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Anthrax Vaccine Manufacturer to Produce COVID-19 Vaccines for Major Companies

By Dr. Meryl Nass
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DOD created a plan to vaccinate its service-members against many biowarfare threats in the 1990s. At the time, of the potential bioterrorism vaccines that were being considered, only anthrax and smallpox vaccines had licenses, so anthrax vaccine initiated the program in March of 1998.

The first 2 million doses of anthrax vaccine came from a stockpile that had been made for the US army by Michigan's state vaccine lab. What was apparently unknown when the program was planned, but became known in November 1997 when the FDA finally performed an inspection, was that the army's 11 million dose stockpile, stored at the Michigan lab, was mostly expired and contaminated, with obvious bacterial and fungal growth in some of the lots. FDA immediately shut down the anthrax vaccine factory, and quarantined 9 million of the 11 million existing doses. Unfortunately, FDA allowed 2 million doses to be used.

The FDA's inspection report, termed a "483" can be read here.

The Michigan state lab was a massive affair with many buildings on a campus in downtown Lansing. It produced a large variety of different vaccines and blood products for the state of Michigan, and some items for other commercial uses. However, over the years it had become run down, and the state had not made the required repairs and updates. After the 1997 FDA inspection, Michigan had to repair the place or close it. Republican **Governor John Engler** decided to privatize the lab, and looked for a buyer.

Meantime, the former head of the Joint Chiefs of Staff, **Admiral William Crowe**, got wind of the Michigan lab. He had come to know the el Hibri family when he was Ambassador to the UK. The el Hibri's had purchased anthrax vaccine from the UK government laboratory at Porton Down just before the Gulf War, and resold it to the Saudi Arabian government at a 10,000% markup.

Admiral Crowe had changed parties to support Presidential candidate **Bill Clinton**, and some suggested that the deal to buy the lab was a reward.

Crowe and the el Hibri family made common cause with several of the lab's officials, and the newly formed group bid to purchase the lab. A good deal was had by all. The purchase

price was about 19 million dollars. The el Hibri's put in about $4 million, the lab employees contributed several hundred thousand, and Admiral Crowe was given a 13% share in exchange for his role as Chairman of the Board, risking none of his own funds. Much of the remaining cost was later paid by the transfer of vaccines to the state of Michigan.

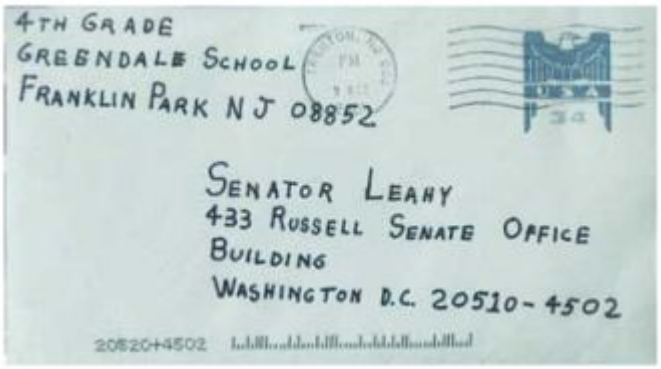
The new company, formed in the first half of 1998, was named Bioport. It sold off most of the licenses for childhood vaccines and other medical products that came with the purchase, choosing to focus on its sales of anthrax vaccine to the Army. However, the new company was deeply concerned about potential liability for the lab's products. So the purchase was delayed until one day after the Secretary of the Army signed an indemnification for injuries that might result from use of anthrax vaccine in soldiers, and also indemnify the company in case the vaccine failed to provide the expected protection against anthrax. In other words, the Army became Bioport's insurance company, at no cost to Bioport. This maneuver disincentivized Bioport to produce the highest quality products.

Although FDA had shut down the vaccine plant for manufacturing defects, the Army paid to bulldoze and then rebuild the anthrax vaccine factory in 1999. But even after it was rebuilt, FDA withheld its approval, and the plant laid idle.

Meantime, the 2 million doses that FDA had failed to quarantine were injected into over 500,000 military service-members between 1998 and 2001. Many thousands became ill. An official report on the program, quoting unnamed government officials, claimed that 1-2% of recipients had developed permanent disabilities. Despite this, the military made the vaccinations mandatory, threatening refusers with a court martial or other punishments and the loss of a month's pay. Nonetheless, seeing the injuries sustained by their colleagues, thousands refused.

