

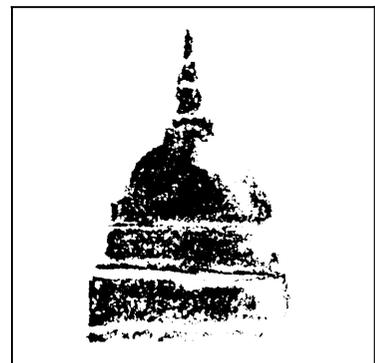
Prospects for the Future

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Over the past two decades, the creation of Federal bioethics commissions resulted from a desire for mechanisms to articulate common values and foster consensus about biomedical advances in the face of cultural and religious heterogeneity. With the accelerated pace of technological innovation, it will become increasingly important for policymakers to understand the bioethical issues of such advances. How best to incorporate bioethical analyses into policy decisionmaking is a challenge facing Congress today (8,26-29,40,42). If Congress decides to create a new Federal bioethics body, what type of effort should it consider based on past experience? Which particular factors promote success, and which should be avoided?

WHAT ROLE COULD A COMMISSION PLAY?

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (National Commission), the Ethics Advisory Board (EAB), 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) were all Federal responses to address ethical disputes in medical practice and the conduct of biomedical research. With the conclusion or demise of each of these efforts came calls for anew Federal entity (1,12,15,18,20,34,48). Today, however, no public body exists for the exclusive deliberation of complex bioethical dilemmas. For nearly 4 years—the longest period of time since bioethics burgeoned as a discipline—the Federal Government has been without a formal forum that addresses bioethical issues. In fact, a fully operational body has not existed in over a decade.



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The current void has not gone unnoticed by either the professional communities or policymakers. Today, both parties increasingly decry the lapse (26,28,83), just as Members of Congress (70) and experts (1) sought a new venue for bioethics after the President's Commission concluded its work. A sense of urgency permeates current appeals for two reasons: the accelerated pace of biomedical innovation and the length of time that has elapsed since the last government initiative.

Even without a formal Federal effort, however, bioethical analyses have been incorporated into selected public policy analyses. Several OTA reports include bioethical analyses (73-82), and at the request of Congress or the executive branch, the Institute of Medicine (IOM)¹ has addressed ethical issues in relevant reports (25,31,33,35, 50,58,71). As described in chapter 2, the Ethical, Legal, and Social Issues programs of the National Institutes of Health (NIH) and U.S. Department of Energy currently fund bioethics research related to the Human Genome Project.

Today, policy decisionmakers find themselves besieged with bioethical issues seeking resolution (8,26-29,40,42). The intellectual fecundity of these issues is apparent by the presence of a growing corps of bioethicists (65) and bioethics organizations. The American Association of Bioethics was launched in March 1993 (5,14), and the International Association of Bioethics held its inaugural congress in 1992. A few State efforts have succeeded in exploring bioethical issues (ch. 2). In addition, many academic or private efforts exist. Several medical or research organizations have formed ethics groups, including the American Medical Association, American College of Obstetricians and Gynecologists, American Fertility Society, American Society of Human Genetics, American Public Health Association, and

American Academy of Pediatrics. And while nongovernmental groups (e.g., the National Advisory Board on Ethics in Reproduction) lack the public sanction and authority that inhere with government-appointed bodies (88), nongovernmental associations play an important role in shaping the bioethics debate and have been particularly effective in framing the dialogue in countries without national bodies (43,64,67,88,90). Still, no Federal initiative with sufficient authority or visibility exists to systematically analyze the ethical implications of important issues such as genetic privacy, embryo and fetal research, and research involving people with mental illness.

Despite the lack of a Federal forum for bioethics, the development of different approaches involving many voices at many levels is viewed as beneficial by some, but insufficient by others. A widespread, pluralistic approach has advantages over a single national commission by fostering diversity; no issue becomes captive to any central authority. Another advantage is that individuals who will be the actual implementors or enforcers of the guidelines have more opportunities to participate in the process. Regional or local approaches also allow a community's values to be integrated into local political processes.

Nevertheless, the diversity in bioethics organizations-while bringing the debate to the State, local, or institutional level-cannot always succeed in addressing areas that require expansive access to information and expertise. As much as a practitioner or local organization would like to keep abreast of developments in bioethical analyses, expedient decisions often must be made. The availability of guidance that is consistent with a broader, national approach can be invaluable and sometimes even preferred (91)-i.e., ad hoc decisions might be appropriate

¹IOM is part of the National Academy of Sciences, a private, nonprofit organization established by Federal charter to advise the Government on scientific matters. The majority of its studies are undertaken at the request of the executive branch. In 1992, it began, on its own initiative, a broad study of methods of bioethical problem solving by society, including government community bodies, professional societies, and religious groups. The study is not confined to formal commissions and agencies, and publication is expected in early 1994.

sometimes, but guidance in the form of generally agreed upon principles helps maintain a level of consistency and comparability across the health and legal professions (60). A Federal body can identify areas of national consensus or division.

