BIOLABS IN YOUR BACKYARD

A USA TODAY NETWORK INVESTIGATION

Reporting by Alison Young,
with Nick Penzenstadler, Tom Vanden Brook
and a USA TODAY NETWORK team

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USA TODAY WEEKEND
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TECH-STOCK MANIA IS BACK
INVESTORS SHOULD BE WARY AS BUYOUT DEALS ON PACE TO SURPASS 1999. IN MONEY

Up to 18 labs got live anthrax

NEWSLINE

IN NEWS
National spelling bee ends in a tie

Vanya Shivashankar, left, celebrates with her sister, Vanya and Gokul Venkatachalam are co-champs.

IN MONEY
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Two Army scientists run tests in a BSL-3 chamber at Utah's Dugway Proving Ground. This is the same facility that recently shipped live anthrax specimens to as many as 18 labs in nine states, CDC officials said Thursday.

AL VOGEL, U.S. ARMY

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Hundreds of accidents, safety violations and close calls put people at risk

ABOUT THIS INVESTIGATION
A team from the USA TODAY Network of journalists at more than 40 Gannett newspapers and television stations reveals:
- Hundreds of safety accidents at labs nationwide
- Oversight is fragmented, self-policing
- Names of 100 labs facing sanctions kept secret
- Some researchers flout rules or experiment without approvals

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Alison Young and Nick Penzenstadler
USA TODAY

Vials of bioterror bacteria have gone missing. Lab mice infected with deadly viruses have escaped, and wild rodents have been found making nests with research waste. Cattle infected in a university's vaccine experiments were repeatedly sent to slaughter and their meat sold for human consumption. Gear meant to protect lab workers from lethal viruses such as Ebola and bird flu has failed, repeatedly.

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Of particular concern are mishaps occurring at institutions working with the world's most dangerous pathogens in biosafety level 3 and 4 labs — the two highest levels of containment that have proliferated since the 9/11 terror attacks in 2001. Yet there is no publicly available list of these labs, and the scope of their research and safety records are largely unknown to most state health departments charged with responding to disease outbreaks. Even the federal government doesn't know where they all are, the Government Accountability Office has warned for years.

The USA TODAY Network of journalists identified more than 200 of these high-containment

STORY CONTINUES ON 4A

Contributing: Tom Vanden Brook

22 Air Force members treated as precaution

Nick Penzenstadler and Alison Young
USA TODAY

The Centers for Disease Control and Prevention said Thursday as many as 18 labs around the country received live anthrax samples. Twenty-two people who may have been exposed at an Air Force base in Korea were medically treated as a precaution.

The incident is the latest high-profile mistake involving federal labs.

The Atlanta-based CDC said labs in nine states received the *Bacillus anthracis* specimens from the U.S. Army's Dugway Proving Ground in Utah. Shipments went to California, Delaware, Maryland, New Jersey, New York, Tennessee, Texas, Virginia and Wisconsin.

Exact lab locations had not been identified, but "they are mostly private, and some are operated by government and public institutions," said Jason McDonald, a spokesman for the CDC.

Richard Ebright, a biosafety expert at Rutgers in New Jersey, called the mistake "gross negligence."

"There is absolutely no excuse. Not for the shipping institution. Not for receiving institutions that failed to confirm inactivation upon receipt," Ebright said. "Both should lose, irrevocably, authorization for work with active or inactivated select agents."

There were no cases of anthrax infection in lab workers and no risk to the public, according to the Pentagon.

One of the samples was shipped to Osan Air Base in Korea. A U.S. Air Force statement said 22 people may have been exposed.

"All personnel were provided appropriate medical precautionary measures to include examinations, antibiotics and, in some instances, vaccinations," the Air Force said. "None of the personnel have shown any signs of possible exposure."

Anthrax spores can spread through the air and cause a deadly infection if not treated.

Army Col. Steve Warren said all 22 people in Osan were under treatment with the antibiotic Ciprofloxacin.

They include 10 soldiers, five airmen, four contractors and three government employees.

Last summer, dozens of CDC workers were potentially exposed to live anthrax after specimens were not properly inactivated before being transferred.

Former House speaker Hastert indicted

Accused of lying to FBI and illegal withdrawals

Aamer Madhani and Susan Davis
USA TODAY

CHICAGO Federal prosecutors on Thursday charged former House Speaker Dennis Hastert with illegally structuring cash withdrawals from bank accounts to conceal payments to someone he committed "prior misconduct" against and lying to the FBI about it.

The charges stem from Hastert, 73, agreeing to pay an individual, whom authorities did not identify, a total of $3.5 million, according to the indictment.

The indictment did not specify the nature of the misconduct. A spokeswoman for the federal prosecutor in Northern Illinois declined to offer further detail about the alleged wrongdoing.

The indictment said the individual was a resident of Yorkville, where Hastert had previously been a teacher and wrestling coach. Hastert has known the person for most of the individual's life, according to the indictment.

The Republican from Illinois is accused of circumventing federal rules that require banks to report withdrawals of more than $10,000. He specifically is accused of withdrawing a total of $952,000 in increments under the threshold that were paid to the individual.

USA TODAY
Dennis Hastert

When asked about it by the FBI in December 2014, he allegedly lied and said he was keeping the cash, according to the indictment.

Hastert did not immediately respond to a message seeking comment.

Around 2010, Hastert and the individual discussed the misconduct that had occurred years earlier, according to the indictment.

The former speaker agreed in that meeting and other meetings to pay a total of $3.5 million.

From 2010 to 2014, Hastert withdrew approximately $1.7 million in cash from various bank accounts and provided it to the person identified in the indictment as "Individual A."

Between June 2010 and April 2012, Hastert made 15 withdrawals of $50,000 each from a bank account. The individual was paid about every six weeks during that period, according to the indictment. By 2013, the FBI and IRS began looking into Hastert's withdrawals. Each count of the indictment carries a penalty of up to five years in prison and a $250,000 fine.

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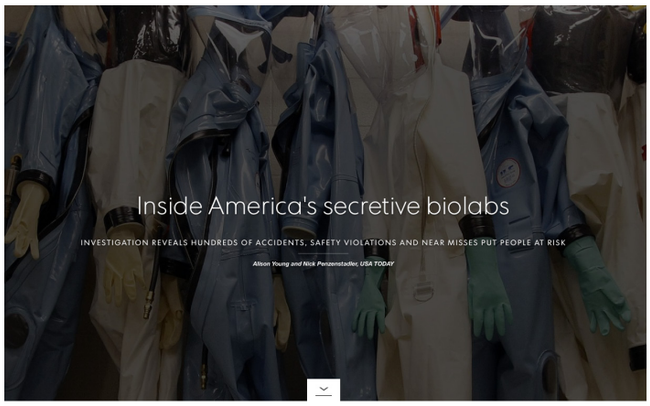

BIOLABS IN YOUR BACKYARD

Probe identifies over 200 biolabs

FROM NEW YORK CITY TO A VALLEY IN MONTANA

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Hundreds of accidents, safety violations and close calls put people at risk

Alison Young and Nick Penzenstadler, *USA TODAY*

CHAPTER 1

Probe identifies over 200 biolabs

From New York city to a valley in Montana

Vials of bioterror bacteria have gone missing. Lab mice infected with deadly viruses have escaped, and wild rodents have been found making nests with research waste. Cattle infected in a university's vaccine experiments were repeatedly sent to slaughter and their meat sold for human consumption. Gear meant to protect lab workers from lethal viruses such as Ebola and bird flu has failed, repeatedly.

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containment that have proliferated since the 9/11 terror attacks in 2001. Yet there is no publicly available list of these labs, and the scope of their research and safety records are largely unknown to most state health departments charged with responding to disease outbreaks. Even the federal government doesn't know where they all are, the Government Accountability Office has warned for years.

A team of reporters who work for the USA TODAY Network of Gannett newspapers and TV stations identified more than 200 of these high-containment lab facilities in all 50 states and the District of Columbia operated by government agencies, universities and private companies. They're scattered across the country from the heart of New York City to a valley in Montana; from an area near Seattle's Space Needle to just a few blocks from Kansas City's Country Club Plaza restaurant and shopping district.

High-profile lab accidents last year with anthrax, Ebola and bird flu at the Centers for Disease Control and Prevention and the discovery of forgotten vials of deadly smallpox virus at the National Institutes of Health raised widespread concerns about lab safety and security nationwide and whether current oversight is adequate to protect workers and the public. Wednesday the Department of Defense disclosed one of its labs in Utah mistakenly sent samples of live anthrax -- instead of killed specimens – to labs across the USA plus a military base in South Korea where 22 people are now being treated with antibiotics because of their potential exposure to the bioterror pathogen. As many as 18 labs in nine states received the samples, the CDC said Thursday.

"What the CDC incidents showed us ... is that the very best labs are not perfectly safe," says Marc Lipsitch, a Harvard University professor of epidemiology. "If it can happen there, it certainly can happen anywhere."

Some people find little reassurance that nobody was sickened in the CDC accidents or in the historically low numbers of serious infections among lab workers generally, or that infections spreading into communities surrounding labs have been rarer still.

"Many of us think that's really a matter of good fortune," said Beth Willis, who chairs a citizen lab advisory panel in Frederick, Md., home to one of the nation's largest high-containment research campuses at the Army's Fort Detrick.

The country's best labs have robust safety programs, said Kenneth Berns, co-chair of a panel of outside lab safety advisers currently examining biosafety at CDC and other federal labs. Yet the systemic safety problems identified at the CDC's prestigious labs have raised questions about what's happening elsewhere. "It's a matter of some concern," said Berns, a distinguished professor emeritus of molecular genetics and microbiology at the University of Florida.

The consequences could be devastating if accidents were to occur with lab-created strains of deadly influenza viruses that are purposely engineered to be easier to spread than what's found in nature, said David Relman, a microbiology professor at Stanford University who is a federal adviser on lab safety and a past president of the Infectious Diseases Society of America.

"You're talking about something that has the ability to take off, and we could not be confident of being able to contain it," he said.

Relman said that not enough is known about the state of safety at labs that perform infectious disease research but emphasized that the kinds of labs drawing concern are the same ones the public needs to discover important new treatments and vaccines. "We have to find some happy blend of minimized risk and enhanced benefit," he said.

CHAPTER 2

Looking for a cure

Daily handling of deadly pathogens like Ebola, plague, anthrax

At the high-containment labs identified by USA TODAY, experiments are underway involving drug-resistant tuberculosis, exotic strains of flu, the SARS and MERS viruses, plague, anthrax, botulism, ricin and the Ebola and Marburg hemorrhagic fever viruses, according to interviews and more than 20,000 pages of internal lab safety records and incident reports obtained from labs across the country.

Studies are also being done on a wide range of bioterrorism pathogens that are less known to the public, such as the agents that cause exotic diseases like tularemia, Q fever and melioidosis. Still others are focused on pathogens that pose serious economic risks to agriculture, such as foot-and-mouth disease, brucellosis and "mad cow" disease.

At a few labs, experiments have been done with strains of flu and other viruses purposely made to be more dangerous in studies that seek to understand how they might mutate naturally. White House science advisers called for a temporary halt of that kind of "gain of function" research last fall while expert scientific panels spend the next year studying its risks and benefits.

The research at BSL-3 and BSL-4 labs — which use special equipment, negative air pressure and numerous safety and security procedures — seeks to better understand how organisms cause disease and ways to protect against them. It's the kind of work that the public doesn't give much thought to until people with Ebola arrive on planes in the United States from an outbreak in Africa, or the current avian flu outbreak forces farmers to kill millions of chickens raising the specter of higher egg prices.

It's impossible to obtain a full accounting of lab accidents or lab-acquired infections because there is no universal, mandatory requirement for reporting them and no system to analyze trends to assess emerging biosafety risks and disseminate lessons learned on a regular basis.

The Federal Select Agent Program, which inspects and regulates the subset of research labs that experiment with about four dozen types of pathogens deemed to pose bioterror threats, requires labs to report potential exposure or release incidents, as well as thefts or losses of specimens.

Richard Din, a 25-year-old researcher, died in 2012 after unknowingly becoming infected by Neisseria meningitides at a lab inside San Francisco's VA medical center.

(Photo: Family photo)

From 2006 through 2013, labs notified federal regulators of about 1,500 incidents with select agent pathogens and, in more than 800 cases, workers received medical treatment or evaluation, limited public data in program annual reports show. Fifteen people contracted laboratory-acquired infections and there were three unintended infections of animals, according to the reports, which do not identify labs and mostly provide aggregated counts of incidents by type. Reported incidents involve events ranging from spills to failures of personal protective equipment or mechanical systems to needle sticks and animal bites.

The program, jointly run by the Centers for Disease Control and Prevention and the U.S. Department of Agriculture, refuses to release copies of detailed incident reports, citing a 2002 bioterrorism law.

Incident records the USA TODAY Network obtained directly from individual labs provide a window on the kinds of mistakes that happen. An animal caretaker in Georgia was potentially exposed to a bird flu virus that kills 60% of the people it infects when a defective respirator hose supplying purified air detached from its coupling in September. A researcher in Wisconsin was quarantined for seven days in 2013 after a needle stick with a version of the same H5N1 influenza virus. A lab worker in Colorado failed to ensure specimens of the deadly bacterium Burkholderia pseudomallei had been killed before shipping them in May 2014 to a co-worker in a lower-level lab who handled them without critical protective gear. None of the workers was infected.

The public and the lab community tend to learn only about the rare instances of serious or fatal lab infections, which sometimes are published as case reports in scientific journals or make national news.

In 2009, Malcolm Casadaban, a University of Chicago scientist with an underlying medical condition, died from an infection with a weakened strain of plague bacteria. In 2012, 25-year-old researcher Richard Din died after being infected during vaccine research involving Neisseria meningitides bacteria at a lab inside San Francisco's VA medical center. Both of their deaths involved research in biosafety level 2 labs, where pathogens are considered to be less dangerous than those worked with in high-containment labs.

Din, who became a researcher to cure diseases like the cancer that killed his mother, developed a fever and started feeling dizzy while out to dinner with friends. He had no idea how serious his symptoms were, his friends and family told USA TODAY. By morning, Din was covered in a splotchy rash and could barely talk, recalled Lawrence Tsai, who raced to Din's apartment to help.

Tsai carried his friend down two flights of stairs and drove him to the hospital. "His body was very hard, very straight," Tsai said. "Only his eyes were open. He could not say anything."

A few hours later, Din was dead. And Tsai said he and his friends were told they, too, were at risk and needed to take antibiotics because of their close contact with him. The bacteria that killed Din can spread from person to person by direct contact with respiratory secretions. About two dozen emergency room workers also were treated with antibiotics as a precaution, according to a presentation about the case at a scientific conference. Nobody else was sickened.

Federal workplace safety investigators, who investigated because the case involved a death, said Din died because the VA failed to adequately supervise and protect workers in the research lab. Among the "serious" issues they cited: Din and other workers in the lab were manipulating specimens of the dangerous bacteria out on tabletops — not inside protective biosafety cabinets that would have reduced potential exposures to droplets or splashes. The lab also failed to train workers about warning signs of infection, violation records show.

CHAPTER 3

Spreading into the community

While rare, an accidental release could be a disaster

Although lab-created outbreaks that spread to people or animals in the surrounding community are rare, they have happened.

"That's what you would worry about," said Gigi Kwik Gronvall, of the UPMC Center for Health Security, an independent think tank that studies biosecurity and epidemics. "But even then the consequences up to now have

been limited to the very close contacts of the person who was infected."

A small, deadly outbreak of severe acute respiratory syndrome in China in 2004 was traced to lab workers at the National Institute of Virology in Beijing. In 2007, an outbreak of foot and mouth disease among cattle in England that required herds to be slaughtered was blamed on leaking drainage pipes at a nearby research complex.

In Louisiana, tests are underway to make sure a deadly bioterror bacterium hasn't colonized the soil and water around the Tulane National Primate Research Center near New Orleans. Late last year, the bacteria got out of one of the center's BSL-3 labs, likely hitching a ride on workers' clothing, sickening two monkeys that lived in outdoor cages and later infecting others. Tulane will spend the next five years testing its outdoor monkey colony as well as wildlife and feral cats around the 500-acre facility to ensure the bacteria haven't contaminated the environment. The CDC and Tulane say they think the bacteria spread only inside the center's buildings, and so far tests outdoors have not detected the bacterium, Burkholderia pseudomallei, which can cause severe and difficult-to-treat illness in people and animals infected by coming into contact with contaminated soil or water.

On a global scale, a lab accident is considered by many scientists to be the likely explanation for how an H1N1 flu strain re-emerged in 1977 that was so genetically similar to one that had disappeared before 1957 it looked as if it had been "preserved" over the decades. The re-emergence "was probably an accidental release from a laboratory source," according to a 2009 article in the New England Journal of Medicine.

However, most pathogens studied in labs, unlike the flu, don't spread easily from person to person. Often, to become infected a person needs to have direct contact with a pathogen, which is why lab workers are most at risk, experts said. For example, people can become infected with anthrax by inhaling the bacterium's spores, but once sickened they are not contagious, according to the CDC.

"I don't think the public needs to be too concerned," said Marian Downing, president of the American Biological Safety Association. "There are multiple levels of checks and balances in place."

Beyond accidental lab-associated outbreaks, federal auditors consider the deliberate theft and misuse of a deadly pathogen to be one of the most significant risks of biolab research. That's what the FBI says happened in the 2001 anthrax letter attacks that killed five and sickened 17. Bruce Ivins, a biologist and anthrax researcher at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) at Fort Detrick, Md., was the perpetrator, the FBI concluded.

The GAO, the investigative arm of Congress, has issued repeated warnings since 2007 that the proliferation of BSL-3 and BSL-4 laboratories has increased the aggregate risk of accidental or intentional releases of viruses, bacteria or toxins.

No single agency tracks the overall number or location of these labs, the GAO has said. Little is known about high-containment labs working with dangerous pathogens such as tuberculosis, the MERS virus and others that aren't on the select agent list and tracked by the Federal Select Agent Program.

National standards for constructing and operating these kinds of labs are lacking, which means labs vary by local building requirements. While voluntary guidance exists for safe lab design and operations, the GAO has found it is not universally followed.

The documents obtained by USA TODAY show power failures at BSL-3 labs at Texas A&M University repeatedly resulted in the labs losing their negative air pressure during 2013, a key safety feature that is among several used to keep pathogens contained inside the lab. The CDC's labs in Atlanta also have had airflow problems over the years, the newspaper previously reported.

"The public is concerned about these laboratories because exposing workers and the public to dangerous pathogens, whether deliberate or accidental, can have disastrous consequences," the GAO's Nancy Kingsbury told Congress at a hearing on the CDC lab incidents last summer.

Lab regulators at the Federal Select Agent Program — whose departments often fund the research they oversee — would not grant interviews despite repeated requests since last year. The program oversees about 262 organizations that operate BSL-3 and eight organizations that operate BSL-4 labs.

The two federal agencies that jointly run the program — the CDC and USDA — operate their own labs, which have been involved in recent high-profile incidents.

"We believe the current system of inspecting/overseeing laboratories is adequate, but we are always open to continued improvements," the CDC said in an emailed statement. USDA officials also declined to be interviewed.

Lab safety officials at the National Institutes of Health, a major research funding agency that operates its own labs and helps set national biosafety guidelines, also declined interview requests.

"There is no 'zero-risk' proposition in the conduct of research," the agency said in a statement. "NIH works extremely hard to minimize all research-related risks."

CHAPTER 4

Lab failures kept hidden

Key details of enforcement actions are secret

More than 100 labs experimenting with potential bioterror agents have been cited by regulators at the CDC and USDA for serious safety and security failings since 2003, USA TODAY has learned.

Yet so much of select agent oversight is cloaked in secrecy, making it difficult to assess regulators' effective-

ness in ensuring safety. In several instances, troubled labs and even federal regulators appeared to misrepresent the significance of the government's enforcement efforts.

Since 2003, the CDC has referred 79 labs for potential enforcement actions by the U.S. Department of Health and Human Services' Office of Inspector General. It has levied fines against 19 of them totaling more than $2.4 million, the CDC said in response to questions.

Some are repeat offenders. Five labs have had "multiple referrals" for enforcement actions, the CDC said. Two labs have been kicked out of the program, and five labs have been suspended from doing any select agent research, the agency said.

Which labs repeatedly failed to address safety problems? The CDC won't name names — not even for the two labs kicked out of the select agent program. The CDC and its regulatory partners at the USDA say the 2002 bioterrorism law requires keeping this information secret.

Yet earlier this year, the CDC publicly announced its suspension of the Tulane National Primate Research Center — after the center's accidental release of a bioterror bacterium became publicly known and was the subject of news reports. The CDC said it balances the public's right to transparency with the risk posed by information being made available to those who might use it to threaten public health or security.

Currently seven labs are under the extra scrutiny of a federal select agent lab performance improvement program, the CDC said. The program is offered as a voluntary alternative to suspension or other regulatory action, the agency said, for labs with a "repeated failure to correct past observation, biosafety and security concerns" or failures to comply with extra security requirements for work with "Tier 1" select agents. Tier 1 agents are those deemed to pose the greatest risk of deliberate misuse with the most significant potential for mass casualties or devastating economic effects.

While under scrutiny of the program, an individual researcher or project must halt the research that has been found in violation, but other select agent research at the institution generally is allowed to continue, the CDC said.

Thirty-three labs have been put on performance improvement programs since 2008, CDC said. Their names are secret too.

Dozens more labs have faced regulatory actions from the USDA, which takes the lead overseeing select agent labs primarily working with animal or agricultural pathogens. The USDA says it has conducted 48 investigations that have resulted in $116,750 in fines.

The USDA said all of its enforcement records about these fines are required to be kept secret because of the 2002 bioterrorism law. The USDA did release a spreadsheet it says documents its actions, but the agency redacted almost all the information on it: lab names, violation types and even dates. Only a few references to warning letters and fines were spared the agency's black marker.

The Federal Select Agent Program says no law or regulation bars the labs themselves from discussing their select agent research. And universities and other research institutions routinely publish their research on select agent pathogens in scientific journals.

Registered labs just aren't supposed to share details of specific security measures, such as locations of keys and codes, that would give access to pathogens. The CDC and USDA said there is nothing that prohibits labs from releasing information or answering questions about any regulatory problems they've had. Yet few were willing to readilydiscuss violations or failed inspections.

Labs at the University of Hawaii-Manoa are among those in the federal performance improvement program, at least as of January, records obtained by USA TODAY show. Although the secrecy provisions of the 2002 bioterrorism law apply only to certain federal agencies, officials at the state-run university cited that law among its reasons for denying requests for records about safety violations and the performance improvement program.

The university inadvertently confirmed that its Honolulu labs had been put in the performance improvement program in records it filed in January with Hawaii's Office of Information Practices, which is deciding USA TODAY's public records appeal. The university wrote that being put on a PIP is something it is "proud" of.

"We do not believe entering into the program is an embarrassment, we think it should be showcased, but that would be improper because as participants in the Federal Select Agent Program, we are obligated to keep this information private," the university wrote to the appeals agency, adding that it "has been an exemplary participant in the Federal Select Agent Program."

University of Hawaii officials declined to be interviewed.

Last year, two labs agreed to pay fines handed down by the HHS Office of Inspector General for select agent violations, records show.

A lab that federal officials would describe only as an "Arizona research university" agreed in 2014 to pay a $165,000 fine for failing to keep accurate inventory records for select agents and not having biosafety procedures adequate for the risks associated with the pathogens they worked with. The lab, the USA TODAY Network's reporting found, was Northern Arizona University in Flagstaff. Lab director Paul Keim said the issues date back to 2010 when the university had difficulty keeping up with changing federal regulations. Since then the university's labs have passed several inspections, he said.

An unnamed Florida laboratory agreed to pay $50,000 to resolve violations that included failing to ensure accurate inventories of select agents and failing to notify the CDC and appropriate law enforcement agencies after discovering a missing select agent.

The inspector general's office, citing regulations stemming from the 2002 bioterrorism law, redacted the names of these labs, as well as all other labs receiving

fines, in documents it provided to USA TODAY under the Freedom of Information Act. Other labs that have been fined over the years for select agent violations are located in Alabama, California, Missouri, South Dakota, Texas, Virginia and Wisconsin, records show.

CHAPTER 5

Congress gets limited, wrong information

A $425,000 fine that disappeared

As a way of providing some oversight, Congress requires a report each year on the number of thefts, losses and releases of bioterror pathogens at labs regulated by the Federal Select Agent Program.

Yet regulators provide scant details of their activities and the problems identified at labs. Usually just three pages long plus a cover page, the reports contain only aggregated counts of lab incidents by type, plus vague information on a few serious incidents.

The select agent program told Congress it had "imposed a $425,000 civil money penalty" on an unnamed lab where a serious biosafety lapse in 2008 had resulted in a cow in a nearby disease-free herd becoming infected with Brucella bacteria, which cause brucellosis.

Brucellosis is a contagious and economically significant agricultural disease — which causes cattle and other livestock to abort their fetuses, produce less milk, suffer weight loss, infertility and lameness. It has been the subject of eradication efforts for decades.

The $425,000 fine would have been one of the largest in the overall select agent program's history — if it had actually been imposed.

But it wasn't imposed, USA TODAY's investigation found, and the USDA never corrected the record with Congress.

USA TODAY was able to identify the Brucella research program at Louisiana State University's AgCenter in Baton Rouge as the likely recipient of the $425,000 fine by examining USDA animal health reports that tallied what states reported brucellosis cases in 2008. Louisiana, which had a case that year, had been declared brucellosis-free in 2000.

LSU officials spent months denying USA TODAY access to its records about the incident, citing among other things select agent regulations unrelated to the requested information. In statements and interviews, LSU downplayed its violations and provided information that was later contradicted by federal records.

"The incident was not found to be caused by a violation of federal regulations; no fines were imposed upon LSU, and the regulatory agencies had uncertainty as to whether the strain of bacteria in the affected cow was the same strain that was being used in the LSU research," LSU officials said in a November 2014 email to USA TODAY.

Yet, in December 2014, when USA TODAY received copies of the incident investigation reports from the USDA and Louisiana's state agriculture department, the documents showed no uncertainty.

USDA records show that investigators documented serious violations. In levying the $425,000 fine, regulators cited LSU for failing to have adequate biosafety measures, resulting in the release of the bacteria that caused the cow's infection. The USDA also cited LSU for violating regulations by sending Brucella-infected cattle that had been part of select agent vaccine experiments to an unregistered slaughter facility where their meat was sold for human consumption.

LSU's Phil Elzer, who at the time ran the Brucella studies and now is a university administrator, said in an interview the practice of sending research cattle to slaughter was declared in the lab's operating procedures that were reviewed and signed off on at each inspection by Federal Select Agent Program regulators. "To all of a sudden say we were doing it wrong was very surprising," Elzer said. LSU appealed, and the USDA eventually dropped the fine, he said.

In January 2010, records show, the USDA sent a letter to LSU saying the case was being closed but reiterating the issues with the infected cow and the use of the unauthorized slaughter plant.

USDA officials acknowledge that they never imposed the $425,000 fine and made a mistake touting it in their report to Congress.

"It should have stated that we were proposing a fine, instead of stating we issued a fine," said Freeda Isaac, USDA's director of Agriculture Select Agent Services, in an emailed statement. Isaac added that the USDA suspended a portion of LSU's select agent registration because of the Brucella incident and "that portion of the registration is still suspended," Isaac said last fall.

CHAPTER 6

Limitations of self-policing

Some researchers ignore biosafety rules

For those labs not in the select agent program — and even those that are — self-policing is the front line of biosafety. Biosafety committees at research institutions, often staffed by scientists' colleagues, assess the risks of proposed research and grant or deny approval for studies. Labs also have other safety staff who may do internal inspections and lab audits, plus additional committees overseeing the use of animals in research.

Yet some researchers appear ignorant of their institutions' biosafety rules. Others brazenly ignore repeated requests by biosafety staff to stop experiments and address issues.

Documents obtained by the USA TODAY Network include at least 50 incidents since 2012 in which researchers were conducting experiments with genetically manipulated organisms without proper approval from internal safety committees. In some cases, records show researchers flaunting their institutional rules.

• At the University of Tennessee Health Science Center

in, biosafety staff concluded in a 2013 report that the root causes of a researcher failing to get her experiments approved included "general indifference of the investigator to institutional rules governing the need for biosafety compliance" as well as a "lack of oversight of research activities." The scientist, the investigation revealed, knowingly launched unapproved experiments — exposing mice to a genetically manipulated strain of Burkholderia thailandensis — in a quest to get a vaccine study manuscript published that reviewers said needed additional data. The research was halted after veterinarians found several cages containing dead and dying mice, yet none of the cages was labeled with the infectious agent and they were in an area not approved for experiments with a BSL-2 pathogen. The incident was "an extremely unusual event," said Sheila Champlin, an assistant vice chancellor at the center, noting corrective actions were taken before the scientist was allowed to resume research.

Beth Willis is chairwoman of the Containment Lab Community Advisory Committee in Frederick, Md., home to one of the nation's largest high-containment research campuses at the Army's Fort Detrick.

(Photo: Jack Gruber, USA TODAY)

• At the University of Iowa, a biosafety officer in February 2014 discovered that a scientist had been conducting experiments with a genetically manipulated strain of the MERS virus since September 2013 without biosafety committee approval. The biosafety officer ordered the investigator to stop all experiments, and the scientist was put on probation and received increased safety monitoring. The work was being done in a BSL-3 lab at the time it was discovered, but started in a BSL-2 lab, the safety officer's investigation found. The university concluded that the scientist did not "effectively communicate" to his staff the importance of getting safety committee approval before starting the experiments with the virus, which can cause a deadly, contagious respiratory disease in people.

• At the University of California-Irvine, a researcher ignored repeated notices from biosafety staff during 2012 and 2013 that a research project's approval had expired, that it needed further revisions and that all work must cease — yet the scientist continued the experiments with a lentivirus, anyway, in the BSL-2 lab. As a result of the incident, the university now sends researchers four notices starting 90 days before approvals expire, said James Hicks, the university's associate vice chancellor of research. As the deadline nears, Hicks is copied on the notices so he can intervene if necessary. "We take a very strong view and a very correct view of the importance of following the regulations and the guidelines," he said in an interview.

• At the University of Nebraska, a biosafety officer in 2013 found that a researcher had continued growing plants as part of an experiment using a transgenic tobacco rattle virus vector — despite being told repeatedly over two months that additional approval was needed from the biosafety committee before research could begin. As a result of the incident, the university said it revised its biosafety guidelines to describe consequences of unapproved research and sent a letter to faculty. "This was an isolated instance that was fully and successfully resolved," the university said.

• At the University of Hawaii-Manoa, biosafety staff discovered a scientist was doing a type of cancer research in 2012 despite being denied biosafety committee approval and being repeatedly told not to do the experiments. Separately, at a March 2013 biosafety committee meeting at the university, members discussed the need for penalties when researchers fail to comply with biosafety rules, stating "there must be some consequence and corrective action other than an email" to the scientist, the minutes say.

Labs that receive funding from the National Institutes of Health and some other federal agencies are required to report incidents to the NIH involving certain types of genetically engineered organisms and recombinant DNA technology. From 2010 through 2014, the NIH received 644 reports of lab incidents during this kind of research.

Most of the reports the NIH receives are for what it says are non-serious incidents, such as small spills, splashes, cuts and equipment failures. Failure to obtain required biosafety committee approvals to do this type of research are among the more common types of non-compliance.

Although it is not a regulatory agency, the NIH said in a statement that agency staff have made site visits to 100 institutions in recent years in an effort to help improve biosafety committee resources and adherence to the NIH Guidelines for operating their labs.

"Most instances of non-compliance result from a lack of full understanding of the requirements of the NIH Guide-

lines, rather than willful disregard, and our emphasis has been on corrective actions through education, which institutions seem uniformly responsive to," the NIH said.

In September 2014, the NIH contacted the University of Louisville after a whistle-blower alleged the university had knowingly failed to report lab incidents as required, according to records obtained under the federal Freedom of Information Act. In response, the university told the NIH that it discovered three incidents that were not reported to the NIH but should have been, the records show.

The records indicate that University of Louisville biosafety officials were aware of some of the unreported incidents as much as six months before the NIH opened its inquiry. William Pierce Jr., the university's executive vice president for research and innovation, in a statement to USA TODAY, said "there was apparent confusion regarding the authority and responsibility for reporting violations to the NIH." Pierce said the university has hired an outside firm to oversee its biosafety committee and created training courses for scientists. "We feel confident the current system is working," he said.

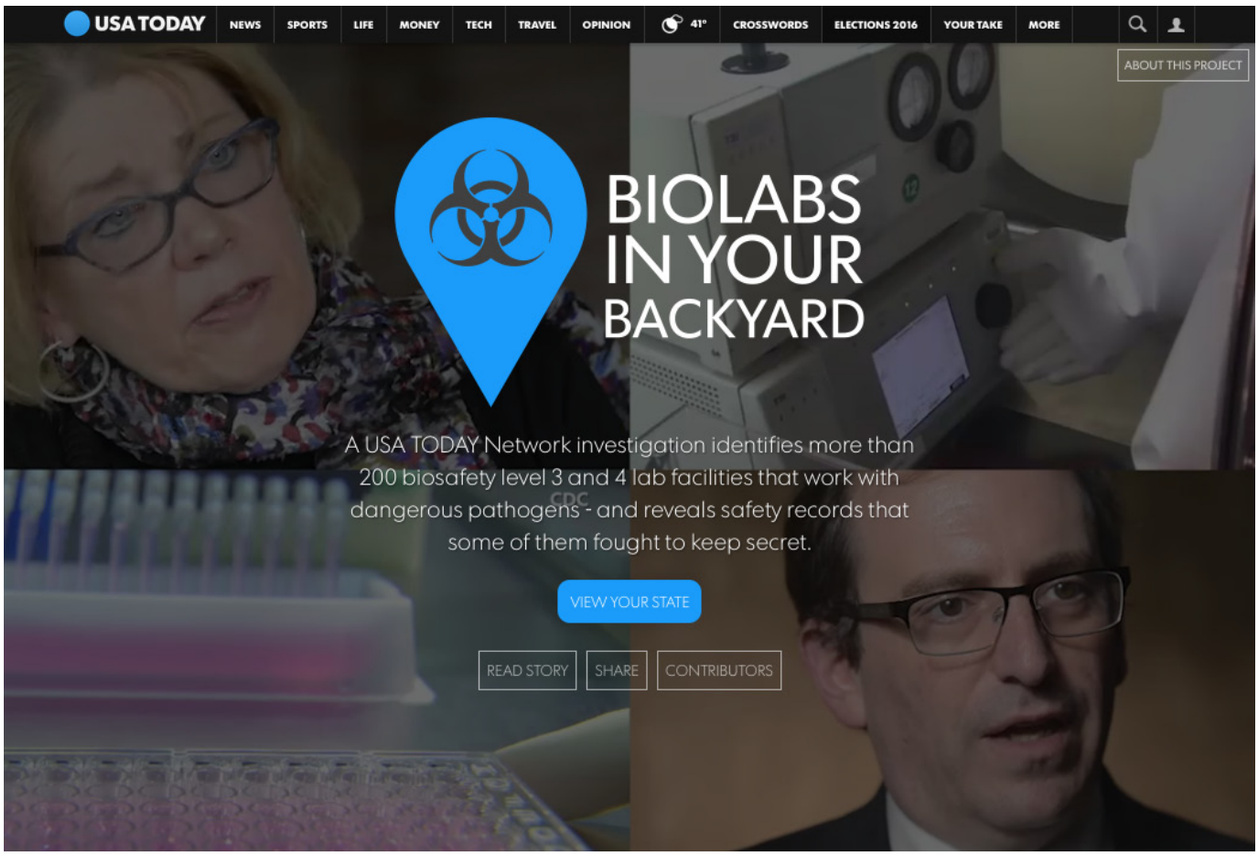
The NIH closed its inquiry after the university answered the agency's questions, filed reports on the previously unreported incidents and agreed to take actions to ensure better reporting in the future.

