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Before pandemic, Trump's stockpile chief put focus on biodefense. An old client benefited.

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After Robert Kadlec was confirmed as President Trump's top official for public health preparedness in 2017, he began pressing to increase government stocks of a smallpox vaccine. His office ultimately made a deal to buy up to \$2.8 billion of the vaccine from a company that once paid Kadlec as a consultant, a connection he did not disclose on a Senate questionnaire when he was nominated.

Under the agreement struck last year with Emergent BioSolutions, Kadlec's office at the Department of Health and Human Services is paying more than double the price per dose it had previously paid for the drug. Because Emergent is the only licensed maker of the vaccine, Kadlec's office arrived at the price through negotiations with the company rather than through bidding.

The 10-year contract is part of an effort by Kadlec to bolster the nation's stockpile of defenses against biological and chemical weapons, a focus he made a priority over preparing for a natural pandemic, an examination by The Washington Post found. Kadlec, a decorated veteran and biodefense expert, has argued for more than two decades in government and the private sector that the nation should devote more of its resources to preparing for bioweapon attacks.

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“Quite frankly, Mother Nature is not a thinking enemy intent on inflicting grievous harm to our country, killing our citizens, undermining our government or destroying our way of life,” he told Congress in 2011. “Mother Nature doesn’t develop highly virulent organisms that are resistant to our current stockpiles of antibiotics.”

In the two years before the coronavirus pandemic, Kadlec aggressively pursued efforts to fulfill his vision for national preparedness, the Post examination found. He assumed greater control over acquisitions for the Strategic National Stockpile, which in 2018 was moved from the Centers for Disease Control and Prevention and placed under his authority, the examination found.

Kadlec scaled back a long-standing interagency process for spending billions of dollars on stockpile purchases, diminishing the role of government experts and restricting decision-making to himself and a small circle of advisers, according to three former officials who spoke on the condition of anonymity to discuss sensitive matters.

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Kadlec committed additional spending to biodefense countermeasures such as smallpox and anthrax vaccines while cutting planned spending on emerging infectious diseases, despite warnings from scientists that a natural contagion could also be devastating. Citing limited resources, his office halted an Obama-era initiative to spend \$35 million to build a machine that could produce 1.5 million N95 masks per day, as The Post previously reported.

This article is based on interviews with more than two dozen current and former government officials, public health experts and contractors, together with a review of hundreds of federal contracting records, correspondence and other documents.

In an interview with The Post, Kadlec acknowledged his role in shifting the focus of preparedness more toward bioterrorist threats. He said that he arrived at HHS determined to shield the public from attacks by America's adversaries and that national intelligence suggested serious and growing threats.

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“Even though the war on terror was still going on, the resurgence of state actors like North Korea, like Iran, like China and Russia, were raising the bar in terms of the risks of WMD offenses against our interests and potentially our homeland,” Kadlec said, referring to weapons of mass destruction.

Kadlec said he overhauled the interagency process for managing the stockpile because it was overly bureaucratic and slow, a view shared by many in private industry. He said he is proud of those changes — and of his government work in general. “I served this country. I’ve served this country faithfully throughout,” he said. “It’s not like some kind of bumper sticker to me.”

Kadlec and an HHS spokeswoman declined to comment on whether his work for Emergent — at least as recently as four years before his nomination — created a conflict of interest or whether he should have disclosed it to the Senate. Kadlec said the deal with Emergent was negotiated by contracting officers.

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“My standing guidance for this contract, and all contracts, is to get the best value and most protection for the American people,” he said in a statement.

The renewal of the vaccine contract was initially sought with more-modest terms while the stockpile was still under the auspices of the CDC.

By the time Kadlec's office finalized the deal, records and interviews show, it had been extended from five years to 10 and the number of doses per year had doubled, to 18 million. An Emergent executive said the price per dose is \$9.44 in the first year, more than twice what the government paid its previous supplier.

Carol Danko, the HHS spokeswoman, said extending the agreement to a decade brought the price per dose down from what it would have been if the contract were for the shorter period proposed in the CDC solicitation.

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Kadlec said the large purchase was necessary to "keep the production base warm," essentially to preserve the nation's capacity to manufacture the vaccine.

As the nominee to lead the Office of the Assistant Secretary for Preparedness and Response, or ASPR, Kadlec also did not mention in filings to the Senate that he had

once been part-owner of a small biodefense company with Fuad El-Hibri, Emergent's founder and chairman.

Kadlec "may not have realized" that his involvement in the start-up "could be characterized as one of 'employment,'" Danko said.

Emergent declined to make El-Hibri available for an interview. The company has been a supplier to the stockpile for more than a decade.

