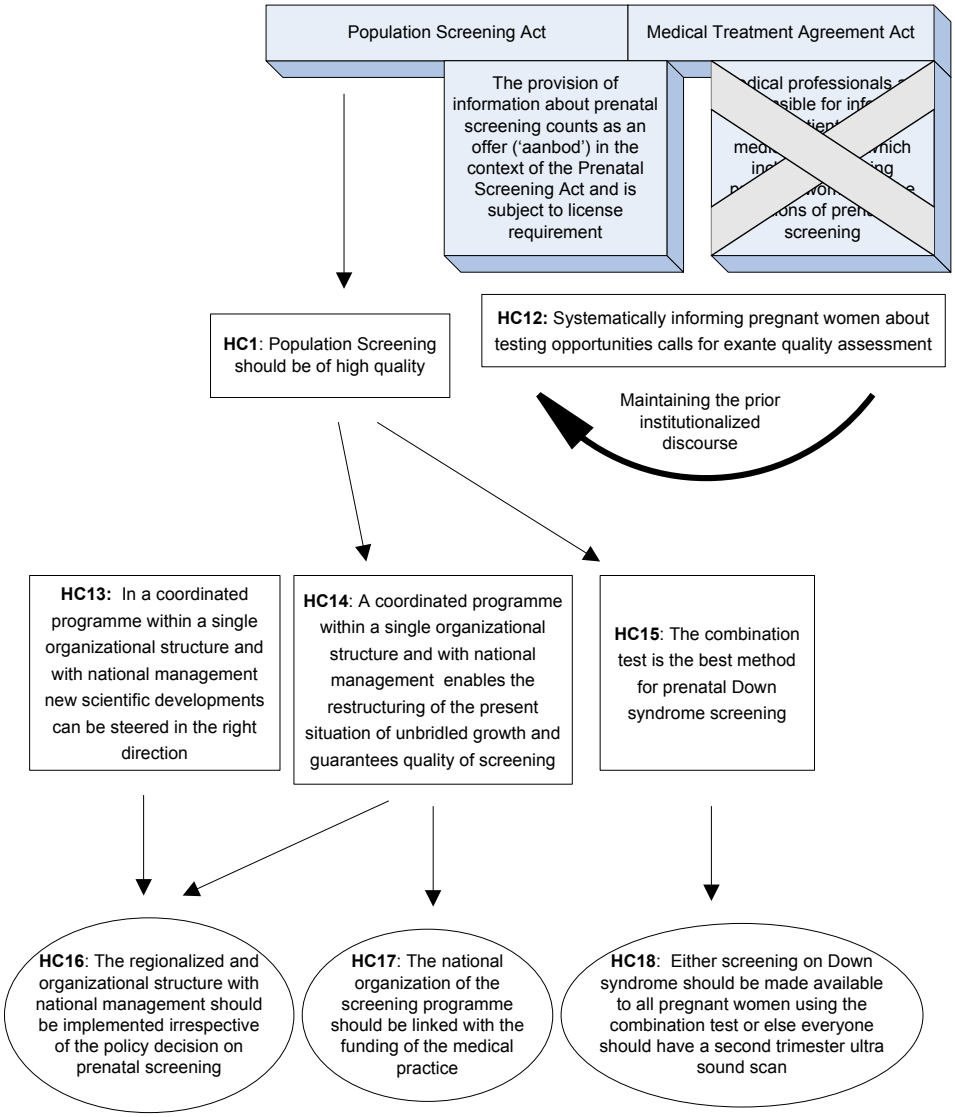

Fig 4.6: The second Health Council advisory report on prenatal screening

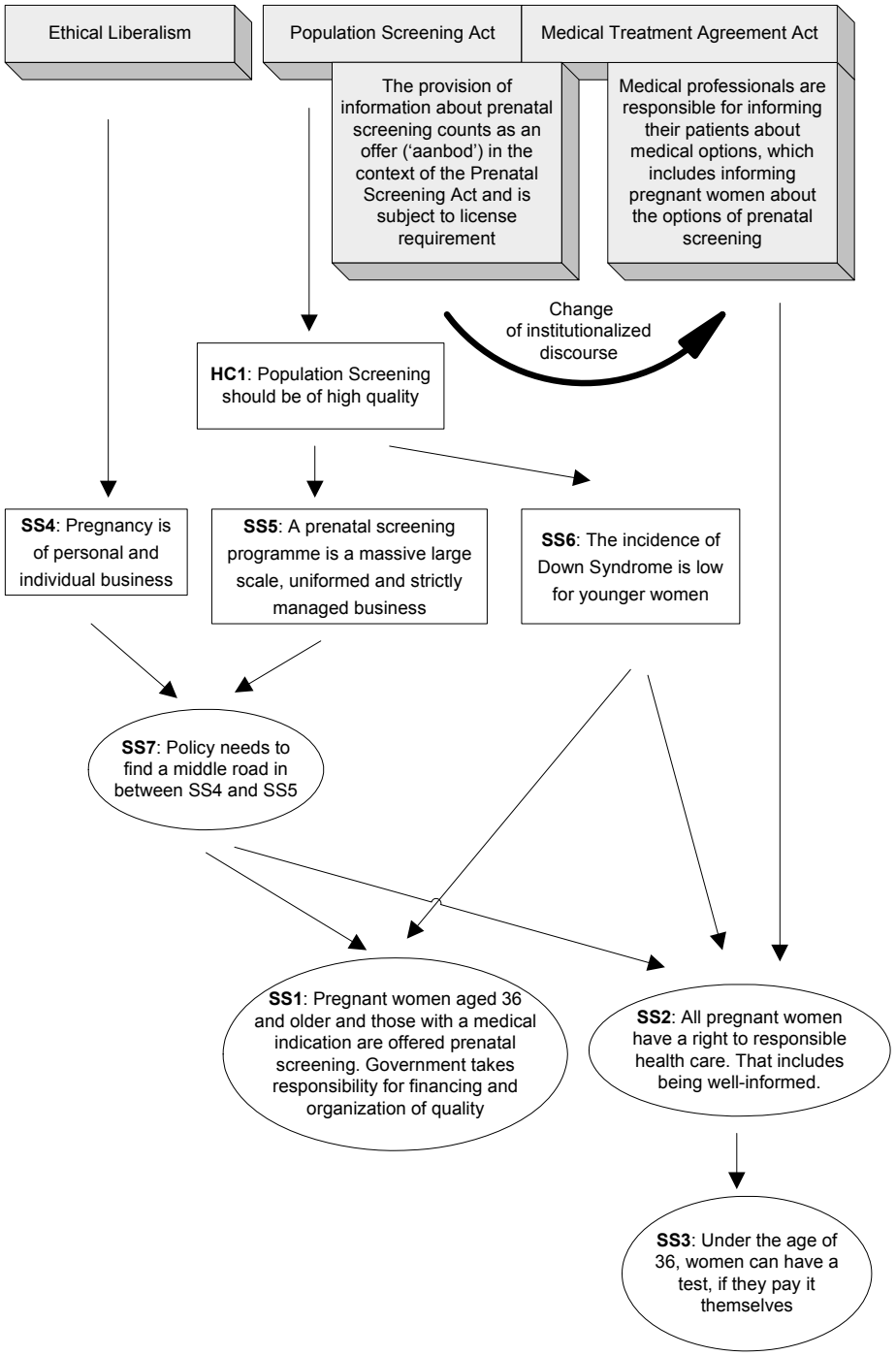

Fig 4.7: The State Secretary's policy response to the second Health Council advice on prenatal screening

4.3.4 Conclusion

So far the analysis has shown that the introduction of prenatal screening involved many changes in the roles and responsibilities of medical professionals, of government and of pregnant women and their partners. As testing opportunities changed over time, the role of medical technology also changed. There was no consensus on the preferred configuration of responsibilities for prenatal screening. Medical practices varied locally and regionally and some of these practices were considered controversial. From the late 1980s onwards, the introduction of prenatal screening on Down syndrome in the Netherlands involved extensive discussion between a large variety of different actors – medical researchers, medical professionals, patient groups, policy makers, members of parliament etc.

In the period analyzed here, 1998-2004, extensive discussions and debates on the preferred configuration of responsibilities took place in different arenas. At the end of the period, the local and regional variety in the medical practice of prenatal screening was still present. Nevertheless progress had been made in the process of organizing responsibilities for prenatal screening. The discussions that took place contributed to articulating and negotiating the relevant moral order, the acceptability and desirability of the changing roles for the involved actors and the affordances of the different medical technical options.

Different arenas took turns in being the focal arena for debate. The different nature of each of these arenas enabled particular contributions in organizing responsibilities for prenatal screening. And the alternation between the different arenas accounts for the overall progress that was made in organizing responsibilities for prenatal screening. A Health Council advisory committee on prenatal screening played an important role as a spokesperson for the different medical technical options that could be used for prenatal screening. The committee wrote two advisory reports in which it described and compared the affordances of these different medical technical options. The committee selected what they thought was the best medical technical option and wrote extensive recommendations on how to embed prenatal screening within the Dutch healthcare system. These recommendations involved a role change of gynecologists and midwives, but also the introduction of regional laboratories and national coordination to guarantee and maximize the quality of the test. The Council's report was well received in terms of the scientific quality of the advice. Thus the arena of the Health Council committee

contributed in organizing responsibilities by forming an authoritative spokesperson for the various medical technical options that could be used in a prenatal screening program.

The larger configuration of responsibilities that was sketched in the Health Council advisory report was not accepted by all actors involved. This became clear when the advisory report was discussed in the diffuse hybrid forum. The report was criticized for carrying implicit contested norms, in particular with regards to the recommendation to abolish the age limit for prenatal screening. My analysis of the discursive structure of the argumentation shows that the arguments and storylines that were deployed by the critics of the Health Council report were structured by the same institutionalized discourses as were the arguments and storylines of the Health Council Committee. The institutionalized discourses of ethical liberalism and the Population Screening Act were inconclusive concerning the question whether or not to abolish the age limit for prenatal screening. The Health Council did not have the authority to conclude the debate as the Council lacks the mandate to write an advice which is considered explicitly normative.

The overall structure of the debate changed and the deadlock in the debate was overcome when Parliament became the focal arena for discussion. The State Secretary, supported by Parliament, was mandated to take an explicit normative decision. And although Parliamentarians were divided on the issue, a change of institutionalized discourse concerning the scope of the Population Screening Act and the Medical Treatment Agreement Act enabled a political compromise to inform all pregnant women about the options of prenatal screening. In the meantime new and qualitatively better testing options were being developed and the change of institutionalized discourse was contested by the Health Council. Both of these circumstances kept the discussion open for a while longer. Eventually they did not occasion a change in governmental policy.

4.4 Discussion on prenatal screening in the Forum Biotechnology and Genetics (2000-2004)

This section presents an analysis of the discussion on prenatal screening that took place in the Forum Biotechnology and Genetics in the period between December 2000 and September 2004. The analysis is based on observations made during Forum meetings, and on e-mail discussions. A detailed analysis was made of who

said what, but because of privacy considerations of the people involved in the discussions, I cannot always give detailed reports to the reader. I will distinguish three episodes in the FBG discussions on prenatal screening. These episodes more or less coincide with the three episodes in the overall debate on prenatal screening that have been discussed in section 4.3.

4.4.1 The first and second episode: How the FBG turned into a microcosm

4.4.1.1 From information exchange to reducing complexity and striving for consensus

In the first episode, that starts from the inception of the Forum Genetics, Health and Healthcare – the precursor of the FBG – in December 2000 and which lasts until the end of January 2004 the issue of prenatal screening was discussed several times. In the meeting of November 7th 2002 – that is 1.5 years after the publication of the first Health Council advisory report and a year before the State Secretary took a policy decision on the advice – one of the Forum members gave a presentation on the Triple test in which he criticized the use of the Population Screening Act as a relevant legal framework for governing the introduction of this test. The presentation is followed by some plenary discussion. It is concluded that individual Forum members can take action as they see fit and that the issue is kept on the Forum's agenda. During the preparation group meeting of 12 December 2002, the issue is discussed again, but in contrast with the plenary meeting of November 2002, the discussion focuses on the development of the policy discussion: who raises his voice and when can a policy decision be expected? A policy decision is not expected as long as a new government has not been established. A similar discussion takes place during the next preparation group meeting of January 30th 2003. In the first episode the issue of prenatal screening never gave occasion to an extensive debate, no attempts were made to develop a shared position. At some point Forum members took action individually, addressing the Ministry of Health and urging it to take a policy decision on the Health Council's advisory report. In this first episode the Forum functioned mainly as a platform in which the various represented parties exchanged information on the state of policy affairs concerning prenatal screening.

During the winter of 2004, some two months after Parliament had discussed the first State Secretary's policy decision not to abolish the age limit for prenatal screening, the nature of the FBG discussion on prenatal screening changed. During

the FBG plenary meeting of January 22nd, the decision was taken to formulate a Forum position on the issue of prenatal screening. This marks the beginning of a second episode in the Forum's involvement with the issue of prenatal screening. The announcement of a round table meeting on prenatal Down syndrome screening and baby mortality, organized by Members of Parliament, formed the immediate occasion. Relative outsiders to the discussion, an insurance industry representative and the Forum's chair, proposed and stimulated the formulation of a Forum position as input for the round table meeting. Although the issue had come up during several earlier Forum meetings, only at this occasion different conflicting viewpoints on prenatal screening clearly came to the fore. Some Forum participants argued that the FBG would not be able to reach a shared position. The Forum's chair, however, persisted in the idea of formulating a Forum position: *'At least we can agree on some points, but we should not enforce consensus.'* There was not much time left to formulate a position, as the parliamentary round table meeting would take place in 2.5 weeks time. Eventually, eleven Forum participants contributed to the formulation of a Forum position by means of extensive e-mail exchange.

It proved difficult to reach even partial agreement on the issue of prenatal screening. The wide range of heterogeneous arguments and considerations, which featured in the wider debate on prenatal screening, were reproduced within the FBG discussion. At various moments throughout the process of formulating a shared position, Forum participants strongly expressed their opinion that it would be better not to bring out a joint Forum position. The Forum's secretary who was faced with the difficult task of composing a letter based on the widely varying input from the different Forum participants, simply added up all that had been said. The secretary listed the different opinions in the FBG and did not actively try to reach consensus.[149] The first draft letter that she wrote reproduced the complexity of the

[149] In the letter it was also explicitly stated that: *'Preceding the round table conference "prenatal screening/baby mortality", the Forum Biotechnology and Genetics (FBG) wants to offer you a summarizing overview of the opinions on this issue that were recorded within the FBG*' (FBG, 2004c, p.1). The secretary's role interpretation was in line with the forum's aim, as referred to in the letter: *'The exchange of information and the assessment of new developments offer important information that can contribute to balanced communication, opinion and decision making by the central government, politics and other involved organizations within the field. In that sense, it can be important for political decision making'* (FBG, 2004c, p.1). Historically this objective can be traced back to the starting phase of the Forum Genetics, Health and Healthcare. Initially there was a strong conviction that parties would not want to participate if reaching joint positions was the objective.

debate. The letter did not attempt to clarify what exactly the main points of controversy were nor on what issues consensus existed. The secretary continued to process new arguments that were brought in, producing a second and third draft version of the letter, while in the mean time more participants expressed the opinion that the letter as it was now compiled should not be sent:[150]

> *'I applaud your attempt to translate the cacophony of voices that have reached you concerning this matter into a letter. However, I feel that this letter is of no aid to the secretary of state, or the minister, or the FBG. (...) I think we ought to try to arrive at a clear position of at most one page, that everyone can support, or otherwise that we should conclude that we cannot come to any agreement and therefore cannot send a letter.'*
>
> (…)
>
> *'I don't believe there is much point to informing the world at large of the fact that one can find a jumble of opinions within our assembly. That can be assumed to be common knowledge.'*

Many Forum participants felt that a reduction of complexity, or reaching consensus on at least a few issues had to be the main objective of a Forum position. One of the Forum participants motivated this opinion by saying that:

> '*the most pleasant swimming water for a politician to swim lengths in, is "when the scientists have not yet reached a decision."'*

In other words, if the Forum is not able to reduce complexity or to reach (partial) consensus, that would keep the politicking going.

The Forum's secretary continued to work on the letter, without actively reducing complexity. Meanwhile the comment that the letter was too complex and that at least partial consensus had to be found was repeated by several Forum participants.

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[150] 'I have a growing suspicion that face to face consultation is the only way towards an eventually unequivocal perception of issues. This requires timely planning. Organization X would be glad to make a room available.' (…) 'The draft letter is primarily an attempt to voice the full range of views within the FBG. Together with X, I wonder how this will look to a reader/member of parliament with or without knowledge of the issues at hand' (quotes are taken from the email discussion on prenatal screening).

Towards the end, the Forum members' objections against a letter in which all kinds of different and partly conflicting arguments and considerations were summed up, turned into their active attempt to reduce complexity and to reach (partial) consensus.

4.4.1.2 The reproduction of complexities in the microcosm of the FBG

The discussion among Forum members reflected very much the contents of the wider debate at that time. The main point of discussion in the FBG concerned the alleged tension between the Population Screening Act and the Medical Treatment Agreement Act. The provision of prenatal screening - and especially the provision of *information* about prenatal screening - falls within a grey area in between the two legal frameworks. There was disagreement in the FBG whether the one or the other framework should prevail. Some Forum members argued that there are tensions between the two legal frameworks, in the sense that both frameworks pose conflicting requirements on the physicians' role responsibility concerning the provision of information about prenatal testing to pregnant women. Others denied that there were tensions. Underneath this difference, there lies a discussion about the preferred configuration of responsibilities for prenatal screening.

Apart from the question whether or not informing women on prenatal screening counts as provision ('aanbod') within the legal framework of the Population Screening Act, something else was at stake which accounts for the confused discussion on the appropriate legal framework. Besides protecting people against detrimental screening programs, the license requirement in the legal framework of the Population Screening Act is a means to govern, or rather to actively construct the quality of screening. To organize the quality of screening at the collective and national level was thought particularly relevant in the case of prenatal screening. Some Forum members doubted whether high quality could be guaranteed, if the framework of the Medical Treatment Agreement Act was to structure the configuration of responsibilities for prenatal screening.

In the e-mail discussion, Forum members tried to gauge, and offer ways to influence, how the legal discussion would evolve. As the Parliamentary debate on prenatal screening had not yet been concluded, there was still room to influence decision making. Within the Forum discussion, considerations concerning the appropriate governance arrangement – which legislative framework should apply – mingled with other considerations on the preferred configuration of responsibilities

in particular regarding the question whether or not the age limit should be abolished.

The ramifications of putting either the one or the other legal framework upfront were uncertain. It made the subsequent discussion very complex. Especially those people, who thought that all pregnant women should be provided with prenatal screening, were faced with a dilemma. The State Secretary had stated that she intended to restrict the provision of prenatal screening to pregnant women above the age of 36 and to provide pregnant women of all ages with information about prenatal screening. The argument that the State Secretary's position was legally not tenable was used to challenge that policy. But it was uncertain what would be the ramifications if that argument was to be accepted. Two scenarios were possible: either the State Secretary would follow the Health Council advice after all and prenatal screening would be provided to all pregnant women, or the State Secretary would maintain the age limit and the provision of information about prenatal screening to pregnant women under the age of 36 would altogether become illegitimate. To challenge the State Secretary's position as legally untenable, there was a chance that – what some considered – the best scenario would unfold: all women would be offered prenatal screening. But there also was a chance that – what some considered – the worst scenario would follow: the provision to women under 36 of information about prenatal screening would become illegitimate.

Forum members' repeated call not to write a position paper that would simply reproduce the complexity of the debate resulted in several attempts to eliminate tensions and controversies from the letter. The Forum's secretary called upon Forum members to contribute to the formulation of a letter, which could carry away everyone's consent. Several suggestions were made. Two Forum participants took up the writing themselves. In their letter proposal, all references to the controversy on the legal frameworks were dropped and so was the reference to the age limit. What remained was a clear message, an argument in favor of a concrete clinical practice: to provide pregnant women of all ages with information about prenatal screening. That position was in accordance with the State Secretary's proposed policy and it left the legislative puzzles for other people to solve.

Leaving out all references to the legislative frameworks, focusing instead on concrete clinical practice, seemed indeed a promising route to pursue, because disagreement and uncertainty about the scope of the two legal frameworks

accounted for much perplexity. For a moment it seemed that a clear and joint position was within reach. Soon however, complexity was brought back into the discussion. Again, the interpretation of the Population Screening Act was at stake, but in a different way than before. In the early stage of the e-mail discussion, Forum participants – on their own account - assumed various positions regarding the scope of the two legal frameworks. In this later stage, reference was made to the position taken by Professor de Wert, an authoritative and well-known professor in bio-medical ethics.[151] In an article in the weekly medical journal 'Medisch Contact', De Wert had argued that the State Secretary's policy was not legally tenable. He argued that the distinction, such as proposed by the State Secretary, between 'routinely providing information about prenatal testing and actually providing these tests was in contradiction with the canonical interpretation of the Population Screening Act.' (De Wert, 2004, translated from Dutch). De Wert's position on the legal issue was brought into the discussion as an additional argument – besides a medical and an ethical argument - to support the storyline to abolish the age limit for prenatal screening.

De Wert's arguments and considerations were adopted by the Forum's secretary to rewrite the Forum's letter yet another time. But Forum agreement on the legal issue did not provide for overall consensus. The Forum's letter as it was now formulated argued that pregnant women of all ages should be provided with the option of prenatal screening. But one of the Forum members argued that the proportion between the benefits and side effects of prenatal screening is better for women of older age groups and that this forms an argument to preserve an age limit for prenatal screening. His position was in line with the formal position of the representative organization he worked for.

To increase the overall consistency of the Forum position letter, this Forum member was asked to give up on his 'minority' position. He did not give in and his 'minority' position was made visible in the supplement to the final position letter. In the main text of the position letter it was stated that the *majority* of the FBG thinks that the State Secretary's policy was medically, ethically and legally unjustifiable:

[151] He is also a member of the Health Council committee on the Population Screening Act and a member of the Health Council committee on Prenatal Screening.

"*legally unjustifiable, because an unjustified distinction is made between informing about and providing prenatal screening; and because for women under the age of 36, legal protection against low quality prenatal screening is undermined; because for women under the age of 36 regulations with regard to for example counseling and/or the organizational aspects of screening will be withheld"* (FBG, 2004c, p.2).[152]

The letter concluded that it had not provided a final solution:

'As you can derive from the above, with this letter the FBG does not yet offer you a solution. Yet the FBG was of the opinion that it had to send you this letter in order to help you in preparing for the round table meeting' (FBG, 2004c, p.3)

4.4.1.3 Conclusion on the nature, working and productivity of FBG interactions in the first and second episode

I have analyzed the nature, the working and the productivity of the Forum's interactions during the first and second episode of the Forum's involvement with the issue of prenatal screening. The nature of the Forum's interactions changed over this period. External incentives and circumstances as well as internal mechanisms played a role in this process of change. In the first episode the FBG was mainly a platform for information exchange on the state of prenatal screening policy affairs. The second episode marks a change in the nature of the Forum. From a platform for

[152] Full quote: 'The FBG, however, does not support the State Secretary's policy that asserts that all pregnant women may be informed about prenatal screening, but that it may not as a rule be offered to women younger than 36. As such the provision of licenses for prenatal screening is limited to women aged 36 or over. The distinction between informing about and offering screening is undesirable according to the FBG, because both informing and offering are seen as aspects of the concept 'offer' in regarding the scope of the Population Screening Act (WBO). Narrowing the concept of 'offer' does not correspond to the advice provided by a number of Health Council committees and previous intentions from the ministry of health to interpret the concept as such. The majority of the FBG feels that the afore mentioned distinction is medically, ethically and legally unjustifiable. Medically unjustifiable because a 28 year old woman also has a chance of giving birth to a child with Down syndrome. Ethically objectionable because the woman is not offered alternative courses of action and is therefore denied the possibility to make a responsible decision. Legally unjustifiable because in the light of the Population Screening Act (WBO) an unwarranted distinction is made between offering information and offering prenatal screening; because for women under 36 years of age the legal protection against substandard forms of prenatal screening is undermined; because for women under 36 years of age prerequisites regarding counseling and organizational aspects surrounding screening will be withheld' (FBG, 2004c, p.2).

information exchange the Forum changed into a hybrid forum for 'representation'[153], in which the individual members stand for a particular (group) interest or expertise, and in which the forum aims to communicate their opinions to the wider world.

There are two circumstances that explain this change. One is related to changes in the overall working of the Forum[154], the other is related to changes in the context of the wider prenatal screening debate. In the earlier stage of the Forum's lifespan, that is the stage preceding the merging of the Forum, Genetics, Health and Healthcare with the Platform Medical Biotechnology, the formulation of shared viewpoints was not a strong objective. There was an initial fear among Forum members to be associated with a Forum position they would not approve of. It was thought that the Forum might fall apart if one attempted to reach joint positions. Furthermore, the secretarial support needed to facilitate discussion and to formulate formal viewpoints was lacking. At the time, Forum interactions focused on the exchange of viewpoints and the sharing of information. When it was thought appropriate to intervene in a debate, it was up to individual members to take action on their own account.

In a later stage, after the Forum Genetics Health and Healthcare had merged with the Platform Medical Biotechnology, the functioning of the Forum changed. The Forum's secretarial support was expanded. Furthermore, the merger with the former Platform Medical Biotechnology brought some change of organizational culture: the Forum became more oriented towards joint action. And joint action became easier when Forum members, though most of them still associated with representative organizations, became formally represented in a personal capacity. And finally, because the Forum relied on uncertain governmental subsidy, there was an increasing pressure for the Forum to improve its external visibility and to prove its right of existence. All these changes made it easier and more desirable for the Forum to formulate joint positions.

The context of the wider debate on prenatal screening forms a second explanation why at this stage of the debate the Forum changed into a representative Forum. In

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[153] See chapter 3 for a more elaborate discussion of the kind of representation present in the Forum.
[154] See chapter 3 for a more elaborate discussion of the change in the overall working of the Forum.

an earlier stage of the wider debate on prenatal screening the authoritative Health Council had taken the lead by writing an advisory report. And all were waiting for the State Secretary to formulate a policy on prenatal screening and to respond to the Council's advisory report. When the State Secretary had finally announced her policy plans, a Parliamentary debate started, which formed a window of opportunity to influence decision making. The organization of a Parliamentary round table meeting provided the occasion to do so.

During the 2.5 weeks of e-mail exchange further changes gradually emerged. The FBG changed from a forum for hybrid representation in which the Forum's secretary just added up all that had been said, into a forum for hybrid *re*-presentation, a forum in which the issue of prenatal screening was presented anew. Re-presentation was the result of the active attempts to reduce complexity of the issue and the active attempts to reach consensus on some aspects. Re-presentation involved the exchange of arguments and storylines between Forum members and the articulation of new arguments and storylines with the aim of finding a common ground. Eventually the combination of external pressure to formulate a position paper and the objections against a paper in which the heterogeneity and complexity of the prenatal screening debate would be reproduced, created the incentive to reduce complexity and to strive for partial consensus.

The discussion and debate in the FBG, which took place when the FBG tried to contribute to the prenatal screening debate by writing a position paper, reflected the wider debate on prenatal screening. The FBG thus functioned as a *microcosm*, a forum in which positions similar to those in the wider debate are present.[155] *Re*-presentation of those positions within the confines of the Forum is than potentially productive to solve the controversy in the wider debate. But reducing complexity and achieving (partial) consensus was not an easy matter in this case. The debate was very complicated, mainly because of uncertainty and disagreement on the scope of the two legislative frameworks. Discussion and debate on this issue very much overshadowed responsibility positioning between the Forum members on the issue of prenatal screening. The attempt to reach a clear position and partial consensus by foregrounding clinical practice and by leaving legislative issues for

[155] That is not to say that all of the involved actor groups were present. Midwives and gynecologists were formally represented in the Forum, but never attended the Forum's meetings.

legal experts to solve was a promising attempt to disentangle the responsibility issues. There appeared to be agreement on the State Secretary's policy to inform all pregnant women about the options of prenatal screening. In that sense this attempt to reduce complexity was successful.

The clarity in the Forum's position letter was only short-lived. The legal issue resurfaced in the Forum discussion, when the opinion of an authoritative legal expert from outside the Forum was quoted. This shows that the Forum is not isolated from the wider world. Eventually the authority of this legal expert was used to settle the Forum's position in the legal debate. The age limit was also brought back into the discussion as it was thought that consensus on the legal issue would also bring consensus on the age limit. But that appeared not to be the case. The inconclusiveness of the wider debate was reproduced in the FBG. Eventually a position letter was written which voiced Forum agreement on the issue of informing and on the legal issue, but in which the controversy regarding the age limit did not get resolved.

4.4.2 The third episode: Discussion on the State Secretary's policy concerning the second Health Council advisory report

On the 29th of April 2004 the Health Council published its second advisory report on prenatal screening in which it recommended making prenatal screening by means of the combination test available to pregnant women of all age groups. A week later, on the 6th of May 2004, one of the Health Council's committee members presented the advice during an FBG meeting. During this meeting it was decided to re-establish the working group that had written the first Forum's position paper on prenatal screening. The aim was to formulate a Forum position on this second Health Council advice. The addressee of this FBG position would be the State Secretary who had announced her policy response to be published at the end of September 2004 (Kamerstukken II, 2003-2004f). But the actual political developments went much faster. Very much to the surprise of the Forum members a policy response to the advice was already issued on the 7th of June. The State Secretary stated that the improved medical technical options did not form a reason to change her former prenatal screening policy. The policy decision was immediately followed on the 8th of June by a general meeting ('algemeen overleg') between the permanent Parliamentary commission for health issues and the State Secretary.

These fast political developments placed the objective of the FBG prenatal screening working group in a new perspective. The political developments were closely followed and the aim of the working group was geared towards the actual political situation. An FBG position merely on the Health Council advice was no longer thought to be relevant. A second parliamentary debate took place on the 29th of June. During this debate a parliamentary motion suggested making prenatal screening a provision for pregnant women of all ages (Kamerstukken II, 2003-2004d). The State Secretary advised against the motion and the motion was adjourned. A vote on the motion would not take place before the beginning of September. The FBG's secretary argued that it was now up to the working group to take a position on the State Secretary's line of policy and, if deemed necessary, to formulate a standpoint so as to try to influence political decision making.[156] The FBG working group on prenatal screening met two times – on July 7th and August 11th - to discuss the issue.

4.4.2.1 The State Secretary's policy as a stepping stone for further responsibility positioning

Regarding the second episode of the FBG's involvement with the prenatal screening issue I concluded that the FBG formed a microcosm in which the various arguments and storylines of the wider debate were re-presented and that the controversy on the age limit was reproduced. This was also recognized and explicitly stated by some of the Forum members, while discussing the State Secretary's policy decision on the second Health Council advisory report:

Forum member A:

> *'I may not be wearing a suit today, but nevertheless today's meeting is an important one. It has been debated for over twenty years in the Netherlands whether prenatal screening on Neural Tube Defects and Down syndrome should or should not be offered. I have witnessed all the arguments of the past twenty years coming by here. Discussion in the FBG in that sense is a good reflection of the discussion within society.'*

Forum member B:

> *In that sense, the FBG functions well.*

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[156] E-mail by FBG secretary, July 5th 2004.

Forum member A:

> *We should not harbor the illusion that we can now conclude that discussion. Even if that would be feasible, it is a real danger that people will say 'Jeez, interesting, but who are you anyway?'*[157]

During the meeting different approaches were taken in trying to reduce the complexity of the discussion. At the start of the first meeting, the controversy on cost figures, which had emerged during the recent parliamentary debates, was subject of discussion. This discussion was put aside. Consensus emerged that the issue of collective payment of prenatal testing is an issue of solidarity, a political issue. It was agreed that it is not up to the FBG to take a position on the issue of payment. The working group chair then concluded that the State Secretary's policy to provide all pregnant women with information about prenatal testing sufficiently meets the recommendations of the Health Council's advice. This statement triggered a short revival of the discussion on the contested interpretation of the Population Screening Act and for a short while complexity was brought back into the discussion. According to the Forum's secretary the legal discussion was still the subject of political debate at the time. Again the working group chair reduced complexity of the discussion. He stated that legal and ethical issues are for others to solve and are not of prime concern to the FBG. Leaving the issue of payment as well as the legal issue for others to decide and to resolve, the complexity of the discussion was reduced once again and consensus was reached:

Forum member B**:**

> *'Everyone agrees on the minimum option of informing all pregnant women. I don't see much opportunity to influence decision making in another direction.'*

The opportunity to influence political decision making had formed the occasion for the FBG to discuss the State Secretary's policy on prenatal screening. With the acceptance of the State Secretary's policy, one might expect the working group to be abolished. Such was also suggested by one of the working group members:

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[157] Quotes taken from the second meeting of the working group on prenatal screening, Aug. 11th 2004.

Forum member C:

> *'If that is the case, we can stop now.'*

But others did not agree:

Forum member B:

> *'No, we shouldn't stop now, because this is only the first part of the discussion. Now we need to argue why counseling is needed.'*[158]

The discussion shifted towards the expected and the preferred implications and ramifications of the State Secretary's policy. It became clear that there were many remaining uncertainties, especially concerning the State Secretary's promise to provide all pregnant women with information about prenatal screening. Did she intend to allocate collective resources in order to compensate medical practitioners for the extra counseling time that is needed? Would she assign the task of determining a tariff for this provision of information to the Health Care Insurance Board?[159] Or was the State Secretary rather of the opinion that extra counseling time is not required and that a patient leaflet is sufficient? One of the working group members gave a minimalist interpretation of what the State Secretary was up to:

> *'Informing people about prenatal screening is no longer liable to penalty. That might sound ridiculous, but in practice medical practitioners were not sure.'*

Discussion in the working group then shifted towards the role responsibility of medical practitioners in these matters. Someone suggested that the State Secretary's policy implied a duty to inform pregnant women. Another Forum member argued that medical practitioners should not start mentioning prenatal screening if there is insufficient counseling time available. He supported the State Secretary's new policy, provided that enough counseling time is available. Another member emphasized that medical practitioners lack knowledge about Down syndrome. She expressed her fear that the organization of counseling would reinforce misconceptions about the seriousness of Down syndrome and questioned whether

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[158] Quotes taken from the first meeting of the working group on prenatal screening, July 7th 2004.
[159] In Dutch: 'College voor Zorgverzekeringen'.

the provision of information about prenatal screening is actually such a good idea. The Forum's consensual agreement on the State Secretary's policy was threatened again. To preserve consensus Forum members were reminded of the general aim of the FBG: the FBG supports the application of genetic knowledge and genetic technology for the benefit of health and healthcare. It was argued that in order to enable beneficial future technological developments a new deadlock in the debate should be prevented and that the political compromise, which had been reached, should be used as a stepping stone to articulate future policy on prenatal screening. With this argument Forum consensus was preserved.