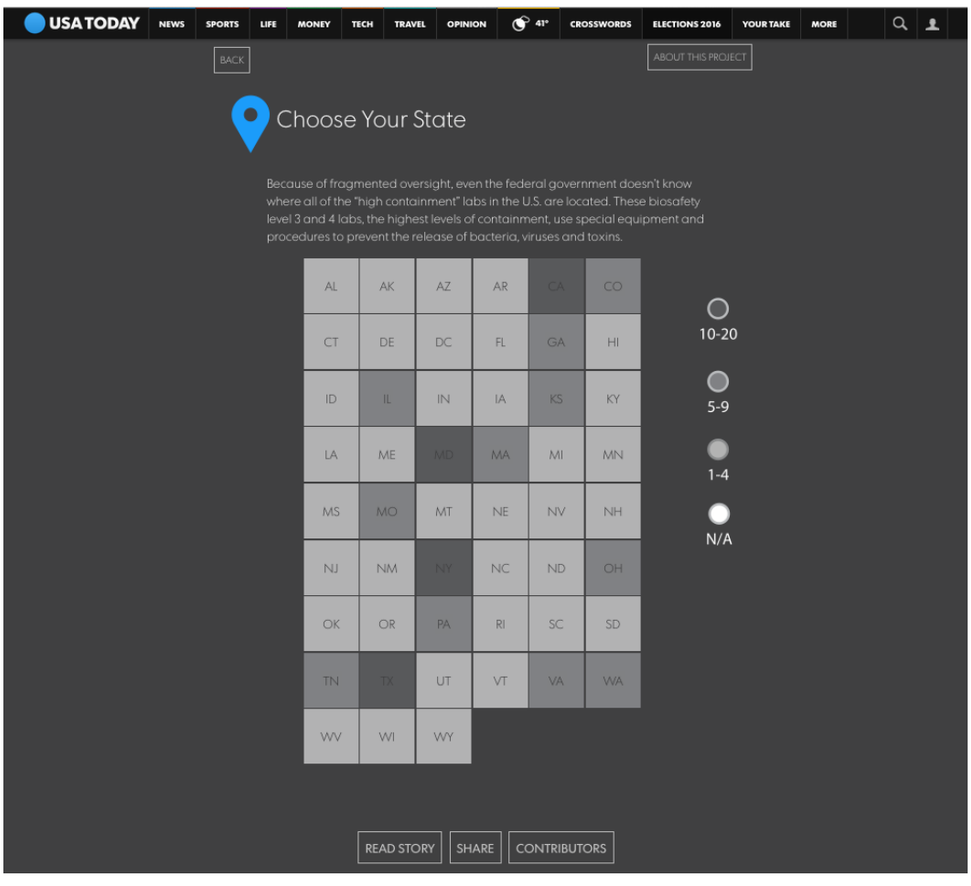
"In investigating the incident, we did not find any evidence of willful non-compliance," the NIH said in response to USA TODAY's questions.

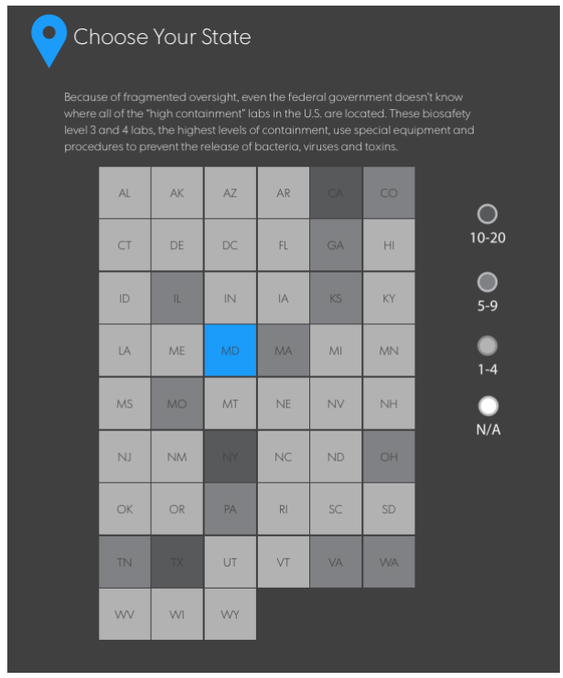
For some residents living near labs, the lack of transparency is frustrating — and worrisome. It's not enough to tell the public the labs have robust safety procedures. "What people are really interested in is how well it's working," said Beth Willis, the citizen lab safety representative near Fort Detrick. "The more people in the community feel that there's secrecy, the more they're distrustful, whether their distrust is warranted or not."

Interactive

http://www.usatoday.com/pages/interactives/biolabs/






Choose Your State
Because of fragmented oversight, even the federal government doesn't know where all of the "high containment" labs in the U.S. are located. These biosafety level 3 and 4 labs, the highest levels of containment, use special equipment and procedures to prevent the release of bacteria, viruses and toxins.
AL AK AZ AR CA CO
CT DE DC FL GA HI
ID IL IN IA KS KY
LA ME MD MA MI MN
MS MO MT NE NV NH
NJ NM NY NC ND OH
OK OR PA RI SC SD
TN TX UT VT VA WA
WV WI WY
10-20
5-9
1-4
N/A


BACK
ABOUT THIS PROJECT
Maryland
Facilities that include BSL-3 or BSL-4 labs identified by USA TODAY's research. Additional "high-containment" labs may also exist in this state.
Baltimore , Maryland BSL-3
Maryland State Public Health Laboratory
Edgewood , Maryland BSL-3
U.S. Army Edgewood Chemical Biological Center
Baltimore , Maryland BSL-3
University of Maryland-Baltimore
Baltimore , Maryland BSL-3
Paragon Bioservices
Bethesda , Maryland BSL-3
National Institutes of Health
Silver Spring , Maryland BSL-3
Walter Reed Army Institute of Research
Fort Detrick , Maryland BSL-4
National Biodefense Analysis and Countermeasures Center
Fort Detrick , Maryland BSL-4
U.S. Army Medical Research Institute of Infectious Diseases
Fort Detrick , Maryland BSL-4
NIAID Integrated Research Facility
Frederick , Maryland BSL-3
Southern Research Institute
Rockville , Maryland BSL-3
BIOQUAL
Rockville , Maryland BSL-3
Sequella
Silver Spring , Maryland BSL-3
FDA Life Sciences-Biodefense Laboratory Complex
Rockville , Maryland BSL-3
MRIGlobal
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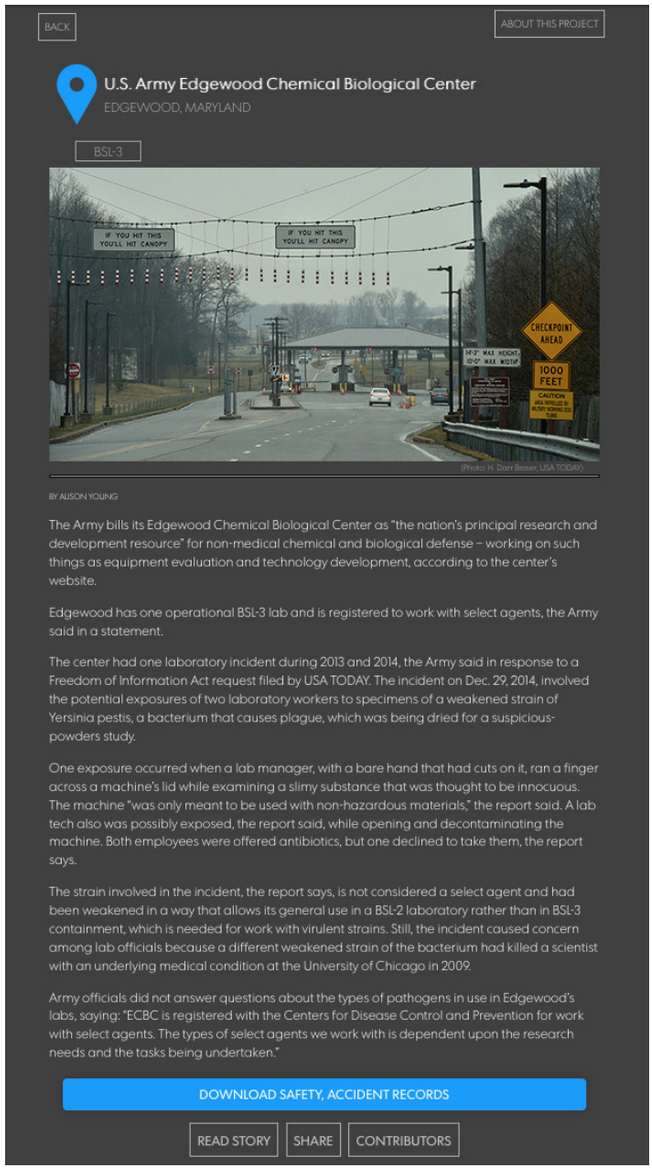
BACK
ABOUT THIS PROJECT
U.S. Army Edgewood Chemical Biological Center
EDGEWOOD, MARYLAND
BSL-3
IF YOU HIT THIS YOU'LL HIT CANOPY
IF YOU HIT THIS YOU'LL HIT CANOPY
CHECKPOINT AHEAD
1000 FEET
(Photo: H. Darr Beiser, USA TODAY)
BY ALISON YOUNG
The Army bills its Edgewood Chemical Biological Center as "the nation's principal research and development resource" for non-medical chemical and biological defense – working on such things as equipment evaluation and technology development, according to the center's website.
Edgewood has one operational BSL-3 lab and is registered to work with select agents, the Army said in a statement.
The center had one laboratory incident during 2013 and 2014, the Army said in response to a Freedom of Information Act request filed by USA TODAY. The incident on Dec. 29, 2014, involved the potential exposures of two laboratory workers to specimens of a weakened strain of Yersinia pestis, a bacterium that causes plague, which was being dried for a suspicious-powders study.
One exposure occurred when a lab manager, with a bare hand that had cuts on it, ran a finger across a machine's lid while examining a slimy substance that was thought to be innocuous. The machine "was only meant to be used with non-hazardous materials," the report said. A lab tech also was possibly exposed, the report said, while opening and decontaminating the machine. Both employees were offered antibiotics, but one declined to take them, the report says.
The strain involved in the incident, the report says, is not considered a select agent and had been weakened in a way that allows its general use in a BSL-2 laboratory rather than in BSL-3 containment, which is needed for work with virulent strains. Still, the incident caused concern among lab officials because a different weakened strain of the bacterium had killed a scientist with an underlying medical condition at the University of Chicago in 2009.
Army officials did not answer questions about the types of pathogens in use in Edgewood's labs, saying: "ECBC is registered with the Centers for Disease Control and Prevention for work with select agents. The types of select agents we work with is dependent upon the research needs and the tasks being undertaken."
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CONTRIBUTORS

BACK

ABOUT THIS PROJECT

Virginia

Facilities that include BSL-3 or BSL-4 labs identified by USA TODAY's research. Additional "high-containment" labs may also exist in this state.

Richmond , Virginia Virginia Division of Consolidated Laboratory Services	BSL-3
Blacksburg , Virginia Virginia Tech	BSL-3
Charlottesville , Virginia University of Virginia	BSL-3
Dahlgren , Virginia Naval Surface Warfare Center Dahlgren Laboratory	BSL-3
Manassas , Virginia George Mason University	BSL-3
Harrisonburg , Virginia SRI Shenandoah Valley	BSL-3
Manassas , Virginia ATCC - American Type Culture Collection	BSL-3
Richmond , Virginia American International Biotechnology (formerly Commonwealth Biotechnologies)	BSL-3
Richmond , Virginia Virginia Commonwealth University	BSL-3

BACK

ABOUT THIS PROJECT

SRI Shenandoah Valley

HARRISONBURG, VIRGINIA

BSL-3

(Photo: Southern Research Institute)

BY ALISON YOUNG

SRI International, a non-profit research firm that works for government and industry, operates a BSL-3 facility at its Shenandoah Valley center in Harrisonburg and another on its headquarters campus in Menlo Park, Calif., said spokeswoman Rebecca Michals.

Although Michals would not say which pathogens are used in research at the facilities, SRI's website says the Shenandoah Valley center does virology research relating to therapies and vaccines for influenza, SARS-CoV, hantaviruses and poxviruses, as well as studies of Middle Eastern respiratory syndrome (MERS) coronavirus.

SRI redacted names of many pathogens from the minutes of its Institutional Biosafety Committee, which oversees research at both sites, before releasing them to USA TODAY. The firm said it could not disclose names of pathogens in its research designated as select agents, because of their potential for use as bioweapons. Yet on its website and in press releases, SRI International has touted its research involving several select agents, including anthrax, plague, tularemia and Venezuelan equine encephalitis virus, as well as ricin, botulinum toxins and abrin, a poison.

SRI International had more than $566 million in revenue during 2012, according to its most recent non-profit tax return posted on Guidestar, an online website that collects tax returns from IRS-registered non-profit groups.

Photo: SRI International in Harrisonburg, Va.

DOWNLOAD SAFETY, ACCIDENT RECORDS

BACK

ABOUT THIS PROJECT

Texas

Facilities that include BSL-3 or BSL-4 labs identified by USA TODAY's research. Additional "high-containment" labs may also exist in this state.

Harlingen , Texas South Texas Laboratory, Texas Department of State Health Services	BSL-3
Austin , Texas Texas Department of State Health Services	BSL-3
College Station , Texas Texas A&M University	BSL-3
Dallas , Texas University of Texas Southwestern Medical Center	BSL-3
El Paso , Texas University of Texas-El Paso	BSL-3
Fort Hood , Texas Carl R. Darnall Army Medical Center Laboratories	BSL-3
Galveston , Texas Galveston National Laboratory	BSL-4
Houston , Texas Methodist Research Institute	BSL-3
Houston , Texas University of Texas Health Science Center	BSL-3
Lubbock , Texas Texas Technological University	BSL-3
San Antonio , Texas Texas Biomedical Research Institute	BSL-4

BACK

ABOUT THIS PROJECT

Texas Biomedical Research Institute

SAN ANTONIO, TEXAS

BSL-4

(Photo: Texas Biomedical Research Institute)

BY ALISON YOUNG

The Texas Biomedical Research Institute operates a lab complex that includes the nation's only privately owned BSL-4 facility. The organization notes that it is also "the only institution in the country to house both a BSL-4 lab and a national primate research center."

Research in the institute's BSL-4 lab includes work with the deadly Ebola virus to develop better detection and treatment methods, the organization says. The institute, which also has BSL-3 and -2 labs, is registered to work with select agents.

The institute's BSL-4 facility was constructed in 1999 and became operational in March 2000. BSL-4 labs are the highest level of containment and are used for research involving the most deadly of pathogens, which have no cures. BSL-4 labs have safety features that include scientists wearing spacesuit-like full-body protective gear with filtered air supplies.

In response to questions from USA TODAY, the institute said its scientists work to develop vaccines and therapies against viral pathogens. "Scientists in the BSL3 laboratory study pathogens such as HIV, West Nile virus, Bacillus anthracis (anthrax) and Yersinia pestis (plague) among others. The BSL4 laboratory is used to study pathogens for which there is currently no vaccine and no cure available. In the BSL4 laboratory we study such pathogens as Ebola virus, Marburg virus, Lassa Fever virus, Sudan virus, and SARS," the institute said in an email.

As a private organization, the institute is not directly subject to state or federal open records laws. It provided copies of its "Recombinant DNA Committee" meeting minutes to USA TODAY, as it is required under the NIH Guidelines as a condition of federal funding. The institute had no incidents reportable to the National Institutes of Health during 2012 through late 2014, said Robert Davey, chairman of the institute's Institutional Recombinant DNA and Nucleic Acids

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May 28, 2015

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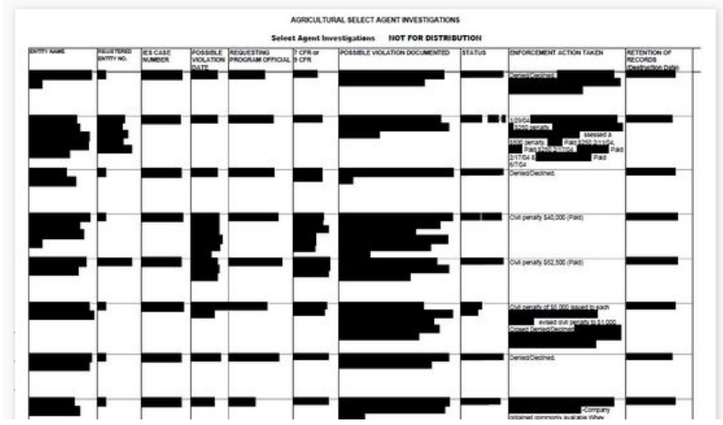
http://www.usatoday.com/story/news/2015/05/28/labs-fight-for-secrecy/26530719/


AGRICULTURAL SELECT AGENT INVESTIGATIONS

Select Agent Investigations NOT FOR DISTRIBUTION

ENTITY NAME	REGISTERED ENTITY NO.	IES CASE NUMBER	POSSIBLE VIOLATION DATE	REQUESTING PROGRAM OFFICIAL	7 CFR or 9 CFR	POSSIBLE VIOLATION DOCUMENTED	STATUS	ENFORCEMENT ACTION TAKEN	RETENTION OF RECORDS Destruction Date
[redacted]								Denied/Declined.	
								[redacted]	
								Civil penalty $40,000 (Paid)	
								Civil penalty $52,500 (Paid)	
								[redacted]	
								Denied/Declined.	
								[redacted]	

The USDA, citing a 2002 bioterrorism law, redacted most of the information in a spreadsheet about enforcement actions taken against laboratories that have violated regulations for working with select agent pathogens.

Universities, feds fight to keep lab failings secret

Alison Young and Nick Penzenstadler, *USA TODAY*

Transparency is an important cornerstone in maintaining public trust in biological research, says the National Institutes of Health, which has issued guidance to laboratories that receive federal funding. While many research organizations answered USA TODAY's questions and provided basic records about their biosafety committees' work, dozens of others were not so forthcoming.

Some ignored information requests or attempted to charge hundreds of dollars in fees for records they are required to make public as a condition of their federal research funding. Others sought to conceal information about the pathogens they experiment with, lab mistakes or disciplinary actions taken by federal regulators. One lab even lobbied its state legislature for a bill to exempt its research records, citing USA TODAY's request for its biosafety records.

Several labs claimed that bioterrorism laws prohibited them from releasing any information about their work with pathogens designated as select agents — the regulatory term for viruses, bacteria and toxins that have the potential to be used as bioterror weapons. And many persisted in these claims even after reporters pointed out the labs' own press releases, websites and research papers touting their work with these same pathogens.

Regulators from the Federal Select Agent Program told USA TODAY there are no rules or laws restricting labs from discussing the type of select agent work they do or the names of the pathogens involved. The only prohibitions involve specific information about security measures — such as locations of keys or security codes.

"With the exception of specific security information (such as IT system passwords, key locations and lock combinations), the select agent regulations place no restrictions on the releasing [of] information related to select agents or toxins by regulated entities," said Jason McDonald, a spokesman for the Centers for Disease Control and Prevention, which co-runs the Federal Select Agent Program with the U.S. Department of Agriculture.

At the USDA, Freeda Isaac, director of Agriculture Select Agent Services, said in a statement: "The CDC and APHIS Federal Select Agent Program has not instructed entities to withhold select agent information from the public."

Last November, the NIH issued a memo to labs reminding them of the importance of transparency and that the names of pathogens or the principal scientists investigating them are "not generally considered private or proprietary" information to be withheld from the public. The NIH issued previous guidance to labs encouraging them to post their Institutional Biosafety Committee records on their websites, though USA TODAY encountered only a few that do this.

Noting information requests being filed by USA TODAY Network reporters, some biosafety officials from major research organizations last November discussed how they find public requests for biosafety information to be burdensome, questioned the qualifications of the public to

review such records and indicated that charging fees may be a way to address their concern about proliferation of public review requests, according to a discussion on the listserv of the American Biological Safety Association.

Here are some labs and agencies where reporters encountered significant transparency issues:

Centers for Disease Control and Prevention; Atlanta and Fort Collins, Colo.

For nearly three years, USA TODAY has been unable to obtain key records about safety and security issues involving high-containment labs operated by the Centers for Disease Control and Prevention.

In June 2012, USA TODAY reported on leaked internal records and emails showing the CDC's labs in Atlanta had experienced significant failures of laboratory airflow systems used to contain pathogens, as well as repeated security lapses in areas where dangerous viruses and bacteria are kept. That same month, the newspaper filed requests under the federal Freedom of Information Act (FOIA) seeking additional records relating to airflow incidents in the agency's BSL-3 and BSL-4 labs; another request sought records of security incidents in a key Atlanta lab building.

The CDC, despite a history of lab safety issues, in 2012 denied USA TODAY's request that the agency search for and release the records on an expedited basis. In August 2014, the agency's FOIA office reversed its position and granted the requests expedited processing status after USA TODAY pointed out that the CDC's most recent lab safety lapses with anthrax demonstrated the public's need to know about biosafety at the agency.

Yet months continued to pass without the release of any records. Late last year, the CDC finally provided an estimated release date for the airflow and security records: Dec. 20, 2015.

Federal agencies often cite backlogs for delays in processing FOIA requests. The CDC reports that its average processing time is 153 days for a "complex" request and 47 days for a "simple" request. The CDC says it handled "expedited" requests in an average of 37 days — with 51 days being the "highest number of days" needed for expedited requests processed during fiscal year 2014, according to the agency's FOIA report.

While those two requests have been pending the longest, the CDC has also been slow to release other lab safety records to USA TODAY or has redacted key information from documents it has made public. Some examples:

• The CDC has not released any reports of incidents at its labs in Atlanta and Fort Collins, Colo., even though the agency said it would process the request on an "expedited" basis. USA TODAY requested the records, covering the period from 2013 through the present, on Jan. 6, 2015.

• The CDC in February 2015 denied USA TODAY's request for a copy of the initial, internal incident reports about a serious lab accident just before Christmas in which a worker was potentially exposed to live Ebola virus. The CDC cited the 2002 bioterrorism law as prohibiting release of the record, and instead directed the newspaper to a report of the incident the agency wrote for public distribution that it posted on its website.

• The CDC also serves as a regulator of other public and private labs that experiment with certain risky pathogens deemed to be potential bioterror agents. In September 2014, USA TODAY requested copies of records relating to enforcement actions the CDC had taken against the labs it oversees. On Jan. 13, 2015, the CDC released 11 pages of records about labs suspended or terminated from the program, but — citing provisions from the 2002 bioterrorism law —– removed the names of the labs it had sanctioned. An attorney for USA TODAY has appealed.

Colorado State University; Fort Collins, Colo.

Colorado State initially tried to charge $340 for copies of its Institutional Biosafety Committee minutes and related incident reports — and it blacked out the names of certain pathogens involved in research and mishaps.

"You really think $340 is excessive? Yikes," Linda Schutjer, a senior legal counsel for the university, wrote in a Nov. 19, 2014, email after USA TODAY objected to the fee as excessive. Schutjer said it took the university 17 hours to gather and review the records, even though it is required under the NIH Guidelines to make them available to anyone who asks as a condition of its federal research funding. After a series of emails, the university waived the fees.

But when the university released the records, USA TODAY discovered the names of many pathogens had been blacked out. The newspaper again filed a series of objections with the university, noting that Colorado State publicizes on its website that its scientists work with what appeared to be many of the redacted pathogens.

The university, in a Nov. 21, 2014, email, said it redacted names of select agents because of "security concerns" and that the decision to do this was based on consultation with "an expert" at the CDC.

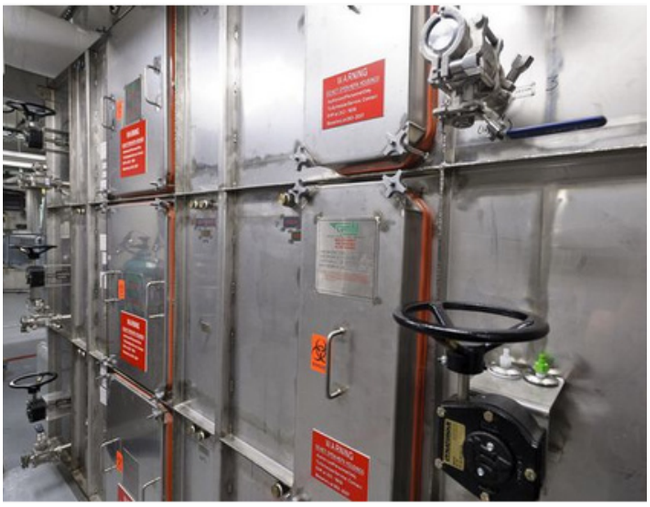
After USA TODAY shared McDonald's statement with the university and said the newspaper would be filing a formal complaint with the NIH alleging violations of the transparency conditions of the university's federal research funding, Schutjer on Dec. 4, 2014, released another set of records that restored names of the pathogens.

University of Wisconsin; Madison, Wis.

University officials provided 420 pages of documents at no charge to USA TODAY. Shortly after the request was filled, university officials pointed to the process as grounds for a new state law that would restrict access to records of university research until that information is published or patented.

Gov. Scott Walker's 2015-17 budget proposed the law, which is similar to 24 other states' exempting university research from records release rules. UW made two prior attempts at passing the law in 2013 and 2014.

A UW spokesman called USA TODAY's request, "a very significant burden" and told a Wisconsin-based reporter



A ventilation system designed to filter the building's air supply through a series of HEPA filters is seen during a tour of the Influenza Research Institute at the University of Wisconsin-Madison on Feb. 13, 2013.

that it "consumed much of one our employee's time for almost three-and-a-half months" because of the painstaking redactions.

However, the records are required to be made public as a condition of federal research funding, so the university spokesman acknowledged the law change would not alleviate the burden. The university also said it could not point to a specific instance of lost intellectual property or misappropriated research due to the existing state records requirements. In April, a top legislative committee removed the item from the budget proposal.

University of Massachusetts; Worcester, Mass.

The University of Massachusetts initially tried to charge $541.50 to release copies of its Institutional Biosafety Committee records, which are required to be made public under the NIH Guidelines as a condition of federal research funding.

Despite objections filed with the medical school that the fees were excessive, Associate Vice Chancellor James Healy said that they were not a deterrent to access and that the university deliberately used the lowest-paid employee to review and redact the records. The school provided a list of six individuals who needed to review the records.

One of those included the top Institutional Biosafety Committee member who would have been paid $60 per hour. After USA TODAY filed a complaint with the National Institutes of Health about excessive fees, the medical school provided the records at no charge.

The Scripps Research Institute; La Jolla, Calif., and Jupiter, Fla.

The institute redacted information from its biosafety committee minutes and incident reports before providing them to USA TODAY in December 2014. The names of pathogens, the topics of research, and information about safety concerns are among the information blacked out from the records.

In an email, Scripps attorney Kevin Cahill said the information was removed because it contained such things as "trade secrets, unpublished scientific hypotheses and research strategies, descriptions of experiments, proprietary methodologies, and materials and other confidential commercial or business information."

In January 2015, USA TODAY filed an appeal with the NIH, alleging that Scripps was in violation of the transparency requirements of its federal research funding and noted that the organization posts information on its website disclosing the research areas of scientists whose information was removed from the records. The appeal is still pending.

Lawrence Livermore National Laboratory; Livermore, Calif.

The lab's biosafety committee minutes, released under the federal Freedom of Information Act, indicate work in recent years with ricin, anthrax and MERS. But the minutes are often written in a way that makes them difficult to decipher without access to other documents that weren't publicly released.

For example, minutes from a June 10, 2014, meeting indicate discussion of a new application for research involving "Genetic characterization of risk group 3 viruses." But almost nothing is disclosed in the minutes about the substance of the project. The minutes say: "A review of the new project was given by the RI. The following changes were requested" and then it lists four changes that reference a document that wasn't released. Those changes say things such as "A.2.9 add isolates and source," and "A.3.1 change viral to MERS" and "A.7.3 add language that materials will be shipped from the university in Trizol."

Rush University; Chicago

The USA TODAY Network filed a request for Rush University's institutional biosafety committee meeting minutes and NIH-reported lab incidents on Nov. 11, 2014. The request was not answered and university officials did not respond to repeated requests for updates.

USA TODAY filaed a complaint with the NIH in April 2015, alleging violations of the transparency requirements of federal research funding. The university promptly provided the records a week later. John Pontarelli, the university spokesman, said there was a misunderstanding about which records were requested.

U.S. Army Medical Research Institute of Infectious Diseases; Fort Detrick, Md.

The lab complex, known as USAMRIID, released nearly 300 pages of reports involving incidents at its labs during 2012, 2013 and 2014 — including dozens of incidents where full-body protective suits developed holes while scientists were working in biosafety level 4 labs. The Army redacted the names of workers, but also redacted significant sections

The U.S. Army Medical Research Institute of Infectious Diseases is the Army's biological warfare research facility.

of information about the nature and the extent of their exposures and the types of pathogens involved in the mistakes. In its response to USA TODAY's FOIA request, the Army said the information was being withheld because it presented a "clearly unwarranted invasion of personal privacy."

University of Kansas

The University of Kansas in Lawrence initially tried to charge $99 and the KU Medical Center in Kansas City initially tried to charge $295 for two sets of Institutional Biosafety Committee records, which are required to be made public under the NIH Guidelines as a conditional of federal research funding.

Despite objections filed with the two campuses that the fees were excessive, records custodian Debra Brogden said they were justified. After USA TODAY filed a complaint with the National Institutes of Health about the excessive fees, the university reduced its fee to $90 for both campuses.

When the university finally released the records in May 2015, it turned out that minutes from a single biosafety committee covered both campuses, and there were only six pages that appeared to be specific to the Lawrence campus, which had sought to charge $99.

The released records were heavily redacted. NIH Guidelines call for minutes to be "judiciously" redacted only for certain security and proprietary information. USA TODAY has filed a second complaint with the NIH about the redactions, which was pending at the time of publication.

University of Hawaii-Manoa; Honolulu

Although the University of Hawaii-Manoa released redacted versions of its biosafety committee minutes and incident reports to USA TODAY, it refused to release any records about enforcement actions taken against its labs for violations of federal rules for working with pathogens that are potential bioterror agents. The university cited the 2002 federal bioterrorism law among its reasons for refusing to release the records about its labs being put by regulators into performance improvement program. USA TODAY has appealed the denial to Hawaii's Office of Information Practices.

In response to USA TODAY's appeal, the university told the appeals office: "We do not believe entering into the program is an embarrassment, we think it should be showcased, but that would be improper because as participants in the Federal Select Agent Program, we are obligated to keep this information private." The university also told the appeals office it "has been an exemplary participant in the Federal Select Agent Program."

According to the CDC, labs are put into the performance improvement program for "repeated failure to correct past observation, biosafety and security concerns" or for failures to comply with certain security requirements.

In a separate letter to Hawaii's information practices office, university chancellor Robert Bley-Vroman said it is critical to keep the disciplinary records secret: "We believe that release of this information would present a danger to both national security and the health and welfare of residents of Hawaii."

In the biosafety committee minutes the university released to USA TODAY, it has redacted information that appears to involve its regulatory problems with the Federal Select Agent Program.

University of Nebraska, Lincoln, Neb.; University of Nebraska Medical Center, Omaha

The university initially sought to charge $540 to provide USA TODAY copies of biosafety committee minutes and NIH-reported incident records for the medical center in Omaha and for labs on its main campus in Lincoln.

After USA TODAY objected that the charges were excessive and not allowable under the transparency requirements of the NIH Guidelines, the university waived the fees.

The university said that although it still believed the fee "is not unreasonable or overly burdensome," it would "make an exception to its ordinary practice and will not charge for the costs of providing the requested minutes and reports. Please note that this exception is not a waiver of the University's right to charge an amount sufficient to cover the costs of providing documents in response to public records requests in the future," wrote Erin Busch, director of university records and associate general counsel.

Some sections of the minutes are redacted in their entirety. In an email, Busch said the redactions were done for security reasons or because the content contained "academic and scientific research work which is in progress and unpublished and other proprietary or commercial information which if released would give advantage to business competitors and serve no public purpose."

Wadsworth Center of the New York State Department of Health; Albany, N.Y.

The center provided copies of its Institutional Biosafety Committee's meeting minutes on Jan. 28, 2015 — only after USA TODAY filed a formal complaint with the National

Institutes of Health, which requires entities receiving certain federal research funding to provide the records to the public on request. USA TODAY had sought the records since Nov. 5, 2014.

Plum Island Animal Disease Center, Plum Island, N.Y.

The Department of Homeland Security, which runs the center, initially refused to release names of certain pathogens that were involved in lab accidents, deleting them from records released in response to a FOIA request from USA TODAY. The department said the 2002 bioterrorism law prohibited their disclosure.

"After further review of these records, we have determined that our withholding of information pursuant to FOIA exemption (b)(3) Public Health Security and Bioterrorism Preparedness and Response Act of 2002 also known as the Bioterrorism Act was asserted in error." Many other redactions remain in the records.

University of Washington; Seattle

USA TODAY faced a series of bureaucratic delays in its efforts to review biosafety committee minutes from the University of Washington.

The newspaper filed a written request in October 2014 seeking copies of its biosafety committee minutes and any incident reports reported to the NIH. The request specified that the records were being sought under the transparency requirements of the NIH Guidelines, a key document labs must comply with as a condition of their federal research funding.

In emails over three months, a top research compliance official at the university told USA TODAY the request was being worked on. "Please rest assured that we are not ignoring your request," Joe Giffels, associate vice provost for research compliance, wrote in a Nov. 24, 2014, email.

After USA TODAY continued to seek updates on when the records would be released, Giffels sent emails in late January 2015 saying the newspaper would need to refile its request. "Please note that your request should state that you wish to receive the records under the Washington State Public Records law (not that you wish to receive them under NIH guidelines)," he wrote.

USA TODAY had told the university in previous emails that it was allowed to process the request under its state open records law, so long as the release of the records complied with the possibly greater transparency required by the NIH Guidelines.

USA TODAY filed a formal complaint with the NIH on Jan. 23, 2015, detailing the university's refusal to process the 4-month-old document request. On Jan. 27, 2015, the university agreed to release the records.

Officials at the NIH said they contacted the university "for an explanation of why this request took so long to fulfill. The University of Washington attributed this delay to a miscommunication regarding whether you consented for the University to process this request through the Washington State Public Records Act. The University of Washington also detailed to us the mitigation measures they are taking to avoid such delays in the future. You may also wish to know that in an effort to be more transparent, the University of Washington has begun posting its 2014 and 2015 IBC meeting minutes on a publicly available institutional website," according a letter the NIH sent to USA TODAY in February 2015.

George Mason University; Manassas, Va.

George Mason University initially sought to charge USA TODAY $167.65 for copies of its Institutional Biosafety Committee minutes and NIH-reportable incident records, which it is required to make public as a condition of its federal research funding. When USA TODAY objected to the fee as excessive for just 114 pages of records and asked for an itemized accounting, the university sent a copy of handwritten notes someone had written on lined paper that claimed even higher costs to release the records: $422.61.

The bulk of that cost involved two highly paid employees spending five hours each to review the records before release, the record said. A third employee spent two hours on the records, the university's breakdown said.

When USA TODAY asked for the dates and times these long reviews occurred, the university said the employees didn't log their time. However the university told USA TODAY it was reducing its fee to $100.59 because it had learned that some of the charges involved the employees meeting with each other about the newspaper's request.

USA TODAY filed a formal appeal with the NIH on Jan. 9, 2015, saying the fees were excessive and violated the NIH Guidelines' transparency requirements. Five days later, the university sent an email saying it was reducing its charges to $25.

"The University would like to note that this is a one-time reduction in cost, and that the cost of future FOIA requests to the University will be calculated according to Virginia law," wrote Elizabeth Woodley, the university's FOIA compliance officer.

The reduction was a result of USA TODAY's appeal to the NIH. "Yes, after consultation with NIH, we decided to further reduce the charge," Woodley said in another email.

Virginia Commonwealth University; Richmond, Va.

Virginia Commonwealth University initially sought to charge USA TODAY $239.09 for copies of its Institutional Biosafety Committee minutes and NIH-reportable incident records, which it is required to make public as a condition of its federal research funding. When USA TODAY objected to the fee as excessive and asked for an itemized accounting, the university sent an invoice that called for review by three workers making $23.67 to $36.05 per hour.

