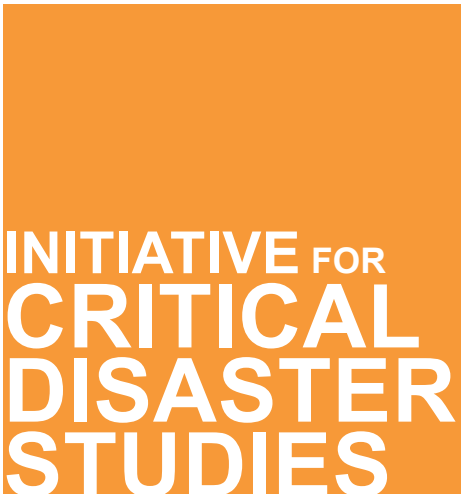

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For Health or For Profit: Covid-19 and the History of Big Pharma in the United States

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For Health or for Profit:
Covid-19 and the History of Big Pharma in the United States

Emma Day

Abstract

Following the outbreak of the Covid-19 pandemic, the world looked to the pharmaceutical industry to develop an effective treatment or vaccine to curb its spread. Despite the faith placed in scientific discoveries, the histories of other epidemics demonstrate that newly approved vaccines and medicines alone are not magic bullets. Instead, diseases are curbed only with universal access to new products.

This paper examines how the competing interests of the pharmaceutical industry, the political establishment, and public health have shaped the trajectories of two other epidemics in U.S. history—poliomyelitis and the Human Immunodeficiency Virus (HIV, the virus that causes Acquired Immunodeficiency Syndrome, or AIDS)—which offer lessons for Covid-19. Namely, the histories of both polio and HIV demonstrate the federal government's ability to intervene in drug distribution to ensure widespread access to life-saving medicines if it wills it. The two case studies therefore reveal that political choices shape the trajectory of health crises as much as epidemiology or scientific breakthroughs.

On February 26, 2020, as the novel coronavirus, Covid-19, spread rapidly across the world, Congress invited Secretary for Health and Human Services (HHS) Alex Azar, a former lobbyist for the pharmaceutical company Eli Lilly, to testify before a congressional budget hearing.

Earlier that week, Azar had asked Congress to approve then-President Donald Trump's request for $2.5 billion in funding to fight the disease, including developing vaccines.[1] Shortly afterward, forty-six members of Congress signed a letter urging HHS to guarantee that any treatment for Covid-19 that is developed with U.S. taxpayer dollars is affordable and accessible to the people who funded it.[2]

During the hearing, Representative Jan Schakowsky (D-Ill.) asked Azar directly whether any eventual treatment or vaccine products for Covid-19 would be "affordable for anyone who needs it?"[3]

Azar repeatedly declined to reassure Schakowsky that Covid-19 treatment researched with taxpayer dollars would be accessible to all. Instead, he maintained that the Trump administration could not cap the price of any products because of the need for private sector investment in Covid-19 research.

Azar's comments were controversial but not surprising. Rather, they spoke to a historic tension that sits at the heart of the struggle over healthcare in the United States; namely, how to incentivize medical innovation while making newly developed medicines available, affordable, and accessible to all who need them. The nature of that struggle in the United States differs from that of countries with a nationalized, single-payer healthcare system in that many see healthcare as a privilege and not a right. This departure in values is not inevitable but a consequence of a series of political choices, especially the patent process and the lack of bulk buying.

This article examines how the competing interests of the pharmaceutical industry, the political establishment, and public health have shaped the trajectories of two other epidemics in U.S. history—poliomyelitis and the Human Immunodeficiency Virus (HIV, the virus that causes Acquired Immunodeficiency Syndrome, or AIDS)—which offer lessons for Covid-19. In 1955, the scientist who invented the polio vaccine, Jonas Salk, decided not to patent the medicine, allowing a number of drug companies to simultaneously produce the vaccine in high quantities and at low costs. The virus was subsequently eliminated from the United States within two decades. In contrast, the drug manufacturer, Gilead Sciences, Inc., has attached a high price to its

1 Lisette Voytko, "Health Secretary Asks For Emergency Coronavirus Funding While Trump Calls For 16% Cut To CDC Budget," February 26, 2020, accessed September 2020, https://www.forbes.com/sites/lisettevoytko/2020/02/26/health-secretary-asks-for-emergency-coronavirus-funding-while-trump-calls-for-16-cut-to-cdc-budget/#d8e1ad057f3f.

2 Ed Silverman, "Lawmakers to Trump: Don't give 'monopolies' to companies that develop coronavirus treatments with taxpayer funds," February 20, 2020, accessed September 2020, https://www.statnews.com/pharmalot/2020/02/20/trump-coronavirus-drug-prices/.

