



U.S. HOUSE OF REPRESENTATIVES

COMMITTEE ON ENERGY AND COMMERCE

February 29, 2016

TO: Members, Select Investigative Panel

FROM: Panel Majority Staff

RE: Hearing on “Bioethics and Fetal Tissue”

On Wednesday, March 2, 2016, at 10:00 a.m. in HVC-210, the Select Investigative Panel will hold a hearing entitled “Bioethics and Fetal Tissue.” The hearing will focus upon ethical issues raised as a result of information recently made public about fetal tissue donations, transfer of fetal tissue, and use of fetal tissue by research institutions. The witnesses will provide testimony relating to their respective fields of philosophy, clinical practice, medical research, and law.

Each perspective will help the Panel understand the ethical questions, both at a theoretical level and a practical level, that arise when fetal tissue is acquired and used in biomedical research.

BACKGROUND

On October 7, 2015, the U. S. House of Representatives passed H. Res. 461, which created the Select Investigative Panel and empowered it to conduct a full and complete investigation regarding the medical practices of abortion service providers and the business practices of the procurement organizations who sell fetal tissue. This Panel centralized the investigations that were already being conducted by the Committees on Energy and Commerce, Judiciary, and Oversight and Government Reform by bringing them primarily under one umbrella.

A. History of Ethical Discussion about Bioethics

Bioethics has its origins as a field of academic inquiry in the early 1960s due to extraordinary advances and development in American medical knowledge and practice: organ transplantation, kidney dialysis, respirators, and intensive care units (ICUs) made possible medical procedures never before imagined. The first heart transplant raised ethical questions relating to the sources of organs for transplantation, how they would be allocated, and payment for these procedures.

Public debates took place and, in response, scholars and academics began to think and write about these issues, and scholars began to fuse theoretical ethics with applied or practical ethics. Since that era, continuing biomedical advances have presented bioethical questions that need to be confronted and addressed by societies..

B. Governmental Involvement in Bioethics¹

The Presidential Commission for the Study of Bioethical Issues continues the nearly 40-year history of groups established by the president or Congress to provide expert advice on topics related to bioethics. These groups have differed in their composition, methods, and areas of focus, but they have shared a common commitment to the careful examination and analysis of ethical considerations that underlie our nation's activities in science, medicine, and technology.

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1974-78) is generally viewed as the first national bioethics commission. Established by the 1974 National Research Act, the National Commission is best known for the Belmont Report.² It identified fundamental principles for research involving human volunteers and was the basis of subsequent federal regulation in this area.

The Presidential Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (1978-83), also established by Congress, produced reports on foregoing life-sustaining treatment and access to health care, among other topics. Its 1981 report *Defining Death* was the basis of the Uniform Determination of Death Act³, a model law that was enacted by most U.S. states.

The Advisory Committee on Human Radiation Experiments (1994-95) was created by President Bill Clinton to investigate human radiation experiments conducted from 1944 -1974 as well as radiation intentionally released into the environment for research purposes. The committee considered the ethical and scientific standards for evaluating these events and provided recommendations aimed at ensuring that similar events could not be repeated.

Since the mid-1990s, each of the past three presidents has established bioethics commissions to explore ethical issues in science, medicine, and technology. The National Bioethics Advisory Commission (1996-2001), created by President Clinton, examined topics including cloning, human stem cell research, and research involving human subjects. President George W. Bush established the President's Council on Bioethics (2001-2009), which issued reports on stem cell research, human enhancement, and reproductive technologies, among other

¹ <http://bioethics.gov/history>, From the Presidential Commission Website.

² www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

³ <http://uniformlaws.org/ActSummary.aspx?title=Determination%20of%20Death%20Act>

subjects. President Barack Obama created the current commission by Executive Order in November 2009.

I. WITNESSES

- **Paige Comstock Cunningham, JD**, is the executive director of The Center for Bioethics & Human Dignity. She is a Fellow at the Institute for Biotechnology and the Human Future, and a Trustee of Taylor University. Cunningham is an adjunct professor of law at Trinity Law School and Trinity Graduate School. Cunningham lectures regularly and has published numerous articles, editorials, and book chapters in the areas of law, bioethics, and public policy. .
- **Patrick Lee, Ph.D.**, is the John N. and Jamie D. McAleer Professor of Bioethics and the director of the Center for Bioethics at Franciscan University of Steubenville. He is known nationally as a keynote speaker and author on contemporary ethics, especially on marriage and the value of human life. He has published over 40 articles in refereed journals or books..

Gerard Kevin Donovan, MD, MA, is Senior Clinical Scholar at the Kennedy Institute of Ethics at Georgetown University. He is also Director of the Pellegrino Center for Clinical Bioethics, and Professor of Pediatrics at Georgetown. Dr. Donovan was the founding Director of the Oklahoma Bioethics Center and has three decades of experience in clinical bioethics and clinical medicine being recognized as one of America's "Best Doctors." He has served on multiple ethics committees for hospitals and national organizations as well as chairing an Institutional Review Board.

- **Kathleen M. Schmainda, Ph.D.** is Professor of Radiology and Professor of Biophysics at the Center for Imaging Research at the Medical College of Wisconsin. She received her Ph.D. in Medical Engineering from Harvard-MIT, and completed her Postdoctoral Fellowship in MRI at Massachusetts General Hospital. .
- **R. Alta Charo, J.D.** is the Warren P. Knowles Professor of Law and Bioethics at the University of Wisconsin at Madison, where she is on the faculty of the Law School and the Department of Medical History and Bioethics at the medical school. Professor Charo has authored or contributed to over 100 articles, book chapters and government reports on law and policy related to environmental protection, reproductive health, new reproductive technologies, medical genetics, stem cell research, science funding, and research ethics. She has served as a member of numerous boards, including the Alan Guttmacher Institute, the Foundation for Genetic Medicine, and the National Medical Advisory Committee of the Planned Parenthood Federation of America.

- **Lawrence S.B. Goldstein, Ph.D.** is Distinguished Professor, Department of Cellular and Molecular Medicine, Department of Neurosciences at the University of California, San Diego School of Medicine. He is also the Director of the UC San Diego Stem Cell Program, the Scientific Director of the Sanford Consortium for Regenerative Medicine, and the Director of the Stanford Stem Cell Clinical Center. Dr. Goldstein's research focus areas include genetics and genomics, membrane trafficking, neurodevelopment and neurodegenerative disease, and stem cell biology. Dr. Goldstein received his Ph.D. in genetics from the University of Washington, Seattle. He was the Leob Chair in Natural Sciences at Harvard University, and has received several awards.

II. ISSUES

A. Today's Bioethical Questions

Today's headlines are full of announcements and predictions that a few short years ago were the subject of speculative fiction. Organ reconstitution, three child parents, personalized medicine, organ cloning, chimeras, gene therapy and editing, and bioinformatics are all recent advances that the public has come to learn and understand. The current director of the National Institutes of Health has proposed compiling DNA information to help inform medical decisions and therapies. While these therapies further knowledge biomedical and scientific information related to medical treatments and therapies, they also present broader ethical questions.”

B. The following issues may be examined at the hearing:

- Does fetal tissue research violate human dignity?
- Should fetal tissue be grown for the purpose of transplant?
- Should anyone profit from fetal tissue? Why not?
- What level of disclosure should a patient have before an abortion? Before a donation of tissue?
- Should an abortion clinic have equipment and expertise for perinatal care for children born alive?
- Who should obtain the fetal tissue donation consent?

III. STAFF CONTACTS

If you have any questions regarding this hearing, please contact March Bell or Rachel Collins of the Committee staff at (202) 225-2927.