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附件：如文

主旨：函轉衛生福利部疾病管制署檢送美國紐約時報本（2014）年7月刊登之「Pathogen Mishaps Rise as Regulators Stay Clear」專題報導1份，如附件，請轉知所屬設置（會員）單位參考，請 查照。

說明：依據衛生福利部疾病管制署103年7月28日疾管感字第1030500476號函辦理（檢附來函影本供參）。

正本：經濟部技術處、財團法人醫藥工業技術發展中心、中華民國生物產業發展協會、台灣生技產業促進協會、台灣製藥工業同業公會、台灣醫療暨生技器材工業同業公會、中華民國製藥發展協會、臺北市生物產業協會、中華民國學名藥協會、中華無菌製劑協會、台北市生物技術服務商業同業公會

副本：本局民生化工組

局長 吳明機

依照分層負責規定授權單位主管決行

電子公文

檔 號：  
保存年限：

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附件：Pathogen Mishaps Rise as Regulators Stay Clear報導1份(附件一)

主旨：檢送美國紐約時報本(2014)年7月刊登之「Pathogen Mishaps Rise as Regulators Stay Clear」專題報導1份，請轉知所轄設置單位參考。請 查照。

說明：

一、有鑑於近期美國CDC發生幾起實驗室生物安全意外事故，引發該國媒體關注，美國紐約時報特撰寫旨揭專文，值得我國各設置單位實驗室借鏡。內容重點摘錄如下：

(一)應充實實驗室工作人員之生物安全知能，並落實實驗室生物安全意外事件之通報。

(二)對於政府部門或最高學術研究單位，從事高危害性病原體之實驗研究以及保存管理，更應有一套嚴密且獨立之監管機制。

(三)對於使用高危害性病原體進行之研究計畫，應審慎評估其安全性及必要性，避免人為疏失洩漏，造成全球浩劫。

(四)相關專家學者就美國實驗室生物安全管理現況提出以下建議：

1、應設置獨立機構監督實驗室操作管制性病原(select agent)。

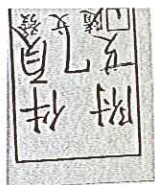
2、管控高防護生物實驗室、管制性病原及實驗室工作

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人員之數量，以降低發生生物安全意外事件之機率。

二、本署再次提醒各設置單位之生物安全會應落實單位實驗室生物安全管理及感染性生物材料保全之監督及審核權責；實驗室主管應確實要求實驗室工作人員正確使用及穿戴適當之個人防護裝備，定期檢測實驗室安全設施及設備之功能，並恪遵優良微生物操作規範。一旦發現實驗室意外事故時，應逐級進行通報，以確保實驗室工作人員、周遭人員及環境之安全。

正本：教育部、行政院農業委員會、經濟部工業局、國防部、衛生福利部食品藥物管理署、中央研究院、財團法人國家衛生研究院、直轄市及各縣市衛生局

副本：本署企劃組、本署預防醫學辦公室、本署研究檢驗及疫苗研製中心、本署各區管制





A rectangular button with a dark, textured background. The text "WATCH THE TRAILER" is written in a white, sans-serif font, with "WATCH THE" on the top line and "TRAILER" on the bottom line.**International New York Times** | <http://nyti.ms/1kGJ61w>

SCIENCE | NYTNOW

# Pathogen Mishaps Rise as Regulators Stay Clear

By DENISE GRADY JULY 19, 2014

The recently documented mistakes at federal laboratories involving anthrax, flu and smallpox have incited public outrage at the government's handling of dangerous pathogens. But the episodes were just a tiny fraction of the hundreds that have occurred in recent years across a sprawling web of academic, commercial and government labs that operate without clear national standards or oversight, federal reports show.

Spurred by the anthrax attacks in the United States in 2001, an increase in "high-level containment" labs set up to work with risky microbes has raised the number to about 1,500 from a little more than 400 in 2004, according to the Government Accountability Office.

Yet there has never been a national plan for how many of them are needed, or how they should be built and operated. The more of these labs there are, the G.A.O. warned Congress last week, the greater the chances of dangerous blunders or sabotage, especially in a field where oversight is "fragmented and largely self-policing."

As the labs have multiplied, so have mishaps. According to a 2012 article by researchers from the Centers for Disease Control and Prevention, the number of reported accidents involving microbes that can cause severe illnesses grew rapidly — from just 16 in 2004 to 128 in 2008 and 269 in 2010, the last year reported. Many of the accidents involved leaks, spills or other releases of infectious material inside the laboratories, potentially infecting workers and often requiring extensive decontamination.



Another report, by the Department of Homeland Security in 2008, provided a rare glimpse into the types of accidents that have occurred at high-level labs around the country, often at universities.

Lab workers at different sites accidentally jabbed themselves with needles contaminated by anthrax or West Nile virus. An air-cleaning system meant to filter dangerous microbes out of a lab failed, but no one knew because the alarms had been turned off. A batch of West Nile virus, improperly packed in dry ice, burst open at a Federal Express shipping center. Mice infected with bubonic plague or Q fever went missing. And workers exposed to Q fever, brucellosis or tuberculosis did not realize it until they either became ill or blood tests detected the exposure.

