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A Tale of Two Standards: Drift and Inertia in Modern Korean Medical Law

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Abstract

Like all nations, the national character of Korea has been shaped by a variety of geographic and historical factors. Some of the characteristics that have emerged from Korea's experience are 'familism' and 'scientism', both of which have had, and are having, a fundamental impact on the content and application of medical law. These phenomena, combined with recent events both inside Korea (eg: a physicians' strike (2000) and the more important Hwang scandal (2005)) and outwith (eg: the spread of 'informed consent' (1980s), the commencement of the Human Genome Project (1990), and the cloning of Dolly the Sheep (1997)), have contributed to a flurry of recent governance activity in Korea. Given the latest legislative proposals offered, we explore two areas of Korean medical law with a view to exposing their trajectories. First, we examine the governance of the patient-physician relationship in the clinical setting, paying particular attention to consent and to liability. Second, we examine the legal-ethical control of biotech research in the medical research setting, paying particular attention to consent, quality control and limits. We conclude that these two arenas appear to be travelling down two dramatically different (if not divergent) roads; in the case of the former, drifting away from traditional practices, and in the case of the latter, remaining mired in imbalance and dominated by antithetical interests.

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1. Introduction

The national character of every country and its peoples is shaped by its unique physical and relational position in the world, and by its particular historic events and (national) responses to the consequences of those events. Korea, of course, is no exception – modern Korea is a product of its geographical position (i.e. a small country between “four elephants”) and its past (i.e. a dynastic state recently subject to colonial rule, war, dictatorship, and, now, democratisation), and how they have shaped its people. Of particular importance – from a medical law perspective – is Korea’s long-standing adoption of Confucian “familialism”,¹ and its relatively recent but deep-rooted tradition of “sciencism”,² both of which have endured to the present.

The national “inclination” toward science, has, despite the Confucian roots of, and social characteristics that still pervade, Korean society, encouraged the rapid uptake of high-tech medical equipment,³ and the aggressive pursuit of biotechnology development,⁴ both of which have had an indelible impact on medicine and healthcare in Korea, the former within the clinical setting and the latter in the research setting. Additionally, these sci-tech trajectories have contributed to schisms and scandals which have further shaped these settings (clinical and research) and the legal structures designed to govern them.

Given the above, this article explores Korean “medical law”⁵ as it pertains to the clinical and research settings, focusing on recent controversial reforms that have been pursued within them. Part 2 considers the governance of the patient-physician relationship in the clinical setting, paying particular attention to consent, which implicates Confucian traditions, “technologisation” trends, medical accidents and therefore liability. Part 3 considers the legal-ethical control of biotech research in the medical research setting, paying particular attention to consent, quality control and

¹ This term is further elaborated in Part 2.1 below, but generally refers to the perceived importance of family cohesion and continuity and the impact that predilection for deferment to family hierarchy has had: see IH Park & LJ Cho, “Confucianism and the Korean Family” (1995) 26 *Journal of Comparative Family Studies* 117-134.

² This term refers to the national inclination to rely on science as a means of regeneration and competition with existing (and colonising) powers, and to elevate science to a national imperative tangled up with nationalism: see SY Song, “The Rise and Fall of Embryonic Stem Cell Research in Korea” (2006) 9 *Asian Biotechnology and Development Review* 65-73, who, at 70, notes that science has consistently been associated with nation-building and economic growth.

³ B M Yang, “Medical Technology and Inequality in Health Care: The Case of Korea” (1993) 8 *Health Policy Planning* 385-393.

⁴ SY Song, *see* note 2.

⁵ Here understood as that collection of regulatory instruments which govern the practice of medicine, including liability for medical negligence, and medical research and biotechnologies.

limits. We suggest that recent activities have been influenced by Korea's "scientism", but that this phenomenon has led the two different settings on divergent paths.⁶

2. The Clinical Setting: Consent, Liability and Recent Governance Activity

In this Part, we explore two elements of the modern clinical experience. First, we examine the roots of the patient-physician relationship, followed by its current and (potential) future status, paying particular attention to the *Medical Services Act 1951*,⁷ (MSA 1951) and related instruments. Second, we examine clinical practice in light of new medical technologies and the recent legislative reform proposals that the new complexity of clinical practice has spawned. The purpose of both investigations is to consider the position of Korean patients and physicians, focusing particularly on the latter's exposure to legal liability.

2.1 'The Corrections' – Confucianism, Consent and Physician Liability

Like patients in almost every country around the world, Korean patients have often struggled to make their voices heard. This is not only true from a public health and health policy perspective, but also from a more personal, relational perspective where "paternalism" and "familialism" have long reigned supreme. This Section considers the Confucian origins of the modern patient-physician relationship, and recent legislative changes that are transforming that relationship.

2.1.1 'A Sentimental Journey' – Traditional Approaches to Consent and the Patient-Physician Relationship

Korea has been fundamentally influenced by "Confucianism", an ancient philosophy imported from China which rests on five virtues, namely *ren* (benevolence, altruism, humanity), *yi* (integrity, uprightness), *li* (propriety, boundaries, rite), *chi* (moral understanding, self-cultivation), and *shin* (honesty, trust), and five principle relationships (eg: government-citizen, parent-child, husband-wife, older sibling-younger sibling, and friend-friend), and through which individuals find identity, duty and responsibility.⁸ Within this belief-system, family cohesion and continuity are seen as central pillars; they are seen as essential for sustaining the community and the state.

⁶ And we draw on SD Yi, *Biotechnology and Law* (Seoul: Dae Woo Acanet, 2003), throughout. See also NK Kim, "Biotechnology and Law" (2004) 90 *Archiv für Rechts und Sozialphilosophie* 457-460, which reviews the introduction to this book.

⁷ Law No. 8651, adopted in 1951, last amended 17 October 2007, available at <http://www.moleg.go.kr> and <http://www.lawkorea.com>.

⁸ See K'ung Fu-Tzu, *The Analects*, China, circa 500 BCE, available at <http://classics.mit.edu/Confucius/analects.html>. For a discussion of these elements of Confucianism, see MJ Park & C Chesla, "Revisiting Confucianism as a Conceptual Framework for Asian Family Study" (2007) 13 *Journal of Family Nursing* 293-311.

This social construction (or ethic) is manifestly relevant to medical practice and indeed influenced the development of medicine and medical practice throughout Asia.⁹ One of the more enduring ways it has influenced practice has been to reinforce traditional familialism, which is characterised by familial solidarity and paternalism within an extended family, which family lives together, and has responsibilities and status allocated according to sex and age.¹⁰ By doing so, it has coloured the clinical relationship, requiring *family determination*, presupposing an *objective conception of the good*, and upholding the value of *harmonious dependence*. The general construct can be described as follows: Every agent should be able to make his or her decisions and actions harmoniously in cooperation with other relevant persons.¹¹

In short, familialism has emphasised hierarchical authority over individualism, not unlike paternalistic Western practices, which have only recently been thrown over by the rise of individual autonomy, and this conception has shaped the clinical relationship in many ways, not least through the structuring of practices for obtaining consent to medical treatment in the clinical setting. Thus, in addition to the patient, family members (eg: spouse, parents, adult children) are very important to the consent process, often retaining final authority:

*[W]hen a patient requests or refuses a treatment while a relevant family member holds an opposite opinion, the physician generally should not simply follow the patient's wish as in the West, even if the patient is evidently competent. Instead, the physician should tell the patient and the family members to negotiate and provide an agreement to him before he can undertake a medical act.*¹²

The importance of family in the clinical setting is exemplified by the Korean *Organ Transplantation Act 1999*.¹³ Subsection 18(3) of that Act stipulates that, although the brain dead or deceased person gave consent for the extraction of her organs when she was competent, her family or survivors can nonetheless refuse consent for the extraction, which refusal must be honoured. Conversely, if there is no evidence of consent or refusal prior to brain death or death, but the family consents to extraction, then the extraction is legal. Section 3 of the Act defines “family or survivors” as the spouse, the lineal descendant, the lineal ascendant, brothers and sisters, and, if none of the others exist, a family relative (eg: cousin).

⁹ K Hattori, “East Asian Family and Biomedical Ethics” in SY Song, YM Koo & D Macer (eds.), *Asian Bioethics in the 21st Century* (NZ: Eubios, 2003) 229-231.

¹⁰ R Chau & WK Yu, “Is Welfare UnAsian?”, 21-45, at 35, and SH Ahn & SC Lee, “The Development of the South Korean Welfare Regime”, 165-186, at 166, both in A Walker & CK Wong (eds.), *East Asian Welfare Regimes in Transition: From Confucianism to Globalisation* (Bristol: Policy Press, 2005).

¹¹ R Fan, “Self-Determination vs. Family-Determination: Two Incommensurable Principles of Autonomy” (1997) 11 *Bioethics* 309-322.

¹² R Fan, *ibid.*, at 316-317.

¹³ Law No. 8852, adopted in 1999, last amended in 2008, available at <http://www.moleg.go.kr> and <http://www.lawkorea.com>.

The physician also has an important role to play in this Confucian-informed relationship. It is the physician's duty to promote the objective conception of the good:

What is important is not that one's clinical decisions must be made by oneself in conformity with one's present desires. It is more important that they are made for one's long-term good impersonally understood. ... This features significantly discounts patients' presently-held desires, preferences or expectations if they do not fit into the objective conception of the good. For instance, if a patient refuses treatment because he judges his life is no longer worth living, while the relevant others do not think so in terms of the objective conception of the good, the patient's wish would not be followed, whether or not the patient is competent.¹⁴

In short, under traditional practices, the physician's duty was to promote the objective conception of the good whether the patient wished it or not.

