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Ensuring A Consistent Supply of Anthrax Vaccine

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Abstract

During the recent anthrax attacks, the country's supply of anthrax vaccine was dangerously low. The reasons for this were (1) the failure of the FDA, the Defense Department, and its contractor, BioPort Corporation, to plan adequately to ensure the production of a consistent supply of the vaccine in accordance with the FDA regulatory process; and (2) the reliance of the Defense Department on a single private supplier of the vaccine with serious financial problems. Careful planning should be employed to prevent such a situation with other biological products which may be needed to save lives during bioterrorist attacks.

Introduction

In October of 2001, shortly after the September 11 attacks, five people died and thirteen others became infected with the anthrax disease after envelopes containing anthrax spores were placed in the mail. During this crisis, due to production problems, the anthrax vaccine was in such short supply that there was not even enough to vaccinate those troops whose inoculation had been planned for a number of years. While the Defense Department's contractor has recently been allowed to release anthrax vaccine again, the country's experience with the anthrax vaccine should not be repeated. Anthrax disease, while the most prominent in the news, is not even the only bioterrorism threat that the country faces. Besides anthrax, the Centers for Disease Control has identified seventeen other diseases which are credible threats for a biological attack.¹ Analysis of the anthrax vaccine situation shows that FDA, the Defense Department, and its contractors all need to plan more carefully in the future to avoid similar shortages of biological products to fight bioterrorism.

About Anthrax

Anthrax, a disease caused by the bacterium *Bacillus anthracis*, has been described by the American Forces Information Service as the "poor man's atomic bomb."² Unlike the atomic bomb, anthrax can be turned

¹See U.S. Centers for Disease Control and Prevention, Biological Diseases/Agents Listing, visited on March 14, 2002, available at <http://www.bt.cdc.gov/Agent/Agentlist.asp>.

²Douglas J. Gillert, Anthrax Vaccine Called Effective Force Protection 3 (November 1998), available at http://www.defenselink.mil/news/Nov1998/n11051998_9811051.html.

into a weapon of mass destruction by persons with a relatively low skill level.³ The Congressional Office of Technology Assessment estimated in 1993 that 100 kilograms of anthrax, released into the wind towards Washington, D.C., could kill between 130,000 and 3 million people.⁴

The anthrax bacterium, once released in the air, is invisible, has no smell or taste, and produces flulike symptoms, and therefore anthrax outbreaks are not easily detected.⁵ Persons with anthrax may not seek medical care until the disease is untreatable.⁶ The vast majority of those infected with inhalation anthrax die within a few days of exposure.⁷

The Anthrax Vaccine

Currently, the only preventive measure against anthrax is the anthrax vaccine.⁸ Antibiotics such as Cipro have been successful in treating the infection once contracted, and it has been suggested that they may have some preventive use as well if taken during an anthrax attack.⁹ However, this use of Cipro is still experimental, having been discovered by scientists studying widespread treatment of postal and media workers with Cipro during the October 2001 terrorist mailings of envelopes containing anthrax.¹⁰

The current anthrax vaccine is known as Anthrax Vaccine Adsorbed or AVA. The vaccine must be given

³See id.

⁴See Thomas V. Inglesby, M.D., et. al., Anthrax as a Biological Weapon, 281 JAMA 1735 (1999), available at <http://jama.ama-assn.org/issues/v281n18/ffull/jst80027>, citing Office of Technology Assessment, US Congress, Proliferation of Weapons of Mass Destruction, Publication OTA-ISC-559 (1993) at 53-55.

⁵See Hearing on Department of Defense Anthrax Vaccine Immunization Program Before the Senate Armed Services Committee 2(April 13, 2000)(statement of Rudy de Leon, Deputy Secretary of Defense), available at <http://www.defenselink.mil/speeches/2000/s20000413-depsecdef.html>.

⁶See id.

⁷See id.

⁸See Center for Biologics Evaluation and Research, Anthrax 1, January 24, 2002, available at <http://www.fda.gov/cber/vaccine/anthrax/htm>.

⁹See Sheryl Gay Stolberg, Antibiotics Found to Have Helped Limit Anthrax Infections, The New York Times, March 8, 2002, at A12.

¹⁰See id.

in a series of six shots over the course of eighteen months, with yearly booster shots thereafter to maintain immunity.¹¹ Researchers are also looking into giving the anthrax vaccine after exposure to prevent infection, or giving fewer shots, but those uses are considered experimental.¹²

The Defense Department's vaccination program, called the Anthrax Vaccine Inoculation Program, or AVIP, has been very controversial.¹³ The Defense Department has been subject to numerous lawsuits from service members claiming injury from the vaccine.¹⁴ The Defense Department has also court-martialed over one hundred service members who refused the vaccine.¹⁵

BioPort Corporation

The vaccine used for the Defense Department program is purchased from BioPort Corporation, the only manufacturer of the anthrax vaccine licensed in the United States.¹⁶ AVA was previously manufactured by the State of Michigan, which manufactured the vaccine since 1970, most recently in its Michigan Biologic Products Institute (MBPI).¹⁷ The State of Michigan decided in 1998 to sell the facility and turn the development of these vaccines over to private enterprise.¹⁸ The state therefore created a corporate entity which

¹¹See The National Academy of Sciences Institute of Medicine, Anthrax Vaccine is Useful But Shortcomings Underscore Need for Replacement 1 (March 6, 2002), available at <http://www4.nationalacademies.org/news.nsf/isbn/0309083095?OpenDocument>.

¹²See id. at 2.

¹³This paper does not purport to examine in detail whether the anthrax vaccine is or is not safe. Instead, this paper focuses on the problems which arose after the Defense Department decided that the vaccine was needed for the national defense and tried to procure it.

¹⁴See, e.g., Minns v. United States, 974 F.Supp. 500 (D.Md. 1997)(claiming that the anthrax vaccine caused birth defects in male service members' children).

¹⁵See Laura Johannes, Worries About Safety of Its Anthrax Vaccine Put the Army in a Bind, The Wall Street Journal, October 12, 2001, at A1.

¹⁶See Nancy Kingsbury. Testimony Before the Subcommittee on National Security, Veterans' Affairs, and International Relations, Committee on Government Reform, House of Representatives 1. October 23, 2001, available at <http://www.gao.gov/>.

¹⁷See id. at 1.

