

# History, Legislative Innovation, and Future Pandemics

Dan Kracov  
Arnold & Porter

Food and Drug Law Journal 2020 Symposium  
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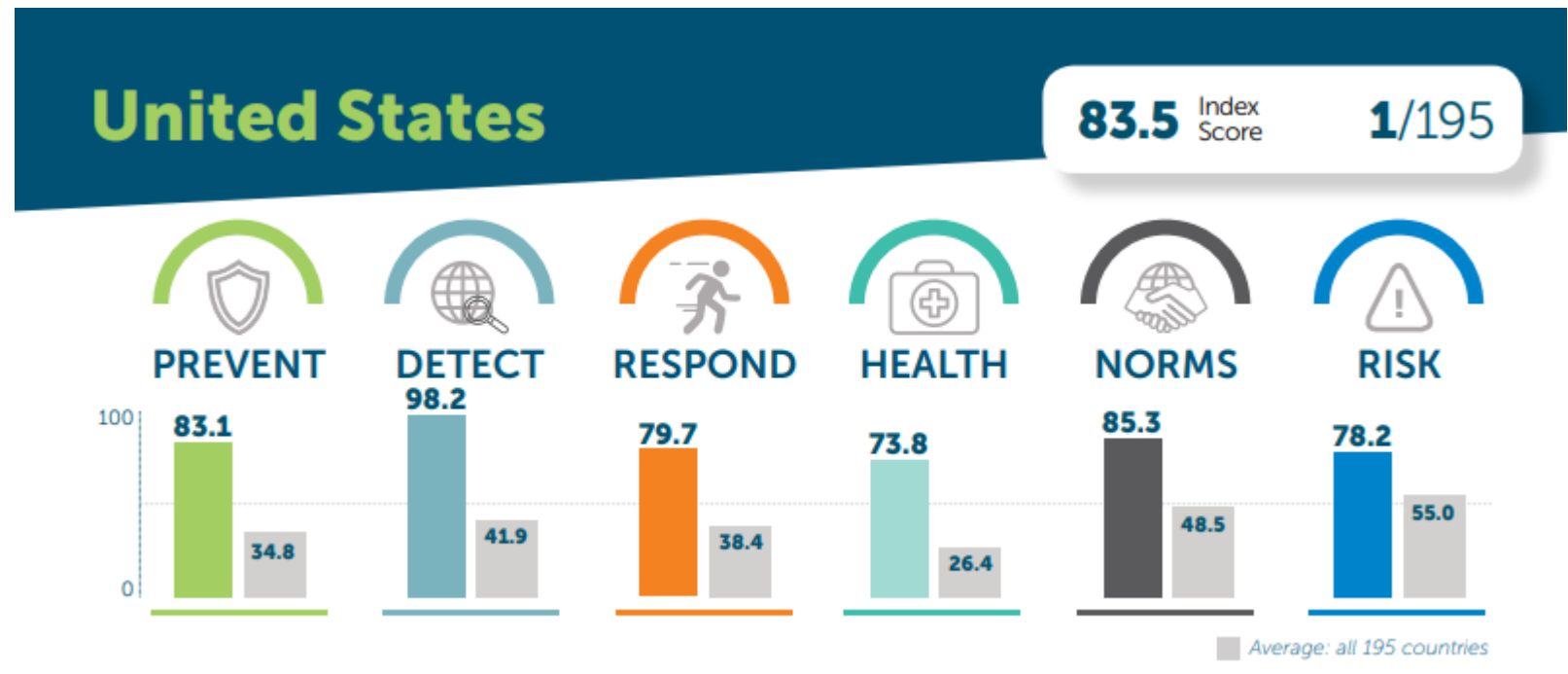
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**GHS INDEX**  
**GLOBAL HEALTH SECURITY INDEX**  
 Building Collective Action and Accountability

October 2019

NTI BUILDING A SAFER WORLD  
 JOHN'S HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH  
 Center for Health Security

Index developed with  
 The Economist INTELLIGENCE UNIT



COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University (JHU)