3 Isabel Togoh, "Health Secretary Alex Azar Refuses to Guarantee Coronavirus Vaccine Would be Affordable For All," *Forbes*, February 27, 2020, accessed September 2020, https://www.forbes.com/sites/isabeltogoh/2020/02/27/health-secretary-alex-azar-refuses-to-guarantee-coronavirus-vaccine-would-be-affordable-for-all/.

HIV prevention medicine, Truvada for PrEP. The high cost of Truvada has hampered the drug's ability to bring the HIV-AIDS epidemic under control in its fourth decade. The ongoing battles over the intellectual property rights of HIV prevention medicine—as opposed to early struggles to bring to market drugs to treat HIV—parallels the example of vaccine development evident in the polio and now the Covid-19 pandemic. Activists for cheaper medicines argue that making Truvada for PrEP accessible to all regardless of their means to pay could end the HIV epidemic without a vaccine.

Nonetheless, the different profit and incentive considerations between vaccines and drugs has impeded the potential of Truvada to eradicate HIV.[4] Vaccines are less profitable than prescription drugs taken daily. If successful, a person need only take a vaccine once or twice to have long-term protection. Vaccines are profitable not because of cost but because of the high levels of coverage required to protect a population. In contrast, drugs that treat chronic illnesses, such as HIV, do not cause their own obsolescence in the same way that a vaccine has the potential to do. In this case, even with a limited period of market exclusivity, a drug manufacturer has many years to potentially recoup investment and maximize profit. As a result of different profit considerations, drug companies are reluctant to give up their patents for treatment for chronic diseases.

Regardless of the actions of pharmaceutical companies, the histories of both polio and HIV demonstrate the federal government's ability to intervene in drug distribution to ensure widespread access to life-saving medicines if it wills it. The two case studies therefore reveal that political choices shape the trajectory of health crises as much as epidemiology or scientific breakthroughs.

The article will first historicize the particularities of the pharmaceutical industry in the U.S., and specifically the power of drug companies to set and raise prices free from government regulation. It will then examine how Salk's decision to keep his research in the public domain, coupled with the government's allocation of millions of dollars toward vaccine distribution, led to the elimination of the disease in the U.S. This history contrasts with the ongoing battles between the federal government and Gilead over widening access to preventative medicine, Truvada for PrEP, to combat HIV. The two case studies invite us to reflect on the means of the government to make medicines available to the public especially after taxpayer money has contributed to their development. They also demonstrate the need to put access before profit in the wake of pandemic outbreaks.

The Power of Big Pharma

Unlike countries with a national healthcare system, the United States has no government panel that either regulates or negotiates drug prices. Instead, each of the thousands of health insurance plans across the country have to separately negotiate their own prices with drug-makers. Because Americans are fragmented across these

4 Louis Galambos and Jane Eliot Sewell, *Networks of Innovation: Vaccine Development at Merck, Sharp and Dohme, and Mulford, 1895-1995* (Cambridge: Cambridge University Press, 1995).

different health insurers, plans have less negotiating power to demand lower prices.[5] In contrast, countries with a national healthcare system are able to buy drugs in bulk and negotiate lower prices from providers. A law passed in the Republican-controlled House of Representatives and Senate in 2003 expressly prohibited the federal government from negotiating cheaper prices for prescription medicines available through the insurance plan Medicare Part D.[6] The Affordable Care Act (ACA) of 2010 similarly barred HHS from negotiating prescription drug prices on behalf of public players. As negotiation is a key counterweight against excessive pricing during market exclusivity, the lack of government negotiation is one of the main reasons why Americans pay the highest prescription costs of anyone in the world.[7] Even with bulk buying, in encouraging monopoly practices, the patent protection process keeps prices artificially high in the United States.

New drugs are often put under patent protection during their development. The drug will then receive both a brand and generic name following completion and approval by the Food and Drug Administration (FDA). The brand name is chosen by the company that has developed the medication, while the drug's active ingredient gives it its generic name. The company that has developed the drug receives an exclusivity period to set the price of the medication and sell it under either its brand or generic name. As the creation of new and better medications requires significant financial and temporal investment in research, patents are intended to encourage pharmaceutical companies to invest in a drug they can profit from without the threat of competition. Patents, which usually last twenty years before a drug becomes generic, incentivize companies to make significant investments in pharmaceutical innovations. While the drug industry acknowledges that, at least in the short term, federal intervention in the marketplace could lower drug prices, it also argues that such a step would kill incentives to develop new medicines.[8] The patent process is therefore intended to give drug companies the freedom to invent and invest in new and improved medications.

When a patent expires, marking the end of the exclusivity period, other manufacturers are able to apply to the FDA to sell generic versions of the brand-name drug under the generic-name medication. Without the costs of research and development, marketing, and promotion incurred by the brand manufacturer, the generic manufacturer is able to sell the medication at lower cost. Generic drugs are therefore intended to be cheaper

5 The Veterans Health Administration, part of the Department of Veterans Affairs, is one government agency that has the power to negotiate drug prices, resulting in lower costs. See Mike McCaughan, "Veterans Health Administration," *Health Affairs Policy Brief*, August 10, 2017, accessed March 2021, https://www.healthaffairs.org/do/10.1377/hpb20171008.000174/full/.

