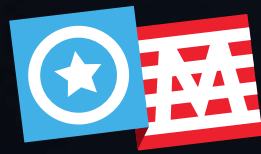


# Corporate Monopoly and the Decline of America's Vaccine Industry



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# Contents

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I. Introduction .....	2
II. Vaccine Production and the Military .....	4
III. The Golden Age .....	6
IV. The Rise of Medical Neoliberalism .....	8
V. The Unraveling .....	11
VI. What can be done? .....	15
Appendix: Timeline .....	17
Endnotes .....	22

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# I. Introduction

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Scientists have been racing since January to develop a vaccine for COVID-19. Worldwide, more than [165](#) COVID-19 vaccines are in development at major pharmaceutical companies and also at smaller biotech firms and academic research institutions.<sup>1</sup> In the United States, a federal government project called Operation Warp Speed is backing [eight candidates](#) with billions of dollars and assistance with clinical trials.<sup>2</sup>

On Nov. 9, Pfizer announced that its vaccine candidate had prevented COVID-19 infections in more than 90% of clinical trial participants; at the same time, Pfizer's CEO acknowledged that the corporation was searching for ways to increase manufacturing capacity.<sup>3</sup> Pfizer – or any manufacturer of a coronavirus vaccine – will confront a massive challenge posed by the lack of vaccine production capacity caused by years of corporate consolidation, the absence of regulation, and government underinvestment in this key facet of public health.

If and when the FDA approves a vaccine or multiple vaccines, the public health crisis won't be over. We'll still have to figure out how to produce the vaccine or vaccines in adequate volume, including the production of vials and syringes needed to administer hundreds of millions of doses. For example, Pfizer's vaccine candidate requires two doses 21 days apart, meaning that the United States would need roughly 650 million doses. Both the Pfizer CEO and the Army general serving as COO of Operation Warp Speed admit today that many Americans will likely have to wait until the third quarter of 2021 for their vaccine shots.<sup>4</sup> And we will still face the challenge of determining exactly how to price and distribute the vaccine to ensure that all U.S. residents are immunized as swiftly as possible.

Americans will also be faced with an even larger task: to rebuild our public vaccine system not only to ensure that it works better in the next crisis but so that it averts the next crisis. Even before the COVID-19 pandemic, America's highly monopolized vaccine industry was marked by rising prices combined with worsening shortages.

The problem is not new. Monopolists have been concentrating control over the production of both vaccines and ancillary components for decades. As a result, even as the federal government has furnished massive subsidies and broad liability exemptions, Americans have witnessed the return of diseases that we thought we had vanquished long ago. At the same time, prices for even

the most basic childhood vaccines have skyrocketed. Yes, populist distrust of vaccines has played a part. But a less publicized obstacle – and one at least as great – is that America’s economic model for producing vaccines is broken.

In this paper, we’ll consider the various problems that impair vaccine production and distribution and show how they relate to dramatic changes in the laws and policies that have governed the industry. Prior to and during World War II, the military played a principal role in researching and producing effective vaccines and other medical advances against infectious disease, including the typhoid vaccine and penicillin, which was initially produced using government-owned labs and production facilities.

After World War II and lasting into the early 1980s, a new political economy emerged in which well-funded, highly competent, professionalized federal agencies played an increasing role in directing biomedical research and coordinating the work of private sector actors, from academic medical centers to private sector drug companies. This era was also marked by strong anti-monopoly regulation by the federal government, including sharp restrictions on the ability to patent ideas of value to the public as a whole. This era was a golden age in the fight against infectious disease, producing effective antibiotics and such breakthroughs as the polio vaccine.

But, unfortunately, it was followed by a third era that continues today, an era in which the political economy of medical science and practice has been turned on its head. Beginning with the Reagan administration, federal biomedical and academic research – as well as key regulatory agencies – were increasingly captured by profit-maximizing corporations, while federal policy simultaneously retreated from antitrust enforcement and began granting thickets of patent monopolies. The disastrous results of this neoliberal policy regime are increasingly obvious. But, importantly, it is not too late to change course. Indeed, the COVID-19 crisis provides us with precisely the opportunity necessary to focus public attention and policymaking on the need to fundamentally reorder the political economy of the U.S. vaccine industry.

