

# The CBW Chronicle

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A periodic newsletter about international and domestic events related to the control and elimination of chemical and biological weapons

## Congress Pursues Program to Strengthen Bioterrorism Response Capabilities

In his State of the Union Address on 28 January 2003, President George W. Bush introduced Project Bioshield—a federal effort intended to subsidize the creation and provision of effective medical means, specifically vaccines and anti-toxins, for countering biological weapons and virulent pathogens. The administration envisioned a program with three central features: establishment of a secure source of funding for purchasing needed biological countermeasures; an increase in the National Institute of Health's (NIH) capability to research and develop vaccines, drugs, diagnostic tests, and other needed treatments; and enabling the Food and Drug Administration (FDA) to make treatments in their testing phase more readily available in the event of an emergency. Both the Senate and the House have bills creating Project Bioshield under consideration.

The program's first feature, the creation of an indefinite funding authority, would attempt to further the development of measures such as vaccines and antibiotics by providing pharmaceutical companies with a guaranteed purchaser for these products. Project Bioshield monies would only be used to purchase those countermeasures for which no commercial market exists. The Department of Health and Human Services projected that under the program \$5.6 billion would be used for smallpox, anthrax and botulinum research over the next ten years. Funding for other research would become available only after potential

products had been screened for viability. The Departments of Homeland Security and of Health and Human Services would collaborate on identifying what countermeasures should be developed by assessing potential threats as well as building on new advances in medicine and public health.

Under the second branch of the project, NIH would receive the authority to expedite research and development in the area of possible bio-terrorism threats via the ability to hire additional biotechnicians, the flexibility to accelerate the grant review and cooperative agreement approval processes, and the capacity to build and renovate research and development facilities.

In an emergency situation, Project Bioshield envisions giving the FDA authorization to use medical treatments still undergoing FDA testing. Authorization to utilize unapproved therapies would require the Secretary of Health and Human Services find that the medical treatment in question is effective, that there is no viable alternative to its use, and that the benefits of releasing the treatment outweigh the risks. Unlike normal medical product approvals, certain limits can also be imposed on treatments that receive emergency authorization, such as the type of medical provider, the patients who can receive treatment, and the conditions of use. The emergency use authorization would remain in effect for no more than a year, unless the government can justify both an extension and prove that the related treatment is providing significant benefits.

The pharmaceutical industry has expressed some skepticism

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## SARS Provides Trial Run for International, US Bioterrorism Response Plans

**A** viral disease called SARS—Severe Acute Respiratory Syndrome—has provided an unexpected dress rehearsal for what could occur if a contagious infectious disease were used in a bioterrorist attack. SARS begins with flu-like symptoms and can escalate to a pneumonia. Aided by air travel, the disease spread to six continents in a matter of months and has killed nearly 800 people. Although the United States has experienced no SARS-related deaths and remains relatively unaffected by the epidemic as yet, US officials are closely monitoring how the country's health and security infrastructure responds to the epidemic, looking for lessons that might be applied in the event of a bioterrorist act. Correcting one criticism of the federal response during the anthrax letter attacks of 2001, US officials moved quickly in the initial stage of the outbreak to provide a clear, authoritative message on the outbreak and have offered ongoing updates on developments to both the public and the medical com-

munity nationwide. Within thirty-six hours of the first WHO disease outbreak alert, the Centers for Disease Control and Prevention (CDC) issued guidelines to physicians on how to recognize and deal with this previously unknown illness.

SARS first emerged in November 2002 in the Guangdong Province of China. Because China initially declined to release any information on the outbreak, international health authorities were predominately unaware of SARS until 11 February 2003, when the World Health Organization (WHO) issued the first disease outbreak alert. Disturbing reports of a disease spreading rapidly in Guangdong prompted WHO's alert. Thus far, the epidemic has taken its greatest toll in Asia, with China experiencing more cases than all other countries combined. In mainland China, SARS has infected thousands and killed over 600 people. In Singapore, thirty-one people have died and in Taiwan, the area hit hardest late in the epidemic, the outbreak has killed eighty-one people.

