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Generating a taxonomy of regulatory responses to emerging issues in biomedicine

Wendy Lipworth (2005)

Abstract

In the biomedical field, calls for the generation of new regulations or for the amendment of existing regulations often follow the emergence of apparently new research practices (such as embryonic stem cell research), clinical practices (such as facial transplantation) and entities (such as Avian Influenza/'Bird Flu'). Calls for regulatory responses also arise as a result of controversies which bring to light longstanding practices, such as the call for increased regulation of human tissue collections that followed the discovery of unauthorised post-mortem organ retention. Whilst it seems obvious that new regulations should only be generated if existing regulations are inadequate (a practice referred to in this paper as 'regulatory syncretism'), this does not always occur in practice. This paper examines the conceptual steps involved in generating regulatory responses to emerging phenomena. Two decision points are identified. First, a stance is taken as to whether the emerging phenomenon raises unique ethical or legal issues (exceptionalism versus non-exceptionalism). Second, the decision is made as to whether new regulation should be generated only for truly unique phenomena (syncretism versus asyncretism). It is argued here that it is important to make a careful assessment of novelty, followed by a reflective and deliberate choice of regulatory syncretism or asyncretism, since each type of regulatory response has advantages which need to be harnessed and disadvantages which need to be managed—something that can only occur if regulators are attentive to the choices they are making.

Keywords: Exceptionalism, regulation, tissue banking, health policy

Part 1: Possible Regulatory Responses to Emerging Phenomena

Biomedical regulators are faced continually with demands for regulatory responses to emerging practices or entities that are seen to raise unique ethical or legal issues. Currently emerging phenomena (to name just a few) include: the 'unprecedented' threat of a 'bird flu' epidemic,(1) the potentially 'shocking' and 'straight out of science fiction' practice of face transplantation (2) and the ever-increasing risk of inappropriate disclosure of personal information as a result of the 'new genetics'.(3)

The conceptual process leading up to a particular regulatory response is complex. At least two major decisions - or assumptions - need to be made. The first decision or assumption ('exceptionalism' versus 'non-exceptionalism') relates to whether or not the emerging phenomenon raises any unique ethical or legal issues. The second decision or assumption ('syncretism' versus 'asyncretism') relates to whether new regulation is to be generated *only* where new ethical or legal issues emerge, or whether new regulation should be generated even for emerging phenomena that overlap ethically and/or legally with pre-existing phenomena. The conceptual basis of each of these decision points will be examined, followed by an outline of the advantages and disadvantages of each approach.

Regulatory Exceptionalism and Non-Exceptionalism

Regulatory responses always involve a stance to be taken on the uniqueness, or otherwise, of an emerging phenomenon. Either an explicit claim or an unconscious assumption is made about the novelty of the phenomenon. The claim or assumption that an emerging phenomenon does raise unique ethical or legal issues is referred to here as *'exceptionalism'*. The claim or assumption that an emerging phenomenon raises no unique issues is referred to as *'non-exceptionalism'*.

The term 'exceptionalism' has been in used by political scientists to refer to the claim that a particular social, political or economic system is unique and has developed in unique ways.(4-7) The sociologist Ronald Bayer is credited with first using the term 'exceptionalism' in the biomedical setting, using it to characterise claims about the ontological uniqueness of HIV infection.(8)

The claim or assumption that an emerging phenomenon is exceptional can be made on judgement of the:

1) Unique *characteristic/s* of the emerging phenomenon

These characteristics may be ontological, epistemological, aesthetic, ethical and/or legal. 'Genetic exceptionalism; for example, refers to the claim that genetic tests are different to all other types of medical tests. While most people now believe that genetic tests raise no unique issues (i.e. issues that are not raised by other kinds of tests), others continue to argue that the information derived from genetic tests is in fact unlike any other type of medical information in that:

1) it remains largely stable throughout life;
2) genetic fingerprints are 'remarkably identifiable';
3) genetic information can 'transcend health status' to reveal personal characteristics, and
4) genetic tests can reveal information about cultural and ethnic groups and about family members.(9:69)

2) Unique *scale* of the effects of a phenomenon

It may be argued that even if an emerging phenomenon (such the ever-increasing accessibility of genetic information) is not qualitatively different from other types of health information, new technologies (such as gene microarrays) have created situations in which enormous amounts of genetic information can be generated in a single test. This is seen by some to threaten privacy to an unprecedented degree, which is seen as sufficient reason to consider genetic testing to be 'exceptional'.(10)

3) Unique characteristics of a *population* being affected by an emerging phenomenon

This type of exceptionalism (here called 'cultural exceptionalism') is based upon the argument that whilst an emerging phenomenon may not itself be unique, the *population* upon which it impacts may be 'exceptional'. In the biomedical setting, cultural policy exceptionalism is evident in the global HIV strategy developed by the United States. Instead of participating in the world MDS battle plan as formulated by the Global Fund and United Nations, the United States - which prefers abstinence to condom-based prevention- has created its own strategy, not only for local AIDS prevention (11) but also for the other countries it funds.(12)

In this paper, the term 'exceptionalism' will refer to the first of these three types of exceptionalism, that is, the claim that an emerging phenomenon has characteristics (epistemological, ontological, aesthetic, ethical, legal, etc.) which set it apart from existing phenomena.