Thus, while OTA uncovered a range of opinions on the optimal framework to incorporate bioethics into U.S. public policy decision-making, OTA found strong sentiment on the need for a Federal initiative, or initiatives, that would involve diversely trained individuals to monitor, analyze, and report on the interface between ethics and medicine, health care, and biomedical and behavioral research. Such organizations could be charged with the responsibility of informing legislators, regulators, judges, health care providers, scientists, and the lay public about the ethical implications raised by new situations in medicine and biomedical research.

There are pitfalls attendant to centralization, however, including a tendency to lose flexibility in interpretation, diffusion arising from forced consensus (6,41,89), and the potential for capture by political interests. Yet, centralization brings authority to a process that is rarely achieved with decentralization. A Federal effort generally can exceed private or State resources. It also carries cachet, as well as a nationwide power to gather data, convene meetings, generate relevant analyses, and invite testimony. The process by which this background paper was produced demonstrates this value: Though allocated a limited budget and a short timeframe, the cooperation of workshop participants, survey respondents, interviewees, and reviewers moved forward because it was a congressional effort. For better or worse, professionals, Members of Congress, or State legislators assign different weight to groups that they have created than to other groups in operation. Nevertheless, private, professional, local, and national approaches are not mutually exclusive; all are desirable.

Government-sanctioned commissions allow debates about contentious issues to go forward in a somewhat less politicized way than is possible on

the floors of Congress or a State legislature. National commissions provide a vehicle to handle issues that are amenable to consensus building, or at least to an elaboration of conflicting views. Ideally, they garner the esteem of policymakers and experts by serving as a forum to:

- **crystallize** a consensus or delineate points of disagreement;
- identify emerging issues;
- defuse controversy or delay decisionmaking;
- propose regulations, develop guidelines, or formulate policy options;
- review implementation of existing law and policies;
- aid judicial decisionmaking;
- educate professionals and the public; and
- promote interdisciplinary research (15,18,53,91).

Still, commissions tend not to be groundbreaking intellectually (13), although they can summarize current thinking into a form meaningful for policymakers (13,15). Further, commissions can clarify issues and offer useful critiques of public policy, but they lack the moral and political authority to decide what ought to be done (57).

Nevertheless, the process of convening a commission for the Federal Government can be an opportunity to create the environment in which political action becomes possible by gathering policy relevant information and injecting it directly into the policy matrix. In doing so, commissions can often consider controversial issues independent of the regular political process and its constraints (72). Commissions cannot quiet all bioethical concerns, but can provide a broadly accepted basis for understanding the issues and propose particular policies to cover most situations (15).

The history of regulations governing the participation of humans in research provides an example of the validating powers of national commissions. In 1973, the then Department of Health, Education, and Welfare (DHEW) proposed rules on research involving human fetuses. The rules,

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which were published in revised form in 1974, generated a storm of controversy and resulted in heated debate in Congress. The bureaucrats who had prepared the rules had done a reasonable job of examining the literature and putting together thoughtful, well-articulated proposals, and they were surprised by the ensuing debate (52). Eventually, Congress created the National Commission and assigned it the task of addressing fetal research, which it did in about the required 4 months (85). What the Commission recommended was similar to that originally proposed, but this time the substance was received with praise and approval from all sides (52). In politically sensitive areas of debate, sometimes the messenger is more important than the message.

WHAT TYPES OF FORUMS SHOULD BE CONSIDERED?

Before considering the specific elements of any future effort, decisions about proposed structure and function must be addressed. Past Federal bioethics initiatives provide a guide should Congress decide to launch a new effort or efforts. OTA identified three basic types of organizational models that should be considered:

- . continuous/standing,
- . term limited, and
- . ad hoc.

Do certain topics or areas of inquiry lend themselves to a particular structure? If so, then the scope and issues Congress believes a commission must address could drive the type of policy body that would be most appropriate to establish. Linking the class of issue to the commission structure might help ensure optimal consideration in a timely, effective, and economic manner. Less than this could endanger patients or research subjects, delay decisionmaking and lead to gaps in policy implementation, or interfere with vital research.

OTA identified two general classes of issues for which bioethical analyses have been applied: specific classes of, or protocols in, bio-

medical or behavioral research involving human subjects (table 3-1) versus broad-based issues related to medical practices, health care, or the social implications of research (table 3-2). The following sections analyze these two categories within the three general models: an ongoing body, a term-limited commission, and an ad hoc effort.

■ Standing Bodies

As part of its work, the National Commission concluded that ethical deliberations involving the review of protocol-r classes of protocols—arising from controversial biomedical and behavioral research (table 3-1) warranted a standing body. Despite its demise, EAB was chartered for this purpose and was the only Federal initiative intended as a continuing body. OTA concurs with the National Commission's recommendation that a standing body is appropriate to consider the ethical implications of certain protocols or classes of federally funded biomedical and behavioral research. Research-related issues—e.g., AIDS vaccine protocols or clinical trials using human growth hormone in children without identifiable disease (2,69)—are ongoing, and any single proposal that raises novel ethical questions can appear suddenly.

