



American Society of Human Genetics

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6120 Executive Boulevard, Suite 500
Rockville, MD 20852

tel: 301.634.7300
email: society@ashg.org
web: <http://www.ashg.org>

June 10, 2021

Chairman Frank Pallone
Committee on Energy & Commerce
U.S. House of Representatives
Washington, DC 20515

Ranking Member Cathy McMorris Rodgers
Committee on Energy & Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Chairman Pallone and Ranking Member McMorris Rodgers:

As national leaders dedicated to advancing science in the House of Representatives, thank you for your strong support for the nation's investment in biomedical research. The American Society of Human Genetics (ASHG), the field's primary professional membership organization comprised of nearly 8,000 human geneticists worldwide, appreciates your robust commitment to the National Institutes of Health (NIH) and to science as an engine to improve the lives and health of Americans.

We write to express deep concern about Section 6102 of Division F in the Senate-passed *U.S. Innovation and Competition Act* (USICA; S.1260) concerning NIH-funded research, human genomics research in particular, and national security. We believe that these provisions, if passed into law, could slow biomedical advances and impose unintended burdens on researchers whose work involves human genomic information. The provisions of concern are in USICA alone and not in the NSF for the Future Act (H.R.2225) introduced by Chairwoman Johnson and Ranking Member Lucas. Instead of these provisions, we ask that Congress commission a study panel, well balanced with scientists and national security experts, to consider and weigh evidence and make recommendations to protect both scientific progress and national security.

We appreciate that the National Science Foundation (NSF) is a major focus of S.1260 and H.R.2225 and that NSF matters are the jurisdiction of the House Committee on Science, Space and Technology. However, we also know that the NIH is the jurisdiction of your committee. As the Committee on Energy and Commerce crafts provisions related to innovation and competitiveness for inclusion in a package to conference with USICA, we therefore ask to engage with you regarding our concerns in S.1260. We would like to work with you to ensure that there we first properly assess relevant issues regarding human genomics research and national security and that we avoid legislation that imposes inappropriate and unnecessary burdens that will slow down discovery, innovation, and new applications.

Now more than ever, the American people are benefiting from new genomic applications that are improving health, saving lives, and contributing to the U.S. economy. As a professional community dedicated to these advances, ASHG stresses the profound role genomic knowledge is playing in the transformation of all of biomedical research – from cancer to heart and lung disease, early child development, rare diseases, Alzheimer's disease, mental health, and so

much more. A [recent ASHG report](#) drives home the impact of human genetics and genomics research for the U.S. economy, finding that it generates \$265B annually, a five-fold increase in just a decade.

For these reasons, we are very concerned that the USICA language has not benefited from due scientific input and the result could harm continued scientific advances and unintentionally harm national security and competitiveness. To avoid this unintended chilling effect on such a promising area of research, it is vital to first secure input from the scientific community, and to secure better understanding about the true breadth and severity of national security considerations that have been expressed, before Congress acts. We are concerned that the provision in S.1260:

- Requires HHS to consider “appropriate national security risks” alongside medical research, without defining the risks, providing a substantial evidence base, or offering further guidance.
- Without justification, singles out human genetics and genomics research as exceptional relative to any other sensitive health data.
- Fails to consider the current legal and policy frameworks for the protection of human participants in federally funded research. These include the Common Rule, the Health Insurance Portability and Accountability Act (HIPAA), the Genetic Information Nondiscrimination Act, and the 21st Century Cures Act, and the NIH Genomic Data Sharing Policy.
- Could add unwarranted, potentially significant administrative burden and restrictions on US researchers through roadblocks to data sharing, which is already heavily regulated and has been an essential scientific component and value since the Human Genome Project launch. This could decrease the global competitiveness of U.S. geneticists, allowing those in other countries to out-compete us for discoveries of both health and economic value. Losing our important advantage of shared data could challenge our leadership in genomics and thus weaken the U.S.
- Blurs lines between important—but very different—policy issues, ranging from the global biomedical research enterprise, to national competitiveness, to abusive human rights violations around the world that the U.S. rightly decries; and
- Potentially harms responsible and vital global scientific collaboration that advances genomics research for the benefit of all.

The human genetics and genomics community takes data privacy and stewardship extremely seriously. For decades, our community has pursued both the opportunity and responsibility that come with research and responsible use of new knowledge. As with most research fields today, responsible large-scale data analysis is essential to advance genomic discoveries and, as with most medical information, these data must have strong protections. ASHG is a major policy advocate to advance these goals, supporting the Common Rule, the Genetic Information Nondiscrimination Act, the 21st Century Cures Act, and responsible NIH genomic data-sharing policies. Just as any scientific knowledge has the potential for misuse and harm, ASHG also speaks out to [oppose the misuse of genetic research](#) that could harm individuals or populations, including opposition to the coerced collection of genetic data, which violates our community’s core values. Finally, genomic research is a global pursuit with valued academic and industry research leadership underway worldwide. Yet, we have shared our concern when cases are reported in which researchers have taken advantage of America’s historically open and inclusive research environment.

To serve the American people, it is vital that the nation prioritize both robust medical progress and national security goals and ensure they co-exist and advance as two top priorities. But before requiring a major new national security framework on NIH-funded human genetics and genomics research, Congress should first commission a study that

brings together leading scientists and national security experts as equals. The commission should determine and document what national threats exist, if any, given the statutory and regulatory frameworks in place protecting the privacy of human genetic information, and provide guidance to HHS and NIH on the interface of scientific and national security goals. If this study concludes that there is a body of evidence establishing a clear threat to national security, scientists should be empowered to work alongside—not subject to—the national security community to determine how to mitigate the threat while ensuring scientific progress.

ASHG is eager to engage you to address these issues and ensure the acceleration of genomic research advances for the health and well-being of the American people. We would like to schedule time to speak with you and your staff about these concerns, and Derek Scholes, PhD, ASHG senior director for policy and advocacy, will contact your office. If you have any questions in the meantime, please contact Derek at dscholes@ashg.org.

Thank you again for your sustained leadership and we look forward to working with you to advance these shared goals.

Sincerely,



Gail Jarvik, MD, PhD
President



Mona V. Miller
Chief Executive Officer