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IMPROVING RISK REGULATION

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PREFACE

On 14 October 2014, IRGC together with the OECD Regulatory Policy Division organised a conference on Improving Risk Regulation[1]. Confronted with the challenge of improving regulatory performance, many governments in the world are looking for ways to better manage risks, in particular those risks that develop in complex systems, with stakeholders from various sectors, and that are marked by uncertainty. The conference discussed in particular:

- Private regulation
- Role of non-governmental actors in regulating risk
- Contributions from behavioural economics and sciences
- Enhancing adaptability and flexibility in pharmaceuticals regulation

Regulation is one of the options for governing risks. With this publication, IRGC's intention is to explore certain developments that may contribute to improving risk governance by governments, in partnership with others.

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In its public conference on Adaptive Risk Regulation, jointly organised with the Department of Science, Technology and Public Policy at University College London, on 7-8 January 2016, IRGC will continue to explore and discuss the concept and application of planned adaptive risk regulation in various sectors[2].

[1] irgc.org/event/annual-conference-2014-summary

[2] irgc.org/event/planning-adaptive-risk-regulation

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INTRODUCTION

by Lorenzo Allio[1]

1. Setting the context: contemporary risk regulation

Designing and implementing public interventions to effectively understand, prevent or mitigate risks has never been straightforward. In contemporary governance, nonetheless, public risk management activities appear to be particularly challenged. Because of the prevalence of systemic risks that span across sectors, actors and countries, and of societal expectation to manage emerging risks, risk assessment, management and communication are being questioned. Established approaches to understanding and addressing risks with impact on the environment, the economy or society may no longer be effective or fully legitimised. Also a major instrument that Western society has adopted to address risks – regulatory interventions – is under the spotlight and its performance and cost-effectiveness is sometimes challenged.

Traditional regulatory risk management – its nature, scope and efficiency – is being tested against changed framework conditions, which emerged because of the concomitance of a number of new global phenomena.

- **Multiple, multiplying and interdependent linkages** – Globalisation is not a mere keyword. The 21st century world is characterised by faster interactions between various actors across levels of established governance. Wiener (2011) describes three dimensions of increasing interconnectedness and risk regulation: (i) the faster and wider propagation of risks across globalising networks (for instance the transmission of pandemic disease, financial crises, terrorist attacks, or cyberwar); (ii) so-called "multi-risk impacts" generated by any intervention to address one risk, including ancillary harms and benefits (because the world is a web of multiple interconnected risks); and (iii) the increasing diffusion of regulatory ideas and learning across regulatory systems, potentially helping to address the first two dimensions. Well-defined and contained territorial and jurisdictional units of governance are no longer the reference system. No single, clearly identifiable and legitimated (public) actor can address complex societal problems. Globalisation has brought unprecedented opportunities for both developed countries and emerging economies but it requires a reorganisation of actions at the local, national and international level, as well as across various types of public and private organisations (Nye and Donahue, 2000; Vogel and Kagan, 2004; Camilleri and Falk, 2009).

[1] European Risk Forum and allio|rodrigoconsulting.

- **Greater complexity and salience** – Regulators are called upon to tackle increasingly complex and multi-faceted challenges. If in the past problems have tended to be tackled singularly as definite entities, today we recognise the presence of – and expect solutions to – risks that cover the widest possible spectrum of the observable (Power, 2004). Action expected from public risk managers ranges from overarching societal problems (such as climate change and population ageing) to specific exposures to single chemicals (e.g. an endocrine disruptor) and the use of novel technologies or processes (for instance, nano- and bio-technologies). Regulators are moreover called upon to manage proven or potential risks which may involve fundamental ethical issues (e.g. application of stem cells research) or pertain to life-style (determined by individual nutritional, smoking or alcohol consumption patterns), which stretch the boundaries of the role of the state (Asveld and Roeser, 2009; Alemanno and Garde, 2013). Furthermore, emerging risks are constantly brought onto the regulators' radar screen (IRGC, 2015). To a greater extent than in the past, risk regulators are now asked not only to react but also to anticipate future risks, deploying diversified rational risk management strategies (Viscusi, 1998; Sunstein, 2002; Hutter, 2010). Finally, the management of systemic risks is also increasingly relevant and in demand – both from the point of view of controlling catastrophic events and system-disruptive threats and as a means, by clustering various (types of) risks, to find suitable approaches to manage an economic and social system (OECD, 2003; Helbing, 2010; Alemanno, 2011).

- **Evolving processes and tools** – Evolving governance modifies decisional processes. The pivotal actor for public risk management is no longer only the 'regulatory state' (Majone, 1996). Increasingly, the goals and standards set out in primary legislation are interpreted and implemented through rule-making by non-state actors as well as administrative decisions or adjudication (Craig, 1990; Fisher, 2007). An "administrative state" has emerged in which the executive frequently acts as the regulator, the administrator and the arbiter, sometimes confusing the traditional separation of powers designed to protect citizens from poor quality or arbitrary decision-making (Richardson, 2002). So-called 'Better Regulation' principles and practices have been widely diffused internationally (OECD, 2015),[2] but their application has yet to fully reflect this development. The development and adoption of substantive guidance, for instance, tends to escape process management standards.[3] Against this background, moreover, new tools for interpreting and managing risk situations are being tested. Insights from behavioural sciences have for instance opened new possible avenues to design and organise public risk management interventions using cues or 'nudges' (Shafir, 2013; Lunn, 2014) or deploying

[2] The diffusion of regulatory impact assessment – initially ex ante and nowadays increasingly ex post as well – is a point in case (DeFrancesco, 2013; Wiener, 2013).

[3] A form of "soft law", substantive guidance is used to set out detailed technical, scientific, or procedural requirements that must be met to fulfil obligations laid down in legally binding acts and to provide detailed interpretations of statutory obligations thereby defining requirements or impacts for affected entities. In many sectors, and for a wide range of risks, substantive guidance is one of the most important means used to implement secondary legislation. It is used to define, for instance, the technical or scientific requirements that businesses must meet if their products, processes, materials, or services are to satisfy standards of safety or quality or efficacy or environmental impact. Substantive guidance may also define complex hazards or clarify the scope and impact of major risk management laws (European Risk Forum, *forthcoming*; Graham and Broughel, 2014).

more experimental approaches such as design thinking and prototyping (Brown, 2009; Bason, 2010; Allio, 2014). Accountability, predictability, the rule of law and the quality of decision-making – and even its very legitimacy – may suffer when public and private decision-makers are dis-jointed from those affected by their decisions.

- **Higher expectations and weaker confidence** – Trust and confidence in government tend to be directly correlated to the public's expectations, and the more citizens are educated and mature, the higher are the demands on high quality and timely policy interventions. This naturally creates gaps between the pace at which institutions and decision-making structures evolve and how societal values and technology evolve. Tensions emerge between preserving stability and acquired affluence on the one hand, and accompanying (or prompting necessary) change on the other. From this perspective, public institutions in general always experience structural variations in public confidence (Fukuyama, 1995). The financial and economic crisis of 2008 has arguably only highlighted and accelerated the steady decline in trust, but it has not triggered it (Blind, 2007; Bouckaert, 2012). The post-crisis recovery context, however, significantly determines how public policy is implemented – and often in negative terms. Despite continued sophistication, accuracy and timeliness in detecting potential harm, the public is increasingly exposed to social amplification of risk that considerably affects public perception and acceptance (Renn, 2008). Winning the challenge of regaining and maintaining trust is crucial for contemporary governments (Lofstedt, 2005; OECD, 2013).

In response to the sophistication of contemporary challenges, governments are revising their analytic and management tools, including for their ability to address unintended negative consequences that arise from regulatory activity, such as so-called 'risk–risk trade-offs'.[4] While the task to manage new forms of risks becomes more formidable, governments are held responsible for both the regulatory costs of detecting and addressing the risks as well as the costs of failing to prevent the risks.

At the same time, risk regulation offers an opportunity to public authorities because it provides ways for public authorities to revisit their role, organisation and functioning and be better equipped to address the double challenge of responding to ever increasing demands by the public for efficient action on the one hand while facing declining levels of trust and resource constraints on the other.

Risk regulation has yielded both successes and failures, and faces pressures to improve in several ways – including by learning from past experience to improve future design and performance. Scientific risk assessment by expert committees is increasingly complemented by assessment of concerns of affected parties, in an open and multi-stakeholder process. Society no longer contents itself with "being told" but requires to "be shown" how risk management options are chosen and are likely to have an impact – and it aspires to "be involved" in decisions (Rothstein et al., 2006).

[4] Decisions taken to manage one single risk may create other countervailing risks (Graham and Wiener, 1995).

2. Rationale and purpose of this publication

If the traditional organisational and procedural frameworks so far used by regulators are put into question, it is imperative to explore various fields and experiences with public and private risk management solutions.

The decision to embark on this publication was stimulated by the high-level annual conference that the International Risk Governance Council (IRGC) organised on "*Improving Risk Regulation. From Crisis Response to Learning and Innovation*", in collaboration with the Organisation for the Economic Co-operation and Development (OECD) and Duke University in October 2014.[5] The conference identified, evaluated and discussed the relevance and effectiveness of new approaches to improving risk governance, both as they result from responding to and learning from crises, and as deliberate innovations in how regulatory power is exercised and shared. The research project organised by Duke University and presented on the first day of the conference will produce a book on policy learning from crises, with the title *Policy Shock: Regulatory Responses to Oil Spills, Nuclear Accidents and Financial Crises*. The sessions on the second day of the conference examined several kinds of regulatory innovations and framed the focus of this IRGC publication.

This publication thus explores new insights for addressing contemporary risks. It rests on the definition of 'risk regulation' as the body of law intended to prevent, reduce or re-allocate the likelihood of harm to individuals and society, and protect health, safety, security, and the environment from a variety of risks (UK Royal Society, 1992; Hood et al., 2001; OECD, 2010) – to then provide an overview of different forms and approaches to risk management by public authorities and the private sector based on interdisciplinary risk governance and multi-stakeholder processes. The publication highlights some innovative approaches to how governments and the private sector collaborate to improving the overall performance and efficiency of regulatory frameworks. **It seeks to stimulate reflection among (public and private) regulators as well as those who are regulated on how best to design and implement risk regulation so as to enhance its impact and efficiency**. In addition, the publication identifies innovative approaches that governments and the private sector may follow to exploit synergies and collaborate to ameliorate public risk management.

[5] The conference programme and the presented slides can be accessed at irgc.org/event/annual-conference-2014-summary

3. Structure of the publication

This publication is the result of a collective effort by several international experts with various backgrounds. It is divided into four chapters, each of which introduces relevant issues and perspectives to modern public risk management. Taken together, the distinct dimensions and approaches presented in the chapters provide insights into how to possibly enhance the effectiveness and legitimacy (credibility) of risk regulation in the 21st century.

The first essay, authored by Colin Scott (University College Dublin), explores the private-public interface in organising and managing societal interactions. Transnational private regulation regimes may provide promising complementary approaches to the governance of risk and innovation. For instance, transnational industry associations may help design technical standards that are voluntary but set performance requirements that are subsequently adopted and enforced by governments. The essay presents illustrative examples of the potential that transnational private regulation has on innovative governance, notably in relation to addressing market coordination problems, to complementing inadequate and inappropriate public regulation, and to building community solidarity (understood here as willingness by all actors to achieve higher societal goals).

Terry Yosie (World Environment Center) explores emerging strategies to manage system-level risk through enhanced collaboration between public and private actors, including non-governmental organisations (NGOs) and leading global companies. The paper presents examples of collaborative arrangements that help understand and manage at various governance levels risks to public health and the environment triggered by contemporary global mega-trends. Such collaboration – the paper argues – yields insights on the scale of risks, new governance models, opportunities for innovation, and specific risk management strategies that incorporate sustainability. Accordingly, regulators should closely examine these dynamics, for they provide relevant information and case studies for the design of future regulatory strategies by modifying the scope and locus of decision-making; improving scientific tools and methods; identifying opportunities for collaboration across government, NGOs and private sector institutions; and developing a future research agenda.

Ortwin Renn (University of Stuttgart) and Marie-Valentine Florin (IRGC) address one of the emerging approaches to public intervention design – applying insights from behavioural sciences. Their essay investigates the scope and challenges for behaviourally-informed risk regulation as not only effective but also legal and legitimate means to achieve desired behavioural change. Dwelling on insights from behaviourally-informed interventions, the authors highlight how management decisions can preserve individual choice, for instance through default rules, smart disclosure and simplification requirements. They argue that the moral and political legitimacy for collective actors to shape human behaviour is granted only if the overarching policy goals have been agreed through the democratic and inclusive process.

The final essay constitutes a case study highlighting a practical sectoral application of new thinking emerging on how to improve regulation on the basis of enhanced collaboration between regulators, industry and the public (patients in this case). It refers to adaptive approaches to pre-market drug authorisation and the essay reports on the related panel organised at the IRGC conference of October 2014 mentioned above. The essay is authored by Kenneth A. Oye (Massachusetts Institute of Technology, MIT), Mark Pearson (OECD), Hans-Georg Eichler (European Medicines Agency), Theresa Mullin (US Food and Drug Administration) and Anton Hoos (Amgen). Against the background of a sector marked by rapid advances in science and technology, the authors highlight the main drivers of the adaptive licensing debate – growing patient demand for timely access to address unmet medical needs; emerging science of precision medicine leading to fragmentation of treatment populations; healthcare systems' budgetary constraints and rising payer influence on product accessibility; and pressure on pharma/investors to ensure sustainability of drug development. The authors focus on international regulatory initiatives to foster innovation while improving use of pre-market and post-market information, thereby striking a better balance over the full life cycle of drugs in the trade-off between uncertain effectiveness and safety of the treatment and its timely application.

The concluding remarks draw lessons from the various approaches and policy areas presented in the publication. They propose possible elements for advancing the risk regulation agenda internationally with a view to improving the performance and efficiency of risk management regulatory interventions. In that light, **public regulators might need to 'reinvent themselves' into providers of platforms that catalyse various approaches to risk management. In doing so, however, they cannot abdicate their role as guardians of transparent and rigorous evidence-based decision-making**.

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CONTRIBUTION OF TRANSNATIONAL PRIVATE REGULATION TO REVISITING RISK REGULATION

by Colin Scott[1]

Introduction

When considering contemporary risk regulation approaches, one tends to think of how companies go about fostering and protecting innovation and reducing corporate risk and consequently about how governments support and affect the environment in which companies operate. A further dimension concerns the ways in which governments and their agencies assess and manage risk as a means to evaluate and implement regulation and other policy activities, with a view to achieving societal goals such as public safety or environmental protection. Governments and companies are closely intertwined in these activities since state action is constitutive of many corporate activities that range from incorporating a company and benefiting from limited liability, to offering the protection of intellectual property law where innovation is concerned, through to establishing regulatory regimes that both target and create risks.

Recently, scholars have emphasised the extent to which the emergence of multinational enterprises and the advent and prevalence of so-called "systemic risks" has generated governance gaps from the perspective of both the market and governmental actors (see also paper by Terry Yosie in this publication). On one view these gaps comprise an insufficiency of norms or rules to address matters that companies must address but which they cannot supply for themselves on their own and which governments cannot or do not want to develop. This largely explains the emergence, in the early part of the twentieth century, of technical standardisation bodies whose mission was to supply the specifications, which enabled companies to rely on standardised components, first in manufacturing and, more recently in management processes, thus facilitating business and trade. In this context, we can see technical standards as a significant, albeit private, component of the regulatory environment. Such standards typically provide clear specification as to requirements in the sector involved, even though, from a formal perspective, their adoption is voluntary.

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Private governance regimes now extend well beyond national and transnational technical standardisation bodies to areas such as the environment, employment, consumer markets, computer security and financial markets. In other words, the remit of the decisions by (and the mandate conferred upon) standardisation bodies has scaled up from affecting specific elements only of a normative regime to now shaping and determining entire regulatory (transnational) systems. They do not wholly replace public governance and there is frequently an explicit relationship between public activity and private rules.

This paper first addresses and explains the concepts associated with the emergence of transnational private regulation. Second, it explores the emergence and effects of transnational private regulation through three brief illustrations in financial markets, food safety and forestry that provide a rationale for the emergence of transnational regimes and/or innovative risk governance. The paper then investigates the various forms of relationship between transnational private regulation and governmental and intergovernmental actors. Finally, some conclusions are offered in respect of the relationship between transnational private regulation, innovation and risk. The paper does not seek to appraise the adequacy or effectiveness of any given regime. Rather the paper describes and outlines reasons for the emergence and functioning of such regimes, with a focus on how the latter can advance risk regulation in modern times.

1. Towards a definition of the notion of transnational private regulation

Transnational private regulation is a key example of innovative governance, which increasingly is shaping market practice. Indeed, the challenge is to explain why transnational private regulation has grown in importance and prominence in recent decades. This section elaborates on the three constitutive elements of the term “transnational private regulation”.

1.1 The evolutionary regulatory context

The first constituent of the term relates to regulation. The concept has gradually established itself as a significant form of governance. An influential definition speaks of the sustained oversight of activities valued by the public by reference to rules (Selznick, 1985). For many, this classic definition conjures up the image of independent regulatory agencies of the kind that were developed notably in the United States during the twentieth century.[2] Canadian scholar John Willis noted that such agencies, popular also in Canada, were ‘governments in miniature’ because they had the capacity to make rules (a legislative task), monitor compliance with rules (an executive task)

[2] One might think, for instance, of the Securities and Exchange Commission and the Food and Drug Administration. The extent to which these agencies are “independent” of the Executive (the President) is a subject of considerable debate (Datla and Revesz, 2013).

and enforce rules (a judicial task) in such a way as to combine all the governmental functions (Doern and Schultz, 1998; Willis, 1958). The intrinsic lack of capacity by legislators to perform expert analysis and hence deliberate on many technical implementing risk regulations has been widely acknowledged in modern government. However, noting the rise of the regulatory state in Europe from the 1980s, it became clear that, contrary to US experience and practice, there was more caution elsewhere in delegating such extensive governmental functions to independent agencies. By contrast, agencies established in European states have typically more limited powers, because of both historical and legal restrictions on the delegation of regulatory powers.[3] Commonly, though not universally, rulemaking powers have been reserved to legislatures, and formal enforcement powers to courts.

The classic model prompted an understating of regulation as a governmental function exercised by public bodies: independent agencies, or a combination of legislature, agencies and courts. As interest in regulation has grown, it has become apparent that, whilst government regulatory regimes, however comprised, may exert important control over businesses (and also others, including NGOs and government itself (Hood et al., 1999)), the control environment in which all manner of organisations operate is not limited to government oversight (Scott, 2004). For many organisations, self-regulatory bodies constitute an important mechanism for setting and enforcing rules (Ogus, 1995). Less formal norms exerted through professional bodies and communities may be important, constituting a form of 'order without law' (Ellickson, 1994). We may even find market mechanisms exerting a form of regulatory control (Marx, 2008).

These insights about the diffuse forms of control which are exerted on organisations led scholars to reconceive regulation from its former rather institutional-specific formulation into a more generic and comprehensive notion. Accordingly, regulation has been defined as a mode of control which comprises not only norms, rules, standards or objectives, but also various mechanisms that supply feedback on compliance with the norms, as well as processes for correcting deviation in behaviour (Hood et al., 2001). Thus agency regulation is an example of where agencies not only set rules, monitor and enforce them, but also where they recognise a wide range of other modes for drawing up standards, providing feedback and correction, including both formal and informal social processes, and possibly market mechanisms. Taking this approach we can recognise that few environments are free of regulation in this broader sense, and a decision of government not to engage in formal public regulation is most likely to leave control to a mix of social norms and market mechanisms (such as contracts).

[3] What pertains the EU-level, reference can be made here to the reluctance by EU Member States to confer further regulatory competences to supra-national bodies (the EU agencies) and their preference to retain control over EU technical regulation through a system of committee-based governance. The so-called "Meroni doctrine" on non-delegation of decision-making powers to de-centralised bodies draws from that concern.

1.2
The nature and scope of private regulation

The second element of the term refers to its private character. Because of the evolving context mentioned above, private regulation assumes a more important role in contemporary governance than might previously have been expected. Companies create norms specifically for their own employees, which are monitored and enforced through contractual relationships (Parker, 2002). Such in-company regulation may often be quite informal in character, even though it has the 'capacity to harden', for example when addressing issues of underperformance or misconduct. Similarly, the measures taken by companies to address corporate social responsibility issues can be characterised as a form of in-company regulation, especially when they are orientated towards developing and implementing norms which address an aspect of company performance in respect to such issues as the environment or equality (Parker, 2007). Demonstrating a capacity for regulatory innovation, governments have become increasingly interested in how companies may contribute to meeting public objectives through corporate social responsibility programmes and have sought to encourage them, for example through mandatory reporting requirements.[4]

The scope of private regulation and its implications are not to be conceived narrowly. On the one hand, private regulation encompasses not only in-company regulation but also a wide range of mechanisms by which standards are set, monitored and enforced through private organisations (Scott, 2002). Self-regulatory or associational regimes emerge where a group of organisations agree to create an association with rules and feedback and enforcement mechanisms (Buthe and Mattli, 2011; Black, 1996). Professional bodies operate in a similar manner. Whilst associational regimes are founded on a form of collective contract that binds the members, bilateral contractual relations can also be used to embed rules set by the parties or introduced by a third party organisation. In practice, such contracts, operated through supply chain contracts and often with third party certification, are extremely important mechanisms for giving effect to rules set down by private organisations, including technical standardisation bodies, associational regimes, and others (Cafaggi and Iamiceli, 2014). We might, of course, expect such bilateral arrangements to reflect the interests of one or both of the parties to the arrangement. In some instances, such provisions are liable to reflect a wider public interest (for example contractual specifications that products are safe or that they should comply with a particular technical standard).

A key challenge for governments which might seek to depend on such contractual regulation is to recognise the conditions under which there is an alignment between public and private interests (with the consequence that no further public regulation is required) and the conditions where private and public interest diverge, requiring public intervention (for example on competition, environmental or consumer protection grounds).

[4] An example is the EU Directive 2014/95/EU on disclosure of non-financial and diversity information by certain large undertakings and groups.

On the other hand, increasingly, the in-company and contractual (collective and bilateral) modes of private regulation have an impact on a wider range of actors and organisations and not exclusively those who are, in a sense, volunteers to the regime. Where third parties are affected by such a private regime to which they are not party, this is potentially problematic as such third parties have no capacity to shape the regime or to decide whether or not to accept it (Scott et al., 2011). Thus many private regimes are established by industry or NGO actors or some combination of the two, with an identity which is autonomous from any particular organisation, and which determine rules and processes for organisations well beyond the scope of their own organisations.

Technical standardisation bodies provide a key example. Firms and other representatives may participate in the process, but many, perhaps most of those who adopt the standards, do not participate in the decision-making and need have no link with the standard-setting organisation. To an even greater extent those who benefit from the standards, such as those who purchase the products, have no involvement, whether directly or indirectly, in drawing up the standards. Increasingly, organisations addressing matters such as environmental protection, employment and human rights are autonomous from those for whom they create the standards, with distinct corporate identity and motivations, but also from those who benefit from the standards.

If such private institutions do not have legislative backing and are not contractually linked to those for whom they write the standards, the question then arises about the effectiveness and binding character of the rules these institutions issue. Answers are varied. In some cases, private standards are adopted by governments in their practices or through legislation (as with some technical standards and financial standards) (Scott, 2002). In other cases effectiveness is dependent on organisations deciding voluntarily to adopt the standards and implement them in-company and/or through specifying them in contracts. In practice, supply chain contracts are very important for giving effect to a wide range of technical and other standards (Cafaggi and Iamiceli, 2014).