¹⁸See Field Hearing on Department of Defense Anti-Biological Warfare Agent Vaccine Acquisition Program at Pine Bluff, Arkansas, Testimony Before the Senate Armed Services Committee, Subcommittee on Personnel 3 (2000)(statement by Dr. Anna Johnson-Winegar, Deputy Assistant to the Secretary of Defense for Chemical/Biological Defense).

owned the vaccine facilities and which could be sold to private entities.¹⁹ BioPort purchased the entity in 1998.²⁰

Until the end of January 2002, BioPort had not had a batch of anthrax vaccine released by the FDA since November 2, 1999.²¹ In 1996, the FDA threatened to revoke the license of MBPI to manufacture anthrax due to “numerous significant violations of the FD&C Act, FDA’s regulations and the standards in MBPI’s license.”²² In response to the threatened revocation, MPPI prepared a “Strategic Plan for Compliance” in 1997 which BioPort agreed to follow when it purchased the facility in 1998.²³

The State of Michigan, prior to the sale of the facility to BioPort, had begun renovations on the facility.²⁴ Therefore, BioPort needed to obtain a license application supplement for the new facility in order to begin marketing anthrax vaccine.²⁵ When the facility began producing new batches of the anthrax vaccine, FDA inspectors found numerous problems and did not approve the licensing supplement.²⁶ FDA’s November 1999 inspection of BioPort found problems with “validation, failure to investigate, deviation reporting, standard operating procedures, stability testing, and environmental monitoring.”²⁷ BioPort’s license application supplements were not fully approved, and new lots of vaccine could not be released, until January 31, 2002.²⁸ On that date, three lots of vaccine submitted to the FDA pre-approval were released.²⁹

¹⁹See Department of Defense, Anthrax Vaccine—Production Issues 1, visited on March 10, 2002, [available at http://www.anthrax.osd.mil/Site.Files/qna/PRODISSUES.HTM](http://www.anthrax.osd.mil/Site.Files/qna/PRODISSUES.HTM).

²⁰See *id.*

²¹See Department of Defense, Lot Documents, visited on March 10, 2002, [available at http://www.anthrax.osd.mil/Site.Files/lot_documents/INDEXlot_documents/LOT_DOCUMENTS/](http://www.anthrax.osd.mil/Site.Files/lot_documents/INDEXlot_documents/LOT_DOCUMENTS/) and Kathryn C. Zoon, Ph.D., Director, Center for Biologics Evaluation and Research, Letter to Robert C. Meyers of BioPort Corporation, November 2, 1999, [available at http://www.anthrax.osd.mil/Site.Files/lot_documents/Release/FDA48.gif](http://www.anthrax.osd.mil/Site.Files/lot_documents/Release/FDA48.gif).

²²Kathryn C. Zoon, Ph.D., Director, Center for Biologics Evaluation and Research, Statement Before the Senate Committee on Armed Services 5, July 12, 2000, [available at http://www.fda.gov/ola/2000/anthraxvaccine2.html](http://www.fda.gov/ola/2000/anthraxvaccine2.html).

²³See *id.*

²⁴See *id.*

²⁵See *id.*

²⁶See *id.*

²⁷See *id.* at 6.

²⁸See U.S. Food and Drug Administration, FDA Approves License Supplements for Anthrax Vaccine, January 31, 2002, [available at http://www.fda.gov/bbs/topics/NEWS/2002/NEW00792.html](http://www.fda.gov/bbs/topics/NEWS/2002/NEW00792.html).

²⁹See *id.*

BioPort is the only U.S. company which is able to produce the anthrax vaccine.³⁰ Some other countries are able to produce the anthrax vaccine, such as the United Kingdom and Russia.³¹ However, BioPort holds the only license to market the vaccine in the United States.³²

The Anthrax Vaccine Shortage

Prior to this latest batch release, all of the batches released by BioPort were prepared by the State of Michigan prior to the transfer of the facility to the private company.³³ Therefore, BioPort did not release any new vaccine for a period of over two years.

This is especially significant because the post-shipping shelf life of Anthrax Vaccine Adsorbed is only two years.³⁴ The regulation mandating the shelf life also permits the manufacturer to store the vaccine for up to one year before shipping.³⁵ However, the permissible additional one-year storage period had probably been run before the November 1999 lot was shipped, as the State of Michigan began its renovations in early 1999. News reports have stated that, until this January, BioPort has never had a batch of its own Anthrax Vaccine Adsorbed approved by the FDA. Instead, it relied on the batches previously prepared by the State of Michigan, which turned the facility over to BioPort in 1998.³⁶

³⁰See Kingsbury, *supra* note 16, at 1.

³¹See Kingsbury, *supra* note 16, at 7; see also Warren Strugatch, L.I. @ Work; A Company's Founder Fights For His Brainchild, *The New York Times*, February 3, 2002 at 14LI5.

³²See Department of Defense, Anthrax Vaccine—Production Issues 1, visited on March 10, 2002, available at <http://www.anthrax.osd.mil/Site.Files/qna/PRODISSUES.HTM>.

³³See Richard Klausner, Special Adviser, President for Counterterrorism Council of the Institute of Medicine, Prepared Testimony Before the Senate Commerce, Science, and Transportation Committee, Federal News Service (February 5, 2002), available via Lexis-Nexis.

³⁴See 21 C.F.R. § 610.53(c).

³⁵See *id.*

³⁶See Richard Klausner, Special Adviser, President for Counterterrorism Council of the Institute of Medicine, Prepared Testimony Before the Senate Commerce, Science, and Transportation Committee, Federal News Service (February 5, 2002), available via Lexis-Nexis.

Indeed, this raises the uncomfortable question of whether the government's stockpile of Anthrax Vaccine Adsorbed was actually, for a period of about two months, entirely expired. This in a situation in which anthrax had recently been used as a weapon against the American civilian population.

According to informational material on the FDA website, it is possible to extend the expiration date of a vaccine.³⁷ Section 21 C.F.R. § 610.53(b) states that “[t]he dating period for a product shall begin on the date of manufacture, as prescribed in § 610.50.” The “dating period” is defined in 21 C.F.R. § 600.3(1) as “the period beyond which the product cannot be expected beyond reasonable doubt to yield its specified results.”³⁸ The “expiration date” is defined as “the calendar month and year, and where applicable, the day and hour, that the dating period ends.”³⁹

Changing the date of manufacture is actually possible and has been done in the past with the anthrax vaccine.⁴⁰ One does so by changing the date of manufacture after the fact, within the constraints of FDA regulations. As seen above, the language of 21 C.F.R. § 610.53(b) states that the date of manufacture must comply with the requirements of 21 C.F.R. § 610.50.⁴¹ That section states:

610.50 Date of manufacture.

The date of manufacture shall be determined as follows:

(a) For products for which an official standard of potency is prescribed in either § 610.20 or § 610.21, or which are subject to official potency tests, the date of initiation by the manufacturer of the last valid potency test.

(b) For products that are not subject to official potency tests, (1) the date of removal from animals, (2) the date of extraction, (3) the date of solution, (4) the date of cessation of growth, or (5) the date of final sterile filtration of a bulk solution, whichever is applicable.⁴²

³⁷See U.S. Food and Drug Administration, Vaccine Frequently Asked Questions (FAQs), January 3, 2001, available at <http://www.fda.gov/cber/faq/vacfaq.htm>.

³⁸21 C.F.R. § 600.3(1)

³⁹21 C.F.R. § 600.3(m).

