2009 Current Fiscal Year Report: President's Council on Bioethics

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1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2009

3. Committee or Subcommittee	3b. GSA Committee No.
President's Council on Bioethics	12151

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	10/01/2007		

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
Yes		09/30/2009

9. Agency Recommendation for Next FiscalYear	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Terminate	No	

11. Establishment Authority Presidential

12. Specific Establishment Authority	13. Effective Date	14. Commitee Type	14c. Presidential?
EO 13237	11/28/2001	Continuing	Yes

15. Description of Committee National Policy Issue Advisory Board

16a. Total Number of Reports 2

16b. Report Date	Report Title
12/31/2008	Controversies in the Determination of Death: A White Paper of the President's Council on Bioethics
12/31/2008	The Changing Moral Focus of Newborn Screening: An Ethical Analysis by the President's Council on Bioethics

Number of Committee Reports Listed: 2

17a. Open 2 **17b. Closed** 0 **17c. Partially Closed** 0 **Other Activities** 0 **17d. Total** 2

Meetings and Dates

Purpose	Start	End
To meet with Council Members and invited guest speakers to discuss bioethics issues.	11/20/2008	11/21/2008
To meet with Council Members and invited guest speakers to discuss bioethics issues.	03/12/2009	03/13/2009

Number of Committee Meetings Listed: 2

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$27,000.00	$0.00
18a(2). Personnel Pmts to Federal Members	$0.00	$0.00
18a(3). Personnel Pmts to Federal Staff	$1,500,000.00	$0.00
18a(4). Personnel Pmts to Non-Member Consultants	$40,000.00	$0.00
18b(1). Travel and Per Diem to Non-Federal Members	$63,000.00	$0.00
18b(2). Travel and Per Diem to Federal Members	$0.00	$0.00
18b(3). Travel and Per Diem to Federal Staff	$30,000.00	$0.00
18b(4). Travel and Per Diem to Non-member Consultants	$28,000.00	$0.00
18c. Administrative Costs (FRNs, contractor support, In-person/hybrid/virtual meetings)	$0.00	$0.00
18d. Other (all other funds not captured by any other cost category)	$612,000.00	$0.00
18e. Total Costs	$2,300,000.00	$0.00
19. Federal Staff Support Years (FTE)	10.00	0.00

20a. How does the Committee accomplish its purpose?

The function of the President's Council on Bioethics has been to conduct fundamental inquiry and research into the ethical implications of advances in biomedicine, biomedical research, and biotechnology. With the fruits of this inquiry and research, the Council has sought to serve several key purposes: (1) first and foremost, to advise the President on these ethical implications and thus to inform and enhance the policymaking process; (2) to provide a forum for national discussion of, and to educate the public on these ethical implications; and (3) to collaborate on the discussion and analysis of the ethical implications of these advances in international forums.Since its establishment in November 2001, the Council has conducted inquiries into a broad range of issues, including: age retardation/life extension; aging and end-of-life care and treatment; enhancement technologies; ethical issues in the care and treatment of children; health care reform; reproductive and research cloning; nanotechnology; neuroethics; newborn screening; genomic medicine; organ donation, procurement, allocation, and transplantation; property in the body; sex selection; adult and embryonic stem cells; research ethics; and the crisis of the health professions. With respect to purpose (1) above, the Council has sent ten reports to the President since its establishment: Human Cloning and Human Dignity: An Ethical Inquiry (2002); Beyond Therapy: Biotechnology and the Pursuit of Happiness (2003); Being Human: Readings from the President's Council on Bioethics (2003); Monitoring Stem Cell Research (2004); Reproduction and Responsibility: The Regulation of New Biotechnologies (2004); Alternative Sources of Human Pluripotent Stem Cells (2005);

Taking Care: Ethical Caregiving in Our Aging Society (2005); Human Dignity and Bioethics: Essays Commissioned by the President's Council on Bioethics (2008); The Changing Moral Focus of Newborn Screening (2008); and Controversies in the Determination of Death (2009). Two additional reports to the President were completed but not published due to the June 2009 dismissal of the members by President Obama: a report entitled Organ Transplantation: An Ethical Inquiry by the President's Council on Bioethics and a white paper entitled Health Care and the Common Good. As for purpose (2) above, the Council's meetings were open to the public. In addition, its reports have been widely disseminated, not only to the President, but also to members of the U.S. Congress, to selected policymakers in the departments of the executive branch, as well as to members of the judicial branch. The reports have been distributed, too, to colleges and universities, academicians, and to interested members of the public. The Council also sought to broaden its meeting venues by holding sessions away from Washington, D.C., and in other locales, such as Chicago, Illinois, and Chapel Hill, North Carolina. Finally, the Council collaborated with educational institutions (i.e., the University of Chicago, Georgetown University, Stanford University, and Harvard University Law School) to hold specialized colloquia for the discussion of bioethical issues under Council consideration.As for purpose (3) above, the Council's chairman and executive director were integrally involved in international forums for the discussion and resolution of bioethical issues. The chairman served as a member of the International Bioethics Committee of UNESCO and was instrumental, during his tenure, in the IBC's development of UNESCO's Universal Declaration on Bioethics

