

November 15, 2005

Colonel Robert P. Kadlec, M.D. (USAF, ret.)
Staff Director
Subcommittee on Bioterrorism
and Public Health Preparedness
United States Senate
217 Russell Senate Office Building
Washington, D.C. 20510-3306

Dear Colonel Kadlec:

Thank you for your call to the National Vaccine Information Center (NVIC)¹ last week to discuss the intent of the Biodefense and Pandemic Vaccine and Drug Development Act of 2005 (S.1873, aka "BioShield II") sponsored by Senator Richard Burr (R-NC). I appreciated the opportunity to briefly discuss our reaction to the bill. I also appreciate your interest in, and consideration of, the enclosed concerns as well as your offer to meet to discuss these issues in the near future.

In short, we object to S.1873 because it: (1) lacks transparency into the research, development, licensure and post-licensure surveillance of biodefense vaccines and drugs; (2) lacks accountability for either manufacturers of these products or government health officials who mandate their use without informed consent; and, (3) lacks justice for those who will inevitably die or suffer chronic illnesses after being compelled to take these products.² This letter will review biodefense policy developments since 9/11, and the attachment will provide some suggested changes to BioShield Act provisions that would begin to address NVIC's concerns.

As I mentioned in our telephone conversation, the NVIC has been monitoring vaccine development, regulation, legislation, policymaking and promotion for the past 23

¹ www.nvic.org

² See: Institute of Medicine, Sox, et.al. (2000): "...Genetic inheritance strongly influences the immune response, both to immunization and to actual infection ([Box 7.1](#)), in animals and humans, which explains why immunologically mediated adverse reactions to vaccination are so variable from one animal, or person, to the next." <http://books.nap.edu/books/030907178X/html/272.html>

years. We are a non-profit, educational organization and our mission has always been to prevent vaccine injuries and deaths through public education while defending the informed consent rights of citizens. Therefore, we have been especially vigilant in monitoring state and federal legislation related to the safety and effectiveness of vaccines released for public use, as well as the ability of citizens to make informed, voluntary vaccination decisions for themselves and their children. NVIC worked closely and collaboratively with Congress, the vaccine manufacturers, and physician organizations to create and promote passage of the National Childhood Vaccine Injury Act of 1986.

Since September 11, 2001, we have been concerned that state and federal biodefense legislation, including BioShield II, has been created and promoted by the pharmaceutical industry and federal health officials with virtually no input from average citizens whose lives will be impacted by this legislation.³ These new laws have eroded the ability of citizens to make fully informed, voluntary vaccination decisions for themselves and their minor children in the event the Secretary of the Department of Health and Human Services (DHHS) declares a “potential or actual public health emergency” and the Governors of states follow suit.

In your previous capacity as the director of biodefense preparedness at the White House and a strategist who worked on national smallpox vaccine policies, I am sure you are familiar with both the new federal laws⁴ as well as the Model State Emergency Health Powers Act (MSEHPA). Given your significant role in post-9/11 biodefense planning, I was surprised when you stated that citizens could not be compelled to take biodefense countermeasures developed under the BioShield Act, as amended by S. 1873. The White House has been planning for martial law in response to bioterrorism for several years.⁵

³ For example, the current BioShield II legislation was based on the recommendations of self-selected industry and government “experts” contained in a 200+ page report sponsored by the Pharmaceutical Research and Manufacturers Association. The report was prepared by a think-tank – CBACI -- that apparently no longer exists. See: "*Meeting the Biodefense Challenge: A "Roadmap" for a National Vaccine Strategy*", Report of the CBACI National Vaccine Strategy Working Group, Chemical and Biological Arms Control Institute, September 2004. (CBACI website no longer online). See also, Washington Times, Oct 13, 2004: <http://washingtontimes.com/upi-breaking/20041013-102231-7074r.htm>

⁴ See:

- Project BioShield Act of 2004 - Public Law No: 108-276 [GPO: [Text](#), [PDF](#)]
- Smallpox Emergency Personnel Protection Act of 2003 -- Public Law No: 108-20 [GPO: [Text](#), [PDF](#)]
- Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (aka Bioterrorism Act of 2002) - Public Law No: 107-188 [GPO: [Text](#), [PDF](#)]
- Homeland Security Act of 2002 - Public Law No: 107-296 [GPO: [Text](#), [PDF](#)]

⁵ In late 2002, General Wayne Downing, USA (ret.), former White House Deputy National Security Advisor for Counterterrorism, stated:

"The United States may have to declare martial law someday in the case of a devastating attack with weapons of mass destruction causing tens of thousands of casualties. This could mean that the military would be given the authority to impose curfews, protect businesses and communities, even make arrests." See:

B. Gellman, "In U.S., Terrorism's Peril Undiminished", Washington Post, Dec 24, 2002
<http://www.washingtonpost.com/ac2/wp-dyn?pagename=article&node=&contentId=A31589-2002Dec23¬Found=true>

The MSEHPA⁶, which was commissioned by the Centers for Disease Control (CDC) long before September 11, 2001 and was expeditiously presented to states in the wake of the anthrax letter attacks, has been passed in one form or another by 37 states. The impetus for these laws to be passed quickly in states was the warning from government officials that acts of bioterrorism, especially using the weaponized smallpox virus, were imminent. Because vaccine and other public health laws constitutionally fall with the jurisdiction of states, it was necessary for federal health officials to ensure that state health officials are legally in a position to work with Governors to carry out a directive from the Secretary of Health and Human Services declaring a “potential or actual” public health emergency. Under the MSEHPA, state public health laws pertaining to emergencies involving infectious pathogens were strengthened and gave expanded authority to public health and other government officials. Under this legislation, Governors may declare an emergency and use the “state militia” to take control of all roads leading into and out of cities and the state; seize citizens' personal property without compensation; and arrest, detain and forcibly examine, vaccinate and medicate citizens and their minor children without informed consent, and not be held liable if these actions result in the death or injury of citizens.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002⁷ (Public Law 107-188) was proposed soon after the post-9/11 anthrax letter attacks began. This law enacted proposed changes to vaccine and drug licensure standards that Congress had declined to pass since FDA first proposed them in October 1999.⁸ Section 123 of this law, known as the “animal efficacy rule,” lowered biodefense vaccine and drug licensure standards by allowing efficacy to proven by clinical trials in one or more animal models, rather than in humans.⁹ This means that biodefense countermeasures licensed under the BioShield Act, although billed by FDA as “fully licensed” (and therefore exempt from informed consent requirements), will be unproven in humans until they are used in mandatory mass immunization programs. Therefore, the risk-benefit analysis of these products, mandated by the Food Drug and Cosmetic Act since 1962, will be unknown.

The Homeland Security Act of 2002 (Public Law 107-296), like the MSEHPA in state legislatures, was passed in Congress after warnings by DHHS and DOD officials that there was a high probability that bioterrorist acts would be carried out against the

⁶ <http://www.publichealthlaw.net/Resources/Modellaws.htm#MSEHPA>

⁷ <http://www.fda.gov/oc/bioterrorism/bioact.html>

⁸ Testimony of William Raub, DHHS Deputy Assistant Secretary For Science Policy, before the Subcommittee on National Security, Veterans Affairs and International Relations, Committee on Government Reform Nov 9, 1999. See: <http://www.fda.gov/ola/1999/newdrugs.html>

⁹ 67 Fed. Reg. 37988-37998 (May 31, 2002). See also: <http://www.fda.gov/bbs/topics/NEWS/2002/NEW00811.html>

U.S. population using the weaponized smallpox virus. As plans were underway to pull old smallpox vaccine supplies out of warehouses where they had been stored for 25 years and create enough vaccine to vaccinate most Americans, vaccine manufacturers asked Congress to protect them from liability from all lawsuits for smallpox vaccine injuries and deaths.