2.1.2 'Such a Long Journey' – From Confucian Tenets to Statutory Guidance

Although Confucianism continues to be important in Korea, its power is diminishing, both generally and in the medical context,¹⁵ and relationships like that described above are less common. For example, note the *Boramae Hospital* case,¹⁶ in which the family of a patient recovering from brain surgery convinced the physician that the objective good, which was largely informed by financial matters, demanded that treatment be discontinued and the patient be discharged to recover at home. Despite knowing that discharge would almost certainly kill the patient, the physician acquiesced. The patient died almost immediately after arriving home. The Korean Supreme Court affirmed the decision of the lower courts to convict the physician for accessory to murder (and the patient's wife of murder). Although this case is primarily about improper motive and physician dereliction of duty, it demonstrates the diminishing relevance of old conceptions of familial consent, clarifies the duties expected of family in circumstances where the patient is incompetent, and upholds the claim that the patient's best interests should be paramount.¹⁷ In the aftermath of this case, hospitals have become reluctant to discharge patients with low survivability despite family desires.

In circumstances where there is no question of incompetence, the patient is now considered a key decision-maker. And this is certainly the case in situations governed by statute, which increasingly reflect international norms and Western influenced conceptions of individualism. Of course, some physicians resist statutory guidance, viewing the management of the patient-physician relationship and the taking of consent as professional matters which should, at best, be governed by professional

¹⁴ R Fan, *see* note 11, at 318.

¹⁵ SH Ahn & SC Lee, *see* note 10, at 165 and 167.

¹⁶ 24 June 2004, 2002 Do 995 (Kor SC).

¹⁷ This should not be taken to mean that all manner of paternalism is evaporating in Korea. Some would argue, including the authors, that there has been a shift to another form of paternalism where courts (or the state) acts on behalf of the individual – a form of national paternalism.

codes.¹⁸ Unfortunately for these physicians, their arguments have fallen on deaf ears and the taking of “informed consent” is mandated by statute in a growing number of circumstances.¹⁹

Modern Korean practice is governed by a number of instruments, perhaps the most important one being the MSA 1951, which was amended in its entirety just once (1973), but has subsequently been revised on a more piece-meal basis, first in response to the needs of modernisation, then to changes to the medical insurance system, and finally as a result of pressure from civil society proponents who have become more active/vocal under the new democratic regime.²⁰ The primary function of the MSA 1951 is to structure and guide the practice of medicine and related activities in Korea, and thereby improve national health. In doing so, it addresses the following:

- qualifying and licensing physicians and establishing physician rules;
- establishing and managing medical institutions;
- introducing new medical techniques;
- controlling medical advertising;
- evaluating and overseeing medical institutions and practices; and
- mediating medical conflicts and complaints.

It stipulates that physicians shall seek the improvement of national health and contribute to securing the health of citizens (s. 2(2)). Physicians, who must be qualified and licensed, are directed to provide treatment and health guidance (s. 2(2)(1)), and to that end are instructed to keep records of medical treatment and to protect the confidentiality of those records (ss. 20 and 21), and to inform patients or their custodians about treatment and recuperative matters (s. 22). Aside from this bland informational provision, the MSA 1951 does not specifically address the consent process.

However, s. 9 of the *Emergency Medical Services Act 1994*,²¹ states that emergency medical personnel should, prior to taking action, explain the emergency medical intervention to the patient. The taking of consent can be put off when (1) the patient is incompetent, or (2) such explanation would delay the necessary emergency treatment and thereby cause serious risk of loss of life or serious mental or physical disability. Similarly, s. 12 of the *Basic Bill of Medical Health Care 2000*,²² states that everyone has the right to self determination, and to be informed sufficiently by his or

¹⁸ See SY Yun *et al.*, “Consent for Emergency Patients: How Far Must We Go?” (2005) 16 *Journal of the Korean Society of Emergency Medicine* 164-170, who conducted a study of emergency physicians.

¹⁹ DY Hyun, “Legal Issues Concerning Informed Consent” (2005) 48 *Journal of the Korean Medical Association* 881-885.

²⁰ For more on the rise of civil society as a political force in Korea, particularly as it relates to welfare infrastructural creation and reform, see SH. Ahn & SC. Lee, *see* note 10. The question of whether civil society organisations are moving Korean policy in an appropriate direction, particularly in the medical field, is very much a matter of debate.

²¹ Law No. 8692, adopted in 1994, last amended 14 December 2007, available at <http://www.moleg.go.kr>.

²² Law No. 6909, adopted in 2000, last amended 29 May 2003, available at <http://www.moleg.go.kr>.

her physician about the therapy intended to be administered, whether for disease, transplantation or research, and to consent to the intervention prior to action being taken. These provisions make clear that *patients* have rights to information and to consent (or refusal of consent), but they are limited to very particular settings (eg: *Emergency Medical Services Act 1994*) or declaratory instruments (eg: *Basic Bill of Medical Health Care 2000*).

In the absence of broader consent guidance, new concepts have emerged which strive to articulate better the nature and purpose of “medical therapy” and the role of “autonomy” therein. For example, the therapeutic relationship has now been characterised as an interaction in which both patient and physician have personal and co-dependent rights and duties. In this approach, the patient-physician relationship is seen as a kind of conversation or “therapeutic communication” between patient and physician.²³ Although patients lack medical training and knowledge, and are therefore unevenly empowered within this conversation, their vulnerability is seen as a promoter of responsibility in the physician, who is expected to appreciate the imbalance, and to empathise with the patient’s feelings and emotions, and to offer and then act on his or her best judgment. Within this construct, the patient’s psychological and physical status determines, in a meaningful way, what s/he is told about the diagnosis, treatment course, alternatives and prognosis, the idea being that to disclose everything would be to shift the medical decision onto the patient thereby raising the possibility that the patient may experience “informed isolation and abandonment” (ie: patients would be dissatisfied if they were regarded as totally independent subjects within a medical decision-making framework).²⁴ Ultimately, patients need information and some control, but they still need protection.

This interpretation of the therapeutic relationship (and autonomy within it) constitutes a bridge between traditional practices and stark statutory statements, attempting to avoid the worst authoritarian elements of old Confucian approaches, and the most damaging individualistic elements of newer conceptions, which appear to be informing recent statutory reforms.²⁵ The provisions of the *Emergency Medical Services Act 1994* and the *Basic Bill of Medical Health Care 2000*, certainly offer the legal space within which this conception of the therapeutic communication could function insofar as they promote conditions, which facilitate understanding and encourage free discourse.²⁶

²³See SD Yi, *The Medical System and Law* (Seoul: Korea University Press, 2000), who coined the term “therapeutic communication” in the Korean context and drew on Habermas in doing so.

²⁴ See NK Kim, “Informed Consent in the Medico-Legal Context” (2007) 15 Korean Journal of Medical Law 10-14, and see J. Dichgans, “Der Arzt und die Wahrheit am Krankenbett” in L. Honnefelder *et al.*, (eds.), *Ärztliches Urteilen und Handeln* (Frankfurt: Insel-Verlag, 1994) 194, who coined the phrase “informed isolation and abandonment”.

²⁵ DY Hyun, *see* note 19.

²⁶ SD Yi, “The Patient’s Rejection of Treatment and the Doctor’s Responsibility” (1998) 22 Korean Journal of Legal Medicine 95-99.

2.1.3 'Red Storm Rising' – Amendments and Dissatisfaction

It has now been suggested that a clearly articulated duty to inform should be included in Korea's fundamental medical instrument (ie: the MSA 1951). In May 2007, the Ministry of Health, Welfare and Family Affairs (MOHWFA) submitted to the National Assembly a wholly amended text for the MSA 1951.²⁷ One of the most controversial reforms in this collection of amendments, from a practitioner's point of view, is the establishment of a "duty to explain" as part of the consent process. For example, s. 3(ii) of the draft states that medical professionals should explain the condition and the therapeutic methodology "to the person under his or her care".²⁸ Although the provision would only be in the declarative part of the law, its presence combined with recent judicial trends (see below) would be to emphasise physician duties to explain to the satisfaction of the patient any treatment/procedure patients receive, including the risks associated with treatment, the risks of non-treatment, and alternative treatment options, and to thereafter seek the consent of the patient before any medical intervention is undertaken.

The introduction of this "new" duty provoked sharp opposition from Korean medical professionals, who advanced a number of arguments against it and other reforms. First, they argued that, despite being contained in the declarative section of the draft law, this provision would accelerate the tendency to initiate lawsuits against doctors, and, in the long run, would lead to the inclusion in Korea's medical law of sanctions against doctors who failed to meet the duty.²⁹ Second, they argued that the imposition of such a duty hinted at a legislative blindness to both the reality of medical practice in Korea and the special relationship between physicians and patients. While not denying the existence or value of autonomy as a principle (or indeed of consent as a practice), they argued that a provision explicitly imposing a duty to explain to the patient was contrary to long-standing practice, and would inject distrust into the doctor-patient relationship.³⁰

The inclusion of a duty to explain in Korea's fundamental medical-legal instrument throws into much sharper perspective the requirements of consenting individual patients, and would appear to bring Korean legislation ever closer to the widely recognised concept of autonomy, which finds its origins in Kantian notions of human dignity and the premise that every person has the right to have his/her bodily integrity

²⁷ Draft No. 17-6615. The text for the amendments can be found on the website of the new Ministry for Health, Welfare and Family Affairs, at <http://www.mohw.go.kr/user/tdf>.

²⁸ This amendment is the most recent in a series, which has served to quantitatively increase the volume of regulation governing medicine. For example, from 1951-2001, the number of letters in the law increased 6-7%, whereas from 2001-2007, it increased by 21% and the number of provisions increased some 30%: see SD Yi, "The Direction of the Amendment of the Medical Services Law", presented at "Principles and Prospects of Medical Law", Conference, 23 November 2007, Sungshin Women's University, Seoul, who argues that the change in the Medical Services Law as a method to systematization of social security medicine is expressed in these quantitative increases.

