



UNITED STATES SENATE
WASHINGTON, D.C. 20510

October 17, 2012

The Honorable Jonathan Woodson, M.D.
Assistant Secretary of Defense
Washington, D.C. 20301

Dear Dr. Woodson,

In recent months, the outbreak of Fungal Meningitis originating from injectable steroids made by the New England Compounding Center (NECC) has raised serious concerns about the apparent lack of scrutiny and oversight of such compounding pharmacy centers.

Recent alarming information indicates that one such compounding center – Ameridose, which has the same owners as NECC – received a sole-source purchase agreement from the U.S. Army Medical Command in July of this year. The contract was to supply specialized compounded pharmaceutical products for the neonatal intensive care unit at the Army's Tripler Medical Center in Honolulu. I am deeply concerned that this contract exposed numerous military families to a drug produced by a compounding center that was not registered with the Food and Drug Administration and not inspected for safety and effectiveness.

In light of the extraordinarily troubling concerns raised about the safety of drugs manufactured by compounding pharmacy centers, please provide me with information about the monitoring and evaluation of the safety and effectiveness of such products by the military health system. Specifically, I would appreciate a review of the process whereby the determination was made for the solicitation (W81K02-12-A-0022) that Ameridose is the only source found that compounds highly specialized pharmaceutical products in the concentrations that are used in the neonatal intensive care unit. I would also appreciate an explanation as to the control mechanisms that the military health system has in place to detect contaminations in its supply of specialized compounded pharmaceutical products. Further, please provide me with how many other such contracts with compounding pharmacies are maintained by the military health system, with whom, and what, if any, general policies apply to contracts with compounding pharmacy centers.

I am sure that you share these concerns.

I will continue to work for all remedies addressing the lack of oversight and safety of drug manufacturing by compounding pharmacies like the NECC, which caused the widespread outbreak of dangerous and deadly disease, and I hope that we can work together to ensure that no

contaminated drug products reach our military families and to further strengthen the military health system. Thank you again for your assistance to address this matter promptly.

Sincerely,

A handwritten signature in blue ink, reading "Richard Blumenthal" with a stylized flourish at the end.

Richard Blumenthal
United States Senate