A recent example of regulatory exceptionalism is the stance that regulators have taken on the novelty of ethical and legal issues raised by 'tissue banking' research. Tissue banking research refers to the practice of using, for research purposes, collections of human tissue that is stored in laboratory archives. In typical "tissue banking research," diseased tissue is screened for the presence of abnormalities in its morphology, genes, proteins, and so forth. The pattern of abnormalities is then correlated with the aetiology, prognosis or treatment responsiveness of the disease in a method that might be called 'laboratory-based epidemiology'. The ethical issues stemming from tissue banking research relate primarily to how consent can be obtained for the long-term storage of tissue, how donor confidentiality can be protected and about ownership of the research material. The stance taken on the ethical/legal uniqueness of tissue banking research has been largely exceptionalist. Despite extensive debate about tissue banking in the bioethical, biomedical and law reform literature, little attention has been paid to the fact that tissue banking research is (epistemologically) very similar to other kinds of epidemiological, clinical and genetic research and (therefore) raises ethical and legal issues that have to a significant extent been addressed in relation to epidemiological and genetic research.

This is not to say that the *entire* response to tissue banking research has been exceptionalist. It has, for example, been recognised that tissue samples overlap ontologically with other types of health information (such as the information contained in medical records and in computer databases). This illustrates the fact that the labels 'exceptionalist' and 'non-exceptionalist' cannot be applied to an entire emerging phenomenon. Aspects of a phenomenon may be considered to be unique, whilst other aspects may be considered to overlap with existing phenomena. The regulatory response to tissue banking will be explored further in the second part of this paper to illustrate the advantages and disadvantages of different approaches to regulatory amendment.

It is important to note that correct assessments of novelty (i.e. accurate exceptionalist or non-exceptionalist stances) are often difficult to make. Such claims require sophisticated reflection on the epistemological, ontological, aesthetic, ethical and legal aspects of a phenomenon and there is no easy way of doing this, or even of deciding which aspects are relevant to exceptionalist/ non-exceptionalist claims. To say, for example, that the HIV organism is a retrovirus like all other retroviruses is not sufficient justification for saying that HW raises no unique ethical or legal issues. Difficulty in making accurate exceptionalist or non-exceptionalist claims is particularly acute during the early stages of emergence of a phenomenon, before it has been well characterised. When AIDS

first emerged, with its unusual cluster of opportunistic infections and cancers, prevailing beliefs included the assumptions that:

1) microbial infections were no longer a threat in industrialised countries;
2) viruses did not cause human cancers like those lymphomas and sarcomas associated with H1V infection, and
3) there was no such thing as a retrovirus that infected humans.(13) Given these prevailing beliefs, and the possibility that the entire sexually active population might be at risk,(14) it was not unreasonable to at least consider the possibility that AIDS was an ontologically unique threat, raising unique ethical and legal issues and therefore requiring separate regulatory responses.

The realisation that an exceptionalist or non- exceptionalist claim is incorrect may, therefore, only be able to be made retrospectively. Indeed, controversy about the uniqueness, or otherwise, of an emerging phenomenon may persist for many years. Many people now argue that HIV exceptionalism may be - or should be - 'drawing to a close'(14:1607) and that, for example, HIV testing should no longer require informed consent that is any more rigorous than consent to other kinds of tests.(15) Yet others continue to believe that, as an infectious disease affecting an already stigmatised population, HIV is still a unique phenomenon raising unique ethical and legal issues. To complicate matters further, new issues may arise a long time after the original emergence of a phenomenon. Indeed, the locus of exceptionalism may shift from uniqueness of biology to uniqueness of phenotype, social impact, service demands, clinical practice. In the case of HIV, for example, some legislators in the United States have passed laws requiring laboratories to report the names of patients with low CD4+ cell counts for public health purposes. CD4+ counts are used primarily to track the severity of previously diagnosed HIV infection and are not used for diagnostic purposes (antibody testing is used for diagnosis). It is increasingly recognised, however, that a low CD4+ count is an 'indicator of HIV' and concern has arisen over the fact that CD4+ testing (and reporting) does not require the same informed consent standards as antibody testing. There is a call for the same rigorous (exceptionalist) informed consent standards to be applied to CD4+ testing as are applied to HIV antibody testing.(15) In this case the locus of exceptionalism has shifted from the biological (retrovirus as novel infectious agent) to social (infection in a stigmatised population) to clinical (unique diagnosis-related issues). For these reasons, current regulation might focus as much on extending HIV exceptionalism as on its 'normalisation'.

