Lessons From the Past 2

In the absence of a single authoritarian church or other mechanisms to handle bioethical issues, American society often turns to government or the courts for resolution of thorny ethical issues. The reemerging interest in the role of bioethics in U.S. public policy signals the increasing importance of medical and biological technologies in daily life. The creation of Federal commissions stems from a desire for mechanisms to articulate common values and foster consensus in the face of growing cultural and religious heterogeneity. The need is not so much for finding moral solutions to complex policy matters, but rather, for identifying problems and either making recommendations or defining tradeoffs among alternatives.

FEDERAL INITIATIVES

Congress has exhibited an enduring interest in bioethics entities. Even before the term bioethics was coined in the early 1970s (73), the U.S. Senate deliberated in 1968 about a National Commission on Health Science and Society to examine "the social and moral" implications of biomedical advances **(90). Since** then, Congress has established three bodies to address ethical issues in medicine and research: the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (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). A fourth Federal initiative, the Ethics Advisory Board (EAB),[1] originated from a recommendation of the National Commission.

[1]Federal regulations (45 CFR 46) call for "Ethical Advisory Boards," and the original charter is for the "Ethical Advisory Board" (40). Soon after the board was constituted, however, it came to be referred to as the 'Ethics Advisory Board "-a change also reflected in the second charter (9).

Box 2-A—Ethical, Legal, and Social Issues Programs, National Institutes of Health and U.S. Department of Energy

Since fiscal year 1988, Congress and the executive branch have made a commitment to determine the location on the DNA of all genes in the human body (e.g., as has been done for sickle cell anemia, cystic fibrosis, and Tay-Sachs disease) (84). The Human Genome Project is estimated to be a 15-year, $3-billion project. It has been undertaken with the expectation that enhanced knowledge about genetic disorders, increased understanding of gene-environment interactions, and improved genetic diagnoses can advance therapies for the 4,000 or so currently recognized human genetic conditions (15).

To address the ethical, legal, and social issues of the Human Genome Project, and to define options to address them, the National Institutes of Health (NIH) and the U.S. Department of Energy (DOE) each funds an Ethical, Legal, and Social Issues (ELSI) program. Funds for each agency's ELSI effort derive from a set aside of 3 to 5 percent of appropriations for the year's genome initiative budget. In fiscal year 1991, DOE-ELSI spending was $1.44 million (3 percent) and in fiscal year 1992 it was $1 .77million (3percent);fiscal year 1993 spending is targeted at $1 .87million (22). NIH-ELSI spending for fiscal years 1990 and 1991 has been $1.56 million (2.6 percent) and $4.04 million (4.9 percent), respectively. For fiscal year 1992, NIH-ELSI spent $5.11 million (5 percent) and aims to spend $5.30 million in fiscal year 1993(5 percent) (37).

ELSI funds bioethics research related to the Human Genome Project to expand the knowledge base in this area. The program operates in the model of peer review competition for grant funds. The ELSI Working Group, which advises both programs, initially framed the agenda and establishes priority research areas. Nevertheless, the nature of grant programs means the ultimate direction evolves from the bottom up-i.e., from the individual perspectives of researchers pursuing independent investigations-rather than from the top down i.e., through policymakers or an overarching Federal body. Furthermore, no formal mechanism exists for ELS1-funded research findings to directly make their way back into the policy process (18,28,30,45,78). And although the ELSI programs have a large funding base for grants, they lack resources for in-house policy analysis. The ELSI Working Group, however, has played a role in policyanalyses related to genetics and the Americans With Disabilities Act, cystic fibrosis carrier screening (88), and genetic research involving several family members (36).

Finally, although issues in human genetics are broad ranging, they comprise only a portion of bioethical issues. Because ELSI is the largest Federal funding source for bioethics studies, there is concern that a brain drain is occurring from nongenetic areas of bioethics to the ethics of human genetics research and applications (2).

SOURCE: Office of Technology Assessment, 1993.

