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Getting Rich on Uncle Sucker

Should the Federal Government Strengthen Efforts to Fight Profiteering?

Scott Lilly October 2010

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CAP's Doing What Works project promotes government reform to efficiently allocate scarce resources and achieve greater results for the American people. This project specifically has three key objectives:

- Eliminating or redesigning misguided spending programs and tax expenditures, focused on priority areas such as health care, energy, and education
- Boosting government productivity by streamlining management and strengthening operations in the areas of human resources, information technology, and procurement
- Building a foundation for smarter decision-making by enhancing transparency and performance measurement and evaluation

This paper is one in a series of reports examining government accountability and efficiency.

Introduction and summary

A few months ago I came across an annual report filed with the Securities and Exchange Commission by a small pharmaceutical company in Maryland. Making sense of such reports is often a challenge but this one was remarkably simple. The company had one product and one customer. It sold a particular type of vaccine to the federal government. But what caught my eye as an old Appropriations Committee staffer was a table in the middle of the report that listed previous year revenues from product sales at $217 million, and the cost of product sales at $46 million.[1]

Even if you allow a generous amount for administration and overhead above the $46 million "cost of product sales," the $217 million in revenue from those sales would indicate a markup in the neighborhood of 300 percent. By comparison, a 2009 study of 6,000 Army and Air Force contracts by the Institute for Defense Analysis found that margins on such contracts typically ranged between 9 percent and 10 percent of production costs.[2]

Based on my years of work in congressional oversight, a markup of even half the size suggested by this annual report seemed mind boggling. But the company, Emergent BioSolutions Inc., had somehow managed to win such a contract. Was this a one time sweet deal? The answer was right there on the same page of the company's Form 10-K. The company had been billing the government with those same giant profit margins for at least four years.

TABLE 1

One sweet deal

Emergent BioSystems 10- K report to the SEC, March 5, 2010 *(in thousands)**

	2009	2008	2007	2006	2005	Total
Revenue from product sales	$217,172	$160,124	$169,799	$147,995	$127,271	$822,361
Cost of product sales	$46,262	$34,081	$40,309	$24,125	$31,603	$176,380
Profit from product sales[3]	$170,910	$126,043	$129,490	$123,870	$95,668	$645,981

* Emergent 2009 10-K filing, part 2, item 6

Further research indicates that over the past decade the government forked over more than $1.3 billion for doses of the vaccine, which had cost the company only about a quarter billion dollars to manufacture—leaving more than a billion dollar difference between revenues and the cost of product sales.[4]

Emergent was contacted and asked to respond to the charge that BioThrax was being sold at exceedingly high profit margins. The company argued that they assumed substantial risk for developing, manufacturing, and securing licensure for the vaccine and that the price paid was fair market value and was "based on independent negotiations with two agencies of the U.S. Government," both of which "determined the price to be fair and justified."[5]

This report attempts to examine the actual level of risk the company assumed and whether the price the government paid and continues to pay for the vaccine is commensurate with that risk. More importantly, it examines the lessons that should be learned from the government's procurement of this vaccine and the opportunity those lessons may provide in reducing spending in the more than half a trillion dollar portion of the annual federal government that now goes to contract procurement.

The mystery of the high margin

After realizing the level of profits the company appeared to be making from government sales, I was certain there had to be more to the story. Perhaps the company was recouping from a vast investment involving years of costly, high-risk research necessary to develop and license the vaccine. But that theory failed to pan out when further exploration showed that the vaccine had not been developed by the company at all. The U.S. Army scientists at Fort Detrick, Maryland developed it in the 1960s,[6] and the Michigan Public Health Service obtained a license to produce the vaccine in 1970.[7] In short, U.S. taxpayers were not only paying the producer extraordinary profit margins but they had also footed the bill for creating the product they were buying.