## II. Vaccine Production and the Military

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The first evidence of people inoculating against communicable diseases dates back at least 1,000 years, to China, where people would inhale ground scabs to protect against smallpox.<sup>5</sup> The process is known as variolation and was practiced in the United States as far back as the 18<sup>th</sup> century, when the entire U.S. Army was variolated against smallpox during the Revolutionary War.<sup>6</sup>

Major credit for the first vaccine is given to Edward Jenner, a British physician, who in 1796 successfully inoculated an 8-year-old from smallpox with cowpox. He called his product “vaccine” for the Latin word *vacca*, or cow. The U.S. military was quick to adopt the new technology, using it during the War of 1812 to vaccinate the Army against smallpox for the first time.<sup>7</sup>

By the end of the 19<sup>th</sup> century, military interest in infectious disease deepened, as America’s military presence extended into tropical zones such as Cuba, Panama, and the Philippines, where many more American soldiers died of diseases than in combat. The eponymous Army Maj. Walter Reed achieved fame at the turn of the 20<sup>th</sup> century not through his treatment of battle injuries but rather through his groundbreaking research into the role that mosquitos played in transmitting yellow fever among Army troops who occupied Cuba after the Spanish-American War. A few years later, deaths from typhoid fever motivated the Army to sponsor research that led to an effective vaccine that was administered first to the military in 1909 and became available to the general public in 1914.<sup>8,9</sup>

The U.S. military’s interest in vaccines grew further after the outbreak of the Spanish flu in 1918, which underscored how infectious disease could be a major factor in the strategic balance of power during wartime.<sup>10</sup> During the 1930s, the military’s role in biomedical research and development became increasingly crucial, as private pharma companies came under the thrall of the mistaken belief that chemotherapy would soon become the primary treatment for more and more ailments and accordingly began closing and consolidating facilities focused on biologics.<sup>11</sup> War planners in this era also took the threat of another pandemic and biological weapons more seriously than other leaders did. In 1940, an NIH panel of consultants, primarily from academia, concluded that “biological warfare was not considered practicable or as constituting a menace to the country.” Military experts disagreed.<sup>12</sup>

America's experience in World War II led to still deeper military control and direction of biomedical research and development, including new antibiotics such as penicillin<sup>13</sup> and the first flu vaccine, which was reviewed by the Armed Forces Epidemiological Board in 1942 and approved for civilian use in 1945.<sup>14</sup> Under pressure from the federal government, private sector manufacturers reversed their retreat from biologics and began expanding their facilities, even though they knew they'd be left with excess capacity when demand slumped after the war. One motivating factor was that company presidents and research directors were ideologically eager and proud to assist with the war effort.<sup>15</sup> They also saw good public relations opportunities and understood that temporary cooperation with the government would yield returns. The success of World War II vaccine development was primarily driven by the government's ability to leverage existing sources of knowledge across academia, the private sector, and the military.

# III. The Golden Age

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After World War II, a new era began in vaccine production. The military was still focused on biomedical research, particularly as competition with the Soviet Union heightened interest in both developing biological weapons and countermeasures to them. But the newly formed Department of Defense took a back seat to other federal agencies, which increasingly forged partnerships with academic and private industry to advance biomedical research and development. The Committee on Medical Research, a federal agency tasked with coordinating scientific research for military purposes, was dissolved in 1947, and the War Research Service, an agency that pursued research related to biological warfare, was incorporated into the Chemical Warfare Service. The Chemical Warfare Service was then instructed to switch military vaccine production to the private sector “to the maximum practicable extent.”<sup>16</sup>

Consistent with this directive, after University of Pittsburgh virologist Jonas Salk developed the first polio vaccine in the early 1950s, private drug companies, not the military, handled production and distribution of the miracle drug. Some of the initial results were tragic. One young boy received the vaccine in April 1955, right after it became available, and eight days later he was completely paralyzed. More cases of paralysis soon appeared, all in children who had received polio vaccines manufactured at Cutter Laboratories in Berkeley, one of five companies licensed by the federal government to produce the polio vaccine. Cutter recalled its vaccines from distributors. But by then, nearly 400,000 Americans, mostly children, had already received it. Testing revealed that one of every three Cutter vaccines contained live instead of inactivated viruses. The bad batches ended up paralyzing 51 children and killing five.<sup>17</sup>

After this disaster, the U.S. government tightened regulation of vaccines by the National Institutes of Health. It also actively involved other federal agencies such as the Communicable Diseases Center (later the Centers for Disease Control and Prevention, or CDC) to help states and local communities acquire and administer vaccines.<sup>18</sup> During the next seven years, public health officials administered 400 million doses of Salk’s vaccine, and cases of polio dropped by 90%.<sup>19</sup> In 1962, another polio vaccine, developed by medical researcher Albert Sabin, became available for widespread use and was even more effective and easier to administer than Salk’s.<sup>20</sup>

Throughout this era, the military continued to play a role, albeit a declining one, in vaccine development. More than half the new vaccines licensed during the second half of the 20<sup>th</sup> century resulted from partnerships between the Department of Defense and private industry.<sup>21</sup> But other public entities also began to play more significant roles. NIH's stature in particular grew, as it coordinated biomedical research through its own labs and issued grants to academic institutions.<sup>22</sup> Meanwhile, federal agencies such as the Federal Trade Commission used increasingly strong antitrust enforcement and other competition policies to fight price fixing, patent abuse, and monopolization in the pharmaceutical industry, while regulatory agencies such as the Food and Drug Administration became increasingly professionalized and science-driven.<sup>23</sup> The federal government also committed resources to international institutions, including the [Pan American Health Organization](#) and the World Health Organization, in the hopes of spreading access to vaccines and other biomedicines abroad. The result was a pluralistic system that, while far from perfect, avoided the pretension that "market forces" alone could take the place of policymaking by elected officials working with informed experts and independent, evidence-driven regulatory agencies.

