

**Legal and Policy Issues to Consider
Before a Bioterrorist Attack**
-A State Perspective-

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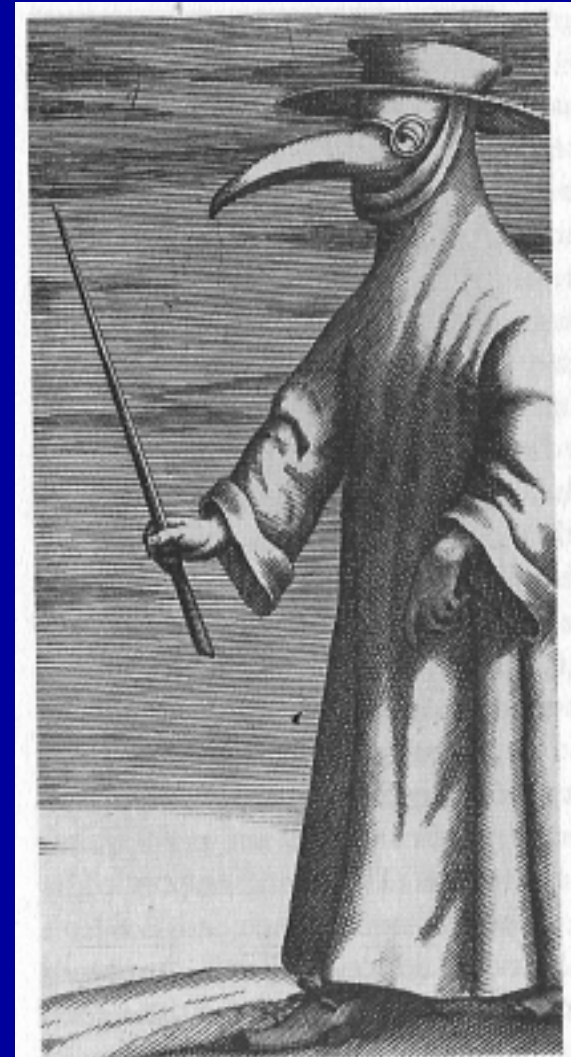
Past epidemics

Plague in Florence, Italy 1630

[Grand Duke] Ferdinando [II] ceded broad discretionary powers to his public health officersó a group of nobleman who answered directly and only to him. Their ordinances, aimed with good intentions at halting the spread of infection, affected every aspect of daily life. Citizens who resented the policing of their private affairs found ways around the law, and the commissioners found themselves sometimes taunted in the streets, pelted by stones, or formally denounced...In defiance of the public health edicts, rich and poor alike often tried to hide their sick in the bosom of the family, rather than relinquish them to the isolation of the hospital.

- from *Galileo's Daughter*, pp 203-4, Dava Sobel, Penguin Books, 1999

-based on Carlo Cipolla, *Fighting the Plague in Seventeenth-Century Italy*; Madison: U. of Wisconsin Press, 1981



Plague doctor in protective costume;
the beak was filled with flowers to ward
off plague vapors

YALE JOURNAL OF BIOLOGY AND MEDICINE 1, 40-54 (1974)

The Pneumonic Plague Epidemic of 1924 in Los Angeles¹

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The Pneumonic Plague Epidemic of 1924 in Los Angeles¹

At 1:00 a.m., November 2, the Macy Street area, which included approximately eight city blocks and which housed approximately 2,500 Mexicans, was placed in quarantine by the City Health Department. All cases of illness occurring within the area were examined by health department physicians and suspicious cases sent to the County Hospital.

The Los Angeles County Board of Charities provided seven-day rations for each household and sought to establish "cubicle isolation" for each house within the quarantine area. A Spanish-speaking priest and social worker were placed in the area to reassure and calm the residents. Public health nurses were also sent to the area and directed to make a house to house inspection in an endeavor to locate other cases or contacts.

Arrangements were made with the County General Hospital to admit all persons who lived at addresses where pneumonic plague had occurred. A total of 114 contacts were admitted but none became ill with plague.

The National Pharmaceutical Stockpile, circa 1924?

5147 MILES

BY MAIL PLANE
EARLY TUESDAY
MORNING 9:00 A.M.