Section 304 of the Homeland Security Act gave the Secretary of Health and Human Services authority to “issue a declaration concluding that an actual or potential bioterrorist incident or other actual or potential public health emergency makes advisable the administration of a covered countermeasure to a category or categories of individuals” and “shall specify in such declaration the substance or substances that shall be considered covered countermeasures for purposes of administration to individuals.” The Act removes liability for injuries or deaths caused by the smallpox vaccine when it is used as a “countermeasure,” including protecting the pharmaceutical companies producing smallpox vaccine and public health officials, doctors and others administering the vaccine to citizens.

The Smallpox Emergency Personnel Protection Act of 2003 (Public Law 108-20)¹⁰ provided limited federal compensation for health care workers and citizens who either administered or were given smallpox vaccine used as a countermeasure during an “actual or potential emergency” declared by the Secretary of DHHS. The compensation scheme was modeled after the vaccine injury compensation program (VICP) created under the National Childhood Vaccine Injury Act of 1986.¹¹ However, unlike the VICP, in the smallpox vaccine injury compensation scheme, the Secretary of Health and Human Services solely determines the procedures for compensation and who will be compensated for their vaccine injuries.

Of the 439,000 U.S. health care workers whom the Secretary asked to voluntarily get smallpox vaccine in order to prepare for a possible bioterrorist attack, over 90 percent refused¹² for three reasons: (1) the bioterrorist threat was only hypothetical despite attempts by DHHS and DoD to convince the public otherwise; (2) the smallpox vaccine in stockpiles was known to be highly reactive;^{13 14} and (3) the federal compensation

¹⁰ <http://www.hrsa.gov/smallpoxinjury/pl10820.htm>

¹¹ Public Law 99-660. See also: <http://www.hrsa.gov/osp/vicp/qanda.htm>

¹² "U.S. Smallpox Official Acknowledges Vaccination “Targets Were Not Achieved” ", Global Security News, Oct 22, 2003.
http://www.nti.org/d_newswire/issues/2003/10/22/a24c7520-4663-444d-88ec-a621cb131645.html

¹³ In 2001, the World Health Organization recommended against mass smallpox immunization because of the known high reactogenicity of the existing smallpox vaccine. These risks were first identified in a study of Finnish military recruits in the 1980s, but were ignored by US government public health officials in 2002-2003. See:
http://www.nti.org/d_newswire/issues/2001/10/26/8s.html

¹⁴ "Experts Say Civilian Smallpox Shots Not Needed", Global Security News, Aug 9, 2004.
http://www.nti.org/d_newswire/issues/2004/8/9/b077d25f-e6a9-49b9-9b1d-4325001b4f02.html

scheme¹⁵ was less fair or generous than the VICP (which turns two out of three vaccine victims away). Due to subsequent deaths and life-threatening illnesses associated with the Wyeth smallpox vaccine (mostly among military personnel¹⁶ compelled to take the vaccine under threat of court-martial), the product label now contains a black box warning¹⁷ about potentially fatal dangers to the heart.

The Bush Administration's 2003 smallpox immunization program ultimately failed so completely that the CDC director even attempted to disavow its existence.¹⁸ The unnecessary deaths and illnesses that resulted from this ill-conceived plan should have served as a caution to those in government who seek to mandate unsafe vaccines to protect against hypothetical threats. Unfortunately, the BioShield II legislation indicates that government's lesson learned was simply that it needed to operate in greater secrecy and to insure zero accountability – from pharmaceutical manufacturers or politicians – the next time.

Congress subsequently passed the Project Bioshield Act of 2004 (Public Law 108-276), ostensibly to implement lessons learned from both the smallpox and military anthrax immunization programs. Under the Bioshield Act, the Secretary of Health and Human Services was given expanded authority to:

- institute “expedited peer review procedures” to prove that experimental vaccines and drugs used as countermeasures are safe and effective.
- declare an emergency based on either an actual or “potential” threat, based on intelligence that may remain secret and not subject to judicial review
- have FDA issue an "Emergency Use Authorization" (EUA) describing the manner by which state authorities and DoD may use biodefense vaccines and drugs on citizens.

