**1NC R5**

**T**

**Interpretation:**

**Reduce means to diminish in size – this excludes refusing to accept future increases**

**Guy, 91** - Circuit Judge (TIM BOETTGER, BECKY BOETTGER, individually and as Next Friend for their Minor Daughter, AMANDA BOETTGER, Plaintiffs-Appellees, v. OTIS R. BOWEN, Secretary of Health and Human Services (89-1832); and C. PATRICK BABCOCK, Director, Michigan Department of Social Services (89-1831), Defendants-Appellants Nos. 89-1831, 89-1832 UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT 923 F.2d 1183; 1991 U.S. App. LEXIS 671)

The district court concluded that the plain meaning of the statutory language does not apply to the termination of employment one obtains on his own. A termination, the court held, is not a refusal to accept employment.

In this case, the plain meaning of the various words suggests that "refuse to accept" is not the equivalent of "terminate" and "reduce." As a matter of logic [\*\*18]  and common understanding, one cannot terminate or reduce something that one has not accepted. Acceptance is  [\*1189]  a pre-condition to termination or reduction. Thus, a refusal to accept is a precursor to, not the equivalent of, a termination or a reduction. n3

n.3 This distinction is also reflected in the dictionary definitions of the words. "Accept" is defined in anticipatory terms that suggest a precondition ("to undertake the responsibility of"), whereas "terminate" and "reduce" are defined in conclusory terms ("to bring to end, . . . to discontinue"; "to diminish in size, amount, extent, or number."). See Webster's New Collegiate Dictionary (9th ed. 1985).

**Violation: they don't reduce ip protections, IE zero companies actually lose their IP rights immediately after the aff passes. The plan is a prevention of future increase, which is different from reduction.**

**Vote neg —**

**A] precision – our definition is grounded in the law and explicitly defines reduction as different from refusal – that's key to predictable limits and pre-round prep that generates deep clash and topic education**

**B] limits and ground – their interp would allow affs that ban any one company from applying for future patents, on any one product – that means we don't get links to topic generics like innovation because there isn't the perception argument about hurting IP in the squo – kills fairness because we have to rely on bad generics like the K**

**C] CX doesn't check – being topical is k2 pre-round prep and changing the aff in CX just means they get to shift out of their advocacy which is worse**

**T is competing interps, drop the debater, no RVIs – it's a basic aff burden and reasonability devolves to judge intervention.**

**CP**

**1NC – UHC**

**The member nations of the World Trade Organization should each implement a healthcare system including the provision of free insulin.**

**IP isn’t the problem stopping insulin access, long standing corruption that forces any entering companies to have extremely long and expensive trials is.**

**Goozner PhD 20**

Merril Goozner (PhD and literally wrote the book on overpriced drugs, called “The 800$ pill), Winter 2020, "Insulin Should Be Free. Yes, Free.," Democracy Journal, <https://democracyjournal.org/magazine/55/insulin-should-be-free-yes-free/> // AW

Insulin Should Be Free. Yes, Free. It wouldn’t be very complicated, and it wouldn’t be nearly as expensive as you think—around $10 billion a year. The impacts would be profound. Charles H. Best and Frederick Banting, co-discoverers of insulin. Predatory pricing by the insulin cartel has triggered a public health crisis. Diabetics are dying after self-rationing their overpriced insulin. The past decade’s exorbitant price hikes have left patients stranded like oxygen-starved hikers on Mount Everest. The insulin debacle has become the public face of a much broader crisis. Sharp increases in out-of-pocket costs have left millions of patients unable to afford their medications. A large majority of Americans now rank the high cost of drugs as their top health-care concern, according to a recent Kaiser Family Foundation poll. And of all the prescription-drug horror stories out there, insulin is the worst. The insulin story illustrates everything that is wrong with the contemporary drug marketplace. Insulin, which is usually produced naturally by the pancreas to process sugar in the blood, was first isolated and used to prevent death from diabetes in the 1920s. Biosynthetic versions of human insulin were invented more than three decades ago and are no longer patented. Yet, the three-firm cartel that controls the insulin market—Eli Lilly, Sanofi, and Novo Nordisk—still does not face competition from low-cost generics, which typically come to market at a small markup above their manufacturing cost (not the 500 percent markups typical of still-patented branded drugs). Why? Those firms have been primary beneficiaries of a well-funded biotechnology industry campaign that convinced the Food and Drug Administration (FDA) to require long and expensive clinical trials for any biosimilars (the industry name for biosynthetic generics), which makes their cost much closer to the brand-name originals. About a quarter of the nation’s 30 million diabetics require insulin, without which they either die or suffer debilitating health consequences. Democratic Senator Amy Klobuchar highlighted the crisis by bringing a Minnesota constituent, Nicole Smith-Holt, to the 2019 State of the Union address. Smith-Holt’s 26-year-old son Alec, a Type 1 diabetic, died in 2017 from an acute case of ketoacidosis, the acid buildup in the blood that results from inadequate insulin, after being forced off his mother’s insurance plan when he turned 26. The $1,300-a-month he had to pay out-of-pocket for insulin was $200 more than his biweekly paycheck. Klobuchar and her Iowa Republican colleague Charles Grassley have included an accelerated pathway for biosimilars in their proposed legislation that would end the patent games drug companies use to delay generics entering the market.

