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THE GROWTH OF HEALTH LAW AND BIOETHICS

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LOOKING BACK over the last fifty years, the growth in health law and bioethics has been nothing short of amazing. Although health law barely existed as a discipline fifty years ago, today health issues have created entire new fields of law, ranging from food and drug law to fraud and abuse law. Similarly, in the last fifty years, law has become an integral (if not universally welcomed) part of medicine. Physician practices are now concerned with privacy notices, informed consent documents, and advanced directives. At most hospitals, expanded in-house legal departments have been joined by related departments of risk management, regulatory compliance, and health information privacy and security.

Overarching both law and medicine is bioethics, a still-emerging discipline that blends philosophy, law, and social science. A major intellectual source of modern bioethics was the enactment of the Nuremburg Code after World War II, although the actual term "bioethics" was not used until the late1960s.[1] Today, bioethics includes research ethics,[2] clinical ethics,[3] distributional ethics,[4] as well as other concerns. Bioethics plays an important role at both the individual and societal levels. It is the link between private morality, professional

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[1] ALBERT R. JONSEN, THE BIRTH OF BIOETHICS vii (1998). *See also* VAN RENSSELAER POTTER, BIOETHICS: BRIDGE TO THE FUTURE 2 (Carl P. Swanson ed., 1971) ("I . . . propose the term *Bioethics* in order to emphasize [the important roles of both] biological knowledge and human values.").

[2] *E.g.*, BARUCH A. BRODY, THE ETHICS OF BIOMEDICAL RESEARCH: AN INTERNATIONAL PERSPECTIVE (1998). *See also* REBECCA DRESSER, WHEN SCIENCE OFFERS SALVATION: PATIENT ADVOCACY AND RESEARCH ETHICS (2001); COMM. ON ASSESSING THE SYSTEM FOR PROTECTING HUM. RES. PARTICIPANTS, INST. OF MED., RESPONSIBLE RESEARCH: A SYSTEMS APPROACH TO PROTECTING RESEARCH PARTICIPANTS (Daniel D. Federman et al. eds., 2003).

[3] *E.g.*, ALBERT R. JONSEN ET AL., CLINICAL ETHICS: A PRACTICAL APPROACH TO ETHICAL DECISIONS IN CLINICAL MEDICINE (John Dolan & P. McCurdy eds., 4th ed. 1998).

[4] *E.g.*, NORMAN DANIELS, JUST HEALTH CARE (Daniel I. Wikler et al. eds., 1985); MEDICINE AND SOCIAL JUSTICE: ESSAYS ON THE DISTRIBUTION OF HEALTH CARE (Rosamond Rhodes et al. eds., 2002).

responsibility, and public policy. Nevertheless, there are no accredited or agreed-upon training programs in the field; there is frequent suspicion of the competence and motives of the self-appointed "secular priests" who serve as bioethicists; and there is no consensus on the weight to be given to bioethical analyses in individual cases or in policy development.

Against this backdrop of explosive growth and poorly defined boundaries in health law and bioethics,[5] it is valuable to attempt to put these developments into perspective. Those who work in health law and bioethics need to recognize the origins of the fields as well as the substantial challenges ahead. I will concentrate my discussion on five areas.

First, health care is now big business. In the United States, health care spending in 2001 was $1.4 trillion, representing approximately 14.1 percent of GDP.[6] The practice of medicine is increasingly concentrated in large conglomerates, including for-profit health care delivery companies and managed care organizations.[7] The biotech, pharmaceutical, and medical device industries are all billion dollar industries, and their importance to medical care continues to grow. Finally, the health insurance industry, by pre-approving or rejecting medical interventions, has in many instances blurred the distinctions between those who provide health care and those who provide reimbursement for health care. Obviously, the practice of medicine today no longer resembles the time when physicians made house calls and received payment in cash.[8]

Second, much of the growth in health care has been driven by new technology. We sometimes take for granted the range of medical miracles of so recent vintage, including advances in areas such as diagnostic imaging, laparoscopic- and micro-surgery, renal dialysis, organ transplantation, artificial joints, assisted reproductive technologies, and genetic analysis. With each new advance in medicine come such inevitable questions as when is a new device, medication, or

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[5] *E.g.*, Mark A. Hall, *Law, Medicine and Trust*, 55 STAN. L. REV. 463, 464-65 (2002) ("[U]nlike other areas of law, no unifying principle or animating concern has yet been identified for the law of health care delivery.").

