

# Appendix A

## International Bioethics Initiatives

In the past few years, bioethics has become a global enterprise, with commissions or institutes in the Americas, Africa, Asia, Australia, and Europe. Though no federally sponsored forum exists in the United States, other governments and multinational organizations increasingly are establishing working groups, committees, or commissions to deal with bioethical issues.

In November 1992, OTA conducted a mail survey of bioethicists and individuals in government offices in 47 countries. Individuals and groups in 35 countries generously responded to OTA's inquiry, and approximately 40 persons active in national and international bioethics committees abroad also contributed by telephone or in-person interviews. This appendix describes national bioethics commissions abroad—as well as a sampling of bioethics activity in regional and multinational groups—based on the survey and information collected through other reports and the literature. The appendix also notes some common themes about the structure and operations of international bioethics entities. Finally, although OTA attempted to be as comprehensive as possible, the limits inherent in a short-term survey are such that the absence of a description for any country does not mean a lack of interest or activity in that country.

### COUNTRY-BY-COUNTRY ACTIVITIES

Abroad range of bioethics initiatives occurs abroad. This section summarizes the wealth of information obtained on individual countries, with a particular focus on national bodies. (See also table 2-1.) The following section describes data on multinational efforts,

#### ■ Argentina

In December 1992, the Secretary of Health, National Ministry of Health and Social Welfare, created the National Bioethics Commission. Its mandate includes establishment and oversight of research subject committees, assessment of research protocols, and consideration of other issues in bioethics. A National Commission of Bioethics and Health Research to enunciate policies and survey bioethics research programs has also been proposed (116).

#### ■ Australia

A number of federal and state bioethics commissions have contributed to health policy development in Australia. For example, the New South Wales Law Reform Commission on Human Tissue Transplants influenced practice and policy in that field in the 1970s

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(73). In 1982, the Medical Research Ethics Committee (MREC) was established within the National Health and Medical Research Council (NHMRC) (analogous to the U.S. National Institutes of Health) to formulate guidelines for medical research. Compliance with these guidelines was a condition of Federal funding of medical research (17,35).

A more general group, the National Bioethics Consultative Committee (NBCC), was established in 1988 by the Joint Meeting of federal and state Ministers of Health and Social Welfare. NBCC's role was to advise the Ministers, and it was composed of professionals from a number of fields. Its reports, primarily concerned with human reproduction, were intended to stimulate debate rather than reflect conventional, mainstream views. While the NBCC's work provoked much public discussion, it was opposed by influential groups including churches, feminist organizations, disability groups, right-to-life organizations, and most bioethics centers. The federal and state Ministers of Health and Social Welfare withdrew their support (47,1 19).

The functions of MREC and NBCC were consolidated in 1991 into the Australian Health Ethics Committee (AHEC) at the NHMRC (16,47,1 19). Like its predecessors, AHEC is multidisciplinary in membership, and its duties include policy development and public education, as well as monitoring institutional ethics committees. In 1992, the federal Parliament changed the status of AHEC to involve broader membership; it will also undertake wider community consultation and will no longer be subject to NHMRC in regard to issuing guidelines. AHEC is not viewed as representing the community, but rather challenging the community (47,1 19). In fact, it has lobbied against bioethical decisions made by state parliaments and committees (47,1 19).

While AHEC operates at a national level, the constitutional responsibility for regulating health care practice and research belongs to Australian states. Thus, it is at the state level that there has been the most bioethics activity, including exhaustive public consultation, consensus seeking, policy development, and legislation. Several committees of inquiry were established in states, and three states have on-going statutory committees composed of a minority of health professionals and a broad range of other professionals and lay people. Most such committees have examined

single topics, such as genetic manipulation, informed consent, or reproductive technologies (17,47,66,1 19).

### ■ Brazil

Brazil's National Health Council considers bioethics in its deliberations. Established in 1937, but reorganized extensively in 1990, participants include government officials, health care providers, consumers, and researchers. Additionally, the Federal Council of Medicine, which was created in 1957 as part of the Professional Councils on Health, is a professional organization of doctors that operates independently of the government. It enforces an ethical code for doctors and oversees several regional councils that provide guidance to professionals (82,87).

### ■ Canada

Both the Canadian Government and several provinces have considered bioethical issues in the context of potential legislation recommended by law reform commissions. In particular, the work of the Canadian Federal Law Reform Commission, which concluded its work in 1992, contributed widely to discussions on bioethical issues. In addition, the Science Council of Canada, now disbanded, produced several bioethics studies (83).

In July 1984, the Medical Research Council (MRC) of Canada established a Standing Committee on Ethics in Experimentation which, with its Working Group on Research Involving Human Subjects, accepted outside consultation and recommended guidelines on research involving human subjects to the MRC. The MRC accepted the report as official MRC guidelines and required that all research it funds be in compliance with them (80). The National Council on Bioethics in Human Research was established in 1989 by the MRC, National Health and Welfare Canada, and the Royal College of Physicians and Surgeons. This body is an advisory group that aims to encourage ethical standards in biomedical and health research involving human subjects. The Council defines guidelines, advises institutional research ethics boards, and promotes professional and public education in research ethics (83).