⁴⁰See Ronald R. Blanck, Lieutenant General, U.S. Army Surgeon General, Letter to the Editor. Belleville (IL) News-Democrat (May 29, 1998), available at http://www.defenselink.mil/other_info/blanck.html.

⁴¹See 21 C.F.R. § 610.53(b).

This permits the manufacturer to extend the date of manufacture by performing a “valid potency test” under the regulation.⁴³ Potency is interpreted in the biologics regulations as:

...the specific ability or capacity of the product, as indicated by appropriate laboratory tests or by adequately controlled clinical data obtained through the administration of the product in the manner intended, to effect a given result.⁴⁴

However, extension of the expiration date by means of a potency test is by no means guaranteed. It is possible that FDA dating periods are intended to be conservative. However, the language of the regulations setting the dating period leaves little room for expectations that the vaccine will last much longer than the dating period. The definition of “dating period” cited above suggests that, when the FDA sets the dating period, it must have a reasonable relation to the expected life of the vaccine.⁴⁵

Furthermore, continuing to extend the dating period may have implications for the efficacy of the vaccine and the willingness of people to take it. Some FDA scientists have raised questions about whether vaccines necessarily are proved potent even if they have passed a potency test.⁴⁶ Reliance on expiration date extensions may also appear to confirm the suspicions of those who are already reluctant to take the vaccine due to safety concerns, and make them even more reluctant to take the vaccine to protect themselves from the anthrax disease. For instance, one anti-anthrax vaccine website features prominently a picture of a vial of anthrax vaccine, with the expiration dates repeatedly crossed out and new ones written in.⁴⁷

However, even if the vaccine itself remains potent, the acceptability of a potency test is still not a foregone conclusion. According to the language of § 610.50, the last potency test must be “valid.”⁴⁸ On its website,

⁴³U.S. Food and Drug Administration, Vaccine Frequently Asked Questions (FAQs), January 3, 2001, available at <http://www.fda.gov/cber/faq/vacfaq.htm>.

⁴⁵See 21 C.F.R. § 600.3(l)

⁴⁶See Bruce D. Meade and Juan L. Arciniega, Efficacy and Safety of New Products: Assays and Laboratory Markers of Immunological Importance, Summary of Presentation Given on December 6, 2000 at Medical Defense Against Bioterrorism Workshop, available at <http://www.fda.gov/cber/summaries/120600bio12BM.htm>.

⁴⁷Anthrax Vaccine Links and Information, available at <http://www.dallasnw.quik.com/cyberella/index.htm>

⁴⁸21 C.F.R. § 610.50.

the FDA suggests how it interprets this word in the regulation:

Any decision made to extend the dating period of a vaccine is predicated and sustained by the data submitted by the manufacturer that verifies the sterility and potency of the product. If the manufacturer can assure FDA, through sound scientific data, that the product is still sterile and potent even after the recommended dating period then (on a case-by-case basis) extending the dating period on the label will be permitted.⁴⁹

This statement makes clear that not all potency tests will be approved by the FDA. Moreover, the FDA's criteria for approving the potency test suggests that it was not reasonable to expect that BioPort would easily produce potency tests acceptable to the FDA. In its inspections of the BioPort facility pre-approval, the FDA inspectors repeatedly noted that BioPort had difficulties with record-keeping and maintaining sterile conditions.⁵⁰

It is true that the FDA's authority to bind regulated parties to this statement, which appears on a website and not in the Federal Register, is questionable. Under United States v. Mead, agencies' interpretations of the organic statute without proper procedure has only persuasive value for courts.⁵¹ However, this problem is purely academic as it would take far too long to litigate to be useful in a situation in which vaccine is due to expire soon. Furthermore, a company with a history of regulatory problems and a controversial product dependent on government funding might not want to take on the FDA in court. Even if the manufacturer did win, the danger of negative publicity would be so great that the Defense Department might find it politically unwise to give it future defense contracts.

Relying on potency tests to extend the life of the vaccine, and thus assure a continuous supply, is therefore at best a gamble. It should not have been relied upon for a crucial supply of vaccine from a sole supplier.

⁵⁰See, e.g., Paula A. Trost, Marsha W. Major, and William D. Tingley. Department of Health and Human Services, Public Health Service, Food and Drug Administration. Form FDA 483 for BioPort Corporation 4. October 26, 2000, available at <http://www.fda.gov/>

⁵¹See U.S. v. Mead Corp., 533 U.S. 218 (2001).

The Defense Department could conceivably have found itself with no unexpired vaccine under this scenario. Regardless of expiration dates, military stockpiles of Anthrax Vaccine Adsorbed were allowed to run dangerously low. On November 30, 2001, Kenneth Bacon of the Defense Department confirmed that the Department had only 60,000 vials of the vaccine available for current use, plus an unspecified “reserve.”⁵² According to the package insert for Anthrax Vaccine Adsorbed at the time, each vial contained 10 doses each.⁵³ In phase one alone of the military’s vaccination program, 75,000 doses a month were required merely to cover all troops deployed to the Persian Gulf or Korea.⁵⁴

Furthermore, those in the military are not the only ones who are likely to be on the front lines in case of an anthrax attack. Currently, BioPort recommends vaccinating emergency response workers, who would likely be the first to respond to a domestic terrorist attack.⁵⁵ The Defense Department also wanted to make the anthrax vaccine available to South Korea in order to discourage an anthrax attack there.⁵⁶ There were also small amounts of the anthrax vaccine sold to the State Department and to persons working with animals likely to be infected with anthrax.⁵⁷ However, since the Defense Department currently owns all of the vaccine being produced by BioPort, those workers cannot be supplied with the vaccine until after BioPort fulfills its obligation to the Defense Department.⁵⁸ And in case of a mass attack on the American civilian population, a shortage of anthrax vaccine could have dire results. When the Johns Hopkins Center for Civilian Biodefense Studies ran an exercise simulating a biological attack upon the United States (in this case using smallpox),

⁵²U.S. Department of Defense, DoD News Briefing 18, November 30, 2000, available at <http://www.defenselink.mil/news/Nov2000/t11302000.t1130asd.html>.

⁵³See BioPort Corporation, Label for Anthrax Vaccine Adsorbed 3 (March 1999) available at http://www.anthrax.osd.mil/Site_Files/articles/INDEXclinical/package_insert.htm.

⁵⁴See U.S. Department of Defense, Briefing on the Anthrax Vaccination and Immunization Program 3, (December 13, 1999)(statement of Major General Randall L. West, U.S. Marine Corps, Special Advisor to the Under Secretary of Defense of Personnel and Readiness on Anthrax and Biological Defense Matters), available at http://www.defenselink.mil/news/Dec1999/t121419999_t213anth.html.

⁵⁵See Sue Ellen Christian, Maker of Anthrax Vaccine Gets OK to Supply Military, Chicago Tribune, February 1, 2002, at 8.

