



CENTER FOR MEDICAL CONSUMERS

February 4, 2016

The Honorable Lamar Alexander
Chairman
HELP Committee
United States Senate
Washington DC 20510

The Honorable Patty Murray
Ranking Member
HELP Committee
United States Senate
Washington DC 20510

Dear Senator Alexander and Senator Murray,

The Patient, Consumer, and Public Health Coalition is an informal coalition of nonprofit organizations representing the interests of patients, consumers, health-care professionals, scientists, and public health experts. As members of the coalition, we strongly support efforts to improve the safety and effectiveness of drugs and medical devices. You are in a unique position

to create policies to improve the lives of all Americans through your work on the Senate HELP Committee. **We urge you to prioritize patient safety in the health legislation that the committee will mark up on February 9, 2016 and in March.**

We strongly support the Preventing Superbugs and Protecting Patients Act. This legislation will reduce the risk of contaminated medical devices, like duodenoscopes and other reusable devices. Drug-resistant organisms from contaminated scopes have hurt and killed many people throughout the United States. This legislation and the safety recommendations in the recent HELP minority staff report will help prevent this from happening in the future. We strongly urge the Committee to support legislation that will reduce and eliminate these deadly infections.

We also support the Advancing Research for Neurological Diseases Act. The bill would provide a foundation for the Department of Health and Human Services (HHS) to learn more about the many factors involved in neurological diseases, such as geographic clusters of diagnoses, variances in the gender ratio, disease burden, and changes in health care practices. In addition, the data collection system would support a wide range of research initiatives, allow for future planning of healthcare needs, and promote disease education about neurological diseases. This could truly be a game-changer for people suffering from neurological diseases and provide critical information to researchers as they work on new treatments and cures. We recommend that you include increased funding for HHS in the bill so that researchers have the resources they need.

We urge you to enhance opportunities for new researchers at the National Institutes of Health by supporting the Next Generation Researchers Act. This legislation recognizes the importance of investing in the brightest young minds of the next generation so they are able to contribute to the advancement of science and improved health. Talented medical researchers from all over the world are now returning to better opportunities in their home countries. The impact of losing a generation of investigators and medical innovators will have repercussions far into the future. We urge you to increase NIH's budget so that it can fund opportunities for new researchers.

We do not support the FDA Device Accountability Act as it favors manufacturers at the expense of patient safety. It requires FDA employees to receive training on the least burdensome requirements (LBR) and it establishes an ombudsman to audit the training of FDA employees on LBR. Recently, thousands of patients have been harmed by surgical mesh, metal-on-metal hips, power morcellators, duodenoscopes, and other medical devices. This bill will promote lower safety standards by discouraging reviewers from seeking the information they need to make informed decisions. **This is not the time to focus more on "least burdensome" principles than on the safety of medical devices. We urge you include training regarding the importance of patient safety considerations to this bill.** In addition, it would be helpful to add an ombudsman to audit the training of FDA employees on device safety and effectiveness.

Lastly, we ask that you increase funding for the NIH and FDA so that urgently needed safe and effective medical treatments are developed and made available. We must ensure that these institutions remain at the forefront of science and medicine for years to come and that patients can trust their drugs and medical devices to improve their health rather than harm it.

Thank you in advance for making sure that you are putting patients before profits as you do this important work.

Sincerely,

American Medical Student Association
Association for Pelvic Organ Prolapse Support
Breast Cancer Action
Center for Medical Consumers
Center for Science and Democracy, Union of Concerned Scientists
Connecticut Center for Patient Safety
Jacobs Institute of Women's Health
Medication-Induced Suicide Prevention and Education Foundation (MISSD)
MRSA Survivors Network
National Center for Health Research
National Consumers League
National Physicians Alliance
National Women's Health Network
Our Bodies Ourselves
Quinolone Vigilance Foundation
The TMJ Association
Washington Advocates for Patient Safety
Woody Matters

Cc: Members of the HELP Committee