An ongoing entity in the model of EAB would be beneficial. Without an EAB-like body to provide guidance, the Federal Government has turned to separate ad hoc panels to perform precisely the functions of an EAB—including the Fetal Tissue Panel and the committee to examine human growth hormone trials in children more recently, as well as groups to evaluate other protocols in children or prisoners in the past. In fact, recognizing new questions can arise with any proposal, NIH recently established standing bodies called protocol implementation review committees to identify potentially sensitive intramural research (68,69); the new panels do not, however, examine extramural research.

Table 3-1—Biomedical Research Topics That May Raise Unresolved Ethical Issues

Clinical trials for anti-addictive medications

Clinical trials in children of synthetic human growth hormone for cosmetic versus therapeutic uses

Clinical trials in women and minorities

Compassionate uses of gene therapy outside controlled clinical trials

Conduct of AIDS vaccine trials

Drug trials and clinical studies of individuals with dementia

Drug trials and clinical studies of individuals with mental illness, e.g., schizophrenia

Embryo research

Fetal research

Genome research on aboriginal human populations

Involvement of women of childbearing age in drug trials

Large family pedigree genetics research

Research involving RU 486

Rules governing research where patients pay for clinical research through service fees

Update of what institutes “minimal risk,” “innovative therapy,” “experimental treatment,” and other terms of art embedded in current regulations

SOURCE: Office of Technology Assessment, 1993.

Nevertheless, the current climate to eliminate nonmandated Federal advisory groups poses a significant barrier to reconstituting an EAB-like body; the Clinton Administration has mandated the termination of not less than one-third of bodies not required by statute (Executive Order 12838; 58 FR 8207). In the face of significantly shrinking numbers of Federal advisory committees, the prospect of DHHS reviving a former body seems unlikely. Thus, Congress could require DHHS to establish an ongoing panel to evaluate ethical issues raised by federally funded biomedical and behavioral research. A congressional mandate for an EAB per se is not necessary, but a directive to establish one and clarify its scope ultimately might be needed. Without legislation, the future of a standing body likely will be held in abeyance—despite the fact that a backlog of research-related issues exists (table 3-1) and that the ever-accelerating pace of biomedical research is sure to generate more. Ironically, though the United

States no longer has an ongoing body of this nature, it is the most common type of effort in other countries.

Term-Limited Commissions

The National Commission, the President’s Commission, and BEAC were all bodies whose terms were limited by Congress through sunset provisions. As mentioned, the National Commission examined issues primarily related to human subjects research. The President’s Commission’s focus was largely policy analysis of broad-based topics related to clinical practice, though it also examined research-related issues. BEAC issued no reports.

Thus, on the surface, commissions that have a freed term appear appropriate for either class of issue. Nonetheless, as just discussed, issues raised by controversial research appear best suited to a standing body. Term-limited entities could attend to the types of issues that were the focus of most reports produced by the President’s Commission—broad-based topics arising from Federal activities or interest in medicine, health care, or research (table 3-2). Again, however, establishing such an entity probably would require congressional legislation because of the move to fewer Federal advisory bodies (Executive Order 12838; 58 FR 8207).

Since the United States established the President’s Commission, similar bodies have been created abroad—most notably in Denmark,

Table 3-2—Possible Bioethical Issues for a Broad-Based Effort

Animal patents

Dilemmas arising in emergency care situations

Euthanasia

Genetic privacy

Health care providers’ equity interests and self-referral

Organ transplantation issues, including availability and xenografts

Patenting human tissues, cells, or DNA

Research collaboration and conflicts of interest

SOURCE: Office of Technology Assessment, 1993.

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France, and the United Kingdom (app. A)-but all appear to be permanent bodies. Despite this, OTA found little sentiment for establishing a permanent, broad-based bioethics initiative modeled after international efforts or those in New York and New Jersey. Of concern is allowing a commission to become a self-perpetuating body in search of a mission.

■ Ad Hoc Initiatives

By its nature, an ad hoc initiative is confined to a single topic, and one may be convened at any time (box 3-A). In these respects, integrating bioethics into public policy decisionmaking in an ad hoc manner offers the advantage of flexibility. Another advantage is that members can be

selected for expertise on the specific topic at hand. Similarly, convening several groups means more people have an opportunity to closely influence the process. And of course if no ad hoc efforts are convened, no money will be spent.

However, OTA found consensus that ad hoc initiatives are the least desirable mechanism to address bioethical dilemmas. Each individual initiative requires a certain critical energy, financial support, and personnel level before it becomes functional. Repeatedly starting committees or panels to review controversial protocols or practices when commonalities among topics exist-and could be analyzed by a single body—not only results in a less than optimal use of time,

Box 3-A—Bioethics and the National Institutes of Health Revitalization Act of 1993

Congress has pursued legislation to prevent the secretary of the Department of Health and Human Services from making unilateral decisions that deny, based on ethical considerations, funding for peer-reviewed, approved projects. Two events prompted this legislation: the secretary's moratorium on fetal tissue transplantation research and the decision to withhold funding of the adolescent sexual behavior survey (59). The National Institutes of Health Revitalization Act of 1993 (S. 1 and H.R. 4) contains language intended to prohibit the Secretary from withholding funds for research on "ethical grounds" unless he or she convenes an ethics advisory board, or "ethics board." No definition of ethical grounds is offered; what constitutes ethical grounds appears to be left to the Secretary.