Beyond these four bodies,[2] which had a general focus, bioethics has been a part of American governance via topic-specific initiatives, including: the Ethical, Legal, and Social Issues (ELSI) programs, National Institutes of Health (NIH) and U.S. Department of Energy (box 2-A), the NIH Human Fetal Tissue Transplantation Research Panel (Fetal Tissue Panel) (box 2-B), the Presidential Commission on the Human Immunodeficiency Virus Epidemic (Executive Order 12601; 52 FR 24129), the National Commission on Acquired Immune Deficiency Syndrome (Public

[2] In January 1993, NIH formally established a Science Policy Studies Center to advise the NIH Director on the ethical, legal, economic, and social implications raised by research; plans for staffing, establishing policies, and setting priorities are under development (1,43).

Box 2-B—The National Institutes of Health Human Fetal Tissue Transplantation Research Panel

Fetal tissue has long been used in research, including research involving transplanting fetal thymus tissue into humans (26,86). In 1975, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research scrutinized ethical issues related to the use of fetuses in research (93) and developed the guidelines that were incorporated into Federal regulations for use of fetuses in research (45 CFR 46). Nevertheless, when scientists began using fetal tissue for neural grafting in the mid-1980s, questions were raised about the adequacy of these regulations for such research because they did not address specifically the therapeutic use of fetal tissue (86). The prospect that Federal funds would be used to support an intramural research protocol for implanting fetal neural tissue from induced abortions into persons with Parkinson's disease pushed matters to a head in 1987.

Lacking an Ethics Advisory Board within the Department of Health and Human Services to turn to, the Director of the National Institutes of Health (NIH) sought guidance from the Assistant Secretary for Health, In turn the Assistant Secretary directed NIH to appoint an ad hoc panel in March 1988, while simultaneously imposing a moratorium on Federal funding for the use of human fetal tissue from induced abortions for transplantation. The NIH Human Fetal Tissue Transplantation Research Panel, established as a subcommittee of the NIH Director's Advisory Committee, consisted of 21 members **representing public interest, clinical, research, ethics, religious and legal perspectives (105).**

The Panel's agenda was set by the Assistant Secretary through ten sets of ethical, social, legal, and technical questions. It met three times from September to December 1988 and, after considering material from invited speakers, public testimony, and commissioned papers (106), issued its report in December 1988 (105). The report concluded-on a 17 to 4 vote-that funding research involving the transplantation of human fetal tissue from induced abortions is acceptable public policy as long as carefully crafted safeguards are in place (105).

The recommendations were accepted unanimously by the NIH Director's Advisory Committee, which recommended the moratorium on fetal tissue transplantation research be lifted; the NIH Director concurred in a memorandum to the Assistant Secretary for Health in January 1989(110). Despite these actions, none of the Panel's recommendations was implemented at that time. The Secretary extended the moratorium indefinitely in November 1989 (75), **until it was lifted by President Clinton (58 FR 7468) when NIH was directed to develop guidelines based on the Panel's report in January 1993.**

The ad hoc approach employed by the Federal Government clearly and publicly articulated the policy and ethical dimensions of fetal tissue transplantation and led to a specific recommendation, albeit with dissent; the process worked, although the recommendations were ignored by the initial client. However, the events leading up to the moratorium, and those that followed, raise questions of their own and add another layer of ethical considerations to the **fetal tissue transplantation controversy: Is the Government's process for bioethical analysis adequate? And, what is the relationship between personal ethical convictions and the appropriate shape of public policy in a pluralistic society?**

SOURCE: Office of Technology Assessment, 1993.

Law 100-607; $241-249, 102 Stat. 4223, 1988), and the U.S. Department of Health and Human Services' (DHHS) Organ Transplantation Task Force (Public Law 98-507). OTA reports also have considered the bioethical dimensions of a range of issues (80-89). Additionally, bioethical considerations have been included as part of the deliberations about gene therapy by the NIH Recombinant DNA Advisory Committee (RAC), though the focus and function of RAC and the

AIDS commissions are less bioethics per se than either the ELSI programs or the Fetal Tissue Panel. The Ethics and Values in Science and Technology Program of the National Science Foundation once supported analyses of ethical issues related to specific issues arising from research, but avoided aspects related to clinical care because they were beyond the agency's mission. Although not involved in policy development, the National Endowment for the Humanities has also supported projects in bioethics-typically courses, book projects, or workshops.