But perhaps this small company had to spend a ton to construct and equip the facilities needed for production? That also proved false. The Michigan Public Health Service owned the original license to manufacture the vaccine, which is now known as BioThrax, a medical countermeasure intended to protect against exposure to anthrax. Michigan manufactured the vaccine for more than 20 years largely to help protect mill workers in the textile industry who processed animal hair contaminated with naturally occurring anthrax. By the late 1980s, the U.S. Department of Defense had developed a keen interest in the vaccine and offered the Michigan Public Health Service a contract to significantly increase production.[8]

But when John Engler—currently the president of the National Association of Manufacturers—became governor of Michigan, the budget for the state public health service became increasingly constrained, and the ability of the state to maintain the manufacturing facility in the condition required to keep an FDA license became increasingly difficult. Engler, who believed such activities belonged in the private sector anyway, ordered the facility sold.[9]

Amazingly, the two individuals whom he put in charge of the sale ended up becoming partners in BioPort, the enterprise that placed the winning bid and the company that later became Emergent BioSolutions.[10] Emergent points out

that "the Michigan State Legislature passed freestanding legislation specifically authorizing these individuals to participate in the acquisition, including providing the institutional expertise necessary to provide continuity of operations."[11] While that is true, the fact that those in charge of the auction and selection of the best bid were themselves also bidders almost certainly did not encourage more bids.

A real bargain

BioPort became a publically traded company in 2006 and changed its name to Emergent BioSolutions. The group was headed by Fuad El-Hibri, a businessman of Lebanese ancestry who at the time of the purchase was a citizen of Germany. In 1998, the El-Hibri group made a very complex offer in a sealed bid auction to buy the facility, which included:

- Twenty-eight buildings containing a quarter of a million square feet of floor space[12]
- Fifty-nine acres of land[13]
- The Food and Drug Administration license to manufacture BioThrax
- Three government contracts with a value of $47 million for remodeling existing facilities, testing the vaccine and maintenance, accountability, and storage of government property[14]
- A contract with the U.S. Department of Defense to purchase millions of doses of vaccine
- Accounts receivable worth $4.5 million

The El-Hibri group paid only $2.25 million at the closing for all of this. The state would remain a lien holder on the property until loans totaling about $11 million were repaid from collection of accounts receivable and earnings from the vaccine contracts. In addition the group would pay the state interest on some but not all of the loans and would pay some amount in future royalties and rent. Altogether the state could expect payments over time (including interest on the money it had lent) to total a little less than $25 million.[15] In other words, the "investors" appear to have had very little at risk and the taxpayers of Michigan and the United States had a great deal.

Emergent disputes this, saying that the company assumed substantial risk and paid $25 million for the facility.[16] Whether the company's real risk was $2.25 million as I contend or $25 million as Emergent contends, the risk was relatively miniscule given the revenues and profit margins that flowed from the investment.

The group not only invested little in buying the facility but also failed to capitalize the new endeavor with sufficient private funds necessary to make the needed upgrades required for approval by FDA, a claim Emergent denies. This is despite the fact that some reports indicate that El-Hibri and his father, a Venezuelan citizen named Ibrahim El-Hibri, operated numerous businesses and had adequate resources to invest much more.[17]

Within months after the purchase of the Michigan facility, El-Hibri informed the Department of Defense that BioPort, like the state of Michigan, did not have the funds needed to bring the facility into compliance with FDA requirements. As a result DoD was forced to renegotiate the contract—not only substantially increasing the amount paid per unit of vaccine, but also agreeing to make payments to BioPort prior to the shipment of the vaccine so that the company would have the cash flow necessary for facility upgrades and debt repayment to the state of Michigan.[18]

TABLE 2

Something for nothing

Taxpayer dollars obligated to Emergent BioSolutions

Fiscal year	Number of awards	Total funding	Available for competition, everyone	Available competition limited pool	Amount cost competed
2000	15	$51, 550,513	$5,199, 284	0	$46, 351, 229
2001	5	$33,728, 721	$33,500,000	0	$228,721
2002	19	$84,067,630	$34,895,902	0	$49,171,728
2003	17	$52,501,224	$9,130,696	0	$43,370,528
2004	8	$44,021,123	$9,725,853	0	$34,295,270
2005	5	$162,398,040	0	0	$162,398,040
2006	9	$174,506,375	0	0	$174,506,375
2007	7	$448,352,001	0	0	$448,352,001
2008	4	$152,493,211	0	$8,019	$152,485,192
2009	9	$192,506,367	0	0	$192,506,367
Totals		$1,396,889,887	$87,252,451.00	$8,019.00	$1,343,358,138