1.3
The scale of application of the regime

The third definitional component of transnational private regulation is the transnational element. This concept is simply explained as describing a regime which crosses national boundaries in its effects but is not public or governmental in origin (Scott and Wai, 2004). Thus transnational activity is contrasted with international governance, the latter occurring between nations and engaging sovereign governments, for example in making and implementing treaties (Scott et al., 2011).

The scope of transnational private regulatory regimes is very broad, with prominent examples found in the many transnational technical standardisation bodies, food safety, advertising, financial markets and environmental protection. Equally, the form such regimes take is quite diverse. Some consist of associations of members (such as the group of national advertising

self-regulatory bodies, the European Advertising Standards Alliance) whilst others originate from NGO activity and draw in industry and NGO members, such as with the Forest Stewardship Council. Each regime can be characterised as constituting a community of actors, and in each case the regimes face not only technical challenges in undertaking their mission, but also legitimacy challenges in justifying their governance actions and subsequent effects on members and third parties (Kingsbury, Krisch and Steward, 2005; Cassese et al., 2012).

2. Emergence and effects: three cases

This section presents brief illustrations in financial markets, food safety and forestry that provide a rationale for the emergence of transnational private regulatory regimes. In some instances, such regimes have emerged to address market coordination problems, where cooperation over standards facilitates market activity. A second rationale for the growth of private regulation lies in concerns about the adequacy and appropriateness of national public regulation for addressing (transnational) risks, especially those labelled as 'systemic risks', marked by international networks, complexity and cascading effects. In these cases, transnational private regulation seeks to impose standards on market actors that go beyond public law requirements, or aims to improve implementation. A third rationale for the emergence of transnational regimes is that of building community solidarity around social objectives at a level greater than that able to be adopted by national governments.

The first two of these rationales address what are primarily market-based concerns. The final one uses various forms of activism to promote adoption of social or community concerns in market settings. In each case the market is of fundamental importance in explaining both the reasons for, and modes of, adoption.

2.1
Market coordination problems

The first case presented in this paper lies in the development and adoption of standards to facilitate market activity. The development of technical standards processes from the early national standardisation bodies, established in the first quarter of the twentieth century, to the creation of an elaborate architecture involving thousands of standardisation bodies with hundreds of thousands of participants in their activities, is directed at providing the conditions for efficient trading and contracting for the supply of products where there is a high degree of specialisation and differentiation of tasks (Brunsson, 2000). Complex manufactured products, for example, may involve dozens of different producers in developing and producing components and manufacturers need to be assured that whoever they buy from, the components they purchase will meet their needs through compliance and a standard specification.

The case of financial markets

Equally, in the area of financial markets, there is a need for reliable standards. A prime example is that of the market for derivatives that emerged as a mechanism for hedging financial risks and which, over time, became a source of systemic risk to the financial system. The issue of reliability with derivatives transactions concerns the terms on which they are written. The parties require certainty concerning what they have agreed; what events will trigger payments contractually; what the effects will be under interlinked agreements; and, in particular, whether the intention of the parties to net the effects of their agreements will be honoured. In the absence of any public regulation of such agreements, the parties write their own contracts. Starting from scratch is both costly and full of uncertainty. The International Swaps and Dealers Association (ISDA), comprising the major dealer banks, was established in the 1990s and amongst its core activities has been drafting the standard terms on which derivatives contracts are made, the ISDA Master Agreement. It is not compulsory to use the Master Agreement, but ISDA is very active, in a number of ways, in ensuring that through drafting, usage and interpretation, its terms should, as far as possible, be predictable for the parties. ISDA may imply that they are not a regulatory body since the standards in the Master Agreement are not mandatory, and implementation and enforcement are matters for the parties. However, it has progressively become clear that the Master Agreement is the de facto in terms of business. Its effects on third parties, including states (for example in respect of derivatives linked to sovereign debt), are such that the role of ISDA goes beyond that of simple setter of technical standards. Indeed, it has an overview of the entire life of transactions and of their terms and enforcement (Biggins and Scott 2012).

2.2
Lack of adequacy and appropriateness of national public regulation: the case of food safety

If technical standardisation is more concerned with market settings where the state has no significant role in drawing up standards, there is another set of conditions where state involvement is significant but inadequate. When, due to insufficient standardisation, public regulatory rules are inadequate or badly implemented, producers run the risk of damaging their reputation and losing sales because of diminished confidence in their products. As from the 1980s a series of scandals involving food products, such as the BSE crisis in Europe in the 1990s or the outbreak of E.coli infection in Germany in 2011, left major food retailers in Europe feeling that the food regulation regime in the member states of the EU, some of which has EU components, was insufficient to create confidence in food products. The industry response was for larger retailers and other key stakeholders to establish a number of standardisation bodies which initially imposed safety standards on producers, wherever they were located within or beyond the boundaries of the EU. These standards are implemented through supply chain contracts and processes of accreditation for producers (Fuchs et al., 2011).

A key example is provided by GlobalGAP[5], established in the 1990s by major European retailers, a forum for setting detailed standards for food products and agricultural practice. If, initially, the group was rather informal, it has progressively constitutionalised itself and drawn into its decision-making a wider range of affected parties, notably food producer representatives. Additionally, it has introduced certification procedures to ensure compliance (Casey, 2009). Thus, over time, the regime has progressively increased its share of those affected by its decision-making as a means to bolster legitimacy through a more democratic structure. In recent years, its reach has been such that GlobalGAP is regarded as jointly empowering producers and retailers. This contrasts with some other regimes which remain retailer dominated (Fuchs et al., 2011).

For retailers who impose GlobalGAP standards on producers, compliance is a condition of contracting and thus a prerequisite for trade. Accordingly, the scope of GlobalGAP activities affects not only supply chain contracts but also trade in general. The appropriate treatment within the global trade regime of private standards, not just in respect of food, but also in respect of other social matters such as the environment and labour rights, is controversial. For some, the solution is to seek to regulate private standards in the same way as public legislation would be controlled if it constituted a barrier to trade. For others, socially constituted standards, though they may affect trade, are a product of community and market actions, and should be accorded a separate space, distinct from the trade regime which regulates attempts by states to protect their producers (Bernstein and Hannah, 2008).

2.3 Building community solidarity around social objectives: the case of forestry

A third case concerns the conditions where market actors are content with public standards and, broadly, seek to comply with, but not exceed them. However, social actors such as environmental NGOs and trade unions strive to adopt more stringent standards on a transnational basis. Given the importance of companies in implementing voluntary standards, these conditions appear unpromising for effective transnational private regulation (Bartley, 2007). However, it has proved possible for NGOs and other social actors to develop both the more stringent standards and market salience for them, to the point that companies have felt it in their market interests to adopt them. By doing so, companies are able to preserve or enhance reputation and thus strengthen their market position (Cashore, 2002). Under pressure from civil society actors, such an exacting adjustment of standards by market actors can be defined as a form of community solidarity.

From this solidarity perspective, transnational private regulation regimes may also address risk, both to companies and to broader society alike. Whilst national governments may be inhibited to adopt more stringent standards for environmental protection and labour rights by fear of national competitiveness, transnational regimes are able to persuade multinational enterprises to take up such standards across their enterprises, thus raising standards transnationally above public norms.

[5] www.globalgap.org/uk_en

A key example of such a phenomenon is provided by the growth in importance of the Forest Stewardship Council (FSC), whose standards on sustainable forestry have been taken up by many larger retailers and applied throughout their transnational supply chains. This is a central example of such socially driven private regulation. A number of regimes have developed over the past two decades, some led by NGOs and others, responding to the NGO regimes, that have a more substantial industry involvement. The FSC, which the World Wildlife Fund (an international environmental NGO) helped establish, provides a significant case (Cashore et al., 2004). The FSC developed standards during the late 1990s and sought to have retailers join their scheme and to sign up to incorporating its standards in their supply chain contracts.[6] The key issues for the FSC regime, similarly to GlobalGAP, concerns how it manages decision-making processes over standards and their implementation and the distributional effects of its regime within the forestry sector (Taylor, 2005).

3. Evaluation of transnational private regulation in relation to risk and to public policy

Risk is a major organisational concept, both for contemporary business and for society at large. Risk is not straightforward to define since it is the combination of the probability and the impact of an adverse outcome. In a recent guide to the vocabulary of risk, the International Organization for Standardization (ISO) offered a simple definition of risk as 'the effect of uncertainty on objectives' (ISO, 2009). Increasingly, organisations of all kinds seek to identify the risks they face so that they can reallocate them (for example through contracts), manage them (for example eliminate them) or, when they cannot be reallocated or eliminated, insure against them.

Regulation is used both for curbing risky activity (for example nuclear power, factory safety and so on) (Hood et al., 2001), and for deploying risk-based analysis to determine the appropriate allocation of resources, for example in considering frequency and stringency of inspections (Baldwin and Black, 2010). For businesses, regulation may be classed as a source of risk that, over and above the detection of breaches, is far more centrally concerned with mandated changes to the operating environment faced by business as, over time, regulatory objectives change in response to changing social or political preference.

Increasingly, regulation is concerned as much with the oversight of risky activities as with the efficient operation of markets. Contemporary risk challenges, for which regulation forms a significant part of the response, include the management of systemic risk – for instance in relation to the adverse effects of anthropogenic climate change; of potentially catastrophic accidents in nuclear power production; and the complex interdependencies in financial markets within a globalised economy.

[6] Similar experiences can be found in other sectors, such as the fishery industry in the form of the Marine Stewardship Council.

A core feature of some modes of transnational private regulation is that businesses and other actors may take on a central role in defining both the objectives and the implementation of the regime. Real world observation suggests that many regimes are centrally concerned with addressing risks. These can include those activities that are inherently risky such as food production; they can arise from activities which generate climate risks, such as forestry; and from those which generate risk because of uncertainty and market imperfections (e.g. in the financial market sector). Thus the numerous private food standards regimes, of which GlobalGAP is a key example, provide a core supplement to public risk regulation over food. Equally, regimes targeted at sustainable forestry constitute a core part of the measures taken to address risks associated with climate change. The ISDA Master Agreement provides a core example of addressing uncertainty. It puts the central focus on being able to establish and test the standards that govern derivatives instruments so that they may be reliably and predictably deployed.

The private regimes that target risky activities also generate risk for businesses. At the extreme, businesses that do not participate, or do not participate effectively, in socially driven regimes concerned with matters such as employment rights or climate change may find they are not able to participate in the market at all, or that reputation and sales suffer as they are identified as a cause of the problem rather than constituting part of the solution. Hence, there is a strong incentive to enter into collaborative agreements among private actors, as also argued by Terry Yosie in this publication. Much of the contestation around socially driven regimes of private regulation is concerned with creating a situation where, due to reputational and market damage, the risk to business in adopting a progressive (and perhaps costly) regime concerning environmental issues or labour rights, is lesser than that of not participating. The Forest Stewardship Council provides an example of a campaigning regime which has progressively persuaded more companies to take on its standards through direct action. It highlights the adverse effects of poor forestry practices (Meidinger, 2003). Facing such campaigns, companies have concluded that the less risky option is to adopt the regime.

Whilst transnational private regulation is defined by its non-governmental character, governments and inter-governmental organisations may be involved in such regimes. Many regimes may be characterised as hybrid, in the sense that public bodies engage in observing and, in some cases, either delegating the making of standards, or adopting standards that have been drawn up through a number of mechanisms. Governmental and inter-governmental organisations are increasingly involved in observing environmental, food, consumer and financial standardisation regimes that operate through private regimes. The European Commission, for example, has taken a close interest in private advertising regulation regimes in the EU and has sought to bolster their standing within national settings so that they may, at least implicitly, hold a place in key regulatory delegations (European Commission, 2006). As a result, the European Commission has set up a ‘community of practice’ concerned with self- and co-regulation as a means to engage all the stakeholders involved in support of both the legitimacy and effectiveness of such private regulation across a wider range of policy areas.

Conclusion

The purpose of this paper was to provide an overview of transnational private regulation, why and where it can be relevant. Whilst private regulation has emerged as an important component of contemporary regulatory governance generally, and risk regulation in particular, there are clear limitations associated with it. First, in some areas, such private regulation may lack the legitimacy to command wide support from market and social actors. Equally, there may be a lack of effective capacity in some transnational private regulatory regimes. There is increasing evidence of these issues being addressed, for example through umbrella organisations such as ISEAL-ALLIANCE (Loconto and Fouilleux, 2014) which offer both capacity and legitimation.

The question of the contribution of transnational private regulation to risk regulation yields a variety of answers because of the wide range of regime types and of their differing origins. Within the coordination type regimes, market issues around risk and innovation could be addressed effectively since the coordinating standards are designed to reduce risks through standardisation. This issue is reflected in debates over standards that regulate matters such as mobile phone networks, video players and computer operating systems. Research on standardisation suggests that a successful standard may not be the most innovative, but rather one which, for reasons other than innovation and effectiveness, secures wide take-up or rewards performance without creating lock-ins to existing technologies or practices. The classic example is the standardised QWERTY typewriter keyboard, which was not ever necessarily the most efficient layout, but has survived into a period where its rationale is long gone because of its ubiquity and the costs of re-learning that would be associated with adopting what might only be a marginally more efficient layout (David, 2001).

The case where public rules are deemed inadequate and are supplemented presents greater challenges for risk. In some cases, transnational private regimes may address risky activities, driven by market actors, to supplement inadequate public regimes. Where well constituted, such regimes may permit market actors to engage their concerns, possibly tackling issues effectively with greater efficiency than could be achieved by public regimes. However, there are always likely to be concerns that such private regimes derive from the market power of key companies, and that they may be used to further enhance market power of these key companies over other actors, whether suppliers or competitors. Thus they represent competition risks to which, increasingly, national competition authorities will need to be attentive.

Socially driven regimes have gradually emerged to address risks associated with environmental issues and with employment rights in transnational settings. These regimes have varying degrees of company involvement in their founding, but they all provide an opportunity to address substantive risks and to engage with important reputation-associated market risks of a social nature. Such regimes represent both a risk and an opportunity. Recognising this factor, competing companies have entered and shaped regimes across a variety of social issues. Such competition between NGOs- and company-led regimes, for example in forestry and labour rights, is likely to be a source of

regulatory innovation, as the various organisations learn what kind of standards are most able to meet the policy objectives and be readily capable of implementation by the firms involved. In this context, because of the more direct participation and market testing of the regime whether in its origin or its implementation, private regulation has the potential to better fit the requirements of innovative markets than traditional public regulation. As it will be apparent in further contributions to this publication, the interaction between private sector actors and NGOs can evolve from (constructive) competition into a more comprehensive joint action. Whatever shape it takes, the question of the effect and impact of private regulation as compared to public regulation is becoming more important both for public and private organisations. If we are to address the problems that contemporary risk management poses us, it is time to devote to this under-researched agenda the full attention it deserves (Loconto and Fouilleux, 2014; Radaelli and Fritsch, 2012).

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EMERGING STRATEGIES TO MANAGE SYSTEM-LEVEL RISKS

AN EXAMINATION OF PRIVATE SECTOR, GOVERNMENT AND NON-GOVERNMENTAL ORGANIZATION INITIATIVES

by Terry F. Yosie[1]

Escalating global megatrends generate new sources of risk to public health and the environment, and present challenges to the effectiveness of existing regulatory processes and management of global companies. Collaboration between non-governmental organizations (NGOs) and leading global companies has intensified leading to a better understanding and management of these risks at local, regional and global levels. Such collaboration is yielding insights into the scale of risks, new governance models, opportunities for innovation, and specific risk management strategies that incorporate sustainability. Discussion of these inter-related issues can generate important information and case studies for the design of future regulatory strategies by: modifying the scope and locus of decision-making, improving scientific tools and methods, identifying opportunities for collaboration across government, NGO and private sector institutions, and developing a future research agenda.

1. The changing context of risk

For several decades, academics, policymakers, business managers and non-governmental organizations have taught, designed and implemented regulatory policies and corporate practices to assess, mitigate and manage individual public health and environmental risks or discrete clusters of risks. The risk agenda has ranged from exposure to individual chemicals (e.g., trichloroethylene in ground water) to groups of inter-related chemical families (e.g., dioxins in soils, or the atmosphere, or the release of ozone-depleting compounds that reach the stratosphere). The many successes in ameliorating the management of such risks have become the foundation for regulatory policy and corporate management systems as well as the international certification standard ISO 14001 developed by the International Organization for Standardization.

More recently, the emerging knowledge of global megatrends related to climate change, water scarcities, challenges to expanding food production,

[1] President & CEO, World Environment Center, www.wec.org

changes in disease vectors, loss of biodiversity and other effects associated with a globalized economy, expanded global population and an increasing middle class has begun to transform the understanding of risk. This changing context of risk, as displayed in Figure 1, developed by the World Economic Forum[2], recognizes several important factors:

- Risks co-exist simultaneously at the local, regional and global levels.
- Economic, geopolitical, environmental, societal and technological risks increasingly co-exist and migrate outside their own boundaries (e.g., water shortages contribute to political conflicts, then failure to invest in infrastructure contributes to water-borne diseases or exacerbation of storm surges and flooding that, in turn, lead to disruptions in the electricity supply).
- Managing inter-connected risks effectively requires the development of new decision-making frameworks and institutional capacity and new types of regulatory arrangements based on collaboration across value chain participants.

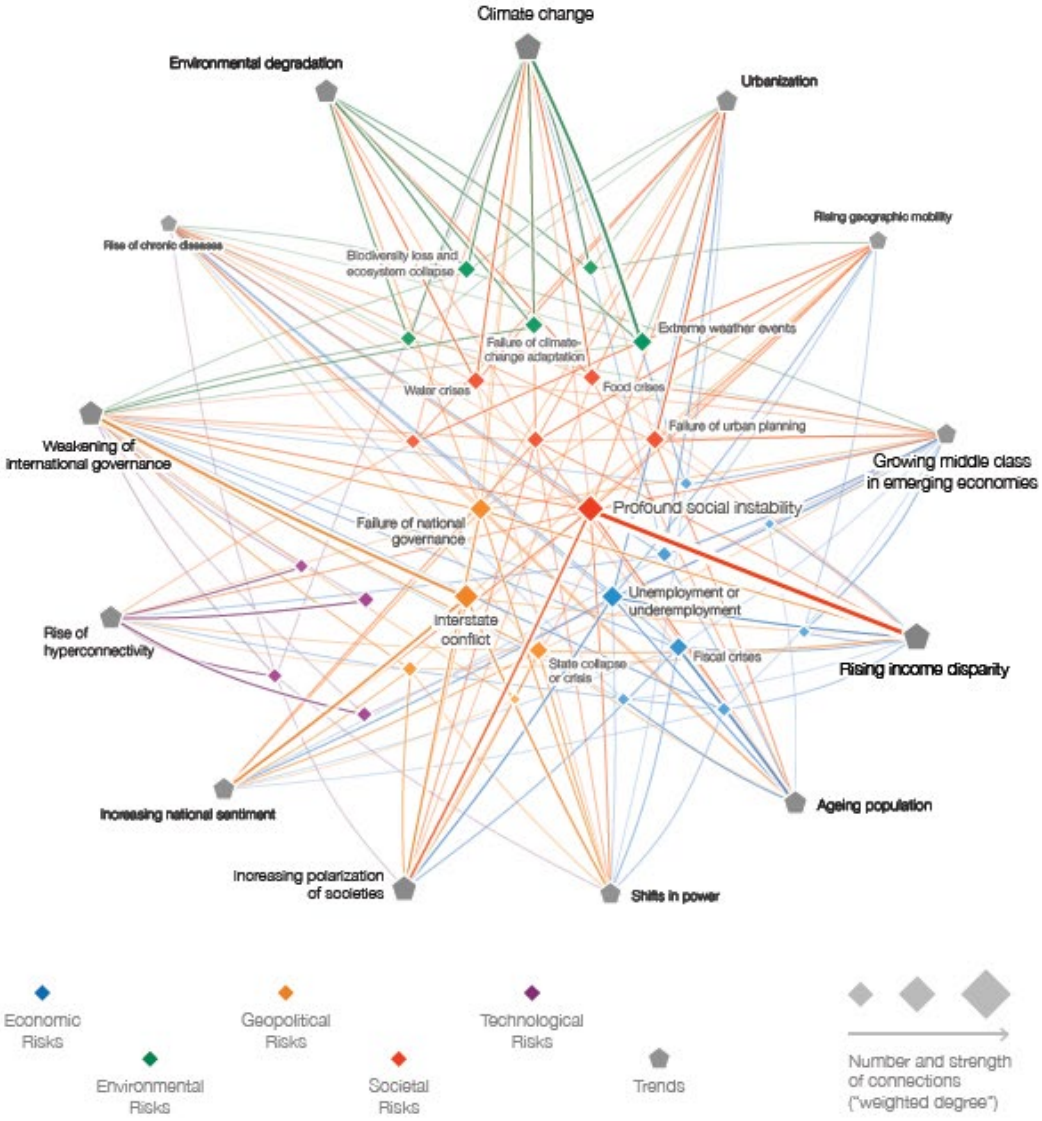

Figure 1: Global Risk Perception Survey 2014, World Economic Forum. Survey respondents were asked to select between three and six trends and to identify for each the risk they believe is most interconnected.

[2] www.weforum.org/globalrisks2015

The transformation of these and other risk characteristics greatly contributes to the growing complexity of decision-making and the potential for disruption at differing levels of scale. Irrespective of whether the risks manifest themselves in turbulent financial markets, the transmission of the Ebola virus or the ability of terrorist groups to fill political vacuums in failed states (e.g. ISIS in the Iraqi and Syrian territories), they have transcended existing decision-making frameworks and institutions and have evolved into broader system-level challenges.[3]

2. Tools and methods for managing system-level risks

System-level thinking and governance in public, private and other non-governmental institutions that have to manage environmental, health, safety and sustainability risks are considerably aided by the emergence of new sets of tools and analytical frameworks. These include:

- End-to-end traceability of ingredients or compounds that provide a system-level view of their movement across supply chains and markets and identify potential risks. For example, traceability systems utilize information technologies that 'track and trace' the sourcing, production, processing, distribution and use of food ingredients from 'farm to fork' to provide a better understanding of growing practices, disease prevention, steps to prevent spoilage and waste and increase consumer safety. The use of traceability sensors that are embedded across these functions provide private companies, regulatory agencies and consumers with additional information to make their individual decisions 'smarter' and timelier. In the US, the 2010 Food Safety and Modernization Act provided the Food and Drug Administration with increased authority and capability to implement such traceability systems. An example of the application of a traceability system in the food production sector is provided in Figure 2.