Under this policy regime, a golden age of vaccine development and distribution flourished, as vaccines became broadly available at affordable prices for such common viral diseases of childhood as measles, mumps, and rubella. So spectacular was the pace of progress during the 1960s and '70s that, as Dr. Anthony Fauci would later recall, medical researchers at the time commonly believed that the fight against infectious diseases had been won.<sup>24</sup> While it was far more difficult to earn profits from vaccines than by making many other drugs, pharmaceutical company managers could still remain committed to vaccine production because they were not yet driven, as they would later become, by the imperative to maximize shareholder value.



## IV. The Rise of Medical Neoliberalism

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After the early 1980s, however, profound changes in economic philosophy and policy altered in dramatic ways the political economy governing biotech in general and vaccines in particular.

One big change stemmed from the deregulation of Wall Street and the imposition of the “shareholder value theory” of corporate governance, which holds that the purpose of the corporation is to maximize profits for owners. In tandem, these changes led to the displacement of corporate managements that did not “maximize shareholder value” by managers fully in alignment with the interests of financiers.<sup>25</sup>

Practically speaking, this made it harder and harder for even the most well-intentioned of executives to invest in new and better vaccines without risking hostile takeovers.<sup>26</sup> Over time, it became hard to defend even the sort of cost-plus manufacturing of the most basic vaccines necessary to protect the public health. Fixed and sunk vaccine production costs tend to be quite high. Lead times for approval are necessarily long, with most cost and risk accruing at the back end of the production cycle, during clinical trials and the start of manufacturing. The fact that a vaccine is taken only once or perhaps twice in a lifetime places a serious limitation on the revenues it can generate. Moreover, production costs tend to be higher for vaccines than for most other drugs, because any product given to a healthy person must clear a higher bar for safety and efficacy. They’re highly perishable, and vaccines are also more susceptible to lawsuits.

Soon after the radical changes in policy in the early 1980s, it became increasingly evident that the new corporations and new investors of the Reagan era had little interest in improving or even maintaining vaccines, even in cases where the returns to public health were clearly enormous. In the mid-1980s, the president of Merck Sharp & Dohme warned Congress that Merck’s future in the vaccine market would depend on profitability.<sup>27</sup> In 1985, the National Academy of Medicine (then known as the Institute of Medicine) noted that “numerous studies ... have raised the concern that our reliance on market incentives to ensure vaccine availability may lead to a failure to meet public health needs [and] may not result in optimal levels of vaccine innovation.” The agency recommended that the federal government consider becoming the vaccine “manufacturer of last resort” or enter into guaranteed contracts with manufacturers for needed vaccines.<sup>28</sup> Instead, Congress and the Reagan administration continued the course, and U.S. investment in vaccine production continued to decline.

A second big shift was a decision by the Department of Justice under Reagan to dramatically cut back on antitrust enforcement. Under the thrall of market libertarians, including Robert Bork and a “law and economics” movement centered in the University of Chicago, the Reagan administration refused to prosecute monopolies except in cases involving proven collusion to raise prices. The result was an explosion of mergers and acquisitions throughout the economy, including an acceleration of an already ongoing trend toward consolidation among a declining number of remaining vaccine-makers.<sup>29</sup> At least in theory, large pharmaceutical firms have access to more research and development dollars, but vaccines’ low profitability puts them at the end of the line when divisions in pharma corporations compete for these funds.

To worsen matters, the new lax antitrust rules allowed large corporations to more easily engage in a form of cartel behavior in which each monopolizes the production of one particular vaccine while assiduously refusing to challenge the dominant positions that other large corporations have captured over other vaccines.

A third large change in the political economy of vaccines involved intellectual property rights and the growth of patent monopolies. When the polio vaccine was approved in 1955, a journalist asked Salk in a television interview who owned it. Salk famously replied, “Well, the people, I would say. There is no patent. Could you patent the sun?” But while patents were not present in vaccine production for much of the 20<sup>th</sup> century, that changed in 1980 as a result of two important developments. In a 5-4 decision, the Supreme Court ruled in *Diamond v. Chakrabarty* that genetically modified organisms could be patented, creating enormous growth potential for the nascent biotechnology industry.<sup>30</sup> Six months later, Congress passed the Bayh–Dole Act, which allowed small businesses and nonprofits, including universities, to retain intellectual property rights to inventions made in their institutions with federally funded research dollars.