THIS YEAR SOUTH OFFICIALS
WILL VISIT MULFORD LABORATORIES
WHICH ARE NOW BEING
REARDED FOR THE
PLAQUE SERUM THAT WILL

APPLIQUE PLASMA PHILIP
SERUM TO PLASMA SERUM

PLAQUE CARRIES
PLAQUE SERUM

PLAQUE WITH ADVANTAGE
SERUM CARRIES FOR COLD

PLAQUE PHARMACIA
SERUM BY PLANE

STATE TAXES
CHARGE AS 25
VICTIMS DIE

5000 MORE DOSES
OF SERUM GO WEST

SERUM FOR PLAQUE
SPEEDS BY PLANE
WILDS ANGELES

SERUM RUSHED
BY AIRPLANE TO
PLAQUE SERUM
TO BE SENT

ANOTHER MULFORD "FIRST"

THE first to span a continent in the air, the immediate relief might be brought to a suffering community. An achievement of distance previous in record time—a solid proof that the Mulford Laboratories can serve any and every part of the continent at a moment's notice.

Other Mulford "Firsts"

- First to produce (lighter) bacteria commercially in the United States at 75 degrees, by the Rotary, in 1918.
- First to produce and distribute Antigenic Serum.
- First to produce (antigenic) Serum, following the production of such by Aulis and Wilmanns (1914) and later by Huxley and Zerkow (1919).
- First to produce an injectable Glass Foci Point, the only "Point" now licensed by the U. S. Government.
- First to supply Biological Products in Plastic Syringes ready for administration.
- First to produce Bacterial Vaccine (Bacterin) commercially in the United States.
- First to produce Sterilized Bacterial Vaccine (Bacterin) commercially in the United States.
- First to separate the pneumococcus infection from human serum—Parasiticus method.
- First to produce Super-Concentrated Bacterin Antidote for cholera, typhoid, and diphtheria.
- First to supply a physiologically investigated and refined Therapeutic (1919).
- First to produce blocking agents for the prevention of Cholera in 1918.

The American Red Cross asked for about 100,000 for the Pacific Area during the war. It is a new building program, completed, and the first was completed in 20 days. The last was placed in record time. Mulford supplies almost part of the first time that pulled out the business from the East after the earthquake.

When need arises for the first time, more than a dozen years, the Mulford Laboratories have made the most important serum products. For the same reasons, look to Mulford—the pioneer industrial laboratory.

H. K. MULFORD COMPANY
PHILADELPHIA, U. S. A.

The Pneumonic Plague Epidemic of 1924 in Los Angeles¹

On November 3, it was agreed that all plague control work was to be coordinated by an Advisory Committee composed of Dickie [State], Perry [USPHS], and representatives of the City and County Health Departments and the County General Hospital.

In Dickie's report he notes that "all control work" was placed under his direction, but the records reveal that formal control was not transferred to the State until November 21. On the 3rd, as a result of the meeting establishing the Advisory Committee, it is difficult to determine just who was in charge since jurisdictional disputes were evident from the start

On November 14, Perry [USPHS] spelled out another area of potential friction. "If the campaign succeeded, Perry wrote, the State Board of Health would receive the credit; but if the work did not meet with success, the Service would be held responsible"

Smallpox in New York City, April 1947
First mention in the New York Times

**Fifty Saved Parking Fines
By Spreader of Good-Will**

Special to THE NEW YORK TIMES.
HACKENSACK, N. J., April 4
—Thomas McGirr believes in being his own ambassador of good-will. As he goes from town to town he carries a pocketful of nickels, and whenever he finds a parking meter with a car parked, but the time elapsed, he deposits a nickel, leaving his card under the windshield wiper. The card reads: "Dear motorist: This is no summons. Your parking time has expired and to relieve you of the trouble of appearing in police court I have deposited a nickel in the meter. Tom McGirr."

Printed on the opposite side is "Mountvale Quarries, Mountvale, telephone Park Ridge 6-0477." "Not for advertising purposes," Mr. McGirr said today, "because, after all, the average person isn't interested in flagstones and slate, but just for good-will, of which there doesn't seem to be much left these days."