SARS' initial symptoms are similar to the flu (body ache, fever, chills, headache, sore throat), progressing to a dry cough and breathing difficulties. Initial estimates indicate that approximately 10-20 percent of those infected will develop severe pneumonia and require artificial respiration. Scientists studying the disease believe the incubation period is two to seven days and the mortality rate is 8 percent. While experts remain unsure as to how the disease is transmitted, possibilities include direct exposure to droplets suspended in the air or exposure to feces and urine.

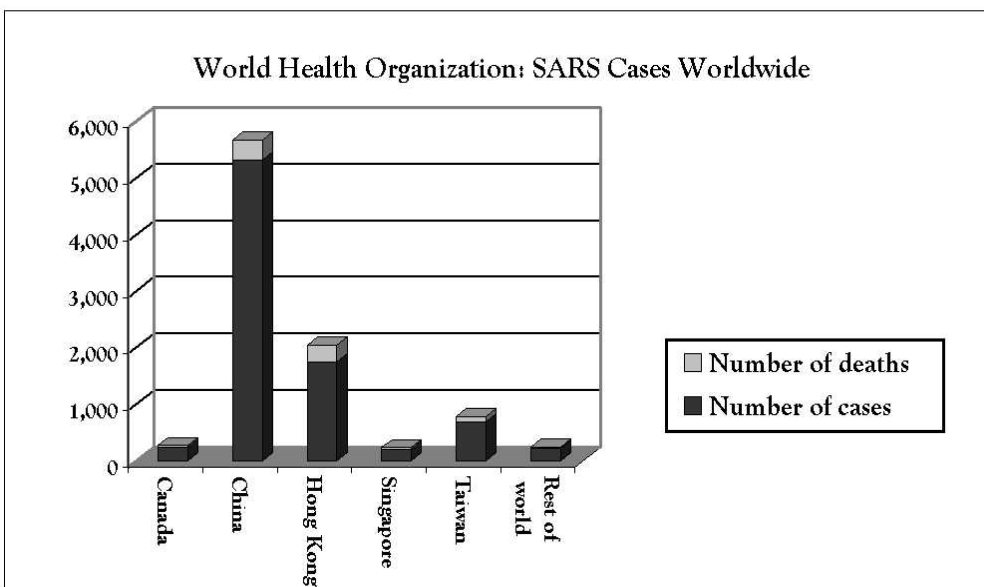
Treatment has also proved a challenge, as antivirals combined with steroids have only been partially successful, and no treatment has cured the disease. Although the pharmaceutical industry and scientific community promptly undertook research for a SARS vaccine, this effort is expected to take several years. For the time being, current treatment methods include respiratory supporting and administering appropriate medicines to countering symptoms, while relying predominately on the patient's own immune system to overcome the disease.

Since initial SARS symptoms are similar to influenza, authorities have struggled as the flu season was winding down to distinguish SARS cases. Health authorities would be similarly challenged in the event of a

### Monkeypox Outbreak Activates Public Health Response

The first US outbreak of monkeypox occurred in May 2003, prompting a response that, like SARS, tested US bioterrorism and overall public health readiness. According to the Centers for Disease Control and Prevention, a majority of the individuals who contracted monkeypox caught the disease from prairie dogs marketed as pets. Monkeypox is in the same family of viruses as smallpox, however, monkeypox kills between 1-10 percent of those infected, in comparison to 30 percent for smallpox. Evaluations of the early response to the disease outbreak, which presents with symptoms similar to smallpox, are mixed. Initially, public health officials took weeks to determine the cause of the outbreak, a time delay that could have had more deadly consequences if the virus had indeed been smallpox. Once the causative disease was identified, however, public health officials immediately disseminated information to ease public concerns. The CDC banned the sale of prairie dogs and is using the smallpox vaccine as a prophylaxis for monkeypox. The smallpox vaccine is the only known method of prophylaxis available. ☒