Another effort is the legislatively established, single-issue Royal Commission on New Reproductive Technologies, which is responsible only to the privy council

and the prime minister. It has been charged with performing a comprehensive and authoritative review of Canadian policies, attitudes, laws, and practices on current and forthcoming reproductive technologies. Like all Royal Commissions, it is well-timed; in fact, it is reportedly the most well-funded bioethics commission in the world—over CN\$20 million, or nearly CN\$1 per citizen. The Commission is chaired by a physician and has four other members and a large professional staff. Through more than 100 outside contracts, it has sponsored extensive research to review existing data. It also has held hearings and open meetings around Canada and expects to publish its reports as required in 1993 (69,110). Royal Commissions examining other bioethical issues can also be created on an ad hoc, time-limited basis (126).

## ■ China

China has no general bioethics commission, although the Ministry of Health created an Ad Hoc Expert Advisory Committee to draft a eugenics law. Membership consists of 20 scientists, physicians, and bioethicists. The Ministry is reportedly planning to create a standing committee on policy issues stemming from technological innovations in health care. The Chinese Academy of Social Sciences, an academic and policy institute that advises the government, also has an active program in bioethics. This program has sponsored several national conferences on bioethical issues, sometimes with support from the Ministry of Health (95).

## Czech Republic

Czechoslovakia's 1989 revolution enabled the Czech Republic to create the Czech National Commission of Medical Ethics (Centrální Etická Komise, or CEC) in 1990. CEC oversees the activities of numerous Local Commissions of Ethics, located in hospitals and other health care units that had previously existed in the former Czechoslovakia. CEC consists of 28 members appointed by the President of the Scientific Council of the Minister of Health Care and two staff. Members are not required to represent particular professions or ideologies and receive no payment. CEC meets once a month with no rules excluding public attendance (56).

## ■ Denmark

Currently, Denmark has two national bioethics commissions with overlapping areas of interest, and sometimes disagreement. The Central Scientific-Ethical Committee (CSEC) has been in operation since 1978 (58). It was created in the wake of the Helsinki II declaration on human subjects research and has been chaired by one of its drafters. It has a well-defined responsibility to oversee all clinical and laboratory medical science research involving humans (98). CSEC originally operated via a voluntary arrangement of professional groups and a government ministry, but in 1992 it was given statutory authority. Currently, it consists of two representatives from each regional human subjects research review board, a layperson, and a researcher. CSEC acts on disputed proposals and in cases where a matter of principle needs to be decided (15). A 1989 report on research involving human subjects by the Ministry of Health had a tangible impact on the current laws on the research ethical committee system (84,98). Also, in 1991, the Danish Medical Research Council gathered a working group to publish a report on scientific dishonesty (27).

In 1988, Parliament created the Danish Council of Ethics to consider a broader range of bioethical issues. The Council is the primary adviser to Parliament on ethical problems in the health sciences, excluding the research-related questions handled by the CSEC (98). The Council appears to be more grassroots than any other in the world, making significant effort to mobilize public discussion. The Council's 17 members are predominately laypersons who are nearly evenly divided by gender (26). Though reports are written by Council members, the Council has a slightly larger staff—three professionals—than is common in Europe; the Council also includes academics for short periods of service (26).

The Council's public education efforts go far beyond anything attempted elsewhere. For example, in considering the definition of death and the ethical issues of protecting human gametes, the Council not only held public hearings, but financed local debates on television. It also distributed elaborate educational materials to high schools, produced award-winning films shown on national television and in movie theaters, produced booklets and brochures for public libraries, and sponsored creative contests for young people. One thousand articles have been published

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over 3 years, along with numerous editorials that drew hundreds of letters to the editor. Although public awareness of bioethics among the general population has been successfully raised—probably due to the small size and homogeneity of the population (108)—it is interesting to note that, even after widespread discussion among the public, the Council's own surveys revealed misunderstandings about brain death (26,39,58,92,98,100,101).

The Council's findings on the definition of death drew criticism from CSEC members. The two commissions also disagreed on the propriety of preserving brain tissue for research and teaching purposes; one of the provisions in the 1992 law establishing the CSEC's legal status was a directive to the two councils to cooperate.

### , Finland

The Finnish National Research Ethics Committee was established in 1991 as a permanent advisory body of the government. Its mandate is to make proposals and give expert statements to the government, function as an expert body, promote research ethics, participate in international research ethics cooperation, and inform the government about issues in research ethics. The Committee consists of 10 members representing the scientific fields and government authorities involved in research ethics. Members of the first Committee have been appointed until 1995, when new members will be appointed (70,77).

The Ethical Advisory Committee for the National Agency for Welfare and Health was founded in 1991 by the Ministry of Social Affairs and Health. Twenty members from various fields have been appointed to serve until 1994 by the Director General of the National Agency for Welfare and Health. The group promotes bioethics and provides advice about ethical issues. It has no formal power, but may propose regulations or legislation (65).

### ■ France

The French National Consultative Ethics Committee on Life and Medical Sciences (Comite Consultatif National d'Et.hique Pour les Sciences de la Vie et de la Sante, or CCNE) was created in 1983 by the President (30). It is one of the first national bioethics committees abroad and was created to play a central

role in the country's deliberations over bioethical issues (62). Additionally, France developed a system of local ethics committees in the 1980s. These committees focus mainly on human research, similar to the function of institutional review boards in the United States. The local ethics committees became subject to national regulation in 1990, but are completely independent of CCNE (89).

CCNE's 41 members are drawn from medicine, law, biology, nursing, social science, ethics, philosophy, and religion; 15 of 41 members are women (89). Members are not paid, although many devote major portions of their professional time to CCNE; staff size is small. The committee is housed at the Institut National de la Sante et de la Recherche Medicale (INSERM) (analogous to the National Institutes of Health) and meets in closed session. A 2-day public symposium is held each year to bring bioethical issues to the public's attention.