"Our calculation was done in good faith and without gratuitous expenses calculation," wrote Leila Ugincius, a university spokeswoman. "I certainly appreciate your concern about a charge, but I hope you will appreciate that as a public research university we get multiple requests for documents each week."

After USA TODAY filed a complaint with the National Institutes of Health, the university "reviewed and reconsidered the original charge" and provided the 134 pages of records for $45. Ugincius argued the time involved to access, copy and redact the documents "easily exceeded that amount."

U.S. Department of Agriculture, Animal and Plant Health Inspection Service

The USDA, along with the CDC, jointly runs the Federal Select Agent Program, which inspects and regulates labs that do research with risky pathogens that have the potential to be used as bioterror weapons or pose significant threats to public health or agriculture.

As USA TODAY sought records and asked questions about USDA's overall select agent enforcement activities, the agency gave a series of conflicting answers over the course of several months.

In October, in response to a public records request for enforcement documents, the USDA said it had no records because it had never needed to impose any fines or suspend or terminate any labs from its part of the select agent program. In November, Isaac, the USDA's select agent director, emailed a statement saying the same thing: "To date, we have not been in a position where we needed to levy a monetary penalty or revoke an entity's registration in full. Instead, we use various corrective actions, including Performance Improvement Plans, suspension of portions of an entity's registration, and letters of warning," Isaac said.

By December, USDA said it had given USA TODAY wrong information, and that the agency had actually conducted 48 enforcement investigations since 2003 that had resulted in $116,750 in fines. The agency, in response to a second public records request, said its enforcement records about these actions are required to be kept secret because of the 2002 bioterrorism law.

USDA did release a spreadsheet it says documents its actions, but the agency redacted almost all the information on it: lab names, violation types, dates. Only a few references to warning letters and fines were spared the agency's black marker.

The USDA also denied a separate FOIA request seeking copies of letters to labs notifying them they were being put in the select agent program's performance improvement program and that explain what violations the labs committed. In a March 2015 letter, USDA said it had identified 479 pages of records. "Unfortunately, we are withholding all 479 pages," the agency said, citing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

USA TODAY has appealed the agency's refusal to release the information about enforcement actions and labs on PIPs.

University of California-Irvine; Irvine, Calif.

The university took three months to provide USA TODAY with copies of biosafety committee minutes and records of NIH-reportable incidents that are required to be made available on request as a condition of federal funding. NIH officials have suggested labs even post the records on their websites, though USA TODAY found that few labs do this.

When the university released its records on Feb. 4, 2015, the most recent records it provided were from a meeting that had occurred five months earlier in September 2014.

After USA TODAY filed a formal complaint with the NIH about the university's processing delays and the lack of recent records, the university on Feb. 28, 2015, released additional safety records covering October 2014 through January 2015. NIH officials, in a letter to USA TODAY, said that the university will be taking actions "to avoid such delays in the future."

Louisiana State University AgCenter; Baton Rouge, La.

LSU provided USA TODAY with copies of its biosafety committee records, but spent months denying reporters access to its records about a serious 2008 lab incident in which a bioterrorism bacteria used in experiments infected a cow in a nearby disease-free herd. An attorney for the university cited select agent regulations among the reasons for denying the newspaper's request under Louisiana's state open records law — and repeated appeals for reconsideration. After USA TODAY received documents about the incident from state and federal agriculture officials in December 2014, the university released the records the newspaper requested in August 2014.

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Netanyahu visit exposes partisan rifts

Over 2 dozen Dems plan to skip speech

Gregory Korte
USA TODAY

WASHINGTON The first time Benjamin Netanyahu addressed a joint meeting of the United States Congress, he called it "a tribute to the unshakable fact that the unique relationship between Israel and the United States transcends politics and parties, governments and diplomacy."

That was in 1996, three weeks after being elected Israeli prime minister. Tuesday, he returns for his third speech to Congress, two weeks before facing re-election.

This time, before he delivers a word of his speech, his appearance is revealing partisan and diplomatic rifts in that unique relationship. More than two dozen Democrats are boycotting his speech, as Republicans have accused President Obama of not being supportive enough of Israel.

Obama says he will not receive Netanyahu at the White House before the speech — as is customary for these occasions — because it's too close to the parliamentary elections in Israel March 17. "The U.S.-Israeli relationship is not about a particular party," he said.

ISRAELI GOVERNMENT PRESS OFFICE
Benjamin Netanyahu and wife Sarah leave Israel for the U.S. on Sunday.

Republicans have used the speech to highlight what they say is a "real conflict" between the two leaders, despite assurances by both that they continue to have a good working relationship.

"The animosity between the White House and the prime minister is no secret in this town. But they've certainly made it worse in the last five weeks," said House Speaker John Boehner, R-Ohio, on CBS' *Face the Nation* Sunday. His invitation to Netanyahu bypassed the White House and State Department and resulted in near-daily headlines in the U.S. and Israel for more than a month.

Beyond the personality conflict lies a disagreement over how to deal with Iran's nuclear program. Many in Congress — egged on by Netanyahu — want to tighten sanctions against Iran in an effort to get a better deal. The White House says that course would unnecessarily provoke a military confrontation with Iran.

▸ AIPAC focus on unity, 3A

NEWSLINE

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USA SNAPSHOTS©
Rating on 'feeling thermometer'
Americans' warmth of feeling for countries on a 0-100 scale, where 0 is very cold, 50 is neutral and 100 is very warm:

Highest	
Canada	79
Great Britain	74
Middle	
Israel	59
Turkey	50
Lowest	
Iran	27
North Korea	23

Source 2014 Chicago Council on Global Affairs survey of 2,108 adults
ANNE R. CAREY AND A. GONZALEZ, USA TODAY

MOSCOW MURDER 'CROSSES ALL THE LINES'

People march in memory of opposition leader and former deputy prime minister Boris Nemtsov on Sunday in Moscow.

Thousands take to streets to mourn opposition leader

Anna Arutunyan
Special for USA TODAY

MOSCOW Tens of thousands of people marched in the sleet Sunday to mourn slain Russian opposition leader Boris Nemtsov, gunned down just steps away from the Kremlin.

"I wasn't planning to go to the rally initially," Tatyana Shakhova said. "But (Nemtsov's killing) crosses all the lines. I have no faith that the organizers of the murder will be found."

Nemtsov's death is a "critical turning point for Russia," said a rally organizer, Gennady Gudkov, a former member of parliament who was kicked out in 2012 because of his opposition activity.

Russian President Vladimir Putin, whom Nemtsov staunchly criticized in the past, condemned Friday's killing and took personal control of the investigation. Russia's Investigative Committee on Sunday pledged to award 3 million rubles (about $50,000) for information on Nemstov's death.

Secretary of State John Kerry said the United States had no intelligence on who was behind the shooting. "We hope there will be a thorough, transparent, real investigation, not just of who actually fired the shots, but who, if anyone, may have ordered ... or been behind this," Kerry said on ABC's *This Week*.

Up to 100,000 people turned out for the march, Gudkov said.

The march was initially planned as a protest against Russia's involvement in Ukraine. Nemtsov, 55, who reportedly had been gathering evidence that Moscow was arming pro-Russian rebels, was to speak at the rally.

USA TODAY INVESTIGATION

Deadly bacteria leaked from lab near New Orleans

Alison Young
USA TODAY

Investigators unsure how exposure occurred

Burkholderia pseudomallei is spread through direct contact with contaminated soil and water.
OREGON STATE PUBLIC HEALTH LABORATORY VIA CDC

A dangerous, often deadly, type of bacteria that lives in soil and water has been released from a high-security laboratory at the Tulane National Primate Research Center in Louisiana. Officials say there is no risk to the public. Yet despite weeks of investigation by multiple federal and state agencies, the cause of the release and the extent of the contamination remain unknown, according to interviews and records obtained by USA TODAY.

The incident has raised concerns that bacteria from the lab may have contaminated the facility's grounds, and although initial, limited tests didn't detect it, some officials are pressing behind the scenes for more action, records show. The safety breach at Tulane's massive lab complex 35 miles north of New Orleans is the latest in a recent series of significant biosafety accidents at some of the most prestigious laboratories in the country where research is performed on bacteria and viruses that are classified as

▸ STORY CONTINUES ON 2A

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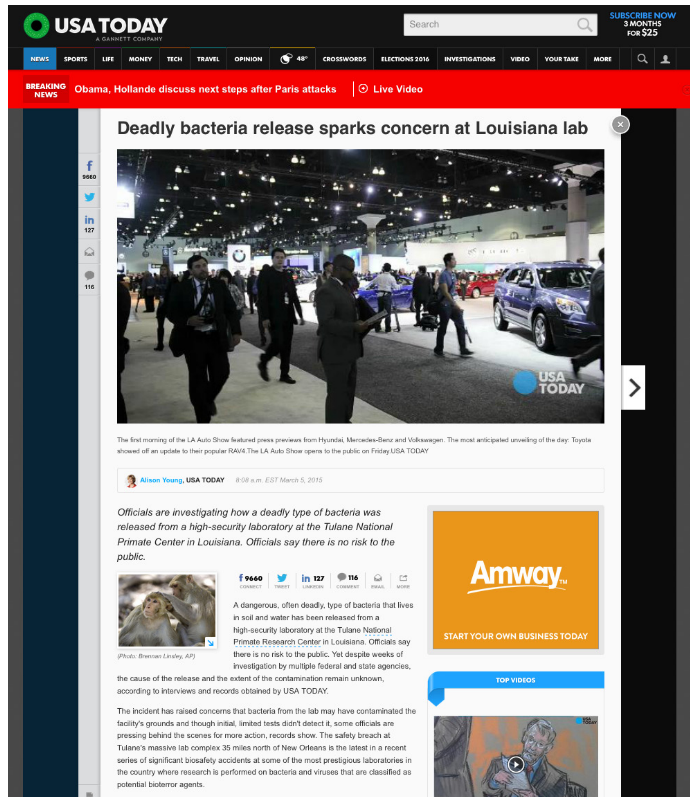

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Deadly bacteria release sparks concern at Louisiana lab

The first morning of the LA Auto Show featured press previews from Hyundai, Mercedes-Benz and Volkswagen. The most anticipated unveiling of the day: Toyota showed off an update to their popular RAV4.The LA Auto Show opens to the public on Friday.USA TODAY

Alison Young, USA TODAY 8:08 a.m. EST March 5, 2015

Officials are investigating how a deadly type of bacteria was released from a high-security laboratory at the Tulane National Primate Center in Louisiana. Officials say there is no risk to the public.

(Photo: Brennan Linsley, AP)

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March 1, 2015

http://www.usatoday.com/story/news/2015/03/01/tulane-primate-bio-lab-bacteria-release/24137053/

Deadly bacteria release sparks concern at Louisiana lab

Alison Young, *USA TODAY*

A dangerous, often deadly, type of bacteria that lives in soil and water has been released from a high-security laboratory at the Tulane National Primate Research Center in Louisiana. Officials say there is no risk to the public. Yet despite weeks of investigation by multiple federal and state agencies, the cause of the release and the extent of the contamination remain unknown, according to interviews and records obtained by USA TODAY.

Burkholderia pseudomallei is spread through direct contact with contaminated soil and water.

OREGON STATE PUBLIC HEALTH LABORATORY VIA CDC

The incident has raised concerns that bacteria from the lab may have contaminated the facility's grounds and though initial, limited tests didn't detect it, some officials are pressing behind the scenes for more action, records show. The safety breach at Tulane's massive lab complex 35 miles north of New Orleans is the latest in a recent series of significant biosafety accidents at some of the most prestigious laboratories in the country where research is performed on bacteria and viruses that are classified as potential bioterror agents.

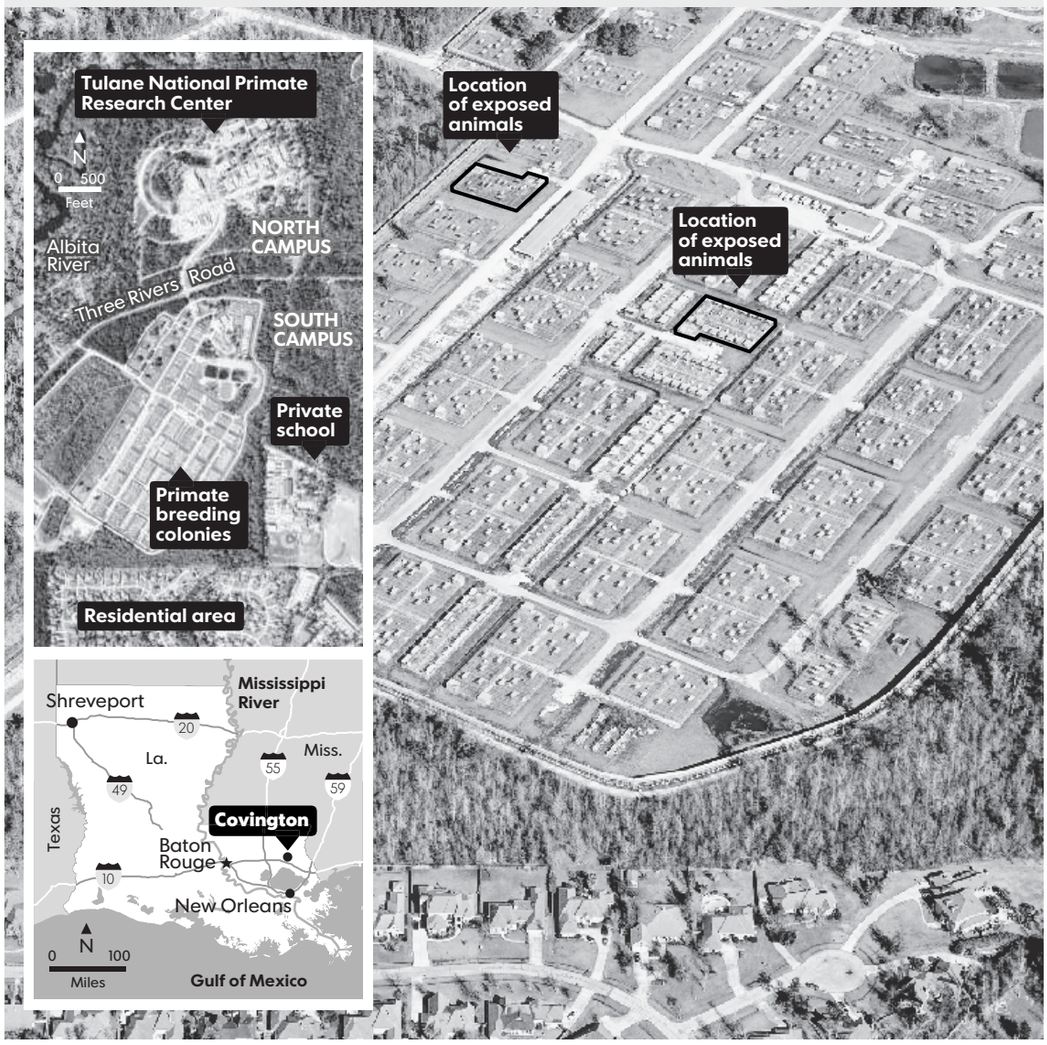
"The fact that they can't identify how this release occurred is very concerning," said Richard Ebright, a biosafety expert from Rutgers University in New Jersey, who testified before Congress last summer in the wake of lab incidents at federal agencies involving anthrax, smallpox and a deadly strain of avian influenza.

The Tulane incident involves the release, possibly in November or earlier, of a bacterium called Burkholderia pseudomallei, which is primarily found in Southeast Asia and northern Australia and is spread to humans and animals through direct contact with contaminated soil and water where it can live and grow. Tulane's research, which has been halted by federal officials, was part of an effort to develop a vaccine against the bacteria. It was conducted mostly with rodents inside a secure biosafety level 3 laboratory with multiple layers of safety equipment that were supposed to ensure the pathogen couldn't get out.

Yet at least four monkey-like rhesus macaques — that were never used in the experiments and were kept in large outdoor cages in another part of the 500-acre facility — have been exposed to the bacteria, initial tests have found. Two of the macaques became ill in November; both eventually had to be euthanized. Meanwhile, a federal investigator, who became ill 24 hours after visiting the facility in January as part of the ongoing release investigation, has also tested positive for exposure to the bacteria — though

TULANE PRIMATE CENTER, COVINGTON, LA.

Research with Burkholderia pseudomallei was done in a secure biosafety level 3 lab in a building on the North Campus. Officials are investigating how four macaques kept in a breeding colony on the South Campus, not used in experiments, became exposed and whether soil and water have been contaminated with the bacteria.



Sources USA TODAY research, EPA soil sampling records, ESRI, Pictometry

ALISON YOUNG AND FRANK POMPA, USA TODAY

it remains unclear whether her exposure may have occurred during international travel and not at the lab.

"We're taking this extraordinarily seriously. It's very disturbing to us," said Andrew Lackner, director of the Tulane primate center. "Right from the beginning we've spent an enormous amount of time trying to figure out how this could have happened."

Lackner said the investigation so far indicates that the four macaques were exposed to the bacteria while being cared for in the complex's veterinary hospital and he emphasized that tests of 39 soil and 13 water samples from the center's grounds have not detected the presence of the bacteria.

"There has never been a public health threat," Lackner said.

Yet studies reviewed by USA TODAY indicate too few samples were taken to detect what can be an elusive bacterium. The Louisiana Governor's Office of Homeland Security and Emergency Preparedness, which is leading the joint federal-state response, expressed concerns about "whether the organism has escaped the compound and whether livestock and domestic animals are at risk," in a Feb. 20 letter from the state to the U.S. Environmental Protection Agency. The state provided a copy to USA TODAY on Friday.

The letter formally asked the EPA for help addressing potential soil contamination where sick macaques were housed, including with testing and assistance "to perform soil remediation in area(s) identified as high-risk as soon as possible to prevent further transmission/transference."

The primate center is located in Covington, La., near wetlands and a river, across the street from a school and close to a neighborhood.

Officials at state and federal agencies responded to some questions via e-mail but did not grant interviews. The Centers for Disease Control and Prevention, which is leading the investigation of the laboratory breach because the bac-

terium is classified as a potential bioterror agent, said its investigation is ongoing and that at this time "there is no known public health threat."

The U.S. Department of Agriculture, which is jointly investigating the lab breach with CDC, said in an e-mail: "USDA is still evaluating if a risk to Louisiana agriculture exists."

SICK MACAQUES SIGNAL A BREACH

The first indication of trouble came in early November, when Tulane staff discovered two sick macaques kept among 4,000 animals in a huge outdoor breeding colony on the compound's South Campus. The two sick animals lived separately in different chain-link enclosures that are among dozens of "field cages" on the campus. They were transported by van to the primate center's veterinary hospital in Building 21, about a five- minute drive away on the facility's North Campus where several buildings with labs and offices are located.

Initially, there was no reason to be concerned, Tulane officials said. "Animals get sick all the time, just like people do," said Lackner, the primate center director.

Yet despite extensive clinical workups, including exploratory surgeries, a diagnosis was initially elusive. One of the macaques became so ill it had to be euthanized on Nov. 26. The other animal initially appeared to recover, but relapsed and was euthanized Feb. 19.

After a series of increasingly specific tests on the two animals indicated that they may be infected with Burkholderia pseudomallei, Tulane sent specimens to CDC's labs, which confirmed the diagnosis. "Things really ratcheted up after that," Lackner said.

By mid-January, additional testing by CDC scientists determined that the strain of bacteria that sickened the two macaques was identical to the strain Tulane was using in its research in a highly secured lab elsewhere on the property. The strain — known as Strain 1026b — was originally recovered from a rice farmer sickened in Thailand in 1993, CDC told USA TODAY. Rice farming is a common way people are infected because the bacteria live in contaminated soil and water and can enter the body through cuts or sores on the skin.

With a lab release confirmed, CDC ordered Tulane's primate center to stop all research involving Burkholderia pseudomallei and all other pathogens that are classified as "select agents," the federal government's term for bacteria, viruses and toxins that pose significant threats to public health or agriculture and have the potential to be used as bioweapons.

The research will remain suspended until the lab breach investigation is completed and any problems are corrected, said the CDC, which jointly runs the Federal Select Agent Program with the USDA. About 10 research projects involving a variety of pathogens have been halted as a result, Lackner said.

Tulane's select agent labs were last inspected in December 2013, CDC said, and no significant problems were cited at that time. The primate center has never been suspended or subjected to regulatory enforcement actions before.

The diagnosis of Burkholderia pseudomallei infections outside Tulane's lab was of special concern because the two animals had been living in outdoor cages and the bacteria have the potential to establish colonies in soil and water — potentially contaminating their cages or spreading into the environment.

The state homeland security agency activated a command center to help coordinate a response. From Jan. 20-24 a team of federal investigators visited multiple locations on the primate center's campus seeking answers to what had happened.

Then, in a surprising development, a day after leaving the facility, one of the USDA select agent investigators became ill and was hospitalized. Results of a Feb. 6 blood test showed she had antibodies indicating a possible current or prior exposure to Burkholderia pseudomallei. She has since recovered from her illness.

Burkholderia pseudomallei can cause a potentially serious disease in people and animals called melioidosis, that has a wide range of non-specific symptoms, such as fever, headache, loss of appetite, muscle and joint pain, and infections are often mistaken for other diseases such as pneumonia or tuberculosis. The time between exposure to the bacteria and the development of symptoms can range from one day to many years, according to the CDC, though most human infections do not cause symptoms.

Several countries have studied using the bacteria as a bioweapon because strains can be obtained from the environment and engineered to be resistant to multiple antibiotics, according to the UPMC Center for Health Security, an independent biosecurity think tank.

In Thailand, where the bacteria is endemic, the fatality rate for patients with melioidosis is up to 50%; in Australia it can be up to 20%, according to published studies. Confirmed infections are relatively rare. There were 176 culture-confirmed cases of melioidosis in Australia's north Queensland during the 10-year period 2000-2009, according to that country's health department.

CDC officials noted that the USDA investigator had a history of international travel to an undisclosed region that could have been the source of her exposure. Blood tests so far show a stable immune response, indicating she likely was not exposed at Tulane, the CDC has said. But further testing is needed.

Richard Ebright, the Rutgers microbiologist and biosafety expert, is skeptical that the USDA investigator was exposed to the pathogen through travel rather than her job inspecting research laboratories. Select agent program inspectors, just like researchers working with these dangerous pathogens, should regularly have blood serum samples taken and stored so they can be checked if an exposure is suspected.

"They shouldn't even need to be speculating that this is probably a prior exposure," Ebright said. "If they don't have reference samples, it's a sign of gross negligence."

The USDA said it does not collect such samples from its select agent inspectors; the CDC says it stopped doing it a few years ago because it felt they weren't as useful as testing after an incident.

After the USDA investigator's potential exposure, federal officials returned to the primate center Feb. 9-12 to take an even closer look at the facility and its procedures, state records show.

By Feb. 25, ongoing tests had identified two additional animals from the outdoor breeding colony that had antibodies to Burkholderia pseudomallei, indicating they had been exposed even though they were not showing any signs of illness. Only two of the four exposed animals shared the same outdoor field cage, Lackner said.

But all four have one thing in common: All had been in the center's veterinary hospital around the same time, which has led CDC and Tulane to say the hospital is the leading suspect for where the animals were exposed to the bacteria.

Even though the two euthanized animals became ill while living outdoors, Lackner said they may have been sick with something else before going to the hospital and their weakened immune systems made them more susceptible to a secondary infection by the bacteria once there. The two other animals that weren't sickened but show signs of Burkholderia exposure were in the hospital because of injuries and not illness, he said.

While investigators suspect the hospital may be ground zero for the macaques' infections, there are no tests from surfaces or equipment in the hospital showing the bacteria was ever present there. It had been decontaminated before the location became a prime suspect.

SEARCHING FOR THE BREACH

The deadly bacteria should never have been in the hospital — or anyplace else where the outdoor macaques could have been exposed to it.

Burkholderia pseudomallei should only have been inside the specific Tulane lab that was doing vaccine development research.

That research was being conducted in a biosafety level 3 laboratory — the second highest containment level — with a wide range of high-tech safeguards, physical barriers and procedures that are supposed to ensure dangerous pathogens can't escape.

The lab, as Tulane describes it, is essentially a "box-within-a-box within a box." The research was being done in a completely contained lab under negative air pressure, inside Building 5. Air leaving the chamber passes through multiple HEPA filters before leaving the building.

Access to the BSL-3 lab is strictly controlled. To enter, staff must have an authorized access card and procedures call for employees to change into protective clothing and use personal protective equipment while in the laboratory. Contaminated gear can't leave a BSL-3 lab without being sterilized. Everything that goes in — cages, animal bedding, supplies — can't come out without being sterilized. Research animals that go into the primate center's BSL-3 labs do not come out alive and never go to the hospital, the center said.

The veterinary hospital, where the macaques may have been exposed, is in Building 21 about a five-minute walk from Building 5, according to Tulane. The breeding colony where they lived on the South Campus is about a five-minute drive, and access to the area is controlled with proximity cards and a double-fence and gate system. The individual field cages are locked.

So how did the bacteria get out of the lab?

"Human error is always the first explanation you should consider for a laboratory accident," Ebright said. "The easiest way to transfer something from one place where it's supposed to be, to another where it isn't supposed to be is by a worker moving from one place to the other."

Sloppy biosafety practices can result in pathogens being tracked out of labs on shoes, coats, gloves, hands or other materials that weren't properly sterilized before being removed, he said.

Federal officials did not provide any information on how they suspect the bacteria got out.

IS THE SOIL, WATER CONTAMINATED?

Despite the focus on the hospital, Louisiana officials are concerned about the potential for the bacteria to have contaminated soil or water on the primate center grounds, according to their Feb. 20 letter to the EPA.

Tulane officials emphasize that tests of soil, air and water have not detected the bacteria outside. And people who live nearby have been reassured by the test results to date.

However, it appears that far too few soil tests were taken to draw any conclusions. Studies have found that that Burkholderia pseudomallei is difficult to detect in contaminated soil without taking a large number of samples because the bacteria form colonies that are like invisible ant hills. They also aren't evenly distributed across an area. So unless a shovel is put in the right spot, the test will yield a false-negative result.

According to the EPA contractor's sampling plan and location report, a total of 39 soil samples were taken in a variety of locations on the primate center's grounds.

In field cage G12, described in the EPA report as the field cage of "an affected macaque," records show just four soil samples were taken. Tulane says its individual field cages are 100 feet by 200 feet — more than half the size of a football field.

Yet to detect this type of bacteria in a cage of this size, more than 100 samples would have been needed, according to a 2010 study of the bacterium's uneven distribution in soil in Thailand. The study recommends that a minimum of 100 sampling points should be taken for an area of land measuring about 98 feet by 98 feet.

EPA provided USA TODAY with a copy of the sampling plan and locations, but it gave little scientific justification for the number of samples done. In a series of e-mails last week, EPA deflected many of USA TODAY's questions and sought to distance the agency from the soil and water sampling plan — often referring the newspaper to state or CDC

officials. None of the agencies would provide answers to questions about the scientific basis for the sampling that was done or whether it was adequate to detect the bacteria if it is present outdoors.

When USA TODAY on Wednesday initially asked the EPA Region 6 office in Dallas about its soil sampling at the primate center, the agency said: "Tulane did the water and soil sampling." EPA press secretary Liz Purchia in Washington, in an e-mail to USA TODAY on Friday night, again re-emphasized that Tulane collected the samples.

But Tulane primate center officials said they lack the expertise to do soil and water sampling. For reasons that are unclear, Tulane says the EPA insisted that primate center staff collect the actual samples — but that the locations and numbers of samples was overseen by EPA team members who were looking over their shoulders.

Louisiana emergency response officials also appear to be having difficulty getting help from EPA. "It [has] come to our attention, that EPA requires a letter to ask for their active participation in this investigative process," wrote Kevin Davis, director of the Governor's Office of Homeland Security and Emergency Preparedness, in his Feb. 20 letter. "To this end, Louisiana is formally requesting EPA's assistance with the following" and he goes on to ask the agency to provide strategic direction and technical guidance to help develop additional sampling and soil clean-up plans for the primate center.

The EPA has not yet replied to Davis' letter, according to an e-mail late Friday afternoon from EPA Region 6 spokesman David Gray. The e-mail did address the soil sampling generally, saying it involved sending "rapid-response environmental samples to CDC for analysis" and that the number of samples was based on CDC's lab capacity. "EPA completed that work and demobilized on February 13," Gray said.

The EPA has provided Tulane with options for decontaminating potentially contaminated soil on the property. The agency has not made any recommendations, Gray said.

In addition to the soil tests, the EPA report shows 13 water samples were taken in adjacent wetlands, ditches and in the sewage- and stormwater treatment system areas, plus EPA did air sampling, although Tulane and others note that the bacteria isn't generally transmitted through the air. Some wipe samples from vans that transported exposed macaques also were tested. No bacteria were detected in any of the samples.

For now, Tulane is not planning to remove soil or fumigate the area. With no bacteria detected outdoors, the center sees "growing evidence that makes it increasingly unlikely that Burkholderia pseudomallei has been in our outdoor breeding colony," said Tulane spokesman Michael Strecker. Testing of the animals in the outdoor breeding colony, however, will continue.

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ONLINE: June 12, 2015
http://www.usatoday.com/story/news/2015/06/12/dugway-live-anthrax-shipments/71093540/

2B
USA TODAY — THE INDIANAPOLIS STAR SATURDAY, JUNE 13, 2015

NATION/WORLD

Ex-IMF chief acquitted of pimping

Strauss-Kahn says he didn't know women were prostitutes

'MANY ... WANTED TO PLEASE'

A drag queen performs during the 17th annual Tel Aviv Gay Pride Parade on Friday.

Gay pride alive, with limitations, in Israel

Tourists flood into Tel Aviv for week of culture, activities

Activists say Israel ... is by far the most progressive country in the Middle East and ahead of the U.S. in some areas.

Dominique Strauss-Kahn led the International Monetary Fund from 2007 to 2011.

USA TODAY INVESTIGATION

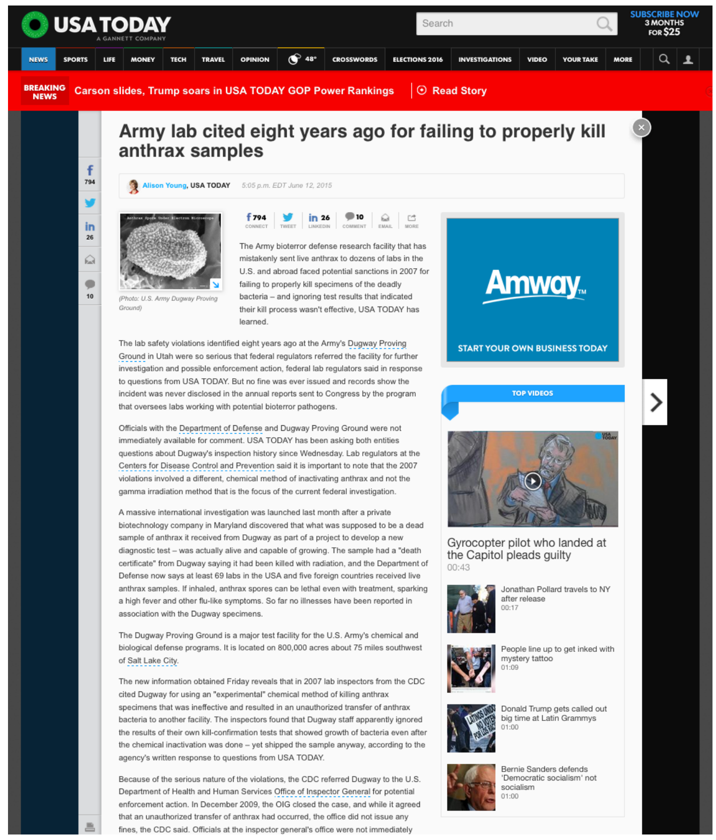
Lab cited in '07 for failing to kill anthrax

No action was taken against Army facility

Alison Young
USA TODAY

The Dugway Proving Ground is a major test facility for the U.S. Army's chemical and biological defense programs.

Corrections & Clarifications



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Army lab cited eight years ago for failing to properly kill anthrax samples

Alison Young, USA TODAY 5:05 p.m. EDT June 12, 2015

(Photo: U.S. Army Dugway Proving Ground)

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The Army bioterror defense research facility that has mistakenly sent live anthrax to dozens of labs in the U.S. and abroad faced potential sanctions in 2007 for failing to properly kill specimens of the deadly bacteria – and ignoring test results that indicated their kill process wasn't effective, USA TODAY has learned.

The lab safety violations identified eight years ago at the Army's Dugway Proving Ground in Utah were so serious that federal regulators referred the facility for further investigation and possible enforcement action, federal lab regulators said in response to questions from USA TODAY. But no fine was ever issued and records show the incident was never disclosed in the annual reports sent to Congress by the program that oversees labs working with potential bioterror pathogens.

Officials with the Department of Defense and Dugway Proving Ground were not immediately available for comment. USA TODAY has been asking both entities questions about Dugway's inspection history since Wednesday. Lab regulators at the Centers for Disease Control and Prevention said it is important to note that the 2007 violations involved a different, chemical method of inactivating anthrax and not the gamma irradiation method that is the focus of the current federal investigation.

A massive international investigation was launched last month after a private biotechnology company in Maryland discovered that what was supposed to be a dead sample of anthrax it received from Dugway as part of a project to develop a new diagnostic test – was actually alive and capable of growing. The sample had a "death certificate" from Dugway saying it had been killed with radiation, and the Department of Defense now says at least 69 labs in the USA and five foreign countries received live anthrax samples. If inhaled, anthrax spores can be lethal even with treatment, sparking a high fever and other flu-like symptoms. So far no illnesses have been reported in association with the Dugway specimens.

The Dugway Proving Ground is a major test facility for the U.S. Army's chemical and biological defense programs. It is located on 800,000 acres about 75 miles southwest of Salt Lake City.

The new information obtained Friday reveals that in 2007 lab inspectors from the CDC cited Dugway for using an "experimental" chemical method of killing anthrax specimens that was ineffective and resulted in an unauthorized transfer of anthrax bacteria to another facility. The inspectors found that Dugway staff apparently ignored the results of their own kill-confirmation tests that showed growth of bacteria even after the chemical inactivation was done – yet shipped the sample anyway, according to the agency's written response to questions from USA TODAY.

Because of the serious nature of the violations, the CDC referred Dugway to the U.S. Department of Health and Human Services Office of Inspector General for potential enforcement action. In December 2009, the OIG closed the case, and while it agreed that an unauthorized transfer of anthrax had occurred, the office did not issue any fines, the CDC said. Officials at the inspector general's office were not immediately

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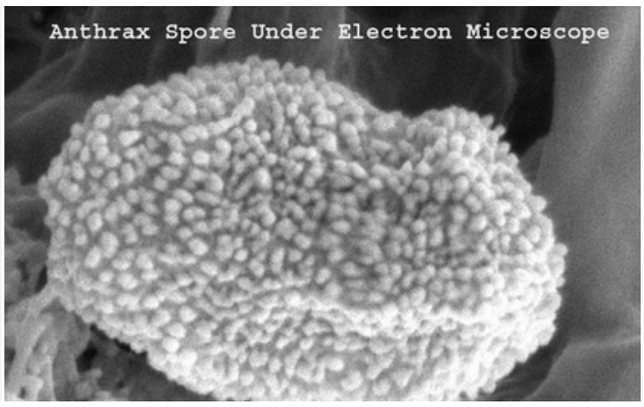

A spore of Bacillus anthracis, which causes anthrax, photographed under an electron microscope at the U.S. Army Dugway Proving Ground in Utah.

Army lab cited eight years ago for failing to properly kill anthrax samples

Alison Young, *USA TODAY*

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A live agent test chamber at the U.S. Army Dugway Proving Ground in Dugway, Utah. Federal officials are investigating how dozens of samples of live anthrax — that were supposed to have been killed by irradiation -- were sent from Dugway to labs across the country and abroad.