6 Stuart Silverstein, "This is Why Your Prescriptions Cost So Damn Much," *Mother Jones*, October 21, 2016, accessed September 2020, https://www.motherjones.com/politics/2016/10/drug-industry-pharmaceutical-lobbyists-medicare-part-d-prices/.

7 Aaron S. Kesselheim et al., "The High Cost of Prescription Drugs in the United States," *JAMA* 316, no. 8 (August 23/30, 2016): 861, accessed September 2020, available at: https://jamanetwork.com/journals/jama/article-abstract/2545691.

8 Silverstein, "This is Why Your Prescriptions Cost So Damn Much."

because prices are not expected to recoup the research investments made by brand manufacturers. Once the patent term ends, several manufacturers can enter the market and compete.

While pharmaceutical companies argue that government regulation of drug pricing would stunt innovation, advocates for lower drug prices argue that too little regulation also restricts people's access to medication. Although pharmaceutical companies often apply for patents before the new drug is approved, meaning that it is rare for a pharmaceutical company to get the full twenty-year exclusivity, patent-protected drugs face no price caps or competitors for the exclusivity period.[9] Market exclusivity means that patent protection effectively grants the pharmaceutical industry a monopoly on drugs, regardless of the human cost.

In 1984, Congress passed the Hatch-Waxman Act, also known as the "Price Competition and Patent Term Restoration Act," in order to make it easier for generic drugs to enter the market, bring drug prices down, and increase public access.[10] According to law professor Robin Feldman, while this measure worked for a while, drug companies developed a series of business and legal strategies to prevent cheaper drugs from entering the market.[11] Several pharmaceutical companies began adding secondary patents to drugs that already existed by making minor medical changes to the dosage or the delivery system. The modifications had little therapeutic effect. Instead, they worked to extend a companies' monopoly.[12] Others, such as professor of medicine Aaron S. Kesselheim, found no link between research and development costs and prices. Instead, Kesselheim argued that prescription drugs are priced primarily on what the market will bear.[13] Critics of the drug pricing system therefore argue that market exclusivity, protected by monopoly rights awarded through FDA approval and patents, primarily serves drug manufacturers at the expense of individuals.[14]

The outbreak of disease has thrown stark light on the tension between the need to improve access to and the affordability of drugs without hampering innovation. In the mid-twentieth century, scientists invented a vaccine to prevent the spread of polio. The invention of the polio vaccine raised the question of whether manufacturers should put profit before access to medicines that taxpayers have helped pay for, as well as what role the government should play to guarantee widespread access. Salk's decision to keep his research in the public domain demonstrates that innovation is not dependent on profit. Moreover, the funding

9 Tahir Amin, "The problem with high drug prices isn't 'foreign freeloading,' it's the patent system," *CNBC*, June 27, 2018, accessed February 2020, https://www.cnbc.com/2018/06/25/high-drug-prices-caused-by-us-patent-system.html.

10 Jeremy A. Greene, *Generic: The Unbranding of Modern Medicine* (Baltimore, MD: Johns Hopkins University Press, 2014), 3-4.

11 Robin Feldman, *Drug Wars: How Big Pharma Raises Prices and Keeps Generics Off the Market* (Cambridge, 2017), 22-24.

12 Joe Nocera, "Why Big Pharma Is Winning the Drug Price Wars," *Bloomberg*, April 8, 2019, accessed February 2020, https://www.bloomberg.com/opinion/articles/2019-04-08/why-drug-prices-keep-rising-despite-congress-s-efforts.

13 Kesselheim et al., "The High Cost of Prescription Drugs in the United States," 858.

14 Elle Mahdavi, "Patents and the Pharmaceutical Industry," *BerkeleyHaas*, May 26, 2017, accessed February 2020, https://cmr.berkeley.edu/blog/2017/5/patents-and-pharmaceuticals/.

President Dwight D. Eisenhower eventually allocated to states to ensure its widespread distribution demonstrates that it is within the government's gift to ensure that everyone has access to life-saving medicines regardless of their means to pay.

Refusing to Patent the Sun

The polio virus resurfaced every summer during the first decades of the twentieth century.[15] The cause and transmission of the disease unknown, the virus seemingly liked warm weather and targeted the young. If it did not kill, it often paralyzed. Approximately 15,000 suffered paralysis a year before the invention of a vaccine. Fear of contagion forced children inside as cinemas, playgrounds, and swimming pools across the country would close amid the summer outbreaks.[16]

Peaking in the 1940s and 1950s, the perception that the polio virus targeted white, middle-class children in suburban, family-oriented communities as opposed to poor and non-white children helped spur the public commitment to helping research efforts.[17] Society had often been quick to stigmatize marginalized groups for carrying diseases.[18] In contrast, these sick, seemingly defenseless children evoked mass sympathy.