This section briefly reviews the history of the four principal, broad-based Federal initiatives: the National Commission, EAB, President's Commission, and BEAC; it discusses their creation, procedures, and products. Chapter 3 analyzes these practices and processes in the context of defining common elements to elucidate alternative Federal forums to integrate biomedical ethics in U.S. public policy. For additional detail, appendix B contains the statutes or legislation establishing the National Commission, President's Commission, and BEAC, as well as the regulations and charters that pertain to the EAB.

■ National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

The National Research Act (Public Law 93-348 (§ 202, 88 Stat. 342, 1974) created the National Commission in July 1974, after earlier attempts at constituting a similar commission failed (23,74,90). In establishing the National Commission, Congress directed it to identify the principles of ethics needed to protect human subjects involved in research and to use those principles to recommend actions by the Federal Government.

Eleven members were appointed by the Secretary of the then Department of Health, Education, and Welfare (DHEW): five scientists, three lawyers, two ethicists, and one person in public affairs (11 1); appointments were for the full term of the commission years. Of the five scientists, three were physicians and two were psychologists (11 1). During its existence, commissioners met on nearly a monthly basis (111). Within the first year, 16 staff were hired, and in May 1975, the National Commission issued its first report, which addressed research involving fetuses (93). By July 1975, this report's recommendations had been translated into Federal regulations. The startling speed with which change was effected was brought about by a clause in the law that forced the Secretary to accept the National Commission's recommendations or make public the reasons for rejection. The clause, however, seemed to have an effect only as long as the National Commission was operative. After it disbanded, DHEW began to ignore the forcing clause for recommendations of later reports (38,39).

Ten reports and many appendixes followed the initial effort (94-102); some as successful, others not. For example, the National Commission's reports on ethical guidelines to protect certain classes of human subjects in research-fetuses, prisoners, and children (93,94,97)-led to Federal regulations (45 CFR 46), and today an NIH office oversees their enforcement (61). The National Commission identified the basic ethical principles to be applied in the ethical evaluation of human subjects research (98), which was also codified (45 CFR 46). More controversial and largely ignored (16,11 1) was the National Commission's work on psychosurgery (96). Its work on research and the ''institutionalized mentally infirm" (101) was never implemented; regulations were proposed after the National Commission's demise, but never finalized-in violation of the law (38,39).

The National Commission brought its work to a close in 1978, but spawned the next broad-based Federal entity, the EAB-again through the forcing clause. Rather than publish objections within 180 days as to why a continuing Federal body should not be established, DHEW incorpo-

rated the National Commission's recommendations into its regulatory framework (45 CFR 46.204) and established the EAB.

■ Ethics Advisory Board

As early as 1970, NIH discussed the need for a body to advise the Secretary and DHEW on controversial ethical, legal, and social issues posed by biomedical research protocols (23,24). Nevertheless, the EAB was not established until 1978, following a recommendation of the National Commission.

The Secretary appointed an n-member Board that included lawyers, a theologian, a philosopher, clinicians, researchers, and a member of the public. Initially, the Board had eight staff, as well as consultants and student assistants. During its approximately 2-year existence, it met approximately 20 times (42). In vitro fertilization (IVF) was the first topic addressed by EAB, and its 1979 report stipulated several criteria to be met for approval of federally funded research in this area. Among the report topics that followed were a report on fetoscopy and items related to Freedom of Information Act inquiries (41). In all, EAB produced four documents (91,92,103,104).

Although Federal regulations define EAB's scope to issues involving the fetus, pregnant women, and human IVF (45 CFR 46.201), the original charter under which the Board operated clearly defines EAB's scope much more broadly as a standing body to review ethical issues of biomedical research (40); the scope and level of activities were further widened with the subsequent charter (9). And in fact, the Secretary used EAB in a broad manner to report on ethical issues raised by research unrelated to the three specified activities (41,103,104).

In contrast to the other three Federal initiatives, EAB was intended as an ongoing, standing board with a mission to examine issues related to specific protocols or types of research as they arose-a logical notion given the quickening pace of biomedical research. Additionally, Federal regulation required an EAB review prior to funding research on human IVF (45 CFR46.204d). Nevertheless, despite the regulatory requirement for an EAB (45 CFR 46.204), DHHS disbanded it in 1980 at the direction of the Office of Science and Technology Policy (35), and thus violated its own regulations (77). The appearance of the President's Commission in 1978 contributed to EAB's demise because policymakers failed to distinguish their distinct purposes. Through its broad charter, EAB was positioned to examine research protocols that raised novel issues and to devise procedures and criteria for their review and implementation. In contrast, the Presidents Commission was a forum for national debate on global issues of bioethical concern.