For these reasons, 'unpopular' exceptionalist or non- exceptionalist stances should not necessarily be labelled as inaccurate. Nor should the terms 'exceptionalist' and 'non-exceptionalist' be applied prematurely in describing a regulatory response. There needs to be room for theoretical uncertainty and discussion about the potentially unique issues raised by a phenomenon. It should be possible to explore intuitions of difference, to question dominant assumptions and to air the possibility that radically new sets of considerations may be raised by an emerging phenomenon without having to commit to a stance that a phenomenon is truly exceptional.

Regulatory Syncretism and Asyncretism

Debates about the uniqueness, or otherwise, of emerging phenomena are well developed in the bioethical and legal literature. It has, however, been observed by some that these debates are not particularly productive. Lazzarini, for example, claims that the genetics exceptionalism debate is

simply 'an old debate ... in which we haggle over the precise nature and scope of ... similarities and differences'(16:149) and argues for cessation of such discussions. This raises an important issue, but a different stance is taken in this paper. It is true that debates about exceptionalism are not particularly useful *on their own*, but the assessment of the exceptional nature of an emerging phenomenon is only the first step in generating a regulatory response.

Once an exceptionalist or non-exceptionalist stance has been taken, two regulatory responses are possible: 'regulatory syncretism' and 'regulatory asyncretism'. The phrase 'regulatory syncretism' is used here to refer to the creation of new regulation for an emerging phenomenon if, and only if:

1) the phenomenon is known (or assumed) to raise unique ethical and/or legal issues, and
2) existing regulation will not suffice.

This use of the term 'syncretism' relates to the philosophical use of the term in that syncretic policy making aims to find, or assumes, an underlying unity amongst apparently disparate emerging and existing phenomena, so that creating of new policy is limited to truly unique phenomena (or aspects) thereof.

'Asyncretism, on the other hand, refers to the situation in which new regulation is created *even though* it is known (or assumed) not to be absolutely necessary. This occurs when:

1) the emerging phenomenon is believed to overlap with existing phenomena;
2) existing regulation could, in theory, suffice and
3) new policy is nonetheless generated.

The phrase regulatory asyncretism could therefore be applied to claims that separate policies should be developed for HIV or genetic testing even by those who recognise that these phenomena overlap ontologically (in the case of HIV), epistemologically (in the case of genetic testing) ethically and legally (in the case of both HW and genetic testing) with existing phenomena.(17, 18) Regulatory asyncretism is not unusual. In the United States, for example, most states have some form of genetics-specific privacy legislation and there are ongoing efforts to pass federal legislation despite the ever-increasing recognition that genetic testing is not unique.(19) Similarly, in the policy-level response to HIV in developed countries, special rules for pre-test counselling, informed consent, notification to authorities and disclosure to personal contacts continue to be implemented despite acknowledgment by most people that HIV is but one of many infectious diseases that might warrant such measures.(18)

Three caveats apply to the labels 'syncretic' and 'asyncretic'. Firstly, these labels refer to the decision made at the time of regulatory amendment based upon the belief (or assumption) *at that time* of the uniqueness, or otherwise, of the emerging phenomenon. Even if the exceptionalist (or non-exceptionalist) stance turns out, in retrospect, to have been inaccurate, the syncretic or asyncretic status of the *original* response - based upon the best information available at the time - remains unchanged. Of course, subsequent regulatory responses may need to be different in light of the new information in order to maintain the syncretic or asyncretic status.

Secondly, there may be a period of time before it is possible to determine whether a syncretic or asyncretic response is preferable in a particular situation. The decision might be made that, pending further analysis, new regulation should be created with the sole aim of limiting action *temporarily*. In

relation to the emerging practice of facial transplantation, for example, a working party convened by the Royal College of Surgeons of England did not identify any clearly unique aspects of facial transplantation. Despite this, it concluded that work on facial transplantation 'should take a much more incremental approach than some of the current hype surrounding it has suggested'.(20) New regulations aimed at achieving temporary control may overlap with existing regulations, but this should not be considered to be regulatory asyncretism.