The work of a philanthropic foundation that President Franklin D. Roosevelt established in 1938 to tackle the epidemic, the National Foundation for Infantile Paralysis (NFIP), later called the March of Dimes, was key to rallying the public support needed to raise the funds required to run the vaccine field trials. The March of Dimes was a largely grassroots organization. By the 1950s, volunteers operated the 3,100 chapters of the NFIP who raised money and delivered aid, spending $233 million on patient care between 1938 and 1955.[19] By 1954, the March of Dimes had raised $66.9 million and became the primary funding source for the vaccine field trials. The public trust that the March of Dimes inspired enabled scientists to carry out a large-scale clinical trial in 1954. With University of Pittsburgh scientist Jonas Salk, the organization launched the Salk Vaccine Field Trials, involving nearly two million elementary-aged school children throughout the country.[20]

The trials proved largely successful, and the Salk vaccine was licensed in 1955. In an unprecedented move, Salk chose not to patent the vaccine, likening it to patenting the sun.[21] Although the decision not to patent the vaccine was not Salk's alone—the National Foundation and the University of Pittsburgh had also contributed to the

15 Naomi Rogers, *Dirt and Disease: Polio before FDR* (New Brunswick: Rutgers University Press, 1992), 150.
16 Paul Offit, *The Cutter Incident: How America's First Polio Vaccine Led to the Growing Vaccine Crisis* (New Haven: Yale University Press, 2005), xi.
17 Naomi Rogers, "Race and the Politics of Polio: Warm Springs, Tuskegee, and the March of Dimes," *American Journal of Public Health* (May 1, 2007): 786.
18 See, for example, Charles E. Rosenberg, *The Cholera Years: The United States in 1832, 1849, and 1866* (Chicago: University of Chicago Press, 1962); Marilyn Chase, *The Barbary Plague: The Black Death in Victorian San Francisco* (New York: Random House, 2003); Kathryn Olivarius, "Immunity, Capital, and Power in Antebellum New Orleans," *The American Historical Review* 124, no. 2 (2019): 425-455.
19 David M. Oshinsky, *Polio: An American Story* (Oxford: Oxford University Press, 2005), 57.
20 David Rose, "A History of the March of Dimes," August 26, 2010, accessed January 2021, https://www.marchofdimes.org/mission/a-history-of-the-march-of-dimes.aspx.
21 Charlotte Jacobs, *Jonas Salk: A Life* (New York: Oxford University Press, 2015), 168.

research and development of the product, and few of the scientific processes were new—his actions gave the impression that the vaccine belonged to everyone. Because of the public's role in fundraising and mass testing, coupled with the knowledge that the success of vaccines depends on universal no-cost or low-cost access, Salk determined that the vaccine should be available to all at no or minimal cost. The decision not to patent the Salk vaccine enabled multiple pharmaceutical companies to simultaneously manufacture the vaccine at low cost and in mass quantities.

In the early stages of vaccine development, President Dwight D. Eisenhower asserted that every child should receive the polio vaccine without setting out a plan to achieve that goal. Moreover, rejecting calls for "socialized medicine," or universal healthcare, circulating at the time, Eisenhower's Health, Education and Welfare Secretary, Ovetta Culp Hobby, also believed that private companies were predominantly responsible for producing Salk's vaccine, licensing six to do so.[22] The government's conviction that the responsibility for distribution lay primarily with private companies meant they lacked a plan to meet the demand for immunization, which led to initial shortages of the medicine and price gouging among physicians. As a result, only those with the financial means could access a vaccine that the public had already helped fund.[23]

In April 1955, news broke that vaccines from one of the six licensed companies—Cutter Laboratories in Berkeley, California—contained live poliovirus that led to the paralysis and death of several children.[24] News of the Cutter crisis prompted Eisenhower to act. Conceding that the government should play a larger role in the distribution and financing of the vaccine, he signed the Polio Vaccination Assistance Act of 1955 which appropriated $30 million in grants to states to ensure that no child was "denied vaccination by reason of its cost."[25] Within a year, 30 million American children had received inoculation. The number of new polio cases in the country dropped by more than 92 percent within six years.[26] Two decades later, in 1979, the U.S. Centers for Disease Control and Prevention (CDC) had declared the polio virus eliminated from the United States.[27]

Salk's decision not to patent his vaccine and the proactive role the government eventually played in funding the distribution of free polio vaccines in the 1950s resulted in the virus's elimination from the United States. These efforts contrast starkly with the reluctance on the part of drug companies to lower the cost of its life-saving medicine in the prevention of HIV. But, following pressure from activists and, after

22 Jonathan Engel, *Poor People's Medicine: Medicaid and American Charity Care Since 1965* (Durham, NC: Duke University Press, 2006), 47.