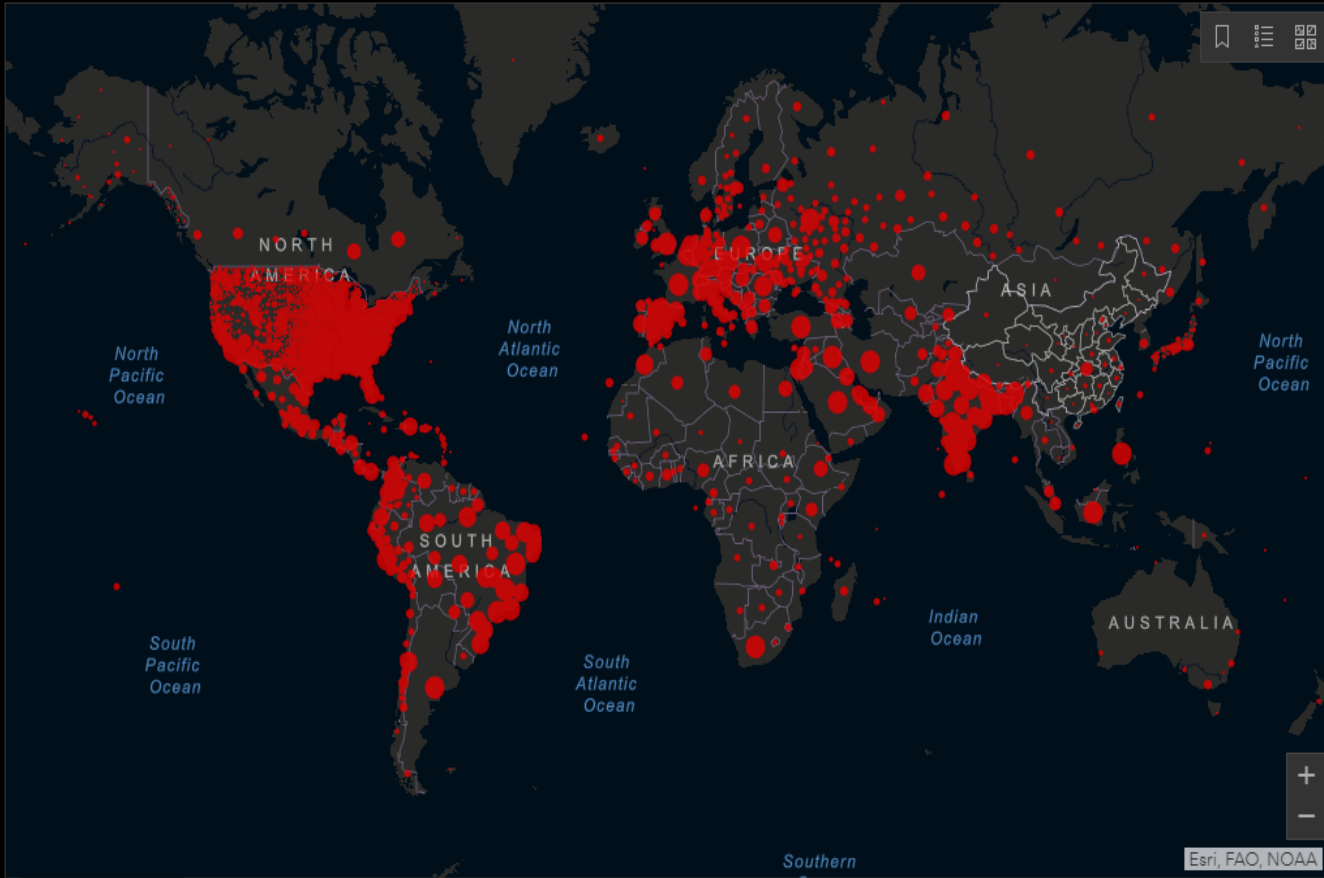
Global Cases  
**49,482,169**

Cases by Country/Region/Sovereignty

9,744,491	US
8,462,080	India
5,631,181	Brazil
1,740,172	Russia
1,709,716	France
1,328,832	Spain
1,228,814	Argentina
1,149,808	United Kingdom
1,127,733	Colombia
955,128	Mexico
917,503	Peru
862,681	Italy
734,175	South Africa
673,250	Iran
653,992	Germany

Admin0 Admin1 Admin2

Last Updated at (M/D/YYYY)  
**11/7/2020, 9:24 AM**



Cumulative Cases Active Cases Incidence Rate Case-Fatality Ratio Testing Rate

**190** countries/regions

Lancet Inf Dis Article: [Here](#). Mobile Version: [Here](#). Data sources: [Full list](#). Downloadable database: [GitHub](#), [Feature Layer](#). Lead by [JHU CSSE](#). Technical Support: [Esri Living Atlas team](#) and [JHU APL](#). Financial Support: [JHU](#), [NSF](#), [Bloomberg Philanthropies](#) and [Stavros Niarchos Foundation](#). Resource support: [Slack](#), [Github](#) and [AWS](#). Click [here](#) to **donate** to the CSSE dashboard team, and other JHU COVID-19 Research Efforts. [FAQ](#). Read more in this [blog](#). [Contact US](#).