The CDC on Friday said: "It should be noted that this incident is not similar to the current investigation where Dugway was using an established irradiation protocol and no growth was observed following the gamma irradiation."

Yet there are similarities. The current anthrax situation involving Dugway shipping dozens of live anthrax samples that were supposed to be dead and, as in 2007, involves failures of the current inactivation process, as well as failures to recognize that it wasn't fully killing the bacteria and its hard-to-kill spores. The military has not answered USA TODAY's repeated questions about Dugway's protocols for killing anthrax and its procedures for conducting verification tests to ensure the process was consistently effective.

A May 29 CDC email obtained by USA TODAY indicates that the radiation process wasn't 100% effective. "We have concern that the inactivation procedures, when followed properly, are inadequate to kill all spores," wrote Daniel Sosin, deputy director of CDC's Office of Public Health Preparedness and Response in the email to state officials.

The CDC on Friday said the Dugway lab was currently using "a scientifically validated procedure" to inactivate anthrax bacteria, and provided a copy of a document that references a 1991 scientific paper that was the basis for Dugway's irradiation method. The select agent regulations require labs to develop biosafety plans that are adequate to address the risks posed by the specific pathogens they are authorized to possess – but leave it up to labs to pick their own methods of achieving safety. "There is no specific regulatory requirement for inactivation verification in the select agent regulations," the CDC said, but added it has issued guidance that notes the need to verify pathogens are killed.Inspectors verified that Dugway was doing sterility testing before issuing death certificates on samples, the CDC said.

Labs like Dugway that do research with anthrax and other potential bioterror pathogens are regulated by the Federal Select Agent Program, which is jointly run by the CDC and the U.S. Department of Agriculture. In the past year a series of high-profile incidents have occurred at labs overseen by the program, including mishaps at the CDC's own labs that have involved accidents with anthrax, Ebola and a deadly strain of bird flu. Last summer, an oversight subcommittee of the House Energy and Commerce Committee held a hearing on the CDC incidents. The recent anthrax mistakes involving Dugway Proving Ground have drawn questions from members of multiple Senate and House committees.

Much of the oversight of select agent labs is cloaked in secrecy, making it difficult to determine whether the current inspection and enforcement program is effective at ensuring safety, a USA TODAY Network investigation found last month. More than 100 labs working with "select agent" pathogens have faced enforcement actions since 2003, the newspaper revealed. Five labs have had "multiple referrals" for sanctions, two labs have been kicked out of the program and five others have been suspended from doing any work with these kinds of pathogens. But the CDC and USDA refuse to release the labs' names, citing a 2002 bioterrorism law they say requires the secrecy.

As a way of providing some oversight, Congress requires the Federal Select Agent Program to report each year on incidents with bioterror pathogens in regulated labs. Yet USA TODAY found the reports provide few details and only occasional vague information on a few serious incidents at unnamed labs. The reports, obtained under the federal Freedom of Information Act, do not include any

incident description that matches Dugway's 2007 failure to kill anthrax specimens.

The Federal Select Agent Program refuses to release lab inspection reports, citing "national security" interests. The CDC said its lab inspectors identified no biosafety concerns when they visited Dugway in January 2015 for an announced renewal inspection. Dugway's institutional biosafety committee minutes, obtained under the federal Freedom of Information Act, show CDC inspectors cited the facility's labs for eight "observations" in 2013, but the minutes don't say what they were. CDC said Friday none of the 2013 infractions involved biosafety concerns. "The eight observations noted in the minutes you referenced had to do with missing references in the lab's standard operating procedures to work with specific select agents and toxins and inventory discrepancies," the CDC statement said.

Late Friday afternoon four bipartisan leaders of the full House Energy and Commerce Committee and its investigations subcommittee sent letters to the CDC and the HHS inspector general's office seeking copies of Dugway's inspection reports and enforcement referrals, as well as answers to questions about the facility's oversight history.

The letters are signed by U.S. Rep. Fred Upton, R-Mich., who chairs the full committee, and its ranking Democrat Frank Pallone, Jr., of New Jersey. It's also signed by subcommittee chair Tim Murphy, R-Pa., and ranking Democrat Diana DeGette of Colorado. In a joint statement, the members said they are "deeply concerned" about recurring problems with inactivation protocols in federal labs. "We hope that the documents will help shed light on how these unacceptable safety lapses have occurred, and how to prevent them from happening again in the future," the group said.

The current massive effort underway to identify and secure all the potentially live anthrax samples sent out from Dugway began May 22, when the private biotech firm in Maryland alerted the CDC Emergency Operations Center in Atlanta that it had a live sample of anthrax that was supposed to be dead. The Maryland company apparently did its own verification test on the specimen to ensure it was dead before working with it. In that test it was able to culture and grow live Bacillus anthracis, the anthrax bacterium. While nobody has been sickened from the specimens, 31 people who had potentially risky contact with them have been put on antibiotics as a precaution, the DOD has said.

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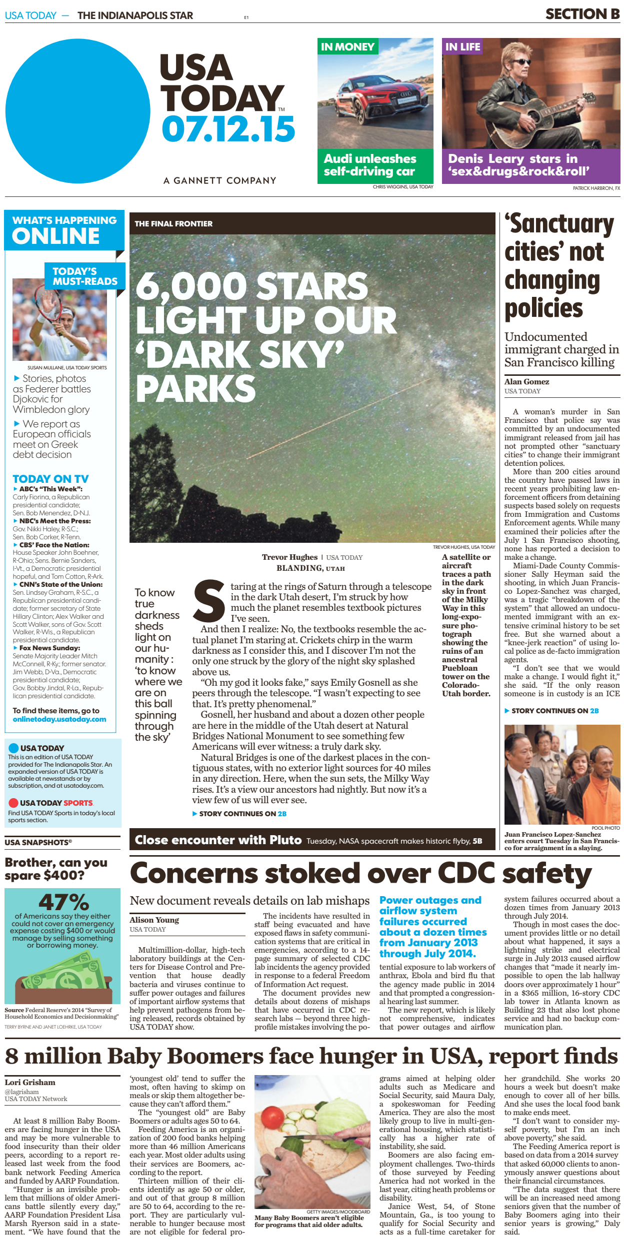
http://www.usatoday.com/story/news/2015/07/09/new-cdc-lab-incidents-airflow/29920917/



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July 9, 2015

http://www.usatoday.com/story/news/2015/07/09/new-cdc-lab-incidents-airflow/29920917/

The Centers for Disease Control and Prevention in Atlanta.

Power, airflow, safety issues plague high-tech CDC labs

Alison Young, *USA TODAY*

Multimillion-dollar, high-tech laboratory buildings at the Centers for Disease Control and Prevention that house deadly bacteria and viruses continue to suffer power outages and failures of important airflow systems that help prevent pathogens from being released, records obtained by USA TODAY show.

The incidents have resulted in staff being evacuated and have exposed flaws in safety communication systems that are critical in emergencies, according to a 14-page summary of selected CDC lab incidents the agency provided in response to a federal Freedom of Information Act request.

The document obtained by USA TODAY for the first time provides new information about dozens of mishaps that have occurred in CDC research labs – beyond the three high-profile mistakes the agency made public in 2014 and that prompted a congressional hearing last summer.

The CDC came under scrutiny last year after three serious incidents that potentially exposed dozens of lab workers to anthrax and one worker to Ebola, and mistakenly sent a specimen containing a deadly strain of bird flu to another lab. Since January, the CDC has refused to release copies of reports of all incidents that occurred in the agency's numerous labs in Atlanta and Fort Collins, Colo., during 2013 and 2014. The CDC has told USA TODAY it will take until sometime in 2018 to collect and release all of the incident reports.

The newly released lab incident summary document, which is likely not comprehensive, indicates that power outages and airflow system failures have occurred about a dozen times from January 2013 through July 2014 – continuing despite congressional scrutiny in 2012 in response to previous reporting by USA TODAY.

Though in most cases the document provides little or no detail about what happened, it says a lightning strike and electrical surge in July 2013 caused airflow changes that "made it nearly impossible to open the lab hallway doors over approximately 1 hour" in a $365 million, 16-story CDC lab tower in Atlanta known as Building 23 that also lost phone service and had no backup communication plan.

"It is unacceptable that the CDC, our nation's premier institution committed to preventing the spread of infectious disease, has not resolved these problems after years of oversight and attention," said U.S. Rep. Diana DeGette of Colorado, the ranking Democrat on a House oversight and investigations subcommittee that has held hearings on CDC's lab safety issues.

"It is more vital than ever that the CDC, from leadership

on down, commit to a strategy that will prevent future lapses in safety," DeGette said.

CDC spokesman Tom Skinner said that addressing airflow issues is critical. He noted that the negative air-pressure systems used in the agency's high-containment labs are only one of several layers of safety protections that keep pathogens from being released. "Airflow is not our primary means of containment," he said.

The newly disclosed incidents, listed among about 170 line items in a spreadsheet, include workers potentially exposed to pathogens through needle sticks and cuts, building maintenance workers propping open doors to restricted lab areas and malfunctions of full-body, spacesuit-like protective gear used to protect scientists from exposures to the most deadly types of viruses, such as Ebola.

But the summary document — which the CDC says was created last year for the agency's director and includes mishaps and selected clinic visits that occurred from 2013 through early August 2014 — provides few details. The CDC also notes that its total number of incidents cannot be tallied by reviewing the spreadsheet. Some incident summaries appear to be duplicates; other line items indicate the description is one of many similar incidents.

Further clouding the agency's lab-safety picture: The CDC has redacted the names of the viruses or bacteria involved in several of the incidents, citing a law that involves oversight of bioterror pathogens. Lab incidents include workers potentially being exposed to prairie dogs and fleas infected with undisclosed bioterror agents, and a fluid leak that possibly contained an undisclosed "Tier 1" bioterror agent, considered among the most dangerous of all. USA TODAY has filed an appeal contending the redactions are not justified under the law.

Sean Kaufman, a biosafety consultant who previously worked for the CDC and has conducted training at the agency, said the limited number of incidents contained in the summary document — given the vast number of labs operated by the agent — raises questions.

"This is not a comprehensive list," said Kaufman, who testified before Congress last summer in the wake of the CDC's anthrax lab incident. "I look at these documents, and it's very clear to me that leadership has not defined for the workforce what is a reportable incident or accident."

In order to identify emerging risks and trends to prevent future accidents, Kaufman said it's important for lab staff to report all incidents and unintentional events, even if they may not seem important at the time.

Marian Downing, president of the American Biological Safety Association and a biosafety consultant, said she couldn't comment on CDC's incident-reporting practices. But when she worked for a major pharmaceutical company, Downing said incidents where a biological exposure occurred — as well as "near-misses" — were entered into a central safety database, and there was a structure in place to determine the root causes of events.

In responses to USA TODAY's questions this week, the CDC gave a series of evolving answers about whether any single office at the agency collects and reviews information about lab incidents of all types to spot emerging safety trends.

The CDC initially said that only lab incidents that result in visits to the agency's health care clinic are reviewed regularly in a centralized fashion and that all other incidents are reported to numerous individual safety directors who oversee separate research programs. Later the agency said that the agency's newly created office of the associate director for laboratory science and safety has been receiving and reviewing all lab incident reports since it was established in late 2014.

The agency said it has a policy that requires reporting of all lab incidents to this new safety office, but it refused to provide a copy of the policy or say when it was enacted. The CDC later conceded the policy only requires reporting of a subset of incidents that meet certain criteria. Reporting is only required for an "exposure" occurring in biosafety level 3 and 4 labs — the two highest levels of containment, or incidents that involve "significant" injury or exposure with a "high likelihood" of infection, treatment for a laboratory acquired infection, or exposure to a potential bioterror agent or genetically manipulated organism, as well as any incident involving a lab visitor.

The criteria do not generally require reporting of near-miss incidents where a worker isn't determined to be exposed or injured and largely leaves it up to individual workers to determine if something must be reported.

"Near-misses are important for obvious reasons because you don't want them to happen again and involve a person next time," Downing said. She also noted that about 60% of laboratory-associated infections are not due to any known exposure.

Kaufman says the CDC's definition of reportable incidents "is too vague and incomplete," offering scientists little concept of what is expected of them. "There is an absence of leadership," he said of CDC's approach to incident reporting.

A year ago, CDC Director Tom Frieden announced plans to hire an associate director for laboratory science and safety — reporting directly to him — to become a "single point of accountability" to establish and enforce agency-wide biosafety policies.

Yet the agency still hasn't hired a permanent employee for the position, which has been staffed with a series of acting directors while the agency continues its search. Steve Monroe, who has been a deputy director of CDC's National Center for Emerging Zoonotic and Infectious Diseases, is the CDC's third interim lab-safety director and has held the spot since May. The agency declined to make him available for an interview.

Skinner emphasized that scientific research is important for the nation to defend against naturally occurring diseases and bioterrorism. "It's impossible to eliminate all the risk that comes with scientific research in the lab. It's complex work," he said. "What we want to do is get to as close to zero risk as possible."

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CDC to review oversight of bioterror labs

Facilities kept experimenting after failing in inspections

Alison Young
USA TODAY

The Centers for Disease Control and Prevention is launching a comprehensive review of how it regulates safety and security at bioterror labs in the wake of an ongoing USA TODAY Media Network investigation that has prompted congressional probes into the agency's effectiveness.

CDC Director Tom Frieden ordered the review last week as USA TODAY prepared to report on newly obtained documents showing that the agency's inspectors have allowed labs to keep experimenting with bioterror pathogens despite failing to meet key requirements on inspection after inspection, sometimes for years. The action also comes as the agency faces a hearing in the House next week.

"This review will be wide-ranging and includes a review of regulatory authority and the exercise of that authority so that we can identify potential modifications to the methods used to inspect labs," the CDC said in a statement this week.

The review, which is likely to take 90 days, will be directed by Stephen Ikedd, director of the CDC's Office of Public Health Preparedness and Response, the CDC said.

A subcommittee of the House Energy and Commerce Committee plans to hold a hearing next Tuesday on the CDC's oversight of select-agent labs, emphasizing recent shipments of live anthrax from a Department of Defense facility in Utah.

This month, citing USA TODAY's reporting, the bipartisan leaders of the full committee and its investigations subcommittee sent letters to the CDC and enforcement officials at the Department of Health and Human Services inspector general's office demanding they provide the names of research labs that have faced sanctions for safety violations as well as other information about select-agent oversight.

"Select agent" is the federal government's term for viruses, bacteria and toxins that have the potential to be used as bioweapons or that pose significant risk to agriculture or public health.


AFP/GETTY IMAGES
Tom Frieden
CDC statement

"This review will be wide-ranging ... so that we can identify potential modifications to the methods used to inspect labs."

A USA TODAY Network investigation published in May uncovered hundreds of accidents that have occurred in biological laboratories nationwide in recent years and revealed that pervasive secrecy obscures failures by regulators to ensure research facilities operate safely and don't unduly put workers and the public at risk. The network's reporting prompted questions about the CDC's regulation of labs from the bipartisan leaders of the Senate Homeland Security and Governmental Affairs Committee.

The network's ongoing investigation has raised questions about whether lax oversight and enforcement played a role in allowing an Army biodefense lab at the Dugway Proving Ground to mistakenly ship live anthrax for more than a decade to dozens of labs in the USA and abroad.

USA TODAY reported in June that the CDC referred Dugway for potential enforcement action in 2007 for failures to deactivate live anthrax with chemicals and for ignoring tests indicating the kill process was ineffective. No fines were levied, and over the years, CDC's inspectors apparently never detected that similar failures continued at Dugway in its routine use of radiation to kill anthrax.

More than 100 labs experimenting with potential bioterror pathogens have faced enforcement actions -- some repeatedly -- since 2003 from the Federal Select Agent Program, which is jointly run by the CDC and the U.S. Department of Agriculture. The government keeps their names secret, citing a federal bioterrorism law.

MAN CHARGED WITH PLANNING ATTACK ON U.S. TROOPS IN U.K.

WILL OLIVER, EUROPEAN PRESSPHOTO AGENCY
Junead and Shazib Khan's next scheduled court appearance is Aug. 10.

Junead Khan, 24, and his uncle appeared in court after being arrested on terrorism charges; the two planned to join ISIL

Jane Onyanga-Omara
USA TODAY

LONDON A British man accused of planning a terrorist attack on U.S. servicemembers in the United Kingdom appeared in court Tuesday.

Junead Khan, 24, and his uncle Shazib Khan, 22, from Luton, a town north of London, were charged by British authorities with intending to commit acts of terrorism.

Deborah Walsh, deputy head of counterterrorism at the Crown Prosecution Service, said the two British men allegedly planned to travel to Syria to join the Islamic State, also known as ISIS or ISIL.

Junead Khan is accused of planning a terrorist attack on U.S. military personnel in the United Kingdom, Walsh said.

The two appeared at Westminster Magistrate's Court in central London and were ordered to remain in custody until their next court appearance Aug. 10 at the Old Bailey, a higher London court.

They were arrested last week.

It's a violation of British law to go to Syria to help the militants, who control parts of Syria and Iraq.

This comes after four U.S. Marines and a sailor were killed last week in attacks by a gunman on two military sites in Chattanooga, Tenn. The attacker, Mohammod Youssuf Abdulazeez, a naturalized U.S. citizen from Kuwait, was also killed.

Donations surge for wounded Tenn. officer

Jennifer Calfas
USA TODAY

A donation Web page for a Chattanooga, Tenn., police officer wounded in Thursday's mass shooting was over halfway to its $20,000 goal after one day.

On Monday evening, the police department created a GoFundMe page for Dennis Pedigo, a 17-year veteran officer who was shot in the ankle while responding to an active shooter call. The gunman killed four Marines at the scene and injured three, including Navy Petty Officer Randall Smith, who died Saturday from his injuries.

The fund will benefit the Pedigo family during "this unthinkably difficult time," said Chattanooga Police Sgt. Gary Martin, who organized the effort.


CHATTANOOGA POLICE
Dennis Pedigo

Chattanooga gunman burdened by depression, debts, drug abuse

Michael Winter
USA TODAY

Two years before he shot dead four U.S. Marines and a sailor, Mohammod Youssuf Abdulazeez wrote about having suicidal thoughts and "becoming a martyr" after losing his job because of drugs, according to his diary and family members, ABC News reported.

When he attacked two military sites in Chattanooga on Thursday, Abdulazeez, 24, was burdened by depression, debts, drug abuse and a looming court appearance for intoxicated driving, a family representative told ABC.

As Abdulazeez was consuming sleeping pills, opioids, painkillers, marijuana and alcohol, he struggled with how to be a devout Muslim.

A Chattanooga police officer killed Abdulazeez at the Navy Operational Support Center, where servicemen were fatally shot with an AR-15 semiautomatic rifle. Minutes before, Abdulazeez shot up a military recruiting office miles away, but no one was hurt.

U.S. officials have not found a clear motive for the attacks and have not linked Abdulazeez to the Islamic State or another terrorist group. He was born in Kuwait to Jordanian parents but grew up mostly in Tennessee and was a naturalized citizen.

A senior U.S. intelligence official told *The New York Times* the diary cited "some pretty radicalized thoughts."


GETTY IMAGES
Mohammod Youssuf Abdulazeez

A Chattanooga police officer killed Abdulazeez at the Navy Operational Support Center, where servicemen were fatally shot with an AR-15 semiautomatic rifle.

IN BRIEF

MAN PLEADS GUILTY IN FATAL PHILLY DEMOLITION

A Philadelphia heavy equipment operator pleaded guilty Tuesday to involuntary manslaughter and recklessly endangering for his role in a botched building demolition that killed six people two years ago.

Sean Benschop wants to "take responsibility for his actions and the responsibility he bears for the loss of life," lawyer Bill Davis told the *Daily News* before the plea was entered. "He cries and prays almost every night for those people who lost their lives and their families."

More than a dozen people were injured when part of the building being demolished collapsed onto a Salvation Army thrift store on June 6, 2013. Rescue workers using buckets and bare hands worked through the night removing bricks and rubble in search of survivors and victims.

Benschop, 44, pleaded guilty to six counts of involuntary manslaughter, 12 counts of recklessly endangering another person and one count of causing a catastrophe.

— John Bacon

TURKEY SUICIDE BOMB VICTIMS BURIED


BULENT KILIC, AFP/GETTY IMAGES
Mourners attend a funeral Tuesday for 32 people killed in a suicide bombing Monday in Suruc, Turkey, near Syria's border. Turkey suspects an Islamic State link to the attack.

MAGNITUDE-4.0 QUAKE ROCKS BAY AREA

A magnitude-4.0 earthquake rattled the San Francisco Bay Area before dawn Tuesday, though no damage or injuries were immediately reported.

The U.S. Geological Survey said the quake struck at 2:41 a.m. It was centered 2 miles northeast of Fremont, an Alameda County city of more than 220,000 people 30 miles southeast of San Francisco.

Commuter rail service was delayed for about 20 minutes in the morning rush while officials inspected tracks for possible damage.

"We felt it. Lots of calls coming in from nervous and scared residents, but no reports of damage at this time," the Fremont police department tweeted.

— Elizabeth Weise

WHAT'S HAPPENING ONLINE

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MATT DUNHAM, AP

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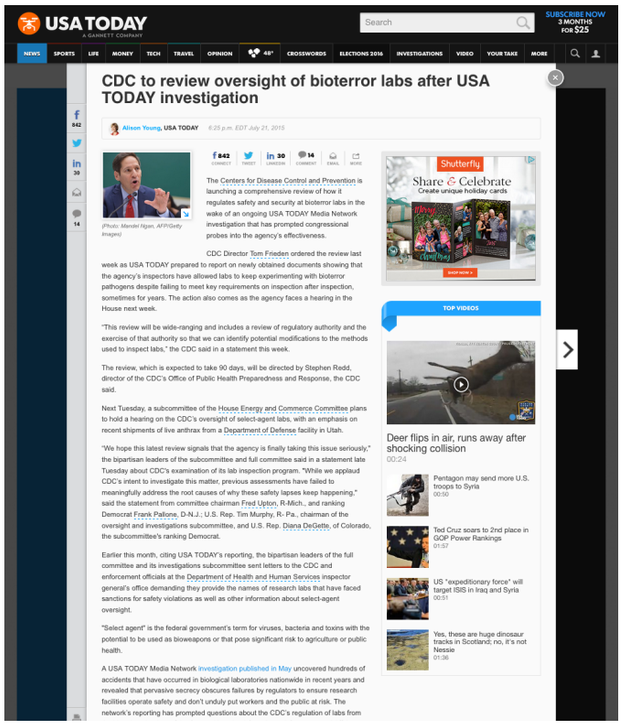

USA TODAY
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July 21, 2015

http://www.usatoday.com/story/news/2015/07/21/cdc-review-oversight-bioterror-labs-after-usa-today-investigation/30458589/

CDC Director Tom Frieden testifies in July 2014 before a House committee on an anthrax lab incident.

CDC to review oversight of bioterror labs after investigation

Alison Young, *USA TODAY*

The Centers for Disease Control and Prevention is launching a comprehensive review of how it regulates safety and security at bioterror labs in the wake of an ongoing USA TODAY Media Network investigation that has prompted congressional probes into the agency's effectiveness.

CDC Director Tom Frieden ordered the review last week as USA TODAY prepared to report on newly obtained documents showing that the agency's inspectors have allowed labs to keep experimenting with bioterror pathogens despite failing to meet key requirements on inspection after inspection, sometimes for years. The action also comes as the agency faces a hearing in the House next week.

"This review will be wide-ranging and includes a review of regulatory authority and the exercise of that authority so that we can identify potential modifications to the methods used to inspect labs," the CDC said in a statement this week.

The review, which is expected to take 90 days, will be directed by Stephen Redd, director of the CDC's Office of Public Health Preparedness and Response, the CDC said.

Next Tuesday, a subcommittee of the House Energy and Commerce Committee plans to hold a hearing on the CDC's oversight of select-agent labs, with an emphasis on recent shipments of live anthrax from a Department of Defense facility in Utah.

"We hope this latest review signals that the agency is finally taking this issue seriously," the bipartisan leaders of the subcommittee and full committee said in a statement late Tuesday about CDC's examination of its lab inspection program. "While we applaud CDC's intent to investigate this matter, previous assessments have failed to meaningfully address the root causes of why these safety lapses keep happening," said the statement from committee chairman Fred Upton, R-Mich., and ranking Democrat Frank Pallone, D-N.J.; U.S. Rep. Tim Murphy, R- Pa., chairman of the oversight and investigations subcommittee, and U.S. Rep. Diana DeGette, of Colorado, the subcommittee's ranking Democrat.

Earlier this month, citing USA TODAY's reporting, the bipartisan leaders of the full committee and its investigations subcommittee sent letters to the CDC and enforcement officials at the Department of Health and Human Services inspector general's office demanding they provide the names of research labs that have faced sanctions for safety violations as well as other information about select-agent oversight.

"Select agent" is the federal government's term for vi-

ruses, bacteria and toxins with the potential to be used as bioweapons or that pose significant risk to agriculture or public health.

A USA TODAY Media Network investigation published in May uncovered hundreds of accidents that have occurred in biological laboratories nationwide in recent years and revealed that pervasive secrecy obscures failures by regulators to ensure research facilities operate safety and don't unduly put workers and the public at risk. The network's reporting has prompted questions about the CDC's regulation of labs from the bipartisan leaders of the Senate Homeland Security and Governmental Affairs Committee.

The network's ongoing investigation has raised questions about whether lax oversight and enforcement played a role in allowing an Army biodefense facility to mistakenly ship live anthrax for more than a decade to dozens of labs in the U.S. and abroad. USA TODAY reported in June that the CDC in 2007 referred the Army's Dugway Proving Ground facility for potential federal enforcement action for failures to deactivate live anthrax with chemicals and for ignoring tests indicating the kill process was ineffective. But no fines were levied, and over the years CDC's inspectors apparently never detected that similar failures continued at Dugway in its routine use of radiation to kill anthrax.

More than 100 labs experimenting with potential bioterror pathogens have faced enforcement actions — some repeatedly — since 2003 from the Federal Select Agent Program, which is jointly run by the CDC and the U.S. Department of Agriculture. The government keeps their names secret, citing a federal bioterrorism law, and even refuses to disclose the names of labs kicked out of the program.

USDA officials could not be immediately reached about whether that agency also is reviewing how it regulates the labs it oversees, which focus on pathogens that primarily threaten agriculture, plants and animals.

Since January, USA TODAY has sought records, using the Freedom of Information Act (FOIA), from the CDC and USDA about their use of performance improvement plan programs — or PIPPs — as an alternative to suspending or revoking a failing lab's authorization to experiment with bioterror pathogens.

The USDA identified 479 pages of records involving letters to labs notifying them they were being put on a PIPP but in March refused to release any of them, citing a secrecy provision in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. USA TODAY has appealed.

The CDC recently responded to a similar FOIA request by sending USA TODAY 91 pages of correspondence with various labs about their enrollment or removal from performance improvement plans from 2011 to 2014. The CDC redacted all of the labs' names — as well as the names of pathogens involved in their safety violations. USA TODAY has appealed the redactions.

The records show that labs experimenting with bioterror pathogens have failed over and over to comply with important safety and security regulations — yet CDC inspectors have allowed some of them to continue operating for years before offering to put them on PIPPs. When inspectors identified significantly lax safety or security practices in work with "Tier 1" select agents, the CDC's letters said only that the agency "strongly recommends" the labs stop work with the pathogens, without mandating it.

Tier 1 select agents are those that federal officials deem to pose the "the greatest risk of deliberate misuse with significant potential for mass casualties or devastating effect to the economy, critical infrastructure or public confidence, and pose a severe threat to public health and safety." They include such deadly pathogens as the Ebola virus, anthrax and botulinum neurotoxin.

It's unclear whether the CDC's approach to oversight is a result of a lack of authority. The agency did not respond to USA TODAY's questions since last week about issues raised by the documents.

The documents released by the CDC include 17 letters that are initial notices to labs that they either need to agree to enter into a federal performance improvement plan or the agency will "begin proceedings to suspend or revoke" the facility's authorization to possess select agent pathogens. Examples include:

• An unidentified lab was cited for nine of the same violations on four consecutive inspections from January 2012 through December 2013, CDC said in a March 2014 letter to the facility. Inspectors said the lab "has a history of noncompliance" that has raised "serious concerns" about its ability to comply with mandates for adequate biosafety and security safeguards. The issues continue to be "a systemic problem" beyond any particular researcher or location at the facility, the letter says.

• An unidentified university lab's ongoing failure to implement requirements for security, biosafety, incident response and training "indicated a serious disregard for these regulatory requirements," the CDC said in a May 2014 letter. Inspectors observed "widespread regulatory non-compliance" during a March 2014 inspection. "Serious" biosafety issues included failure to enroll staff working with Tier 1 agents in an appropriate occupational health program and an inconsistent use of respiratory protection that "can result in increased risk of exposure to infectious agents." The CDC said it "strongly recommends" the university cease all work with Tier 1 agents until the improvement plan has been completed.

• An unidentified company that works with botulinum neurotoxin was cited for numerous violations during inspections in November 2013 and January 2014 — and its failure to adequately address the problems even after being given a deadline extension until October 2014. The company, the CDC's November 2014 letter says, failed to install required security for possessing the potential bioterror toxin, including not ensuring a minimum of three security barriers and having an intrusion detection system. It also failed to restrict access to the toxin to only fed-

erally authorized individuals — and even gave access to a person who "was denied access approval," the letter says. The company was cited for "not currently working with select toxins safely." The CDC noted that staff described the use of toxins "in areas that do not have sufficient biosafety and containment procedures" and that staff handled the toxins without appropriate protective equipment and did not decontaminate work surfaces and equipment as required. The company also failed to ensure that employees understood their training.

• An unidentified lab drew "significant concerns" from CDC inspectors during a May 2014 inspection that identified failings with biosafety, security, incidence response and record-keeping requirements. Lab workers were engaged in "propagation" of an undisclosed species of pathogen in an unapproved location that lacked sufficient building design and construction to contain it, and the staff were using insufficient safety procedures, the CDC wrote in a September 2014 letter. Other workers handled select agents in long-term storage without wearing protective gear, and staff told inspectors they did not routinely decontaminate gear after experiments and before reuse. The lab "did not use a validated method for the inactivation of select agents" before using materials in unregistered locations, the inspectors found. The lab also lacked an adequate incident response plan describing what would be done in the event of a theft, loss or release and how it would coordinate with local emergency responders.

• An unidentified lab's responsible official provided three different security plans to the CDC's inspectors yet "was unsure which plan the entity followed at the time of the inspection." And inspectors noted that the keys to the "select toxin inventory are located in an unsecured drawer within a laboratory that does not have security barriers to prevent unauthorized access." During business hours the lab's door is kept open "with only a chain across the entrance which would not impede access to select toxins," the CDC's January 2014 letter to the lab said. The same lab also had a history of performing aerosol-generating experiments with "large quantities of toxin" outside of a biosafety cabinet that is needed to contain the airborne particles. This lab was cited over and over for the same kinds of issues from November 2010 through November 2013: 17 of 39 citations in December 2012 were repeats from a Nov. 2010 inspection report; 16 of 35 violations cited in a Nov. 2013 report were repeated failures from a Jan. 25, 2013 report, the document says.

• An unidentified lab that received a letter from the CDC in February 2014 saying the lab "has failed to address safety issues over the course of the last four years." This facility had repeated issues in 2013 involving the discovery of select-agent specimens in its labs that the organization was not authorized to possess. Yet when regulators inspected the facility in December 2013, inspectors noted that the facility still had not done an audit of its approximately 230 storage freezers and refrigerators. The letter notes that the facility failed to correct all violations noted in its inspection reports of 2009, 2011 and 2012. The letter notes that inspectors observed failures to conduct biosafety and security training for staff in 2011, 2012 and 2013. A top lab official told the CDC it "could take years" for human resources officials at the lab to give the OK to do security suitability assessments of lab staff with access to Tier 1 select agents, which were required of all labs by April 2013.

• The CDC told a university lab in an October 2014 letter that inspectors have "significant concerns" that it was capable of possessing and experimenting with select agents "in a manner which does not endanger public health and safety." The letter notes that numerous violations were identified a month earlier, including failures to enhance security, implement an appropriate occupational health program for workers in labs using Tier 1 agents and not ensuring all workers receive adequate training. The university was found to have granted staff access to "Tier 1" select agents without conducting security suitability assessments, failed to do ongoing suitability assessments and hasn't created a system for peer-reporting of incidents that impact an individual's suitability. Because of the serious nature of the issues, the letter adds that the CDC "strongly recommends" the university cease all work with Tier 1 agents.

It's unclear why the CDC handled the cases as it did because the agency would not grant any interviews or respond to questions. In a statement, the CDC said generally that "regulatory penalties are imposed based on the degree of danger resulting from the violation; however, we'll be able to better answer your questions at the conclusion of this review."

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Pages 1A

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http://www.usatoday.com/story/news/nation/2015/08/04/secret-sanctions-revealed-against-university-hosting-125-billion-biolab/31075709/

Bioterror lab faced secret sanctions

Kansas State facility repeatedly violated safety rules, feds say

Alison Young
USA TODAY

Kansas State University — where a controversial $1.25 billion biosecurity lab facility is under construction — secretly faced federal sanctions last year after repeatedly violating safety regulations during its research with bioterror pathogens, records obtained by USA TODAY show.

Kansas State's "history of noncompliance" during four consecutive inspections over two years shows a "systemic problem" and has "raised serious concerns" about the university's ability to ensure safety and containment of dangerous pathogens, according to a March 2014 letter from federal lab regulators.

The university's biosecurity officer, Julie Johnson, said Tuesday the letter's harsh language was surprising because nearly all the violations involved administrative paperwork issues that posed no security threat. Yet in the letter, regulators threatened to suspend or revoke the university's permits to do research with bioterror pathogens. Johnson said the issues were resolved in April.

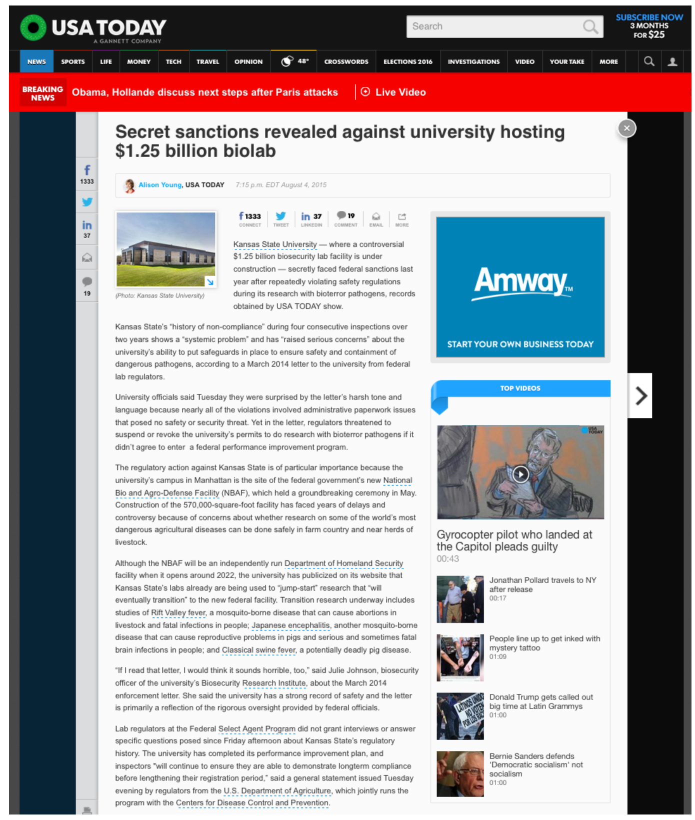
The action against Kansas State is of particular importance because the university's campus in Manhattan is the site of the federal government's new National Bio and Agro-Defense Facility (NBAF), which has faced years of delays because of concerns about whether research on agricultural diseases can be done safely near herds of livestock.

