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THE ROLE OF LAW IN THE DEVELOPMENT OF AMERICAN BIOETHICS

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I. INTRODUCTION

There are many definitions of bioethics, including "the systematic study of the moral dimensions – including moral vision, decisions, conduct, and policies – of the life sciences and health care, employing a variety of ethical methodologies in an interdisciplinary setting." [1] There are also differing opinions of when bioethics was "born" or "developed" in the United States.[2] The earliest date for which an argument could be made is 1847, the year the American Medical Association (AMA) published the first edition of its *Code of Medical Ethics*.[3] Based on the work of English physician Thomas Percival,[4] the AMA Code was instrumental in transforming a loose, unstructured, and largely unregulated craft into a learned profession based on scientific principles and devoted to the service of patients and society.[5]

Another possible starting date for bioethics is exactly one century later, 1947, In that year, following the trial and conviction of 20 Nazi doctors and three medical administrators for their role in fiendish medical experiments on concentration camp prisoners, the Nuremberg Code was published.[6] The Nuremberg Code established the ethical requirements for biomedical research on human subjects. By today's standards, the Code is vague and not demanding. Yet, if marked a formal, international declaration of the limits of experimentation. The Code's widely cited first principle is that no research may be conducted without the informed consent of the subject. "The voluntary consent of the human subject is absolutely essential."[7] The Nuremberg Code provided the ethical justification and intellectual impetus for regulation of research in the United States and throughout much of the world.

Another possible beginning date for bioethics is 1970, when the term "bioethics" was first used in print. An article by University of Wisconsin oncologist Van Rensselaer Potter was titled "Bioethics, the Science of Survival."[8] Potter published the first bioethics book the following year, *Bioethics: Bridge to the Future*.[9] Andre Hellegers also is credited with using the term bioethics at this time in connection with the newly-established Kennedy Institute at Georgetown University, the nation's first bioethics institute.[10]

In my view, it is difficult and not especially illuminating to identify a precise starting date for the field of bioethics. It is more important to identify the historical context in which bioethics arose and the societal institutions and dynamics that quickly transformed an esoteric amalgam of theology, moral philosophy, medical ethics, and other fields into an interdisciplinary avenue of intellectual inquiry widely embraced by health professionals, policy makers, and the public. It is my contention that the emergence of bioethics in the United States was greatly influenced by the law's adoption of bioethics principles, arguments, methods, and analyses beginning in the 1970s.

II. THE 1970s: DECADE OF BIOETHICS

Regardless of its date of birth, the field of bioethics reached prominence in the 1970s. This was a tumultuous and transformational decade in modern American history. The United States military involvement in Vietnam, which escalated in the 1960s, became a cultural and generational divide by the early 1970s. Many of the "Baby Boomers," the 78.2 million individuals born between 1946 and 1964,[11] came of age in the 1970s. Besides protesting the war and the military draft, these teenagers, college students, and young adults rebelled against the social conventions of their parents' generation. To many young people, it was a time to effectuate the optimism, idealism, and individualism that had begun during the civil rights movement of the 1960s and was catalyzed by the anti-war movement.

Another important political event in the United States during the 1970s was the government corruption investigation known as "Watergate." Journalistic exposes, congressional investigations, high-profile convictions, and the resignation of President Richard M. Nixon raised familiar themes of abuse of power and political corruption. These events also spurred a national dialog of introspection and debate about ethics in government and ethics and morality more broadly.

In the context of bioethics, the 1970s witnessed the emergence of a new formula for societal change. New scientific and technological advances plus newly formulated values equaled the adoption of new social policies. For example, during the 1970s, technological advances in reproductive health included safe and effective methods of birth control, home pregnancy test kits, and the development of *in vitro* fertilization (Louise Brown, the first baby conceived through *in vitro* fertilization was born in 1978). The values included "women's liberation," gender equality, and repudiation of earlier social conventions constraining sexuality. The result was unprecedented reproductive freedom, including greater access to family planning, prohibition of pregnancy-based discrimination, and legalization of abortion.

The 1970s also witnessed the following events that directly affected the emergence of bioethics: (1) development of safer and more successful solid organ transplantation techniques, thereby raising the issue of how to allocate the supply of scarce organs; (2) establishment of hospital ethics committees to deal with organ transplant allocation, end-of-life issues, and other matters; (3) the deinstitutionalization of many individuals with mental illness, often as a result of litigation; (4) debates about the safety of new recombinant DNA technology, including the Asilomar Conference in 1975; and (5) the beginning of medical ethics classes at American medical schools.