The State Secretary's policy correlates with a change in institutionalized discourse. With regards to the provision of information, the Medical Treatment Agreement Act came to prevail over the Population Screening Act. In line with this change, accountability for the provision of information shifted from the Minister towards the level of medical practice:

Forum member X:

> *"By Dutch standards, a large step has been taken in the discussion. One can either agree with that or not. Some feel that it is too limited, others that it reaches too far. As far as I am concerned, we should be content with what has been decided."*

Forum member Y:

> *"It does offer a lot of space in the consulting room. The responsibility is attributed to the individual doctor-patient relationship."*[160]

The acceptance of this change in institutionalized discourse had a clear impact on the kind of discussions that took place in the FBG working group. The meta-discussion on the appropriate legislative framework, which had taken place when formulating the first FBG position paper on prenatal screening, was left behind and the discussion became more focused on the implications for the configuration of responsibilities for prenatal screening. The two issues that were most prominently discussed were: organization of quality; and a new general policy framework for

[160] Quotes taken from the second meeting of the working group on prenatal screening, Aug, 11th 2004.

genetic screening. Both issues derive their prominence from the overall change in the governance arrangement for prenatal screening.

With the decision not to make the information about prenatal screening a provision which is subject to license requirement, it was unclear how the quality of screening would be organized. For the members of the working group on prenatal screening, quality was still of great concern and they started articulating alternative ways to organize quality. Many possible interpretations of the State Secretary's policy were reviewed, uncertainties were addressed and disagreement became apparent. It appeared that a new type of healthcare provision was at issue: a provision of information on diagnostic opportunities, for which there is no collective compensation. Customary role patterns had not yet stabilized for this new type of healthcare provision. It was unclear to what extent government would still take responsibility to steer developments or whether it would rather let things develop freely. As can be read in the notice letter ('signalement') the FBG advises government to assume a steering role:

> *"If government chooses not to take action, then the developments in the area of prenatal testing are left to the whims of social forces, thus minimizing the possibilities to stimulate the formulation of guidelines, quality management and monitoring. Therefore, the FBG does not consider this a desirable option. Furthermore, the FBG feels that the situation should be prevented that prenatal tests become available on the free market without the necessary personalized information provision and counseling''* (FBG, 2004d, p.2, translated from Dutch).

Regarding the quality of information and counseling, the letter states:

> *'According to the FBG [FM: quality can] only be realized if the involved professional groups are allowed to allot time to the process of personalized information provision and counseling'* (FBG, 2004d, p.2, translated from Dutch).

A second main issue in the discussion concerned the policy framework for genetic screening. Some members of the working group argued that the assessment framework of the Population Screening Act and the role of Health Council advice in

this framework had fallen short as a framework for the introduction of prenatal screening. Criticism concerned in particular the lack of opportunity – in the old framework - to take societal concerns regarding Down syndrome screening into account. Others did not agree and argued that the Health Council had carefully considered ethical and normative issues. Whether or not one thought the old framework had shortcomings, it was clear that the Population Screening Act no longer applied to the provision of information about prenatal screening and that for that reason a new framework was needed. It was also known that the Ministry of Health intended to revise the existing policy framework for prenatal screening.

With regard to this proposed policy of the Ministry of Health the letter stated that the FBG *'would like to be of help in developing this framework.'* The letter also suggests that more than had been the case in the current process of decision making and analysis – which had been focused on the reliability of the test – the societal perception of the condition for which the screening applies should play a role.[161] Furthermore an updated policy framework on (genetic) screening is considered important, in light of *'dozens of other conditions for which prenatal and postnatal screening options come available now or in the future. (...) A widely supported policy framework might possibly enable government and politicians to keep aloof, without parting with steering on ethical grounds*' (FBG, 2004d, p.3, translated from Dutch).

4.4.2.2 From unproductive reproduction of complexity to productive responsibility positioning

As in the second episode, in the third episode the FBG formed a microcosm in which conflicting arguments and storylines of the wider debate on prenatal screening were re-presented. The result of that re-presentation was more productive in the third episode than it had been in the second episode. In the second episode the controversy on the age limit had been reproduced in the FBG discussions. In the third episode the controversy on the age limit was overcome as the State Secretary's policy compromise was accepted. Arguments on the role of the FBG were used to narrow down the scope of the discussion in order to reach consensus. It was argued

[161] 'The FBG notes that up till now the reliability of prenatal tests has been the main focus of attention in scientific analyses and political decision making relating to prenatal screening The possibilities of prevention and treatability, and the societal perception of the disorders to be screened for have been largely disregarded and maybe could be emphasized more on the agenda of a general policy framework' (FBG, 2004d, p.2, translated from Dutch).

that the legal, ethical and political aspects of the discussion were considered issues not to be discussed by the FBG. This argumentation was constructed ad hoc and did not form a prior part of the Forum's established way of doing things. The Forum's formal objective "to support the interest of public health and healthcare with regards to developments in human genetics and medical biotechnology"[162] was successfully used as an argument to support the State Secretary's policy compromise. Working group members considered it more important to establish and accept a ground for further policy development than to defend their own position at all costs.

The acceptance of the State Secretary's policy compromise did not conclude the discussion on the configuration of responsibilities for prenatal screening. The policy compromise still gave rise to numerous new questions concerning role responsibilities. This became very clear from the discussion in the prenatal screening working group. In the FBG working group the uncertain ramifications of the State Secretary's policy were articulated. With the shift in legislative framework from Prenatal Screening Act to Medical Treatment Agreement Act the accountability for the provision of information shifted from government to the medical profession. It is interesting to see how the FBG working group members (in particular the medical professionals) indeed felt accountable for the provision of information and how they started to articulate their responsibility in these matters. In their second notice letter they put the issue of quality high on the agenda. They emphasized that medical professions need to be enabled to spend time on counseling and that the development of quality guidelines, quality policy and monitoring were needed. Interestingly, they handed the responsibility for these issues back to government, advising government to assume a steering role in these matters.

The Forum positioning government in a steering role means that prior dilemmas and challenges reoccurred. In her second policy letter the State Secretary pointed out the tension between on the one hand pregnancy as a personal and individual matter and on the other hand a prenatal screening program as a massive, large scale, uniform and strictly managed business (SS4 and SS5 in fig 4.7. p.145). The State Secretary's policy aimed at a middle course in between these two developments

[162] (Staatscourant, 2004b).

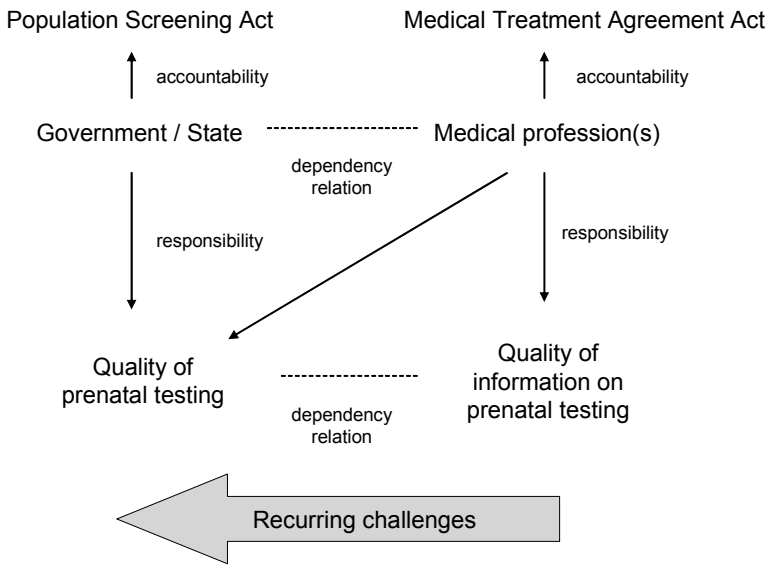

Fig 4.8: Recurring challenges in the governance arrangement for prenatal screening

(SS7 in fig 4.7, p.145). The articulations in the FBG working group show that it is not at all clear whether such a middle course is feasible. Figure 4.8 depicts the dependency relations between the quality of prenatal testing and the quality of information on prenatal testing and between medical professions and government. The shift from Population Screening Act to Medical Treatment Agreement Act changed the accountability structure, but the challenge to organize quality of prenatal screening remained the same. The organization of quality still requires a central steering and medical professionals now positioned government in a steering role.

An FBG member, a representative of the Ministry, acknowledged the importance of the issues that had been raised by the FBG working group. He said he was quite content with the second notice letter. In his opinion it did justice to the nuanced political debate and the issues mentioned were worth being examined. He also stated that at the Ministry they were already working on these issues:

"To what extent the Ministry accepts a shared responsibility for the developments is now at stake. It is not an easy task to develop a policy framework for genetic screening."[163]

Later the State Secretary would send the FBG a letter, saying that:

'Your letter reveals a constructive attitude of the FBG concerning the implementation of prenatal screening on Down and NTD, as well as any screening in a broader sense. I appreciate this. (...) At the moment within the Ministry of Health we are working on a further practical interpretation of this policy framework. The issues that you bring up in your letter, are also part of this' (State Secretary of Health, 2004).

4.5 Conclusions

I have analyzed the debate on the introduction of prenatal Down syndrome screening in terms of the role responsibilities that are implicated. I showed how responsibilities were contested, how some responsibilities shifted, how the governance arrangement for prenatal screening changed and how this raised new types of responsibility issues that were still debated when I ended the analysis of this case in September 2004. In section 4.5.1 I will draw conclusions on the overall process of organizing responsibilities for prenatal screening. In section 4.5.2 I will conclude on the nature, the working and the productivity of FBG interactions and how these contributed to the process of organizing responsibilities for prenatal screening.

4.5.1 Organizing responsibilities for prenatal screening – conclusions on overall process

I have shown that the introduction of the Triple test in Dutch healthcare involved changes in the configuration of responsibilities for prenatal screening, including the role of medical technology itself. There was no consensus on the preferred configuration of responsibilities. Medical practices varied locally and regionally and the legitimacy of some of these practices was contested. In the period of analysis between 1998 and 2004 the issue of prenatal screening was intensely

[163] FBG plenary meeting, 09-09-2004.

debated in a number of different arenas. These discussions contributed to articulating and negotiating the relevant moral order, the acceptability and desirability of the changing roles for the involved actors and the affordances of the different medical technical options. Through these articulations and negotiations, progress was made in organizing responsibilities for prenatal screening. That is not to say that overall consensus was reached or that the practice of prenatal screening was harmonized by the endpoint of my analysis. In 2004 the process of organizing responsibilities for prenatal screening was still ongoing. In this section I will discuss what the progress that was made in the years between 1998 and 2004 constitutes and how it came about.

A first conclusion concerns a general characterization/description of the process of organizing responsibilities and relates to the variety of settings in which the issue was discussed. The process of organizing responsibilities involved different forums/arenas for discussion, which took turns in being the focal arena for debate. The different nature of each of these arenas entailed different ways of framing the issue of prenatal screening, foregrounding the discussion on certain aspects, while backgrounding other aspects. The alternation between these different arenas – with their different ways of framing - accounts for the overall progress that was made in organizing responsibilities for prenatal screening. In this case the successive focal arenas for debate were: the Health Council committee on prenatal screening, the diffuse hybrid forum, Dutch Parliament, again the Health Council on prenatal screening and again Dutch Parliament. The Forum Biotechnology and Genetics (FBG) formed a parallel arena, but never was the focal arena for debate.

A second conclusion concerns the role of the Health Council. The Health Council advisory committee on prenatal screening played an important role as spokesperson for the different medical technical options that could be used for prenatal screening. The Committee gave an account of the technologies' affordances. In writing extensive recommendations on the organizational embedding of prenatal screening within the Dutch health care system, the Council also positioned various actors in the actor-network for prenatal screening in specific role responsibilities. As the facts that were presented by the Health Council committee were broadly accepted, the Council contributed to organizing responsibilities by forming an authoritative spokesperson for the various medical-technical options to be used in a prenatal screening program. But the Council did not settle the debate. Not all actors involved

accepted the Council's recommendation to abolish the age limit and the role responsibilities that were implicated. This became clear when the advisory report was discussed in the diffuse hybrid forum.

A third conclusion concerns the role of the diffuse hybrid forum. The diffuse hybrid forum contributed to the process of organizing responsibilities as it formed an arena in which accountive responsibility positioning took place. People that had not been involved in the Health Council advisory report made clear that the configuration of responsibilities that had been sketched by the Health Council was unacceptable to them. It appeared that the Council's strategy to circumvent explicit normative judgment by using the existing practice of prenatal diagnostics as a normative yardstick was not successful outside the Health Council's arena: the Council's report was criticized for carrying implicit and contested norms. More specifically this critique concerned the fact that the Council had downplayed that the quality of the prenatal screening test was dependent on a pregnant woman's age. While downplaying had enabled the Council to come to a conclusion regarding the introduction of the test, the prioritization of this fact within the diffuse hybrid forum made it difficult to resolve the controversy on the age limit. Normative plurality, as well as tensions between the institutionalized discourses and legal frameworks which together form the governance arrangement for prenatal screening, explain why the debate on the age limit for prenatal screening remained inconclusive.

A second stage of debate was entered and the deadlock in this debate was overcome when Parliament became the focal arena for discussion. The State Secretary, supported by Parliament, was mandated to take an explicitly normative decision to thus conclude the debate on the age limit. By taking a decision on the age limit, the State Secretary used her political authority to bypass the inconclusive governance arrangement. This political decision was followed by a political compromise to inform all pregnant women about prenatal screening. The compromise involved a change in the institutionalized discourse on the scope of the Prenatal Screening Act and the Medical Treatment Agreement Act and implicated a shift in governance arrangement. This brings me to a fourth conclusion which concerns the role of the political arena. The political arena is productive in the process of organizing responsibilities as it forms an arena where explicit and legitimate normative decisions can be taken which can circumvent or change elements from institutionalized governance arrangements and thus either bypass, transcend or

change the internal tensions within governance arrangements that structure responsibility positioning. Furthermore, the political arena is productive because it forms the primary arena in which government positions itself regarding their responsibility.

The different ways in which the various arenas/forums contributed to the process of organizing responsibilities are summarized in table 4.2. Within this table a cross means that the element from the process of organizing responsibilities was not present within the arena/forum.

Elements in organizing respons. / **Forum/Arena**	**Prospective responsibility positioning**	**Representation of a novelty's affordances**	**Concluding normative conflicts**
Health Council	Various actors are positioned (pregnant women, medical professionals, government)	The Triple test is a more effective screening method than the existing screening based on age - The combination test is better than the Triple test	
Diffuse hybrid forum	Accountive responsibility positioning by various actors in response to Health Council advice - Normative plurality is foregrounded	Age dependency of the quality of the Triple test is foregrounded	
Political arena	Government positions itself		Political decision not to abolish the age limit – Change in governance arrangement

Table 4.2: Overview of the different forums and elements/dynamics that played a role in organizing responsibilities for prenatal screening

4.5.2 The role of the FBG: how a hybrid forum with a weak mandate can contribute to organizing responsibilities

In the period of analysis (2000-2004), I distinguished three episodes in the FBG discussion on the issue of prenatal screening. The form of interaction and type of productivity was different for each of these episodes (for a summary see table 4.3). In the first episode of the FBG debate the issue of prenatal screening appeared regularly on the agenda, but never gave occasion to an extensive discussion. While it was clear that in the world outside the Forum, opinion on prenatal screening varied widely between different parties, that controversy hardly was represented in the FBG. Rather, the FBG formed a platform for the exchange of information on the state of affairs in policy development and political decision making.

Only during the second episode, when the FBG tried to formulate their first joint position on prenatal screening, differences in opinion between the different Forum participants were articulated. The occasion for formulation of a position was the wider debate on prenatal screening in which it was up to Parliament to formulate an opinion on proposed governmental policy. The opportunity to increase the Forum's visibility and to justify its existence were the main incentives for formulating a joint position. The Forum developed into a microcosm in which positions, arguments and storylines similar to those we found in the diffuse hybrid forum were represented. But positions were not merely represented. The FBG was different from the diffuse hybrid forum in the sense that it formed an entity, and expectations developed that the FBG as an entity should produce tangible products. While initially the Forum secretary compiled a notice letter in which the variety of positions and arguments were listed, Forum members felt that the letter should do more than reproduce the complexity of the prenatal screening debate. This created the incentive to try to reduce the complexity and to strive for partial consensus. In that respect the FBG differed from the diffuse hybrid forum and resembled a commissioned hybrid forum.[164] The attempts to reduce complexity implied that positions were not merely

[164] The first FBG position paper on prenatal screening is the result of what Strathern called "framing heterogeneity through creating heterogeneity" (Strathern, 2002, p.254). While Strathern, referring to Callon's plea for hybrid forums, is somewhat skeptical about attempts to frame heterogeneity by creating heterogeneity, the FBG provides an example of how *creating* heterogeneity (creating a forum with a heterogeneous composition) can induce the *incentive to frame* heterogeneity. While framing heterogeneity or reaching consensus was not a formal Forum objective, external legitimization pressure created a strong incentive to reduce complexity and to reach partial agreement.

	Period / date	Event	Form of interaction	Forum characterization	Productivity of FBG interactions in the process of organizing responsibilities
First episode	December 12, 2000	Foundation of the Forum Genetics, Health and Health Care	Information exchange in the preparatory group and in the plenary Forum meeting	Platform for the exchange of information on the state of affairs in policy development and political decision making	Not applicable
	April-October 2003	PMB and FGHH merge into Forum Biotechnology and Genetics			
Second episode	Jan/Feb 2004	E-mail discussion on first FBG position paper	E-mail discussion between a selection of Forum Participants	Hybrid forum with a weak mandate	Incentive to reduce complexity - Resulting in reproduction of complexity
Third episode	July 7th 2004	First FBG working group meeting on prenatal screening	Two working group meetings and a plenary Forum meeting	Hybrid forum with a weak mandate	Incentive to reduce complexity - Resulting in acceptance of the State Secretary's political compromise - Articulation of new responsibility issues - built on acceptance of the State Secretary's political compromise
	August 11th 2004	Second FBG working group meeting on prenatal screening			
	September 9th 2004	The FBG plenary meeting approves the second notice letter on prenatal screening			

Table 4.3: Summary of events, interactions and effects in the FBG discussion on prenatal screening

represented, but they were *re*-presented, the hyphen indicating that the positions were presented anew. Such re-presentation is potentially productive for organizing responsibilities, because the articulation of new arguments and storylines may resolve former disagreement on mutual role responsibilities.

While the FBG resembled a commissioned hybrid forum in the sense that concrete products were expected, the FBG also differed from a commissioned hybrid forum, since there was neither a specific advisory request nor a specific mandate.[165] The lack of a specific mandate implies that there is no pre-given problem framing, and that there is no pre-given way to reduce complexity. All sorts of considerations are allowed. In the second and third episode of the FBG's involvement with prenatal screening various attempts to re-present the issue of prenatal screening were made which all aimed to reduce complexity by reducing the scope of the issue under discussion. These attempts involved a variety of arguments on the role of the FBG. It was argued for example that it was not up to the FBG to resolve legal issues, or to take a position on issues that were considered political such as the issue of collective payment of screening. These arguments were developed ad hoc. Reducing the scope of the issue under discussion can provide partial consensus, which can then be used as a stepping stone to negotiate consensus on the broader issue as well. Though there is no guarantee that consensus will be achieved.

In the second episode the uncertainty over the appropriate legal framework for prenatal screening and the controversy over the age limit were reproduced in the FBG. The discussion was complex. In the end the external authority of a legal expert brought Forum agreement on the legal issue, but the controversy on the age limit did not get resolved. As I argued before, the controversy was structured by inconclusive governance arrangements and normative plurality, which made it very unlikely that re-presentation in a hybrid forum like the FBG would resolve the issue. Political decision making was needed to end the deadlock in the debate.

Only in the third episode of the FBG's involvement with the prenatal screening debate did the interactions in the Forum actually seem to contribute to the process of organizing responsibilities. In the third episode, when it appeared that the State

[165] This characterization concerns the FBG in the context of the prenatal screening debate. Within other contexts the FBG may need to be characterized differently. See chapter 3 for an extensive characterization of the FBG.

Secretary was not willing to change her policy, it was acknowledged by members of the FBG's working group on prenatal screening that they would not be able to decisively influence policy. And even if consensus could be reached – which was hardly expected – the FBG did not have a strong mandate and it was questioned whether its position would have any effect on political decision making. The FBG's working group on prenatal screening decided that it would be better to accept the political situation. This was yet a different way in which reduction of complexity was achieved. As a result the support for the State Secretary's policy became stronger.[166] In that way the FBG interactions contributed to the process of organizing responsibilities.

This was not the only way in which the FBG's discussions of the third episode were productive. Once the State Secretary's policy was accepted, the nature of the debate changed and a different form of interaction became dominant, which contributed in a different way to the process of organizing responsibilities. Discussion became more future-oriented and members no longer positioned themselves with respect to the specific policy decision, but rather took this policy decision as a point of departure for further responsibility positioning. Instead of exchanging arguments to either support or reject the abolishment of the age limit, or to give priority to either the one or the other legal framework, members of the working group started to articulate the consequences of the State Secretary's policy decision. And it soon appeared that there were many remaining uncertainties. New responsibility issues regarding the quality of prenatal screening and the need to monitor were articulated and discussed. In the third episode, the FBG working group was productive because prospective responsibility positioning occurred. Members reflected on their own and other actors' role responsibilities in prenatal screening. Productivity in this case is not related to reduction of complexity, but to the articulation of mutual role responsibilities with the aim of reaching a configuration of responsibilities in which all responsibilities are covered and well-aligned.

As I showed in chapter 3, overall the FBG should be characterized as a multiple knot in a sociotechnical policy network. In the specific context of the prenatal

[166] There is no direct data from which to deduce whether it created support more widely. But because many members of the FBG are important spokespersons in the configuration of responsibilities in which prenatal screening is embedded, I expect there was a wider effect.

screening debate the FBG developed into an intermediate type in between the diffuse hybrid forum and a commissioned hybrid forum. It developed into a hybrid forum with a weak mandate. The mandate is weak in the sense that the Forum's authority is weak, and in the sense that the Forum's order is weakly defined. The Forum's weak authority is an incentive for the FBG to align the timing of the issues on their agenda with those of more authoritative actors and arenas. And the Forum's weak order provides them with the flexibility to do so. In the case of prenatal screening the FBG's working method was adjusted according to this need. In the second episode for example there was only little time left for the FBG to contribute to the round table meeting and e-mail provided the means to formulate a position without having a face-to-face meeting. In the third episode policy developed much faster than had been expected. The FBG responded flexibly by changing the objective of their position letter. The weak mandate also implies that the FBG has various modes of reducing complexity which can be flexibly deployed. This means that they have a wide range of means to contribute to organizing responsibilities.

In section 4.5.1 I concluded that the alternation between different arenas – with their different ways of framing - accounts for the overall progress made in organizing responsibilities. A hybrid forum with a weak mandate can be one of the arenas. Its specific function derives from the fact that it does not have a predefined way of framing the issue, but rather that it possesses the flexibility to apply different ways of framing. Thus a hybrid forum with a weak mandate is productive, because alternation between different ways of framing occurs within the forum, independently of alternation between different settings or arenas. This is a specific way in which a hybrid forum with a weak mandate can contribute to organizing responsibilities.

Elements in organizing Responsibilities / Forum/Arena	Prospective responsibility positioning	Representation of a novelty's affordances	Concluding normative conflicts
FBG – hybrid forum with a weak mandate	Third episode: Related to the shift in governance arrangement, new responsibility issues got articulated		Third episode: FBG supported political compromise

Table 4.4: Contribution of the FBG to the process of organizing responsibilities

4.5.3 Afterthought

I did not analyze the debate any further than September 2004, but the discussion on the organization of prenatal Down syndrome screening continued for at least another three years.[167] I did not analyze this later period in the debate, but the

[167] In the context of the FBG positioning the Ministry with the responsibility for steering, it is interesting to briefly sketch how things developed after September 2004. This concerns in particular the fact that the Population Screening Act was still used to license the provision of prenatal screening. This was first formally announced in a letter to Parliament on the 30th of June 2005(Kamerstukken II, 2004-2005). There is still an important difference compared to the organization of previous national screening programs. Prenatal screening is not collectively financed. It may be covered by an extended/supplementary health policy or else it is provided at the expense of individual pregnant couples. As a result a tariff and a diagnose treatment combination (dbc, 'diagnosebehandelingcombinatie') had to be determined in consultation between health care insurers and medical professional groups. The tariff and dbc had to cover all the costs of the screening program, including data exchange, counseling and the national coordination centre. The Ministry of Health only subsidized the making of a standard protocol for informing pregnant couples on prenatal screening. On the fifth of October 2005, the Health Council Population Screening Act committee published an interim report on eight license applications for prenatal screening. The committee concluded that the information provided was insufficient to advise on the applications. Nonetheless, at the 22nd of December 2005, the Minister granted provisional permissions for prenatal screening. By doing so, he legalized existing medical practices in which the provision of prenatal screening was already established. Until the first of January 2008, eight regional centers were licensed for prenatal screening. Obstetricians in primary care who want to offer prenatal screening need to ally with one of these regional centers. At a national level the screening program is coordinated by the RIVM (the National Institute for Public Health and the Environment) Centre for Population Screening. On the 17th of December 2007 the Health Council Population Screening Act committee published an advice that recommended issuing permanent permission for prenatal screening.

responsibility issues that were articulated in the second FBG notice letter point at some of the obstinacies in organizing responsibilities for prenatal screening, which may explain why the process continued for at least another three years. By foregrounding the Medical Treatment Agreement Act and physicians' responsibility for informing pregnant women about prenatal screening, a political compromise had become possible. But it had not made it any easier to organize quality. The FBG in their second notice letter advises government to take up a steering role to guarantee quality, while government had just shifted some of its responsibilities in these matters to the medical professions.

To conclude, the result of the intensive discussions on prenatal screening is somewhat disappointing. The conscious and broad reflections and discussions on the introduction of prenatal screening in Dutch healthcare seem to have complicated rather than eased the achievement of realignment in the configurations of responsibilities for prenatal screening. In chapter 7 of this thesis I will further reflect on this paradoxical situation.

5

Organizing responsibilities for FH and insurance selection

5.1 Introduction – FH screening and insurance selection, a hybrid debate

In the spring of 2000, the proposal to set up a national large scale genetic screening program for Familial Hypercholesterolemia (FH) opened up a debate on FH and insurance selection. FH is a hereditary disposition to coronary heart disease for which preventive treatment options had become available. Therefore it was considered important to trace all people that have a genetic predisposition for FH. The question arose whether and how private insurers could take such information into account. Responsibility storylines got articulated and discussed. The issue of genetic testing and insurance selection was not new and had been discussed before. It had led to a fragile accommodation of the governance arrangement for private life and disability insurance to the development of presymptomatic DNA diagnostic testing. The debate on FH and insurance selection took place against the background of this accommodated governance arrangement. The governance arrangement structured the storylines in the debate, while at the same time being itself up for debate. FH screening was the first large scale genetic screening program for a late onset disease to be introduced in Dutch healthcare. It involved some new aspects which had not been encountered before and so it formed a test case. In the end the discussions led to a new configuration of responsibilities.

While a small-scale pilot program of genetic screening for FH was running since 1994, the issue of insurance selection only drew general attention when preliminary findings of an evaluation study of the pilot program were published in March 2000 and led to questions in Parliament. A hybrid debate ensued in which different but entangled storylines evolved. This chapter will trace the debate as it was taken up in different arenas and forums: the Ministries responsible, Parliament, the Health Council, public media, a mandated hybrid forum and in informal consultation and negotiation between patients' representatives, medical practitioners and insurers. In these arenas and forums, different aspects of the issue were foregrounded, depending on the mandates in place, and the stage of the debate.

For the Ministry of Health, the debate was settled by April 2003, when a new configuration of responsibilities had been agreed upon, and the decision to extend the FH screening program could be taken. In the meantime, roles and responsibilities had been debated and negotiated, and key storylines had been

articulated, starting with the storyline that FH, as a treatable disease, should be an insurable disease. I see this storyline, as it became articulated, as the key novelty encountered by the existing configuration of responsibilities. A second storyline, about the interpretation of the Medical Examinations Act, was important because it fuelled the first round of questions in Parliament, and because its argumentation was unavoidably linked to the first storyline. I shall analyze these and other storylines as they functioned in the debates in quite some detail, because their entanglement drove the debate.

In this introduction I will outline the situation at the beginning of the year 2000, where my detailed reconstruction of the hybrid debate starts. I shall pay particular attention to the challenges for insurers and the accommodated governance arrangement that had emerged because that is where FH screening and insurance selection are linked.

Familial Hypercholesterolemia (FH) is a late onset hereditary disorder of the fat metabolism. Due to increased blood cholesterol levels, people with FH have a high risk to develop coronary heart disease at a relatively young age.[168] Since the introduction of statins - a cholesterol lowering drug - in 1989, therapy had become more effective (Gezondheidsraad, 2001b). FH was thus considered a treatable genetic disease. The availability of DNA diagnostic testing opened up the opportunity for early diagnosis and preventive treatment of FH patients. That was the reason why a small pilot program of screening for FH was set up in 1994.

When genetic testing first became available for some diseases, the issue of access to such information was raised. The right not-to-know became articulated as an important right to be protected. It raised difficult issues, especially because genetic information is not confined to individuals but reveals information about family members as well. One family member's right-to-know could oppose another family member's right not-to-know. The protection of genetic privacy and the right not-to-know was considered of particular importance, if the disease in question could not

[168] In the past, the diagnosis of FH was entirely based on clinical symptoms, such as a very high (LDL)-cholesterol level, often combined with the presence of xanthomen and xanthelasmata. A family history of early occurrence of coronary heart disease could also raise the suspicion of FH. From clinical practice it is known that a large number of people with FH are unfamiliar with their condition. Most people are diagnosed only after they have had a heart attack. In the 1970s, the first mutations of the LDL-receptor gene of clinically diagnosed FH-patients were found.

be treated. The question of treatability creates a link with insurance selection, because under the rules of the Medical Examinations Act of 1998, the restrictions for insurers to enquire about medical data concerning diseases that have not manifested themselves are more stringent when diseases are untreatable. As a result people with an untreatable genetic disease are a little bit better protected against insurance selection than are people with genetic diseases which are considered treatable.[169]

In the case of predictive genetic testing, there is the concern that insurers would want to use the information in their medical selection procedures, in particular medical selection for life insurance and disability insurance. For these insurance products people with a known lower life expectancy or a higher risk of disability have to pay a higher premium, because the chance that the insurer has to pay out is above average. In exceptional cases, people with a low life expectancy or a high disability risk are not able to obtain life insurance or disability insurance at all.

This situation can be viewed from a solidarity perspective or a market perspective. The market or contract view applies to both sides; the sellers and the buyers of insurance. Life insurance and disability insurance are provided on a free, private insurance market. People are not obliged to take out insurance, and insurance candidates can opt for different types of contract (e.g. the amount of money to be

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[169] "Articles 3 and 5 entail a restriction of the contract freedom of the insurer in the form of a prohibition of research into, and the posing of questions about, among other things, serious hereditary diseases which *cannot be treated*. The answer to the question whether a disease is 'treatable', then is one of the determining factors in setting the scope of articles 3 and 5 concerning a particular disease. This advice is not the place to extensively discuss the protection that the WMK offers to people with a particular disease (but do see § 4.3). It is, however, possible to state in general that, independent of the treatability of a disease, below the question limit an insurer is not allowed to ask any questions about the (results of) heredity screening performed on the insurance candidate or his relatives (article 5); is not allowed to use already known hereditary data regarding the insurance candidate or his relatives (article 5); the insurer is always allowed to do research or have it done and to ask questions concerning the presence of diseases that have already manifested themselves in the insurance candidate (articles 3 and 5). With regard to a serious hereditary disease, treatability does matter in answering the question whether the insurer is allowed to do research or have it done concerning the chance that that disease will manifest itself in the future and whether the disease is present but dormant (only allowed in case of treatability – article 27 of the Medical Examinations Act 3) (on the other hand, regarding diseases that are not serious, the treatability within the scope of article 3 is not relevant; in this case, examination is always allowed in principal), and whether an insurer is allowed to ask about the chance or the dormant presence of that disease in the insurance candidate or of the chance of or (dormant or manifest) presence of this disease in relatives (is only allowed in case of treatability – article 5) (this last point is only applicable below the question limit; above the question limit, the questions may also be posed if the disease is nót treatable)." (Gezondheidsraad, 2001b, p. 27,28)

paid out in case the insured person dies, or the term of the contract). On a free market, where being insured is not compulsory, there is so-called adverse selection: people who know that they have a low life expectancy or a high disability risk will be more inclined to take out a life insurance or a disability insurance and when they do not share that information with the insurer, they can profit from average premiums.

Because of adverse selection, the average life expectancy within a pool of insurance candidates will be lower that the average of the population at large. Thus, the argument of insurers is that, in order to run a safe and profitable business, they need to know about the risks so as to be able to calculate and set the insurance premiums so that these cover the expected costs of insurance claims. Subsequently, as a business strategy, insurers can decide to use information about the known medical risks and the health status of an insurance candidate to differentiate insurance premiums according to the relative risk of the insurance candidate. In contrast to collective healthcare insurance systems[170], on the free, private insurance market there is no solidarity between insurance takers who have a low life expectancy and those who have a high life expectancy. There is only a form of de facto solidarity between insurance takers who are classified in the same risk category. This is also called chance solidarity, to emphasize the distinction with solidarity as a moral principle.

Still, insurance companies do more than reducing their financial risks. In order to allay social concerns that developments in genetic testing might be used to refine their risk assessment, a Moratorium on the use of genetic testing was established by the insurance business in 1990: genetic testing would never be a condition to obtain insurance. Furthermore, below a certain capital insured sum, insurance applicants are not obliged to inform the insurance company about genetic testing results. In 1998, this Moratorium was included in the then established Medical Examinations

[170] It is important to note that the discussions about insurance selection did not concern healthcare insurance. Here, insurance selection was not considered an issue, because at the time of the debate there were well-developed plans to reform the collective healthcare insurance system. Those plans included that all people would be required to be insured for a standard healthcare package (in Dutch: 'basispakket') and that insurance companies would be required to accept all insurance candidates without selection.

Act. The Moratorium and the Medical Examinations Act restrict insurers' right to inquire about genetic data.

Thus, by 2000, there were two arrangements governing the configuration of responsibilities for genetics and insurance: the Moratorium on genetic testing and the Medical Examinations Act. This is visualized in figure 5.1 (cf. Ch. 2). The figure also indicates how at the local level, a novelty, i.e. presymptomatic genetic diagnostic screening (in this case for FH), links two sociotechnical contexts – that of predictive genetic population screening and that of private insurance - in which role responsibilities are structured by two different governance arrangements. Responsibility positioning then occurs across the boundaries of these two sociotechnical practices, which creates a new configuration of responsibilities: the configuration of responsibilities for genetics and insurance, which spans the local practices of genetic population screening and that of private insurance. There is no simple alignment in this configuration of responsibilities. Insurers need not accept the responsibilities that are attributed to them by medical geneticists and genetic patient groups. The attributions might actually be in conflict with the rules and regulations that govern the private insurance business. The Moratorium on genetic testing and the Medical Examinations Act form what I call a bridging governance arrangement in between the medical governance arrangements on the one hand and the private insurance governance arrangements on the other hand. Restricting the information rights of insurers, this bridging governance arrangement can be regarded as an attempt to block the unwanted linkages between the two local sociotechnical practices.