Backers of these two legal changes promoted the theory that such intellectual property rules would stimulate private-sector production of new products, including vaccines. In practice, they mainly stimulated the increasingly extreme profiteering that had been made possible by the changes in antitrust enforcement and corporate governance. Rather than develop new vaccines, drug companies sought multiple patents on existing vaccines, with the result that, starting in the 1990s, vaccine patent applications rose tenfold even as vaccine production declined.<sup>31</sup>

Intellectual property manipulation is hardly unique to the vaccine sector. As the Open Markets Institute has documented elsewhere, the pharmaceutical industry has grown highly skilled and aggressive in using patents to strangle

competition.<sup>32</sup> The acquisition of patent monopolies generates large profits spent not on new research and development so much as fighting to preserve those monopolies through thickets of additional patents and other legal maneuvers.

A fourth big change in the political economy of vaccine production came about with the capture, gradual disarmament, and corruption of the key federal agencies. Starting in the Reagan administration, political appointees increasingly insisted that their agencies treat as clients the corporations they were supposed to regulate.<sup>33</sup> Meanwhile, as revealed by a growing literature of “medical neoliberalism,” drug regulation and subsidization became less and less the purview of independent scientists and more and more a matter for economists, who saw their task as measuring the overall “efficiency” of how society uses its productive and human resources rather than returns to public health.<sup>34</sup>

In 1992, Congress passed the Prescription Drug User Fee Act, which meant that the once prestigious and science-driven Federal Drug Administration no longer had a secure, independent source of financing but rather had to depend on payments from drug companies.<sup>35</sup> At roughly the same time, following the end of the Cold War, the military largely retreated from involvement with vaccines, while policymakers in both parties increasingly denigrated any attempt by government to engage in planning or setting coherent and coordinated industrial policy as “picking winners and losers.”<sup>36</sup> “The era of big government is over,” President Bill Clinton declared in his 1996 State of the Union address.

One early result of this new neoliberal order was higher vaccine prices. From 1980 to 1995, vaccine prices rose faster than the Consumer Price Index and the Producer Price Index.<sup>37</sup> As more and more drugmakers either merged or got out the vaccine business to pursue more lucrative investments, the pricing power of those that remained continued to increase. By 1996, only eight firms and laboratories were still producing recommended childhood vaccines for the U.S. market. By 2002, only four firms remained.<sup>38</sup> And a single firm was the sole supplier for five of the key vaccines that children needed.<sup>39</sup>

Given the importance to public health of ensuring that all children are vaccinated against certain diseases, the Clinton administration and Congress responded by creating special programs to help low-income families afford the vaccines.<sup>40</sup> But the government soon found that it too had to pay higher, monopoly prices for the vaccines. The new, powerful drug monopolies were able to demand ever higher rates in negotiations with government purchasers. Thus, the percentage discounts available to the federal government went down, not up, from about 75% less than the sticker price in 1987 to 50% less a decade later. Varicella (chicken pox) and pneumococcal conjugate vaccines (pneumonia, meningitis), introduced in 1995 and 2000, had federal discounts of just 9% and 22%, respectively.<sup>41</sup>

# V. The Unraveling

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By the turn of the millennium, the failures of the neoliberal system of vaccine production were becoming increasingly apparent. Between fall 2000 and summer 2002, the U.S. experienced nationwide shortages of five childhood vaccines. An Institute of Medicine study from 2003 concluded that vaccine shortages:

appear to result from specific and apparently unrelated causes rather than a single overriding factor. Vaccines affected by the shortages are both new, such as pneumococcal conjugate, and long-standing, such as MMR, and shortages have affected both sole-supplier and multiple-supplier vaccines.<sup>42</sup>

Between 2000 and 2005, there were vaccine shortages for nine of the 13 diseases for which children were immunized. Meanwhile, the number of manufacturers producing seasonal flu vaccine for the U.S. market fell from four in 1999 to just two by 2004.<sup>43</sup>

These failures came in the context of increasing alarm over the nation's lack of pandemic preparedness. The 9/11 and anthrax terrorism attacks brought a new focus on how unprepared the nation was to meet the threat of bioterrorism. Meanwhile, the outbreak of SARS and Asian avian influenza ("bird flu") underscored growing vulnerability to infectious disease. Then, in 2004, came a reminder that even routine vaccine production was in danger of collapse.

In October of that year, as Americans began gearing up for flu season, Britain announced that it would be suspending the license for Chiron Corporation, one of just two flu vaccine manufacturers for the United States. British regulators had found bacterial contamination in Chiron's Liverpool factory, just as the United States had been waiting for it to ship 48 million doses.<sup>44</sup> Almost immediately, America's vaccine supply was cut nearly in half, and policymakers had little recourse. The shortage became an issue for Bush on the campaign trail, amid stories of price gouging,<sup>45</sup> long waiting lines, and threats to jail or fine doctors who vaccinated those not deemed high risk.<sup>46</sup> Concentration in manufacturing capacity had made such a shortage more likely, as the number of vaccine manufacturers for the United States had been shrinking for years.