and Human Rights. The executive director served as the lead observer delegate to the twice-yearly meetings of the Council of Europe's Steering Committee on Bioethics in Strasbourg, France, and has also participated in and contributed to such international forums as the 7th Global Summit of National Bioethics Committees held in Paris, France in September 2008.

20b. How does the Committee balance its membership?

The Council had 18 members, drawn from a diversity of disciplines and fields, including theology, biochemistry, ethics, public policy, economics, medicine, the law, psychiatry, philosophy, and political theory. They were, as well, diverse in terms of their religious and political perspectives.

20c. How frequent and relevant are the Committee Meetings?

The Council met four to five times per year. As for relevance, the meetings were critical to the Council's deliberations and thus to the development and finalization of its ten reports (and the two completed but not published reports on organ transplantation and health care reform).

20d. Why can't the advice or information this committee provides be obtained elsewhere?

Since the mid-20th century, American and other societies and cultures have been the beneficiaries of undeniable advances in medicine, research, and biotechnology—but they have also had to contend, not only with the benefits but also the often troubling ethical challenges that come with these benefits. These challenges have profound implications: for our established system of law and policy, for resource allocation, and for the quality

of our individual and collective lives. Nearly every country in Europe and North America (and increasingly in South America, Asia, and Africa) has established some body to explore these challenges and offer consultative advice and recommendations to policymakers at various levels of government. In brief, bioethical issues are inextricably bound up with the promotion and the sustenance of the civic good, which is the goal and object of government. A group like the President's Council on Bioethics is a necessary means to this end.

20e. Why is it necessary to close and/or partially closed committee meetings?

The Council's meetings were always open to the public.

21. Remarks

The Council has initiated and been engaged in numerous inquiries since its establishment (as described under the section of this report entitled "performance measures"). Ten reports have been issued as a result. Two additional reports (on organ transplantation and health care reform) were completed but not approved for dissemination due to the June 2009 dismissal of the Council members. The Council could initiate an inquiry, gather information and data through expert presentations, seek to clarify the ethical questions (especially those of relevance to the need for public education and for policy formation by the President and/or U.S. Congress), and yet conclude that these questions are such that the Council has no unique contribution to make to debate "in the public square." Or, it could decide that it did have a unique contribution to make and thus should devote the requisite staff resources (and Council effort) to an inquiry that will issue in a

report to the President and the public. With any one of these potential results, the process was neither "quick" nor superficial. Of the topics pursued by the Council, the members ultimately decided not to move forward to the issuance of a report on such topics as the ethics of clinical research, children and bioethics, neuroethics, and the crisis of the health professions. With the topic of nanotechnology, although the Council decided not to pursue and issue a comprehensive report, it did publish a memorandum summarizing its findings and its conclusion that this topic does, indeed, merit close monitoring and ongoing inquiry as its consequences and implications become more clear—and, perhaps, worthy of a more in-depth treatment. The process of moving forward with an inquiry that issues in a report usually entailed additional research, staff drafting of the text, and then the distribution of the draft text to selected experts in the field, prior to finalizing the text. This process was implemented in an effort to ensure that the ultimate product of our work was conceptually sound, empirically/factually correct, and of the best quality possible to present to the President, and consequently for dissemination to members of the U.S. Congress and the general public. Finally, with respect to stem cell research, the Council held a session on this topic in November 2006. The Council Chairman, Dr. Edmund Pellegrino, consulted with President Bush on legislative activity in this topic area, thus fulfilling the first and foremost mission of the Council, to advise the President on advances in biotechnology, biomedicine and biomedical research.