The anthrax vaccine *label*, a legal document that describes what is known about the product, listed the CDC's definition of Gulf War syndrome as a possible adverse effect of the vaccine. (It has since been removed.)

Five Congressional hearings were held throughout 1999 on different aspects of the anthrax vaccine program by the House Committee on Government Reform and National Security (now known as the House Committee on Oversight and Reform). Additional hearings held by other Congressional committees also touched on the vaccine program. The Government Reform and National Security Committee wrote up its findings in a report titled Unproven Force Protection.



But Bioport has had remarkable luck. Although the Pentagon was considering ending the anthrax vaccine program in the summer of 2001, the sudden appearance of the anthrax letters after the 9/11 attacks breathed new life into the vaccine program, and turned

Bioport's fortunes around. DHHS Secretary **Tommy Thompson** announced in November 2001 that the anthrax vaccine plant would finally open and begin production. At the end of January 2002, FDA gave the go-ahead, and that is what happened.

But that was not the end of Bioport's problems. Soldiers challenged the legality of the vaccine's license in federal court. It was learned that while there had been efficacy testing of an earlier version of the vaccine, the current vaccine formulation had never undergone either efficacy or safety testing in a clinical trial. Aware of this major omission, FDA had withheld the issuing of a "final rule and order" for the anthrax vaccine for over thirty years.

The soldiers prevailed on the legal issues, and First District Court **Judge Emmett Sullivan** rescinded the vaccine license in 2004, based on the company's failure to prove efficacy or meet basic FDA standards for licensure.

Unwilling to bow to mere judicial authority, the Defense Department rolled out a backup plan. A new regulatory authority had just been created, the Emergency Use Authorization (EUA). An EUA was slapped on the unlicensed anthrax vaccine, and DOD quickly restarted its mandatory vaccinations.

The attorneys for the soldiers took the case back to court, and Judge Sullivan ruled that even if a medical product was given an EUA, it was still experimental and could not be mandated. The law required that EUA products be offered with informed consent. To receive an EUA (unlicensed) product, the recipient must be apprised of the risks and benefits of the product, be informed of alternatives to the product, and no coercion in any form could be applied. Ergo, no mandate.

FDA waited about 18 months, and then issued a full license for Bioport's anthrax vaccine, although there were still no efficacy data. FDA instead claimed that a 1950's era trial of a very different anthrax vaccine was sufficient for licensure, even though that trial failed to show benefit against inhalation anthrax.

When the soldiers and their attorneys challenged the licensing decision in court, the next judge ruled in favor of FDA on the basis of "deference"—meaning that FDA could ignore its own regulations and make its own determinations on safety and efficacy, with or without acceptable data. In 2006 mandatory vaccination restarted.

Bioport then shed its old skin in an attempt to leave its baggage behind. It renamed itself Emergent BioSolutions.

Emergent BioSolutions (EBS) then branched out, buying other companies, primarily those making other sole source biodefense products, including smallpox vaccine. The military continued to mandate anthrax and smallpox vaccines for service-members. Eventually EBS purchased the smallpox company as well, and the cholera and typhoid vaccines used in the US.

A 2010 report on Emergent BioSolutions, written by Scott Lilly for the *Center for American Progress*, was titled, "*Getting Rich off Uncle Sucker*." It revealed 300% profit margins, unique for a government contractor.

The company's business plan was to rely on insiders to sell sole source biodefense products to the US government, most of which were stockpiled and never used–inking contracts with

multiple federal agencies, including CDC, DOD, NIAID, the State Department, ASPR and BARDA.

In 2012 EBS got one of three fat DHHS contracts to house a so-called Center for Innovation in Advanced Development and Manufacturing (CIADM) that could be used to produce pandemic or biodefense products in the event of emergencies. With this grant EBS purchased and expanded what became its *Bayview* factory in Baltimore. The CIADM contract essentially guaranteed Emergent a big role in any future pandemic response.

Emergent then acquired the maker of *Narcan* nasal spray, the opioid overdose antidote. Soon FDA began recommending to prescribers that they write a *Narcan* script whenever they wrote a narcotic script, just in case. States started buying large quantities for free distribution. Sales rose 600% after EBS bought the company.