⁵⁶See U.S. Department of Defense, Briefing on the Anthrax Vaccination and Immunization Program 4, (December 13, 1999)(statement of Major General Randall L. West, U.S. Marine Corps, Special Advisor to the Under Secretary of Defense of Personnel and Readiness on Anthrax and Biological Defense Matters), available at http://www.defenselink.mil/news/Dec1999/t121419999_t213anth.html.

⁵⁷See id.

⁵⁸See id.

the Center concluded that “The lack of sufficient vaccine or drugs to prevent the spread of disease severely limited management options,” including containing the spread of disease and preventing public panic.⁵⁹

The Defense Department did reduce its usage of the vaccine, starting in 2000, in direct response to the problem of a vaccine shortage.⁶⁰ However, this meant not vaccinating many troops, including those in the vicinity of North Korea.⁶¹ That area had previously judged to be a high-risk area for an anthrax attack due to North Korea’s possession of biological weaponry.⁶²

In June of 2001, the Defense Department stopped being able to vaccinate all troops headed for Southwest Asia.⁶³ Iraq is currently known to possess weaponized anthrax.⁶⁴ After the curtailment of vaccinations in Southwest Asia, Marine Major General Randall West expressed regret at being unable to vaccinate those troops and suggested that a lack of a vaccination program in Southwest Asia might be endangering American troops.⁶⁵ At the time of writing of this paper, the only persons the Defense Department was vaccinating were “small special operations units” and persons participating in research.⁶⁶

However, curtailing usage, while it would keep the stores from running low, would not solve the problem of expiration dates. The Institute of Medicine has recommended further research into a vaccine which would remain potent for longer periods so that it could be more easily stockpiled by the government.⁶⁷ However, this could take years to develop. Until then, it is necessary to work with the constraints posed by the current

⁵⁹Tara O’Toole, M.D., MPH, et al., Shining Light on Dark Winter 4, available at <http://www.hopkins-biodefense.org/lessons.html>.

⁶⁰See U.S. Department of Defense, DoD News Briefing 1, November 30, 2000, available at http://www.defenselink.mil/news/Nov2000/t11302000_t1130asd.html.

⁶¹See *id.* at 18.

⁶²See U.S. Department of Defense, DoD News Briefing 4, September 28, 2000, available at http://www.defenselink.mil/news/Sep2000/t09282000_t0928asd.html.

⁶³See Jim Garamone, DoD Slows Anthrax Vaccination Program Again, American Forces Information Service, June 11, 2001, available at http://www.defenselink.mil/news/Jun2001/n06112001_200106112.html.

⁶⁴See U.S. Department of Defense, Briefing on the Anthrax Vaccination and Immunization Program 2, (December 13, 1999)(statement of Dr. Sue Bailey, Assistant Secretary of Defense for Health Affairs), available at http://www.defenselink.mil/news/Dec1999/t121419999_t213anth.html.

⁶⁵See Jim Garamone, DoD Slows Anthrax Vaccination Program Again, American Forces Information Service, June 11, 2001, available at http://www.defenselink.mil/news/Jun2001/n06112001_200106112.html.

⁶⁶See *id.*

⁶⁷See The National Academy of Sciences Institute of Medicine, Anthrax Vaccine is Useful But Shortcomings Underscore Need for Replacement 2 (March 6, 2002), available at <http://www4.nationalacademies.org/news.nsf/isbn/0309083095?OpenDocument>.

vaccine.

Interrupting the anthrax vaccination program for lack of vaccine may cause other problems. Since the anthrax vaccine is approved only for use on a particular schedule of six inoculations, with a yearly booster shot thereafter, suspending the vaccination program means that some participants in the anthrax vaccination program may have received only a partial schedule of shots or received shots later than recommended. The Defense Department's response to reader mail on its anthrax vaccination website confirms that this has occurred.⁶⁸ It is not yet known what health effects interrupting an anthrax vaccination schedule will have.⁶⁹ It is also not known whether the vaccine will remain effective.⁷⁰ This might cause some who have received partial vaccination schedules to be lack caution when exposed to anthrax because they think they are protected. Finally, deviations from the schedule have not yet been approved by FDA.⁷¹

What Went Wrong

BioPort failed numerous inspections, mostly on grounds of improper sterilization procedures.⁷² BioPort only gained the approval of the FDA to release the latest batch of AVA after it hired a subcontractor, Hollister-Stier, to bottle its vaccine in sterile vials.⁷³ The General Accounting Office, in a study requested by the House Subcommittee on National Security, Veterans' Affairs, and International Relations, also found that

⁶⁸See "Angela" from DoD AVIP Agency, Response to "Colonel Z", visited on March 10, 2002, available at http://www.anthrax.osd.mil/Site_Files/reader_mail/Mail/091001.htm.

⁶⁹See Kathryn C. Zoon, Ph.D., Director, Center for Biologics Evaluation and Research, FDA, Letter to Sue Bailey, M.D., Assistant Secretary of Defense for Health Affairs, September 29, 1999, and Jane E. Henney, M.D., Commissioner of Food and Drugs, Letter to Sue Bailey, M.D., September 28, 1999, available at <http://www.fda.gov>.

⁷⁰See id.

⁷¹See id.

⁷²See, e.g., Paula A. Trost, Marsha W. Major, and William D. Tingley. Department of Health and Human Services, Public Health Service, Food and Drug Administration. Form FDA 483 for BioPort Corporation 4. October 26, 2000, available at <http://www.fda.gov/>

⁷³See U.S. Food and Drug Administration, FDA Approves License Supplements for Anthrax Vaccine, January 31, 2002, available at <http://www.fda.gov/bbs/topics/NEWS/2002/NEW00792.html>.

BioPort had changed its manufacturing processes numerous times without reporting these changes to the FDA.⁷⁴ This was a violation of FDA regulations on good manufacturing practices.⁷⁵ The GAO found that in some cases, these changes affected the antigen content of the vaccine, but was unable to state whether this change would lead to greater adverse reactions.⁷⁶ In testimony before a House Subcommittee, Nancy Kingsbury of the GAO recommended that either the FDA or the Defense Department, or both, institute “an aggressive active surveillance program to ensure the early identification and analysis of adverse reactions.”⁷⁷

⁷⁴See Kingsbury, supra note 16.

⁷⁵See Kingsbury, supra note 16, at 2, citing 21 C.F.R. §§ 600-680.

⁷⁶See Kingsbury, supra note 16.

⁷⁷See Kingsbury, supra note 16, at 8.