The NBAF will be independently run by Homeland Security when it opens around 2022, and federal officials said the university's regulatory issues are unrelated to the new facility.

Lab regulators at the Federal Select Agent Program did not answer specific questions about Kansas State's regulatory history. The university has completed a performance improvement plan, and inspectors "will continue to ensure they are able to demonstrate longterm compliance," the program said in a statement.

Bill Bullard, CEO of the cattle industry trade group R-CALF USA, said the violation letter "reinforces our concern that there will likely be an inadvertent release of one of these dangerous pathogens from that site."

The NBAF is to replace the Plum Island Animal Disease Center off the coast of New York's Long Island. It is the only lab in the U.S. allowed to work with live foot-and-mouth disease virus.



Secret sanctions revealed against university hosting $1.25 billion biolab

Alison Young, USA TODAY 7:15 p.m. EDT August 4, 2015

(Photo: Kansas State University)

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University officials said Tuesday they were surprised by the letter's harsh tone and language because nearly all of the violations involved administrative paperwork issues that posed no safety or security threat. Yet in the letter, regulators threatened to suspend or revoke the university's permits to do research with bioterror pathogens if it didn't agree to enter a federal performance improvement program.

The regulatory action against Kansas State is of particular importance because the university's campus in Manhattan is the site of the federal government's new National Bio and Agro-Defense Facility (NBAF), which held a groundbreaking ceremony in May. Construction of the 570,000-square-foot facility has faced years of delays and controversy because of concerns about whether research on some of the world's most dangerous agricultural diseases can be done safely in farm country and near herds of livestock.

Although the NBAF will be an independently run Department of Homeland Security facility when it opens around 2022, the university has publicized on its website that Kansas State's labs already are being used to "jump-start" research that "will eventually transition" to the new federal facility. Transition research underway includes studies of Rift Valley fever, a mosquito-borne disease that can cause abortions in livestock and fatal infections in people; Japanese encephalitis, another mosquito-borne disease that can cause reproductive problems in pigs and serious and sometimes fatal brain infections in people; and Classical swine fever, a potentially deadly pig disease.

"If I read that letter, I would think it sounds horrible, too," said Julie Johnson, biosecurity officer of the university's Biosecurity Research Institute, about the March 2014 enforcement letter. She said the university has a strong record of safety and the letter is primarily a reflection of the rigorous oversight provided by federal officials.

Lab regulators at the Federal Select Agent Program did not grant interviews or answer specific questions posed since Friday afternoon about Kansas State's regulatory history. The university has completed its performance improvement plan, and inspectors "will continue to ensure they are able to demonstrate longterm compliance before lengthening their registration period," said a general statement issued Tuesday evening by regulators from the U.S. Department of Agriculture, which jointly runs the program with the Centers for Disease Control and Prevention.

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August 4, 2015

http://www.usatoday.com/story/news/nation/2015/08/04/secret-sanctions-revealed-against-university-hosting-125-billion-biolab/31075709/

The Biosecurity Research Institute at the Kansas State University in Manhattan has biosafety level 3 labs.

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Alison Young, *USA TODAY*

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Some cattle industry groups are concerned about the potential for a dangerous pathogen being released from research facilities in Kansas and spreading to nearby herds.

Johnson said the violations have been corrected and the university was released from the federal performance improvement program in April.

Select agent is the government's term for a list of 65 viruses, bacteria and toxins that could be used as bioweapons or that pose severe threats to health or agriculture.

Officials at the Department of Homeland Security said Tuesday that any regulatory issues at Kansas State's labs have no impact on the work that will be done at the new federal facility. "It doesn't reflect on the NBAF. It's a totally separate entity," said James Johnson, executive director of the NBAF program. The federal lab, once built, will have its own accreditation process and federal permits for doing research.

Leaders of some cattle industry groups said the violation letter fuels their concerns about building the massive federal lab in America's farm country where a release of an animal pathogen could spread to nearby livestock herds.

"The fact that they are not currently capable of meeting necessary safety standards reinforces our concern that there will likely be an inadvertent release of one of these dangerous pathogens from that site," said Bill Bullard, CEO of R-CALF USA, a trade association for cattle producers. "This entire proposal is irresponsible and reckless, particularly given that we have a safe location where this research has been conducted since the 1950s."

The NBAF is being built to replace the federal government's aging Plum Island Animal Disease Center, which is located off the coast of New York's Long Island and is the only lab in the country allowed to work with live foot-and-mouth disease virus — which is highly contagious and considered one of the most economically devastating livestock diseases in the world.

When NBAF opens in about seven years, foot-and-mouth disease research will move from the island location to the Kansas facility. Foot-and-mouth research will occur only in the federal facility, not in the university's labs, according to information on Kansas State's website.

After a series of high-profile accidents at federal labs, an ongoing USA TODAY Media Network investigation has uncovered hundreds of incidents at public and private research facilities across the country and revealed how the secrecy that surrounds the oversight of biological and select agent research shields failures by labs and regulators from public scrutiny.

Federal regulators have refused USA TODAY's repeated requests for the names of more than 100 research facilities that have faced enforcement actions since 2003. They have cited secrecy provisions in a bioterrorism law as justification for redacting lab names from enforcement letters they released to the newspaper under the federal Freedom of Information Act. USA TODAY, through its reporting, has obtained names of sanctioned labs such as Kansas State University.

In the March 2014 letter to Kansas State, federal lab regulators wrote that "it is our determination that the failure of the KSU select agent program to comply with the select agent and toxin regulations continues to be a systemic problem unrelated to any one particular Principal Investigator, location, or project."

A chart in the letter illustrates how the university failed to comply with nine of 10 types of safety and security requirements on each of its four previous inspections since January 2012, including biosafety and containment practices, incident response and security plan requirements and training of staff.

"Why can you fail nine of 10 inspection points and still be operating?" asked Tyler Dupy, executive director of the Kansas Cattlemen's Association. "There's a need for the research, but can we trust that the safeguards are in place to

keep this stuff in place? One little mistake and it's all over."

The letter said issues at the university's labs included:

• Failing repeatedly to develop written biosafety plans commensurate with the risk of its registered select agent pathogens.

• Repeatedly failing to have safeguards sufficient to ensure biosafety and biocontainment of select agent pathogens.

• Continuously failing to provide appropriate training and ensure personnel understood the training provided and failing to document the training claimed to have been performed.

• Repeatedly failing to implement the requirements of the university's security plan to ensure select agents are protected against unauthorized access, theft, loss or release.

The records show that KSU was cited for the same types of failings in January 2012, August 2012, February 2013 and December 2013.

The issues behind the violations, to hear Kansas State officials describe them, involve administrative minutia.

For example, Johnson said inspectors took issue with the university's incident response plan saying only that a top official would be notified of an incident but not specifying how it would be done. The violation was corrected by adding words to specify that the official would be notified by phone, fax or e-mail, she said.

Violations related to failing to ensure staff understood training involved another kind of documentation issue, she said. The university kept copies of quizzes given to staff after training sessions and attached them to a dated sign-in sheet. The inspectors didn't consider the documentation adequate because each quiz wasn't individually dated, she said.

The university says these kinds of bureaucratic issues are typical of nearly all the violations that precipitated the March 2014 enforcement letter. The only issue that wasn't administrative, the university says, involves a 2012 citation for select agent research done in an unregistered area. Johnson said research on a rice plant pathogen was conducted in a space where it had been worked with long before the pathogen was added by federal officials to their list of select agents. The university said it immediately ceased the work and has since required all select agent work occur only in their Biosecurity Research Institute.

USA TODAY asked Kansas State for copies of its select agent inspection reports. University officials said they would consider the request but noted that the reports and the university's response letters are voluminous and would need to be redacted for security issues, which might take some time.

The March 2014 enforcement letter gives no indication that the violations involve minutia.

"Since 2011, KSU has expanded its select agent research program with the addition of new registered areas, select agents and work objectives, but KSU repeatedly failed to develop and implement plans to address this expanded scope of work," said the letter, which is jointly signed by officials from the USDA and CDC.

Though regulators noted the university's researchers were cooperative and eager to comply, they "had not been provided adequate guidance from KSU leadership to enable them to do so."

The CDC, in a statement, referred questions about Kansas State to the USDA, which it said is the lead agency that inspects the university's labs. The USDA did not grant interviews or provide any response to USA TODAY's questions submitted last Friday about its oversight of the university's labs and why it took failures on four consecutive inspections before enforcement action was taken. The USDA also didn't respond to Kansas State's characterization of the violations as primarily involving administrative issues.

Kansas State University was part of a coalition of Kansas state leaders that campaigned for the NBAF to be located on their campus. U.S. Sen. Pat Roberts, R-Kan., a key ally of the project, said the federal lab will create as many as 500 high-paying federal jobs and bring additional research jobs to the state. Over a 20-year-period, he said, the facility is estimated to have a $3.5 billion impact on the Kansas economy.

As part of the Kansas bid for the federal lab, Kansas State University offered the use of its biosafety level 3 labs at its Biosecurity Research Institute until the adjacent NBAF was completed. Roberts helped secure state funding for the university's lab in 2002, according to his news releases. The university named the lab's building "Pat Roberts Hall."

Roberts did not respond to interview requests about the university's inspection history.

The NBAF has been dogged by years of controversy and questions about whether the Department of Homeland Security downplayed the risks of putting the massive research facility in the center of the country's agricultural heartland.

The potential risks posed by the NBAF — which will for the first time in decades bring foot-and-mouth disease virus research to the U.S. mainland — have been the subject of much study and controversy.

In 2012, the Department of Homeland Security estimated the risk of a foot-and-mouth disease release is tiny — less than 0.11% over 50 years. Independent scientific experts convened by the National Research Council concluded in 2010 that the risk was as high as 70% over 50 years, and in 2012, they said the DHS was not adequately assessing the risks based on "overly optimistic" assessments of the potential for human error.

In its 2010 report, the National Research Council expert panel said the economic impact of a lab release of foot-and-mouth virus from the NBAF could be as much as $50 billion. Because of the risks posed by human error, the experts said staff at the new facility will need "adequate ongoing training, education, and evaluation of skills. Furthermore, there will need to be zero tolerance of deviations from biosafety standards and practices recommended by the CDC and USDA."

Documents obtained by USA TODAY show the CDC and

USDA have in the transition period allowed Kansas State's select agent researchers to have what the letter says are serious violations on inspection after inspection, including with training and biosafety — threatening to put the university on a performance improvement plan only after problems on four consecutive inspections.

Last month, the CDC launched a comprehensive review of how it regulates safety and security at select agent labs in the wake of USA TODAY's investigation, which revealed the agency's inspectors allowed labs to keep experimenting with bioterror pathogens despite failing marks on inspections for years. USDA officials have not responded to USA TODAY's questions since July 20 about whether that agency is conducting a similar self-review of its oversight performance.

Bipartisan members of Congress have expressed concerns about whether the oversight of labs is adequate. In the wake of questions asked by USA TODAY, committees in the House and Senate have told the Federal Select Agent Program they want the names of labs that have faced enforcement actions.

The CDC has provided the information requested by the Senate Committee on Homeland Security and Governmental Affairs, said Melinda Schnell, a spokesperson for committee chairman Ron Johnson, R-Wis. The committee is not publicly releasing the information at this time, she said.

"We will continue to do oversight of the program and are very concerned about the repeated failures on the part of Kansas State to safely manage its Select Agent research program," Schnell said in an email.

Officials with the House Energy and Commerce Committee, which also has requested information about labs that have faced enforcement action, were not available for comment Tuesday.

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Pages 1B, 2B

USA TODAY — THE INDIANAPOLIS STAR — SECTION B

USA TODAY 08.30.15

IN MONEY: Why Fed shouldn't wait to raise rates

IN LIFE: Author nervous about resurrecting 'Girl' series

HURRICANE KATRINA: 10 YEARS LATER

A prayer for all victims of Katrina

Obama: Climate change is here

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Labs cited for lax security in bioterror germ research

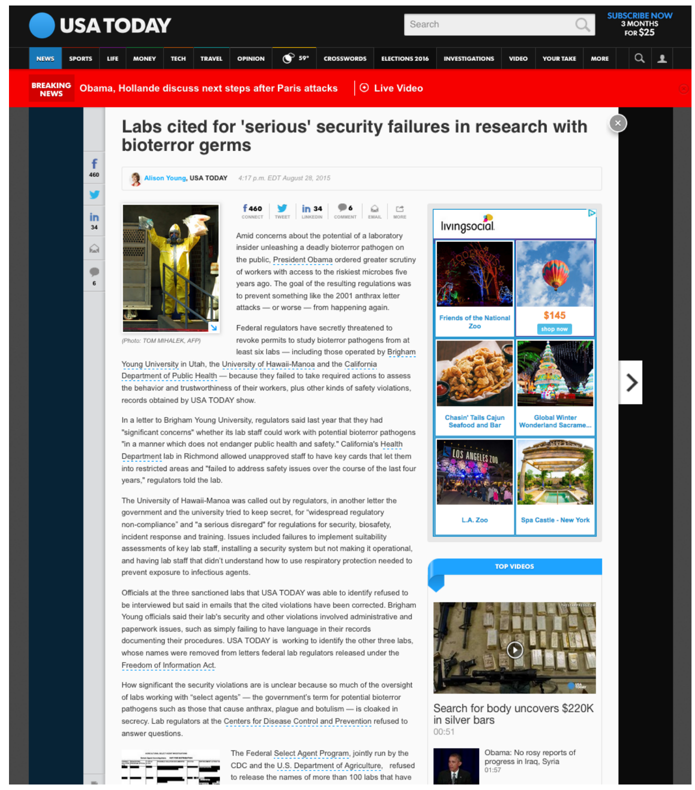
Federal officials are concerned a lab insider could unleash a pathogen on the public

"It is clear that this system is not working."

Thai police arrest foreign suspect in Bangkok bombing

'Dozens of passports' found in apartment

ONLINE: August 28, 2015
http://www.usatoday.com/story/news/2015/08/28/lab-security-violation-bioterrorism-select-agent-regulation/32439491/



USA TODAY

Labs cited for 'serious' security failures in research with bioterror germs

USA TODAY
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August 28, 2015

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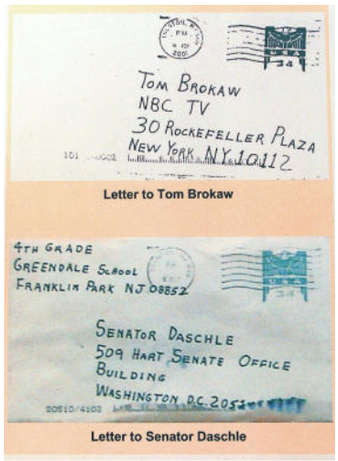
Labs cited for 'serious' security failures in research with bioterror germs

Alison Young, *USA TODAY*

Amid concerns about the potential of a laboratory insider unleashing a deadly bioterror pathogen on the public, President Obama ordered greater scrutiny of workers with access to the riskiest microbes five years ago. The goal of the resulting regulations was to prevent something like the 2001 anthrax letter attacks — or worse — from happening again.

Federal regulators have secretly threatened to revoke permits to study bioterror pathogens from at least six labs — including those operated by Brigham Young University in Utah, the University of Hawaii-Manoa and the California Department of Public Health — because they failed to take required actions to assess the behavior and trustworthiness of their workers, plus other kinds of safety violations, records obtained by USA TODAY show.



FILE PHOTO BY CHRIS KLEPONIS, AFP

An October 2001 FBI photo shows evidence in the anthrax letters case that killed five and injured 17 others.

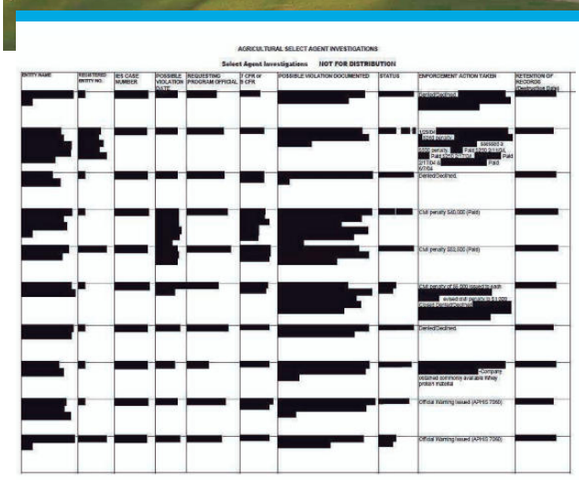
In a letter to Brigham Young University, regulators said last year that they had "significant concerns" whether its lab staff could work with potential bioterror pathogens "in a manner which does not endanger public health and safety." California's Health Department lab in Richmond allowed unapproved staff to have key cards that let them into restricted areas and "failed to address safety issues over the course of the last four years," regulators told the lab.

The University of Hawaii-Manoa was called out by regulators, in another letter the government and the university tried to keep secret, for "widespread regulatory non-compliance" and "a serious disregard" for regulations for security, biosafety, incident response and training. Issues included failures to implement suitability assessments of key lab staff, installing a security system but not making it operational, and having lab staff that didn't understand how to use respiratory protection needed to prevent exposure to infectious agents.

Officials at the three sanctioned labs that USA TODAY was able to identify refused to be interviewed but said in emails that the cited violations have been corrected. Brigham Young officials said their lab's security and other violations involved administrative and paperwork issues, such as simply failing to have language in their records documenting their procedures. USA TODAY is working to identify the other three labs, whose names were removed from letters federal lab regulators released under the Freedom of Information Act.

How significant the security violations are is unclear because so much of the oversight of labs working with "select

THE UNIVERSITY OF HAWAII



AGRICULTURAL SELECT AGENT INVESTIGATIONS

Select Agent Investigations NOT FOR DISTRIBUTION

ENTITY NAME	REGISTERED ENTITY NO.	IES CASE NUMBER	POSSIBLE VIOLATION DATE	REQUESTING PROGRAM OFFICIAL	7 CFR or 9 CFR	POSSIBLE VIOLATION DOCUMENTED	STATUS	ENFORCEMENT ACTION TAKEN	RETENTION OF RECORDS (Performed 2007)
[redacted]									

The University of Hawaii-Manoa was called out by regulators.

An investigator emerges from a post office in West Trenton, N.J., during the investigation into the mailing of letters containing anthrax.

A spreadsheet of enforcement actions was heavily redacted by the Federal Select Agent Program before being released to USA TODAY. The program is jointly run by the CDC and the USDA.

2001 PHOTO BY TOM MIHALEK, AFP

agents" — the government's term for potential bioterror pathogens such as those that cause anthrax, plague and botulism — is cloaked in secrecy. Lab regulators at the Centers for Disease Control and Prevention refused to answer questions.

The Federal Select Agent Program, jointly run by the CDC and the U.S. Department of Agriculture, refused to release the names of more than 100 labs that have faced enforcement actions for a wide range of safety violations since 2003 — even those kicked out of the select agent program. The program cites a 2002 bioterrorism law as justification for redacting lab names from records released to USA TODAY. The news organization has identified several of the labs through its reporting.

The lack of public information makes it difficult to gauge the risks posed by the violations and whether federal inspectors are focusing on issues that have a real impact on improving safety and security, said biosecurity experts and policymakers.

"It's so hard to say how this should be interpreted," said Gigi Kwik Gronvall of the UPMC Center for Health Security, a think-tank, when asked about the suitability assessment violations at the Utah, Hawaii and California labs. Gronvall said she's long heard complaints from labs that inspectors focus on paperwork and minutia, but it's difficult to know whether that's the case.

The bipartisan leaders of the House Energy and Commerce Committee, which has held two hearings on lab safety and oversight in the past year, said they are continuing their investigation to find root causes and solutions to serious safety incidents at U.S. research facilities. Among the high-profile blunders was the discovery this spring that a U.S. Army biodefense lab had been mistakenly shipping hundreds of live anthrax specimens — that it told recipients had been killed — for more than a decade, despite inspections by federal regulators. The problems continued undetected despite regulators previously citing the lab in 2007 for failing to properly kill anthrax.

"After repeated, inexcusable blunders with anthrax, smallpox and other dangerous pathogens, it is clear that this system is not working," said committee chairman Rep. Fred Upton, R-Mich., and Rep. Frank Pallone Jr. of New Jersey, the committee's ranking Democrat, in a statement to USA TODAY.

A CDC inspection report released to USA TODAY by the California Department of Public Health — the only one of the three sanctioned labs willing to release any inspection records — provides a rare glimpse into what lab regulators examine and cite during their visits. Though some violations involved potential safety issues, many of the violations cited at the Richmond, Calif., lab appear to involve missing language in policy manuals found during paperwork reviews.

Less emphasis should be placed on the paperwork and

more on actions that assess and improve safety cultures, some lab experts said.

"Sure, we need regulations and oversight," said David Franz, a former commander of the U.S. Army Medical Research Institute of Infectious Diseases in Maryland. "But safety and security are not enhanced by nit-picking bureaucratic policy manual reviews, arbitrary interpretation of regs and agonizingly slow communication with the labs."

Lab regulators at the CDC are in the midst of a 90-day review of how the agency regulates safety and security at hundreds of public, private and government labs working with select agent pathogens. The review was launched in July in the wake of the USA TODAY Media Network's ongoing investigation that has revealed government inspectors allowing labs to keep experimenting despite failing to meet key requirements on inspection after inspection.

Lab regulators at the USDA are doing a similar review of their part of oversight program. It was launched in June, a spokeswoman said Thursday.

CDC officials declined to be interviewed or to answer questions about their enforcement of the enhanced security regulations, many of which took effect in April 2013 and require initial and ongoing "suitability" assessments of lab workers with access to Tier 1 select agents. This group of pathogens is deemed by the government to pose the greatest risk of deliberate misuse with the most significant potential for mass casualties or devastating economic effects. It includes the bacteria that cause anthrax, botulism and plague, the Ebola virus and several other agents.

The regulations require a variety of security enhancements, including evaluating unusual behaviors, incidents or life changes among lab workers in ways that go beyond FBI background checks. They stem from an executive order signed by President Obama in 2010.

The Federal Select Agent Program cites the anthrax letter attacks in October 2001 — which the FBI says were the result of a U.S. Army microbiologist — as an example of how deadly and financially costly the misuse of a pathogen by a lab "insider" can be. Five people were killed and 17 others sickened. The contamination caused by the anthrax letters disrupted businesses and closed parts of government, costing more than $23 million to decontaminate one Senate office building, according to a guidance document on the suitability regulations. The Postal Service lost about $2 billion in revenue, and there was up to $3 billion in additional costs to the Postal Service for decontamination and getting mail-sanitizing equipment.

Among the ways a lab worker could pose a threat, federal officials say:

• A person with ill intent infiltrates a research facility under the guise of a researcher to steal, release or divert dangerous pathogens.

• A person working at the facility is coerced or manipulated into providing access or expertise to people intending harm.

• A person legitimately working with pathogens who experiences a "significant life changing event" that prompts misuse, release or diversion of pathogens.

Letters sent to each of these three labs show that the CDC threatened to suspend or revoke their authorizations to work with select agents if they didn't agree to enter into a federal performance improvement program. Violations at each lab included failures related to the enhanced Tier 1 security requirements as well as other problems.

Brigham Young University in Provo, Utah: An Oct. 30 letter from the CDC to BYU officials noted "serious regulatory deficiencies" in the areas of security, biosafety and incident response. It said BYU failed to establish procedures for pre-access and ongoing assessments of suitability for staff with access to Tier 1 pathogens. Though regulators said "physical security" of select agent pathogens appears to be in place, "the near complete failure to establish written procedures and provisions to address the requirements for possession of Tier 1 select agents resulted in inspectors being unable to measure the implementation of the required security and safety measures."

Inspectors found that BYU had given staff access to Tier 1 pathogens without conducting pre-access suitability assessments, failed to assess suitability on an ongoing basis and failed to establish procedures for colleagues to report incidents or concerns about a peer's suitability, the letter says. The CDC, it says, has "significant concerns" about whether the university can work with select agent pathogens "in a manner which does not endanger public health and safety."

In emailed answers to USA TODAY's questions, BYU officials said the university's one lab that works with select agents agreed to be put on a performance improvement plan, and it halted select agent research until it completed the plan in in April. The university said the violations noted by the CDC involved paperwork issues: "To clarify, BYU had taken action to verify the suitability of those accessing select agents. However, some of our administrative processes to document our compliance with the assessment standards were in need of improvement."

The CDC letter said BYU "has failed to establish an occupational health program specific to the Tier 1 select agents used and possessed by the university and enroll individual with access ... in said program as required." The university told USA TODAY, "BYU did not fail to establish an occupational health and safety program." BYU has such a program, it said, but "had simply not referenced this program in the written biosafety plan."

BYU, a private institution sponsored by the Church of Jesus Christ of Latter-day Saints, said it would not release a copy of the inspection report that prompted the CDC to send the October 2014 letter threatening its lab's suspension or revocation from the select agent program if the university didn't go into the performance improvement program.

Citing "safety and security reasons," BYU would not answer USA TODAY's questions about which Tier 1 pathogens were involved in the research that was suspended

in the wake of the CDC's letter. According to information posted on BYU's website, the chairman of the university's microbiology department lists two Tier 1 agents among his research interest: Burkholderia pseudomallei, a bacterium that causes a potentially fatal disease called melioidosis, and Burkholderia mallei, which causes a disease called glanders.

"BYU is confident that ongoing work in the [biosafety level 3] laboratory can be conducted in a safe and compliant way, and the CDC certification of our facility and operation confirms this," the university said in a statement.

University of Hawaii-Manoa: A May 2014 letter from the CDC to the university said findings on inspections had "indicated a serious disregard for these regulatory requirements resulting in observed compliance departures in the security, biosafety, incident response, and training requirements of the select agent regulations." Regulators said the university had "serious regulatory deficiencies" that included failure to implement procedures for pre-access and ongoing suitability assessments of lab workers with access to Tier 1 pathogens. Though the university had installed the hardware for a required intrusion-detection system in Tier 1 pathogen areas, the university "has failed to render this system operational," the CDC wrote.

Regulators expressed concerns about "serious biosafety departures," including "misunderstandings" among staff on the proper use of respiratory protection against exposure to pathogens. Such issues, the letter said, "can result in increased risk of exposure to infectious agents by entity personnel that are not properly equipped or do not understand the use of the respiratory protection provided." The letter said the CDC "strongly recommends" the university cease all work with Tier 1 select agents and enter into a storage-only status until it completed a federal performance improvement program.

University officials declined to be interviewed and did not answer most of USA TODAY's questions. In an email, spokesman Daniel Meisenzahl said the university "fulfilled all requirements of the performance improvement plan," and the CDC renewed the university's registration in June to allow work with select agent pathogens through June 2017. "This is an example of government functioning properly with [CDC's] continuing vigilance toward constant improvement," he said.

The university has refused since last year to release records to USA TODAY about its select agent violations and enrollment in the PIP. In response to USA TODAY's open records appeal to Hawaii's Office of Information Practices, the university told the information office in January that it is "proud" of being put on the PIP and that it "has been an exemplary participant in the Federal Select Agent Program."

Hawaii State Sen. Sam Slom, a University of Hawaii alum and legislative watchdog over the school, said Wednesday that although some secrecy may be warranted, "I think we overuse that as an excuse." He said he'll ask tough questions when the Legislature begins its 2016 session in January and discusses the university's state funding.

"They look at being under the PIP as a point of honor, as if they've done something right — which is wrong," said Slom, the Legislature's minority leader and lone Republican. "My point of view is if you have serious regulatory issues here, particularly that involve public safety, you tell the university: Here's your funding request. We'll hold it until you adequately answer questions."

California Department of Public Health: A February 2014 letter from the CDC expressed "significant concerns" about the Richmond, Calif., facility's oversight of select agent pathogens as observed during an inspection in December 2013 — as well as about repeated failures to correct issues identified during inspections going back to 2009. Regulators noted that the lab failed to meet requirements for suitability assessments for staff with access to Tier 1 agents because procedures were "pending approval from the Human Resources Department" in a process that inspectors wrote they were told "could take years."

Regulators noted that lab personnel who were not approved to have access to select agent pathogens had "unrestricted card key access," and some had "master keys that override the card key access system, allowing them unrestricted access" into areas where select agent pathogens are used. "This same observation had been cited in the 2011 and 2012 inspection reports, but remains uncorrected," the letter said.

The Health Department lab does diagnostic testing as well as research that includes working with strains of bacteria that produce the toxin that causes botulism. Such strains are classified as Tier 1 select agents

Other issues cited by the CDC letter included the lab failing "to meet inventory record keeping requirements over the course of the last four years," and failing "to address safety issues over the last four years," including a lack of evidence since 2009 that all biosafety cabinets — used to protect researchers from exposure to select agent pathogens — were certified annually.

The Health Department said in emails that it entered into a federal performance improvement plan in March 2014 and that the lab was waiting to hear from the CDC on release from the plan after completing the last requirement Aug. 5.

Despite the CDC's citation, the department said it had been conducting the required staff suitability assessments since the regulation took effect in 2013. The department said the issue involved not having all the assessment guidelines incorporated into the lab's security procedure manuals. The manuals have all since been updated, the department said.

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John Kasich tries to emerge as the establishment choice

Not every candidate is following his lead

Chrissie Thompson
@CThompsonENQ
The Cincinnati Enquirer

MARK J. TERRILL, AP

Ohio Gov. John Kasich takes part in the GOP presidential debate Wednesday in Boulder, Colo.

MARK J. TERRILL, AP

Florida Sen. Marco Rubio.

"Folks, we gotta wake up. We cannot elect somebody that doesn't know how to do the job."

Gov. **John Kasich**, R-Ohio

BOULDER, COLO. What is it going to take to beat Donald Trump and Ben Carson?

The question has reverberated through GOP establishment circles for months, without an answer in sight.

This week, Ohio Gov. John Kasich took his shot, throwing up his hands and calling their proposals "crazy." At the opening of Wednesday's Republican debate, he railed against the political outsiders' ideas.

"Folks, we gotta wake up," he pleaded. "We cannot elect somebody that doesn't know how to do the job."

With the tactic aimed squarely at New Hampshire's first-in-the-nation primary voters — many of whom are more moderate than those in other early voting states — Kasich hopes to emerge as the establishment GOP candidate of choice.

But Kasich's approach carries risks. Chief among them: Many Republican voters don't think of themselves as "mainstream" any more, and polls have shown a growing number prefer an outsider candidate.

On Wednesday night, Trump and Carson largely stuck together at the debate at the University of Colorado Boulder — furthering the divide between their candidacy and that of the race's current and former officeholders.

Not every candidate with mainstream appeal is following Kasich's lead.

Marco Rubio is using his youth and immigrant family history to avoid the "establishment" label, while knowing those GOP voters likely have him on their list.

Chris Christie may be employing a similar "truth-teller" approach as Kasich, but on Wednesday he focused more on challenging CNBC moderators than his opponents. Jeb Bush, meanwhile, is trying to bounce back after a widely panned debate performance that included a jab at Rubio that fell flat.

Kasich's approach reflects much of what he's heard in town-hall meetings in New Hampshire. On a recent four-day swing through the Granite State, some voters praised his qualifications, while asking him how he could stop Trump.

"He's trying to be the adult in the room. So why not just go for broke on it?" said Kyle Kondik, managing editor for *Larry Sabato's Crystal Ball* political forecasting newsletter.

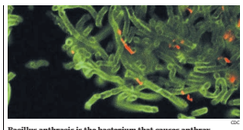
Still, a strategy tailored to winning New Hampshire's moderate Republicans could backfire in other primaries, said University of New Hampshire political scientist Dante Scala.

"When you behave in an exasperated way toward, say, Carson, toward Trump, toward the so-called crazies, you're also implicating a fair number of Republican primary voters, who actually think that Trump and Carson have something to say," Scala said.

Indeed, some Republicans approached after the debate at the University of Colorado-Boulder took issue with the notion of being considered establishment GOPers.

In the end, GOP observers agreed: Kasich should stick with the strategy, because it just might work.

"Kasich is a good communicator, he's got a good track record, he's just got to stick with it and see what happens," Feehery said. "If he can stick in there, he can be the last establishment man standing."



CDC

Bacillus anthracis is the bacterium that causes anthrax.

WHITE HOUSE URGES TOUGHER LAB SAFETY

Recommendations follow serious incidents with anthrax and other deadly pathogens

Alison Young
@alisonamyyoung
USA TODAY

In response to high profile incidents at labs working with dangerous bioterror pathogens, White House science advisers issued a series of recommendations to improve safety and set deadlines to ensure they happen.

The 187-page memo was issued by Lisa Monaco, assistant to the president for homeland security and counterterrorism, and John Holdren, assistant to the president for science and technology.

The recommendations highlight the need for "transparency, swift incident reporting and accountability to the public, and material stewardship that includes strong inventory management and control measures," Monaco and Holdren said in a blog posting Thursday afternoon.

The recommendations focus on labs registered to work with about 65 dangerous "select agent" pathogens that the government considers to pose potential bioterrorism threats. They call for increased training to create and strengthen cultures of biosafety and security; requiring that a qualified entity validate laboratory protocols used to kill infectious materials, and providing information about incidents to the public "to the maximum extent feasible."

After a series of serious incidents with specimens of anthrax, smallpox virus and a deadly strain of bird flu at federal labs in 2014, the White House Office of Science and Technology Policy sought public comment this year on the impact of the approach to regulation of select agent pathogens, including the program's benefits, costs and limitations.

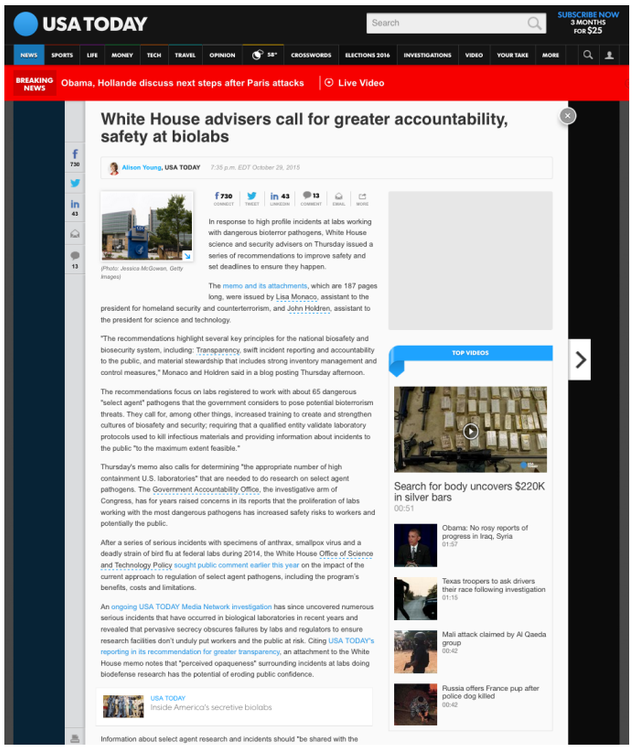
A USA TODAY Media Network investigation has uncovered numerous serious incidents at biolabs in recent years and revealed that pervasive secrecy obscures failures by labs and regulators to ensure labs don't unduly put workers and the public at risk.