**Implementing UHC gets insulin to the uninsured.**

**Goozner PhD 20**

Merril Goozner (PhD and literally wrote the book on overpriced drugs, called “The 800$ pill), Winter 2020, "Insulin Should Be Free. Yes, Free.," Democracy Journal, <https://democracyjournal.org/magazine/55/insulin-should-be-free-yes-free/> // AW

Later in the year, on the eve of the second Democratic Party debate, Senator Bernie Sanders, who has made Medicare-for-All his signature policy proposal, took a busload of diabetics to Canada to purchase insulin that is one-tenth the United States price. **Sanders’s single-payer system would go beyond negotiating lower prices** as is done in Canada and other industrialized nations. **It would completely eliminate the copays and deductibles that stand in the way of many patients**—including some who are well-insured—getting the medications they need. That our health-care system fails to provide essential medicines to people who face immediate death or injury without them is morally outrageous. The pricing and access policies of profit-seeking drug companies also make that failure quite literally a human rights violation. Those companies—and the government that fails to control them—are flagrantly ignoring the World Health Organization’s constitution, which calls “the highest attainable standard of health a fundamental right of every human being.” The document, which the United States signed in 1946, also says that “understanding health as a human right creates a legal obligation on states to ensure access to timely, acceptable, and affordable health care of appropriate quality.”

**Insulin needs to made free DIRECTLY – even after IP removal, new laws + industry subsidies to keep big pharma in power**

**Goozner PhD 20**

Merril Goozner (PhD and literally wrote the book on overpriced drugs, called “The 800$ pill), Winter 2020, "Insulin Should Be Free. Yes, Free.," Democracy Journal, <https://democracyjournal.org/magazine/55/insulin-should-be-free-yes-free/> // AW

But flagrant violations of international norms have not convinced Congress to put an end to this human rights abuse. The drug industry’s protectors include virtually every member of the Republican Party, which marches in lockstep with the army of lobbyists deployed by Big Pharma. Last year, the drug industry spent $169.8 million on lobbying, more than any other industry. It’s on track to spend even more this year, having poured $129.4 million into its Washington influence machine through September, according to the Center for Responsive Politics. Despite their numerous protests, many Democratic Party leaders remain conflicted about how to solve the problem. Too many legislators buy into the industry’s assertions that high prices are necessary to incentivize innovation. Most Democrats also accept drug and insurance industry campaign contributions, making them reluctant to pursue dramatic changes in the status quo. And conflicted members are in key positions for making policy. Since the beginning of 2019, New Jersey Democratic Representative Frank Pallone, chairman of the House Energy and Commerce Committee, raised $130,700 from medical professionals and $66,500 from drug companies, which together represented nearly 13 percent of his total campaign contributions. Democrat Anna Eshoo, who chairs that committee’s health subcommittee and is a vocal defender of her Silicon Valley district’s biotech companies, raised $115,700 from Big Pharma and $106,350 from medical professionals. That is fully 26 percent of her campaign contributions so far this year. Drug and biotechnology companies are concentrated in areas (eastern Pennsylvania/New Jersey, Boston, and San Francisco/Silicon Valley) that are heavily Democratic.

**UHC will solve COVID inequalities, structural violence, and has long-term impact on the healthcare system**

**Walcott MD PhD 4/21**

**David Alexander Walcott,** (MD., Ph.D. MSc. Entrepreneur and Rhodes Scholar)**, 4-1-2021, "COVID-19 vaccine success can enable universal healthcare – here's how," World Economic Forum,** <https://www.weforum.org/agenda/2021/04/covid-19-vaccine-success-enable-universal-healthcare/> **// AW**