The biggest problem was probably that the State of Michigan had torn down its old facility and begun to build a new one.⁷⁸ According to the Defense Department, this was not due to any action on the part of the FDA but rather in response to the increased production capacity required by the Defense Department.⁷⁹ As the company was using a new facility to manufacture the vaccine, the company then had to go through the entire FDA approval process to obtain a new licensing supplement for that facility.⁸⁰ In December of 1999, the Defense Department was estimating that this entire process could be done in six months to a year.⁸¹

As a small business, BioPort had few other sources of income besides the anthrax vaccine. A statement by BioPort corporation explains that it gave up its other products to make sure the company was “focused” on the anthrax vaccine.⁸² However, an audit by the Defense Contract Audit Agency found that BioPort was losing money on its other commercial products, which might endanger its ability to continue producing anthrax vaccine.⁸³ A Defense Department background briefing states that BioPort was not even expected to make a profit off the anthrax vaccine sold to the Defense Department, even after the contract renegotiation.⁸⁴ Furthermore, an audit by the Defense Contract Audit Agency found that BioPort’s accounting system was insufficient for dealing with government contracts.⁸⁵ The company did correct the deficiencies, but the

⁷⁸See U.S. Department of Defense, DoD News Briefing 19, November 30, 2000, available at http://www.defenselink.mil/news/Nov2000/t11302000_t1130asd.html.

⁷⁹See Department of Defense, Anthrax Vaccine—Production Issues 1, visited on March 10, 2002, available at <http://www.anthrax.osd.mil/Site.Files/qna/PRODISSUES.HTM>.

⁸⁰See Kathryn C. Zoon, Ph.D., Director, Center for Biologics Evaluation and Research, Statement Before the Senate Committee on Armed Services, July 12, 2000, available at <http://www.fda.gov/ola/2000/anthraxvaccine2.html>.

⁸¹See U.S. Department of Defense, DoD News Briefing 2 (December 13, 1999)(statement of Dr. Sue Bailey, Assistant Secretary of Defense for Health Affairs), available at http://www.defenselink.mil/news/Dec1999/t12131999_t213anth.html.

⁸²BioPort Corporation, Media Backgrounder, November 20, 2001, available at <http://www.bioport.com/NewsRoom/NewsReleases/BioPort/2001-1>.

⁸³See Hearing on Audits of BioPort Corporation, U.S. House of Representatives Committee on Armed Services, Military Personnel Subcommittee 4 (2000)(statement of April G. Stephenson, Chief, Policy Programs Division, Defense Contract Audit Agency).

⁸⁴See U.S. Department of Defense, Background Briefing: Anthrax Vaccine Contract Briefing 11(August 5, 1999)(statement of unnamed briefer), available at http://www.defenselink.mil/news/Aug1999/x08051888_x0805ant.html.

⁸⁵See Hearing on Audits of BioPort Corporation, U.S. House of Representatives Committee on Armed Services, Military Personnel Subcommittee 7-8 (2000)(statement of April G. Stephenson, Chief, Policy Programs Division, Defense Contract

problems with the accounting system had meant that neither BioPort nor DCAA really knew how much it cost to produce the anthrax vaccine.⁸⁶

FDA's Response to the Shortage

The FDA could have taken two special regulatory actions to relieve the anthrax vaccine shortage. First of all, despite the problems with the supply of anthrax vaccine, the FDA never declared a drug shortage of anthrax vaccine.⁸⁷ If a drug shortage were declared, the FDA policy is that it must be addressed whenever possible.⁸⁸ The FDA does recognize that its own enforcement actions, among other factors, may lead to a drug shortage.⁸⁹ Potential drug shortage situations arise about once or twice per month, according to the FDA's drug shortage coordinator.⁹⁰ The FDA considers drug shortages to be of a high priority if the drug is considered to be "medically necessary."⁹¹ The anthrax vaccine certainly ought to be considered medically necessary for the prevention of anthrax, even though anthrax is relatively rare in this country. Furthermore, regardless of whether anthrax vaccine should be considered a medical necessity, it is a necessity for the national defense. Since terrorist acts involving anthrax are by nature unpredictable, the vaccine may still be necessary for defense preparedness even if the FDA assesses the medical risk at any given time and finds it to be minimal. As has been seen above, the FDA did not take action to stop a drug shortage with anthrax vaccine until the situation became a crisis. It may be necessary to take congressional action in order to

Audit Agency).

⁸⁶See id.

⁸⁷See Food and Drug Administration, Drug Shortages, January 29, 2002, available at <http://www.fda.gov/>.

⁸⁸See Michael G. Friedman, Lead Deputy Commissioner of FDA, Statement Before the House Committee on Government Reform and Oversight, Subcommittee on Human Resources, May 7, 1998, available at <http://www.fda.gov/ola/immune.htm>.

⁸⁹See Hearing on Audits of BioPort Corporation, U.S. House of Representatives Committee on Armed Services, Military Personnel Subcommittee 7-8 (2000)(statement of April G. Stephenson, Chief, Policy Programs Division, Defense Contract Audit Agency).

⁹⁰See Tamar Nordenburg, Inside FDA: When A Drug Is In Short Supply, FDA Consumer, November-December 1997, available at <http://www.fda.gov/>.

⁹¹Food and Drug Administration, Drug Shortages, January 29, 2002, available at <http://www.fda.gov/>.

mandate FDA consideration of national defense issues in addition to medical necessity.

Another possible response to the lack of anthrax vaccine could be to designate the anthrax vaccine an orphan drug. The anthrax vaccine is not currently designated as an orphan drug.⁹² One barrier to designating the drug as an orphan drug is that it must be applied for prior to marketing the product.⁹³ If the vaccine had been designated as an orphan drug, government funds could have been made available for clinical testing of the vaccine, in the amount of one hundred thousand to two hundred thousand dollars per year.⁹⁴ A tax credit would also be available for additional clinical testing.⁹⁵ Although this is a relatively small amount of money compared to the large amounts needed to get BioPort up and running again, it might have been helpful to BioPort while it was having financial difficulties.

However, what was really needed from the FDA in this situation was quick, responsive FDA action in reviewing BioPort's attempts to comply with FDA's prior comments. An FDA press release states that BioPort is already receiving expedited treatment from FDA. The press release quotes Bernard A. Schwetz, DVM, Ph.D., FDA's Acting Principal Deputy Commissioner, as stating, "FDA has worked as quickly as possible to review these license supplements, including resolving outstanding issues with the firm, for the supplement to be approved."⁹⁶ According to BioPort, BioPort Corporation filed the necessary documentation for its supplemental Biologic License Amendment on October 12, 2001.⁹⁷ The FDA completed its pre-approval inspection of the BioPort facility on December 19, 2001, and approved BioPort's facility on December 27, 2001.⁹⁸ FDA then inspected Hollister-Stier's facility during the period of January 7-10, 2002 and approved

⁹²See Food and Drug Administration, List of Orphan Designations and Approvals, visited on February 27, 2002, available at <http://www.fda.gov/orphan/DESIGNAT/list.htm>.

⁹³See Food and Drug Administration, OOPD Frequently Asked Questions, visited on February 27, 2002, available at <http://www.fda.gov/orphan/faq/index.htm>.