He has spent \$2.50 in nickels since he started his project three days ago.

**SMALLPOX IN CITY,
INOCULATION URGED**

Three Cases; First Since 1939,
Reported—Weinstein Advises
All to Be Vaccinated

BUSINESS MAN CARRIER

Came Here From Mexico City
With Illness, Died in 2 Days
—Hospital Staffs Treated

Three cases of smallpox, the first found in New York City since 1939, were reported yesterday.

While Health Commissioner Israel Weinstein gave assurance that the chance of an epidemic of the contagious disease in New York was slight, he appealed nevertheless through the press and on the radio for every New Yorker who had not been vaccinated since early childhood to receive an inoculation soon.

The disease was reintroduced into New York by an American business man who arrived in a bus on March 8 from Mexico City, where he had been living for twenty years. Ill when he got to this city, the man was taken to Bellevue Hospital and later to the Willard Parker Hospital for Contagious Diseases. When the patient died on March 10 the cause was given as bronchitis with hemorrhages.



THE HEALTH COMMISSIONER TAKES CARE OF HIS STAFF



Dr. Israel Weinstein vaccinating employes against smallpox

WEDNESDAY, APRIL 9, 1947.

VACCINATION PLEA RENEWED BY CITY

Protection Urged on Residents as Fourth Positive Smallpox Case Is Established

Smallpox was established definitely yesterday as the illness in one suspected case at Willard Parker Hospital. The total since the outbreak was revealed here last Friday stands at four positive cases—one of which has proved fatal—and two suspicious cases. All five patients are in Willard Parker, the city institution for contagious diseases.

The case confirmed yesterday was that of a woman from the household of a young Puerto Rican man who was removed to the hos-

pital with positive diagnosis of smallpox on March 27.

Health Department inspectors continued their search for "contacts" of all the patients, urging them to be vaccinated immediately.

The department's campaign to get protection for every New Yorker

also went on. Health Commissioner Israel Weinstein himself worked for a while in the central clinic at Worth and Center Streets.

During the day, Dr. Weinstein said, 1,487 persons were vaccinated at all neighborhood clinics of the department, bringing the aggregate since last Friday to 5,542. This was in addition to 23,700 employes of the Health and Hospital Departments. The 5,500 workers of the Welfare Department will take their "shots" today.

Among city residents vaccinated yesterday were twenty-five children, from babies of 2 months to adolescents of 13 years, at the West Side center of the Children's Aid

Society, 419 West Thirty-eighth Street. Dr. Vincent H. Pascale, an interne at St. Vincent's Hospital, did the vaccinating. Mrs. Margaret Odalovich, nurse at the children's center, assisted. Some mothers took the treatment with their children.

Private physicians, Dr. Weinstein

estimated. His department already has distributed 100,000 doses of vaccine to physicians, hospitals and pharmacists. Although the department has 500,000 such units, Commissioner Weinstein asked druggists to buy their vaccine from private manufacturers, to save the free vaccine supplied by the city for the poor.

The city's Board of Health expressed yesterday its "entire confidence" and "approval" of measures taken by Commissioner Weinstein to forestall a smallpox epidemic in New York. Since 1922 there have been only three cases of smallpox here before the present outbreak.

One strategy to stop
the spread of
smallpox:

Voluntary mass
vaccination

!* →
Wow
!* →

HALF MILLION HERE VACCINATED IN DAY

City's Drive Against Smallpox
Pressed as Shortage of
Vaccine Is Overcome

2,000,000 NOW IMMUNIZED

85 Police Stations Opened as
Clinics—Death in Camden
From Disease Reported

Half a million New Yorkers were vaccinated yesterday as a temporary shortage of vaccine, which was delaying the city's three-week program of protecting the population against smallpox, was overcome.

Dr. Israel Weinstein, health commissioner, estimated that 2,000,000 persons had been immunized during the campaign. With the receipt of 4,000,000 units of vaccine from pharmaceutical manufacturers, the 250 free public vaccination clinics in the city had adequate supplies.