Source: USAspending.gov

An investigation by the Defense Department inspector general in 2000 stated that the department "amended the September 1998 contract with BioPort and provided a net $24.1 million in relief, including an $18.7 million interest free advance payment. The number of doses in the contract options was reduced from 7.9 million to 4.6 million." As a result, the price was increased from less than $3.00 a dose to $10.64.[19]

Emergent argues that it was forced to make a substantial effort over a period of three years to win licensure of the facilities, and that "This was done at risk by Emergent in cooperation with the federal government? The company says that "in total, Emergent placed in excess of $25 million at risk."[20] The Defense IG would appear to document that nearly all of what Emergent put at risk came from the U.S. taxpayer.[21]

Emergent also argues that the company "provided doses to the DoD at substantially below market price."[22] This is a rather peculiar argument because it is difficult to say what a "market" price is with a product that has only one supplier and one customer. If one were to argue that such a sale constituted a market, it would then follow that the market price was whatever price the buyer and seller agreed to. Cost of production data from the Emergent's 10-K indicates that the company is now manufacturing the vaccine at a cost of about $6.00 a dose. The price it initially sold the product to the government for of $10.64 would appear to have left room for a handsome profit.[23]

It is understandable why the U.S. Army—facing the possibility that they might someday need to deploy troops to a battle zone in which they would be subject to an anthrax attack—would provide payment upfront and accept a steep increase in price in order to insure that the production capacity was available. It is less clear why they would not use the opportunity presented by the renegotiation to insist on a lower price and a more reasonable profit margin once they had given the funds necessary for the upgrades and the license had been granted.

But there appears to be no explanation on the public record for why the government continued to allow the price to increase on the vaccine after October of 2001 when the upgrades were complete and the new license had been granted. According to the SEC report cited earlier, the company is currently working under a multiyear contract with the U.S. government to provide 14.5 million doses of BioThrax at a price of $400 million, or $27.59 per dose, which they pay less than $6.00 to produce. Federal costs for the vaccine are now 12 times what they were when the production facility belonged to the state of Michigan.[24]

Emergent argues that "Many factors enter into the pricing of biodefense countermeasures including costs to maintain an FDA-compliant manufacturing facility, standard inflation adjustments, and the governments desire to maintain mission-critical facilities as part of the overall defense industrial base" and that "dozens of audits and financial reviews have been conducted by various government agencies and each has concluded that the pricing structure is both fair and reasonable."[25]

Putting taxpayer dollars to work

But there is another shoe in this sad story.

For a number of reasons, BioThrax is an old and inadequate vaccine. First, it can cause serious side effects in some individuals. According to Drugs.com, a website that offers "free, accurate and independent advice on more than 24,000 prescription drugs, over-the-counter medicines & natural products," the side effects of BioThrax include severe local reactions including edema or induration, arm motion limitation; gastrointestinal side effects such as nausea and vomiting; musculoskeletal side effects; transient headache, fever, fatigue, malaise, chills and hypersensitivity including lesions and hives.[26]

A 2002 report by the Institute of Medicine of the National Academy of Science outlined other shortcomings in the drug. These include the fact that individuals must undergo a series of six shots (this has now be reduced to five); it requires 18 months to establish full immunity in a individual, meaning that only those inoculated well in advance of an event would be protected; a yearly booster shot is required for each individual wishing to maintain immunity and finally, the estimated shelf life of BioThrax is only three years so that vaccines bought for storage must be replaced regularly even if they are never used. Consequently, the institute concluded that the current vaccine was "far from optimal" and that "a new vaccine, developed according to more modern principles of vaccinology, is urgently needed."[27]

Emergent contends that it is inaccurate to refer to BioThrax as "old and inadequate" and to suggest an unsatisfactory safety profile. They argue that the Food and Drug Administration has reaffirmed that BioThrax is a safe and effective vaccine with a safety profile consistent with that of other commercially available vaccines. Nonetheless, Emergent lists the following possible side effects on their website:

The most common (occurring in more than 10 percent of individuals inoculated) local (injection-site) adverse reactions observed in clinical studies were:

- Tenderness
- Pain
- Erythema
- Arm motion limitation

The most common (occurring in more than 5 percent of individuals inoculated) systemic adverse reactions observed in clinical studies were:

- Muscle aches
- Fatigue
- Headache
- Serious allergic reactions, including anaphylactic shock, have been observed during post-marketing surveillance in individuals receiving BioThrax.[28]

An article recently published in the *Proceedings of the National Academy of Sciences* by a group of leading scientists representing the Food and Drug Administration, the Veterans Affairs Medical Center, the National Cancer Institute, and other organizations had this to say about BioThrax:

In addition to concerns regarding adverse effects associated with this vaccine, its undefined composition, lot-to-lot variation, and the requirement for multiple doses over a protracted period to achieve adequate levels of protective immunity make this vaccine less than optimal for use in response to a bioterrorism incident. Furthermore, the limited shelf life of ≈4 y of Biothrax/AVA results in the need for periodic replenishment of vaccine in the strategic national stockpile. Therefore, a compelling need exists for a better vaccine against B. anthracis that can confer rapid immunity with an abbreviated immunization schedule that can be stored long term and deployed quickly in the event of a bioterror event.[29]

Beating the competition

While a new vaccine would certainly be good news for the country, it would be not be good news from the perspective of an investor who was sharing in the large profits BioThrax generates.[30] That probably explains why Emergent BioSolutions appears to have made every effort to defend its lucrative franchise using a significant portion of its profits to defend against potential competitors.

Based on the most recent disclosures to the U.S. Senate by the company and its lobbyists, Emergent—with less than a quarter of a billion dollars in annual revenues—retains three in-house and 24 contract lobbyists.[31] Federal Election Commission reports indicate that the company also operates a surprisingly large political action committee for a small company, and that its officers and contract lobbyists make generous contributions to political candidates and committees well beyond amounts made by the Emergent PAC.[32]

To put Emergent's lobbying in perspective one might compare it with Merck, one of the most heavily represented companies in Washington, which has close to 40 registered lobbyists. But Merck has nearly a hundred separate products on the market and annual revenues estimated for the current year at more than $40 billion, or roughly 160 times the revenues of Emergent. To have the same ratio of lobbyists to revenues as Emergent, Merck would have to hire more than 4,000 additional lobbyists.[33]

One example of how Emergent has used this political arsenal was explored by a 2007 investigation by the *Los Angeles Times* published under the headline, "New Anthrax Vaccine Sunk by Lobbying." The newspaper concluded, "The episode illustrates the clout wielded by well-connected lobbyists over billions in spending for the Bush administration's anti-terrorism program."[34]

At issue in the *LA Times* report was a contract signed by Health and Human Services Secretary Tommy Thompson in November 2004 to try to create a competitor to BioThrax. The contract was with a California-based biotechnology company called VaxGen that had the rights to develop a genetically engineered vaccine for anthrax, which tests indicated would be more uniform, expose recipients to fewer side effects, and require fewer inoculations.[35]

As is nearly always the case, however, the development of the new vaccine was not without bumps in the road. Each time VaxGen's test results were less than had been hoped for, Emergent pounded VaxGen with a highly orchestrated campaign to overstate the problems and discourage government support of the effort.[36]

Allen Shofe, Emergent's chief lobbyist and previously a lobbyist for the tobacco industry, described the company's efforts to the *Times*, "We had 500 employees who were about to lose their jobs, and we went out and became advocates for them."[37] Obviously Shofe was advocating for a lot more than the employees whose salaries (based on the company's 10K reporting) amounted to less than one-fifth the money that the company was receiving in federal payments.[38]

The high-powered team working under Shofe included two former aides to Vice President Dick Cheney and the former acting assistant secretary of HHS for emergency preparedness who had been involved in the decision to award the VaxGen contract in the first place.[39] After two years of sniping, tough questioning of the contract by Emergent-friendly members of Congress, and numerous meetings with high-ranking administration officials the Bush administration reversed itself and canceled the contract.[40]

Dr. Noreen A. Hynes, who was at that time in charge of the office at HHS responsible for vaccine development, pointed out to the *Times* that the law allowed advance payments to companies attempting to develop needed new vaccines to help solve the kind of problems VaxGen was facing. She told the *Times* that she asked for permission to use that authority but it was denied. "I was told that the administration had decided there would be none," Hynes said she did not know who made the decision but that it flowed from "the highest level."[41]