bioterrorist attack, as many bioagent infections also present with flu-like symptoms at the outset. One method to detect atypical rises of illness in a community as early as possible is syndromic disease surveillance. This approach monitors indicators of illness (e.g., certain types of 911 calls, sales of some over-the-counter medication sales) for increases in activity that would be abnormal for a given community at a



particular time of year. Spurred by bioterrorism concerns, some US cities are testing syndrome surveillance systems, but the low number of SARS cases has not tripped any alarms. Had the surveillance systems detected a possible anomaly, public health officials would be tipped to investigate the cause of the alarm further, thereby enabling prompt lifesaving intervention. Rapid reaction can be very important with diseases that are curable in early stages but later become severe and deadly, such as smallpox. Awareness of a possible epidemic can also give public health officials time to quarantine patients before they infect others, a key technique successfully used to address SARS.

Quarantine (segregation of individuals believed to have been exposed to a disease) and isolation (segregation of those infected) are vital in fighting and containing outbreaks of infectious disease, whether natural or man-made. In Asia, several governments enforced quarantines in an attempt to contain SARS. Singapore forcibly quarantined thousands of people and Hong Kong isolated entire hospitals. Quarantine can be difficult to enforce, however. In Hong Kong, residents thwarted some attempts, fleeing in fear before officials could quarantine them. In Toronto, Canada, the city most affected outside of Asia, the government ordered a compulsory quarantine for nine people who refused to isolate themselves. However, the majority of those affected in Toronto, 500 people voluntarily stayed home for the recommended ten-day period.

On 4 April 2003, President George W. Bush signed Executive Order 12452 adding SARS to the list of communicable diseases for which the US government can quarantine individuals, forcibly, if necessary.

Scenarios of mass quarantine in the United States are not optimistic. Many states have not updated laws relating to quarantine for decades, which could foster confusion regarding the implementation of this procedure. Bioterrorism concerns have moved some state legislatures to pass new laws to remedy gaps and failings, but many of these efforts have been controversial, generating debate about maintaining balance between public health protections and civil liberties.

China's initial embargo on information and denial of the SARS outbreak eventually led to panic among the Chinese public when real statistics emerged. Many exposed individuals likely spread the illness because they initially did not know of their condition and subsequently fled Chinese cities in fear. In contrast, the United States disseminated information on the disease immediately. On the heels of WHO's outbreak announcement, CDC Director Julie Gerberding appeared on TV to discuss the issue.

In response to SARS, the US public health system implemented many of the same plans that would be utilized in the event of an intentional pathogen release, highlighting the dual use nature of such preparations. In Atlanta, Georgia, an eighty-three-year old woman, who had just returned from China, came into the hospital complaining of respiratory difficulties. Upon examination, the woman's nurse, who had just received training about SARS, put the patient in a special isolation unit built with monies for bioterrorism preparation. In another case, a patient in West Virginia was quickly isolated after doctors implemented procedures developed with bioterrorism funding. ❏

## Health, Funding Concerns Partially Derail Smallpox Vaccination Program

Six months after President George W. Bush's 13 December announcement of a nationwide smallpox inoculation plan, the program has fallen short of expectations. The vaccination plan, one of the administration's most high profile efforts to protect against potential bioterrorism attacks, has proven to be less popular, more costly, and potentially riskier than expected.

The president's original plan called for the vaccination of approximately one hundred health workers per US hospital capable of handling smallpox patients—about 450,000 people—within thirty days of the program's implementation. The plan further called for vaccinations to be extended to a wider group that includes first responders—such as firefighters, police and paramedics—potentially bringing the total number of vaccinees to more than ten million people. So far, this goal remains out of reach. An April 2003 General Accounting Office report on the challenges of the program reported that only 31,297 health care workers had received the vaccine at the time of publication. Representatives from the Centers for Disease Control and Prevention (CDC) recently stated that as few as fifty thousand vaccinees would be sufficient for dealing with a possible smallpox outbreak, leading to questions regarding the discrepancy between the numbers originally given and this most recent statement.