In 1988, OTA's report on medical and social issues of infertility (84) forced the debate over DHHS 's failure to maintain an EAB to the surface (77,79). Federal funding for peer-reviewed, approved projects was clearly blocked without an EAB.[3] DHHS promised to reestablish the Board and published a proposed charter for a new EAB in 1988 (53 FR 35232). The new charter called for an expanded membership of 21 individuals—drawn from specific, but diverse fields of expertise-to serve for overlapping 4-year terms. Meetings were to take place approximately 10 times annually. The comment period generated nearly 200 signatories to various positions-with a clear majority in favor, although with caveats about the frequency of meetings, number of individuals, and other details. A revised charter was drafted, but never signed in the waning days of the Reagan Administation, and no EAB materialized during the Bush administration.

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3 NIH estimated this de facto ban on federally funded research related to human IVF was such that more than 100 grant applications in this area were not submitted between 1980 and 1987 because of a widespread awareness that while such grants might be approved, they would go unfunded because no EAB would exist to review them (27,84).

■ President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research

Congress created the President's Commission in 1978 (Public Law 95-622; 42 U.S.C. Ch.6A). As just mentioned, amid confusion that the President's Commission's mandate overlapped the EAB's, Congress convinced DHEW to divert its appropriations to support the new body (18). And though funding for the President's Commission eventually came from other sources (13), EAB remains dormant. Congress also elevated the new body to independent presidential status, in contrast to the National Commission, which had operated autonomously within DHEW. The scope was extended beyond human subjects research to include medical practice, and the commission was granted broad authority to expand beyond the seven mandated topics to report on emerging issues on its own initiation or at the request of the President or the head of an agency.

Appointment powers resided with the President. By summer 1979, the 11 commissioners had been appointed for rotating terms, and the first meeting was held in January 1980. By law, commissioners were drawn from specific areas: three who practiced medicine, three biomedical or behavioral researchers, and five from other fields. Over the President's Commission's duration, this latter category included individuals from law, sociology, economics, and philosophy, as well as a homemaker and a businessman. In all, 21 different commissioners served on the President's Commission. The body was well staffed: During the 3 years the President's Commission functioned, about 30 to 40 people worked for it, but generally only 20 at any given time.

Like the National Commission, the legislation creating the body also had a forcing clause. But unlike the National Commission, the reports of the President's Commission-as a matter of explicit policy-made few specific recommendations (108) to which agencies needed to respond. **Instead, the** President's Commission produced consensus reports that largely articulated mainstream views (108) on the mandated topics, as well as three additional reports not requested in the original legislation; a summary document of the Commission's work was also published, as well as several appendixes and proceedings (62-72). These documents were highly regarded and many have had sustained policy influence (109).

For example, its report on the definition of death became the foundation for statutory changes adopted throughout the Nation (12). Its report on foregoing life-sustaining treatment-undertaken on the Commission's own initiative-was probably the most influential (7,13,35) and remains an important point of reference for courts and legislatures. The Commission's report on recombinant DNA research (66) led the NIH RAC to establish a working group to consider both technical and ethical aspects of human gene therapy. On the other hand the report on health care access was less influential (4,6,20,21). Still others suffered inattention at the time of their release+. g., the report on genetic screening and genetic counseling and the report on whistleblowing in biomedical research (13)-but were remarkably prescient about issues that surfaced in the 1990s (8,88,112).

After one 3-month extension for its authority, the President's Commission expired in March 1983. Its recommendation that a similar body be created on its termination became the focus of almost immediate attention (18), thus setting the stage for the most recent congressional sortie into institutionalizing biomedical ethics.

■ Biomedical Ethics Advisory Committee

In May **1985,** Congress looked to itself to house the fourth, and most recent, Government-sponsored bioethics body: BEAC (Public Law 98-158). With the President's Commission's sunset in March 1983, Congress repeatedly expressed interest in reconstituting some type of

bioethics coremission (16-18,76). Overseeing BEAC was the Biomedical Ethics Board (BEB), modeled on the Technology Assessment Board that oversees OTA: 12 Members of Congress equally divided by chamber and political affiliation.

