DISSENTING VIEWS OF HON. HENRY A. WAXMAN, HON. ROD R. BLAGOJEVICH, HON. TOM LANTOS, HON. MAJOR R. OWENS, HON. ELEANOR HOLMES NORTON, HON. ELIJAH E. CUMMINGS, HON. DANNY K. DAVIS, HON. JOHN F. TIERNEY, HON. HAROLD E. FORD, JR., AND HON. JANICE D. SCHAKOWSKY

We agree with many points set forth in the report. We submit dissenting views, however, because we disagree with the report's primary recommendations regarding whether to suspend the Department of Defense [DOD] program and reclassify the anthrax vaccine as "experimental."

I. ASSURED PRODUCTION AND CAPACITY

We agree that the anthrax program is vulnerable to supply shortages. Because the producer has been unable to obtain the Food and Drug Administration [FDA] approval to reopen its renovated production facility, no source of anthrax vaccine currently exists. Without a guaranteed supply, DOD will continue to experience difficulty meeting the demand it has created through its program to vaccinate all 2.4 million service members.

We also agree that the program is vulnerable to price increases. Within a year of agreeing to produce anthrax vaccine for DOD, the producer and DOD renegotiated the terms of the contract. The producer obtained advance payments, a price increase, and permission to sell on the open market, despite DOD's need for the vaccine. Explanations about the foreseeability and need for this renegotiation were unsatisfactory.

Although we acknowledge that DOD enters into exclusive contracts as a regular course of business, we agree that accelerating research and testing on a second-generation, recombinant anthrax vaccine may encourage competition and enhance production stability. One potential benefit of such a vaccine is that it could be produced in various facilities rather than a single, dedicated facility. In addition to enhancing competition, diversifying the source of anthrax vaccine could reduce security risks at production sites.

II. COMPLEXITY OF PROGRAM

The anthrax vaccination program is logistically complex. The FDA-licensed shot regimen requires six shots over a period of 18 months and a booster shot annually thereafter. The report correctly raises serious concerns about DOD's ability to perform successfully this regimen for certain members of its force. For example, it is difficult for DOD to deliver timely shots to Reserve and Guard service members who report for duty less frequently than active duty members.

We also agree that DOD's "timeliness goal" of vaccinating 90 percent of service members within 30 days after vaccinations are due

is insufficient. Under this standard, the first three vaccine inoculations—which FDA requires in 2-week intervals—instead could be delivered on the same day and still be considered "timely." We note that FDA wrote to DOD in September 1999 expressing concern with potential deviations from the approved schedule.[1]

If DOD continues the vaccination program, we recommend that DOD take measures to improve the administration of its program. We note that DOD has accomplished significant improvements, such as the utilization of the Defense Enrollment Eligibility Reporting System to combine service-based record systems into one central repository. In addition to upgrading these recordkeeping systems through the Composite Health Care System, we recommend that DOD revise its timeliness standard from 1 month to a window of days.

III. SAFETY MONITORING

We agree that vaccine safety could be monitored more thoroughly and comprehensively. The report acknowledges that, "[a]s with any vaccine, anthrax inoculation can cause adverse health events in some individuals . . .." The report also points out that, at the rates of adverse reactions cited by DOD, implementation across the entire force could produce thousands of systemic and local reactions. Although only a small percentage of these would require extended treatment or hospitalization, we agree that aggressively managing this anticipated caseload must be a priority for DOD.

The report suggests that the program may not be capable of performing adequate monitoring because of DOD's "institutional resistance to associating health effects with the vaccine." The subcommittee heard from several service members who relayed accounts of inappropriate behavior by DOD personnel. Although the subcommittee did not verify the prevalence or accuracy of these accounts, we do not doubt that such actions inevitably occur, whether or not officially sanctioned. While we disagree that DOD is incapable of performing adequate safety monitoring, we believe DOD should meet a higher standard. We recommend several measures to raise DOD's performance.

As part of its safety monitoring program, DOD relies on the Vaccine Adverse Event Reporting System [VAERS]. Under this system, FDA collects reports of symptoms temporally related to the receipt of the anthrax vaccine. DOD requires its physicians to file VAERS reports only if such reactions result in hospitalization or the loss of 24 hours of work. Although DOD physicians are permitted to file VAERS reports in cases below this threshold, it appears this is seldom done. We recommend that DOD require its physicians to file VAERS reports for all adverse events that result in hospitalization, any amount of missed duty, or any other negative health effects considered relevant by service members or their physicians.

The subcommittee also heard from several service members who claimed they were never told about VAERS forms or were unable to access them. DOD has been proactive in this regard by, in addition to taking other steps, placing on its website a direct link to the on-line FDA VAERS form. To augment this effort, we suggest

[1] Letter from Dr. Katherine C. Zoon to Dr. Sue Bailey (Sept. 29, 1999).

that DOD consider distributing paper copies of VAERS forms with each dose of anthrax vaccine administered.