In June 2002, President Bush signed the Public Health Security and Bioterrorism Preparedness and Response Act into law. Pledging \$1.08 billion to state and local governments for fiscal year 2003, the act was designated specifically for bioterrorism planning. After the government released these funds, many states began devoting these funds to meet a range of relevant objectives: upgrading laboratories, establishing better communications systems, training staff, and planning for possible unconventional terrorist attacks. Six months later, states were informed that these original monies were expected to cover the costs of implementing the smallpox inoculation plan as well.

A study by the Association of State and Territorial Health Officers found that smallpox immunization, from screening through follow-up, costs an average of \$265 per person, significantly more than the original CDC estimate of \$13. Steep costs and demands on time have forced some participating hospitals and public health departments to divert resources from traditional health care services, such as prenatal care, HIV/AIDS prevention, flu vaccines, and regular immunizations. According to a National Association of County and City Health Officials survey of 539 health departments, 79 percent found that the inoculation effort diverted money from other terrorism preparedness activities as well.

Another challenge arose when health officials began to suspect that smallpox inoculation may be linked to heart problems in some recipients. As of April 2003, the CDC suspected heart problems in approximately twenty patients, three of whom had died. The Advisory Committee on Immunization Practices, a 15-member panel of immunization experts, recommended that people at high risk for heart complications—including those individuals with at least three risk factors for cardiac disease (e.g., smoking, high blood pressure, or diabetes)—not

### Congress Creates Vaccine Compensation Fund

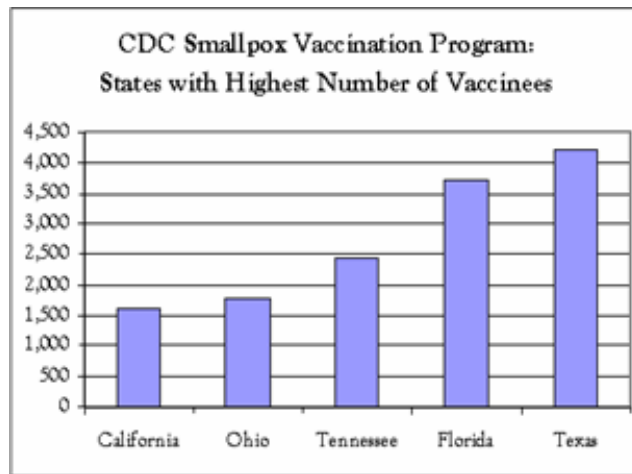
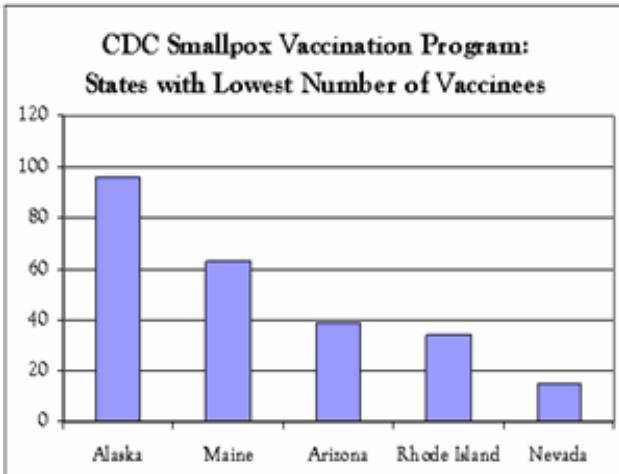
On 11 April 2003, Congress approved a compensation plan for those individuals harmed by the smallpox vaccine. The plan is expected to provide dependent families of those whose vaccination results in death with up to \$50,000 a year to replace lost wages until the deceased's youngest child reaches age eighteen. Individuals who become permanently and totally disabled will receive the same amount until they turn sixty-five. The plan also allows for individuals suffering temporary disability or permanent partial disability to collect up to \$262,100 in lost wages. A person who misses ten or more days of work due to complications from the vaccine will receive pay for all days missed. Additionally, if someone with no dependents dies, the family of the deceased will receive a lump payment of \$262,100. Government and public health officials hope that the plan will encourage those health care workers and first responders concerned about the vaccine's potential side-effects to volunteer for the vaccine. ☒

get the vaccine. Six percent of potential health care worker vaccinees would be excluded from being inoculated under this recommendation. Several states suspended their programs until the link to heart disease is further investigated.

