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July 13, 2005

Chairman Tom Davis
Committee on Government Reform
U.S. House of Representatives
2157 Rayburn House Office Building
Washington, D.C. 20515

Re: Committee hearing, "One Year Later: Evaluating the Effectiveness of Project BioShield."

Dear Chairman Davis:

As president of the oldest vaccine safety advocacy organization in the United States, I am writing to voice support for the theme of your July 14th hearing and to express hope that this hearing will be just the start of much needed oversight of the implementation 2004 Project BioShield Act, as well as the Bioterrorism Act of 2002 and the biodefense-related sections of the Homeland Security Act of 2002.

It is especially appropriate that the Committee hearing occur this week, since five years ago this week the Senate Armed Services Committee[1] (SASC) and House Armed Services Committee[2] (HASC) held hearings on the prototype[3] for the vaccine-centric Project BioShield Act, the Department of Defense (DoD) Anthrax Vaccine Immunization Program (AVIP).

These July 12-13, 2000 hearings validated the concerns raised in a scathing April 2000 report[4] by the Committee on Government Reform: repeated failures by the anthrax vaccine manufacturer to meet regulatory standards even with multiple financial bailouts by the Pentagon; the FDA's failure, since 1972, to properly review and validate the vaccine license; DoD's cover-up of anthrax vaccine adverse reactions; and the FDA's failure to regulate the Pentagon's unlawful use of the vaccine.[5] Yet, even after two SASC and HASC hearings on July 12-13, 2000, and two subsequent hearings by the

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[1] http://armed-services.senate.gov/hearings/2000/c000712.htm
[2] http://commdocs.house.gov/committees/security/has195020.000/has195020_0f.htm
[3] When AVIP was announced on Dec 15, 1997, the "senior military official" conducting the briefing (who refused to be named) stated: "This is *essentially the first step* in a medical force protection program under a health force protection program that the President has talked about, I believe, on 8 November. This will be the *prototype* program ...."
http://www.defenselink.mil/news/Dec1997/x12181997_x1215mfp.html
[4] House Report 106-556, April 2000
[5] Elaine Sciolino, "Anthrax Vaccination Program Is Failing, Pentagon Admits", New York Times, July 13, 2000. http://query.nytimes.com/search/advanced

Committee on Government Reform on October 3 and 11, 2000, Congress ultimately did nothing.

Revelations about the DoD anthrax vaccine program over the past year (see attachment) only validate the criticisms Congress heard in 2000 and are instructive as to the consequences of Congressional inaction on biodefense issues.

In short, if the DoD anthrax vaccine program is the prototype for BioShield, then the American people are at grave risk. Unfortunately, based on the government's actions in implementing BioShield over the past year, this appears to be the case. These include:

- Unelected Cabinet secretaries delegating their "emergency use" responsibilities under the BioShield Act to unelected subordinate political appointees, so as to insulate themselves and the President from accountability for the consequences of using unproven or unlicensed biodefense vaccines and drugs on the American people.

- DoD asserting an unproven and highly questionable anthrax threat to invoke the BioShield Act "Emergency Use Authorization" (EUA) provisions in order to circumvent a federal court injunction against its mandatory anthrax vaccine program.

- HHS committing[6] $878 million for the purchase of the experimental VaxGen recombinant anthrax vaccine for the Strategic National Stockpile, when the vaccine had only completed a Phase I clinical trial on 100 humans that looked only for short-term adverse reactions. Since granting the award, HHS has been forced to admit (under pressure from Senator Charles Grassley[7]) that its assertions of the vaccine's efficacy were unproven. Further, NIH is simultaneously developing a different recombinant anthrax vaccine that is also in clinical trials, raising questions about the timing of the VaxGen contract.