Despite the confusing terminology created by using "Ethics Advisory Boards" [sic] out of historical context, the entities created by this Act would be wholly dissimilar to the original EAB. These bodies would be implemented only if the Secretary refused to fund a successfully peer-reviewed proposal. Thus, they are ad hoc in nature, and can be viewed as a subset of review panels because they are instituted only in the rare instances in which funding is withheld or withdrawn on ethical grounds. A wide range of research proposals that are funded-but might benefit from an EAB review-go unevaluated.

In the event a Secretary withholds funds, he or she must appoint an ethics board after considering nominations for 30 days; 180 days later, the body must submit a report to the Secretary and Congress. The legislation directs that an ethics board shall be composed of 14 to 20 individuals and shall include at least one attorney, one practicing physician, one ethicist, and one theologian. No fewer than one-third and no more than one-half shall be biomedical or behavioral scientists. The board would be staffed by the National Institutes of Health and would expire 30 days after it submits its report.

Should the majority of the ethics board recommend that the Secretary not withhold the monies for the research on ethical grounds, the research shall be funded unless the Secretary finds that the board's recommendations were "arbitrary and capricious."

SOURCE: Office of Technology Assessment, 1993, based on "S. 1," *Congressional Record* 139:S1906-S1 03, 1993; and "HR.4," *Congressional Record* 139:H1184-H1185, 1893.

money, and people, but does the public, policy-makers, and other interested parties a disservice.

Additionally, the initial learning and acculturation process of any group requires time and effort (23,52,92) and must be repeated each time an ad hoc panel is convened. Later reports of the President's Commission, for example, were considered better by its executive director because of this phenomenon (17). The work of the National Commission also improved substantially over time; its report on prisoners was much more polished and sophisticated than its preceding report on fetuses (48,49).

Continuity also can contribute to a body's credibility (53). Because ad hoc efforts cease to exist after a topic is addressed, any credibility gained with the passage of time or completion of projects is immediately lost. That is, a standing or fixed-term body, by doing a good job on one topic, garners the respect of a variety of constituencies and can transfer that credibility to its handling of new topics (52).

WHAT ELEMENTS ARE IMPORTANT?

The experiences of the National Commission, EAB, President's Commission, and BEAC illuminate a variety of key considerations for any future effort to create a national bioethics board or commission. In devising a strategy for addressing bioethical issues in a national policy context, OTA found six factors predominate regardless of the type of body established:

- budget, including staffing;
- the charge (i.e., mandate and flexibility to control the agenda);
- appointment process;
- bureaucratic location;
- target audience(s); and
- reporting and response requirements.

Absent from this list is politics; the very nature of creating a new entity subjects each of these factors to the pressures and whims inherent in the political process. An inadequate or ill-suited

approach in any single area can undermine the successful implementation of a new national commission or board, and a deficiency in a single aspect—e.g., funding or the appointment process—can doom an effort to total failure.

■ Funding

Although each factor is important, funding is foremost. A successful initiative begins with adequate funding (box 3-B). Sufficient funds to hire an adequate number of qualified, professional staff are essential; otherwise the entity is staffed piecemeal or by castoffs. Also necessary are monies for contract papers and public hearings or meetings beyond the Washington, DC locus. Commissions are most successful when they can weigh both empirical information and conceptual analyses to derive useful policy options. Thus, they must have the capability to gather data. Public meetings and hearings—providing an educational function for both commissioners and the public—are imperative. Finally, providing funds for publication and dissemination of a commission's work is essential.

The National Commission and the President's Commission had reasonable funds for staffing and activities—as initially did BEAC. Likewise, the commissions and their staffs had broad contracting authority and funds to bring in additional expertise, as well as to hear witnesses. Both capabilities served the staff well by expanding their knowledge base; staffing can also provide balance. For example, staff can weigh and analyze the persuasiveness of particular points of view without regard for the sophistication or eloquence of the defender of that position. Without staff to mediate between the more and less sophisticated presentations, a commission's policy documents run the risk of becoming skewed (4,8,14,17).

The National Commission did not have a specific appropriation, but during its 4-year lifespan received about \$5 million from DHEW (93). Nevertheless, the need for specific appropri-

Box 3-B—What Might a New Effort Cost?

Estimating a potential budget for a new bioethics entity depends on many factors, including the number of members, staff, meetings, and reports. Start-up capital costs also will vary based on size and whether a new body is housed within an existing Federal agency or office, or created as an independent body. Despite these caveats, funding projections are possible. Budgets can be constructed by examining current Federal commissions and agencies performing policy analysis. Examining the expenditures of previous bioethics bodies is less useful because of the significant changes in basic business costs since their existence—e.g., rent, computer hardware and software, telecommunication technologies, travel for commission members, and salaries.