It took a while before the national large scale screening program for FH was set up. In March 2000, researchers who had been evaluating the pilot screening program published results showing that people diagnosed with FH might experience difficulties when taking out a life insurance policy. This triggered a hybrid debate, in which the three poles of the medical-scientific, the legislative-regulative and the sociopolitical economic were entangled (see chapter 1). The three main issues discussed were: 1) the interpretation of the Medical Examinations Act, primarily a legislative-regulative question; 2) the interpretation of the treatment options for FH, primarily a medical-scientific question; and 3) the mutual role responsibilities of the various actors involved, primarily a sociopolitical question. As befits a hybrid debate, it remained unclear whether disagreement between actors about the

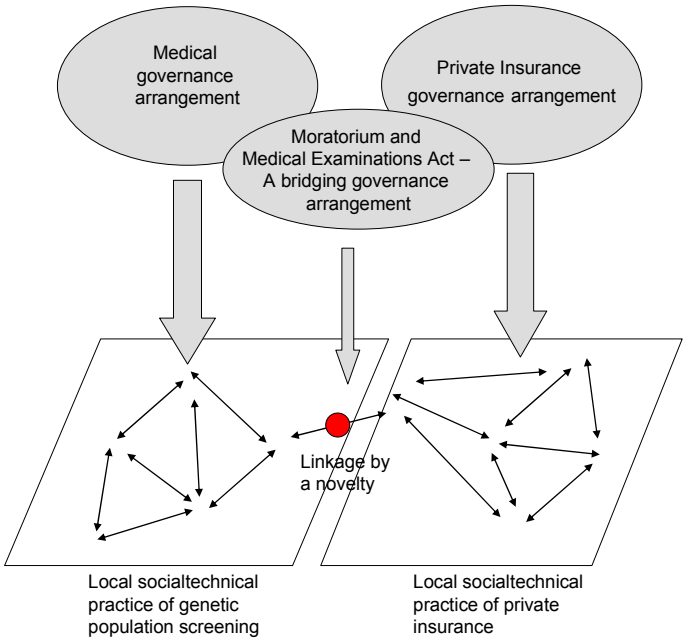

Fig. 5.1: Schematic presentation of the governance arrangements that enable and constrain responsibility positioning in the configuration of responsibilities for genetics and insurance

configuration of responsibilities drew on disagreement about mutual social role responsibilities, about the interpretation of the Medical Examinations Act or about the treatment options for FH.

5.2 FH as a treatable disease is an insurable disease – the introduction of a new storyline

In the spring of 2000 the plan to introduce a large scale public screening program for FH started off a discussion about the configuration of responsibilities for FH screening and insurance selection and about the adequate interpretation of the arrangements that govern this configuration. I will show how a new storyline was introduced in the debate on genetics and insurance, a storyline that reads that FH as a treatable disease should and could be an insurable disease. I will follow how this and other storylines traveled from one arena to the other, how different actors

positioned themselves in their role responsibility and how the debate came to a conclusion.

A small scale pilot program for genetic screening for FH existed in the Netherlands since 1994. The screening program was carried out by the Foundation for Early Diagnosis of Hereditary Hypercholesterolemia (StOEH), which was founded by clinical genetic researchers and financed by the Dutch national public health insurance fund. Some FH patients were not satisfied with the progress that was made in the screening program. Only a small percentage of the total number of people with a predisposition for FH were approached and diagnosed. In December 1997, these patients founded 'Stichting Bloedlink', a foundation for people with hereditary cardiovascular diseases. This proactive patient organization lobbied with the Minister of Health to scale up the FH screening program. Before taking a decision on upscaling, the Minister first awaited the results of an evaluation study of the pilot program which was carried out by researchers from the Academic Medical Centre (AMC).

On the 10th of March 2000, a Dutch national newspaper published a frontpage article accusing insurance industry of violating the Medical Examinations Act[171] regarding people with Familial Hypercholesterolemia (FH). The article referred to research results published that same week in 'Medisch Contact', a weekly journal by the Royal Dutch Society for Medicine[172] (Van Maarle et al., 2000). Four days later, the two articles gave rise to parliamentary questions directed to the State Secretary of Social Affairs and Employment and to the Minister of Health, Welfare and Sports. The Minister responded on May 12th 2000, saying: "The AMC [FM: Academic Medical Centre] findings cause me to further investigate whether or not FH counts as a serious hereditary disease in terms of section five, subsection one of the Medical Examinations Act, about which insurance companies are not allowed to inquire" (Kamervragen II, 1999-2000, p.2812).

The full findings of the evaluation study were only published by September 2000 (Marang-van de Mheen et al., 2000). The study evaluated (cost) effectiveness of the program , but also psychological and societal consequences of FH-screening. The latter was in line with the recommendations on Genetic Screening made by the

[171] In Dutch: 'Wet Medische Keuringen' (WMK)
[172] In Dutch : 'Koninklijke Nederlandse Maatschappij tot bevordering der Geneeskunst' (KNMG)

Health Council (Gezondheidsraad, 1994). The evaluation of societal consequences included the question whether people who had been genetically diagnosed with FH, experienced problems on the insurance market. The study reported that approximately one out of three people had experienced difficulties in getting insurance. The reason was unclear, but in their report the researchers mention three possible explanations: "either those applying for an insurance policy are unfamiliar with the Medical Examinations Act (because they provide data, while they are not obliged to do so), or insurance companies are unfamiliar with the Medical Examinations Act (they inquire while in fact they are not allowed to ask) or the formulation of the Medical Examinations Act itself is not sufficiently strict." (Marang-van de Mheen et al., 2000, p.11). One can infer that the researchers thought that there ought to be no insurance problems for people with FH, but whether or not insurers actually violated the Medical Examinations Act was not clear.

One can see the first storyline –'FH-diagnosed patients should be insurable'- at work here. This storyline already featured when the provisional results of the study were published in the article in Medisch Contact of March 2000. As I noted, this publication triggered the debate on FH screening and insurance selection. First, the AMC researchers called attention to the supposed negative consequences that people diagnosed with FH encounter when applying for insurance (Van Maarle et al., 2000). The article pointed out that the treatment options that are currently available take away any objective reason insurance companies had to deny these people standard insurance coverage.[173] Thus, they positioned insurers as having an unfair restrictive underwriting policy, so implying the insurers were accountable for the insurance problems of FH patients. They could do so by using the storyline that FH, as a treatable disease, should and could be an insurable disease.

Second, the authors of the article recommended "to intensify the control concerning the observance of the Moratorium and the Medical Examinations Act". Such a recommendation suggests that some insurers may be violating the Medical

[173] "It seems to be the case that insurance companies do not take sufficiently into account the current insights on the treatment options for FH. After all, the treatment for FH is often effective and leads to a reduced risk of coronary heart disease. Following this reasoning, there is no objective reason for insurers to deny these people standard insurance coverage." (Van Maarle et al., 2000, translated from Dutch)

Examinations Act. Thus, a second storyline emerged in which insurers were held accountable for the problems that people with FH encounter when taking out a life insurance. A national newspaper reporting on the AMC findings took up this second storyline and presented it as a fact: "Insurers violate the Medical Examinations Act. (…) People with hereditary high cholesterol blood levels experience problems in getting insurance" (Volkskrant, 2000). In the public and political reactions that followed the AMC publication, confusion and disagreement on how to interpret the Medical Examinations Act and how to deal with FH and insurability became apparent. The Association of Insurance Companies[174] for example, issued a press release, saying that in their view the Medical Examinations Act does not by definition protect people with FH against insurance selection (Verbond van Verzekeraars, 2000).

As a result of the media attention on FH and insurance selection, Members of Parliament posed written questions to the Minister of Health, Welfare and Sports on the 14th of March 2000. In the questions, and the answers that followed, the two storylines with which the AMC researchers had positioned insurers as accountable for the insurance problems, reoccurred. One of the parliamentary questions concerned fairness of insurance selection for people with FH:

> *'Do you share the opinion of the AMC researchers that there is no objective ground to deny insurance to people with hereditary high cholesterol (FH) or to subject them to additional conditions? If not, why not?'* (Kamervragen II, 1999-2000, translated from Dutch)

Another Member of Parliament posed a more general question, asking whether insurers' selection policy was wrong:

> *"Do you agree with the researchers that insurers in a number of cases wrongly took into account the results of heredity examinations?"* (Kamervragen II, 1999-2000, translated from Dutch).

The MP did not specify why such a selection policy would be wrong: because of violating the Medical Examinations Act or for other reasons. For example, as

[174] In Dutch: 'Verbond van verzekeraars'.

suggested in the AMC evaluation study, because treatment options for FH are not taken into account.

To these two Parliamentary questions, the Minister of Health responded with one answer, issued on May, 12th 2000. The Minister did not pursue the first storyline that FH as a treatable disease should and could be an insurable disease. Rather, she followed up on the second storyline about insurers violating the Medical Examinations Act, as she addressed the question whether or not FH belongs to a disease category for which insurers' right to enquire is restricted by the Medical Examinations Act. According to the Minister this was not a clear-cut matter. She attributed part of that ambiguity to the circumstance that the Medical Examinations Act contains a self-regulation measure, giving representative organizations of insurers, patients and medical practitioners the opportunity to fill in details of the regulation. At the time, though, negotiations between these representative organizations had not yet started, thus, detailed regulation was not available. Because the time span of three years allotted to reach agreement had almost come to an end, the Minister took up her responsibility to bring clarity in the debate.[175] She announced that she would investigate whether FH falls under the restrictions of the Medical Examinations Act (Kamervragen II, 1999-2000).

5.3 The representation of Familial Hypercholesterolemia by the Dutch Health Council

The debate moved to another arena when the Minister of Health, in September 2000, commissioned the Health Council, a scientific advisory council, to write an advisory report regarding FH and the Medical Examinations Act. This reflected her promise to Parliament to investigate whether FH belongs to a disease category which falls under the restrictions of the Medical Examinations Act. When answering the Parliamentary questions, the Minister had neglected the storyline that FH as a treatable disease could and should be an insurable disease. In the Health Council advisory trajectory, however, both storylines reappeared. In its final advisory report the Council came to the conclusion that FH does not belong to a disease category which falls under the restrictions of the Medical Examinations Act.

[175] The provision for self-regulation included the condition that if, after a three-year period, self-regulation would fail, government reserved the right to put an Order in Council (in Dutch: 'Algemene Maatregel van Bestuur') in place.

This conclusion led to rest the storyline that insurers were violating the Medical Examinations Act. At the same time the other storyline, that FH as a treatable disease should and could be an insurable disease, became stronger, as it was repeated in the Health Council advisory report. In this section, I will show how the Health Council came to their advice.

5.3.1 The request for advice to the Health Council

When the Health Council was assigned the task to address the hybrid discussion, this entailed that an apolitical and scientific approach would be taken. The Health Council has a clear mandate: by law, it has to inform both government and Parliament concerning state-of-the-art scientific knowledge with respect to public health issues (Healthcare Act, article 22). The Health Council derives its authoritative position from its front stage position of apolitical, objective scientific advisory council (Bal et al., 2002). In practice, to safeguard this authoritative position, responsible Council's staff members had to 'distill' from the hybrid and partly political discussion on FH screening and insurance selection, questions that allowed as much as possible an apolitical scientific answer. Much of this 'distillation' work took place when negotiating the formulation of the advisory request. First, a civil servant from the Ministry of Health had formulated a question that related to medical as well as insurance issues:

> *"Do people with FH represent such a high risk to insurers that it is fair to quote them a higher premium?"*[176]

This question made perfect sense if one thinks of the debate preceding the request to the Health Council. It related to the storyline, as introduced by the AMC researchers, that FH as a treatable disease could and should be an insurable disease. For the Health Council's staff member though, it was immediately clear that this was not an appropriate question for the Health Council. He stated:

> *"At that time, I think he [FM: the civil servant from the Ministry] had drafted two questions. But those were more of an insurance-technical nature and we as Health Council translated them into more scientific questions. For it is the Health Council's role to merely provide state of the art scientific knowledge,*

[176] Interview with Health Council staff member, 3-12-01, the Hague.

that's the way it is. (…) So to questions like that, of course, we do not wish to respond. We wouldn't even want to see those questions. It is not up to the Health Council to judge whether insurers' underwriting policy is fair."[177]

Consultation between the Health Council's staff member and the civil servant from the Ministry of Health resulted in a rephrased request. The final, formal, request for advice contained the following two questions:

1. *"Does, according to the current level of scientific knowledge, Familial Hypercholesterolemia count as a serious, untreatable disease as meant in section three subsection 2a of the Medical Examinations Act?"*
2. *"What is the life expectancy of people with FH, who are being treated for this condition?"* (Gezondheidsraad, 2001b, p.20,21)

The first question – although not purely a scientific one – was a question the Council could deal with because the relevant normative framing was specified by the Minister and thus given. Existing legislation, the Medical Examinations Act, served as the agreed upon normative framework guiding the scientific advice. In the context of the wider debate, this first question was relevant for it addressed the storyline 'that insurers were violating the Medical Examinations Act'. The second question regarding the life expectancy of people with FH was relevant in relation to the storyline that FH as a treatable disease could and should be an insurable disease. The reasoning in this storyline is that treatment increases life expectancy, that increased life expectancy reduces the risk of adverse selection and that a reduced risk of adverse selection would enable insurance companies to calculate a standard insurance premium. The Health Council Committee restricted its advice to the first part of this reasoning, addressing the question concerning the effect of treatment on life expectancy of people with FH. This question allowed a purely medical scientific answer. The second part of the reasoning that is implicated in this storyline, involves considerations that are of insurance technical nature and which include a choice of business strategy. How these actuarial considerations work out for insurability of FH patients may differ between insurance companies. How an increase in life expectancy could or should translate into insurability was not

[177] Ibid.

explicitly addressed by the Health Council, as these questions were considered to be normative.

Thus, in the final advisory questions, the problem of people with FH facing insurance selection was translated into questions that would allow the Health Council to formulate a scientific answer. This is a longstanding practice, which allows requests for advice to be brought in accordance with the Health Council's front stage position of an independent and apolitical scientific advisory council (Bal et al., 2002).

5.3.2 The Health Council positions FH as a treatable and insurable disease in its advisory report

While recognizing some remaining scientific uncertainties, the Health Council advisory report concluded that *"FH is a treatable disease in the meaning of Section 3 [FM: of the Medical Examinations Act]."* (Gezondheidsraad, 2001b, p.12) Below the question limit, insurers are not allowed to ask for genetic test results. This applied to FH as well. But, the conclusion that FH was a treatable disease implied that insurers were allowed to enquire about a family history of FH, and thus that they were not violating the Medical Examinations Act if they did so. How did the Council arrive at this conclusion? First of all and in line with the formulation of the Medical Examinations Act, 'treatability' in the Council's advice is defined as a broad category (Gezondheidsraad, 2001b, p.28). The Medical Examinations Act already considers a disease treatable, if medical intervention can stabilize the course of disease at a certain stage. In its further interpretation of the treatability category within the Medical Examinations Act, the Council followed the definition as used in another legislative context, that of the Population Screening Act. The Council interpreted treatability as follows:

> *"The course of a disease can 'be made stationary by medical intervention' when medical intervention can slow down the natural course of a disease, as a result of which life expectancy increases (diabetes, hiv/aids), or – in case the disease does not have impact on life expectancy – when the quality of life can be considerably improved (worn-out hip joint) (Gezondheidsraad, 1997b). For this [FM: to count as treatable in the sense of being made stationary] it is not*

required that life expectancy can be normalized." (Gezondheidsraad, 2001b, p.30, translated from Dutch).[178]

This broad definition of treatability is related to the Act's objective of balancing insurers' rights and insurance candidates' rights. Insurers are allowed to inquire about medical data unless this infringes disproportionately on the insurance candidate's right not-to-know about having a disease or unless it forms a disproportionate invasion of the insurance candidate's privacy. This is called the proportionality principle. The protection of a patient's right not-to-know and a patient's right on privacy is considered more important in case a disease cannot be treated.

The Council's report presented quite a lot of uncertainties concerning the treatment options for FH, yet concluded that in the context of the Medical Examinations Act it should be considered a treatable disease, arguing that

> *"The raise of the cholesterol level (...) can successfully be treated with cholesterol lowering therapy, in combination with a healthy lifestyle. This can diminish the progression of atherosclerosis or even achieve regression of the vascular anomalies, and thus a CHD [FM: Coronary Heart Disease] can be prevented in a large number of cases or, if a CHD does occur, a second CHD can be prevented or postponed. This means that a substantial increase of the life expectancy is attained through medical intervention. The committee concludes, especially because of the (primarily) preventive effect on the occurrence of CHD that FH is a treatable disease in the sense of the Medical Examinations Act*" (Gezondheidsraad, 2001b, p.44).

The Council's conclusion that FH should be considered a treatable disease was in line with earlier studies in which treatment options for FH had been discussed, like the FH screening evaluation study (Marang-van de Mheen et al., 2000) (Zorg Onderzoek Nederland, 2000b), and a Health Council advisory report on cholesterol lowering therapy (Gezondheidsraad, 2000). Optimistic expectations on treatment options and life expectancy for FH prevailed.

The optimistic narrative with respect to treatment options and life expectancy for FH had also become part of the policy discourse. On June 19th 2001, about half a year before the Health Council would publish its advisory report on FH, the Minister of Health had made the principle decision to scale-up the FH-screening program and she had asked the Health Care Insurance Board[179] to prepare and coordinate the program. She argued:

> *"Using family tree analysis and DNA diagnostic testing it is possible to trace this category of people [FM: with FH] and to provide them with treatment for high plasma cholesterol. In this way preventive treatment can be started in time and their mortality risk decreases sharply, probably to approximately the level of the population at large."* (College voor Zorgverzekeringen, 2001; Minister of Health Welfare and Sports, 2001, translated from Dutch).

While the advisory report mainly dealt with reviewing medical scientific literature to assess treatment options and life expectancy of people with FH, the Health Council committee also took the opportunity to comment on the Medical Examinations Act. Thus, the committee also assessed the legislative and regulative rules which had framed the advisory request. The committee pointed out a gap in the Medical Examinations Act. It claimed that, while the Act is founded on the assumption that treatable diseases are in principle insurable, it fails to provide that protection because the Act does not regulate insurers' underwriting policy. The Council positioned insurers as accountable for using generally accepted medical knowledge in their risk assessment. In the summary of the advisory report they were willing to refer to the concerns brought up in the public debate:

> *"Lastly, the committee concludes that, as the Act does not interfere with the freedom of insurers to set their own policies on premiums and acceptance, its answers to the questions put by the Minister only partly allay the concern felt in society about the position of FH carriers when taking out insurance. To allay this concern it needs to be evident that insurers base their premium and acceptance policies on accepted medical understanding, in particular as regards the treatability of diseases.* ***Only if insurers base their assessment of risk on accepted medical understanding will the assumption upon which the***

[179] In Dutch: 'College voor Zorgverzekeringen'.

***Act is founded, that treatable diseases are in principle insurable, be justified**. The committee therefore recommends that insurers make it clear how they gauge risk in the case of insurance for FH carriers."* (Gezondheidsraad, 2001b, p.17, bolds by FM)

The Council's claim that the Medical Examinations Act is founded on the assumption that treatable diseases are in principle insurable was controversial. In the follow-up of the debate it would be contested by the Association of Insurance Companies (see section 5.4). By making this claim about the Medical Examinations Act, the Health Council introduced some ambiguities in the advisory report. By claiming that the Act is founded on the assumption that treatable diseases are in principle insurable, the Council suggests that treatability in the context of the Medical Examinations Act relates to normal life expectancy. This is also how the Minister would later interpret this category, when discussing the issue in Parliament (see section 5.4). However, when the Council defined FH as a treatable disease, they used a broad definition of treatability in which normal life expectancy was *not* a prerequisite for a disease to be categorized as treatable. Neither did the Council take actuarial considerations into account.

5.3.3 Reception of the Health Council's advisory report

Initially, these nuances were lost when the advisory report traveled into the wider world of public media and parliamentary debate. The Health Council had categorized FH as a treatable disease, and it had stated that a treatable disease is in principle an insurable disease if insurers base their assessment of risk on accepted medical understanding. In sum, the advisory report conveyed the message that FH as a treatable disease should and could be an insurable disease. This was also the message of the press release that was issued with the advice:

"Hereditary high cholesterol does not stand in the way of insurability. Insurers use out-of-date medical knowledge if they regard the hereditary disorder 'Familial Hypercholesterolemia' as a disease that cannot be treated" (Gezondheidsraad, 2001a).

The press release avoided making strong reproaches against insurers, but definitely suggested that at least some insurers underestimated the treatment options for FH. It also suggested that it would be reasonable to accept people with FH against

standard premium rates. That in any case is the way in which the advice was reported and interpreted in the media. The daily newspaper 'NRC Handelsblad' as well as the medical weekly 'Medisch Contact' blamed insurance companies for not having an underwriting policy in line with the latest medical knowledge. *"Insurance business 'unfair' about FH disease"*[180] reported the NRC headline (NRC, 2001).*"Insurers use out-of-date medical knowledge when considering Familial Hypercholesterolemia to be a non-treatable disease*"[181] claimed 'Medisch Contact'[182] (Medisch Contact, 2001).

An illustrative exchange took place when the issue of FH and insurance was covered during a radio broadcast.[183] Guest in this program was Ms. Homsma, a representative of the Association of Insurance Companies. Ms. Homsma was asked how insurers would deal with a man who is diagnosed with FH. She responded that different individual factors are involved which determine insurers' policy. Therapy might not yet or only recently have been started; the man's cholesterol level might be raised or not. Furthermore, she explained that often the insurance period for life insurance is very long, about thirty years, and that in making a risk assessment insurers take these long periods into account:

> *'It is not yet so certain what the health situation (of this man) will be like in ten, twenty or thirty years time.'*

The radio interviewer then countered:

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[180] "Insurance business 'unfair' about FH disease. A number of insurance companies put unreasonable acceptation and premium demands on life, pension, and disability insurances in the case of people suffering from familial hypercholesterolemia (FH). Insurers are said to consider the disease, which usually causes a very high cholesterol level, to be untreatable. For this reason, people who possibly carry the disease often don't dare to have themselves screened, to see whether they actually have it." (NRC, 2001)

[181] "Obsolete. Insurers adhere to obsolete medical insights when they consider familial hypercholesterolemia (FH) to be an untreatable disease. This is what the Health Council told minister Borst in its advice entitled FH and the Medical Examinations Act. Based on this incorrect estimation, fewer people have joined the screening program for FH, because the insurance companies have placed exceptional acceptation requirements. The Council concludes that the life expectancy of people with FH can be considerably lengthened if the person involved starts to take statin drugs on time and keeps to a healthy lifestyle. Furthermore, there is a need of clearer rules regarding the questions that insurers are allowed to ask about the hereditary characteristics of the applicant in a medical examination." (Medisch Contact, 2001)

[182] 'Medisch Contact' is a weekly journal published by the Royal Dutch Society for Medicine.

[183] Quotes are taken from the radio program "De Ochtenden", broadcasted by the EO at Jan.17, 2002 from 11.00 until 12.00 a.m.

'Well, but the Health Council recently made a statement about it, right … for this disease. And they have said that it is possible to cure this disease so that you are just as healthy as someone who does not have this predisposition.'

Ms. Homsma disagreed:

"That is not completely true, what you say. Men with this condition have a two to three times bigger chance of developing coronary heart disease and if treatment has just been started, then it is 30% less and not yet at a normal level, as you suggested."

Interviewer:

"But the Health Council has said that these people in principle have the same life expectancy."

Ms. Homsma:

"That is not exactly the way it was said in the advisory report."

Insurers – here represented by Ms. Homsma - did not accept the allegation that they were neglecting medical knowledge about treatment options for FH. They *did* accept to be positioned as responsible for taking the latest medical scientific knowledge into account in their underwriting policy, and they *did* accept the medical scientific data as presented in the Health Council advisory report, but they did not regard FH as a condition for which by definition a standard insurance premium would apply. Ms. Homsma brought forward the specific context of the insurance practice to account for the position taken by insurers in relation to FH. Individual differences between FH patients are taken into account and there is no general policy for FH patients. Thus, she tried to rewrite, rather than replace, the dominant story line that a treatable disease should or could be an insurable disease.

5.4 Mutual responsibility positioning in the parliamentary arena

The debate and articulation of positions continued. Two months after the Health Council had published their advisory report, the issue of FH and insurance selection reappeared in the parliamentary arena. It became one of the topics in a broad Parliamentary debate on Biotechnology and Genetics which took place at the end of January 2002. It was not only a site where considerations were voiced and

articulated, but also an occasion for actors, in particular the insurers, to raise their voice in an attempt to counteract the way they were positioned. Subsequently, the Minister repositioned herself.

5.4.1 Three main storylines in the Parliamentary debate

One element in the parliamentary debate and in subsequent governmental communications was the storyline about FH being a treatable and thus insurable disease and how it again evoked responsibility positioning. The debate also addressed negative societal consequences of predictive medicine more generally. Specifically, Parliamentarians advocated solidarity and urged the Minister to take responsibility to guarantee insurability also for those with an untreatable disease. In the first part of the debate, on the 21st of January 2001, a member of Parliament opened her speaking time as follows:

Swildens-Rozendaal (PvdA[184]):

> *"We represent a different motto: move forward, but do not forget solidarity. (...) In this context, I would like to point out the research on heredity with all its consequences for the redistribution of responsibilities (...) for example in the case of familial cholesterol disorder we now can observe the problems involved"* (Kamerstukken II, 2001-2002b).

A third storyline on solidarity was introduced in the debate to position the government in her role responsibility. In her response, however, the Minister reflected on the situation of FH patients, evoking again the first storyline on FH as a treatable and insurable disease, but she did not react to the solidarity storyline as it was used by the MP. Interestingly, she did broaden the scope of responsibility positioning, now to include patients' responsibility for compliance with medical treatment.

The Minister responded:

> *"Regarding life insurances, the firm guarantee of the insurers is still effective, that they will not demand examinations nor ask questions about previous heredity tests under a certain financial threshold. It is in this context that the*

[184] The Social Democratic Party.

case of treatable diseases is relevant. There are, for instance, people who suffer from hereditary hypercholesterolemia. This can now be traced in an early stage. ***If people start taking medication at this stage, and follow the dietary prescriptions of the doctor, their risk is no higher than that of anybody else.*** *Yet still people find that they are confronted with trouble when taking out an insurance policy*" (Kamerstukken II, 2001-2002b, bolds inserted by FM, translated from Dutch).

The definition of what should count as a treatable disease was also discussed. The Minister suggested that a disease should be considered treatable when people who are treated have a normal life expectancy. It is a definition which allows a link between treatability and insurability (the first storyline), and supports the idea that a standard premium rate is in order. However, in equating treatability with normal life expectancy, a different interpretation of the term treatability was given than had been done before by the Health Council. The Minister seemed aware of the ambiguous use of the 'treatability' category. She declared that she had asked the Health Council for a new advice concerning the *definition* of a treatable disease:[185]

"I have asked the Health Council to thoroughly define once more how the term 'treatable disease' should be interpreted. This specifically entails diseases of which the genetic characteristics are known, but for which a treatment is available which keeps the sickness- and death risk at the same level as those of others who do not have these characteristics" (Kamerstukken II, 2001-2002b, translated from Dutch).

'Life expectancy' became a key notion because treatability of a disease was defined in terms of the availability of treatments which would give people with FH a normal life expectancy. This line of argument opens an area of contestation: what is the basis for claims about life expectation of FH patients and potential FH patients? In particular, as the insurers will emphasize, there are individual and situational factors which can make life expectancy lower than the standard. For the moment however, Members of Parliament and the Minister of Health felt free to criticize insurers for being self-interested, and ask them to look at the issue from the other side as well.

[185] A formal advisory request on the treatability category was only issued in March 2004.

The Minister of Health:

> "*Sometimes insurers have a peculiar view on what impacts someone's life expectancy. And of course they tend to figure to their advantage, whereas we on the other hand are inclined to say that they should also look at it from the other side"* (Kamerstukken II, 2001-2002b).

The second storyline, about the interpretation of the Medical Examinations Act, was visible as well. Following the plenary consultation of January 21, the Minister of Health clarified governmental policy with respect to issues of genetics and insurance, by sending a letter to Parliament (Kamerstukken II, 2001-2002d). In this letter, sent on the 24th of January, the Minister agreed with the recommendations as stated in the Health Council advisory report on FH and the Medical Examinations Act. Further regulation should be developed regarding the admissibility of insurers' questioning about the hereditary background of insurance applicants, and insurers should take generally accepted medical scientific knowledge with respect to treatability into account in their policy. In addition to this general positioning of insurers, the Minister placed the responsibility to act on these recommendations with the parties that must negotiate - in the context of the self-regulation process – on the Insurance Examinations Protocol. I will come back to this process, which had already started when the Minister wrote her letter, in section 5.5. When on the 28th of January the plenary debate on Biotechnology and Genetics continued, the issue of genetics and insurance appeared on the agenda again. Interestingly, Members of Parliament were skeptical whether self-regulation would resolve the issues, and pushed the Minister to take responsibility herself.

5.4.2 The specific case of FH vs. the general concern with solidarity

Storylines intertwined in the Parliamentary debate and the interactions stimulated further articulation. In particular, the Parliamentarians' concern with solidarity led to further discussion of insurability. The Minister was also forced to explain her position on treatability because of an intervention of the Association of Insurance Companies.

The claim that insurers should accept people with FH against standard premium rates, is supported by an argument about actuarial fairness[186] and thus follows and confirms general principles of a private insurance market. In that sense, the debate on FH treatment options and insurance selection is market negotiation, rather than a fundamental debate on the principles of the insurance market or insurers' changing role responsibility in an era of predictive medicine.[187] The concern with actuarial fairness contrasted with another concern, more dominant in the Parliamentary genetics and insurance debate, a concern with solidarity. This concern with solidarity was used to argue that insurers should not take into account predictive genetic diagnostic knowledge and they should give up on actuarial fairness and focus on solidarity instead. In the case of FH, insurers were only reproached for not providing actuarial fairness.

In the parliamentary debate of January 28, the tension between the concern with actuarial fairness in the specific case of FH and parliamentarians' more general concern with solidarity was visible (See frame 5.1). The Minister recognized that there was a tension and explained that her remarks on treatability were made in the particular context of FH. She made clear that for health insurance the problem would be solved with the new standard healthcare package in which insurers are obliged to accept everyone without selection. For life insurance, insurers are indeed allowed to take life expectancy into account in their insurance policy. As yet solidarity cannot be commanded. The Minister promised a letter on this subject matter in which the dilemma would be sketched in light of the concern with solidarity.

The parliamentary debate on biotechnology and genetics was spread over three days within a period of two weeks. Thus, actors outside the parliamentary arena could intervene and influence the course of the debate. This occurred when the Dutch Association of Insurance Companies sent a letter both to government and Parliament to point out what they thought were misrepresentations and misunderstandings in the preceding plenary debates. The letter was discussed in the

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[186] The principle of actuarial fairness holds that the premium that an insurance taker pays is proportional to the risk he or she brings to the insurance pool.

[187] Similar negotiations take place for other non-genetic diseases for which treatment options have become available. In March 2005, for example, HIV infected people managed to obtain a life insurance product.

Ms. Ross-Van Dorp:

> (…) The CDA [FM: Christian Democratic Party] feels it is necessary that the cabinet clarifies in what way it intends to prevent exclusion and guarantee societal solidarity. It is necessary that the minister unambiguously expresses that even when somebody evidently runs a greater risk of a serious form of breast cancer or another serious from of a hereditary disease, preventive and curative treatment may not lead to a higher premium. By commenting in her letter that insurers can use the treatability of a disease as a starting point, she undermines solidarity. This is what I mean by that. It is a bad thing to separate society into two groups: the treatable and the non-treatable. From the perspective of predictive medicine it remains a question what treatability entails.

Later, she repeats her concern:

Ms. Ross-van Dorp:

> Regarding the insurers, the minister maintains that treatability could be an important criterion to impose solidarity. I feel this is a dangerous route to take, for you run the risk after all of creating the categories treatable and non-treatable. In the context of predictive medicine, that is exceptionally difficult to indicate.

Minister Borst-Eilers:

> This is true, but I made that comment in reply to complaints of members of families suffering from hereditary high cholesterol values. At one point, they admitted their disease to the insurer, commenting at the same time that they strictly hold to the prescriptions concerning diet and use of medication and that **scientifically it has been proven, that in actuarial terms, their life expectancy is the same as that of someone without this disorder**. They demand that insurers deal with them as such, because it is a treatable disease. For the record, I am not referring to health insurance. I'll come back to that later. It cannot be denied that a person's life expectancy will play a role to a life insurance company, In the case of treatable diseases, when the patient conforms to the guidelines, reduced life expectancy is not at issue anymore. The insurer is not allowed to pretend this is an issue. Maybe this was formulated somewhat awkwardly in the letter, but that was the only point in which treatability inevitably is at issue.

Ms. Ross-van Dorp:

I am happy that the minister also feels that health insurances should not be about treatability and such. In case of other insurances, for instance in connection to mortgages, it can become an issue after all. If treatability then becomes a criterion, this will certainly hamper solidarity.

Minister Borst-Eilers:

(...) In the case of health insurances it will then stop being an issue, but that doesn't do away with the fact that in the case of life insurance, an estimation is made of the life expectancy of the insurance candidate.

Mevrouw Ross-van Dorp:

I am still not fully satisfied with this reply. I can imagine that the minister promises us a letter concerning this issue in which she clearly describes the dilemma and presents the content of the problem. The minister does not desire exclusion either, but prefers solidarity. However, I think that we must take measures at some point, considering the dilemma described. We then cannot keep our distance.

Minister Borst-Eilers:

I would like to put together such a memo with a number of colleagues in our cabinet. I understand that the problem should be clearly described in this memo, and that it must be assessed to what extent it is desirable that solidarity, as it were, is imposed. This will indeed necessarily have to be done by law. After all, for this type of insurances, there is no regulation applicable at present which expresses that one is not entitled to account for life expectancy. (…)

Minister Borst-Eilers:

Madam Chairwoman. I have understood that the Chamber, in accordance with my own wishes, despite the unequal position of people desires that there should be solidarity as much as possible, in such a way that insurances are part of the normal possibilities for everybody. In this light, we will compose an answer. (Kamerstukken II, 2001-2002c)

Frame 5.1: Tension between the concern with actuarial fairness in the specific case of FH and Parliamentarians' more general concern with solidarity.

concluding plenary parliamentary debate of January 30th 2002 (Kamerhandelingen II, 2001-2002). It was clear that insurers and the Minister of Health disagreed about the treatability and insurability of people with FH. In the preceding plenary memo meeting ('notaoverleg'), the Minister had said "They run no greater risk than anyone else" and also "scientifically it has been proven, in actuarial terms, that their life expectancy is the same as that of someone who does not have this disorder" (Kamerstukken II, 2001-2002c). On the other hand, insurers were of the opinion that from an actuarial perspective, FH people's life expectancy was still lower than for people without FH. In her response in the concluding plenary debate, the Minister was somewhat less outspoken concerning the life expectancy of people with FH than she had been before. But she maintained that insurers over the last couple of years had underestimated the life expectancy for people with FH who are being treated. She stated that

> "*the life expectancy of FH patients who fully comply with doctor's prescriptions, is* ***not entirely equal*** *to that of the population at large, but also not as low as insurers have claimed over the last years."* (Kamerhandelingen II, 2001-2002, bolds inserted by FM, translated from Dutch).

She called on the insurers *"to set their underwriting policy according to the latest medical scientific knowledge*" (Kamerhandelingen II, 2001-2002). Interestingly, there is again positioning of patients as having a responsibility for compliance with medical treatment.