Nearly a year passed before the House and Senate leaderships appointed Board members, who in turn were charged with appointing a 14-member BEAC. Two lay members and representatives from law, ethics, biomedical research and clinical care were appointed-2 1/2 years later. Less than 1 week before it was scheduled to expire, BEAC held its first meeting in September 1988.

Two full-time staff worked for BEAC, which initially was to analyze three mandated topics: human genetic engineering (i.e., gene therapy), fetal research, and feeding and nutrition of dying patients (18). To address the first topic, it held its second meeting in February 1989. Shortly thereafter, however, Senate BEB members deadlocked on choosing a chairman along partisan, prochoice-antiabortion lines (18). BEAC's proposed budget—sufficient for 12 staff to address the mandated topics—was cut and spending made contingent on a fully constituted BEAC. BEAC expired in September 1989 having issued no reports.

STATE ENTITIES

Although bioethics forums were initially confined to federally funded efforts, more recently, State legislatures and executive branches have begun formal efforts to incorporate bioethics in their analytic and decisionmaking processes (34). Most State panels have been devoted to a single issue, particularly health care access (e.g., California (14), Minnesota (1 1), Oregon (25), Vermont (107)). The Minnesota House of Representatives created a bioethics subcommittee and held hearings during its 1991-92 session (10). At least three States—New Jersey, New York, and Colorado-created entities designed to consider a broad range of issues, though New Jersey's commission currently is unfunded and Colorado's effort has not yet been funded (13,44).

■ New Jersey Commission on Legal and Ethical Problems in t he Delivery of Health Care

New Jersey's efforts to address bioethical issues developed from a series of landmark decisions by the State Supreme Court, beginning in 1976 with the ''Karen Ann Quinlan case"—the first case to address refusal of life-sustaining treatment (32). In 1985, the court dealt with a proposal to withdraw a feeding tube from a debilitated and demented elderly nursing home patient (31). In both cases, the court stated that the opinions were not intended to set guidelines for life-sustainin g treatment decisions and that these issues are more suitably addressed by the legislative process, which can accommodate the different needs and interests represented in New Jersey's communities.

In November 1985, the State legislature created the New Jersey Commission on Legal and Ethical Problems in the Delivery of Health Care (New Jersey Bioethics Commission) as a permanent legislative commission (New Jersey Public Law 1985, Chapter 363). Though currently unfunded, it operated for 5 years with the mandate to "provide a comprehensive and scholarly examination of the impact of advancing technology on health care decisions [in order to] enable government, professionals in the fields of medicine, allied health care, law, and science, and the citizens of New Jersey and other States to better understand the issues presented, their responsibilities, and the options available to them.

The New Jersey Bioethics Commission was comprised of a diverse, multidisciplinary group of 27 appointed members. Commissioners were drawn from a broad spectrum of expertise and opinions, including medicine, nursing, health care administration, natural science, social science, law, the humanities, theology, ethics, and public affairs. By law, the Coremission included

representatives of the State legislative and executive branches, major professional and health care associations, and professional and public communities. Fourteen at-large members were appointed by the Governor, the Senate President, and the Speaker of the General Assembly. One Commissioner represented the Citizens' Committee on Biomedical Ethics-demonstrating the trend toward grassroots organizations in bioethics and health care decisionmaking (19,29,34).

The Commission's statutory mandate was broad, and it enjoyed substantial freedom to set its own agenda. Areas addressed included: determination of death, advance directives, and decisionmaking for incompetent patients without advanced directives (46-48,50,5 1). Following the decision in the ''Baby M case" (33), the Commission undertook a study of surrogate motherhood (49).

During its approximately 6-year existence, fiscal support varied widely. Staffing ranged from five full-time professionals and two part-time consultants to two full-time professionals and two consultants (3,60). Staff to the Commision had broad freedom to consult outside experts, select papers for presentation to the Commission, hold public hearings, and do empirical research on life-sustaining treatment, determination of death, and reproductive issues. At least one former staff member, however, believes the Commissioners and staff did not have adequate access to the Governor or ongoing cooperation from the Governor or the Legislature (5). Conflicts between staff and commissioners over substantive and nonsubstantive issues also hampered some deliberations (5).