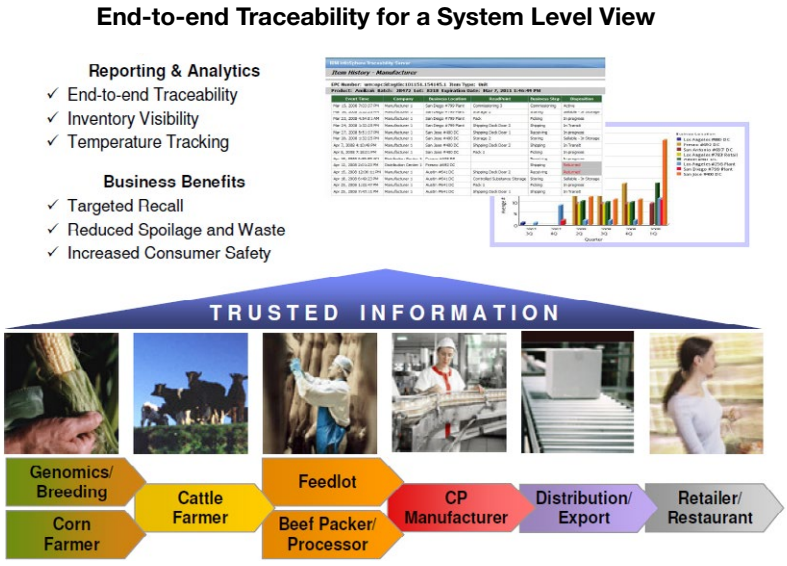

Figure 2: IBM-World Environment Center, Innovations for Environmental Sustainability Council Workshop, February 2012

Traceability technologies, and the data reporting and analytics that result from them, are finding increased and more diverse applications across a range of business functions. They include chemical companies that seek to prevent the diversion of chemical products into weaponry; pharmaceutical producers committed to preventing the development of counterfeit drugs and medical devices; automotive and technology companies that have to manage thousands of sourced materials in the production of cars

[3] Terry F. Yosie, "Rethinking Governance for a Changing World," www.greenbiz.com, April 18, 2013.

or mobile phones and ensure a robust recycling system for the afterlife of product components.

- Emergence of value chain analysis. A value chain consists of the economic participants involved in the creation and use of a product or service. The functions involved in a value chain include: product or service design; sourcing and storage of raw and processed materials; procurement of goods and services from suppliers; manufacturing, packaging, distribution and logistics for produced goods, customer/consumer use; and re-use or recycling of the goods, materials and waste for the product afterlife. As an illustration, Figure 3 presents the value chain for the natural gas sector. In recent years, as concerns about the adequacy of food supplies, water and other essential materials have emerged, business managers and policymakers have focused their attention on leveraging value chains for sustainability objectives. Companies such as Marks & Spencer and Unilever, for example, have applied a value chain approach to estimate and offset their global greenhouse gas releases. Such analyses build upon the evaluation of their respective carbon and water footprints and have informed corporate goal setting, development of strategic initiatives and collaboration with other business partners and stakeholders. The US Environmental Protection Agency's proposed controls of greenhouse gases for existing power plants has also utilized a value chain approach for reducing pollution.[4]

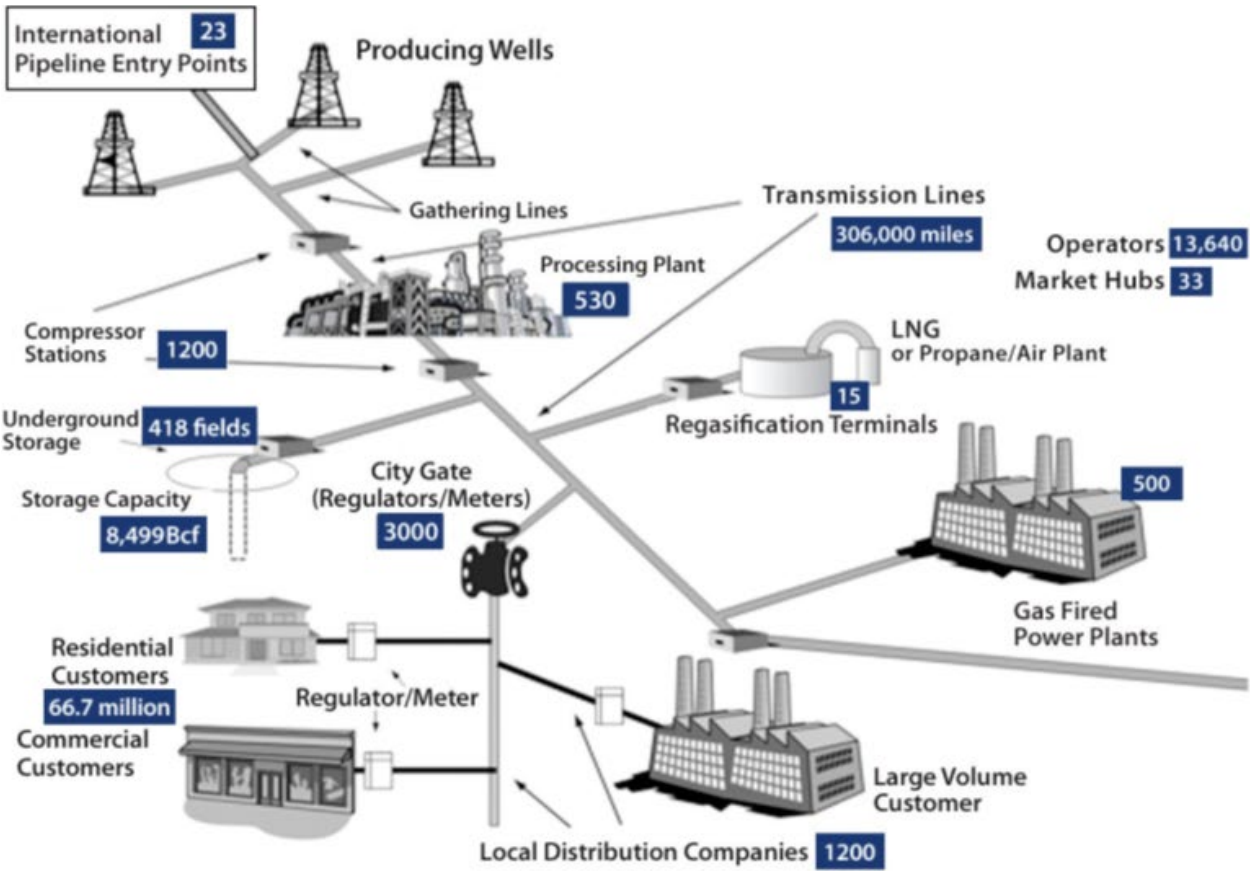

Figure 3: The natural gas infrastructure in the United States, Massachusetts Institute of Technology, 2010, p. 59.

[4] Yosie T. (2015), "The Marketplace as Policy Innovator," in The Environmental Forum (January-February), www.eli.org

- Expansion of financial and sustainability reporting. For decades, the standards for corporate financial reporting have focused on 'material' issues: those issues that impact, or are reasonably expected to affect, company decisions, including liquidity, capital resources, operational performance and broader reputation. Such reporting parameters shape both business planning and disclosure to shareholders. More recently, environmental and sustainability reporting has begun to incorporate aspects of materiality as it has an influence on the economic, environmental and social impact of a company. These 'materiality assessments,' as recommended by the Global Reporting Initiative and other entities, survey both internal and external stakeholder expectations concerning issues such as: risks facing the company; business priorities; and future performance outcomes. A growing number of companies have decided to integrate their financial and sustainability reporting to acquire a more systemic view of risks and opportunities and to strengthen the understanding of the relationship between sustainability and business strategy among senior managers and executives. The evolution of more formal processes and standards for integrated reporting, such as those being developed by the Sustainability Accounting Standards Board (SASB), will provide a further incentive to achieve integrated reporting and to embed sustainable development more formally into the corporate governance process.[5]

The National Research Council of the US National Academies recently issued a report evaluating a broad array of existing and emerging tools and methodologies for improving the policy frameworks of environmental sustainability. The recommendations of the report are based on an examination of global megatrends, private sector case studies and an evaluation of collaboration initiatives between non-governmental organizations and global companies. A major purpose of the report, funded by the US Environmental Protection Agency (EPA), was "to strengthen a system-thinking approach" by EPA.[6]

3. Emerging strategies to manage system-level risks

An examination of strategies to manage system-level risks reveals an increasing degree of experimentation across government, business institutions and NGOs to develop programmes and initiatives that can be scaled to the level of the problems presented. These efforts are also noteworthy for their innovations in areas such as the scale of collaboration with independent partners; emergence of improved governance processes; and the thought leadership agenda. What follows are a set of examples that illustrate the transition towards managing system-level risks.

[5] See, for example, the recommendations being developed by SASB, www.sasb.org

[6] National Research Council (2014), Sustainability Concepts in Decision-Making: Tools and Approaches for the US Environmental Protection Agency, US National Academies.

3.1
Coca-Cola's global water strategy

Because water is the single largest resource utilized in the company's supply chain, a resource that is under increasing pressure, the company began to assess water-related risks in its business more than a decade ago. In 2004, it conducted a qualitative assessment of water risks to individual business units. The risk portfolio included wastewater compliance, water supply economics and efficiency, water resource sustainability and supply reliability, and societal risks. This initial assessment was followed by a more detailed, plant-level quantitative risk assessment prepared in 2005 and 2008-2009.

From these evaluations emerged the conclusions that Coca-Cola needed to manage water risks as part of a core business framework that included four elements: plant performance, watershed protection, sustainable communities and global awareness and action. It developed specific goals and made them public to improve water efficiency 20% by 2012 using a 2004 baseline; recycle 100% fully treated effluent water; by 2020, replenish water supplies to communities and watershed to the same level as they had been withdrawn; achieve more sustainable water sourcing plans for all plants by 2012; and integrate the company's supply chain – encompassing water use, soil health, biodiversity, and sugarcane production – into its water strategy.

To implement these and other initiatives, Coca-Cola developed a series of partnerships with organizations that had strong technical capabilities, on-the-ground presence in major watersheds and markets, and global scale. These partners have included the US Agency for International Development, the United Nations Development Programme, the World Wide Fund for Nature (WWF), The Nature Conservancy, the International Finance Corporation, and the Global Water Challenge. The company periodically provides public updates on its performance for each of the major global water strategy elements.[7]

3.2
Unilever's Sustainable Living Plan

Unilever is a global consumer products company that, beginning in November 2010, has committed to decoupling its future growth from environmental impacts, while increasing the benefits of its products and other activities to society. Through the Unilever Sustainable Living Plan (USLP), the company is seeking to achieve three large goals supported by the attainment of nine specific commitments by 2020. The three goals include: 1) helping more than one billion people take action to improve their health and well-being; 2) reducing environmental impact by halving the greenhouse gas impacts of its products across the lifecycle, and achieving a 50% reduction in water consumption associated with the consumer use of its products; and 3) enhancing livelihoods.

As part of its analysis of global environmental risks and challenges, Unilever has conducted a global carbon footprint analysis. Its 2014 analysis reveals that only 8% of the company's global carbon footprint is attributable to its own operations (manufacturing, transport and retail operations), while another 1% results from the disposal of waste. Approximately 21% of emissions result from upstream sourcing of raw materials, and 70% of emissions are attributed

[7] www.coca-cola.com/sustainability

to consumer use of Unilever products (resulting primarily from energy used in heating water for showers or cleaning laundry).[8]

Because so much of Unilever's global carbon footprint is not directly within the company's management control, it has evolved a strategy to collaborate with both consumers and upstream business partners and suppliers to offset and/or reduce greenhouse emissions. Specific initiatives include:

- Integrating sustainability into the company's multiple brands as a means to educate and ultimately transform consumer behaviour.
- Developing carbon offsets by protecting biodiversity and changing agricultural practices.
- Collaborating at market scale with other consumer goods and retail companies through the Consumer Goods Forum for the phase-out of hydrofluorocarbons, a potent class of greenhouse gases used in refrigeration, by 2015.

These and other steps are often either incremental or experimental and assist the company in learning how to develop more innovative products and achieve sustainability results at a greater scale. Moreover, its USLP provides Unilever with the ability to demonstrate shorter-term successes, while building momentum with its employees and consumers for larger scale changes that will also involve transformation in consumption patterns and behaviour.[9]

3.3
WWF and the transformation of risk governance

WWF, a global non-governmental organization, has invested many years in research, collaborative efforts with the private sector and development institutions, and public policy advocacy to address the inter-related issues of population growth, food production and the world's natural resource base. From this work has emerged a rising level of concern about the stewardship of planetary resources and, in particular, the ability to provide sufficient food supplies for a global population expected to reach 9 billion people by the year 2050.

Several key assumptions underlay WWF's recent efforts to manage the global risks of insufficient food supplies. They include:

- Population growth that, per se, is not the principal defining issue for maintaining sufficient food supplies in the future. Rather, increases in per capita income levels are driving current and future food consumption (and the kinds of food being produced). The speed of global change in food consumption is the game changer.
- The world has not yet experienced the full impact of increased demands from India for natural resources, and manufactured and consumer goods.
- Governments at the national and international levels have proven ineffective at managing the necessary steps (e.g., eliminating water subsidies,

[8] Unilever Sustainable Living Plan Update (2014), Scaling for Impact Global Summary, "Unilever's Greenhouse Gas Footprint," p. 5.

[9] For an update on the Unilever Sustainable Living Plan, please refer to www.unilever.com/sustainability.

adopting policies that reflect the true cost of food production, preventing soil erosion) to ensure that food production can be sustained over the longer-term.

One innovative approach in thinking about the challenge of feeding a world with 9 billion people is to redefine it as an opportunity to transform risk governance. Jason Clay of WWF and his colleagues have examined the multiple complexities of food production in the marketplace and concluded that there are multiple leveraging opportunities for introducing a sustainable production of key food commodities. For example, a number of the world's major food commodities (e.g., beef, cocoa, palm oil, sugar, salmon) are produced, processed and marketed by a relatively small number of very large companies. Many of these companies co-exist in common food value chains and, thus, have pre-existing business relationships with each other, or they possess detailed knowledge of each other's operations because they are competitors. Figure 4 illustrates the participation of major companies in key food commodity sectors.[10]

Figure 4: Participation of major companies in key food commodity sectors, Jason Clay (2013)

Using its power to act as an independent convener of global food companies, WWF has assembled roundtables of key commodity producers for a number of purposes: sharing best practices for sustainable food production; collaborating to share information where they possess a common interest; and building support for voluntary standards. Believing that such partnerships with marketplace actors can move faster and achieve more substantial results than the slower pace of government policy, WWF is aiming to transform agricultural production through a new model of networked governance.[11] This model addresses issues such as soil health, food waste reduction, opportunities for technological innovation, information sharing and learning, creation of new metrics to better define productivity, environmental impact and nutrition, and development of certification standards.

[10] Clay J. (2013), "Feeding 9 Billion," in tedxtalks.ted.com/video; and Clay, J. (2013), "Spawning a Sustainable Industry for Farm-Raised Salmon", in Guardian Sustainable Business, August 14, 2013.

[11] Clay, J. (2013), "Feeding 9 Billion".

3.4
New York's PlaNYC[12]

One of the most comprehensive sustainable governance initiatives (PlaNYC, Plan a Greener, Greater New York) has been developed in New York City. Originally published in October 2007, PlaNYC received added impetus, definition and scope in the aftermath of Hurricane Sandy in October 2012. The core goal of PlaNYC is not only to develop an economically stronger metropolitan area but also to ensure its economic, environmental and social resilience over time through its ability to manage and adapt to a widening range of risks and opportunities.

As presently designed, PlaNYC represents a comprehensive rethinking of managing housing and neighbourhoods, water supply and waterways, energy sourcing and distribution, wastewater management and economic development. PlaNYC currently involves 25 participating city agencies and multiple stakeholders from academia, business, community, environmental and other organizations.

This collaboration has committed to implementing a number of specific goals for each major PlaNYC element, including the application of 5 million square feet (464,515 m^2) of reflective rooftops and other energy efficiency measures; upgrading building codes (e.g., installing flood-proof equipment and elevating critical energy and wastewater treatment equipment to higher levels – even within existing buildings); planting 850,000 trees; reducing carbon emissions by 19% since 2005 as part of an overall commitment to achieve a 30% reduction by 2030; investing in natural systems; upgrades to wastewater treatment facilities to protect against storm surges; redesign of storm water drainage infrastructure; and restoring coastal ecosystems (PlaNYC, 2014).

To guide city officials and their stakeholders in understanding infrastructure vulnerability to climate change impacts, the city applies a climate change advisory process with leading scientists and engineers evaluating current and longer-term climate scenarios through the 2050s for average temperature changes, sea level rise and other variables.[13]

3.5
San Francisco Bay Region's resilience initiatives

Infrastructures of other urban areas are threatened similarly by climate change and other risk factors. In addition to its on-going concerns about earthquake damage, the San Francisco Bay region is at risk from sea level rise estimated to range between 16 to 55 inches (40.64 to 139.7 cm) by 2100 even while the region expects to experience continued population growth. To extend this analysis to a more granular level, significant portions of the railway lines, stations and other infrastructure within the Bay Area Rapid Transit (BART) system are at varying degrees of risk from sea level rise. An Alameda County Vulnerability Assessment (encompassing the area that includes the City of

[12] www.nyc.gov/html/planyc/html/home/home.shtml

[13] www.nyc.gov/planyc, and author interview with Carter H. Strickland, Jr., Commissioner, New York City Department of Environmental Protection, September 10, 2013.

Oakland) continues to examine options for making BART and other transportation assets, habitats, and land use more resilient with significant investments in infrastructure being planned.

Within the City of San Francisco, a set of goals to improve the sewer system are balancing green and grey infrastructure to address the following challenges: an aging collection system, excess storm water, seismic activities, sea level rise and optimization of operations. Specific improvement goals call for a compliant, reliable and flexible sewer system that can also respond to catastrophic events. Collecting and treating both sewage and storm water, the system modifies the resilience of the sewer system to adapt to climate change (including sea level rise). It looks to achieve economic and environmental sustainability while maintaining ratepayer affordability.

City officials are applying a Triple Bottom Line (TBL) assessment model to identify planning options and optimize their decision-making. The TBL evaluation criteria include capital, operational and other costs, environmental factors (e.g., climate, habitat, water use, water quality, air quality, natural resource inputs), and social factors (e.g., ratepayer affordability, recreation and open space, employment, cultural resources, construction impacts, the pedestrian environment, noise and odor). The TBL model works as a screening process, but also embodies a ratings system of potential responses across financial, environmental and social variables. A TBL Community Values Survey is used as an overlay to inform the TBL model.[14]

4. Required skills and behaviours for system-level risk management

The transition in thinking to establish new policy frameworks, business strategies and market-scale collaboration efforts is well underway. A major by-product of this development is the redefinition of important skills and behavioural attributes that are critical for future success. Evaluation of these issues has yielded a clearer understanding of the critical skills that need to be taught in business, engineering and public policy schools. These skills include:[15]

- Expertise in one or more areas of foundational knowledge: economics, finance, marketing, operations management, and physical, biological or social sciences.
- Understanding of basic legal standards or requirements (e.g., clean air or clean water legislation and regulation).

[14] San Francisco Public Utilities Commission, Citizen's Advisory Committee, Wastewater Subcommittee, *Triple Bottom Line Analysis*, June 14, 2012.

[15] Examples of recent thinking on these evolving skills' needs include: "Business Skills for a Changing World: An Assessment of What Global Companies Need From Business Schools", in *World Environment Center and Net Impact* (October 27, 2011); Neil C. Hawkins, Robert W. Patterson, John Mogge, and Terry F. Yosie, "Building a Sustainability Road Map for Engineering Education", in *Sustainable Chemistry and Engineering* (November 2013); and Terry F. Yosie, "Sustainable Innovation for Private and Public Sector Infrastructure: Next Generation Challenges for Engineering Education", in *American Society of Civil Engineers International Conference on Sustainable Infrastructure*, Long Beach, California, November 8, 2014.

- Comprehension of how markets function and the role of customers' needs and expectations in stimulating market responses and change.
- Integration of sustainability into core business processes – sourcing of materials, supply chain management, manufacturing, logistics and distribution and post-consumer materials management – or public sector decision-making (e.g., command and control regulation, calculating the social cost of carbon or water, integrating risk assessment and life cycle analysis methodologies).
- Understanding the role of 'smart' technologies and knowledge of data analytics to identify core trends and recognition of data patterns for the purpose of designing more 'intelligent' business processes and public policies.
- Ability to work in teams that have differing skills, behaviors, cultures and geographic locations.
- Knowledge of how to manage complexity and disruption to existing business models or processes, policy assumptions and outcomes.

One expression of how new skill sets emerge is through an examination of efforts to value natural capital. The idea that nature itself contains tangible forms of economic value has long been established as evidenced by businesses that provide eco-tourism services, pharmaceutical companies that obtain critical ingredients for new or modified products from tropical rainforests, and the emergence of green accounting methodologies.

Advocates for protecting key environmental resources and ecosystems from excessive human development and other risks have increasingly focused on natural capital valuation, or the extension of the economic definition of capital (e.g., manufactured means of production) to environmental goods and services. Natural capital is thus the stock of natural ecosystems that yield valuable goods and services, now and into the future. By better understanding the interrelationships that convert wastes into nutrients, for example, economists can better calculate the quantitative and qualitative value of ecosystem resources in the marketplace and help design policies that harmonize their use and preservation for longer-term societal needs.

Emerging from this examination of natural capital is not only a refinement in the skill sets needed but also new collaboration strategies that involve business and non-governmental organizations (principally) but sometimes include government agencies and universities. A recent example is the partnership between The Nature Conservancy, one of the world's largest non-government organizations, and the Corporate Eco Forum, another NGO but with business members. Together, they mobilized approximately 25 global companies and their in-house experts to examine natural capital valuation approaches and identified a growing number of opportunities to apply them in business operations for purposes such as wetlands preservation, pollution abatement and infrastructure planning.[16]

[16] Corporate Eco Forum and The Nature Conservancy (2012), *The New Business Imperative: Valuing Natural Capital*.

5. Additional factors in building new collaboration strategies and policy frameworks

Corporations, non-governmental organizations and other major institutions increasingly conclude that they will be more successful in attaining their individual objectives by collaborating with other partners with aligned interests. This realization has accelerated because of the emergence of a growing number of global scale problems – e.g., water resource scarcities, challenges to producers in providing sufficient quantities of food products, limits for key raw materials in manufacturing operations – as well as a heightened understanding that there is no single institution capable of providing a solution to these and other challenges.

The practice of collaboration is a familiar one to most organizations as it is a normal feature of customer-supplier relationships, specific government-business partnerships or through individual initiatives that are developed with non-governmental organizations, universities and other partners. What is changing the collaboration imperative is both the need and the scale for new kinds of thinking about partnerships that goes beyond the traditional focus on individual topics such as plant performance, mitigation of discrete environmental risks or management of research projects. Succeeding this traditional focus is an agenda aimed at addressing newer sources of disruption and risks to businesses and natural systems; the need for new business models that can sustain profitability while providing solutions for societal needs; strategies for optimizing natural resource management, product and service innovation; and differentiation of brand value, to name a few.[17]

As efforts to build global-scale collaboration evolve, additional insights have emerged. They include:

- **Business executives and policymakers must possess a 'system-level' understanding of societal and environmental changes that are transforming the global economy and civil society**. An important consideration in the design of future collaboration strategies is the skill set of senior executives of global companies, governmental agencies and NGOs. Where they possess competencies in collaborating with partners outside their sectors, these were not generally obtained through formal academic training but, rather, through on-the-job experience, a personal open mindedness about other organizations and cultures, and a recognition of potential value creation. Another major hurdle that many executives need to overcome is a tendency to consider themselves as solvers of individual problems rather than builders of systems of inter-connected capabilities and solutions. Policymakers in regulatory agencies, for example, are often slow to recognize and modify decisions that account for pollution as part of an entire value chain of economic relationships. Instead, they focus on emissions from an individual firm or source category. Some business executives are beginning to learn that issues such as population growth, accelerated urbanization, concerns over food security and natural resource

[17] Jane Nelson (2013), "Scaling Up Impact Through Public-Private Partnerships," in L. Chandy, A. Hosono, H. Kharas and J. Linn, ed., *Getting to Scale*: Brookings Institution Press, pp. 305-362.

scarcities may impact their firms in ways that can significantly affect return on investment metrics or payback periods for invested capital.