CCNE's mission, as defined by the decree establishing it, is to advise the government on questions of bioethics; questions can be brought to CCNE by members of the government, the presidents of the two houses of Parliament, or by public institutions involved in research. To date, CCNE has issued over **30 reports or statements** on topics that include research on human subjects, embryo research, genetic testing, the use of fetal tissue for medical procedures, surrogate motherhood, testing of drug addicts in employment settings, use of RU486, and sex determination procedures at the Olympics.

CCNE's unusually large size permits wider representation of views and interests. It not only carries out studies of major bioethical issues, but also involves itself in day-to-day controversies arising in the hospitals and courts. High in visibility and prestige, its annual public meetings have been addressed on several occasions by the President of the Republic, and its deliberations and findings are covered extensively by the press.

Finally, the French Parliament currently is considering a wide ranging bioethics bill, which has cleared the Assembly and is awaiting Senate action (89,91). A National Center of Medical Ethics was created by presidential decree in 1992, but has not yet been assembled (12).

## ■ Germany

The former West Germany<sup>1</sup> has had a number of inter-ministry ad hoc commissions and legislative ad hoc commissions. In 1985, a joint commission with representatives from several federal ministries and academic institutions issued a report on in vitro fertilization, genome analysis, and gene therapy. Known as the Benda Commission, this body was chaired by the President of the Constitutional Court. The report led the federal Ministry of Justice to introduce the Embryo Protection Law (45,103). The federal Parliament has also created ad hoc commissions, known as Enquete commissions, on bioethical issues. The Gentechnologie Enquete Commission focused on biotechnology and produced a report in 1987 (46). Another Enquete commission focused on technology assessment and the social acceptability of technology; a third, established in 1988, focused on the public health care system (102). Rather than simply fostering anticipatory moral debate, the Benda Commission and the Enquete commissions generally used worst case scenarios for determining the moral and social acceptability of modern medical technology, applied general principles such as “human dignity” to specific cases, and recommended the criminalization of future technological possibilities (103).

The Scientific Council of the Federal Chamber of Physicians established two ethics commissions in 1985 that involved philosophers, theologians, and health administrators; the Scientific Council examined issues of in vitro fertilization and embryo research (11). In 1986, the German Society for Medical Law addressed the issue of withholding treatment from severely handicapped newborns (33), and the German Society for Anthropology and Human Genetics issued guidelines concerning withholding information from parents about the sex of their fetus (32,103).

The former West Germany also has had ethics committees in medical schools, as well as chambers of physicians that assist physicians in consultation on and assessment of moral and legal issues of human experimentation. In 1986, an association was formed by these ethics committees to regulate their activities and memberships; it meets once a year (4).

The role of bioethics in German public policy is somewhat unusual in light of the Nazi era. In 1989, a visiting British bioethicist’s lectures on bioengineering and mental retardation had to be canceled after anti-biotechnology and disability rights groups accused him of advocating the rekindling of the Nazi’s “euthanasia” program of persons with disabilities. Subsequent to this, other public protests forced the cancellation of lectures and courses on bioethics. The anti-bioethics protesters feel that public discussion of contemporary bioethics will make “despicable and dangerous” views seem more respectable (125).

## Greece

In 1987, a nongovernmental group called the Hellenic Society of Medical Ethics and Deontology was created by individuals interested in medical ethics. The Society then played a role in persuading the Ministry of Public Health to begin to establish a National Center of Medical Ethics and require an ethics committee in every Greek hospital (12,67,71). It also succeeded in obtaining legislation establishing a National Medical Ethics and Deontology Board, consisting of professionals in health, law, and theology, all to be appointed by the Minister of Health (67,71).

## ■ Hungary

The Hungarian Scientific Health Council established a Scientific and Research Ethics Committee in 1987. Comprised of 20 individuals, including physicians, theologians, ethicists, and lawyers, it is the parent forum overseeing human subjects research in Hungary. It coordinates the regional research ethics committees and defines and publishes unified principles for research ethics.

The Parliament Committee on Social, Health, and Family Welfare established a bioethics commission of 16 professionals, health officials, sociologists, and philosophers in 1990. It seeks to be an advisory forum for legislation and to advise lawmakers. Quarterly meetings are not formally announced and consequently are unknown to the public (10,63).

<sup>1</sup>Though OTA only has information on the former West Germany, this is not to imply that no bioethics activities took place in the former East Germany.

### **Israel**

The Director General of the Israeli Ministry of Health convenes a Supreme Helsinki Committee—i.e., a human subjects review committee operating on provisions of the Helsinki Declaration, which has been incorporated into Israeli law—when research in sensitive areas is proposed. One such area has been “experiments regarding the human genetic code, and its focus in recent years has been reproductive medicine. This same subject will also be addressed by a new commission jointly created by the Ministries of Health and Justice. In addition, the Israeli Society for Medical Ethics has its own committee that has provided testimony to various public agencies (106).