- HHS committing[8] $123 million for purchase of the BioPort anthrax vaccine for the Strategic National Stockpile, when the vaccine is the subject of a federal court injunction that declared the vaccine both "investigational" and "unapproved for its intended use" when used to prevent inhalation anthrax[9]; and when this vaccine is the likely cause of most of complex, and in some cases debilitating, illnesses in 1,200 servicemembers who were assessed or treated by the DoD National Vaccine Healthcare Center(s) over the past two years.[10]

- The National Institutes of Health planning to conduct an unethical and possibly illegal anthrax vaccine experiment on 100 first- and second-grade children with both unsafe

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[6] http://www.hhs.gov/news/press/2004pres/20041104a.html
[7] http://finance.senate.gov/press/Gpress/2005/prg040505.pdf
[8] http://www.hhs.gov/news/press/2005pres/20050506.html
[9] http://www.govexec.com/dailyfed/1104/110504gsn1.htm
[10] David Ruppe, "Military Vaccines Trigger Special Treatment for 1,200", Global Security Newswire , May 6, 2005.
http://www.nti.org/d_newswire/issues/2005_5_6.html#325532E2

and experimental vaccines. (After media exposure[11] [12] in late June, NIH has now stated any decision to experiment on children has been "delayed".)[13]

- DoD repeatedly threatening[14] the already minimal funding of four joint DoD-CDC Vaccine Healthcare Centers that are the only government entities that objectively study, treat, and report on serious adverse reactions and chronic illnesses associated with vaccines, particularly biodefense vaccines like anthrax and smallpox. The objective, but suppressed evidence developed by these centers undermines the orthodoxy of the government's vaccine-centric approach to biodefense.

The lessons learned from the first year of Project BioShield, some of which were described in the Wall Street Journal just this week[15], are predictable. When government increased biodefense spending 18-fold from $414 million to $7.6 billion[16] [17] per year in just four years, it was certain – absent any effective Congressional oversight – that pro-vaccine institutional bias, bureaucratic self-interest, and corporate profitability would drive the outcome.[18] Proposed "BioShield 2" legislation will only exacerbate this trend by providing financial incentives without effective regulatory oversight to insure biodefense vaccines and drugs are truly safe, as well as effective.[19]

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[11] Thomas D. Williams, "Critics Blast Anthrax Vaccine Test
National Institutes Of Health Officials Plan Trial On 100 Children",
Hartford Courant, June 23 2005
http://www.courant.com/hc-anthraxkids0623.artjun23,0,2223559.story

[12] David Goldstein, "Plans to test anthrax shot on children questioned", Kansas City Star, Jun 27, 2005.
http://www.kansascity.com/mld/kansascity/news/local/11993587.htm

[13] David Ruppe, "National Institutes of Health Decision Delayed on Anthrax Vaccine Testing on Children", Global Security Newswire, July 8, 2005
http://www.nti.org/d_newswire/issues/2005_7_8.html#56E710CB

[14] David Ruppe, "U.S. Army Provides No Funds for Vaccine Care Centers", Global Security Newswire, May 18, 2005
http://www.nti.org/d_newswire/issues/2004/5/18/b047b91a-baae-4469-a369-ce894037d5a1.html

[15] Bernard Wysocki Jr., "U.S. Struggles for Drugs to Counter Biological Threats", Wall Street Journal, July 11, 2005
http://www.post-gazette.com/pg/05192/536248.stm

[16] Jonathan B. Tucker, Ph.D., "Biological Threat Assessment: Is the Cure Worse Than the Disease?", Arms Control Today, Oct 2004
http://www.armscontrol.org/act/2004_10/Tucker.asp

[17] Ari Schuler, "Billions for Biodefense: Federal Agency Biodefense Funding, FY2001-FY2005, Biosecurity & Bioterrorism 2(2):86-96, 2004.
http://www.medscape.com/viewarticle/482307

[18] Elizabeth MacDonald Robert Langreth, "Spore Wars", Forbes Magazine, Jun 6, 2005
http://www.forbes.com/business/forbes/2005/0606/162.html