As one example, future investment decisions to upgrade power generation systems will need to take into account demand for electricity from individual and networked passenger vehicles, or the interconnected energy and water use in building design and maintenance. Only a 'system-level' understanding of the characteristics and goals across these functions will enable executives and policymakers to develop more innovative approaches to understand both customer and societal needs. Organizations and their partners that accelerate their common learning on system-level challenges will, over time, accrue important advantages in their ability to deliver business or policy solutions to their customers and citizens.

- **Voluntary collaboration initiatives are important but not sufficient to develop solutions to global scale problems**. For two reasons, it is unrealistic to expect that voluntary collaboration alone can ultimately provide effective responses to emerging megatrend challenges: 1) there are too many free riders in the private sector who will seek to avoid modifying their business plans in ways that may affect short-term financial returns; and 2) policymakers in many nations will seek to game any system of collaboration in order to protect subsidies, tax, trade or other advantages against other national competitors. At the same time, despite numerous proposals for some form of global authority to regulate the behavior of enterprises or nations, this option lacks legitimacy in most national, regional or global forums. A more viable alternative at the present time is the creation of global company networks, national agencies, multi-lateral institutions, NGOs or foundations, such as those created for the cross-border regulation of pharmaceutical products or the eradication of malaria. Jointly, they can develop licensing standards and transparency practices.[18]

6. Implications for regulatory policy

Existing regulatory policies that focus on the management and abatement of individual risks such as air and water pollutants, hazardous wastes and other chemical risks will continue to be needed to provide protection to public health and the environment from identified risks. The transition to more collaborative decision-making frameworks can also be applied to current regulatory bottlenecks such as the introduction of negotiated sustainable remediation technologies as an addition or substitute to traditional pump-and-treat approaches in hazardous waste management. Another example is the mandatory phase-out of hydrofluorocarbons through the international Montreal Protocol process that is combined with the voluntary initiative taken by the Consumer Goods Forum (a global organization of major consumer goods and retail companies) to accelerate the phase-out of key ozone depleting and/or greenhouse gases.

[18] For a discussion of these and other issues involved in greater scale collaboration, see, Terry F. Yosie, "How Collaboration Creates Value and Accelerates Change," in www.greenbiz.com/blog/2013/04/29/how-collaboration-creates-value-and-accelerates-change.

However, as the scale of global economic activities accelerates, and as sustainability challenges transcend multiple boundaries, new policy frameworks are needed. There are several critical areas where regulatory policies need to be rethought if governments and their stakeholders are to effectively respond to and prevent global-scale risks. These elements include:

- Policymakers should invite as observers or contributors those experts from business or NGOs who have expertise and have engaged in designing and implementing approaches previously described. Those who are familiar with the processes necessary for creating new collaboration strategies can provide valuable and practical insights to establish policy frameworks that are more suited to the challenges posed by system-level risks.
- Policies should embody a 'systems' approach to effectively assess and manage risks. The examples cited previously provide evidence of various efforts that are underway to build policy frameworks and capacities. They need to be expanded and accelerated across a host of system-level problems.
- More emphasis should be placed on the development and use of integrated tools and methodologies to aid policymakers, business managers and others charged with evaluating and reducing risks.[19]
- Policymakers should work to transition from the regulation of individual pollution sources and sectors to the design and implementation of regulatory frameworks for entire value chains. Regulatory agencies such as EPA and the US Food and Drug Administration have developed processes and accumulated experiences to make this transition. They and other agencies need to accelerate planning to keep pace with sustainability impacts in the marketplace.
- Regulatory policies need to be guided by the insights provided by smart technologies and data analytics to discern key trends and opportunities for policy interventions. Greater investments in policy analysis that embody data analytics and expanded partnerships with the private sector are pathways towards this outcome.
- The co-benefits of reducing system-level risks (e.g., the additional public health benefits that accrue by reducing ambient particulate matter through the control of greenhouse gases or the adoption of energy efficiency measures) should be identified and communicated in a more transparent manner with key stakeholders.[20]
- Regulatory agencies should develop more formal plans to identify and recruit the critical skills and competencies necessary to evaluate and manage system-level risks.

In considering these elements, there are two additional factors that are important to keep in mind: 1) public agencies (regulators) possess important convening authorities to assemble the requisite data and stakeholders and, where appropriate, effective and legal, they should consider directly facilitating processes aimed at resolving system-level risks; and 2) the range of

[19] US National Research Council, *Sustainability Concepts in Decision Making*, cited above, is a good start in identifying and evaluating the utility of a variety of tools, methods and forms of collaboration between regulators and affected parties, for a variety of sustainability-related challenges.

[20] A series of co-benefit examples can be found in US EPA (2015), *Climate Change in the United States: Benefits of Global Action: Office of Atmospheric Programs*, EPA 430-R-15-001.

governance options for system-level risks will continue to expand and will range from traditional command and control regulation, voluntary initiatives, expanded reporting, to ultimately shared forms of governance that are co-designed and implemented by government authorities, regulated entities and non-governmental organizations. Such creativity should be encouraged not only to enhance problem-solving but also to build trust among stakeholder organizations and the public and attempt to de-politicize risk governance without forgetting the importance of designing and maintaining sufficient provisions for transparency and improved performance.

As additional experience is gained with system-level risk governance alternatives, it will be important to develop practical guidelines, or suggested typologies, that further delineate the capabilities, roles and responsibilities of regulatory agencies, the private sector, NGOs and the affected publics to better answer such basic questions as “who is responsible for doing what?”.

Conclusion

As the understanding of emerging risks grows and stimulates additional thinking on the design and implementation of system-level solutions, inevitably, new roles and responsibilities for regulatory agencies, private sector and non-governmental organizations will also arise. Respectively, their evolving roles and relationships will continue to depend on the implementation of tasks where they currently maintain core competencies – e.g., to develop and enforce essential public health and environmental protection, improve living standards by creating additional wealth, and provide essential oversight and advocacy for major societal needs. Just as importantly, these and other institutions need to branch out, simultaneously developing additional capabilities and collaborative approaches to resolve planetary-wide challenges that are beyond their individual capacities. While the need for such a transition is beginning to be recognized, the unresolved question is whether or not it can be successful in a sufficiently timely fashion.

POTENTIAL SCOPE AND CHALLENGES OF BEHAVIOURALLY INFORMED REGULATION

IMPLICATIONS FOR MODERN REGULATORY RISK MANAGEMENT

by Ortwin Renn[i] *and Marie-Valentine Florin*[ii,iii]

Introduction

This paper looks at how behavioural sciences and the relevant knowledge can be applied by public authorities to design, test and implement interventions that help society and consumers make choices that are both sustainable and to their well-being while remaining compatible with legitimate collective decision-making. Used in the context of comprehensive risk governance, behavioural insight (here abbreviated as BI) is valuable and useful in helping define a problem in the first instance and providing an understanding of the risks and shortfalls before any designing regulation even begins. More specifically, this paper addresses the possibility of intervening in individual or group behaviour, and discusses effectiveness and legality. The legitimacy of such interventions is derived from the overall governance process that recommends a democratic and inclusive selection rule for choosing a specific transformation path over other alternatives. If such a legitimate decision has been made, then it is morally and politically justified for collective actors to shape human behaviour through interventions. However, it is essential that such approaches are fully transparent and open to public scrutiny and critique.

The literature on shaping human behaviour describes five generic intervention strategies: direct legal prescriptions (laws); economic incentives (subsidies, certificates, taxes, tariffs); informational and educational material (labelling, certification, training, communication); influencing choice architecture ('nudging') and changing institutional contexts (facilitating or impeding specific behavioural options). Each scientific community has established its own methods and published dedicated scientific journals. There is a fair degree of competition between the communities as far as the relevance for explaining people's behaviour is concerned and the legitimacy of each approach with respect to democratic or ethical principles. It is important to bridge the gaps

[i] Stuttgart University.
[ii] International Risk Governance Council (IRGC).
[iii] The authors are grateful to Faisal Naru (OECD), Wandi Bruine de Bruin (Leeds University) and Lorenzo Allio for their contribution to this paper.

between these communities and to consider all five intervention methods as appropriate and effective depending on the context and situation. No one method should be favoured over another. The respective potential of each needs to be defined together with its limits and drawbacks, while emphasising that effective behavioural change is most likely to be achieved through a combination of interventions.

There is much interest in choice architecture as a type of intervention that is complementary to others such as information and educational material, economic incentives, or contextual and institutional changes. Direct legal prescriptions will not be discussed in this paper as most analysts agree that this is more or less a last resort when any other (more voluntary) incentive fails or is inappropriate. Indeed, in certain circumstances direct legal prescriptions are required and constitute the correct form of intervention. In this case, behavioural scientists can provide insights on their implementation. However, many of the other interventions depend, at least to a certain extent, on the legal framework allowing these interventions to become effective. Finally, all five intervention options have to be seen as partially complimentary and partially substitutive. The most interesting aspect with respect to transformative science (see Box 1) is the effect that various combinations of all intervention strategies and their potential interactions have jointly.

Box 1: Transformative science

Transformative science involves new and innovative approaches to generating and using scientific expertise in policymaking. This is often required when public authorities need to encourage new types of well-being or development. Transformation requires a three-step scientific process of knowledge production and transfer. The first step is to *develop knowledge of systemic interactions* between scientific and technological development, organisational changes, governance structures and human behaviour. Human actions are considered to be the main current drivers of natural and cultural evolution. The new role of society as co-creator of evolution necessitates a better and more intimate understanding of the interconnections between nature, technology and society. By investigating the systemic connections between these three major elements, systems knowledge is created. Such systemic knowledge is needed to understand a system as a whole before one attempts to change it.

The second stage in knowledge generation and utilisation is the *creation of orientation science*. Orientation implies providing guidance about the goals or objectives one intends to achieve. This requires both knowledge about the likely outcome of taking one option as opposed to another and understanding how desirable or ethical the consequences of each option will be seen by decision-makers and the public concerned. Hence, this step includes two major objectives. The first is to develop a normative framework for the objectives and goals (of sustainability) that human interventions into the network of technology, nature and society are to pursue. Sustainability is a deeply normative concept that needs to be specified in terms of medium and long-term objectives, including the selected endpoints of development and the legitimate means and instruments necessary to reach these goals. In line with the aim of IRGC to help develop inclusive governance, this normative exercise requires input from various stakeholders, plural publics and individuals concerned. The second aspect of orientation is to develop scenarios that help understand the transitions that are necessary to reach the normative goals that have been negotiated through participatory processes. These scenarios help decision-makers, as well as the populations affected, to understand the necessary trade-offs between conflicting goals and to understand the potential risks and side effects that are associated with each scenario.[1]

The third and final step is to *design, implement and test interventions* that can help guide society into following the general direction that the most favoured scenario suggests. These interventions are, in an ideal case, enlightened by the consensus that this specific scenario is to be preferred over a set of alternative scenarios. They also require a governance process that is able to facilitate the transition towards the implementation of this preferred scenario. The main goal here is to define, investigate and monitor policy interventions according to the main evaluative criteria such as efficiency, effectiveness, fairness and resilience.

Interventions based on insights gathered from BI are expected to improve social well-being by changing the way policy is being designed and implemented, in combination with economic incentives, context variation and regulatory measures, i.e. public authority prescriptions. This paper reviews the overall scope and challenges of interventions directed at changing individual behaviour. The starting point and rationale for this paper results from the gaps in regulatory efficacy and efficiency. Questions that regulators are invited to consider include: How can behavioural sciences help improve regulatory effectiveness? Can regulators influence fundamental and lasting behaviour change? What can they do when industry reacts in sectors where freedom of consumption choice is protected by law? Can public intervention based on behavioural insights substitute, or complement regulation? Is it always legal or ethical? If not, how can it be made legal and ethical?

This paper is organised into four sections. Section 1 looks at the contribution of behavioural sciences to risk governance where national authorities are concerned. Section 2 discusses the scope of application of behavioural insights. Section 3 looks at the challenges: issues of effectiveness, legality and acceptability. Section 4 proposes general recommendations for implementation. Additional references and notes have also been provided for further reading on specific topics.

1. Contribution of behavioural sciences to risk governance

The work of social scientists is to understand and interpret human decisions and actions. It can explain people's behaviour with regard to activities that incur risks, whether to themselves or to others. Peer-to-peer persuasion and using subconscious factors or other such emotionally driven interventions can be valuable approaches for managing risk.

1.1 Behavioural sciences

Behavioural sciences study human behaviour. Scholars in this field are researching the motives and drivers behind people's behaviour and, based on these insights, looking for relevant opportunities and limitations of influence. Their interest is in designing interventions and policies in ways that are cognisant of and informed by insights of empirical behaviour observation.

- Behavioural economists recognise that people do not act merely out of self-interest or strict cost-benefit analyses. They stress the importance of symbolic (suggesting positive ideas or qualities) or monetary incentives for sustaining or changing behaviour.
- Behavioural psychologists are interested in studying human behaviour that is often conditioned by routines and tradition. They stress the importance of both salient information and choice architecture to make people more cognisant and ready to change their behaviour.

- Behavioural social scientists stress the importance of context factors and institutional constraints such as social recognition; social norms; and situational constraints that shape the conditions for individuals considering or choosing alternative options for their own actions.

Especially in view of the prevalence of heterogeneous consumer segments, for example in the energy sector – a new field of interest, it is essential to integrate these three traditions in behavioural research if final energy consumption is to be modified in line with energy policy objectives.[2]

Psychology and other social sciences offer new insights that help regulators ameliorate the effectiveness of the economic instruments governments use in their broad regulatory function. This includes those to remedy market failures, redistribute income, and collect tax revenue. Some generic findings of behavioural sciences are useful for policy makers and regulators. For example, people work with 'mental models'[3] as their psychological representations of real, hypothetical, or imaginary situations. This helps them anticipate events, reason, decide and provide explanation. Mental models may not be accurate or scientific representations of reality. They are influenced by a number of factors, including social norms[4], i.e. unwritten rules about how people behave in social contexts at a particular time or 'decision point'. The existence of social norms explains that peer-pressure is important in triggering change. What others think, expect and do influences our preferences and decisions. However, different people may have varying reasons or motives for their behaviour (beyond their opinion or attitude). There are various types of rationality, which behavioural scientists aim to explore, understand and analyse, often with a view to provide recommendations for intervention.

The concepts of 'expected' utility, symbolic gratification and a multitude of subjective rationalities, rather than a single instrumental rationality, are central to this debate. Theoreticians will explain why certain behaviour seems irrational, according to the classic economic theory (that people tend to maximise their profit), and behavioural economists have greatly contributed in sharing the understanding that what may not appear 'rational', according to the principle of maximising utility, may in fact be rational with respect to the objectives of the decider in the light of his or her own logic. For example, following social norms is a rational behaviour in its own domain, although this may not lead to perfect economic optimisation.

1.2 Cognitive biases

Behavioural insights can be extremely useful in understanding the predispositions that affect how people take decisions and then build on those biases to help obtain a better outcome. Biases and intuitive heuristics relate to processing information on risk aspects such as exposure, probability or uncertainty. Biases that individuals often apply to judge risks or to draw inferences from probabilistic information[5] include[6]:

- **Availability**: Events that come to people's mind immediately (e.g. events highlighted in the mass media) are rated as more probable than events that

are less in their thoughts. In food consumption behaviour, if people have a tendency to grab the first food they see (due to the availability heuristic or satisficing choice strategies), then it is recommended that they see the healthy food first.

- **Status quo or choice avoidance**: people have a tendency not to change their behaviour. If their inclination is to stick with the default retirement plan that is proposed to them, then authorities need to make sure that the default retirement plan is the one that is best for them.
- **Anchoring effect**: Probabilities are not adjusted sufficiently taking into account new information when it becomes available. People retain the perceived significance of the initial information so that, for example, if they associate eating fish with heavy metal contamination, they are likely to ignore that eating fish, even lightly contaminated, is still healthier than eating red meat.
- **Personal experience**: Single events either experienced directly by people, or in associated circumstances, are considered more typical than the information related to the actual frequencies of those events. People who, by chance, have observed that woman drivers were involved in the last two accidents they witnessed are likely to infer that women cause more accidents (which, in fact, is not true).
- **Avoidance of cognitive dissonance**: In an attempt to attenuate cognitive dissonance, information which challenges perceived probabilities that are already part of a belief system will either be ignored or minimised, in an attempt to attenuate cognitive dissonance. Autonomous cars are perceived to be less safe than others because the overriding belief is that humans are better drivers than machines, even though experts demonstrate that, in general, machines cause fewer accidents than humans. In the case of autonomous vehicles, industry and regulators will need to campaign more to explain why they can be safer than conventional ones.

1.3
Use of behavioural sciences in governmental organisations

Behavioural sciences involve a new type of systemic thinking about old problems, especially when there are difficult trade-offs to be made such as those involving freedom and privacy or efficacy and efficiency. Indeed, interventions based on behavioural insights require embeddedness in appropriate political agendas and support. According to the reckoning of certain leading international organisations however, these interventions are worth the effort it takes to make them work effectively and legally. In their guide for policy-makers entitled “Applying behavioural sciences to EU policy making”, the European Commission concluded that “well-designed behavioural studies can offer useful insights to policy-makers by generating the evidence required to improve policies”[7]. Back in 2010, the OECD Consumer Policy Toolkit[8] (a roadmap for policy choices) recommended governments consider studies by social scientists. The OECD provided further endorsements in a 2014 publication, “Regulatory Policy and Behavioural Economics”, which included a review of numerous country trials[9]. The World Bank also demonstrated its interest in tools to help advance a new set of development approaches based on a fuller consideration of psychological and social influences[10].

In governments, interest in BI goes in pair with a desire to change public authority culture and regulation. Vocabulary used includes 'team' in the UK[11], 'initiative' in the US[12] or 'network' in the Netherlands[13] (to foster the impression of an operating net of various department teams), terms that are not frequently associated with public administration. Communication is aimed at people on a personal level (e.g. 'you and your neighbours'). Beyond improving the performance of regulatory effectiveness and triggering individual behaviour, this approach demonstrates a sense of individual responsibility toward risk (which is expected to result in reducing the burden of risk management costs on governments). The aim is to develop a new way of enhancing mutual trust between authorities and citizens.

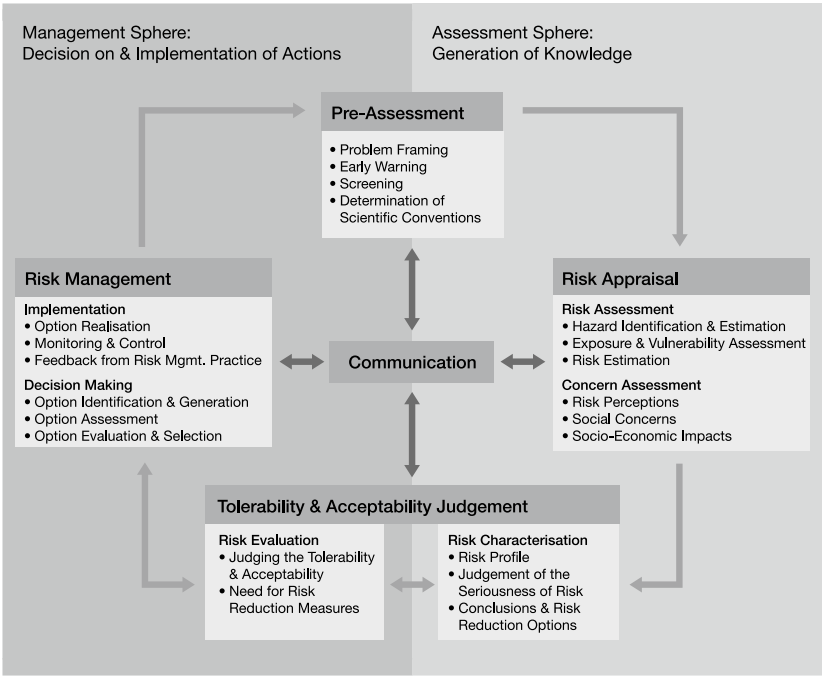

Figure 1: IRGC risk governance framework

1.4 Use of behavioural sciences in the broad context of risk governance

Risk governance implies taking a holistic approach to assessment and management. It requires: careful scientific appraisal and weighing how people perceive risk; evaluating the acceptability of risk in order to decide whether or not, as well as how, risk needs to be managed in a particular context; considering various management options before selecting a single one or several; and, finally, placing risk communication at the centre of the process. The whole process aims to establish dialogue, transparency and confidence. Figure 1 illustrates the IRGC risk governance framework[14] (IRGC, 2005).

Risk governance takes a multi-disciplinary approach aimed at including all stakeholders in the management decision about the risk issue. Knowledge gained from behavioural sciences is thus useful at various stages in the process and can contribute to its success:

- By helping develop a more complex but complete picture of the risk at hand and understanding the importance of frames when risk problems are defined in a pluralistic society. Framing provides an image of the problem which explains the expectations that different groups and individuals associate with a risk.
- As a source of information for assessing concern as an integral part of the risk appraisal: Concerns underlie the behavioural responses of people when making judgements about risks and their impacts. Concerns do not determine behavioural reactions but do influence them.
- For making trade-offs when evaluating tolerability or the acceptability of a risk. Trade-offs are manifestations of people's preferences and

values. Regulatory trade-offs may or may not coincide with individual or group-preferences. If the gap between public and individual trade-offs is particularly broad, one can expect protest movements or civil disobedience.

- For evaluating various risk management options aimed at dealing with the source of the risk or its impact on the parties affected and the consequences. For example, for risk matters that are not regulated by law, insurance companies involved in developing risk transfer mechanisms are segmenting their client base using behaviour (such as smoking or the regular practice of a physical activity) as a determinant of coverage or pricing conditions.

2. Scope of the application of behavioural insights

For risk management there are three broad types of application where BI can improve the effectiveness of public intervention: implementing regulation, changing behaviour beyond the scope of regulation and changing the design of regulation[15].

2.1 Implementing regulation

Improving regulatory implementation, thus refining compliance with laws and regulation, is the first objective of those governments applying BI. Examples include making people pay their taxes on time, or recycling waste in an appropriate manner. The aim is to improve the effectiveness of regulation and its cost efficiency[16]. BI helps regulators implement and enforce regulation in a way that corresponds well with people's spontaneous behaviour. Those who enforce regulation will help those who are regulated to comply with specific requirements, by demonstrating how it is (or could be) to their benefit, instead of blaming or punishing them. The OECD report on "Regulatory Policy and Behavioural Economics"[17] provides numerous examples of how applying behavioural economics to policy can improve regulatory delivery, interpretation and enforcement of existing rules, as well as regulatory design. We cite two here:

- Several countries have followed the successful work carried out in the UK to increase tax compliance. They undertook random controlled trials to assess the impact of various forms of communication – in particular letters that were sent to noncompliant individuals and businesses – to increase the repayment rate of taxes that were overdue. Some of the lessons learned from studying the effectiveness of various messages show that personalising letters is needed, for example by harnessing the power of social norms and drawing comparison with other taxpayers in the neighbourhood (if the average compliance is higher), or making it extremely simple to pay taxes in time. A first trial boosted repayment rates by up to 15% in the first 6 weeks[18].
- Another example where regulatory enforcement can be improved is that carried out by the US Consumer Financial Protection Bureau and the UK Financial Conduct Authority. They recruited behavioural scientists to assist

their own managerial staff, for example in investigating a potential breach of regulation or action that could be detrimental to the consumer. These agencies expect this will help them improve company understanding of observed behaviours and enable managers to form better judgements.