Global Deaths  
**1,245,446**

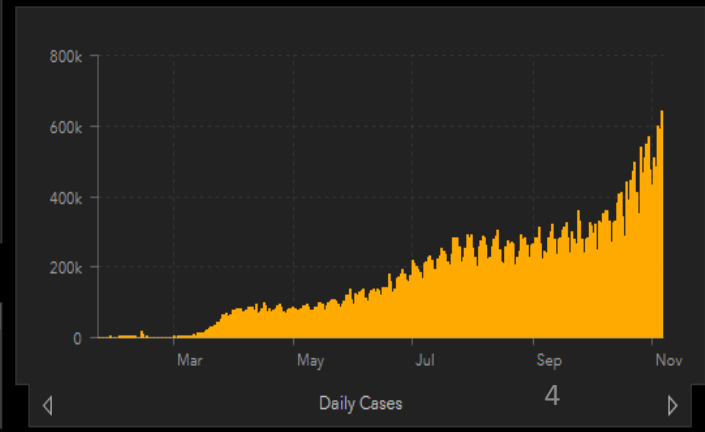
236,178 deaths	US
162,015 deaths	Brazil
125,562 deaths	India
94,323 deaths	Mexico
48,565 deaths	United Kingdom
40,638 deaths	Italy
39,916 deaths	

Global Deaths Global Recovered

US State Level  
**Deaths, Recovered**

33,664 deaths, <b>80,368</b> recovered	New York US
19,046 deaths, <b>807,008</b> recovered	Texas US
17,938 deaths, <b>recovered</b>	California US
17,014 deaths, <b>recovered</b>	Florida US
16,416 deaths, <b>37,818</b> recovered	New Jersey US
10,397 deaths, <b>recovered</b>	Illinois US
10,106 deaths, <b>131,646</b> recovered	

US Deaths, Recovered



# COVID-19 Vaccines Blaze New Path In the History Of Vaccine Development

20 Oct 2020 | **NEWS**

by **Brenda Sandburg** | @brendasandburg | Brenda.Sandburg@informa.com

## Executive Summary

Vaccine experts, including R&D leaders at Pfizer and Sanofi, describe what has been unique in developing a vaccine for the novel coronavirus, lessons learned from previous vaccines, and challenges that lie ahead.

## Commentary

May 9, 2007

# The Next Influenza Pandemic Can It Be Predicted?

Jeffery K. Taubenberger, MD, PhD; David M. Morens, MD; Anthony S. Fauci, MD

» Author Affiliations

*JAMA*. 2007;297(18):2025-2027. doi:10.1001/jama.297.18.2025

“It is currently impossible to predict the emergence of a future pandemic other than to strongly suspect that one will eventually occur, or to predict when or where a future pandemic will occur, what subtype it will be, and what degree of morbidity and mortality it will produce....”

“Thus, it is essential that while carefully monitoring current and identifiable risks, pandemic prevention strategies must also be based on expecting the unexpected and being capable of reacting accordingly.”

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2504708/>

## CORONAVIRUS

# How Climate Change Is Contributing to Skyrocketing Rates of Infectious Disease

A catastrophic loss in biodiversity, reckless destruction of wildland and warming temperatures have allowed disease to explode. Ignoring the connection between climate change and pandemics would be “dangerous delusion,” one scientist said.

by Abrahm Lustgarten, May 7, 5 a.m. EDT

## VIEWPOINT

David M. Cutler, PhD  
Department of  
Economics, Harvard  
University, Cambridge,  
Massachusetts.

Lawrence H.  
Summers, PhD  
Harvard Kennedy  
School, Cambridge,  
Massachusetts.

## The COVID-19 Pandemic and the \$16 Trillion Virus

The SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) pandemic is the greatest threat to prosperity and well-being the US has encountered since the Great Depression. This Viewpoint aggregates mortality, morbidity, mental health conditions, and direct economic losses to estimate the total cost of the pandemic in the US on the optimistic assumption that it will be substantially contained by the fall of 2021. These costs far exceed those associated with conventional recessions and the Iraq War, and are similar to those associated with

recessions continue, an estimated 625 000 cumulative deaths associated with the pandemic will occur through next year in the US.

Although putting a value on a given human life is impossible, economists have developed the technique of valuing “statistical lives”; that is, measuring how much it is worth to people to reduce their risk of mortality or morbidity. This approach has been used as a standard in US regulatory policy and in discussions of global health policy.<sup>2</sup>

There is a lengthy economic literature assessing the

# Filling the Gaps in Pandemic Preparedness

***Given the uncertain biological attributes of future pandemic pathogens, as exemplified by the aerosol nature of SARS-CoV-2 transmission, a future pandemic – or bioterror threat -- may place an even greater premium on the availability of effective diagnostics, prophylactics and treatments -- at large scale -- at the earliest stage of a pandemic.***

- How many lives, jobs, and businesses would have been saved if we had already developed and stockpiled vaccines and/or therapeutics that had effectiveness against a range of coronaviruses?
- What would have happened if massive diagnostic testing had been available virtually immediately, instead of the deep problems seen in national coordination in the COVID-19 pandemic?
- What if the next epidemic or pandemic is bacterial in nature, and we are still struggling to create a system that produces clinically meaningful new antibiotics?

# History





"The cow-pock - or - the wonderful effects of the new inoculation" Gillray, James, 1756-1815, artist

[Library of Congress](#)



Dr. James Smith  
Rembrandt Peale  
Baltimore Museum of Art



An Act authorising a Lottery for the preservation and distribution of the Vaccine Matter, for the use of the Citizens of this State. Lib. TH. No. 2, fol. 299.

