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Before the Subcommittee on Military Personnel

Steve Buyer, Chairman

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Thank you very much for the opportunity to offer written testimony on the anthrax vaccine immunization program. The following is an update of things I've learned since providing testimony to Congressman Shays' subcommittee on the anthrax vaccine on April 29, 1999.

Dr. Sue Bailey, Assistant Secretary of Defense for Health Affairs, provided an 11-page briefing document to members of Congress titled "Information on General and Commonly Asked Questions about the Anthrax Vaccine and the Department of Defense (DoD) Anthrax Vaccine Immunization Program (AVIP)."

I would like to point out 24 inaccuracies in this document, identify problems with FDA oversight of the anthrax vaccine, draw a series of conclusions, and then provide additional materials in support of my testimony.

1. "On December 15, 1997, Secretary of Defense Cohen approved the plan to immunize the total force against anthrax contingent on the successful completion of four conditions . . . Both the Accelerated and Total Force AVIPs were approved by the Secretary of Defense and implemented after the successful completion of the four conditions set by Secretary Cohen on December 15, 1997."

The centerpiece of Secretary Cohen's pre-conditions concerns supplemental testing designed to prove that the vaccine is sterile, safe, potent, and pure. I am including documentary evidence with this testimony to show you that the Joint Program Office for Biological Defense, which mandated the supplemental testing and paid for it, had no intention of following Secretary Cohen's admonition. In fact, an information paper to Lt. Gen. John Kusick written by Dr. Mike Gilbreath of the JPO states, "Supplemental testing has little technical or regulatory utility, but is being done as directed by DoD." Furthermore, DoD did not intend to complete supplemental testing on all lots before they were shipped out for use. In fact, prior to beginning the vaccinations, Gilbreath's paper was intended to "support waiving of the DoD-directed supplemental testing to meet developing contingency use requirements." He further pointed out, "The FDA-approved lots can be used without supplemental testing with a high degree of confidence in the product quality and integrity."

Dr. Bailey's paper was dated April 5, 1999. Gen. Eddie Cain, who testified before Shays' committee on April 29, 1999, reported that "GPOBD suspended supplemental testing and sent a tiger team of subject matter experts to help resolve the problem (control values and potency essays)" He also said, "As of 15 April 1999, doses available for immediate use include one undistributed lot that has completed supplemental testing along with four additional lots recently released by FDA. These latter four lots are not part of the original DoD stockpile and did not undergo supplemental testing because lot release data were recently completed and submitted to FDA for review and approval."

The four lots that were supposedly not part of the original DoD stockpile in fact had their release testing done in November of 1997, and therefore were in fact in the DoD stockpile one month prior to Secretary Cohen's announcement. A more likely reason for not testing these lots is that as a result of initial supplemental testing, only six of 31 lots passed, and the DoD probably did not want to learn that these four lots required for vaccinations that were

coming due, would also forfeit approval when faced with supplemental testing. Gen. Cain admitted in his April testimony that 21 lots of the original stockpile remained quarantined pending resolution of supplemental testing or FDA regulatory issues.

2. "For more than 25 years, the FDA-licensed anthrax vaccine has been recommended for veterinarians, laboratory workers, and livestock handlers in the US. The FDA-licensed anthrax vaccine is safe and has an excellent safety record."

In contrast, may I quote Dr. Kwai Chan of the GAO in his verbal testimony of April 29, 1999:

"In our discussion with scientists at Ft. Detrick, the estimates of number of people who may have received this vaccine over 30 years range from somewhere between 200 to about 2,000 at the most. And we don't know who those individuals are. There has been no follow up."

". . . The long-term safety of the vaccine has not yet been studied, and therefore one cannot conclude that there are no known long-term effects."

3. "DoD policy requires that the anthrax schedule approved by the FDA be followed."

An enclosed article from the Hartford Courant last month by Thomas D. Williams shows that the DoD is not following the FDA schedule with any regularity.

4. "Several national scientific groups, to include the Presidential Advisory Committee on Gulf War Veteran's Illnesses, have closely examined this issue and found no evidence to link the FDA-licensed anthrax vaccine with illnesses among Gulf War veterans."

