

Recommending a New Presidential Bioethics Commission

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For nearly half a century, federal commissions have advanced public dialogue and government policy on difficult ethical issues raised by emerging technologies, biomedical research, and health care. Yet since 2017, the U.S. has not had a bioethics commission to address such issues, or the increasingly complex questions raised by the COVID-19 pandemic, health inequities, genetic editing of living beings, artificial intelligence, and the accelerating climate crisis. These developments call for ethics analysis from an expert group that is interdisciplinary and publicly accountable. Such a commission can address the values conflicts underlying policy debates, promote public consensus, and inform decisions by regulatory and policy-making bodies that may not be authorized to consider broad ethical issues.

The current administration should follow the example of nearly every administration in the last 25 years and appoint a presidential bioethics commission.

History

Our nation has benefited from five major bioethics commissions since 1974 (see Appendix A). While the first two were created by Congress, since 1996 all Presidents except the last have appointed a bioethics commission to provide advice on governance of emerging technologies, ethically challenging advances in medical care, and protection of research participants. The work of these commissions has promoted the health, safety, and rights of patients and research participants, and has shaped oversight of emerging technologies. Assessments by the National Academies and RAND have documented the impact of these commissions, including their influence on the research community, federal agency guidelines, professional society policies, public policy debates, and both state and federal law.²

¹ Co-Chairs of the Bioethics Commission Working Group, convened by the National Academy of Sciences leadership.

² See Institute of Medicine, *Society's Choices: Social and Ethical Decision Making in Biomedicine* (National Academies Press, 1995); Elisa Eiseman, *The National Bioethics Advisory Commission: Contributing to Public Policy* (RAND, 2003). The extensive literature on national bioethics commissions includes articles collected in "Goals and Practice of Public Bioethics: Reflections on National Bioethics Commissions," *Hastings Center Report* May/June 2017(47):S1-S56.

Past bioethics commissions have produced seminal reports leading directly to policies still in force today. This includes the *National Commission* in the 1970s and its groundbreaking “Belmont Report,” which laid the foundation for today’s oversight system for research with human participants. In the early 1980s, the *President's Commission* recommended the “Common Rule” for all federally supported research with human participants, while some of its other reports shaped norms and law surrounding end-of-life care.³ The *National Bioethics Advisory Commission*’s work in the 1990s informed today’s policies for ethical use of banked human biological materials and transnational research in low-resource countries. In the 2000s, the *President's Council on Bioethics* issued reports with influential analysis of the dangers and opportunities posed by new technologies for human enhancement.

Most recently, the *Presidential Commission for the Study of Bioethical Issues*, convened by the Obama-Biden Administration, produced reports that anticipated challenges posed by synthetic biology and shaped federal investment in The BRAIN Initiative®.⁴ Its reports on “Ethics and Ebola: Public Health Planning and Response” and “Safeguarding Children: Pediatric Medical Countermeasure Research,” analyzed ethical issues in public health, which have become matters of urgent national concern during the COVID-19 pandemic.

Need for a New Commission

The United States has not had a federal bioethics commission since 2017. In the interceding five years, a global pandemic has raised profound ethical issues in public health research, clinical practice, and public policy—issues that require attention to the public good as well as individual autonomy. Those include how to formulate public policy in the face of uncertainty, how best to conduct rapid research on vaccines and treatments, how to reconcile population research with individual patient needs, how to allocate access to therapeutic interventions in times of scarcity, and how to address the devastating health disparities the pandemic has revealed.

³ As noted in Appendix A, the President’s Commission was followed by a failed effort to create a Biomedical Ethics Board in the legislative branch with six Senators and six Representatives equally divided between the two major parties. More specialized executive branch panels have included the Advisory Committee on Human Radiation Experiments (1994-95) established to investigate human radiation experiments and the intentional release of radiation between 1944 and 1974 and to recommend appropriate standards for evaluating the responsibility of individuals and institutions for those past acts.

⁴ The Brain Research Through Advancing Innovative Neurotechnologies® (BRAIN) Initiative. <https://braininitiative.nih.gov/>.

At the same time, our world faces a climate crisis that imperils the natural environment and human health. No prior bioethics commission has canvassed the ethical issues raised by research and interventions that can alter ecology, including genetic modification of insect populations to control transmission of certain deadly diseases, or using genome editing to rescue endangered species and perhaps even to revive some that are extinct. Nor has any commission addressed the health and equity implications of heat waves and heat stress, changes in the distribution of vector-borne diseases, flooding and displacement, and increased ozone pollution, to mention just a few effects of climate change. Yet ethical concerns—including our obligations to future generations—are central to understanding and solving these environmental problems.

