This essay seeks to explore some theoretical and practical obstacles to developing a coherent and comprehensive theory for the interpretation of health legislation. One obstacle considered involves the academic and professional reluctance to direct critical attention to interpretive actions outside the judicial sphere; in this case to those by health administrators, health professionals and patients. Another concerns a similar reticence to formally acknowledge the widespread utilization by such interpreters of principles derived from normative traditions distinct from many domestic legal systems, in particular those of medical ethics and international human rights. The third obstacle relates to the difficulties raised for interpretation of health legislation by community demands for greater transparency and quality assurance in the health care sector. Linked with this is the question whether interpretation of health legislation should be approached with a presumption that it promotes core social and professional virtues (such as justice, fairness and loyalty to relief of patient suffering) in the life narratives of those most directly affected.

I  INTRODUCTION

Health legislation, resembling its current form, arose from political negotiations between a medical profession seeking monopoly privileges for income protection and the state desiring to secure its population from the threat of epidemic disease (in particular, by quarantine, as under the Plague Act of 1604) or injury by ‘quacks.’¹ The legislation of Henry VIII, for example, which incorporated the Royal College of Physicians in London in 1523, declared its primary purpose to be protecting the
public from unskilled practitioners. The genre of public health legislation which thus developed has rarely been said to create unique problems for statutory interpretation.

Contemporary health legislation, however, increasingly concerns the intricacies of doctor-patient relations and morally complex questions of bioethics. The relevant legislative norms are being created rapidly against a backdrop of complex and interpretively challenging changes in medical research and technology. Frequently cited examples include the possibility of human reproductive cloning, public health legislation (such as that dealing with bioterrorism and unusual infective diseases) infringing on the human rights of patients and doctors, challenges to clinical governance structures (systemic failure to detect and act upon medical error in public hospitals) as well as professional concerns over the justice of healthcare funding and rising indemnity costs.

A relatively recent example of the involvement of health legislation in the intricacies of doctor-patient regulation involved United States Federal statutes that banned ‘partial-birth abortions’ (performed by the dilatation and extraction method), without seeking medical justification or giving adequate consideration of patient safety. An even more extreme instance was legislation passed in Florida to overturn a judicial decision that had permitted doctors to follow the wishes of a patient’s proxy decision-maker, her husband, and withdraw treatment from the patient (a 39 year old woman in a persistent vegetative state for 13 years as a result of a cardiac arrest following a potassium deficiency).

This essay seeks to explore some theoretical and practical obstacles to the development of a coherent and comprehensive theory for interpretation of health legislation. I intend to use the word ‘coherent’ here in a very broad sense. It will refer not only to correspondence amongst the various elements of the legal system, but involve the normative traditions of medical ethics, international human rights and the system of virtue ethics focusing on issues of the interpreter’s conscience and life narrative.

The first such obstacle is a professional and academic reluctance to direct serious academic attention to interpretive actions outside the judicial sphere; in this case particularly by health administrators, health professionals and patients. The second concerns a similar reticence in acknowledging the capacity of all such interpreters, including the judiciary, to draw upon principles and rules derived from professionally important normative traditions often somewhat removed from domestic legal systems, in particular medical ethics and international human rights. The third considers the implications in this context of community demands for greater transparency and quality assurance in the health care sector. A related issue is the value of a statutory presumption that any interpretation of health legislation should promote foundational social and professional virtues such as justice, fairness and loyalty to the relief of patient suffering.

II NON-JUDICIAL INTERPRETATION

Modern regulatory theory supports the proposition that, for an area such as health care, the function of legislative text is invariably affected by not only judicial interpretation, but a variety of other decentralized mechanisms that support its effective operation. This is not an ‘originalist’ position of statutory interpretation. It does not emphasise as pre-eminent the constitutionally authorised historical intention of the legislative drafters. Neither does it claim that interpretation is chiefly about judges allowing a legislative text to evolve congruently with contemporary ideals and dynamic social conditions. It also should be distinguished from Eskridge’s claim that constant interaction between construction and application lies at the heart of dynamic

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The primary difference is that all these theories of statutory interpretation remain very judge-focused.