Even with the recent creation of a smallpox compensation plan for those injured by the vaccine (see inset), a number of public health officials and physicians argue against trying to inoculate such a large number of people. These critics contend that the risks of the vaccine outweigh the likelihood of a smallpox attack, and that diversion of funds to support the program could leave communities unable to respond to other types of problems.

A 27 May 2003 report by the Institute of Medicine

emphasized the need for continued monitoring of those already vaccinated, and suggested that pausing between the first and second stages of the vaccination process might prove beneficial in identifying further safety issues and modifying the inoculation plan to fit the necessary circumstances. However, the review committee also stressed the organization's support of the smallpox inoculation plan, remarking that the effective response to SARS was partially assisted by efforts to prepare for smallpox, especially in regards to communication and cooperation between the organizations involved. Additionally, the close monitoring of vaccinees helped bring the cardiac problems to the forefront immediately, enabling health care workers to respond in a more effective manner. ☒



## Project Bioshield Bills Pending in Congress

(Continued from page 1)

about the Bioshield Project. Biodefense is viewed as a risky market, as drugs created for terrorism response may go unsold if need for them never arises. Industry therefore wants the government to guarantee higher profits and create fewer restrictions than those included in the current bills.

Senator Judd Gregg (R-NH) introduced the Bioshield bill, which the Senate Health, Labor and Pensions Committee approved unanimously. The House bill, introduced by Representative Billy Tauzin (R-LA), remains in the Select House Committee on Homeland Security.

The legislation faces more opposition in the House, where some members have expressed unease over the provision allowing the use of medications and

vaccines prior to FDA approval. For example, Congressman Henry Waxman (D-CA) put across the concerns that the project could lead to "widespread distribution of unapproved drugs."

The House bill also differs slightly from its Senate counterpart in its approach to funding the first aspect of the plan—guaranteeing a market for countermeasures. The House bill authorizes up to \$6 billion to be appropriated between 2004-2013 and placed in a special fund. The Senate bill creates neither a new funding mechanism, nor places limits on timeframes or amounts, instead authorizing and appropriating "such sums as may be necessary" for this program for the indefinite future. ☒

# Chemical Industry Security Improvements Debated in Congress

Concerns over the vulnerability of US chemical industry facilities to terrorist attack spawned a General Accounting Office (GAO) report and two key bills in the Senate in the first half of 2003. The GAO report highlights the Environmental Protection Agency (EPA) assessment that terrorists could cause catastrophic loss of life if they attacked some US chemical plants. The EPA estimates that attacks on one hundred particular US chemical facilities could kill over one million people per facility. By attacking chemical facilities, terrorists could unleash extremely harmful chemicals without having to produce and disperse one of the classic warfare agents (e.g., mustard, sarin). Senators Jon Corzine (D-NJ) and James Inhofe (R-OK) each introduced bills to increase security at chemical facilities. Both bills were referred to the Senate Committee on Committee on Environment and Public Works. The bills differ considerably in how active the federal government would be in addressing this issue.

Currently, any security improvements made by chemical industry specific to countering a possible terrorist threat are voluntary. The GAO report notes that the federal government requires other security precautions that could be relevant, such as mandating facilities housing hazardous waste to have surveillance systems, physical barriers, and guards at the entry. However, these regulations do not apply to all facilities, nor may they be sufficient for those determined to gain access.

Provisions of the Clean Air Act are also relevant to terrorism preparedness, although not targeted as such. This law requires facilities that deal with hazardous substances to conduct risk assessments and develop plans enabling prompt mitigation of any accidental releases. While the legislation specifically mentions accidents, the mandated preparations would also be relevant to intentional releases of chemicals—as either type of incident requires similar response and mitigation techniques. Because the legislation specifically mentions accidents, however, the GAO found that the EPA could not legally use the Clean Air Act to force facilities to address specific vulnerabilities for terrorism.