The eighty-five police stations were opened for public vaccinations at noon, and at 10 P. M. they had cared for 119,486 persons. Some precincts had crowds of three or four times that number, long queues forming around the blocks.

The Anthrax Outbreak 2001

THE DENVER POST / AMERICA STRIKES BACK

Friday, November 9, 2001

32,000 have been given antibiotics

Officials warn of overreaction to anthrax find

By Loran Neergaard

The Associated Press

WASHINGTON — About 32,000 people have been prescribed antibiotics in the anthrax scare since the Sept. 18 attacks.

Medical authorities said in new guidelines that merely finding traces of anthrax clinging to surfaces does not warrant closing buildings or prescribing antibiotics.

where scientists are working around the clock to deal with the anthrax that has killed four people and sickened 13 others.

Postmaster General John Potter asked Congress for \$5 billion to offset the toll of the attacks by mail. He said the government should pay for safety equipment and other recovery.

"They should be considered costs of homeland security," Potter told a Senate Appropriations subcommittee.

In the most stunning picture yet of how far anthrax has reached, the CDC disclosed that 32,000 Americans have taken antibiotics for at least several days while scientists raced to tell who was truly



Associated Press / Daniel Veselky

A worker checks the production of the anthrax remedy Cipro at the Slovakofarma pharmaceutical company in Hlohovec, Slovakia.

exposed to the germs. Of them, 5,000 were found at risk for anthrax infection and told to take antibiotics for 60 days.

Cipro, the main drug prescribed, can cause some severe side effects. But a quick study of 490 Floridians taking it and other antibiotics

found that 20 percent reported only minor side effects.

The Food and Drug Administration plans the unprecedented step of contacting all 32,000 antibiotic recipients to better understand side effects — and ensure that no one has a relapse after ending medication.

In addition, 300 post offices and other buildings have been tested for anthrax, the CDC said. Most heavily contaminated are the Hart Senate Office Building, where an anthrax-tainted letter to Majority Leader Thomas Daschle was opened, and Washington's Brentwood central post office, which processed that letter. Officials say the majority of other buildings have had no or very little contamination.

"We will never remove every spore" in a building cleanup. Dr. James Baker Jr., a University of Michigan bioterrorism expert, told Congress. As for Hart, "you will not sterilize that building no matter what you do."

Simply finding anthrax clinging to surfaces is not enough to close buildings or prescribe protective antibiotics, the CDC guidelines say. Anthrax is deadliest when it is in the air, not when the sticky spores have settled to the ground.

"We've learned that the cases of anthrax have occurred in environments that are very heavily contaminated, and that we don't see cases in environments where there is not significant contamination," said CDC anthrax specialist Dr. Julie Gerberding.

Environmental Decontamination

-Theory

CONSENSUS STATEMENT

Journal of the American Medical Association, May 19, 1999

Anthrax as a Biological Weapon Medical and Public Health Management

Objective To develop consensus-based recommendations for measures to be taken by medical and public health professionals following the use of anthrax as a biological weapon against a civilian population.

However, decontamination of large urban areas or even a building following an exposure to an anthrax aerosol would be extremely difficult and is not indicated.

-Practice

Senate Offices Hard To Cleanse of Spores

WASHINGTON, Dec. 28 (AP) — A renewed effort to kill lingering spores of anthrax in the Hart Senate Office Building began today, with technicians pumping a poisonous gas into the building's heating and ventilation system.

Lt. Dan Nichols of the Capitol Police said deadly chlorine dioxide gas would be concentrated in the ventilation system of the building's southeast quadrant, an area that tested positive for anthrax spores after an earlier fumigation effort.

The building has been closed since Oct. 17, two days after a letter contaminated with anthrax was opened in the offices of Senator Tom Daschle, Democrat of South Dakota.

After a first cleanup effort of the Daschle offices, tests showed that some spores lingered. A second effort last week failed when equipment problems kept the fumigant from reaching the saturation level believed needed to kill the spores.

ANTHRAX

Senate Offices Refumigated But Still Closed

WASHINGTON, Dec. 31 (AP) — A second effort to kill trace amounts of anthrax spores with poison gas in the Hart Senate Office Building was completed today. But liquid and foam decontaminants and particle-filtering vacuums were still being used in the offices of 11 senators.