The alternative proposed here is that interpretation of health legislation be considered merely as one regulatory technique, as open to sociological research about its quality and safety as any other. Health legislation should be recognised, according to this approach, as most commonly interpreted and applied by persons such as Health Complaints Officials, Medical Board officers, hospital quality and safety staff and members of clinical ethics committees. Most of these people have no formal legal training and do not seek expert legal opinions in making their interpretations. They view their interpretations of health legislation as only one component in a strategy to develop a harmonious workplace that respects features such as human dignity, efficiency and safety, none of which may be mentioned in the statute. Factors influencing these interpretations include availability of leave, staffing levels, office space and outlook. Similarly important are likely to be decentralised esteem, or what may be termed virtue-critiquing workplace sanctions (shunning, vilification, humiliation or ridicule).

Interpretations of health care legislation, be they by bureaucrats, professional regulators or the judiciary, which fail to take into account these contextual factors may make obedience and regulatory enforcement difficult, or create excessive and inappropriate demands on institutional goodwill and bureaucratic discretion. They may displace undesired activity spatially or temporally. Excessively complex

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statutory biotechnology licensing schemes, for example, may promote collusion between enforcers and offenders, or the diversion of public funds into the maintenance of regulatory bureaucracies.\textsuperscript{13} Stringent legislation against hypothetical bioethical risks (such as, currently, human reproductive cloning), may exacerbate existing ones, possibly promoting increasingly refined avoidance behaviour.\textsuperscript{14}

These regulatory insights probably appear unremarkable to the majority of bureaucratic and professional persons routinely interpreting health legislation. Yet, the considerable academic reluctance to investigate and analyse them alongside judicial interpretations may have created a major obstacle to the development of a coherent theory of statutory interpretation in this area. Driedger has claimed that legislatures cannot be expected to ‘engage in continuous monitoring and adaptation of legislation.’\textsuperscript{15} One is forced to ask, however, why this must be accepted in an age when continuous quality review and improvement is considered a crucial part of most regulatory components in the health care system.

It is difficult to think of two more contentious areas of interpretation of health legislation than abortion and euthanasia. Yet, it is the interpretation of statutory discretions in these areas by health professionals, clinical ethics committees and hospital administrators that probably has the most significant effects on the majority patients and families so involved. I say ‘probably’ because little, if any, rigorous research has been undertaken on this issue. Such interpretations may conflict, or be regarded by the judiciary as erroneous, but unless they are litigated, or become, for

\textsuperscript{[1997]} 2 All ER 687; Anne Schiff, ‘Arising From The Dead: Challenges of Posthumous Procreation’ (1997) 75 \textit{North Carolina Law Review} 901.


\textsuperscript{15} Elmer Driedger, \textit{Driedger on the Construction of Statutes} (3\textsuperscript{rd} ed, 1994) 139.
example, the subject of a quality and safety inquiry, the relevant reasoning never comes to light.

The paucity of such research, given the crucial importance of these interpretations to many patients and their families, is likely to create uncertainty in the community that the system truly involves respect for the rule of law. Relevant research questions might involve the extent to which unspecified discretion is routinely applied in accordance with ethical standards arising from the official or the institution. Another might concern health professionals engaging in conscientious non-compliance. This is an act of deliberate disobedience to the law, done in private (though with the understanding that subsequent public explanation may be required) and oriented primarily to the altruistic goal of enhancing relief of patient suffering.

One step toward a coherent and comprehensive theory, possibly arising from such research, might involve the creation of processes whereby professional and bureaucratic interpretations of health legislation could be systematically recorded, analysed and checked for consistency. Judges would surely benefit from being able to review research analysing how their interpretations were being translated in practice by officials and what effect this was having on patients. Valuable insights about the regulatory role of legislation could thereby be obtained for use by both the judiciary and legislature.

III INTERPRETIVE ASSUMPTIONS AND EXTRINSIC MATERIALS: MEDICAL ETHICS AND INTERNATIONAL HUMAN RIGHTS

This section examines whether a barrier to a coherent theory of interpretation of health legislation may be removed if judges or other interpreters analyse health legislation with the presumption that it will not conflict with basic principles of medical ethics as well as medically-related international human rights. It also considers the extent to which basic documents of medical ethics and medically-related human rights should be routinely used as extrinsic aids in the interpretation of health legislation.
Courts routinely approach the interpretation of legislation (including health legislation) with presumptions about the protection of fundamental rights or freedoms in mind. Optimistically, some view this as a judicial attempt to provide a common law bill of rights that protects fundamental freedoms in the absence of a ‘clear expression of an unmistakable and unambiguous intention to abrogate or curtail [them].’

