November 9, 2017

The Honorable John McCain
Chair, Senate Armed Services Committee
United States Senate
218 Russell Senate Office Building
Washington, DC 20510

The Honorable Jack Reed
Ranking Member, Senate Armed Services Committee
United States Senate
728 Hart Senate Office Building
Washington, DC 20510

The Honorable Mac Thornberry
Chair, House Armed Services Committee
United States House of Representatives
2208 Rayburn House Office Building
Washington, DC 20515

The Honorable Adam Smith
Ranking Member, House Armed Services Committee
United States House of Representatives
2264 Rayburn House Office Building
Washington, DC 20515

Dear Senators McCain and Reed, Representatives Thornberry and Smith:

As former Commissioners of the U.S. Food and Drug Administration (FDA), we write to express our objections to Section 732 of the Senate's version of the National Defense Authorization Act. This language, now being considered in conference committee, would allow the Department of Defense to approve certain drugs and medical devices for emergency uses by members of the U.S. Armed Forces or "individuals associated with deployed members of the armed forces."

For more than 100 years, the U.S. Congress has empowered the FDA to ensure the safety and efficacy of medical products for U.S. consumers, including our military personnel. In contrast, the proposed review panel in the Department of Defense will never have the resources or the expertise that the FDA brings to ensure the safety and efficacy of medical products, even in the limited cases of emergency use. These five external advisors are not likely to have the requisite knowledge about the chemistry, manufacturing, and controls that are part of every FDA review, nor will they have access to the raw data that are part of every new product application to the FDA. They will have no authority to require post-market studies, as the FDA does, and it is unclear how they will be able to monitor post-market safety more generally.

The current law is very clear in giving the sole statutory authority for drug and medical device review to the FDA. Recent Congressional efforts to address the FDA review process and ensure timely reviews—such as the 21st Century Cures Act—have recognized that statutory framework and built upon it. With bipartisan support from Congress, FDA has taken many administrative actions over the years to address these challenges as well, such as the development of expanded access programs and other innovative review and approval mechanisms for countermeasures for bioterrorism and for other threats, including threats to military personnel.

Access to better therapies to protect war fighters is a critical public priority. Because the development of and access to reliable and effective treatments for military personnel in harm's way also depends on the latest science and effective review mechanisms, medical innovation for these personnel is best served by utilizing the expertise and support that the FDA brings to medical product development. Building on the FDA's capabilities and tradition of adapting to address new public health problems, the FDA Commissioner and bipartisan members of Congress are working to assure that the agency has the necessary authorities and initiatives in place to address urgent military needs for medical products. We support these efforts.

This provision, on the other hand, undermines that longstanding statutory framework and likely increases the risks for our military personnel. It is often assumed that products that are relatively advanced in the development process are highly likely to be safe and effective. However, the FDA recently published a report documenting "22 case studies of drugs, vaccines and medical devices since 1999 in which promising phase 2 clinical trial results were not confirmed in phase 3 clinical testing." According to the report, "[p]hase 3 studies did not confirm phase 2 findings of effectiveness in 14 cases, safety in 1 case, and both safety and effectiveness in 7 cases."[1] The provision under conference committee discussion would allow the emergency uses of medical products not even this far along in the review process. FDA often approves products based on limited evidence; however, given the potential gaps and limitations in such evidence, these decisions require extensive expertise not only in the clinical subject matter but also in areas such as study design and post-approval follow-up.

We urge the Congress and the Department of Defense to address the critical issue of military access to the best possible therapies by working with the FDA leadership to build on existing FDA expertise and capacity. This approach can address any issues that may be arising in specific military situations by fully utilizing the FDA's expanded access programs, rapid approval authorities, and expertise in ensuring the safety and effectiveness of medical products. This approach can address current concerns about access to needed therapies without undermining more than 100 years of progress toward ensuring the safety and efficacy of medical products used by U.S. citizens, especially those already putting their lives at risk for our nation.

Sincerely,

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[1] U.S. Food and Drug Administration. (2017). 22 case studies where phase 2 and phase 3 trials had divergent results. *U.S. Food and Drug Administration*. Available at https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM535780.pdf.

Margaret A. Hamburg, MD (Commissioner, 2009-2015)

Jane E. Henney, MD (Commissioner, 1998-2001)

David A. Kessler, MD (Commissioner, 1990-1997)

Mark B. McClellan, MD (Commissioner, 2002-2004)

Andrew C. von Eschenbach, MD (Commissioner, 2006-2009)