

Bioethics and the Law: Trends and Future Directions

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History: The Legal Foundation of Bioethical Analysis

In recent decades, almost no theoretical discipline has exerted more influence on the practice of health law policy in this country than bioethics. Shaped by historical events such as the Nuremberg Trials and the Tuskegee Syphilis Study conducted by the U.S. Public Health Service (1932-1972), bioethical principles first entered our legal lexicon through the Belmont Report, issued by the National Commission for the Protection of Human Subjects (1979)¹ and the 1991 Federal Policy for the Protection of Human Subjects in Experimentation, referred to as “the Common Rule.”² The core principles comprising traditional bioethical analysis—*patient autonomy* from which informed consent and privacy interests are derived; *beneficence* requiring a risk/benefit analysis for all medical procedures; *non-maleficence*, embodying the standard that medical professionals should “do no harm”; and *justice*, referring to the equitable distribution of medical services and advances among all populations, including vulnerable populations—were articulated in a landmark work by Beauchamp and Childress (1983).³ In turn, these principles have shaped the legal foundation for the conduct of clinical care and medical research, as well as provided guidance for the behavior of physicians, hospitals, insurers, pharmaceutical companies and other stakeholders in the health care system.

In coming years, bioethical principles will continue to exert a powerful sway on health law policy in the face of rapidly changing medical and technological advance. As one example, the Common Rule was recently revised to address issues concerning the use of bio-specimens such as blood, tissue and other biological material. Are these substances individual property or a donation? Do patients and research subjects providing such samples retain privacy rights over genetic information? How should these samples be collected, stored and eventually used for future investigations? As medical knowledge advances, these types of questions will invariably arise.

Human rights law has also influenced the development of bioethics. From a policy perspective, the pursuit of health and well being is the goal of all developed and developing societies, recognized by the World Health Organization and under international law as a fundamental human right. But this goal remains elusive for many peoples across the globe, even in light of the inalienable human right to health.⁴ The International Covenant for Economic, Social and Cultural Rights established the right to “the enjoyment of the highest attainable standard of physical and mental health,”^{5,6} which is operational-

ized by nations through availability and accessibility of adequate health systems and services. Through the early work of Jonathan Mann and Lawrence Gostin, it is now well understood that there is a reciprocal and interdependent relationship between health and human rights such as rights to food, housing, education, and dignity.^{7,8} Yet in the practical sphere many individuals and peoples are denied equitable access to care and live in states of chronic pain and suffering and the absence of dignity. In the United States, the Institute of Medicine reported in 2011⁹ that an estimated 100 million Americans are living with chronic pain. The locus of these concerns may be an ethics of rights or an ethics of care, sometimes competing frameworks. Within these frameworks, bioethical inquiry explores questions of moral experience, ethics and law from the perspectives of seriously ill persons, as well as professionals, and asks the overarching questions: what is the relationship between health and well-being and ethics? And what is the relationship of health and ethical interests to the law? There is a growing tension between a broad professional, common sense understanding of health as an achievement of technical rationality and natural science paradigms upon which health systems and services have been built, and the lived experience of health as an achievement of ethics grounded in social practices.

Recent trends in scholarship suggest that there are converging perspectives between bioethics and public health, ecological ethics, humanism, as well as the qualitative research movement. These influences are expanding the boundaries of bioethics beyond traditional domains of interest, and affording bioethics opportunities to engage meaningfully in dialogues with professionals, scholars and advocates across diverse forms of inquiry and policy. For example, compelling narratives of suffering experience for which natural science provides no cure or solution, and stories of responsive care, caregiving and community that locate possibilities for agency and self-actualization, well-being, resilience, recovery and human flourishing in relationship to others, are challenging the advances of medicine and technology.

Medical Research: The Regulatory Schemes of the NIH and the FDA, and Legislative Protections for Patients and Clinical Trial Subjects

Medical research in America occurs under the legislative auspices of the National Institutes of Health (“NIH”), the largest source of funding for scientific investigations in the world, acting through the Public Health Services Act¹⁰ and other legislative mandates, as well as through the Food and Drug Administration (“FDA”), the regula-

tory agency empowered to enforce the Food, Drug & Cosmetic Act (“FDA Act”).¹¹ Funded by the congressional budgetary process, the NIH’s research mission is impressive. In a related fashion, the FDA oversees the process whereby pharmaceutical and medical device companies receive regulatory approval for marketing, advertising and distributing safe and effective products. Some notable controversies have surrounded the drug approval process, including the thalidomide incident of the late 1950s and the push to hasten or “fast track” drug approval during the height of the AIDs crisis in the 1990s.