In response to these failures, Congress approved \$99 million in 2004 for flu vaccine production<sup>47</sup> and passed the Project BioShield Act, which authorized \$5 billion for purchasing vaccines in the event of a bioterrorist attack.<sup>48</sup> A year later, Congress passed a controversial law providing vaccine manufacturers

with more immunity from tort lawsuits. The law was tacked onto a huge military spending bill and came with \$3.8 billion, far less than the \$7.1 billion the Bush administration had originally requested.<sup>49</sup> The president also convened a meeting with six pharmaceutical companies in the fall of 2005 to rally their support for ramping up vaccine production in the event of a flu pandemic.<sup>50</sup>

As a result of the Bush administration's efforts, the U.S. gained significantly more influenza vaccine capacity. By 2005, there were three influenza vaccine manufacturers for the U.S., and by 2006 there were four, producing 150 million doses, up from 61 million doses in 2004. GlaxoSmithKline purchased a new vaccine manufacturing facility in Marietta, Pennsylvania, in 2005; it opened in 2010.<sup>51</sup> A new public-private cell-culture vaccine facility opened in Holly Springs, North Carolina, in 2009, backed by \$487 million from HHS.<sup>52</sup> Also, with a \$77.4 million contract from HHS awarded in 2007, Sanofi's Swiftwater, Pennsylvania, plant was able to double its existing vaccine manufacturing capacity.<sup>53</sup>

Yet while capacity increased, production of new vaccines lagged behind. Project BioShield had the goal of shepherding more vaccine candidates through commercial development by guaranteeing federal funding for a 10-year period. But the actual amount allocated – \$5.6 billion over a decade – fell far short of being enough to induce more private sector production, especially since pharmaceutical companies could earn much higher profit margins by investing in more lucrative drugs. By statute, BioShield profit margins were not to exceed 10%, which proved too low to entice the larger pharmaceutical companies to compete for the projects. As a result, smaller, inexperienced biotech firms sought out the BioShield contracts, and they moved slowly, raising the cost of development even more.<sup>54</sup>

The weaknesses of America's neoliberal system of vaccine production became further apparent during the early months of former President Barack Obama's first term, with the arrival another novel influenza strain, H1N1, also known as swine flu. After it first emerged that spring in Mexico,<sup>55</sup> the U.S. government emphasized that a vaccine would be ready by the fall. But by October, U.S. health officials were realizing that their expected supply of H1N1 vaccine was not on schedule to arrive.<sup>56</sup> CDC officials hadn't realized that vaccine yields were lower than expected, because the tests used to measure those yields had also been delayed.<sup>57</sup> The new machines that manufacturers had installed to put the H1N1 vaccines into vials also ended up experiencing malfunctions, which caused additional delays.<sup>58</sup>

A study produced by Obama's team of science advisers in August 2010 reported that, given existing capacity constraints, producing an adequate supply of H1N1 vaccine for the nation would have taken 48 weeks.<sup>59</sup> This timeline was too slow by approximately three to five months, so only 27% of the population was

ultimately vaccinated.<sup>60</sup> Though H1N1 was fortunately a relatively mild strain of virus, it still infected between 43 million to 89 million Americans, leading to between 8,870 to 18,300 deaths. Obama’s advisers estimated that more than 2,000 lives – mostly young people – could have been saved if vaccination had begun even one month earlier.<sup>61</sup>

In light of these findings, the Obama administration recommended spending roughly \$1 billion per year for the next few years to improve its response to future influenza outbreaks. Some of the administration’s ideas included moving away from egg-based influenza vaccines, developing faster potency tests, and investing in better machines to fill vials.<sup>62</sup> Notably, Republican Sen. Susan Collins successfully stripped \$870 million in flu pandemic preparation money out of the 2009 stimulus package.<sup>63</sup> While some aspects of the Obama administration’s recommendations were eventually adopted, public health experts say more could have been done and done faster.<sup>64</sup>

In January 2010, a bipartisan congressional commission gave the Obama administration and Congress an “F” for failing to boost the nation’s capacity to protect residents from biological attacks. “Especially troubling is the lack of priority given to the development of medical countermeasures – the vaccines and medicines that would be required,” the commission report said.<sup>65</sup>

Following this damning report, a separate HHS study concluded that the country “lacks the domestic manufacturing capacity to rapidly produce and package a vaccine for the American public in the face of a pandemic.” One major recommendation from this report was to establish Advanced Development and Manufacturing (ADM) facilities to boost domestic capacity to develop medical countermeasures, in part by working with private sector partners.<sup>66</sup> The thinking was that these public-private facilities could help spur development of new vaccines, drugs, and diagnostic devices, and provide manufacturing surge capacity during both public health emergencies and national security threats.