Health legislation will generally be interpreted so as to not abrogate established common law rights, such as, presumably, the protection of a patient’s physical integrity and confidentiality. It has likewise been accepted that such legislation is presumed not to conflict with fundamental international values (for example, the right to life, the right to progressive realization of a standard of living adequate for health and medical care and the right to share in scientific advancement and its benefits expressed in the *Universal Declaration of Human Rights*). The question to be considered here is why health legislation should also be presumed not to abrogate or contravene established principles of medical ethics, or bioethics as the broader field is known.

One factor that might be alleged to inhibit this usage of medical ethics and bioethics is that there is no consensus about their content. Many claim, for example, that the principles of medical ethics were simply ‘invented’ by professional bodies (mostly without lay representation) that periodically enunciated them in codes of conduct. Others have alleged that developments in medical technology, such as enhanced premature neonatal intensive care, artificial ventilation permitting brain death criteria

and advanced genetic diagnosis, require completely new ethical principles that bear little relation to those emerging from the historical struggles of the profession to support its privileged status and lucrative state monopoly from competitors.\(^ {21}\)

The initial thrust of the bioethics movement in the 1970’s concerned intra-professional attempts to ensure that patient autonomy and privacy were protected against state legislative intrusions in areas such as abortion.\(^ {22}\) Bioethics subsequently became more concerned about critiquing health policies and legislation that adversely affected the just allocation of resources.\(^ {23}\) The so-called ‘four principles’ of medical ethics were developed by Beauchamp and Childress during this period to create a common language for the ‘identification, analysis, and resolution of moral problems in biomedicine.’\(^ {24}\) The authors indicated quite clearly that that these ‘clusters’ of \textit{prima facie} principles were derived from extra-legal sources, from ‘considered judgments in the common morality and medical tradition.’\(^ {25}\)

Principles of medical ethics, in the minds of most judicial interpreters of health legislation, appear to be viewed as of ‘subservient’ or ‘secondary’ importance to legal principles.\(^ {26}\) Codes of conduct, such as guidelines prepared by professional

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regulatory bodies are likewise frequently considered a species of ‘professional law’ or ‘quasi-law’ — a type of research exercise for the enunciation of legal rules.

For those statutory interpreters adopting the legal positivist tradition, principles of medical ethics are norms enunciated by the institutions of the medical profession that do not meet conservative legal positivist pedigree or sources criteria for recognition as law. Included amongst them are ‘mid-level,’ ‘interstitial’ or ‘interpretive’ principles practically necessary to either sustain the consensus within which so-called ‘foundational’ ethical principles are developed and applied, or to resolve conflicts between them. Ethical rules, such as are found in the codes enunciated by medical professional associations are more specific or goal-focused formulations of ethical ‘principles.’

Medical ethics, particularly since the Nuremberg Nazi doctor’s trials, has valued its capacity to express opposition to laws perceived to be contrary to a patient’s best interests. The Geneva Declaration, the World Medical Association’s restatement of the Hippocratic Oath requires doctors to vow that the health of their patient will be their first consideration and that, even under threat, they will not to use their medical knowledge contrary to the laws of humanity.

In 1964 the World Medical Association in the Helsinki Declaration reaffirmed it was imperative that doctors practised medicine with conscience to safeguard the health of


28 Montgomery, above n 27, 12.


30 Hart, above n 26, 110, 246


people, though this duty was not to take precedence over the wellbeing of the individual research subject, whose privacy and dignity must be respected.33

In 1975 the World Medical Association’s Declaration of Tokyo on torture and other cruel, inhuman or degrading treatment or punishment, reaffirmed the profession’s foundational ethical principles in terms clearly indicating their potential for conflict over the professional’s obedience to norms enunciated in health legislation. It stated that:

[t]he doctor’s fundamental role is to alleviate the distress of his or her fellow men, and no motive, whether personal, collective or political, shall prevail against this higher purpose.34

Permitting a presumption of compliance with basic principles of medical ethics might, it could thus be argued, open the door to a type of natural law radicalism — a critique against canons of conscience and professional virtue — in the interpretation of health legislation. This possibility is discussed in more detail in the third section of this essay.