Finally, it should be noted that just as some aspects of emerging phenomena may be exceptional whilst others are not, the labels 'syncretic' and 'asyncretic' cannot be applied to an entire regulatory response to an emerging phenomenon. Some aspects of the response may be syncretic, whilst others may be asyncretic.

An Illustrative Example

The following example illustrates exceptionalist, non- exceptionalist, syncretic and asyncretic responses to regulation: Suppose that a new test for a genetic predisposition to breast cancer became available (i.e. an emerging clinical practice). First, a stance would need to be taken on the uniqueness, or otherwise, of this test. In other words, an exceptionalist or non-exceptionalist stance would be taken. It may be assumed, or become clear upon reflection that this test raises no ethical or legal issues that are not already raised by existing genetic tests (i.e. a non- exceptionalist stance is taken). On the other hand, it may be assumed or become apparent upon reflection that this test is somehow different to existing tests because, for example, it suggests a particular occupational exposure to carcinogens rather than an inherited genetic predisposition (i.e. an exceptionalist stance is taken).

Once an exceptionalist or non-exceptionalist stance is taken, the decision needs to be made as to whether a syncretic or asyncretic regulatory response is needed. If, for example, the test was seen to raise no new issues (i.e. a non-exceptionalist stance was taken), then a syncretic response would result in no new regulation being generated. An asyncretic response would involve the generation of new regulation even though no new ethical or legal issues are raised. If, on the other hand the test is determined to be unique (i.e. an exceptionalist stance was taken) then the syncretic regulatory response would involve developing new regulation (e.g. regulatory provisions for workplace testing and workers compensation) and an asyncretic response would involve no new regulation being developed. These regulatory responses are summarised in Figure 1. Regulatory syncretism is outlined in Figure 2.

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Figure 1: Possible regulatory responses to emerging phenomena