The New Jersey Bioethics Commission conducted its deliberations publicly, believing that openness to public participation and scrutiny was necessary if the Commission was to be responsive and credible; it also held numerous public hearings. At times, the meetings were highly politicized. In particular, the four legislators on the Commission were often divided; three didn't approve of the Commission's existence and spent much of their time trying to disband the Commission rather than participate in discussions on a particular issue (5). On the other hand, including elected representatives and executive branch officials established an important liaison to those who ultimately effect change; it worked well sometimes, but was obstructionist on other occasions (3,60).

The Commission also created five ad hoc task forces for detailed studies of new reproductive practices, institutional ethics committees, public and professional education, AIDS, and protection of vulnerable patients. Each task force consisted of 12 to 20 members, including both Commissioners and others selected for their specialized expertise. Task Forces made recommendations to the Commission, which retained authority to accept, reject, or modify the proposals.

For each of the topics it studied, the New Jersey Bioethics Commission, sometimes jointly with a task force, published reports designed to explain "the intent and spirit of the recommendations" and to ''enhance understanding and promote discussion of bioethical issues by policymakers, members of the legal and health care communities and by all New Jersey citizens" (48). The Commission published six documents, ranging from comprehensive policy analyses to a guidebook for health professionals to consumer-targeted information documents (46-51), one of which also was published in Spanish (47). Commission work in several areas resulted in specific State laws, including: the New Jersey Declaration of Death Act (New Jersey Public Law 1991, Chapter 90) and the New Jersey Advance Directives for Health Care Act (New Jersey Public Law 1991, Chapter 201).

New York State Task Force on Life and the Law

In the early 1980s, New York State faced a mounting crisis over "Do Not Resuscitate" (DNR) orders, directives that advise physicians whether to resuscitate a patient. A grand jury investigation revealed widespread abuses associ-

ated with DNR orders in health care facilities, and the grand jury's findings and accompanying public outcry helped lead to the establishment in 1984 of the New York State Task Force on Life and the Law. The Task Force still functions today, receiving funds on an annual basis. Designed to provide counsel on a broad range of topics-e. g., surrogate parenting, determination of death, and physician assisted suicide-it makes policy recommendations to the State executive and legislative branches; its agenda is established in consultation with the Governor and New York State Department of Health (44).

The Governor appoints all Task Force members, who include doctors, nurses, and representatives of different religious communities and public interest groups. Members are chosen from both political parties and to reflect different perspectives within the State. The role of the Task Force is purely advisory; it is not involved with final policy determination. The group was set up as an independent entity, not as a division of an existing department. Nevertheless, by factoring in the views of representatives from various State communities, it has been able to identify points of consensus and recommend proposals that were acceptable to the legislature, State agencies, and the Governor (44).

In addressing a topic, the Task Force examines existing literature and takes into account the range of political and social concerns in the State to create generalized guidelines that fit the vagaries of New York State's legal and cultural climate (44). The Task Force has been well staffed and is further aided by consultants, who participate on a pro bono basis.

Because the Task Force is advisory, it has been exempt from open meeting laws that apply to other State bodies. To date, its meetings have not been open to the public. Nor has the Task Force held public hearings, although after recommendations have been made, hearings have been held as part of the legislative process. One former staff member believes that the ability to conduct closed meetings has contributed to the Task Force's success—i.e., that private deliberations insulate members from political pressures that can surround issues under consideration (44).

The Task Force has produced eight reports supporting its recommendations (52-59). Most included legislative or regulatory proposals, and all recommendations were drafted and enacted in some form. Topics addressed include: organ and tissue transplantation, determination of death, health care agents, surrogate parenting, and surrogate decisionmaking for incapacitated patients. Reflecting the difficulty of achieving consensus, abortion has not been a Task Force issue.

INTERNATIONAL EFFORTS

In the past few years, bioethics has become a global enterprise (table 2-l). Hospitals the world over have established ethics committees, and many academic and professional bioethics forms have been created in other countries. The governments of at least 27 nations on 6 continents have established national commissions of some type or currently have legislation pending. Thus, while U.S. Government-sponsored bioethics forums have disappeared, government initiatives are on the rise elsewhere. Multinational organizations have also begun to analyze bioethical issues through committees or coremissions. Appendix A chronicles these and individual country efforts; this section summarizes some common themes and highlights some differences.