These BioShield authorities have already been abused. On January 14, 2005 former Secretary of Health and Human Services Tommy Thompson declared¹⁹ an anthrax threat emergency under the Bioshield Act in the absence of any credible threat

¹⁵ <http://www.hrsa.gov/smallpoxinjury/>

¹⁶ "Military Personnel Suffer More Heart Troubles Than Expected After Smallpox Vaccinations, Researcher Says", Global Security News, May 13, 2004. See: http://www.nti.org/d_newswire/issues/2004/5/13/2720eb81-1e4b-4850-a4df-f851533e3aa4.html

¹⁷ <http://www.fda.gov/cber/products/smalwye101105.htm>

¹⁸ "CDC Director Denies Existence of U.S. Smallpox Immunization Program", Global Security News, Nov 18, 2003. http://www.nti.org/d_newswire/issues/2003/11/18/1e571176-df2a-49c6-aa55-9fc7dcf53385.html

¹⁹ <http://www.fda.gov/OHRMS/DOCKETS/98fr/dhhs-oc0523-let0001.pdf>

information.²⁰ This emergency was declared to circumvent a federal court injunction against the Pentagon ordering that military personnel be given the right to informed consent prior to being administered the improperly licensed, experimental Bioport anthrax vaccine.²¹ The FDA commissioner subsequently issued an emergency use authorization that specifically allowed DoD to deny informed consent to servicemembers who volunteered to take anthrax vaccine.²²

According to arguments by Department of Justice attorneys in federal court,²³ the factual basis for the Secretary's anthrax emergency declaration is not reviewable by either the Congress or the judicial branch of government. This means that mandatory mass vaccination of the American people with untested vaccines and drugs could be based on questionable threat intelligence, just as the true facts underlying questionable weapons of mass destruction (WMD) threat assertions used to justify the war with Iraq were never disclosed to the people.

Unfortunately, the once mandatory DoD anthrax vaccine program -- exemplified by a DoD-FDA cover-up of deaths and illnesses²⁴ associated with the BioPort anthrax vaccine -- appears to be the template for Project BioShield. Before legislation removing more liability from drug companies making vaccines is passed, Senator Burr and other members of the HELP Committee should include in the bill a bipartisan mandate to Attorney General Gonzales for an independent criminal investigation of the cover-up of deaths and illnesses caused by the BioPort anthrax vaccine.

The Biodefense and Pandemic Vaccine and Drug Development Act of 2005 (S. 1873) and a similar bill in the House (H.R. 3970) are being forwarded during a time when federal health officials are warning that an avian flu pandemic is imminent.²⁵ As you know, currently there is no evidence that the avian flu virus in question has mutated so that it would be capable of being transmitted from human to human. Therefore, there is

²⁰ "Lawmaker questions Pentagon's plan to resume anthrax vaccinations", Government Executive, Dec 17, 2004. <http://www.govexec.com/dailyfed/1204/121704c1.htm>

²¹ On Oct 27, 2004 the Doe v. Rumsfeld judge, federal Judge Emmet Sullivan, ruled that FDA had never properly licensed an anthrax vaccine that the agency had allowed DoD to use for 32 years. See: <http://www.dcd.uscourts.gov/03-707c.pdf>

²² <http://www.fda.gov/cber/vaccine/anthraxvax.htm>

²³ Doe v. Rumsfeld, oral arguments in D.C. federal district court, Feb 14, 2005.

²⁴ "Military Vaccines Trigger Special Treatment for 1,200", Global Security News, May 6, 2005. http://www.nti.org/d_newswire/issues/2005_5_6.html#325532E2

²⁵ HHS Secretary Mike Leavitt, CDC Director Dr. Julie Gerberding, et.al., at John R. La Montagne Memorial Symposium on Pandemic Influenza Research: Meeting Proceedings (2005), Institute of Medicine (2005), p. 15, et seq. <http://www.nap.edu/books/0309097312/html/15.html>

no reason to push through this legislation without any public debate on policies that will impinge on constitutionally protected civil rights.