2.2
Changing behaviour in a non-regulated field

This second type of application applies to cases where there is no regulation. It involves decision-making, helping people decide and behave in a manner that is less risky to themselves and society. This field is noticeable in that it helps people improve their own individual risk management without sacrificing welfare. It aims to reinforce personal decisions on various aspects of living where risk is involved. The major constraint in these approaches is that individuals need to remain free to take their own decisions. In other words, they cannot be forced into certain choices but retain freedom of choice, both democratically and ethically.

Governments can deploy techniques that influence consumer choice, often without their being aware, i.e. when consumers are not made explicitly aware of the desirable choice (for example, pre-checked boxes in questionnaires about saving for retirement that prompt employees towards a 'default option', one which prefers long-term savings over short-term consumption). This can also help people reach their own objectives.

BI can be used in many ways and there are positive experiences in various fields such as:

- Public health, for example to suggest healthier foods. "5 A DAY" fruit and vegetable campaigns have been instigated by many governments[19].
- Pension coverage, for example in countries where compulsory schemes provide insufficient pensions, to encourage people to save for their retirement in addition to compulsory schemes. Employers and voluntary insurance schemes propose automatic pension admission, in which employees need to check a box if they do not want to enrol. In the US, this small change appears to have boosted savings by over to 40%[20]. The "Kiwisaver" auto-enrolment scheme in New Zealand (2007) led to a 50% pension coverage increase. This type of nudging is based on the fact that behaviour tends to be driven by relying on default options, by myopic attitudes or by habit.
- Organ donation: a study across 22 countries and over 10 years indicates that actual organ donation rates are 25 to 30% higher in *presumed*-consent countries than in *informed*-consent countries. This analysis has triggered a switch from informed to presumed consent in many countries[21].

In addition to the fields of finance, health, food and, to a certain extent tobacco and energy efficiency, there are many other sectors that could benefit from BI insights. These include energy behaviour, nutrition, exercise, drug abuse and many others. Applications might include the triggering of individual commitment and actions towards climate change mitigation; stimulating a positive change with regards to reduction of exposure and vulnerability to

natural hazards (insofar as exposure and vulnerability result from individual decisions and choices); or activating data protection and privacy (in order to reduce the spread of cyber security risk). Development policy bodies and developing countries are also implementing behavioural insights[22].

2.3 Changing the design of regulation

When the root causes of individual and collective behavioural decisions and the feedback effect of deliberate interventions to change people's behaviour are well analysed and understood, regulators can consider using insights from behavioural sciences to design new or re-design existing regulations, i.e. as a means of selecting one type of intervention over another. For example, where command and control regulation does not work, an incentive-based instrument might be preferred. The cyber world, for example, is a possible new field for regulators where individual behaviour to prevent or stop malicious intrusion will need to be better understood, before creating new rules. Empirical analysis of how people use (or not) passwords and anti-virus software should guide administrators and regulators on how to design security within the systems, rather than by imposing external constraints that many people try to bypass. Also, motivation and behavioural patterns of cyber attackers need to be better understood to improve threat assessment and design standards for safer Internet design.

An interesting example is that of the trend to deregulate electricity markets. In deregulated electricity markets consumers can choose their suppliers and often their pricing schemes. Providing them with a choice potentially creates new risks if competition is too fierce. In fact, findings from some regulators have shown that too much choice is damaging, in that it creates consumer confusion and inertia. Thus regulators need, in parallel, to produce new types of indirect measures that serve the goal of regulation intended, for example showing how energy suppliers can market their products.

It is clear that insights from behavioural sciences can be used to support new thinking on relations between various levels and types of governance and regulation. As explained by other authors in this publication, the attitude of public and private actors with regards to regulation are changing.

Conclusions

The three fields of application (regulation implementation, behaviour change beyond the scope of regulation and regulation design change) benefit from the findings of behavioural sciences. However, there are certain differences. In particular, the question of creating an appropriate choice architecture, or nudging to induce a change of behaviour that is in the interest of individuals and society is specific to the second type of application. It is here that opposition is more active, and opponents claim that governments may go into so-called 'soft-paternalism', a governance style that some governments may avoid.

Nudging was first described in 2008 by Thaler and Sunstein[23] as a soft and liberal way to achieve policy outcome – a contrast to command-and-order instruments. It comprises a set of tools that governments and regulators can consider using when they face serious problems or risks either caused by citizens or affecting citizens, and which the usual regulatory instruments fail to address. For example, people continue to die from smoking; obesity is still increasing; unemployment affects primarily poor people and governments do not know how they will finance retirement pensions in the future. Nudging is only one facet of BI and related to the choice architecture that is provided to people by regulatory bodies or other authorities. It offers an alternative to command-and-control regulation since it retains the factor of choice. But it requires appropriate checking, control and restriction on how it is used. Nudging can be used in combination or as an alternative to economic incentives or educational/communication tools.

3. Challenges: how to make it work; is it legal, acceptable?

Early applications of behavioural insights, particularly in designing interventions that aim to nudge people into taking certain decisions or adopting specific behaviour, have raised concern about their effectiveness and legality (especially where ethical acceptability beyond legal prescriptions is concerned). In addition, industry and non-governmental organisations (NGOs) may be opposed to nudging since it relies on a form of paternalism that shapes people's behaviour in a specific direction, often without their even noticing let alone approving. This section reviews some of the questions and lessons gleaned from experience and the opinion of experts.

3.1 Effectiveness

The first issue concerns effectiveness. Is the performance of public interventions specifically designed using BI superior to a monetary incentive system that aims for the same result?

The characteristics of effective behaviour-informed interventions are in a way similar to those of marketing instruments used in the private sector. Social marketing has been used by philanthropic or humanitarian organisations, and governments can learn from their experience. There are positive outcomes in many countries. With regard to regulatory implementation and design, it is obvious that a better understanding of how those regulated actually behave improves impact and efficiency.

When it comes to modifying consumer behaviour, studies indicate that these interventions are more effective when *people are unaware* that some 'hidden' persuasion is built into the proposals that are being made to them; when complexity is simplified and decision appears to be 'simple'; or when social norms and group pressure are brought to the front to trigger a certain change.

In order to be effective, tools that influence behaviour and present people with choices must also carefully *structure* the task of the choice, i.e. determine what information is supplied, and then *describe* the choice options, presenting them in an attractive manner[24]. However, the question remains as to whether such interventions, even if effective in the first place, continue to work after a first initial period of interest or even enthusiasm. Experience here has been diverse. For example, communication to improve energy efficiency or savings (through reduction of energy bills) seems to lose its attractiveness as time passes, probably because of the large price elasticity[25]. The time horizon is an important factor in gauging the effectiveness of nudges. So, policy-makers, regulators and behavioural scientists need to continue to work together and learn from each other. Experience of using placebos in the medical sector can be useful: placebos can work when people are unaware of them, but they pose ethical issues concerning prior consent.

Another dimension worth mentioning is that of interventions that can be effective for some population segments and not for others. Interventions need to be tested with a targeted audience before being deployed.

3.2
Legality and legitimacy

A second, important question that legislators have to consider is whether the application of behavioural insights to trigger certain decisions or behaviour changes is always entirely legal and legitimate. This specifically concerns regulators who might consider developing a regulatory context and conditions in order to 'host' interventions to change people's behaviours. In liberal states, special legal problems can arise. These include constitutional limits[26]. There are institutional mechanisms and features – such as the principles of legality, impartiality and judicial oversight[27], which ensure that laws respect fundamental rights such as equality of treatment, fairness, freedom of choice and expression, and privacy. But if governments use instruments other than laws or regulation, it is possible they extend beyond what citizens want or expect in a democratic regime and is largely dependent on the amount of trust they have in their government. The question of whether and when nudging is a legitimate and acceptable approach is thus important.

Scholars who work on this debate have compared nudging to 'soft-paternalism' or 'patronising' and there is much questioning as to whether or not this is acceptable and desirable[28]. According to some, nudging goes against empowerment, freedom and fairness[29]. Those who claim that soft-paternalism is unacceptable have identified three issues. One is that it is based on a subjective evaluation of what is in the best interest of a person. Another is that it does not help individuals build their own autonomy. Finally, it neglects the dynamic feedback effects of behaviourally-informed policy interventions[30].

Those who admit that it is, or can be, legal and acceptable note that guiding individuals through various possible choices is often unavoidable, and therefore cannot morally be inherently problematic. Thus, when it is impossible to avoid shaping people's choices, some forms of behaviour change have to be permissible[31]. However, there are three main requirements. The

first is that all citizens should be treated equally. Nudging should not cause any form of discrimination between those who behave as regulators wish them to behave, and those who do not. The second is that interventions are designed or implemented using a choice-preserving approach. Freedom of choice (self-determination) must be maintained, even if it implies increased individual or public risk, or if it means that decisions will not be optimised. Finally, autonomy also needs to be retained. Nudging should not be considered as a manifestation of the exercise of public power.

Often, legitimacy is attributed to a collective process by which the goal and the means to reach these goals are approved by democratic deliberative decision-making or participatory processes. The practice of nudging needs to be supervised by a democratically elected body which ensures that interventions and choice framing do not prevent or compromise individual choices. The common good needs to be substantiated by a relevant process but not approved by each individual involved.

The concerns reviewed here should be understood to be cautionary considerations. Dialogue between those who design nudge interventions and those who critique them needs to be formalised[32] and frameworks developed for the responsible use of behaviour-informed regulations can be developed[33]. Also, such strategies need to be evaluated according to whatever regulatory instruments can ensure they are publicly checked and controlled[34]. Alemanno and Spina (2014) suggest that a legal framework be developed to ensure that the benefits of behavioural insights are able to inform regulatory processes in a way such that citizens' rights and freedom are guaranteed.

3.3 Industry and NGOs may be opposed to nudging by public authorities

A related issue that should be mentioned here is the role played by commercial players and NGOs. Increasingly these have an impact on consumer behaviour and regulators have to develop new, more appropriate ways to respond, rather than simply deciding on standards, norms or bans, when issues of security or safety are at stake. When evidence concerning safety, security or environmental sustainability issues is contested, relying on that evidence, or the common good, can no longer be sufficient. For example, it would be extremely useful if behavioural insights were able to help re-design traditional policies such as those on tobacco, obesity or antimicrobial resistance, where most current policies fail to deal with the risk in a satisfactory manner. With these three examples in mind, it is not difficult to imagine that, if governments massively engaged in successful nudging, and in the absence of a deliberative process that determines *what people want*, industry would be an opponent and argue that freedom of choice should be preserved. Using behavioural insights will perhaps not make policies more acceptable to industry, especially if it makes the policies more acceptable to people.

There is an active debate on the topic of labelling. For example, so-called 'traffic light' labelling[35] where, for example, a red sticker implies that "this product is not good for you" and a green sticker translates as "this one is

good for you", can be attractive to people and efficient in influencing customer choice. But this type of labelling needs to be acceptable to regulators as well as industry. The latter is able to work around constraints such as disclosure requirements imposed by efficient labelling.

There is opposition in industry and we can anticipate that, for example, if regulators were to consider regulating product layout in supermarkets and cafeterias (so that healthy products were placed at eye level, and less healthy products at higher or lower display levels) they would face industry opposition, both from retailers and producers. In 2012, New York Mayor Bloomberg, proposed a ban on the sale of soft drinks in large cups in public places. The ban was inspired by empirical findings from behavioural scientists and, on that basis, justified as one of the measures, among others, in the fight against obesity and diabetes. The ban was approved by the New York City Board of Health and later countered in court. Many people were outraged by what they thought was an illegitimate reduction of their freedom of choice[36]. Like nudging people to quit smoking, interventions to help people change their behaviour need to be based on what people really want. Therefore, as suggested in the introduction and Box 1, interventions based on behavioural insights need to be a part of democratic and inclusive governance.

4. Concluding remarks

Elaborating on considerations of effectiveness and legality, this section proposes a form of roadmap and key recommendations for regulators who are considering applying behavioural insights.

Setting and achieving the objective

Regulators who decide to apply BI begin by defining the objective of their decision to do so. This entails identifying what it is that has to be improved in risk regulation or management. They can begin by asking the following questions: what is wrong with the current regulation and how is it implemented? Are existing risk reduction measures both effective and efficient?

Regulators then invite those who are affected by the regulation to think about their own objectives and motivation: what matters to them? What do they really want? Those who are concerned by a regulation will react more positively if they recognise that in doing what the regulators suggest it will help them reach their own personal objectives. The process by which regulators assist the regulated in revealing their personal objectives is necessary to every successful intervention. For example, risk managers in finance departments are faced with the financial risks related to aging populations, of being able to pay retirement pensions in the future. They aim to transfer some of this risk to individuals, and experiment with ways to trigger greater individual savings. Providing concrete examples of the additional welfare that people would receive after retirement if they increased their saving now, provides a positive incentive to save money for the future.

Working to assess and understand, before managing

Like in a risk management process, regulatory interventions based on behavioural insights begin with an assessment of people's actual needs and perception of their actions, their present behaviour and the risks involved, the benefits associated with the activity, and the benefits associated with a behaviour change. In general, people need to perceive a risk before they are willing to change their behaviour with regard to the activity causing the risk. Only after a careful analysis of people's motivations, attitudes and behaviour can the management phase begin.

When communicating the implementation of a government intervention, it is important to place the user at the centre. He/she, as a citizen or consumer, is the subject, not the object. Users must be involved in the discussion about their behaviour. They become instrumental in their own regulation[37].

In the field of law enforcement, an intervention decided on the basis of BI should not be intended as either substituting or complementing a law or regulation. Instead, it will aim to assist people in doing what they are obliged to do (such as paying taxes) or what is good for their own health or well-being (such as avoiding overweight). In 2014 the City of Philadelphia carried out an experiment to improve compliance with city regulations on littering and waste recycling. In order to improve law enforcement, it was decided not to blame and fine people in poor neighbourhoods, but to announce publicly that city staff would be coming to inspect the streets. This resulted in the streets being cleaned before they arrived. This approach neither substitutes nor complements the law, it *assists* citizens in doing what they have to do, *piloting* and focusing on outcome.

Testing and experimenting

Most prescriptions and communication messages need to be tested before being implemented, to gain knowledge about how people really behave. For example, it was found that people did not know how to wash their hands in order to eliminate the flu virus and avoid contamination during outbreaks. Communication campaigns on washing one's hands were thus ineffective until they included clear instructions on how to go about this. It is extremely important to evaluate how communication campaigns are understood before they are deployed. Even if communication appears obvious, certain segments of the population may understand it differently to others. People behave differently in different cultures and situations.

Practitioners have learned, and continue to learn, how to test ideas and communication messages before they implement them. Too often it is a poor understanding of those individuals who are targeted in a campaign that explains the difference between an expected 'rational' behaviour and the actual behaviour. Public services need to learn that testing is necessary, and regulators might consider including this requirement in legislation (ex-ante impact assessment) in addition to ex-post impact assessment. In this sense, random field trials have proven to be successful in evaluating the effectiveness of public policy intervention[38]. However after a few years of testing in various countries and with differing population segments, there are some

cases when testing is no longer necessary because sufficient knowledge has been collected.

Major recommendations

Analysis of trials so far have led to three generic recommendations as to how governments can use behavioural insights to improve regulatory impact and effectiveness[39]:

1. Make it simple, easy, attractive, timely and social for people to make choices or change their behaviour to their benefit and harmlessly. This helps individuals deal better with complexity.
2. Make the relevant option more salient and provide default options where appropriate (but not always, as there may be some perverse effects as well); require active participation to opt out – as opposed to not opting in, of the more beneficial option – that is the one that will be applied if the individual does not choose any specific one. This helps individuals deal better with uncertainty and inter-temporal decision-making. Default options have been widely studied by scholars and practitioners[40].
3. Respect freedom of choice. 'Opting out' must always be possible and should be proposed while ensuring that individuals can build on their own autonomy, in particular where future choices are concerned.

These three recommendations also demonstrate the difficult trade-offs that regulators face in their task of helping people take better decisions. The case of Internet websites is exemplary: on the one hand, 'pre-checked' boxes are used widely to make decision-taking easier and the 'right' option more salient. On the other hand, human inertia, framing and a bias towards the status quo need to be taken into account, and this should limit the use of pre-checked boxes[41]. For example, under EU law, pre-checking the travel insurance box is not illegal.

The current attention being paid to how BI can be integrated in regulation focuses on disclosure requirements such as regulatory tools, default rules, and simplification[42].

Sharing information between scientists and practitioners, and between countries

The OECD and others have set up a repository to share the experience and practice of others, their knowledge and design metrics, to provide benchmarks and a source of learning. For example, it is useful to know which common themes, such as 'make it simple', or 'set the preferred option as the default option', work in most contexts and settings, and what type of variation can be expected. Such a repository will help countries improve their learning curve and benefit from the experience of others. The aim is to create an ecosystem in which various stakeholders from differing cultural groups and scientific disciplines work together.

Policy implications, institutional and management issues

Trials in various countries have produced various recommendations for integrating behavioural insights into public institutions as well as policy and regulatory processes:

- The experience gained by the UK Behavioural Unit Team (BIT) and the US Office of Science & Technology Policy (OSTP) Social and Behavioral Sciences Team (SBST) in the White House indicate that these government-integrated units need first to obtain political buy-in and then create the demand from others in government. They have to trigger curiosity and interest, for example by getting some of the results in quickly, to gain credibility and overcome institutional inertia before undertaking long-term tasks.
- It is recommended that Behavioural Units are located within central government. The UK BIT was set up in 10 Downing Street and the Cabinet Office. It is now partially outsourced with a 4-year contract binding it to Government while also allowing it to provide consultancy services to other bodies.
- Other initiatives can be organised as part of a network. Some of these are internal to government such as in the Netherlands and Singapore. In Denmark the networks are more holistic and are organised externally to government with a wide range of stakeholders e.g. industry, not-for-profit organisations, academia, etc.
- These initiatives need to recruit the right people, with the relevant expertise. It is unusual to find experts in behavioural sciences working in traditional public administrations and so external recruiting is very often necessary. As part of a secondary stage, training can be set up for others to increase capacity.
- Building up connections with academia is useful, and in particular within the business sector, communications and marketing schools, even if the latter are not familiar with the specificities of the public sector.
- Maintaining connections with industry is also useful, in particular to counter opposition from industry, as discussed in section 3.
- Interventions inspired by behavioural initiatives will require (as well as most probably contribute to) a change of culture in public administration, for example by forming a network of change agents. To generate the necessary conditions for success, governments are advised to give change agents space for manoeuvre and shelter. In this manner they are able to learn from experience and even from failure.

BI-based interventions will only succeed if there is a feeling of confidence between the regulators who design them and those to whom they are targeted. At the same time, well-designed interventions that meet people's objectives and their needs can contribute to restoring trust in regulatory authorities. Overall, they reduce the cost of regulatory compliance and improve the general efficiency of risk management.

Notes and bibliography for further reading

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[17] See note 9

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In "Public Policies, Made to Fit People" (New York Times, Aug 24, 2013, available on nytimes.com/2013/08/25/business/public-policies-made-to-fit-people.html?_r=1), Richard Thaler writes of his conviction "about how research findings in social and behavioral science can improve policy", for problems such as learning difficulties of children in poor families, domestic violence, or health compliance.
Cass Sunstein (2014), "*Nudging: A Very Short Guide*", in *Harvard Law School, discussion Paper 799*, available on www.law.harvard.edu/programs/olin_center/papers/pdf/Sunstein_799.pdf

[24] This is described in a paper by Eric Johnson et al. (2012) "Beyond nudges: tools of a choice architecture", in Marketing Letters, 23(2): 487-504, available on link.springer.com/article/10.1007%2Fs11002-012-9186-1#page-1

[25] Experiences in California and the UK

[26] See Anne van Aaken (2015) "Constitutional Limits to Paternalistic Nudging in Germany", available on verfassungsblog.de/en/constitutional-limits-paternalistic-nudging-germany/#.VQL25eHK75s

[27] Alberto Alemanno and Alessandro Spina (2014): "Nudging legally - On the Checks and Balances of Behavioural Regulation", in *International Journal of Constitutional Law*, 12(2), available on papers.ssrn.com/sol3/papers.cfm?abstract_id=2337459
See also: Anne-Lise Sibony and Alessandro Alemanno (2015): "The Emergence of Law and Behavioural Science: A European Perspective", in *HEC Paris Research Paper* No. LAW-2015-1084, available on papers.ssrn.com/sol3/papers.cfm?abstract_id=2562322

[28] When behaviourally informed policy interventions serve to influence or "nudge" people, the term of "libertarian paternalism" is often used, as in:
- Cass Sunstein and Richard Thaler (2003), "Libertarian paternalism is not an oxymoron", in *The University of Chicago Law Review*, 70(4):1159–1202
- Richard Thaler and Cass Sunstein (2003), "Libertarian paternalism", in *The American Economic Review*, 93(2):175–179.

[29] This is extensively described by Tom Goodwin (2012) in "Why We Should Reject Nudge", in *Politics*, 32(2): 85–92.
Goodwin also argues that nudging may be paternalistic and ineffective. A critique of Goodwin was published by Chris Mills (2013) in "Why Nudges Matter: A Reply to Goodwin", in *Politics*, 33(1):28-36. Mills suggests that deliberative democracy may be preferred to nudging, but is much harder to implement and they do not need to be mutually exclusive.

[30] Description of various issues with soft-paternalism and possible ways to fix limits as to what is acceptable have been proposed by M. Binder and L. Kades (2014) in "Autonomy-enhancing Paternalism", in *Levy Economics Institute, Working Paper* No. 800, or by B. Fateh-Moghadam and T. Gutmann (2013) in "Governing [through] Autonomy. The Moral and Legal Limits of 'Soft Paternalism'", in Working Papers of the Centre for Advanced Study in Bioethics No 60.

[31] Daniel Hausman and Brynn Welch, in *Journal of Political Philosophy*, 18(1): 123–136, March 2010

[32] The OECD is creating a repository of behaviourally-informed policy and regulatory intervention.