Citing USA TODAY's reporting, an attachment to the White House memo notes that "perceived opaqueness" could erode public confidence.

The Federal Select Agent Program, which is jointly run by the Centers for Disease Control and Prevention and the U.S. Department of Agriculture, oversees about 300 laboratories that are registered to work with any of about 65 types of bacteria, viruses and toxins on the government's select agent list.

Read USA TODAY's ongoing investigation of safety issues at laboratories nationwide, and look up information about labs near you online at biolabs.usatoday.com

ONLINE: October 29, 2015
http://www.usatoday.com/story/news/2015/10/29/white-house-memo-lab-safety-select-agents/74695652/



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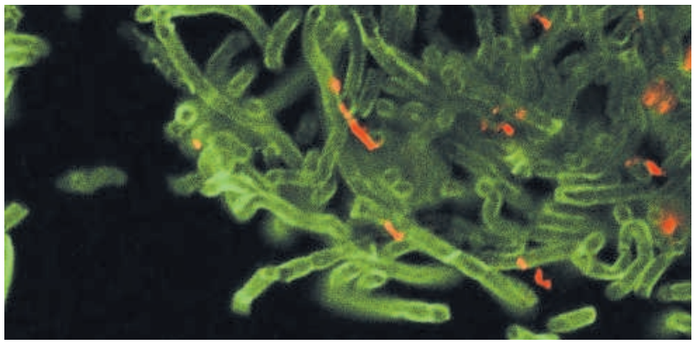

CDC

Bacillus anthracis is the bacterium that causes anthrax.

White House advisers call for greater accountability, safety at biolabs

Alison Young, *USA TODAY*

In response to high profile incidents at labs working with dangerous bioterror pathogens, White House science and security advisers on Thursday issued a series of recommendations to improve safety and set deadlines to ensure they happen.

The memo and its attachments, which are 187 pages long, were issued by Lisa Monaco, assistant to the president for homeland security and counterterrorism, and John Holdren, assistant to the president for science and technology.

"The recommendations highlight several key principles for the national biosafety and biosecurity system, including: Transparency, swift incident reporting and accountability to the public, and material stewardship that includes strong inventory management and control measures," Monaco and Holdren said in a blog posting Thursday afternoon.

The recommendations focus on labs registered to work with about 65 dangerous "select agent" pathogens that the government considers to pose potential bioterrorism threats. They call for, among other things, increased training to create and strengthen cultures of biosafety and security; requiring that a qualified entity validate laboratory protocols used to kill infectious materials and providing information about incidents to the public "to the maximum extent feasible."

Thursday's memo also calls for determining "the appropriate number of high containment U.S. laboratories" that are needed to do research on select agent pathogens. The Government Accountability Office, the investigative arm of Congress, has for years raised concerns in its reports that the proliferation of labs working with the most dangerous pathogens has increased safety risks to workers and potentially the public.

After a series of serious incidents with specimens of anthrax, smallpox virus and a deadly strain of bird flu at federal labs during 2014, the White House Office of Science and Technology Policy sought public comment earlier this year on the impact of the current approach to regulation of select agent pathogens, including the program's benefits, costs and limitations.

An ongoing USA TODAY Media Network investigation has since uncovered numerous serious incidents that have

occurred in biological laboratories in recent years and revealed that pervasive secrecy obscures failures by labs and regulators to ensure research facilities don't unduly put workers and the public at risk. Citing USA TODAY's reporting in its recommendation for greater transparency, an attachment to the White House memo notes that "perceived opaqueness" surrounding incidents at labs doing biodefense research has the potential of eroding public confidence.

Information about select agent research and incidents should "be shared with the public, to the maximum extent possible," said the October report from the federal Fast Track Action Committee on the Select Agent Regulations, which is incorporated into the White House memo. While information about certain work characterizing biological threats can't be released fully for security reasons, the committee said: "In most cases, withholding this information has negligible security value, since the research, researchers, institutions, and agents involved with (select agent) research are often published in scientific journals or can readily be inferred from public materials."

The Federal Select Agent Program, which is jointly run by the Centers for Disease Control and Prevention and the U.S. Department of Agriculture, oversees about 300 laboratories that are registered to work with any of about 65 types of bacteria, viruses and toxins on the government's select agent list. Regulated pathogens include those that cause anthrax, botulism, plague and Ebola.

The USA TODAY investigation has raised questions about whether lax federal oversight and enforcement played a role in allowing an Army biodefense lab at the Dugway Proving Ground in Utah to mistakenly ship live anthrax for more than a decade. Despite CDC inspectors referring Dugway for enforcement action in 2007 for failures to deactivate live anthrax and ignoring tests that showed the kill process wasn't fully effective, no fines were ever levied and inspectors never discovered the ongoing issue with a different anthrax kill method. The problem was instead identified in May by a Maryland biotech company that tested a sample of the supposedly killed anthrax it had received from Dugway and discovered it could still grow.

The recommendations in the new White House memo are "positive steps," said Richard Ebright, a biosafety expert at Rutgers University in New Jersey who has testified before Congress on lab safety issues. He said the major changes involve creating an entity to validate that the protocols labs are using to kill pathogens, the addition of periodic public reporting on select agent incidents and the effort to determine how many high-containment labs are really needed to do research on select agent pathogens. Most of the other changes are minor, "positive but not especially meaningful," he said.

"It is disappointing," Ebright said, "that the document does not call for the change that many consider most important: namely, re-assignment of responsibility for select-agent oversight from the CDC and the USDA to an independent federal entity that does not perform and does not fund select agent work."

Amesh Adalja, a senior associate at the UPMC Center for Health Security, a think-tank that studies policy issues relating to biosecurity, said the most important aspect of the White House memo is that the recommendations have deadlines associated with them. "They're all valid and good recommendations. But recommendations only go so far if they are not implemented." Many of the deadlines are in early 2016.

Scott Becker, executive director of the Association of Public Health Laboratories, praised the recommendations and said they incorporated all of the fixes his group of regulated health department labs had pushed for. "The devil is in the details and we've got to keep holding them accountable in ensuring it actually gets done," he said. "I can also say your (USA TODAY) reports have really focused the issue," Becker said, noting that "no one has paid attention until we had incidents."

On Thursday, the CDC separately released results of its own internal review of how it regulates safety and security labs that work with select agent pathogens. CDC director Tom Frieden ordered the review in July as USA TODAY was about to report on documents showing that CDC's select agent inspectors have allowed labs nationwide to keep experimenting despite failing to meet key requirements on inspection after inspection – sometimes for years.

The CDC review has resulted in several recommendations for improving the federal inspection process, including a greater emphasis on lab activities that pose the greatest risks.

"What we've done is review the program to ensure the work done with these agents is done as safely and securely as possible," said Stephen Redd, director of CDC's Office of Public Health Preparedness and Response. Redd directed the internal CDC review, which recommends working with regulated labs to do risk assessments of their work, finding ways to characterize the relative severity of inspection findings and prioritizing enforcement actions to focus on the highest risk violations.

The CDC workgroup also called for increased public release of information about inspection processes and findings at select agent laboratories. The current recommendation is only for the release of "aggregate information" on inspection findings — but not information about named, individual labs. But Redd said that as the content of select agent inspection reports evolves in response to the other recommendations, it's possible more information might be disclosed to the public. "This is not final, it's where we're starting," he said.

The timetable in the White House memo calls for the Federal Select Agent Program to begin an annual public release of aggregate information on laboratory incidents by June 2016.

The USDA has said it has been doing its own self-review of how it oversees select agent labs, and that review is still underway, the agency said Thursday.

Separately, a report released Wednesday by several high-profile biodefense experts said a "major reassessment" of the Federal Select Agent Program and its approach to oversight "is long overdue." It called on Congress to ensure that a systematic and independent review is done by the National Science Advisory Board for Biosecurity, a federal advisory committee of outside experts. The report was issued by the Blue Ribbon Study Panel on Biodefense, which is co-chaired by former Homeland Security secretary Tom Ridge and former U.S. senator Joe Lieberman, who chaired the Senate's homeland security committee before he left Congress in 2013.

While the select agent program has been "an impediment to would-be attackers," the report said the program's oversight "does not fully address underlying issues in pathogen safety and security, including how to prevent and deal with human error, how to ensure standards for safety and security awareness are met, and how to be more transparent within statutory confines about lapses and problems within the system." The report also raised concerns about select agent regulations being overly burdensome and an impediment to research.

The panel, sponsored by the Hudson Institute and partially funded by biotech companies, also included former Health and Human Services secretary Donna Shalala and former U.S. senator Tom Daschle, whose office received one of the anthrax-laced letters in the 2001 attacks.

The Government Accountability Office for years has recommended improvements in federal oversight of labs, including the need to establish a single federal entity to oversee high-containment laboratories. These laboratories operate at biosafety levels 3 and 4, the two highest safety levels. Many of the pathogens that need the special safety controls used in these labs are on the government's select agent list, but not all of them.

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Pages 1A

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USA TODAY 12.09.15

NFL TOM PELISSERIO
CARROLL'S FINISHING TOUCH
Winners of three straight, Seahawks' late-season success trademark of Pete Carroll teams
IN SPORTS

USA TODAY NETWORK INVESTIGATION

CDC LAB LEADER REPLACED AFTER LAPSES

Official directed division that dealt with biotoxins

Alison Young
USA TODAY

The Centers for Disease Control and Prevention replaced its longtime director of national lab regulation in the wake of several high-profile incidents involving bioterror pathogens and an internal review that identified areas of improvement for the oversight program, USA TODAY learned.

In a statement Tuesday, the CDC declined to say why it replaced Robbin Weyant on Nov. 9 as director of the agency's Division of Select Agents and Toxins, which regulates hundreds of U.S. labs working with the organisms that cause anthrax, plague, Ebola and other deadly diseases that are deemed to pose bioterror risks.

The change occurred 18 days after the completion of an internal CDC review of the national lab oversight program that was launched after a USA TODAY NETWORK investigation prompted congressional probes and revealed that CDC inspectors have allowed labs to keep experimenting despite failing to meet key safety requirements on inspection after inspection, sometimes for years.

Weyant served as select-agent director since 2006, according to his LinkedIn profile, and he lists his current job with CDC as a senior adviser in the agency's newly created lab safety office. Weyant declined to comment on the reason for the job change.

In a statement, Rep. Fred Upton, R-Mich., chairman of the House Committee on Energy and Commerce, and oversight subcommittee Chairman Tim Murphy, R-Pa., said, "We'll be taking a close look at CDC's actions and are disappointed the agency did not consult with the Committee prior to its announcement. Strong and effective management of the select agent program is our top priority, and we want to know whether this signals deeper problems that CDC has not yet disclosed."

Biosafety experts have complained that the oversight of "select agent" labs focused too much on paperwork reviews and bureaucratic minutiae, rather than meaningful measures of safety and security. Select agent is the government's term for viruses, bacteria and toxins that are subject to regulation because they could be used as bioweapons.

Read USA TODAY's investigation at biolabs.usatoday.com.

USA TODAY'S FINDINGS

- Hundreds of safety mishaps have occurred at government, university and private labs handling dangerous pathogens.
- Government secrecy obscures failings by labs.
- More than 100 labs have faced enforcement actions, but regulators keep their names secret.
- CDC inspectors failed to detect that an Army lab had been mistakenly shipping live anthrax for a decade, despite finding a similar problem in 2007.
- More online at biolabs.usatoday.com

NEWSLINE

IN NEWS
Violence shatters Ukraine cease-fire

Feds examining deposit linked to California shooter

IN MONEY
Oil plunge hurts steel industry
Producers drastically cut drilling activity, lessening need for steel pipes.

IN LIFE
Frank Sinatra at 100: Ol' Blue Eyes is remembered

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TERRY SVRLUGA AND VERONICA BRAVO, USA TODAY

Pope Francis kisses Pope Emeritus Benedict XVI, right, before pushing open the Holy Door. AP

MAURIZIO BRAMBATTI, EUROPEAN PRESSPHOTO AGENCY

Pope Francis opened the Holy Door at St. Peter's Basilica on Tuesday, marking the start of the Jubilee of Mercy — a special Holy Year for Catholics — amid heightened security. An extra 5,000 security officers were deployed around Rome, and a no-fly zone has been imposed to protect the millions of pilgrims. IN NEWS

If Trump bolts GOP, backers would, too

Poll taken before his call to bar Muslims

Susan Page
USA TODAY

WASHINGTON Donald Trump not only continues to lead the Republican presidential field in a new USA TODAY/Suffolk University Poll, the overwhelming majority of his supporters say they would vote for him if he bolted the GOP and ran as an independent.

The national poll was taken before the latest Trump firestorm, this time over his statement Monday calling for a "complete and total shutdown" on all Muslims entering the USA until concerns about terrorism can be addressed.

In TV interviews Tuesday morning, he refused to back down in the face of criticism, not only by Democrats but also leading Republicans.

He likened his actions to those taken by President Franklin Roosevelt during World War II against Japanese Americans and others. "If you look at what he was doing, it was far worse," he said on MSNBC.

In a chilling sign for the GOP, 68% of Trump's supporters say they would vote for the billionaire businessman if he ran as an independent rather than a Republican; just 18% say they wouldn't.

The telephone survey of 1,000 likely voters, taken Wednesday through Sunday, finds a trio of Republican candidates who show emerging national strength — Trump, Texas Sen. Ted Cruz and Florida Sen. Marco Rubio — as other once-serious contenders struggle for traction.

Among Democrats, Hillary Clinton has widened her lead over Vermont Sen. Bernie Sanders to 56%-29%.

New attacks on U.S. Muslims

Mosques threatened, shop owner beaten

Oren Dorell
USA TODAY

Anti-Muslim attacks are on the rise since last week's massacre in San Bernardino, Calif., and recent comments by presidential candidate Donald Trump could make the situation worse, Muslim and Arab-American leaders said Tuesday.

Recent vandalism and threats at mosques represent a spike in anti-Muslim sentiment, said Ibrahim Hooper, spokesman for the Council for American-Islamic Relations (CAIR), which has asked American Muslims to report incidents of bias. "We don't literally have time to issue a statement on every incident because they're coming in so fast and furious," Hooper said. "When the leading Republican presidential candidate can say, 'Bar all Muslims coming to America' and know he can get more support for it — it is truly frightening."

The Anti-Defamation League has reports of about two dozen anti-Muslim attacks since the terror attacks Nov. 13 in Paris, ranging from a cab driver shot in Pittsburgh to vandalism against mosques and other buildings, plus verbal or written threats.

"We're definitely seeing anti-Muslim bigotry escalating around the country," said Oren Segal, director of the Anti-Defamation League's Center on Extremism.

Trump called Monday for "a total and complete shutdown of Muslims entering the United States." Tuesday, the candidate said his plan has "tremendous support" by his followers, despite condemnation from Republicans, Democrats and world leaders.

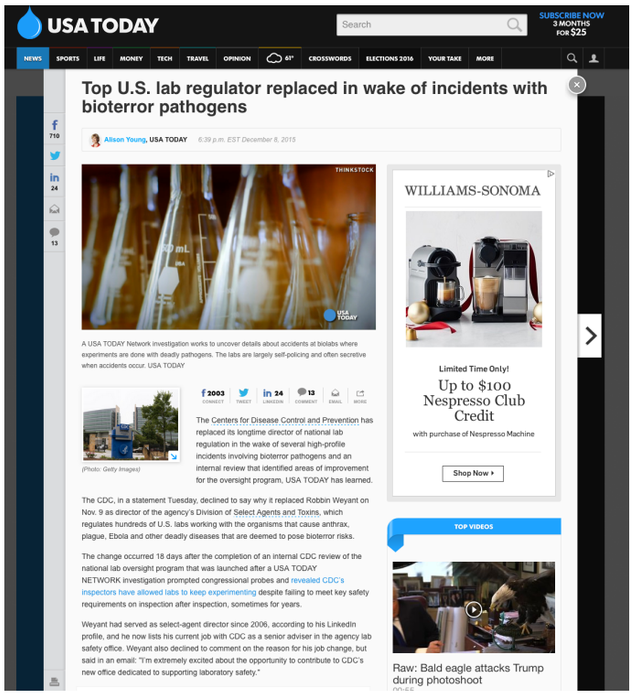
Trump's words came as Philadelphia police and the FBI investigated who left a severed pig's head at the Al-Aqsa Islamic Society mosque.

Sarker Haque, who owns Fatima Food Mart in New York said he was beaten by a customer who promised to "kill Muslims."

Sarker Haque AFP/GETTY IMAGES

STATE-BY-STATE 4A AMERICA'S MARKETS 4B MARKETPLACE TODAY 4D PUZZLES 4D SCREEN CHECK 5D WEATHER 6A YOUR SAY 6A

ONLINE: December 8, 2015
http://www.usatoday.com/story/news/2015/12/08/cdc-bioterror-lab-regulator-replaced/76976554/



USA TODAY
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December 8, 2015

http://www.usatoday.com/story/news/2015/12/08/cdc-bioterror-lab-regulator-replaced/76976554/

Top U.S. lab regulator replaced in wake of incidents with bioterror pathogens

Alison Young, *USA TODAY*

The Centers for Disease Control and Prevention has replaced its longtime director of national lab regulation in the wake of several high-profile incidents involving bioterror pathogens and an internal review that identified areas of improvement for the oversight program, USA TODAY has learned.

The CDC, in a statement Tuesday, declined to say why it replaced Robbin Weyant on Nov. 9 as director of the agency's Division of Select Agents and Toxins, which regulates hundreds of U.S. labs working with the organisms that cause anthrax, plague, Ebola and other deadly diseases that are deemed to pose bioterror risks.

The change occurred 18 days after the completion of an internal CDC review of the national lab oversight program that was launched after a USA TODAY NETWORK investigation prompted congressional probes and revealed CDC's inspectors have allowed labs to keep experimenting despite failing to meet key safety requirements on inspection after inspection, sometimes for years.

Weyant had served as select-agent director since 2006, according to his LinkedIn profile, and he now lists his current job with CDC as a senior adviser in the agency lab safety office. Weyant also declined to comment on the reason for his job change, but said in an email: "I'm extremely excited about the opportunity to contribute to CDC's new office dedicated to supporting laboratory safety."

In a statement, Rep. Fred Upton, R-Mich., chairman of the House Committee on Energy and Commerce, and Oversight & Investigations Subcommittee Chairman Tim Murphy, R-Pa., said: "We'll be taking a close look at CDC's actions and are disappointed the agency did not consult with the Committee prior to its announcement. Strong and effective management of the select agent program is our top priority, and we want to know whether this signals deeper problems that CDC has not yet disclosed. Our important work continues."

Some biosafety experts have complained that the oversight of "select agent" labs has focused too much on paperwork reviews and bureaucratic minutiae, rather than meaningful measures of safety and security. Select agent is the government's term for certain viruses, bacteria and toxins that are subject to regulation because they have the potential to be used as bioweapons.

"This is a great opportunity for leadership to make much needed changes in the implementation of the Select Agent Rules," David Franz, a former commander of the U.S. Army Medical Research Institute of Infectious Diseases in Maryland, said in an email. "With a right approach [CDC regulators] could minimize the damaging drag that the creeping bureaucracy has placed on progress within the enterprise in recent years and actually enhance lab security and safety."

The USA TODAY NETWORK's ongoing investigation has raised questions about whether lax oversight and enforcement by the CDC played a role in allowing the Army's biodefense facility at the Dugway Proving Ground in Utah to mistakenly ship live anthrax for more than a decade to dozens of labs in the U.S. and abroad. The lax procedures at Dugway's labs were discovered only in May after a private biotech company happened to test an anthrax specimen

it received from the Army as part of a project to develop a new diagnostic test. Despite having a certificate from Dugway saying the anthrax had been killed with radiation, the company found it was alive and capable of growing.

USA TODAY reported in June that the CDC in 2007 referred the Dugway lab for potential federal enforcement action for failures to deactivate live anthrax with chemicals and for ignoring tests indicating the kill process was ineffective. But no fines were levied and, over the years, CDC's inspectors apparently never detected that similar failures continued at Dugway when it used radiation to kill anthrax research specimens.

The CDC's report of its internal review of the oversight program, dated Oct. 22, identified several areas for improvement, including the need for regulators to better characterize risks on inspection reports, then prioritize and strengthen enforcement actions for the highest-risk violations.

The CDC has named Dan Sosin as acting director of its select-agent division, according to a Nov. 17 email, obtained by USA TODAY, that the agency sent to lab officials. Sosin previously was deputy director of CDC's Office of Public Health Preparedness and Response.

The CDC would not answer any questions about the change in leadership or whether Sosin's appointment will be permanent. The agency, in a statement, would say only that Weyant is now working "as a senior advisor with our newly formed Office of the Associate Director for Laboratory Science and Safety to add his extensive expertise in lab safety and security to our ongoing improvement efforts."

Supplemental Material

PRINT: March 26, 2015
Page 2A

ONLINE: March 25, 2015
http://www.usatoday.com/story/news/2015/03/25/senators-seek-answers-tulane-lab-accident/70453068/

Bipartisan bills under fire

Abortion politics threaten to derail other proposals

Erin Kelly
USA TODAY

Anti-abortion protesters pass the Supreme Court during the annual March for Life event in January. Lawmakers are battling over anti-abortion measures attached to broader legislation.

"Each side is asking the other: How important is this bill to you? ... I think the answer for now is that they prefer stalemate."

House passes $3.8 trillion budget

Beefed up Pentagon spending was key to the budget's passage

Susan Davis
USA TODAY

House Budget Committee Chairman Rep. Tom Price, R-Ga., backed changes to bill.

Senators scrutinize bioterror lab accident

Alison Young
@alisonannyoung
USA TODAY

The Senate's homeland security committee, citing reporting by USA TODAY, wants answers from three federal agencies about their handling of an ongoing investigation of the risks posed by the recent release of a deadly bioterror bacteria from a laboratory in Louisiana, according to letters sent Wednesday.

Understanding how the bacteria got out of a high-security lab at the Tulane National Primate Research Center near New Orleans is "imperative" because of the potential bioterrorism threat posed by the organism, said the letters signed by committee chairman Sen. Ron Johnson, R-Wis., and ranking Democratic Sen. Thomas Carper of Delaware. The letters were sent to the Centers for Disease Control and Prevention, the U.S. Department of Agriculture and the Environmental Protection Agency.

The senators note that the Tulane accident follows other incidents at labs as the country has faced potential threats from infectious diseases ranging from measles to avian influenza and Ebola. "These events are reminders as to how vulnerable our nation may be to a serious biological incident," the letters said.

Federal officials have been investigating how a deadly, foreign bacterium called Burkholderia pseudomallei got out of a high-security lab on the primate center campus, sickening three monkeys not involved in any experiments. They say the bacteria probably were carried out of the lab on the clothing of workers using sloppy biosafety practices.

The incident has raised concerns that the bacteria may have contaminated soil or water in the facility's large outdoor primate breeding colony. The CDC has said it is unlikely there is any threat to the general population, but the investigation is ongoing.

Tulane officials have said they don't believe the bacteria have gotten outdoors and have pointed to tests of 39 soil samples that didn't detect the bacteria. Citing USA TODAY's reporting that found too few samples were tested to detect the elusive bacteria, the senators said they want the EPA to explain the "scientific justification" for its soil testing plan.

The senators also want to know more about plans to monitor wildlife and domestic animals in the vicinity for signs of exposure. Other questions seek to examine how the agencies have coordinated their investigation. The letters set an April 8 deadline for the agencies to respond.

TULANE UNIVERSITY
The Tulane National Primate Research Center is located on 500 acres in Covington, La.

Read more at biolabs.usatoday.com

IN BRIEF

TORNADO KILLS 1, DESTROYS MOBILE HOMES NEAR TULSA

SINGAPORE MOURNS LONGTIME PM

People pay their last respects to Singapore's former prime minister Lee Kuan Yew, 91, on Wednesday at Parliament House. Yew, who died Sunday, served from 1959 to 1990.

OBAMA TO DISCUSS NEW PAYDAY LENDING RULES

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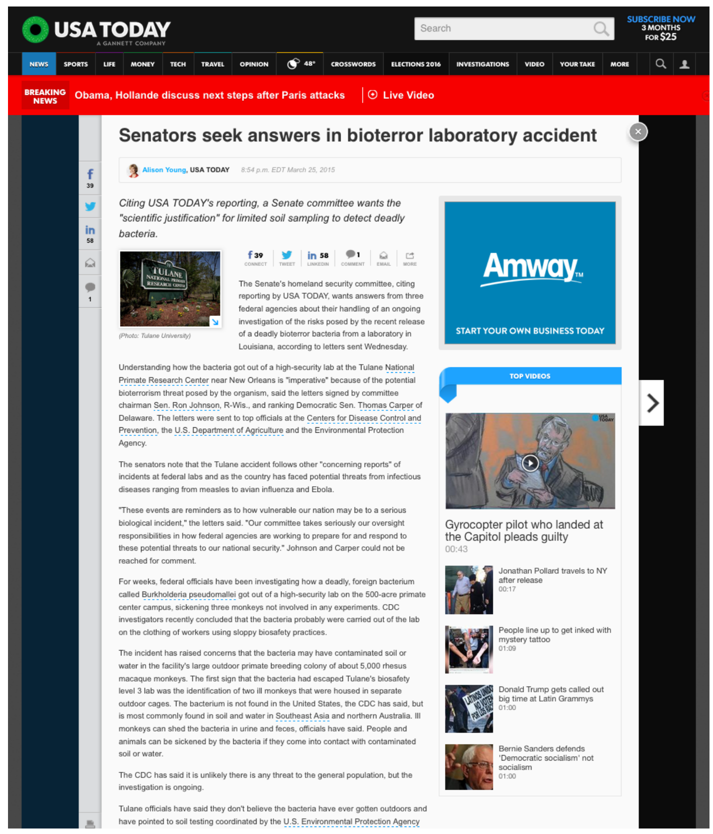

Senators seek answers in bioterror laboratory accident

Alison Young, USA TODAY 8:54 p.m. EDT March 25, 2015

Citing USA TODAY's reporting, a Senate committee wants the "scientific justification" for limited soil sampling to detect deadly bacteria.

(Photo: Tulane University)

The Senate's homeland security committee, citing reporting by USA TODAY, wants answers from three federal agencies about their handling of an ongoing investigation of the risks posed by the recent release of a deadly bioterror bacteria from a laboratory in Louisiana, according to letters sent Wednesday.

Understanding how the bacteria got out of a high-security lab at the Tulane National Primate Research Center near New Orleans is "imperative" because of the potential bioterrorism threat posed by the organism, said the letters signed by committee chairman Sen. Ron Johnson, R-Wis., and ranking Democratic Sen. Thomas Carper of Delaware. The letters were sent to top officials at the Centers for Disease Control and Prevention, the U.S. Department of Agriculture and the Environmental Protection Agency.

The senators note that the Tulane accident follows other "concerning reports" of incidents at federal labs and as the country has faced potential threats from infectious diseases ranging from measles to avian influenza and Ebola.

"These events are reminders as to how vulnerable our nation may be to a serious biological incident," the letters said. "Our committee takes seriously our oversight responsibilities in how federal agencies are working to prepare for and respond to these potential threats to our national security." Johnson and Carper could not be reached for comment.

For weeks, federal officials have been investigating how a deadly, foreign bacterium called Burkholderia pseudomallei got out of a high-security lab on the 500-acre primate center campus, sickening three monkeys not involved in any experiments. CDC investigators recently concluded that the bacteria probably were carried out of the lab on the clothing of workers using sloppy biosafety practices.

The incident has raised concerns that the bacteria may have contaminated soil or water in the facility's large outdoor primate breeding colony of about 5,000 rhesus macaque monkeys. The first sign that the bacteria had escaped Tulane's biosafety level 3 lab was the identification of two ill monkeys that were housed in separate outdoor cages. The bacterium is not found in the United States, the CDC has said, but is most commonly found in soil and water in Southeast Asia and northern Australia. Ill monkeys can shed the bacteria in urine and feces, officials have said. People and animals can be sickened by the bacteria if they come into contact with contaminated soil or water.

The CDC has said it is unlikely there is any threat to the general population, but the investigation is ongoing.

Tulane officials have said they don't believe the bacteria have ever gotten outdoors and have pointed to soil testing coordinated by the U.S. Environmental Protection Agency

USA TODAY
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March 25, 2015

http://www.usatoday.com/story/news/2015/03/25/senators-seek-answers-tulane-lab-accident/70453068/

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Alison Young, *USA TODAY*

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TULANE UNIVERSITY

The Tulane National Primate Research Center is located on 500 acres in Covington, La.

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The CDC has said it is unlikely there is any threat to the general population, but the investigation is ongoing.

Tulane officials have said they don't believe the bacteria have ever gotten outdoors and have pointed to soil testing coordinated by the U.S. Environmental Protection Agency that didn't detect the bacteria. The committee wants the EPA to explain the "scientific justification for the soil sampling plan ... particularly as it pertains to the number of soil samples taken at the site."

The letter cites USA TODAY's reporting that found only 39 soil samples were tested — far too few to detect the elusive bacteria if present. The newspaper reported that in parts of the world where the bacteria has lived for decades, studies have found it is difficult to detect without a large number of samples because it forms underground colonies like invisible ant hills that aren't evenly distributed across an area.

The senators also want to know more about the agencies' efforts to determine whether soil and water conditions near the lab could support colonization of the bacteria, as well as the status of plans to monitor wildlife and domestic animals in the vicinity for signs of exposure. Other questions seek to examine how the agencies have coordinated their investigation. The letters set an April 8 deadline for the agencies to respond.

EPA and USDA officials could not immediately be reached.

"I think that Congress understands how important the work at Tulane and other institutions is across the country, but they've raised concerns that this work is not being done safely," CDC spokesman Tom Skinner said Wednesday evening. "CDC concurs that this work must be done safely and we will be responding to the senators' letter accordingly."

USA TODAY
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March 5, 2015

Online Only
http://www.usatoday.com/story/news/2015/03/05/at-risk-monkeys-released-from-tulane-hospital/24471615/

Monkeys at risk for bioterror bacteria put outdoors

Alison Young, *USA TODAY*

More than 175 monkeys that were potentially exposed to a bioterror bacteria inside a major Louisiana research complex were returned to their outdoor cages before officials knew the deadly pathogen was on the loose from a lab accident.

The new admission by the Tulane National Primate Research Center, in response to repeated questions from USA TODAY, raises further questions about contamination of the environment outside of the massive research campus north of New Orleans. The bacteria, which is not found in the United States and can cause severe disease in people and animals, can live and grow in soil and water.

"Some animals were released from the vet clinic early on, but the key thing is that all the animals have been traced," said Tulane spokesman Michael Strecker. Testing of the animals is ongoing to determine if they have been exposed to the bacterium, Burkholderia pseudomallei.

The primate center is next to wetlands, near a river and neighborhoods and across the street from a school.

If infected, animals that become ill can shed the bacteria in their urine and feces and the organism can colonize soil and water, said Jay Gee, a research biologist and expert on the pathogen at the Centers for Disease Control and Prevention. The colonies can spread to other areas if carried by water runoff when it rains.

Soil scientists from the U.S. Department of Agriculture are currently studying the bacteria's ability to survive in North America, Gee said Thursday. USDA officials could not be reached.

The USDA has previously said it is still studying whether the situation at Tulane's primate center in Covington, La., poses a risk to agriculture. The CDC has said there is no evidence at this time of a public health threat.

The veterinary clinic on the primate center's 500-acre campus north of New Orleans is the current focus of federal and state investigations as the likely place where five monkeys were infected or exposed to the bacteria around November or December. None of the monkeys were involved in experiments with the bacteria – and the pathogen should never have been in the clinic or anyplace else outside the high-security lab where Tulane was doing vaccine-development research.

Officials do not know when or how the bacteria got out of its lab, despite weeks of investigation by the CDC and numerous state and federal environmental, agriculture and emergency management agencies.

In response to repeated questions from USA TODAY since Tuesday about how many animals had passed through the veterinary hospital during the period of suspected contamination, Strecker replied on Wednesday: "No animals are being released from the hospital until the results of testing are known."

After further questioning, Strecker on Thursday afternoon said that 177 rhesus macaque monkeys had been treated and released from the hospital during the period of concern, which spans from November to February. He emphasized that all of the animals are being tested to determine if they have been exposed to the bacteria. It was unclear Thursday evening how many of these 177 monkeys have test results back yet.

So far, Tulane has sent samples to the CDC from more than 340 monkeys that either spent time in the veterinary hospital or that had lived with animals in large outdoor cages that later tested positive for the bacteria while in the hospital. Results are back on more than 160 of the samples, Strecker said, and have identified five monkeys that were exposed. Three of the monkeys, rhesus macaques, became so ill they were euthanized. Two others are currently healthy though tests have detected antibodies to the bacteria indicating they were exposed.

People and animals exposed to the bacteria can take one day to several years to show signs of disease. Most of those exposed by contact with contaminated water or soil will never show signs of illness, Gee said, but the bacteria can hide for years in the body. Much is unknown about which people will be sickened and which won't, though diabetes and cirrhosis of the liver are among conditions that may make a person vulnerable to developing symptoms.

Burkholderia pseudomallei can cause a wide range of symptoms, from fever to localized skin infections to deadly pneumonias. For those who develop disease from the bacteria, the fatality rate can be as high as 50%. Successful treatment with antibiotics can be long and difficult in severe cases, said Henry Walke, CDC's branch chief for special pathogens.

Pat Brister, president of St. Tammany Parish, where the lab is located near homes, expressed frustration that she was learning about the 177 monkeys from USA TODAY rather than directly from Tulane. "It is unacceptable to me that I'm hearing this information from you," she said Thursday night. "It certainly raises a red flag to me that I'm not hearing everything from them."

Strecker said Thursday night that the movement of animals to the outdoor cages from the hospital is an issue known to the "Unified Command," the group of local, state and federal agencies working on the investigation and response. The parish has a representative in the group, he said.

Brister said the parish is considering holding a public meeting to help answer the growing number of questions that local residents are asking about the bacteria and the investigation.

Meanwhile, as a precaution, other research facilities across the country are testing animals they have received recently from the Tulane primate center, which breeds and supplies macaques for use in projects nationwide. In December, before the lab breach was known, Tulane sent a group of Chinese-origin rhesus macaques to an out-of-state research facility, Strecker said Tulane officials contacted the facility, which he wouldn't identify, as soon as they knew there was an issue.

"We have since learned that some of these animals have been sent on to other institutions," Strecker said. The CDC has contacted the other institutions and is helping with testing. All of the shipped animals tested so far have been negative for exposure to the bacteria. Tulane did not say how many animals were shipped.

None of these Chinese-origin macaques were in Tulane's veterinary hospital during the period of suspected contamination, Strecker said. These animals are kept in a different area of the outdoor breeding colony from most of the other monkeys at the facility, which are Indian-origin rhesus macaques, he said.

In other developments, test results released on Thursday indicate that a federal investigator was not exposed to the bacteria while investigating the lab accident at Tulane in January. The CDC said tests show her level of antibodies remain the same as they have for several weeks, indicating her exposure is not new. The inspector has traveled to an undisclosed part of the world where the bacteria is commonly found. The bacteria is mostly found in Southeast Asia and northern Australia.

Officials with the Louisiana Governor's Office of Homeland Security and Emergency Preparedness have asked for federal help investigating potential soil contamination around the facility.

Although a limited number of soil and water tests have not detected the bacteria outdoors, USA TODAY reported Sunday that studies indicate that too few samples were taken to detect what can be an elusive bacterium. Tulane says it believes the soil testing was adequate because samples were taken in areas where monkeys perch and their waste falls.

PRINT: June 29, 2015
Pages 1A, 2A

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USA TODAY 06.29.15
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IN SPORTS
WIMBLEDON
Serena Williams goes for 3rd Open title of '15

MELBOURNE, JAN. 31 PARIS, JUNE 6 REUTERS

NEWSLINE

IN NEWS

Second N.Y. prison escapee captured
David Sweat was caught Sunday, just days after fellow inmate Richard Matt was killed.

IN MONEY

No vacation cash? Stay away from credit cards
Almost half of people who travel go into debt.

IN SPORTS

Lakers going after elite free agents
Los Angeles boss Jeanie Buss tries to return team to its glory days.