Section 15AB of the Acts Interpretation Act 1901 (Cth) provides that in certain circumstances consideration may be given to extrinsic material capable of assisting in the ascertainment of the meaning of a provision. The first such circumstance is to confirm that the meaning of the provision is the ordinary meaning conveyed by the text of the provision taking into account the Act’s context, purpose and underlying object. The second is to resolve ambiguity or obscurity, or determine the ordinary meaning of a provision, taking into account the Act’s context, purpose and underlying meaning, when it would otherwise lead to a result that is manifestly absurd or unreasonable.


A considerable collection of authoritative sources of medical ethics now exists, ranging from the *Geneva Declaration, the International Code of Medical Ethics, the Nuremberg Declaration* and the *Helsinki Declaration*. The United Nations Educational, Scientific and Cultural Organisation (‘UNESCO’) is in the process of drafting a *Declaration of Universal Norms of Bioethics* that may involve the first steps towards incorporating norms of bioethics into the corpus of customary international law. Given existing presumptions that legislation will not seek to controvert basic principles of the common law or international law, it seems reasonable to assume that health legislation will not normally seek to overturn basic ethical principles of the doctor-patient relationship. Similarly justified would be an assumption that health legislation will not contravene basic ethical protections accorded research subjects through authoritative ethical codes and guidelines. Of like importance, as will be discussed, could be an assumption that health legislation will not attempt to abrogate the primary obligation of a doctor to remain loyal to the relief of patient suffering.

Another relevant class of interpretive assumptions maintain that legislation should be construed as consistent with clearly established rules of international law. As O’Connor J stated in *Jumbunna Coal Mine NL v Victorian Coal Miners Association*:

> every Statute is to be so interpreted and applied as far as its language admits as not to be inconsistent with the comity of nations or with the established rules of international law.

Judicial statements have been made that might restrict this presumption to resolving ambiguities and uncertainties in legislation enacted to give effect to obligations created by a treaty or international convention. The Australian High Court, however, has applied the principle more broadly. In *Minister for Immigration and...*
Ethnic Affairs v Teoh: Mason CJ and Deane J expressly extended it to all legislation.  

Presumptions of statutory interpretation, pertinent in this instance, also establish that administrative discretions should normally not be exercised inconsistently with an international human rights instrument. Similar assumptions concern the unreasonableness of delegated legislation. Interesting questions arise about judicial review for error of law when a non-judicial decision-maker misdirects himself or herself as to the content of an international human rights instrument.

The work of physicians John Locke and Benjamin Rush indicates that a close conceptual connection existed from a very early point between the principles of medical ethics and human rights. The language of rights only occasionally appeared judicially, however, amongst basic common law principles related to doctor-patient relations prior to the Second World War.

After that time, the development of international first generation civil and political human rights became a major means of politically or judicially asserting individual claims for patient respect against contrary state assertions of utilitarian communal good. This was particularly true where legislation promoted genocide, torture and discrimination, especially for vulnerable groups of patients such as women and

39 Minister for Immigration and Ethnic Affairs v Teoh (1995) 183 CLR 273
41 Minister for Foreign Affairs and Trade v Magno (1992) 37 FCR 298.
42 Gunaleela v. Minister for Immigration and Ethnic Affairs (1987) 15 FCR 543, 560–561 (Sweeney, Lockhart and Gummow JJ). See also R v Secretary of State for the Home Department, Ex parte Launder [1997] 1 WLR 839, 867 (Lord Hope of Craighead (Lords Browne-Wilkinson, Steyn, Clyde and Hutton agreeing)).
44 ‘Every human being of adult years and sound mind has a right to determine what shall be done with his own body.’ Justice Cardozo, Schloendoff v Society of New York Hospital, 211 NY 125 (1914).
children. The European Court of Human Rights has built up a considerable body of jurisprudence concerning the application of human rights norms in the *European Convention on Human Rights* to health legislation.

The right to health is included amongst second generation economic, social and cultural international human rights, requiring positive state action to be fulfilled. This right was influentially set out in the preamble to the *Constitution of the World Health Organisation* as well as article 25 of the *Universal Declaration of Human Rights*, article 33 of the *American Declaration on the Rights and Duties of Man*, article 12 of the *International Covenant on Economic, Social and Cultural Rights*, article 11 of the *European Social Charter* and article 16 of the *African Charter on Human and People’s Rights* as well as many other Conventions and Constitutions.