### **Italy**

The President of the Council of Ministers created a National Committee on Bioethics (Comitato Nazionale per le Bioetica) in 1990 to provide advice to the Parliament. Its functions include formulating opinions and proposing solutions to ethical and legal problems that could arise in conjunction with advances in research in the life and health sciences or in the development of clinical therapies. It is also mandated to promote the formation of codes of conduct for individuals in the life and health sciences and to promote the provision of accurate information to the public. By decree, topics include genetic therapy and safety of biological materials (127). Thirty-six members have been chosen based on disciplinary background, and four represent professional organizations, including the Italian Medical Association. The Committee meets in closed sessions and has no professional staff. The Committee strives for consensus, reserving the use of voting if necessary, and has produced more than 10 reports (107).

In 1990, the Prime Minister established a working group of scientists, physicians, philosophers, and legislators to produce legislation on the ethical and legal problems involved in assisted procreation procedures and in scientific research concerning human embryos (18). In addition, the Italian National Research Council has an 11-member Committee of Bioethics, as do several medical specialty societies, including the Italian Society of Neurology and the Italian Society of Fertility and Sterility. A number of local groups also exist (124).

### **Japan**

Japan has no standing bioethics commission, but has established the Prime Minister’s Ad Hoc Committee on Brain Death and Organ Transplantation—a subject that is highly controversial in Japan (59,78). Its deliberations were closed to the public. In January 1992, the Committee issued a report—with dissents—that endorsed a definition of brain death.

Additionally, Japan’s Human Genome Project has granted funds for the study of ethical issues, and a 20-member Ethical, Legal, and Social Issues Working Group has been established. To date, it has convened two international conferences (50,114).

### **Luxembourg**

In 1988, the government of Luxembourg established a National Ethical Consultative Commission for the Life and Health Sciences. The Commission is attached to the Ministry of the State and serves as an advisory agency to the government. It is responsible for the multidisciplinary study, either at its own initiative or at the request of the government, of the ethical aspects of various problems arising in the life and health sciences. It also examines the solutions and means to be employed to address these problems (96).

### **Malta**

In 1989, Malta’s Minister of Social Policy formed a National Ethical Health Committee (12). The government is also interested in developing policies and programs to enhance the lives of the elderly and to mitigate any negative effects resulting from the aging population’s impact on development (3).

### **Mexico**

In Mexico, a federally sponsored National Bioethics Commission (Comisión Nacional de Bioética) that reports to the Ministry of Health was established in 1992. The Commission’s President is the Secretary of Health, who appoints the 10 commission members and an executive general secretary, all health professionals. The body holds monthly meetings and additional sessions when the need arises. Its goals include research, education of the public, and recommendations for legislation. Besides medical issues, its broad mandate includes oversight on environmental matters (85).

## ■ The Netherlands

The Netherlands has had a bioethics commission since 1977. The Health Council, the scientific advisory board of the government in the fields of public health and environmental hygiene, sponsors a permanent Commission on Health Ethics and Health Law (CHEHL). CHEHL is a standing advisory group that transmits findings to the government of subject-specific ad hoc committees organized by the Health Council. CHEHL's 10 to 20 members, all scientists, meet 6 times a year in closed sessions. Currently, the vice president of the Health Council chairs CHEHL. The staff consists of two lawyers and one ethicist. Among national bioethics commissions, only CHEHL is known to have undergone an evaluation, in this case from the Parliament in 1991; the outcome was favorable.

In 1989, the Minister of Health established the Dutch Interim Central Committee on Ethical Aspects of Medical Research (Kerncommissie Ethiek Medisch Onderzoek, or KEMO) and located it at the premises of the Health Council. KEMO is a national advisory commission for the assessment of planned medical research involving ethical, legal, and social issues. It directly advises local medical ethics boards of health care institutions, not the government; recommendations are nonbinding (18). From 1989 to 1990, KEMO met bimonthly and responded by confidential letter to requests for advice from four local ethics committees (72,97). In 1991, KEMO published its first annual report (1,36). The Federation of Health Care Organizations in the Netherlands and the Royal Dutch Medical Association have also been active in bioethics (29, 121,122).

## , New Zealand

New Zealand has a single governmental body responsible for bioethical issues, the Health Research Council Ethics Committee. Established in 1990, the Committee advises the Health Research Council on ethical issues related to research. It also advises ethics committees established by other bodies (e.g., hospitals) on standards, procedures, and membership. In New Zealand, the chair of an ethics committee and at least 50 percent of members are not health care professionals.

Other government activities include a review of assisted reproduction and reports commissioned

through agencies such as the Medical Council and the Core Health Services Committee. Establishment of a National Health Ethics Committee is also under consideration (14). The Law Reform Division of the Department of Justice has also been active and, in March 1985, released a paper on artificial reproductive technologies (48).

## ■ Norway

In 1989, the Norwegian Parliament passed a law establishing three national research ethics committees. One, the National Committee for Medical Research Ethics already existed on a nonstatutory basis, and two were created to work in the fields of social sciences and science and technology (43). The National Committee for Medical Research Ethics has nine members, including two Members of Parliament. In the past, the Committee answered to the Medical Research Council, but it is now independent. Its professional staff consists of a theologian-bioethicist, a secretary, and a consultant. Additionally, a National Medical Ethics Committee has been proposed to investigate patient rights and health care rationing (75). Also in 1989, the Parliament voted 16 million kroner for the Medical Research Council to establish a Center for Biomedical Ethics in Oslo (43).