Officials said they hoped they would not have to use the gas, chlorine dioxide, again in the building, where half of the Senate's 100 members have offices.

**The legal framework for
managing bioterrorism
epidemics**

What's wrong with the old statutes?

Colorado's 1947 Sabin statutes

The department [of health] has the following powers and duties:

- (a) To investigate and control the causes of epidemic and communicable diseases...
- (b) To establish, maintain, and enforce isolation and quarantine, and to exercise such physical control over property and the persons of the people within this state as the department may find necessary for the protection of the public health;
- (c) To close theatres, schools, and other public places, and to forbid gatherings of people when necessary to protect the public health;
- (d) To abate nuisances when necessary for the purpose of eliminating sources of epidemic and communicable diseases affecting the public health;
- (g) To regulate the disposal, transportation, interment, and disinterment of the dead;

The old statutes do not recognize that
bioterrorism isÖ

Not just an epidemic.

Itís also an emergency and a crime and
a matter of national security.

The response to bioterrorism may involve:

- ï Surveillance and contact tracing
- ï Isolation or quarantine of persons
- ï Requesting and receiving medical supplies from the National Pharmaceutical Stockpile
- ï Operating special clinics to distribute antibiotics and vaccines
- ï Crowd control
- ï Transferring or ceasing admission of patients to selected hospitals and setting up new, temporary hospitals
- ï Safe disposal of corpses and infectious wastes
- ï Preventing contamination of food and water
- ï Providing information to the public and answering their questions
- ï Providing mental health support
- ï Assuring **SUFFICIENT NUMBERS** of health care providers on the job

What does it take for hospital staff, health department staff, and health care providers to show up for work?

- ï Personal protective equipment
- ï Protection for family members
- ï Legal protection

What does it take for there to be sufficient numbers?

- ï Workers may be re-assigned to new tasksó it will not be ìbusiness as usualî
- ï Good communications, good supervision

Who's in charge?

- The Mayor
- The Governor
- The President

Who's *NOT* in charge?

- The Health Officer
- The State Epidemiologist

House Bill 00-10776 Colorado's 1st Bioterrorism Bill

Signing Ceremony with Gov. Bill Owens on March 15, 2000



Political leaders may not be involved in the details of plans and training exercises, but in the real event they want to do big things to show that the situation is under control and to allay fears of the public.

Purchasing smallpox vaccine 2001

Smallpox Vaccine Production Accelerated

The New York Times

Responding to increasing concerns about bioterrorism, the company making a smallpox vaccine is sharply accelerating production and now plans to deliver 40 million doses to the federal government next year, a spokesman for the health and human services secretary, Tommy Thompson, said yesterday.

Acambis, a company in Cambridge, Mass., had previously said it would deliver the vaccine in 2004.

Kevin Keane, a spokesman for Mr. Thompson, said that government officials began meeting with company officials soon after terrorists attacked New York and Washington on Sept. 11 to determine how the 40 million doses could be manufactured more quickly. The discussions included officials from the Food and Drug Administration, which regulates what testing must be done before a vaccine can be used.

Mr. Keane said it was agreed that some tests and development procedures could be done simultaneously so that the vaccine could be delivered as early as the middle of next

year.

The vaccine will be placed in a national stockpile that could be quickly drawn from in case of an attack that infected people with the smallpox virus. Experts say that such an attack is unlikely but possible.

New York Times Oct 2, 2001

November 28, 2001

Bush Administration to Buy Smallpox Vaccine

By THE ASSOCIATED PRESS

Filed at 9:09 p.m. ET

WASHINGTON (AP) — The Bush administration signed a contract Wednesday to buy 15.5 million doses of smallpox vaccine from a British firm, preparing for the possibility terrorists would try to spread the deadly virus.

The contract with Acambis Inc. will bring the nation's stockpile to 286 million doses of the vaccine by the end of next year, promising protection for every American should bioterrorists attack with the all-but-extinct virus.

"The risk does exist and we must be prepared," said Health and Human Services Secretary Tommy Thompson.