23 Jacobs, *Jonas Salk*, 181-2.

24 Allan M. Brandt, "Polio, Politics, Publicity, and Duplicity: Ethical Aspects in the Development of the Salk Vaccine," *International Journal of Health Services*, Vol. 8, no. 2 (1978): 265.

25 James C. Hagerty, Press Secretary to the President, "Press Release Statement by the President About the Polio Vaccine Situation," May 31, 1955, 3, accessed January 2021, https://www.eisenhowerlibrary.gov/sites/default/files/research/online-documents/salk/salk-g.pdf.

26 Nathanial L. Moir, "Revisiting the Cutter Polio Vaccine Incident during Operation Warp Speed," *Journal of Applied History* (September 2020): 17-35.

27 J. Hamborsky et al., *Epidemiology and Prevention of Vaccine Preventable Diseases*, 13th edition, April 2015, 308, accessed February 2020, https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/polio.pdf.

years of federal unwillingness to act, in November 2019 the U.S. government entered into a legal battle with the pharmaceutical giant, Gilead Sciences, Inc., over its patents. The battle over Truvada for PrEP again reminds us of the ability of the government to act in the interest of public health.

Taking on Big Pharma

In June 1981, the weekly journal of the CDC, the *Morbidity and Mortality Weekly Report* (MMWR), published reports of an increased occurrence of the rare cancer, Kaposi's sarcoma, and the rare pneumonia, *Pneumocystis carinii* pneumonia—diseases that indicated a person's immune system was not working—in young, previously healthy, gay men.[28]

Three years after the first official reports of what became known as the AIDS epidemic, in the spring of 1984, scientists in Washington D.C. and Paris discovered that the Human Immunodeficiency Virus, or HIV, caused AIDS. The discovery of HIV led the Secretary of Health and Human Services, Margaret Heckler, to announce that, with the cause of AIDS now known, scientists would likely develop a vaccine within two or three years.

Despite Heckler's assurances, no vaccine arrived. Heckler, like many in the Reagan administration, lacked urgency and demonstrated weak leadership in tackling an epidemic so closely associated with some of the most marginalized groups in society.[29] The reluctance on the part of the Reagan administration—as well as pharmaceutical companies—to invest in research into and treatment of HIV-AIDS significantly hampered early efforts to combat the virus. In response, HIV-AIDS activists mobilized to pressurize the National Institutes of Health (NIH), drug manufacturers, and the FDA to speed up drug development, testing, and approval.[30] These early grassroots efforts set the precedent for how activists would challenge the profiteering of the pharmaceutical industry in subsequent decades.[31]

In 1996, scientists reported on the breakthrough news that combinations of three antiretroviral agents (also known as antiretroviral therapy or ART) prolonged the lives of people infected with HIV.[32] With the advent of ART, HIV increasingly became about the prevention of a chronic, manageable illness. As ART was extremely expensive, costing approximately $10,000 per patient per year, AIDS activists now turned their attention toward confronting the question of how to distribute the lifesaving medicine to the people who lacked the resources to pay for them.[33]

28 CDC, "*Pneumocystis* Pneumonia—Los Angeles," *MMWR* 30, no. 21 (June 5, 1981): 250-252.

29 Jennifer Brier, "Reagan and AIDS," in *A Companion to Ronald Reagan*, ed. Andrew L. Johns, (Malden, MA.: Wiley Blackwell, 2015), 227.

30 Deborah Gould, *Moving Politics: Emotion and ACT UP's Fight Against AIDS* (Chicago: University of Chicago Press, 2009), 369-72. See also, Steven Epstein, *Impure Science: AIDS, Activism, and the Politics of Knowledge* (Berkeley: University of California Press, 1996); David France, *How to Survive a Plague: The Inside Story of How Citizens and Science Tamed AIDS* (New York: Alfred A. Knopf, 2016).

31 Emily K. Hobson, *Lavender and Red: Liberation and Solidarity in the Gay and Lesbian Left* (Oakland: University of California Press, 2016), 159.

32 Jennifer Brier, *Infectious Ideas: U.S. Political Responses to the AIDS Crisis* (Chapel Hill: University of North Carolina Press, 2009), 158.

33 Brier, "Reagan and AIDS," 228.

Over the course of the next decade, the field of HIV prevention exploded with scientists focusing on the development of a pill that taken once a day reduces the risk of contracting HIV. In 2010, a global trial in gay men and a small number of transgender women who have sex with men confirmed that the pill version of tenofovir could reduce new HIV infections when taken once a day—a strategy called PrEP (pre-exposure prophylaxis)—by 92 percent.[34]

The California-based pharmaceutical giant, Gilead Sciences Inc., sold the pill version of tenofovir disoproxil fumarate (TDF) in combination with the drug emtricitabine under the brand name Truvada. In 2004, the FDA approved Truvada for HIV treatment, first issuing Gilead's patent on the two drugs it contains and the coformulation. In March 2012, the FDA approved Gilead's proposal to sell the combination pill Truvada as an HIV prevention—becoming the first drug that the FDA approved for the prevention of HIV. The new approval for use of the medication for prevention enabled the company to extend its patent, and Truvada for PrEP has dominated the field of HIV prevention in the years since.