The presumption of interpretive consistency with international law in this context could extend to ensuring that interpretations of ambiguities and uncertainties in health legislation are consistent with the international law prohibition on ‘cruel, inhuman or degrading treatment’ and the requirement for ‘free consent’ before

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medical or scientific experimentation in Article 7 of the International Covenant on Civil and Political Rights.\textsuperscript{48}

The role of a presumption that legislation affecting the doctor-patient relationship should be consistent with the international right to health, is not clear cut.\textsuperscript{49} The interpretive task is not made easier here by the fact that the international right to health has been held to refer to not only emergency medical care, access to health care or the preconditions of health, but even the baseline standard of health below which a state should not allow its citizens to fall.\textsuperscript{50}

The right to health in domestic constitutions mirrors that in international law. It has been invoked to make states, such as Columbia and Venezuela, pass legislation providing basic medical care (including drugs) and develop treatment policies concerning HIV/AIDS patients.\textsuperscript{51} In 2002 the South African Constitutional Court unanimously found the government in breach of s 27(1) (‘right of access to health care services’) and 27(2) (‘progressive realisation’) concerned with the right to health in that Constitution.\textsuperscript{52}

\footnotesize
\begin{itemize}
\item \textsuperscript{48} International Covenant on Civil and Political Rights, opened for signature 16 December 1966, 999 UNTS 171 (entered into force March 23 1976); Minister for Immigration and Ethnic Affairs v Teoh (1995) 183 CLR 273, 287 (Mason CJ and Deane J).
\item \textsuperscript{49} Collective rights to development, particularly emphasised in southern or developing nations, were less obviously influenced by the liberal individualist tradition of rights, the latter being perceived as created primarily for the benefit of privileged social groups: see Philip Alston, ‘Revitalising United Nations’ Work on Human Rights and Development’ (1991) 18 Melbourne University Law Review 216; Hilary Charlesworth and Christine Chinkin, The Boundaries of International Law: A Feminist Analysis (2000) 204–209.
\item \textsuperscript{52} Minister of Health v Treatment Action Campaign (2002) Case CCT 8/02 (5 July 2002). See also C Ngwena ‘Access to Health Care Services As a Justiciable Socio-Economic Right under the South African Constitution’ (2003) 6 Medical Law International 13. The court held that the government’s policy of restricting the anti-HIV drug ‘nevirapine’ to 18 sites was unreasonably rigid and inflexible, denying babies of HIV-infected mothers outside those areas a potentially life-saving therapy. The court took note of the fact that the drug was apparently affordable, easy to administer and recommended by the World Health Organisation (‘WHO’). The Court’s order for the government to expand its policy to facilitate greater availability of the drug was tempered with the caveat that the government had the discretion to adapt the Court’s order if equally appropriate or better methods of preventing mother-to-child transmission of HIV became available.
\end{itemize}
Rapid global spread of infectious disease, such as HIV/AIDS, Severe Acute Respiratory Syndrome (SARS), or the threat of bioterrorism (ie: through terrorist use of agents such as anthrax or smallpox) have overcome many barriers of state sovereignty and necessitated international legislative co-operation in the interests of public health.\(^{53}\) This *microbialpolitik* and *microbialterrorism* may also support consideration of a statutory presumption that public health legislation will not unduly or unreasonably interfere with basic human rights expressed in the doctor-patient relationship.

A state’s desire for immediate, effective control of health care apparatus in a bioterrorism disaster may arguably provide a compelling and justiciable minimum core public health component of the economic, social and cultural human right to health. As such it could justifiably entitle a state to impose proportional and necessary restrictions on international civil and political human rights such as freedom of movement, freedom of thought, conscience or religion, freedom of expression, peaceful assembly and freedom of association.\(^{54}\) It is important, however, that such restrictive health legislation be assumed not to contravene basic principles of medical ethics and basic norms of international human rights, such as respect for patient confidentiality, egalitarian and beneficent care in an emergency and the requirement for free consent before medical treatment.

International trade liberalisation and patent protection arrangements negotiated bilaterally or through the World Trade Organisation, increasingly threaten to inhibit the purpose of legislation attempting to achieve equality of health care delivery.\(^{55}\) Health legislation passed to give effect to such bilateral and multilateral treaties could

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be presumed to not violate, interfere with or limit basic principles of medical ethics and similar normative standards emerging from the right to health under international law, requiring universal access to affordable medicines.

