Billing Code 4154-06P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Comments on Issues Related to Incidental Findings that Arise in the Clinical, Research, and Direct-To-Consumer Contexts

AGENCY: Department of Health and Human Services, Office of the Secretary, Presidential Commission for the Study of Bioethical Issues.

ACTION: Notice.

SUMMARY: The Presidential Commission for the Study of Bioethical Issues is requesting public comment on the ethical, legal, and social issues raised by incidental findings that arise from genetic and genomic testing, imaging, and testing of biological specimens conducted in the clinical, research, and direct-to-consumer contexts.

DATES: To ensure consideration, comments must be received by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. Comments received after this date will be considered only as time permits.

ADDRESSES: Individuals, groups, and organizations interested in commenting on this topic may submit comments by e-mail to info@bioethics.gov or by mail to the following address:

Public Commentary, Presidential Commission for the Study of Bioethical Issues, 1425 New York Ave., NW, Suite C–100, Washington, DC 20005.

FOR FURTHER INFORMATION CONTACT: Hillary Wicai Viers, Communications Director, Presidential Commission for the Study of Bioethical Issues. Telephone: 202-233-3960. E-Mail: hillary.viers@bioethics.gov. Additional information may be obtained at http://www.bioethics.gov.

SUPPLEMENTARY INFORMATION: On November 24, 2009, the President established the Presidential Commission for the Study of Bioethical Issues (the Bioethics Commission) to advise him on bioethical issues generated by novel and emerging research in biomedicine and related areas of science and technology. The Bioethics Commission is charged with identifying and promoting policies and practices that ensure ethically responsible conduct of scientific research and healthcare delivery. Undertaking these duties, the Bioethics Commission seeks to identify and examine specific bioethical, legal, and social issues related to potential scientific and technological advances; examine diverse perspectives and possibilities for international collaboration on these issues; and recommend legal, regulatory, or policy actions as appropriate.

The Bioethics Commission is considering the distinct ethical issues raised by incidental findings in the contexts of clinical care, research, and direct-to-consumer testing. Emerging medical technologies, changing cost structures, and evolving medical practice make the likelihood of discovering incidental findings in the clinical, research, and direct-to-consumer contexts a growing certainty. At its meeting on April 30, 2013, the Bioethics Commission heard from

ethicists, practitioners, and recipients of incidental findings in each of these contexts, and began its consideration of the ethical obligations that clinicians, researchers, and providers of direct-to-consumer testing owe to patients, participants, and consumers.

The Bioethics Commission is interested in receiving views of individuals, groups, and professional communities regarding the ethics surrounding incidental findings resulting from large-scale genetic testing, imaging, and testing of biological specimens in the clinical, research, and/or direct-to-consumer contexts. The Bioethics Commission is particularly interested in receiving public commentary regarding:

- information about the likelihood of incidental findings arising in large-scale genetic testing, imaging, and testing of biological specimens in the clinic, research, and/or direct-to-consumer contexts and any case studies of such;
- what, if anything, patients, participants, and/or consumers should be told about incidental findings resulting from large-scale genetic testing, imaging, and testing of biological specimens *before* tests are conducted;
- any duties or ethical obligations that clinicians, researchers, and direct-to-consumer companies might have to actively look for certain incidental findings;
- best practices, methods, and mechanisms for determining *when* incidental findings ought to be returned to patients, participants, and/or consumers and *how* the return of these findings should occur;
- the acceptability of holding back information—such as establishing "no return" policies, or stipulations in advance of clinical intervention, research, and/or consumer interactions that no incidental findings will be returned; and,

- any best practices or recommendations regarding incidental findings that apply no matter the type of test or context.

To this end, the Commission is inviting interested parties to provide input and advice through written comments.

Comments will be publicly available, including any personally identifiable or confidential business information that they contain. Trade secrets should not be submitted.

DATED: May 22, 2013

Lisa M. Lee

Executive Director,

Presidential Commission for the Study of Bioethical Issues

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