Despite the drug's potential to drastically curb the spread of infection, only ten percent of those it is estimated could benefit are currently taking PrEP.[35] Activists for cheaper medicines largely attribute the relatively low access to the drug to its high cost, which results from Gilead's ability to set and raise its price as high as it wants.[36] They also cite high drug prices as the reason why many diagnosed with an HIV infection in the United States do not have the virus under control, or that only around half of HIV-positive individuals are retained in ongoing care, and that just over a half are virally suppressed.[37]

Gilead's patent on the two active substances in Truvada—emtricitabine and tenofovir disoproxil—expired in other parts of the world in 2019, enabling countries to sell the unbranded version of the drug for a much lower price. For example, while Gilead set the price of Truvada at approximately $2,000 per month in the United States for a pill that can be manufactured for a fraction of that amount, generic versions available outside the country are sold monthly for as little as $3.[38] Before Gilead's U.S. patent on Truvada expired in September 2020, Gilead was able to legally set and raise prices as high as they wanted them to be, suing companies that tried to bring generic versions to the

34 Jim Pickett and Mitchell Warren, "Men & Women Demand Rectal Microbicides," *Achieve* 5, no. 4 (2013): 11.

35 Asia Russell, "AIDS Activists Disrupt Gilead Shareholder Meeting Over Access," *Health Gap Global Access Project*, May 8, 2019, accessed February 2020, https://healthgap.org/press/aids-activists-disrupt-gilead-shareholder-meeting-over-access-to-hiv-prevention-medicine/.

36 Health GAP, "AIDS Activists Disrupt Gilead Shareholder Meeting," May 8, 2019, available at: https://www.facebook.com/healthgap/videos/373025566641540/?v=373025566641540.

37 CDC, "HIV in the United States and Dependent Areas," November 2020, 2, accessed March 2021, https://www.cdc.gov/hiv/pdf/statistics/overview/cdc-hiv-us-ataglance.pdf.

38 Daniel Summers, "The Battle for Truvada: A pharmaceutical company charges thousands of dollars for a drug that could halt the AIDS epidemic. Does it have an obligation to value patients over profit?" *Slate*, May 31, 2018, accessed January 2021, https://slate.com/human-interest/2018/05/act-up-is-challenging-gilead-to-make-truvada-more-accessible.html.

United States and keeping them out of the market after out-of-court settlements.[39]

When the FDA first approved Truvada for HIV treatment in 2004, the pharmaceutical manufacturer charged $800 for a one-month supply. Since the FDA approved Truvada for HIV prevention in 2012, Gilead has steadily raised the drug's price, despite the medicine not undergoing any therapeutic changes.[40] Gilead earned $3 billion from sales of the drug in 2018 alone, and since 2004, the company has recorded approximately $36 billion in revenue from the medicine.[41] While the company's CEO, Daniel O'Day, has defended the high price as necessary for recouping investment in research, the organization AIDS Vaccine Advocacy Coalition (AVAC) argue that public and philanthropic investment in PrEP research exceeded that of commercial entities, stating that Gilead's main role in supporting the studies was limited to donating the medication itself.[42] Truvada's high U.S. cost, which puts the drug beyond the reach of many, is a consequence of the particularities of the United States health care market and regulation.[43]

The precedent for combating polio in the previous decades has inspired AIDS activists. In July 2018, the PrEP4ALL Collaboration, an advocacy organization seeking to widen access to the drug, released a 40-page call to action entitled "A National Action Plan for Universal Access to HIV Pre-Exposure Prophylaxis (PrEP) in the United States." In it, the authors argued that "America's success in fighting polio proves what is possible when our society dedicates itself to fighting for better health for all."[44] They outlined the steps that the government could take to cancel the patent on the drug that enables Gilead's monopoly on Truvada and, as the drug is nearly 100 percent effective in blocking the virus, end the HIV epidemic without a vaccine. Under the bipartisan Bayh-Dole Act of 1980, a provision in American law called march-in rights means that if a drug was developed using federally

39 Daniel Victor, "Trump Administration Sues Gilead, Maker of HIV-Prevention Drugs," *New York Times*, November 7, 2019; Andrew Buncombe, "AOC asks pharma CEO why $2,000 HIV drug costs just $8 in Australia: 'People are dying for no reason,'" *The Independent*, May 17, 2019, accessed February 2020, https://www.independent.co.uk/news/world/americas/us-politics/aoc-hiv-drug-cost-us-australia-ceo-gilead-video-a8919316.html. In 2018 the UK high court overturned Gilead's patent extension on Truvada, meaning that unbranded versions of the drug can be legally prescribed. National AIDS Trust (NAT), "PrEP Drug Patent Overturned in UK—NAT Respond," Tuesday 18, 2018, accessed February 2020, https://www.nat.org.uk/press-release/prep-drug-patent-overturned-uk-nat-respond.

