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Advisory Commission

CONTRIBUTING
TO PUBLIC POLICY

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About the cover: The picture portrays nature, science, and the impact of man on both. "DNA Nucleotides between Dogwood & the Judas Tree," stoneware wall plaque, by Jane W. Larson, Bethesda, MD. Photograph by Philippe C. Bishop.

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BACKGROUND ON THE NATIONAL BIOETHICS ADVISORY COMMISSION

The National Bioethics Advisory Commission (NBAC) was established by Executive Order 12975 in October 1995 to advise the National Science and Technology Council and other appropriate government entities regarding “bioethical issues arising from research on human biology and behavior.” NBAC was established in response to an unmet need for a national commission to address a broad set of ethical issues. NBAC was the fifth federal bioethics commission created to contribute to the development of public policy and to promote a national discussion on complex bioethical issues. NBAC met for the first time on October 4, 1996. On October 3, 2001, the commission’s charter expired, and NBAC’s tenure ended. During its tenure, NBAC met 48 times and submitted six major reports to the White House.

The NBAC reports offered 120 recommendations designed to improve the protection of human participants in research while also supporting the continued advancement of science and the promotion of ethically sound research. Three of the reports were requested by the president—*Cloning Human Beings*, *Ethical Issues in Human Stem Cell Research*, and *Ethical and Policy Issues in Research Involving Human Participants*—and three were initiated by the NBAC commissioners—*Research Involving Persons with Mental Disorders That May Affect Decisionmaking Capacity*, *Research Involving Human Biological Materials: Ethical Issues and Policy Guidance*, and

Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries.

THE RESPONSE TO NBAC'S REPORTS AND RECOMMENDATIONS

This report provides a detailed account of the responses to each of NBAC's six reports by the president, U.S. Congress, federal and state government, professional societies, philanthropic foundations, organizations representing private industry, patient advocacy groups, other countries, and international organizations. These entities are responsible for decisionmaking and policy formulation in regard to scientific issues in this country and abroad. Therefore, their response to NBAC's reports and recommendations can be used as an indication of the extent to which NBAC's work is reflected in public policy and public discourse.

The response was tracked by collecting documents that referred to or were based on any of NBAC's reports and recommendations, including but not limited to federal and state legislation; congressional testimony; presidential administration and federal agency guidelines, statements, policies, and procedures; statements from various professional and academic societies, organizations, and foundations; and laws, regulations, and guidelines from other countries and international organizations. Discussions on NBAC's reports and recommendations in the academic literature and in the media were also tracked.

Whether or not policy recommendations are implemented depends in part on how those recommendations are formulated and to whom they are targeted. NBAC took this into account when it was formulating its recommendations by carefully considering the types of policy changes it was recommending and to whom they were directed. For example, NBAC made several recommendations directed to Congress, state governments, and federal agencies that called for a variety of actions, including legislation, regulations, guidance documents, and support for both professional and public education. NBAC also made several recommendations to the scientific and medical communities, a number of which were directed specifically to professional societies, funding institutions, and the private sector,

and appealed to the private sector for voluntary compliance with many of its recommendations. Furthermore, in some of its reports, NBAC recommended international cooperation.

NBAC's reports and recommendations prompted responses from the president of the United States and the presidential administration, Congress, state governments, federal agencies, professional societies, philanthropic foundations, organizations representing private industry, patient advocacy groups, other countries, and international organizations. The responses varied from a passing mention of NBAC to the introduction of state and federal legislation based on NBAC's recommendations and adoption of NBAC's recommendations into guidance and policy statements. However, not all of the responses to NBAC's reports and recommendations were favorable. Some of its recommendations were criticized as being cumbersome, impractical, and in danger of impeding valuable research, while some were criticized for not being restrictive enough.

Government Response

Several types of policy were implemented in response to NBAC's recommendations. Although no federal or state legislation was signed into law, federal and state bills based on NBAC's recommendations were introduced, and Congress was informed about NBAC's work through congressional testimony by NBAC commissioners and others. Thirteen bills were introduced in Congress that mentioned NBAC—four were introduced in response to the human cloning debate, eight dealt with the privacy of genetic and medical information, and one addressed the system for oversight for the protection of human research participants. In addition, bills on human cloning, decisionmaking capacity, and genetic privacy that mentioned NBAC or were based on NBAC's recommendations were introduced in the state legislatures of four states. In addition, NBAC commissioners and staff testified before Congress 18 times after being invited by subcommittees of the House and Senate to discuss ongoing work and completed projects.

