September 16, 2015

The Honorable Lamar Alexander  
Chairman  
Committee on Health, Education, Labor and Pensions  
U.S. Senate  
Washington, DC 20510

The Honorable Patty Murray  
Ranking Member  
Committee on Health, Education, Labor, and Pensions  
U.S. Senate  
Washington, DC 20510

Dear Chairman Alexander and Ranking Member Murray:

The American Association for Cancer Research (AACR) is the world’s first and largest scientific organization focused on every aspect of high-quality, innovative cancer research, from bench to bedside. The mission of the AACR and its more than 35,000 members in all fifty states and around the world is to prevent and cure cancer through research, education, communication, and collaboration. Our members include basic, translational, and clinical researchers; patient advocates and other leaders in the cancer research and care community.

We thank you for your bipartisan leadership of the Senate Health, Education, Labor & Pensions (HELP) Committee, and we commend your commitment to advancing medical innovation through the discovery, development, and delivery of new therapies to patients, especially those individuals who are suffering from the more than 200 diseases we call cancer. As you work on legislation under the Innovation for Healthier Americans Initiative, we would like to share our priorities for the bill.

**Funding for the National Institutes of Health (NIH) must be a top priority to ensure the health and economic security of our Nation.**

The HELP Committee has long recognized the critical importance of NIH funded-research to improving our nation’s health, sustaining our leadership in medical research, and remaining competitive in today’s global information and innovation-based economy. Therefore, we urge you to make NIH funding a top legislative priority. The federal government has an irreplaceable role in supporting medical research, and the AACR believes that the inclusion of specific funding provisions, including, but not limited to, mandatory funding streams that **supplement** increased funding for NIH allocated through the annual appropriations process. These funding increases are urgently needed for sustained, predictable growth to the NIH budget and to restore the funding that has been lost over the past decade through budget stagnation and outright cuts. Annual budget increases of at least 7 percent would boost the current levels of funding, resulting in fiscal year (FY) 2020 funding levels for the NIH of $42.5 billion.

**The Food and Drug Administration (FDA) must have adequate funding to expedite approval of innovative medicines for the patients who need them**

The AACR urges you to make a parallel commitment and equally important commitment to ensuring that the FDA has the resources it needs to carry out its regulatory and oversight functions. Advances in regulatory science should parallel advances in basic, translational, and clinical science. If not, promising new medical therapies may never reach patients simply
because we lack the tools to recognize their potential and resort to outmoded evaluation methods that delay or deny their approval.

Since the Committee aims to improve medical innovation and expedite the delivery of novel therapies to patients, we believe that legislation must include funding provisions that facilitate these goals without compromising the quality of medical product reviews or the ability of the FDA to execute its critical oversight functions. Doing so will ensure that any new mandates can be carried out effectively and efficiently.

**Additional Recommendations:**

**Ensure that Agencies have flexibility to carry out their missions**

Science and technology, our understanding of cancer biology, and our approaches to developing medical products and delivering cancer care are evolving. It is important that the Committee considers, when drafting language, ways to support the NIH and the FDA and their respective abilities to be nimble and respond to emerging scientific opportunities and/or health needs.

The NIH Institutes and Centers should have the flexibility to set research priorities and make the type and size of awards that are best suited to advance science and medicine with the ultimate goal of improving health and reducing the burden of diseases such as cancer. The peer review process administered by the NIH is second to none in the world, and has set a “gold standard” for the selection of the most meritorious proposals that countries around the world seek to emulate.

Similarly, the regulatory environment in the U.S. should reflect the advances being made in scientific discovery, thus ensuring modernization of our regulatory approaches while allowing for Agency flexibility. It is important that legislation facilitate and support the work of the FDA, since one of the hallmarks of the Agency is its ability to employ discretionary judgment as it considers various medical product applications. This level of autonomy has allowed the agency to make risk/benefit assessments in the context of life-threatening diseases and various unmet medical needs. Thus, while we embrace the Committee’s desire for a modernized regulatory framework to oversee regulation of innovative medical products and ensure their safety and efficacy, we suggest that this can be achieved by allowing the Agency to incorporate the most up-to-date evidence-based regulatory science principles on an ongoing basis.

**Ease travel restrictions on Agency personnel**

The AACR urges the Committee to include language that supports the participation of NIH and FDA staff scientists in scientific meetings and conferences, such as the AACR’s Annual Meeting, which this year drew record attendance of more than 19,000 scientists and health care professionals from around the world. Attending scientific meetings and research conferences is an important way for NIH and FDA staff to stay abreast of the latest developments and be connected with their respective communities and vice versa. These meetings provide opportunities for public discussions of the latest findings and help academics, government, industry, and nonprofit sector stakeholders keep up with scientific advances. Supportive language could help to relieve some of the restrictions currently placed on Agency personnel and will help facilitate the scientific collaborations that lead to breakthroughs and cures.
Conclusion

The AACR deeply appreciates your thoughtful consideration of the priorities we have outlined above, and we commend you, your fellow Committee Members, and your staff for your efforts to develop a proposal with the goal of accelerating the pace of cures and medical breakthroughs in the U.S. by ensuring that our laws are keeping pace with scientific and medical innovation.

Cancer remains a formidable opponent. This year alone, it is estimated that 1.7 million Americans will be diagnosed with cancer, and we will lose one person, every minute of every day in the U.S. to this devastating disease. The number of cancers diagnosed is steadily increasing; therefore, a consistent effort to strengthen our nation’s commitment to medical research, and to cancer research in particular, is critical now more than ever before.

An increased investment in NIH funded research, a renewed commitment to training the next generation of scientists; support for policies that promote a patient-centered, collaborative approach to cancer research and care and, the optimization of our regulatory processes through a well-funded FDA are all required to meet the current challenges in cancer research and care.

The AACR and its more than 35,000 members look forward to continuing to work with you to ensure that the NIH and FDA have the resources and tools needed to continue to spur innovation and deliver hope to patients and their family members all across our great nation and throughout the world.

Thank you for your dedication to this vitally important cause.

Sincerely,

Jose Baselga, MD, PhD
President

Margaret Foti, PhD, MD (hc)
Chief Executive Officer

William S. Dalton, PhD, MD
Chair, AACR Science Policy & Government Affairs Committee