Beginning in 2012, the Obama administration invested in four large ADMs, in North Carolina, Florida, Maryland, and Texas. While the sites are expected to help manufacture any FDA-approved COVID-19 vaccine, the four sites are not taking leading roles in the COVID-19 crisis response and have run into other issues since they were developed. Robert Kadlec, the HHS assistant secretary for preparedness and response, launched two reviews of the four sites and documented a series of problems. Kadlec concluded that their “operational capability” had not been adequately developed and that year-to-year “sustainment” of the centers with both government and commercial projects had not been successful. The second review, which Kadlec commissioned and which was completed in late 2019 by outside consultants, found similar problems, according to a March 2020 investigation published by *The Washington Post*.<sup>67</sup>

While the Obama administration was relatively successful in enticing more companies to enter the influenza vaccine market, the federal government under both Bush and Obama invested far less in developing vaccine capacity for other infectious diseases. This blind spot has implications not only for coronavirus pandemics but also for other kinds of public health threats. For example, following a 2013 Centers for Disease Control and Prevention report that found that roughly 23,000 people die each year from antibiotic-resistant infections,<sup>68</sup> the Obama administration released a five-year National Action Plan to combat antibiotic-resistant bacteria.<sup>69</sup> But the National Vaccine Advisory Committee critiqued this Obama administration effort for failing to consider how increased vaccine uptake is crucial to the goal of substantially decreasing the problem of antibiotic-resistant infections.<sup>70</sup>

The second major test for the Obama administration was the Ebola outbreak. As with SARS and H1N1, experts have concluded that the U.S. largely got lucky with Ebola, since the disease is hard to catch, easy to test for, and originated in a part of the world with minimal airline connectivity to the United States. After the outbreak was contained, a comprehensive “lessons learned” [report](#) involving 26 departments and federal agencies identified numerous deficiencies in the federal government’s infectious disease response infrastructure, including some challenges similar to those encountered with COVID-19, such as insufficient supplies of PPE and disinfectant.<sup>71</sup>

One positive change to come out of the Ebola report was the creation in 2016 of a dedicated office within the National Security Council to coordinate pandemic response and raise the appropriate alarms early. But this office was consolidated and disbanded under Trump in 2018.<sup>72</sup> In addition, Congress appropriated a \$5.4 billion supplemental package after Ebola, but, just as with other infusions of funding following public health emergencies, those needed investments were not sustained.<sup>73</sup>

With the coming of COVID-19, the deficiencies of the neoliberal system of vaccine production have been laid bare. Even if a safe and effective vaccine emerges, producing and distributing enough doses to avoid unnecessary fatalities will require massive government intervention in a broken vaccine market. To compensate for the lack of vaccine production capacity, the Trump administration is turning to contract manufacturers and stockpiling hundreds of thousands of doses of still unproven vaccines.<sup>74</sup> Meanwhile, critical bottlenecks in the private sector production of vials, syringes, and rubber stoppers also threaten to needlessly add hundreds of thousands more Americans to the COVID-19 death toll.

## VI. What can be done?

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Incremental reforms can be of some benefit but will be insufficient to construct the functional vaccine production and distribution system that we so desperately need. Instead, we must think on a much broader strategic level. The current neoliberal policy regime needs to be largely dismantled. In its place, we need to recreate and improve upon the pluralistic but government-directed political economy that prevailed during the golden age of vaccines and other biomedical advancement, roughly from the end of World War II until the 1980s.

The first order of business should be reforming our broader competition policies. That means rolling back the deregulation of Wall Street and the financial sector generally beginning in the 1980s that left corporations, including drugmakers, increasingly under the control of financiers – from corporate raiders armed with junk bonds to the vulture capitalists deploying private equity funds. Unless we unwind the ongoing financialization of the economy, corporate managers will be forced to maximize short-term shareholder returns rather than pursue societal interests. A broad literature provides many policy levers that can help to accomplish this strategic course correction, from reforms of corporate governance to tighter regulation and deconsolidation of the financial sector.<sup>75</sup>

We also need antitrust enforcers to once again make full use of antitrust law. No new legislation is needed to do that; rather, prosecutors should simply return to the same prosecutorial guidelines that prevailed before the 1980s, when the government used antitrust suits not just in narrow cases of price fixing but also as a means of promoting larger public purposes, such as preserving resiliency and competition in industrial systems vital to national security. In the future, these purposes could include preserving the resiliency of vaccine production by using antitrust laws to ensure against sole-source providers and monopolized supply chains.<sup>76</sup>

Congress must also overhaul intellectual property law and, where necessary, renegotiate (or, if necessary, abrogate) international trade agreements to reduce the systematic abuse of patents by large drug firms to stifle competition. In 2000, the pneumococcal conjugate vaccine Prevnar-7 ushered in a new era of monopoly prices for children's vaccines. Protected by a thicket of patents, Prevnar-7 was priced as high as the combined prices of all the other recommended pediatric vaccines.<sup>77</sup> More recently, a replacement drug, Prevnar-13, approved in 2015, became Pfizer's top-selling drug, bringing in \$23.4 billion in sales in just four years. A single Prevnar-13 shot cost \$195 in