Although a comprehensive survey of budgets for commissions, taskforces, or committees was not possible, funding levels for a new standing body (like the Ethics Advisory Board (EAB)) and a new term-limited commission (like the President's Commission) are presented based on OTA's experience with producing policy reports and a brief inspection of a few other efforts. For each, certain assumptions are described. Clearly, changes in any assumption would affect the funding required.

Standing Body: \$744,000 annually. This budget assumes such a body will be located within an existing agency. It assumes 20 members will be appointed; by comparison, the charter proposed in 1988 for a reconstituted EAB envisioned 21 members (53 FR35232). The cost also assumes five staff (i.e., five full time equivalents (FTEs) represented by four analytic and one support staff). Compared to the initial EAB's eight staff, this represents about a 40 percent reduction in FTEs. The cost also assumes contracting authority at 30 percent of staff costs. As with the proposed charter, it assumes ten 1-day meetings will be held—at least three outside of Washington, DC—and, thus, includes funds for travel and per diem, as necessary. The annual budget assumes three small documents (on the order of position papers, not full report and one full report per year, and includes printing and distribution costs. Overhead costs of computer literature searches, books, and journal subscriptions are included. However, because this body is assumed to be housed within an existing Federal agency or office, the budget does not include costs such as rent or utilities. Nor are costs associated with personnel who manage procurement, reimbursement, computer support or other general services included.

Term-limited Body: \$1,920,000 per year for 4 years. This estimate assumes a new term-limited body will operate as an independent commission. The budget assumes 15 members will be appointed—4 more than the President's Commission. It also assumes 12 FTEs (9 professional and 3 support positions) will staff the new effort—approximately 40 percent below that of the President's Commission. The cost includes six 2-day meetings in Washington, DC, and four 1-day field hearings outside Washington, DC, annually. Also included are initial outlays for equipment and annual costs for rent, utilities, and other items (e.g., supplies, books, journals) and services (e.g., mail, photocopying, and computer support). The budget also assumes six reports will be produced over the 4-year term, and includes contracting authority—for papers and editing—equivalent to 40 percent of staff costs, as well as printing and distribution costs. In the first year, funds will be needed for certain capital costs (e.g., computers, phones, facsimile machines, and photocopiers) that will not be needed in subsequent years. However, contracting, meeting, and publication costs will be incurred chiefly in later years as the commission begins its formal work. OTA's calculations revealed the average annual cost would be about the same between the first and later years, despite the shift in spending priorities.

SOURCE: Office of Technology Assessment, 1993.

ations can be critical; EAB's experience demonstrates this point. EAB was born from the National Commission, which had anticipated that EAB would be a continuing body. However, in the course of congressional deliberations after the National Commission's conclusion, the President's Commission was established with funds initially diverted from the EAB because policymakers failed to distinguish their distinct purposes (17,18). On the other hand, fiscal support could have been drawn from other U.S. Department of Health and Human Services (DHHS) funds after 1980—as presumably was intended when plans to recharter EAB emerged in 1988 (53 FR 35232).

■ Mandate and Agenda Setting

The focus and mandate—global issues versus research issues, regulatory or advisory—influence an initiative's authority or lack thereof. Additionally, as discussed earlier in this chapter, the form a bioethics body takes—standing versus limited term—can be linked to its agenda and mandate. Thus, delineating a mechanism to set the scope of topics also is a consideration for Congress.

A commission's charge should be structured to provide guidance, if not requirements, for the selection of topics or issues for study. Circumscribing too narrow a function obviates the potential early warning benefit of bioethics commissions. Drawing too broad a boundary could move a commission to examine issues—e. g., health care reform—that Congress or the President have tasked to others.

Since Federal regulation over medical practices or biomedical research is limited to federally funded activities, Congress might restrict an agenda to areas with clear Federal authority—e.g., patenting animals. On the other hand, an agenda need not be limited by current Federal regulatory authority. Issues that are currently entirely matters of State law—e. g., assisted suicide (32)—could fall under the Federal rubric

should they someday involve Federal reimbursement policies. Moreover, government deliberations can provide important information and identify common ground in areas generally the domain of States+. g., animal-to-human organ transplants or assisted suicide—even when no Federal regulatory or funding role exists.

Each of the three previous congressionally created bioethics bodies was required to assess certain specific topics, but their flexibility to embark on analyses of other issues varied. A combination of mandated studies and the opportunity for commissioners and staff to identify emerging issues maximizes the use of talent, time, and money. No single best mechanism, however, clearly prevails.

One approach would be for the commission itself—rather than the sponsor—to initiate studies of nonmandated topics, under the belief that members and staff are in the best position to select study topics because of their expertise and detachment from political structures. That is, if properly and appropriately appointed, a commission should embody the capacity to select topics that are of shared concern to all (21). On the other hand, federally funded commissions are public bodies created by officials who will be held accountable to the public. To address this conflict, Congress or the President could be permitted to suggest or mandate topics—with the Commission retaining, or not retaining, the authority to refuse such suggestions.