[19] See, for example, the report that serves as the intellectual underpinning for "BioShield 2" draft legislation (S.3 and S. 975), in which vaccines are considered as the only alternative for biodefense. The CBACI working group was co-chaired by the CEO of VaxGen (winner of the HHS recombinant anthrax vaccine contract) and by a former commander of the Army's biodefense research facility at Ft. Detrick, MD; contributors included pro-vaccine industry, Executive branch (White House, HHS, DoD, etc.), and Congressional staffers.
"Meeting The Biodefense Challenge: A "Road Map" For A National Vaccine Strategy", Report Of The CBACI National Vaccine Strategy Working Group", Chemical & Biological Arms Contorl Institute, Sep 2004. http://www.cbaci.org/pubs/reports/vaccineroadmap.pdf

In response to these lessons learned, Congress should act quickly modify federal statutes to insure BioShield fulfills the original intent of Congress – to truly protect the American people, including their civil rights. These statutory changes should include:

1) Make the President the sole approval authority for BioShield emergency use provisions (as is already the case with 10 U.S.C. 1107).

2) Prohibit any Cabinet secretary from delegating any of their emergency use responsibilities under the BioShield Act.

3) Require the Director of National Intelligence to validate the threat, and concur with, any request for an emergency declaration under the BioShield Act by either the Secretary of Defense or Secretary of Homeland Security, and/or with a unilateral declaration by the Secretary of Health and Human Services.

4) Specify that any Executive Branch invocation of the BioShield emergency use provisions predicated on a "potential" (as opposed to an "actual") attack is challengeable in federal court, and mandating significant fines and imprisonment for federal officials who fraudulently invoke these provisions or provide fraudulent threat assessments to substantiate them.

5) Specify that any government use (including DoD) of prophylactic biodefense vaccines must be predicated on a validated threat, and may not be conducted for the purpose of financially supporting a biodefense vaccine-industrial base.

6) Require active monitoring of all recipients of vaccines and drugs licensed or procured under BioShield or the DoD Joint Vaccine Acquisition Program, unless precluded by immediate combat or bioterror attack exigencies.

7) Fully fund the joint DoD-CDC Vaccine Healthcare Centers as a separate Congressionally directed line-item, and require public disclosure of the adverse reactions and chronic illnesses documented at these centers.

8) Specify significant fines and imprisonment for any federal official, bureaucrat, or military officer who willfully fails to report or disclose adverse reactions and chronic illnesses related to biodefense vaccines and drugs.

9) Direct the Department of Justice to appoint and fully fund a special prosecutor to investigate the Department of Defense Inspector General's failure to pursue on-going or previously closed investigations[20] of alleged lawbreaking related to the AVIP, to include whether unlawful DoD and NIH experimentation[21] with squalene adjuvants[22] has occurred.[23]

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[20] DoD IG Hotline case No. 84-142, DCIS memo, Nov 20, 2002, referring case to FBI and FDA. (available on request). There is at least one other substantive DoD IG complaint that was filed in March 2005.

[21] GAO Report, NSIAD-99-5, "Questions About the Presence of Squalene Antibodies in Veterans Can Be Resolved", Mar 1999
http://www.gao.gov/archive/1999/ns99005.pdf

[22] Pacific Stars & Stripes, Oct 5, 2000.
http://www.pstripes.com/article.asp?section=104&article=5304&archive=true

10) Specify that it is the intent of Congress that HHS, to the extent allowed by available technology, use BioShield funds; and also to DoD use Joint Vaccine Acquisition Program (JVAP) funds; to preferentially research, develop and procure, in order: (a) post-exposure treatments; (b) post-exposure prophylactics; and, in lowest priority, (c) pre-exposure prophylactics.

Thus far, Congress has sent one overriding message to government agencies tasked with implementing BioShield and related biodefense policy: America's political leaders are willing to settle for unethical experimentation, unlawful regulation, and junk-science biased by parochial interests[24] [25] to create the façade of a BioShield against politically-charged bioterror pathogens, while defenses against naturally occurring disease remain underfunded or ignored.[26]

To quote Dr. David Ozonoff of Boston University:

> *"If you wanted to beef up public health in this country, you sure wouldn't want to do it this way. It is sort of like trying to...make Tang by inventing the space program."*[27]

I hope your July 14th hearing is the beginning of a shift in public policy that will place the law, medical ethics and proven science before politics. If the Congress is intent on pursuing a vaccine-centric biodefense policy, the American people deserve objective reporting of vaccine safety risks and significant statutory sanctions against those who cover them up.