Most recently, landmark federal legislation in the form of the 21st Century Cures Act¹² is currently pending in the U.S. Congress. Designed to stimulate a more robust research environment, leading to the streamlined approval of drug and device therapies, the Act has garnered widespread bipartisan support. At its core, the Act significantly increases funding for projects at the NIH that will target diseases with no known cure, including many forms of cancer. In addition, the Act infuses the FDA with budgetary and other enhancements designed to accelerate the process of drug development, testing and agency approval for marketing.

The pace and direction of medical research have also been affected by patient advocates eager to gain access to promising but not yet authorized treatments. Beginning with the *Abigail Alliance* case (2008),¹³ individuals have been more assertive in pressing for a right to promising drugs that have not completed the process of regulatory review. Although a constitutional right to obtain experimental treatment for terminally ill patients was ultimately rejected by the court in *Abigail Alliance*, many states have taken up this cause and recently passed “Right to Try” laws intended to promote access to investigational drugs by the terminally ill. Indeed, such a law is currently pending in the New York State legislature.¹⁴ While the likelihood of the New York bill’s passage remains uncertain, it is clear that health law policy will play an important role as the public becomes more involved in advocating for treatments and cures for intractable medical conditions.

Brave New World: Legal Challenges Posed by Biotechnologies, Stem Cell Research and Genetic Testing

Few would dispute that emerging biotechnologies, stem cell research and access to the human genome have sparked notable changes in the legal landscape with respect to reproductive rights and access to innovative treatments. As some illustrations, laws governing parental surrogacy, the *in vitro* creation of embryos, and fetal testing and surgery—topics beyond imagination not that long ago—are now the norm in many states.

At the same time, however, medical progress has also triggered an increased awareness of the sensitivity of personal health and genetic data, as well as the potential for discrimination as a result of the misuse of these categories of information. The first key federal legislation directed at such individual privacy concerns is, of course, the Privacy Rule of the Health Insurance Portability and Accountability Act (“HIPAA”) of 1996.¹⁵ More recently, the completion of the Human Genome Project in 2003 and the subsequent ability to map an individual’s unique genomic profile have reignited the discussion about how such information will be used.

A key challenge to the characterization of genetic information was at the heart of the *Myriad Genetics* case,¹⁶ in which the U.S. Supreme Court held that naturally occurring DNA is a product of nature and not patent eligible, while also observing that the artificial creation of new DNA sequences *might* be patent eligible. It is important to emphasize that preserving rights related to genetic information may pose unique legal challenges, since an individual’s genomic profile contains not only key health information about the particular individual, but also about children and other relatives. The Genetic Information Nondiscrimination Act of 2008,¹⁷ dubbed by some as the first civil rights legislation of the twenty-first century, was a landmark statute designed to prohibit the misuse of genetic information for purposes of obtaining health insurance and in the employment arena. Currently, several challenges under this law have focused on the use of “wellness programs” by employers. No doubt, as further progress is made in understanding the blueprint of our genetic code, additional legal challenges may be anticipated.

Organ Donation and Transplantation: The Legal and Ethical Rationing of Scarce Medical Resources

Since the first successful kidney transplantation operation in the U.S. in 1954, the ethical and legal ramifications associated with these procedures have been debated. The dramatic medical success of transplantation surgery and its record of achievement in saving the lives of desperately ill patients cannot be denied. Yet, numerous controversies continue to surround this medical specialty. Among these issues are: (a) formulating criteria for determining when death occurs so that organs may be harvested; (b) developing an equitable process so that scarce organs may be fairly allocated; and (c) establishing guidelines relating to the decision-making process for organ donation.

This innovative field of medicine is governed by three key statutes: (a) the Uniform Anatomical Gift Act and revisions thereto (1968, 2005);¹⁸ (b) the National Organ Transplant Act (“NOTA”) and subsequent amendments (1984, 1990)¹⁹ which outlaw the sale of human organs and provide for an Organ Procurement and Transplantation

Network; and (c) the Uniform Determination of Death Act (1981)²⁰ which was intended to provide a “comprehensive and medically sound basis for determining death in all situations.”