Under the Trump administration retired Air Force Colonel, physician and Beltway Bandit **Robert Kadlec** was appointed to the position of Assistant Secretary of DHHS for Preparedness and Emergency Response (aka ASPR). You may remember him for having coined the phrase "*Dark Winter*" during a pandemic tabletop exercise. Kadlec had also been a consultant and business partner of EBS' founder and chairman **Fuad el-Hibri.** Kadlec had omitted this information from the required disclosures for Senate confirmation. Once confirmed as Assistant Secretary, Kadlec was able to transfer responsibility for the National Strategic Stockpile (containing the US stockpiles of pandemic remedies and equipment) from the CDC into his own agency. Kadlec then gave multiple sweetheart deals to EBS, until the value of EBS' contracts with ASPR exceeded those of every other contractor.

ASPR Kadlec was blamed for cancelling a federal contract to make N95 masks while buying more and more anthrax and smallpox vaccines, pre-Covid.

Covid-19 presented a huge opportunity for Emergent BioSolutions. EBS received $628 million from DHHS to retool its CIADM factory. It inked additional contracts with Astra-Zeneca, Johnson and Johnson, Novavax and VaxArt companies to provide bulk manufacturing of their vaccines in its Baltimore (*Bayview*) CIADM facility. Altogether its pandemic contracts were worth about $1.5 Billion. It was slated to manufacture 9 separate medical products to address Covid-19, all of which would bear the primary name of the company that designed them, not EBS.

But there were serious potential problems.

While it had a storied Board of former federal officials, Emergent BioSolutions had never brought a single product to market. Its expertise was in contracting and acquisitions, not production. It had a history of production failures, and had demanded that the federal government bail the company out, or else the sole source products the company provided would become unavailable. Some of this was detailed in the Congressional report Unproven Force Protection. Entering the pandemic, EBS was still making the same mistakes it had been guilty of twenty years earlier:

- EBS sold and continues to sell nerve gas auto-injectors to federal agencies which have been defective and are not licensed. According to the law, these products can neither be produced in the US nor sold here. Instead, Emergent manufactures them in Germany and restricts its sales to US embassies overseas.
- In July 2020, the Soligenix company requested arbitration against Emergent BioSolutions, claiming a loss of $19 million, because EBS had manufactured its experimental ricin vaccine, used in a human trial, which failed to meet specifications.

EBS did not have an active workforce in Baltimore. On September 30, EBS held an online job fair which it titled "Warp Speed Careers Event." The event sought to recruit 300 employees. Yet EBS had begun inking vaccine contracts 5 months earlier, and could have hired and trained a workforce that was ready to go when FDA gave it the go-ahead. Instead, doing things on the cheap, EBS hired late, failed to provide adequate training to its employees, and experienced a spectacular series of production failures. Many millions of doses of its Johnson and Johnson and its Astra-Zeneca Covid vaccines had to be dumped. J and J missed its 20 million dose quota for the end of March, and FDA, despite repeated inspections, would not give the plant an authorization so its products could be used.

Despite this, somehow millions of doses were shipped to Canada and Mexico, unauthorized. How did that occur? We don't know. Did any get distributed in the US? We can't be sure none did.

As of last week, EBS was facing another lawsuit from its shareholders, and its stock price had fallen to half its value from the peak earlier this year. However, Emergent's CEO Robert Kramer exercised his stock options in January and February, near the stock's peak, earning himself over $7 million dollars profit.

In summary, EBS, despite considerable manufacturing shortcomings, has been extremely successful at obtaining government contracts and earning huge profits. But its products have repeatedly been unreliable. The company has managed to turn failures into success, especially when its products, like civilian stockpiles of anthrax and smallpox vaccine, and nerve gas auto-injectors, are stockpiled but not used.

The public has only gradually been learning that the vaccines it thought were being produced by huge Pharma companies Astra-Zeneca and Johnson and Johnson were in fact being manufactured by the anthrax vaccine company, Emergent BioSolutions. How did it come to pass that the federal government, and these established pharmaceutical companies, bet the farm on EBS' production of Covid-19 vaccines?

The House Committee on Oversight and Reform and the Select Subcommittee on the

Coronavirus Crisis will be looking into this question on May 19, when they hold a joint hearing on the subject.

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Articles by: **Dr. Meryl Nass**