Passed Jan 6, 1810

WHEREAS it appears to this general assembly, that it is of great importance to the public that a regular and uninterrupted supply of the genuine vaccine matter should be secured to, and distributed among, the citizens of this state free of expense, from a source which may be always relied on with safety: And whereas Doctor James Smith, of the city of Baltimore, hath proposed to use his best exertions to accomplish this desirable object; therefore,

Preamble.

2. BE IT ENACTED, by the General Assembly of Maryland, That William Wilson, Robert Stewart, Luke Tiernan, Henry Shrøder, Aaron Levering, Samuel Harden, Doctor John Cromwell, Doctor William H. Clendenen, James W. Collins, John W. Glenn, Andrew Agnew, Alexander McDonald, Edward G. Woodyear, Edward J. Coale, Peter Hoffman, jun. and Doctor James Smith, are appointed managers, and they, or a majority of them, may institute and establish a lottery or lotteries in the city of Baltimore, to raise a sum of money, not exceeding thirty thousand dollars, clear of expenses, sufficient to procure a piece of ground, and to build thereon a convenient house for the purpose of a vaccine institution, and to defray all other expenses incurred by Doctor James Smith to procure and distribute the vaccine matter, free of any costs, to the citizens of this state; *Provided however*, that before the managers above appointed proceed to the sale of any ticket or tickets in the said lottery or lotteries, the aforesaid Doctor James Smith shall give bond to the state of Maryland, with security to be approved of by the mayor of the city of Baltimore, in the penalty of ten thousand dollars, conditioned, that he, the said James Smith, shall use his best exertions to procure, and well and faithfully to preserve, the genuine vaccine matter, and distribute the same, with instructions, if required, for the use thereof, for a period of six years from this time, free of expense, to any of the citizens of this state applying for the same, and it shall be the duty of the said James Smith to lodge the said bond in the clerk's office of Baltimore county court, there to be recorded, within sixty days after it may be executed and approved of as above mentioned; *And provided also*, that before the managers above appointed proceed to the sale of any ticket or tickets in said lottery or lotteries, they, or a majority of them, shall give bond to the state of Maryland, in the penalty of sixty thousand dollars, conditioned that they will well and truly apply the monies arising therefrom, within six months after the drawing thereof, to the payment of any prizes to whom they shall be due, and that after deducting all necessary expenses incurred in the management thereof, they shall pay over to the aforesaid Doctor James Smith the neat profits arising from said lottery or lotteries, to be by him applied to the purposes above mentioned, and to carry this law into full effect; and the said bond shall be lodged in the clerk's office of Baltimore county, to be there recorded, and upon such bond, or any office copy thereof, suit or suits may be instituted for any breach or noncompliance with the conditions thereof.

Managers appointed, and authorised to institute lotteries.

Provisos.

“...the genuine Vaccine Matter shall be furnished, at all times, from this Institution, to any Surgeon or Surgeons Mate, in the service of the United States; or to any Person, applying for the Same by Post, from the District of Columbia, *free of any Expence*, postage having been paid. Whenever required, sufficient directions, also, shall accompany each portion of the Matter; so as to put it, in the power of any intelligent person, to use it, with safety, & to conduct the whole process of vaccination, without danger and with every Certainty of Success.”

Letter from James Smith to James Madison, (June 18, 1809)  
(<https://founders.archives.gov/documents/Madison/03-01-02-0281>).

# Vaccine Act of 1813

Feb. 27, 1813.

Repealed by Act of May 4, 1822, ch. 50.

Agent to be appointed for preserving the genuine vaccine matter.

It may be sent through the medium of the post-office.

Oath or affirmation to be taken by agent.

He must write to the postmasters and send a copy of this act.

Packets not exceeding half an ounce and relating to vaccination, to go free of postage to and from the agent.

Proviso.