2019 – a 5% increase over 2018 and a 79% increase over 2010.<sup>78</sup> Though many vaccines are not covered by patents, many key ones are – and many more could be in the future. Done right, patents can help spur innovation, but when granted too promiscuously or with rights that last too long, they can produce the opposite effect.<sup>79</sup>

A whole toolkit of policies is available to ensure that patent rights are properly balanced with the public interest, including so-called “march-in” rights that, under current law, the federal government can use to claw back patents in cases of price gouging or insufficient production.<sup>80</sup> In cases where drug companies are charging excessive prices for vaccines, the United States could follow Australia’s and the United Kingdom’s leads in specifying an allowable profit margin.<sup>81</sup>

In some cases, where no amount of market restructuring is likely to produce a needed vaccine, direct subsidies and incentives should also be part of the mix. Granted, this approach can have pitfalls if directed by a corrupt or incompetent administration. But this only underscores the need for another key reform, which is to restore independent financing for key regulatory agencies such as the FDA and to commit to rebuilding them as professional, science-driven institutions managed for the public interest. We may also want to consider handing back more responsibility for vaccine research and development to the Department of Defense, which has suffered less of a brain drain and loss of strategic planning ability than most other federal agencies during the last several decades.

A final option is to build a network of government-owned and government-controlled production facilities to compete with or provide a backup for private vaccine production. The Obama administration took initiatives in this direction with construction of the four Advanced Development and Manufacturing facilities. These facilities have drawn criticism from the Trump administration for not sufficiently developing their operational capacity, and an unreleased report by the Mitre Corp., done in late 2019, reportedly came to a similar conclusion.<sup>82</sup> But even if there have been problems with the execution of these particular projects, the success of other facilities owned and controlled by the government, most notably during World War II, shows that there is nothing intrinsically flawed with the concept and much to recommend it. One advantage here would be that it might spur private competition on the “public option” model that was considered (and later rejected by Congress) for Obamacare. It could also provide surge capacity in times of crisis. And it could serve as a valuable backstop in instances where no amount of subsidies or changes in competition policy will result in the protections we so desperately need against current and future pandemics.

# Appendix: Timeline

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1796

Edward Jenner, a British physician, successfully inoculated an 8-year-old from smallpox with cowpox. He published his research five years later, calling his product “vaccine” for the Latin word *vacca*, or cow.

1879

French chemist Louis Pasteur discovered that cultures of chicken cholera had lost their pathogenicity but retained other aspects of the disease in attenuated form. When he inoculated chickens with this culture, he found chickens were fully resistant to getting ill.

1881-85

Pasteur created an attenuated form of anthrax to elicit immunity, and he tested them on sheep, goats, and cows. Four years later, he developed a vaccine for rabies, his first time testing this method on humans. Pasteur named these “vaccines” in honor of Edward Jenner.

1901

Nine children in Camden, New Jersey, died from smallpox vaccines that had been somehow contaminated with tetanus. That same year, 13 children in St. Louis died from a diphtheria antitoxin contaminated with tetanus. An NBC affiliate aired a one-hour documentary called DPT: Vaccine Roulette, which alleged a number of serious risks of DPT. Despite its journalistic flaws, it was heavily influential and won an Emmy Award.

1902

The U.S. government passed the Biologics Control Act, setting forth safety regulations that manufacturers had to follow when producing vaccines.

1905

In 1905, in *Jacobson v. Massachusetts*, the U.S. Supreme Court said mandatory vaccination was within the rights of a state.

1909

The U.S. military developed a vaccine for typhoid fever. It was introduced on a voluntary basis for troops in 1909, a mandatory basis in 1911, and released to the general public by 1914.

1914

A vaccine for pertussis, or whooping cough, is licensed.

1926

A toxoid vaccine was developed for diphtheria, which had been a leading cause of death among children.

1938

While the first tetanus toxoid vaccine was produced in 1924, a more effective version was introduced in 1938 and used on a compulsory basis for the military in World War II.

**1938**

The National Foundation for Infantile Paralysis was launched to raise money for polio vaccine research. It was later renamed the March of Dimes.

**1942**

With support from the U.S. military, researchers develop the first inactivated flu vaccine. It was approved for military use in 1945 and civilian use in 1946.

**1948**

The diphtheria, pertussis, and tetanus vaccines were combined into one shot, known as DPT.

**1948**

Federal vaccine oversight was transferred from the NIH's Division of Biologics Control to a new NIH division called the National Microbiological Institute, which later was named the National Institute of Allergy and Infectious Diseases.

**1955**

A polio vaccine, developed by Jonas Salk and his team at the University of Pittsburgh, was licensed.

**1960**

The Surgeon General's Office built a contract manufacturing facility in Swiftwater, Pennsylvania, to develop limited-use vaccines.

**1963**

The first measles vaccine was developed.

**1967**

The first mumps vaccine was developed by Maurice Hilleman, who harvested strains of the disease from his own daughter's throat.