My testimony of April 29th deals with this issue in depth. The Presidential Advisory Committee and several other national scientific groups were briefed by Department of Defense briefers and did not examine any of the published or unpublished literature which reviews the relationship between anthrax vaccine and Gulf War Illness. Only one study has been published. The primary author is Catherine Unwin. It was funded by the Department of Defense. I include a copy of the article with this testimony. Unwin's study showed that there was a statistically significant relationship between receiving the anthrax vaccine, between having documentation of receiving that vaccine, and subsequently developing Gulf War Illness in British Gulf War Veterans. Furthermore, she points out that in veterans of the Bosnia conflict who have records that document anthrax vaccination, there is an even stronger relationship between being vaccinated and developing symptoms consistent with the Gulf War Illness definition of CDC.

Lea Steele reported in a talk "Major Findings Of The Kansas Gulf War Veterans Health Initiative Advisory Board," January 15, 1999, that among Gulf-era veterans who were never deployed to the Gulf, rates of Gulf War Syndrome were 11% for those who recalled anthrax vaccination compared to 4% for those who did not recall being vaccinated.

Dr. Han Kang of the VA has data on many thousands of Gulf vets which includes their recollection of having received anthrax vaccination. He has not yet reported what the relationship is between being vaccinated and subsequently developing illness consistent with Gulf War Syndrome, although he told me in late 1998 that he would be able to extract that information from his data.

5. "There have been no long-term side effects reported with the FDA-licensed anthrax vaccine."

So far, Shays' Subcommittee has heard testimony from six servicemembers who report chronic illnesses which followed rapidly upon being vaccinated with the anthrax vaccine, and one nurse reported illnesses in over 30 servicemembers who were vaccinated at Dover AFB. I have collected anecdotal reports of illness from 200 servicemembers who have been vaccinated.

The Department of Defense initiated a study at Tripler Army Medical Center in Hawaii last September to explore possible long-term side effects from anthrax vaccine. Initial data from

this study was reported by the GAO. The rate of adverse systemic reactions was 48% in the 603-member cohort of medical personnel at Tripler Army Medical Center who were enrolled in this study. (289 people had a systemic reaction.) There was no control group. The problem is that this study has been ongoing for one year, but the principal investigator, Col. Glenn Wasserman, has not released any data about long-term adverse effects, although long-term data should be readily available. It is very important for Congress to review the chronic health status of the 603 persons in the Tripler study.

Department of Defense spokespersons recently announced a meeting to begin to prepare a “first” study of long-term side effects from anthrax vaccine. Since the Tripler study was, in fact, the first such study to evaluate long-term effects, I fear the DoD may have decided to halt this study because of high adverse event rates, or may try to hide any results that accrued from the study.

6. “To date, there have been 46 reports submitted to the FDA and Center for Disease Control and Prevention’s Vaccine Adverse Event Reporting System of reactions following administration of the anthrax immunization (an adverse reaction rate of 0.007 percent).”

On July 21, the GAO provided Shays’ Subcommittee with a careful critique that showed that using VAERS data does not give an adverse event rate. It gives a rate of VAERS reporting only. In the civilian world, FDA has estimated that formal reporting of adverse events from drugs probably underestimates serious adverse reactions by a factor of 100. In other words, only one in 100 serious reactions gets reported to FDA. In the case of military reporting, in which the anthrax vaccine implementation program has specifically directed medical providers to not report to the VAERS system unless one of three relatively uncommon conditions is met, the reporting rate is probably well under 1/100th of the adverse events which occur.

7. “All Service members, to include the latter individual with the more serious illness, are doing well and returned to duty.”

This is not true. We are aware of scores of servicemembers who have not returned to full duty. This includes pilots at Dover and elsewhere that have been off flying status for up to a year. More details will be provided today.

8. “The safety of our AVIP was recently confirmed by an independent review of the program by an expert in the field, Dr. Gerard N. Burrow.”

Dr. Burrow provided written testimony to Congressman Shays’ Subcommittee stating that he was not an expert on anthrax or biological warfare and was only providing “general oversight” of the program, which amounted to suggesting the Department of Defense convene “focus groups” to convince servicemembers of the utility of vaccination.

9. “The Committee on Infectious Disease, American Academy of Pediatrics (1994), states that “the vaccine is effective in preventing or significantly reducing the occurrence of cutaneous and inhalation anthrax in adults.”