CHAP. XXXVII.—*An Act to encourage Vaccination.*

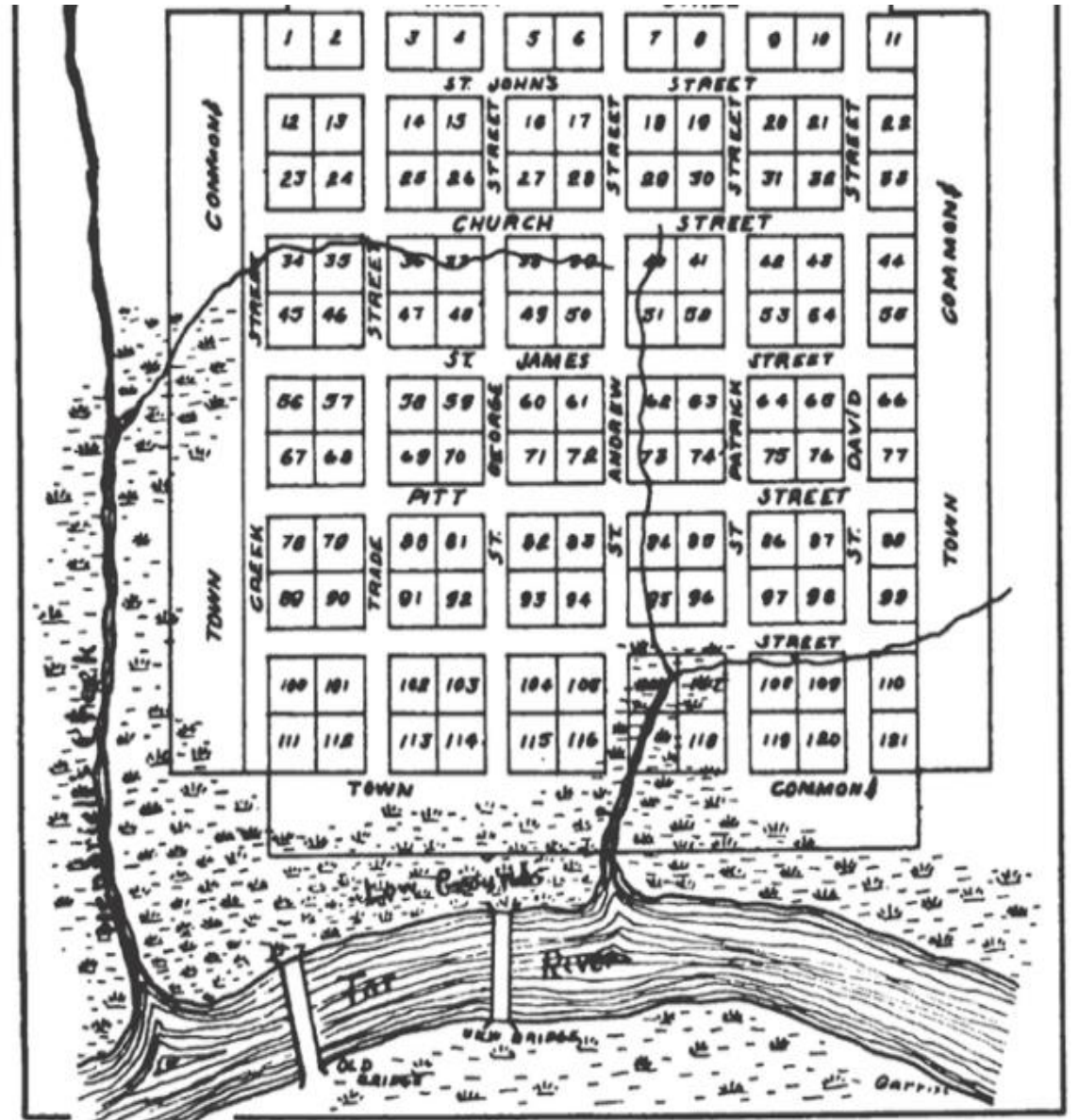
*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,* That the President of the United States be, and he is hereby authorized to appoint an agent to preserve the genuine vaccine matter, and to furnish the same to any citizen of the United States, whenever it may be applied for, through the medium of the post-office; and such agent shall, previous to his entering upon the execution of the duties assigned to him by this act, and before he shall be entitled to the privilege of franking any letter or package as herein allowed, take and subscribe the following oath or affirmation, before some magistrate, and cause a certificate thereof to be filed in the general post-office: "I, A. B. do swear (or affirm, as the case may be) that I will faithfully use my best exertions to preserve the genuine vaccine matter, and to furnish the same to the citizens of the United States; and also, that I will abstain from every thing prohibited in relation to the establishment of the post-office of the United States." And it shall be the duty of the said agent to transmit to the several postmasters in the United States a copy of this act: and he shall also forward to them a public notice, directing how and where all application shall be made to him for vaccine matter.

SEC. 2. *And be it further enacted,* That all letters or packages not exceeding half an ounce in weight, containing vaccine matter, or relating to the subject of vaccination, and that alone, shall be carried by the United States' mail free of any postage, either to or from the agent who may be appointed to carry the provisions of this act into effect: *Provided always,* that the said agent before he delivers any letter for transmission by the mail, shall in his own proper handwriting, on the outside thereof, endorse the word "*Vaccination,*" and thereto subscribe his name, and shall previously furnish the postmaster of the office where he shall deposit the same with a specimen of his signature; and if said agent shall frank any letter or package, in which shall be contained any thing relative to any subject other than vaccination, he shall, on conviction of every such offence, forfeit and pay a fine of fifty dollars, to be recovered in the same manner as other fines or violations of law establishing the post-office:

*Provided also,* that the discharge of any agent, and the appointment of another in his stead, be at the discretion of the President of the United States.

APPROVED, February 27, 1813.

# The Tarboro Tragedy





VACCINATION.

MARCH 1, 1827.

Read, and laid upon the table.