Designated Federal Officer

Frank D. Davis Executive Director

Committee Members	Start	End	Occupation	Member Designation

Bloom, Floyd	04/04/2006	06/11/2009	Professor Emeritus in the Molecular and Integrative Neuroscience Department at The Scripps Research Institute	Special Government Employee (SGE) Member
Carson, Benjamin	03/10/2004	06/11/2009	Professor and Director of Pediatric Neurosurgery, Johns Hopkins Medical Institution	Special Government Employee (SGE) Member
Dresser, Rebecca	01/16/2002	06/11/2009	Daniel Noyes Kirby Professor of Law and Professor of Ethics in Medicine, Washington University, St. Louis	Special Government Employee (SGE) Member
Eberstadt, Nicholas	04/04/2006	06/11/2009	Henry Wendy Chair in Political Economy, American Enterprise Institute	Special Government Employee (SGE) Member
Elshtain, Jean	06/24/2008	06/11/2009	Laura Spelman Rockefeller Professor of Social and Political Ethics in the Divinity School, The University of Chicago; Thomas and Dorothy Leavey Chair, Foundation of American Freedom, Georgetown University	Special Government Employee (SGE) Member
Foster, Daniel	01/16/2002	06/11/2009	John Denis McGarry, Ph.D. Distinguished Chair in Diabetes and Metabolic Research, UT Southwestern Medical Center, Dallas, TX	Special Government Employee (SGE) Member
Gazzaniga, Michael	01/16/2002	06/11/2009	Director of Sage Center for the Study of Mind, University of California, Santa Barbara	Special Government Employee (SGE) Member

George, Robert	01/16/2002	06/11/2009	McCormick Professor of Jurisprudence, Director of the James Madison Program in American Ideals and Institutions, Princeton University	Special Government Employee (SGE) Member
Gomez-Lobo, Alfonso	01/16/2002	06/11/2009	Ryan Family Professor of Metaphysics and Moral Philosophy, Georgetown University	Special Government Employee (SGE) Member
Hurlbut, William	01/16/2002	06/11/2009	Consulting Professor, Neurology and Neurological Sciences, Stanford Medical Center, Stanford University	Special Government Employee (SGE) Member
Landry, Donald	06/24/2008	06/11/2009	Professor of Medicine, Director of the Division of Experimental Therapeutics; Chair, Department of Medicine, Columbia University	Special Government Employee (SGE) Member
Lawler, Peter	03/10/2004	06/11/2009	Dana Professor and Chair of the Department of Government and International Studies, Berry College	Special Government Employee (SGE) Member
McHugh, Paul	01/16/2002	06/11/2009	University Distinguished Service Professor of Psychiatry, Johns Hopkins University School of Medicine	Special Government Employee (SGE) Member
Meilaender, Gilbert	01/16/2002	06/11/2009	Richard and Phyllis Duesenberg Professor of Christian Ethics, Valparaiso University	Special Government Employee (SGE) Member

Pellegrino, Edmund	09/19/2005	06/11/2009	Profesor Emeritus of Medicine and Medical Ethics, Center for Clinical Bioethics, Georgetown University Medical Center.	Special Government Employee (SGE) Member
Rowley, Janet	01/16/2002	06/11/2009	Blum-Riese Distinguished Service Professor of Medicine, Molecular Genetics and Cell Biology, and Human Genetics, Pritzker School of Medicine, Unviersity of Chicago	Special Government Employee (SGE) Member
Schaub, Diana	03/10/2004	06/11/2009	Professor and Chairwoman of Political Science, Loyola College	Special Government Employee (SGE) Member
Schneider, Carl	06/14/2006	06/11/2009	Chauncey Stillman Professor of Ethics, Morality, and the Practice of Law, and Professor of Internal Medicine, University of Michigan	Special Government Employee (SGE) Member

Number of Committee Members Listed: 18

Narrative Description

The U.S. Department of Health and Human Resources (HHS) has promulgated a strategic plan for FY2007-FY2012 with four goals; the third goal is to promote the economic and social well-being of individuals, families and communities and the fourth goal is to advance scientific and biomedical research and development related to health and human services. The social well-being of individuals, families, and communities depends, in part, on health interventions that are not only clinically effective but also ethically valid; moreover, the optimal advancement of scientific and biomedical research depends not only on funding and well-conceived goals but also upon thoughtful analysis of the ethical questions that are, inevitably, generated by such progress.

