In a message dated 11/10/2001 10:29:34 AM Eastern Standard Time, [person] writes:

<<Your first e-mail was brought to the SAC in Charge of the Anthrax Investigation in the FBI- NYO and has a copy to be analyzed for pertinent facts to the case by the Task Force.>>

Sir,

Other appropriate background info you should have on this most complex issue are the clear cut legal implications that revolve around the anthrax vaccine dilemma, irrespective of the current national crisis:

1. The vaccine is being used, just as it was in the Gulf War, in an "investigational" manner by the DOD, with the complicity of FDA. This conclusion was drawn by a Senate Veteran's Affairs Committee staff report -- Senate Report 103-97 -- in 1994. The US Congress investigated the current vaccination program, concluding the vaccine’s use was "experimental," in House Report 106-556 in 2000. Russ and I contributed to this 2000 report. This illegality issue is covered in a Federal Declaratory Judgment Act suit, filed by a USAF Reserve JAG on behalf of military members, against the company supplying the vaccine, the FDA, and the Defense Secretary. The illegal part is that the vaccine cannot be mandated on the troops based on this status, but the DOD has ignored this law -- 10 USC 1107...

2. The second legal issue is the adulteration of the vaccine. This is the most clear cut and was validated by GAO testimony on 23 OCT 01. The adulteration is due to a myriad of issues, and is laid out in Russ' and my False Claims act suit in the Western District of Michigan that was investigated for the past year by the Department of Justice. The DOJ admitted to us privately that violations have occurred, but that they are not intervening in the fraud case due to political considerations and as a result of DOD's and FDA's heavy involvement and prior knowledge of the regulatory violations...

3. The adulteration issue, making the vaccine illegal to transport via interstate commerce, is also one of four actions in Russ' and my Citizen Petition, filed under Title 21 of the US Code. The Citizen Petition is pending on the FDA's docket as of 15 OCT 01. Key legal aspects of the Petition, beyond improper licensure of the vaccine covered in action 1, and the adulteration of the vaccine covered in action 2, are
the contracts for the vaccine, which were clearly contrary to government policy, according to the FDA's own Office of Regulatory Affairs (this is covered in action 3). The Attorney General's office here in CT concurs that this policy carries the weight of law, which means contracting for the anthrax vaccine is against the law for this additional reason, beyond being experimental and adulterated. The Citizen Petition is located on the FDA website at:

http://www.fda.gov/ohrms/dockets/dailys/01/Oct01/101501/cp00001.pdf

Hope this additional information helps Sir to understand the depth of what we've uncovered on this issue. Feel free to contact Russ (860-568-8767), or myself, at any time (860-668-1512).

"Buzz"

Maj. Tom Rempfer

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Subj: More info for your FBI investigation Sir, with respect to the anthrax vaccine

Date: 11/10/2001

To: 

CC: 

...PS. Clipped below is the text of the Sen. Daschle letter to the Defense Secretary provided to the White House Office Senior Advisor to the President, Mr. Karl Rove:
June 21, 2001

The Honorable Donald Rumsfeld
Secretary of Defense
The Pentagon
Washington, DC 20301-1000

Dear Secretary Rumsfeld:

As you continue your strategic review of the Defense Department’s strategy and policies, we write to express our interest in and concern about reports regarding the Pentagon’s continued use of an anthrax vaccine on our military personnel. We recognize that your review is addressing a myriad of issues with large implications for our national security. However, we think you will agree with us that no issue you are currently considering is more important than how to best ensure the health and well being of our military personnel while they serve their country.

As a result, we are troubled by several reports and actions that raise questions about whether continuing to administer the current anthrax vaccine is in the best interests of our personnel. First, we have been made aware of the fact that a number of military and civilian personnel have come to believe that the vaccination given to our military personnel is neither safe nor effective for its intended use. As you know, the Food and Drug Administration’s underlying prerequisite for the approval of any vaccine or drug is that it be proved safe and effective for its intended use. A growing number of people believe that the use of the anthrax vaccine as currently formulated to protect humans against inhalation of anthrax spores fails to meet this test.

Second, earlier this month, the Defense Department announced that it will further slow the administration of the anthrax vaccine. The current slowdown, the third in less than one year, was brought about by the continuing inability of the vaccine manufacturer to obtain FDA approval of its production facility. Under the revised policy, the scope of the vaccination program will be limited to special mission units, manufacturing and research personnel, and congressionally mandated research. In light of the questions surrounding the safety and effectiveness of the vaccine and the inability of the vaccine manufacturer to obtain FDA approval, many have asked why the Pentagon has not halted the vaccination program for all military personnel until these outstanding questions are satisfactorily addressed.

Third, the Defense Department has already taken disciplinary action against a number of people who have refused to take or administer the anthrax vaccination and has stated its intention to pursue legal action against others who act similarly in the future. Although a number of questions about the safety and effectiveness of the anthrax vaccination would appear to remain unanswered, the Pentagon has made it clear that it does not intend to revisit either the punishments already meted out or its decision to discipline those who act similarly in the future.
We all acknowledge that the threat posed by biological weapons, including anthrax, is a real one that the Administration and the Congress have a responsibility to address. Ignoring such threats is not an option. However, we also have an obligation to our military personnel to ensure that we do nothing to increase the risks they already face for their decision to serve their country. We would welcome your response to the issues raised here. In addition to your written response, our staff is prepared to discuss this matter with appropriate Defense Department officials.

Sincerely,