Bioethics evolved from the need to bring the perceived chaos of biology and medicine into the order of moral principle.[13] Individuals from various disciplines entering the emerging field of bioethics in the 1970s had many issues to explore and many approaches and methodologies to use. As discussed in the next section, from the outset, legal perspectives played a prominent part.

III. LAW AND BIOETHICS

In 1831, Alexis de Tocqueville, a 25 year-old Frenchman, traveled the United States for nine months.[13] Four years later, based on his experience, he published his astute observations in *Democracy in America.*[14] Although he is known today mostly as an historian and political observer, Tocqueville was a lawyer who was serving as auditor-magistrate at the court of Versailles when he and substitute prosecutor Gustave de Beaumont were sent to the United States by the French government to study the American prison system.[15] In his visit and in his writing, Tocqueville focused on a broad range of political and social issues. Because of

his legal background, Tocqueville's insights into the role of law and lawyers in American life are especially noteworthy.

> In America there are neither nobles nor men of letters, and the people distrust the rich. Lawyers therefore form the superior political class and the most intellectual portion of society… There is almost no political question in the United States that is not resolved sooner or later into a judicial question.[16]

Today, law (including legislation, regulation, and litigation) is even more important than in Tocqueville's time. There are far more law schools (over 200),[17] lawyers (over 1.1 million),[18] and lawsuits (over 17 million civil actions per year)[19] in the United States than in any other country in the world. I will leave to others the task of exploring the reasons for this state of affairs as well as the economic and social consequences. I will note only that a great surge in law school enrollment occurred in the 1970s, a time when there was also a substantial increase in the number of female and, to a lesser extent, ethnic minority lawyers and law students. The 1970s was a Vietnam – and Watergate – inspired period in which many Baby Boomers intent on "changing the world" decided that the way to do it was through law.

The rise of bioethics in the 1970s paralleled this growth in the law. During the 1970s many issues of abstract, academic concern to bioethics scholars were quickly transformed into social policy through legislation, regulation, and litigation. There were numerous landmark cases decided in the 1970s that helped to shape the growing field of bioethics. For example, beginning with *Canterbury v. Spence*[20] in 1972, courts in every state embraced the principle that knowing, informed consent by the patient is a prerequisite to ethical medical care. Truth telling, informed consent, and patient autonomy became established legal doctrines before their widespread acceptance in medical ethics.[21] Another landmark case is the U.S. Supreme Court's 1973 decision in *Roe v. Wade*,[22] which held that a woman's constitutional right to privacy prevented excessive state restrictions on abortions. Finally, in *Tarasoff v. Regents of the University of California*.[23] the California Supreme Court held in 1976 that when a mental health professional learns during psychotherapy about a credible threat of violence or death to an identifiable victim, there is a duty to act, including warning the intended victim. This controversial decision led to a still-ongoing debate in law and bioethics about health care providers' duty to maintain confidentiality versus their obligations to third parties and the public.

The following section discusses in somewhat greater detail two other important issues arising in the 1970s that illustrate the symbiosis of bioethics and law. Bioethics helped to conceptualize problems, elucidate essential values, and influence the development of legal doctrines and processes.[24] In turn, legal mechanisms often were devised to produce consistent, institutional responses to the issues that bioethics alone could never achieve.

A. Research on Human Subjects

Reports of widespread and outrageous mistreatment of human subjects of research in the United States occasionally appeared in the professional literature during the 25 years following the adoption of the Nuremberg Code in 1947,[25] but a newspaper story in the *Washington Times* on July 25, 1972, described such prolonged and appalling conduct that it shocked the government and research community.[26] In 1932, the Public Health Service had begun a study of syphilis in Macon County, Alabama. The subjects were about 600 African American men, mostly poor and uneducated from Tuskegee, Alabama. About 400 of the men had diagnosed syphilis. They were induced to participate by promises of free hot lunches, free medical care, and free burials. The men were not informed that they were part of a research study or their diagnosis. They were merely told that they were being treated for "bad blood." The most shocking part of the story is that in 1947 penicillin became a widely

available and effective treatment for syphilis. Yet, the men were never informed of the availability of treatment and the government-run study continued for another 25 years. The outrageous events did not come to light until a government employee named Peter Buxton learned of the experiment and disclosed it to a journalist.