IN LIFE

INVASION FOR THE GRATEFUL DEAD

The Grateful Dead starts mini-tour of farewells

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PRIDE NATION

NEW YORK CITY

JOHN TAGGART, EPA

SAN FRANCISCO

TONY AVELAR, AP

In New York, Chicago and San Francisco, the scene was similar: Revelers marching Sunday in gay pride parades supercharged by the historic Supreme Court ruling extending marriage rights to same-sex couples in all 50 states. "So now I have two things to celebrate," said Barry Holt, a nurse from Raleigh, N.C., one of millions who participated nationwide. Story, IN NEWS

BIOLABS INVESTIGATION

Senators, health experts want action to address lab mishaps

Lack of transparency and poor oversight stirs concerns

Alison Young
USA TODAY

CDC

A scientist works in a biosafety level 3 lab at the Centers for Disease Control and Prevention.

Key members of Congress, public health leaders and biosecurity experts demand better oversight and accountability for laboratories in the wake of a USA TODAY Network investigation that revealed widespread safety lapses and pervasive secrecy that obscures failings by researchers and regulators.

The investigation uncovered hundreds of lab accidents and near-miss incidents that occurred in biological laboratories working with dangerous pathogens in recent years, putting scientists and sometimes even the public at risk. Oversight of labs is fragmented and largely self-policed, and even when labs commit the most egregious safety violations, they are allowed to keep operating and their names are kept secret by federal officials, the investigation showed.

The "lack of transparency and significant variability in how safety lapses are reported and reprimanded across all levels of government is very concerning," said U.S. Sen. Ron Johnson, chairman of the Senate Committee on Homeland Security and Governmental Affairs.

Johnson, R-Wis., said research on high-risk pathogens is important to protecting public health, but "we need to ensure agencies are holding labs accountable and shoring up trust in this program through reasonable transparency and communication with the public."

U.S. Sen. Tom Carper of Dela-

▶ STORY CONTINUES ON 2A

SPACEX ROCKET FAILS ON LAUNCH

Craft was carrying food and supplies for space station

James Dean and Emre Kelly
Florida Today

CAPE CANAVERAL While SpaceX searched the Atlantic Ocean for Falcon 9 rocket debris, NASA on Sunday pledged to press ahead with International Space Station operations despite the outpost's third lost resupply mission in eight months.

And space agency officials said Sunday's failure by a SpaceX rocket expected to fly astronauts within a few years, while disappointing, only underscored the wisdom of choosing two companies, not one, to launch crews. "This is a reminder that space-

AFP/GETTY IMAGES NASA TV
Explosion may delay future missions.

flight is an incredible challenge, but we learn from each success and each setback," NASA Administrator Charles Bolden said.

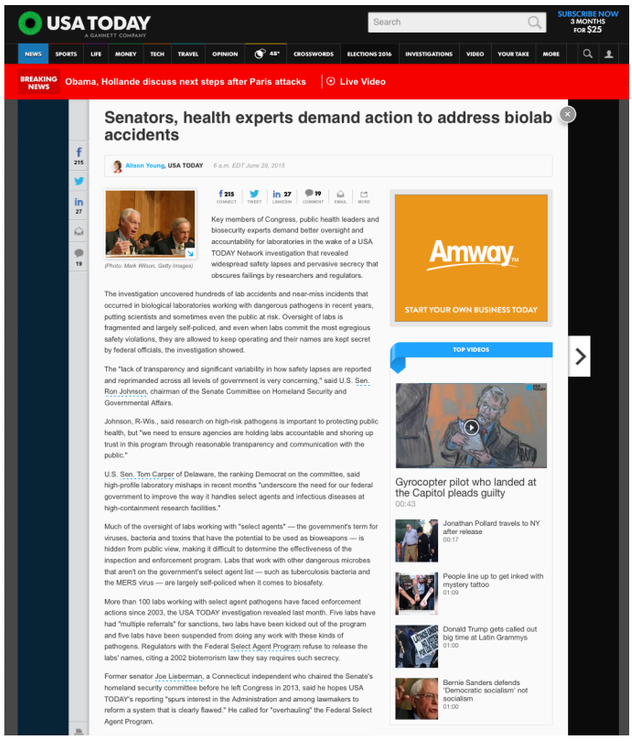
SpaceX will lead an investigation into what caused a Falcon 9 rocket to break apart 2 minutes and 19 seconds after a 10:21 a.m. ET blastoff from Cape Canaveral Air Force Station, dooming the capsule packed with more than 4,000 pounds of ISS supplies.

Among the cargo was a docking ring that two future U.S. crew vehicles would have used, SpaceX's Dragon and Boeing's CST-100.

SpaceX initially focused on an oxidizer tank in the rocket's upper stage, which SpaceX CEO Elon Musk said became overpressurized. "Data suggest a counter-intuitive cause," he said on Twitter, adding no more could be said before an analysis of data.

The failure was the first by SpaceX's Falcon 9 rocket after 18 successful launches, including five this year. It followed the loss in late April of a Russian resupply ship, and last October's explosion of an Orbital Sciences Corp. Antares rocket shortly after their liftoff from Virginia's Eastern Shore. NASA said the space station now has enough food to last until October, and several more cargo missions are planned before the end of the year.

ONLINE: June 29, 2015
http://www.usatoday.com/story/news/2015/06/29/actions-needed--improved-lab-safety/29296625/



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Senators, health experts demand action to address biolab accidents

Alison Young, USA TODAY 8 a.m. EDT June 29, 2015

(Photo: Mark Wilson, Getty Images)

Key members of Congress, public health leaders and biosecurity experts demand better oversight and accountability for laboratories in the wake of a USA TODAY Network investigation that revealed widespread safety lapses and pervasive secrecy that obscures failings by researchers and regulators.

The investigation uncovered hundreds of lab accidents and near-miss incidents that occurred in biological laboratories working with dangerous pathogens in recent years, putting scientists and sometimes even the public at risk. Oversight of labs is fragmented and largely self-policed, and even when labs commit the most egregious safety violations, they are allowed to keep operating and their names are kept secret by federal officials, the investigation showed.

The "lack of transparency and significant variability in how safety lapses are reported and reprimanded across all levels of government is very concerning," said U.S. Sen. Ron Johnson, chairman of the Senate Committee on Homeland Security and Governmental Affairs.

Johnson, R-Wis., said research on high-risk pathogens is important to protecting public health, but "we need to ensure agencies are holding labs accountable and shoring up trust in this program through reasonable transparency and communication with the public."

U.S. Sen. Tom Carper of Delaware, the ranking Democrat on the committee, said high-profile laboratory mishaps in recent months "underscore the need for our federal government to improve the way it handles select agents and infectious diseases at high-containment research facilities."

Much of the oversight of labs working with "select agents" — the government's term for viruses, bacteria and toxins that have the potential to be used as bioweapons — is hidden from public view, making it difficult to determine the effectiveness of the inspection and enforcement program. Labs that work with other dangerous microbes that aren't on the government's select agent list — such as tuberculosis bacteria and the MERS virus — are largely self-policed when it comes to biosafety.

More than 100 labs working with select agent pathogens have faced enforcement actions since 2003, the USA TODAY investigation revealed last month. Five labs have had "multiple referrals" for sanctions, two labs have been kicked out of the program and five labs have been suspended from doing any work with these kinds of pathogens. Regulators with the Federal Select Agent Program refuse to release the labs' names, citing a 2002 bioterrorism law they say requires such secrecy.

Former senator Joe Lieberman, a Connecticut independent who chaired the Senate's homeland security committee before he left Congress in 2013, said he hopes USA TODAY's reporting "spurs interest in the Administration and among lawmakers to reform a system that is clearly flawed." He called for "overhauling" the Federal Select Agent Program.

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Senators, health experts demand action to address biolab accidents

Alison Young, *USA TODAY*

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The investigation uncovered hundreds of lab accidents and near-miss incidents that occurred in biological laboratories working with dangerous pathogens in recent years, putting scientists and sometimes even the public at risk. Oversight of labs is fragmented and largely self-policed, and even when labs commit the most egregious safety violations, they are allowed to keep operating and their names are kept secret by federal officials, the investigation showed.

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CDC

A scientist works in a biosafety level 3 lab at the Centers for Disease Control and Prevention.

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Lieberman co-chairs a Blue Ribbon Study Panel on Biodefense examining U.S. readiness for bioterrorism and emerging disease. The panel, sponsored by the Hudson

MARK WILSON MARK WILSON, GETTY IMAGES

Sen. Ron Johnson, R-Wis., left, and Sen. Tom Carper, D-Del., have concerns about labs working with dangerous pathogens.

Institute think-tank and funded in part by biotech companies, includes former Homeland Security secretary Tom Ridge and former Health and Human Services secretary Donna Shalala.

Regulation by the Federal Select Agent Program "does not fully address underlying issues in pathogen security, including human error and an inadequate culture of transparency and security awareness," Lieberman said. Some aspects of the program are "so burdensome and drawn out" that they discourage scientists from doing biomedical and biodefense research.

Lab regulators at the Centers for Disease Control and Prevention and the U.S. Department of Agriculture, which jointly run the Federal Select Agent Program, did not respond to requests for comment on criticisms of the program.

Since last summer, lab safety has drawn concern from the public and policymakers in the wake of several high-profile accidents at federal laboratories. Last year, labs at the CDC had serious mishaps with anthrax, Ebola virus and a deadly strain of avian influenza, and forgotten vials of deadly smallpox virus were discovered in an unauthorized storage room at the National Institutes of Health. In recent weeks, the Pentagon has scrambled to locate dozens of live anthrax specimens an Army lab in Utah mistakenly shipped to labs across the country and abroad for 10 years that were believed to have been killed with irradiation but weren't fully inactivated.

These incidents are just a few of the hundreds that have occurred in recent years at labs operated by universities, private defense contractors and government agencies, the USA TODAY investigation revealed.

"The number of lapses in biosafety that were uncovered is alarming," said Amesh Adalja, a senior associate at the UPMC Center for Health Security, a think-tank that studies policy issues relating to biosecurity, epidemics and disasters.

Gregory Koblentz, deputy director of the biodefense graduate program at George Mason University in Virginia, expressed similar concern. "The overall scope of what you uncovered was surprising," he said. "Another really compelling point your series highlighted is how fragmented our oversight system is on biosafety. ... We really need to have a nationwide, centralized biosafety oversight system."

Richard Ebright, a biosafety expert at Rutgers University in New Jersey who has testified before Congress, said lab oversight by the CDC and USDA is clearly ineffective. Ebright said both agencies have conflicts of interests as regulators because they conduct research in their own labs and their departments fund studies at facilities receiving inspections.

Koblentz and Adalja noted that in 2009 — in the wake of another string of lab incidents — a task force of several federal agencies made numerous recommendations for improving biosafety. Adalja said, "The degree to which the task force's recommendations have or have not been implemented — and if not, why not — merits investigation in its own right."

The recommendations of the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight included identifying or establishing a federal agency to coordinate biosafety for all BSL-3 and BSL-4 labs and mandating compliance with key biosafety measures, which are considered to be guidelines. It called for creating a voluntary and non-punitive lab incident reporting system to analyze trends.

Six years later, it appears such recommendations have not been implemented. The task force was co-chaired by the U.S. Department of Health and Human Services and the USDA. It's unclear what happened after the recommendations were made or who was responsible for acting on them.

HHS officials did not answer USA TODAY's questions, instead issuing a general statement that the department "is strongly committed" to ensuring lab safety and security and that since the 2009 report, "we have and continue to implement concrete measures to improve the handling of hazardous microbiological agents and toxins in our labs." HHS provided no examples of actions taken to identify a single federal agency to oversee biosafety, mandate compliance with biosafety guidelines or create a better incident reporting system.

Former HHS secretary Kathleen Sebelius, who held the position at the time the task force issued its recommendations, was traveling and unavailable for an interview. USDA officials involved with the task force were traveling and unavailable for comment, a spokesperson said.

Officials with the White House Office of Science and Technology Policy did not respond to requests for comment about the 2009 recommendations, but they noted other recent actions taken to improve safety and assess the select agent regulations.

Creating a better lab incident reporting system — and process for disseminating lessons learned — is critical to reducing lab accidents, several experts said.

"People need to learn from those mistakes, but it's awfully hard to learn about mistakes that are made and what can be learned from them if you never hear about them," said Eric Blank, senior director of public health systems at the Association of Public Health Laboratories.

Blank said the United States needs to create a more comprehensive biosafety program for laboratories and not focus only on select agents with an emphasis on security. He said Canada's system of lab oversight could serve as a model.

The lack of transparency about lab incidents, federal oversight and enforcement actions — and even the whereabouts of research facilities experimenting with risky pathogens are other issues that need addressing, some public health experts and community advocates said.

Of particular concern are high-containment labs that work with the most dangerous microbes, yet there is no publicly available list of the facilities and even health departments and the federal government don't know where they all are. USA TODAY's "Biolabs in Your Backyard" project identified more than 200 biosafety level 3 and 4 lab facilities nationwide and disclosed in an online interactive database information about their research and more than 20,000 pages of their safety records collected lab-by-lab.

USA TODAY's database of labs is a "good start," but it's not comprehensive and local public health officials need federal regulators to share information about the labs and the types of pathogens they work with, said Blank, whose association's members include health department laboratories that monitor and detect health threats in their communities and respond to outbreaks.

"It's a challenge, as you noted in the article, to get information from the various federal programs. They're not particularly forthcoming, and that's kind of puzzling," Blank said.

"Public health is supposed to be a full partner in homeland security issues," said Jeff Levi, executive director of the Trust for America's Health, a national non-profit group that watchdogs public health issues.

Health officials must know about labs and lab incidents in their communities to be prepared to respond quickly to assess for any threat to public health, identify those who may have been exposed and, if needed, assist in arranging quarantine or ensuring infection control, said Chris Aldridge, senior director for infectious diseases and informatics at the National Association of County and City Health Officials.

The mistakes with shipments of live anthrax by the Army's Dugway Proving Ground are an example of how local public health labs and officials become the front-line responders when incidents happen, Aldridge and Blank noted.

Transparency about labs and incidents needs to extend to the public, said Scott Yundt, an attorney for Tri-Valley CAREs, a community-based watchdog group in Livermore, Calif., that has monitored activities at the Lawrence Livermore National Laboratory since 1983.

"Once these labs are operating, there really is no engagement with the public at all," Yundt said. He said there needs to be legislation to require regular disclosures of lab operations and incidents, similar to weekly public reporting required about safety issues at nuclear facilities done through the independent Defense Nuclear Facilities Safety Board.

Yundt said the public and policymakers should be able to readily find out, at least in general terms, the kinds of pathogens and research underway at each facility. Without that information, it's difficult to compare what labs are doing and determine whether efforts are duplicated and taxpayer money is used efficiently. He said labs' claims that releasing information poses a terrorism risk are overblown.

Koblentz at George Mason University said the issues around biosafety have more traction than they have in several years.

"I think there is a window of opportunity here to put in place some much more effective oversight mechanisms," he said. "We've been lucky that the incidents that happened last summer and that are ongoing with Dugway, as far as we know, haven't involved any infections. This is a wakeup call."

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USA TODAY INVESTIGATION

LEADERS DEMAND BIOTERROR LAB INFO

House panel wants details on sanctions

Alison Young
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USA TODAY

Bipartisan leaders of a congressional oversight committee, citing a USA TODAY Network investigation, demand that federal regulators provide the names of research laboratories that have faced sanctions for safety violations while working with potential bioterror viruses and bacteria, according to a letter the committee sent Monday.

USA TODAY's "Biolabs in Your Backyard" investigation revealed more than 100 labs have faced enforcement actions since 2003 because of serious safety violations while working with "select agent" pathogens such as anthrax. Yet lab oversight is cloaked in secrecy, making it difficult to determine the effectiveness of the federal inspection and enforcement program. Even when labs commit the most egregious safety violations, the investigation found, they often are allowed to keep operating and their names are kept secret by regulators.

The House Committee on Energy and Commerce wants details about labs that have been fined or faced other enforcement actions, including suspension or revocation of federal authorizations to work with "select agents," the government's term for viruses, bacteria and toxins that could be used by terrorists.

The letter, which sets a deadline of July 20, was sent to the Health and Human Services inspector general, which handles enforcement actions for lab inspectors at the Centers for Disease Control and Prevention.

More than 100 labs have faced enforcement actions since 2003 because of serious safety violations while working with ... pathogens such as anthrax.

The committee, the letter says, "is examining the adequacy of federal select agent oversight" in the wake of recent revelations that an Army lab in Utah mistakenly sent live anthrax, instead of killed specimens, to labs in the USA and abroad for 10 years. It notes that the USA TODAY investigation, published in May, reported that since 2003, the CDC had referred 79 labs for potential enforcement actions, and more than $2.4 million in fines were levied against 19 organizations.

USA TODAY found that some labs have repeatedly been referred for enforcement actions. Five labs have had "multiple referrals" for enforcement. Two labs have been kicked out of the program, and five labs have been suspended from doing any select agent research, the CDC told the newspaper. Seven labs were in a federal performance improvement program. Neither the CDC nor the HHS inspector general would name names.

The committee's letter seeks the names of labs that have been suspended or kicked out of the Federal Select Agent Program, which oversees labs working with potential bioterror pathogens.

Dan White, a spokesman for the HHS inspector general's office, said the office received the letter, will give it careful consideration and take appropriate action. CDC spokesman Tom Skinner said the agency will provide the inspector general's office with whatever information it needs to respond to the House committee's inquiry.

The Federal Select Agent Program is jointly run by the CDC and the U.S. Department of Agriculture. Beyond the labs the CDC referred to the HHS inspector general, dozens more have faced regulatory actions from the USDA.

Read full coverage of USA TODAY's investigative reporting on laboratory safety and security issues at biolabs.usatoday.com

CONFEDERATE FLAG

SOUTH CAROLINA SENATE VOTES FOR REMOVAL

JIM WATSON, AFP/GETTY IMAGES

South Carolina Gov. Nikki Haley called for the removal of the Confederate battle flag, which flies on Statehouse grounds.

Bill would oust symbol from Capitol grounds

Tim Smith
The Greenville News
John Bacon
USA TODAY

"We've been pulling the band-aid off really slowly, and it hasn't been good for us."
Sen. **Vincent Sheheen**

The South Carolina Senate gave key approval Monday to remove the Confederate battle flag from the Statehouse grounds.

The 37-3 vote came after several hours of debate and defeat of a handful of proposed amendments. Under Senate rules, it must pass by a two-thirds majority again in a final vote Tuesday.

State lawmakers began debate Monday on the fate of the flag, less than three weeks after a deadly shooting at a predominantly black church brought renewed attention to the controversial Southern symbol.

The Senate proposal, which would remove the flag from a Confederate monument on the Statehouse lawn, would go to the House for consideration. The bill requires a two-thirds majority in both the House and Senate to be sent to Gov. Nikki Haley, who strongly supports it.

Voting against the measure were three Republicans: Senate Majority Leader Harvey Peeler of Gaffney, Sen. Lee Bright of Spartanburg County and Sen. Danny Verdin of Laurens.

Sen. Vincent Sheheen, a Democrat and chief author of the flag bill, told the Senate that "quiet bigotry" still exists in the state.

"It's about how to heal wounds that stretch back many years," Sheheen said of removing the flag. "We've been pulling the band-aid off really slowly, and it hasn't been good for us."

Sen. Larry Martin, a Republican, said his view on the flag changed after the June 17 attack that left nine people dead at the historic Emanuel AME Church in Charleston. Police say accused shooter Dylann Roof reportedly shouted racial epithets during the bloodbath, and several photos of the suspect showed him posing with a Confederate flag.

"It isn't part of our future. It's part of our past," Martin said.

Bright had earlier asked for an amendment to require a non-binding public referendum on the issue.

State Sen. Darrell Jackson, a Democrat, was a part of a 2000 compromise that put the flag at the monument. Now, he would like to see the issue resolved once and for all.

"Hopefully the fight about the Confederate flag at the Capitol will be over," Jackson said.

Contributing: Sonia Gutierrez, WLTX-TV, Columbia

Researchers plan for global Armageddon threats

Traci Watson
Special for USA TODAY

It's no ordinary meeting when a bad decision could spell global catastrophe.

For the experts assembled at a conference hall in Italy this spring, the choices were agonizing. A gigantic space rock was bearing down on Earth. If it slammed into the planet, it could damage an area the size of Ireland. But a campaign to push the rock, known as an asteroid, off course could shatter it, possibly widening the devastation, if not done correctly.

The officials opted to shift the monster's path, and it prevented unfathomable devastation. There was just one problem: A chunk of the asteroid broke away and made a beeline for Bangladesh.

The looming space rock was imaginary — and utterly realistic. Researchers crafted every last detail of the scenario, which was unveiled at a scientific meeting to test how the world would respond to an incoming asteroid.

While it may sound like science fiction, real researchers are designing asteroid deflection tools and sketching out rocket missions to large space rocks. A pair of telescopes set to come online by the end of 2015 will give humanity a last-minute alert of an invader headed our way.

"People are starting to realize that it's not just a totally stupid idea that an asteroid might cause big damage," says the University of Hawaii's John Tonry, head of the late-alert telescopes.

As if to prove the point, a space rock exploded over Chelyabinsk, Russia, in 2013, shattering thousands of windows. Yet the Chelyabinsk asteroid, at 55 to 65 feet, was a trifle. More than 600,000 asteroids that swing close to Earth are 150 feet wide or bigger — big enough to destroy New York City in a direct hit.

UNIVERSITY OF CALIFORNIA-SANTA BARBARA

A laser hits an asteroid-like material in a simulation.

If something big does come this way, researchers are working on the "death ray" technique, as it was dubbed on Twitter. Still in early testing, it would send a spaceship to aim lasers at an asteroid's surface. The jet of vaporized debris would propel the rock out of its original path. There's also the Hypervelocity Asteroid Intercept Vehicle, which would carry a nuclear bomb to shatter the asteroid.

Nudging asteroids off course could be effective as well, if there's plenty of warning. For this method, a spacecraft slams into the asteroid at more than 20,000 mph, pushing it onto a new path. A ship too small or slow would botch the job, so researchers have been working to predict how a collision affects rocks of different shapes and compositions.

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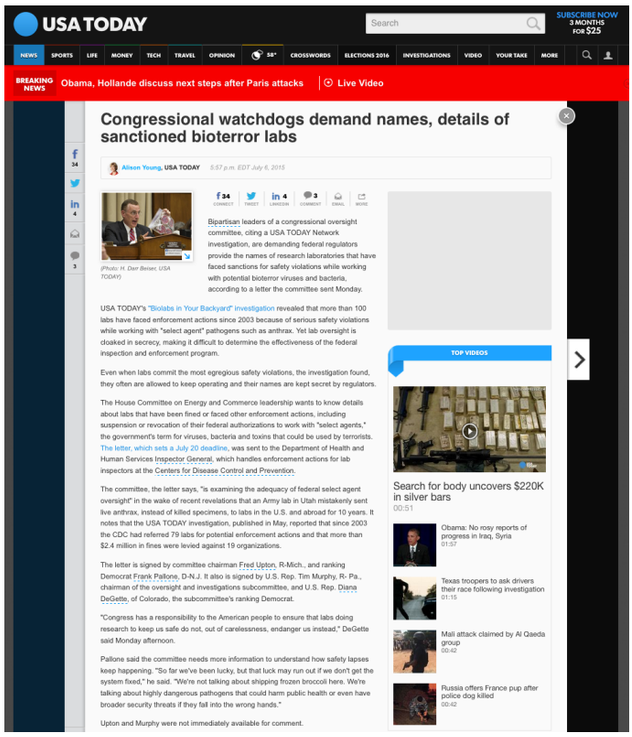

USA TODAY
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http://www.usatoday.com/story/news/2015/07/06/bioterror-lab-sanctions/29768513/

At a July 2014 hearing on lab incidents at the Centers for Disease Control and Prevention, U.S. Rep. Tim Murphy, R-Pa., chairman of the House Energy and Commerce Committee's oversight and investigations subcommittee, holds up a Ziploc bag as an example of how pathogenic agents were handled at the CDC.

Congressional watchdogs demand names, details of sanctioned bioterror labs

Alison Young, *USA TODAY*

Bipartisan leaders of a congressional oversight committee, citing a USA TODAY Network investigation, are demanding federal regulators provide the names of research laboratories that have faced sanctions for safety violations while working with potential bioterror viruses and bacteria, according to a letter the committee sent Monday.

USA TODAY's "Biolabs in Your Backyard" investigation revealed that more than 100 labs have faced enforcement actions since 2003 because of serious safety violations while working with "select agent" pathogens such as anthrax. Yet lab oversight is cloaked in secrecy, making it difficult to determine the effectiveness of the federal inspection and enforcement program.

Even when labs commit the most egregious safety violations, the investigation found, they often are allowed to keep operating and their names are kept secret by regulators.

The House Committee on Energy and Commerce leadership wants to know details about labs that have been fined or faced other enforcement actions, including suspension or revocation of their federal authorizations to work with "select agents," the government's term for viruses, bacteria and toxins that could be used by terrorists. The letter, which sets a July 20 deadline, was sent to the Department of Health and Human Services Inspector General, which handles enforcement actions for lab inspectors at the Centers for Disease Control and Prevention.

The committee, the letter says, "is examining the adequacy of federal select agent oversight" in the wake of recent revelations that an Army lab in Utah mistakenly sent live anthrax, instead of killed specimens, to labs in the U.S. and abroad for 10 years. It notes that the USA TODAY investigation, published in May, reported that since 2003 the CDC had referred 79 labs for potential enforcement

actions and that more than $2.4 million in fines were levied against 19 organizations.

The letter is signed by committee chairman Fred Upton, R-Mich., and ranking Democrat Frank Pallone, D-N.J. It also is signed by U.S. Rep. Tim Murphy, R- Pa., chairman of the oversight and investigations subcommittee, and U.S. Rep. Diana DeGette, of Colorado, the subcommittee's ranking Democrat.

"Congress has a responsibility to the American people to ensure that labs doing research to keep us safe do not, out of carelessness, endanger us instead," DeGette said Monday afternoon.

Pallone said the committee needs more information to understand how safety lapses keep happening. "So far we've been lucky, but that luck may run out if we don't get the system fixed," he said. "We're not talking about shipping frozen broccoli here. We're talking about highly dangerous pathogens that could harm public health or even have broader security threats if they fall into the wrong hands."

Upton and Murphy were not immediately available for comment.

USA TODAY's investigation found that some labs have repeatedly been referred for enforcement actions. Five labs have had "multiple referrals" for enforcement. Two labs have been kicked out of the program, and five labs have been suspended from doing any select agent research, the CDC told the newspaper. Seven labs were currently in a federal performance improvement program. But neither the CDC nor the HHS inspector general would name names — not even for the two labs kicked out of the select agent program, and they have redacted the names of labs from documents released under the federal Freedom of Information Act (FOIA). USA TODAY has filed several FOIA appeals since October seeking release of the names of labs that have faced enforcement actions.

In a departure from general secrecy surrounding the names of sanctioned labs, earlier this year the CDC publicly announced its suspension of the Tulane National Primate Research Center — after the center's accidental release of a bioterror bacterium became publicly known and was the subject of news reports. The CDC said it balances the public's right to transparency with the risk posed by information being made available to those who might use it to threaten public health or security.

The letter the committee sent Monday seeks the names of labs that have been suspended or kicked out of the Federal Select Agent Program, which oversees labs working with potential bioterror pathogens. It also seeks a list of all labs that have had multiple referrals for enforcement actions, that have been fined or that are on performance improvement plans.

Don White, a spokesman for the HHS inspector general's office, said the office has received the letter, will give it careful consideration and take appropriate action. CDC spokesman Tom Skinner said the agency will provide the inspector general's office with whatever information it needs to respond to the committee's inquiry.

The Federal Select Agent Program is jointly run by the CDC and the U.S. Department of Agriculture. Beyond the labs CDC referred to the HHS inspector general, dozens more have faced regulatory actions from the USDA, which takes the lead overseeing select agent labs primarily working with animal or agricultural pathogens. USA TODAY reported that the USDA says it has conducted 48 investigations in recent years that have resulted in $116,750 in fines.

The USDA said all of its enforcement records about these fines are required to be kept secret because of the 2002 bioterrorism law, but released a spreadsheet about the actions that has most of the information blacked out.

Last week USA TODAY reported on calls for better lab oversight and transparency from the bipartisan leaders of the Senate Committee on Homeland Security and Governmental Affairs, as well as public health leaders and biosecurity experts.

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http://www.usatoday.com/story/news/2015/06/16/cdc-lab-incident-reports-foia/28806263/

After serious lab mishaps, CDC says it needs 3 years to release records

Alison Young, *USA TODAY*

The Centers for Disease Control and Prevention — which has publicly disclosed three serious laboratory accidents during the past year involving Ebola, anthrax and a deadly strain of bird flu — says it will take three more years before it will release copies of all incident reports for the agency's labs in Atlanta and Fort Collins, Colo.

On Jan. 6, in an effort to determine the extent of lab accidents at the agency, USA TODAY filed a request under the federal Freedom of Information Act (FOIA) seeking copies of all incident reports at CDC labs during 2013 and 2014. The CDC granted the request "expedited" processing status because USA TODAY had demonstrated there is a compelling public need for the information. The agency initially said it anticipated responding by June 4.

But in a letter sent Friday, the CDC now says it anticipates it will take another three years to release its laboratory-incident reports. CDC Director Tom Frieden did not respond to interview requests.

In an emailed statement, the CDC on Tuesday said: "This request by USA Today likely involves thousands of records, and there are over a million pages of documents in the queue ahead of this one. These all need to be carefully reviewed for security, confidentiality and other restrictions and thus the time needed to respond will be significant."

Two members of Congress who have been investigating CDC's lab-safety mishaps expressed concern about the agency's expected delay in releasing the records.

"CDC should be transparent, cooperative, and publicly accountable, and that would include properly responding to Freedom of Information Act requests in a timely fashion. When it comes to lab safety, there is no room for time or error lapses again," said House Energy and Commerce Committee Chairman Fred Upton, R-Mich., and oversight subcommittee chairman Tim Murphy, R-Pa., in a joint statement Tuesday.

The CDC did not answer USA TODAY's questions this week about how many incidents had occurred in its labs during 2013 and 2014, even though the agency has compiled a 14-page summary report with information about each of them.

On May 26, the CDC sent a letter to USA TODAY offering to provide a redacted version of the 14-page lab-incident summary report instead of the full incident reports the newspaper asked for in January. "If you are amenable to accepting these records as a final response, please let us know and we will send these records to you immediately," said the letter, signed on behalf of CDC FOIA officer Katherine Norris.

USA TODAY did not agree to drop its request for copies of the actual incident reports and the summary report wasn't released. On June 8, the newspaper filed a separate FOIA request seeking the 14-page summary document. That

document, despite being offered for immediate release last month, still has not been released and the CDC on Tuesday wouldn't say how many incidents are listed on it.

On May 28, USA TODAY published a series of reports documenting hundreds of lab incidents at public and private research facilities nationwide. The investigation noted that many labs, including the CDC, have fought to keep records secret about incidents and regulatory actions.

For nearly three years, USA TODAY has been unable to obtain other records about safety and security issues at CDC labs in Atlanta. In June 2012 — after receiving leaked internal agency records — USA TODAY reported that CDC's labs in Atlanta had experienced significant failures of laboratory airflow systems used to contain pathogens, as well as repeated security lapses in areas where dangerous viruses and bacteria are kept. That same month, the newspaper filed FOIA requests seeking additional records about the incidents. The agency still hasn't released any of the records and has said in correspondence it anticipates it will take until Dec. 20, 2015 to make the documents public.

In the CDC's email to USA TODAY on Tuesday about its anticipated three-year delay in releasing its more recent lab incident reports, the agency said: "CDC responds to approximately 1,000 FOIA requests a year and provides hundreds of thousands of pages of records to requestors."

Adam Marshall, a legal fellow at the Reporters Committee for Freedom of the Press, a national non-profit that advocates for transparency, said the FOIA requires agencies to make a determination on records requests within 20 days and they can take an additional 10 days in certain unusual circumstances.

"I think what's reasonable is compliance with the law," Marshall said Tuesday. "In cases like yours where there is a really heightened need for the public to have access to this information, it's incredibly important that the agency comply with its statutory obligation. It's a travesty for the American public that they aren't."

Federal agencies often cite backlogs for delays in processing FOIA requests in the time the law requires. The CDC reports that its average processing time is 153 days for a "complex" request and 47 days for a "simple" request. The CDC says it handled "expedited" requests in an average of 37 days — with 51 days being the "highest number of days" needed for expedited requests processed during fiscal year 2014, according to the agency's FOIA report.

USA TODAY's January request for lab-incident reports and its 2012 requests for airflow- and security-incident records were all granted expedited processing status by the agency.

Marshall said there has been an increase in recent years in federal agencies seeking to keep records or parts of records secret by citing an increasing number of exemptions to the FOIA that allow government officials the discretion to withhold certain types of information, even though secrecy isn't required. "Part of the reason there is so much of a backlog is so much time is being spent trying to figure out what is the maximum amount of information we can withhold from the public," Marshall said.

Earlier this month, the House Oversight and Government Reform Committee held hearings on the Freedom of Information Act and delays in agencies releasing public records.

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The Centers for Disease Control and Prevention in Atlanta.

CDC lacked key lab incident reporting policy despite scrutiny, promises

Alison Young, *USA TODAY*

Despite several serious, high-profile lab accidents and promises to Congress of reforms, the Centers for Disease Control and Prevention didn't issue a policy until last week to ensure the agency's top lab safety official received reports of mishaps, documents obtained by USA TODAY show.

The revelation is contrary to what the CDC told USA TODAY for a July 9 article about recent lab accidents at the agency and whether CDC staff are failing to report "near miss" incidents. The CDC, in a written statement for that article, had said it already had a policy in place for centralized reporting — a critical component for identifying safety trends.

But that was not true, according to a copy of the policy — dated in 2013 — that USA TODAY obtained under the federal Freedom of Information Act (FOIA) late last week.

The CDC did not issue to its staff a new version of its policy, which requires reports be sent to the top lab safety office, until July 20, according to records the CDC provided to USA TODAY on Monday. The agency said it made a mistake in the information it previously provided to the newspaper on July 8. The agency said its updated incident reporting policy was under development at the time USA TODAY asked its questions but wasn't finalized.

"There's what's being said, and what's being done," said Sean Kaufman, a biosafety consultant and former CDC employee, who testified before Congress last summer about the agency's lab safety issues.

"A fear of the congressional staff was that CDC was just going to say they were going to do things to put the fire out and not really do things. And that appears to really be what's happening," Kaufman said Monday.

While Congress last summer focused on failures at labs operated by the CDC, an investigations subcommittee of the House Energy and Commerce Committee will hold a hearing at 10 a.m. Tuesday to examine the adequacy of the oversight CDC lab inspectors provide to hundreds of other research facilities working with potential bioterror

pathogens. The hearing will focus on lax testing and biosafety practices that resulted in an Army biodefense facility mistakenly shipping live anthrax specimens that. as of Monday. had been located in 192 labs in the USA and seven foreign countries.

Citing an ongoing USA TODAY investigation of lab safety nationwide, the subcommittee has said it plans to explore larger questions about whether regulation of labs working with "select agent" pathogens needs to be strengthened. "Select agent" is the federal government's term for 65 viruses, bacteria and toxins that have the potential to be used as bioweapons or that pose severe threats to public health or agriculture. They include anthrax, Ebola and the pathogens that cause smallpox, plague, botulism and other serious diseases.

Oversight and Investigations Subcommittee Chairman Tim Murphy, R-Pa., said Tuesday's hearing "is an important opportunity for Congress to hold the agencies' feet to the fire" and demand a more careful system.

"When it comes to handling select agents, there is no room for error; however, repeated lapses from federal agencies have raised serious concerns, both from the committee and the press," Murphy said Monday. "This newspaper in particular has brought to light a number of serious concerns about the lack of a consistent and thorough protocol among agencies."