From early 2004, UNESCO was in the process of drafting a Declaration on Universal Norms of Bioethics and an International Bioethics Convention that would commence the process whereby norms of medical ethics or bioethics become part of the corpus of international customary law and possibly treaty law (should a convention on the subject enter into force).56 These developments will increasingly provide an influential and important backdrop to the process of interpreting provisions in health legislation. Extrinsic materials explaining this process may be justifiably resorted to by such interpreters, provided they can reasonably be assumed to have been in the minds of the drafters of health legislation and are being used to resolve some textual ambiguity or uncertainty. It should not appear that such extrinsic sources are being used to supplant the intention of the legislature.

IV SCIENTIFIC APPRAISAL OF THE EFFECTIVENESS OF INTERPRETATION OF HEALTH LEGISLATION

This section draws upon the previous two in exploring a regulatory model that may assist the development of a coherent approach to interpretation of health legislation by facilitating scientific appraisal of its effectiveness, including its capacity to encourage right action.

A recent article in the Statute Law Review compared the following passage by Dr Samuel Johnson to a well drafted section of a statute:

> He therefore that would govern his actions by the laws of virtue must regulate his thoughts by those of reason; he must keep guilt from the recesses of his heart, and remember that the pleasures of fancy and the emotions of desire are more dangerous

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as they are more hidden, since they escape the awe of observation, and operate equally in every situation without the concurrence of external opportunities.57

Medicine and healthcare have a particular attraction for many in the social sciences because they appear to involve interpretations of phenomena that are somehow more ‘true’ than man-made laws. Law in other words, allegedly uses concepts not only categorically distinct from natural science, but less likely to be precise.58 The ‘hermeneutic’ enterprise of statutory interpretation, however, may not be qualitatively distinct from the scientific enterprise of examining natural phenomena.

The good sought by any regulatory system may be termed a telos and philosophies designed to achieve its maximisation are known as ‘teleological.’ Many forms of utilitarianism, those underpinning public health legislation, for example, focus on the telos of overall community welfare.59 They have the regulatory advantage of providing clearly determined guides to action, but often do so at the expense of devaluing individual human rights.60 Yet, health care regulation (of which health legislation is described here as but one component) appears in practice to possess a unique individually-focused utilitarian telos.61 When formulated prescriptively this may be described as the foundational duty of health care professionals, or indeed the health care system as a whole, to be loyal to the relief of patient suffering. In such a guise, it takes on the characteristics of a master principle, relating complementary and interstitial interpretive principles.62 Relief of individual patient suffering is

60 Whether a theory of virtue ethics in the context of doctor-patient relations can lay claim to the teleological advantages of providing a determinate guide to action is explored subsequently.
61 The term primary telos implicitly covers relief of individual patient suffering as both an extrinsic end for a regulatory system to aim at, as well as a personal ideal condition of functioning.
62 It allows, for example, medical boards, judges and legislators to calibrate other regulatory components in accordance with the side constraints set out by the complementary ethical principles of autonomy, beneficence, non-maleficence and justice. Doctors and external regulators may disagree about whether a particular course of action will actually relieve patient suffering, but commitment to the foundational virtue of therapeutic loyalty ensues that they at least enter the debate, and do so with this as the prima facie focus.
formulated here as a *prima facie*, rather than an absolute duty. This is chiefly because human suffering may be so broadly defined.

The influential model of Ayers and Braithwaite considers that regulation of any human activity may be conceptualized as a ‘pyramid.’ Each metaphorical ‘layer’ of this regulatory image represents a regulatory technique and the amount of space that virtual tier occupies, reflects its likely proportion of overall regulatory activity.63 It is also inversely proportional to the strength of state enforcement power that the regulatory technique can readily bring to bear.

Most regulation of the professions, according to such a model, occurs at the base under the influence of often relatively intangible, decentralised self-regulation. Rational incentive for compliance is facilitated here by the threat of escalation up the ‘pyramid’ through such areas as, in turn, enforced self-regulation (warning letter, rebuke from a role model leading to repentance and penitence), command regulation by legal rules with discretionary punishment (civil and criminal damages and penalties, license suspension and revocation) to, ultimately, command regulation by legal rules with nondiscretionary punishment and a greater implicit threat of state-enforced physical violence upon breach.64

In relation to health legislation, the great social and professional virtues, justice, fairness and loyalty to the relief of patient suffering, may be viewed as forming the base of the healthcare regulatory ‘pyramid.’65 The next tier comprises general principles of medical ethics, then institutionally enunciated ethical rules or guidelines, the common law, health legislation and finally constitutional and, in some settings, international human rights.