Despite the inclusion of chemical industry on the key US infrastructure list, the government has not completed a comprehensive evaluation of the chemical industry's possible vulnerabilities to terrorist attack. In

1999, Congress required the Justice Department to review and report on the vulnerability of US chemical facilities to terrorist attack. Justice missed the deadlines for both the interim and final reports, conducting just the methodology study before Congress transferred funding for this project to the Department of Homeland Security (DHS) in 2003.

Senator Corzine's legislation would attempt to enhance chemical facility terrorism preparedness by first empowering the EPA to create regulations and preparedness requirements similar to those under the Clean Air Act, but specific to intentional releases. The bill then requires chemical facilities to submit risk management plans, which contain information about worst case chemical release scenarios, not only to the EPA, but also to DHS. Should DHS grade any plan insufficient to deal with possible terror risks, it would notify the facilities and require changes in the plan.

Senator Corzine's bill also requires chemical facilities to reduce the ramifications of an intentional release by switching to less dangerous and toxic chemicals for their activities when possible. Contra Costa, California, authorities first implemented this approach for local chemical facilities. After September 11th, some chemical facilities escalated these types of changes voluntarily. For example, water treatment facilities can change from highly explosive chlorine to sodium hypochlorite, essentially household bleach. Senator Corzine's legislation then includes provisions to penalize industry facilities that do not meet the proposed regulations.

Senator Inhofe's bill outlines significantly less intrusive and possibly redundant measures. The Inhofe legislation requires DHS alone to develop new regulations mandating that chemical facilities conduct an intentional release risk assessment and create an emergency response plan. Such plans would be separate from those prepared for the EPA. DHS may develop standards for these plans, but is not required to do so. The Inhofe bill does not require chemical companies to utilize safer technology or submit their risk management plans to DHS unless specifically requested to do so. The penalties envisioned in Senator Inhofe's bill address only the unauthorized release of information submitted to the government. ❖



## Chem-Bio Blurbs: Recent developments in the field

### Mayors Express Concern Over Distribution of Homeland Security Grants

April 2003: President Bush announced that \$2.3 billion for homeland security would be distributed within sixty days to state governors, who would then decide how much their cities and counties would receive. States can use up to 20 percent of the money for administrative purposes before allocating funds to the local level. At the 5-10 June 2003 US Conference of Mayors in Denver, a group of mayors asked Undersecretary of Homeland Security Michael Brown if money could be given directly to the cities and counties because state distribution of the money can be inconsistent and political, making it difficult to secure adequate funding for local first response needs. ☒

### Postal Facility Contaminated by Anthrax to Reopen

5 March 2003: US Postal authorities announced that the Joseph Curseen, Jr. and Thomas Morris, Jr. Processing and Distribution Center in northeast Washington, DC would reopen in the summer of 2003 after a shutdown of over eighteen months. Contaminated by the anthrax letters sent to Senators Thomas Daschle (D-ND) and Patrick Leahy (D-VT) in the fall of 2001, the Brentwood Distribution Center was renamed to honor the two postal workers who died after contracting pulmonary anthrax while working at the facility. Following decontamination procedures, thousands of samples were taken from the air and various surfaces within the 14,000 square foot building, none of which showed signs of anthrax spores. While reoccupation will not take place until an environmental committee reviews the results and performs other required tests, officials called the fumigation of Brentwood with chlorine dioxide gas a success. ☒

### TOPOFF 2 Rehearses Biological Terrorism Response in Chicago

12 May 2003: A week-long Department of Homeland Security training exercise simulating an intentional release of plague in Chicago and a dirty bomb explosion in Seattle took place in May. The exercise, which cost approximately \$16 million, involved more than 8,000 federal, state and local officials, as well as some Canadian officials. To evaluate how emergency responders would deal with simultaneous but unrelated events, the Chicago exercise also simulated the collapse of a building and a crash involving a commercial airliner. A report on the findings of the TOPOFF 2 exercise will be released in fall 2003. ☒