[6] CENTERS FOR MEDICARE AND MEDICAID SERVICES, REPORT DETAILS NATIONAL HEALTH CARE SPENDING INCREASES IN 2001, *at* http://cms.hhs.gov/media/press/release.asp?Counter=693 (Jan. 8, 2003).

[7] *E.g.*, MARY R. ANDERLIK, THE ETHICS OF MANAGED CARE: A PRAGMATIC APPROACH 179 (2001) ("Corporations have long been a part of health care. What is unprecedented is the consolidation among corporations and the extension of the corporate domain to include physicians.").

[8] PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE 66-71 (1982).

procedure ready to move from research to the clinic; who should have access to it; who will pay for it; and how will it be regulated.[9] The ability to attempt more complex medical procedures, along with the diffuse responsibility for care, means an increased risk of adverse outcomes. Efforts to reduce medical errors and to compensate victims of error continue to be sources of great controversy.[10]

Third, numerous specialty areas of health law practice and study have been created by the enactment of federal and state regulatory statutes. Medicare, Medicaid, and other government-sponsored health finance programs, originally opposed in the mid-1960s by organized medicine,[11] dominate today's health care reimbursement system, and require a detailed knowledge of specific laws and regulations. Subsequent legislation included the Employee Retirement Income Security Act (ERISA),[12] Emergency Medical Treatment and Active Labor Act (EMTALA),[13] Americans with Disabilities Act (ADA),[14] Health Insurance Portability and Accountability Act (HIPAA),[15] and other laws regulating such issues as health finance, health services, disability discrimination, and privacy. While rejecting comprehensive reforms, the U.S. health care "system" has mutated incrementally into an amorphous mass of laws and regulations, each enacted with good intentions but, cumulatively, achieving unsatisfactory results by nearly any measure of population health. Increasingly, policy makers will need to focus on substantially improving measures of population health, such as infant mortality rates, childhood immunization rates, and life expectancy.

Fourth, patients have changed over the last fifty years, and so have their relationships with health care providers. The physician-patient relationship fifty years ago was characterized by paternalism, in which largely white, male, generalist physicians provided care on their own terms. It was common for doctors to withhold diagnostic

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[9] *See* ETHICAL DIMENSIONS OF HEALTH POLICY (Marion Danis et al. eds., 2002) (exploring questions of regulatory authority, resource distribution, and their influence on each other).

[10] *See generally* COMM. ON QUALITY OF HEALTH CARE IN AMERICA, INST. OF MED., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM (Linda T. Kohn et al. eds., 2001). *See also* E. HAAVI MORREIM, HOLDING HEALTH CARE ACCOUNTABLE: LAW AND THE NEW MEDICAL MARKETPLACE (2001); MARGIN OF ERROR: THE ETHICS OF MISTAKES IN THE PRACTICE OF MEDICINE (Susan B. Rubin & Laurie Zoloth, eds., 2000).

[11] STARR, *supra* note 8, at 367-78.

[12] 29 U.S.C. §§ 1003-1191 (2000).

[13] 42 U.S.C. § 1395dd (2000).

[14] 42 U.S.C. §§ 12101-12213 (2000).

[15] Pub. L. No. 104-191, 110 Stat. 1936 (1996) (codified as amended in scattered sections of 42 U.S.C.).

and prognostic information from their patients on the grounds that they wouldn't understand the information or were better off not knowing.[16] Physicians are more diverse today in terms of ethnicity and gender, and patients are usually more informed about and interested in their own health. Diagnosis and treatment are based on principles of informed consent, patient autonomy, and shared decision making after disclosure of all relevant information.[17] Growth in telemedicine and e-health, the expanding scope of practice by allied professionals, and complementary and alternative medicine will further complicate physician-patient relations.

Fifth, the Human Genome Project, which formally began in 1990, has committed three to five percent of its annual scientific research budget to the study of the ethical, legal, and social implications of genome research.[18] This Ethical, Legal, and Social Implications (ELSI) program has channeled millions of dollars into bioethics and health law research. Both the amount of money and the timing of the ELSI research (concurrent with the scientific research) are unprecedented.[19] The ELSI program has been subject to various criticisms, including that it is an attempt to buy off potential critics.[20] Nevertheless, ELSI grantees have generated a substantial number of excellent studies and publications, many with applications well beyond genomics, which have served to promote an awareness of key issues.[21] It remains to be seen whether other biomedical research undertakings

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[16] *See, e.g.*, DAVID J. ROTHMAN, STRANGERS AT THE BEDSIDE: A HISTORY OF HOW LAW AND BIOETHICS TRANSFORMED MEDICAL DECISION MAKING 1-2 (1991) ("Well into the post-World War II period, decisions at the bedside were the almost exclusive concern of the individual physician, even when they raised fundamental ethical and social issues.").