Having erred in publishing the above statement in 1994, since there was no data to support it, the Committee on Infectious Diseases removed this statement from their 1997 edition, which said “a cell-free vaccine has been developed for persons at significant, continuing risk of acquiring anthrax. The vaccine is effective in preventing or significantly reducing the occurrence of cutaneous anthrax in adults, and it causes minimal adverse effects. No vaccine effectiveness or reactogenicity information for children are available, and the vaccine is not currently licensed for use in children or pregnant women.”

10. “. . . anthrax vaccine provided greater than 95% protection against high-dose aerosol challenge with anthrax in the monkey model. Human antibody response to the FDA-licensed anthrax vaccine provides further suggestive evidence that the FDA-licensed anthrax vaccine will protect against inhalation anthrax.”

Dr. Walter Brandt disagreed with this in an Army memo I include with this testimony, dated 8 March 1996. He said, "A preliminary review of the data indicates there is insufficient information to support a licensure amendment because there is no correlation between protection in vaccinated non-human primates and antibody levels in vaccinated humans."

11. "Russian scientists have reported the creation of an antibiotic resistant strain of anthrax—a relatively simple technical manipulation. . . That strain was resistant to the Russian anthrax vaccine unless the vaccine was modified to contain the same genes. This genetically engineered strain likely causes disease by a different mechanism than used by naturally occurring anthrax strains. Such an organism would essentially be a new organism and not anthrax, as we know it."

In an attempt to evade the question of whether our vaccine will protect against a known Russian strain of genetically engineered anthrax, Dr. Bailey recasts the new strain as "not anthrax as we know it." Such a strain would be "anthrax as we don't want to know it." The evidence is there for all to see: such strains have been created, and Russian scientists who produced them have likely moved to a variety of countries, and may well be engaged in producing biological weapons. Such strains will almost certainly overcome immunity provided by the U.S. human anthrax vaccine.

The two statements below confirm that DOD and FDA share these concerns.

The former Assistant Secretary of Defense for Health Affairs, Dr. Steven Joseph, wrote, "A concern, however, that must be addressed is the possibility that an adversary could develop, by genetic engineering or other means, an organism capable of circumventing the protective effect provided by this vaccine," in a letter I enclose dated 25 October 1996.

Finally, Dr. Kathryn C. Zoon, head of the Center for Biologics Evaluation and Research at the FDA, proposes that an activity of the FDA to counter bioterrorism should include "developing techniques for detection of genetic modification of microorganisms to make them more toxic or antibiotic- or vaccine-resistant." (Emerging Infectious Diseases Vol. 5 No. 4 1999, Centers for Disease Control. "Vaccines, Pharmaceutical Products, and Bioterrorism: Challenges for the U.S. Food and Drug Administration)

A New York Times article that reported this controversy is included.

12. "The laboratory press release implied that mixtures of anthrax strains might overcome the protection afforded by anthrax vaccine."

This refers to research done by Dr. Paul Jackson at Los Alamos, in which he felt that multiple strains isolated from autopsy specimens from persons who died of anthrax in Sverdlovsk in 1979 suggested that the Russians used multiple strains in order to evade vaccine-induced protection. Ft. Detrick officials put pressure on Los Alamos to rescind this statement and Los Alamos complied. I have enclosed a New York Times article which discusses this matter. It is clear that once the decision was made to implement the anthrax vaccine immunization program, all data, even Department of Defense-generated data (from Los Alamos) which suggested that the vaccine could be defeated would have to be suppressed.

13. "The current US-licensed anthrax vaccine is considered to be highly effective against naturally occurring strains of anthrax, including antibiotic resistant strains."

I supplied Congressman Shays' Subcommittee data from a study done by Bruce Ivins et al at Fort Detrick and presented in September 1998 at the International Anthrax Conference. Thirty-three naturally occurring strains of anthrax were selected from around the world and guinea pigs immunized with the human anthrax vaccine were injected with these 33 strains. Twenty-seven of the 33 strains killed at least 50% of immunized guinea pigs.

Experiments with multiple anthrax strains have only been performed in guinea pigs. The monkey experiments have used only one strain of anthrax. Therefore, experiments in neither

species support the claim that the human vaccine is effective against all or most naturally-occurring anthrax strains.