Another point of discussion between insurers and the Minister concerned the interpretation of the definition of treatable disease as outlined in the Medical Examinations Act. The Dutch Association of Insurance Companies argued that the definition of treatability does not imply that there is an increase in life expectancy. The Minister stuck to her earlier interpretation and argued the opposite:

> "*The Association [FM: of Insurance Companies] however also writes something with which I do not agree, namely that to keep [FM: a disease] in a stationary state is something else than life extension. I think that this is not correct, because to keep [FM: a disease] in a stationary state means that the patient does not lose equilibrium. To lose such equilibrium however means a deteriorating [FM: health] state which results in the passing away of the*

patient. Thus, to keep [FM: a disease] in a stationary state means to stay alive and in my opinion to stay alive means to live longer." (Kamerhandelingen II, 2001-2002)

The storyline that FH as a treatable disease could and should be an insurable disease which was quite visible in the parliamentary debate on Genetics and Biotechnology, was used to reproach insurers and to position insurers as responsible for taking the latest medical scientific knowledge into account when determining insurance premiums. Other actors were now positioned as well: The role responsibility of patients to comply with medical treatment and doctor's prescriptions was explicitly stated. When the solidarity storyline was introduced in the debate, government was urged to take up responsibility for the insurance problems of people with untreatable diseases. This was a shift compared with the earlier focus on insurers. While the discussion on government's responsibility to preserve solidarity concerned in particular untreatable diseases, it was also relevant for the discussion of FH and insurability. Insurers had made clear that they did not regard treatable disease as a disease for which by definition life expectancy can be normalized and in the specific case of FH they claimed there was no evidence that treatment of FH in all cases normalizes life expectancy.

We see storylines intertwine and shape the positions taken and arguments put up. Over time, this can lead to reconsideration, as we will see in the next subsection.

5.4.3 The Minister's Letter – Government Positions Itself

At the time of the Parliamentary debate, the Minister and the Dutch Association of Insurance Companies disagreed on the question whether and to what extent insurance selection for FH-carriers was fair. But fair or not, insurers still had the legal right to determine their own underwriting policy and up till then, no mention was made of enforcing insurability of FH people by government. Government's responsibility in these matters became explicated later, in a letter to Parliament, sent on March 6th, about a month after the Parliamentary debate (Kamerstukken II, 2001-2002a). In much more detail than she had done in the plenary parliamentary debates, the Minister sketched the general picture of government's responsibility for solidarity in private insurance. The more social goods are considered important for individual or societal well-being, the more government takes a responsibility in preserving these, and in compensating for inequality. For insurance products

provided on a private market, such as life insurance, compensation for inequalities can be partial at best. The letter stated that government had already taken its responsibility in that respect by means of the Medical Examinations Act.

Given this general statement on government's limited responsibility for solidarity in private insurance markets, the Minister still wanted to express her concern about the question whether insurance selection against FH people is fair, and she continued to discuss the situation around FH in detail. It is striking how the different treatment options for FH and the uncertainties related to these options were stressed, and evaluated differently compared with the response to the Health Council's advice regarding FH of just a month earlier.[188] The shift in the categorization of FH as treatable, visible already in the parliamentary debate, was further articulated. FH was now presented as a treatable disease for which there is no current proof that life expectancy can be normalized:

> "*Furthermore the Health Council declared to have found indications, but **not proof**, that the life expectancy of people with FH can be practically normalized when the cholesterol lowering therapy is started in time."* (Kamerstukken II, 2001-2002a, p.3, bolds inserted by FM, translated from Dutch)

In fact, insurers were positioned differently than before. Instead of the general criticism of not taking into account relevant medical knowledge, the letter stated:

> "*Lawful questions and examinations can lead to a situation in which there is reason for an insurer to charge a higher premium. The Medical Examinations Act stipulates rules for medical examinations, but not for the premium and acceptance policy. Yet, insurers do need to take accepted medical knowledge as their starting point for premium and acceptance policy, especially regarding treatability. Only then can treatable diseases in principle be properly insurable*." (Kamerstukken II, 2001-2002a, translated from Dutch)

So actuarial fairness was still a concern, and insurers were required to take accepted medical scientific knowledge into account. But it had now become an open question

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[188] Governmental position on the Health Council's FH advice, published 1st of February 2002 (Kamerstukken II, 2001-2002e).

whether they actually failed to fulfill this duty. This is reflected in the announcement of further studies to assess the insurability of FH in practice.

The original storyline that a treatable disease should be an insurable disease had a general character, and was introduced in this way in the debate on insurance and genetics by the AMC researchers who were evaluating the pilot program for FH screening. The Health Council in their advice reinforced this storyline and they strongly suggested that insurers do not always take current medical scientific knowledge into account when setting their underwriting policy. In the Parliamentary debate, the storyline recurred but it was also challenged. First, insurers – who had not been represented in the Health Council – joined the discussion and contested the claim that people treated with FH have a normal life expectancy. They also challenged the Minister's claim that the category of treatability - as was used in the Medical Examinations Act - relates to life expectancy. The Parliamentary debate pushed the Minister to explicate her responsibility in these matters. It was stated that government only takes limited responsibility to compensate for inequality on a private insurance market. At the same time FH was re-positioned as a disease for which it is still uncertain whether life expectancy can be normalized. Thus, insurers' underwriting policy was now considered legitimate. The original storyline of FH as a treatable *and* insurable disease was undermined.

Things came to a head in June-July of 2002 because the extension of the FH screening program was at stake. At the end of November 2001 the Health Care Insurance Board[189] [190] had already issued a report on the FH screening program , in which they had recommended the government to pursue the extension of the program (College voor Zorgverzekeringen, 2001). But the whole issue of insurance selection was reason for the government to postpone the implementation of these recommendations. By now, the Minister was locating the responsibility with the insurers, when she said that an acceptable arrangement from insurers' side to settle insurance problems had to be awaited (Minister of Health Welfare and Sports,

[189] At the time the Health Care Insurance Board (CVZ) coordinated "the implementation and funding of the Health Care Insurance Act (Zvw) and the Exceptional Medical Expenses Act (AWBZ). The CVZ adopts an independent position: in between policy and practice, in between central government on the one hand and the health insurers, care-providers and citizens on the other" (source: http://www.cvz.nl).
[190] In Dutch 'College voor Zorgverzekeringen' (CVZ).

2002b). A few weeks earlier, on June 26 2002, the Minister wrote a letter to the Dutch Association of Insurance Companies pressing the importance of settling the insurance problems – and emphasizing that the solution should be at the level of the group of FH patients as a whole:

> "*To prevent that the extension of the aforementioned screening program would come to a standstill due to lack of clarity about the access to insurance, I insistently appeal to you to come to a proper solution as soon as possible. The success of the intended extension of the screening program critically depends on the ultimate solution of this issue.* ***To regard FH as a treatable disease in the meaning of the Medical Examinations Act concerns the group as a whole. Therefore it is reasonable to find a solution for access to insurance as implicated in the Medical Examinations Act for the group as a whole as well. And in such a way that the group as a whole, thus without discriminating between sub groups, can be offered an acceptable policy with the same premium, and one which takes into account the risks represented by the group as a whole****."* (Minister of Health Welfare and Sports, 2002a, bolds inserted by FM, translated from Dutch).

While the Minister tried to uphold the storyline that a treatable disease is an insurable disease, she also articulated it further. She observed that in the context of the Medical Examinations Act and in the context of the Health Council's advice treatability had been defined as a *collective* category, referring to the group of FH patients as a whole. Insurers on the other hand took into account *individual* differences when assessing FH risks. With this observation the Minister provided an opening for a way-out of the disagreement between the government and the insurers: insurers should also take a group-level approach, particularly in the envisaged screening program.

5.5 The change of governance arrangements through hybrid self-regulation

Whereas government had decided not to assume responsibility for the compensation of inequality in the private insurance market, they still had to take a decision regarding the extension of the FH screening program. The Minister had linked this decision to the issue of access to insurance in her letter of June 26th 2002 (see

section 5.4.3). She could do so because the Medical Examinations Act does not contain detailed regulations on each and every aspect, but delegates some parts to a process of self-regulation involving established representatives of insurers, doctors and patients, the Association for Insurance Companies, the Royal Dutch Medical Society and the Interest Group for Employment, Insurance and Health.[191] Already earlier, in the context of the Parliamentary debate, the Minister had called on these parties, referring to the Health Councils' recommendations (Kamerstukken II, 2001-2002d).[192] The deadline for this self-regulatory process was set on July 1st, 2002. If parties would fail to reach an agreement before that date, the Minister would take over and put in place an Order in Council.[193]

While the Minister would make clear that she was not going to regulate the private insurance market, she did not leave the problems to be settled through the free market, either. The insurance market was called upon to regulate itself but under conditions set by the Minister, including the requirement to reach an agreement with representative parties of patients and medical professionals. Thus, a hybrid forum of patients', doctors' and insurers' representatives was given the opportunity and was called upon to take on a meta-responsibility for governing the issue of genetics and insurance. It was the third arena (after Health Council and Parliamentary debate) in which the issue was discussed and became further articulated.

There was another hybrid forum parallel to this one: soon after the publication of the AMC Report in 2000 the Association of Insurance Companies, FH patient organization 'Bloedlink' and the FH screening program organization 'StOEH' had started discussions among themselves about access to insurance for FH patients. These discussions were not public. The possibility of addressing the problem at the group level, which would be pushed by the Minister, was soon abandoned.

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[191] In Dutch: 'Verbond van Verzekeraars', 'Koninklijke Nederlandse Maatschappij voor Geneeskunde' (KNMG) and 'Breed Platform voor Verzekerden en Werk' (BPVW).

[192] "The Council deems it is desirable that specific rules are formulated regarding the admissibility of questions concerning the hereditary background of insurance candidates. The Council believes it is important that insurers in their premium and acceptance policy use accepted medical scientific knowledge when the treatability of diseases is at issue. I endorse the Council's wish. In the spirit of the Medical Examinations Act, I prefer such rules to be created through the self-regulation consultation concerning insurance examinations in which the parties are involved." (Kamerstukken II, 2001-2002d)

[193] In Dutch: 'Algemene Maatregel van Bestuur' (AMvB).

Eventually, an important result was the design of an information leaflet for patients, which would help to reinforce the insurers in their position (see section 5.5.2).

5.5.1 The Insurance Examinations Protocol

The Minister, in the end, was willing to wait until the negotiations between the parties representing patients, doctors and insurers, Association for Insurance Companies, The Royal Dutch Medical Society and the Interest Group for Employment, Insurance and Health resulted in the 'Insurance Examinations Protocol' in March 2003.[194] Overall, the Protocol reaffirmed the principles of a free market. In the introduction to the Protocol it is emphasized that 'freedom of contract' is the starting principle of the private insurance market. This concerns the insurance candidate as well as the insurance company. In order to accept insurance candidates, insurers need information to be able to make a risk assessment. In order to prevent self-selection, it is important that there is equality of information between insurer and insurance candidate (Verbond van Verzekeraars et al., 2003, p.1).

The other striking feature is that the individual approach is chosen. While the hybrid negotiations to establish the Protocol provided the opportunity to discuss the category of treatable disease and to reconsider which diseases counted as untreatable in the context of the Medical Examinations Act (Welwezen, 2003, p.11), they did not change prior definitions. The Protocol did not adopt the definition that had been proposed by the Minister, in which treatability relates to life expectancy and from which insurability may follow. This was recognized as important, for example, in an insurance publication commenting on the Protocol, where the chair of the Insurance Association's Working Group on Genetics stressed that treatability in the context of the Medical Examinations Act does not imply that people can get insurance at standard rate. She stressed that the Medical Examinations Act is not meant to be a form of social legislation and that insurers cannot take responsibility in that matter.[195]

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[194] In Dutch: ' Protocol Verzekeringskeuringen'.

[195] "Homsma, finally, does not dispute that people with a predisposition for hereditary disorders can still be confronted with a number of obstructions when taking out an insurance, despite the intentions of the Medical Examinations Act. "But", she says "the basic assumption in is apparently widespread that the Medical Examinations Act must ensure everybody – outside of existing social legislation – of the right to have an ample income, the right to a house, life insurance, etcetera. But that is not what the law says and that is also not the intention of the law. And furthermore, insurance companies are not able to do this" (Welwezen, 2003, p.13).

Important for the governance arrangement that would come into place is that the Protocol's Explanation stipulates that when categories like treatability give rise to interpretative problems in practice, the parties that signed the Protocol would confer and suggest solutions. Thus, these parties positioned themselves as the arrangement, instead of the Health Council, to assess treatability (Verbond van Verzekeraars et al., 2003, p.6).

5.5.2 An Acceptable Settlement for the FH Screening Program

In the context of the Dutch public health care governance arrangement, the government had the responsibility to weigh the potential benefits of a population screening program against the potential negative side effects, including negative psychological or societal effects. This governance principle has been formalized as part of the Population Screening Act.[196] The Minister chose to exert this responsibility, first, by postponing the scaling up of the FH screening program as long as the insurance position of FH people was contentious and unclear, and second, by holding the insurers responsible for solving the problems.

The agreement that had been reached regarding the Insurance Examinations Protocol in March 2003 contributed to this solution as it filled in some of the ambiguities of the Medical Examinations Act (State Secretary of Health, 2003a). A further contribution was provided by the Association of Insurance companies, which in consultation with the FH patients' organization 'Bloedlink' and the FH screening organization 'StOEH' had developed a leaflet for participants in the FH screening program to inform them about their insurance position and rights. For the Ministry of Health, this leaflet settled the issue of FH screening and insurance selection. In April 2003, the decision to extend the FH screening program was finally taken (State Secretary of Health, 2003b).[197] The settlement included acceptance, by the Minister, that her preferred approach, to regard FH people as a

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[196] According to the formal rules of the Population Screening Act (in Dutch: 'Wet Bevolkings Onderzoek' (WBO)) of that time, a license for FH screening was not required. But the Act was under critical evaluation and many people were of opinion that it ought to be changed and that – amongst others - FH screening should become subject to license requirement.

[197] In the same period, the Minister of Finance also had reported - in a letter to parliament - on the findings from studies on the accessibility of financial products and services, including insurance products for people with a high risk (1st of April 2003). It is concluded that problems appeared not so bad, though it is also noted that due to a lack of data quantitative conclusions cannot be drawn (Kamerstukken II, 2002-2003).

group and to determine an insurance policy for the group as a whole, was not taken up. The patient leaflet stated that:

> *"For people with FH it is not always possible to get insurance at standard conditions or standard rates"* (Verbond van Verzekeraars, 2003).

It further made clear that the health status of people with FH is assessed on an individual basis and similar to the way it is done with people lacking FH. Not the genotype - or genetic make up - but the phenotype - that is clinical indicators - determine whether or not substandard insurability conditions apply. That means that blood cholesterol level and additional risk factors, such as weight, blood pressure and smoking are used as risk indicators to determine the insurance rate. The possibility of a remission, allowing a lower rate, is also pointed out as the leaflet states that:

> *"If treatment reduces cholesterol level, this can be taken into account"* (Verbond van Verzekeraars, 2003).

A preventive treatment scheme, such as may follow when people are diagnosed with FH, includes medical treatment and lifestyle changes such as quitting smoking, changing diet, and physical exercise, where compliance is the responsibility of the patient. This duty to comply with therapy is reinforced by the constellation of the insurance system, where a lower premium is possible when compliance is proven. Thus, individuals with FH are positioned as co-responsible for fulfilling the promise that FH is a treatable as well as an insurable disease.

In addition to patient's responsibility to comply with prevention/therapy, doctors were also held accountable. A year after the screening program was scaled up, an article was published on FH screening and insurability. It was observed that in many cases "*FH-patients are not treated and checked sufficiently*" (Homsma et al., 2004, p.495). Doctors were reproached for not providing adequate therapy and control:

> "*When dealing with an insurance application, it turns out, as a rule rather than an exception, that according to the measured laboratory values either an insufficient dosage is prescribed, or adequate check-ups are lacking*" (ibid.)

Both the Health Council and the Minister had urged insurers to take the latest medical scientific knowledge into account in their underwriting policy. But means to enforce this responsibility were absent. Interestingly, the leaflet constructs a settlement: competition between different insurance companies on a private insurance market would do the trick:

> *'Insurers' underwriting policy is based on latest medical knowledge and constantly takes into account the latest results of relevant studies. The insurance business does not however have a general policy for FH. Exactly because of market forces and strong mutual competition, conditions and premiums may differ between insurance companies. It is therefore worthwhile to apply for coverage at several insurance companies before finally taking out your insurance'* (Verbond van Verzekeraars, 2003).

The text of the patient leaflet confirmed the constellation of a private insurance market and drew attention to insurance applicants' role within this market. In order to create a competitive market in which insurance companies are pushed to offer insurance products with sharp prices, insurance applicants need to act as rational consumers. Insurance candidates are held jointly responsible for finding the best insurance conditions.

In its letter to Parliament of April 1 2003, the government restated that insurers on the private insurance market are free to determine their own acceptance policy and to determine their own premiums. While a concern with solidarity with those who have a high risk had not completely disappeared from the government's considerations, solidarity was considered to be a joint responsibility of insurance companies and consumers in a free insurance market:

> "*Obviously, in setting the insurance conditions, an insurer will take into account the implications for his public image. Thus, ideas about corporate responsibility and solidarity can play a role. Consumers can also take into consideration such elements, when choosing a certain insurer. In the context of private insurance this makes solidarity between groups with different risk profiles in the end a choice of those who offer insurance and of consumers."* (Kamerstukken II, 2002-2003, p.6)

To conclude, individual FH-carriers are now held co-responsible for making FH into a treatable and an insurable disease. As rational consumers on a free insurance market they need to give insurers incentives to offer insurance products against sharp prices. And as responsible patients they need to comply with treatment schemes and lifestyle changes. There was still a storyline about treatability and insurability, but looking at how it started in 2000, one might think it had evolved almost beyond recognition. What started as a discussion on insurance selection ended by highlighting the work to be done by FH patients in order to fulfill the promise that FH is a treatable disease and an insurable disease.

5.6 Conclusion: organizing responsibilities for FH screening and insurance selection

In its reconstruction of the history of FH genetics screening and insurance selection, this chapter addressed my first research question on the nature of the process of organizing responsibilities. I have shown how the configuration of responsibilities for genetics and insurance selection became the subject of debate when the pilot program for FH screening was evaluated. The discussion traveled between different arenas and related governance practices and different actors positioned themselves and others. In the end, a new configuration of responsibilities was achieved, linked to changes in the interpretation of the main storyline. In section 5.6.1 I summarize the case focusing in particular on the role of the different intertwined storylines. Section 5.6.2 addresses the question what the process of organizing responsibilities looked like, focusing on the different elements and dynamics and the different arenas that played a role.

5.6.1 The interaction of storylines

I will summarize the history in terms of the conceptual framework developed in Chapter 2. There, I argued that prospective responsibility positioning at the supra-local level of governance practices and hybrid forums is shaped by the interaction of storylines. Mutual responsibility positioning does not take place directly like in first and second order positioning. It is mediated by storylines which open up responsibility positions. Storylines also play an important role as linkages between different governance practices and hybrid forums.

The storyline which had been introduced by the AMC researchers, that FH as a treatable disease could and should be an insurable disease, traveled easily between the different governance practices and hybrid forums in which the issue of genetics and insurance was discussed. Thus the storyline, independent of whether it was accepted or not, formed a strong linkage between these different arenas. One effect of the storyline was how it shaped acts of responsibility positioning. The storyline functioned like a terse story[198] about the configuration of responsibilities for FH screening and insurance selection. By uttering the storyline - or even part of the storyline[199]- the configuration of responsibilities that lies behind was invoked, and could be responded to. Actors used reference to the storyline to position themselves and others. In the AMC publication in 'Medisch Contact', the storyline was used to position insurers as accountable for the difficulties that some FH patients encountered when buying life insurance. At a much later stage in the debate, the storyline invoked positioning of patients as co-responsible for insurability and treatability.

A second storyline focused on insurers violating the Medical Examinations Act, or at least interpreting its ambiguities to their own advantage. While for the AMC researchers this was just a possibility (even as it led to a recommendation to "intensify the control on the observance of the moratorium and the Medical Examinations Act"), newspapers took over this storyline and presented it as a fact. This then led to questions in Parliament.

At the early stage of the debate on FH screening and insurance selection, sometimes the one, sometimes the other storyline structured the interactions, but none of the two gained dominance over the other. In answering the Parliamentary questions, the Minister of Health limited herself to the question whether or not FH belongs to a disease category for which the Medical Examinations Act poses additional restrictions on insurers' right to enquire – a question that is important in the second storyline. But she returned to the first storyline on FH as a treatable and insurable disease when she asked the Health Council for advice on this matter.

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[198] I have taken the idea of a terse story from Boje who uses the term to refer to stories that require "the hearer to fill in silently major chunks of storyline, context, and implication" (Boje, 1991, p.106). As Boje points out "terse telling can be a power strategy of purposeful mystification (Fisher, 1984) or tactical ambiguity" (ibid, p.124).

[199] For example that FH is a treatable disease.

Given its mandate as a scientific advisory council, the Council did not feel entitled to address the question of insurability. It took up the other storyline by addressing the question whether or not FH should be considered as a serious, untreatable disease for which the Medical Examinations Act imposes additional restrictions on insurers' right to enquire. The Council's negative answer to this question made it less easy to maintain the storyline that insurers were violating the Medical Examinations Act. At the same time it put the first storyline back on stage. From then onwards the storyline that FH as a treatable disease could and should be an insurable disease dominated the interactions. By saying that a storyline is dominant, I mean to say that it structures responsibility positioning. It is pervasive in the debate and it is hardly possible not to relate to this storyline when engaging in the discussion. But the storyline and implicated positions are not necessarily accepted by or credible for all actors involved in the debate. A storyline can dominate and be contested at the same time.

There are at least three reasons which explain why this storyline was dominant. An obvious reasons is that it was an attractive storyline for those actors who wanted to hold insurers accountable for the insurance problems that were encountered by FH patients, also after the other storyline with which insurers were held accountable – the claim that insurers were violating the Medical Examinations Act - had lost credibility because of the publication of the Health Council advice. Secondly, the storyline that FH as a treatable disease could and should be an insurable disease became more dominant when it was articulated in the Health Council advisory report, even if this occurred in an implicit manner. In the Netherlands the Health Council has a strong position as a trustworthy and authoritative scientific advisory council (Bal et al., 2002) which means that a storyline that is taken up in a Health Council advisory report becomes more forceful.

A third reason resides in the ambiguity of the storyline, particularly about the categorization of FH as a treatable disease. There were two dimensions to the treatability category where ambiguity was visible. First, there is a narrow versus a broad interpretation of the treatability category. In passing judgment on the categorization of FH as a treatable disease in the context of the Medical Examinations Act, the Health Council Committee had used a broad definition of treatability, which did not require that treatment would lead to a normal life expectancy. But between the lines, the advisory text strongly suggested that this

legal categorization would also imply that insurers have no scientific grounds to charge FH-carriers a higher than standard insurance premium. In the parliamentary debate that followed two months after the publication of the Health Council advisory report the ambiguity of the category of treatable disease became salient. The Minister announced that she would commission a Health Council advisory report on the definition of the category of treatability and she suggested using a much stricter definition than had been used in the Health Council advice on FH and the Medical Examinations Act. The Minister suggested that a disease should be considered treatable if people who are treated for this disease have a normal life expectancy. Such a narrow definition of treatability would make the storyline that a treatable disease is an insurable disease more credible and acceptable. But using such a narrow definition would also reopen the question whether FH counts as a treatable disease. The Association of Insurance Companies made clear that they did not agree with the Minister that this narrow definition of treatability applies in the context of the Medical Examinations Act. A second dimension of the treatability category where ambiguity is visible concerns whether the category is perceived as a category that applies to the group of FH patients as a whole or whether it is seen as a category which applies to the individual FH patient.

I have described the (evolving) positions of actors on the different definitions of treatability. The Minister first went for a definition in terms of normal life expectancy, was criticized by the Association of Insurance Companies, and then moved to a position where she argued that insurers should treat the whole group of FH patients equally, to finally allow that individual differences could be taken into account. Exactly because the storyline could accommodate the various interpretations, it continued to be the umbrella for the hybrid debate. Until it became linked, in 2003, with a new configuration of responsibilities (including those of individual FH patients), and settled into a particular interpretation.

So gradually the ins and outs of this storyline became further articulated. Interactions (up to contestation) of the actors, who make up the configuration of responsibilities, are occasions to clarify and further define the meaning of the storyline. As it became clear that insurers would not in all cases provide people with FH with a standard insurance premium, the articulation of the storyline was also occasion for another storyline to gain dominancy in the debate. With this third storyline, on solidarity, Members of Parliament pushed government to take

responsibility. But, in a Letter to Parliament, government explicitly stipulated its (limited) responsibility for warranting solidarity on a private insurance market.

The various actors involved in the configuration of responsibilities felt positioned by the evolving versions of the storyline that FH as a treatable disease should be an insurable disease and they responded by accepting, rejecting or specifying their role responsibility in relation to this storyline. The positioning act of one actor had consequences for other actors' responsibility positions, which made other actors position themselves as well. In doing so, the storyline was further articulated, became less ambiguous and the configuration of responsibilities that is represented by this storyline took a more definite shape. The Insurance Examinations Protocol, concerning the issue of genetics and insurance in general, and the patient leaflet relating to the specific issue of FH screening and insurance selection, are the endpoint of the debate and attempts to achieve a settlement. The patient leaflet, with its specific perspective, not only indicates what the settlement is about, but also stabilizes it, because of its material presence and its acceptance by the Minister.

5.6.2 Organizing Responsibilities for FH Screening and Insurance Selection – what various arenas and forums contributed

The discussion concerning the issue of FH screening and insurance selection alternated between a number of different forums and arenas, which contributed in various ways to the overall process of organizing responsibilities. This is similar to what I found in the prenatal screening case, but the details are different, both in terms of the kinds of forums and arenas that played a role as well as in terms of the content of the issue. Normative plurality and inconclusive governance arrangements formed a great challenge to the organization of responsibilities in the case of prenatal screening, whereas in the case of FH screening and insurance selection clarifying the ambiguities in the main storyline was important to conclude the debate. Here, I will discuss the different elements that played a role in organizing responsibilities and how the different arenas contributed to this process. A concise summary of these findings is presented in table 5.1ab (p. 222, 223).

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When confronted with Parliamentary questions on the interpretation of the Medical Examinations Act for FH, the Minister had recourse to the Health Council. The Health Council played a major role in representing the novelties' affordances. It was successful in the sense that the scientific facts that they presented remained uncontested and were used as reference in later stages of the debate. The Council's

contribution to finding realignment in the configuration of responsibilities can be judged as productive and unproductive at the same time. Within the wider debate there were two main intertwining storylines in which insurers were positioned as accountable for the problems that FH patients encountered when taking out insurance. Given its mandate, the Council chose to address only the storyline on insurers violating the Medical Examinations Act. The pre-given normative framework of that Act enabled the Council to write an apolitical advisory report. The advisory report contributed to the process of organizing responsibilities for it clarified insurers' rights and restrictions in enquiring about FH. Thus, it stabilized a small part of the responsibility puzzle.

However, each of the two storylines were built on the argument that FH is a treatable disease and the Council's advisory report was easily interpreted as also supporting the storyline which it had not explicitly addressed. The case shows how a narrowly framed scientific advice, set within a specific legal context and addressing a specific storyline, is interpreted as having much broader implications, when it intertwines with another storyline in the debate in which a similar discursive category figures. There was a strong discursive affinity between the two storylines, in which "discursive elements not only resemble one another but flow over into one another" (Hajer, 1995, p.67) (cf. chapter 2).[200] As a result the advisory report ambiguously represented FH as a treatable and insurable disease. Later this storyline was contested and successfully rewritten by insurers.

When characterizing the role of the Council's advisory report in the process of organizing responsibilities, a resemblance with the dancing procession of Echternach comes to mind. The storyline on the Medical Examinations Act was taken three steps further because the Council's advisory report came to be an authoritative reading. But simultaneously the storyline on FH as a treatable and insurable disease was taken two steps backward, because it was ambiguously supported by the Council's report. This pattern was not the outcome of conscious

[200] Hajer (1995) proposes to use the term 'discursive contamination' for strong discursive affinities. In this case I prefer not to use that term, because it suggests that somehow we are able to distinguish correct meanings from contaminated meanings. Whereas what is the correct meaning in this case is not pre-given, but the outcome of social interactions and related to the interpretation of the Medical Examinations Act and to the acceptance/rejection of implicated responsibility positions.

positioning acts but the contingent result of the discursive format of intertwining storylines.

The diffuse hybrid forum, in particular public media, was important at the start of the debate in turning the issue of FH screening and insurance selection into a public and a political issue. The medical journals and public media played a crucial role in transferring the issue from a research context (the AMC evaluation) to the political arena of Dutch Parliament. The diffuse hybrid forum was also important as a space where insurers could raise their voice, in particular concerning the way in which the Health Council had positioned FH as a treatable and insurable disease. Interesting in this particular case, is that we saw that the diffuse hybrid forum extended into the Parliamentary arena. The Parliamentary debate was spread over different occasions and insurers managed to take part in the debate by sending a letter to Parliament and the Minister. Both the diffuse hybrid forum as well as the Parliamentary arena enabled accountive positioning by insurers, which was important for correcting the idea that insurers did not take the latest medical scientific knowledge into account and could thus be blamed for insurance problems of people with FH.

It was not a matter of choice for insurers to take a position on the advice: other actors referred to the advisory report to justify their actions, in particular when reproaching insurers. This happened in the media as well as in the Parliamentary debate on Biotechnology and Genetics. Insurers had to respond. They pointed at uncertainties and individual differences in the results of treating FH, and they made clear that they would not accept all FH patients at a standard rate, but would take individual differences into account. They reconstructed the storyline which had derived its strength from the discursive affinity between the two storylines as well as from the authoritative position of the Health Council. Thus the diffuse hybrid forum was productive for bringing to the attention the discrepancy between the responsibility positions that seemed implicated in the storylines that dominated at the level of governance practice and governance arrangements and the responsibility positions that were actually taken up on the level of sociotechnical practices. Insurers' position on treatability and insurability forced the other actors, government in particular, to make explicit their role responsibility in these matters and take the insurers' position into account.

The political arena was not only important because its debate was a continuation of the diffuse hybrid forum, but also because it was the arena where normative

considerations which went further than those that had already been institutionalized in governance arrangements were discussed and in which Parliamentarians spurred the government to position itself regarding these broader normative considerations. In this case it concerned solidarity on a private insurance market. Government indeed positioned itself, arguing that it would not take responsibility to provide for solidarity on the private insurance market. This formed an affirmation of the existing governance arrangements.

The explicit positioning by government seems important, because it can account for the success of the last stages in the process of organizing responsibilities. Firstly the hybrid negotiations that took place in the mandated self-regulatory process on the details of the Medical Examinations Act. From the government's position it followed that realignment in the configuration of responsibilities had to be found within the boundaries of the private insurance market. As this was also the position of the insurers, the government's positioning, set the space for negotiation among the representative parties. It explains at least part of the success of the hybrid self-regulatory process in which agreement on the Insurance Examinations Protocol was reached. It was improbable that letting the self-regulatory process break down and having the Minister determine the details of the Medical Examinations Act, would yield a better outcome than which could be reached through the hybrid negotiations.

As expected the Protocol did not entail any substantial changes in the configuration of responsibilities for insurance and genetics. The main achievement of the Protocol was that some earlier responsibility positioning was confirmed[201]; some details of the Medical Examinations Act were filled in; and it was formally accepted by the three representative organizations of insurance companies, medical professionals and patients. This gave the agreement on mutual responsibilities a broad social basis. It was not the end point of the self-regulatory process[202], but at the time for the Minister the agreement on the Protocol partly contributed to resolving the unclear insurance position of people with FH and thus it contributed to her decision to start the extension of the FH screening program. The patient leaflet on FH

[201] In particular: insurers' responsibility to build their selection criteria on medical scientific knowledge; and the positioning of FH as a treatable disease in the context of the Medical Examinations Act.

[202] A year later agreements were reached on a standardized health questionnaire, to be used by insurers. Further negotiations concerned, among others, the establishment of a body where insurance candidates could file complaints.

screening and insurance selection, written by the Association of Insurance Companies in consultation with the FH screening organization and the FH patient organization, brought further clarity and for the Minister it formed an acceptable settlement for the issue of FH screening and insurance selection.

Important for my research question on the nature of the process of organizing responsibilities is that both the Protocol and the patient leaflet point at an element in this process which I did not identify before. Both Protocol and patient leaflet played a role in translating agreements that had been reached on the supra-local level of governance practices to the local level of sociotechnical practices. The Protocol contributed to translation, first because it was made available to the members and the represented constituencies of the parties that negotiated in the self-regulatory process and secondly because the fact that it resulted from a self-regulatory process contributed to the acceptance of the outcome by the actors that were represented.[203] The patient leaflet is more specific than the Protocol as it deals with FH in particular and is directed at FH patients. It plays a similar role in translating agreements on responsibility positions on the supra-local level of governance practices, to the local level of sociotechnical practices while simultaneously further articulating details of the configuration of responsibilities. In particular, individual insurance candidates were positioned in the role of rational consumers and compliant patients and insurers were positioned as responsible for enabling remission.

Finally it is interesting to note that the settlement that was eventually achieved – as reflected in the Protocol and the patient leaflet – was different from what the Minister had envisioned as a solution. Apparently the fact that there was a settlement, accepted by the involved parties, was enough reason for the Minister to decide on the extension of the FH screening program. It shows that consensus that is reached in hybrid forums can create legitimacy for the outcome, also if - as was

[203] In a later stage of the process of self-regulation, a standardized health questionnaire was developed, which structured mutual role responsibilities between insurance candidates and insurers, so there is no need for these actors knowing the legal framework of the Medical Examinations Act. This standardized health questionnaire played a similar role in translation between supra-local level and local level. The mutual role obligations between insurance candidate and insurer as laid down by the Medical Examinations Act are translated in the materialized script of the standardized health questionnaire and the interpretative difficulties are overcome.

the case for the hybrid negotiations on the patient leaflet - a forum does not have a formal mandate.

Acknowledgements:

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Elements in organizing respons. / Arena's/ Forums	Prospective responsibility positioning	Representation of the novelty's affordances	Resolving normative issues/ conflicts	Translation of responsibility positions from supra local to local level
Health Council	Insurers are implicitly positioned as responsible for making FH an insurable disease	FH is a treatable disease in context Medical Examinations Act – Ambiguous representation of FH as a treatable and insurable disease		
Diffuse hybrid forum	Accountive positioning: Insurers position themselves	Insurers emphasize: Individual differences in treatability of FH		
Political arena	Accountive positioning: Insurers position themselves – Government positions itself	Insurers emphasize: Individual differences in treatability of FH	Private insurers cannot be held accountable for solidarity - The social good that is at stake is not considered so important that government assumes responsibility for solidarity	

Table 5.1A: Overview of the different forums and elements/dynamics that played a role in organizing responsibilities for FH screening and insurance selection

Elements in organizing respons. / Arena's/ Forums	Prospective responsibility positioning	Representation of the novelty's affordances	Resolving normative issues/ conflicts	Translation of responsibility positions from supra local to local level
Mandated hybrid forum (self-regulation) on Medical Examinations Act	Mandated forum positions itself as responsible for assessing treatability of diseases Insurers take latest medical scientific knowledge into account	FH is a treatable disease in context Medical Examinations Act		
Bottom-up hybrid negotiation on FH patient leaflet	Patients are positioned as rational consumers on a private insurance market – insurers position themselves as enabling remission	Treatment of FH does not in all cases enable a standard insurance premium		Insurance Examinations Protocol Patient leaflet

Table 5.1B: Overview of the different forums and elements/dynamics that played a role in organizing responsibilities for FH screening and insurance selection

6

A genetic disease is not a genetic disease: Contesting the ‘genetic’ as a relevant category

6.1 Introduction

My analyses of the case on prenatal screening and the case on FH screening and insurance selection show that legislative frameworks play an important role as governance arrangements that structure mutual responsibility positioning. In both cases, difficulties in reaching mutual adjustment between the various participants in the configuration of responsibilities were related to how legislation was phrased. In the prenatal screening case, two legislative frameworks strongly structured responsibility positioning, but they were inconclusive in settling the configuration of responsibilities for prenatal screening. In the case of FH screening and insurance selection, the Medical Examinations Act – more in particular the legal category of treatable disease - gave rise to a lot of interpretative difficulties. The two cases suggest that processes of organizing responsibilities for novelties may be improved by (early) reflection and anticipation on the suitability of the legislative and regulative frameworks that govern these novelties. This chapter presents an example of such an anticipatory exercise. It analyzes a hybrid consultation meeting organized by an advisory committee that was asked to evaluate existing legislation and regulation in light of expected future developments in the health care application of genetic knowledge. The consultation meeting analyzed here, dealt with the use of hereditary data by employers and insurers.