Shortly after the government's cancellation of the VaxGen contract, the company imploded. A little more than a year later, Emergent paid $2 million (less than 2 percent of the amount VaxGen and the federal government had spent in development costs) for the rights to the VaxGen vaccine—the same vaccine that Emergent had vociferously argued for three years offered little prospect of providing an effective countermeasure to anthrax.[42]

In disputing the *Los Angeles Times* accounting of the fall of VaxGen, Emergent says that it did not play "any role in the government's determination that VaxGen failed to meet its contractual obligations." Further, they argue that they purchased the VaxGen vaccine through fair market negotiations and have spent millions of dollars to successfully develop the vaccine.[43]

A similar story seems to be unfolding with HHS's second attempt to develop a BioThrax alternative. PharmAthene, an Annapolis, Maryland-based company, has purchased the rights to produce a next-generation anthrax vaccine known as SparVax. In February of this year, HHS awarded PharmAthene a $78 million contract to further test and develop SparVax.

Emergent lobbyist Shofe tersely offered *Wall Street Journal* reporter Alicia Mundy his view of the department's latest effort at finding an alternative vaccine and supplier. PharmAthene, according to Shofe, is "a virtual company run by a bunch of political hacks" operating "out of a warehouse." Mundy noted that regard-

less of whether Emergent succeeds in efforts to derail the HHS initiative with PharmAthene, Emergent, "will maintain its monopoly until a new vaccine is ready—which could be years."[44]

PharmAthene told CAP:

> *The accusations by EBS are irresponsible, offensive and simply untrue. PharmAthene has over 130 dedicated, highly professional employees in three countries. This scientific and industrial team has been involved in the development and commercialization of 15 marketed biopharmaceutical products. The PharmAthene team is developing medical countermeasures in partnership with UK, Canada, and the US. PharmAthene has raised from the private sector over $150,000,0000 to co-invest with the USG in the develop of urgently needed, new and improved products for our national security and public health."*[45]

Emergent contends that it does not direct company profits at "preventing newer technologies from becoming available" and that the company "consistently reinvests in appropriate vaccine and therapeutic technology to address government stated national security risks."[46]

Possible arguments for why these margins should be acceptable

One argument in support of Emergent's huge profit margins might be that pharmaceutical industry as a whole has high margins. Generally, that is true. Drug development is an expensive business. Investors must put forth sufficient capital to pay for selecting the most promising compounds, demonstrating that they can produce them in a consistent and uniform manner, testing them to determine if the are effective in preventing or treating a specific disease, and testing them to determine that they do not pose undue risk to the populations to which they might be administered.

The financing of drug development is sometimes referred to as the "valley of death" because of the considerable amount of capital needed to win licensure and because of the many seemingly promising drugs that fail to win final approval. To take such risks, investors must be well compensated for success.[47]

But in the case of the BioThrax vaccine the venture capitalist was the taxpayer. It was the taxpayer who developed the vaccine, paid for its testing and licensure, set up the manufacturing facilities, and refurbished and reequipped those facilities once they were taken over by a private for-profit enterprise. The taxpayer, however, was not only not rewarded for that risk but was bilked a second time by having to pay excessive prices for the product from a company that had taken almost no risk. The taxpayer was bilked a third time when the profits from this excess pricing were used to discourage the development of better and safer drugs.[48]

Emergent contends that it and its predecessor BioPort have "consistently assumed substantial risk for the development and manufacturing of BioThrax and did bear substantial risk associated with securing licensure of BioThrax at the facilities located in Michigan."[49] But it is difficult to identify significant risk that BioPort investors faced beyond the initial $2.25 million payment to the state of Michigan. Had the company failed to secure relicensure by the FDA or failed to maintain the federal contract, it could have walked away and left the underfunded corporate entity in bankruptcy.

