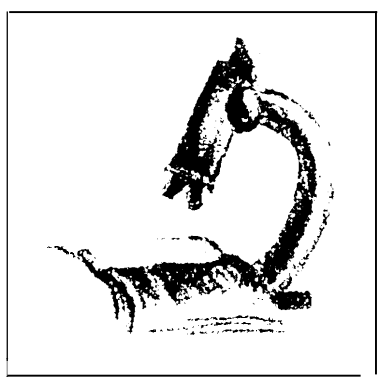
Introduction 1

Ethics and science need to shake hands.

Richard Clarke Cabot (1868-1939)
The Meaning *of* Right and *Wrong*

Though penned decades ago, today these words ring more true than ever. Increasingly, physicians, researchers, policymakers, and the public face numerous quandaries brought on by advances in biology and medicine advances the law is often ill-equipped to address. Years ago, a physician facing a frail newborn, such as 'Baby Doe,' had only to counsel the parents, perhaps call in a minister for additional family support, and offer the limited care then available until the child died. Now, such simplicity is nonexistent.

Scientific breakthroughs and novel medical technologies have led society to a point where pig and baboon livers have been transplanted into terminally ill persons (l-3), women with severe brain damage have been kept alive mechanically to continue their pregnancies (8), and research to help patients with Parkinson's disease has slowed due to a ban on federally funded protocols that use fetal tissue from induced abortions for transplantation (21). Even advances in medically assisted reproduction are simultaneously considered a blessing and immoral (20).



Often these dilemmas call for tragic choices, where two positive motivations are in conflict, such as a societal incentive to cut costs in the final weeks of life and the individual desire to keep a dying relative alive (19). Even when a legal imperative seemingly exists, more often than not decisionmaking blurs because of ethical and moral considerations. That is, while courts

have issued decisions involving surrogate motherhood (e.g., the ‘‘Baby M“ case), termination of life support (e.g., the cases of Karen AM Quinlan and, more recently, Nancy Cruzan), and assisted suicide (e.g., the situation with Dr. Jack Kevorkian), ethical questions still remain.

Once generally the province of philosophy and religion, discussions about these and other highly complex and contentious issues have entered the political arena. During the past two decades, such discussions have crystallized into a discipline referred to, alternatively, as ‘‘biomedical ethics” or ‘bioethics. ’ Today, how to set boundary rules for policy purposes amidst a web of ethical complexity has become extremely critical. As the 21st century approaches, Congress faces policy dilemmas for which informed decisions require understanding bioethical considerations, as well as legal or economic dimensions. Furthermore, situations that demand ethical analysis are likely to arise with greater frequency and urgency.

WHAT IS BIOETHICS?

The late 1960s and early 1970s marked the turning point in how Americans viewed medical innovation and biomedical research (16). Human subjects research in the United States reached its nadir with revelations of the Tuskegee syphilis study (box l-A) and other abuses, such as the injection of liver cancer cells into patients at the Jewish Chronic Disease Hospital in Brooklyn, New York, and the intentional infection with hepatitis of residents of the Willowbrook State School for the Retarded (4,7,16). At about the same time, the term bioethics was coined by V’ Rensselaer Potter, a cancer researcher in Madison, Wisconsin (15).

Originally, the word was envisioned as broadly encompassing an examination of the ethics of all biological science=. g., ecology and agriculture (14)-not just biomedical research, medicine, and health care. With time, however, bioethics has become synonymous with biomedical ethics. This report uses bioethics and biomedical ethics interchangeably, excluding areas of inquiry that others might include (e.g., environmental implications or the use of animals in experimentation).

Bioethics evolved from the need to bring the perceived chaos of biology and medicine into the order of moral principle (12). Today, although most Americans might lack knowledge of bioethics as a discipline, the issues within its domain touch thousands each day; millions more are acquainted with them. Through mass media popularization, for example, few Americans are likely to be unfamiliar with the dilemmas raised by euthanasia or surrogate motherhood.

Bioethics is a field of study and a practice that involves professionals of many backgrounds—including philosophers, theologians, attorneys, clinicians, and researchers-who have a range of opinions; no one individual or profession can represent the breadth of perspectives that exist. Tens of thousands of individuals serve on Institutional Review Boards to review research involving human subjects or on institutional ethics committees in health care settings to consider ethical problems that arise in patient care (9). About 20 universities now offer degrees in bioethics (17), though the curricula vary widely (18). The growing importance of bioethics in society reflects both social change and the increased impact and complexity that advances in biology and medicine have brought to American life-advances that raise delicate policy questions.

ORIGINS AND ORGANIZATION OF THE REPORT

The social and cultural revolutions of the 1960s gave rise to the belief that government ought to seek resolution of issues raised by biomedical research and medical technology in a secular manner, consistent with pluralism. Ethical analysis has evolved as a useful tool for the evaluation and governance of new technologies, and biomedical ethics has been long of interest to

Box I-A—The Tuskegee Syphilis Study

Just over 60 years ago, the U.S. Public Health Service (PHS) and several foundations began a study on approximately 600 African American males in Tuskegee, AL (5,6,11,13). At that time, the Tuskegee area had the highest incidence of syphilis in the Nation, and more than 400 of these men had this sexually transmitted disease, for which limited treatment was then available.

The men were lured into participating by the promise of free medical treatment, food, and burials. Initially, they were treated with mercury and arsenic compounds-then standard therapy-when the drugs were available. However, they also endured spinal taps without anesthesia and were denied penicillin long after it became apparent in 1945 that this antibiotic was the preferred drug. In fact, to prevent participants from receiving treatment by the US. Army, PHS also instructed draft boards not to induct them. Under congressional scrutiny, PHS officials offered the excuse that treating the subjects with penicillin would have arrested the disease and made following the long-term effects of syphilis impossible (11).