The analysis focuses on the role of institutionalized categories.[204] I will discuss the importance of the 'genetic' category in the debate on insurance and genetics, how this category influences responsibility positioning and how it impacts on the process of organizing responsibilities. In the course of the consultation meeting the distinction and boundary between the 'genetic' and the 'non genetic' were repeatedly disputed. The 'genetic' as a relevant and manageable institutional category became contested. Over the years, with developments in genetic knowledge and research proceeding, the kind of phenomena to be known as and associated with genetic knowledge or genetic disease broadened rapidly, bringing together a wide variety of different phenomena. At the level of sociotechnical practices, genetic exceptionalism became more and more problematic, up to the

[204] In 'How Institutions Think' Mary Douglas (1987) drew attention to the institutionalization of categories and how such categories constrain us in the way we conceive of social problems and solutions. Thanks to Willem Halffman for pointing out this reference.

point that the boundary between the ‘genetic’ and the ‘non-genetic’ became blurred. Over the same time period, at the level of governance arrangements, the discourse on ‘the genetic as something exceptional’ had become more and more institutionalized.

During the consultation meeting the institutionalized discourse of ‘the genetic as something exceptional’ and the ‘blurred boundary’ discourse of local sociotechnical practices collided with each other. Although many invited participants in the meeting voiced a blurred boundary discourse on genetics, the Committee was reluctant to give up on the distinction between the ‘genetic’ and the ‘non-genetic’. It appeared that the institutionalization of the discourse was strong, which made it almost impossible to pass it over. Reluctance to give up on the ‘genetic’ category can further be attributed to the uncertain consequences that would follow. Giving up on the ‘genetic’ category had uncertain consequences for the way the problem of insurance selection and genetics was perceived and the kind of social solutions to be developed in answer. While they shared the opinion that the ‘genetic’ category had become obsolete, insurers, medical geneticists and patient representatives did not agree on the consequences of that opinion. On the one hand there were participants who argued that special legislation and regulation for genetics and insurance is no longer needed. On the other hand, some participants proposed to broaden the concern with genetics and insurance selection to a more general concern with predictive medical data and insurance selection, thus suggesting a change of relevant category, from the ‘genetic’ to ‘predictive medical data’.

This categorical shift was associated with a relative shift in the normative framing of problems of insurance and genetics. In the Netherlands, legislation to govern problems related to issues of ‘genetics and insurance’ is formally based on privacy and the ‘right not-to-know’ as core values to be protected. The blurring of the boundary between the ‘genetic’ and the ‘non genetic’ weakened the discourse on ‘the genetic as something unusual’ and made the argument that the ‘genetic’ requires special privacy protection less strong. The emerging shift to ‘predictive medical data’ as a new relevant category put solidarity more strongly on the agenda as a value to be protected.

In the conclusions of this chapter I will reflect on the role of hybrid consultation meetings in processes of organizing responsibilities, in particular in relation to the

role of institutionalized discourse and governance arrangements. Furthermore I will reflect on the influence of institutionalized categories on organizing responsibilities.

6.2 The institutionalization of 'genetic exceptionalism'

In the Netherlands, the institutionalization of 'genetic exceptionalism' dates back to the late 1970s, early 1980s, when a new medical specialism of 'clinical genetics' was established. Through a licensing regime, a number of clinical genetic practices were restricted to the responsibility of the medical profession of clinical genetics, organized in regional clinical genetic centers. Initially, these practices concerned only prenatal diagnostics and chromosome analysis. Later on, DNA diagnostic testing was also successfully incorporated in the restrictive regime of clinical genetics. The Dutch restrictive regime for clinical genetics is unique in the world. The regime is characterized by a strong normative reflection on the ethical and social aspects of developments in clinical genetics (Nelis, 1998).[205]

Patient autonomy was a central rule that governed behavior and decisions in clinical genetic practice. The emphasis on patient's autonomy implied reluctance to actively approach people for genetic screening. With the introduction of the first presymptomatic genetic test, a marker test for Huntington's disease in 1987, discussion arose whether at all presymptomatic testing should be offered. Huntington's disease is a very serious disease for which no treatment is available. What would be the psychological effects of knowing? A further dilemma existed with respect to one of the ground rules of the clinical genetic regime, the rule of individual patient autonomy. With respect to Huntington's disease the autonomy of several family members to choose for presymptomatic testing is simultaneously at stake and may give occasion to a conflict of interests. Presymptomatic diagnostic testing offers information about the family as a whole, not just about the individual. Take for example the situation in which an adolescent son wants to know whether

[205] In that respect, it is telling how a Health Council committee, which was asked to advise on the developments in medical genetics, criticized the initial formulation of the ministerial request for advice (Gezondheidsraad, 1989). The committee argued that more attention was needed for the ethical, societal and legal aspects of the developments in genetics and the committee distanced itself from the Ministry's suggestion that reduction of medical costs – induced by the reduced costs for chronic care – could be an argument to stimulate genetic counselling. According to the committee, that suggestion flatly opposed patient autonomy, the ground rule of the clinical genetic regime (Bal et al., 2002, p.194).

he has inherited Huntington's disease from his grandfather whereas the adult parent does not want to know. In that case individual autonomy does not offer a decisive rule of conduct. With respect to the problematic aspect of individual autonomy the rule was articulated that the right not-to-know deserves more protection than the right-to-know (Nelis, 1998).

In the Netherlands discussion on the issue of genetics and insurance also started in the late 1980s. The discussion was embedded in a broader debate about the social and ethical aspects of genetic research and genetic testing. At that time the issue could quite easily be framed as *something unusual* for which special regulation should apply. In 1989, on request of the Dutch government, a Health Council Committee issued an advisory report entitled "Heredity: Science and society. On the possibilities and restrictions of genetic diagnostics and gene therapy" (Gezondheidsraad, 1989). The Health Council committee in its advice restated that in the context of presymptomatic testing the right not-to-know outweighs the right to-know (Nelis, 1998). Furthermore, the Health Council Committee paid a lot of attention to the use of genetic knowledge outside the medical setting, notably by insurers and in the labor setting. It recommended that government would regulate the use of genetic knowledge by insurers and employers in order to prevent abuse. Furthermore, the Health Council committee anticipated on the development of population screening programs and it discussed conditions in relation to the right not-to know. The Heredity: Science and Society report was agenda and trendsetting. The Medical Examinations Act (WMK) – which regulates amongst others the use of genetic knowledge by insurers and employers – as well as the Population Screening Act (WBO) were built on the recommendations in this report (Bal et al., 2002, p.195).

Over the following years the initial normative framing, laid down as the right not-to-know, remained dominant in framing the discussion on genetics and insurance. When the Health Council Committee on genetic screening pleaded for government to take legislative measures against the use of genetic information by insurers, they used the argument that

> *"The freedom of people with a known family history of non treatable hereditary disease to evade possibilities for genetic testing is under pressure. For these people the possibility to receive a social good is at stake. They have*

access to insurance only if they can prove not to have inherited the genetic disposition. Financial circumstances can force these people to have a genetic test for which freedom of choice generally counts as a precondition." (Gezondheidsraad, 1994, p. 98)

As a result of the Health Council's advice on Heredity and Society as early as 1990 the insurance industry, united in the Association of Insurance Companies[206] voluntarily agreed upon a moratorium on the use of genetic test results (Marang-van de Mheen et al., 2000). The moratorium prohibits that insurance companies require insurance candidates to undergo genetic testing. Furthermore, up to a certain capital insured sum, candidates for insurance are not obliged to mention the outcome of former genetic diagnostic testing. This is known as the question limit.[207] With the moratorium on genetic research, insurance industry has slightly changed its practice of underwriting. In doing so – and at a relatively early stage of discussion – they, to a certain extent, positioned themselves as responsible and accountable. In their own account, they have taken up responsibility to prevent hindrance for the development of medical technology:

"The assumption that the negative impact of genetic testing on access to insurance could result in an important hindrance to participate in such research forms the background of the moratorium. As a consequence the advance of medical technology could be threatened" (Welwezen, 1997).

In December 1995 the moratorium was extended for an indefinite period of time and in 1998 the prohibition embedded in the moratorium became a part of the Medical Examinations Act. This Act does not in detail regulate all subjects. It comprised a provision for self-regulation by representative organizations of medical practitioners, patients and insurance companies. The Medical Examinations Act is quite a complex piece of legislation. The Act distinguishes between many disease categories: serious and non-serious, treatable and non-treatable, manifest and non-manifest, hereditary and non-hereditary, and further distinguishes between genetic and non-genetic test results. The Act regulates the kind of information which

[206] In Dutch: 'Verbond van Verzekeraars'.
[207] The exact height of the question limit is determined by the Minister of Health and has changed over time as it is regularly adjusted for inflation. On April 26th 2004 the question limit for life insurance was set at € 159,505 (Staatscourant, 2004a).

insurers are allowed to ask for. The Act does not regulate the acceptance and premium policy of insurers. Depending on the categories that apply in a specific case, an insurance company is or is not allowed to ask for known genetic test results and to enquire about family history data. A concern with protecting privacy and the right not-to-know formed the formal motivation for this part of the Medical Examinations Act.[208;209] Although in practice the amount of protection that was offered against insurance selection was rather limited[210], the institutionalization of both the Moratorium on genetic tests and the Medical Examinations Act strengthened the overall discourse of 'the genetic as something unusual'; the idea that hereditary diseases, genetic testing, genetic research and hereditary health data are essentially different from non-hereditary disease and non-genetic testing and that therefore special attention, regulation and legislation is justified. This was clearly visible in the case of FH screening and insurance selection, where many people argued that people with FH needed to be protected against insurance selection (see chapter 5).

Over the years the institutionalized discourse of 'genetic exceptionalism' became increasingly challenged by actual developments in genetic research and applications. Since the start of the debate on 'genetics and insurance' in the late 1980s, research in genetics and DNA diagnostic testing developed rapidly. Whereas in the early years of development genetic research concerned relatively rare and so-called monogenetic diseases, later on research broadened in scope to more frequently occurring multifactorial diseases such as cancer, diabetes and coronary heart disease. For monogenetic diseases, a DNA diagnostic test predicts with almost a hundred percent certainty whether or not someone will develop a disease. Furthermore, monogenetic diseases follow a simple Mendelian inheritance pattern. For multifactorial diseases on the other hand, a (large) number of different genes, in

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[208] 'The use of hereditary and medical data is primarily approached as a privacy issue in Dutch law and regulatory practice' (ZonMw, 2003, p.80).

[209] The regulation of the use of medical and genetic examinations and data by private insurers is only one element of the Medical Examinations Act. The Medical Examinations Act also regulates medical and genetic examinations of job applicants by employers.

[210] For serious, non-treatable, non-manifest and hereditary disease (Huntington's disease and Muscular Dystrophy in particular) the Medical Examinations Act forbade insurers the use of predictive medical information below the question limit, including the use of family history. De facto, this regulation meant that people with a predisposition for Huntington's disease and for Muscular Dystrophy were protected against insurance selection. Thus for certain types of conditions the Medical Examinations Act provided de facto solidarity.

combination with environmental influences such as for example nutrition lead to an increased chance of developing a certain disease, and patterns of inheritance are also more complex.

Nowadays the bulk of genetic research – especially if one takes into account the number of patients involved - is no longer focused on rare, monogenetic diseases, but on multifactorial diseases. Furthermore, research in genetics aims not only to predict a disease, but also to understand disease mechanisms and find new targets for treatment and drug development. Thus over the years the difference between what once constituted the 'genetic' and the 'non-genetic', became ever smaller and the boundary between the two became increasingly blurred. Note that I use the terms 'genetic' and 'non-genetic' to refer in general to a broad collection of related dichotomies: genetic vs. non-genetic health data, tests, research or disease and hereditary vs. non- hereditary health data, tests, research or disease. Whereas in their exact meaning these terms differ from each other, in the discursive practice concerning the issue of 'genetics and insurance' these dichotomies are often used and interpreted as if they are interchangeable. There is a high discursive affinity between these dichotomies, which accounts for an often confused discussion (Hajer, 1995).[211]

In the 'genetics and insurance' debate the shift from monogenetic to multifactorial disease is exemplified by Familial Hypercholesterolemia (FH), a hereditary type of coronary heart disease.[212] In the context of a national population screening program, it appeared that people with FH faced difficulties in obtaining life insurance. A controversy arose over the question whether the Medical Examinations Act did and should protect people with FH against insurance selection. It appeared that FH differed considerably from monogenetic diseases such as Huntington's disease and Muscular Dystrophy, for which the Medical Examinations Act provided protection

[211] A core assumption in the theory on discourse coalitions is that a text – whether written or spoken – in general derives its political force from its multi-interpretability. Hajer uses the term 'discursive affinities' to explain multi-interpretability: "Separate elements might have a similar cognitive or discursive structure which suggests that they belong together. In that case actors may not understand the detail of the argument but will typically argue that 'it sounds right'. This element of the explanation of a discursive order thus does not primarily refer to the actors and their intentions but explicitly operationalizes the influence of discursive formats on the construction of problems." (Hajer, 1995, p.66,67) Both conceptually and empirically Hajer emphasizes how discourse can build coalitions between people that perceive their positions and interests differently.

[212] For an extensive analysis see chapter 5.

against insurance selection. FH is a case where the boundaries between the 'genetic' and the 'non-genetic' are blurred. FH can be diagnosed with a genetic diagnostic test, but it can also be clinically diagnosed by testing the blood cholesterol level in combination with assessing family history. Although people with FH are not obliged to inform insurers about the outcome of genetic diagnostic testing if the capital sum insured does not exceed the question limit, they are not protected against insurance selection. After all, insurers are still allowed to inquire about blood cholesterol levels and family history. Moreover, blood cholesterol levels have for a long time been an important criterion for insurers to rate risks associated with insurance applicants and to set their insurance premium accordingly. It appeared that people with a genetic predisposition for FH did not enjoy the same level of protection against insurance selection as did people with a genetic predisposition for Huntington's disease. Furthermore, the FH case brought to the fore that all people with high cholesterol levels face insurance selection[213], whether or not their disease is categorized as 'genetic'. Following that conclusion, concern with insurance selection shifted easily from privacy aspects to broader concerns with solidarity and actuarial fairness.

6.3. The discourse of institutions meets the discourse of sociotechnical practices

In the consultation meeting discussion that I draw upon in this section, the institutionalized discourse of genetic exceptionalism was mainly voiced by members of the advisory committee, whereas many of the invited experts and representatives spoke in terms of the blurred boundary discourse on genetics. The discussion that took place during this consultation meeting shows the persistency of the two discourses and the difficulty to bring the two together.

6.3.1 Situating the consultation meeting

In 2000 the Dutch Minister of Health, Welfare and Sports approached ZonMw[214] with a request for a type of advisory report, they had not dealt with before. As part

[213] I use the term insurance selection broadly. Insurance selection does not necessarily imply that insurance companies reject insurance candidates. More often it will mean that they have to pay a raised insurance premium.
[214] The Netherlands Organization for Health Research and Development.

of a wider anticipatory policy on the implications of genetic research for healthcare, the Ministry wanted to know whether, given the expected future developments in genetics, new legislation and regulation was needed (Ministry of Health Welfare and Sports, 2000). While ZonMw through its 'Legislation Evaluation Program'[215] had gained expertise and a prior role in the ex post evaluation of legislation in the healthcare domain, the organization had not before dealt with ex ante evaluation of legislation and regulation. An important difference between the two types of evaluation concerns the normative starting points of advice. Whereas in ex post evaluation existing legislative frameworks provide the normative ground, in ex ante evaluation the norms itself may be up for discussion. As ZonMw had no experience with this type of advice they initially hesitated to accept the Minister's request for advice.[216] And when the advisory request was accepted, the Legislation Evaluation Committee, which normally supervises the 'Legislation Evaluation Program', decided to establish a separate, 'Genetics Committee' to formulate an answer (ZonMw, 2003).

The advisory report was written to answer the following question: "To what extent do laws, regulations and their founding principles need to be adjusted in relation to the consequences of the use of genetics for the legal status of the patient/the individual?" (ZonMw, 2003, p.4). In nominating members of the Genetics Committee, the aim was to put together a broad composition of members. In the Committee's words: "Members have a legal, ethical or medical-scientific background, or are knowledgeable with respect to genetic applications and the potential consequences for the patient/the individual. Members are appointed in personal capacity" (ZonMw, 2003, p. 3). The Genetics Committee was a commissioned hybrid forum with a new type of mandate. The committee organized the advice around five thematic issues. Apart from extensive deliberations amongst committee members, five thematic expert consultation meetings were organized and formed input in the advisory trajectory. This chapter draws on observations made during one of these consultation meetings; a meeting on the use of hereditary data by employers and insurers. A variety of experts/representatives were represented in the meeting, including patient organizations, labor union, clinical geneticists and

[215] In Dutch: 'Programma evaluatie regelgeving'.
[216] Personal communication with Paul Francissen (Ministry of Health, Welfare and Sports), 09-09-2004, Leiden.

insurance companies. The starting point of the meeting was a discussion paper, written by one of the members of the Genetics Committee. The account that I give of this consultation meeting does not intend or claim to cover this meeting in its entirety. I focus specifically on those parts of the meeting in which the discourse of 'genetic exceptionalism' collided with the blurred boundary discourse.

6.3.2 Genetic exceptionalism as a boundary device

In section 6.2 of this chapter I described how genetic exceptionalism came to be institutionalized within the Dutch governance arrangement for developments in clinical genetics. The Genetics Committee was tied into this governance arrangement. During the consultation meeting members of the committee reproduced the 'genetic' as an important category as they drew on existing national and international legislative and regulative discourse. However, the position of the Genetics Committee, within the Dutch governance arrangement is not the only explanation for them to embrace genetic exceptionalism. At an early stage of the consultation meeting, it appeared that the 'genetic' category also served an internal committee purpose. The 'genetic' category served as a boundary device.

The consultation meeting started off with a round of general comments. At this initial stage of the meeting, the chair asked one of the invited experts/representatives whether a comment he had made was actually *specific* for genetic issues. If it concerned a broader problem, then the issue was deemed irrelevant for the Genetics Committee's task at hand. A couple of months earlier, the Genetics Committee had organized a consultation meeting on one of the other sub themes that were dealt with in the advisory report. On that occasion the consulted experts and representatives had come up with many issues that were only loosely related to the development of genetics. The discussion wandered off in too many directions to be productive. At that time the chair - in what seemed to be a more or less ad hoc way - drew a boundary between issues *specific* for genetics, and more general medical issues. During the consultation meeting that is analyzed here, the chair formulated the demarcation as a more or less established aspect of the Committee's advisory work.

Considering the Committee's task, it makes sense for the chair to restrict the discussion in some way. The work of the advisory committee as well as the expert consultation meeting require a focus in the discussion in order to reach some sort of

a product within a limited timeframe. The use of the 'genetic' category as a boundary device raised the question where to put the boundary of the 'genetic' category. One of the consulted experts/representatives observed that the terms 'genetic applications and hereditary data' as used in the discussion paper were not very well defined. Did these terms refer to genetic testing or to genetic data? The chair explained that the term 'genetic applications' was taken over from the government's White Paper on 'The application of genetics in health care' in which the intention for the advisory request was first laid down (Ministry of Health Welfare and Sports, 2000).[217] The Committee's secretary elaborated that the Committee used the term 'genetic applications' in a broad sense. Thus on the one hand the 'genetic' category was used as a boundary device to confine the debate, on the other hand it was sufficiently broad to encompass a variety of related issues. From this point on the discussion developed and what eventually got challenged was the underlying assumption that the 'genetic' can at all be meaningfully distinguished from the 'non-genetic'.

6.3.3 A discourse of genetic exceptionalism meets a blurred boundary discourse

In our medical judgment we do not distinguish ... Take overweight for example. Is that or is that not genetically determined? It is determined by family. We try to keep making a distinction to a minimum.

(…)

It is very difficult to make this distinction, since almost every condition has or will be found to have a hereditary component.

(…)

It is possible to distinguish between monogenetic diseases. But considering polygenetic disease we're on slippery terrain; a distinction is not relevant anyway.

(…)

Then why was and is a distinction made anyway?

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[217] The terms thus reflect the Genetics Committee's relation and mandated position towards the commissioner of the advice.

The quotations above are from different invited participants to the consultation meeting. There appeared to be a broad agreement that it is difficult and often irrelevant to make a clear distinction between the 'genetic' and the 'non-genetic' in local sociotechnical practices - whether these concern a clinical diagnostic practice, a research practice or the medical underwriting department of an insurance company. Patient representatives, insurers as well as medical genetics researchers all agreed that the 'genetic' had become a problematic category in framing the problems of genetics and insurance. Yet, to do away with the distinction was not so easy since the advisory committee was tied to institutions in which the distinction was firmly embedded. For the Committee, the institutionalized distinction between the 'genetic' and the 'non-genetic' is as real and forceful as are the complexities and uncertainties of heterogeneous practices that were referred to by the participants of the consultation meeting. Referring to the political, legal and international context in which the Genetics Committee operated, members of the Committee tried to enroll the participants of the consultation meeting in the discourse of genetic exceptionalism:

A: A distinction is relevant in the context of the WBPG (Act on Protection of Personal Data), because genetic information can disclose information about others. People have a right not-to-know, but people also have a right to information [FM: about themselves]. The circle of privacy protection is larger in case of genetic data.

B: I agree with X that a distinction is not relevant. The fact that you are a man is genetically predetermined.

C: *Overweight is determined by family, but possibly not inherited. But in those cases the circle of privacy protection is also larger.*

A: (...) We do not have to decide on the boundary between the genetic and the non-genetic. Several things evidently belong to genetics and heredity. Choices have been made already for all sorts of reasons, sometimes for good reasons. If you think a distinction is sometimes not needed, we invite you to say so.

B: Replace heredity by HIV/AIDS and you have exactly the same discussion. It is a subtle difference.

D: We can make a distinction between hereditary conditions in which no environmental influence plays a role and conditions in which both heredity and environment play a part.

The attempts to enroll the participants of the meeting in the Committee's perspective were not very successful. Time and again the conflict between the institutionalized discourse of 'genetic exceptionalism' and the 'blurred boundary' discourse of sociotechnical practice reappeared on the scene. Conflicting discourses such as these need not be a problem. Local sociotechnical practices will always be more heterogeneous than the institutionalized categories that regulate these practices. Some interpretation and contextualization is always needed in order to apply institutionalized categories or classifications to actual cases. In dealing with the conflicting discourses, Committee members did not actually challenge the 'blurred boundary' discourse as such. They did not question the relevance of that discourse within the medical or insurance context; rather, they tried to enroll the invited experts/representatives and urged them to translate the 'blurred boundary' discourse into the institutionalized discourse of 'genetic exceptionalism'. But, apparently, it was not so easy to translate between these two discourses.

It is difficult to oppose to the genetic exceptionalism discourse and withdraw from it, since it is omnipresent. At one point, one of the Committee members confronted one of the experts with the fact that the organization he was representing had itself a working group on genetics. Thus, he suggested that - on other occasions at least - this organization was well able to make a distinction between the 'genetic' and the 'non-genetic'. At a later stage in the consultation meeting the expert/representative accounted for this apparent contradiction, saying that:

We would never have had a working group on genetics if it hadn't been for the banal reason that we are confronted with this topic by politics.

In other words, the working group on genetics is part of this organization's response to being confronted with a political and institutionalized discourse on genetics. It does not reflect a discourse that is relevant in their own sociotechnical practice. Or so this representative claimed.

Experts and representatives that argue against the institutionalized discourse of genetic exceptionalism can be mistrusted for (secretly) advocating and pushing a

particular moral position in the debate on genetics and insurance. And indeed, as we will see in the next section, abolishing the genetic category does have (uncertain) moral consequences. But normative grounds alone cannot explain the broad coalition on a blurred boundary discourse that existed among the experts/representatives in the consultation meeting. After all, the experts/ representatives that voiced a blurred boundary discourse did not all share the same opinion on the consequences of that discourse.[218] One reason that explains why many experts/representatives in the consultation meeting resisted the committee's pressure to translate their blurred boundary discourse into the institutionalized discourse of 'genetic exceptionalism' seems to lie with the manageability of the category. According to the invited experts/representatives a point is reached in which the translation between the 'genetic' as an institutionalized category on the one hand and the always more heterogeneous practices on the other hand has become hard to manage and may furthermore produce negative side effects. One of the committee members tried to redirect the discussion from the question whether there is a distinction between the 'genetic' and the 'non-genetic' to the question whether the distinction has any relevance; a question which relates to the normative grounds for making a distinction:

> *We should be careful not to abolish the distinction between genetic and non-genetic. Analytically the distinction can convincingly be made. Internationally the distinction is made. The second question is: does the distinction have any relevance?*

But according to the response of one of the invited experts/representatives (normative) 'relevancy' is not at stake here:

> *I understand that differently. I understand, listening to Ms. Y (genetic epidemiologist) that the distinction is indeed difficult to make.*

What is at stake – so claimed this expert/representative – is the difficulty as such to make a distinction. He doubted the feasibility of the 'genetic' category in the

[218] In that respect the discourse coalition that existed among many of the participants in the consultation meeting did not signify a coalition in the political sense.

context of local sociotechnical practice. A genetic epidemiologist concurred with him:

> *For a number of frequently occurring diseases the distinction is unclear. The influence of smoking and (genetic) susceptibility for lung cancer for instance; to distinguish between those two factors, that is difficult.*

In an earlier stage of the discussion, this genetic epidemiologist had hinted at the negative side effects of a 'genetic exceptionalism' discourse:

> *More distinctions are necessary. You can't lump BRCA1*[219] *together with Huntington's disease. Half the people with BRCA1 will not develop breast cancer. The example of Hemochromatosis has caused a shock in the world of genetic research. It was thought to be a monogenetic disease. People should be screened and get treatment [*FM: viz. regular blood transfusion*]. An article in the Lancet, last June, shows that homozygous people do not develop the disease. People with Cystic Fibrosis and Huntington develop the condition, all right, (but) in the model disease for genetic screening, FH, the gene is not found.*

Apart from being difficult to apply in a complex and heterogeneous practice, a discourse of 'genetic exceptionalism' can have negative repercussions, some of which are indicated by the warning voice of the genetic epidemiologist. Medical scientific knowledge evolves and what once was known as a monogenetic disease, for which a screening program should be developed, can all of a sudden turn into something much more complex. A monogenetic discourse on a certain disease does not stay for long within the confines of medical research laboratories and journals. Especially when treatment options are available genetic screening programs will soon be initiated. If then at a later stage, a condition turns out to be less monogenetic than was initially thought, much harm may already have been done. People may have been put on medical treatment for no good reason, and people may have been unnecessarily frightened. A legal and political discourse that constitutes a distinction between the 'genetic' and the 'non-genetic' can have

[219] BRCA1 is the name of a genetic mutation, which is related to the development of breast cancer.

similar negative repercussions, as such a discourse translates easily into excessively simplistic public perceptions on genetic conditions. The reluctance from the side of the genetic epidemiologist quoted above to translate the 'blurred boundary' discourse into the legal and political discourse of genetic exceptionalism can thus be understood.

6.3.4 Abolishing the genetic category: uncertain ramifications

It seems that discourse institutionalization alone does not explain why members of the Genetics Committee were reluctant to align with the blurred boundary discourse that was shared among many invited participants to the consultation meeting. Uncertainty on the consequences that may follow upon the abolishment of the genetic category forms an additional explanation for this reluctance. Since institutionalized categories frame the way in which we perceive problems as well as the kind of social solutions that are conceivable (Douglas, 1987), pushing aside the genetic category is not without consequences. On the consequences of taking up a blurred boundary discourse, opinions varied amongst Committee members as well as amongst the invited experts/representatives. At one point the Committee's chair argued:

> *Legally this distinction between the genetic and the non-genetic is made. That is also the case in the discussion paper. We could neutralize the distinction everywhere... In that case, our job can be concluded in a few minutes.*

A participant replied:

> *The job cannot be concluded in a few minutes, because it does not change the question whether regulation is sufficient.*

Chair:

> *Do you need specific regulation in that case?*

Abolishing the distinction, thus reasoned the chair, the Committee's mandate would preclude any further advice on the issue of insurance and genetics. Others articulated consequences with even wider implications. An argument of consistency and fairness was put forward to criticize the genetic exceptionalism as it was institutionalized in the Medical Examinations Act. Such critique had become easier

now that the categories of the 'genetic' and 'non-genetic' had come to overlap to a larger extent:

> *Below the question limit of 150,000 Euro Huntington patients[220] get a normal insurance premium. Someone with Familial Hypercholesterolemia has to pay a higher premium. That is inconsistent and unfair. (...) You may need to abolish the question limit.*

It may not come as a surprise that other participants to the meeting did not agree. Now that the discussion had shifted to consequences, more disagreement came to the fore:

> *Why not the other way around? Why not say: "don't ask about diabetes below the question limit"?*

Whereas some proposed to consider DNA diagnostic data as 'nothing unusual', as similar to conventional health data, others instead proposed to broaden the concern with genetics and insurance to a more general concern with insurance selection. They argued that the problems encountered with predictive hereditary data apply equally to non-hereditary predictive medical data. Instead of abolishing the question limit in the Medical Examinations Act, they proposed to broaden its scope. In the opposite conclusions that were drawn, the impact and importance of institutional categorization on problem framing becomes most clearly visible. Declaring the 'genetic' category to be obsolete has consequences for the possible continuations the discussion can take. A storyline that easily follows is one in which the problem of genetics and insurance itself as well as related solutions disappear from the scene. That is, unless a new category is found that can substitute the old category. A new category did indeed emerge in the debate. During the consultation meeting, but also in the final advisory text, it was suggested that in many respects predictive medical data is the appropriate category of concern, no matter whether these are hereditary or non-hereditary data.

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[220] The participant means to say people with a predisposition for Huntington's disease that have not yet developed the disease.

> *Before the access to both domains is discussed it should be emphasized that the consultation exhibited that the future (legal) questions and dilemma's do not essentially differ from the issues that have received attention for some time already. For instance, the consultation showed that the questions and dilemma's regarding hereditary information usually do not essentially differ from the questions and dilemma's that can come up, at least in the context of work and private insurances, with non-hereditary health information that contains a certain predictive value, for instance asthma or an HIV-infection. Why should a person carrying Huntington's disease have a stronger claim to legal protection than a person suffering from asthma?* (ZonMw, 2003, p.74,75)

Shifting the concern with insurance selection from the specific category of genetic data to the broader category of predictive medical data, offered the opportunity to embrace the blurred boundary between the 'genetic' and the 'non-genetic', without loosing the ability to position insurance and genetics as a problematic issue. It is a shift with further ramifications on the normative level. The main formal argument to consider the 'genetic' as a category in need of special legislation and regulation had been protection of privacy and the right not-to-know. Specific privacy protection was thought relevant for genetic data, since genetic data can reveal information about family (cf. *The circle of privacy protection is larger in case of genetic data*). And recall how the Health Council (see section 6.2) had argued that

> '*The freedom of people with a known family history of non treatable hereditary disease to evade possibilities for genetic testing is under pressure* [FM: i.e. the right not-to-know]. *For these people the possibility to receive a social good is at stake. Only in the case that they can prove not to have inherited the genetic disposition they have access to insurance. Financial circumstances can force these people to have a genetic test for which freedom of choice generally counts as a precondition.'* (Gezondheidsraad, 1994, p. 98).

For the category of predictive medical data however, such specific privacy argumentation does not apply. Neither is the right 'not-to-know' of relevance. Participants to the consultation meeting agreed that shifting from the 'genetic' category to the category of predictive medical data, implied a shift in framing the problem from a privacy issue into a solidarity issue. When someone argued that the

Medical Examinations Act should not be abolished, someone else pointed out that from a solidarity perspective the Medical Examinations Act is unfair, because some diseases (Huntington) are protected against insurance selection whereas other diseases (Diabetes) are not.

> *A: You do not want to test actively. Therefore we should not abolish the Medical Examinations Act. And the question limit is an extremely important element.*
>
> *B: Yes,* ***if*** *you want to maintain a solidarity principle. But in that case you have to treat Diabetes like Huntington.*

A concern with solidarity was also voiced in the final text of the advisory report:

> *'In the fourth place, it seems that the Medical Examinations Act's framework, dominated by the right on privacy, in a number of respects falls short for offering protection. Further reflection on the above points is appropriate. That also concerns the extent of solidarity that may be expected from a private insurance market.' (...) 'Most important recommendations: ' (...) '4. Where solidarity on the private insurance market can be expected, but is not guaranteed, government interventions are justified.'* (ZonMw, 2003, p.88)

The concern with solidarity that emerged in the discussion, led to further discussion:

> *X; Is solidarity our point of view?*
>
> *Y: Political solidarity and chance solidarity are different.*

When it comes to discussing solidarity in the Dutch debate on insurance and genetics, the distinction between chance solidarity and political solidarity is often referred to. It is a neat distinction, which clarifies that private insurance companies can provide for de facto solidarity between insurance candidates who are categorized within the same risk group. In English the term actuarial fairness best captures the principle of chance solidarity, though the two words have quite

different connotations.[221] For the insurance companies, de facto solidarity is an occasional, lucky by product of underwriting practice. For private insurance companies solidarity is not a goal or a norm that guides their underwriting practice. Such would be political solidarity and that is something insurers cannot afford, so they claim.