It also might be argued that Emergent's unseemly profit margins are not really that high because a portion of those profits are being reinvested in research on new products and another portion goes to covering "selling, general, and administrative expenses" leaving reported income from operations at $40 million, or a little less than 20 percent of revenues. In their most recent annual report, Emergent states that it is conducting research on vaccines for Tuberculosis, Typhoid, Influenza, and Chlamydia, but warns "we have derived substantially all of our product revenues from sales of BioThrax to the

U.S. Department of Defense, or DoD, and the U.S. Department of Health and Human Services, or HHS, and expect for the foreseeable future to continue to derive substantially all of our product revenues from the sale of BioThrax to U.S. government customers."[50]

This raises two questions. First, why should the U.S. government pay a highly profitable company to conduct this kind of research? Secondly, if they were to make such a payment shouldn't they select a company that has successfully developed a drug and brought it to market? Emergent has not.

We do not know in any detail what the money that Emergent spends on "selling, general, and administrative" expenses each year is going for beyond the large sums spent on lobbying, with additional large amounts probably being spent on legal support, public relations, and other such consulting fees. But according to a 2007 story by the *American Journal of Public Health* there have long been issues regarding the company's administrative expenditures. In the summer of 1999—when the company had still not obtained FDA approval for BioThrax production and had once again notified the Defense Department that it was running out of cash—the Defense Department Inspector General examined the books and, according to the *American Journal of Public Health,* found that $1 million in government funds urgently needed for upgrading production facilities had gone instead to renovate and refurnish offices including $23,000 in furniture for the CEO's office and another $1.28 million was spent on senior management.[51]

The Defense Department inspector general makes nearly all unclassified IG reports available online.[52] For some reason, the March 22, 2000 report entitled "Contracting for Anthrax Vaccine" is not available. When we purchased the report from a private vendor providing government documents we found that it was a "special version of the report," which had been revised to omit contractor proprietary data." On page 14 the report states (with * indicating where information was omitted):

*BioPort spent * on items that in light of their financial condition may not have been appropriate. BioPort spent about * that could have been postponed until BioPort was more financially stable. These expenditures also included approximately*. In addition BioPort spent about *.*[53]

Emergent insists that it has "consistently complied with the requirements of all contracts it has executed with the federal government, applying payments to their designated purposes" and that "Government officials and auditors (including the DCMA) have repeatedly recognized this fact. No bonuses were paid to senior management and all renovations were necessary and appropriate and importantly approved by the government as a permissible use of funds."[54]

Recently there have been reports of other activities by Emergent that are likely to be included with in this category, including expanded efforts to sell BioThrax to various countries in the Middle East. And only weeks ago there was a report of a joint venture between Emergent and the government of Malaysia to build the first Biosafety Level 4 Laboratory in that country.[55]

While there are certainly some corporate administrative costs that should be counted in the pricing of this vaccine, they should be relatively modest given the nature of the contract. After all, the government is the sole customer and the long term relationship that has evolved in the production and procurement of the vaccine.

The broader question

Developing a new vaccine against anthrax is important, but in my judgment, the importance of this story transcends that important priority. Anthrax is only one of more than a dozen possible agents that could be used by terrorists or foreign militaries.

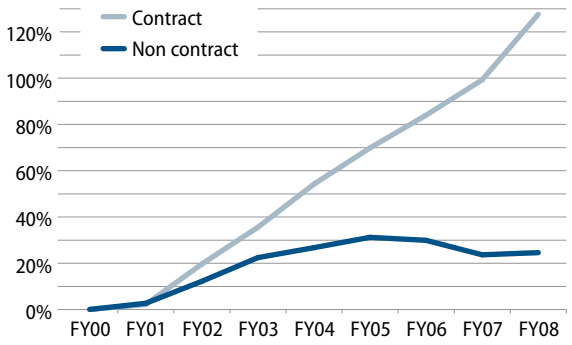
Developing countermeasures to biological weapons is only a tiny fraction of the things that the federal government tries to accomplish every day through contracts with private sector providers.

Between 2000 and 2008 federal contracting grew by 150 percent, from a little more than $200 billion in annual spending to more than $500 billion. By 2008 we were spending more than two and a half times as much on federal contracts as we were spending on the total compensation of the entire civilian workforce of the executive branch of the federal government. Nearly 70 percent of the growth in contracting during that eight-year period was in contracts like the one for BioThrax—contracts that were not competitively bid.[56]

How does the government protect itself from price gouging when contracts are not competitive? One way is to threaten to turn to an alternate provider if a more reasonable price can't be negotiated. But that is not an option in the case with Emergent because the government helped to create a private, for-profit sole provider without any apparent guarantees on future pricing of the product that the government clearly needed in large quantities over a period of many years.