²⁹ For more on these points, see Human Rights & Justice Committee, Korean Bar Society, *Report of Symposium on the Amendment of Medical Services Law*, 22 March 2007, available at <http://www.koreanbar.or.kr>.

³⁰ With respect to practice, a recent study has demonstrated that many medical actions, including the giving of anaesthesia, which is a relatively high-risk action, are not preceded by information disclosure and consent: JY Sim *et al.*, "Survey of the Informed Consent for Anaesthesia Practice in Korea" (2005) 48 *Korean Journal of Anesthesiology* 117-123.

protected against invasion by others,³¹ and which has underwritten the concept of “informed consent”, a term which was “invented” in the US,³² made its way to the UK,³³ and eventually surfaced in Korea.³⁴ Despite judicial resistance to its inexorable expansion in a number of jurisdictions,³⁵ its use as a means to found medical negligence suits on the basis of non- or inadequate-disclosure cannot be denied. Thus, for example, in *Chester v Afshar*,³⁶ the UK House of Lords confirmed that an action will lie against a physician where consent is tainted by reason of inadequate disclosure of information. In setting out the burden on the aggrieved patient basing an action on inadequate information disclosure, the House of Lords reaffirmed the significance of autonomy, holding that all material risks of a procedure (as determined by a responsible body of medical opinion) must be disclosed if the patient’s right to choose was to be protected.³⁷ It further confirmed that, though a physician might, in appropriate circumstances, withhold information that might be considered psychologically damaging to the patient, this privilege is extremely circumscribed.³⁸

As it went in the UK, so it followed in Korea, where the concept of “informed consent”, if not the term itself, has already been used to found liability against physicians. Generally, where there has been a failure to explain, the courts have found liability. For example, in *Hong v H-Hakwon*,³⁹ wherein a patient suffered from an undisclosed but not uncommon drug complication, the Korean Supreme Court held that it is part of the physician’s duty to inform the patient in advance about the method and means of treatment, its necessity, foreseeable risks, and prognosis. In determining what information to provide, the physician should take into consideration things that would be important to the patient. If the patient suffers an injury from a risk that was not disclosed, then one can claim emotional distress as a result of the injury. Thus, even if it is found that the injury was not caused by the physician’s negligence, the fact of its foreseeability and non-disclosure makes it compensable

³¹ See J Mason & G Laurie, *Mason & McCall Smith’s Law and Medical Ethics*, 7th ed. (Oxford: OUP, 2006) at 395. Indeed, the premise that everyone has a right to bodily integrity has been recognised internationally as a human right: see *YF v Turkey* (2004) 39 EHRR 24 (ECHR), wherein it was held that Article 8 of the European Convention on Human Rights protects the physical and psychological integrity of the person, and that (compulsory) medical interventions represent an interference with this right.

³² See *Salgo v Leland Stanford Junior University Board of Trustees* (1957) 317 P 2d 170 (Cal CA).

³³ It was first mentioned in the UK in *Chatterton v Gerson*, [1981] 1 All ER 257 (QB).

³⁴ An early case of acknowledgement in Korea is *Cha v Il-Song Hakwon*, 28 April 1987, 86 Da Ka 1136 (Kor SC).

³⁵ See *Rogers v Whittaker* (1992), 109 ALR 625 (HC) in Australia, *Sidaway v. Board of Governors of the Bethlem Royal Hospital*, [1984] 1 All ER 1018 (CA) and *Re T (adult: refusal of medical treatment)*, [1992] 4 All ER 649 (CA) in England, and *Moyes v Lothian Health Board*, [1990] 1 Med LR 463 (Ct Sess) in Scotland.

³⁶ [2004] 4 All ER 587 (HL).

³⁷ Lord Steyn, at para 14, states: “Surgery performed without the informed consent of the patient is unlawful. The court is the final arbiter of what constitutes informed consent.”

³⁸ A proposition which was made clear in *Sidaway v Board of Governors of the Bethlem Royal Hospital*, [1985] 1 All ER 643 (HL).

³⁹ 15 April 1994, 92 Da 25885 (Kor SC).

insofar as it causes emotional distress to the patient. In *Jeon et al. v Kim*,⁴⁰ the Court reaffirmed that a patient is entitled to at least nominal compensatory damages for the emotional distress of losing the right of self-determination. A patient need only prove the fact that the physician provided no or insufficient information to her for liability to follow; she need not demonstrate a causal relationship between the medical act and the injury which triggered the emotional distress.

As these and other cases demonstrate, regardless of whether one resists the term “informed consent”, information must, in the modern setting, pass from physician to patient, and where that information disclosure is inadequate, a case of medical negligence might follow.⁴¹ Moreover, these cases suggest that Korea may be moving in an explicitly autonomy-founded direction (as exemplified in the UK by *Chester v Afshar*), though it is still too early to claim that autonomy-based arguments will expel (modified) Confucian concepts. For its part, the draft amendment to the MSA 1951 does little to elucidate the extent of the disclosure (what particular details should/must be divulged) or by what general standard that information should be judged when conflicts arise.⁴² In the absence of such guidance in support of this mechanism, which is often viewed uncomfortably by the profession, it is perhaps understandable that physicians feel at greater risk of litigation than ever before, particularly in light of the fact that the number of medical negligence lawsuits based on the failure to obtain proper “informed consent” is already on the rise in Korea.⁴³

2.2 ‘The Difference Engine’ – Technology, Complexity and Physician Liability

The increasing insinuation of medical technologies into this personal, clinical relationship has made the struggle against liability all the more difficult, putting strains on practices such as “informed consent”, and frameworks such as the “patient-physician relationship”.⁴⁴ This Section considers the technological changes that have been occurring within Korean medical practice, and the concomitant legal vulnerability of physicians practicing “at the coal face” (ie: in the clinical setting).

2.2.1 ‘Great Expectations’ – New Technologies in Healthcare Delivery

The technologisation of Korean medical practice began in the 1980s and accelerated in the late ‘80s and ‘90s as a result of a desire by the new democratic government to be “modern”.⁴⁵ Examples of new technologies that have been taken up include computer tomography scanners (CTs), magnetic resonance imagers (MRIs), ultrasonographs, automated chemical analysers, gamma cameras, linear accelerators, and the use of sophisticated healthcare information systems. Adoption rates for such new,

⁴⁰ 10 February 1995, 93 Da 52402 (Kor SC).

⁴¹ As asserted by J Mason & G Laurie, *see* note 31, at 397.

⁴² For more on how these issues have been approached in the UK, see J Mason & G Laurie, *ibid*, at 397-399.

⁴³ SY Yun *et al.*, *see* note 18.

⁴⁴ BM Yang, *see* note 3.

⁴⁵ A Son, “Modernization of Medical Care in Korea (1876-1990)” (1999) 49 *Social Sciences and Medicine* 543-550, and JG Kim & D Bates, “Results of a Survey on Medical Error Reporting Systems in Korean Hospitals” (2006) 75 *International Journal of Medical Informatics* 148-155.

high cost technologies (mostly imported from Germany, Japan, the Netherlands and the USA) jumped dramatically with the introduction of national health insurance,⁴⁶ and were such that during the 1990s the growth rate in Korean health spending was two-times higher than the average of all OECD countries.⁴⁷ More recently, that growth rate has been supported by pharmaceutical spending.

Obviously, the introduction of medical technologies can improve the quality of healthcare; they can enhance the effectiveness of treatments and the efficiency of procedures. However, perhaps counter-intuitively, an increasing reliance on high technology in medical practice can also (1) reduce the quality (and equality) of care, and (2) increase the difficulty of recovering damages when one is injured by a medical procedure, both of which have been experienced in Korea.

With respect to the first concern, medical technologies are only useful if physicians are trained to use them appropriately and to interpret their outputs properly. Unfortunately, there has been a lag in the adoption of training programmes and implementation policies for many of the new technologies.⁴⁸ Related to this, there has been a lag in the ability of physicians to integrate their proper use into clinical practice.⁴⁹ The problems associated with technology are compounded in Korea by the operation of a dual medical system, with traditional herbal physicians in one branch, and Western trained physicians in the other (often antagonistic) branch. Indeed, the latter have reported that, despite a government order directing the traditionalists – who have a lack of technical training – to desist from using new technologies in their practice, they have continued to use them.⁵⁰ Consequently, they say, there have been medical accidents based on the misuse of technology, though it seems more likely that responsibility for the medical accidents to which technology has contributed is shared between the two factions.

The embedding of technologies into clinical settings (or treatment systems) has also contributed to the second concern – complexity and responsibility for medical injuries. It is well recognised that, in modern technologically-driven and team-delivered medical practices, accidents often result from adverse events that are complex.⁵¹ As such, it can sometimes be impossible to determine the causes of the accident for purposes of attributing legal liability. Compounding the problem, very few Korean hospitals have any sort of official channel through which to report medical errors.⁵² As a result, patients face significant hurdles when trying to recover from injuries they sustain during treatment.

⁴⁶ BM Yang, *see* note 3.

⁴⁷ OECD, “OECD Health Data 2007: How Does Korea Compare” (2007), available at <http://www.oecd.org/dataoecd/46/10/38979986.pdf> [3 April 2008].

⁴⁸ For an example of the difficulty of integrating new and high-tech services into general practice, see YR Um, “A Critique of a ‘Wrongful Life’ Lawsuit in Korea” (2000) 7 *Nursing Ethics* 259-261.

⁴⁹ See BM Yang, *see* note 3, who assesses the situation in the context of MRI utilisation.

⁵⁰ Korean Medical Association, *The 85-Year History of the Korean Medical Association* (Seoul: KMA, 1993), at 158.

⁵¹ JG Kim & D Bates, *see* note 45, and J Dew, “Using Root Cause Analysis to Make the Patient Care System Safe” (2002), at <http://bama.ua.edu/~st497/UsingRootCauseAnalysis%20.htm> [2 April 2008].