Another domain not previously addressed by a bioethics commission is the growing integration of artificial intelligence (AI), machine learning, and software algorithms into medical and public health practice. The ethical challenges are profound. If complex algorithms are based on inadequate or unrepresentative data, their use risks magnifying and cementing racial and other bias into research and clinical care, while undermining professional expertise and shared decision-making with patients. Regulators face daunting challenges, such as ensuring the quality of adaptive algorithms that evolve as they are used. Ethical issues raised by AI in health care and public health call for exactly the kind of path-breaking analysis and consensus building that a bioethics commission can offer.

A bioethics commission could also advance analyses of existing technologies whose rapid development continues to raise unresolved issues. Genetic and genomic technologies, for example, offer an expanding range of predictive and screening tools – including direct-to-consumer tests -- with continuing debate over appropriate uses and safeguards. The growing use of such tools risks placing undue emphasis on genetics to the exclusion of social determinants of health. Genetic testing is also being used in areas such as immigration and law enforcement, raising privacy issues distinct from those raised by uses in health care. Meanwhile, emerging technologies that can alter the genetic makeup of animals and human beings challenge current oversight systems to protect responsible innovation while preventing abuse.

Creating a New Commission

The Executive Orders that created the past three bioethics commissions provide useful guidance. In general, they established committees with a dozen or more experts in biomedical, health, and social sciences, with members also drawn from law, philosophy, theology, and the humanities. Some commissions have included

individuals from the general public. Each Executive Order has anticipated application of the Federal Advisory Committee Act (FACA) and every commission has adopted means to ensure public participation. Past commissions had professional staff and resources to engage consultants. Regardless of which federal unit provided funding and administrative support, the commission was expected to provide independent analysis and advice.

Past Executive Orders have listed topics to be considered as well as criteria the commission should use in choosing additional topics for analysis. Such criteria have included the topic's significance, the need for regulatory and policy guidance, the availability of other deliberative fora, and the topic's relevance to the federal science and technology agenda. Commissions have been free to consider topics recommended by the federal government or the public.

While past Executive Orders provide a ready template, new topics—such as public health, climate change, and AI—warrant inclusion of members versed in these areas as well as behavioral science. The centrality of health disparities and health equity concerns in multiple domains requires a diverse and inclusive membership to perform searching ethical analyses of policy options. Even with an inclusive membership, a renewed bioethics commission should enrich the avenues for public participation.

Concluding Remarks

Across administrations of both major parties, bioethics commissions have modeled civil exchange of conflicting views, careful analysis, and well-considered advice. They have tackled problems that cross disciplinary lines, departmental and agency silos, and often state and federal jurisdiction. They have produced analyses leading to coordinated policy responses, while creating educational materials and catalyzing broad public discussion. They have also provided a means to address historic wrongs, to respond to presidential requests for ethical analysis of looming and disruptive developments, and to coordinate global responses by working with their counterparts in other countries. A bioethics commission appointed by the Biden-Harris Administration could similarly provide much-needed analysis of the major ethical challenges and policy choices facing our nation in public health, biomedicine, and climate science.

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Appendix A:

History of Bioethics Commissions & Reports⁵

Since 1974, the nation has benefited from five major federal commissions on bioethics. Each is listed below with a brief description and roster of reports. In the last 25 years, all Presidents have appointed a bioethics commission except the last administration: the National Bioethics Advisory Commission (NBAC) (1996-2001, appointed by the Clinton-Gore Administration); the President's Council on Bioethics (2001-09, appointed by the Bush-Cheney Administration); and the Presidential Commission for the Study of Bioethics Issues (2009-17, appointed by the Obama-Biden Administration).

The **National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1974-78)** was created by the National Research Act (P.L. 93-348) after revelation of the horrors of the Syphilis Trials conducted at Tuskegee. The commission produced ten reports, including the groundbreaking "Belmont Report," creating the basis of today's regulatory and institutional oversight system for human subjects research.