Mr. CONDUCT, from the select Committee appointed on the 27th ult. presented the following

REPORT:

*The Select Committee, charged with the memorial of Doctor James Smith, and his letter of December 19, 1825, addressed to the Speaker of the House of Representatives, respectfully report:*

That they did, at the last session of Congress, diligently inquire into all the facts and circumstances, connected with the introduction of small-pox into Tarboro, in North Carolina, in 1821-2, and into the grievances alleged by the memorialist; and whilst they deplore the affliction which was visited upon the inhabitants of that place, it affords them much consolation to find, that the occurrence has not shaken the confidence heretofore reposed in vaccination, as an efficient antidote and preventive against small-pox. On the contrary, it affords additional testimony of its value; and a full development of all the facts has served to quiet the fears and doubts, which for a time distracted the public mind on this subject.

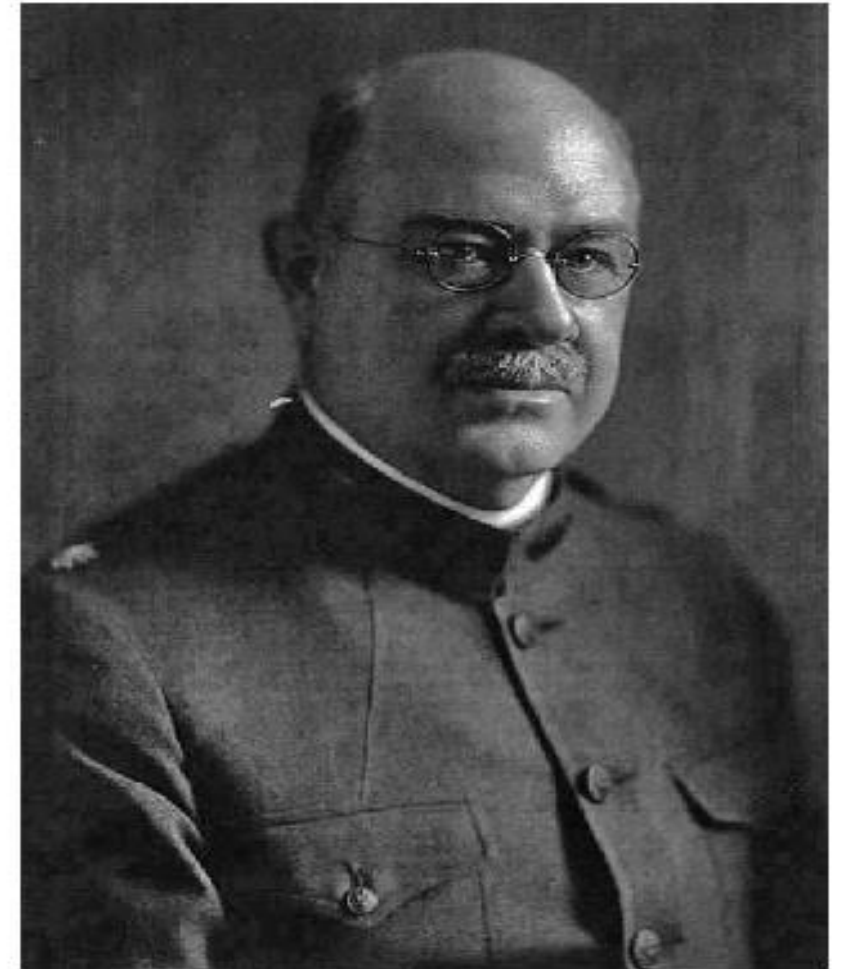
The Committee have scrutinized the mode in which the business of the vaccine agency has been conducted by Dr. Smith. They have examined his books of original entries, or the memoranda of supplies of vaccine virus furnished to individuals, with the distinctive marks or characters used by him to designate both small-pox and vaccine virus. They have also examined many letters from Physicians in Tarboro, and the answers of Dr. Smith. But a minute detail of all the facts and circumstances presented for examination, would make this report too voluminous. They will therefore confine themselves to a brief recital of those deemed most important.

By the book of entries kept by Dr. Smith, it appears that, on the 1st November, 1821, he addressed manuscript letters to Doctors Ward and Hunter, of Tarboro, and enclosed therein, to each, two parcels of vaccine virus, on glass. Doctor Hunter received the letter addressed to him, with the vaccine matter, as enclosed. But after diligent inquiry, and much investigation, no traces of the letter to Doctor Ward, or of its contents, can be found. No allusion is made to it by Doctor Ward, in any of his communications, and the Committee are induced to believe it never came to his hands. He did, however, receive a printed circular, purporting to be from Doctor Smith, containing scabs,

# Legislative Innovation



FIG 2 The original MHS (Marine-Hospital Service) Hygienic Laboratory on the first floor of the main building of the rented Marine Hospital, Stapleton, Staten Island, New York. The image is undated but is presumably from 1887 to 1891. The building is still standing but is unoccupied. The actual location of this room, in one of eight similar rooms on the ground floor of the central building, is not currently known. The two men in the picture have not been identified but neither appears to be Kinyoun or any of the other MHS officers known to have played an early role in the Laboratory (photograph courtesy of the National Institutes of Health).



Joseph James Kinyoun, M.D.