⁹⁴See id.

⁹⁵See Food and Drug Administration, Tax Credit for Testing Expenses for Drugs for Rare Diseases or Conditions, visited on February 27, 2002, available at <http://www.fda.gov/orphan/taxcred.htm>.

⁹⁶See Food and Drug Administration, Press Release, January 31, 2002, available at <http://www.fda.gov/bbs/topics/NEWS/2002/NEW000792.html>.

⁹⁷See BioPort Corporation, Media Backgrounder, November 20, 2001, available at <http://www.bioport.com>.

⁹⁸See Food and Drug Administration, Press Release, January 31, 2002, available at <http://www.fda.gov/bbs/topics/NEWS/2002/NEW000792.html>.

Hollister-Stier's facility on January 31, 2002. The military's entire supply of AVA would have been expired for over two weeks before FDA completed even the first inspection of BioPort. The delay of two months in inspecting the facility is completely unexplained.

FDA policies with regards to dealing with drug shortages, such as the Fast Track Designation Request program, are mostly focused on getting new drugs approved.⁹⁹ Such policies do not deal with helping the manufacturer overcome manufacturing problems which might cause a shortage. While the problem of slow FDA approval for new drugs is certainly important, solving it would not prevent what happened at BioPort because the anthrax vaccine had already been approved for thirty years. What was really needed from the FDA is quicker responses to the manufacturer's attempts to correct manufacturing problems.

The FDA should not, however, adopt any special standards for evaluating the anthrax vaccine which give special consideration to the importance of anthrax vaccine for national defense. While the FDA assisted in evaluating reports of adverse effects after the vaccine has been administered and reviewed a draft of the Defense Department's vaccination program, the agency was not involved with Defense Department procurement of the vaccine.¹⁰⁰ While the expertise of FDA officials in biological products would certainly have been useful in avoiding manufacturing delays, having FDA officials too involved in the Defense Department procurement process for anthrax vaccine presents problems of its own. Since the anthrax vaccination program is so controversial, Defense Department officials have often pointed to the independence of FDA inspectors in order to assure the public and members of the services that the vaccine is safe.¹⁰¹ If FDA became involved in assuring a consistent supply of vaccine to the Defense Department, it might be considered to have a political stake in ensuring adequate supplies and thus jeopardize its credibility with members of the public as to the vaccine's safety. Therefore, while the FDA needs to speed up its own procedures to ensure that critical

⁹⁹See Food and Drug Administration Modernization Act of 1997, 21 U.S.C. § 506 (1997).

¹⁰⁰See Hearing on the Anthrax Vaccine, Senate Committee on Armed Services, April 13, 2000 (written statement of the Food and Drug Administration), available at <http://www.fda.gov/ola/2000/anthraxvaccine.html>

¹⁰¹See, e.g., Department of Defense, Vaccine Safety, visited on March 13, 2002, available at http://www.anthrax.osd.mil/Site.Files/safety/safety_info.htm.

inspections are done immediately, it should not relax its standards in any way in evaluating the product.

BioPort's Response to the Shortage

Despite the problems with the FDA's response, the fact that BioPort waited until October to file the application for the licensing supplement is even more problematic. The company would have known that the military's supply of AVA was due to expire the next month. In 2000, the FDA set the following goals for reviewing manufacturing supplements to license applications as part of the re-authorization of the Prescription Drug Manufacturing Act of 1992 (PDUFA):

The time frame for priority applications and clinical efficacy supplements and for manufacturing supplements that do not contain clinical data and do not require prior approval will continue to be 6 months. The time frame for manufacturing supplements that do not contain clinical data but do require prior approval will become 4 months over the time of PDUFA 2. Complete review comments are communicated to the applicant in an action letter, which stops the review clock. Other comments not constituting a complete review may be transmitted in an information request (IR) or discipline review (DR). Neither an IR nor a DR stops the review clock. Responses to an IR or DR, and unsolicited information may be received from the applicant during the review of an application or supplement. These submissions are amendments to the pending file. Each submission to a pending application is assessed for its effect on the review clock. Receipt of a major amendment to an application within three months of the action due date will extend the action due date by three months. Minor amendments will not affect the due date.¹⁰²

The FDA has also committed to reviewing a manufacturer's response to an action letter following the resubmission of a licensing application in six months.¹⁰³ What is important to realize is that these periods of times, as long as they are, are still only goals. The fact that the FDA had to set these goals suggests that the usual time frame was even longer. Therefore, leaving such a short amount of time for the licensing

¹⁰³See Center for Biologics Evaluation and Research, Food and Drug Administration, Procedures for the Classification of Resubmissions of an Application for a Product Covered by the Prescription Drug User Fee Act (PDUFA), May 20, 1998 (SOPP 8405.1), available at <http://www.fda.gov/cber/regsopp/84051.htm>.

application to clear the FDA was clearly unrealistic. In the company's defense, the filing that it sent to FDA in October weighed between seven and eight thousand pounds.¹⁰⁴ However, this was all the more reason for the company to leave the FDA as much time as possible to review it. Furthermore, if the company's license amendment was rejected again, there was no reason to believe that new batches could be quickly prepared before the Department of Defense ran out of vaccine altogether. It takes 22 weeks to prepare a new batch of vaccine, five of which are devoted to FDA batch release.¹⁰⁵ If the FDA had found that the company was still using improper manufacturing processes, therefore, it would have taken five and a half months to make new batches—after whatever manufacturing problems the FDA were to find were fixed. This is a significant risk.

This problem should not be treated as a mere coincidence, but inherent in the structure of the situation. BioPort, as the country's sole manufacturer of the vaccine, has little to fear in terms of losing its contract with the military to a competitor in the short term. Therefore, it does not have the incentive to ensure that the military's vaccine supply is always up to date. The Defense Department, which does have the incentive to maintain an up-to-date supply of vaccine, is unable to apply for the supplements on BioPort's behalf. Therefore it may be anticipated that similar problems will occur in the future unless corrective action is taken. The Defense Department should require in its contract with the vaccine manufacturer that the manufacturer file any necessary FDA approvals several months before their supply is due to run out.

In fact, it is possible that these problems could have been anticipated months or even years earlier. On May 21, 2001, BioPort issued a press release stating that it expected to complete all of its FDA approvals in "early 2002."¹⁰⁶ This was already a problem given that the current supply of the anthrax vaccine was due to expire

¹⁰⁴See BioPort Corporation, Did You Know?, available at <http://www.bioport.com>.

¹⁰⁵See The National Academy of Sciences, The Anthrax Vaccine: Is It Safe? Does It Work? 139-140 (2002), available at <http://www.nap.edu/openbook/030983095/html/50.html>.

¹⁰⁶BioPort Corporation, Press Release, May 21, 2002, available at <http://www.bioport.com/NewsRoom/NewsReleases/BioPort/2001-May21.asp>.

in late 2001. It should have been apparent to the Defense Department at this time that, according to the manufacturer's own representations, the manufacturer was probably not capable of assuring it a consistent supply of vaccine.