[33] Such as by P. Hansen and A. Jespersen (2013) in "Nudge and the Manipulation of Choice, A Framework for the Responsible Use of the Nudge Approach to Behaviour Change in Public Policy", in the *European Journal of Risk Regulation*, 1/2013, available on lexxion.de/pdf/ejrr/02%20Nudge%20and%20the%20Manipulation%20of%20Choice.pdf

[34] See for example Cristian Munoz (2013), "Motivational Strategies, Redistributive Policies and Individual Choice", available on noticide.files.wordpress.com/2013/10/cperez-redistribution.pdf

[35] For information about the Nordic, UK and French traffic-light labelling and targeted opposition from the EC regulator, if the traffic-light labelling system were to create obstacles to trade which are in violation of EU laws see www.foodnavigator.com/Policy/Nordic-keyhole-vs.-UK-s-traffic-light-nutrition-label

[36] In “Was Mayor Bloomberg a Nanny?” in *Harvard Public Health Review*, Vol.1, May 2014 available on harvardpublichealthreview.org/wp-content/uploads/2014/05/HPHRv1-Sunstein.pdf

[37] An attitude to risk defines the approach to assess and eventually pursue, retain, take or turn away from risk. The concept of risk tolerance defines the readiness to bear the risk after risk treatment (process to modify the risk) in order to achieve its objectives

[38] See *Test, Learn, Adapt – Developing Public Policy with Randomised Controlled Trials*, a report from the UK Behavioural Insight Team (2014) available from www.gov.uk/government/uploads/system/uploads/attachment_data/file/62529/TLA-1906126.pdf

[39] In *Empirically Informed Regulation, Cass Sunstein* (2014) reviews some components of behaviour-based regulatory instruments: the use of disclosure as a regulatory tool, default rules and simplification, increasing salience, and referring to social norms. The essay is available on lawreview.uchicago.edu/sites/lawreview.uchicago.edu/files/uploads/78_4/Sunstein_Essay.pdf

[40] A thorough review of causes of default effects was made by Craig Smith, Daniel Goldstein and Eric Johnson (2013) in “Choice Without Awareness: Ethical and Policy Implication of Defaults”, in *Journal of Public Policy and Marketing*, 32(2): 159-172 available on dangoldstein.com/papers/Smith_Goldstein_Johnson_Choice_Without_Awareness_Defaults_JPPM_2013.pdf. The authors conclude that defaults (vs. active choices) can be considered as “hidden persuaders” and are effective. Because of the potentially large impact on consumer welfare, autonomy or privacy, the use and misuse of default must be considered in view of ethical and policy implications.

[41] Social networks such as Facebook use “terms of conditions” that include pre-selected options. Their privacy policies evolve regularly and have now become complex and opaque for users, regulators and for the administrators themselves.

[42] See note 23.

Glossary

EFPIA	European Federation of Pharmaceutical Industries and Associations
ENCePP	European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
EMA	European Medicines Agency
EU	European Union
FDA	Food and Drug Administration
HTA	Health technology assessment
MAPP	Medicines Adaptive Pathways for Patients
OECD	Organisation for Economic Co-operation and Development
PCORnet	National Patient-Centered Clinical Research Network
PML	Progressive multifocal leukoencephalopathy
RCTs	Randomised controlled trial
R&D	Research And Development
REMS/RMS	Risk Evaluation and Mitigation Strategies
US	United States of America

MANAGING UNCERTAINTY IN DRUG DEVELOPMENT AND USE INFORMED REGULATION

ENHANCING ADAPTABILITY AND FLEXIBILITY IN PHARMACEUTICALS REGULATION

by Kenneth A. Oye [1], Mark Pearson [2], Hans- Georg Eichler [3], Theresa Mullin [4] and Anton Hoos [5]

The pharmaceuticals sector provides an archetypical example of proactive public sector risk governance. Unlike ordinary consumer products, drugs may not be marketed without advance regulatory approval. Licensing is based on projections of safety, efficacy, and acceptable manufacturing quality, with revisions to the conditions of licenses as safety, efficacy or quality issues arise in use. On 10 October 2014, the OECD and IRGC sponsored a panel on risk governance in pharmaceuticals, with a mandate to describe sources of innovation in pharmaceuticals development and use, to present regulatory, patient and industry perspectives on managing benefits and risks, and discussing current European Medicines Agency (EMA) and US Food and Drug Administration (FDA) approaches to the management of risks and uncertainty over the full life cycle of drugs. The panelists jointly produced this distillation of presentations and summary of discussion themes.

1. Defining the context for pharmaceuticals risk governance: Crises and evolutionary pressures

Kenneth Oye of the MIT Center for Biomedical Innovation and Mark Pearson of the OECD defined the context within which current benefit and risk management reforms are taking place. They described a series of crises that have prompted reforms in drug licensing within the OECD nations. In the late 1950s and early 1960s, birth defects produced by Thalidomide prompted adoption of more stringent standards for demonstration of efficacy and safety in advance of approval and to strengthening of adverse effects reporting systems. In the 1970s and 1980s, the demands of HIV and cancer patients for earlier access to live saving medicines prompted development of accelerated approval and conditional marketing authorization pathways, with deferred validation of biomarkers. In the 2000s, adverse effects caused by Vioxx, Accutane and other drugs prompted improvements in aftermarket surveillance programs and to

[1] MIT; [2] OECD; [3] European Medicines Agency; [4] US Food and Drug Administration; [5] Amgen.

requirements for programs to manage known risks (REMS/RMS). Finally, backlogs in licensing developed, produced by the regulatory challenge of simultaneously improving standards for demonstration of safety and efficacy, providing early access to drugs, managing known risks and strengthening registries and aftermarket surveillance. In the US, the backlog was cleared as pharmaceutical firms covered the costs of licensing through payment of prescription drug user fees. These crisis-driven reforms have improved detection of severe adverse effects, improved management of identified risks and accelerated patient access to drugs for unmet life threatening medical needs.

Figure 1: Evolutionary Pressures for Reform

First, within both the United States and Europe, increasing late stage failures during clinical trials have contributed to rising costs of drug development. In addition, drug companies in the US have added pharmacoeconomic studies to traditional safety and efficacy studies. Marketing requirements, specifically the need to support the addition of new drugs to managed care drug formularies, have contributed to a rise in drug development costs. Globalization of markets has also led to multi-regional clinical trials and additional data collection needs. As Figure 2 suggests, in the United States, R&D efficiency has been declining steadily, with the 2010 cost of bringing a drug to market running at about $US 1.5 billion. Within Europe, the cost of bringing a complex new drug to market now approaches € 1.7 billion, heavily loaded toward the cost of trials conducted at the back end of the process.

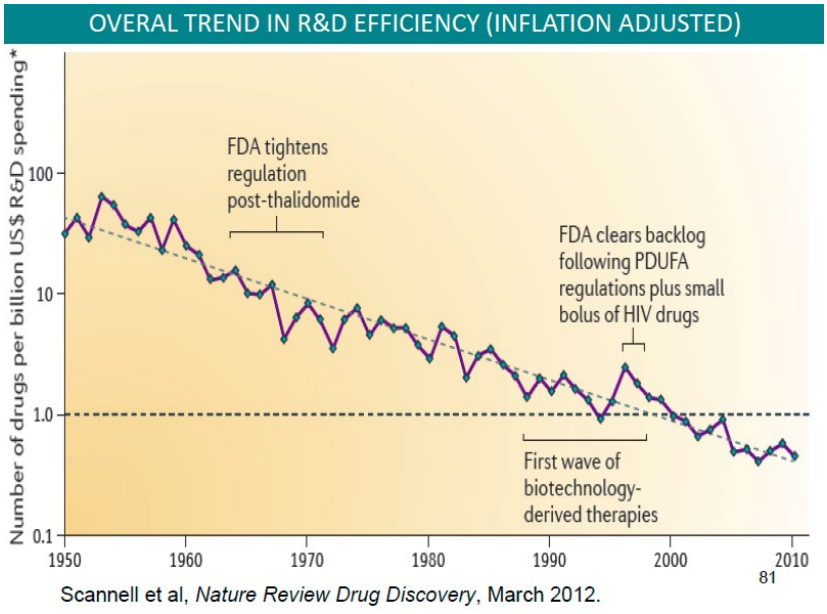

Figure 2: Trends in US R&D Efficiency in Drug Development

Second, as the scientific revolution in genetics reshapes medicine, an increasing number of treatments in development now target smaller genetically defined sub-populations instead of larger heterogeneous populations. This splintering of disease populations and narrowing of labelled indications is improving the effectiveness of medicine. It is also increasing the difficulty of recruiting adequate numbers of confounder cleansed subjects for the clinical trials that provide an evidentiary basis for projecting the safety and efficacy of drugs. As Figure 3 suggests, drugs serving small numbers of patients are priced high. The splintering of

indications has also created smaller market niches that are often filled by only one drug rather than two or more competing drugs, weakening or eliminating market pressures to ease pricing. Smaller market niches affect the size of the base from which sponsors may recover costs, as development and testing expenses are spread across fewer patients. Taken together, these evolutionary changes have simultaneously increased drug development costs and raised drug prices.

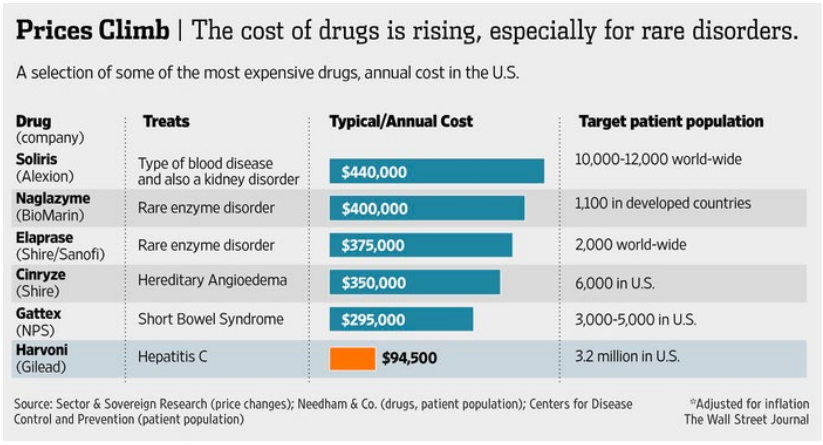

Figure 3: Drug Costs for Selected Rare Disorders

Third, subjects with comorbidities and subjects taking other drugs are excluded from clinical trials to optimize for detection of treatment effects. But because patients often suffer from more than one ailment, take other drugs, and fail to adhere to labels, confounder cleansed subjects taking drugs in trials are imperfect surrogates for patients taking drugs in the real world. **Confounder cleansing of populations of subjects taking drugs in trials increases the ability to detect a drug effect if it is there, but decreases external validity**. Progressive reduction of resulting uncertainties will need to be achieved by way of subsequent studies that could range from clinical trials to the use of data from observational studies. Observational studies should complement, not replace, RCTs. Capabilities within three key domains are important to make observational studies a valuable source of information: data and infrastructure, methodology to address the inherent limitations of non-randomised information, and, lastly, operational enablers including, for example, organisational processes, mind-sets and legal frameworks.

These developments define a complex setting for benefit-risk management in pharmaceuticals. Risk management in medicine now entails engaging with risks associated with medical and other health products, risks to public budgets from the adoption and coverage of new therapeutics, and risks to patient privacy from novel uses of medical data. The European Union and the United States have been converging in their approaches to drug licensing, with substantial areas of commonality and some differences remaining. With reference to speed, the US FDA approves cancer drugs more quickly than the EU EMA. With reference to process, the US FDA is more demanding than the EMA for biosimilars. The EU offers generalized handling of PROMS while the US retains a symptom specific approach. With reference to outcomes in licensing of oncology drugs, 50 percent of drugs are treated identically, 30 percent of drugs have some differences in labelling and in 20 percent of cases a drug is accepted by one and rejected by the other. Contrary to conventional wisdom, there do not appear to be differences in attitude to risk on population level, with some differences in regulation on a case by case basis. Future trends suggest continuing convergence, with greater patient involvement in defining willingness to accept risks, with life cycle approaches to the management of risks of product and with integrated assessments of benefits as well as risks.

As will be discussed by Hans-Georg Eichler, Theresa Mullin, and Anton Hoos, OECD nations face four challenges.

First, market entry regulation will be under sustained pressure for reform. New therapeutic technologies will continue to focus on smaller populations, uncertainty over the efficacy, safety and effectiveness of these emerging technologies will continue to rise, and novel products will strain market entry regulations. For example, therapeutics that are half medicine and half medical devices, regenerative medicines and other living therapeutics simply do not fit easily within existing licensing frames.

Second, clinical trials need to be harmonized and streamlined. In 2013, the OECD issued recommendations on the governance of clinical trials. These recommendations aimed at improving consistency in the interpretation of national regulations, introduced a proportionate regulatory approach, and enhanced protection of trial participants. Both the US and European Union have launched initiatives to simplify and improve regulation of clinical trials.

Third, regulatory science needs to be modernized. This will entail encouraging dialog between innovators and regulators, to improve understandings of scientific developments while maintaining sensitivity to risks of regulatory capture. This also entails increasing transparency in decision-making processes with open acknowledgement of ethical concerns, open recognition of local values and open engagement with patients and providers as well as payers and sponsors.

Finally, the traditional focus on benefit-risk in the context of evidence generation on safety and efficacy for licensing must now be broadened to include a second focus on benefit in the context of evidence generation on the effectiveness for treatment and reimbursement. Faced with rising costs for pharmaceuticals and increasing political pressure to contain costs, patients, physicians and payers are demanding better information on the effectiveness of drugs. Although beyond the purview of traditional pharmaceuticals regulatory agencies such as the EMA and FDA, the acquisition, analysis and interpretation of evidence on effectiveness of drugs in use will be an increasingly significant element of health care policy.

2. Developments in Europe: Managing uncertainty over the life-span of drug development and use

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Hans-Georg Eichler, Senior Medical Officer of the European Medicines Agency, described recent EMA developments including pharmacovigilance legislation, greater trials data access, the EMA/EUnetHTA Post Market Data Plan, and the EMA adaptive licensing pilots. Regulators have to manage competing objectives. Under traditional approaches to drug licensing, drug companies rely on models, in vitro studies and animal studies and randomized clinical trials using confounder cleansed subjects to demonstrate the safety and superior efficacy of a drug. Former FDA Deputy Commissioner Murray Lumpkin speaks of the “magic moment” when a drug is either approved or

rejected. Carefully monitored subjects become lightly observed patients, experimental therapeutics become accepted treatments, drugs are transformed from unproven to safe and effective.

This traditional binary model of drug approval, described by the upper diagram in Figure 4, is now changing rapidly toward explicitly adaptive approaches to licensing with patient experience contributing to evidence development. The bottom diagram describes an adaptive approach to licensing. At the front end, approval would come earlier, would be limited to patients with the most favorable priors benefit/risk and would be conditional. At the back end, observations of patient experience would be strengthened through greater reliance on registry and electronic health records, with systematic analysis of that experience to evaluate safety and effectiveness, and with modification of labels and the terms and conditions of licensing based on patient experience. Conditions now favor implementation of adaptive approaches to risk governance, with both demands for more adaptive approaches to licensing and factors enabling implementation of adaptive approaches. The arguments below are developed more fully in Eichler *et al.* "From adaptive licensing to adaptive pathways: Delivering a flexible life-span approach to bring new drugs to patients", in *Clinical Pharmacology & Therapeutics*, Volume 97, Issue 3, pages 234–246, March 2015.

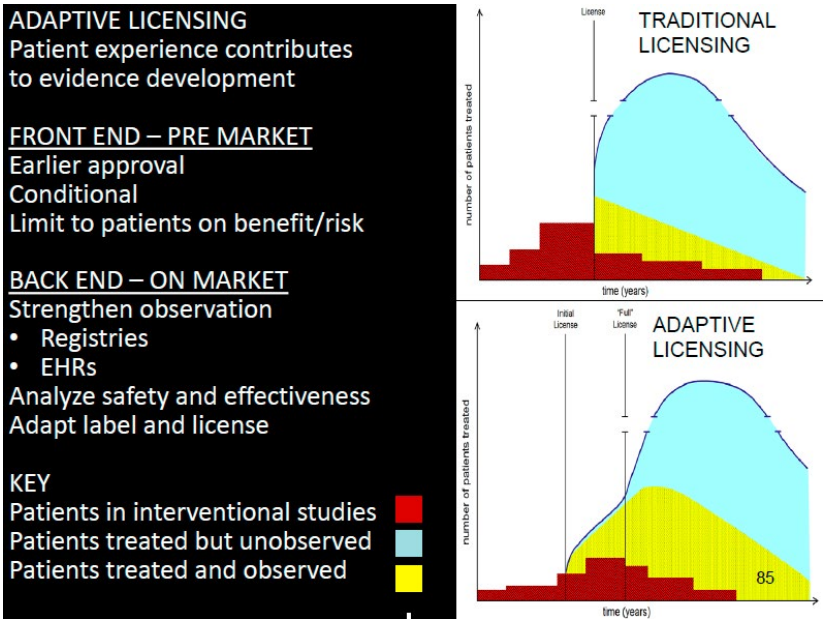


Figure 4: Traditional and Adaptive Licensing

2.1 The demand side: Conditions creating support for adaptive licensing

Four environmental changes described below have converged to heighten interest in the use of adaptive pathways for the development of new drug products.

Demand from patients for timely access to address unmet medical needs: A key driver for adaptive pathways is growing pressure for timely access by patients and their advocates. In the words of a patient representative, "I do not benefit from a drug that is approved on the day of my funeral. The safest drug that one cannot afford or that arrives too late is of no benefit to a patient." Calls for rapid access to new treatments originally came from advocates for patients with HIV, cancer and orphan conditions. Patients with chronic, slow irreversibly progressing diseases with unsatisfactory treatment options are now making the same plea for urgent access as do those with fast progressing conditions. From a patient's perspective, duration of the disease course should not be the key input variable when making the access

versus evidence trade-off. Adaptive pathways recast this ethical dilemma to achieve an appropriate trade-off between 'unmet need' and 'less certainty.'

First, under an adaptive licensing approach, patient-access to treatment should be driven by the likelihood that the treatment will succeed in addressing an unmet need. Decisions on whether to accept a new treatment on a smaller evidence base can be guided by response rates on surrogate endpoints in small patient cohorts or by considerations laid out in FDA criteria for breakthrough therapy designation.

Second, adaptive licensing is not about changing benefit-risk trade-offs. Under any licensing or coverage paradigm, expected benefits should outweigh expected risks for a defined patient population. Anything else is unethical. The issue is whether uncertainties around benefit and risk estimates must be resolved at the time of initial licensing and coverage decisions or whether positive decisions may be based on the balance of probabilities with continuous monitoring.

Third, any acceptance of 'less certainty' about a product can only be temporary, even in the face of high unmet need. Adaptive licensing is designed to foster the progressive reduction of uncertainty by way of pre-agreed evidence generation plans and timeframes, with tight utilization management, monitoring in the marketplace, and an ability and political willingness to restrict or withdraw a product if benefit-risk or value for money is less than expected. Together, these precautions should reduce realized risks for patients relative to current approaches.

Demand for regulations appropriate to stratified treatment populations: Improved understandings of pathologies have led to a growing number of defined treatment subpopulations, with disease stratifications based on genotypic biomarkers and dedicated companion diagnostics.

First, screening-out those likely to develop serious toxicity may allow others to continue to benefit from a drug. In the past, without the ability to identify those patients likely to experience serious adverse events, many patients were denied potential benefits of treatments. Over the next decade, increasingly sophisticated sub-stratification will pose challenges for decision-making on licensing and coverage. Heterogeneity and complexity will result in a large number of narrowly defined patient subgroups. For example, some mutations are more common than others and conventional RCTs will be feasible for some subgroups and not for others. As a consequence, obtainable levels of evidence at the time of licensing decisions will vary across mutation groups. For less common mutations, benefit-risk information may be based on real-world data accrued late in a product's lifespan.

Second, the trend is from subgroup specific medicines toward 'custom-made' medicines. For example, patients receive individualized treatments in gene therapies based on modified patient-derived cells, antisense oligonucleotides and other types of advanced therapies. Treatment-eligible populations are now approaching an 'n of 1'. Basket licensing of a family of products with individual variations may be the only viable route to market, but even minor changes in the molecular structure of a drug could result in significant

changes in toxicity profiles. An adaptive development and licensing approach with modification of initial basket licensing decisions grounded on rigorous observation of patients may be needed.

Finally, ethical questions on trade-offs between the interests of future versus current patients will likely have different answers for each individual sub population. Acceptable uncertainty will be dependent on patient subgroup disease burdens, potential for benefit, and declared preferences on trade-offs across uncertainty and access to new therapies.

Demands from payers for evidence-based reimbursement: Only a small and shrinking fraction of expensive new drug treatments are paid out-of-pocket by patients. Decisions by third party payers on whether and how to reimburse are gaining increasing importance to both patients and marketing authorization holders. Regulatory approval is a necessary but not sufficient pre-condition for effective patient access. There is growing awareness among many payers that they, like the regulators, cannot escape the acrimonious debate over access versus evidence. Payers recognize that the distinction between experimental versus medically necessary is based on a simplified view of evidence and uncertainty, with explicit recognition of the evolving strength of evidence. Many payers are shifting from seeing decisions on reimbursement as a one time binary decision, to seeing reimbursement decisions as on-going processes aiming at providing greater certainty about value for money as evidence accumulates. Once a coverage decision has been made, payers have an interest in limiting initial use to subpopulations with the best benefit-risk ratios, in improving patient adherence, in monitoring treatment outcomes and in modifying conditions of reimbursement in light of evidence on effectiveness.

Demand from pharma/investors for sustainable drug development: The low productivity of bio-pharmaceutical R&D is the result of factors largely beyond the scope of this paper. However, part of the problem rests on factors that may be partially addressed through **harmonized** adoption of adaptive approaches to drug development, licensing and reimbursement. Industry is moving from blockbuster to niche buster business models, even as payers increase evidence requirements for reimbursement and regulators seek to revise licensing terms in light of evolving evidence from use. While regulators have achieved some degree of inter-regional harmonization of evidence standards, payers are at an earlier point in that dialog. The lack of alignment results in differences in standards for drug development. How will adaptive pathways help? Because adaptive licensing requires early engagement with all stakeholders, an adaptive approach to licensing should catalyze consensus building among payers both within and across regions. In fact, the European Federation of Pharmaceutical Industries and Associations (EFPIA) is now working to create a framework for implementation of ‘Medicines Adaptive Pathways for Patients’ (MAPPs).

2.2
The supply side: Conditions enabling adaptive licensing

Even as the factors discussed above have increased demand for adaptive licensing, other developments have improved the prospects for implementation of adaptive pathways.

Better understanding of disease: The revolution in genetics noted above and the use of epidemiological data in reanalysis of past clinical trials may improve the efficiency of RCTs and improve validation of surrogate endpoints. This may reduce the need for concurrent control groups in rare diseases and provide better reference points against which post-licensing evidence generation may be assessed.

Innovative clinical trial designs: Adaptive trial designs offer an opportunity to use accumulating results to focus on patient subgroups that respond better to a therapy and to evaluate populations of patients similar to targeted patient groups. Adaptive trials provide a method for improving operational continuity from pre to post-authorization phases. Adaptive trial designs can also improve the terms of trade-offs between robust evidence generation and patient access to promising therapies in trials by minimizing placebo exposure of patients through interim adjustments.

Rapid learning systems in the healthcare environment: While imperfect, electronic data in health records or dedicated registries are increasingly standardized, reliable and complete. Data on patient reported outcomes, treatment adherence data, morbidity, and daily activities are likely to become more available as e-health records expand and data compatibility is increased. At the same time, methodologies have been developed to address, to the extent possible, confounding and selection biases in observational studies. Finally, data owners are now developing common data models, protocols to query data sets, and governance models. These developments have resulted in significant improvements in the detection of safety signals and evaluation of effectiveness in the real world, including the US FDA Mini-Sentinel Initiative, the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) and the US Patient-Centered Outcomes Research Network called 'PCORnet'.

Bringing patients to the table: Patients' views should be paramount when judging the acceptability of levels of clinical uncertainty for a given treatment scenario. Obtaining representative views from patients is an on-going mutual learning process for both patient representatives and decision-makers. Regulators and HTA bodies now invite patients to declare their preferences on clinical trial endpoints and benefit-risk-uncertainty trade-offs, with promising results to date. Most fundamentally, actively engaging patients in decision-making about their own care enhances transparency, earns trust and enlists patient support for the secondary use of health data to enable evidence generation through the post-licensing phase.