Despite the strength of this foundational legislation and the overarching structure for managing an equitable system of organ allocation, NOTA has come under criticism primarily because it prohibits any form of compensation for the donation of human body parts. As one example, in *Flynn v. Holder*,²¹ a 2012 Ninth Circuit case, the court issued a narrow yet noteworthy ruling, holding that the selling of bone marrow extracted through a special technique would not violate the NOTA ban. Other challenges have been brought relating to the organ allocation regulations and guidelines used by the United Network for Organ Sharing. As transplantation techniques become more sophisticated and increasing numbers of US citizens are eligible for life-saving transplantation, the challenge will be to insure that the legal guidelines in place are equitable and fair in terms of access, and that as many patients as possible are able to benefit from this medical breakthrough.

Serious Illness and the End of Life: Controversial Legal and Bioethical Decisions

Advances in biomedical technology have enabled physicians to sustain life under circumstances that would have caused certain death just a few decades ago. In this regard, some of the most challenging issues in bioethics concern the provision of marginally beneficial or non-beneficial care, or the prolongation of suffering in serious illness or at end of life. In light of judicial policy making in the landmark case of Karen Ann Quinlan (*In re Quinlan 1976*)²² and in U.S. Supreme Court decisions in *Cruzan v. Dir., Mo. Dept. of Health* (1990),²³ *Vacco v. Quill* (1997)²⁴ and *Washington v. Glucksberg* (1997),²⁵ issues such as individual rights and liberty interests, as well as the legal authority of health care agents and surrogates to make decisions when an individual no longer has capacity, have taken center stage. Federal and state legislation and regulations have been designed to address these difficult circumstances, including the Federal Patient Self-Determination Act,²⁶ the New York Health Care Proxy Law,²⁷ the New York Family Health Care Decisions Act²⁸ and the MOLST Program.²⁹ In New York, there is a right to palliative care under existing palliative care laws.^{30, 31}

Historically viewed as legally and ethically distinct from decisions to forgo life-sustaining treatment, Aid-in-Dying is being actively debated in many states. Bills have been introduced in the New York State legislature (A. 5261-C (Paulin)/S. 5814-A (Bonacic);³² S. 3685 (Savino) /A. 2129A (Rosenthal)³³). However, public policy issues such as the basis of social allocation or who benefits, the benefits to be allocated, how the benefits will be financed and delivered, and impact upon the public’s health, espe-

cially vulnerable persons and groups who may not have equitable access to palliative and end-of-life care, have not been addressed in proposals advanced to date.

Bioethics as Lived Social Practice: Education and Training

The existential structure of this orientation is grounded in a view of ethics as giving expression to and making visible lived moral experience that is socially constituted. The focus of this orientation is on practice and the life-world, not on expertise or technique. Ethics is not imposed from the outside through appeal to expertise or authority. Methodology is instead viewed as a tool that gives access to lived moral experience and social practices, but in itself is not a source of authority. The focus under this orientation is on the life-world, the intentionalities of the patient, evaluation of the patient’s pain and suffering, and processes of engagement with the patient that involve an ethical stance of non-neutrality and surrendering of authority in order to respond responsibly to the call of the patient as the suffering other. It envisions the full integration of ethics into a palliative approach to care, which seeks to relieve pain and suffering through provision of both appropriate medical care and social support to the patient and family as the unit of care. This view is also grounded in the notion that ethics is accessible to all persons who participate in the social world, and is not a property of the elite.

On the professional side, integration of bioethics education in medical and graduate school curricula, as well as in mandated continuing professional education for physicians and all health care practitioners, is imperative. Such education is consistent with goals of the Affordable Care Act to strengthen the generalist level workforce. Equally important, however, is diffusion of bioethics content into education and end-of-life decision counseling for seriously ill persons and their family caregivers.

Conclusion: The Integration of Bioethical and Legal Paradigms in Formulating Future Health Law Policy

As this discussion has suggested, applying a bioethical perspective has enabled policymakers to address numerous challenging legal issues emerging from advances in medicine and biotechnology. Whether the topic is clinical care, human subject research, the implications of genetic knowledge, the role of the professional in treating illness and the alleviation of suffering, organ donation and transplantation, or the controversies surrounding medical interventions at the beginning and the end of life, in each instance bioethical principles have offered an indispensable framework for developing laws and policies grounded in individual autonomy, equity and human rights. As medical and scientific knowledge moves inexorably forward, it is likely that the union of bioethics and

law will continue to serve as a touchstone in the evolution of health law policy.

Endnotes

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