Duplication of the facilities during construction could have been an important preventive measure to avoid shortages of the vaccine. One Defense Department official asserted that the old plant would need to be burned once the new one was completed.¹⁰⁷ If the old building would need to be destroyed, this would indeed be expensive. However, this is perhaps a false cost savings, considering the number of lives at stake if the military were to experience an anthrax attack.

The Defense Department's Response to the Shortage

In 1999, the Defense Department restructured its contract with BioPort in order to "preserve the financial viability of BioPort in order to ensure uninterrupted production of the anthrax vaccine."¹⁰⁸ According to a Defense Department news release, "[i]n June 1999, BioPort requested extraordinary contractual relief under Public Law 85-804 because it had insufficient cash to continue operations after August 1 and was unable to borrow additional funds."¹⁰⁹ Even after receiving extraordinary contractual relief, an audit of BioPort found that BioPort was still having cash flow problems in early 2000.¹¹⁰

The Defense Department granted extraordinary contractual relief in order to keep BioPort from going into

¹⁰⁷See U.S. Department of Defense, DoD News Briefing 15 (December 13, 1999)(statement of Mr. David Oliver, Principal Deputy Under Secretary of Defense for Acquisition), available at http://www.defenselink.mil/news/Dec1999/t12131999_t213anth.html.

¹⁰⁸U.S. Department of Defense, News Release 1, August 5, 1999, available at http://www.defenselink.mil/news/Aug1999/b08051999_bt367-99.html.

¹⁰⁹Id.

¹¹⁰See Hearing on Audits of BioPort Corporation, U.S. House of Representatives Committee on Armed Services, Military Personnel Subcommittee 4-5 (2000)(statement of April G. Stephenson, Chief, Policy Programs Division, Defense Contract Audit Agency).

bankruptcy.¹¹¹ A bankruptcy could have been even more disastrous for delivery of the anthrax vaccine, even if the firm kept operating instead of liquidating. In the event of bankruptcy, besides waiting for the FDA to release batches of the vaccine, the Defense Department might have had the additional burden of persuading a bankruptcy judge to lift the automatic stay placed upon most creditors at the time of a bankruptcy filing, which would prevent it from collecting units of vaccine which it had paid for but not received pre-filing.¹¹²

If the FDA ever takes enforcement action in the future which adversely affects the supply of Anthrax Vaccine Adsorbed available, delays of the length seen here will not be acceptable. The FDA has set the new expiration date for the new batches filled at Hollister-Stier at eighteen months from the date of manufacture.¹¹³ The expiration date can only be extended with “the submission [to the FDA] of supporting data as a supplement to your biologics license application for review and approval.”¹¹⁴ Such “review and approval” will take time, both for the manufacturer to research the data and prepare the documentation and for the FDA to perform its review and reach a decision. Therefore, FDA and the Defense Department cannot expect that last-minute action will be acceptable. There may not be time to wait until a batch of vaccine is rejected close to the expiration date. The manufacturer will need to begin preparing the extension request several months before the expiration date of the military’s cache of anthrax vaccine. The FDA could demand this, as a condition of approving the batch releases or the Defense Department could have it written into its contract with the manufacturing facilities. Congress can also mandate that certain vaccines be given expedited review by FDA.

¹¹¹See Hearing on Department of Defense Anthrax Vaccine Immunization Program, Senate Armed Services Committee 7 (April 13, 2000)(statement of Rudy de Leon, Deputy Secretary of Defense), available at <http://www.defenselink.mil/speeches/2000/s20000413-depsecdef.html>.

¹¹²See 11 U.S.C. § 362.

¹¹³See Steven A. Masiello, Director of the Office of Compliance and Biologics Quality, Food and Drug Administration, Letter to Lallan Giri, Ph.D., BioPort Corporation, dated January 31, 2002, available at <http://www.fda.gov/cber/products/biopava0131021.htm>.

¹¹⁴Id. at 1.

The Department of Defense must also examine whether it is realistic to expect private enterprise to take over the manufacture of this vaccine. The State of Michigan estimated at the time of sale that it had been underwriting the manufacture of the vaccine sold to the Defense Department in the amount of approximately \$5 million per year.¹¹⁵ A Defense Department briefing, not on the record, stated that BioPort had not realized that Michigan was previously providing state janitorial services and utilities, for example, which were not accounted for in the price it was charging the State Department for anthrax vaccine.¹¹⁶

Currently, many vaccines are in short supply due to the lack of incentives to produce them in the private sector.¹¹⁷ In testimony before a Senate committee, Dr. Anna Johnson-Winegar, Deputy Assistant to the Secretary of Defense for Chemical/Biological Defense stated that “major pharmaceutical firms typically expect their products to produce in excess of \$200 million in annual sales. At most, the Defense Department will provide a small piece of this revenue expectation.”¹¹⁸ Dr. Johnson-Winegar also noted that vaccine manufacture requires expensive facilities dedicated to one product, manufacturers often find themselves blindsided by political changes, and that manufacturers had concerns the potential for monitoring by international weapons inspectors which might disclose trade secrets.¹¹⁹ The State of Michigan began manufacturing anthrax vaccine in the first place at the request of the Department of Defense because no private manufacturer was willing to take it on.¹²⁰

The government is currently considering whether to build its own anthrax vaccine production plant.¹²¹ This,

¹¹⁵See U.S. Department of Defense, Background Briefing: Anthrax Vaccine Contract Briefing 8(August 5, 1999)(statement of unnamed briefer), available at http://www.defenselink.mil/news/Aug1999/x08051888_x0805ant.html.

¹¹⁶See *id.* at 6-7.

¹¹⁷See Richard Klausner, Special Adviser, President for Counterterrorism Council of the Institute of Medicine, Prepared Testimony Before the Senate Commerce, Science, and Transportation Committee, Federal News Service (February 5, 2002), available via Lexis-Nexis.

¹¹⁸Field Hearing on Department of Defense Anti-Biological Warfare Agent Vaccine Acquisition Program at Pine Bluff, Arkansas, Testimony Before the Senate Armed Services Committee, Subcommittee on Personnel 3 (2000)(statement by Dr. Anna Johnson-Winegar, Deputy Assistant to the Secretary of Defense for Chemical/Biological Defense).

¹¹⁹See *id.* at 3-4.

¹²⁰See BioPort Corporation, Media Backgrounder, November 20, 2001, available at <http://www.bioport.com/NewsRoom/NewsReleases/BioPort/2001-Nov20.asp>.