Dr. Kwai Chan, on April 29, 1999, also stated, "In the 80's, the military collected efficacy data on animals specific to inhalation anthrax. All of these studies have supported the view that in those models, the vaccine can protect against some anthrax strains, but not all." He added, "Taking all the evidence into account, it's likely that the vaccine does give some protection, but to what extent, against what amount of anthrax, against which strains and how long protection lasts, are not known."

14. "While vaccines offer the best means of protection and are an important component of our overall passive defense posture, physical protection in the form of the mask remains a critical element in our defense against biological weapons."

The mask is the most important means of protection and the only one likely to defeat any strain of anthrax and most microorganisms. In an undated and unsigned DoD information paper enclosed for your review, is the statement "all medical prophylactic modalities described should be viewed only as secondary 'i.e. backup', and are not to be relied upon as primary protective measures. Agent exposures near the source of dissemination will be high, and likely to overwhelm any medical protective measure. The precise efficacy of available medical countermeasures has, of course, never been evaluated in actual field circumstances, but is largely inferred from laboratory studies on non-human primates. While these extrapolations may be inexact, they strongly support the efficacy of vaccines and drugs at some agent doses." This document also says, "Preventing exposure of the respiratory tract and mucous membranes to infectious and/or toxic aerosols through use of a full-face respirator will prevent exposure, and should, theoretically, obviate the need for additional measures. Chemical protective masks effectively filter biological hazards.

15. ". . . a number of deficiencies with the manufacturing process were cited by the FDA. However, none of the deficiencies that were cited were considered significant enough to warrant closure of the facility or the recall of previously manufactured lots of the anthrax vaccine."

I can't tell you the difference between the terms "recall" and "quarantine", but the FDA requested that BioPort quarantine at least 11 lots of vaccine following their February 1998 inspection. That letter accompanies this testimony. Whether closure and rehabilitation of the manufacturing facility were FDA-directed or not remains moot, but the FDA threatened closure of the facility in 1995 and 1997.

According to the information paper written by Mike Gilbreath, "the FDA 11 March letter instructed MBPI to "conduct a review of all observations listed on the form FDA483 issued 27 November 1996, to determine whether or not product quality has been affected, including addressing the need for possible product recall of product if deemed necessary. MBPI completed a review with respect to potential effect on product quality and the necessity of initiating a recall and reported their findings to the FDA in the 09 April 1997 30-day response to the FDA letter of 11 March 1997."

It is astounding to me that the FDA allowed the manufacturer to make its own determination of whether its products should be recalled by the FDA.

16. "While not required by the FDA, MPBI has performed, and as the newly formed BioPort, continues to perform supplemental or additional testing on all 31 lots of anthrax vaccine that were in the DoD's stockpile in December 1997 when the Secretary of Defense approved the policy to immunize the Total Force against anthrax."

Included with this testimony are charts detailing the lots in the MBPI stockpile, the dates of release, and some of the supplemental testing issues that have led to their quarantine. The statements previously cited by Dr. Gilbreath and Gen. Cain indicate that not all lots have been, or were intended to be, supplementally tested.

17. "Any manufacturer of a pharmaceutical or biological product can request and receive an extension from the FDA on the expiration date of the product after federal requirements for product extension have been successfully met."

I have enclosed a four-page memo from within the FDA dated December 10, 1997. In it is revealed the fact that although the Michigan manufacturer had been redating lots of anthrax vaccine since initial licensure in 1970, no supplement to the product license which would have provided a legal basis for this redating had ever been submitted or approved.

18. "Since all vials of FAV016 previously shipped to DoD had been approved by the FDA for lot release and had been visually checked for particulate material by the manufacturer before shipment, with those that were found to contain particulate material discarded, no recall of vaccine lot FAV016 that had been shipped to DoD was instituted by the manufacturer nor was it requested by the FDA."

The approximately 20,000 bottles of FAV016 were visually checked and those which had obvious particulates were discarded. Those that did not obviously have particulates were used. No additional testing for the presence of particulates appears to have been done. A fair assumption is that tiny particles of gasket material were injected into servicemembers receiving vaccine from this lot.

19. "While not required by the FDA, supplemental testing was requested by the Department to provide additional assurances of the safety, potency, sterility, and purity of the anthrax vaccine in the stockpile, some of which had been in storage for a number of years (once placed in vials and labeled, the anthrax vaccine has a one year shelf-life)."