Sincerely,

Barbara Loe Fisher
President

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[23] Senator Joseph Biden, Sen Thomas Carper, Rep Michel Castle, letter to Secretary of Defense Rumsfeld, Oct 13, 2004. (available on request)

[24] Susan Wright, Ph.D., "Taking Biodefense Too Far", Bulletin of the Atomic Scientists (vol. 60, no. 6), November/December 2004, pp. 58-66.
http://www.thebulletin.org/article.php?art_ofn=nd04wright

[25] David Ruppe, "Terrorism - Threat-Mongering?", National Journal, April 23, 2005.
http://nationaljournal.com/ (subscription required)

[26] "An Open letter to Elias Zerhouni", Science, Mar 4, 2005. In this letter to the editor, a group of more than 700 scientists criticized the "unintended consequences" of the 2001-02 NIH/NIAID decision to "prioritize research of high biodefense significance but low public-health significance."
http://www.sciencemag.org/feature/misc/microbio/

[27] CNN, Paula Zahn Show, transcript, Dec 14, 2004.
http://transcripts.cnn.com/TRANSCRIPTS/0412/14/pzn.01.html

Attachment

cc: Rep. Henry Waxman, Ranking Member
Rep. Christopher Shays, Chairman, Subcommittee on National Security, Emerging Threats and International Relations
Sen. Richard Burr, Chairman, HELP Subcommittee on Bioterrorism and Public Health Preparedness
Sen. Charles Grassley, Chairman, Senate Finance Committee

Attachment

"One Year Later: Evaluating the Effectiveness of Project BioShield"

DoD Anthrax Vaccine Immunization Program Developments Since Passage of the Project BioShield Act

1) The current anthrax vaccine manufacturer, BioPort, hyped the supposed anthrax threat at both the Republican[28] and Democratic[29] political conventions to get politicians to pressure HHS to purchase its controversial vaccine for civilian use as part of the Strategic National Stockpile. HHS had steadfastly refused[30] to do so since at least 2002, presumably because of concerns express by government officials about the vaccine's known safety.[31]

2) On September 17, 2004 the St. Petersburg Times reported on Airman Cristina Kutz, who developed chronic gastro-intestinal illness and other autoimmune symptoms after she received the DoD anthrax vaccine.[32] The FDA did not investigate.

3) On September 26, 2004 the Charlotte Observer reported on the case of Air Force TSgt Lavester Brown, a 32-year make in excellent physical condition who required a heart transplant after developing congestive heart failure within 24 hours of receiving an anthrax vaccine shot. The article also reported a likely anthrax vaccine-related death of a Marine officer that DoD had never reported to VAERS. The FDA did not investigate.

4) On October 27, 2004 a federal Judge Emmet Sullivan declared[33] the mandatory DoD anthrax vaccine program to be "illegal" and enjoined further mandatory use of the vaccine.[34] Judge Sullivan ruled the vaccine to be both "investigational" and "unapproved for its intended use" – contrary to seven years of assertions by DoD and FDA that the vaccine was "fully licensed" and could therefore be given without informing servicemembers of its safety risks.

5) On December 22, 2004 FDA bureaucrats quietly added a report to the anthrax vaccine regulatory docket increasing the number of deaths associated with the

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[28] Judith Miller, "Wrangling Impedes Transfer of Civilian Anthrax Vaccine", New York Times, Aug 20, 2004
http://www.nytimes.com/2004/08/20/politics/20anthrax.html

[29] Chris Andrews and Katherine Hutt Scott, "BioPort promotes vaccine", Lansing State Journal, July 29, 2004
http://www.lsj.com/news/local/040729_notebook_10a.html

[30] Katherine Hutt Scott, "BioPort urges civilian anthrax program - Company study recommends new vaccinations", Lansing State Journal, Oct 18, 2002.
http://www.lsj.com/news/local/021018_bioport_1b.html