IV. VACCINE SAFETY

The report does not conclude that the anthrax vaccine is unsafe. The report states that the vaccine "may be as safe as many other approved products" and "can be considered nominally safe." In their appearances before the subcommittee and committee, officials from the General Accounting Office [GAO] never stated that they believed the vaccine is unsafe. Instead, both the committee report and GAO argue that the vaccine's safety has not been demonstrated sufficiently to date.

FDA testified on several occasions before the subcommittee and the full committee that the agency believes the vaccine is safe. On April 29, 1999, FDA stated, "[w]e believe anthrax vaccine is a safe and effective vaccine for the prevention of anthrax disease."[2] At a later hearing, FDA officials reported that "FDA continues to view the anthrax vaccine as safe and effective for individuals at high risk of exposure to anthrax, when used in accordance with the approved labeling."[3] At another hearing, FDA officials explained why they believe the vaccine is safe:

> Our confidence in this vaccine, like all vaccines, is based upon four components: first—the review of manufacturing and clinical trials and subsequent clinical laboratory experience with the vaccine; second—ongoing inspections of the manufacturing facility; third—our lot release requirements; and fourth—our ongoing collection and analysis of adverse event reports. So far, the data gathered from VAERS reports on anthrax vaccine do not signal concerns about the safety of the vaccine.[4]

Without additional information to the contrary, we are not in a position to overturn FDA's judgment. Unlike FDA officials, we have little or no medical expertise. In our opinion, the report's criticism of a lack of studies demonstrating safety is insufficient to overturn FDA's findings based on the vaccine's 30-year history.

In addition, we fear the report's expectations for the safety of a new generation vaccine may be overly optimistic. The report recommends that DOD suspend its program only until it obtains "approval for use of an improved vaccine." Yet the recombinant vaccine envisioned by the report may be no safer than the existing version. The report concedes that "an improved vaccine based on recombinant technology may not necessarily have better safety characteristics than the current vaccine," but it offers no further explanation.

---

[2] *Anthrax (II): Safety and Efficacy of the Mandatory Vaccine,* Hearing before the Subcommittee on National Security, Veterans Affairs, and International Relations, House Committee on Government Reform, 106th Cong., 1st sess. (Apr. 29, 1999) (testimony of Dr. Katherine Zoon, Director, Center for Biologics Evaluation and Research).

[3] *Anthrax Vaccine Adverse Reactions,* Hearing before the Subcommittee on National Security, Veterans Affairs, and International Relations, House Committee on Government Reform, 106th Cong., 1st sess. (July 21, 1999) (testimony of Susan S. Ellenberg, Ph.D., Director, Division of Biostatistics and Epidemiology, Center for Biologics Evaluation and Research).

[4] *Defense Vaccines: Force Protection of False Security?* Hearing before the House Committee on Government Reform, 106th Cong., 1st sess. (Oct. 12, 1999) (testimony of Dr. Katherine Zoon, Director, Center for Biologics Evaluation and Research).

We would encourage further safety research on a new anthrax vaccine. In addition, we agree with the report's recommendation to pursue testing of the safety and efficacy of a shorter anthrax inoculation regimen. We also agree with the report's emphasis on continued testing for intramuscular injections, which may reduce reaction rates generally and address proportionally higher reaction rates among women.

V. CLASSIFICATION OF THE VACCINE AS "EXPERIMENTAL"

With respect to reclassification of the vaccine, we also defer to FDA's opinion that DOD's current use of the anthrax vaccine should not be considered "experimental." On November 3, 1999, Representatives Burton, Shays, Gilman, and Jones wrote to FDA essentially proposing the report's recommendation to reclassify the vaccine as "experimental" and conduct investigational new drug [IND] testing.[5] The rationale for this argument was that FDA had approved the vaccine for use against "cutaneous" infection (through the skin) during occupational use, but not against "inhalation" infection (through the lungs) during wartime.

In a November 26, 1999, response, FDA found no basis for this proposal.[6] FDA corrected a misconception that the vaccine is licensed only for use "by a limited population of individuals at risk for cutaneous exposure to anthrax."[7] FDA also stated that "use of the vaccine for protection against both cutaneous and inhalation anthrax exposure is not inconsistent with the labeling."[8] Addressing the proposal directly, FDA stated:

> There is presently no basis for concluding that the anthrax vaccine, a licensed product, when used in accordance with current labeling, should be used pursuant to an IND application or, as requested in your letter, that FDA "place the anthrax vaccine back under IND status."[9]

VI. RECOMMENDATION TO SUSPEND THE PROGRAM

Whether to suspend the vaccination program is a decision that must be made by security experts based on the most complete information relevant to all risks and benefits. These factors are sometimes unquantifiable; indeed, some are unknowable and will remain so until ultimately tested in combat. Because the report is not based on classified information regarding the likelihood of an anthrax attack, it provides insufficient information to overturn DOD's decision to pursue the vaccination program.