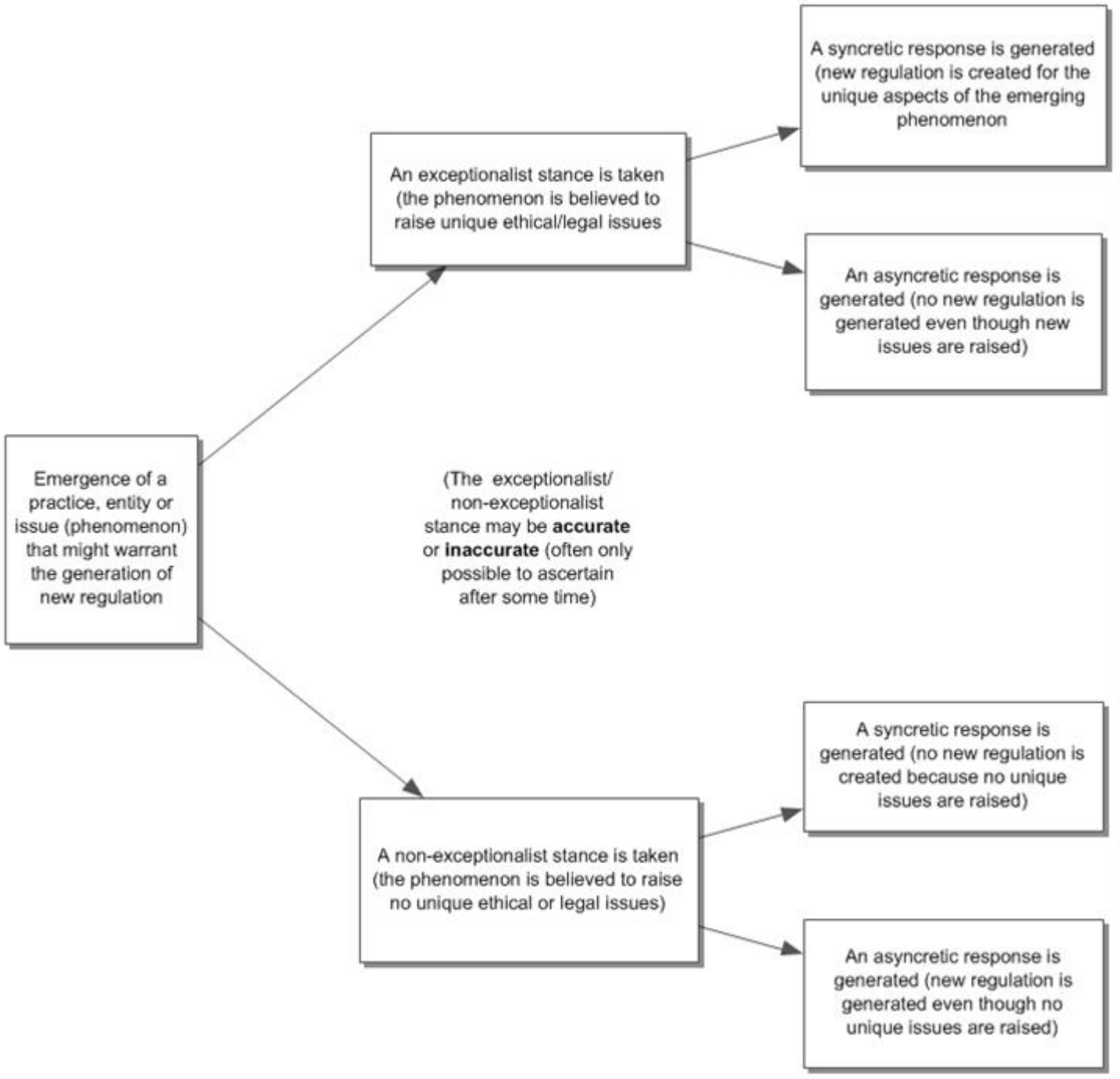

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Figure 2: Regulatory syncretism in more detail (using facial transplantation as an example)

Step 1: Identify the (possibly) unique emerging phenomenon for which a regulatory response is required

It has become evident that technical skills and anti-rejection medications are developing in such a way that face transplantation may become technically possible and that a regulatory response is needed.(20)

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Step 2: Elucidate the epistemological and ontological underpinnings of, and the aesthetic, ethical and legal issues raised by, this emerging phenomenon

Facial transplantation might be seen as: 1) a therapeutic (reconstructive surgical) procedure; 2) a (cadaveric) transplantation procedure and 3) a quality-of-life enhancing (as opposed to life-saving) form of medical therapy. It will, therefore, raise all the ethical, legal, social and political challenges associated with reconstructive, transplantation and quality-of-life enhancing procedures.

↓

Step 3: Determine whether the emerging phenomenon is in any way unique

In the case of face transplantation, for example, there will be much epistemological/ontological and ethical overlap with other types of 1) reconstructive surgery, 2) transplantation surgery and 3) quality-of-life enhancing treatment. It is possible, however, that face transplantation will also raise aesthetic and ethical concerns that are not raised by any other kinds of facial reconstructive and/or transplantation surgery.

At this stage a separate policy response might be generated with the aim of limiting action pending further analysis. This does not constitute an asyncretic response as long as it is seen as temporary.

↙ ↘

Step 4A (non-exceptionalist syncretism)

Response to phenomena - or aspects thereof- in which there is overlap (epistemologically, ontologically, aesthetically, ethically and/or legally) between the emerging phenomenon and existing phenomena:

Examine existing regulations to identify any that are likely to be relevant to the emerging phenomenon.

In the case of facial transplantation, existing regulations relating to (facial) reconstructive surgery, trans- plantation surgery and quality of life-enhancing surgery would need to be appraised.

↙ ↘

Step 4Ai) Where relevant regulation exists, steps should be taken to ensure that the emerging phenomenon is clearly recognised as being within its scope. This may be as simple as adding "face transplantation" to lists of reconstructive and transplantation procedures. If it is not clear that existing regulation covers the emerging phenomenon, then this might signify a problem with the construction of existing regulation. If, for example, general transplantation regulation is not clearly of relevance to facial transplantation, this might suggest a conceptual problem with general transplantation policy.

Step 4Aii) Where no relevant regulation exists, regulation should be created that incorporates both the emerging phenomenon and other relevant phenomena (that exist or may foreseeably arise in future). There may, for example, not be any policy dealing with the ethical issues raised by reconstructive surgery in general. If this is the case, policy should be developed that regulates reconstructive surgery in general, which would cover both facial transplantation and any other (immediately foreseeable) kind of reconstructive surgery. Not to do so (such that separate new policies are generated for similar phenomena) might constitute a variant of regulatory asyncretism.

Step 4B (exceptionalist syncretism)

Response to phenomena - or aspects thereof- which appear to be unique to the emerging phenomenon:

Create new regulation

If, for example, it is discovered that face transplantation raises aesthetic and ethical issues that do not apply to any other type of facial reconstructive or trans- plantation surgery, then separate policies should be generated to deal with this.

This step is important because failure to recognise the need for new policy where truly new issues have arisen is potentially just as problematic as non-syncretism.

As in Step 4aii, this regulation should be broad enough to incorporate both the emerging phenomenon and other relevant phenomena (that exist or may foreseeably arise in future.