In response to the remark about the difference between chance solidarity and political solidarity, someone put forward that developments in genetic research can change the practices of insurance selection. Risk groups used by insurers might get smaller, due to an ever more refined subdivision of risk. As a consequence de facto solidarity could decrease. It follows that genetic developments in the context of insurance should not be too easily dismissed as 'nothing unusual' as one participant states:

> *Risk groups change. There are now 300 known Cystic Fibrosis varieties. Splitting up of genetics is important for this discussion.*

Other people in the meeting shared the concern with de facto solidarity. But how to deal with this concern was not so clear. Some argued that jointly insurance companies can agree to take responsibility for solidarity. To support that argument reference was made to the establishment of the Moratorium on genetic testing, when insurance companies had also collectively agreed to adjust their underwriting practices. Others warned that insurers cannot provide political solidarity:

> *I do agree that the Committee should pay attention to the ethical and normative aspects. But you are balancing on a thin edge. If you say that insurers have a social role, then you put the onus on insurers.*

This is not the place to elaborate on the intricacies of the private insurance market and on the question whether or not insurance companies can take up social responsibility to preserve a broad de facto solidarity. But it is worth noting that the uncertain ramifications which result from the categorical shift concern not only the

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[221] I never came across the terms chance solidarity and political solidarity in the UK debate on genetics and insurance. The term actuarial fairness emphasizes that it is fair not to pay more insurance premium than is needed in order to cover the risk you bring to the insurance pool. The term chance solidarity emphasizes the de-facto solidarity provided by private insurance systems between people that carry risks of similar size.

normative framing of the issue, but also the means by which the issue can be dealt with. A concern with privacy or with the right not-to-know can be dealt with through legislation that restricts insurers' rights to inquire after someone's genetic predispositions. But when the concern is with solidarity, other type of measures - not necessarily legislative and regulative - become relevant, for example measures in the sphere of social welfare. But the Genetics Committee's mandate concerned the question whether new legislation and regulation was needed. One of the Committee members clearly expressed the difficulty in dealing with the explicit political character of the solidarity issue:

> *But from what perspective do you take a political standpoint? If you put the solidarity issue on the table here, we won't come to a resolution.*

6.4 Conclusion and reflection

6.4.1 From 'privacy' to 'solidarity': reversal through institutionalization of genetic exceptionalism

With the Moratorium on genetic testing (1990) and the Medical Examinations Act (1998), formal regulation and legislation was established to govern problems related to insurance and genetics. The Moratorium and the Medical Examinations Act changed the further course of the debate. Privacy concerns became the formal motivation to restrict insurers' use of hereditary data. The institutionalization of special regulation and legislation on the use of genetic test results by insurers strengthened a discourse of genetic exceptionalism; the idea that in general the 'genetic' is different from the 'non-genetic' and that therefore special attention is required. It should be noted that the institutionalization of the discourse on 'genetic exceptionalism' or 'genetics as something unusual' is not exclusively or predominantly to be located in the debate on genetics and insurance. It is the outcome of many more stories that position developments in genetic research as either a promise or a threat.[222]

The discussion that took place in the consultation meeting organized by the Genetics Committee shows the effects of such an institutionalized discourse.

[222] Including research programs, both in genetic research and in ELSA (ethical, legal and social aspects) studies of genetic research.

Whereas many invited experts/representatives in this meeting agreed that – in light of the developments in genetic research - genetic exceptionalism had become a very problematic concept, members of the Genetics Committee found it hard or impossible to give up on genetic exceptionalism, given that it is institutionalized in (inter)national regulation and legislation and given their own mandate as an advisory committee.

In the context of the two opposite dynamics, institutionalization of a discourse of genetic exceptionalism on the one hand and the blurring (in local sociotechnical practices) of the boundary between the 'genetic' and the 'non-genetic' on the other hand, two problem framings became more important for structuring the debate on genetics and insurance. In chapter five I showed how in the context of a national population screening program for Familial Hypercholesterolemia, a multifactorial genetic disease, actuarial fairness emerged as an important way to frame the problem at hand. The analysis in this chapter has shown how the shift from monogenetic to multifactorial diseases made it difficult to position the 'genetic' as 'something unusual' in a discussion with experts/representatives. A new category was proposed as relevant for the discussion: predictive medical information. This category has the advantage that it is reconcilable with a blurred boundary discourse, while at the same time still providing a relevant problem framing. A relative shift in normative framing from privacy to solidarity accompanied this categorical shift. The growing importance of actuarial fairness and solidarity as a way to frame the problem at this stage of the debate, relates to these two problem framings being applicable to broader problems of insurance selection. In a 'blurred boundary' discourse on genetics, actuarial fairness and solidarity are still productive problem framings, whereas privacy is less so.

How could the discourse on 'genetic exceptionalism' have become so strong? Institutionalization is accompanied by what one could call a reversal. In an early stage of the debate 'genetics' had to be actively positioned as 'something exceptional' in order to receive special attention and in order to justify special rules of conduct. Once the discourse on genetic exceptionalism became institutionalized, the tables turned. At this stage, anything that belonged to the category of the 'genetic' - a category which in the meantime had become much broader – was automatically seen as 'something exceptional', something for which an extensive

argumentation was needed in order to get it back into the 'nothing unusual' category.

Reversal is a common social pattern. It has been discussed in relation to a number of different technical developments (Disco & Van der Meulen, 1998a, 1998b; Van den Ende, 1994) and also specifically in relation to genetic research (Nelis, 1998).[223] My case shows what can be further effects of reversal, in particular what happens if an institutionalized category meets changing practices. The institutionalized discourse of 'genetic exceptionalism' opposes the recognition of genetic research developing into a broad and diverse range of practices. This resistance against discursive change paradoxically leads to an increased social and political awareness of broader problem framings, such as solidarity and actuarial relevance. These are problem framings that bring to the centre of attention problematic aspects of medical risk selection as it has been practiced by insurance companies for years, long before the first genetic tests were introduced.

6.4.2 On the role of governance arrangements and hybrid consultation meetings in organizing responsibilities

While the analysis presented in this chapter does not address a concrete case of organizing responsibilities, the case offers much insight into the overall process of organizing responsibilities, in particular about the role of governance arrangements in framing responsibility issues. The analysis has shown how governance arrangements – in this case the Medical Examinations Act and the Moratorium on genetic testing – strengthened the institutionalized discourse of genetic exceptionalism. In addition, I focused on the way this institutionalized discourse increasingly diverged from the blurred boundary discourse of local sociotechnical practices up to the point that it became difficult to translate between the local discourse and the institutionalized discourse. So paradoxically, the governance arrangements that were once meant to structure the configuration of responsibilities for genetics and insurance in a later stage created problems for organizing

[223] Nelis (98) posed that with the uptake of DNA diagnostic testing in the regime of clinical genetics, a *reversal* took place: 'Not any longer is DNA diagnostic testing an enabling technology within the clinical genetic regime. DNA diagnostic testing itself creates new practices and applications that without DNA-technology had not been possible. (…) (I)t is possible to speak of a DNA-regime. In this (DNA)-regime it is no longer clinical genetics that structures the application and use of DNA technology, but it is DNA technology that structures clinical genetics.' (Nelis, 1998, p. 243)

responsibilities. It follows that the process of organizing responsibilities involves not only mutual adjustment between the role responsibilities of actors on the local level of sociotechnical practices, but also involves ongoing adjustments between the level of governance arrangements and that of local practices.

In four different ways, the hybrid consultation meeting that I analyzed in this chapter contributed to the process of organizing responsibilities (see table 6.1 for a summary). First of all the consulted experts contributed to the process of organizing responsibilities as they represented the novelty of genetic testing and genetic disease. This representation differed from the way genetic testing and genetic disease were represented within the institutionalized discourse. The interaction between the discourses of the consulted experts/representatives and the discourse of the Genetics Committee members, made the discrepancies between the institutionalized discourse of governance arrangements and the discourse of local sociotechnical practices clearly visible. This was the second way in which the hybrid consultation meeting was productive. Thirdly, a new category (predictive medical data) was articulated which could possibly substitute the problematic 'genetic' category, provide a new type of problem framing (solidarity) and inspire the outline for a new governance arrangement. Finally, the hybrid consultation meeting functioned as a microcosm or playground in which the newly articulated category and problem framing were tested and the possibilities for organizing responsibility for solidarity were discussed, which included responsibility positioning of both insurers as well as government.

Apart from showing in what ways a hybrid consultation meeting can be productive, the case also shows the restrictions of this particular forum and how these limit its role in organizing responsibilities. Limitations became apparent when a Committee member pointed out the political nature of the solidarity issue and how that would make it difficult to come to a conclusion. The ZonMw Genetics Committee was asked to reflect on the legal and regulative adjustments that are needed in light of the consequences of future developments in medical genetics for the legal position of patients and individuals. Taking a political standpoint on the solidarity issue appeared to exceed the Committee's mandate. While the Committee could point out the relevance of the solidarity issue, it could not itself discuss the issue. To further the debate on organizing responsibilities along these lines, the issue had to be taken up in other arenas.

Elements in org. resp. / Forum / Arena	Prospective responsibility positioning	Representation of a novelty's affordances	Resolving normative conflicts	Articulation of new categorizations and problem framings	Articulation of discrepancies between governance arrangements and local practice
Hybrid Consultation Meeting	Third-order accountive prospective responsibility positioning takes place as options for political solidarity and chance solidarity are discussed	The boundary between the genetic and the non-genetic becomes increasingly blurred		Predictive medical data and solidarity	Institutionalized discourse of genetic exceptionalism conflicts with the blurred boundary discourse of local sociotechnical practices

Table 6.1: Productive elements in organizing responsibilities in the ZonMw hybrid consultation meeting

6.4.3 Reflection: a discourse on heterogeneity is lacking

To declare the 'genetic category' irrelevant or hard to manage in sociotechnical practice is easily interpreted as tantamount to saying that there is no problem with genetics and insurance, so no reason to do something. Such an interpretation makes it hard to question the appropriateness of the category without risking that the ability to act on the problem is lost. In order to maintain a sense of problem and maintain the possibility to act upon it, the articulation of a new category seems necessary.

Reluctance to give up on the 'genetic' category and to replace it by the category of predictive medical data seemed in part related to the uncertain ramifications that could follow. Along with a shift in category a shift in problem framing would come, as well as a change in the kind of governance arrangements that can provide a solution. That might be problematic. As yet, there is no robust governance arrangement for the protection of solidarity on a private insurance market. Insurers argue that they cannot provide for political solidarity and the case of FH, discussed in chapter five, has shown that so far government is not inclined to take

responsibility for political solidarity either. It is thus uncertain whether the moral argument of solidarity will prove strong enough to regulate insurance practice.

I have also shown that the moral argument of solidarity could easily be turned against itself as it was used to declare genetic exceptionalism contained in the Medical Examinations Act unfair, and to argue for abolishing the question limit in the Medical Examinations Act. From that perspective, reluctance to give up on the genetic category is understandable. On the other hand, there is a growing number of diseases that are hard to classify as either hereditary or non-hereditary disease, which leads to interpretative difficulties.

The analysis in this chapter focused on the way in which discourses and institutionalized categories frame the debate on genetics and insurance. It has traced emerging conflicts and emerging shifts in discourses as well as the ramifications that follow from these shifts. Although some of these ramifications have clear normative implications, I do not aim to take a position on these normative issues. Rather, I hope that my analysis has clarified how discourses structure debate and how this sometimes impedes productive interactions. As discourses are embedded in the situation it is difficult to escape from them. But recognizing their influence can help to counter them if needed.

When observing the discussion of the ZonMw consultation meeting it struck me that the discourses of genetic exceptionalism and that of a blurred boundary were often presented as each other's opposite, as if the 'genetic' forms a homogeneous category. It seemed to make the debate unnecessarily complicated. Therefore, to improve the productivity of the discussion I would suggest to introduce and allow for a discourse on heterogeneity and to position the 'genetic' explicitly as a heterogeneous category. A discourse on heterogeneity could form a bridge between the discourse of genetic exceptionalism and the blurred boundary discourse. On occasion such a discourse on heterogeneity is hinted at or touched upon, for example when it is stated in the advisory report that:

> *'What is mentioned below therefore applies in many cases also to non-hereditary data with a predictive value. Which, perhaps needless to say, does not imply that the distinction between genetic and non-genetic has become irrelevant for the problem in question.'* (ZonMw, 2003, p.75)

A wording is chosen, which recognizes blurring without giving up on the exceptional status of the 'genetic'. Though acceptance of heterogeneity is hinted at, the above quotation still reads more as a compromise between those who use a blurred boundary discourse on genetics and those who use a discourse on genetic exceptionalism. To count as a discourse of heterogeneity, the discourse on heterogeneity should oppose a discourse on homogeneity. From a discourse on heterogeneity it follows that not all that belongs to the broad category of the genetic should necessarily be treated equally. Within a discourse on heterogeneity it may for example be argued that whereas Huntington's disease and FH are generally considered to both belong to the category of genetic diseases, yet there are still many differences between the two diseases that may well justify treating the two differently. If accepted, such reasoning would be an instance of a discourse on heterogeneity. It seems at present to be lacking in the discussions on genetics and insurance.

7
Conclusion, discussion and reflection

7.1 Introduction

The introduction of novelty in society involves reorganization of sociotechnical configurations of responsibilities. The aim of this thesis was to better understand this process of organizing responsibilities and to develop substantiated ideas on how to improve this process. In this chapter I will bring together the main results of my empirical chapters and draw overall conclusions. In chapter 2 I argued that the process of organizing responsibilities needs to be conceptualized as a multi-level process which involves reaching mutual adjustment between the role responsibilities of different human and non-human actors in a configuration of responsibilities at the local level and which may involve a change in governance arrangement at supra-local level. The main question of this thesis concerned the nature of this process of organizing responsibilities. What is involved in this process and how do various governance forums and arenas contribute? This question will be addressed in section 7.2.

In my two main cases, on prenatal screening and on genetics and insurance, it appeared that both concerned novelties that were not radically new, governance arrangements for dealing with these types of novelties were already in place. It also appeared that the challenge of organizing responsibilities for these novelties concerned not only finding mutual adjustment between the various role responsibilities at the local level but also involved finding resolutions for the tensions and discrepancies within the governance arrangements, and in between the supra-local level of governance arrangement and the local level of sociotechnical practice. In section 7.3 I will reflect on some of the specific challenges that played a role in my cases.

One purposively hybrid forum, the Forum Biotechnology and Genetics, was studied in detail: how it evolved as a governance practice; the various modes of representation that appeared in this forum; and how these can be seen to play a role in organizing responsibilities, in general as well as in the specific case of prenatal screening. The results will be discussed in section 7.4.

I will conclude with an epilogue in which I present some reflections on the aim which motivated my research: to make organizing responsibilities for novelties the objective of governance. I will show how some of the paradoxes and in some respects disappointing outcomes of my cases are the result of taking a modernist

approach to organizing responsibilities. As an alternative I will argue to regard organizing responsibilities for novelties as the objective of re-modernist governance.

7.2 Organizing responsibilities as a distributed governance process

Table 7.1 summarizes the results of the two empirical cases studies in which I analyzed the process of organizing responsibilities. The process was distributed over different forums and arenas. The table shows that in both the prenatal screening case and the FH case the three main elements/dynamics were visible: prospective responsibility positioning was very visible and representation of the novelty and resolving normative issues/conflicts was at issue in some forums and arenas.

In the prenatal screening case the focus of debate successively changed from the Health Council to the diffuse hybrid forum, the political arena, once again the Health Council and once again the political arena. The purposively hybrid Forum Biotechnology and Genetics formed a parallel arena, with some productive characteristics though it did not play a decisive role in the process of organizing responsibilities. In the case of FH screening and insurance selection the focus of debate successively changed from the diffuse hybrid forum, the political arena, the Health Council, the diffuse hybrid forum, and the political arena. Two purposively hybrid forums formed parallel arenas throughout the debate, and took up a decisive role in the latest stage of organizing responsibilities.

The various forums and arenas differ in terms of the type of contribution that was made. The Health Council played the main role in representing novelties and the political arena played the main role in resolving normative issues and conflicts. In all arenas and forums that were involved prospective responsibility positioning occurred. Decisive steps in bringing forward the process of organizing responsibilities were made as the focus of the debate changed from one forum or arena to the next. It is the alternation between different forums and arenas that accounts for the overall progress that is made in organizing responsibilities. Or to put it differently, because a variety of forums and arenas is involved, organizing responsibilities for novelties is a distributed governance process. Below, I will discuss in more empirical detail the different forums and arenas and how these played a role in organizing responsibilities.

Elements in organizing respons. / Forums / Arenas	Prospective responsibility positioning	Representation of the novelty's affordances	Resolving normative issues / conflicts
FBG – microcosm with weak mandate	General (3)[224] Prenatal screening(4)		Prenatal screening (4) supportive role
Health Council	Prenatal Screening (4) FH (5)	Prenatal screening (4) FH (5)	
Diffuse hybrid forum	Prenatal screening(4) FH (5)	Prenatal screening (4) FH (5)	
Political arena	Prenatal screening (4) FH (5)	FH (5)	Prenatal screening (4) FH (5)
Mandated hybrid forum (self-regulation) on Medical Examinations Act	FH (5)	FH (5) Role is claimed	
Bottom-up hybrid negotiation on FH patient leaflet	FH (5)	FH (5)	
Hybrid Consultation Meeting	ZonMw (6)	ZonMw(6)	

Table 7.1:Organizing responsibilities as a distributed governance process - collected empirical findings

7.2.1 The role of the Health Council

In both cases the Health Council acted as the official novelty's spokesperson and played the main role in representing the novelty's affordances. In both cases the

[224] The numbers in between brackets refer to the relevant empirical chapters.

scientific facts that were presented by the Council remained undisputed and the Health Council contributed to organizing responsibilities by being the authoritative novelty's spokesperson. Also, in both cases, the Council's advisory report not only represented the novelty's affordances, but also positioned actors involved in the configuration of responsibilities in a specific role. In both cases the Council's responsibility positionings of actors were not completely accepted and did not result in mutual adjustment in the configuration of responsibilities. I argue that the conditions that make the Health Council productive in representing a novelty's affordances at the same time constrain the Council's potential to contribute to finding mutual adjustment in the configuration of responsibilities.

It should be noted that the two cases differed with regard to the Council's aspiration to contribute to organizing the configuration of responsibilities. In the advisory request for the prenatal screening report, the Council was asked for a truly hybrid advice. They were asked to assess the affordances of different prenatal screening tests that could be used in a prenatal screening program, but also to reflect on the ethical, legal and social aspects of introducing a screening program and to propose how best to implement and organize a prenatal screening program. The prenatal screening advisory report contained detailed recommendations and read like a blueprint on how to implement prenatal screening and on the specific role responsibilities of a number of actors.

The formal aim of the advisory report on FH and the Medical Examinations Act was less ambitious. Although the issue of FH screening and insurance selection was clearly a hybrid issue that involved a debate on how to organize the configuration of responsibilities, the Health Council chose not to address that issue explicitly, but rather to concentrate on those questions that would allow for a scientific approach. They addressed the question whether FH counts as a treatable disease within the legal framework of the Medical Examinations Act and they addressed the question what the life expectancy is of people who are treated for FH. Still, in the way the advisory report was phrased and how it was taken up by other actors in the debate, it strengthened a storyline in which insurers were positioned as accountable for the problems that people with FH experience when taking out a life insurance policy.

The two cases illustrate what we could call the bandwidth of hybridity of Health Council advice: to what extent non-scientific considerations frame Health Council advisory reports and to what extent Health Council advisory reports can contribute

in organizing responsibilities. The FH case shows that it is actually difficult for the Council not to play a role in the process of organizing responsibilities. Even as the Council chose not to explicitly address the wider role responsibilities involved in the issue, others still interpreted and used the advice in order to position insurers. The purpose of a scientific advisory council is of course to asses and present the scientific facts in such a way that they can be used by non-scientific actors, and in writing their advice the Council tends to anticipate on the relevance of the advice for societal actors and on the way in which societal actors will receive and interpret their advice. In an extensive and detailed empirical study of the Health Council, Bal, Bijker and Hendriks (2002) have shown that even if front stage – that is publicly visible – the Health Council maintains the 'illusion' that their advisory work is purely scientific, back stage political and societal elements play a role in a carefully orchestrated process of mixing and purifying science, policy and society in order to create productive advice.

The scientific front stage is by no means merely a front, put up for outside use. It is taken seriously, and it shapes what can and will be done by the Health Council. Maintaining a scientific front stage requires keeping the scientific part of the advice clear and objective in the sense that there is no interpretation of scientific facts and research results in order to reach politically desired outcomes. Otherwise, trust in the authority of the Health Council would erode. Furthermore the scientific front stage also influences what can be achieved when trying out productive alignments between science, policy and society in the hybrid backstage. Both cases show how in trying to find mutual alignment the Council refrains from taking an explicitly normative position. In both my cases this constrained the Council's room for finding and presenting mutual adjustment between the novelty's affordances and the wider configuration of responsibilities. This was most clearly visible in the FH case, where the Minister's advisory request was rephrased in order to enable a scientific approach, since *"It is not up to the Health Council to judge whether insurers' underwriting policy is fair"*. In the FH case these constraints were recognized and acknowledged in the text of the advisory report:*" Its answers to the questions put by the Minister only partly allay the concern felt in society about the position of FH carriers when taking out insurance"*.

The case of prenatal screening was somewhat different, because an advisory request was accepted which went further than scientific advice. However, in finding and

presenting mutual adjustment between the novelty's affordances and the wider configuration of responsibilities, the Council was still constrained as it could not just propose any normative framing. First, the advice was bound to the legal framework of the Population Screening Act and a structuring discourse of ethical liberalism. Another restraint was introduced as the Council took the existing practice of prenatal diagnostics, as a yardstick for quality. It could be presented as a norm broadly shared within society and enabled the Council to refrain from taking an explicit normative position. Finally, the Council decided not to discuss a new age limit, arguing that there were no objective criteria available to decide on such a limit. This again put restraints on the margins available for mutual adjustment.

So in trying to find mutual adjustment between the novelty's affordances and the wider configuration of responsibilities, the Council remained within the normative boundaries of existing governance arrangements. It meant that in addition to the requirements of scientific objectivity there was a second (de facto) requirement to accept given normative boundaries. In both cases it appeared that it was not possible to reach mutual alignment within the normative boundaries of the existing governance arrangements. In the case of prenatal screening the existing governance arrangements appeared to be inconclusive. And in the case of FH screening and insurance selection, it was questioned whether the Medical Examinations Act actually met its own objective to balance the rights and interests of patients with the rights and interests of insurance companies. The Council brought up this normative question, but did not feel entitled to answer it.

To conclude, the Health Council was successful as a novelty's spokesperson. But the Health Council was not a spokesperson like any other. Spokespersons that represent human actors can suggest changing the moral order of a conversation, when positioning themselves and others in trying to find mutual alignment in a configuration of responsibilities. The Health Council, on the other hand, stayed within the normative boundaries of its scientific apolitical front stage, and accepted existing governance arrangements.

The forum of the Health Council was hybrid in the weak sense: in the advisory process a heterogeneous set of questions, problems and arguments coexisted and coevolved. But because of the Council's scientific front stage the Council was not hybrid in the strong sense, as it was defined by Callon and Rip (1992). Within the Council's advisory work, the three poles of the techno-scientific, the legislative-

regulative and the sociopolitical-economic remain "(relatively) distinct spaces/universes between which the (…) experts are searching for adjustments" and the three poles are *not* "characterized by a *strong* interpenetration of actors and of debate" (Callon & Rip, 1992).

7.2.2 The role of the diffuse hybrid forum in accountive prospective responsibility positioning

In both my cases the diffuse hybrid forum played a role in accountive prospective responsibility positioning as well as in re-presenting the novelty's affordances, but not in resolving normative conflicts/issues. The role of the diffuse hybrid forum was crucial in the process of organizing responsibilities, because it enabled actors to respond to the way they had been positioned within other forum discussions, in which they had not participated: it enabled accountive positioning, as well as further responses to accountive positioning.

An example of this is how in both cases the diffuse hybrid forum played an important role as a setting in which actors that had not been represented in the Health Council committee could respond to the responsibility positions that were attributed to them in the advisory report. In the case of prenatal screening, through publications in medical journals, some gynecologists made clear that they did not accept the configuration of responsibilities that had been proposed by the Health Council, in which the age limit for prenatal screening was abolished and in which pregnant women of all ages were given the responsibility to choose whether or not to be tested. The critics argued that for younger women the test sensitivity was so low, that the medical profession should take over the responsibility for decision making from these women and collectively decide not to offer them the option of prenatal screening.

Even though their criticism derived from their assessment of the quality of the test, these gynecologists did not challenge the *scientific* quality of the Council's advice, meaning that they did not challenge the scientific facts as they were represented by the Council. Rather their critique was that a specific quality aspect – the fact that the sensitivity of the test decreases at younger age - had not been taken into account in sketching the configuration of responsibilities for prenatal screening. Whether one thinks this quality aspect matters for considering how to organize the configuration of responsibilities is a normative issue, not a scientific question. As different aspects of quality were prioritized in the diffuse hybrid forum, the

affordances of novel screening tests as had been sketched by the Health Council were looked at from a different perspective and thus were re-presented.

In the case of FH screening and insurance selection, the diffuse hybrid forum was important as a setting where insurers could position themselves with regard to the storyline that FH as a treatable disease should be an insurable disease. This storyline had been strengthened by the Health Council advisory report. Although the Health Council had not explicitly addressed the affordances of FH treatment in terms of insurability of FH, due to discursive affinity and intertwining between storylines the Health Council's conclusions on life expectancy and treatment options for FH were used to suggest that if insurers took latest medical scientific knowledge into account, people with FH would no longer encounter problems when taking out a life insurance policy. Thus realignment was projected in the configuration of responsibilities. But in this projection the voice of insurers was absent.

That changed when the debate shifted towards the diffuse hybrid forum, when the advice was published and discussed in the media. Insurers were positioned, but now accountive responsibility positioning was possible and occurred. Although insurers accepted being positioned as responsible for taking latest medical scientific knowledge into account in their underwriting policy, and also accepted the medical scientific data as presented in the Health Council advisory report, they did not regard FH as a condition for which by definition a standard insurance premium would apply. They raised the specific context of the insurance practice to account for the position taken by insurers in relation to FH. Individual differences between FH patients are taken into account, insurers do not have a general policy for FH patients. The affordances of FH treatment in terms of insurability were re-presented and insurance representatives made clear that the projection of realignment gave a false impression.

To conclude, in the diffuse hybrid forum accountive prospective responsibility positioning took place and the novelties' affordances came to be seen in a different light. This was relevant for organizing responsibilities as it brought to the attention that realignment in the configuration of responsibilities had not yet been reached. In both cases the focus of debate then shifted to the political arena.

7.2.3 The role of the political arena – ongoing positioning and resolving normative issues

In the case of prenatal screening the existing governance arrangements were inconclusive regarding the question whether or not to abolish the age limit for prenatal screening. In the case of FH screening and insurance selection the question was raised whether the Medical Examinations Act was still adequate to govern the configuration of responsibilities for genetics and insurance. In both cases the political arena was productive in the process of organizing responsibilities as it formed an arena where explicit and authorized decisions were taken regarding the governance arrangements and because it formed the primary arena in which accountive responsibility positioning of the government occurred.

In the case of prenatal screening the deadlock in the debate on the age limit had been difficult to resolve because of internal tensions within the governance arrangements. It was only overcome once the debate shifted towards the political arena. This shift formed the start for a second phase in the process of organizing responsibilities. Arguments, institutionalized discourses and responsibility positions started to change once the State Secretary announced her decision not to follow the Health Council's recommendations to abolish the age limit for prenatal screening, but to maintain it. Young pregnant women who asked for the test could have one if they paid for the test themselves. By not making prenatal testing a collective provision, the State Secretary made a clear statement that in her opinion prevention of the birth of children with Down syndrome is not a responsibility of public healthcare.

While this ended the impasse in the debate, the State Secretary's decision also raised new kinds of questions. During a debate in parliament on the State Secretary's decision new normative considerations and a new interpretation on the boundary between governance arrangements were proposed. As women could still obtain the test on their own initiative, it was argued that the State Secretary's policy increased the differential access between women who are better educated and well-informed and women who are not well-informed and often less well educated. Reference was made to the Medical Treatment Agreement Act (WGBO) to argue that medical professionals had the obligation to inform all pregnant women about prenatal screening options. As a result of this political debate the State Secretary decided to make a distinction between *provision* ('aanbieden') of prenatal screening and *informing* about prenatal screening. Government decided that all pregnant

women should be informed about prenatal screening, but that it should not be made a collective provision. This implied a change in the then prevalent interpretation of the sphere of action of the legal framework of the Population Screening Act and the Medical Treatment Agreement Act.

Shifting the financial responsibility from the collective level to the individual level, the internal tension between collective responsibility for offering high quality screening and the individual responsibility for decision-making was reduced. A configuration of responsibilities was projected with a strong individual responsibility for prenatal testing.[225]

In the case of FH screening and insurance selection, the political arena was important as a site where parliamentarians discussed the issues with government. Thus, discussion whether the governance arrangement of the Medical Examinations Act was still adequate was enabled. It also made it possible to reach an authorized outcome of that discussion on which further organizing of responsibilities could build.

One of the issues concerned whether government had a responsibility to command solidarity between insurance candidates. The debate was not only between parliamentarians and government. By means of a letter to both government and parliament, the Dutch Association of Insurance Companies intervened in and influenced the course of the parliamentary debate. They raised their voice to counter the way they were positioned. In that respect the political arena formed a continuation of the diffuse hybrid forum, as it opened up space for accountive positioning. Government made clear that they would not command solidarity between insurance candidates on a private insurance market. Further responsibility positioning between government and insurance companies regarding the FH screening case took place. Government tried to convince insurers to adopt a collective insurance policy for all FH patients, but they were not successful, as insurers kept to their prior policy of assessing insurance candidates on an individual basis. In the end, government had recourse to the outcome of the negotiations in the purposively hybrid forums that were dealing with this issue.

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[225] From here onwards the process of organizing responsibilities was focussed on negotiating the more concrete roles in prenatal screening. The organization of the quality of screening remained an issue. But this last phase was not analyzed as part of my case.

To conclude, the political arena played an important role in resolving normative issues in the process of organizing responsibilities. In the prenatal screening case it was the authorized arena for cutting the knot when the wider debate had reached a deadlock. In the FH case it was the authorized arena for confirming the validity of existing governance arrangements, thus upholding the outcomes of (mandated) hybrid forum negotiations.

7.2.4 The role of purposively hybrid forums in a distributed governance process

In both cases discussion and negotiation in purposively hybrid forums played a role in the process of organizing responsibilities. Discussion and negotiation occurred parallel to the main trajectories in which the focus of debate alternated between Health Council, diffuse hybrid forum and parliamentary arena. The hybrid forums in the two cases were of a different nature. The Forum Biotechnology and Genetics in which the prenatal screening issue was discussed was a forum with a weak mandate and a broad agenda. The two hybrid forums that played a role in the FH screening case on the other hand were specifically dedicated to the issue of genetics and insurance. One was a forum in which three parties, established representatives of insurers, doctors and patients, negotiated on the details of the Medical Examinations Act, which contained a self-regulation measure. It was thus a mandated forum. The other hybrid forum dealt with FH in particular and concerned consultation between insurance representatives, the FH screening organization and the patient organization for FH patients. It did not start as a mandated forum, but eventually the Ministry of Health had recourse to this forum and agreement reached within this forum was accepted by the Minister.

Negotiations in the mandated forum for self-regulation had not yet started at the time when the issue of FH screening and insurance appeared in the political arena, and the Minister of Health first had recourse to the Health Council.[226] Later the issue was also prominently discussed in the parliamentary arena. The parallel trajectory of the mandated self-regulation was not redundant though. After the government had reaffirmed the validity of the existing governance arrangements for insurance and genetics, the outcome of the negotiations in the mandated hybrid

[226] Later, the parties of the mandated hybrid forum would position themselves as the arrangement, instead of the Health Council, to assess treatability (Verbond van Verzekeraars et al., 2003, p.6).

forum contributed to the Minister's decision to start the extension of the FH screening program. Agreement was reached on an Insurance Examinations Protocol in which details of the Medical Examinations Act were filled in. The Protocol did not entail substantial changes in responsibility positions. But it played an important role as it was formally endorsed by the involved representative organizations, providing the agreements with a broad societal basis. For the Minister it was important that there was now clarity on the issue. Further clarity was provided by the outcome of the hybrid negotiations on FH: a leaflet for participants in the FH screening program to inform them about their insurance position and rights. Even though the configuration of responsibilities that was sketched in this leaflet was different from what the Minister had envisoned as a solution, it brought clarity and formed reason to extend the screening program.

For the FBG there are two ways in which we can assess its productive role. First we can consider whether the discussions in the FBG and the notice letters that were sent played a direct role in the overall process of organizing responsibilities for prenatal screening. Concerning the first notice letter this was not the case. This can be explained by the fact that discussion in the FBG came late and was partly redundant. The first notice letter, reproduced the normative plurality and the inconclusiveness which had already become visible in the wider debate. Concerning the second notice letter there was a productive role, because the FBG interactions created support for the State Secretary's policy decision. Whether this was very important for the overall process is difficult to assess. One possibility is that the Forum position influenced the positions taken by the individual organizations that were represented in the Forum and thus contributed to a broader support for the State Secretary's policy.

In the distributed governance process of organizing responsibilities where many actors and arenas play a role it is partly contingent upon the situation whether or not a purposively hybrid forum like the FBG is productive. Therefore it is interesting to reflect in more general terms on how a forum like the FBG can be productive. I can do that on the basis of my detailed empirical analysis of the internal interactions in the FBG. As the FBG did not have a strong specific mandate, all sorts of considerations were brought up in its discussions. As there was also a strong incentive to come to (partial) consensus, different ways of reducing complexity were tried out: one example was the suggestion to leave legal or financial issues out

of the discussion. Thus, in the FBG discussion on prenatal screening we saw alternation between different ways of framing, foregrounding some aspects, while back grounding others. Organizing responsibilities is a process of distributed governance and alternation between different arenas – with their different ways of framing[227] - accounts for the overall progress that is made in organizing responsibilities. In a purposively hybrid forum with a weak mandate alternation between different ways of framing can occur within the forum, independent of alternation between different settings or arenas. I propose that this is a specific way in which a purposively hybrid forum with a weak mandate can contribute to organizing responsibilities.

7.2.5 Conclusion and discussion

In both cases the process of organizing responsibilities appeared to be a hybrid process in which the pole of techno-science, the pole of legislation and regulation and the pole of the sociopolitical economic were strongly intertwined. Some of the entanglement is directly visible in the various forums and arenas in which the issues were discussed. And further intertwinement between the three poles becomes visible when we look at the distributed governance process from a distance and see how the discussion alternated between different forums, some of which targeted primarily the techno-scientific aspects, while others focused on legislative and regulative issues or sociopolitical and economic considerations.

The alternation between these different forums accounts for the overall progress in organizing responsibilities that was made. Because of this alternation there was a de facto sequencing which enabled different forums to build on the outcomes of prior forums, concerning for example the affordances of a novelty or legitimate decisions regarding the normative framework. Alternation between forums was also important because it enabled actors that were excluded from certain forums to react to the way they were being positioned in a certain role responsibility. The diffuse hybrid forum in particular was productive in enabling such acts of accountive responsibility positioning.

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[227] Primarily scientific in the case of the Health Council, primarily normative in the case of the political arena.

Because sequential alternation between different forums was needed, it took quite a while to make progress. Sometimes an issue was debated repeatedly in the same forum. This was the case for example with prenatal screening, which was discussed twice in the Health Council and twice in parliament. The need for alternation supports the general proposition I developed in the beginning of this thesis, viz. that purposively hybrid forums would be productive when the actors involved in a configuration of responsibilities do not normally meet and can now engage in accountive prospective responsibility positioning. And when these forums are mandated, participants will share an intention to reach mutual agreement. Thus the hypothesis is that purposively hybrid forums share the role of other hybrid forums – notably the diffuse hybrid forum – in that they enable accountive responsibility positioning, but in addition purposively hybrid forums have more potential in achieving realignment because of their mandate.