Federal agencies have issued guidance and policy statements in response to NBAC's reports and recommendations. The National Institutes of Health (NIH), the government agency responsible for the majority of federally funded research involving human participants,

has issued guidance based on recommendations made in three of the NBAC reports—*Research Involving Persons with Mental Disorders That May Affect Decisionmaking Capacity*, *Research Involving Human Biological Materials*, and *Ethical Issues in Human Stem Cell Research*. The Food and Drug Administration (FDA) has adopted NBAC's terminology and recommendations on informed consent found in the *Research Involving Human Biological Materials* report, and the National Institute for Occupational Safety and Health (NIOSH) at the Centers for Disease Control and Prevention (CDC) has instructed all investigators who perform research involving persons with developmental disabilities to review NBAC's recommendations on informed consent in the *Research Involving Persons with Mental Disorders That May Affect Decisionmaking Capacity* report.

Response from Professional Societies, Organizations, and Foundations

A number of professional and academic societies, organizations, and foundations have taken note of NBAC's reports and have released policy statements, issued guidance documents, and developed educational materials based on NBAC's recommendations for their members to consider. Several professional and scientific societies, as well as organizations representing the biotechnology and pharmaceutical industries, have called for a five-year voluntary moratorium on human cloning, as recommended in the *Cloning Human Beings* report. The Alzheimer's Association funded research on the potential impact of NBAC's recommendations in the *Research Involving Persons with Mental Disorders That May Affect Decisionmaking Capacity* report. Intermountain Health Care issued policies and procedures for institutional review boards (IRBs), and the Online Ethics Center for Engineering and Science developed an online teaching module, both of which were based on NBAC's recommendations in *Research Involving Human Biological Materials*. The Endocrine Society in its Code of Ethics and the American Medical Association (AMA) in official policy supported the NBAC's *Ethical Issues in Human Stem Cell Research* report and the recommendations in it.

International Response

Other countries and several international organizations have studied NBAC's reports and have supported some of the commission's recommendations. The United Kingdom's Human Fertilisation and Embryology Authority (HFEA) and the Human Genetics Advisory Commission (HGAC) supported NBAC's recommendations in *Cloning Human Beings*, and the Nuffield Council on Bioethics endorsed some of the recommendations in *Ethical Issues in Human Stem Cell Research*. NBAC's reports and recommendations have been cited in various publications in Australia, Canada, Japan, and the United Kingdom and in reports by several international organizations, including the Organisation for Economic Co-operation and Development (OECD) and the United Nations Educational, Scientific, and Cultural Organization (UNESCO). In addition, the NBAC reports have been widely circulated internationally, and have been translated into Japanese and published in a German science and ethics journal.

SHORT-TERM AND LONG-TERM ASSESSMENT OF NBAC'S WORK

Even though NBAC's tenure has concluded, debate on many of the issues addressed by NBAC has continued, and will continue for some time to come. Therefore, this report represents an early assessment of the response to NBAC's work. However, given the complex nature of the issues addressed by NBAC and the usual pace of the policy-making process, the response to NBAC's reports and recommendations should also be assessed over time to determine both their immediate and their long-term impact.

Succeeding administrations and bioethics commissions, and in particular the President's Bioethics Council, should be very interested in what NBAC recommended and the response to its work. During its deliberations, NBAC examined the work of several previous commissions, including the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, and the Advisory Committee on Human Radiation Experiments.

NBAC has increased the awareness of the U.S. and foreign governments, international groups, the research community, and the public about complex bioethical issues, providing a forum for their public debate, and making recommendations that have been incorporated into the system of oversight for the protection of human research participants. Several of the issues that were addressed by NBAC in its reports, including human cloning, human stem cell research, and the protection of human research participants, are currently under discussion or are being examined by Congress, the President's Council on Bioethics, some federal agencies, and various other groups for legislation, recommendations, or other actions. Therefore, NBAC's reports and recommendations will continue to be relevant to ongoing policy debates on bioethics issues.