Congress struck a balance in the authority it gave the President's Commission. It required that specific topics be addressed, but also provided an elastic clause that allowed either the Commission or the President to add additional topics. To prevent the use of the President's Commission for special interests, Congress explicitly excluded itself from being able to provide further topics; a practice, however, that would seem unlikely to work for a standing body. In fact, the President's Commission responded to a single additional request by President Carter and his Science Advisor and explored the ethics of gene therapy

(17). Similarly, the President's Commission undertook the issue of foregoing life-sustaining treatment on its own volition, and the report became one of its most influential and lasting (10,17,18,37). The National Commission also initiated topics on its own (49).

Finally, depoliticizing a commission's mandate is impossible (6), but a priori avoiding extremely politicized issues, such as abortion, enables a commission to be more efficient and productive (as in the case of the New York State Task Force (56)). The short life of BEAC—caught in the abortion controversy crossfire—provides the most persuasive argument for this approach (19).

■ Appointment Process and Composition

A commission's mandate affects the nominating process. In turn, commission (and staff) structure and composition shape substance (62). With a narrow scope and small size, the tendency might be to select individuals with narrow, predetermined ideologic views for membership, thus diminishing the chances for success. On the other hand, a mandate created for specific topical needs, as for the National Commission, New Jersey Bioethics Commission, and New York State Task Force, can be executed effectively if the body's membership is balanced to reflect diversity and specific areas of expertise.

Today's explosive growth in the field of bioethics and in the number of individuals described as bioethicists has enhanced the Nation's capacity to discuss bioethical issues. At the same time, these developments increase the risk of bodies rendering commentary that is ingrown or out of touch with the real worlds of health care providers, scientists, or the lay public. Thus, any new organization must be representative of society at large.

Diversity in race, ethnicity, gender, and professional experience is a paramount factor in appointing commissioners and staff (17,44,66).

Ethics involves values, and a commission with monolithic membership or staffing cannot hope to adequately represent the diverse range of perspectives in American society. Additionally, the processes of a bioethics commission—that of formulating guidelines or regulations—is part social knowledge (appreciation of the problems rooted in experience) and part theory (ethical, legal, and philosophical). This means a deliberative body should be comprised of both practitioners and theoreticians.

The National Commission's success, for example, has been credited to its multidisciplinary and multiexperiential composition (44,66), although whether it was stacked in favor of research has been debated (3,38,61). Similarly, the success of the President's Commission has been attributed to the broad range of professionals that comprised it (17,62), although whether philosophy was adequately integrated has been questioned (11); on the other hand, questions also have been raised about the role of philosophers in addressing public policy issues (7,39,47,54,55).

Ideology is a destructive criterion in appointing a bioethics committee. While selecting members solely on the basis of their stance on a particular issue—such as abortion—might be viewed by special interests as useful, such an approach is shortsighted and likely to create gridlock. There is no way of predicting which way people will move on issues with which they are unfamiliar. Focusing solely on the views of potential panelists for one contentious issue, such as abortion, can delay the actual work of a committee, perhaps indefinitely; other issues, for which there might be broad consensus, are not given the floor.

The experience with BEAC illustrates this point. When BEAC was formed, it was believed that, although the membership was deliberately and strategically split on abortion, the panel would split in many different ways once it addressed more general issues—such as genetics. This supposition was apparent by the second meeting. It never got the chance to develop,

however, because the rancor over abortion-and congressional focus on the prochoice/antiabortion makeup of BEAC members—prevented the congressional Biomedical Ethics Board (BEB), the oversight body comprised of Senators and Representatives, from permitting further work to proceed (18,20).

OTA found no consensus on the optimal size of a commission. A smaller body, e.g., the National Commission with 11 members, lends itself to quicker development of the interpersonal dynamics and collegiality necessary for consensus building; it is also easier to handle administratively, but might bog down in ideological demagoguery. In contrast, a larger body, such as the current 41-member French commission, could be more inclusive and might be less susceptible to political line drawing (46). On the other hand, a body this large might be unwieldy and require subcommittees or task forces to work effectively, which adds an additional layer of bureaucracy.

OTA also found no consensus on the ideal mechanism to appoint members. Successful commissions have been appointed wholly by the President, his agency designee, or by a statutorily prescribed formula that usually involves the President, the Speaker of the House, the House Minority Leader, and the Senate Majority and Minority Leaders (72). Another model is the Advisory Panel for Alzheimer's Disease. This independent panel is congressionally mandated to advise DHHS and is staffed by the National Institute on Aging, but OTA appoints panel members—a process viewed as both impartial and expeditious (20). OTA also successfully appoints members to the Prospective Payment Assessment Commission and the Physician Payment Review Commission. BEAC's members were appointed solely by its congressional oversight board, the BEB, and BEAC expired due to BEB's infighting when a vacancy needed filling.

