Alliance
FOR AGING RESEARCH

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March 6, 2016

The Honorable Lamar Alexander
Chairman
U.S. Senate
Committee on Health, Education, Labor and Pensions
727 Hart Senate Office Building
Washington, D.C. 20510

The Honorable Patty Murray
Ranking Member
U.S. Senate
Committee on Health, Education, Labor and Pensions
428 Hart Senate Office Building
Washington, D.C. 20510

Dear Chairman Alexander and Ranking Member Murray,

The Alliance for Aging Research is the leading non-profit organization dedicated to accelerating the pace of scientific discoveries and their application to improve the experience of aging and health. The Alliance believes that advances in research help people live longer, happier, more productive lives and reduce health care costs over the long term. We support policies that encourage medical research and innovation and address the needs of aging patients. For this reason, the Alliance for Aging Research supports efforts in Congress to improve the way in which combination products are reviewed by the U.S. Food and Drug Administration (FDA). We applaud you for bringing proposals before the Senate Health, Education, Labor, and Pensions Committee for consideration that address key challenges with the current approach to combination product review employed by the FDA.

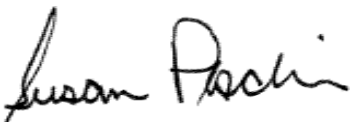
There are two specific problems with the current process for combination product review that we feel impede their timely and transparent evaluation. The first relates to the existing definition of a device. The current device definition allows for combination products to be incorrectly classified as a drug, even in instances where there is minimal chemical action. In cases where there has been an inappropriate designation, there is no clear explanation shared with the product's sponsor for why the FDA has chosen to classify a combination product as a drug and there are insufficient channels for dispute resolution. A possible solution for Congress to consider in these instances are to require that FDA provides product sponsors with a scientific rationale supporting its conclusion that chemical action is responsible for a combination product achieving its intended purpose. If there is still disagreement about a drug designation for a combination product, FDA should have the flexibility to offer sponsors the option of a single study intended to resolve discrepancies over chemical action.

Our second concern is rooted in governance of the combination product review process. It is our understanding that product sponsors do not have a predictable regulatory path to follow for combination products. These governance challenges are due to misalignment among consulting FDA centers on data requirements and communication with sponsors. As an initial step, we urge Congress to request that FDA clarify the roles and responsibilities for combination product review among primary and consulting centers at the agency. We also ask you to consider a requirement for FDA to work with combination product sponsors in the future on review plans that detail clinical study requirements, timelines, good manufacturing practices, and a description of safety and effectiveness questions and incremental risks posed by combination products.

We understand that implementing the suggested changes proposed in this letter would place additional workload on the FDA and require restructuring. We ask that Congress provide additional funding for the agency commensurate with these added responsibilities and activities.

The unmet health challenges of older adults are an enormous financial and human burden. More rapid access to novel innovations, including combination products, are needed to address these challenges. Your support of an improved combination products review process will do much to ensure that the medical products industry remains vibrant and nimble to produce breakthroughs that will improve the lives of aging Americans. If you have any questions, or if we can be of assistance as you continue advancing the Senate's Innovation Agenda please do not hesitate to contact us at (202) 293-2856 or by email at speschin@agingresearch.org and cbens@agingresearch.org.

Sincerely,



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