Part 2: The Choice of Regulatory Syncretism or Asyncretism

Part 1 has outlined four possible regulatory responses (exceptionalist syncretism, exceptionalist asyncretism, non- exceptionalist syncretism and non-exceptionalist asyncretism). Whether or not a regulatory response is exceptionalist or not should depend upon the belief in the uniqueness, or otherwise, of the emerging phenomenon. Whilst such assessments are not always easy, as discussed previously, the decision should ultimately be made on the grounds of whether or not the phenomenon is believed to be unique.

The choice of regulatory syncretism or asyncretism is more complicated. There is no objective criterion (such as the uniqueness of the emerging phenomenon) upon which to base this decision. Instead, the decision has to be made on more complex socio-political grounds. Whilst it may seem as though syncretism is clearly preferable, there are in fact several advantages of taking an asyncretic approach. This section illustrates the advantages and disadvantages of both syncretism and asyncretism, showing that there are good arguments for both approaches.

Advantages of Regulatory Syncretism (and Corresponding Disadvantages of Regulatory Asyncretism)

Regulatory simplicity and coherence

Regulatory syncretism has the advantage of reducing the overall length and number of regulatory documents, since new regulation is generated only where absolutely necessary. Asyncretism, on the other hand, results in the creation of new, separate regulation that can be difficult to manage. An examination of the Australian response to increasing concerns about tissue retention illustrates how the generation of new, separate policy for tissue-based research has resulted in enormous regulatory complexity. In one State (New South Wales) any researcher or administrator wishing to apply all relevant regulation would need to be cognisant of (at least):

1) Common Law relating to assault and confidentiality;
2) Legislation such as *the Privacy Act 1988* (Cth); *Privacy and Personal Information Act 1998* (NSW); *Health Records and Information Privacy Act 2004* (NSW); and *Human Tissue Act 1983* (NSW);
3) National guidelines such as the *National Health and Medical Research Council's National Statement on the Ethical Conduct of Research involving Humans*;
4) NSW Health Department policies such as the I*nformation Privacy Code of Practice and Requirements Of The Human Tissue Act 1983 In Relation To Research Utilising Human Tissue: Guidance For Human Research Ethics Committees*, and
5) Organisational policies such as the Royal College of Pathologists of Australia (RCPA) *Policy statement on the secondary use of human tissue samples collected for diagnostic purposes*, the *Guidelines for Human DNA Banking* from the Human Genetics Society of Australasia and the National Pathology Accreditation Advisory Council *Guidelines for the Retention of Laboratory and Diagnostic Material*.

Many scientists have voiced concern about the difficulties associated with carrying out research in such a complex regulatory environment (10, 21) and some ethics committees have been compelled to generate policies specifically aimed at ensuring compliance with existing regulation.

Application of existing insights to regulation of the emerging phenomenon

Regulatory syncretism allows for existing regulation, when available, to be used. Often this regulation will have been refined over many years, and the insights gained from these refinements can be applied to the emerging phenomenon. Asyncretic responses, on the other hand decrease the likelihood that the insights contained in established policy will be transferred completely into the brand new ('from scratch'), separate regulation of the (purportedly) 'new' phenomenon. If, for example, new regulatory documents are created for tissue banking research, it is unlikely that all the nuances that have gradually been incorporated into existing epidemiology and genetic research regulation will be transferred into tissue banking policies.

Application of existing ethical norms to the emerging phenomenon

Just as syncretism encourages application of existing, nuanced, regulation to emerging phenomena, it also encourages the application of well-established ethical norms to emerging phenomena. Regulatory asyncretism, on the other hand, increases the risk that regulatory responses may be used as a political tool to undermine well-established values. By portraying something as requiring new regulation, it becomes easier to divorce it from existing ethical and legal norms. There is, for example, an ethical norm in our society that patients cannot be enrolled in research studies without their consent. The realisation that tissue archives (in which leftover tissue from diagnostic tests are stored) are useful research resources have led some people to argue that consent requirements should be bypassed since it is too difficult to re-contact all patients whose tissues have been stored.(3, 10, 22-33) This is not necessarily ethically wrong- there is a genuine ethical dilemma between, on the one hand, the desire to protect patient autonomy and, on the other hand the desire for science to progress. Considering tissue banking research as a phenomenon requiring its own regulatory response, however, increases the likelihood that regulations governing autonomy and privacy - which are well-established in epidemiological and genetic research regulations - will fail to be transferred into tissue banking regulation without appropriate recognition of the significance of such a shift in ethical norms.