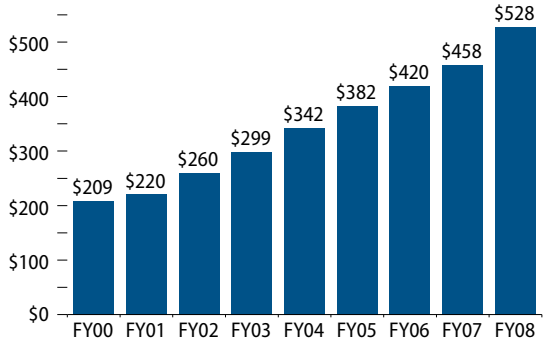
Real Discretionary Spending Growth

Contract vs. Non Contract Spending FY 2000–FY 2008



Growth in Government Contracting

FY2000–FY2008, in billions



A second method of controlling price would be to subject a company to public criticism for profiteering—the principle tool used by the Truman Committee to tamp down profiteering in the years leading up to World War II—an option that those responsible for protecting taxpayer interests in this matter have seemed remarkably reluctant to pursue.[57] The fact that profit margins of the magnitude negotiated by Emergent were not only agreed to but were not a point of major controversy within the agencies that agreed to them raises broader questions about the integrity of the procurement system and places a question mark on the issue of how many other ultrahigh-margin contracts are currently being funded throughout the government.

While the percentage of such contracts may be relatively small as a share of all contracts signed by the government in a year, the number could still run into the thousands and the loss to the taxpayers from the payment of excess profits under these contracts could easily amount to billions.

Richard C. Loeb, who teaches procurement law at the University of Baltimore Law School and who served as a senior procurement official in both the Clinton and Bush administrations, says that he has seen government contracts with even higher gross margins than the ones negotiated with BioPort/Emergent. He adds that no one really knows how many such contracts exist because of the changes in reporting requirements made in federal acquisition law over the past 15 years.[58]

The Truth in Negotiations Act, or TINA, which was signed into law in 1962, required that companies seeking a negotiated government contract (as opposed to one that was won through sealed bidding) would not only have to submit "cost and pricing" data but would also have to certify that the data was current, accurate, and complete on the date that the contract was signed. If the data were later determined to not be complete or accurate, the contract price would be reduced accordingly.[59]

TINA did not require cost and pricing data for so-called commercial items, which were defined as items sold to the general public in substantial quantities. But in 1994 and again in 1996 TINA was amended and the term "commercial item" was significantly broadened and the number of products and services for which the government required cost and pricing data required was greatly reduced. As a result, Loeb believes that no one (including the contracting officers) really knows how many high-margin contracts the government is on the hook for.[60]

Emergent is relatively unique among government contractors because it is a public corporation with a remarkably simple business model—one product, one customer. As a result, it's possible to gain much more insight into the profitability of Emergent's government sales than it is with the vast majority of contractors

The issue of excessive profits being collected from the government for goods and services needed to protect the nation's security has been with us since the early days of the American Revolution. But it is hard to imagine that any attempt to reduce federal outlays and shrink the size of the budget deficit will be credible if it does not address the issue of high-margin contracts. One step in addressing that problem might be to require the company seeking the contract and the government contract officer managing the procurement to each certify that the contract does not provide margins above a certain limit—say 30 percent. If either party is unable to make that certification then full cost and price data disclosure will be required regardless of whether the item purchased is a "commercial" item or not. Further agencies would be required to notify Congress, the Office of Management and Budget, and the Government Accountability Office of all contracts on which such a certification could not be obtained. .

Each of those entities could use information to track high-margin contracts and challenge agencies that sign them. Explanations for such margins could be demanded and options for government to obtain the needed products or services at more reasonable prices could be explored. The urgency for making such purchases could also be reexamined.