## ■ The Philippines

In 1987, the Philippine Council for Health Research and Development published *National Guidelines for Biomedical Research Involving Human Subjects* which, among other matters, created a National Ethics Committee and institutional review committees (93). These committees are primarily concerned with the ethical review of research activities, though they are expected eventually to review other medical and health care practices (28). The National Ethics Committee is dominated by nonphysicians: By law, it includes one homemaker, one attorney, one environmentalist, one social scientist, one representative of the religious community, one medical researcher, and one representative of the Philippine Medical Association. The membership of the National Ethics Committee is indicative of a trend in the Philippines toward greater public involvement in a previously physician-centered activity (28).

## ■ Poland

The Ethics Review Committee in Biomedical Research was founded in 1977 by the Ministry of Health and Social Welfare and has been active in bioethics. A Commission for Supervising Research on Human Subjects was also created in 1982 by the Ministry of Health and Social Welfare to advance proper policy for research involving human subjects; this commission is chaired by a physician in the Ministry of Health and Social Welfare, and the Minister appoints the members.

A Commission for Research Ethics was created in 1991 at the Scientific Council of the Ministry of Health and Social Welfare. This commission meets once a year in closed session to draft legal regulations for human subjects research, review and inspect research on human subjects, review local research ethics committees, and publish its findings (88,1 15).

## Portugal

Following an initiative of the Parliament, the national government created the National Council on Ethics for the Life Sciences in 1990 (94). The group presents annual reports to the Prime Minister on the application of new technologies to human life and the relevant clinical and social implications. The 20 members serve 5-year terms, and membership consists of 10 medical professors or doctors of certain specialties, 4 jurists, 3 philosophers, 1 biologist, 1 engineer, and 1 Catholic moralist (18). The Council's chairperson is appointed by the Prime Minister six members are elected by Parliament, and 14 others are appointed by ministries and by scientific and professional organizations. Monthly meetings are closed to the public, but press conferences are held regularly. The Council strives for consensus, but publishes dissents. A single administrative officer staffs the Council (105).

## ■ Romania

In 1990, the Academy of Medical Sciences established a Bioethics Committee out of a need to "correct the numerous deficiencies left by the 45 years of Communist regime" (79). It is independent of the government and consists of 20 members, including physicians, jurists, psychologists, and priests; the current president is a geneticist. Members meet four times a year and are not paid. The Committee has

played a role in the withdrawal of a Ministry of Health draft law to legalize active euthanasia and in the establishment of bioethics groups in several clinics of pediatrics, surgery, and endocrinology (79). It has organized conferences on medical ethics and bioethics, and is currently attempting to develop ethics curricula in each Romanian medical school (12).

## ■ Russia

In 1992, a Russian National Committee on Bioethics was formed on the initiative of the Russian Academy of Sciences and the Russian Academy of Medical Sciences (102). Its tasks include identifying and defining ethical issues raised by recent advances in biomedical research and practice. The Committee's role is advisory, though it can make arrangements for examining and reporting on bioethical issues and formulating new guidelines or laws. The Committee recognizes the need to inform and promote public debate and discussion on bioethical issues, and it is expected to consult widely, publish reports, and make recommendations (102). The Committee's first act was organizing the Commission on Protection of Animals as Subjects of Scientific Experimentation (118). In 1991, the Committee cosponsored, with the United Nations Educational, Scientific, and Cultural Organization (UNESCO), an international symposium on bioethics (12).

Additionally, the Center of Biomedical Ethics and Law was organized in Moscow in 1990. The center conducts regular interdisciplinary debates on problems in Russian medicine, and will submit a proposal to the President of Russia to establish an all-Russian Committee on biomedical research. This committee would be involved in ethical assessment and regulation, and would not be controlled by medical or academic authorities (118).

## ■ South Africa

The South African Medical Research Council prepares ethical guidelines for medical research; a revised document will be issued in late 1993 (9). The South African Law Commission recently issued a draft report on surrogate motherhood (48).

## ■ Spain

The Ministry of Health has considered creating a national committee on bioethics, however, these dis-



cussions were recently suspended. The Ministry's multidisciplinary Advisory Council has examined several bioethical issues (99), and numerous government-sponsored ad hoc commissions also have studied bioethics (2). In 1990, legislation requiring that clinical trials and research projects involving drugs be approved by hospital ethics committees was enacted. Thus, the number of hospital ethics committees is rising in Spain. The Spanish Medical Association also has dealt with bioethics through its Commission of Deontology (99).

### ■ Sweden

Sweden's National Council on Medical Ethics has been functioning since 1985. It is advisory to the government, and works under the Ministry of Health and Social Affairs. The Council consists of 18 members, including 7 Members of Parliament and experts in ethics, the arts, and religion, as well as representatives of certain organizations. The Council's task is to shed light on fundamental medical ethics issues, keep abreast of state-of-the-art research, and to act as a link between science, the public, and political decisionmakers. The Council has the ability to choose topics on its own initiative. It meets in closed session, but holds a "day of ethics" to bring bioethics to the public's attention. The Council does not carry out its own investigations, but is designed to monitor trends and analyze problems in medical ethics.

Additionally, numerous ad hoc, topic-specific committees have also been formed by the Swedish government before it prepares a bill. These committees have published reports and influenced legislation, sometimes through the National Council on Medical Ethics. In 1987, the Minister of Health and Social Affairs appointed a special Swedish Committee on Transplantation, which has written a number of reports (11,112). Sweden's Medical Research Council houses a central committee that oversees local research ethics committees concerned with individual research projects (64,113).