⁵² JG Kim & D Bates, *ibid*, who, at 151, report that only 3% of Korean hospitals use their healthcare information systems for medical error reporting.

2.2.2 'The Battle of Life' – Legal Responses to Medical Injuries

Against the above background of technologies, team healthcare delivery and complexity, it has been reported that the percentage of patients who have successfully recovered for injuries suffered as a result of medical accidents has declined markedly since the 1990s, partially because courts are less sympathetic and are making greater evidentiary demands on patients.⁵³ Bearing this in mind, particularly the difficulties faced by those who have been injured in proving physician liability for their loss, the *Medical Accidents Compensation Bill*⁵⁴ was introduced.

Proposed in 2005-2006 by certain members of the National Assembly and supported by certain NGOs,⁵⁵ the controversial *Medical Accidents Compensation Bill* addresses civil remedies (eg: monetary compensation) for injuries suffered during medical interventions. Perhaps the most radical provision in the Bill is s. 4, which states that the medical institution is liable for any injury to body, life or property caused by the medical treatment provided by a healthcarer belonging to the institution, unless the institution can prove that the healthcarer did not breach the standard of care expected of him/her, and that there was no problem with the equipment, procedures or human resources with respect to the event complained of. This provision essentially reverses the burden of proof in medical lawsuits, shifting it from the complainant patient to the defendant physician (or his/her employer). In short, physicians would always bear the burden of proving that damage following on from a medical accident was not caused by his/her negligence.⁵⁶

Supporters of the Bill rallied around the slogan, “the sufficient guarantee of patients’ rights”, and justified the introduction of a reverse onus on the basis that patients face daunting hurdles in their efforts to prove fault on the part of medical practitioners, and thus often fail to win any or sufficient compensation when it might nonetheless be justified. Indeed, they argued that proving liability against physicians is well nigh impossible. As such, in addition to having limited medical knowledge or insight,

⁵³ SC Kwon, “Winning a Medical Suit is No Easy Operation”, 28 March 2008, JoongAng Daily, available at <http://joongangdaily.joins.com/article/view.asp?aid=2887842> [3 April 2008].

⁵⁴The idea of this Bill was first discussed some 15 years ago, and a draft, Bill 3596 (Draft No. 17-3596), was finally proposed by Assemblyman KW Lee on 8 December 2005. Another draft, called the *Medical Mediation Bill*, No. 4413, was proposed by a small group led by Assemblywoman MO. Ahn on 23 May 2006, but for purposes of this paper this latter Bill is not the most interesting Bill and will not be referred to further.

⁵⁵The most prominent NGO, the Citizens’ Coalition for the Establishment of the Medical Compensation Act, was formed in October 2005 and remains active. It is a coalition of a number of NGOs who wished to advance a common objective, including the Citizens’ Coalition for Economic Justice, the Consolidation for Medical Consumers, the Health Rights Network, the YMCA Seoul, and more.

⁵⁶ This approach should not be confused with a “no-fault” system or a “strict liability” system, both of which are very different frameworks. It is unclear how onerous the burden placed on the physician would be. For example, it is not known whether it would simply be a matter of *res ipsa loquitur* such that, in order to discharge the burden, the physician need only demonstrate that there is at least one other reasonable explanation for the adverse outcome which does not require negligence. Presumably, jurisprudence would have clarified this point.

patients have to rely, from an evidentiary perspective, on the physician-recorded chart notes concerning diagnosis, treatment and physician-patient exchanges.⁵⁷

The proposed provision, more than any other legislative initiative in the modern era, evinces an erosion of the gilded position of physicians in Korean society.⁵⁸ It runs contrary to the principle, well established in Korea and beyond, that one cannot without further evidence infer medical negligence (or non-fulfilment of medical obligations) simply from the outcome of the intervention.⁵⁹ Indeed, the provision represents *such* a shift in theory and precedent that, in the National Assembly debates, the MOHWFA spoke out against it, claiming that it might increase litigation against physicians, particularly if, as envisioned, it removed medical mediation as a necessary prerequisite to litigation.⁶⁰ Additionally, the Chief of the Medical Policy Unit within the MOHWFA, stated that, “it is unforeseeable as to what kind of influence this draft would cause because of the variety, complexity and professionalism of the medical services.”⁶¹

2.3 Summary & Conclusion: Principle Drift in the Clinical Setting

Governance structures and governing principles associated with medical practices in the clinical setting have largely conformed to cultural concepts of propriety in the physician-patient relationship. However, there has been a recent flurry of legislative activity in this arena (including the proposed amendments to the MSA 1951 and the *Medical Accidents Compensation Bill*), which suggest a “drift” in principles and a “vulnerability” on the part of physicians. The MSA 1951 amendments introducing a “duty to explain” are suggestive of a “drift” from old characterisations of the physician-patient relationship to new ones, which are informed to a greater extent by international constructs. They are evidence of a turning away from old (authoritarian) ideals, and this has been reproduced and given explicit voice in Korea’s medical law as it pertains to the clinical setting. The introduction of the *Medical Accidents Compensation Bill* is also suggestive of a “drift” from old ways of dealing with interventions which result in harm to a new regime which reverses traditional burdens of proof such that defendant physicians face greater evidentiary hurdles and therefore greater legal vulnerability.

It should be noted, however, that the National Assembly’s Committee for National Health and Welfare have not made the above legislative changes a priority, and the

⁵⁷ Indeed, physician-recorded chart notes are often considered to be conclusive evidence: see SS. Kwak, “The Medical Accidents Compensation Act Should No Longer Be Delayed”, 29, August 2007, Korean Doctors’ Weekly, at <http://www.docdocdoc.co.kr/news/>.

⁵⁸ A position which was certainly shaken by the physicians’ general strike of 2000, which was received with greatly divergent degrees of support by the public: SN Kang, “Professional Medical Ethics in the Korean Context: Towards a Moral Contract” in SY Song, YM Koo & D Macer (eds.), *see* note 9, 294-297.

⁵⁹ See *Ahn v. Yonsei University*, 13 December 1988, 85 Da Ka 1491 (Kor SC), and *Hong et al. v Yonsei University*, 27 July 1993, 92 Da 15031 (Kor SC).

⁶⁰ EJ Jeong, “The Government Opposed to the Compensation in Medical Accidents Act”, October 2007, No. 1991, Korean Hospital News, at p. 3.

⁶¹ SK Kim, “The Ministry of Health and Welfare Actually Opposed to the ‘Shift of the Burden of Proof’”, October 2007, Korean Doctors’ Weekly, available at <http://www.docdocdoc.co.kr/news/>.

most recent session of the Assembly ended in May 2008 without their passage (meaning that they will have to be re-introduced if they are to be realised).⁶² The subcommittee is concerned about the opposition that will be aroused, not only in the National Assembly, but also in the public. Indeed, on 11 October 2007, the Korean Medical Association, the Association of Korean Oriental Medicine, the Korean Dental Association and the Korean Assistance Nurses Association issued a Joint Statement expressing their strong objection to some of these reforms and threatening to return their licenses if these reforms were passed unaltered. One might have little sympathy for physicians resisting the introduction into their basic governing instrument of a duty to explain (dialogue and engage with patients) and thereby show respect, but one might equally have sympathy for their position with respect to the shift of the burden of proof in negligence cases. One might also have sympathy for the patients themselves, for such a move might well lead physicians to practise “defensive medicine”,⁶³ which would negatively affect the delivery of healthcare to the Korean public.

Given the instruments introduced, the resistance generated against them, and their failure to achieve promulgation in the most recent legislative session, it is unclear what path Korea is on (ie: whether it is slipping toward individualism, clinging to old practices with autonomy as a rhetorical tool, or adopting Yi’s modified therapeutic relationship approach). The early evidence, which includes the above attempted legal reforms and increased medical litigation, might suggest the former, but some of the evidence is categorical. For example, in the transplantation context, Confucian concepts of familialism are still important. Generally, Korea is in a state of flux the trajectory of which will become clearer in the coming years.

3. The Research Setting: Ethical Oversight and Recent Governance Activity

With the commencement of the Human Genome Project in 1990 and the rise to fame of Dolly the Sheep in 1997, interest in biotechnologies and their potential for medical applications took off around the world. Korea was no exception, adopting a platform of biotechnology and information technology development as a means of economic development.⁶⁴ There followed an impressive array of research activity. But at the height of the euphoria, Korea experienced a singular, socially defining and polarising

⁶²See SJ Ko, “Committee of Health and Welfare Reserve the Review of the Draft Medical Services Law”, 30 January 2008, available at <http://www.mediगतenews.com>.

⁶³The term “defensive medicine” refers to medical practices designed to avoid liability or avert future medical malpractice suits rather than to benefit the patient. It often leads to increased though less well-planned and medically warranted interventions, and thereby increases healthcare costs and, ironically, exposes patients to increased levels of risk (through excessive testing) without actually increasing the quality of care. For more on this phenomenon, see the definitions in MedicineNet (<http://www.medterms.com/script/main/art.asp?articlekey=33262>), the Online Medical Dictionary (<http://cancerweb.ncl.ac.uk/cgi-bin/omd?defensive+medicine>), and others.

⁶⁴For more on this policy, see Ministry of Science and Technology, *Biotechnology 2007* (Seoul: MST, 2007), which outlines Korea’s “Fundamental Plan for Biotechnology Development”, also known as the “Bio-Vision 2016 Plan”, which includes primary objectives including the intensification of core infrastructure for industrialisation, the uptake of global techniques, and the creation of an affluent bio-economy. This Plan is a follow-on from the 1994 plan called “Biotech 2000”.

incident – the Dr. Woo-Suk Hwang scandal.⁶⁵ In this Part, we briefly examine (1) the meteoric rise of Dr. Woo-Suk Hwang and pre-scandal research governance landscape, (2) the new research governance regime that was formulated in the shadow of that success, namely the *Bioethics and Biosafety Act 2005*,⁶⁶ (3) the cataclysmic fall of Hwang and his team, and (4) the legislative changes that have been proposed in the wake of the scandal. The purpose of the investigation is to assess the impact of that scandal and consider the position of the modern Korean researcher and participant in the post-scandal era.