40 Donna Young, "Gilead CEO defends HIV drug Truvada's price, insists CDC patents invalid," *S&P Global*, May 16, 2019, accessed February 2020, https://www.spglobal.com/marketintelligence/en/news-insights/latest-news-headlines/51879834.

41 Ned Pagilarulo, "Gilead CEO pressured on PrEP pricing at House hearing," *Biopharmadive*, May 17, 2019, accessed February 2020, https://www.biopharmadive.com/news/gilead-ceo-house-hearing-prep-hiv-drug-pricing/555028/.

42 AVAC, "HIV Prevention Research & Development Funding Trends, 2000-2014: Investing in innovation in an evolving global health and development landscape," June 2016, https://www.avac.org/sites/default/files/resource-files/RTWG2015_vJune2016.pdf.

43 Sony Salzman, "Trump Touted Gilead's Donation of HIV-Prevention Medication, But Doctors Want Generics—Not Charity," *Rewire.News*, May 23, 2019, accessed February 2020, https://rewire.news/article/2019/05/23/trump-touted-gileads-donation-of-hiv-prevention-medication-but-doctors-want-generics-not-charity/.

44 The PREP4ALL Collaboration, "A National Action Plan for Universal Access to HIV Pre-Exposure Prophylaxis (PrEP) in the United States," 4.

funded research, the government can take the patent away from a company if it is not available at a reasonable price and assign it to somebody else.[45] The federal government had issued $50 million in grants to researchers developing Truvada as PrEP.[46] This means that U.S. taxpayers paid for Truvada through the NIH and, according the PrEP4ALL, still retain the relevant intellectual property rights to break Gilead's patent on the drug because of the march-in rights written into Bayh-Dole.[47]

The NIH responded to *Washington Post* coverage of the PrEP4ALL report by stating that it is not within its purview to control the price of drugs. However, besides the example of polio vaccination, a more recent precedent exists for the government taking a patent license away from pharmaceutical companies in the wake of national health emergencies.[48] One week after the 9/11 attacks on the United States in 2001, the threat of an anthrax outbreak loomed large across the country. Bayer Pharmaceuticals held the patent on the most prominent anti-anthrax drug, ciprofloxacin, and charged $13 a pill. When the government wanted 200 million pills for its stockpile, they asked Bayer to lower the price and threatened to take away their patent on Cipro if it refused. Bayer agreed and lowered the price to $1.50 a pill.[49] For advocacy groups like PrEP4ALL, the government's refusal to take the same steps to lower the price of Truvada for PrEP demonstrated a lack of commitment on the part of the former Trump administration to halt the spread of HIV.

Following the precedent set by early AIDS activists to broaden access to new treatments, and in the wake of initial federal inaction, nine activists took this fight to the courts, launching a class action antitrust lawsuit against Gilead Sciences Inc. and several other manufacturers of HIV drugs in May 2019.[50] Without a shift in either the health care system or the patent process, activists argue that PrEP will continue to be beyond the reach of many, with women, people of color, people living with multiple disabilities, people detained in prison, and people living in poverty continuing to bear the heaviest burden of the epidemic as a result of inequities in the distribution of health care.[51]

Six months later, in an unexpected move, the Trump administration filed a lawsuit against Gilead claiming that the company had infringed on patents owned by HHS and reversing its decision not to file an infringement suit to enforce a 2015 patent

45 The PREP4ALL Collaboration, "A National Action Plan for Universal Access to HIV Pre-Exposure Prophylaxis (PrEP) in the United States," 36-40.

46 Christopher Rowland, "An HIV treatment cost taxpayers millions. The government patented it. But a pharma giant is making billions," *Washington Post*, March 26, 2019, https://www.washingtonpost.com/business/economy/pharma-giant-profits-from-hiv-treatment-funded-by-taxpayers-and-patented-by-the-government/2019/03/26/cee5afb4-40fc-11e9-9361-301ffb5bd5e6_story.html.

47 #BreakThePatent Campaign, accessed February 2020, available at: https://breakthepatent.org.

48 Trenton Straube, "Here's How We Can Get Universal Access to PrEP," *POZ*, July 25, 2018, accessed February 2020, https://www.poz.com/article/universal-access-prep-hiv-prevention.

49 Heather Stewart et al., "Bayer bows to pressure on anthrax antidote," *The Guardian*, October 23, 2001, accessed February 2020, https://www.theguardian.com/business/2001/oct/23/anthrax.businessofresearch.