The good news is that relatively few lab workers have become ill from accidental exposures: only 11 from 2004 to 2010, according to the C.D.C. report. None died, and none infected other people.

Richard H. Ebright, a molecular biologist and laboratory director from Rutgers University, said he had “no confidence” in the safety of the many labs that have sprung up since 2001. He suggested there was a culture of complacency at some of them, as well as hubris among some researchers who believe they do not need oversight or management.

The most recent revelations have underscored potentially serious lapses at the government’s premier institutions. In June, dozens of C.D.C. employees may have been exposed to live anthrax. In another case disclosed this month, a C.D.C. lab accidentally contaminated a relatively benign flu sample with a dangerous H5N1 bird flu strain that has killed 386 people since 2003 — and then shipped it to a lab at the Department of Agriculture. In yet another episode this month, vials of smallpox and other infectious agents were discovered in a government laboratory on the campus of the National Institutes of Health after being stored and apparently forgotten about 50 years ago.

Six or seven government agencies were involved in the growth spurt of labs across the country focusing on dangerous pathogens, with no overall strategic plan, according to Nancy Kingsbury, the managing director of applied research and methods at the G.A.O., who testified



last week before a House Energy and Commerce subcommittee.

For years, the accountability office has warned that there was no one federal agency overseeing all the laboratories. In fact, it has said, the real number of high-level labs is not even known because the only ones required to register with the government are those handling “select agents” — microbes that can cause serious illness in people, animals or crops. Other high-level labs handle pathogens that may be dangerous but are not listed as select agents, the office said, adding that not much is known about them.

Both Dr. Kingsbury and Dr. Ebright, who also testified before Congress last week, said there should be one independent national agency to oversee work with select agents. Dr. Ebright said that many of the labs should be shut down, and that no more than 25 to 50 were needed nationwide.

Dr. Thomas Frieden, director of the C.D.C., has also said the number of high-level labs, dangerous pathogens and people with access to them should be reduced to “the absolute minimum necessary.” Testifying on Wednesday, he said the more such labs there were, the greater the risk of accidents.

The recent mistakes at federal labs have opened the door to a much broader criticism of the risks posed by the expanding research into risky pathogens, especially the efforts to create dangerous strains of flu not currently circulating, or to manipulate already deadly flu viruses to make them more contagious.

Researchers who conduct that work, sometimes labeled “gain of function” research, say its purpose is, in part, to help scientists recognize changes in natural viruses that may help predict which ones are becoming more deadly or more contagious. But it provoked a public outcry in 2011 because of fears that a lab accident might release the altered viruses and start a lethal pandemic.

The studies were halted for about a year while governments and research organizations tried to develop safety rules, but the work has since resumed in several laboratories.

Scientists who oppose the research issued a statement last week

urging that the experiments be curtailed until their risks and benefits can be reconsidered.

They expressed particular concern about the possibility of accidents involving newly created strains of highly transmissible, dangerous viruses, saying they could cause outbreaks that would be difficult or impossible to control. Once transmission of a new flu strain becomes established, the statement said, it can infect a quarter of the world's population within two years.

One of the signers, Marc Lipsitch, a professor of epidemiology and director of the Center for Communicable Disease Dynamics at the Harvard School of Public Health, said, "These experiments knowingly put large numbers of human lives at risk."

Then on Wednesday, the European Center for Disease Prevention and Control, funded by the European Union, also expressed concerns about the flu research, stating, "Recent incidents remind us that laboratory accidents and laboratory escapes can happen with dangerous pathogens, even if the highest security standards are applied."

Focusing specifically on recent work at the University of Wisconsin by Yoshihiro Kawaoka — who used genetic engineering to create a bird-flu virus similar to the one that killed millions of people in 1918 — the group said accidents would pose a risk to lab workers and the public.

Dr. Kawaoka said in an email message that the accidents at the C.D.C. were "very troubling." Even so, he said, the flu studies have to continue because "these pathogens exist in nature, and they could be used as bioweapons."

He said that at his lab, "we continue to take every precaution to ensure risks are as low as possible." And he added that to be approved for the research, his lab had to submit to unannounced inspections, and had one in the first half of July.

Ron Fouchier, a virologist who does similar work on flu viruses at the Erasmus Medical Center in the Netherlands, said the recent lab errors had no bearing on his work.

"Just because there were incidents in one institute does not mean



others have the same problem,” Dr. Fouchier said by email. He said the fact that no one had contracted anthrax from the accident at the C.D.C. proved that adequate safety measures were taken.

“One cannot bring down the number of incidents in labs to zero, but one can reduce the risks to negligible,” he wrote.

Dr. Fouchier dismissed as irrelevant the finding of forgotten vials of smallpox at the National Institutes of Health.

“Box found,” he wrote. “Contained. Destroyed. Done.”

Donald G. McNeil Jr. contributed reporting.

A version of this article appears in print on July 20, 2014, on page A1 of the New York edition with the headline: Pathogen Mishaps Rise as Regulators Stay Clear.

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