OTA did find general consensus on the merits of rotating membership. With the National Commission, members were appointed and toiled for the full 4 years of the commission's life. One

former member of the National Commission commented that by the conclusion of its work, ideas had become less fresh and responses reflexive, rather than open and discursive (44). Infusing new ideas and personalities by limiting members' terms carries some cost, however. Commission dynamics take time to develop; overly short term lengths would strain a consensus building process. The membership of the President's Commission was rotated and, on occasion, rotations disrupted the process of completing reports in progress (15,17). Nevertheless, rotating membership keeps a body from appearing to be politically locked in and should be favored.

■ Location

Deciding where to locate a Federal bioethics organization depends on its mission and purpose. In some cases it might be best to locate an ethics advisory group in the agency whose work it reviews, thereby maximizing the chance that its recommendations will be implemented. In other cases, the work of the advisory body might be too closely related to the work of the agency to accomplish anything-i.e., an independent body would be optimal.

The National Commission, for example, was formed because of growing concern about the treatment of human subjects in research. A crucible of debate over fetal research forced the issue, resulting in policy discussions on research involving human subjects. Most of these issues fell squarely in the domain of DHEW/DHHS, and Congress placed the National Commission within that agency in 1974. In retrospect, although the National Commission operated with a good deal of autonomy (63), one factor that contributed to the Commission's success was its close proximity to the agency it was reviewing and to which it made its recommendations (23,52). On the other hand, locating a body within the concerned agency could create a perception of conflict-i. e., that the ethics body is not wholly independent. EAB was housed within DHEW/DHHS, and

although the impact of this body was less than that of the National Commission, it was significant (51). Had it been given time, its effectiveness in reviewing the Department's work could have been fully evaluated: Either its work would have been successful in terms of departmental implementation or it would have been embedded in the bureaucracy and ignored (52).

In contrast, the President's Commission has been deemed a success, in part due to its independent standing and freedom from Congress and the executive branch. Had it been integrated within DHHS, it is uncertain whether the Commission would have survived political interference by Congress and the executive branch, given the political climate of the early 1980s (17).

A prime example of location undermining a body's success was the failed 1985 attempt to establish BEB and BEAC. BEB created a partisan logjam along abortion lines that prevented the deliberative committee—BEAC—from ever completely considering an issue, and BEAC's demise can be attributed directly to congressional wrangling and lack of independence (18-20).

Besides these models—within an agency of the executive branch, an independent commission of the Federal Government, and attached to Congress—proposals also have suggested that OTA or IOM house a bioethics body (1,70). When such proposals were under consideration 8 years ago, OTA, as a congressional agency, was perceived as potentially subject to excessive politicization (1). IOM was criticized as a body ultimately captured by medical interests (1), even though IOM policy and membership includes nonmedical perspectives. The passage of time and the increased experience and prominence of both OTA and IOM might now mute these objections. Notably, IOM is not subject to the Federal Advisory Committee Act (5 U.S.C. Ap. 2, §1 et seq.), which requires open meetings. IOM routinely reserves the right to conduct closed committee meetings, which is seen as a strength (30) or a weakness (14,15,92). With the exception of the New York State Task Force, all Federal and

State bioethics bodies that OTA examined did not hold closed deliberations, though many international entities do.

Thus, in considering location, Congress can look to a range of historical models and proposals. It could also examine whether the locus for a bioethics commission should be in the Executive Office of the President—e. g., attached to the Office of Science and Technology Policy (OSTP). OSTP, however, has limited familiarity with biomedical ethics issues, although the legislation establishing the President's Commission mandated that OSTP's director have a liaison with the Commission (42 USC § 300v). Furthermore, while locating a commission in OSTP might lend stature to the effort, Congress would need to address the historical understaffing of this office (24,45).

■ Client

Target audiences for the work of a new bioethics entity include Congress, the executive branch, the academic community, health care providers, and the public. As just discussed, a body's bureaucratic location might define the primary client, but any new effort will affect—and hence should strive to serve—all parties. For a bioethics entity to operate effectively, restraints and controls must be in place to discourage or prevent political meddling with the staff or the conditions for operation—regardless of where the body is housed or who the principal client is. OTA found consensus on the need for autonomy and independence from both congressional interference and mischief from the executive branch.

Through the 1970s, Members of Congress, the President, and executive branch agency personnel—regardless of political affiliation—largely viewed commissions from the perspective of patrons of a process, not players in it (23). This culture reversed in the 1980s, resulting in executive branch interference with Federal regulations—e.g., the lack of an EAB to review protocols for

human in vitro fertilization (IVF) (ch. 2; 77). Also, if an EAB had been in place, the piecemeal funding and staffing of the NIH Fetal Tissue Transplantation Research Panel would have been unnecessary. Similarly, intrusion by Congress resulted in the failure of BEAC to ever initiate a project (17,18).

Finally, as mentioned in chapter 2, the lay public is increasingly interested in and involved with resolving bioethical issues. The ability to operate in relative obscurity in the early history of biomedical ethics contributed to the success of the National Commission (44,66,92). Such a situation would be impossible today; intense public scrutiny exacerbated the difficulties experienced by BEAC (16,20).