¹²¹See Emmett George, Arkansas Pitch Arsenal Site to Rumsfeld, Arkansas Democrat-Gazette, February 26, 2002, at B6.

however, is estimated to cost much more than working with BioPort. Senator Tim Hutchinson estimates that building a government plant will cost \$386 million, versus the \$120 million that the government has already spent on BioPort.¹²² The plant will also take a number of years to construct and gain FDA approval. Although more expensive, it would, however, solve many of the problems associated with private production of vaccines, such as the possibility of a private company running into financial difficulty.

It is uncertain whether, without changes in the law, a government-owned plant would be able to completely avoid the laws which allow FDA to regulate its manufacturing facilities. A government entity might plausibly be able to get around some parts of the Public Health Services Act by claiming that it was not introducing the product into interstate commerce. For instance, the Public Health Services Act, 42 U.S.C. § 262(a) states that “No person shall introduce or deliver for introduction into interstate commerce any biological product unless... a biologics license is in effect for the biological product.”¹²³ However, a federal district court case refused to extend the interstate commerce language of Section 262(a) to other parts of Section 262, and thus ruled that Section 262(b), which deals with false labeling, to apply regardless of whether the product was introduced into interstate commerce.¹²⁴ If this reasoning were followed by other courts, Section 262(c), which allows the FDA to inspect biologics production facilities, and Section 262(d), which allows FDA to recall unsafe biological products, would apply to products produced by, for instance, the Defense Department, and thus still allow FDA some measure of control over the product.¹²⁵

Under the Food, Drug and Cosmetic Act, a similar result obtains. Although the FDA chooses to do its biologics enforcement under the Public Health Services Act, the FD&C Act is applicable to biologics.¹²⁶

Under the Food, Drug and Cosmetic Act, the “good manufacturing practices” required under the FD&C

¹²²See Harold Kennedy, *Chem-Bio Attack Looming, Say U.S. Officials: According to Sen. Tim Hutchinson, “The Unthinkable Has Become Thinkable”*, National Defense, March 1, 2002, at 18.

¹²³42 U.S.C. § 262(a).

¹²⁴See *United States v. Calise*, 217 F.Supp. 705 (S.D.N.Y. 1962), citing 42 U.S.C. §§ 262(a) and (b).

¹²⁵See 42 U.S.C. §§ 262(c) and (d).

¹²⁶See Center for Biologics Evaluation and Research, *Frequently Asked Questions*, January 17, 2001, available at <http://www.fda.gov/cber/faq.htm>.

Act only apply to those drugs which are shipped in interstate commerce.¹²⁷ However, other provisions of the FD&C Act, such as the provision which requires all producers of drugs to register, and which prohibits them from refusing inspection, are applicable to all drugs regardless of whether they enter interstate commerce.¹²⁸ The inspectors themselves are not authorized to inspect drugs unless they are intended for interstate commerce.¹²⁹ Nevertheless, the agency would probably not want to be involved in litigating this matter.

Vaccine could even be manufactured by the Department of Health and Human Services under Section 42 U.S.C. § 263, which states that “[t]he Service [The Public Health Service, now the Department of Health and Human Services] may prepare any [biological] product... for the use of other Federal Departments or agencies, and public or private agencies and individuals engaged in work in the field of medicine when such product is not available from establishments licensed under such section.”¹³⁰ The language of this section, “from establishments licensed under such section,” suggests that such a facility would not need to be licensed.¹³¹ However, the wholesale transfer of the preparation of an important biological product from the private sector to the Department of Health and Human Services would likely be seen as a conflict of interest for the FDA and perhaps undermine public confidence in the fairness of FDA’s regulation of biological products.

Regardless of whether a government agency producing anthrax vaccine has the ability to sidestep FDA regulation, it is unlikely that such an agency would choose to do so. Special treatment for biological products manufactured by the government might arouse public fears that the products were less safe. Therefore, regardless of whether an agency making vaccines chose to accept FDA regulation or had it imposed upon them by the law, a government plant might still be unable to release vaccine at some point in the future due to actions by FDA.

¹²⁷See 21 U.S.C. § 351(a)(1)(B) and 21 U.S.C. § 331(a).

¹²⁸See 21 U.S.C. §§ 351(p) and (q)(1) and 21 U.S.C. § 360.

¹²⁹See 21 U.S.C. § 374.

¹³⁰42 U.S.C. § 263.

¹³¹Id.

Therefore, the government would need to focus on having an alternative source of vaccine in case one plant was unable to distribute vaccine due to FDA enforcement actions. The most secure option would be to have two plants, both constantly producing the anthrax vaccine, in order to avoid any start-up delays if one plant has problems. While a government plant would create an alternative to BioPort, it is possible that no private plant would be able to compete with it. The business press has speculated about whether BioPort would be able to remain in existence if a government plant were built.¹³² Therefore, the government would need to make sure that both plants could reasonably be expected to stay in existence, either by encouraging two private-sector plants, perhaps with government subsidies if necessary, or by providing two government plants.

Health and Human Services Secretary Tommy Thompson has stated that BioPort is expected to produce two million doses of the anthrax vaccine this year and three to eight million next year.¹³³ However, Dr. David S.C. Chu, Undersecretary of Defense for Personnel and Readiness, estimates that the military will be unable to extend the vaccination program to all its personnel for two or three years at least even if BioPort performs at expected levels.¹³⁴

Conclusion

At the time of writing of this paper, the Defense Department is currently considering whether to continue

¹³²See, e.g., Kristen Philipkoski, Why Anthrax Vaccine is Scarce, Wired News, October 10, 2001, available at [wysiwyg://7/http://www.wired.com/news/conflict/0,2100,47410,00.html](http://www.wired.com/news/conflict/0,2100,47410,00.html).

¹³³See Associated Press, A Nation Challenged: The Vaccine Maker; Troubled Company Is Allowed To Resume Making Vaccine, The New York Times, February 1, 2002, at A13.

¹³⁴See Hearing on the Defense Authorization Request for 2003 Before the Senate Armed Services Committee, Subcommittee on Personnel, 107th Cong. (2002) (statement of the Honorable David S.C. Chu, Undersecretary of Defense for Personnel and Readiness), available at LEXIS, News Library, FDCH File.

the anthrax vaccination program and if so, the scope of the program.¹³⁵ Nonetheless, the President's Budget for 2003 includes stockpiling an improved anthrax vaccine and smallpox vaccine for civilian use.¹³⁶ In order to stockpile these vaccines, a consistent supply of vaccines from the manufacturers will be needed in order to avoid the expiration date problem set out above. Shortages like the recent anthrax vaccine shortage can be avoided by careful long-range planning involving FDA, the manufacturers and whichever government agencies are responsible for purchasing the vaccines.

¹³⁵See U.S. Department of Defense, Anthrax Vaccine Announcement Expected Within the Month 1 (February 26, 2002), available on LEXIS, News Library, FDCH File.

¹³⁶See Office of the White House Press Secretary, Defending Against Biological Terrorism, Press Release, February 5, 2002, available at <http://www.whitehouse.gov/news/releases/2002/02/20020205-1.html>.