Since January, the CDC has refused to release toUSA TODAYcopies of all its lab incident reports for facilities in Atlanta and Fort Collins, Colo., during 2013 and 2014. The agency, in response to the newspaper's FOIA request, has said it will take until sometime in 2018 to compile and release the records — even though it has granted the request "expedited" processing status in recognition of a compelling need for the public to have access to the information. USA TODAY has appealed the delays as excessive.

USA TODAY filed its FOIA request for a copy of the CDC's lab incident reporting policy on July 13 because earlier in the month the agency had refused to voluntarily provide a copy of the policy or even say when it was enacted. Before saying it had a policy that sent all lab incidents to a newly created top lab safety office, the CDC had given a series of changing answers about whether any single office at the agency collects and reviews lab incidents to spot emerging safety issues.

Ultimately the policy document, referenced by its formal name in the agency's July 8 statement to USA TODAY, turned out to be from 2013 and did not require routing of incident reports to the top lab safety office — which was created last year amid congressional scrutiny. Only as the CDC FOIA Office prepared to send a copy of the existing 2013 policy to the newspaper last week did the agency's top lab officials send out a revised policy on July 20.

The latest documents obtained byUSA TODAY also show that the CDC's acting top lab safety official emphasized in a memo last week the importance of reporting all incidents as well as "near misses" that occur in labs. The memo follows USA TODAY's reporting earlier in the month that raised questions about whether CDC staff are reporting all potential lab mishaps, or only a narrow subset of the most serious potential exposures to pathogens.

"CDC requires reporting of all incidents; however, the best safety programs also track 'near misses' to fix potential problems before someone gets hurt," wrote Stephan Monroe, the CDC's acting associate director for laboratory science and safety, in the July 20 memo. "We encourage you to evaluate whether otherwise minor incidents meet the definition of a near miss, and if so, to report them."

The CDC declined to make Monroe available for an interview. Under the policy documents issued last week, incident reports now eventually go to Monroe's office. This top lab safety office was created a year ago by CDC Director Tom Frieden to be the agency's single point of accountability on lab safety issues in the wake of serious CDC lab incidents with anthrax, Ebola and a deadly strain of bird flu that called into question the agency's safety culture and prompted the congressional hearing last summer.

Yet a permanent director for the office still hasn't been hired. Monroe is the office's third interim lab safety director; he has held the position since May.

The CDC's evolving lab incident reporting policy and failure to find a full-time lab safety director raised questions among some biosafety experts about whether the agency had taken meaningful action to address its safety problems.

"They keep making the same mistakes. It's incredible," said Richard Ebright, a biosafety expert from Rutgers university in New Jersey, who also testified at last summer's hearing on the CDC's lab safety issues. "They set up this office so they could say they were doing something."

Ebright said the CDC's July 20 lab incident reporting policy and a diagram for who decides what should be reported is overly complicated, provides too many layers of bureaucratic review and appears to be designed to avoid — rather than encourage — documentation and independent review of incidents that could prevent future mishaps.

"This is intentionally designed to ensure that nothing or almost nothing reaches the office," Ebright said after reviewing the documents released to USA TODAY. He said all potential incidents should be reported directly to the top lab safety office so a consistent review standard is applied.

"The root cause of all of this is a lack of accountability: Incidents don't get reported and consequences don't occur," Ebright said.

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CDC hires official to address lab safety

Priorities include best practices to prevent lapses

Alison Young
USA TODAY

The Centers for Disease Control and Prevention hired a permanent top official to oversee laboratory safety at the agency, more than a year after a string of high-profile lab incidents with anthrax, Ebola and avian influenza started becoming public.

Stephan Monroe, who has been the CDC's acting associate director for laboratory science and safety since May, is being permanently appointed to the position, the agency said Tuesday.

Monroe was deputy director of the CDC's National Center for Emerging and Zoonotic Infectious Diseases and has served in a variety of leadership positions during 28 years at the Atlanta-based agency.

Monroe said his top priorities include looking for patterns in lab safety incidents and identifying best biosafety practices and promoting their use across the agency's more than 150 labs, which are primarily located in Atlanta and Fort Collins, Colo.

"What was clear from the previous incidents is that we were responding to incidents one at a time and not seeing that there tended to be a pattern," Monroe said. "Because of the work that CDC does and the work that goes on in our laboratories, there will always be some measure of risk. Our focus is on eliminating risk where we can."

Lab safety has been under scrutiny at the CDC and other federal labs because of several high-profile incidents in the past year — including an Army lab mistakenly shipping live anthrax, instead of killed specimens, to unsuspecting researchers for more than a decade. An ongoing USA TODAY Media Network investigation has revealed numerous issues at government, university and private labs across the country and prompted increased scrutiny by Congress.

In July 2014, CDC Director Tom Frieden announced he was appointing a top lab safety official — reporting directly to him — to become a "single point of accountability" and establish and enforce agency-wide biosafety policies. Since then, the agency has had three different employees serve as an interim top lab safety official.

"This appointment is long overdue as the situation has only gotten worse," said U.S. Rep. Fred Upton, R-Mich., chairman of the House Energy and Commerce Committee, which has held two recent hearings on lab safety problems.

To identify emerging safety patterns at the CDC, the agency's lab workers need to report all incidents. Monroe said he recognizes the challenges he faces in this area.

This year, a group of outside lab safety experts, appointed by the agency, warned that a significant percentage of CDC staff have concerns that they will face negative repercussions for reporting lab incidents.

"It's not an easy task to change culture," Monroe said, but he added that he sees progress.

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Jennifer Jacobs
The Des Moines Register

6 things to watch for in the GOP debate

SIMI VALLEY, CALIF. Republican presidential candidates will enter Wednesday's debate with at least one similar goal: Pull off a game-changing performance that will challenge Donald Trump's front-runner status.

The latest USA TODAY GOP Power Rankings show Trump continues to sit atop the crowded field while Scott Walker is fading.

Eleven candidates will stand on the main stage at the Ronald Reagan Presidential Library, while four face off in an earlier undercard debate. Here are six things to watch for:

1 Any cracks in the Trump concrete
Will any candidate find the small crack that erodes momentum for Trump?

Republican strategist Kevin Madden said audiences walk away from these debates remembering candidates' moments of strength or moments of weakness.

"What if Trump emerges from a gang tackle still holding the ball?" he said.

2 The 11th podium
The addition of Carly Fiorina, the only woman in the GOP race, to the main stage could slow down any candidate on the Testosterone Express, conservative analysts said.

"Having 'The Donald' confront the female recipient of his recent insults on national television could be the most intriguing subplot of the second debate," said Ford O'Connell, a GOP strategist.

3 The exclamation point
This isn't a do-or-die debate for Jeb Bush, but he could benefit from controlling a news cycle, said Jeff Stein, an Iowa non-partisan political analyst.

"Jeb! needs to put an exclamation point behind his performance," Stein said, referring to Bush's campaign slogan, adding that "people are waiting to see that he can rally their hearts and minds."

Fiorina still No. 3 in our rankings. Find more at usatoday.com.
CHERYL EVANS

4 Ronald Reagan reaches
The GOP idol figures to be invoked frequently.

GOP pollster Frank Luntz said the location of this debate makes it ideal for putting pressure on Republicans who have made comments on immigration that are "diametrically opposed to Reagan."

5 The Hugh Hewitt trip wire
Will anyone get tripped up in the foreign policy exam?

One of the questioners will be conservative radio host Hugh Hewitt, and he has a reputation for tough policy questions, Luntz said. Trump has already laid the groundwork for a defense by complaining that Hewitt asks "gotcha questions."

6 The prime-time musical chairs
Luntz predicted none of the 11 on the main stage will fall off the debate cliff, but the undercard debaters are in jeopardy.

If they aren't in the top 10 for the next debate Oct. 28, Luntz said, "the networks have a legitimate reason not to do that second debate at all."

One in three California homes prone to wildfires

Doyle Rice
USA TODAY

A third of homes in California are in areas prone to wildfires, according to data from the U.S. Forest Service, a statistic that helps explain the destruction of hundreds of homes over the weekend.

More devastation is likely as people continue to build houses close together in vulnerable areas and fires become more common as a result of prolonged droughts and higher temperatures partly blamed on global warming, Forest Service and climate data show.

The federal agency estimated in its latest report that 4.5 million homes in California were built in areas designated as the "Wildland-Urban Interface" (WUI), where developments are built very close to forests.

California wildfires destroyed more than 750 houses and hundreds of other buildings in the past week, according to CalFire, the state firefighting agency. The Valley Fire near Sacramento has been one of the most destructive this year, CalFire said.

"The large majority of homes destroyed by the Valley Fire so far have been WUI homes," Susan Stewart, a Forest Service scientist, said in an e-mail.

Nationwide, less than 10% of land is a wildland-urban area, but 100 million Americans live there, the Forest Service said.

That's a record 44 million homes built close together in these fire-prone forests as of 2010, a 16% increase from 2000, the Forest Service said in its report, using the latest national data available for analysis.

These expanding wildland-urban regions are a critical issue for firefighting and conserving forests, said Robert Bonnie, an undersecretary at the U.S. Agriculture Department, which oversees the Forest Service.

"Our firefighters must commit greater resources to protect homes and property, which dramatically increases the cost of fire suppression," Bonnie said.

Almost 9 million acres has burned in the USA this year — a total surpassed in only three other years, most recently in 2012, the National Interagency Fire Center said. The Forest Service has spent $1.4 billion this year to fight fires.

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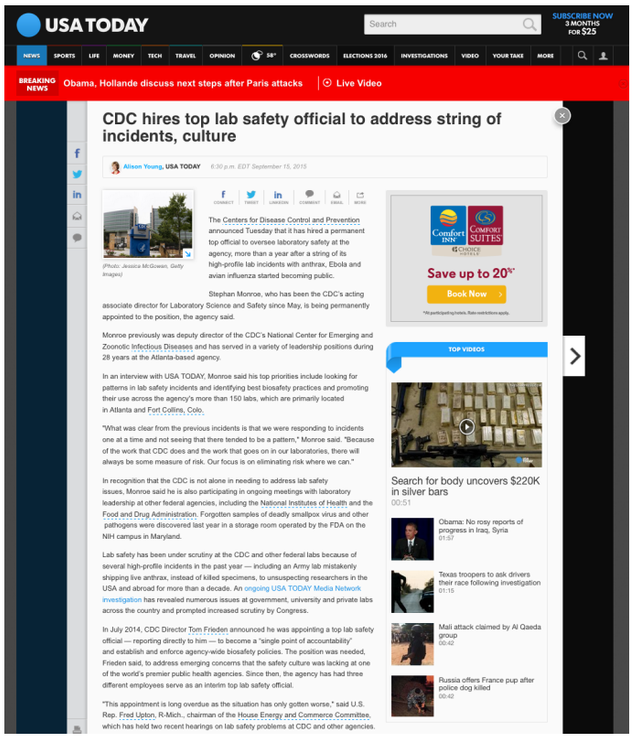

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CDC hires top lab safety official to address string of incidents, culture

Alison Young, USA TODAY 6:30 p.m. EDT September 15, 2015

(Photo: Jessica McGowan, Getty Images)

The Centers for Disease Control and Prevention announced Tuesday that it has hired a permanent top official to oversee laboratory safety at the agency, more than a year after a string of its high-profile lab incidents with anthrax, Ebola and avian influenza started becoming public.

Stephan Monroe, who has been the CDC's acting associate director for Laboratory Science and Safety since May, is being permanently appointed to the position, the agency said.

Monroe previously was deputy director of the CDC's National Center for Emerging and Zoonotic Infectious Diseases and has served in a variety of leadership positions during 28 years at the Atlanta-based agency.

In an interview with USA TODAY, Monroe said his top priorities include looking for patterns in lab safety incidents and identifying best biosafety practices and promoting their use across the agency's more than 150 labs, which are primarily located in Atlanta and Fort Collins, Colo.

"What was clear from the previous incidents is that we were responding to incidents one at a time and not seeing that there tended to be a pattern," Monroe said. "Because of the work that CDC does and the work that goes on in our laboratories, there will always be some measure of risk. Our focus is on eliminating risk where we can."

In recognition that the CDC is not alone in needing to address lab safety issues, Monroe said he is also participating in ongoing meetings with laboratory leadership at other federal agencies, including the National Institutes of Health and the Food and Drug Administration. Forgotten samples of deadly smallpox virus and other pathogens were discovered last year in a storage room operated by the FDA on the NIH campus in Maryland.

Lab safety has been under scrutiny at the CDC and other federal labs because of several high-profile incidents in the past year — including an Army lab mistakenly shipping live anthrax, instead of killed specimens, to unsuspecting researchers in the USA and abroad for more than a decade. An ongoing USA TODAY Media Network investigation has revealed numerous issues at government, university and private labs across the country and prompted increased scrutiny by Congress.

In July 2014, CDC Director Tom Frieden announced he was appointing a top lab safety official — reporting directly to him — to become a "single point of accountability" and establish and enforce agency-wide biosafety policies. The position was needed, Frieden said, to address emerging concerns that the safety culture was lacking at one of the world's premier public health agencies. Since then, the agency has had three different employees serve as an interim top lab safety official.

"This appointment is long overdue as the situation has only gotten worse," said U.S. Rep. Fred Upton, R-Mich., chairman of the House Energy and Commerce Committee, which has held two recent hearings on lab safety problems at CDC and other agencies.

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"This appointment is long overdue as the situation has only gotten worse," said U.S. Rep. Fred Upton, R-Mich., chairman of the House Energy and Commerce Committee, which has held two recent hearings on lab safety problems at CDC and other agencies. "When dealing with these dangerous pathogens, there is zero room for error. We will continue to hold the agency fully accountable and expect Dr. Monroe to uphold the highest safety standards moving forward. It is time for the safety lapses to end once and for all."

Monroe, the CDC said in an announcement Tuesday, will permanently lead laboratory science and safety initiatives at the agency, which has more than 2,000 scientists working in its labs.

"Dr. Monroe brings critically important experience to further strengthen science and safety across all CDC labs," Frieden said in a statement. He said Monroe's "established leadership experience and groundbreaking scientific research make him an ideal choice to lead CDC's new Office of the Associate Director for Laboratory Science and Safety."

In order to identify emerging safety patterns at the CDC, the agency's scientists and other lab workers need to report all incidents, including near misses that may not have resulted in an infection or injury. Monroe said he recognizes the challenges he faces in this area. Earlier this year a group of outside lab safety experts, appointed by the agency, warned that a significant percentage of CDC staff have concerns that they or the agency will face negative repercussions as a result of reporting lab incidents.

"It's not an easy task to change culture," Monroe said Tuesday. Monroe said he has held listening sessions with lab staff and that he hopes his many years working in CDC's labs will help bring credibility to efforts already underway to encourage reporting incidents and near misses. "People appreciate that I know what it's like at the bench," he said.

USA TODAY previously reported that it wasn't until July that the CDC issued a policy to ensure reports of lab incidents reached the top lab safety position that Frieden had announced a year earlier. The CDC has also said it will take until sometime in 2018 to compile and release copies of its lab incident reports for 2013 and 2014, sought since Jan. 6 by USA TODAY under the federal Freedom of Information Act. The agency has said it is processing the request on an "expedited" basis.

The CDC does not have a centralized incident reporting system or database, something that some outside lab safety experts have said is helpful in documenting mishaps and monitoring trends across organizations. Incidents at the CDC are reported through a variety of channels depending on what labs they occur in, whether they result in a clinic visit, or whether they involve an equipment or building issue.

Monroe said he's confident that he's receiving the information he needs to monitor lab safety at the agency and identify any emerging trends. But he said information management is one area where his office will be looking for best practices in both the public and private sectors. Monroe said he's cautious about not creating any system that makes reporting incidents burdensome.

"The kinds of things that have been reported so far have thankfully been very minor," Monroe said. He said there have been no incidents of the types that occurred last year that potentially exposed workers to anthrax, a deadly strain of bird flu and the Ebola virus. Nobody was infected in the incidents.

"Everyone is aware of those incidents because CDC has been very open and transparent about reporting things," Monroe said. "If there were to be another incident comparable to those incidents, we as an agency would be very forthcoming about describing what's happened."

CDC's Freedom of Information Act (FOIA) office has heavily redacted or completely withheld much of the lab incident information that's been sent to Monroe since he became the agency's acting lab safety official in May. In an emailed response Tuesday afternoon to a FOIA request from USA TODAY that sought copies of all incident reports received by Monroe, the CDC said it had identified 63 pages of records. But the agency withheld in their entirety 10 pages of records and it heavily redacted information from another 33 pages. USA TODAY has posted the redacted records online for public review.

The CDC largely cited rules relating to a 2002 bioterrorism law that governs regulation of "select agent" pathogens as the reason for withholding the names of infectious agents and other information about incidents, even in some cases where the subject line of the email specifies the incident does not involve a select agent. Select agent is the federal government's term for certain viruses, bacteria and toxins — such as those that cause anthrax, plague, Ebola and botulism — that have the potential to be used as bioweapons.

Incidents where descriptive information wasn't removed show a mishap involving a broken vial of H5N1 influenza virus that CDC shipped to another undisclosed facility, a tuberculosis expert who had a test result indicating potential occupational exposure to the disease, and a lab worker who was potentially exposed to a non-cholera vibrio pathogen after getting splashed in the eye while not wearing protective eyewear.

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FDA hiring top official to improve lab safety in wake of smallpox incident

Alison Young, *USA TODAY*

Laboratories operated by the U.S. Food and Drug Administration lack key data for tracking safety incidents, fail to require important training and need to establish more consistent procedures, according to a report by outside experts examining federal biolabs in the wake of high-profile mishaps with deadly pathogens.

The FDA Is addressing the issues by hiring a top safety official, improving training and taking several other actions, said Luciana Borio, the agency's acting chief scientist. The FDA's scientists do research with bacteria and viruses that cause food-borne illnesses as well as those with potential to be used as bioweapons as part of the agency's work regulating a wide range of products.

"I thought the report was extraordinarily important for us," Borio said Wednesday. The agency has a "tremendous commitment" to improving safety and putting new agency-wide training and specimen inventory programs in place by next year, she said.

In the summer of 2014 forgotten vials of the virus that causes smallpox — a deadly disease that has been eradicated globally — and other dangerous pathogens were discovered in an FDA storage room on the campus of the National Institutes of Health in Bethesda, Md. The smallpox virus poses such a significant health threat that under international agreement only two labs in the world are allowed to possess any samples of it: The Centers for Disease Control and Prevention in Atlanta and another lab in Russia.

In addition, a serious string of lab accidents became public last year at the CDC, including one that potentially exposed dozens of that agency's workers to live anthrax bacteria, as well as other mishaps with specimens of Ebola virus and a deadly strain of avian influenza. Meanwhile an ongoing USA TODAY Media Network investigation has revealed numerous other serious safety and security incidents at labs nationwide operated by other government agencies, universities and private companies.

Since last year, a group of outside lab safety experts has been evaluating biosafety at research facilities operated by the CDC, NIH and FDA, which are all part of the U.S. Department of Health and Human Services. The advisers' report on the FDA's labs was posted Friday on the agency's website without any announcement.

In a separate examination of labs operated by the NIH, the safety advisers largely offered praise. "The commitment of NIH leadership toward laboratory safety is evident and is demonstrated at all levels examined..." said that report, which was posted online in July, and made several recommendations, including for the NIH to do more to ask scientists to consider alternative methods that might further reduce risks of their research.

Alfred Johnson, the NIH's director of research services, in an interview Wednesday said NIH was pleased with the report's findings and that the agency has already addressed most of the recommendations. Johnson said that recent lab incidents have prompted greater discus-

sion and collaboration among federal agencies on ways to improve safety.

"Incidents like the ones you mention tend to make people refocus," he said. "We're all now committed to making sure we have better safety programs in place."

In January the safety advisers issued a scathing report on the CDC's labs, warning that the agency was "on the way to losing credibility," that staff feared reporting accidents and agency and leadership lacked commitment toward safety. The CDC last week announced it had hired a permanent top official to oversee safety in its labs.

The FDA's lab safety deficiencies, while not as egregious as what the federal advisers found at the CDC, further illustrate the need for the country to have a single lab safety oversight agency, say some experts.

The Government Accountability Office, the investigative arm of Congress, has repeatedly warned lawmakers since 2007 that there is a lack of national standards for operating high-containment laboratories and that there is no single federal entity responsible for oversight of these kinds of labs, which work with some of the world's most dangerous viruses, bacteria and toxins.

Richard Ebright, a microbiologist at Rutgers University who has testified before Congress on lab safety issues, said "the reports underscore the fact that there are gaps and inconsistencies in the implementation and enforcement of federal biosafety guidelines, even in federal agencies."

Ebright said the findings by the advisory group shows "the need to replace the spottily implemented and utterly unenforced current federal biosafety guidelines with uniform and enforced biosafety rules."

The House Energy and Commerce Committee has held multiple hearings on lab safety problems over the years, including two since the latest string of troubling lab accidents became public beginning in 2014. The incidents have continued this year with the discovery in May that an Army lab had been mistakenly shipping live anthrax samples – instead of fully killed specimens -- to unsuspecting labs for more than a decade.

"There's no hiding the recent failures of federal agencies to implement appropriate and necessary lab safety standards involving some of the world's deadliest pathogens," said U.S. Rep. Fred Upton, R-Mich., the committee's chairman.

"These repeated blunders have put lives at risk and jeopardized the country's bioterrorism response efforts," Upton said. "The committee will continue its due diligence in determining how best to stop this reckless trend, and that includes examining the merits of a single lab oversight agency. One thing is for certain – the status quo that has fostered these mishaps is unacceptable."

The committee's ranking Democrat, Frank Pallone, Jr. of New Jersey, added: "We continue to have specific concerns that this important area may lack sufficient and coordinated oversight, and we hope to do additional bipartisan follow-up with the relevant stakeholder agencies and GAO to determine how to ensure strong and effective oversight over these important functions."

Oversight of biological research labs is fragmented, often secretive and largely self-policing, USA TODAY has found. The Federal Select Agent Program – jointly run by the CDC and the U.S. Department of Agriculture, inspects and regulates only a subset of research labs that work with certain pathogens deemed to pose bioterror threats, such as those that cause anthrax, plague, botulism and Ebola. But the regulated pathogens don't include other dangerous viruses and bacteria – such as deadly strains of influenza and tuberculosis – that need to be worked with in high-containment labs equipped with special safety measures.

Many of the recent lab safety incidents drawing concern have occurred in labs currently regulated by the Federal Select Agent Program, raising questions in Congress about the effectiveness of the program.

At a committee hearing on lab safety in July, Pallone asked the GAO's director of healthcare, Marcia Crosse, to elaborate on her organization's longstanding recommendation for establishing a single federal entity to oversee lab safety not just at labs working with "select agent" pathogens, but any microbes that require high-containment safety precautions.

"We continue to believe that such an entity -- or some other mechanism to ensure higher level oversight -- is needed in the face of the continuing proliferation of high-containment laboratories and the ongoing failures by agencies to fix their problems on their own," Crosse testified.

"We've been lucky so far," Crosse told the committee, referring to recent lab incidents. "If the types of mistakes we've seen were to occur with a particularly transmissible pathogen, like certain strains of influenza, not only would the laboratory workers or their close contacts be at risk, an epidemic could be triggered with consequences far beyond what we've seen to date."

The newly released report on FDA's labs, which is dated July 17, praised how FDA staff responded last year to the discovery of the smallpox vials. "Most importantly, this incident demonstrated that FDA staff feels empowered to report incidents in spite of their potential negative impact," the report said, also commending the FDA's plans to develop a centralized electronic inventory system for its labs.

But the report raised concerns about inconsistencies in safety approaches across a wide range of labs operated by multiple, separate divisions within the agency.

"In this environment, (FDA's divisions) have developed important aspects of the research safety program independently, with some safety programs more fully developed than others," the report said.

In one division, the report said, "staff did not seem to know procedures for whom to call in emergency medical situations." Consistent training also was lacking, the report said, and "it appears that at some sites important training is not mandatory and that competency assessments (post tests) are not performed."

Staff working in the FDA's Center for Biologics Evalua-

tion and Research, which is involved in regulation of products such as blood, tissues, and cellular and gene therapies, told the reviewers they felt their safety program works. Yet the report said those working in the agency's Center for Food Safety and Applied Nutrition, which is involved with the safety of the food supply and prevention of microbial and chemical hazards, "indicated a need for a stronger biosafety presence" and more training.

The report said the agency needs to have "concrete data" on lab accidents and incidents so it knows how many accidents have occurred in labs operated by each of its divisions and can identify emerging safety problems. It noted that the NIH has a good system of centralized tracking of incidents.

The co-chairs of the advisory group — Joseph Kanabrocki, associate vice president for research safety at the University of Chicago, and Kenneth Berns, an emeritus professor from the University of Florida — did not respond to interview requests.

Borio said for the first time in the FDA's history, the agency is in the process of consolidating many of its lab operations onto a large campus in Silver Spring, Md., which will be helpful in creating more uniform approaches to safety.

The FDA also has created a new high-level Director of Laboratory Safety and Security to be the agency's new central point of accountability and expects to have the position filled in October, she said. A new core curriculum of lab safety training is also being developed, she said.

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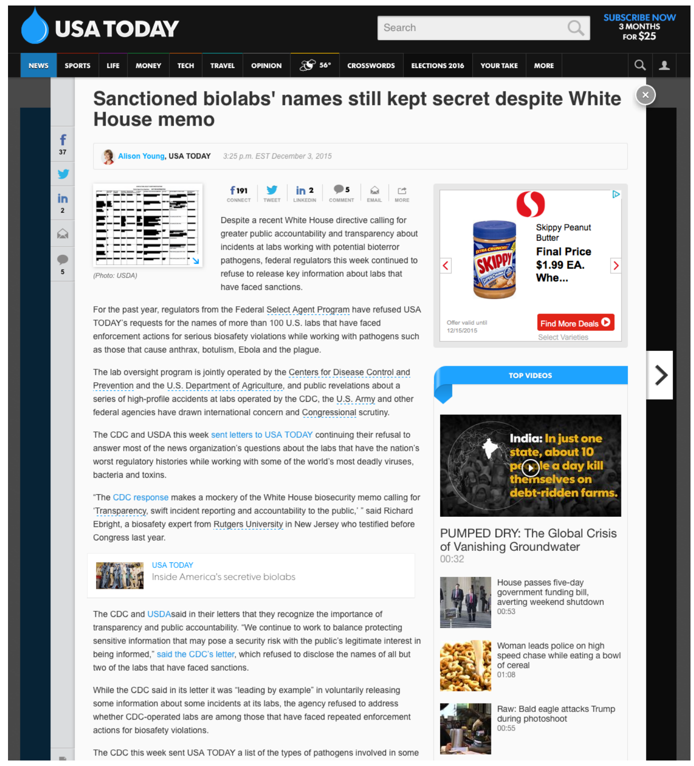

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SANCTIONED BIOLABS' NAMES STILL KEPT SECRET DESPITE WHITE HOUSE MEMO

Alison Young, *USA TODAY*

Despite a recent White House directive calling for greater public accountability and transparency about incidents at labs working with potential bioterror pathogens, federal regulators this week continued to refuse to release key information about labs that have faced sanctions.

◀ Until recently, Beth Willis chaired a citizens advisory committee on laboratories in Frederick, Md. One of the nation's largest biodefense research campuses is nearby at the Army's Fort Detrick.

For the past year, regulators from the Federal Select Agent Program have refused USA TODAY's requests for the names of more than 100 U.S. labs that have faced enforcement actions for serious biosafety violations while working with pathogens such as those that cause anthrax, botulism, Ebola and the plague.

The lab oversight program is jointly operated by the Centers for Disease Control and Prevention and the U.S. Department of Agriculture, and public revelations about a series of high-profile accidents at labs operated by the CDC, the U.S. Army and other federal agencies have drawn international concern and Congressional scrutiny.

The CDC and USDA this week sent letters to USA TODAY continuing their refusal to answer most of the news organization's questions about the labs that have the nation's worst regulatory histories while working with some of the world's most deadly viruses, bacteria and toxins.

"The CDC response makes a mockery of the White House biosecurity memo calling for 'Transparency, swift incident reporting and accountability to the public,' " said Richard Ebright, a biosafety expert from Rutgers University in New Jersey who testified before Congress last year.

The CDC and USDAsaid in their letters that they recognize the importance of transparency and public accountability. "We continue to work to balance protecting sensitive information that may pose a security risk with the public's legitimate interest in being informed," said the CDC's letter, which refused to disclose the names of all but two of the labs that have faced sanctions.

While the CDC said in its letter it was "leading by example" in voluntarily releasing some information about some

incidents at its labs, the agency refused to address whether CDC-operated labs are among those that have faced repeated enforcement actions for biosafety violations.

The CDC this week sent USA TODAY a list of the types of pathogens involved in some incidents at its labs. The agency refused to say which pathogens corresponded with each of the incidents. The pathogens on the list include anthrax, monkeypox and a dangerous type of avian influenza. The CDC acknowledged that an incident involving a missing flea involved a study involving plague bacteria.

A report from federal science and homeland security experts attached to the White House memo notes that withholding information about "select agent" labs "has negligible security value" since the labs routinely publicize their research in scientific journals and their work often is easily found through other public sources of information, such as on their own websites. Select agent is the government's term for about 65 pathogens that are specially regulated because of their potential risk of use as bioweapons.

The White House in a statement said the CDC's letter to USA TODAY was consistent with previous White House guidance.

"We place a premium on public transparency, and the CDC laboratory disclosures set an example," said the statement Wednesday from the White House's National Security Council. "As the new recommendations are implemented, we urge regulated facilities to be transparent with the public while also factoring in national security concerns related to disclosing information about infractions."

Within the next year, the CDC and USDA said they will for the first time begin publishing periodic reports with aggregate information about lab incidents and inspection findings. Such aggregate reports, the agency notes, are among the recommendations of a federal advisory group's report that is part of the White House memo. The agencies said they are working with federal labs to develop a policy that promotes transparency, and they noted that the White House memo encourages non-federal labs to voluntarily be transparent with the public.

Citizen lab safety advocate Beth Willis said labs have little incentive to voluntarily release information about incidents. Willis said the public has a right to know more than just anonymous statistics, including whether public, private or academic labs operating near them have had serious lab safety violations or have faced sanctions. She noted that the nuclear industry is required to publicly disclose details of incidents at individual facilities. The Nuclear Regulatory Commission posts "event notification reports" on its website that include the names of the facilities where they occurred.

"It's a community rights issue," said Willis, who until last summer chaired a citizen lab advisory panel in Frederick, Md., where one of the nation's largest biodefense research campuses is located at the Army's Fort Detrick. The lack of information has the potential to erode public confidence, she said, and makes it difficult to have a fact-based conversation about risks, lab oversight and compliance.

"The CDC as a regulator is not going to say anything unless the law is changed," Willis said. "It also seems to me that they're generally saying as little as they feel they can get away with."

A USA TODAY Network investigation has uncovered numerous serious incidents in public and private biological laboratories and revealed that pervasive secrecy obscures failures both by labs and regulators. Despite the secrecy and denials of access under the federal Freedom of Information Act, reporters have identified several major labs that have faced sanctions and enforcement actions in recent years, including those operated by Kansas State University, the University of Hawaii at Manoa, the California Department of Public Health, Brigham Young University, Northern Arizona University and the Louisiana State University AgCenter.

While the CDC and USDA continued this week to refuse to release the names of most of the labs that have faced regulatory actions, the CDC agreed for the first time in 11 months to answer USA TODAY's questions about what labs had been kicked out of the Federal Select Agent Program. The two labs, the CDC said in its letter, were operated by the state health departments in Florida and Colorado.

Scott Becker, executive director of the Association of Public Health Laboratories, said the limited information CDC released this week to USA TODAY "is a good first step." Even though the two named labs are members of his organization, Becker said: "I think it's perfectly fine that these are disclosed because now we might be able to ask those individual labs what happened and what needs to be avoided by others as a lesson learned."

Becker said it is critical for state health officials — who are responsible for responding to serious lab accidents — to know about lab safety issues in their communities.

The CDC said it revoked the select agent registration of the Florida Department of Health's lab in Pensacola in March 2012 "due to inadequate progress" on a performance improvement plan (PIP) and insufficient administrative oversight to ensure compliance with regulations, the CDC's letter said.

Florida Department of Health spokesperson Mara Gambineri said the CDC put the seven-employee lab on a PIP because of a "discrepancy in inventory." Given the "cumbersome protocols" required by regulators, she said, the department decided the small lab would no longer work with select agents and its registration was revoked. Three other Florida Department of Health labs remain authorized to work with select agents, she said.

The CDC said it revoked the select agent registration of a lab run by the Colorado Department of Public Health and Environment in 2010 because the department "no longer owned the laboratory." Larry Wolk, the department's executive director, said the revocation involved a former lab in Grand Junction, Colo., and occurred after its operations were consolidated into a Denver lab, which remains registered to work with select agents.

The White House's Oct. 29 memo to federal agencies

called for a wide range of actions to improve biosafety at laboratories working with select agent pathogens. The top two areas for action highlighted in the memo involved improved transparency and accountability to the public. The memo and its attachments are 187 pages long.

Citing a USA TODAY NETWORK investigation last May in its recommendation for greater transparency, an attachment to the White House memo noted that "perceived opaqueness" surrounding incidents at labs doing biodefense research has the potential of eroding public confidence.

On Nov. 3, USA TODAY sent letters — citing the White House memo and setting a Nov. 30 deadline — to CDC Director Tom Frieden and Secretary of Agriculture Tom Vilsack seeking information that both agencies had previously refused to release voluntarily as well as under formal requests under the federal Freedom of Information Act.

USA TODAY's letters sought among other things the names of labs that have faced various sanctions, including those repeatedly referred for enforcement actions, and those that have been fined or had their permits to work with select agent pathogens suspended or revoked. USA TODAY also asked the CDC to release details it had previously kept secret about certain incidents inside its own labs in Atlanta and Fort Collins, Colo.

Much of the information USA TODAY has been seeking was requested in July by the bi-partisan leadership of the House Energy and Commerce Committee, which has been investigating lab safety and oversight issues. The committee members cited the USA TODAY Network's investigation in their letter to the CDC asking for the names of labs that had faced sanctions.

The CDC provided answers to the committee's questions last summer, including the names of labs that have faced regulatory actions. But so far, the committee has not made the information public. In response to a Freedom of Information Act request, CDC released to USA TODAY what it sent to the committee with the labs' names removed.

In response to USA TODAY's request for an unredacted copy of the CDC's correspondence with the committee and the names of the sanctioned labs, staff for the committee's Republican leaders issued a statement saying the committee was not able to release it at this time because of security concerns, but did not specify what they were. A spokeswoman for the committee's Democratic leadership said more time is needed to evaluate concerns from the CDC and security agencies about releasing the information. "We hope to work with the Majority in the coming days and weeks to do so," said the spokeswoman, Christine Brennan.

It's unclear what security threat could be posed by the release of the lab names contained in the CDC's response to the committee. The redacted documents describe violations only in vague terms.

Meanwhile, many of the troubled labs listed in the document likely are operated by federal agencies. According to a briefing memo prepared by the committee's staff for a hearing last summer, federal laboratories working with bioterror pathogens are "the leading offenders" and repeatedly have been referred for sanctions because of serious safety violations. Yet, regulators largely have responded with violation letters to get them to fix problems.

The CDC and USDA say a 2002 bioterrorism law bars them from releasing information about select agent labs under the federal Freedom of Information Act. Lawyers for USA TODAY have argued that the agencies have viewed specific restrictions in the bioterrorism law too broadly.

Meanwhile the CDC occasionally has released information about select agent incidents and enforcement actions at its labs and also at labs it regulates. Earlier this year, after USA TODAY and local news organizations reported on a release of deadly bacteria from a lab at the Tulane National Primate Research Center, the CDC issued a statement disclosing the findings of regulators' investigation and noted the Tulane lab had been suspended from the select agent program. In its letter to USA TODAY this week, CDC said it follows a "standard practice" and it publicly released information about Tulane "only after local authorities and the regulated entity held a press conference to publicly disclose the incident."

The CDC did not respond to requests this week for further explanation of the policy.