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64 Enforced self regulation requires the subject ‘to propose its own regulatory standards’, which the subject is then required to enforce. If it fails to comply with the standards, ‘the privately written rules can be publicly enforced’: ibid 101.

Understood in this way, the authority of health legislation cannot be perceived as relying in a positivist manner primarily on the authority of its source. Health statutes interpreted in such a structure gain community legitimacy by being seen to arise directly from and foster the foundational social and professional virtues: justice and fairness (predictability and certainty) and loyalty to the relief of patient suffering. One significant implication, for present purposes, relates to the legitimization of research designed to show that the implementation and operation of health legislation are in fact coherent with those basic social and professional virtues.

As dissonance is perceived in what may be termed ‘hard’ cases involving interpretation of health legislation, this conceptual device may be viewed as essentially comprised of equally authoritative principle at every tier, evaluated in a much more relativistic and probabilistic manner. Another useful way of considering the regulatory structure from this deliberative perspective is as an enunciation of prima facie norms from different regulatory sources, all equally important to the ultimate telos, and which must be interpreted coherently to maintain public legitimacy.66

Dworkin terms a similar interpretive approach utilized chiefly by judges ‘law as interpretation’ (‘law as integrity’ being its adjudicative component). Dworkin claims it requires a judge to act as a literary critic, or more contentiously, the author of a chain novel, trying to develop the most coherent interpretation of relevant law and principle.67 This interpretive approach has rightly been viewed as a form of hermeneutics where understanding involves personal ‘engagement.’68 Rawls terms a like process ‘reflective equilibrium.’69

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66 Beauchamp and Childress refer to certain norms as ‘virtually absolute,’ the given example being ‘prohibitions of cruelty and torture, where these actions are defined as gratuitous infliction of pain and suffering.’ Such ‘absolute’ norms would be better described in the 21st century as violations of distinct human rights. See Beauchamp and Childress, above n 25, 32–33.


68 The term hermeneutics derives from Hermes, the messenger of the Gods whose task was to explicate and interpret the wishes of the divine to the secular and so in reverse. See Costas Douzinas,
Judicial or administrative interpretation of health legislation may appear deceptively definitive in apparently ‘easy’ cases through a type of ‘close-reading’ or explication des textes norm-defining approach.\textsuperscript{70} This will be so to an even greater extent if such interpretations claim coherence with the social and historical facts alleged to grant authority to the statute.\textsuperscript{71} Ordinary meanings remain the place to start any approach to statutory interpretation because they can be presumed to arise from the conceptual inheritance of a particular community and so enhance the great, personified social virtues of predictability and certainty in relation to justice and fairness.\textsuperscript{72} An interpretation is legitimate (which is not to the same as correct) only insofar as it purports to interpret some language of the document and only insofar as the interpretation is within the boundaries suggested by that language.\textsuperscript{73}

Under the approach proposed here, however, all regulatory participants first engage their professional conscience about a situation and only thereafter seek coherence with the principles, rules and rights that appear most relevant to it.\textsuperscript{74} The legislative interpreter then tries to ‘fit’ that understanding with a knowledge of a ‘community of principle’ derived from many regulatory sources including medical ethics, health law and the list of values found in the corpus of international human rights.

This process bears comparison with the attempt of canonical literary criticism to not only locate a fictional narrative within a genre, but to become a focus of

\textsuperscript{70} Lars Ole Sauerberg et al, \textit{The Practice of Literary Criticism} (1983) 23.
\textsuperscript{71} ‘In literary criticism, positivism led to an interest in the systematic analysis of the factors behind the creation of the text’: ibid 24.
\textsuperscript{73} Frederick Schauer, ‘Easy Cases’ (1985) 58 \textit{Southern California Law Review} 399, 431.
\textsuperscript{74} Patients are regulatory participants in the sense of being able to critique the ‘integrated’ structure, though, of course, they are not bound by most of its norms.
interpretation itself. An important component of that genre or ‘community of principle’ are principles central to the ‘life narrative’ of individual human beings. All these understandings indicate that this type of theory for the interpretation of health legislation endorses detailed sociological and even psychological research about the relative regulatory effectiveness of statutory schemes.