Please see a memo signed by Brig. Gen. Bruce T. Miketinac from the Gulf War era. In point F, he states "store vaccines in bulk to extend shelf life to greater than ten years to minimize fiscal impact while maximizing BW defensive capabilities." A second declassified memo points out that DoD should "store quantities of licensed products in bulk to maximize shelf life. The only licensed products in the inventory are anthrax vaccine, smallpox vaccine, and plague vaccine. Licensed products held in bulk can be retested before final packaging in order to ensure potency. Once packaged in multidose vials, the licensed products have a relatively short shelf life of one to three years. On the other hand, investigational new drug (IND) products can be held indefinitely since they are bottled and labeled with the date of manufacture but have no expiration date. It may be feasible to keep all the IND products in multidose vials." These memos make clear that long-term, indefinite, storage of vaccines are not an aberration, but rather policy of the Department of Defense.

No meaningful testing to assure quality of long-stored vaccines has ever been undertaken.

The concept that routine, long-term storage of vaccines is safe and acceptable needs to be abandoned immediately.

20. "Before any of the 31 lots of anthrax vaccine in the stockpile as of December 1997 can be used by the DoD, it must successfully complete supplemental testing."

We have seen that this statement does not accurately reflect DoD policy, in which lots of vaccine were used that did not go through the supplemental testing process.

Data reported by the supplemental testing program may not be consistent with reports by FDA; for instance, the 11/13/98 table reports that lot FAV031 has no problems with supplemental testing. However in a May 4, 1998 letter from FDA to MBPI, Lot FAV031 is cited as a lot for which MBPI must "provide your plan for the disposition of these lots should the volume studies show that the remainder of the lots' vials were not adequately filled and/or should the container/closure integrity studies be unsatisfactory."

Supplemental testing did not review either the volume of product contained in the vials, nor container/closure integrity.

Was this lot released for use, and did FDA test the volumes present in the vials, and assure closure integrity?

21. “. . . the test vaccine is no less potent than the reference vaccine.”

The problem with potency testing is that the reference used was lot 009, whose release date was March of 1991. Presumably, potency diminished between the time of production and the supplemental test dates. Since the other lots were tested against a 7 or 8-year-old lot which may not have maintained its potency, the test lots also had uncertain potency.

22. “All independent oversight of supplemental testing is performed by Mitretek, which observes all aspects of supplemental testing and provides a written report to the DoD prior to any of the 31 lots being approved by DoD for use and shipment.”

Mitretek's reports have not been available to the public. I was informed by a journalist who had interviewed Mitretek's scientists, that they had spent only two weeks at MBPI in January of 1998 performing oversight.

23. “. . . the anthrax vaccine is fairly well-known and widely administered to people who deal with animals which might have been infected with anthrax.”—a quote from President Clinton, December 16, 1997.

DoD spokesmen have now admitted that this statement is an exaggeration, as reported by Debbie Funk in the Army Times. It was never widely administered, and virtually no veterinarians or livestock workers have been vaccinated with it. The reason is simple. Animal workers get cutaneous anthrax, which responds to antibiotic treatment and is virtually never fatal. There is less than one case per year reported in the US currently. Why go through an extensive series of vaccinations for a rare disease that responds to penicillin?

24. “I know of no expert opinion that would say that those of us that are essentially in the civilian population in the United States should be vaccinated.”—another quotation by President Clinton from the same date.

I, and other non-governmental experts on biological warfare, feel that anthrax is a good terrorist weapon, but a poor battlefield weapon. It would seem that certain civilians, such as State Department employees, are at greater risk than servicemembers, many of whom are never deployed to threat areas. How was the decision made to require anthrax immunization of all servicemembers, regardless of deployment status? How was the risk to servicemembers estimated?