50 Liz Highleyman, "Drug Company Antitrust Trial Gets 2022 Court Date," *Poz*, January 23, 2020, accessed February 2020, https://www.poz.com/article/drug-company-antitrust-trial-gets-2022-court-date.

51 CDC "HIV," accessed September 2020, https://www.cdc.gov/hiv/default.html .

on Truvada from the CDC.[52]

The battle over patents is rapidly evolving and, at the time of writing, the outcome of the government's lawsuit against Gilead over Truvada for PrEP remains unknown, especially given the transfer in power from the Trump to the Biden administration. Nonetheless, the lawsuit reflects a larger political desire to reduce prescription drug prices and signals a shift on the part of the political establishment toward holding drug companies accountable for the high cost of their medicines which may result in government regulation. The government's actions demonstrate the political will required to pressurize drug companies to lower the cost of its drugs, as well as the power of indefatigable collective action to move the government to act.

The tension between profit and public health evident in both the polio and HIV epidemics is historic and enduring. The same concern that the profiteering of the pharmaceutical industry might hamper the accessibility and affordability of HIV treatment has shaped the debate over the distribution of vaccines for Covid-19. The power of a vaccine, similar to preventative medicines such as Truvada for PrEP, depends on its price, as the medicine is only effective with universal use. The histories of polio and AIDS remind us that, in the midst of an ongoing epidemic, governments have a responsibility to make medicines available to the public.

Lessons for Covid-19

For those following HHS Secretary Alex Azar's refusal to guarantee access to any Covid-19 treatment or vaccine back in February 2020, the Trump administration's pledge to provide a future vaccine to those unable to afford it just four months later may have come as a surprise. But, in June 2020, perhaps with the upcoming 2020 U.S. election in mind, the Trump administration committed to distributing any future vaccine to people free of charge, with or without health insurance. His administration set up Operation Warp Speed which contributed $10 billion to vaccine research and development.[53] In his first week in office, President Joe Biden also committed to purchasing an additional 200 million vaccine doses.

In the face of significant public and political scrutiny, manufacturers have diverted in their approaches to vaccine distribution. Pfizer-BioNTech has taken a more traditional approach to its intellectual property rights, refusing to renounce exclusive rights to the vaccine and defended the companies' right to make a profit on their investment in Covid-19 treatments. In contrast, AstraZeneca has committed to providing access to its partner, Oxford University's, vaccine-related intellectual property, stating that it will not make a profit from vaccine sales during the pandemic. Johnson & Johnson has similarly committed to "not-for-profit" pricing of its vaccine. Both AstraZeneca and Johnson & Johnson have only committed to keeping the

52 Donald G. McNeil Jr. and Apoorva Mandavilli, "Who Owns HIV-Prevention Drug? The Taxpayers, U.S. Says," *New York Times*, November 8, 2019.

53 Katie Jennings, "How Much Will a Covid-19 Vaccine Cost?" *Forbes*, November 17, 2020, accessed January 2021, https://www.forbes.com/sites/katiejennings/2020/11/17/how-much-will-a-covid-19-vaccine-cost/?sh=7899abdc576d.

price near cost of production until mid-2021, offering only a short-term commitment to facilitating universal access.

Moderna, Inc. has also pledged not to enforce their Covid-19 related patents against those making vaccines intended to combat the pandemic. According to the consumer advocacy group Public Citizen, the federal investment in research and development means that the U.S. government has partial rights to the Moderna coronavirus vaccine patents, and the decision not to enforce its patents may stem from a desire to avoid costly patent litigation similar to that taking place between Gilead and the government over Truvada for PrEP.[54] Moreover, while the manufacturer has committed not to enforce its vaccine patents against other companies during the pandemic, the company remains open to licensing and profiting from its mRNA technology and earning a profit in the future.

The different approaches drug manufacturers have taken to vaccine distribution reinforces that pharmaceutical companies have the ability to choose to put access before profit if they wish. And, as the histories of polio, anthrax, and HIV also attest, the government can ensure low-cost access to life-saving medicines by either committing funding to distribution, pressurizing drug companies to lower the cost of its medicines, or to compel them to revoke their patents by evoking its march-in rights.

The pharmaceutical industry cannot end Covid-19 with vaccines alone. As historian Allan Brandt wrote in 1985, drugs are rarely "magic bullets."[55] Instead, diseases are curbed only with universal access to new products. The Covid-19 pandemic offers the U.S. government and the world at large an opportunity to learn from earlier pandemics, pursuing solutions to curb the crisis that puts health before profit.

54 Eric Sagonowsky, "Moderna won't enforce COVID-19 vaccine patents during pandemic," October 8, 2020, accessed January 2021, https://www.fiercepharma.com/pharma/leading-vaccine-player-moderna-won-t-enforce-patents-against-other-companies-during-pandemic.

55 Allan M. Brandt, *No Magic Bullet: A Social History of Venereal Disease in the United States Since 1880* (New York: Oxford University Press, c.1985, 1987).

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