In 1972-four decades after it began-front page news reports brought this notorious abuse of human research subjects to an end (10). Elucidation of the Tuskegee syphilis study, along with other abuses in research involving human subjects (4,7,16), marked the start of bioethics' role in US. policy decisionmaking.

SOURCE: Office of Technology Assessment 1993.

Congress (7,16). Federal interest in integrating bioethics into policy decisionmaking stems from a desire to understand the ethics surrounding Federal support for certain types of research, delivery of services in Federal programs, or payment for services in programs such as Medicare and Medicaid. The appeal of an institutionalized role, however, has waxed and waned over the past two decades. At present, no national policy forum exists for generally analyzing ethical issues associated with biological research and new medical technologies, though bioethicists test@ before Congress and serve on Federal advisory committees.

In spring 1992, Congress signaled renewed interest in a formal role for bioethics in American governance during the Senate debate on reauthorization for the National Institutes of Health. Three factors stimulated this revived awareness and led to the congressional request for this background paper:

- concern about the many bioethical issues that have not been analyzed at the Federal level;
- the prospect that bioethical issues will arise with increased frequency and urgency in the future; and
- recognition that a national, institutional body to explore the role of biomedical ethics in U.S. public policy was nonexistent.

In September 1992, Senator Mark O. Hatfield, Ranking Minority, Committee on Appropriations; Senator Edward M. Kennedy, Chairman, Committee on Labor and Human Resources; and Senator Dennis DeConcini, Chairman, Subcommittee on Patents, Copyrights, and Trademarks, Committee on the Judiciary, asked the Office of Technology Assessment (OTA) to conduct a study that would assist Congress in determining possible approaches to examine policy problems with biomedical and ethical dimensions. That is, if Congress decides to create a new bioethics entity, what options should be considered?

Specifically, the congressional request sought a brief review of the history of broad-based Federal bioethics initiatives such as the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

Table l-l—Broad-Based Federal Policy Bodies in Biomedical Ethics[a]

Year	Initiative	Locus
1974-78[b]	National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research	Department of Health, Education, and Welfare
1978-80[c]	Ethics Advisory Board	Department of Health, Education, and Welfare[d]
1978-83[e]	President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research	Independent executive branch commission
1985-89[f]	Biomedical Ethics Advisory Committee	Congress

a Currently, as part of the Human Genome project, the National Institutes of Health and the U.S. Department of Energy each fund grants through an Ethical, Legal, and Social Issues (ELSI) program. A joint ELSI Working Group advises both programs, but it is not a policy body.
b Public Law 93-348 (§ 202, s8 Stat. 342, 1974) created the National Commission in July 1974.
C Although disbanded i„19@, current DHHS regulations provide for the existence of an EAB (45 CFR 48.2'04). in fact, efforts to reestablish and recharter an EAB stalled in 19SS (53 FR 35232).
d With reorganization of the Department in 1980, EAB became part of the Us. Department of Health and Human Services.
e Public Law 95-622 (42 U.S.C. Ch.6A) authorized creation of the President's Commission in November 1978 and set its termination fOr December 1982. Public Law 97-377 extended this date through March 1963. Due to delays in appointments and funding, the President's Commission was actually operational for just over 3 years.
fin reality, BEAC functioned for approximately 1 year. Public Law 99-158 established BEAC in May 1985. It was overseen by the Biomedical Ethics Board (BEB), which was comprised of Members of Congress. Almost a year elapsed before BEB was appointed and then nearly 2 1/2 more years before BEAC was constituted.

SOURCE: Office of Technology Assessment, 1993.

(National Commission), the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (President's Commission), and the Biomedical Ethics Advisory Committee (BEAC), and asked OTA to analyze three questions based on this background material. First, what lessons could be learned from each of these entities? Second, what worked, or did not work? And finally, why?

To place these questions in context, chapter 2 briefly reviews the history of biomedical ethics in policy decisionmaking. In keeping with congressional interest and prerogative, the report focuses on the successes and failures of the three Federal bodies just mentioned, as well as the Ethics Advisory Board (EAB) of the Department of Health and Human Services. It also presents information on State and international initiatives; appendix A describes international bioethics bodies in greater detail. Appendix B presents the statutes or legislation establishing the National Commission, President's Commission, and BEAC, as well as the regulations that pertain to EAB and the charters under which it has operated. Federal bioethics initiatives devoted to a single issue are not analyzed in detail. Also excluded are the large number of academic bioethics centers, privately funded centers, and ethics committees of professional societies.

Chapter 3 examines the potential outlook for biomedical ethics in policy decisionmaking. It discusses what type of Federal effort might be created, factors to consider in launching a new body, and the role of Congress in such deliberations. The chapter is based, in part, on an OTA workshop convened in December 1992, in which participants from past Federal, State, and international bioethics forums, as well as individuals who observed (or used products of) these forums, discussed lessons from the past in light of future demands. As Senator Hatfield noted in opening the l-day OTA workshop:

> . . . in public policy, if there is a vacuum, government eventually will fill it, right or wrong, good

> or bad. We just can't let difficult bioethical matters evolve at will, we ought to help direct them.

For, as then OTA Director John H. Gibbons pointed out, biology and medicine raise so many ethical issues of both a personal and public nature that:

> [in] a Nation that is extraordinarily more pluralistic, traditional authorities-for instance a single church or cultur-can no longer provide guidance that will be acceptable to all. Thus, these issues come to rest with our government.

This report is intended to provide Congress with background material on what form a new Federal bioethics body could take and what might make a commission function effectively, not whether a commission should be established. Thus, discussions of specific bioethical dilemmas or an analysis of what issues are pressing are beyond the scope of this background paper.

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