### ■ Switzerland

Currently, no broad bioethics commission exists, but the Swiss Department of the Interior and Department of Justice and Police jointly created an Expert Commission on Human Genetics and Reproductive Medicine (the Arnstad Commission), which met from

1986 to 1988. Its mandate was to discuss new reproductive technologies and their social, ethical, and legal impacts, point out abuses, and write recommendations for the government. The 21-member group met 17 times in closed session and released its report in 1989 (117). In addition, the Swiss Academy of Medical Sciences maintains a nongovernmental Central Ethics Commission that has issued guidelines to clinicians on a number of ethical matters (57).

### ■ Turkey

The Higher Council of Health, established by legislation in 1930, consists of nine health care professionals chosen by the Minister of Health. Its scope of activity includes some bioethics issues, but it does not publish its work. In the near future, a Central Ethics committee will be established in the Ministry of Health to administer human subjects guidelines through institutional review boards (90).

### ■ United Kingdom

In the United Kingdom, bioethics is incorporated into policy in several ways and in many institutions. The Medical Research Council publishes an ethics series that primarily focuses on human research subject issues. Most prominent among the bioethics councils was the 1982-84 Warnock Committee on embryos and reproductive technology under the auspices of the then Department of Health and Social Security (31); its recommendations were largely embodied in new legislation. Recently, the House of Lords established a Select Committee on Medical Ethics to consider a number of issues. The British Medical Association has a Medical Ethics Committee and the Royal Colleges (e.g., of Physicians or Psychiatrists) have also issued numerous guidelines and position papers. In addition, the General Medical Council has issued guidelines on the commerce of human organs (48).

Nevertheless, in contrast to other European nations, the government has rejected suggestions to create a national bioethics commission with a broader mandate (13); it has preferred to establish multiple committees that each offer advice on specific issues. Prominent bioethicists in the United Kingdom have complained that without a national commission, they cannot identify and pursue the "British position" on important issues in pan-European councils and conferences (123,124). Thus, with interest in a British commission

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rising, a private solution was pursued. Following extensive consultation with professional, scientific, legal, and consumer groups, the Nuffield Foundation, an educational and charitable trust, founded a private body in 1991. The Nuffield Council on Bioethics is designed to function similarly to governmental bioethics bodies elsewhere in Europe. Its 15 members, 8 of whom are women, do not represent constituencies, but were chosen with diversity in mind. The Council aims to stimulate coordination among the many parties now contributing to bioethics policy, to anticipate new problems, and to increase public awareness of the issues and their importance. Several working groups have been established. An executive secretary and two administrative assistants comprise the staff (107).

The Nuffield Council on Bioethics, as a private body, has no regulatory role; it is advisory only. Nevertheless, the Foundation's initiative was welcomed by the government. One staff member is government salaried and the Council is regarded as the national voice within the British bioethics community. In fact, in composition and procedures, the Council conducts business as if it had been created by the government. Nevertheless, to date, many European bioethics forums have been intergovernmental, and government officials represent the United Kingdom. Thus, whether the British government will accord the Nuffield Council the same influence and authority in intergovernmental deliberations over bioethical issues as other European counterparts enjoy is uncertain (53,54,68,76,107).

### MULTINATIONAL ORGANIZATIONS

Beyond efforts tailored to individual countries, ongoing efforts exist to address multinational, cross-cultural, or shared concerns about bioethical issues. This section briefly reviews some of the activities sponsored by international groups.

#### ■ United Nations System

In January 1993, the General Director of the United Nations Educational, Scientific, and Cultural Organization (UNESCO) asked its Scientific and Technical Group to submit proposals for establishing an International Consultative Committee of Bioethics (120). The Committee will consist of 40 experts; its first task will be considering whether an international convention on the human genome should convene. The convention

would deal with subjects linked to bioethics and human rights, especially problems stemming from trade of human tissues and cells, the use of genetic tests, eugenics, and cloning (120). The United Nations Fund for Population Assistance (UNFPA) has also provided funds for conferences that included bioethical issues (104).

In March 1993, the United Nations Commission on Human Rights adopted a Decision on Human Rights and Bioethics that seeks to ensure that the life sciences develop in a manner respectful of human rights. The Commission also promotes exchanges between national consultative bodies (48).

WHO has developed *Guiding Principles on Human Organ Transplantation* (endorsed in 1991 by the World Health Assembly). WHO's Health Legislation Unit also serves as a global clearinghouse for legislation, codes, and other measures in the field of bioethics. WHO reports on legislation and associated literature in a quarterly journal (48).

The Pan American Health Organization (PAHO) serves as the regional office of WHO for the Americas. Through publications and consultations, PAHO has fostered the development of bioethics in Central and South America. PAHO published the first regional survey of Latin American bioethics (19). PAHO and the University of Chile are also currently planning the establishment of a Pan American Institute of Bioethics, to be located at the University of Chile in Santiago. The Institute, slated to begin its work in 1994, will provide a "permanent place for . . . discussion of bioethical subjects," and its primary mission will be to support research and training in bioethics for the region (49).

#### ■ Council for International Organizations of Medical Sciences

The Council for International Organizations of Medical Sciences (CIOMS) is an international, nongovernmental organization established in 1949 by two United Nations agencies (WHO and UNESCO). It began as a vehicle to facilitate the exchange of scientific information in the medical sciences through coordination of international organizations of medical sciences and support of international congresses on medical sciences. Since 1966, CIOMS has focused less on purely scientific medical subjects and more on the social and cultural impacts of medical science. The main activity of CIOMS has become the convening of broadly

based, multidisciplinary, and internationally representative conferences concerned with the impact of progress in biomedical science on society, and in fields such as bioethics, health policy, drug development, and medical education, CIOMS, with WHO, has published the proceedings of many conferences and offered international ethical guidelines on a number of topics (6,7,24,25,128). In 1985, CIOMS constituted a steering committee on bioethics with representatives from a range of professional backgrounds and geographical locales, which in turn has organized “international dialogues” on ethical issues arising from many subjects, including human genome research (5).