From prediction to monitoring: A common adage among regulators used to be that once a drug 'is out the door' their powers to monitor and steer use and to detect or mitigate risks was limited. In recent years, progress has been made on two fronts that may enable regulators to move from a prediction to a monitoring paradigm.

First, regulators can now impose and enforce on marketing authorisation holders an array of post-licensing requirements to improve information on benefits and risks. Although the imposition of post-licensing information gathering requirements is less common in the US than in the EU, the legal authority to impose additional post-licensing requirements exists in both jurisdictions.

Second, post-licensing identification of adverse drug effects has improved dramatically, see Figure 5. In the 1950s and 1960s, thalidomide use in pregnancy caused phocomelia, a highly visible adverse effect with a low background incidence. It took around 10,000 cases before healthcare professionals made the connection between thalidomide use and phocomelia. Contrast this tragically slow learning with recent rapid detection of adverse effects. Adverse effects of tysabri natalizumab were detected after only three cases of PML were reported. Adverse effects of H1N1 pandemic flu vaccine Pandemrix were investigated after the Swedish Medicines Agency received only six reports of narcolepsy following vaccination. Yet our ability to detect adverse drug reactions with small risk ratios on high-background events is limited.

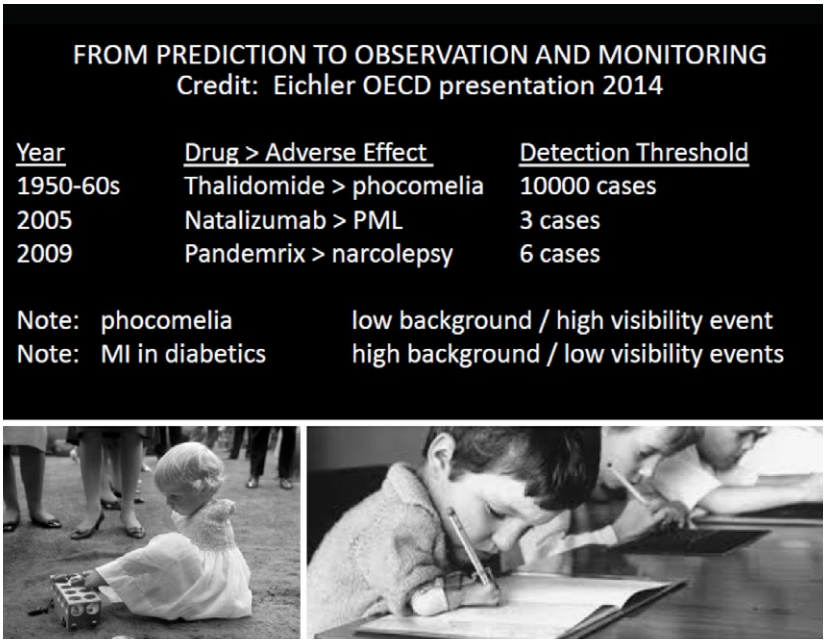


Figure 5: From Prediction to Observation and Monitoring

Targeted prescribing: When a drug is initially intended for use by a well defined subset of patients, wide-spread use by patients outside of the target group might open the door to negative patient outcomes. Regulators have some limited tools to steer drug utilization by way of controlled access programs, prescriber restrictions, educational requirements, and clinical reminder systems. In practice, payers, healthcare systems providers and professional societies, rather than regulators, are the stewards of appropriate prescribing. As new premium priced drugs enter the market, payer interests in effectiveness and cost-containment are leading to increasingly regimented use through pre-authorization requirements, prescribing audits, prescriber restrictions, tiered co-payments and mandatory treatment protocols. Regulator and payer actions in cooperation with the bodies that produce clinical practice guidelines are likely to improve prescription controls, particularly for diseases that are treated in specialist centers.

2.3
Conclusion

This presentation treats environmental changes that have increased demand for adaptive approaches to benefit-risk management and that enable the transition from traditional to adaptive approaches. However, significant challenges remain if the potential benefits of adaptive approaches to licensing are to be realized.

Some potential problems are technocratic and legal. Adaptive approaches to risk governance require the integration of lessons from post-marketing observational data and data from experimental trials in a manner that compensates for the weaknesses of each. Observational data including payer records and electronic health records are subject to selection biases, misrepresentations of indications, simple errors and noise, presenting problems in terms of internal validity of inferences. The development of methods of data standardization and curation and methods of causal inference suited to data with biases and selection effects present technical challenges. Clinical trials of limited duration, with high patient adherence in populations cleansed of comorbidities and use of other drugs present problems in terms of external validity – generalization from trials to ordinary treatment populations. The integration of observational and trial-based information, including working back from hypotheses generated from post-market observational data to limited trials to confirmatory targeted trials, presents legal as well as technical challenges. To make adaptive licensing function effectively will require work on terms of access to data, including analysis of intellectual property rights, human subjects protocols and privacy rules.

Some potential problems are political and economic. First, experience has shown that it is politically challenging to remove a drug from the market or to restrict payment should the initial benefit-risk balance not be confirmed post approval. Once patients have access to a drug, resistance to withdrawal can be intense. These issues will require substantial discussion before rather than after conditional approval of drugs, with inclusion of patient groups as critical stakeholders. Second, once early access is obtained, not all developers will be interested in making good on controls, observation and potential narrowing of terms of access that constitute the 'back end' of adaptive licensing. Care must be taken to ensure that this post-marketing 'back end' of adaptive licensing is fully implemented. Controls on initial prescriptions, systematic post-marketing observation of safety and effectiveness of drugs-as-used, and modification of the terms of licensing and reimbursement based on real world experience are critical to effective management of uncertainty over the life cycle of drugs. In practice, this will depend on engagement with payers – with a clear interest in evaluating effectiveness - as well as sponsors.

Finally, implementation of adaptive pathways will be more difficult in the US than the EU. For example, limiting access to an approved drug to a subset of the population will be more difficult in the US, where the practice of medicine allows for off-label use, than in the EU. While sponsors, regulators, HTA bodies and payers are now collaborating in the EU, other jurisdictions, notably the US, do not have national healthcare systems with centralized management on access and payment. Conditions within the EU have allowed the EMA

to conduct pilot projects to assess the feasibility of adaptive pathways to licensing. At the end of the day, the characteristics of adaptive approaches to licensing will be shaped by differences in national and regional conditions and by observation, analysis and feedback from regulatory experience.

3. Developments in the United States: Managing risk and uncertainty through the drug life cycle

Dr. Theresa Mullin, Director of the Office of Strategic Programs of the US Food and Drug Administration Center for Drug Evaluation and Research, described recent US developments, including patient-focused drug development, FDA Breakthrough Product Designation, formalized benefit-risk assessment, and use of pharmaceutical quality metrics. A benefit-risk approach frames all FDA risk management decisions across the life cycle of a drug, with emphasis on transparency and continuous learning. FDA initiatives include Patient Focused Drug Development and FDA Breakthrough Product Designation early in the drug life cycle, the use of pharmaceutical quality metrics in manufacturing of generics late in the drug life cycle to cover off-patent drugs 80 percent of which are generic, and the use of benefit-risk analysis throughout the life cycle.

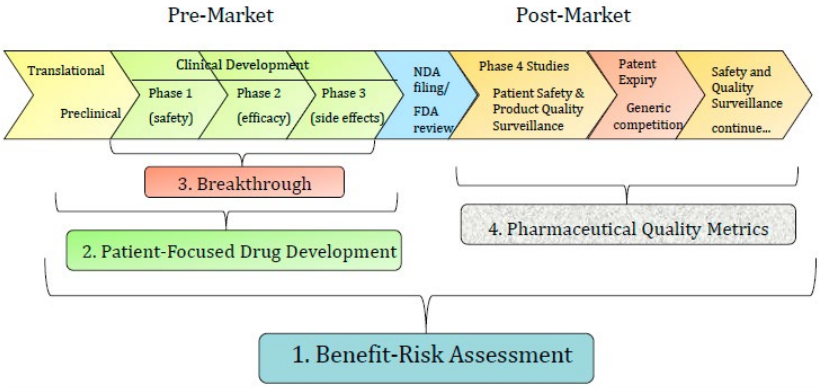


Figure 6: Initiatives in Context of Drug Life Cycle. Source: US Food and Drug Administration, www.fda.gov

The FDA uses a **Formalized Benefit-Risk Assessment** approach to structure and manage the technical complexity of new drug assessment, see Figure 6. This assessment is informed by science, medicine, policy, and judgment. The law and regulations concerning the drug review process generally provide broad principles and are not case-specific, so FDA works to develop consistent policy in taking action within its legal and regulatory authority, to make decisions in a way that is fair, not arbitrary or capricious. FDA communicates this policy through guidance. However, in a given case it may determine that a generally applicable guidance is inappropriate, and in such cases retains the flexibility to take a different approach. Since each decision either is made in the context of established policy or establishes new policy, this serves FDA as a sort of 'case law'. Although the quantity of information to be evaluated and considered by FDA is substantial, there are residual uncertainties resulting, for example, from the gaps in the data or current scientific understanding, and human judgment and values must come into play. The framework for benefit-risk decision-making summarizes the relevant facts, uncertainties, and key areas of judgment, and clearly explains how these factors influence a regulatory decision. This helps inform and clarify the regulatory discussion. It also serves to communicate the basis for FDA's regulatory decision to the public, while documenting the decision for reference as FDA considers similar benefit-risk assessments in the future.

As shown in Figures 7 and 8, the FDA framework for benefit-risk assessment is structured in terms of the following five major considerations (corresponding to the rows): the analysis of severity of the disease condition being targeted by the drug; a review of current treatment options to determine the degree of unmet medical need; benefits observed in clinical trials; risks reflected by the safety findings from clinical trials; and consideration of whether the identified risks can be managed to ensure benefits would exceed risks. Each of these five considerations is further structured into two areas to identify (a) the facts that are known versus residual uncertainties for each consideration, and (b) the conclusions and reasons of the reviewers' assessment of the evidence and uncertainties.

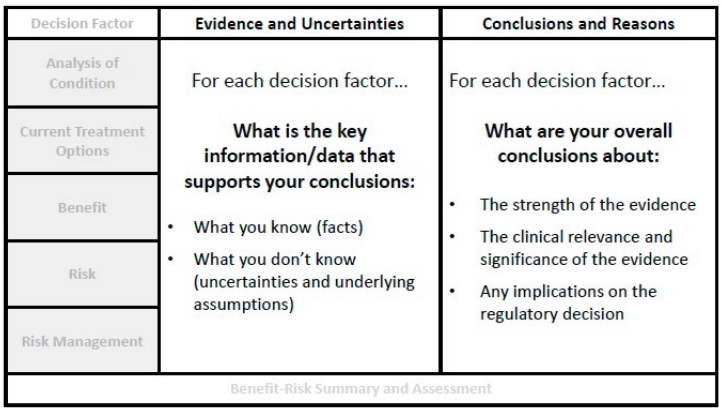


Figure 7: FDA Benefit-Risk Framework (Columns). Source: US Food and Drug Administration, www.fda.gov

The FDA uses a qualitative approach that is grounded in quantification of data elements at the time of marketing approval. Benefits are grounded in data on efficacy endpoints from controlled clinical trials. Risks are grounded in data on harms reported in clinical trials and from spontaneous adverse effect reports. The evaluation of benefits and risks is dynamic, with understandings of both benefits and risks evolving over the product life cycle. This is not a mechanistic process.

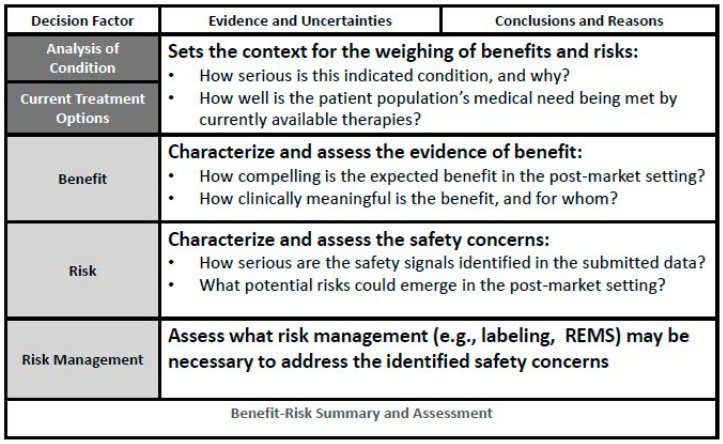


Figure 8: FDA Benefit-Risk Framework (Rows). Source: US Food and Drug Administration, www.fda.gov

FDA developed the **Patient Focused Drug Development program** (PFDD) in recognition that patients are uniquely qualified to inform clinical context for FDA's benefit-risk assessment: in particular the impact of disease on patients, i.e., the analysis of condition, and the effectiveness of currently available therapies in treating the disease impacts that matter most to patients. The traditional patient representative program only enabled participation of individual patients who received conflict of interest screening and some regulatory process training, and those patient representatives have had burden of speaking for all those with a disease. Yet one size does not fit all who are afflicted with a given disease. The FDA needed more diversity. In a pilot exercise, FDA is setting up 20 different public webcast meetings in 20 different disease areas. Only patients are allowed to speak. The patient input in the meetings held since the start of this initiative in 2013 have been well-attended by patients and have provided powerful insights for FDA reviewers and also for industry sponsors who have attended the meetings. Public stakeholders and industry have identified this initiative as a priority for further expansion in the coming years, see Figures 9 and 10.

The FDA established **Breakthrough Therapy Designation** to foster more rapid development of drugs that offer the potential of substantial improvement in patient outcome. The FDA Safety and Innovation Act (FDASIA) of 2012 Section 902 provided for a new Breakthrough Therapy Designation. A breakthrough therapy is a drug which: (a) is intended alone or in combina-

tion with one or more other drugs to treat a serious or life threatening disease or condition and; (b) preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough designation is based on preliminary clinical evidence of potential improvement on a clinically significant endpoint relative to available therapies. By contrast, Fast Track designation is based on nonclinical or clinical evidence of the potential to address unmet medical needs. Both Breakthrough and Fast Track programs are intended to expedite the development and review of drugs for serious or life threatening conditions.

- Establishing the therapeutic context is an important aspect of B-R assessment
  - Patients are uniquely positioned to inform understanding of this context
  - Current mechanisms for obtaining patient input are often limited to discussions related to specific applications under review
- PFDD offers a more systematic way of gathering patient perspective on their condition and treatment options
  - FDA will convene at least 20 meetings on specific disease areas over the next five years
  - Meetings can help advance a systematic approach to gathering input

Figure 9: Patient-Focused Drug Development. Source: US Food and Drug Administration, www.fda.gov

If a drug is designated as a Breakthrough Therapy, FDA will expedite development and review of the drug. The program is establishing a rolling review process with additional engagement between FDA staff and applicants. Prequalification based on the criteria outlined in Section 902 is required. Requests for breakthrough designation may be submitted with the Investigation of New Drug (IND) application with at least one phase I trial complete. Breakthrough designation has substantial benefits to the sponsor, with almost unlimited meetings to discuss study designs and development processes to avoid delays and mistakes. These measures have reduced clinical development time by half, down from an average of 7 to 10 years, with clear benefits for sponsors seeking to reduce development costs and patients seeking earlier access. As of October 2014, 190 applications for breakthrough designation had been submitted and 57 applications had been accepted, see Figure 11.

FY 2013 (Conducted)
- Chronic fatigue syndrome/myalgic encephalomyelitis
- HIV
- Lung cancer
- Narcolepsy

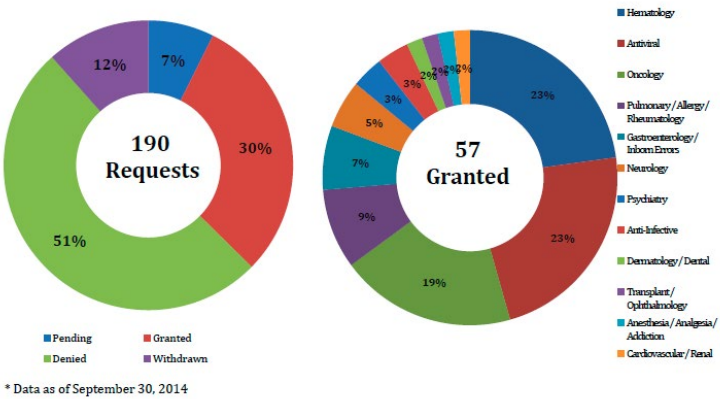
FY 2014 (Conducted)
- Sickle cell disease
- Fibromyalgia
- Pulmonary arterial hypertension
- Inborn errors of metabolism
- Hemophilia A, B, and other heritable bleeding disorders
- Idiopathic pulmonary fibrosis

FY 2014 – 2015 (to be announced)
- Alpha-1 antitrypsin deficiency
- Breast cancer
- Chronic Chagas disease
- Female sexual dysfunction
- Functional gastrointestinal disorders
- Parkinson's disease and Huntington's disease

*FDA will initiate another process to determine the disease areas for FY2016-17.

Figure 10: PFDD Meetings FY 13-15. Source: US Food and Drug Administration, www.fda.gov

The FDA **Pharmaceutical Quality Metrics Program** addresses risk management challenges in global regulatory oversight of drug manufacturing, which is relevant to both premarket evaluation of facilities and subsequent monitoring of the state of manufacturing quality control for marketed drugs later in their life cycle. With increasingly global supply chains, active ingredients, excipients, and finished dosage forms are typically produced overseas in different facilities in different countries some of which have limited regulatory capacity and less developed infrastructure. Because consumers and health care payers (i.e., the market) often cannot discern differences in quality there has been less of a market incentive for manufacturers to invest in quality. As shown in Figure 12, failures to invest in manufacturing quality, presumably in order to remain cost competitive, have



* Data as of September 30, 2014

Figure 11: Breakthrough Therapy Designations. Source: US Food and Drug Administration, www.fda.gov

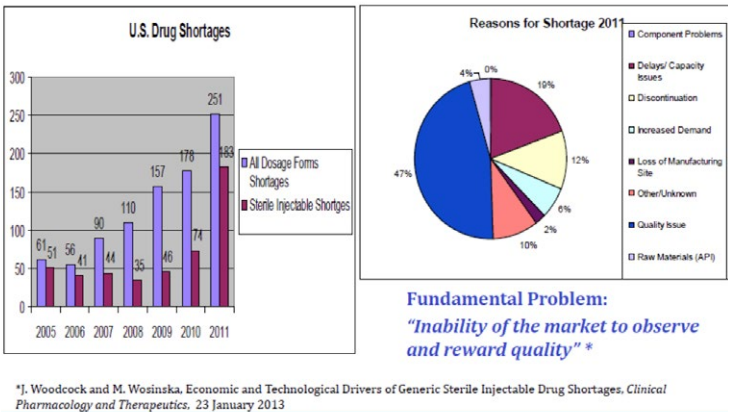


Figure 12: Drug Shortages and Quality Problems. Source: US Food and Drug Administration, www.fda.gov

been identified as a leading factor in recent and widely publicized drug shortages. FDA's new program to explore the use of manufacturing quality data that is already required by statute to be provided to FDA investigators upon inspection of a facility, could help inform this important dimension of value.

The intention of the program is to induce industry to improve manufacturing and oversight of manufacturing and to facilitate a more risk-based inspection schedule, via improving FDA surveillance of the state of the firms' quality systems and product and process capability, with less frequent inspections for better performing sites. The program should also support the aim of achieving enhanced product quality without the need for extensive regulatory oversight and ultimately may help to drive a reduction in quality-related shortages and recalls.

4. A call for adaptability and flexibility from a patient and industry view

Anton Hoos, Principal of M4P (Medicines4Patients) Consulting at the time of the conference and currently Vice President of Amgen, examined EMA and US initiatives from the perspectives of industry and patients. He examined sponsor interests in how regulatory reforms mesh with product development realities and patient interests in access to safe and efficacious medicines. All stakeholders in the health area must serve the needs of patients and society, but the collective and individual needs of patients vary widely. The range of expectations of the benefit associated with a particular medication and the potential risk a patient / caregiver is willing to accept depends on the condition to treat or to prevent. For vaccination of healthy individuals, acceptance of potential adverse effects is typically low. For life threatening conditions that may lead to death within a very short period of time, acceptance of potential adverse effects is typically substantial, see Figure 13.

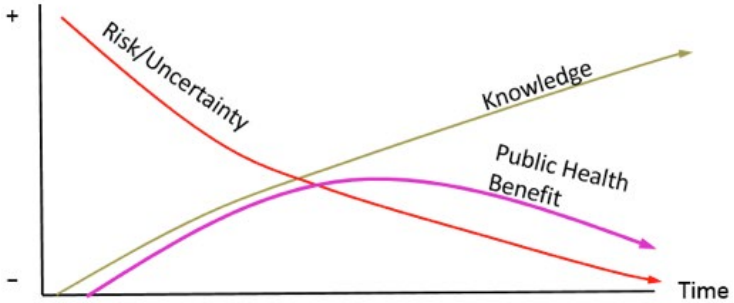


Figure 13: Risk/Uncertainty Reduction vs. Public Health Benefit

In this context it is important to reach an understanding across all stakeholders about the benefit and risk of a therapeutic or prophylactic intervention and the degree of uncertainty associated with the available data at any point in time. The more data that is requested for a particular therapy or intervention the more time or cost will be required to make a therapy available. Historically all gatekeepers involved in the health system have requested more data to optimize their individual data set without coordination with other parties. This is true of regulators, HTA agencies and payers, both within and across each of these silos. This has led to an enormous increase of cost for the pharmaceutical sector and it may lead to a net disadvantage in terms of public health benefit.

Compared to any other sector, R&D expenditure in pharmaceutical industry are enormous:

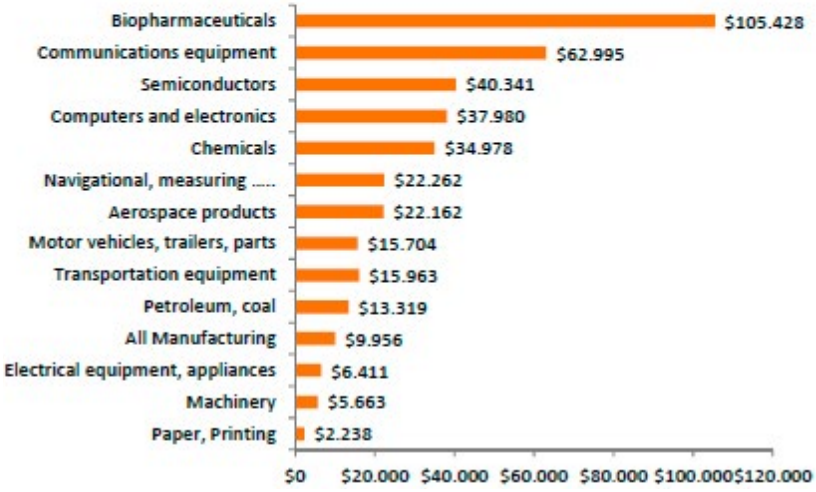


Figure 14: R&D Expenditure per Employee 2000–2007

While all stakeholders are making an effort to work with patients, their voice has not been heard sufficiently. A recent study by the UK Genetic Alliance reported that patients find the current regulatory process slow, bureaucratic, paternalistic and opaque. A European insight derived from the UK Genetic Alliance study reveals that some 50 percent of patients would like to see joint decision-making from setting the research agenda via designing clinical trials to regulatory decisions:

Q12-15 How much do you think patients should be involved in...	Setting the research agenda	Designing clinical trials	Marketing authorisation decisions	Post-marketing authorisation decisions
	%	%	%	%
Patient decides	10.1	7.8	10.1	10.3
Joint decision making	57.8	48.8	48.6	55.1
Involvement	18.9	27.2	23.0	19.8
Consult before deciding	13.2	16.3	18.3	14.8
Total	100	100	100	100

Figure 15: Patients' View on Decision-making

Interestingly many patients would be open to accept higher risk and uncertainty when offered access to new medicines. As Figure 16 suggests, patients believe that regulators should allow patients to secure access to medicines even if earlier access means that tests would rely on smaller numbers of subjects in trials and that approvals would be granted with more uncertainty over efficacy and safety. However, patients expressed reluctance to accept serious side effects and significant risk of death as the price of early access.