The vaccine can be administered four days after exposure to smallpox and still offer protection. For that reason, and because the vaccine can cause some rare but deadly side effects, officials have no plans to resume the routine vaccinations of Americans that ended in 1972.

Thompson said that buying the new vaccine is sure to prompt demand for the shots by some Americans and debate in Congress and at the White House over whether vaccinations should resume.

The government already has 15.4 million doses of smallpox vaccine on hand, and officials are preparing to dilute each of them to create five doses, bringing the total to 77 million. Researchers are studying whether each dose could be further diluted, to get 10 doses from each one.

In either case, the diluted vaccine would only be used if the new doses had not yet been delivered, or if they ran out, said Dr.

The intent of Colorado's Bioterrorism/Pandemic Influenza Law enacted in March 2000

- Provide expert advice to the Governor
- Remove legal barriers to working together
- Plan for an emergency epidemic
- No new powers for the State Health Officer or the Governor were created

Coloradoís Bioterrorism and Pandemic Influenza Law enacted in March 2000

- Creates the Governorís Expert Epidemic Emergency Response Committee which has three main functions:
 - a) Develop a plan that sets the prioritization of antibiotics, antivirals, and vaccines ó completed June 2001
 - b) In a crisis, review available data and advise the Governor to declare a disaster emergency
 - c) In a disaster emergency, provide expert advice to the Governor concerning measures to reduce or prevent spread of the disease

Coloradoís Bioterrorism and Pandemic Influenza Law enacted in March 2000

- Provides legal immunity to members of the Committee
- Gives the State Board of Health authority to adopt regulations requiring hospitals and health departments to make plans to prepare for and respond to bioterrorism ó *adopted May 2001; plans were submitted Dec 2001*
- Provides legal immunity to hospitals and health care providers who fully comply with executive orders of the Governor and Board of Health regulations

Colorado's Bioterrorism and Pandemic Influenza Law enacted in March 2000

- Provides for compensation if property was commandeered or otherwise used by the State in coping with an emergency epidemic
- Includes health care workers in the definition of "volunteer civil defense worker"
- Includes illnesses resulting from bioterrorism or pandemic influenza as compensation allowed to civil defense volunteers

Colorado regulations pertaining to preparations for a bioterrorist event or pandemic influenza

Requirements for hospitals and health departments:

- 1) Maintain an up-to-date notification list of clinics operated by the hospital; offices of physicians on the staff of the hospital; and the local public health agency;
- 2) Test the notification system twice a year by broadcast FAX or other communications method
- 3) Develop and submit a plan by 12/31/01 addressing staffing, personal protective equipment, infection control, operations center, disposal of corpses, security, coordination with other hospitals

What is under development?

- 1) Amending the statute to explicitly permit sharing confidential surveillance information with the FBI

- 2) *Draft Executive Orders of the Governor* addressing:
 - ï Pharmacy regulations
 - ñ Permitting other health care workers to dispense meds
 - ñ Permitting distribution based on generic orders
 - ï Suspension of certain regulations concerning physician and nurse licensing, e.g. volunteers from out-of-state
 - ï Commandeering antibiotics and radio communications equipment in a disaster
 - ï Transferring patients from one hospital to another in the context of federal EMTALA regulations
 - ï Suspension of certain regulations concerning disposal of infectious waste
 - ï Isolation, quarantine, and other types of personal movement restriction

Considerations when issuing isolation, quarantine, or restrictive orders

- ï Which persons and how many are affected by the order
 - ñ Epidemiologically determined group vs. specifically identified individuals
 - ñ Essential workers
- ï Duration of order affected by
 - ñ Incubation period of disease
 - ñ Surveillance efficiency
- ï Centralized vs de-centralized
 - ñ Logistics are easier if centralized
 - ñ Control of transmission may be improved if de-centralized
- ï Enforcement
 - ñ What happens to persons who disobey
- ï Due process for affected persons

Information on the internet about Colorado's bioterrorism statute and regulations

- i Colorado bioterrorism statute:
<http://64.78.178.9/stat01/index.htm> , click on
Search by words and then type in *emergency
epidemic*
- i Colorado bioterrorism preparedness regulations:
www.cdphe.co.state.us/op/dceedregs.asp