The story of die infamous Tuskegee Syphilis Study has been told in great detail many times and need not be repeated here. I want to focus on the aftermath. The month after the story broke, the Secretary of the Department of Health, Education and Welfare (HEW) appointed a panel of nine citizens, including renowned bioethicist Dr. Jay Katz, to investigate and issue a report. In 1973, after a series of hearings, Congress enacted the National Research Act.[27] which, among other things, established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The National Commission operated from 1974–1978, and it was succeeded by a series of other public ethics bodies including the National Bioethics Advisory Commission (1996–2001) and the President's Council on Bioethics (2001–2009). The precedent was established that difficult public policy issues, such as research ethics, human cloning, and stem cell research should be considered by experts in bioethics in a deliberative, open, and public process.[28]

The most notable work product of the National Commission was the "Belmont Report," which began to take shape at a retreat held February 13–16, 1976, at Belmont House, the Smithsonian Institution's Conference Center in Elkridge, Maryland.[29] The Belmont Report attempted to identify and analyze the ethical principles governing research with human subjects. The Belmont Report applied its three basic ethical principles of respect for persons, beneficence, and justice to describe the role of informed consent, assessment of risks and benefits, and selection of subjects.[30]

Although regulations governing research on human subjects were published by HEW in May 1974[31] pursuant to the National Research Act, the Belmont Report led to a redrafting of federal policies in the 1980s. In 1991, the Federal Policy for the Protection of Human Subjects was published.[32] The set of regulations issued by the Department of Health and Human Services (successor to HEW) also was adopted by 14 other federal agencies conducting or sponsoring research on human subjects. Consequently, it became known as the "Common Rule." A separate but similar set of regulations applies to research involving drug-development for approval by the Food and Drug Administration.[33] Special rules also have been promulgated to regulate research involving the following classes of vulnerable subjects: fetuses, pregnant women, and *in vitro* fertilization;[34] prisoners;[35] and children.[36]

The Common Rule establishes a variety of substantive and procedural protections for human subjects. One essential protection is that a precondition of lawful research is the favorable review of the protocol by a neutral board, known in the United States as an Institutional Review Board (IRB). Virtually every university and research institution conducting research on human subjects has its own IRB. The IRB must determine that the risks to subjects are minimized, the risks to subjects are reasonable in relation to anticipated benefits, selection of subjects is equitable, informed consent will be sought from each prospective subject, informed consent will be appropriately documented, data will be monitored to ensure the safety of the subjects, and there are provisions to protect the privacy of subjects and the confidentiality of data.[37]

A lively debate remains ongoing in the American bioethics literature about the viability of the principles enunciated in the Belmont Report, the wording and interpretations of the Common Rule, and the effects of IRBs on research.[38] Yet, the role of bioethics is not in dispute. Bioethics led to the development of the legal rules that have become an integral part of the research enterprise. The law institutionalized and made mandatory the analytical

framework for the ethical conduct of research developed by experts in the new field of bioethics.

B. End-of-life Decision Making

On April 15, 1975, 21 year-old Karen Ann Quinlan became unconscious upon returning home from a party and twice stopped breathing for 15 minutes or more. After paramedics took her to the hospital she lapsed into a coma and then a persistent vegetative state, in which she had motor reflexes but no significant cognitive function. Following several months in the hospital, it became clear that she would not improve and her parents asked that she be taken off the ventilator on which she was dependent. When the hospital refused, her parents brought a lawsuit to order the hospital to comply with their wishes. The New Jersey Supreme Court held that if a consultative medical body at the hospital, such as an ethics committee, agreed that there was no reasonable possibility that Karen could emerge from her persistent vegetative state, life support must be withdrawn in accordance with the request of her parents. Furthermore, the court held that the medical personnel removing her from the ventilator would not be subject to any civil or criminal liability.[39]

The *Quinlan* case established that physicians are not legally required to keep patients alive despite their objections or, in the case of incompetent patients, the objections of their legally authorized decision makers. It also endorsed the role of hospital ethics committees in addressing end-of-life concerns. The *Quinlan* case received great publicity; it represented a public tragedy in which the ethical, legal, and religious issues raised by providing life sustaining treatment for grievously and terminally ill patients were debated.[40] Although the *Quinlan* case involved the less common situation of a previously-healthy young woman, the more general issue of the role of “high tech” medicine at the end of life was increasingly being played out on a daily basis in hospitals and nursing homes across the country. To a great extent, the ethical issues were raised by new technologies, such as mechanical ventilators, which assisted some individuals to recover from serious illnesses, but also prolonged the lives of other individuals who had little quality of life and no realistic chance of improvement.