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Emergent spokeswoman Nina DeLorenzo said in a statement that Kadlec's work as a "strategic adviser" for the company and his ties to El-Hibri had no impact on the smallpox vaccine contract.

DeLorenzo praised Kadlec's management of the stockpile. "We have more clarity and certainty as to what the government needs and when," she said. "We also have seen the better coordination, communication, and streamlined decisionmaking that we had hoped for."

In March, Kadlec was designated by HHS Secretary Alex Azar to lead the department's response to the pandemic.

Facing intense criticism for the stockpile's inadequate supplies of protective gear and other medical equipment, Kadlec's office has recently announced new contracts worth billions of dollars for respirator masks, ventilators and other medical supplies. Among the contracts was one worth \$62.3 million for masks from O&M Halyard, the contractor whose design for a rapid mask machine was shelved in 2018.

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A career-long focus

Less than a year after 9/11, Congress voted to establish the Strategic National Stockpile. The move expanded an earlier federal warehouse of pharmaceuticals and vaccines to ensure that the country would be prepared "in the event of a bioterrorist attack or other public health emergency." Many government experts have since

6/4/2020 Strategic National Stockpile chief Robert Kadlec focused on biodefense -- and a former client, Emergent BioSolutions, benefited - The Wa...
attack or other public health emergency. Many government experts have since
warned that emerging infectious diseases should be regarded as the most likely
large-scale threat.

Last year, a simulation organized by Kadlec's office dubbed "Crimson Contagion" revealed how unprepared the government was for a pandemic. An internal report on the exercise found officials would face "cascading" funding and supply-chain shortages, including "scarce medical countermeasures such as personal protective equipment, diagnostics, and antivirals."

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A bipartisan panel of former lawmakers and officials had urged Kadlec a year earlier to create "a framework for combating emerging infectious diseases."

But Kadlec, a physician and retired Air Force colonel, had spent his career focused on the dangers of attacks by adversaries.

He wrote chapters on germ warfare and bioweapons for a U.S. Air War College textbook in the 1990s. He argued that the government should build reserves of

drugs to shield against anthrax and smallpox attacks, calling bioweapons “as lethal and potentially devastating as a nuclear device.”

“Stockpiles of necessary antibiotics, immunoglobulins, and vaccines would have to be procured, maintained, and be readily available to administer within hours,” he wrote.

In the mid-1990s, Kadlec was part of an elite Air Force operations unit and served as a U.N. weapons inspector hunting the Iraqi desert for Saddam Hussein’s suspected stores of anthrax and botulism. He was awarded the Bronze Star Medal for service in Iraq.

He held a teaching job at the National War College in the District but left after the attacks of Sept. 11, 2001, to work as biodefense director on President George W. Bush’s Homeland Security Council.

In 2005, Kadlec took a job working for Sen. Richard Burr (R-N.C.) as a staffer on what was then a subcommittee on bioterrorism and public health preparedness. Kadlec helped draft the sweeping law that established a framework for much of the government’s preparedness spending today, including the office that he now leads.

Kadlec left government in 2009, when Barack Obama took office, and records show that he started his own business, RPK Consulting, two years later. He was an outspoken critic of the new administration’s biodefense policies, especially of its management of the stockpile and the interagency process that was used to decide what should be acquired.

Kadlec wrote in a government security journal in 2012 that, for contractors, the “extensive bureaucracy resembles the Politburo.” Asked a few months later who was in charge of U.S. biodefense policy, Kadlec told an interviewer from Johns Hopkins University, “The reality is, it doesn’t seem to be anyone is in charge at the current time.”

Ties not disclosed

In the summer of 2012, Kadlec and El-Hibri formed the small biodefense company East West Protection with W. Craig Vanderwagen, who had worked in the Bush administration as the first leader of ASPR. Records show that Kadlec was managing director and a part-owner of the firm.

The firm sought a contract from Saudi Arabia to build a biodefense system, Vanderwagen told The Post. It did not ultimately win the business with the kingdom, he said. It sold services to authorities in Alaska and Wisconsin.

As a self-employed biosecurity consultant, Kadlec was paid more than \$451,000 in 2014, according to a disclosure form he submitted when Burr hired him the following year, this time as a staffer for the Senate Intelligence Committee. He also disclosed his involvement in the biodefense company with El-Hibri.

Kadlec reported that 13 clients had each paid him more than \$5,000 for consulting work between 2013 and 2014, including a pharmaceutical trade group, an industry lobbying organization and companies such as Emergent and Danish pharmaceutical company Bavarian Nordic.

He promoted the companies' medical products overseas, said a senior HHS official with knowledge of Kadlec's work, speaking on the condition of anonymity to discuss sensitive matters.