The corrosive effects of high margins

Excessive profits in government purchasing are not simply wasteful; they are also corrosive. BioThrax is not the only example of a government contract that became so lucrative that it generated large political contributions and heavy duty lobbying.

One case in point: A former Defense Department official named Mitchell Wade created a company in the 1990s named MZM Inc. That company went from having no revenues in 2002 to *The Washington Post*'s list of the top 100 government contractors in only three years. Contrary to most published reports, Wade's company was not the beneficiary of congressional earmarks. Wade was receiving

hugely profitable contracts from the Defense Department's Counter Intelligence Field Activity and the Army's National Ground Intelligence Center, two agencies that were created by Defense Secretary Donald Rumsfeld in the early years of the first George W. Bush administration.[61]

Wade became famous for offering the biggest known bribes in history, providing former Rep. Randy "Duke" Cunningham of California more than $1 million in gifts and other gratuities, according to Justice Department documents. In return, Cunningham increased the budgets of the agencies where Wade had inside connections and could renew and expand his lucrative contracts.[62]

The years immediately after 9/11 were boom years for many contractors cashing in on public concern over future terror attacks and the apparent willingness of government to ignore procurement safeguards and circumvent requirements for competitive bids and accept higher margins. The Iraq War and Hurricane Katrina extended that boom. But there has been no systematic effort to examine how big of a mess was created and what steps are necessary to get government procurement back on an even keel. It is time that process begins and a review of high margin contracts would be an excellent place to start.

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16 Emergent BioSolutions. Response to the Center for American Progress, October 1, 2010.

17 A 2002 article in *Mother Jones* reported that Fuad El-Hibri "operated a dizzying array of companies, including a Panama-based franchise operation called BurgerLand International." The El-Hibri's had also been heavy investors in the purchase and privatization of a British based anthrax vaccine producer which they named Porton International Ltd. National security reporter Laura Rozen accurately predicted in 2001 that "BioPort could be poised to make a fortune—as its CEO Fuad El-Hibri did working with the British seller of anthrax vaccine, Porton International, during the Gulf War a decade ago." Rozen interviewed Fuad El-Hibri's secretary at his Rockville, Maryland venture capital firm, East West Resource Management. She stated that BioPort was only one of 15 companies that El-Hibri was in charge of including cell phone companies in El Salvador, Venezuela, and Jamaica.

In 1999, Fuad El-Hibri testified before House Government Reform Committee stating, "Three companies currently hold voting equity in BioPort: Intervac LLC and Intervac Management LLC, which are both Maryland limited liability companies, and Michigan Biologic Products, Inc., a Michigan corporation. Intervac LLC is the controlling shareholder. Intervac LLC is owned by Admiral William J. Crowe, Jr., my wife Nancy and me, and I&F Holdings N.V., a Netherlands Antilles investment company owned by my father Ibrahim El-Hibri. As mentioned earlier, I&F Holdings is an investment company in biotech operations, which previously had invested in the management buy-out of Porton Products Ltd. Admiral Crowe and I are the controlling members of Intervac LLC." Based on a variety of reports it appears that about 30 percent of the equity in BioPort was allocated to the Michigan State Employees. Another 13 percent belonged to Admiral Crow who openly stated that he had not "paid a penny" for his shares. Apparently nearly all of the remaining 57 percent of the equity in BioPort belonged to the El-Hibris. Interestingly, when Emergent BioSolutions filed disclosure forms associated with making a public stock offering it indicated that Fuad El-Hibri would own close to 90 percent of the stock even after the offering, valued at $60 million. [Bill Hogan, "A Biodefense Boondoggle," *Mother Jones*, January/February 2002, available at http://motherjones.com/politics/2002/01/biodefense-boondoggle and Laura Rozen, "The Anthrax Vaccine Scandal."

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Scott Lilly is a Senior Fellow at the Center for American Progress. He also is a part-time consultant to the University of Pittsburg Medical Center, a nonprofit corporation that is the largest health care provider in Western Pennsylvania. UPMC is not presently engaged in the development or manufacture of an anthrax vaccine but may become a candidate for a grant from the U.S. Department of Health and Human Services that would involve development of a variety of vaccines and medical counter measures for potential biological weapons including anthrax. UPMC did not contribute to the preparation of this report and bears no responsibility for its content.

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