### ■ Council of Europe

The Council of Europe (CE), an intergovernmental organization that seeks consensus among its 26 members on cultural and human rights issues, is active in bioethics. Following a 1985 resolution presented by the French Minister of Justice to the European Ministerial Conference on Human Rights, CE created an Ad Hoc Committee of Experts on Bioethics (CAHBI) to further the interests of member states in bioethical issues (42). In 1989, it held its First Symposium on Bioethics (20,74). In 1992, CE elevated CAHBI to full legal status within CE and changed its name to the Steering Committee on Bioethics (Comite Directeur sur la Bioethique, or CDBI).

CDBI consists of a diverse group of professionals and civil servants from member states and has delivered a number of reports from its working groups to the CE Committee of Ministers. Its activities have included a recommendation on international exchange and transportation of human substances, an opinion requested by the Netherlands government on voluntary euthanasia, and a report on assisted human reproduction. CDBI also has been particularly interested in issues of genetic screening, genetic testing, as well as forensic applications of DNA tests (21,64).

CDBI aims “to fill the political and legal gaps that may result from the rapid development of biomedical sciences,” but to do this it must achieve the consensus of member states. It deals with this challenge in several ways: by “promoting] constructive dialogue between the member states;” by attending to the “principles and values which must guide any regulation in bioethics;” and by making “special efforts in order to

identify the fundamental points on which the member States are unanimous” (22).

In 1989, CAHBI considered a proposal to create a European Bioethics Committee, but in 1992 it judged this step premature (23). Nevertheless, the CE has held meetings of the chairpersons of various national ethics committees and special symposiums (64). CDBI is currently preparing, pursuant to a 1990 request from the Committee of Ministers, a Convention for Bioethics. The Convention will consist of a framework of fundamental principles, based loosely on the European Convention on Human Rights (86). The Convention will incorporate general principles rather than detailed regulations, though these statements of principles could eventually become the basis for detailed protocols (109). Currently, protocols in organ transplantation, medical research involving humans and embryos, and the use of genetic information for nonmedical purposes are under preparation (23). The Convention is expected to be ready in 1994 and will be open to nonmember states (64).

### European Community

Bioethics has emerged as an important human rights element of the European Community’s (EC) scientific research policy (38). The Commission of the European Community recently decided to undertake a number of initiatives in bioethics and has established several working groups. For example, the Working Group on Human Embryos and Research intends to “determine] the area of consensus . . . and development of a common [legal] code,” with the goal of pressuring member states to enact legislation where regulations are weak or nonexistent (44). In 1992, the EC formed a working group on the ethics of biotechnology (44).

The Working Group on Ethical, Social, and Legal Aspects (ESLA) of Human Genome Analysis has educational functions, but has also been charged to “make recommendations for future Commission initiatives-including legislation. Its charter requires it to take account of specific documents on human rights, including the Universal Declaration of Human Rights issued by the United Nations in 1948. Following a call for proposals, ESLA has funded 18 studies on ethical issues. The studies vary from applied to theoretical and examine a variety of key issues in human genetics (38,41).

The EC also empaneled an international commission on ethical issues in reproductive technology, called the Working Party on Ethical and Legal Issues Raised by New Reproductive Technology, or the Glover Commission. Despite cultural differences among the members and very little staff, the Glover Commission produced a report that is distinctive in its dissection of the moral arguments and premises on which rival positions on these issues rely (124). Though CE had no plans for publication, the Commission's chair, on his own initiative, brought the Commission's findings to public attention by arranging for their publication by academic presses (54,55).

In 1991, the EC identified general biomedical ethics as a fundamental research area in the Biomedical and Health Specific Program (37,40). The EC has established a research program in bioethics that appears to be the world's sole general fund for investigator-initiated general bioethics research. Proposals were solicited, and grants were provided for work that evaluates biomedical ethics issues and assesses the social impact and risks of current biomedical and health research programs. To date, eight projects have been funded, including grants addressing organ transplantation, artificial procreation, and AIDS. Initial funding for the eight grants was approximately 1.9 million ECU. Total funding under the program, approved for 1990-94, is slated at 4.67 million ECU (8).

## ■ European Parliament

The European Parliament seeks technical advice from its Scientific and Technological Options Assessment (STOA) Programme. STOA recently commissioned a major study that provides an analysis of the status of bioethics in Europe (42). The preliminary report indicates that the goal of European bioethics is regulation to ensure safety and to protect fundamental human rights. The report finds that "generally the first step toward the creation of successful regulation is the constitution of ethics committees to study the consequences of the various biological and genetic technologies" (42). The report recognizes that not every country has established a national ethics committee, "so the theory of harmonization of regulation will be difficult to put into practice," though the report nevertheless urges inter-European harmonization of law and recommendations (42).

The STOA report also discusses bioethics in the CE and EC and finds that the scope of these efforts largely overlaps. According to one EC official, however, the CE and EC have different roles to play in bioethics (44). The former gives general recommendations; the latter can submit proposals on specific regulations to the European Parliament. The CE can inspire new law, but it will be the law of member states. The CE and the EC are now taking steps to ensure cooperative activity in the field (70).