While the 2004 Project BioShield Act primarily addressed bioterror pathogens and countermeasures, S.1873 now also includes blanket liability protections for those who make and administer vaccines used during “natural outbreaks” of disease and “pandemics.” These provisions will further erode the freedom and ability of citizens to make fully informed, voluntary vaccination decisions for themselves or their minor children. Specifically, S. 1873:

- creates a new agency (BARDA) within the Department of Health and Human Services (DHHS) to oversee the development of experimental or licensed vaccines and drugs defined as “countermeasures” which American citizens will be directed to use by the Secretary of DHHS after the Secretary declares an actual or potential public health emergency due to deliberate, accidental or natural outbreaks of illness. This agency will not be subject to the Federal Advisory Committee Act (FACA) or Freedom of Information Act (FOIA), meaning there will be no transparency into BARDA deliberations. Its duties, activities, working groups and advisory boards also will not be subject to judicial review. [Sec. 3(f)(1)(2)]; and
- prevents American citizens from exercising their Seventh Amendment right to a trial by jury in the civil court system if they or their minor children are injured or die from use of experimental or licensed vaccines and drugs that the Secretary of Health and Human Services directs citizens to use after declaring “an actual or potential public health emergency.” [Sec.6(b)(1)(A)(i)].

Additionally, the proposed Bioshield II legislation (S. 1873) gives the unelected Secretary of Health and Human Services the sole authority to decide whether a drug company violated laws governing safety and efficacy of vaccines. The bill bans citizens from challenging the Secretary's decision in the civil court system. Under Bioshield II, blanket immunity is given to vaccine makers, as well as to administrators who give citizens experimental vaccines and drugs without informed consent, whenever the Secretary declares an “actual or potential emergency” and Governors follow suit.

So, citizens who are injured or die from the effects of biodefense vaccines and drugs that are developed by federal health agencies and drug companies in secret will be left to fend for themselves. They will not be allowed to sue either the pharmaceutical manufacturers or the federal government for compensation, because S.1873 leaves any federal compensation mechanism scheme solely to the discretion of the Secretary of Health and Human Services. As has been demonstrated in the vaccine injury compensation program (VICP) for children, the DHHS and the Department of Justice have long been reluctant to either acknowledge the reality of vaccine-induced injury and death -- or to provide compensation for vaccine victims. Out of the more than 6,018 vaccine injury claims that have been filed with the VICP since its implementation in 1988 (excluding 4,895 petitions alleging mercury poisoning from thimerosal containing

vaccines), only 1,945 vaccine victims have been awarded compensation. The public record of what DHHS and Justice -- with the enthusiastic endorsement of industry -- have done since 1988 to gut the VICP and turn these vaccine victims away, is tragic.

Although the pharmaceutical industry has repeatedly told Congress and the American people that civil litigation has driven drug companies out of the vaccine business, the facts show this claim to be false. In 1982, there were four drug companies marketing vaccines in the U.S.: Wyeth, Lederle, Merck and Connaught., Today, after several decades of corporate mergers and acquisitions, there are twice as many drug companies selling vaccines to American citizens: Wyeth, Merck, Sanofi Pasteur, GlasxoSmithKline, Medimmune, Chiron, Bioport and Vaxgen.

There are substantial profits to be made by drug companies marketing vaccines that are mandated to be used by every child born in America. The National Childhood Vaccine Injury Act of 1986 has successfully protected the manufacturers and doctors from almost all lawsuits. There are only ten current pending vaccine injury lawsuits in U.S. civil courts, most involving the highly reactive whole cell DPT vaccine no longer distributed in the U.S..²⁶

The National Vaccine Information Center is informing citizens about the threat to civil liberties and constitutional freedoms that the biodefense legislation enacted after September 11, 2001 poses to all Americans. We believe it is our duty to do this so citizens can exercise their constitutionally protected rights to contact their elected representatives and voice their views about provisions in S.1873 that:

- expands the already unprecedented authority given to one unelected political appointee - the Secretary of Health and Human Services - to make life-and-death decisions affecting the lives of citizens without any confirmation by the nation's elected political leaders: the President and the Congress.
- denies citizens access to the judicial system to exercise their Seventh Amendment right to a jury trial of their peers, which serves as the Constitutional check and balance against abuse of power by the executive branch of government.