FDA Oversight Issues

The 10 December 1997 FDA memo indicates that relevant personnel at FDA allowed the Michigan Manufacturer to redate anthrax vaccine lots without meeting the legal requirements since 1970, and when they did find this out, they let at least a year go by without vigorous pursuit of a legal supplement or protocol to the license. Only after FDA noticed that the Department of Defense was stating that FDA was testing every lot did FDA bother to inquire whether FDA was testing the anthrax vaccine lots. At that time, they could not find any recent lots that FDA had tested. Instead FDA had accepted data provided from the manufacturer as to the viability of lots and accepted retest data of potency. According to FDA, the data provided by the manufacturer indicated that every lot passed retesting. However, when the lots were subjected to supplemental testing, even though this appears to have been cursory, based on the memo of Mike Gilbreath, 25 of the 31 initially passed lots failed.

This, coupled with the fact that FDA did not actually inspect the anthrax manufacturing facility until one month before vaccinations of servicemembers commenced, indicates a widespread pattern of neglect of its regulatory role by FDA.

Instead of acknowledging that its standards were lax, FDA has responded by suggesting that it should further weaken its own standards for approval of biological warfare vaccines. In the

just published article by Dr. Zoon, in Emerging Infectious Diseases titled "Vaccines, Pharmaceutical Products, and Bioterrorism: Challenges for the U.S. Food and Drug Administration," Dr. Zoon suggests that efficacy should be determined for a product using animal data alone, and that the product should be given an unrestricted license without safety data. She then suggests that safety data be acquired after licensure.

"Once a product is approved, long-term post-marketing surveillance, inspections, and product testing are performed to ensure the quality, safety, and efficacy of the product, as well as appropriate product-labeling."

What she fails to acknowledge is that FDA did not perform inspections, did not do product testing and did not require any post marketing surveillance of anthrax vaccine. Is institutionalizing the lack of oversight evidenced by FDA in the anthrax vaccine controversy an appropriate response to the large number of new biological warfare vaccines under development by DoD?

But Dr. Zoon doesn't stop there. She suggests that the product review process be expedited as well and implies that complete review of marketing applications be limited to six months.

An FDA advisory panel reviewed anthrax vaccine in December of 1985, and recommended that the vaccine be placed in Category 1 (safe, effective and not misbranded) and that the appropriate license be continued because there was substantial evidence for this product. Since the only human efficacy trial used a different vaccine, and no long-term safety data has ever been supplied to FDA, I wonder what substantial evidence FDA reviewed in 1985. Perhaps Congress would like to request the data.

Dr. Miles Braun of FDA said that FDA did not want to require active surveillance of anthrax vaccine recipients (although it has the right to do so) as it did not want to set a precedent in this regard. If this is so, what kind of long-term post-marketing surveillance is Dr. Zoon referring to?

Because the Defense Department limits VAERS reporting to FDA through several mechanisms, requiring that medical providers not report via VAERS unless

- a) a servicemember is hospitalized,
- b) loses at least 24 hours of duty time, or
- c) vaccine contamination is suspect, and
- d) requires that VAERS reports are not sent directly to FDA or CDC, but rather be sent to a DoD clearinghouse, and
- e) because DoD physicians feel it may not be in their patients' best interest to report adverse reactions through the VAERS system, as they may adversely impact on service members' careers, the VAERS system is inadequately assessing adverse vaccine reactions. The problem is, it is the only system FDA uses to perform surveillance on the safety of licensed vaccines.

Overall Conclusions:

1. The Department of Defense has used a succession of deceptions to justify the anthrax vaccine immunization program.
2. The Food and Drug Administration has not properly performed a single one of its oversight functions with respect to the licensed human anthrax vaccine.
3. The mechanisms proposed by Dr. Zoon, head of FDA's CBER, would be a regulatory disaster.
4. Between five and 15 percent of servicemembers vaccinated with human anthrax vaccine are suffering chronic medical problems, based on informal data obtained from a number of different military installations.

5. Because these illnesses officially do not exist, since anthrax vaccine, according to DoD protocols, cannot cause the symptoms described, no meaningful medical assistance has been provided to servicemembers suffering from these illnesses. I hope Congress will see fit to mandate civilian-directed appropriate medical evaluations and treatment studies for these servicemembers and will provide appropriate compensation for those who are discharged from military service as a result of their illnesses.

This concludes my formal written testimony. I will be glad to elaborate for the committee on any of the items touched on in this report. Thank you very much for the opportunity to provide you with this information.

I was asked to provide questions to the Subcommittee.