- Research on the Fetus (1975)
- Research Involving Prisoners (1976)
- Research Involving Children (1977)
- Psychosurgery: Report and Recommendations (1977)
- Disclosure of Research Information Under the Freedom of Information Act (1977)
- Research Involving Those Institutionalized as Mentally Infirm (1978)
- Ethical Guidelines for the Delivery of Health Services by DHEW (1978)
- Appendix to Ethical Guidelines for the Delivery of Health Services by DHEW (1978)
- Institutional Review Boards (1978)
- Implications of Advances in Biomedical and Behavioral Research (1978)

⁵ The roster of reports in this Appendix (and corresponding links) is taken from the Bioethics Archive at Georgetown University, at https://bioethicsarchive.georgetown.edu/pcbe/reports/past_commissions/ (presented "As a public resource"). That webpage includes a list with links of the reports of the four major presidential bioethics commissions through 2009, ending with the President's Council on Bioethics. The roster of projects and reports in this Appendix from the fifth and most recent commission, the Presidential Commission for the Study of Bioethical Issues, is taken directly from the Commission's website which is archived on the Georgetown University site, at <https://bioethicsarchive.georgetown.edu/pcsbi/studies.html>.

- The Belmont Report: Ethical Principles and Guidelines for Protection of Human Subjects of Research (1978)

Congress then created the **President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (1980-83)** (P.L. 95-622), which crossed the Carter-Mondale and Reagan-Bush administrations. The commission produced 17 volumes including 12 reports. Among those were high-impact reports on “Defining Death” (1981) and “Deciding to Forego Life-Sustaining Treatment” (1983), and multiple publications on human subjects research.

- Defining Death (1981)
- Protecting Human Subjects (1981)
- Whistleblowing in Biomedical Research (1981)
- IRB Guidebook (1982)
- Compensating for Research Injuries (1982); Volume 2: Appendices
- Splicing Life: The Social and Ethical Issues of Genetic Engineering with Human Beings (1982)
- Making Health Care Decisions (1982); Volumes 2 & 3: Appendices
- Deciding to Forego Life-Sustaining Treatment (1983)
- Implementing Human Research Regulations (1983)
- Screening and Counseling for Genetic Conditions (1983)
- Securing Access to Health Care (1983); Volumes 2 & 3: Appendices
- Summing Up (1983)

The President’s Commission was followed by a failed effort between 1988 and 1990 to continue to address bioethical issues through a Congressionally appointed Biomedical Ethics Advisory Committee; the committee’s work was halted while the Biomedical Ethics Board to which it reported—which consisted of six senators and six representatives, evenly divided between the two major parties—attempted, unsuccessfully, to agree on how to fill a vacancy on the committee. More specialized committees were appointed to examine issues such as the Cold War radiation experiments and the use of fetal tissue in research. It was not until 1996 that a presidentially appointed commission was successfully created by Executive Order to work on a broad range of bioethics issues.

In 1996 President Clinton appointed the **National Bioethics Advisory Commission (NBAC) (1996-2001)** (E.O. 12975). NBAC produced six reports, including “Cloning Human Beings” (1997), “Ethical Issues in Human Stem Cell Research” (1999), and several reports on ethics in research with human

participants as well as “Research Involving Human Biological Materials: Ethical Issues and Policy Guidance” (1999).

- Cloning Human Beings
 - Executive Summary (1997)
 - Volume I: Report and Recommendations of the NBAC (1997)
 - Volume II: Commissioned Papers (1997)
- Research Involving Persons with Mental Disorders That May Affect Decisionmaking Capacity
 - Volume I: Report and Recommendations of the NBAC (1998)
 - Volume II: Commissioned Papers (1999)
- Research Involving Human Biological Materials: Ethical Issues and Policy Guidance
 - Volume I: Report and Recommendations of the NBAC (1999)
 - Volume II: Commissioned Papers (2000)
- Ethical Issues in Human Stem Cell Research
 - Volume I: Report and Recommendations of the NBAC (1999)
 - Volume II: Commissioned Papers (2000)
 - Volume III: Religious Perspectives (2000)
- 1998-1999 Biennial Report
- Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries
 - Volume I: Report and Recommendations of the NBAC (2001)
 - Volume II: Commissioned Papers (2001)
- Ethical and Policy Issues in Research Involving Human Participants
 - Volume I: Report and Recommendations of the NBAC (2001)
 - Volume II: Commissioned Papers (2001)

President George W. Bush then created the **President’s Council on Bioethics (2001-09)** (E.O. 13237) in 2001. The Executive Order stated that the Council’s mission was to “advise the President on bioethical issues that may emerge as a consequence of advances in biomedical science and technology” through exploration of the ethics and policy questions, offering a venue for national discussion, and exploring international collaboration. The Council produced nine reports, including “Monitoring Stem Cell Research” (2004) and “Beyond Therapy: Biotechnology and the Pursuit of Happiness” (2003).