**1969**

The first rubella vaccine was developed, also by Hilleman. Two years later, it was combined with the measles and mumps vaccines into one shot, known as MMR.

**1972**

The smallpox vaccine was no longer routinely administered to the American public, after the disease had been successfully eradicated.

**1972**

Federal vaccine oversight was transferred from NIH to the Food and Drug Administration.

**1974**

Congress passed the National Research Act, which mandated new human subject research regulations. This led both to increased safety and increased costs for companies.

**1976**

Of the 45 million people vaccinated against the swine flu outbreak, approximately 450 individuals developed Guillain-Barre syndrome, a frightening disease that attacks the nervous system. The public relations fallout impacted the private sector's interest in future vaccination campaigns.

1980

The U.S. Supreme Court ruled in *Diamond v. Chakrabarty* that genetically modified organisms could be patented.

1980

Congress passed the Bayh-Dole Act, which allowed universities and other nonprofits to patent inventions they developed with federal funding.

1981

The first hepatitis B vaccine was licensed.

1982

An NBC affiliate aired a one-hour documentary called DPT: Vaccine Roulette, which alleged a number of serious risks of DPT. Despite its journalistic flaws, it was heavily influential and won an Emmy Award.

1985

A vaccine for Hib, the leading cause of bacterial meningitis, was licensed.

1986

Congress passed the National Childhood Vaccine Injury Act. This law established the National Vaccine Injury Compensation Program to protect companies from frivolous lawsuits, as well as created new systems for parents and health care providers and recipients to report health problems after getting vaccinated.

1993

After the Department of Defense failed to produce enough anthrax vaccine and botulinum antitoxin prior to the first Gulf War, a federal task force concluded a government-owned, government-controlled facility dedicated to producing medical countermeasures would benefit the U.S. and provide needed surge capacity. The recommendation was not executed.

1993

A measles outbreak in the late 1980s among individuals who were never vaccinated spurred Congress to pass a new federal entitlement program: Vaccines for Children, which pays for the vaccination of children under 19 whose families lack health insurance or can't afford it.

1995

The first U.S. vaccine for varicella, or chicken pox, was licensed. A booster dose was added in 2006.

1995

The first vaccine for hepatitis A was licensed. Six years later, the FDA would approve a combined hepatitis A and B vaccine.

1998

The first vaccine for rotavirus was approved.

1999

Stricter FDA factory standards took effect and led to more compliance violations and a spate of pediatric vaccine shortages in 2000.

1999

As a precautionary measure, the CDC and AAP recommended the removal of thimerosal from pediatric vaccines.

**2000**

The FDA licensed a pneumococcal conjugate vaccine, which was priced as much as the entire cost of the recommended vaccine schedule then.

**2001**

The DOD published the Report on Biological Warfare Defense Vaccine Research & Development Programs, which proposed establishing a government-owned, government-controlled vaccine R&D facility. The report was ultimately shelved.

**2004**

The U.S. experienced a severe seasonal flu vaccine shortage, when one of its two manufacturers had to abruptly cease production. The shortage motivated the federal government to focus on increasing flu vaccine manufacturing capacity.

**2004**

Congress passed the Project BioShield Act, which called for \$5 billion for purchasing vaccines in the event of a bioterrorist attack.

**2005**

Congress passed the Public Readiness and Emergency Preparedness Act, which largely helped reduce liability for vaccine manufacturers.

**2006**

Congress passed the Pandemic and All Hazards Preparedness Act. This law created the new Assistant Secretary for Preparedness and Response in HHS and established the Biomedical Advanced Research Development Authority, which works with industry to develop medical countermeasures.

**2006**

FDA approved the first human papillomavirus vaccine for girls ages 11 to 26. In 2011, the Advisory Committee on Immunization Practices recommended its routine use for boys, too.

**2006**

The first shingles vaccine was licensed and recommended for people over 60.

**2008**

University of Pittsburgh Medical Center researchers recommended the Pentagon build at least two government-owned, government-controlled facilities for biodefense. The Army major general who was then in charge of the military's defense against biological and chemical weapons publicly disagreed.

**2009**

A study by the Tufts Center for the Study of Drug Development, commissioned by President Bush, endorsed contract manufacturing over the government operating its own dedicated manufacturing facilities.

**2009**

During the H1N1 swine flu pandemic, vaccine production was delayed. A federal study estimated that more than 2,000 lives could have been saved if vaccination had begun a month earlier.

**2010**

The Obama administration released a report recommending increased government investment in domestic vaccine manufacturing capacity.

**2012-13**

HHS and the Pentagon invested in four large manufacturing sites in North Carolina, Florida, Maryland, and Texas.

**2016**

Following the Ebola epidemic of 2014, the Obama administration created a dedicated office at the National Security Council to coordinate pandemic responses. This office was disbanded under Trump in 2018.

**2019**

The FDA approved a preventative Ebola vaccine for adults.

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