Questions for the FDA:

1. Dr. Susan Ellenberg provided written testimony to Shays' Committee on July 21, 1999, which discussed the issue of relating adverse events to vaccines. She listed four criteria that would help establish causality:
 1. Biologic plausibility.
 2. A laboratory result confirms association.
 3. Positive rechallenge.
 4. A controlled clinical trial shows a greater risk of adverse events among vaccinated than unvaccinated groups.

She neglected to say that when adverse events are first identified, it is often in the absence of biologic plausibility, such as the recent linkage of intussusception with rotavirus vaccine, the fact that lab results are rarely available to assign association, the fact that positive rechallenge is often a dangerous procedure, and the fact that in the case of anthrax vaccine, no controlled clinical trial looking for adverse effects has ever taken place.

Furthermore, she neglected to point out the major way adverse effects may be causally attributed to vaccines: when a large number of people develop the same adverse effect in temporal relationship to the administration of a single vaccine.

Why did her testimony ignore these important points?

2. Why were procedures so lax at FDA that it took 27 years to discover that the anthrax vaccine manufacturer never filed the required forms for redating? Why did FDA ignore the Code of Federal Regulations in its oversight procedures used with the anthrax vaccine manufacturer? For one thing, the CFR requires inspections at least every two years of vaccine manufacturers.
3. Does FDA intend to make permanent the "interim rule" which allowed the Department of Defense to administer investigational new drug products (INDs) to servicemembers without informed consent? The interim rule is the first challenge to the protections offered US citizens against medical experimentation by the Nuremberg Code, since the Code was created.

Allowing DoD to administer IND products to servicemembers without informed consent, also provides DoD an opportunity to indefinitely store IND vaccines and use them however they see fit, while acting in accord with FDA's regulations. Has FDA any plans to regulate IND products more strictly?

4. What data were used in the 1985 FDA review which determined that the anthrax vaccine was safe and effective? Did these include human studies? If so, these missing studies should be provided to the committee.

Questions for the Department of Defense:

1. A study was conducted at Fort Bragg between 1992 and 1995, of 480 servicemembers who had received anthrax and/or botulinum toxoid vaccines in Operation Desert Storm. The study was designed to see if booster doses of vaccine, administered after a period of several years had elapsed, would still act to "boost" immunity generated years earlier. The Ft. Bragg study required that all participating servicemembers have records of their original injections of anthrax and botulinum toxoid vaccine at the time of the Gulf War. This study is evidence that the Department of Defense is able to obtain immunization records from the time of the Gulf War when necessary for their purposes. Why haven't the other Gulf War immunization records come to light? And why haven't these 480 servicemembers, whose immunization status is known and who received subsequent boosters, studied for possible long-term adverse effects from the anthrax vaccine?
2. Why haven't the data on long-term adverse effects from the ongoing Tripler Army Medical Center study been made available to the GAO and to Congress?
3. I would suggest that Congress obtain the raw data from Dr. Unwin's study of 4,000 British Gulf War veterans. In oral presentations, she has commented in marked differences in adverse event rates for those who received anthrax vaccination while on deployment as opposed to those who were vaccinated prior to deployment. She has also not published information on the Gulf era cohort, and their vaccination status would be interesting as it relates to adverse effects. Since the Department of Defense paid for this study, the raw data should be made available to the GAO for further evaluation.
4. The VA data collected by Dr. Han Kang of many thousands of Gulf War veterans should be evaluated for the relationship between subsequent illness and recalled anthrax vaccine status. This material should be requested by Congress.
5. I would suggest Congress obtain Mitretek's report on its oversight of BioPort's supplemental testing. An included budget document suggests that Mitretek was budgeted for over \$1 million in fiscal year 1997, but that no funds were budgeted for them for fiscal year 1998. Does this mean that Mitretek did not oversee any supplemental tests that were performed in Michigan during fiscal year 1998?
6. Why have employees of the State Department and the Defense Threat Reduction Agency been offered voluntary anthrax vaccinations? Why are only mandatory vaccinations in order for other Department of Defense employees?
7. Why did Gen. Cain state in his April 29, 1999 testimony to Shays' Committee say that "our system does not discourage reporting any VAERS temporally associated with the vaccine," when in fact the anthrax vaccine implementation program guidelines specifically prohibit reporting adverse events that do not meet the three criteria I have mentioned earlier?