

Congress of the United States

Washington, DC 20510

November 6, 2017

Chairman John McCain,

We write to express strong concerns regarding a provision in the National Defense Authorization Act that creates an authority for the Secretary of the Department of Defense (DoD) to authorize the use of medical products not approved by the Food and Drug Administration (FDA) for military service members. We respectfully request that you replace this authority with a bipartisan solution drafted by the Chairs and Ranking Members of the authorizing committees of jurisdiction over the FDA that would better protect our military troops.

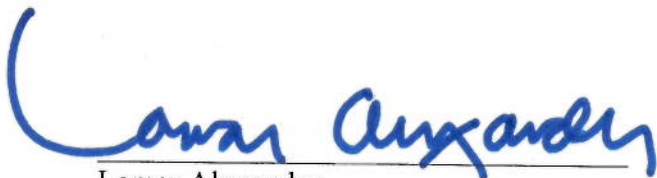
The FDA has the sole responsibility and authority to make decisions about the approval of medical products, including those authorized for use during an emergency. Only the FDA has the medical and scientific expertise to review and approve medical products. Creating a new authority separate and apart from FDA could result in DoD permitting the use of experimental medical products that could harm military service members, or providing our military with ineffective medical products.

Currently, there is a successful, streamlined, science-based process within the FDA to authorize the emergency use of medical products for military emergencies related to threats from chemical, biological, radiological, or nuclear agents. We support a bipartisan solution that would expand FDA's existing authorities to allow FDA to authorize the emergency use of medical products related to life-threatening injuries or other threats that warfighters may encounter on the battlefield or in combat, such as an Improvised Explosive Device (IED). This language is supported by the Chair and Ranking Members of the Senate and House authorizing committees with oversight over the FDA. A copy of that language is attached for your review.

We share your goal of ensuring military service members have access to safe life-saving medical products during battlefield emergencies or combat settings. The language currently in the bill does not meet that test, and if it remains unchanged we will not be able to support the 2018 National Defense Authorization Act.

We would appreciate the opportunity to work together on a solution to protect American warfighters.

Sincerely,



Lamar Alexander
U.S. Senator



Richard Burr
U.S. Senator