3.1 ‘Our Mutual Friend’ – The Rise and Rise of Dr. Hwang

As previously noted, Korea has adopted a policy of development through biotechnology. Indeed, the biotech industry was being promoted as early as the 1980s through the *Genetic Technology Support Act 1983*,⁶⁷ which Act coloured the environment thereafter.⁶⁸ Although many factions of Korean civil society expressed concerns about the possible dangers of biotechnologies and their advancement in the reproductive context at the turn of the millennium,⁶⁹ they were largely drowned out by the public enthusiasm for both science-led economic development and the national honour that scientific leadership would generate.⁷⁰ Their concerns were further muted by the apparent success of Dr. Hwang, then professor of biotechnology at the Seoul National University.

In February 1999, Hwang announced that he had succeeded in cloning a cow by “somatic cell nuclear transfer” (SCNT). Though he failed to offer any scientifically verifiable data (claiming that he did not keep careful records because he did not think

⁶⁵Of course, the UK experienced its own scandal in the biomedical research context, namely Alder Hey and Bristol. For more on this incident, see D Hall & J Lilleyman, “Reflecting on Redfern: What Can We Learn from the Alder Hey Story?” (2001) 84 *Archives Disease Childhood* 455-456, J Robinson & P Furness, “In the Wake of Alder Hey”, 17 April 2004, *Guardian*, at <http://www.guardian.co.uk/society/2004/apr/17/medicineandhealth.comment>, K Liddell & A Hall, “Beyond Bristol and Alder Hey: The Future Regulation of Human Tissue” (2005) 13 *Medical Law Review* 170-223, A Plomer, *The Law and Ethics of Medical Research* (London: Routledge Cavendish, 2005), ch. 5.

⁶⁶Law No. 7150, adopted 29 January 2004, last amended March 2005.

⁶⁷Law No. 3718, adopted December 1983, re-enacted as the *Biotechnology Support Act 1995*, Law No. 4938, adopted in January 1995.

⁶⁸The only oversight provision contained in this Act was s. 15, which directed the government to issue biotech research guidelines to prevent biohazards and ethical problems; none were forthcoming until 1997 when the government issued the *Guidelines on Recombinant DNA Experiments*, Ministry of Health and Welfare, 22 April 1997, Public Notice No. 1997-22. These Guidelines contained only a single provision on ethical control of biotech research: Article 23 stated that the head of the ministry, agency or institute, together with industry, should develop measures to prevent ethical problems that might be caused by biotech experiments.

⁶⁹Note the Korean National Commission for UNESCO, *Report of the 2nd Korean Consensus Conference on Cloning*, September 1999, Seoul, available at <http://www.unesco.or.kr/cc/eng.html>, which called for a comprehensive but temporary ban on all attempts to clone any human life forms, including pre-embryos.

⁷⁰See SD Yi, “Legalising Embryo Cloning in the Midst of a Paralysed Public Discourse” (2006) 11 *KIATS Theory Journal* 58-66.

the research was of major importance),⁷¹ the many publicity events that followed turned him into a national hero, the media stoking the public's imagination of the economic prospects ahead. Between September 1999 and August 2000, the Ministry of Science & Technology (MOST) awarded him US\$1.6 million to mass produce high-capacity dairy cows by SCNT. Although the project failed completely, Hwang's reputation remained intact not least because of his many, well-timed public announcements.⁷²

In February 2004, the euphoria grew and Hwang shot to global fame when he published a paper in *Science* to the effect that his team had managed to clone a human embryo from which they had cultivated embryonic stem cells.⁷³ He claimed that, using 242 unfertilised human eggs from 16 donors, they had created a human embryo through SCNT and had extracted stem cells from that embryo. Although ethical concerns were raised,⁷⁴ and despite declaring that they would discontinue their research until national legislation was in effect, Hwang's team resumed in October 2004 and published another paper in 2005,⁷⁵ in which they claimed to have created, using 185 unfertilised human eggs, eleven patient-specific, immune-matched human embryonic stem cells by SCNT. In short, he claimed to have created tailored stem cells for a patient, raising exciting possibilities for personalised therapies as well as commercialisation.

The announcement of this most recent breakthrough cemented Hwang's superstar status in Korea, made him the envy of biotech scientists around the world, and, it has been argued, prompted the government to "sanctify" his research and to deliberately set out to make him a national hero (nominating him as a "Supreme Scientist" and providing him with special guards).⁷⁶ Korean Air gave him two first class tickets valid for 10 years. Ethicists were all too eager to celebrate his work and clamoured to join his World Stem Cell Hub. As a consequence of this celebrity, there could be

⁷¹A common criticism at the time was that his achievements were never properly documented: see P Shanks, "The Hwang Saga Continues: A Genetic Crossroads Exclusive" (2006) at <http://geneticsandsociety.org/article.php?id=2620>.

⁷²For example, he declared that he would attempt to clone a Siberian tiger, the national symbol of Korea, as well as sterilised miniature pigs (for which he received US\$5.5 million), and BSC-resistant cows (for which he received US\$4.3 million): Board of Audit, *An Intermediate Briefing on the Inspection of Government-Funded R&D Projects: Pertaining to Dr. Hwang Woo Suk's Execution of Research Projects* (Seoul: Republic of Korea, 2006).

⁷³WS Hwang *et al.*, "Evidence of A Pluripotent Human Embryonic Stem Cell Line Derived From a Cloned Blastocyst" (2004) 303 *Science* 1669-1674.

⁷⁴D Cyranoski, "Korea's Stem Cell Stars Dogged by Suspicion of Ethical Breach" (2004) 429 *Nature* 3, YM Koo, "A Research Ethics-Based Analysis of the Korean Scientists' Human Embryonic Stem Cell Research" (2004) 5 *Journal of the Korean Bioethics Association* 1-12, and Korean Bioethics Association, "Research in Medical Science and Biotechnology Must be Conducted in Accordance with Bioethical Principles" (2004), available at <http://www.koreabioethics.net/pub.htm>.

⁷⁵WS Hwang *et al.*, "Patient-Specific Embryonic Stem Cells Derived from Human SCNT Blastocysts" (2005) 308 *Science* 1777-1783. The continued perceived merit of his work is somewhat surprising given his claims that it was possible to give every patient the treatment with no immune reactions.

⁷⁶SD. Yi, *see note 70*, and M. Cho *et al.*, "Lessons of the Stem Cell Scandal" (2006) 311 *Science* 614.

little criticism about the work, and Hwang rebuffed those he deigned to respond to at all, making it almost impossible to instigate serious debate in Korea.⁷⁷

This discursively oppressive environment does not mean that Hwang and his team conducted their “research” in a regulatory vacuum. Though there was not much in the way of binding rules, there existed the *MOHWFA Guidelines for Good Clinical Practice 1987*,⁷⁸ the *KHIDI Guidelines on Human Stem Cell Research and Supervision 2001*,⁷⁹ the *KMA Guidelines of Ethics for the Medical Professional 2001*,⁸⁰ and the *SCRC Guidelines for Review of Research Proposals 2003*.⁸¹ Additionally, in response to a 1998 allegation of human cloning at the Kyunghee Fertility Clinic, the Korean Medical Association struck an Investigative Committee (on which Hwang sat),⁸² which led to issuance of the *Guidelines on Research on Cloning Lives 1999*.⁸³ Article 4 prohibits (1) research on human embryos for cloning purposes, (2) implantation of cloned embryos into a woman’s uterus, and (3) experimentation on embryos after 14 days post-fertilisation. Article 8 prohibits the trading of sperm, eggs or somatic cells. Many of these were at least partially relevant, suffering rather from poor monitoring and general ineffectiveness.

3.2 ‘A Fine Balance’ – Ethical Oversight and Biotech Promotion in the New Regime

Hwang’s international stature was in zenith, and with it general interest in biotech development, when the *Bioethics and Biosafety Act 2005* (BBA 2005) neared

⁷⁷For more on the elevation of Hwang and the impossibility of serious ethical debate, see SD Yi, *ibid*, SY Song, *see note 2*, P Shanks, *see note 71*, and Editors, “Human Cloning and Scientific Corruption” (2006) 11 *The New Atlantis* 113-117.

⁷⁸Ministry of Health and Welfare, 28 December 1987, Public Notice No. 1987-87. These guidelines are intended to protect human subjects of clinical drug trials, and are directed at research institutions and pharmaceutical companies. Made binding in 1995 (Ministry of Health and Welfare, 27 July 1995, Public Notice No. 1995-39), and amended in 2000 to bring them in line with the International Conference on Harmonisation (Korean Food and Drug Administration, 4 January 2000, Public Notice No. 1999-67), these guidelines articulate the need for local ethical oversight, stating that documents, particularly consent documents, must be reviewed, and that special attention must be paid to trials that may include vulnerable subjects (ie: people who may be unduly influenced by the expectation of benefits or retaliatory responses from within a hierarchy) (Article 7).

⁷⁹Korean Health Industry Development Institute, *Guidelines on Human Stem Cell Research and Supervision*, adopted September 2001.

⁸⁰Korean Medical Association, *Guidelines of Ethics for the Medical Profession*, adopted November 2001. These are non-statutory professional rules which the KMA have the power to enforce with sanctions. They reiterate the physician’s general duties to act ethically and direct physicians to secure consent to treatment (Article 23), refrain from trading in human eggs (Article 55), and limit cloning research to curing and preventing specific diseases (Article 68). They also recommend the establishment of ethics committees in hospitals and research institutes (Articles 74-75).