Not surprisingly, the purposes of bodies in other countries vary widely. Some advise parliaments directly, others exist to stimulate and educate the public. Still others assume the role of distilling and articulating the country's sensibility on bioethics matters.

Each country integrates biomedical ethics into its policymaking structure in a different manner, and no single approach predominates. Unique cultural aspects are key and influence the development of bioethical approaches in a particular country; what might be viewed as acceptable in one country could be unethical in another. Until

Table 2-1—Typology of International Bioethics Commissions[a,b,c]

	National commission	Other government commission	Hospital	Professional	Academic	Private
Argentina	1[d]		Y		Y	Y
Australia	1	e	Y	Y	Y	Y
Austria[f]			Y		Y	
Belgium	[d]	e,g	Y	Y	Y	
Botswana						Y
Brazil	1		Y	Y	Y	
Canada	2	a,g	Y	Y	Y	
Chile			Y	Y	Y	Y
China	[d]	g			Y	Y
Columbia[h]		i		Y	Y	Y
Croatia		i	Y		Y	
Cyprus[f]	[d]			Y		
Czeoh Republic	1	e	Y			
Denmark	2	e	Y		Y	
Egypt					Y	
Finland	2				Y	
France	1		Y	Y	Y	Y
Germany[j]		g,l		Y	Y	
Ghana[k]				Y	Y	
Greece	1		Y	Y	Y	Y
Holy See[f]		l	Y			
Hungary	2		Y	Y	Y	
Iceland			Y	Y		
Ireland[f]			Y			
Israel	2			Y	Y	Y
Italy	2	e,g	Y	Y	Y	Y
Japan		g	Y		Y	Y
Kuwait"					Y	
Liechtenstein[l,n]						
Luxembourg	1					
Malta	1	g			Y	
Mexico	1		Y		Y	Y
The Netherlands	2		Y	Y	Y	Y
NewZeaiand	1[d]	g,o	Y	Y	Y	
Norway	3				Y	Y
Peru			Y	Y		
The Philippine@	1		Y		Y	
Poland	3		Y		Y	
Portugal	1		Y	Y	Y	
Romania			Y	Y	Y	
Russia	1				Y	Y

recently, most bioethics commissions in other countries have been temporary bodies devoted to one or a small number of topics selected in advance by the sponsor. In 1983, however, France created abroad-based bioethics commission, and since then several other European nations have followed suit.

In contrast to the United States, many of the national commissions abroad limit public access, and meetings are generally closed; in some cases, members of the public may offer their views through periodic public symposia. As in the United States, however, most governments strive to include membership of non-health care professionals; in some cases, physicians and scientists are a clear minority-such as on the 17-member Danish Council of Ethics, where laypersons represent the majority.

	National commission	Other government commission	Hospital	Professional	Academic	Private
Scotland%			Y			
South Africa		r		Y	Y	
Spain		g,l	Y	Y	Y	Y
Sweden	1	9	Y	Y	Y	Y
Switzerland		g	Y	Y	Y	Y
Turkey	I[d]		Y	Y	Y	
United Kingdom		9	Y	Y	Y	Y
United States		e,9	Y	Y	Y	Y
Uruguay			Y	Y	Y	