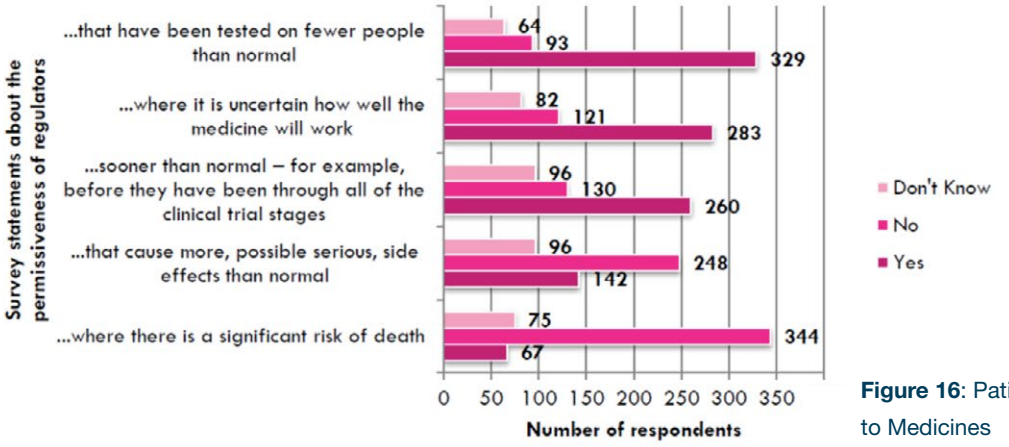


Figure 16: Patients' View on Access to Medicines

Patients are increasingly engaging in the drug development, approval and reimbursement process with the goal to secure timely access to medicines that they need. The US National Health Council published their view about patient involvement in the regulatory process as follows:

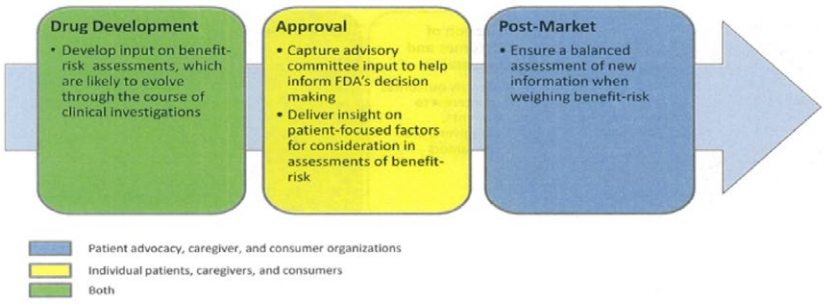


Figure 17: Patients' View on Engagement

The mandate of all regulators is to license safe and efficacious medicines. Given that all stakeholders, first and foremost patients, seem to be willing to accept a higher degree of uncertainty in return for earlier access to much needed medicines, adaptive approaches to drug licensing and reimbursement are needed. Key aspects will include joint prospective planning, agreement on the acceptable degree of uncertainty and risk as well as continuous evaluation of benefit and risk during a gradual broadening of access to patients. In March 2014 the EMA started its pilot program for adaptive licensing to determine whether and how these principles might be translated into practice.

5. Discussion

Theresa Mullin and Hans-Georg Eichler emphasized similarities in the US and European approaches to risk management. Mullin spoke of flexibility and discrimination within the US process, with degrees of acceleration, strength of controls on initial use, and reliance on adaptive elements tuned to patient interests in safety, efficacy and early access to address unmet needs. Eichler spoke of how the US and EU share common goals, with similar upstream pre-licensing processes, similar policies addressing quality problems in licit, counterfeit and illegal drugs, and emerging differences in post-licensing downstream risk management.

Those downstream differences are a product, not of philosophical differences, but of sharp differences in the structure of reimbursement. The EU has public payers while the US has a plethora of public and private payers. Within Europe, payer policies on reimbursement may control off-label use and limit inappropriate utilization and prescription. Within the US, the FDA may indirectly affect utilization and prescription by altering labels and issuing warnings, thereby reshaping liability exposure and altering payer and provider behavior. Mark Pearson noted that European public payers had a theoretical option to "dereimburse" drugs if warranted by emerging evidence on safety or effectiveness. Although not widely used, a payer-based approach to adherence could be used to encourage physicians and patients to practice evidence-based medicine, with practices updated on the basis of emerging information. Anton Hoos reinforced Pearson's observation on controls of inappropriate drug

use, noting that industry as well as payers could exercise some controls on distribution and use by physicians. Theresa Mullin picked up on the theme of improving physician risk-benefit governance, stressing the need to set up accessible information systems and risk management protocols.

Hans-Georg Eichler offered some cautionary words, noting that many of the proposed remedies are self-limiting. Risk management by limiting the right to prescribe to trained physicians can work well, as it has done with the re-introduction of thalidomide. But this approach can only work for a small number of therapeutics and physicians. Similarly, relying on physicians and payers to analyze dossiers to establish patient eligibility with complex screening criteria can work well, but is personnel intensive. Decision support tools will be needed if that strategy is to be used more broadly. Finally, drug prices will affect the viability of complex benefit-risk management strategies. As a drug becomes cheaper, industry interest in addressing risks to market the drug will decline.

6. Questions from the floor

Question: Double blind randomized placebo controlled clinical trials are commonly viewed as the gold standard. How prepared are regulators to deal with non-randomized data? For basing decisions on information other than RCTs?

Response: Hans-Georg Eichler noted that RCTs are the best tool that we have to avoid bias and selection effects. But regulators commonly authorize drugs on the basis of information from sources other than large RCTs. Many drugs today never see this randomization. Regulators expect to see smaller targeted RCTs, more case studies, and observational studies with real life data. Regulators will need to learn to use all of these data sources and are moving on this trajectory. Theresa Mullin agreed. She noted that Bayesian methods needed to be used in analysis of evidence from RCTs and in extrapolating from that evidence base to post-licensing observation of drug benefits and risks. She added that the expanded use of clinical trial data from multiple regions with heterogeneous patient populations could improve the quality of those inferences by increasing variation within study populations, but that international variations in standards governing the conduct of trials posed challenges. Agencies from the US, EU, Japan and others are now actively conferring on harmonization of regulatory standards for multi-regional clinical trials data. Finally, Kenneth Oye noted that the traditional sequence of RCTs first and observational data second might have to be altered. As hypotheses on safety, efficacy and effectiveness emerged from studies based on observational data, targeted RCTs to confirm or disconfirm hypotheses emerging from observational studies and to probe causal inferences will come to be used more frequently.

Question: How will these developments affect developing countries?

Response: Theresa Mullin suggested that generalizations across the extremely diverse set of non-OECD countries may be ill advised. RCTs are now

conducted on a global basis. For example, most US companies have sites for conducting trials in other continents and secure marketing authorization in many countries. While differences in the terms of licensing are common, there is significant work sharing. Developing countries typically look at licensing decisions by advanced industrial countries and may reference approval elsewhere. The New Pharmaceutical Regulators Forum came together to discuss operational issues and to leverage the experience and knowledge of others.

Question: Will adaptive licensing be useful for approval of biosimilars? What are the potential challenges for international harmonization on biosimilars?

Response: Hans Georg Eichler suggested that regulators seek to make new technologies available as soon as is justified by need and risk profile. By that definition, a biosimilar is not an innovation. Biosimilars have a place at the table because they break monopolies, not to provide access to a new therapy. It is not clear why levels of certainty should be reduced if patients already have an option. Kenneth Oye noted that as indications splintered and target treatment populations grew smaller, more and more monopolies could be expected. He suggested that breaking monopolies should be viewed as a legitimate factor in drug licensing. Mark Pearson noted that the ultimate objective of regulatory policy is not just to license drugs, but rather to deliver better health care to populations. Pearson urged regulators to consider licensing drugs to break monopolies and increase access, but also noted that such decisions had to be mindful of preserving incentives to innovate.

Question: What are the prospects for drawing on innovations in information technology to improving monitoring for efficacy and adverse effects? These innovations include digital prescribing with better records, individual bracelets that track exercise, sleep, and vital signs, and drug delivery systems that report on use to central locations.

Response: Anton Hoos described an extensive set of initiatives that make good use of new technologies for monitoring use with apothecaries, hospitals, and doctors. The FDA Sentinel project, Optum Laboratories data analysis systems, and Myownmed.com are among many initiatives that capture data and make data bases talk. Industry is definitely coming to this big time. Hans-Georg Eichler and Theresa Mullin agreed. Without improvements in technologies for monitoring, we would be back in the Thalidomide age. The technologies are developing and it would be foolish not to use them. Risk Evaluation and mitigation strategies can work better with these new tools. Mark Pearson, Theresa Mullin and Kenneth Oye offered some notes of caution. New online data sources are useful only if they are used. Only four OECD countries are linking primary care data to hospitals in a manner that allows evaluation of the effects of care. Finally, technical issues matter. Data standards, fundamental infrastructure, linkages across data bases and tools to extract information from unstructured data are needed. To whom is data provided, at each phase in the life cycle of drug development and use? How could utilization of data affect the size of markets and rates of reimbursement? Private owners of data often lack incentives to place that information into the public domain.

CONCLUDING REMARKS

FROM RISK REGULATION TO AN INNOVATIVE RISK GOVERNANCE

by Lorenzo Allio[1]

Over the past two centuries, societal problems and citizens' concerns for safety and security have mainly been addressed through public forms of risk management. Today, government action mainly seeks to manage risks posed by technologies, products, economic and financial activity, and lifestyle choices. To be effective, **public risk managers must strike a balance between fostering innovation and prosperity on the one hand and maximising security and equity on the other** – a balance that changes over time.

Like any other actor facing globalisation, **regulators are called upon to grasp and react to increasingly inter-connected and intricate problems** whose emergence, type, scale and evolution are difficult to anticipate and control. What more, they have to do so in a context of higher demands from stakeholders and the public with regards to transparency, accountability and participation in all stages of the risk management cycle – from the identification of the mischief to formulating options and assessing impacts, to sharing implementation and enforcement tasks and review.

Traditionally, governments have so far responded to the growing sophistication of the societal challenges by engineering increasingly refined technical solutions without denaturing the intrinsic organisational and cultural rationale of the public sector. The model based on ever more specific and numerous silos of deep expertise and on typically command-and-control regulation is no longer the only model fit for purpose – it needs to be refined and complemented, and **governments now work at the intersection of multi-disciplinary and multi-actor knowledge, to integrate various perspectives**.

[1] European Risk Forum and allio|rodrigoconsulting.

1. Grasping approaches to improving risk regulation

This publication looks at different approaches that have emerged across various policy areas and on the initiative of various actors over time, which may set the basis for designing innovative risk governance. On the basis of the collected papers, these concluding remarks try to shed a light on how to 'read' them and how to internalise key lessons from those experiences. They result in an embryonic roadmap to renovate risk management by public authorities – a stimulating agenda ahead. The ambition is to **contribute to improving the exercise of the regulatory power (through co-decision, shared responsibility and transformation) and, by so doing, restoring trust and confidence between regulatory authorities and the regulated**.

The rationale for public risk management is expanding both in nature and scope – from economic and discrete to also social and systemic.

Regulatory interventions are no longer exclusively dictated by the willingness and necessity to curb economic inefficiencies and market failures, as modelled by neo-classical economic theories. Regulators still seek to intervene when in presence of non-competitive markets, externalities and sub-optimal supply of public goods. Yet, social regulation is increasingly adopted. It strives to achieve societal objectives, shifting for instance from guaranteeing minimum standards for public safety to achieving 'well-being' in a more normative way. This is not at all wrong per se, but it clearly raises the stakes of what regulators ought to do and can do (well).

The desirability and indeed **necessity to widen the remit of risk management to embrace more comprehensive approaches** is a recurring theme of the publication. Indeed, various perspectives of such an 'expanded risk management' are presented across the papers.

▶ **Colin Scott**'s analysis of transnational private regulation regimes stresses the intrinsic potential of private arrangements, either in terms of direct efficiency gains compared to traditional risk management solutions by public authorities, or because of socially-driven incentives to enhance risk management options – what he labels 'community solidarity'. Societal added values may be swifter and smoother coordination and functioning of markets and more generalised and effective implementation of risk management solutions. In addition to the stakeholder collaboration highlighted by Yosie, Scott's paper draws the attention also to the competitive nature implicit in much of the transnational private regulatory regimes – and how this needs to be managed to avoid distortions or detrimental re-allocation solutions. In any event, the examples brought forward show the leadership of private actors in topping government action across national boundaries.

▶ **Terry Yosie** reviews private sector initiatives for the management of systemic risks, presenting approaches to private public partnerships based on well-defined goals, flexibility to reach these goals and an effective checks and balances control system. He highlights how piece-meal or discrete approaches might

no longer suffice and that systemic risk management is an attempt at clustering various (types of) risks so as to better manage a system. It is simplistic to imagine effective management through individual and disconnected actions, if we acknowledge that economic, social, geo-political and environmental risks co-exists and affect simultaneously both the 'micro' and the 'macro'.

There are then risks that individually have the potential of disrupting entire systems through cascading or ramification effects. Energy black-outs and natural disasters are points in case. They can interrupt production or distribution chains that paralyse whole organisational systems. Public managers face moreover the challenge of the unpredictability of the occurrence of such risks and subsequently the urgency to deploy contingency plans. Stress tests are therefore applied periodically to ensure the readiness and effectiveness of the planned management options and anticipate bottlenecks. Diversification by using right asset allocation mix strategies or insurance helps mitigate such systemic risks but it is usually almost impossible to completely avoid them.

Like in Yosie's line of argument, **the trans-boundary nature of systemic risks (and the related risk management schemes) testifies here of the virtual impossibility to confine interventions within discrete jurisdictions and limit them to public actors**. We face by definition multi-actor, multi-disciplinary networked governance. The next step will be to design schemes to measure success of private and public-private initiatives to deal with systemic risks, including through benchmarking, and to monitor progress of coordinated action. There is a variety of evaluation or monitoring schemes, such as those of the Global Reporting Initiative[2], but robust standard approaches to measure progress in systemic risk management and sustainability is yet to emerge. The relatively recent origin of system-level risk assessments that incorporate sustainability account for the high interconnectivity of the technological, organisational, social and political dimensions offers the private sector great opportunities to develop more effective and efficient management solutions than in the past.

A further expansion of the traditional risk management concept draws from the imperative acknowledgment that any risk management intervention is, by its nature, designed to trigger behavioural changes in citizens or companies, or both.

▶ As **Ortwin Renn and Marie-Valentine Florin** report, regulators are increasingly considering insights from behavioural sciences to best exploit the marginal potential for change in behaviour. The authors underscore the importance of making risk management interventions align well with how people behave spontaneously, hence leveraging on existing (revealed or latent) preferences and incentives. This not only helps overcome inefficiencies linked to command-and-control regulation but it also shifts the emphasis on incentive-based, performance-based and outcome-driven solutions. Understanding the root causes of individual behaviour and preferences becomes increasingly important to achieve effective risk management and to address management trade-offs. The challenge is for risk managers to then be able and capable to exploit the acquired knowledge and leverage on our heuristic and cognitive biases and shortcuts.

[2] See www.globalreporting.org.

Public regulators need to enrich their risk management portfolios – from being direct managers to serving as catalyst platforms – but they must assert themselves as the guardians of transparent and rigorous evidence-based decision-making

Systemic, private-driven (multi-stakeholder) risk regulation presents many challenges and it might be utopic to foresee its implementation at a global level. It has in particular to pass two arduous tests.

- The first test is about trade-off choices: what needs to be given up for what? Who should be affected and how? Solutions to these questions may well vary from region to region, from issue to issue, but in a systemic perspective the calibration of the management solutions might be limited and certainly is controversial.
- The second test is about the wide-spread lack of trust between the private sector (and multinational corporations in particular) and NGOs and the citizens, and the often difficult communication between these actors and public authorities. On individual technologies, products or 'issues', barriers can be (and indeed have been) levelled down. However, many systemic policy issues are admittedly still majorly controversial – such as authorisation of GMOs, biocides, antibiotics and endocrine disruptors or exploitation of non-conventional fossil resources (e.g. shale gas).

Contemporary risk management needs therefore to rely on ever more porous interfaces and thicker dialogue among all involved actors.

▶ This is clearly an issue that emerges from the insights offered by the discussion on adaptive licensing in pharmaceutical regulation and the search for ever better performing risk management systems, which **Ken Oye and colleagues** highlight in their conference report. The innovative licensing approaches developed by EU and US drug regulators take great account of the rationales, constraints and motivations of the affected actors, while risk assessment practices remain grounded in high quality scientific evidence, and cost-benefit appraisals inform risk management decisions. The authors stress how greater adaptability of management solutions can address risk acceptance of specific (individual) patients that await new but not yet accessible treatment. This results from the integration of feedback from patients groups and the deployment of mechanisms for policy learning from past experience along the entire life-cycle of research, product development and licensing.

The new forms of risk management presented in the papers stretch the limits of conventional wisdom when it comes to defining the legitimacy of the solutions deployed. So dwell Renn and Florin on the very legality of nudging, coming to the conclusion that behaviourally-informed risk regulation to prevent or restrict risky behaviour in fields where freedom is protected by the law may be legitimate, as long as it is rooted on democratically (socially) agreed societal goals. In turn, the adaptive licensing case study illustrates how such an approach is an attempt to walk the thin line trading off uncertainty about cost effectiveness and safety on the one hand, and access to new therapies and investment cost recovery on the other. While stemming from different

rationales, both approaches allow for a conceptual shift from the traditional risk management towards more or less controlled forms of what might be labelled 'enlightened experimentalism'. Both behaviourally-informed and adaptive regulatory designs are applied to increasingly refined target groups, thereby fragmenting solutions that traditional risk regulation has by contrast tended to apply erga omnes.

Flexible, adaptive and responsive forms of risk regulation bear great potential for effectively meeting societal demands and stimulating innovative and efficient solutions. They nonetheless also raise the question about the capacity of public regulators to institutionalise and replicate these approaches in such a way that public risk management still meets other compelling imperatives for government action like the principles of legitimate expectations and legal certainty. The issue of precaution remains the elephant in the room in this respect. Risk managers are hence invited to invest in continuous re-evaluations of the risks as a function of changing contexts – be the latter determined by advances in (scientific) knowledge, by changes in individual exposure to the risk or by re-definition of the underlying trade-offs. In the case of drug authorisation processes, for instance, between the expectations and risk perceptions among patient groups on the one hand, and structural constraints by the public health care systems and the need for return in investment by industry on the other hand. There hence is a reiterated need to ground all risk management choices, no matter their nature, in robust, transparently and timely accessible evidence.

2. Revisiting risk regulation – Towards a roadmap

How can then regulatory action be improved on the basis of the practices currently in place? What follows are initial elements of a possible roadmap which urges public risk managers to work along four distinct yet intimately intertwined strands of action:

1. **Creating and maintaining favourable framework conditions** – Public regulators need to deepen their understanding of, and facilitate, the competition–collaboration dynamics that characterise the interaction between stakeholders, with a view to create a positive 'race to the top' in terms of conceiving or implementing superior risk management solutions. Such solutions are superior if they prove their effectiveness but also their credibility and legitimacy.

   One way forward would be developing forms of participatory decision-making, exactly to reap the potential of stakeholder comparative advantages, to achieve early acceptance (if not consensus) and enhanced legitimacy by addressing and eventually internalising potential conflicts.

   This has impacts on the way public policies are designed – i.e. how strategically decision-makers link policy objectives across the various government interventions and how consistent and proportionate the instruments regulators deploy are with respect to those objectives and the related impacts.

2. **Using the best available and impartial (scientific) evidence** – Recourse to the best evidence should be determined by the underlying scientific rigour, irrespective of its origin. Regulators must ensure that excellence and independence are the two key criteria to be applied when producing and using scientific advice.

   Excellence is achieved by sticking to the principles of the scientific method (replicability and verification of assumptions, methodologies and findings through internationally respected and validated standards); independence is essentially achieved by ensuring full transparency of interests and biases. Only this way can evidence of risk and harm be assessed and presented along with other legitimate factors that inform risk management decisions.

3. **Better understanding the wider impacts of (regulatory) risk management decisions** – Eventually, the effectiveness of harm prevention measures is assessed by each of us individually but public decision-makers must strike a balance between macro and micro consequences. Impacts of risk management decisions on innovation for instance, which is the single most powerful factor for economic growth in Western economies and on job creation, must be investigated alongside various aspects including public health, consumer welfare and the preservation of the environment.

   In practical terms, this calls for regulators to appropriately identify and measure societal benefits to gain from risk management options while at the same time grasping the indirect implications that their decisions may have for instance in terms of changes in capital allocation by private sector actors across an industry's value chain (e.g. in relation to R&D investment patterns). Such changes induced by regulatory choices may significantly impact innovation, job creation, and subsequently societal prosperity.

   This strand of action also corroborates the need for making risk management as flexible as possible through timely integration of feedback from stakeholders and the affected actors and by allowing for scaling up of solutions and for continuous learning from new scientific or empirical insights.

4. **Organising the communication of risks and risk management decisions** – This action does not mean monopolising risk communication. Rather, it refers to bridging domains as wide but necessary as the ones of scientists, regulators, decision-makers, stakeholders and laymen (the public), not least with respect to the notion of uncertainty and innovation, and the impossibility of managing everything and reducing risk down to zero.

   This takes the shape, for instance, of explaining that high quality harm management ensues from making decisions on the basis of risk (i.e. they should be proportionate to exposure, based on real world experience) as opposed to hazard.

When it comes to risk management, policy-makers must be fully aware of – and objectively communicate – what factors took priority in their decisions next to scientific evidence and why, and what are the consequences of those decisions onto society and the economy as a whole. Due process is required through the regulatory cycle, ensuring compliance with the principles of transparency, accountability, predictability and proportionality.

About IRGC

The International Risk Governance Council (IRGC) is an independent non-profit foundation with an aim to help improve the understanding and management of risks and opportunities by providing insight into systemic risks that have an impact on human health and safety, on the environment, on the economy and on society at large.

Established in 2003 at the initiative of the Swiss government, IRGC is based at École Polytechnique Fédérale (EPFL) in Lausanne, Switzerland, with network partners in Europe, the US and Asia.

As a science-based think tank and neutral collaborative platform with multidisciplinary expertise, IRGC's mission includes developing concepts of risk governance, anticipating major risk issues, and providing risk governance policy advice for key decision-makers. It also aims to build bridges between science and policy in today's challenging governance environment.

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