In short, S. 1873 enshrines in federal statute an abdication of power by elected political leaders so that one unelected individual can deny Americans' civil rights and mandate mass experimentation with vaccines and drugs, while allowing citizens no legal recourse to question what is being done to them. In essence, this bill and other federal laws passed since 9/11 represent a de facto militarization of US civilian biodefense and disease control policy.

In any emergency situation, biodefense and disease control countermeasures jointly developed by government and the pharmaceutical industry will only be successful

²⁶ *Marcelo Ferrari v. American Home Products; Tristan Cravello v. American Home Products; Bruesewitz v. American Home Products; Totterdale v. Lederle (Wyeth); Militrano v. Lederle; Romero v. Wyeth; Tenuto v. Lederle; Mann v. Lilly, et al; Gurin v. Lilly, et al; Wright v. Lilly, et al.*

if the American people trust the government officials in charge of implementing the plan. A plan that does not include the principles of transparency, accountability and justice will fail to win the trust of the people.

As presently written, BioShield II (S. 1873) fails to adhere to these principles and is arguably unconstitutional.

Very truly yours,

A handwritten signature in black ink, appearing to read "Barbara Loe Fisher", is centered on a light pink rectangular background.

Barbara Loe Fisher
Co-founder & President

cc: David Dorsey

Attachment (1)

To begin to address shortcomings in BioShield legislation, Congress should insure S. 1873 directs:

- 1) That the authority to declare an emergency under the BioShield Act should be elevated to the President of the United States and must be affirmed by the Congress within 30 days.
- 2) That authority to request a declaration of emergency under the BioShield Act, or to declare an emergency, may not be delegated by Cabinet secretaries (as was already done by Secretary of Defense Rumsfeld on Dec 10, 2004).
- 3) That all actions by executive branch agencies, including DoD, related to research, development and licensure of BioShield products, the mandate of their use, and monitoring of their safety with post-licensure surveillance, will be reviewable by the federal courts and subject to the Freedom of Information Act and Federal Advisory Committee Act.
- 4) That federal government civil servants and political appointees will be subject to investigation and prosecution for licensing decisions and failures to conduct post-licensure surveillance that violate the Food Drug and Cosmetic Act, Public Health Service Act, or other applicable federal statutes. (S. 1873 limits such accountability to “manufacturers, distributors, administrators, and healthcare providers.”)
- 5) That to the extent pharmaceutical manufacturers of BioShield countermeasures are indemnified, the federal government must provide adequate liability coverage for injuries experienced by those who are forced to take these biodefense products. This coverage must be stipulated in law, not subject to the discretion of a political appointee, and reviewable by the federal courts. Citizens who die or are injured after obeying an order to take these products should have no less coverage than the victims of 9/11 at the World Trade Center and the Pentagon.
- 6) That if liability for injuries from BioShield countermeasures is assumed by neither pharmaceutical manufacturers nor the federal government, then citizens – including military personnel -- must be granted the right to refuse these products without legal

sanctions, including quarantine, or denial of employment, housing, medical care or schooling, etc.

- 7) That the definition of covered BioShield countermeasures is not broadened to include drugs and vaccines, especially childhood vaccines, used to prevent or treat normal pathogens that are unlikely sources of pandemic or bioterrorism.
- 8) That Attorney General Alberto Gonzales appoint an independent special counsel charged to conduct a criminal investigation of the cover-up by DoD and HHS employees, as well as the manufacturer, of deaths and serious illnesses caused by the BioPort anthrax vaccine used by the Department of Defense since the 1991 Gulf War.