The theory may give rise to its own specific interpretive principles. Vertical coherence is an interstitial principle which requires that any such interpretation should be consistent with some existing and authoritative tradition of principle, though not necessarily identical with any particular conclusions. Horizontal coherence necessitates that a similar interpretation should be given to any substantially identical subsequent narrative. Such interpretive or interstitial principles (the ‘resemblance condition’ and ‘universalizability’ of Beauchamp and Childress are related examples) assist to quell concerns about unpredictability and uncertainty in this interpretive method.

Legislation is often promoted as a rapid cure for basic conflicts in moral and bioethical principles, such as were involved in the issues of access to and control of artificial reproductive technologies, including in vitro fertilization, surrogacy and human reproductive cloning. One point emphasised by this proposed theory of

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75 ‘Poems…are neither about ‘subjects nor about ‘themselves.’ They are necessarily about other poems; a poem is a response to a poem, as a poet is a response to a poet, or a person to his parent’: Harold Bloom ‘Poetic Origins and Final Phases’ in David Lodge (ed), Modern Criticism and Theory: A Reader (1988) 241, 247 (emphasis in original).

76 The terminology is Dworkin’s but based on the principles of literary criticism. Ronald Dworkin, Freedom’s Law: The Moral Reading of the American Constitution (1996) 83. Similarly relevant principles from musical contrapuntal technique are dissonances (conflicts between principles) generally only accentuated on weak beats (ie: where any contrary social consensus in terms of the community of principle is low) and normal and inverted as well as forward or retrograde motion involving the harmonic triad of medical loyalty, personal and professional narrative coherence and community of principle. See Christoph Wolff, Johann Sebastian Bach: The Learned Musician (2000) 337. Another such principle might be that where the melody is familiar (ie, a strong social consensus supports the principle), the most audacious harmony (variations of principle) can be permitted:’ Albert Schweitzer, J S Bach (Ernest Newman trans, 1966) Vol II, 32.

77 Beauchamp and Childress refer to such principles as ‘safeguards’ to ‘protect against faulty coherence construction’: Beauchamp and Childress, above n 25, 25–26.

‘personal and professional coherence,’ however, is that without sufficient prior social consensus, consultation and research, such statutes have the potential to enhance public mistrust of the law as an effective tool of regulation in this area.

Consider, for example, legislation requiring that the creation of an embryo outside the body can only be licensed where it is necessary or desirable for the purpose of providing treatment services related to assisting women to carry children. Doctors looking at those provisions could use them as an excuse not to help parents who wanted to perform pre-implantation genetic diagnosis and tissue typing on an embryo in order, for example, to obtain umbilical cord stem cells to treat an existing child’s beta thalassaemia. Such an interpretation of the legislation would be simple and legally correct, but hardly likely to enhance trust in the relevant doctor-patient relationship. It would be incoherent, in other words, with other key components of the regulatory system, in particular foundational principles of bioethics and international human rights (for instance beneficence and possibly the right to health).

Once it is accepted that interpretation of health legislation needs to be proven by sound research to be consistent with foundational social and professional virtues such as justice, fairness and loyalty to the relief of patient suffering, a major barrier to the development of a coherent and comprehensive theory in this area may have been overcome.

V CONCLUSION

This essay has sought to explore some theoretical and practical obstacles to developing a coherent and comprehensive theory for the interpretation of health legislation. The three suggestions made involve broadening the focus on who is doing the interpretation, expanding the use of presumptions to include extra-legal norms particularly from medical ethics and international human rights and developing a

79 See Human Fertilisation and Embryology Act 1990 (UK). Sections 2, 11 and sch 2 paras (1) and (3).
virtue based regulatory theory which has legislation as a component. All these options interrelate and support each other.

The major differences with the interpretive theory of ‘personal and professional coherence’ proposed here for health legislation and that of Dworkin and Rawls, may be briefly summarized. First, the foundational virtues are not just those related to law (justice and fairness) but include those of the professions (loyalty to the relief of patient suffering in this case). Second, there is no barrier for such virtues not including those derived from different cultural traditions (ren, wa and taqwa for example). Third, the interpretive theory applies to all interpreters and not just judges. Fourth, it aims to arrive at the best regulatory solution, whether or not law is involved. Fifth, it emphasizes the overriding importance of individual conscience in a coherent and comprehensive regulatory system.