⁸¹Stem Cell Research Centre, *SCRC Guidelines for Review of Research Proposals*, adopted May 2003. Applicable to any research which the SCRC funds, these require that stem cell research be supported by surplus IVF embryos that are about to be discarded, and they prohibit the production of human embryos for stem cell research.

⁸²For more on this, see JS Kim, “The Position of the Korean Medical Association on Human Cloning Research” (1999) 42 *Journal of the Korean Medical Association* 826-829.

⁸³ Korean Medical Association, *Guidelines on Research on Cloning Lives*, adopted May 1999.

completion. In fact, the BBA 2005 was the culmination of a series of attempts by competing stakeholders (MOHWFA, the National Assembly's Committee on Health and Welfare, bioethicists, certain NGOs versus MOST, which sought to establish its pre-eminence in the field of biotechnology, the National Assembly's Committee of Science, Technology, Information and Telecommunication, scientists) to introduce bioethical legislation in Korea.⁸⁴ Despite the turf wars that marked its creation, the BBA 2005 was eventually passed and went into effect on 1 January 2005.

From an administrative and procedural perspective, the BBA 2005 establishes a National Bioethics Committee (ss. 6-8), requires research institutions to create Institutional Review Boards (ss. 9-10), and directs the Ministry to perform oversight of research institutions (ss. 18-21 and 38-44, 47). From a more substantive point of view, the BBA 2005 addresses cloning (ss. 11 and 22-23), chimera production (s. 12), embryo production, storage, disposal and research (ss. 13-17, 20, 21), DNA testing (ss. 24-30), DNA banking and genetic information protection (ss. 31-35), and gene therapy (ss. 36-37). Finally, the BBA 2005 contains provisions imposing sanctions for breaches of the rules (ss. 49-55).

As a consequence of both the Hwang success and the negotiations undertaken between the two primary drafters (MOHWFA and MOST), what was ultimately adopted by the National Assembly was a reproductive medicine and biotech research regime with a dual function. Its two roles are well articulated in s. 1, which states:

This Act aims to enhance the health of human beings and the quality of human life by creating conditions that allow for the development of life sciences and biotechnologies that can be used to prevent or cure human diseases. Additionally, this Act aims to protect human dignity and to prevent harm to human beings by ensuring that these life sciences and biotechnologies are developed safely and in accordance with the principles of bioethics.

This duality is further recognised in s. 4, which states that the national or regional governments shall adopt all necessary measures to deal effectively with bioethical and biosafety problems that may arise during the development and utilisation of life sciences and biotechnologies. For present purposes, it is the balancing of these two roles – that of promoting biotech development, on the one hand, and of protecting human dignity and patient safety, on the other – that is of interest, for the outcome of this balancing says something about the direction of Korean reproductive medical practice and research.

⁸⁴It was preceded by the unsuccessful work of the Korean Bioethics Advisory Commission and by some 12 aborted attempts by various factions within the Korean legislative community to introduce legislation: see SG Han *et al.*, "New Cloning Technologies and Bioethics Issues: The Legislative Process in Korea" (2003) 13 *Eubios Journal of Asian and International Bioethics* 216-219. For more on the legislative process, see SH Gwak, "The Legislation of the Bioethics and Biosafety Act and Policy Issues" (Winter 2003) *Technology Trends in the Health Industry* 152-162, YR Um, "South Korea: Human Embryo Research" (2003) 12 *Cambridge Quarterly of Healthcare Ethics* 268-278, YR Um, "Dispute Over Scientific Research Involving Human Embryos in South Korea" in SY Koo, YM Koo & D Macer (eds.), *see note 9*, 56-57, and HK Kim, "Bioethics and Biosafety Law in Korea" (2004) 13 *Journal of the Association of Policy Studies* 45-71, who argues that the National Assembly attached more importance to the development of biotechnology than to its ethical control.

Although the MOST didn't get everything it wanted, the BBA 2005 contains a number of features which strongly enhance Korea's capability to undertake cutting edge research, particularly embryonic and stem cell research, thereby facilitating the policy of development through biotechnology. First, it classifies embryos according to the manner in which they are produced. Subsection 2(2) defines "embryos" as a fertilised egg from the moment of fertilisation to the point at which all organs have developed. Subsection 2(3) defines "remaining embryos" as embryos that are created through IVF procedures but not implanted in a woman. Subsection 2(5) defines "somatic cell embryo clones" as embryos formed by the act of somatic cell nuclear transfer (SCNT). It then requires a different purpose for the production of these different objects, and regulates them in different ways. For example:

- Embryos are regulated by s. 13, which states that no one shall provide sperm or oocytes for the purpose of financial reward, and no embryo shall be produced other than for the purpose of pregnancy (with the consequence that no artificial insemination shall be undertaken for research purposes). However, under s. 16, embryos can be stored for up to 5 years (with the consent of the originators), after which they must be destroyed, unless they are to be used for research. As such, given that the almost inevitable consequence of IVF treatment is the production of excess embryos, embryos are indeed created with the (tacit) knowledge that some will be destined for research, and ss. 19 and 20 address the procedures for transferring such embryos from "embryo producing institutions" to "embryo research institutions".
- According to s. 17, remaining embryos are those that have passed the storage period, and such embryos may be used – prior to the appearance of a "primitive streak" – for research, but only for research (1) aimed at developing contraception and infertility treatments, (2) aimed at curing rare or incurable diseases as decreed by the President, or (3) approved by the President after being reviewed by the National Bioethics Committee.
- Conversely, somatic cell embryo clones are regulated by ss. 22 and 23. These provisions stipulate that no one shall conduct SCNT other than for research aimed at curing rare or currently incurable diseases, as decided by the President after review by the National Bioethics Committee.

However, as should be clear from the above, embryos created by one means or for one purpose can find their way into another category, thereby opening up their use dramatically.

The second feature which clearly enhances the pursuit of biotechnology research is that, although the BBA 2005 clearly prohibits reproductive cloning (s. 11) and implantation of an animal's somatic cell nucleus into a human oocyte whose nucleus has been removed (s. 12(2)), it contains no provision prohibiting the act of implanting a human nucleus into an animal oocyte. As such, it has been claimed that Korea is the first country in the world to permit nuclear transfer between species.⁸⁵

Third is the deployment of consent within the regime. At first blush, the BBA 2005 appears to embrace fully individual autonomy insofar as it erects rights of consent and self determination. For example, with respect to reproductive treatment, s. 15 states

⁸⁵ HK Kim, *ibid*, at 65, SY Song, *see note 2*, at 67, and UJ Pak, *Bioethics, Research Ethics and Regulation* (Seoul: Seoul National University Press, 2005), ch. 8.

that medical institutions which collect sperm or oocytes to produce an embryo shall obtain written consent from both sperm and oocyte donors, the artificial insemination patient and her spouse. It then goes on to outline the content of the written consent, which must include:

- (1) details of the purpose for producing the embryo (ie: it must be for implantation);
- (2) details of the retention period for the embryos;
- (3) details of the embryo disposal procedures;
- (4) an inquiry about whether consent is given to use remaining embryos for purposes other than pregnancy; and
- (5) information on the procedures for withdrawal of consent, the protection of consent information, and other necessary information set by the Ministry.

However, several aspects of the consent provisions suggest that research enablement was a prime motivator. For example, the key self determination provision near the beginning of the instrument (s. 5) appears to place the patient in a rather passive position of “becoming” the subject of research. Additionally, under s. 17, a new consent to use remaining embryos for research is only required if they are intended to be used before the 5-year storage period has run its course; in short, the originator appears to lose control after 5 years.

The above features serve to make the BBA 2005 a very liberal (open) regime as far as governance of biotech development (ie: embryo research and SCNT related thereto) is concerned, though it might be unfair to characterise it as radically different from regimes which exist in other jurisdictions. However, in light of this liberal approach, issues of management and oversight (or a means to address ethical concerns and ensure patient safety) is critically important. In short, the decision-making and monitoring frameworks that are erected and their overall effectiveness are key.

At the outset, s. 4 directs researchers to “endeavour” to safeguard human dignity and to carry out their work in accordance with the “principles of bioethics and biosafety”. However, aside from this reference to that popular but amorphous term (dignity),⁸⁶ the BBA 2005 contains no explicit reference to any mid-level guiding principles nor to any relevant international instruments. All that is offered are the consent provisions and the specific prohibitions identified above and the admonition that care must be exercised when storing, handling and disposing of remaining embryos (s. 21(2)), and research must be halted or appropriate measures taken when research poses a significant or potential threat to “bioethics or biosafety” (s. 21(3)).

Section 6 calls for the establishment of a National Bioethics Committee (NBC), which is to review matters implicating bioethics and biosafety, including policies, research projects on remaining embryos or involving SCNT, DNA test prohibitions, gene

⁸⁶For more on the fragilities of this term as a guiding legal principle, see R. Macklin, “Dignity is a Useless Concept” (2003) 327 *British Medical Journal* 1419-1420, S Harmon, “Ethical Rhetoric: Genomics and the Moral Content of UNESCO’s ‘Universal’ Declarations”, forthcoming in the *Journal of Medical Ethics*, and more.

therapy target diseases, and other issues of social or moral significance implicated by life sciences research. The NBC was formed some three months after the BBA 2005 came into force,⁸⁷ and was composed of seven departmental Ministers, seven research/academic/industry experts, and seven civil society represents.⁸⁸ However, it is not clear whether the NBC is intended to be primarily a policy advisory committee, or a research oversight committee. Given its general elevation from the daily activities of research labs, it is probably best equipped as the former, and so the BBA 2005 also calls for the establishment of Institutional Review Boards (IRBs) by each Embryo Research Institution (ERI).