Kadlec had become a familiar presence in industry circles and was widely known to lobbyists, contractors and others as "Dr. Bob."

“Everybody loves Dr. Bob,” said Steve Cash, a former CIA officer and founder of Deck Prism, a federal contractor that retained Kadlec as a consultant. In an email to The Post, Cash called Kadlec a “national treasure.”

In July 2017, Trump nominated Kadlec to lead ASPR. Kadlec was required to submit to the Senate health committee a detailed ethics form reporting his professional and financial activity in recent years.

One section of the Senate questionnaire asked for details of any “business relationship, dealing or financial transaction which you have had during the last five years whether for yourself, on behalf of a client, or acting as an agent, that constitutes a potential conflict of interest with the position to which you have been nominated.”

At the time, Emergent and Bavarian Nordic — his former consulting clients — were working as medical supply contractors for the government office he was nominated to lead. His involvement in the start-up with El-Hibri had ended 30 months earlier.

Kadlec answered: “None.”

In a section that asked for details of “all of your employment activities,” Kadlec reported having had 14 jobs dating to the 1980s, along with periods of education, military leave and a spell of unemployment. He listed RPK Consulting but did not identify its clients. He did not mention East West Protection.

Danko said Kadlec “received neither earned nor investment income” from East West Protection. “At the time of his 2017 confirmation by the Senate to be the ASPR, no potential conflict existed,” Danko said.

Records show that he sold his stake in the firm to El-Hibri for \$20,000.

In paperwork filed with the Office of Government Ethics, Kadlec said he would “not participate personally and substantially in any particular matter that to my knowledge has a direct and predictable effect on the financial interests of” his consulting work.

Overhauling the office

Once confirmed, Kadlec assumed his post in mid-August 2017 and immediately began pivoting ASPR’s focus, according to former senior officials and Kadlec himself.

“There was definitely a shift in thinking and to some extent a shift in priorities,” one former official told The Post. “More focus on biologic attacks, intentional attacks, terrorist attacks, and definitely away from natural disease outbreaks.”

Kadlec moved swiftly to change the process for supplying the stockpile. Called the Public Health Emergency Medical Countermeasures Enterprise, or PHEMCE, the process brought together a large group of senior officials from HHS, the Defense Department, the Department of Homeland Security and other agencies. As the chief of ASPR, Kadlec led its senior council.

Even supporters acknowledge the PHEMCE process could be laborious. But officials from multiple administrations said in interviews that it ensured expertise and open debate from across government before important decisions about the acquisition of vaccines and other vital supplies.

At the heart of PHEMCE for more than a decade was an executive committee of senior officials, a layer below the council led by Kadlec. The executive committee met twice a month and oversaw a network of expert working groups that supplied

detailed data on threats such as flu, emerging diseases and smallpox, and others.

Kadlec considered that approach to be too “bottom-up.” Under his leadership, the office has adopted a “top-down” approach, according to the senior HHS official with knowledge of his work.

Kadlec has largely replaced the old system for making final buying decisions with more-exclusive gatherings in a sensitive compartmented information facility, or SCIF. Invitees often include his deputy and his counterpart for chemical and biological defense at the Pentagon, the official said.

In the interview with The Post, Kadlec said deliberations needed to be shielded from foreign spies.

“There has been foreign penetration by hostile governments stealing not only our intellectual property but our national security information. And that was something that I wanted to correct. So we don’t hold it in the open anymore,” he said. “So that’s why that changed dramatically on my watch. And again, I can’t say I have any regrets.”

The changes in part prompted George W. Korch, a career official who chaired the committee Kadlec scrapped, to leave Kadlec’s office, according to three former officials.

Kadlec said that he had the “greatest regard” for Korch and that Korch left to take a job leading a government laboratory at Fort Detrick, Md. “As he shared with me, the opportunity allowed him to go back to his science roots and his home,” Kadlec said in a statement.

Korch declined to comment on his departure.

Shifting the stockpile

Executives at Emergent specifically identified transferring the stockpile from the CDC to ASPR as part of its annual corporate strategy for 2017, according to people familiar with it. Like many large contractors, the company has long cultivated relationships in Washington, and it has spent almost \$45 million on lobbying since 2005, records show.

DeLorenzo, the Emergent spokeswoman, confirmed that the company encouraged the transfer of the stockpile, saying it believed the move would “streamline the delivery” of products and “reduce bureaucracy.”

The company was not alone in that sentiment.

Other suppliers were also frustrated by the CDC’s stewardship of the stockpile, according to former officials and executives involved in the process. Some saw the CDC as set in its ways and uninterested in new products, they said.