## ■ Other International Organizations

Other multinational bioethics organizations also are being created and include academic, government-sponsored, and professional groups and societies.

With the support of two U.S. foundations—Ford and Rockefeller—and WHO and UNFPA, the International Islamic Center for Population Studies and Research, A1-Azhar University in Cairo, Egypt hosted the first conference on the ethics of human reproduction research in the Muslim world in December 1991. The conference resulted in the adoption of ethical guidelines for human reproduction research in the Muslim world and the creation of the first Ethics Committee for Human Reproduction Research at A1-Azhar University, Cairo, Egypt (60,61,104). Similarly, the Islamic Organization for Education, Sciences, and Culture collaborated with the Faculty of Sciences at Qatar University to organize a meeting in February 1993 on the ethical implications of and guidelines for genetic research (104).

In 1987, the Medical Research Council of Canada and Canada's Department of National Health and Welfare convened an International Summit Conference on Bioethics (81). In 1990, the International Association of Human Biologists and the Japan Society of Human Genetics convened an International Panel Discussion on Education and Ethics in Medical Genetics (51). Hosted by the National Health Council of the Netherlands, with the support of the EC, the International Association of Bioethics (IAB) held its inaugural congress in 1992. IAB, headquartered in Australia, provides a forum for diverse views on bioethical issues, but it does not take positions. The International Association of Law, Ethics, and Science gathers individuals interested in bioethics and pub-

lishes a journal partly devoted to the works of national and international bioethics commissions (113).

International bioethics has also received the support of the United States' Hastings Center, which has held international bioethics conferences in Eastern Europe and other areas (34). The Eubios Ethics Institute in Christchurch, New Zealand and Tsukuba, Japan is a nonprofit group that holds international bioethics conferences, and publishes proceedings and newsletters (52). Among other public and private international bioethics groups are: the Fundacion Dr. Jose Maria Mainetti Escuela Latinoamericana de Bioetica, the European Association of the Centres of Medical Ethics, the International Federation of Catholic Universities' International Study Group on Bioethics, the Nordic Council's Bioethics Group, and the European Society for Philosophy of Medicine and Health Care, which has a Section for Medical Ethics in the Nordic Countries (2,64,70,1 16).

## COMMON THEMES

Existing international commissions vary, and it is impossible to reach conclusions linking structure to performance. Because the commissions of each country exist in a unique cultural, political, social, and moral climate, it is dangerous to generalize too broadly or to transfer specific details too directly. Nevertheless, OTA's survey revealed several common points among international commissions: scope, sponsorship, public access, professional dominance, evaluation and soundness, role, structure, and a national voice. In particular, many countries' activities in bioethics stem from their interest in human rights.

Until recently, most bioethics commission abroad have been topical-i. e., devoted to one or a small number of issues-and temporary. Topics were selected, in advance, by the sponsor. The French commission, however, is wide ranging and seemingly permanent, with the freedom to choose its own topics. Other commissions established in Europe since the founding of the French commission also have been general, self generating, and open ended. Among the most influential commissions have been some single-topic efforts, such as the Wamock Committee in the United Kingdom. The clear trend, however, is toward a permanent bioethics commission that addresses new issues as they arise (124).

The independence of the commission is regarded by all observers as essential to its authority. Whether based in the legislature or in the executive branch, all but the United Kingdom's commissions are public. Most answer to, and are located in, the ministries of health, in contrast to the United States' President's Commission, which was located administratively outside the departmental structure of the executive branch. Responses to OTA did not reveal that existing commissions were perceived as overly beholden to their ministries.

Most national commissions in other countries limit public access, and meetings are generally closed. In some cases, members of the public may offer their views through periodic public symposia. One reason offered for the lack of public access is that some commissions rule on particular cases requiring confidentiality.

All governments have tried to ensure membership of non-health care professionals. In some cases, physicians and scientists are a clear minority. No survey data exist regarding public perceptions of the commissions as independent versus captured by special interests, but where separate committees exist to oversee human subjects research, these tend to be perceived as protective of the interests of physicians and scientists-even when lay members are present or even a majority (124).

Though bioethics commissions can be evaluated for productivity, influence, and soundness, little has been done in any country to date. Fragmentary though the responses to OTA's questionnaire were, however, it was striking that respondents' academic credentials were inversely related to their opinions about the soundness of the bioethics commission reports (124). Complaints that findings of various commissions are poorly argued, or not argued at all, were common.

National bioethics commissions abroad differ in their basic purpose. In some instances, they are directly advisory to parliaments; their existence is justified by their government's perceived need to develop legislation on complex technological and scientific issues through a slower and more deliberative process than allowed by usual legislative procedures. Other commissions exist to stimulate and educate the public, and still others assume the role of distilling and articulating a national sensibility on bioethical matters.

Particularly in international councils, national bioethics committees are increasingly seen as defining their nation's position on bioethics issues. To this extent, committees, and sometimes their members, act as or are viewed as national spokespersons (124).

All foreign bioethics bodies have a chair and numerous members, though they vary in size by a factor of four. Larger bodies can be more representative, but **sacrifice** working efficiency (65). More striking is the difference in the size of the staff, and complaints about lack of staff were frequent among responses to OTA's survey. Most have few-one to two-though isolated initiatives have larger staffs and more senior individuals. Only Canada has provided its Royal commissions a staff comparable to that found in the United States.

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