# Biologics Control Act of 1902 (Virus-Toxin Law)



*Production of diphtheria antitoxin by inoculating horses required great care to maintain purity and avoid contamination. Courtesy of National Archives and Records Administration.*

Suzanne White Junod, PhD,  
Biologics Centennial: 100 Years of Biologics Regulation  
<https://www.fda.gov/files/Biologics-Centennial--100-Years-of-Biologics-Regulation.pdf>

[https://en.wikipedia.org/wiki/Jim\\_\(horse\)](https://en.wikipedia.org/wiki/Jim_(horse))

# Federal Food, Drug, and Cosmetic Act

**U. S. Races Death to Save 700 From Elixir**  
**Recovery of Pint Bottles Sold to Patients Goal as Deaths From Poison Reach 36**

By Associated Press.  
CHICAGO, ILL., October 24.—A nation-wide race with death, its object recovery of more than 700 bottles, mostly pint, of a new liquid medicine, named Elixir of Sulfanilamide, which has already caused 36 verified deaths, was described today at the headquarters here of the American Medical Association.

Every agent of the United States Food and Drug Administration, said Dr. Morris Fishbein, spokesman of the Medical Association, is touring the country to recover the bottles. By some time on Monday, said J. O. Clarke of the Food and Drug Administration, it is hoped that all of the "outstanding" shipments will be recovered.

lies in the fact that large dosages are customary with sulfanilamide preparations.

The medicine stops the kidneys. At Medical Association headquarters his efforts were said to be like those of hydroxide of mercury. The sulfonamide is known as, The "Elixir" is made of sulfanilamide and diethylene glycol, a near relative of auto antifreeze fluid. The diethylene glycol is blamed for the lethal effect, although not listed as such a poison.

The principal shipments, said Mr. Clarke, went to the South and Midwest. But in addition consignments have been traced to the Northern Peninsula of Michigan, to a distributing house in New York City and to another in San Francisco. An



# 1962 Kefauver-Harris Amendments



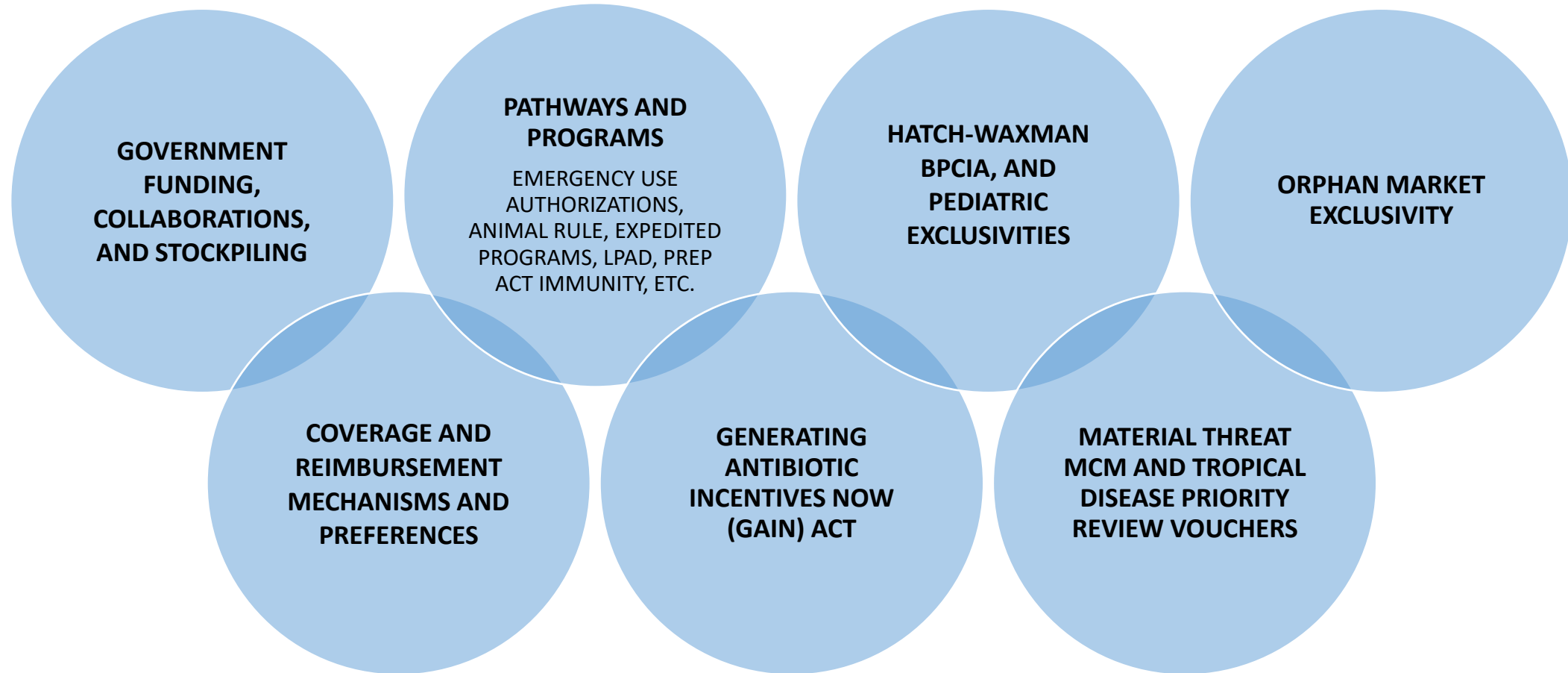
Source: FDA

<https://www.fda.gov/consumers/consumer-updates/kefauver-harris-amendments-revolutionized-drug-development>