Kadlec acknowledged in a 2018 interview with The Post that the move was a priority for contractors. “I don’t know specifically about the pushes they have done, but I do know that from a standpoint of efficiencies and effectiveness and cost savings . . . having a centralized, single point of contracting is going to probably make it easier for the companies,” he said.

At HHS, the idea of transferring the stockpile had been discussed at least as far back as the summer of 2017, shortly before Kadlec’s nomination, according to an email obtained by The Post. Chris Meekins, a former congressional staffer who was

then an applicant for a senior position in ASPR, wrote the email to document a conversation he had had with Tom Price, then the HHS secretary.

Meekins, who had close ties to the biodefense world and later became Kadlec's chief of staff at ASPR, wrote that he had told Price that putting the stockpile under the control of the assistant secretary would improve the nation's response in a crisis.

In February 2018, the administration signaled in its proposed budget for the following year that it intended to transfer the stockpile, with contents worth \$7 billion, to Kadlec's office.

Some public health officials found the idea perplexing.

"I remember thinking, 'That's crazy!'" said Peter Kyriacopoulos, chief policy officer at the Association of Public Health Laboratories. "I started scratching my head — 'Why is this happening?'" he said. "I'm still scratching my head."

The move detached the stockpile from grant programs administered by the CDC to prod state and local governments to better prepare for public health emergencies and ensure they knew when and how to call on the stockpile for assistance.

Some senior officials at the CDC and the White House National Security Council told Kadlec the move would be a mistake, one current and one former official said. But HHS leaders pressed ahead, and the transfer took effect on Oct. 1, 2018.

In the interview, Kadlec said he backed the move. "I supported it from the standpoint that it was the right thing to do," he said. "And also, quite frankly, it was more efficient."

Business booms at Emergent

in July 2017, four days after Kadlec's nomination, Emergent announced that it was acquiring the rights to the smallpox vaccine, known as ACAM2000, from the government's previous supplier.

That supplier's 10-year contract was worth about \$425 million. A spokesman for Sanofi Pasteur, the supplier, said it was charging \$4.27 per dose by the end of its involvement.

A notice issued by the CDC in August 2018 said the agency intended to contract Emergent to supply the smallpox vaccine for up to five years, starting with 9 million doses per year.

When Kadlec announced the contract in September, for 10 years, he said in a statement: "The virus remains a potential threat to national and global health security. Having vaccines and treatments at-the-ready will be imperative to saving lives."

The new contract called for 18 million doses per year and for Emergent to be paid \$9.44 per dose in the first year, a figure that will rise in the coming years, according to Robert Burrows, Emergent's vice president for investor relations.

Danko declined to confirm the price per dose, citing national security and business privacy concerns.

Kadlec said the terms of the contract are "consistent with what you find sometimes in the Department of Defense when you extend a contract over 10 or more years. What you're finding is that you pay a little bit more." He did not elaborate.

The stockpile was already well supplied with smallpox vaccine in 2018, according to a senior official then involved in the process. The CDC said on its website in June 2019 — and continues to say — that it had enough smallpox vaccine for every American. The doses must be replenished as they expire.

Kadlec told The Post that the scale of the contract was aimed at ensuring that “you basically have a sustainable supply of this, God forbid you ever need it.”

Kadlec’s office has also awarded Emergent a contract worth up to \$535 million to supply a product that treats side effects caused by smallpox vaccinations in a small percentage of patients. Last year, his office exercised a \$260 million option to extend an Obama-era contract with Emergent for an anthrax vaccine. And Emergent has a deal worth up to \$67.1 million to supply Kadlec’s office with a drug to treat cyanide exposure.

In all, records show, ASPR has paid Emergent more than \$733 million since Kadlec took over, making the company his office’s top contractor.

The company’s annual payments from the federal government have risen under Trump and are 50 percent higher than in the Bush and Obama years. Federal contracts now account for about one-third of the company’s revenue.

In an annual report filed to the Securities and Exchange Commission in February, Emergent said its business “could be materially harmed” if the government’s priorities for the stockpile were to change.

Weeks into the coronavirus pandemic, records show, Kadlec’s office has signed contracts totaling \$468 million with six mask suppliers. It has signed deals for more than \$2.3 billion worth of ventilators. Last month, it awarded Emergent a contract worth up to \$22 million to develop a covid-19 therapy.

Testifying to Congress in March, Kadlec said that he and other architects of the government’s preparedness system had not fully accounted for a scenario like the

covid-19 crisis.

“We did not consider a situation like this today,” Kadlec told a House committee on March 12. “We thought about vaccines. We thought about therapeutics. We never thought about respirators being our first and only line of defense for health-care workers.”

Lena H. Sun and Alice Crites contributed to this report.

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