■ Reporting and Response Requirements

To whom and how the group shall report, in what manner, and what response should be required are key factors for congressional consideration. In fact, to whom a group should report its final work seems to raise little controversy; what is problematic is injecting politics during the deliberative process. In practice, a new commission could be required to report to Congress, the executive branch, or both. For example, a new body could be responsible primarily to the executive branch, with Congress maintaining its traditional oversight role.

Even the most successful attempts to tackle bioethical issues will be ineffective if the results of those deliberations are censored or poorly distributed. The National Commission published its own work, which was inadequately distributed, and EAB's work remains even more difficult to trace because of poor dissemination. In contrast, the President's Commission greatly improved the manner in which findings were reported and distributed; reports were published and sold by the U.S. Government Printing Office. Because one goal of bioethics commissions is public and professional education, adequate funds

and a plan for widespread public dissemination and reporting beyond the designated client are vital.

Nevertheless, whether and how the client must respond is probably more important than how the commission must report and disseminate (23,52). Should Congress create a new commission or board, it could include a forcing clause for accountability of the target client(s). For example, EAB addressed such controversial issues as fetoscopy, research with the human embryo, and freedom of information and the early release of clinical trial data. Its recommendations, however, were largely ignored by its client, the executive branch—even when the report was unanimously approved (52). The most glaring example of this was the 1979 report on IVF (84). Yet, by using it as background for professional practice guidelines, the American Fertility Society and other organizations interested in conducting IVF research in a responsible and ethical manner implicitly endorsed this report.

In contrast, Congress included a “forcing clause in the legislation that created the National Commission. The clause did not require the Secretary to accept every recommendation made, but it did require the Secretary to accept recommendations within 180 days or publish reasons for not accepting them in the *Federal Register*. Such a clause forces some sort of decision or action on the part of Federal officials in response to a report. In fact, EAB was created as a result of a National Commission recommendation. The Secretary had to accept the recommendation or publish reasons for not accepting it, and the political untenability of rejecting an EAB was greater than the risk of creating it (52). Ironically, an unanticipated outcome was Secretarial censorship of EAB activities because the regulations associated with chartering EAB, unlike the legislation creating the National Commission, forced no response to EAB reports (52). Even so, a forcing clause does not guarantee responsiveness: In violation of the law (48), DHHS has failed to

issue final regulations related to the National Commission's work on research involving the "mentally infirm" (87).

Finally, an open question is whether a commission should be directed to achieve and report consensus on an issue or to consider and articulate the merits of competing values (1,41,89). Congress could look to three successful models: the National Commission and President's Commission for consensus and OTA for analyzing the range of viewpoints.

SUMMATION AND PROSPECTUS

Does the United States need a government-sanctioned body, or bodies, dedicated to deliberating about the ethical issues raised by biomedical research, medical innovation, and health care? What have past efforts accomplished?

In only two decades, the U.S. Government's forays into bioethics have had lasting, measurable impacts (15,22,36,48,62). Federal regulations to protect human research subjects owe their existence in their current form to the National Commission-e.g., the National Commission's report on research involving children (86) raised controversial issues, but the guidelines finally proposed received praise and approval from all sides (49). In clinical practice, for example, the President's Commission shaped subsequent public debate in health care settings, legislatures, and courts about patient directives on life-sustaining treatments.

If Congress decides to create a new bioethics commission, it can look to the history of Government's involvement in bioethics for a wealth of experience and information. Although it is difficult to generalize whether a particular factor is specifically associated with ultimate success or failure—each commission had a slightly different model or existed in a different political climate—lessons can be learned from the National Commission, EAB, President's Commission, and BEAC.

By examining this rich history of activity, OTA found six specific elements contributed to the success or failure of past efforts and so should be considered in devising future strategies. Not surprisingly, the budget is important, but mandate, appointment process, bureaucratic location, targeted client, and reporting and response requirements are also key. Absent from the list is politics, since creating a new body is inherently political, and the system will affect each factor.

Whether a standing, term-limited, or ad hoc commission should be established might depend on the type of issues Congress would like analyzed. An ongoing body in the model of EAB appears superior for examining questions raised by controversial research involving human subjects. A term-limited body like the President's Commission can address both research-related issues and broad-based topics in bioethics, but might be best for the latter if a standing body is available to address research topics. Still, in an era of *shrinking* numbers of Federal advisory bodies, the barriers involved in creating two forums, though for distinct purposes, could prove insurmountable. Ad hoc commissions can handle both categories, but OTA found consensus that ad hoc panels are less desirable-i.e., to be favored only as a last resort.

Past Federal bioethics efforts have been varied, innovative, and largely successful, but not enduring. Today, Congress stands at a crossroad. How best to incorporate bioethical analyses into policy decisionmaking is the issue currently facing Congress—one made especially difficult as fiscal realities mean fewer Federal advisory bodies and fewer staff to support them. Congress must decide what opportunities to seize, and when and how to move forward. Regardless of whether it creates a new, broad-based commission, directs DHHS to establish an EAB with a new mandate, or both, Congress should somehow provide a voice for biomedical ethics in public policy.

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