Protection against political 'hijacking'

Syncretism also protects against 'hijacking' of the regulatory response by powerful political groups who wish to use regulatory change as a tool for getting their issue of interest onto the public agenda - something that is far more difficult if evidence of true uniqueness of emerging practices or phenomena is required before new regulation is generated. Claims of such 'hijacking' are made by those who observe that the issues that generate the most (new) regulation are not necessarily those that warrant the most attention and that they seize this attention, at least partly, through claims that the emerging phenomenon is unique and in need of new, separate regulation. Suter, for example,(34) argues that genetic privacy issues are unlikely to be the greatest concern to large segments of the population who have far more fundamental health concerns. The groups who are concerned about genetics use claims of its 'unique' status, and the urgent need for new regulation, to generate interest. On a similar note, Everett refers to the 'genetic privacy movement' as a movement that arose in response to the Human Genome Project and that was 'spurred by a proposal for national legislation by a group of prominent bioethicists'.(10) (p274) The power of such groups is evident in the ongoing creation of genetics-specific legislation despite arguments against this approach put forward by prominent lawyers and public health practitioners(18). There is

arguably a similar 'tissue privacy' movement that is using unwarranted claims of the uniqueness of tissue banking research as a means to get their privacy concerns onto the political agenda.

Improvement of pre-existing regulation

Syncretic regulatory responses have the advantage of highlighting problems with existing regulation and encouraging improvement - and even complete reconsideration of- existing regulation. It may, for example, become clear that, whilst an emerging phenomenon is not unique, existing regulation is inadequate or flawed. Regulatory syncretism would lead to improvement of existing regulation, thereby improving the regulation of pre-existing phenomena at the same time as addressing the issues raised by the emerging phenomenon. Asyncretism, on the other hand, precludes such reconsideration, or at least removes any impetus for it to occur. In the case of tissue banking regulation, asyncretic approaches preclude consideration of the reasons why existing epidemiological and genetic research policies have failed to account (in a way that is obvious to regulators) for the epistemologically similar emerging phenomenon of laboratory-based epidemiology. If 'tissue banking research' has much in common with epidemiological and genetic research, yet is not easily and obviously covered by existing epidemiology and genetic research regulations, then this suggests a deficiency in existing epidemiology and genetic research regulations. Indeed it might signify the need for an overhaul of all research regulation.

Syncretism may also improve pre-existing regulation by encouraging the application of new ways of thinking to the regulation of pre-existing phenomena. When considering consent to tissue banking, for example, it may become apparent that tissue collections can be viewed usefully as community resources and that consent can be reconceptualised as a community-level - rather than entirely individualistic - process. If it is recognised that tissue banking overlaps with epidemiological and genetic research, then these insights - and the associated, conceptually novel regulatory approaches - can be applied also to these other forms of research. If, on the other hand, tissue banking research is treated as requiring separate regulation from that of (other kinds of) epidemiological and genetic research, then insights gained in the process of creating tissue banking-specific regulation will not be transferred into regulation of these other research practices.

Encouragement of identification of truly novel aspects of the emerging phenomenon

Regulatory syncretism results in the generation of new regulation only where this is absolutely necessary. This means that more time is available to consider what might be truly unique about an emerging phenomenon and to think about novel regulatory approaches to these specific issues. Regulatory asyncretism, on the other hand, may result in truly novel aspects of an emerging phenomenon being obscured in the relatively unfocused effort it takes to (re)create policy from scratch. If, for example, new laws are created for tissue banking research, the areas of overlap with epidemiological and genetic research will receive just as much attention as any areas of true epistemological, ontological or ethical novelty such as:

1) the significance of the ontological, aesthetic and even religious differences between human tissues and other kinds of research data; and
2) the unique issues raised by the scale of information that can now be extracted from a single tissue sample.

Despite the extensive regulatory response to tissue banking, little discussion has surrounded these truly unique aspects of tissue-based research.

Minimising unwarranted fear and mystique

Regulatory syncretism makes it explicit that an emerging phenomenon, whilst *apparently* new and uncontrolled, is in fact familiar and, to some extent at least, already regulated. Regulatory asyncretism, on the other hand, portrays emerging phenomena as novel and unregulated. This might lead to unwarranted exacerbation of mystique and generation of fear. Rather than recognising, for example, that tissue banking research is (to some extent at least) just a variant of epidemiological and genetic research with which we are familiar, it is portrayed as an unprecedented threat to patient autonomy and confidentiality. Consider, for example, the title of a journal article published in the medico-legal literature: *Retained human tissues: a molecular genetics goldmine or modern grave robbing?*(35)

Similarly, the following newspaper headlines capture the sensitivity surrounding tissue retention without consent:

> *'How doctors stole little kids' hearts'* (The Age, 4 February 2001); and
> *'The body snatchers'* (Ninemsn, 18 March 2001).