Section 9 states that IRBs are to review all matters relating to research undertaken by their host ERI, including ethical and scientific validity, consent measures, safety measures, and other matters. The IRB must approve research protocols before commencement of work (s. 19(2)). Additionally, where there is a serious threat or potential threat “to bioethics and biosafety” due to research being undertaken at the host ERI, the IRB must be summoned to conduct a review (s. 9(3)). Unfortunately, there is no elucidation of any mechanisms to alert the ERI when this is necessary, and, in any event, the IRB does not have an independent or “arms length” relationship with the host ERI insofar as the head of the ERI appoints the 5-9 members of the IRB (s. 10).

All ERIs must register with, and must meet the facility and personnel requirements set by the MOHWFA (s. 18). Further, ERIs must submit an embryo research protocol to the MOHWFA before commencing work (s. 19(1)). Neither the approval criteria, nor the evaluation process, nor the documents required are elucidated; they “shall be decided by the Ministry” (s. 19(4)). Chapter 7 goes on to state that the MOHWFA may (1) conduct inspections, (2) demand reports from ERIs, (3) order the disposal of embryos, (4) order the improvement of facilities, (5) revoke ERI registrations or authorisations (after a hearing), and (6) issue fines for non-compliance (ss. 38-43). However, s. 47 states that the MOHWFA may delegate part of its authority, including managing ERIs, to the heads of other institutions, and can reward those institutions with financial compensation.

Despite the weakness of the mechanisms put in place to promote “bioethics” – a term which remains conceptually vague and short of content – it is still conceivable that the oversight framework could function. This would, of course, require a certain level of effectiveness and competence of those in supervisory roles. Unfortunately, the NBC had no role in individual research projects, the operation of the IRBs was delayed, and, in any event, were either ineffective or utterly captured by vested interests.⁸⁹ All

⁸⁷ Pursuant to Presidential Decree No. 18621, 30 December 2004.

⁸⁸ More about the NBC can be found at <http://bioethics.go.kr>.

⁸⁹ Indeed, it is widely suspected that both the 1-year delay before the BBA 2005 and its IRB oversight mechanisms came into force, and the attachment of an Addenda which permitted existing SCNT research to continue with only Ministerial consent, was the work of KY. Park, Advisor to the President, who wished to give Hwang time to finish existing work under the old regime, and who was named as a co-researcher on two Hwang projects during the drafting of the BBA 2005: AR Han, “The Ethical and Regulatory Problems in the Stem Cell Scandal” (2007) 4 *Journal of International Biotechnology Law* 45-68.

told, as found by the eventual NBC investigation, the IRBs performed poorly.⁹⁰ Of course, they would not have been helped by the fact that no body was clearly assigned an inspectorate function.

On the whole, the BBA 2005 might be characterised as a triumph of scientific interests, a common perception being that it attaches much greater importance to the development of biotechnology than to bioethics. This may not be a completely fair characterisation, particularly given the many and complex interests that shaped its formulation, but the shortcomings of the BBA 2005, from an ethical oversight perspective, are apparent. From a functional perspective, it did little to invigorate ethical debate or enforce ethically-grounded limitations on actions.⁹¹ As a consequence, Korea found itself embroiled in, and embarrassed by, the Hwang scandal.

3.3 ‘That Was Then and This Is Now’ – The Unravelling of a National Icon

Despite being muted, ethical questions about Hwang’s research – ranging from rumours about draconian egg donation demands/practices, to concerns about the validity of the scientific evidence, to worries about financial impropriety – were raised and would not go away. One long-term sceptic, the Catholic Church of Korea, voiced its concerns regularly and announced a plan to raise funds for adult stem cell research.⁹² In the autumn of 2005, Dr. Ryu, a former collaborator, posted a confidential message about his suspicions of fabrication, and Dr. Schatten, a University of Pittsburgh researcher, ceased his collaboration, citing concerns about the egg donation process. Later that month, a popular Korean investigative TV program, “PD Notebook”, reported that eggs had been obtained unethically. Indeed, one interviewee stated that Hwang became very angry when she refused to donate her eggs, and claimed that, once she finally agreed, she donated eggs in the morning and then conducted research on them in the afternoon.

A national discussion (finally) followed, as well as several investigations, most notably by the Seoul National University,⁹³ the National Bioethics Committee,⁹⁴ the Korean Board of Audit,⁹⁵ and the Seoul Central District Prosecutors’ Office.⁹⁶ By early 2006, it was concluded that:

⁹⁰National Bioethics Committee, *Intermediate Report on the Ethical Problems of Dr. Woo Suk Hwang’s Research*, 2 February 2006.

⁹¹See HK Kim, *see* note 84, SY Song, “A Brief Report on the Bioethical Events Associated with the Korean Bioethics Association Since ABC4 in Seoul” (2004), at <http://eubios.info/EJ141/ej141e.htm>, and OJ Kim *et al.*, “Current Status of the Institutional Review Boards in Korea: Constitution, Operation and Policy for Protection of Research Participants” in SY Song, YM Koo & D Macer (eds.), *see* note 9, 17-27.

⁹²TG Kim, “Catholic Church Funds Adult Stem Cell Research”, 5 October 2005, *The Korea Times*, available at <http://times.hankooki.com/1page/200510/kt2005100517255110160.htm>.

⁹³ Seoul National University Investigation Committee, *Final Report on Prof. Woo Suk Hwang’s Research Allegations*, 10 January 2006.

⁹⁴ NBC, *supra*, note 90.

⁹⁵ Korean Board of Audit, *see* note 72.

⁹⁶ Seoul Central District Prosecutors’ Office, *Report: Investigation of the Fabrication of the Stem Cell Paper*, 12 May 2006.

Egg Donation

- some 2,221 eggs from some 138 women, were used in the research;
- some women were introduced through an egg broker and almost 100 of them were paid;
- at least two of the women (who donated some 31 eggs) were junior researchers under Hwang, who distributed consent forms to them and personally escorted at least one of them to the hospital for the egg extraction procedure;
- extractions took place at four hospitals, and those sourced from the MizMedi Hospital did not undergo any IRB scrutiny whatsoever;
- most of the women received no or insufficient information regarding possible side effects of hyper-stimulation, or were not consented at all;
- many of the women received insufficient follow-up treatment;

Scientific Fraud

- co-authorships on the various research papers were offered arbitrarily (and apparently in exchange for favours given);
- evidence was falsified, including the number of cell lines actually created and the photos used in support of the claims made such that there were no scientific data to prove any of their stem cell related claims;

Embryo Abuse

- given that Hwang's research could contribute nothing to scientific understanding, the embryos that were used and/or created were wasted to no valuable end and were therefore shown no respect;⁹⁷

Financial Impropriety

- Hwang had inappropriately mixed research funds with personal income and accounts;
- Hwang had used research funds to pay exorbitant consultant honoraria., buy his wife a car, pay egg brokers, pay politicians, and, toward the end, bribe co-researchers into silence; and
- Hwang was unable to account for US\$31.8 million in public money and US\$6.2 million in private donations.

Ultimately, *Science* retracted both of Hwang's articles, Hwang was expelled from the Seoul National University, the Korean government rescinded its financial support, and Korean prosecutors indicted Hwang and certain co-researchers for fraud, embezzlement and breach of the new medical laws which had been adopted over the course of the saga.⁹⁸ Hwang remains only partially contrite and still has fanatical support amongst the public.

⁹⁷ E Jackson, "Fraudulent Stem Cell Research and Respect for the Embryo" (2006) 1 *Biosocieties* 349-356.

⁹⁸ D Kennedy, "Editorial Retraction" (2006) 311 *Science* 335. More particularly, Hwang was indicted for fraud and embezzlement under the criminal law, fraud under the *Proceeds of Crime Act*, and

3.4 'Brave New World' – Redressing the Ethical/Promotional Balance?

As the Hwang incident broke and devolved into scandal, attention was drawn anew to the risks of an uncritical devotion to the development of biotechnology, and the fatal weaknesses in the BBA 2005's capability to govern effectively were exposed. Eventually, the Korean government admitted the need to amend research governance and a Standing Committee of the National Assembly was given two proposals to consider, one a "wholesale" amendment recommended by the MOHWFA,⁹⁹ and the other a "partial" amendment prepared and supported by some 130 Members of the National Assembly.¹⁰⁰ The MOHWFA also put before the Standing Committee the *Reproductive Cells Utilisation and Supervision Bill*.¹⁰¹ And pursuant to its powers, that Standing Committee voted in support of these instruments, which are now considered "priority items".

Given the terrific failures of the various IRBs to monitor Hwang's research effectively over the preceding years, it is unsurprising that IRB oversight is addressed in the MOHWFA's amending Bill (Bill 7702). Section 9 encourages the establishment of IRBs in institutions which, though not generating stem cell lines, uses stem cell lines in the conduct of their research, which is intended to result in treatments for humans. Section 11 states that, with respect to IRB governance, the MOHWFA will supervise and assess IRB action taken in response to executive orders. Whereas hybridisation is permitted in the BBA 2005, Bill 7702 clearly prohibits nuclear transfer between species (s. 13). With respect to stem cell research more particularly, s. 22 imposes on those producing or importing stem cell lines the need to register with the MOHWFA. Section 23 states that where such institutions offer their lines to others, the proposed research has to go through IRB review. Section 24 sets boundaries for stem cell use, requiring that research be directed at the diagnosis, prevention or treatment of diseases, or at the characterisation and specialisation of stem cells themselves. If other research objectives are envisioned, it must first receive scrutiny by the NBC and be followed by an order or permission from the MOHWFA. In either case, the research must receive the assent of the relevant IRB.

