

*For Immediate Release:  
October 18, 2012*

Contact: Nu Wexler (202) 689-4295  
[Nu\\_Wexler@blumenthal.senate.gov](mailto:Nu_Wexler@blumenthal.senate.gov)

## **BLUMENTHAL CALLS ON DOD TO EXPLAIN CONTRACT WITH COMPOUNDING PHARMACY CENTER LINKED TO DEADLY MENINGITIS OUTBREAKS**

(Hartford, CT) – Today, in a letter to Assistant Secretary of Defense Jonathan Woodson, Senator Richard Blumenthal (D-Conn.) called on the Department of Defense (DOD) to explain details of its contract with a compounding pharmacy center linked to the deadly meningitis outbreak that has killed 19 people in 15 states.

Blumenthal wrote, "**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. "**

Blumenthal continued, "**I would appreciate your informing me as to the reasons for the sole source contract with Ameridose, which has the same owners as NECC, the compounding center responsible for broad dissemination of blatantly contaminated drug products. Please also provide me with how many other such contracts with compounding pharmacies are maintained by the Military Health System, and with whom, and what, if any, general policies apply to contracts with compounding pharmacy centers."**

Compounding is a process of combining, mixing, or altering ingredients in order to create a drug for a particular patient. Compounding pharmacy centers can make drugs for patients that are not typically available commercially, such as a drug made in a lower dosage for a child or a drug made without a dye or preservative for a patient with a specific allergy.

Pharmacists that compound drugs have been subject to less federal regulation because they make drugs in response to a valid patient prescription, making the safety and efficacy trials required for drug manufacturing impractical and unnecessary. Compounding drugs without a patient prescription crosses the line from traditional compounding in limited quantities for a specific patient to mass production of drugs without proper FDA oversight.

Below is a text of the letter Blumenthal sent to DOD:

Dear Assistant Secretary 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 unregistered with the FDA and uninspected for safety and effectiveness.

I would appreciate your informing me as to the reasons for the sole source contract with Ameridose, which has the same owners as NECC, the compounding center responsible for broad dissemination of blatantly contaminated drug products. Please also provide me with how many other such contracts with compounding pharmacies are maintained by the Military Health System, and with whom, and what, if any, general policies apply to contracts with compounding pharmacy centers.

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 will continue to work for all remedies addressing the lack of oversight and safety of drug manufacturing by compounding pharmacies like the New England Compounding Center, which caused the widespread outbreak of dangerous and deadly disease, and I hope that we can work together to ensure that safe and effective drug products are provided to our military families.

Thank you again for your assistance to address this matter promptly,

Sincerely,

Richard Blumenthal  
United States Senate

A copy of the letter can be found here:

<http://blumenthal.senate.gov/download/dod-woodson-letter>

###