a Unless otherwise indicated, information is based an OTA survey of international government officials and bioethics experts. However, because survey responses varied widely, this table likely represents an incomplete picture of activities in the area of hospital, professional academic, and private entities. Hence, conclusions should not be drawn about absences for any particular entry.
b Numbers under the "National commission" column indicate how many federally sponsored entities currently exist to examine either bioethical issues, generally, or research-related issues, specifically. "Hospital" refers to hospital ethics committees or research ethics boards. "Professional" refers to subcommittees within or between professional groups, such as medical or nursing associations. "Academic" refers to departments or curricula in medical schools or other academic institutions. "Private" refers to private organizations devoted to the study of bioethics, excluding professional or academic groups. "Y" indicates these activities in a country.
c Though no all-encompassing international organization exists, several multinational organizations (e.g., the Council of Europe and the commission of the European Community) have issued policy statements and sponsored forums for discussing bioethical issues (app. A). In addition, regional bioethics commissions and/or regional private groups have begun to collectively organize (e.g., in Central/Eastern Europe, Scandinavia, and Latin America).
d Legislation is pending to create a new, or additional, national bioethics commission.
e Local or regional commissions have existed.
f S. Le Bris, "National Ethics Bodies," contract document for the Council of Europe, Ad Hoc Committee of Experts on Bioethics, Round Table of Ethics Committees, Madrid, Spain, Mar. 24, 1992.
9 Ad hoc, topic-specific commissions have existed.
h F. Sanchez-Torres, "Background and Current Status of Bioethics in Columbia," *Bioethics: issues and Perspectives*, S.S. Connor and H.L. Fuenzalida-Puelma (eds.) (Washington, DC: Pan American Health Organization, 1990).
i Laws addressing specific bioethical issues have been enacted.
j H.-M. Sass, "Blue-Ribbon Commissions and Political Ethics in the Federal Republic of Germany," *Journal of Medicine and Philosophy* 14:465-472, 1989; and D. Wilder and J. Barondess, "Bioethics and Anti-Bioethics in Light of Nazi Medicine: What Must We Remember," *Kennedy Institute of Ethics Journal* 3:39-55, *1993.*
k J, Hevi, "In Ghana, Conflict and Complementarily," *Hastings Center Report 19(4)*:S5-S7, 1989.
l Religious leaders have formed committees to discuss bioethical issues.
m M. Al-Mutawa, "Health Care Ethics in Kuwait," *Hastings Center Report* 19(4):S11-S12, 1989.
n No ethics bodies exist in this country.
o The government has commissioned reports from individuals.
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r The government has issued guidelines and reports in bioethics, but not through commissions.

SOURCE: Office of Technology Assessment, 1993.

WHAT WORKED?

Each past effort existed in unique circumstances that contributed to its success or failure. It's largely acknowledged that three of the four Federal efforts succeeded. However, the most recent endeavor, BEAC, failed, New Jersey and New York approached biomedical ethics with different approaches, but each State's effort worked for its own jurisdiction. Commissions abroad offer a rich array of options to evaluate, although until recently most have been topical. France, Denmark, and the United Kingdom, however, have well-developed, wide-ranging efforts, and all have their strengths.

What generally made bioethics bodies successful? Many factors—tangible and intangible—contributed to success. Timing and personalities were important, but were difficult to predict beforehand. A few themes, nevertheless, persisted across the success stories and were notably

absent in the failure. As elaborated in the next chapter, adequate staffing and funding improved the chances for success. Successful commissions were relatively free of political interference, had flexibility in addressing issues, were open in their process and dissemination of findings, and were comprised of a diverse group of individuals who were generally free of ideology and had wide ranging expertise.

Individually examining past Federal bioethics commissions reinforces this assessment. The National Commission was formed in response to a critical need to resolve several biomedical research issues that had accumulated over time. Its appearance was well-timed, and it was well staffed. Its placement within the agency it would guide-the U.S. Department of Health, Education, and Welfare-and requiring this agency to respond to its recommendations were critical to the National Commission's subsequent contribution in ensuring ethical conduct in federally funded research involving humans. The EAB's structure allowed for a flexible agenda to respond to the biomedical research community's pressing needs for guidance, and as a standing unit it also could respond quickly. The President's Commission was able to distance itself from political influence, was adequately funded and well staffed, and received abroad mandate. In contrast, BEAC and its congressional board suffered from insufficient staffing, political conflict, and excessive debate over its agenda.

Lessons from State efforts can also be drawn, though New York provides a less useful model because it holds closed deliberations-a process that would be illegal for any new Federal effort presumably subject to the sunshine provisions of the Federal Advisory Committee Act that require open meetings (5 U.S.C. Ap. 2, §1 et seq.). Still, both bodies in New Jersey and New York were well staffed, had leeway to consult experts outside the commission, and had flexible agendas.[4] In contrast, international commissions are poorly staffed compared to U.S. efforts and most, like New York, hold closed meetings. Public funding for outreach in Denmark, the wide media and government attention paid to France's effort, and the unusual cooperation of the U.K. Government with its private council are striking and undoubtedly contribute to their success.

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