The report recognizes that "[t]hreat assessment requires objective and subjective analyses of U.S. vulnerabilities, enemy capacity, and enemy intentions." The report also acknowledges that "much of the information regarding the BW [biological weapons] capabilities and intentions of potential adversaries, and even allies, is classified." Yet the report bases its conclusions only on unclassified information. Members received no classified information at the full

---

[5] Letter from Representatives Burton, Shays, Gilman, and Jones to Dr. Jane E. Henney (Nov. 3, 1999).
[6] Letter from Melinda K. Plaisier to Representative Walter B. Jones (Nov. 26, 1999).
[7] Id. at 2.
[8] Id.
[9] Id. at 3.

committee level, and the subcommittee had no closed hearings in which it could consider such information.

As a result, the report's conclusions—that "the threat remains tactically limited and regional" and that the program "is designed to reach far beyond those at risk"—do not reflect DOD's full judgment about the actual extent of the threats involved. The report states that "DOD has determined the threat is real and imminent, and has concluded it would be irresponsible not to deploy an available countermeasure to protect the lives and fighting capability of U.S. forces." Without additional information to the contrary, we defer to DOD's conclusion.

VII. KEVIN EDWARDS

At the committee meeting to consider this report, Representative Dan Burton, chairman of the Committee on Government Reform, raised the case of Kevin Edwards. He began his statement by displaying photographs of Mr. Edwards's bruised body. He then said:

> We have spoken to many individuals who have been ill for a very, very long time. One example is Mr. Edwards of North Carolina. I want you to look at these pictures. I think these pictures will show what can happen when there really is a bad reaction or an adverse event. Mr. Edwards has what appears to be third degree burns on much of his body but in fact, it is a condition that developed after receiving the anthrax vaccine.

Subsequent investigation by the minority does not substantiate Mr. Burton's allegations. While Chairman Burton attributed Mr. Edwards's illness to the anthrax vaccine, he failed to disclose that Mr. Edwards's case had been considered by the Anthrax Vaccine Expert Committee. Although the Privacy Act protects Mr. Edwards's medical records, the findings of the Expert Committee were fundamentally different from Chairman Burton's conclusions.

Exhibit 1 to these views is a letter from Representative Henry A. Waxman, ranking minority member, that sets forth additional details related to Mr. Edwards's case.[10]

HON. HENRY A. WAXMAN.
HON. ROD R. BLAGOJEVICH.
HON. TOM LANTOS.
HON. MAJOR R. OWENS.
HON. ELEANOR HOLMES NORTON.
HON. ELIJAH E. CUMMINGS.
HON. DANNY K. DAVIS.
HON. JOHN F. TIERNEY.
HON. HAROLD E. FORD, JR.
HON. JANICE D. SCHAKOWSKY.

[10] Letter from Representative Henry A. Waxman, ranking minority member, to Representative Dan Burton, chairman (Mar. 17, 2000) (exhibit 1).

March 17, 2000

The Honorable Dan Burton
Chairman
Committee on Government Reform
2154 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Burton:

At last week's Committee meeting to consider the anthrax report, you spotlighted the case of Kevin Edwards of North Carolina. You began your statement by displaying photographs of Mr. Edwards's bruised body. You then said:

> We have spoken to many individuals who have been ill for a very, very long time. One example is Mr. Edwards of North Carolina. I want you to look at these pictures. I think these pictures will show what can happen when there really is a bad reaction or an adverse event. Mr. Edwards has what appears to be third degree burns on much of his body but in fact, it is a condition that developed after receiving the anthrax vaccine.

Your display of Mr. Edwards's photos took me and other Democratic members by surprise. Although Mr. Edwards developed his symptoms in 1998, his case was never presented at any of the seven hearings before the Subcommittee or Committee. You also did not give me or other Democratic members any advance warning of your intention to introduce Mr. Edwards's case just moments before voting on the report. As a result, I was unable to respond to your allegations during the meeting.

Since the meeting, however, my staff has investigated the case of Mr. Edwards. What we have learned casts doubt on your assertions.

We have learned that the Anthrax Vaccine Expert Committee recently analyzed Mr. Edwards's case. This interagency group, which consists of medical experts drawn largely from outside government, was established to examine conditions reported in the Vaccine Adverse Event Reporting System that might be related to the anthrax vaccine. The Expert Committee reviewed substantial documentation from Mr. Edwards's medical file and, although the Privacy Act protects Mr. Edwards's medical records, I understand the Committee's conclusions conflict fundamentally with your assertions. I also have been advised that — as chairman of a full committee — you could have obtained a copy of the Committee's findings regarding Mr. Edwards's case if you had sought one.