My empirical results indeed confirm that purposively hybrid forums – both with weak and strong mandates - were productive in this respect. Even a hybrid forum without a mandate achieved realignment (patient leaflet in FH case), which was then accepted by government and thus the Forum received a mandate in retrospect. Yet, my empirical results also indicate some reservations concerning the productive role of purposively hybrid forums. In both cases governance arrangements were in place which structured mutual responsibility positioning and in both cases the governance arrangements itself were up for discussion. Making progress in organizing responsibilities involved debate and normative decision making about these governance arrangements. Here the political arena played an essential role and purposively hybrid forums were at best of secondary importance.

Because of the complexities that arise from a multi-level process, involving both local level actors as well as supra-local level governance arrangements, mutual responsibility positioning is not necessarily the main dynamics contributing to achieving realignment. Thus when reflecting on the role of purposively hybrid forums we need to take into account that purposively hybrid forums are part of a larger process of distributed governance. When constructing or developing a purposively hybrid forum, one should take into account how other types of governance practices will influence what *is* done, what *can* be done and what *needs* to be done in a hybrid forum.

Can we be more specific than that? There is a de facto sequence in how an issue travels from one forum and arena to the next, so purposively hybrid forums may fit in productively at a certain moment and not at another. A recurrent feature is that government can have recourse to scientific expertise, in my case to Health Council advice, which works as a shunt with respect to overall dynamics, i.e. can create waiting time. Subsequently, the assessment of the relevant affordances of the novelties involved provides a shared ground for further accountive responsibility positioning, even if the advice itself is not accepted. A purposively hybrid forum can do parallel hybrid work, which the Health Council does not elect to do, but which is necessary for actual alignment. A second recurrent feature in my cases is how governance arrangements had to be discussed, after a Health Council advice failed to result in realignment. Here the political arena was productive in resolving (or just cutting through) the normative conflicts. Actors who interact in a purposively hybrid forum may also play a role in the political debate, but one cannot indicate a special role and timing for the hybrid forum as such in the political debate. A third recurrent feature is how purposively hybrid forums became productive after the discussion on normative aspects had been concluded in the parliamentary arena. This can be linked to the earlier finding that productivity of a hybrid forum decreases when the hybridity, here of the issue, becomes too large (cf. chapter 2). If external circumstances reduce the extent of normative plurality, productivity is restored.

7.3 The multi-level challenge of organizing responsibilities

In my analysis of organizing responsibilities I focused on processes of responsibility positioning and on how various forums and settings contribute to that process. Governance arrangements form the supra-local backdrop shaping those processes. From the perspective of organizing responsibilities as an objective of governance, it is relevant to reflect on the governance arrangements themselves and how governance arrangements enable and constrain processes of organizing responsibilities. One can consider for example how governance arrangements can offer more or less space to responsibility positioning at the local level and how to evaluate this. Although governance arrangements were studied as the backdrop and did not form the focus of analysis, my cases give occasion to reflect on the governance arrangements that played a role.

Organizing responsibilities in the case of prenatal screening was a laborious and lengthy process. Mutual responsibility positioning between the actors involved in the configuration of responsibilities did not easily lead to realignment. In section 7.3.1 I will argue that organizing responsibilities was particularly difficult because of tensions between the two main norms of the governance arrangement for prenatal screening.

The example of prenatal screening shows how achieving realignment involves the supra-local level as well as the local level. The source of dealignment in a configuration of responsibilities is therefore not necessarily the result of changing distributions of agency brought about by the introduction of novelty in local sociotechnical practices. Rather dealignment can also originate from this multi-level process as there can be mismatches, discrepancies or interpretative gaps between the supra-local level of governance arrangements and the local level of sociotechnical practices. In section 7.3.2 I will discuss an example of such discrepancies and how a purposively hybrid forum was productive in signaling a discrepancy between the local and supra-local level.

7.3.1 Inconclusiveness in the governance arrangements for prenatal screening

In the case of prenatal screening normative controversy on the value of the novelty made it difficult to organize the configuration of responsibilities. The debate was inconclusive and the deadlock in the debate was only ended after political decision making. But even after the political compromise was accepted, organizing the configuration of responsibilities remained difficult. I did not analyze the debate any further than September 2004, but the process of organizing prenatal Down syndrome screening continued for at least another three years. The ongoing difficulties to organize the configuration of responsibilities for prenatal screening signify reoccurring challenges which, as I will argue below, can be attributed to internal tensions within the governance arrangements for prenatal screening. I will discuss these in some detail, because they are an example of tensions that can occur in any attempt to govern the organization of responsibilities. Thus the case gives occasion to some broader reflections/lessons.

As said, normative plurality regarding the value of the novelty characterized the case of prenatal screening. Furthermore, the governance arrangements for prenatal screening contained two main norms structuring responsibility positioning. The first

norm, strong patient autonomy, implied that the judgment on the benefits of screening was delegated to the local level of clinical practice to be the express responsibility of pregnant couples. In the Health Council's recommendations on how to organize prenatal screening, the norm of patient autonomy was placed center stage. The Council committee explicitly refrained from any normative judgment on the benefits of prenatal screening (apart from offering options of choice). The norm of patient autonomy in a certain way embraced the normative plurality. Thus normative plurality is not only a description of actual normative diversity, but also became a meta-norm for governing prenatal screening practices.

At first sight, it seems that the meta-norm of normative plurality, embedded in the norm of patient autonomy forms a neat way to deal with normative diversity within a society, but upon further reflection it appears that this norm leads to tensions when it is combined with the second main norm that structured responsibility positioning: that prenatal screening should be of high quality. The tensions between the two norms result from the way they are enacted and are not a matter of apparent conflicts between the content of the normative propositions. Both norms/objectives are like labels or point representations of two distributed networks, the one providing high quality screening, the other constructing and maintaining autonomous choice. These distributed networks are formed by a collective of actors and materialities, in which the specific role responsibilities need to be aligned in order to produce the label. In other words, the label is only the tip of an iceberg. Tensions between the two norms arise as the construction of the two norms place conflicting requirements on the role responsibilities of the actors in the local sociotechnical configurations (see fig. 7.1).

In the case of ensuring quality, its distributed nature is relatively easy to recognize. The triple test is a particularly strong case, because here in order to predict the chance on Down syndrome other women's test results are needed as reference values. The more measurements are done within a specific laboratory, the more accurate the test results will be. In order to provide high quality screening, analyses need to be concentrated in a few laboratories and local practices need to cooperate by sending their samples to these laboratories. The point also holds for other tests. In the case of ultrasound, quality also improves when ultrasound operators are trained for their job and have ample experience, which also forms an argument for concentration.

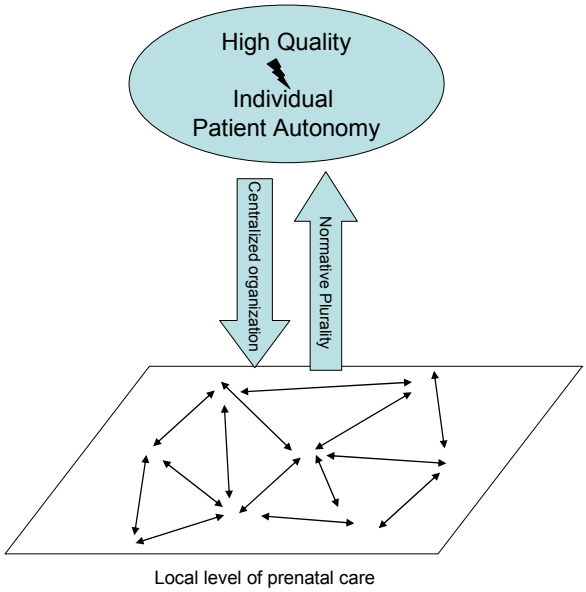

Figure 7.1: Inherent tensions in the governance arrangements for prenatal screening: quality versus patient autonomy

It is less easy to recognize that the enactment of autonomous choice is also distributed over a network of actors. The concept of individual responsibility is misleading in that sense. Pregnant couples' individual responsibility for decision making is actually a collective achievement of a network of actors. Actors need to adopt specific role responsibilities in order to enable pregnant couples to make an autonomous choice about the use of the triple test. In communicating with their patients, doctors need to adopt a non-directive style; patient leaflets are needed which present all the information which may be relevant in the decision making process; again the style of the leaflet should be non-directive; and financing arrangements are needed that allow for longer counseling hours. Most importantly, there is no individual responsibility for decision making on a triple test, without the test itself. And if anything is distributed over a network of actors, then it is the development and provision of the triple test. In other words, on the level of governance arrangements it may be possible to attribute responsibility for decision making to individual parents, but on the level of local sociotechnical practices this

individual responsibility is co-constructed by and thus distributed over a large sociotechnical network. The concept of individual responsibility is misleading, because the distributed nature of responsibility, more in particular the distributed nature of agency, is overlooked (see chapter 1).

What is ultimately individual about the individual responsibility for decision making is that pregnant couples are *individually accountable* for the choice they have made. That is to say that they are answerable to the normative question why they decided as they did. The corollary of this individual normative accountability is that the collective is not answerable to this question. This restriction of normative accountability to pregnant couples, leads to frictions, because clinicians take co-responsibility to construct 'patient autonomy' and to offer pregnant women the individual choice of prenatal testing. Clinicians feel normatively accountable for offering that choice and thus for the question whether prenatal screening is a sensible choice.

Even if the conflict between two norms, is not explicitly articulated, actual decision making can contain de facto choices that foreground one norm over the other. Such indeed happened in the prenatal screening case, when the State Secretary announced here policy decision. The norm of patient autonomy was temporarily prioritized over the norm of quality, but the dominance did not endure. So what exactly were the conflicting requirements arising from a collective responsibility for quality versus an individual responsibility for choices? On the one hand to guarantee high quality screening the sociotechnical network of prenatal screening had to be centrally organized and preferably coordinated by national government. If national government would take such responsibility, this would carry the implicit norm that Down syndrome screening is a sensible choice. On the other hand the sociotechnical network of prenatal screening had to be set up in such a way as to prevent any implicit normative steering, providing individual pregnant couples with a truly autonomous choice.

When the State Secretary decided to provide all pregnant women with information on the option of prenatal screening, but not to make such screening a collective health care provision, she foregrounded the norm of patient autonomy and reduced some of the tensions arising from the two norms. Prenatal screening became more explicitly an individual responsibility, as the responsibility to pay for the test shifted from the collective level to the individual level. It was suggested that the quality of

screening should become a responsibility of the medical profession and be regulated by the Medical Treatment Agreement Act instead of being a governmental responsibility and regulated under the licensing framework of the Population Screening Act. Later developments have shown that this shift in responsibility for the quality management of screening from government to medical professions was not carried through, as a license was still issued. Apparently, quality of screening has remained an important value for which government decided to assume responsibility. That the norm regarding the high quality of prenatal screening would resurface – or maybe it is better to say that it never really left the scene - was already visible in my analysis. In its second notice letter on prenatal screening the FBG addressed its concerns about the quality of prenatal screening and urged government to take up a steering role in organizing and monitoring the quality.

I started this thesis with the idea that the introduction of a novelty creates dealignment in existing sociotechnical configurations of responsibilities and that realignment can be reached by subsequent mutual positioning of the actors involved. Because of conflicting norms within the governance arrangement, this appeared rather hard in the prenatal screening case. In itself, conflicting norms need not be a problem. Positioning theory claims that when there are conflicting norms and responsibility positioning is not accepted, the discussion will shift to a higher level and the moral order itself will be discussed. In the case of prenatal screening that did not happen. Partly it seems, because the conflicts between the two norms were not fully recognized, partly also because both were strong norms that were not easily abandoned. We need to conclude that dealignment was deeply ingrained in the governance arrangement of prenatal screening and that mutual responsibility positioning did not bring an easy and quick resolution.

It is important to observe this, because I expect that there are many more novelties for which this applies. Patient autonomy is an important norm more generally within healthcare, but there are also examples outside the domain of healthcare where individual freedom of choice is important as a meta norm to deal with value differences in society. Freedom of consumer choice is a central part of the regulation of GM-food and a way to deal with societal resistance. Government took responsibility for freedom of consumer choice by creating conditions for a GM-free food chain. But, as was the case for prenatal screening, it was difficult to organize

plurality. In practice it appeared hard to keep the GM-food chain completely separate from the non-GM food chain and the norm for non-GM food was set at a maximum of 1% contamination with GM-food. So plurality was organized, but it was not perfect.

Organizing responsibility for plurality can be especially problematic when a technology is distributed over a larger network. Strongly networked technologies require standardization and homogenization over different localities and require a centralized organization. In the case of the triple test we saw how the quality of the test improves with scale of use and central organization. Because of phenomena like path dependency, obduracy, embeddedness, economy of scale, etc, the structure and materiality of technology often create uniforming instead of pluralizing effects. There is not an easy way out, so it seems, and the examples lead to further questions on how to deal with normative diversity within society and how normative plurality as a meta norm relates to the objective of organizing responsibilities. I will come back to this question in the epilogue.

7.3.2 Discursive representation of novelties as source of structural discrepancy

Above I have shown the difficulty of aligning the normative plurality at the local level with the uniformity requirements at the supra-local level. There were other instances, where the relation between local level of sociotechnical practice and supra-local level of governance arrangements was problematic. A clear example came up during the hybrid consultation meeting that was organized by the ZonMw Genetics Committee. During this meeting there was a recurring conflict between two discourses. The one was an institutionalized discourse, rooted in supra-local governance arrangements and governance practices, portraying the ‘genetic’ as an exceptional category for which special attention was required. The other discourse was rooted in local sociotechnical practices and entailed that the ‘genetic’ as a category cannot be meaningfully discerned from the ‘non-genetic’.

The conflicting discourses of the ZonMw consultation meeting are the result of the discursive representation of novelties and draw attention to a source of structural discrepancy between the local level and the supra-local level. Outside the immediate context of local sociotechnical and scientific experimental practices novelties are represented in human actors’ accounts. These accounts bring into play and draw on discursive categories. Discrepancies between the local level and the

supra-local level can arise when the correspondence between the discursive categories of the local level and those of the supra-local level disappears. This can occur in all multi-level governance processes, but it is more likely to occur in governance of novel techno-scientific developments. Then the discourse of the local level will continually be adjusted to accommodate new technological developments and scientific findings, whereas the discursive categories of governance arrangements will not change at the same time. Rather, at the level of governance arrangements the structuring effects of discursive categories have become institutionalized and spread over a wider network and thus difficult to change even when new developments appear to require so.

In the ZonMw case discrepancies arose as over time the focus of medical genetic research changed from monogenetic to multifactorial causation of disease and the boundary between the 'genetic' and the 'non-genetic' became increasingly blurred. It caused interpretative difficulties as to how the existing governance arrangements are meant to govern responsibility positioning. The ZonMw case shows how the establishment of governance arrangements that are meant to govern the organization of responsibilities in an early stage of development, in a later stage can create problems, as actual developments diverge from what was anticipated.

For organizing responsibilities it means that next to the dynamics/elements that have been discussed before (prospective responsibility positioning, representing novelty's affordances and resolving normative issues/conflicts) other elements become relevant. One such element is that attention is drawn to the discrepancies between governance arrangements and local practice. Hybrid forums, especially those that bring together governance actors with local actors, as was the case in the hybrid consultation meeting of the ZonMw Genetics Committee, can create interactions that are productive in that way.

If the discrepancies grow too large repair work is needed. Again the ZonMw case shows how hybrid forums can be productive. The hybrid consultation meeting contributed to the articulation of alternative categories and problem framings which better represented novelties and which gave less rise to interpretative difficulties.

7.4 The Forum Biotechnology and Genetics as governance practice

In section 7.2 I discussed the productive role of hybrid forums in the context of two specific cases of organizing responsibilities. Here I will discuss one particular forum, the Forum Biotechnology and Genetics (FBG). The FBG differs from the other hybrid forums discussed in this thesis. In establishing the other hybrid forums concrete objectives played a role, which were related to a specific hybrid issue and most of the forums were temporary. The hybrid forums were meant to be instrumental within a well defined context and can be evaluated as such. The FBG on the other hand did not have a specific instrumental role. And although it was formally established by the Ministry of Health, it did not have a clear institutional role. It is difficult to pin down in a few words what the FBG actually is. It is many things at the same time, which means that there are also different ways in which it can be productive in organizing responsibilities. These are visible in the internal working of the FBG. Three specific ways in which the FBG interactions are productive will be discussed in section 7.4.1. In section 7.4.2 I will argue that the FBG's overall productivity is related to its protean nature. I will conclude with a brief reflection on the question whether hybrid forums - the FBG in particular - are typical exponents of a Dutch political and policy culture of consensual decision making or if hybrid forums are rather phenomena characteristic for contemporary societies.

7.4.1 The Forum Biotechnology and Genetics: a multiple knot in a sociotechnical policy network

FBG participants represented a wide variety of organizations and constituencies that were somehow involved with developments in medical genetics or medical biotechnology. At the start, many of them were already part of the policy network for medical genetics and medical biotechnology. Information exchange was an important function and reason for people to participate. The FBG primarily started of as a knot within a sociotechnical policy network, where actors, but also policy documents, information on policy trajectories and visions on future developments were brought together. The effects of this bringing together varied from occasion to occasion and also evolved over time, as participants learned what they could do, and as external expectations and ideas on the FBG's role influenced what was done. When focusing on the FBG's objectives/intentions, various characterizations apply, from lobby group to discussion forum, sounding board for policy consultation,

advisory board to study group. When aiming for an overall characterization of the FBG, the bringing together of different actors and constituencies is essential, while the effects vary. Therefore I characterize the FBG as a multiple knot in a sociotechnical policy network.

My observations of FBG meetings revealed three different ways of internal hybrid forum productivity that can be of relevance in organizing responsibilities. One of these, the FBG as a setting for prospective mutual responsibility positioning, was anticipated when I started observing the FBG meetings. Two others, the FBG as a sounding board and the FBG as a bridging setting, turned out to be relevant when reflecting on my observations.

The FBG as a sounding board

In its role of sounding board, the FBG is of service to other forums and arenas that play a role in the distributed process of organizing responsibilities. As was discussed before, alternation between different arenas and forums accounts for the overall progress that is made in organizing responsibilities. Within this process the diffuse hybrid forum plays an important role as an arena in which actors that are elsewhere excluded from the interactions can react on the storylines and responsibility positionings that develop. This concerns for example the storylines that are written in advisory reports. Policy advisors used the FBG as a means to anticipate the reception of an advice in the diffuse hybrid forum, when they presented forum participants with a preview of their ideas in order to examine the response before finalizing their advice and making it public.

The Health Council was one of the advisory councils that used the FBG as a sounding board. Not only did the Council present a preview of one of its advisory reports, it also maintained a more permanent relation with the FBG, as the secretary of the Council's standing committee on genetics attended the Forum's meetings as an observer. The linkage that was thus created between Health Council and FBG seems important for the process of organizing responsibilities in the domain of medical genetics and medical biotechnology. Through this linkage the Health Council is tuned in to the various sentiments, interests and positions that exist among societal actors who are involved in this domain. This can help the Council in writing advisory reports in which science, policy and society are well-aligned.

The FBG as a microcosm for prospective responsibility positioning

I expected that hybrid forums such as the FBG would be productive in organizing responsibilities by forming a microcosm in which actor positions from the world at large are represented, which enables mutual and accountive positioning between actors who are constituents of a configuration of responsibilities, but who do not normally interact on the local level of sociotechnical practices. Furthermore, a hybrid forum that functions as a microcosm can serve as a playground in which anticipation on new developments takes place and prospective responsibility positioning helps to find new alignments in configurations of responsibilities. The FBG did indeed on some occasions function as a microcosm for prospective responsibility positioning, but that did not form the Forum's main identity. The FBG originated from a policy network, and accordingly FBG members primarily positioned themselves and other FBG members as governance actors and less in terms of the actor group or constituency that they represented.

Third-order responsibility positioning did not occur spontaneously, but was typically induced by the introduction of storylines that enticed forum members to position themselves and/or by facilitators or others actors pushing FBG members to position themselves. In the FBG plenary meetings this occasionally occurred in response to storylines that were introduced by invited speakers. In the FBG working group on prenatal screening prospective responsibility positioning also occurred, in this case in response to the storylines that were developing in the wider debate on prenatal screening.

The FBG as bridging setting

A governance actor position that occurred frequently within the FBG interactions was that of innovation enactment actor (Garud & Ahlstrom, 1997). In terms of my conceptualization of responsibility positions, these enactment actors take up what we could call a meta-responsibility to create novelties and to enable innovative developments. Considering that the FBG emerged from the policy network for medical genetics and medical biotechnology, the frequent occurrence of this position is not a surprise. One of the ways in which innovation enactment actors try to foster particular innovations is by advancing policies that are beneficial for innovation development.

The presence of innovation enactment actors in the FBG partly explains why third-order mutual responsibility positioning only rarely occurred in the FBG plenary

meetings. Forum members would often engage in first and second order positioning as innovation enactment actors, rather than play out the roles of the constituency or actor group they represented. For example, a patient's representative would position him/herself predominantly as pushing for innovation desired by patients, but only rarely as questioning the role of patients in the configuration of responsibilities.

While the presence of innovation enactment actors may not be a favorable condition for the functioning of a hybrid forum as a setting for third-order responsibility positioning, their presence can also be evaluated as positive because it enabled another type of hybrid forum productivity. Those FBG members who were strongly motivated to realize the application of genetic and biotechnological innovations in Dutch healthcare, tried to enroll the FBG in promoting specific sociotechnical scenarios. In doing so, they were confronted with FBG participants who had interests, opinions and knowledge which were not necessarily in accordance with these scenarios. Thus, Forum interactions generated what Garud and Ahlstrom (1997) called bridging events, events where those who try to enact certain techno-scientific scenarios and those who need to be involved to make these scenarios come true, probe each others' "realities". This has a learning effect, and when it appears that actors who need to be involved in enacting the envisioned innovation scenarios do not share the reality of that scenario, bridging can form a starting point for developing other types of scenarios that better reflect the interests and realities of those involved. Also, innovation paths are looked for that are most promising, in terms of development as well as societal embedding.

There is an indirect, but important relation with organizing responsibilities for novelties, because the stage of research and innovation development and the stage of societal embedding are strongly interwoven. The promises and expectations that act to create support for research and innovation development, anticipate on, and thus prepare for, societal embedding. Hybrid interactions in the early stages of research and innovation development can offer an interesting contribution to processes of organizing responsibilities because they provide for early anticipation. Besides, this type of interaction fits well with actual actor strategies and motives, which makes it more likely that deliberate attempts to create these interactions will be successful.

7.4.2 Advantages of a weak identity

As the FBG was many things at the same time, it did not have a strong identity of its own. How could such a curious beast with such a weak identity survive? Part of the answer is exactly the incompletely defined nature, so that it could be productive in different ways.

One example of the incompletely defined nature is the ambiguity of FBG membership. On the one hand the FBG's standing is based on the fact that important spokespersons and organizations were represented, yet FBG members speak in a personal capacity. The status of forum membership is ambiguous and often a point of discussion. The representative status was continuously constructed anew. It provided room for maneuver in which the drawbacks of formal representation could be mitigated while there still was a link between the positions taken inside the Forum and those taken by organizations or groups from which the Forum members came.

Since the FBG has no clear role, to survive it cannot fall back on a mandate that protects it. As it turned out, this is exactly where part of the productivity of the Forum comes from. Where other forums can fall back on their appointed role, the FBG has to find itself a role (or actually different roles in different contexts) which others recognize as useful. Doing so, it can flexibly seize upon the situation and try to do what is most useful given the wider circumstances.

The prenatal screening case provides a clear example. The opportunity to increase the Forum's visibility and to justify its existence were the main incentives for formulating a joint position on prenatal screening. The Forum's weak authority was an incentive for the FBG to align the timing of the issues on their agenda with those of more authoritative actors and arenas. And the Forum's weak mandate provided them with the flexibility to do so. The first notice letter on prenatal screening was meant to be input for a Parliamentary round table meeting. As there was only little time left, the standpoint was formulated based on e-mail discussion. When writing the second notice letter, policy developed much faster than had been expected and the FBG responded by changing the objective of its letter. The Forum's weak mandate also means that the FBG has different modes of reducing complexity. In the case of prenatal screening these were flexibly deployed. There were different ways in which the FBG could contribute to organizing responsibilities.

These functional and process considerations are important to understand what the FBG did, how it survived and how it was productive. They convey the message that fixating the FBG's role, or creating a more recognizable profile for outsiders, will be counterproductive. It is not the whole story though, because it is also important to consider the Dutch political culture of consensual decision making. Particularly for the "curious beast" FBG, but to some extent for hybrid forums generally.

The Netherlands are well-known for their 'poldermodel', which refers to the consensus negotiations on labor issues in the tripartite consultation between government, employers' organizations and labor unions. Consensus decision making between different sociopolitical groups is a more general attribute of Dutch political culture, which has multiple historical roots. In the period after World War II, the (partly religious) sociopolitical groups ('pillars') decided to work together to rebuild the Netherlands. Earlier roots of consensus decision making can be traced back as far as the Middle Ages, when citizens, farmers and noblemen had to collaborate and take a shared responsibility for water management. With such a long history of consensual decision making, a hybrid forum is particularly well-tailored to Dutch political culture. In general, I expect that hybrid forums as governance practices are likely to be most productive in democracies that share many characteristics of what Lijphart (1999) has called consensus democracies. Majoritarian or Westminster[228] democracies, on the other hand, are typically characterized by a two-party system in which consensual decision making is not needed, because a simple majority of votes rules. These bipartite democracies seem to have a political culture in which hybrid forums are less likely to become successful as a governance practice.

In that respect the UK provides an interesting case for comparison. Since the 1999 'Review of the governance of biotechnology' the UK science governance system has been made very transparent and open (Cabinet Office & OST, 1999). An example is the Human Genetics Committee, the UK Government's advisory body on new developments in human genetics. The Committee's meetings are open to the public and via consultation processes, a broad range of actors contribute to its

[228] Great-Britain presents a typical example of this type of democracy, hence the name 'Westminster' democracy.

advisory work. The open governance approach formed a response to the decline of public trust experienced in the UK controversy over GM crops and the BSE scare.

Salter and Jones (2006) analyzed the effects of this policy reform for the domain of human genetics and describe a clash between a culture of secrecy of the core policy community on human genetics, which was situated within the government departments and ministries, and the open approach of the Human Genetics Committee which remained on the periphery of the policy community. They conclude that *"The experience of the human genetics policy domain shows us that there may be a considerable gap between the awareness of a policy community of the need for change and its ability, or willingness, to implement it"* (Salter & Jones, 2006, p.363).

It should be noted that the Human Genetics Commission and the FBG are not directly comparable as governance practices, since the former is much better facilitated and much more directed at openness and broad consultation. Yet, the comparison with the UK is interesting because it indicates two things. First of all, it is clear that initiatives for broad and hybrid consultation are taken in Majoritarian democracies as well as in consensual democracies. Hybrid forums are thus not just a reflection of a specific political and policy culture. Rather, initiatives to develop hybrid forum governance practices seem to derive from the recognition that a technocratic approach to science governance no longer works. On the other hand, the UK example also shows that the success of hybrid forum governance practices is indeed influenced by existing political and policy culture.

Epilogue

My thesis as a whole, with its focus on realigning configurations of responsibilities, may give the impression that realignment of configurations of responsibilities is always important, that order is the goal. My empirical material and analysis already showed that things are more complex. In this epilogue, I will briefly reflect on the theme of disorder (or just plurality) and order. In a first round, I will argue that disorder can be the preferred stage and that non-resolution of controversies and normative plurality has a function as well. In a second round, I will go a step further, and show how attempts at strong alignment might actually be counterproductive. An alternative – which I call (inspired by Latour) 're-modernity'- can be envisaged.

So there are reservations to be made regarding the goal of aligning responsibilities to create order. A first reservation has to do with the substance of actor's view. Sometimes, for example when the established order is suppressing, disorder rather than order may be the preferred stage. In the case of prenatal screening, opponents as well as proponents of large scale screening may well prefer a disorganized situation in which there is no guarantee on the quality of the test, over a situation which is nicely organized yet not according to their normative values. In other words, being neatly organized is not enough for a configuration of responsibilities to be qualified as good or just. In analyzing how hybrid forums can be productive, I stayed away from such normative judgments on the quality per se of specific configurations of responsibilities.

A second reservation regarding my focus on organizing responsibilities lies in the methodological implications of such an approach. When positioning dealignment as a temporary effect and as something to be overcome, possible positive effects of dealignment or disorder are not seen and not studied. The prenatal screening case provides an example. In section 7.3.1 I showed how normative plurality and the aim of organizing responsibilities for novelties are at odds with one another, because normative plurality can make it far more complicated and sometimes unfeasible to organize responsibilities. Taking up the meta-norm of normative pluralism, may hinder a collective process of organizing responsibilities, and may impede the development of novelties for which a certain scale is needed. That raises the question how the meta-norm of normative plurality relates to the objective of

organizing responsibilities. Do we need to give up on normative plurality for the sake of organizing responsibilities or should we rather put normative plurality upfront and allow for some dealignment and disorder?

This is not the place to elaborately reflect on that question. But there is one aspect I would like to discuss, because it concerns a positive aspect of normative plurality and dealignment, which is easily overlooked when the focus is on organizing responsibilities. Normative plurality is not per se about conflicting norms between people with radically different normative frameworks (say for example people who argue against abortion on religious grounds vs. people who argue for the right to abortion on liberal grounds). Normative plurality also refers to people who share a set of values, yet draw different conclusions when these values cannot all at once be met and need to be weighed against each other. In the case of prenatal screening this latter type of normative plurality played a role in the controversy concerning the age limit for prenatal screening. Many actors in the debate valued both the high quality of screening as well as pregnant women's right to self-determination. But in weighing these two values against each other different actors arrived at different conclusions. For some the quality of the test was too low to offer pregnant women the right to self-determination, for others it was not.

In the course of the debate on prenatal screening, new testing opportunities were being developed and that was reason for the Health Council to write a second advisory report on the various characteristics of available tests. The ongoing technological developments had the potential to resolve prior normative conflicts. Indeed some of the new testing opportunities had better test characteristics than the tests that had been discussed in the early stage of debate and these were therefore recommended by the Health Council. In the end the quality improvement did still not convince the State Secretary to abolish the age limit on prenatal screening: pregnant women under the age of 36 had to pay for the test themselves. However, the quality improvements were a reason to implement the newer tests as the standard for prenatal screening.

The prenatal screening case shows that there can be positive effects when a controversy persists and dealignment is not resolved. As long as collective choices to offer a certain screening method were not made, there was room for the implementation of new and better testing methods. So, disorder can be a transitory stage towards a new and better order, but then we need to allow dealignment. This

is reason to value normative plurality positively, even if in the short run it makes it difficult to organize responsibilities. Attempts to organize responsibilities are still important though, because the values that are articulated in that process can shape the trajectories of technological developments that are being pursued.

Besides these substantial and functional arguments to allow for dealignment, the analysis of my cases has shown that straightforward attempts to organize responsibilities may have repercussions which complicate rather then contribute to the achievement of alignment in configurations of responsibilities. If these complications are unavoidable, maybe my plea for making organization of responsibilities the objective of governance is not such a good idea. In this second part of the epilogue I will argue that this negative diagnosis hinges on a particular perspective on governance, the modernist perspective. If that perspective is not followed (and there are good reasons not to follow it), the picture changes. What was seen as undermining the attempts to organize responsibilities appears to be part and parcel of what is actually going on and should be taken into account.

In a modernist perspective, prudence combined with the aim of controlling and "commanding" developments forms the rationale behind anticipation on expected developments. From a modernist point of view, the situation in my cases is paradoxical. By trying to organize the situation extra complexities were introduced which subsequently changed the situation so that it became more difficult to organize it. If this is unavoidable, should one give up arranging for governance of responsibilities?

A way out might be to argue for modifying the modernist perspective into what one could call a second order or reflexively modernist perspective on anticipation. In such a reflexive perspective one is aware of the potential side effects of governing attempts, and prudence takes on a broader meaning. Prudence refers not only to the expected sociotechnical developments, but includes anticipation of the potential side effects of the attempts to govern the developments. Although a second order modernist perspective on organizing responsibilities may avoid some or all of the extra complexities which arise from a first order modernist approach, there is no guarantee that the reflexive modernist approach will itself not also give rise to new complexities. Another round of reflection would then be in order, now on the

reflexive modernist approach itself. Taking this argument to the extreme would lead to endless loops of reflections. This is not meant as an argument against reflexivity. Rather I present these considerations to support the claim that we cannot escape from the paradox of modernism through introducing higher orders of modernism, as that will only result in higher order paradoxes.

Because of the paradoxes that arise, the modernist and reflexive modernist approaches to prudence can at best only provide partial orderings of responsibilities. We can start on the other side, however: accepting the imperfections of the configurations, rather than seeing them as falling short of an ideal of optimal order. Such a perspective is an alternative to that of modernism. I have come to this perspective through reflection on my case studies and analysis, but I can develop it further by drawing on Latour's perspective of re-modernization.

In 'We have never been modern' Latour (1993) has argued that the modernist perspective does not reflect the reality of the sociotechnical world in which we live. The modernist perspective makes us believe that scientific reasoning gives us command and control over the world. Thus, because of our belief in the unproblematic power of science we introduce all sorts of novelties into the world: novelties that are supposed to make our lives better, more comfortable for example or to make us live longer and healthier lives. While we manage to achieve those aims to some extent, we also always introduce new relationships in the world of which the effects may be negative and which cannot be foreseen. Thus we create further complexities in our sociotechnical world. We can map the new relations and act on them, but that often involves introducing novelties of other sorts, which again create new complexities. We will never defeat our own creation of complexity. In other words, if we were to take the modernist perspective seriously, we have never been modern, and cannot hope to become modern. Modernity, as a characterization of the world, is an illusion.

If, following Latour, we consider modernity to be an illusion, then the paradox of organizing responsibilities is no longer a paradox, but only a confirmation of the complexity of the world we live in. What then is the next step? Is the unavoidability of the defeat of modernity (according to modernity's own criteria) an argument to 'become – or go back to being – premodern?' (Latour, 1993, p.134), and give up on any attempts to organize responsibilities? Or does it mean that we 'have to resign

ourselves to becoming antimodern' (Latour, 1993, p.134) stopping the introduction of novelties altogether?

Latour suggests that we need not fall back on premodernity or anti-modernity, but that an alternative is possible which he called re-modernization (Latour, 2003). It is an alternative in which we don't give up on the merits of modernity, but recognize its key limitation: thinking in terms of clear dichotomies (nature vs. society, science vs. politics, order vs. chaos) and the conviction that one should "purify" complexities so as to arrive at such dichotomies.[229] While actually the world is full of hybrids, which proliferate unseen. Latour suggests 'to replace the clandestine proliferation of hybrids by their regulated and commonly-agreed-upon production' (Latour, 1993, p.142). He is not very specific on what this would look like in practice. I would suggest that a re-modernist governance focus on organizing responsibilities for novelties is one concrete version of Latour's vision. The objective of re-modernist governance is the organization of hybrid sociotechnical configurations of responsibilities, recognizing hybrids for what they are instead of denying their existence (as modernists would do). Re-modernist governance would also support the role of hybrid forums, where deliberate negotiation on the configuration of responsibilities occurs without there necessarily being a conclusive resolution.