### New Theory on Anthrax Attacks Leads FBI to Drain Pond in Frederick, Maryland

10 June 2003: After recovering laboratory equipment from a pond near Frederick, Maryland last winter, the Federal Bureau of Investigation (FBI) decided to drain the waterhole to facilitate the search for additional items. The FBI is investigating whether the person responsible for the fall 2001 anthrax attacks could have used these items to fill the envelopes with spores in a manner that would decrease exposure. As of yet, no definitive connection has been made to the attacks. Divers originally found a clear box with holes capable of accommodating gloves, as well as several vials wrapped in plastic. The search of the pond, which was drained gradually to minimize disturbance of aquatic life, is expected to take a month. ☒

## Editor's Note

In its October 2000 report *Ataxia: the Chemical and Biological Terrorism Threat and the US Response*, the Chemical and Biological Weapons Nonproliferation Project warned that some of the greatest chemical and biological threats that the United States faces are in our midst everyday. Nature could unleash outbreaks of new diseases (see SARS, page 2). Attacks on facilities that handle hazardous chemicals could unleash poisonous clouds (see *Chemical Facility Security Legislation*, page 6) like the one that killed almost 4,000 and injured thousands more in Bhopal, India in 1984. This issue of the *CBW Chronicle* highlights the recent developments in these areas.

What is disheartening is the lack of progress the United States has made in following through on some necessary steps to address such issues. Not for lack of recognition, but for dearth of execution.

In 1999, Congress ordered the Justice Department to conduct a vulnerability assessment of US chemical industry facilities. The report was to include an assessment of whether actions chemical facilities took under the Clean Air Act to prepare for chemical accidents would be relevant to intentional releases. The deadline for an interim report was August of 2000, with the final report due in August 2002.

The Justice Department submitted a classified, twelve-page interim report to Congress in May 2002 that, according to the General Accounting Office, contained observations about eleven chemical manufacturing facilities. These eleven facilities had been visited in 2001 while Justice employees were working on a separate but related project with Sandia National Laboratories—to develop a methodology to assess chemical facility vulnerability to terrorism. The Justice Department relied on observations from this small sample in its subsequent interim report to Congress, delivered almost two years late. The Justice Department under-

standably noted that caution should be exercised in extrapolating its findings across the chemical industry, in part based on the limited sample and in part because only 1,500 of the facilities covered by relevant parts of the Clean Air Act are chemical manufacturing facilities like the eleven visited. The Department of Justice rightly recognized that observations of the 13,500 other types of operations that handle threshold quantities of hazardous chemical substances might yield other conclusions.

The Justice Department characterizes its inability to complete the vulnerability assessment as a victim of the battle of competing budget priorities. The GAO notes that the law originally requiring the report authorized whatever funds were necessary to complete it. While the Justice Department estimated costs could run as high as \$7 million, the department waited until its fiscal year 2003 budget request to ask for the \$3 million to begin the overdue report.

Congress agreed to the figure, but do not expect to see a report in the near future. The conference report for the Justice Department appropriation transfers that \$3 million to the Department of Homeland Security, for the purpose of chemical plant vulnerability assessments. On 5 June 2003, Homeland Security Assistant Secretary for Information Analysis Paul Redmond told Congress that he had one staff member working for him. Redmond declined to brief the members in closed session about the bioterrorist threat, stating he lacked access to intelligence information.

Two very different pieces of legislation to address chemical facility vulnerability are pending in the Senate. One bill says chemical industry needs more regulation and monitoring; the other implies that voluntary initiatives are addressing this concern. Perhaps Congress should truly understand the problem prior to legislating additional security measures, an understanding that would no doubt be facilitated by the long overdue report. Horse before the cart, anyone? ☒

### About the Newsletter, the Stimson Center, and its CBW Programming

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The Henry L. Stimson Center was founded in 1989 as a non-profit, nonpartisan institution devoted to public policy research. The Stimson Center concentrates on particularly difficult national and international security issues where policy, technology, and politics intersect.

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