[31] Dr. Anthony Fauci, NIAID director, PBS NewsHour, Dec 19, 2001.
http://www.pbs.org/newshour/bb/health/july-dec01/fauci_12-19.html

[32] Susan Aschoff, "The shots of war", St. Petersburg Times, Sep 17, 2004.
http://www.stpetetimes.com/2004/09/17/Floridian/The_shots_of_war.shtml

[33] http://www.dcd.uscourts.gov/03-707c.pdf

[34] Marc Kaufman, "Court Orders Pentagon to Stop Anthrax Vaccinations", Oct 28, 2004.
http://www.washingtonpost.com/wp-dyn/articles/A3691-2004Oct27.html

BioPort anthrax vaccine from six to 16. Yet, FDA has not required the manufacturer to amend the FDA-approved package insert[35] to reflect these deaths, not has it required DoD to disclose these deaths to servicemembers who are now offered the vaccine under a "voluntary" program which, under the BioShield Act, is conducted without informed consent.

6) On January 14, 2005, former HHS Secretary Thompson declared[36] an anthrax "emergency" under the Project BioShield Act, but only for U.S. military forces – despite the fact that only civilians were attacked in 2001. When this declaration was challenged in federal court on February 14, 2005, government lawyers told the judge that the supposed threat on which emergency declaration was based could not be challenged "by anyone."[37] This emergency declaration was then used to resume voluntary anthrax immunizations – without informed consent -- of military servicemembers deployed to areas where the biological weapons "threat" has thus far proven non-existent.[38] [39]

7) On March 22, 2005 the Village Voice reported on the case of former sailor Jesse Kearns, who developed chronic blood clotting after receiving the DoD anthrax vaccine.[40] Kearns subsequently suffered a heart attack and stroke due to this condition, even though he was not yet 25 years old. After publication of the Village Voice article, Kearns was awarded a 100% service-connected disability – two years after he was discharged from the Navy with no resolution to his medical condition and no medical coverage. The FDA did not investigate.

8) On May 6, 2005 it was reported[41] that approximately 1,200 U.S. military personnel who received vaccinations against biological agents during the past two years developed complex, in some cases debilitating, illnesses that were assessed or treated by the DoD National Vaccine Healthcare Center(s)[42]. These reports directly contradict DoD and FDA assertions that the anthrax vaccine is "as safe as other vaccines."[43]

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[35] http://www.fda.gov/cber/label/biopava0131022LB.pdf
[36] http://www.fda.gov/OHRMS/DOCKETS/98fr/dhhs-oc0523-let0001.pdf
[37] Dee Ann Divis, "DoD wants anthax injunction change", UPI, Feb 16, 2005
http://www.washtimes.com/upi-breaking/20050216-033217-5621r.htm
[38] Mike Allen and Dana Priest, "Report Discounts Iraq Arms Threat: Inspector Says Hussein Lacked Means", Washington Post, October 6, 2004; Page A01
http://www.washingtonpost.com/wp-dyn/articles/A9790-2004Oct5.html
[39] Dana Priest, "Report Finds No Evidence Syria Hid Iraqi Arms", Washington Post, April 26, 2005.
http://www.washingtonpost.com/wp-dyn/content/article/2005/04/25/AR2005042501554.html
[40] Kareem Fahim, "Soldiers Fear the Needle - The Pentagon still fights for its anthrax vaccine", Village Voice, Mar 22, 2005.
http://www.villagevoice.com/news/0512,fahim,62301,6.html
[41] David Ruppe, "Military Vaccines Trigger Special Treatment for 1,200", Global Security Newswire, May 6, 2005.
http://www.nti.org/d_newswire/issues/2005_5_6.html#325532E2
[42] David Ruppe, "U.S. Army Provides No Funds for Vaccine Care Centers",
Global Security Newswire, May 18, 2005
http://www.nti.org/d_newswire/issues/2004/5/18/b047b91a-baae-4469-a369-ce894037d5a1.html
[43] http://www.anthrax.osd.mil/vaccine/default.asp