The re-modernity perspective has further implications, which can be linked to the insights achieved in this study. First, modernity is not written off completely. A form of prudence still applies, although it is recognized that the objectives we try to achieve in organizing responsibilities can be out of our reach. In a re-modernist approach to governance we still have the modernist aspiration to make things better, but we also fully acknowledge our limitations in commanding and controlling developments. In practice this could take the form of what Rip (2003) called a modulation-type approach to governance, where "the governance actor recognizes that, being part of the evolving patterns, s/he can at best modulate them – just as all the other actors are modulating the patterns through their actions and interactions, intentionally or unintentionally."

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[229] Latour wants to 'maintain all the advantages of the moderns' dualism without its disadvantages – the clandestiness of the quasi-objects' (Latour 1993, p.134).

Second, there is the issue of democracy. For Latour, his ideal of democracy forms a main argument to promote a re-modern way of handling hybrids (up to creating a "Parliament of Things"). Indeed normative choices are involved when introducing novelties into society, which require a form of political judgment, including some form of democratic legitimization and control. In my cases I have shown that the political arena played an important role in the process of organizing responsibilities, but I also concluded that other forums were relevant and that organizing responsibilities is a distributed governance process. Not all parts of this process are under democratic control: democracy in re-modernity takes a different shape from what we have been used to.

Third, Latour believes that the proliferation and public recognition of hybrid issues cannot be without consequences for modernity and that modernity defeats itself so to say: "If, as I have been saying all along, the [FM: modern] Constitution allows hybrids to proliferate because it refuses to conceptualize them as such, then it remains effective only so long as it denies their existence" (Latour, 1993, p.132) Conversely, Latour predicts that the proliferation of hybrids would slow down, once we start recognizing them for what they are. Interestingly, for the cases studied in this thesis where recognition of hybridity was forced on the actors (cf. irresolvable contrasts between norms, discourses and storylines) this appeared to happen. It took years of discussion to introduce prenatal screening in the Dutch healthcare system and the upscaling of the FH screening program was deferred because of the debate on the insurance issues.

Latour's claims about re-modernity are strongly theoretical. My study started with the observation that hybrid forums proliferate in our society (Ch. 1.5) and showed empirically how these play a role in organizing responsibilities without themselves resolving complexity. They are now also intentionally constructed and maintained. Something like re-modernity must be emerging.

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Annex 1

Overview of FGHH, PMB and FBG meetings and interactions that were observed and analyzed

12-12-00	Founding meeting of the FGHH*
10-05-01	Plenary Meeting FGHH
22-11-01	Plenary Meeting FGHH
23-05-02	Plenary Meeting FGHH
25-06-02	Preparation Group meeting FGHH*
04-09-02	Preparation Group meeting FGHH
07-11-02	Plenary Meeting FGHH
12-12-02	Preparation Group meeting FGHH
30-01-03	Preparation Group meeting FGHH
20-02-03	Plenary Meeting FGHH
12-03-03	Platform Medical Biotechnology
7-04-03	Joint meeting of FGHH and PMB
5-06-03	Preparation Group meeting FGHH
5-06-03	FBG plenary meeting
12-08-03	FBG working group on the integrated ethical assessment framework
26-08-03	Meeting FBG Medical Biotechnology Committee
26-08-03	Meeting FBG Genetics, Health and Healthcare Committee
6-10-03	FBG working group on the long-term policy plan
23-10-03	FBG plenary meeting
6-11-03	Meeting FBG Medical Biotechnology Committee
18-11-03	Meeting FBG Genetics, Health and Healthcare Committee

* Meetings that are marked with an asterisk were not attended. Analysis is based on the minutes of the meeting.

22-01-04	FBG plenary meeting
22-01-04 / 09-02-04	E-mail discussion on the first FBG notice paper on prenatal screening
26-02-04	FBG plenary meeting
06-05-04	FBG plenary meeting*
07-07-04	FBG working group meeting on prenatal screening
11-08-04	FBG working group meeting on prenatal screening
09-09-04	FBG plenary meeting

Overview of attended meetings related to the FBG

Jan 2000	Second Invitational Conference "A Joint Policy on Genetic Research'
June 2001	Round table meeting Parliamentary Committee Terpstra
10-12-02	Working conference on human gene patents
25-03-03	Invitational Conference 'Erfocentrum'
8-05-03	Human Genetics Commission plenary meeting in Birmingham
26-09-03	Round table meeting Integrative ethical assessment framework biotechnology, Rathenau Institute
5-11-03	Consultation on biotechnology between members of parliament and members of government
29-01-04	National Dialogue Genetics 'Preconception healthcare for future parents'
12-02-04	Round table meeting organized by the permanent parliamentary committee on Healthcare on prenatal screening & perinatal mortality
19-02-04	BOB ('Biotechnology as open policy process') Invitational Conference

Samenvatting

De introductie van nieuwe technologie of nieuwe kennis in de maatschappij gaat gepaard met veranderingen in rolverantwoordelijkheden van mensen. Dat kan verschillend uitpakken. Soms vergt nieuwe technologie dat mensen nieuwe verantwoordelijkheden op zich nemen, soms neemt technologie verantwoordelijkheden van mensen over. Ook kan de introductie van nieuwe technologie en kennis tot verschuivingen leiden in de verdeling van rolverantwoordelijkheden tussen verschillende groepen mensen. De veranderingen kunnen klein en lokaal zijn, zoals bijvoorbeeld bij de installatie van een deurdranger, waar de technologie de verantwoordelijkheid over neemt om de deur achter je dicht te doen. In andere gevallen vinden de veranderingen op veel grotere schaal plaats en is er een betrokkenheid van een groot netwerk van verschillende groepen mensen. De introductie van prenatale screening bijvoorbeeld – één van de casestudies die ik in dit proefschrift heb onderzocht – brengt veranderingen met zich mee in de rolverantwoordelijkheden van zwangere vrouwen, verloskundigen, gynaecologen, artsen, de overheid en ziektekostenverzekeraars. In dit proefschrift analyseer ik de introductie van nieuwe technologie als een proces waarin bestaande configuraties van rolverantwoordelijkheden ter discussie komen te staan en nieuwe afstemming gevonden moet worden in het netwerk van onderling verbonden menselijke rolverantwoordelijkheden en technische mogelijkheden. Dit is ook een maatschappelijke uitdaging: introductie van nieuwe technologie vergt dat verantwoordelijkheden opnieuw georganiseerd worden.

De vraag die centraal staat in dit proefschrift is hoe dit proces van organisatie van verantwoordelijkheden eruit ziet en verloopt. Inzicht in de aard van dit proces is van belang, omdat het vertrekpunt kan vormen voor het verbeteren van dit proces. Verschillende zorgpunten kunnen daarbij aan de orde zijn, en twee daarvan wil ik met name noemen. Ten eerste is er de zorg over falende introductie van nieuwe technologie, met verlies van investeringen en mogelijke onderbenutting van maatschappelijke voordelen als gevolg. Een gebrekkige afstemming van verantwoordelijkheden kan één van de oorzaken zijn van een dergelijke falende introductie. Inzicht in het proces van organiseren van verantwoordelijkheden kan dus bijdragen aan een betere benutting van technisch potentieel. Ten tweede is er de zorg dat de introductie van nieuwe technologie zich in veel opzichten onttrekt aan

politieke besluitvorming en normatieve legitimatie, terwijl zij wel een enorme impact kan hebben op ons dagelijks leven. Die impact manifesteert zich onder andere in nieuwe verantwoordelijkheden die diverse groepen van mensen toebedeeld krijgen. Een van de aspecten binnen het proces van organisatie van verantwoordelijkheden dat voor verbetering in aanmerking zou kunnen komen, is dus de manier waarop het proces uitkomst is en kan zijn van bewuste politieke en maatschappelijke besluitvorming.

Uitgangspunt voor mijn analyse is dat het organiseren van de configuratie van verantwoordelijkheden rondom nieuwe technologie de betrokkenheid van een heterogene groep actoren en van heterogene vormen van expertise vergt. Wetenschappelijke en technologische kennis is nodig om de mogelijkheden van de nieuwe technologie in te schatten, terwijl daarnaast discussie nodig is en een afweging van belangen tussen de betrokken actorgroepen over de vraag welke verantwoordelijkheden zij kunnen en willen dragen. Organisatie van verantwoordelijkheden houdt dus een proces in, waarin maatschappelijke domeinen, welke gewoonlijk los van elkaar staan sterk met elkaar verweven raken. Dat betreft het domein van techno-wetenschap, het socio-politieke en economische domein en het domein van wet- en regelgeving. Callon en Rip (1992) introduceerden de term hybride fora om te verwijzen naar fora voor discussie en overleg, waarbinnen actoren, problemen en argumenten uit die verschillende domeinen samen komen en waarbinnen de genoemde verwevenheid te vinden is. De operationele vraag die in dit proefschrift centraal staat is hoe zulke hybride fora kunnen bijdragen aan het proces van organisatie van verantwoordelijkheden.

In hoofdstuk 2 wordt een conceptueel kader ontwikkeld dat een eerste orde antwoord vormt op mijn twee onderzoeksvragen. In de daaropvolgende hoofdstukken worden de twee onderzoeksvragen empirisch benaderd. Het organiseren van verantwoordelijkheden wordt primair beschouwd als een proces waarin de verschillende actoren die betrokken zijn in een configuratie van verantwoordelijkheden elkaar positioneren in een bepaalde rolverantwoordelijkheid en zo tot wederzijdse afstemming proberen te komen. Technische artefacten spelen ook een rol in dit proces van verantwoordelijkheidspositionering, omdat ze – in metaforische zin - een bepaald script met zich meedragen, waarin ‘gelezen’ kan worden welke rol verondersteld wordt van menselijke actoren. Een voorbeeld is hoe

automobilisten het script van een verkeersdrempel ‘lezen’ als dat ze geacht worden hun snelheid te verminderen.

Het proces van organiseren van verantwoordelijkheden wordt geconceptualiseerd als een multi-level proces: de wederzijdse verantwoordelijkheidspositionering op het niveau van lokale praktijken vindt plaats tegen een achtergrond van supra-lokale governance arrangementen die als het ware de speelruimte en de spelregels bepalen waarbinnen afstemming van verantwoordelijkheden gezocht moeten worden. Dergelijke governance arrangementen kunnen gevormd worden door wet- en regelgeving, geïnstitutionaliseerd discours en financieringsarrangementen. In sommige gevallen kan het lastig zijn om binnen de regels van de bestaande governance arrangementen afstemming te vinden. In dat geval kunnen de governance arrangementen zelf ter discussie komen te staan. Het proces van organisatie van verantwoordelijkheden vergt dan een aanpassing van de regels van de governance arrangementen.

Hybride fora vormen settings voor zogenaamde derde orde verantwoordelijkheids-positionering, dat wil zeggen dat verantwoordelijkheidspositioneringen plaats heeft buiten de directe context van de lokale praktijken, waar de verantwoordelijkheden worden genomen. Hybride fora zijn potentieel productief omdat wederzijdse verantwoordelijkheidspositionering zich kan uitstrekken tot groepen actoren die weliswaar deel uitmaken van dezelfde configuratie van verantwoordelijkheden maar welke elkaar normaal gesproken in hun dagelijkse praktijk niet tegen komen. Ook bieden hybride fora de mogelijkheid tot interactie tussen actoren van het lokale niveau van de sociotechnische praktijken en de actoren die zich op het supra-lokale niveau van de governance arrangementen bevinden. Tot slot biedt discussie binnen hybride fora de mogelijkheid tot anticipatie op nieuwe ontwikkelingen zodat de verantwoordelijkheidspositionering binnen hybride fora een sterk prospectief karakter kan hebben.

De empirische hoofdstukken hebben alle betrekking op nieuwe ontwikkelingen op het gebied van de medische genetica. De medische genetica is een domein van wetenschappelijke en technologische vernieuwing dat sterk in de belangstelling staat. Er bestaat veel maatschappelijke en politieke aandacht voor de mogelijkheden maar ook voor de eventuele ongewenste gevolgen van de ontwikkelingen. Het domein is daarom bij uitstek geschikt om het proces van organisatie van verantwoordelijkheden en de rol van hybride fora te onderzoeken.

Hoofdstuk 3 presenteert en analyseert observaties van de bijeenkomsten van het Forum Biotechnologie en Genetica. Dit is een forum waarbinnen verschillende betrokken actoren de ontwikkelingen op het gebied van biotechnologie en genetica bespreken met als achterliggende doelstelling deze ontwikkelingen ten goede te laten komen aan de gezondheidszorg. De totstandkoming en ontwikkeling van dit forum wordt beschreven en er worden vier karakteristieke aspecten van dit forum geschetst, die zicht geven op de mogelijke rol van dit forum in het proces van organiseren van verantwoordelijkheden. Het betreft: a) de ambigue wijze waarop forumdeelnemers vertegenwoordiger zijn van een achterban; b) het forum als 'bridging setting' in een sociotechnisch beleidsnetwerk; c) derde orde prospectieve verantwoordelijkheidspositionering; en d) het forum als klankbord voor beleidsmakers. De analyse van de observaties vormt de basis voor het formuleren van vier lessen, gericht aan governance actoren die hybride fora doelbewust willen inzetten ten behoeve van het proces van organiseren van verantwoordelijkheden.

Les 1: In het doelgericht opzetten en ontwikkelen van een hybride forum als governance praktijk moet men rekening houden met de relatie tot andere governance praktijken. Deze relatie is van invloed op wat gedaan zal worden, wat gedaan kan worden en wat gedaan moet worden in een hybride forum.

Les 2: Deelnemers aan het FBG waren op ambigue wijze vertegenwoordigers van een achterban. Aan de ene kant waren ze nadrukkelijk op persoonlijke titel vertegenwoordigd, aan de andere kant waren ze vaak een belangrijke woordvoerder van een bepaalde partij of organisatie. Deze ambigue vertegenwoordiging geeft speelruimte waarbinnen de nadelen van formele vertegenwoordiging gemitigeerd kunnen worden, zonder dat daarbij de verbinding verloren gaat tussen enerzijds de posities die - op persoonlijke titel - binnen het forum ingenomen worden en anderzijds de posities die ingenomen worden door de partijen en organisaties welke door forumdeelnemers vertegenwoordigd worden.

Les 3: Hybride fora kunnen functioneren als setting voor derde orde prospectieve verantwoordelijkheidspositionering, maar derde orde verantwoordelijkheids-positionering ontstaat niet spontaan. Ze komt tot stand door de aanwezigheid van verhaallijnen waardoor forumleden zich genoopt voelen zichzelf en anderen te positioneren en/of door de aanwezigheid van facilitators die forumdeelnemers aansporen zichzelf te positioneren.

Les 4: Hybride fora kunnen functioneren als zogenaamde ‘bridging settings’ (Garud & Ahlstrom, 1997), settings waar een ontmoeting plaats vindt tussen enerzijds actoren die de ontwikkeling van nieuwe technische mogelijkheden proberen te stimuleren en anderzijds actoren die betrokken moeten worden om de ontwikkelingen mogelijk te maken. In ‘bridging settings’ worden deze actoren met elkaars realiteit en actorwereld geconfronteerd, wat een essentiële stap is in de richting van afstemming.

In de hoofdstukken 4 en 5 wordt het overall proces van organisatie van verantwoordelijkheden geanalyseerd aan de hand van twee specifieke casestudies. Hoofdstuk 4 gaat over de introductie van prenatale Down syndroom screening in de Nederlandse gezondheidszorg. Het analyseert de interacties hierover in de periode 1998-2004. Het zwaartepunt van het debat bevond zich afwisselend binnen verschillende arena’s: de Gezondheidsraad, de publieke media - wat als een diffuus hybride forum gezien kan worden - en de politieke arena. De Gezondheidsraad evalueerde de kwaliteit van verschillende prenatale screeningsopties en adviseerde de overheid om alle zwangere vrouwen prenatale screening middels de Triple test aan te bieden. Publicatie van dit advies leidde tot een controverse. Tegenstanders betoogden dat de Gezondheidsraad ten onrechte geen rekening had gehouden met het feit dat voor jongere vrouwen de kwaliteit van de test veel lager is dan voor oudere vrouwen en bepleitten de handhaving van een leeftijdsgrens voor het aanbieden van prenatale Down syndroom screening. Uit een analyse van de argumentatiestructuur van het debat blijkt dat zowel voor- als tegenstanders van het opheffen van de leeftijdsgrens hun argumenten ontleenden aan dezelfde geïnstitutionaliseerde discoursen. Het discours van de Wet op het bevolkingsonderzoek (WBO) vereist dat bevolkingsonderzoek aan hoge kwaliteitseisen voldoet en het discours van ethisch liberalisme benadrukt keuzevrijheid en autonomie van de patiënt. Deze bestaande governance arrangementen voor prenatale screening bleken de discussie over de gewenste configuratie van verantwoordelijkheden niet te kunnen beslissen. De impasse in het debat werd pas doorbroken toen de staatssecretaris van volksgezondheid het politieke besluit nam om de leeftijdsgrens voor prenatale screening niet op te heffen. Tweede Kamerleden waren verdeeld over dit besluit en uiteindelijk werd er een compromis gevonden. De Wet op de Geneeskundige Behandelings Overeenkomst (WGBO) werd aangehaald om te beargumenteren dat alle zwangeren

geïnformeerd zouden moeten worden over de mogelijkheden van prenatale Down syndroom screening. Alleen zwangeren boven de 36 krijgen de test ook daadwerkelijk vergoed. Dit compromis indiceerde een verandering in de toen gebruikelijke interpretatie van de afbakening tussen de Wet Bevolkingsonderzoek en de Wet op de Geneeskundige Behandelings Overeenkomst.

De discussie over de introductie van prenatale Down syndroom screening werd ook gevoerd in het Forum Biotechnologie en Genetica. Het was één van de eerste onderwerpen waarop het Forum twee standpunten naar buiten bracht. De totstandkoming van deze standpunten is geanalyseerd om te zien op welke wijze discussie in een hybride forum zoals het FBG productief kan zijn. Bij de bepaling van het eerste Forum standpunt was de uitkomst van de politieke besluitvorming nog open. De discussie in het FBG reproduceerde de controverse en complexiteit van het bredere debat en het Forum kwam niet tot consensus. Bij de bepaling van het tweede Forum standpunt was de uitkomst van de politieke besluitvorming een stuk duidelijker geworden en kozen de Forum leden ervoor om het politieke compromis te accepteren. De discussie in het FBG werd nu veel productiever: het compromis vormde een soort vlonder waarop de discussie in het FBG kon voortbouwen, zonder daarbij te verdwijnen in een moeras van niet doorslaggevende argumenten. Het bleek dat er nog veel onduidelijkheden waren over de precieze implicaties van het politieke compromis. Dat betrof met name de verantwoordelijkheid voor het organiseren en monitoren van de kwaliteit van de screening. Het Forum adviseerde de overheid deze verantwoordelijkheid niet over te laten aan partijen in het veld maar zelf een sturende rol in te nemen.

Hoofdstuk 5 gaat over de uitbreiding van de opsporing van mensen met de erfelijke aandoening Familiaire Hypercholesterolemie (FH), waarvoor al een aantal jaren een kleinschalig test programma bestond. Het besluit om dit programma op te schalen naar een landelijk bevolkingsonderzoeksprogramma kwam ter discussie te staan, omdat er onduidelijkheid en onenigheid was over de gevolgen van genetische screening op de verzekerbaarheid van mensen met FH. Dit leidde tot een debat over de wederzijdse verantwoordelijkheden van verschillende betrokken actoren. De kwestie werd besproken in verschillende arena's: de Gezondheidsraad, de parlementaire arena, het diffuse hybride forum, een gemandateerd hybride zelfreguleringsoverleg, en een informeel hybride overleg tussen betrokken partijen (verzekeraars, patiënten en screeningsorganisatie).

Het debat over de wederzijdse verantwoordelijkheden ontvouwde zich aan de hand van drie betwiste verhaallijnen. In de eerste verhaallijn wordt FH gepositioneerd als een behandelbare en verzekerbare ziekte. Een tweede verhaallijn stelt dat verzekeraars de Wet op de Medische Keuringen (WMK) overtreden, en in een derde verhaallijn over solidariteit wordt de overheid als verantwoordelijk gepositioneerd. Gebruikmakend van deze verhaallijnen positioneren de actoren elkaar in een bepaalde rolverantwoordelijkheid. De verhaallijnen zijn sterk aan elkaar gekoppeld: wanneer één van de verhaallijnen aan geloofwaardigheid verliest, gaat een andere verhaallijn de discussie overheersen. De verhaallijn, die verzekeraars als verantwoordelijk positioneert, omdat ze de Wet op de Medische Keuringen zouden overtreden, verloor geloofwaardigheid nadat de Gezondheidsraad haar advies over FH en de WMK had gepubliceerd. De andere twee verhaallijnen werden daarmee dominanter. De eerste en de tweede verhaallijn zijn ook aan elkaar verknoopt doordat in beide de ambigue categorie van behandelbare ziekte een rol speelt. Deze categorie werd door sommigen geïnterpreteerd als een brede categorie (er is een behandeling) en door anderen als een smalle categorie (behandeling leidt tot een normale levensverwachting). Door sommigen werd de categorie beschouwd als een categorie die betrekking heeft op de gehele groep van FH patiënten, anderen beschouwden behandelbaarheid als een categorie die afhankelijk is van individuele karakteristieken van de patiënt. Door de ambiguïteit van de categorie is de verhaallijn rondom behandelbaarheid en verzekerbaarheid van FH voor meerdere interpretaties vatbaar. Gedurende de gehele discussie bleef deze verhaallijn dominant, maar de interpretatie en implicaties in termen van verantwoordelijkheden verschoven totdat de verhaallijn uiteindelijk stabiliseerde in een bepaalde interpretatie en het besluit tot opschaling van de screening genomen werd.

Hoofdstuk 6 analyseert de discussie die plaats vond tijdens een hybride consultatiebijeenkomst, welke georganiseerd werd door de ZonMw Commissie Genetica.[230] Deze Commissie Genetica had als opdracht om bestaande wet- en regelgeving te evalueren in het licht van toekomstige ontwikkelingen in de toepassing van genetische kennis binnen de gezondheidszorg. De consultatiebijeenkomst, had specifiek betrekking op het gebruik van

[230] ZonMw is de overheidsorganisatie die onderzoek op het gebied van medische wetenschap en gezondheidszorg financiert.

erfelijkheidsgegevens door verzekeraars en werkgevers. De analyse in dit hoofdstuk is gericht op de rol van geïnstitutionaliseerde categorieën in de discussie, in het bijzonder op de rol van de categorie 'genetisch'. Commissieleden hanteerden het onderscheid tussen 'genetisch' en 'niet-genetisch' om hun adviesonderwerp af te bakenen. Dit leidde tot problemen in de discussie omdat deelnemers aan de consultatiebijeenkomst betoogden dat het onderscheid tussen 'genetisch' en 'niet-genetisch' in de praktijk lastig te maken is. Commissieleden hanteerden een discours waarin 'genetisch' een afgebakende en herkenbare categorie is. De deelnemers aan de bijeenkomst daarentegen hanteerden een discours waarin sprake is van een vervagende grens tussen de categorieën 'genetisch' en 'niet-genetisch'. Het conflict tussen de beide discoursen is wijder verbreid dan deze specifieke bijeenkomst en reflecteert een groeiende discrepantie tussen enerzijds het discours op het supra-lokale niveau van governance praktijken en governance arrangementen en anderzijds het discours van lokale sociotechnische praktijken waarin categorieën niet simpel te onderscheiden zijn. Deze discrepantie bemoeilijkt het proces van organisatie van verantwoordelijkheden omdat het onduidelijk is hoe het discours van het governance arrangement vertaald moet worden naar het niveau van lokale sociotechnische praktijken. Tijdens de consultatiebijeenkomst werd als alternatief de nieuwe categorie 'voorspellende medische gegevens' voorgesteld, welke mogelijk tot minder interpretatieproblemen zou leiden. De verschuiving naar deze nieuwe categorie is niet zonder gevolgen. Ze gaat gepaard met een verschuiving in de morele inkadering van het probleem van verzekeringsselectie. In de bestaande governance arrangementen voor verzekeringsselectie wordt het recht op niet-weten en het recht op privacy gehanteerd om aan 'genetische' ziekten en 'genetische' diagnostiek een bijzondere status toe te kennen. Wanneer de categorie van 'voorspellende medische gegevens' wordt gehanteerd, wordt het probleem van verzekeringsselectie verbreed en verschuift het argument van zorg om privacy en recht op 'niet-weten' naar zorg om solidariteit.

Het is duidelijk dat de organisatie van verantwoordelijkheden niet alleen een voortdurende afstemming vergt tussen de wederzijdse rolverantwoordelijkheden van de actoren die betrokken zijn in de configuratie van verantwoordelijkheden, maar ook afstemming vergt tussen het supra-lokale niveau van de governance arrangementen en het lokale niveau van de sociotechnische praktijken. De hybride consultatiebijeenkomst leverde een productieve bijdrage aan het proces van

organisatie van verantwoordelijkheden omdat de discrepantie tijdens deze bijeenkomst gearticuleerd raakte, een alternatieve categorie geïntroduceerd werd in de discussie en de implicaties en bruikbaarheid van deze alternatieve categorie uitgetest werden.

Hoofdstuk 7 begint met een samenvatting en discussie van de belangrijkste resultaten en conclusies van de empirische hoofdstukken. In beide casestudies die ik heb onderzocht bleek het proces van organiseren van verantwoordelijkheden een hybride proces te zijn, waarin het domein van techno-wetenschap, het domein van wetgeving en regulering, en het sociopolitieke en economische domein sterk met elkaar verweven zijn. De verwevenheid van deze domeinen is direct zichtbaar in de verschillende fora en arena's waarbinnen de issues bediscussieerd werden. Daarnaast manifesteert de verwevenheid zich ook in het overall proces van organiseren van verantwoordelijkheden, waarin de focus van de discussie zich verplaatst van het ene naar het andere forum, welke elk een specifiek aspect van de discussie uitlichten. Door de afwisseling tussen verschillende soorten fora en arena's wordt voortgang bereikt in het proces van organiseren van verantwoordelijkheden. Er is de facto een opeenvolging van verschillende fora, welke het mogelijk maakt dat de discussie in het ene forum voortbouwt op de uitkomsten van de discussie in de voorafgaande fora. Dergelijke uitkomsten betreffen bijvoorbeeld de mogelijkheden van nieuwe technologie of legitieme beslissingen aangaande het normatieve kader, welke de speelruimte vastleggen waarbinnen de configuratie van verantwoordelijkheden verder georganiseerd moet worden.

Dit is zichtbaar in hoe de Gezondheidsraad een gezaghebbend woordvoerder was voor nieuwe technische mogelijkheden en zo een belangrijke rol speelde in het proces van organiseren van verantwoordelijkheden. In zijn adviezen schetste de Raad niet alleen de mogelijkheden en karakteristieken van nieuwe technologische mogelijkheden, maar expliciet of impliciet schetste de Raad ook zijn voorkeur voor een bepaalde configuratie van verantwoordelijkheden. De Gezondheidsraad werd daarin wel beperkt. Woordvoerders van menselijke actoren kunnen de suggestie doen om de morele orde van een discussie te veranderen wanneer zij hun achterban en andere actoren positioneren in hun pogingen om verantwoordelijkheden te organiseren. De Gezondheidsraad daarentegen kon dat niet, omdat zij opereerde binnen de normatieve grenzen van haar formele mandaat als wetenschappelijke

apolitieke adviesraad en de bestaande governance arrangementen accepteerde. Hierdoor had de Gezondheidsraad minder speelruimte om afstemming in de configuratie van verantwoordelijkheden te vinden.

De politieke arena speelde een belangrijke rol in het oplossen van normatieve vraagstukken. In de prenatale screening casus was de politieke arena de gezaghebbende arena waarbinnen een knoop doorgehakt kon worden toen het bredere debat in een impasse was geraakt. In de FH casus vormde de politieke arena de gezaghebbende arena waarin de legitimiteit van de bestaande governance arrangementen bevestigd werd. Dit legde de speelruimte voor verantwoordelijkheidspositionering vast en droeg daarmee bij aan het succes van de onderhandelingen die plaatsvonden in de verschillende hybride fora.

De afwisseling tussen verschillende fora was ook van belang omdat het aan actoren die uitgesloten waren van deelname aan bepaalde fora de mogelijkheid gaf om alsnog te reageren op de wijze waarop zij door anderen gepositioneerd werden. Met name het diffuse hybride forum - waarvan de publieke media de drager zijn - was in dit opzicht van belang, omdat het voor iedereen toegankelijk is en in principe alle betrokken actoren de mogelijkheid geeft om hun stem te laten horen.

Het organiseren van verantwoordelijkheden is dus een gedistribueerd governance proces, waarin door de afwisseling tussen verschillende soorten fora en arena's voortgang wordt geboekt. De betrokken fora en arena's verschillen in de mate van hybriditeit. De politieke arena kan in bepaalde situaties een hybride karakter hebben, maar hybriditeit vormt niet het belangrijkste kenmerk. De Gezondheidsraad neemt een middenpositie in tussen hybride fora en niet-hybride fora. Publiek presenteert de Raad zich als een niet-hybride, want wetenschappelijke adviesraad, maar achter de schermen is er sprake van een hybride proces van mengen en zuiveren van wetenschap, beleid en maatschappij ten einde afstemming te vinden tussen wetenschappelijke feiten en politieke en maatschappelijke kwesties en overwegingen. Daarnaast speelden er twee soorten expliciet hybride fora een rol: het diffuse hybride forum en doelgericht hybride fora, zoals het Forum Biotechnologie en Genetica (FBG) in de prenatale screening casus, hybride fora voor zelfregulering in de FH casus, en de hybride consultatiebijeenkomst die georganiseerd werd door ZonMw.

Doelgericht hybride fora kunnen op verschillende wijzen bijdragen aan het proces van organiseren van verantwoordelijkheden. In de eerste plaats doordat ze de belangrijke dynamiek van wederzijdse verantwoordelijkheidspositionering faciliteren. In de FH casus zagen we dat de betrokken partijen in het hybride zelfoverleg daarbij ook in staat waren om tot overeenstemming te komen en afstemming te bereiken in de configuratie van verantwoordelijkheden. Voor de Minister droeg dit resultaat bij aan haar besluit om de opschaling van het FH screening programma door te zetten. Mijn analyses laten ook zien dat wederzijdse verantwoordelijkheidspositionering niet altijd tot overeenstemming leidt en dat doelgericht hybride fora dus niet in alle fases van het proces een productieve bijdrage leveren. Zo waren de interacties in het FBG tijdens de eerste standpuntbepaling op prenatale screening niet productief: de controverse van het bredere debat werd gereproduceerd. De bijdrage van het FBG kwam op een moment in het proces waarop alleen politieke besluitvorming in staat was om de impasse in de discussie te doorbreken.

De analyse van de interne interacties binnen het FBG geeft zicht op een specifieke manier waarop een hybride forum met een zwak mandaat zoals het FBG productief kan zijn. Het FBG had geen sterk mandaat, geen duidelijk rol en geen duidelijke identiteit. Juist dit onbepaalde karakter is verantwoordelijk voor de geheel eigen wijze waarop het FBG productief is. Het onbepaalde karakter maakt dat het FBG zijn bestaansrecht actief moet waarmaken. Er is geen mandaat dat het Forum beschermt en daar waar andere fora terug kunnen vallen op de hen toegewezen rol, moet het FBG zelf een rol zien te vinden die anderen als nuttig herkennen. Daarbij kan het Forum flexibel inspringen op een specifieke situatie en datgene doen wat gezien de omstandigheden het meest nuttig is. Door zijn zwakke mandaat is het Forum bovendien flexibel in de wijze waarop een bepaalde kwestie wordt geframed en complexiteit wordt gereduceerd. Wisseling tussen verschillende manieren van framing – van belang om voortgang te boeken in het overall proces - kan intern binnen het forum plaats vinden en is niet afhankelijk van wisseling tussen verschillende soorten forums en arena's.

In beide omvangrijke casestudies die ik onderzocht heb was sprake van de introductie van een type technologie, die niet radicaal nieuw was, dat wil zeggen dat er al governance arrangementen waren, specifiek gericht op dit type technologie. Het bleek dat de opgave om verantwoordelijkheden te organiseren meer vergde dan

alleen het vinden van wederzijdse afstemming tussen de diverse rolverantwoordelijkheden op het lokale niveau. In het geval van prenatale screening was het organiseren van verantwoordelijkheden erg lastig omdat er inherente spanningen bestonden tussen de twee belangrijkste normen van het governance arrangement. Het voorbeeld laat zien dat de oorsprong van een gebrekkige afstemming binnen een configuratie van verantwoordelijkheden niet noodzakelijkerwijs primair het gevolg is van veranderende verdelingen van rolverantwoordelijkheden en technische mogelijkheden op het lokale niveau. Gebrekkige afstemming kan ook zijn oorsprong hebben in het multi-level proces, in die zin dat er spanningen en discrepanties bestaan tussen het niveau van governance arrangementen en het niveau van lokale praktijken. Het voorbeeld van de ZonMw hybride consultatiebijeenkomst laat zien dat hybride fora productief kunnen zijn in het signaleren van dergelijke discrepanties en in het articuleren en testen van mogelijke oplossingen.

De analyses in dit proefschrift laten enerzijds zien hoe voortgang in het proces van organisatie van verantwoordelijkheden tot stand komt, maar ook dat een georganiseerde nieuwe configuratie van verantwoordelijkheden vaak moeilijk te bereiken is. Sterker nog, bewuste pogingen om verantwoordelijkheden te organiseren werken soms contraproductief of geven aanleiding tot verwarring. Deze paradoxale en in sommige opzichten teleurstellende bevindingen werpen de vraag op of het doel van organiseren van verantwoordelijkheden niet te hoog gegrepen is en mogelijk beter opgegeven kan worden. In een epiloog betoog ik dat een dergelijke conclusie onjuist is, omdat ze gebaseerd is op een modernistisch referentiekader. In modernistische termen zijn mijn conclusies teleurstellend, maar binnen een ander referentiekader hoeven ze dat niet te zijn. Als alternatief – en in navolging van Latour - bepleit ik een re-modernistische benadering, waarin complexiteit en hybriditeit niet een probleem vormen maar de manier waarop onze maatschappij zich de facto op orde houdt. Herkenning en erkenning daarvan leidt dan tot een betere omgang met complexiteit en hybriditeit.

About the author

Femke Merkx (1972) was born in Bleiswijk. She took her final A level exam (athenaeum B) at the Gertrudislyceum in Roosendaal. In 1996 she obtained a master's degree in Molecular Sciences at Wageningen University and Research Centre (honor: cum laude) and in 1998 she obtained a master's degree in Philosophy of Science, Technology and Society at the University of Twente (honor: cum laude). After graduation she worked as a researcher for the department of Philosophy of Science and Technology[231] at the University of Twente. For Stichting WeTeN she wrote a literature review on risk communication concerning developments in the life sciences. She further participated in two EU funded projects. One project was about foresight exercises and innovation management (Formakin project) and the other was about public participation in decision making processes regarding GM crops field trials (Paradys project). In 2003 she visited the Science and Technology Studies Unit (SATSU) at the University of York as a Marie Curie fellow. Since October 2005, Femke has been working for the Science System Assessment department at the Rathenau Institute in the Hague. Her current research is about transdisciplinary knowledge development.

[231] Nowadays the department is called the department of Science, Technology, Health and Policy Studies (STeHPS).