This is not only unpleasant for those who are frightened, but can also exacerbate inaccurate understandings of science and prevent important research from progressing. It would be a serious transgression if, for example, tissue banking research was stunted by unmanageable regulatory requirements *simply* on the basis of misinformation that portrayed it as being fundamentally different to other forms of epidemiological and genetic research.

Advantages of Asyncretism (and Corresponding Disadvantages of Syncretism)

Conceptual simplicity

Whilst regulatory asyncretism may seem 'illogical', it is not surprising that such approaches commonly accompany the emergence of new phenomena. This could be because it is conceptually simpler to generate a single, new piece of regulation than to carefully amend existing regulation such that the emerging phenomenon is weaved into place within it. Asyncretic regulatory responses might also make regulation more comprehensible to those who need to apply it (even if the number and length of regulatory documents is increased). For people carrying out tissue banking research, for example, it may be simpler to identify rules specifically referring to 'tissue banking research' than it is to have to apply broad rules for research in general, and then consider the various nuanced rules that are specific, for example, to whether the research in question uses tissue, medical records or computer databases, etc.

Stimulation or funding and public interest

Several of the disadvantages of asyncretism discussed above (hijacking of the policy responses, bypassing of existing ethical norms and generation of fear and mystique) may also be used as arguments for regulatory asyncretism. Asyncretism may, for example, facilitate the attainment of funding for important regulatory processes. It is not uncommon to find that calls for increased

funding are prefaced by an account of the novelty of the issues raised by the phenomenon or practice in question, and the associated need for funding for new regulation.

In addition to improving funding opportunities, asyncretic regulatory responses are more likely to stimulate public interest. This justification is based upon the recognition that public interest is best stimulated by the perception of novelty and uniqueness, and a preference for what Sowell refers to as 'categorical', rather than nuanced, responses. As Sowell notes: 'No one is going to man the barricades for a little more of A and a little less of B'(36:144) People are far more likely to be engaged in a debate about how doctors should be prevented from stealing babies' hearts (The Age 4 February 2001) than in debates about the importance of autonomy in all kinds of epidemiological research, including practices that are well- established and not causing much public concern.

Stimulation of innovative responses

It was argued above that regulatory syncretism has the advantage of enabling new approaches to be applied to existing phenomena and incorporated into existing policy. This is balanced by the capacity that asyncretism has to stimulate innovation by allowing for new forms of social management to be tested on an emerging phenomenon and then gradually incorporated into existing regulation. This might be an equally good, if not better, way to stimulate novel regulatory approaches. Such an approach might involve at first portraying tissue banking research (on its own) as a community-owned endeavour, testing the effects of such a conceptual and regulatory shift and then, gradually applying this to other kinds of epidemiological and genetic research.

A Call for Increased Scrutiny of Regulatory Responses to Emerging Phenomena

There are, therefore, advantages and disadvantages associated with both regulatory syncretism and regulatory asyncretism. What does this mean for regulators?

First, it means that there is no 'right' or 'wrong' regulatory response to emerging phenomena. For even if all relevant factors are considered, there will never be a 'formula' that will determine whether syncretism or asyncretism is preferable in a given situation. This recognition could be used to argue that careful reflection is unnecessary since no regulatory response is wrong a priori and any approach, whether based upon uncritical assumptions or deliberate decisions, will have advantages and disadvantages. This is an appealing argument in a political environment that demands rapid regulatory responses (whether syncretic or asyncretic) to emerging phenomena which have even a small chance of raising truly unique issues. In relation to HIV, for example, Rosenbrock et al. note that upon emergence of the disease, policies had to be 'conceptualised, decided on, implemented with a high degree of uncertainty, with sometimes considerable political tensions and within a short time frame'.(14:1608)The conceptual gymnastics required for careful reflection on the uniqueness, or otherwise, of the emerging phenomenon, followed by a deliberate decision to pursue either a syncretic or asyncretic regulatory strategy, may simply be untenable in the current regulatory environment.

For these reasons there may be occasions where relatively unreflective response to an emerging phenomenon is demanded. In such situations, there might be considerable merit in acknowledging that such regulation is temporary and that it may need to be revised in response to later critical reflection. It is important that such reflection occurs. Whilst each approach has advantages and disadvantages, this does not mean that they are equivalent, and there may be some situations in

which one response is clearly preferable. Furthermore, it is only through conscious reflection on the exceptional or non-exceptional status of an emerging phenomenon, followed by a deliberate decision to generate syncretic or asyncretic regulation, that regulators can harness the advantages, and manage the disadvantages, of their chosen approach. Whilst this creates logistic, conceptual and political challenges, the control afforded by conscious regulatory decision-making is likely to lead to long-term benefits which balance, if not outweigh, the immediate disadvantages.

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