The *Reproductive Cells Utilisation and Supervision Bill*, which was clearly motivated by the deficiencies in the consent process that characterised the Hwang scandal, reiterates the right of self-determination. Section 4 states that self-determination applies to decisions about whether to allow reproductive cells to be extracted or donated or used to produce embryos. Additionally, the person who donates the cells (and his/her spouse) must be sufficiently informed about the potential side-effects and consequences of extraction and/or donation. Subsection 14(1) stipulates that all egg donors must be over 20, must be independent (a term which is not specifically defined), and must be both physically and psychologically healthy. If independence

providing and utilising oocytes for the purpose of receiving financial reward or other benefits under the BBA 2005. The case has not yet reached final disposition.

⁹⁹ The *Bioethics and Biosafety Amendment Bill*, Draft No. 17-7702, 6 November 2007.

¹⁰⁰ The *Bioethics and Biosafety Amendment Bill*, Draft No. 17-8096, 21 January 2008, which will not be discussed, but the most interesting aspects of which are the abolition of the NBC and provisions aimed at encouraging prompt decisions regarding bioethics and biosafety.

¹⁰¹ Draft No. 17-7703, 6 November 2007, abrogated by the closing of the 17th Assembly in May 2008.

is in question, the extraction must be considered and confirmed by the relevant IRB. Under s. 14(2) these criteria need not be met where the egg donation is part of the woman's treatment for her own, or other women's infertility, or where it is for research on a rare and intractable disease from which the woman suffers. Egg donation for general research is forbidden, but supernumerary IVF eggs can be used for such research provided the donor has included in her written consent permission to do so (see s. 19). Section 17 states that, where super-ovulation is relied on, the number of egg extractions and the minimum time which must pass between them are to be set by order of the MOHWFA. Finally, s. 6 makes clear that neither the use nor offer of reproductive cells or embryos shall be induced by money or profit. In short, reproductive cells cannot be bought or sold; commercial dealings are forbidden and only actual expenses are permitted to be recovered, although it should be noted that this provision is limited to dealings between researchers and donors; commercial transactions between labs are not addressed.

Although Bill 7702 is characterised as a "wholesale" amendment, there are in fact no fundamental changes with respect to the government's position on the importance of biotechnology to economic development. Indeed, in many ways Bill 7702 lightens the administrative burden on stem cell researchers; where the BBA 2005 required both producers *and* users of stem cells generated through SCNT to register with and obtain approval from the MOHWFA (s. 23), Bill 7702 requires only producers to so register. Researchers relying on stem cell lines already generated need only submit a research protocol to the embryo-producing institution. Similarly, in the case of DNA testing for research purposes, the duty to report to the Minister is abolished (ie: only IRB review is necessary). Additionally, although Bill 7702 directs the government to ensure that researchers comply with bioethical principles, it still fails to enunciate any underlying principles of bioethics and biosafety; it offers some directions and prohibitions, and it mentions human dignity (again without defining its use of the term), suggesting that human life has value, but there is no mechanism for balancing these values against research. Moreover, this lacunae is not really filled by anything in the *Reproductive Cells Utilisation and Supervision Bill*.

Would Hwang's "research" have been caught earlier or stopped if this proposed regime had been in place? In the absence of a dramatic dampening of public support for science and associated nationalist sentiment, and a simultaneous increase in a willingness to question and scrutinise research activities, a different course seems seriously in doubt. In both proposals, control and support (for example for educating and training IRB members and researchers in bioethics) rests with the MOHWFA, an institution which proved spectacularly inept at this function during the Hwang era. Indeed, there is no evidence that either the MOHWFA or the (new) IRBs are approaching stem cell research and/or SCNT any more critically than in the past.

3.5 Summary & Conclusion: Regulatory Inertia in the Research Setting

The Hwang period – a period of national zenith and nadir, from a medical research perspective – constitutes a turbulent backdrop against which medical law reforms might be considered, and it is difficult to overstate the significance of Hwang to both the BBA 2005 and to the subsequent amendment proposals. Despite extensive political jockeying and multiple drafts, it is perhaps not unfair (though certainly ironic) to suggest that the BBA 2005 did not receive the sober consideration it should have. And it reflects the defects in its creation through an imbalance in its two core

objectives (ie: the uneasy alliance between biotech promotion and patient safety). That flawed regime and its more flawed application (in respect to Hwang) is central to the medical law crossroads at which Korea now stands.

Clearly, biotechnology is (or promises to be) a dynamic and exciting vehicle for change, and medicine is one of its primary beneficiaries. Korea at the turn of the millennium is an example of what can happen when one gets seduced by that promise. The objective of new legislative efforts in this field in Korea should be to temper the excitement and enforce a better balance between “value-rationality” and “goal-rationality” conduct, the latter of which has held sway.¹⁰² Unfortunately, it is not clear that the new legislation (eg: Bill 7702 and the *Reproductive Cells Utilisation and Supervision Bill*) can, in the long term, redress the existing imbalance. In short, the law in this area demonstrates a certain and regrettable “inertia”. Having said this, we would not like to be taken as espousing the imposition of additional or more complex regulation. Korea could achieve a better balance through a simple but clear instrument. A valuable feature of that instrument, in addition to the provision of the proper training of monitors, could be the introduction of random inspections of research institutions and facilities by a statutorily empowered body.

4. Conclusion: Drift and Inertia in Bio-Medical Governance

We have examined the clinical setting and the research setting in Korea because both of these arenas have been the subject of intense legislative scrutiny in recent years, and have been the targets of rather dramatic reform proposals. In the first case, the clinical setting, technology has played no small part in the motivation for change. In the latter case, it is the very heart and being of the regime in consideration. But despite the strikes and the scandals, the hurdles and abuses, and the almost frenetic political/legislative activity that has resulted, there has been no great paradigm shift in Korean medical law. There has been a shift, but it has been more muted – even subtle – and it has manifested differently in the two arenas, taking them in curiously different directions.

In the clinical setting, reform efforts (ie: amendments to the MSA 1951 and introduction of the *Medical Accidents Compensation Bill*) evince a “principle drift” insofar as they disclose a slow but steady growth in the recognition of individual patient rights and an erosion of the vaulted position of physicians. This transformation is closely connected to evolutions in medical practice (eg: technologisation and specialization), and evolutions in society (eg: the rise of a contract culture). These evolutions are transforming the physician-patient relationship from a traditional one of guardianship to a new one of partnership whereby a tacit treatment contract is entered into. Although this reshaping appears to be in keeping with Western practices, one should be cautious about that claim. The contours of the traditional manifestation of that relationship are not being precipitously abandoned in favour of an excessively individualistic emphasis; patient rights, which are founded on respect of persons, are important and need not be resisted in the Korean context, but it is important to recall the two-way and multiple duties that exist within that relationship. We would argue that clinical reforms should

¹⁰² For more on these concepts, see MJ Koo & JS Yang, “Reflections on the Human Dignity in Genetics” in SY Song, MJ Koo & D Macer (eds.), *see note 9*, 165-171.

focus on the protection and re-construction of mutual respect, trust and empathy between physician and patient, and that some of the recently-introduced reforms, particularly those contained in the *Medical Accidents Compensation Bill*, fail to do so. Wholesale acceptance of the proposed reforms – which is unlikely given that the 17th Korean National Assembly has now been concluded – would represent a “drift” that takes Korea too far from its traditional values and practices, and would not necessarily result in more respect for patients or better protection of their rights.

In the research setting, reform efforts (ie: amendments to the BBA 2005 and introduction of the *Reproductive Cells Utilisation and Supervision Bill*) represent some improvement over the old regime, but nonetheless evince a certain “inertia” insofar as they cling to the desire to promote biotechnology and not unduly hinder biotech development. In short, the balance achieved between biosafety promotion and reproductive health, on the one hand, and biotech promotion, on the other, is still questionable. This lack of transformation is probably the fault of Korea’s scientism, its ongoing desire to link economic development with biotech innovation, continuing public hope in the field, and powerful stakeholders with strong interests that resist ethical oversight and boundary-setting. Nonetheless, we do not wish to criticise the proposed new regime too harshly; it is an improvement and there is some evidence of an attempt to re-balance. The key, of course, is what happens next. Will researchers once again be left in a largely unscrutinised position, or will the oversight framework be better deployed and supported? These are questions that will require the generation of empirical evidence. Parenthetically, given the nature of the regime and its intimate link with, indeed reliance on, reproductive medicine, we suggest that the purpose of pregnancy needs to play a greater role in shaping Korea’s biotechnology trajectory.¹⁰³

All told, we conclude that Korean medical law, at least as embodied in the two fields examined above, is characterised by “drift” and “inertia”. Drift has seen the clinical setting exhibit an erosion of physician and family authority in both law and practice. This phenomenon has not been reproduced in the research setting, where inertia has ensured that, despite (best?) efforts to impose oversight, the reality is the continuation of a fairly *lassaiz faire* attitude, which appears unprepared to change dramatically. As such, we claim that the current condition is a ‘tale of two standards’ inasmuch as the result has different implications for practitioners in each field. On the one hand, physicians are being constrained, and stricter standards are being applied to their conduct. On the other hand, researchers, though facing a new regime, are not labouring under similar constraints, and it is unclear that stricter standards will be applied.

¹⁰³ For more on the purpose of pregnancy in biotechnological innovation, see NK Kim, *Leben als Lebensgeschichte und subjektives Tatbestandsmerkmal bei der Präimplantationsdiagnostik* (Berlin: Peter Lang Verlag, 2007), at 99 and following. Generally, “respect for the purpose of pregnancy” could mean that the early stages of biotech innovation, if not aimed directly at pregnancy, should be more respectful of embryos which, regardless of their genesis (eg: natural, IVF or SCNT) have the potential to become human beings. On the other hand, Kim considers it to be a complex proposition whereby we must respect the way people (women, patients, etc.) live (ie: the choices they make) and recognising that pregnancy is a process within which we must consider all the life involved, including that of the embryo, its present and future status.