- 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)
- White Paper: Alternative Sources of Pluripotent 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: An Ethical Analysis by the President's Council on Bioethics (2008)
- Controversies in the Determination of Death: A White Paper by the President's Council on Bioethics (2008)

Most recently, President Obama created the **Presidential Commission for the Study of Bioethical Issues (2009-17)** (E.O. 13521). The Commission completed ten projects, including reports on neuroscience research and synthetic biology, on unacceptable research recently uncovered in Guatemala 1946-48, and on emerging issues in research ethics, such as how best to handle incidental or secondary findings. Taking on issues in public health, the commission also analyzed “Ethics and Ebola: Public Health Planning and Response” (2015) plus “Safeguarding Children: Pediatric Medical Countermeasure Research” (2013).

- New Directions: The Ethics of Synthetic Biology and Emerging Technologies (2010)
- "Ethically Impossible" STD Research in Guatemala from 1946 to 1948 (2011)
- Moral Science: Protecting Participants in Human Subjects Research (2011)
- Privacy and Progress in Whole Genome Sequencing (2012)
- Safeguarding Children: Pediatric Medical Countermeasure Research (2013)
- Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to-Consumer Contexts (2013)
- Gray Matters: Integrative Approaches for Neuroscience, Ethics, and Society (2014)
- Ethics and Ebola: Public Health Planning and Response (2015)
- Gray Matters: Topics at the Intersection of Neuroscience, Ethics, and Society (2015)
- Bioethics for Every Generation (2016)

Since 2017, there has been no presidential bioethics commission, though the issues calling for such a commission have become even more urgent.

Appendix B: List of Bioethics Commission Working Group Members

The experts that served on this working group include members of the past three presidential commissions for the study of bioethical issues (President Obama's Presidential Commission for the Study of Bioethical Issues, President George W. Bush's President's Council on Bioethics, and President Clinton's National Bioethics Advisory Commission) and experts in two of the fields presenting emerging bioethics issues (AI/big data and the environment):

- **Susan M. Wolf, JD** (Co-Chair, National Academy of Medicine [NAM] member), Regents Professor; McKnight Presidential Professor of Law, Medicine & Public Policy, University of Minnesota; member, COSEMPUP at NASEM and NAS Strategic Council; past-member, National Science Advisory Board on Biosecurity (NSABB); testified before Presidential Commission for the Study of Bioethical Issues – <https://law.umn.edu/profiles/susan-m-wolf> and <https://med.umn.edu/bio/dom-a-z/susan-wolf>
- **R. Alta Charo, JD** (Co-Chair, NAM member), Warren P. Knowles Professor Emerita of Law and Bioethics, University of Wisconsin - Madison; Co-Chair, NASEM Committee on Emerging Science, Technology & Innovation in Health and Medicine (CESTI); past-member, National Bioethics Advisory Commission (NBAC) – <https://secure.law.wisc.edu/profiles/racharo>
- **Alexander Capron, LLB** (NAM member), University Professor; Scott H. Bice Chair in Healthcare Law, Policy & Ethics; Professor of Law and Medicine, University of Southern California, Exec. Dir., President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research; past-member, NBAC; Director, Department of Ethics, WHO (2003-06) – <https://gould.usc.edu/faculty/?id=205>
- **Rebecca S. Dresser, JD**, Daniel Noyes Kirby Professor of Law Emerita, Washington University, St. Louis; past-member, President's Council on Bioethics – <https://law.wustl.edu/faculty-staff-directory/profile/rebecca-dresser/>
- **Helene D. Gayle, MD, MPH** (NAM member), President and CEO for The Chicago Community Trust; past-CEO of CARE; 20 years at the Centers for Disease Control and Prevention -- <https://www.cct.org/people/dr-helene-gayle/>
- **Christine Grady, MSN, PhD** (NAM member), Chief, Department of Bioethics, National Institutes of Health; past-member, Presidential Commission for the Study of Bioethical Issues -- <https://irp.nih.gov/pi/christine-grady>
- **Marion Hourdequin, PhD**, Professor of Philosophy, Colorado College; Vice President of the International Society for Environmental Ethics -- https://www.coloradocollege.edu/basics/contact/directory/people/hourdequin_marion_elizabeth.html
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