“The regulations and the government shepherding of the drug business did what the free market had failed for at least sixty years to do -- it weeded out the brutal, the stupid, and the needless that prevented the pharmaceutical industry from becoming a great engine of discovery and sales. The tough markets had prevented companies from carrying out expensive and detailed research. The laying down of the scientific standard came first, and the creation of the modern pharmaceutical industry followed. A scientific standard, administered by somebody outside industry itself, was the essential ingredient.”

P. Hilts, *Protecting America's Health: The FDA, Business, and One Hundred Years of Regulation* (Knopf (2003)) at 106-107.

# Incentives, Pathways, and Mechanisms



# Future Pandemics

# Preparing for the Next Pandemic

**A WHITE PAPER**

**By: Senator Lamar Alexander of Tennessee**  
Chairman  
U.S. Senate Committee on Health,  
Education, Labor and Pensions

**“Looking at lessons learned from the COVID-19 crisis, many of the challenges Congress has worked to address during the last 20 years still remain. Additionally, COVID-19 has exposed some gaps that had not been previously identified.”**





# COVID-19

The Biden-Harris plan to beat COVID-19

**T**he American people deserve an urgent, robust, and professional response to the growing public health and economic crisis caused by the coronavirus (COVID-19) outbreak. President-elect Biden believes that the federal government must act swiftly and aggressively to help protect and support our families, small businesses, first responders, and caregivers essential to help us face this challenge, those who are most vulnerable to health and economic impacts, and our broader communities – not to blame others or bail out corporations.

The Biden-Harris administration will always:

- **Listen to science**
- **Ensure public health decisions are informed by public health professionals**
- **Promote trust, transparency, common purpose, and accountability in our government**

President-elect Biden and Vice President-elect Harris have a seven-point plan to beat COVID-19.



# New bill would create a subscription payment model to jumpstart antibiotic development

By ED SILVERMAN [@Pharmalot](#) / SEPTEMBER 30, 2020

[Reprints](#)



# Proposal: Customized Incentive Models/RFPs

- The problems emerging in the COVID-19 pandemic add to existing factors suggesting that we need more powerful push and pull incentives for public health countermeasure technology development.
- Unlike existing non-patent incentive frameworks, which provide a meaningful but largely generalized approach to incentivization across a range of disparate products, one potential approach to addressing these needs is to go beyond existing measures to create and offer customized “Incentive Models” that are tailored to clearly identified countermeasure development and stockpiling goals and offer a customized set of push and pull incentives tailored to the particular preparedness need or goal.
- Incentive Model RFPs, either via authorization and appropriations associated with the enabling legislation or a subsequent, fast tracked congressional approvals, could be responded to by individual companies or collaborative groups, who would then be awarded various Incentive Model benefits upon the achievement of specific milestones.

***In addition to funding and stockpiling, and existing incentives,*** Incentive Models could draw from a rich history of legislative and academic proposals framing a variety of “push and pull” incentives, including:

- Mechanisms for strongly incentivizing voluntary, **pre-competitive collaboration** across life sciences companies, which could help optimize research and development on future pandemic treatments or tools, such as surveillance systems and databases, and prevent siloed or duplicative research efforts.
- Awarding “**wild card**” or **tradable exclusivity vouchers** that can extend the existing patent life or exclusivity of a new product in return for successful efforts to develop important countermeasures for diseases of pandemic concern.
- **Exclusivity incentives to spur research to demonstrate whether old drugs lacking intellectual property protections can be repurposed for emergent disease uses.**
- Government program **add-on payments and subscription approaches** that may encourage the development and appropriate use of “dual use” products needed for conventional healthcare settings, with surge and stockpiling capacity for emergencies.
- Financial incentives for maintaining sufficient domestic, advanced, on demand, manufacturing capacity for key public health countermeasures, such as through **tax and other incentives.**
- **Market entry rewards** -- potentially in the billions -- for drug, biologic or device developers that achieve approval of a novel product meeting an important pandemic preparedness need.

CORONAVIRUS

## Government watchdog will probe Trump officials' interference at CDC, FDA

Democrats had requested the GAO probe earlier this month, citing reports of political appointees seeking to steer the science agencies' policies and communications.



By DAN DIAMOND  
10/19/2020 02:31 PM EDT

# Ring-Fencing Pandemic Preparedness and Response Mechanisms



Thank you!