[17] *E.g.*, A HISTORY AND THEORY OF INFORMED CONSENT 274-82 (Ruth R. Faden et al eds., 1986) (explaining the role of the patient or research subject in authorizing treatment or experimentation rather than merely assenting or acquiescing). *But see* CARL E. SCHNEIDER, THE PRACTICE OF AUTONOMY: PATIENTS, DOCTORS, AND MEDICAL DECISIONS (1998) (discussing research that shows that many patients do not want autonomy, the reasons why, and what decisions they should be required to make).

[18] ROBERT M. COOK-DEEGAN, THE GENE WARS: SCIENCE, POLITICS AND THE HUMAN GENOME 255 (1994).

[19] *See id.* at 245-55 (1994) (describing the ELSI program as "an attempt to articulate the values that should govern the research, and to anticipate adverse social consequences of science in time to avert them." *Id.* at 248.).

[20] Eric T. Juengst, *Self-Critical Federal Science? The Ethics Experiment Within the U.S. Human Genome Project*, 13 SOC. PHIL. & POL'Y 63, 67 (1996) (evaluating various criticisms of the ELSI program).

[21] For a list of ELSI publications, refer to their website, http://www.genome.gov/10001798.

will similarly commit to studying the ethical, legal, and social implications of their research.

One thing is clear from this brief review: health law and bioethics are here to stay. In a culture dominated by law, health law establishes the standards for individual, professional, and institutional conduct and relations. In a pluralistic and diverse society, bioethics serves to frame the secular moral discourse on issues ranging from cloning to physician-assisted suicide. Yet, health law and bioethics must move beyond a boutique area of law practice and an abstract academic pursuit. Professional education and health policy development present important challenges for health law and bioethics.

A major limitation on incorporating health law and bioethics into the legal and health professions is that legal and medical educators have yet to determine whether or how to integrate health law and bioethics into professional and continuing education. Although the proliferation of health law courses at some law schools suggests a growing recognition of the importance of the subject; at even those law schools with an emphasis on health law, curricular coherence and integration are often lacking. At most law schools, health law is barely a part of the curriculum. Furthermore, very few law schools offer any instruction in public health law, now an important part of national security planning and infection control at all levels of government.

The ethics education situation is even worse at schools of medicine, dentistry, nursing, and public health. For example, medical ethics instruction typically has involved a series of lectures by nonclinician faculty members. Because the material is usually neither on medical school examinations nor national boards and the subject is not taught by "real doctors," medical ethics instruction usually has been received with little enthusiasm by medical students. There is an urgent need to modernize medical ethics instruction, to integrate it over the four years of medical school, to relate it more closely to the study and practice of medicine, and to include essential legal principles. In mid-2004, the United States Medical Licensing Examination (Step 2) will begin including a clinical skills examination.[22] If, in the future, a clinical ethics component were added to the national clinical skills examination it would quickly lead to a greater emphasis on ethics instruction in medical schools and an integration of ethics into clinical instruction.

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[22] United States Medical Licensing Examination, *Step 2 Clinical Skills Examination: Frequently Asked Questions*, *at* http://www.usmle.org/news/cse/step2csfaqs1103.htm (last updated Nov. 5, 2003).

Health law and bioethics also need to play a more important role in the political process. The occasional national commissions and task forces charged with bioethics analysis have been too haphazard, politicized, and ad hoc to develop any continuity or stature in influencing the political process. Bioethics must both inform and be informed by public attitudes; it must apply rigid analytical tools and methods;[23] and it must promote our unique national mores while recognizing the increasing importance of international perspectives. Those of us who work in the field of health law and bioethics need to become more involved in the political process. We need to move beyond sound bites and clever quotes in the media to help delineate the values, interests, and legal foundations on which the health policy of the future will be based.

[23] *See generally* METHODS IN MEDICAL ETHICS (Jeremy Sugarman & Daniel P. Sulmasy eds., 2001) (explaining that empirical evidence is necessary to avoid premature value judgments and moral inferences).