As the nation’s principal forum for public bioethics—for advising the President and for educating the public—the President’s Council on Bioethics has contributed to the accomplishment of these goals. As a public body established by and responsible to the President, the Council has sought to illuminate these ethical questions in practical, useful ways, for both policymakers and the public at large. The Council's purpose has been to advise the President on bioethical issues related to advances in biomedical science and technology. In connection with its advisory role, the mission of the Council has included the following functions: (1) to undertake fundamental inquiry into the human and moral significance of developments in biomedical and behavioral science and technology; (2) to explore specific ethical and policy questions related to these developments; (3) to provide a forum for a national discussion of bioethical issues; (4) to facilitate a greater understanding of bioethical issues; and, (5) to explore possibilities for useful international collaboration on bioethical issues. Since its establishment in November 2001, the Council has conducted inquiries into a broad range of bioethical issues and topics, some of which have issued in the publication of reports aimed at informing the President and other policymakers and at educating the American public. The topics that have been addressed by the Council include: the ethical implications of an increasingly aged population; age-retardation and life extension; reproductive and research cloning; embryonic and adult stem cells; ethical issues in the care and treatment of children, including pediatric psychoactive drugs; standards for the determination of death; property in the body; enhancement technologies for, e.g., boosting memory and other cognitive functions, physical performance, etc.; newborn screening; genetic technologies for diagnostic and therapeutic purposes; nanotechnology; the crisis of the health professions; organ transplantation; health and medical care reform; the ethics of clinical research; conscientious refusals in medicine; futility and end of life care; and neuroethics. The Council has issued, to date, ten reports: Human Cloning and Human Dignity: An Ethical Inquiry (2002); Beyond Therapy: Biotechnology and the Pursuit of Happiness (2003); Being Human: Readings from the President's Council on Bioethics (2003); Monitoring Stem Cell Research (2004); Reproduction and Responsibility: The Regulation of New

Biotechnologies (2004); Alternative Sources of Human Pluripotent Stem Cells (2005); Taking Care: Ethical Caregiving in Our Aging Society (2005); Human Dignity and Bioethics: Essays Commissioned by the President's Council on Bioethics (2008); The Changing Moral Focus of Newborn Screening (2008); and Controversies in the Determination of Death (2009). As of September 2009, two additional reports have been completed but have not been approved for publication: Organ Transplantation: An Ethical Inquiry by the President's Council on Bioethics and Health Care and the Common Good.

What are the most significant program outcomes associated with this committee?

	Checked if Applies
Improvements to health or safety	✓
Trust in government	✓
Major policy changes	✓
Advance in scientific research	✓
Effective grant making	
Improved service delivery	
Increased customer satisfaction	
Implementation of laws or regulatory requirements	✓
Other	

Outcome Comments

NA

What are the cost savings associated with this committee?

	Checked if Applies
None	
Unable to Determine	✓
Under $100,000	
$100,000 - $500,000	
$500,001 - $1,000,000	
$1,000,001 - $5,000,000	
$5,000,001 - $10,000,000	

Over $10,000,000 ☐
Cost Savings Other ☐

Cost Savings Comments
NA

What is the approximate Number of recommendations produced by this committee for the life of the committee?
18

Number of Recommendations Comments
Since its inception, the Council has issued ten reports. Among other purposes, these documents have served as vehicles by which the Council conveys its formal recommendations to the President. Summaries of Council recommendations herein are solely for the purpose of responding to this FACA questionnaire and should be viewed in that context. The reports themselves stand as the final word on the recommendations the Council has made. With that background in mind, the following is offered as an account of the Council's recommendations to date. In its report, Human Cloning and Human Dignity, the Council made three formal recommendations: a majority and a minority of council members recommended a ban on cloning-to-produce-children; a majority of council members recommended a four year moratorium on human cloning-for-biomedical-research while a minority recommended regulating the use of cloned embryos for biomedical research; and a majority of council members recommended a federal review of current and projected practices of human embryo research, pre-implantation genetic diagnosis, genetic modification of human embryos and gametes, and related matters. In its report, Reproduction and Responsibility, the Council unanimously made three categories of recommendations with multiple proposals in each of the following areas: federal studies, data collection, reporting, and monitoring regarding the uses and effects of reproductive technologies; increased oversight by professional societies and practitioners; and targeted legislative measures. And in Taking Care: Ethical Caregiving in Our Aging Society, the Council unanimously made one formal recommendation, already noted above, as well as several less specific proposals. In addition, in its white paper on newborn screening, the Council made seven specific recommendations, directed at policymakers at both the state and federal levels. Finally, in its white paper, Controversies in the Determination of Death, the Council makes one overarching recommendation, i.e., that the current standards for declaring death—the neurological and the cardiorespiratory standards—be maintained by the states and in clinical practice. In the white paper, however, the Council does offer a novel justification for the neurological standard as a means of strengthening the ethical basis for the

standard, especially in the face of often radical proposals for change, some of which would substitute “higher brain” formulations for “total brain failure” as a criterion for declaring that an individual with severe neurological injury is dead.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?
10%