The *Quinlan* case was an impetus for the creation of ethics committees by numerous hospitals. It also spurred the enactment of laws in every state providing for advance directives for end-of-life care. The nature and provisions of these documents vary by state, but they include durable powers of attorney for health care, living wills, and medical directives. Despite enactment of this legislation, only about 10% of patients took advantage of the new laws and sometimes the expressed preferences of patients were ignored by hospitals and physicians concerned about medical ethics or legal liability. In typically American style, wider implementation of advance directives did not occur until after another high-profile legal case.

In 1990, the United States Supreme Court decided the case of Nancy Beth Cruzan, a woman who in 1983, at the age of 25, was grievously injured in an automobile accident resulting in her being in a persistent vegetative state. After several months and no improvement or prospects for improvement in her condition, her parents requested that the hospital terminate the artificial nutrition and hydration that was keeping her alive. When their request was denied, they brought suit. The Supreme Court held that a competent person has a constitutional “liberty” interest in refusing life sustaining nutrition and hydration, and these rights could be asserted by Nancy Oman’s parents.[41] The Court also held that the United States Constitution permits a state to require the provision of life-sustaining care unless there is clear and convincing evidence that the patient authorized the foregoing of such treatment before losing decision making capacity.[42] Consequent, evidence of the patient’s preferences regarding health care was extremely important.

The *Cruzan* case led Congress to enact the Patient Self-Determination Act of 1990.[43] This federal law conditions Medicare and Medicaid payment to health care providers on their doing the following: (1) providing patients with written information about advance directives; (2) documenting in the medical record whether the patient has an advance directive; (3) not conditioning care on whether an individual has an advance directive; (4) ensuring compliance with state law regarding advance directives; and (5) providing staff and consumer education on advance directives.[44]

Even with the advent of advance directives, decision making at the end of life is still complex and difficult for providers, patients, and their families.[45] Occasionally, it becomes the center of a major political imbroglio, as illustrated by the case of Terri Schiavo in 2005.[46] The starting point in this series of events was the *Quinlan* case in 1976. By 1990, the year of the *Cruzan* case, of people who died in hospitals in the United States, 70% died after a decision was made to forego at least some type of life-sustaining treatment.[47]

IV. CONCLUSION

Bioethics developed in the United States in the 1970s at a time when the legal profession and the role of law in bringing about social change in American society were expanding. At this time, advances in science, technology, and health care delivery raised a new array of contentious moral and social issues. Medical advances were no longer regarded as always entirely beneficial, but there was no consensus on the criteria to use in weighing harms and benefits. It was also not clear how to imbue the research and health care enterprises with the new societal emphasis on individual rights and responsibilities that grew from the civil rights movement of the 1960s.

Bioethics helped fill this void by adding moral principles and analyses to modern health dilemmas. During the 1970s, as bioethics emerged, the law relied on bioethics for guidance and supplied a decisional framework in return. Bioethics concepts, such as autonomy and respect for persons, were embraced by the law. Legal concepts, such as procedural due process and freedom of speech and inquiry, were embraced by bioethics. Over time, the relationship between bioethics and law has strengthened and each field continues to have important effects on the other.

The connection between bioethics and law in the United States, and no doubt in other countries as well, raises several challenges, not all of which have been adequately addressed. In contemplating the future of bioethics and law, at least the following three issues should be considered.

First, law usually does not change as quickly as science or even societal values. Because law frequently lags behind these other areas, individuals working in the law need to be careful that today's law is not addressing the scientific or bioethics problems of yesterday. Laws need to be reassessed continually and, if necessary, revised to reflect current conditions.

Second, the law's emphasis on procedural regularity is essential to criminal law and other areas of the law. When similar procedures are applied to science, technology, and health care, however, the result sometimes can be slow, formalistic, burdensome, and expensive processes that interfere with scientific research, clinical care, and other important interests. Accordingly, laws and procedures regulating biomedical research and health care should be designed carefully and with due consideration for their consequences.

Third, law and bioethics have similar – but not identical – aims. In matters such as privacy, conflicts of interest, and respect for persons, the law usually sets minimum standards of what *must* be done. By contrast, codes of ethics of health professionals and scholarship in

bioethics generally set loftier goals of what *ought* to be done. As legal requirements enter more areas of the health sciences and professions, it is important that minimum legal standards of conduct not replace more demanding ethical standards.

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