According to news reports, Mr. Edwards was diagnosed with Stevens Johnson Syndrome (SJS). In investigating this illness, my staff obtained information from the SJS Foundation that indicates that this condition can be caused by almost any drug, including over-the-counter drugs. We also learned that a preliminary Department of Defense analysis indicates that the prevalence of SJS and related sicknesses among service members has declined over the past few years and has continued to decline since the implementation of the anthrax vaccine program. Whether or not you agree with these findings, they seem inconsistent with your supposition that the anthrax vaccine caused his condition.

This case also conflicts with a statement you made at a May 27, 1999, hearing on dietary supplements. You argued then that government descriptions of adverse events should include disclaimers and additional information "so that people can realize that this might be an isolated case that might be related to something else that they were taking at the same time." You further said, "What we need is good information so the American people can make good decisions, and the Congress as well." Unfortunately, your use of Mr. Edwards's case does not meet this standard.

I am pleased that the Subcommittee was able to investigate the Department of Defense anthrax vaccine program in a fair and even-handed manner, and I hope you will consider amending the Committee record as necessary to ensure that it is accurate with regard to Mr. Edwards's case.

Sincerely,

Henry A. Waxman
Ranking Minority Member

cc: Members of the Committee on Government Reform

SUPPLEMENTAL VIEWS OF HON. BERNARD SANDERS

The chairman of the Subcommittee on National Security, Veterans Affairs, and International Relations is to be commended for the extremely thorough hearings he has held leading up to this report. He is also to be commended for the extremely well documented report, itself, and the decisive recommendations contained therein. All of these recommendations are fully supported by the testimony presented to the subcommittee—testimony which raised serious questions about the anthrax vaccine, its manufacturer, and the Department of Defense's [DOD] vaccination program.

As the report documents, the anthrax vaccine is of questionable efficacy and safety. DOD's mishandling of the vaccination program has exacerbated these concerns. Questions about efficacy have been compounded by the failure of DOD to administer the six shot regimen in accordance with the FDA-approved vaccination schedule. Safety concerns have been heightened by DOD's failure to track and record adverse reactions. Moreover, DOD's refusal to even acknowledge the concerns raised by members of the armed services has created significant morale problems among active service members, as well as National Guard and Reserve forces.

DOD also must shoulder the blame for failing to pursue a more effective and safe vaccine against anthrax. Had DOD acted immediately after the Persian Gulf war to find an alternative; a safer, more effective vaccine would be available now.

Against this backdrop of DOD mismanagement and stonewalling, some service members have refused to be vaccinated against anthrax. As a result, service members have been disciplined, including being discharged from the armed services. While I fully understand the need for the military to insist on compliance with lawful orders, DOD cannot escape its own responsibility for the refusal of its members to take the vaccine.

The subcommittee's report expressly "makes no recommendation regarding the status of those service members who left the armed forces voluntarily, or as the result of disciplinary action, due to the anthrax vaccine." Some have questioned whether the order to take the vaccine itself is lawful. The subcommittee did not set out to answer that question and the testimony it received was not adequate to resolve it.

DOD's position is buttressed by the Food and Drug Administration's [FDA] view that DOD's anthrax program does not represent an off-label use. However, given the documented failure of DOD to administer the vaccine in accordance with the FDA's approved schedule, DOD's insistence on deploying service members before the six shot regimen is complete, and the insufficiency of scientific evidence to support claims of efficacy against weaponized anthrax, it is not clear that the FDA's position would pass muster under the

Administrative Procedures Act's "arbitrary, capricious or contrary to law" standard.

This ambiguity and the well documented DOD mishandling of its anthrax vaccine program argues strongly that, at a minimum, DOD should exercise extreme leniency in its treatment of service members who have refused to take the anthrax vaccine, including removing derogatory findings and comments in service records, reversing reductions in rank and pay, and permitting the re-enlistment of members who have been discharged.

If DOD accepts the subcommittee's recommendation—as it should—to recategorize its anthrax program as being in Investigational New Drug status then future disciplinary proceedings will be unnecessary because service members will only receive the vaccine after providing their informed consent.

If there is one thing that the subcommittee learned from its review of DOD's anthrax vaccination program it is that the trust of many service members has been severely shaken. Acceptance of the recommendations in the subcommittee's report and reversal of prior disciplinary actions will go a long way toward rebuilding the trust of service members in the DOD and would be in the best interest of our Nation's armed forces.

HON. BERNARD SANDERS.

○