% of Recommendations Fully Implemented Comments
In its 2005 report, Taking Care, the Council recommended the establishment of a Presidential Commission on Aging, Dementia, and Long-Term Care. As of this date, no action has been taken on this recommendation. The Council’s May 2005 publication, Alternative Sources of Human Pluripotent Stem Cells: A White Paper, and the Council discussions with scientists that preceded it [for example, at the meeting December 2-3, 2004 (see transcript at www.bioethics.gov)], set the stage for experimental work that could ameliorate the political and ethical disputes that continue to surround stem cell research.The Council’s Beyond Therapy report, which was released in 2003 and which raises ethical concerns about the use of performance enhancing drugs in sports, was echoed in the President’s State of the Union remarks in January, 2004, and has served to inform the debate as Congress and the professional sports industries have worked to strengthen standards and penalties in this area. Similarly, the Council’s Cloning report has been an important source of information for the Congress as it grapples with legislative proposals in the field of human cloning, including consideration of a ban on human cloning. Even international developments seem to have progressed in a direction similar to that of the Council’s majority opinion, for example, when on March 8, 2005, the United Nations General Assembly adopted a Declaration calling on all nations to pass legislation that would ban the cloning of human embryos. And finally, based on published scientific studies of which we are aware, it appears that biomedical researchers in this country have effectively adhered to a moratorium on cloning-for-biomedical-research and have refrained from cloning-to-produce-children.The Council’s white paper on newborn screening was instrumental to considerations by the Secretary of Health and Human Services regarding federal support for state based screening programs.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?
30%

% of Recommendations Partially Implemented Comments
The staff has never attempted a comprehensive study to determine, with precision, the

impact of the Council's recommendations. Although the Council is a presidential advisory body, PCBE reports are also sent to other branches of the federal government, heads of relevant agencies, international bodies, scientific and legal research organizations, public associations and the like. They are distributed at no charge to the public and posted electronically on our website. Consequently, the potential audience for our recommendations is extremely broad. It is not possible to determine with accuracy whether actions taken by an institution or an individual are directly attributable to a specific recommendation made by the Council. Nevertheless, we think it appropriate to point out several developments that may have been influenced at least in part by the Council's recommendations. As discussed in the response above, the Council made three categories of recommendations in its report entitled Reproduction & Responsibility. The first category included a recommendation that the federal government undertake a study of the impact of assisted reproductive technologies on the health and development of children born with their aid. In response, the federal government's upcoming "National Children's Study will have a special focus on children conceived with assisted reproductive technologies (assuming the funding is granted). And the National Institute for Child Health and Development is funding laboratory research to better assess the vulnerability of the developing egg and early embryo."The second category was a call for increased oversight by professional societies and practitioners and included a recommendation to strengthening informed patient decision-making. In direct response to the Council's report, the American Infertility Association (now the American Fertility Association), issued a press release calling for "simple language, uniform patient consent forms." The report received a similarly positive reception from a number of other professional societies, including those representing practitioners.The third category of recommendations was directed to Congress and included a proposal to prohibit issuing patents on claims directed to or encompassing human embryos or fetuses at any stage of development. The Weldon Amendment, which became law several months before the release of the Council's Cloning report, accomplishes this task by preventing federal funds from being used to issue such patents. Also in this third area, the Council recommended a prohibition on the buying and selling of human embryos. In his 2005 State of Union Address, President Bush stated, "I will work with Congress to ensure that human embryos are not created for experimentation or grown for body parts, and that human life is never bought or sold as a commodity." President Obama's new policies in this arena are, as well, aligned with these ethical principles.The Reproduction and Responsibility report, in that it constitutes a review of current ART-related practices, is itself in partial fulfillment of the Cloning report's majority recommendation to conduct a review of current and projected practices of human embryo research, pre-implantation diagnosis, genetic modification of human embryos and gametes, and related matters. Finally, it is possible to speculate, cautiously, on the probable impact of the Council's inquiries and reports on

newborn screening and the determination of death. The white paper on newborn screening has been hailed as a moderate, practical approach to some of the dilemmas encountered in this domain of public health. The white paper on the determination of death has been reviewed by experts in neurology and been received there as an impressively thorough examination of the issues and an important contribution to the field.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?

Yes ☐ No ☐ Not Applicable ☑

Agency Feedback Comments

NA

What other actions has the agency taken as a result of the committee's advice or recommendation?

	Checked if Applies
Reorganized Priorities	☐
Reallocated resources	☐
Issued new regulation	☐
Proposed legislation	☐
Approved grants or other payments	☐
Other	☐

Action Comments

The Council is not aware of other actions.

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

NA

How is access provided to the information for the Committee's documentation?

	Checked if Applies
Contact DFO	☑
Online Agency Web Site	☑
Online Committee Web Site	☑
Online GSA FACA Web Site	☑

Publications	☑
Other	☐

Access Comments

N/A