For more than 200 years, human beings managed to avert widespread pestilence with vaccines. While not a silver bullet, vaccines provide us with the freedom to engage with the world without the fear of debilitating disease. As we reflect on the global relevance of vaccines during World Immunization Week, we quickly acknowledge that persistent societal disparities have affected our ability to equitably vaccinate, a phenomenon that has been illuminated by COVID-19. As we pursue systems designed to equal the playing field in the spirit of collective global welfare, we must consider whether immunizations are simply products of universal access, or are themselves are enablers of this global target. Global value of immunization diminished by health inequalities Despite the target for global equitable access to immunization by organizations such as GAVI and the World Health Organization, there remains a [huge gap](https://pubmed.ncbi.nlm.nih.gov/30646979/) in levels of vaccine accessibility at both national and global levels. Low and middle-Income CountrieS have notably reduced access to vaccines, and within countries, social factors such as like conflict and [destitution](https://pubmed.ncbi.nlm.nih.gov/19884162/) have detrimental effects on immunization. Despite the global successes we have achieved with elimination of smallpox and near-elimination of polio, inadequate access remains a challenge in many regions in the world. Up to [15% of the world’s children](http://www.who.int/news-room/fact-sheets/detail/immunization-coverage) have no access to immunization, and [millions of children](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4024226/) still die from infections, including pneumonia and diarrhoea, many cases of which could be prevented by vaccination. Data showing that COVID-19 mortality rates are higher among BIPOC communities. Global vaccine inequity has been seen even more starkly in the pandemic where low-income countries have struggled to get access to vaccines. As of 4 March 2020, [many such countries](https://www.sciencenews.org/article/covid-19-global-inequity-vaccines-deaths-economy-pandemic) had yet to administer a single dose while many of their larger contemporaries had enough doses to inoculate their populations several times over. Our pleasant illusions of equitable access were quickly supplanted by the harsh reality of the perennial global economic disparities, and their tangible effects on global health were impossible to ignore. Vaccines are not a simply a product of UHC, they also drive UHC Regarding global health inequities, it is clear that universal health care (UHC) is an enabler of widespread immunization given its inclusive mandate of bringing all under the net of healthcare access. Greater access to healthcare services inevitably translates into greater opportunities for immunization. Interestingly, one may argue that this relationship also exists in the reverse, where the pursuit of routine and universal immunization itself can serve as a potent platform towards enabling coverage for all. Immunization is one of the few platforms that bring most households into contact with healthcare systems [five or more times](https://www.gavi.org/sites/default/files/publications/Immunisation%20-%20a%20platform%20for%20universal%20health%20coverage.pdf) during the first year of a child’s life. This offers a clear opportunity for providing additional primary healthcare services at these touchpoints, and we must consider whether it can serve as a platform upon which additional healthcare outcomes can be built. Furthermore, vaccines have indirect effects on driving access to healthcare resources through influencing the distribution of healthcare services. Through averting preventable diseases which consume copious health resources, vaccines permit the deployment of capabilities towards those who need them most. Immunization programmes take pressure off healthcare systems, enabling allocation of resources to the underserved, particularly around non-communicable diseases which are now responsible for [over 70%](https://www.who.int/news-room/fact-sheets/detail/noncommunicable-diseases) of global mortality. This phenomenon is shown in the pandemic, where greater levels of vaccine uptake have finally allowed for the allocation of resources towards other socially valuable initiatives. Graph showing how vaccines have reduced the burden (and therefore spending) of certain infectious diseases (measles, mumps, rubella). Finally, considering that poverty is a key factor standing in the way of UHC, it is clear that immunization permits the maximization of our economic potential and drives poverty reduction. It has been projected that vaccines administered between 2016 and 2030 will [prevent 24 million](https://www.gavi.org/sites/default/files/publications/Immunisation%20-%20a%20platform%20for%20universal%20health%20coverage.pdf) people in 41 of the world’s low and middle-income countries from falling into poverty, and has been shown to drive [significant value-creation](https://www.gavi.org/sites/default/files/publications/Immunisation%20-%20a%20platform%20for%20universal%20health%20coverage.pdf) – with every $1 invested in immunization driving a return of $54 in social and economic value. Speed of vaccine development brings hope for UHC COVID-19 has been our most pressing challenge, and our world has managed the mammoth task of condensing several years of vaccine development into a single year. The global health community has never been more connected, engaged and collaborative, and levels of interest in supporting immunization services, vaccine development and effective procurement systems have never been higher. True to the theme of World Immunization Week, vaccines have indeed “brought us closer” to economic, social and psychological normality. Necessity has been the mother of invention and several of the assets developed through this pandemic – immunization programmes, embracing health technology, and greater public health awareness – will serve us well in the days to come. The spirit of collaboration demonstrated between competing companies such as Pfizer and BioNTech illustrate the potential unlocked through collaboration and the power of resolve. With the second wind of hope promised by our experience with vaccines, it is hoped that we will be able to solve the problems in vaccine development against more complex infections, such as malaria and HIV, which have seen substantial but modest success in recent times. Significant progress has also been made in vaccine development against many non-infectious diseases such as Alzheimers and diabetes, and [therapeutic cancer vaccines](https://clincancerres.aacrjournals.org/content/27/3/689) remain promising. Greater levels of prevention, treatment and access to care are expected in the days to come and vaccines will continue to offer opportunities for expanding our ability to influence global health. No arm left behind Though we face an uncertain future, the pandemic has reminded us that we now live in a global village and that no one is safe until there is safety for all. It is hoped that we are able to take our immunizations, our learnings and our resolve and maintain commitment to the Immunization Agenda 2030 and SDG3. True to the words of Tedros Adhanom Ghebreyesus, Director-General of the [World Health Organization](https://www.devex.com/organizations/world-health-organization-who-30562), “There is no health for all without vaccines for all…” As we move beyond the pandemic and reflect on the idea that vaccines have indeed “brought us closer” let us ensure that in the days to come there is no man, woman or arm left behind.

**CP Competes: Striking a balance is K2 innovation – development won’t be financially viable without protections**

**Krattiger 13**

**(Anatole Krattiger; Global Challenges Division at WIPO, Adjunct Prof. School of Integrative Plant Science Plant Breeding and Genetics Section, works on strategic and intellectual property aspects related to ag-biotech and global health at the crossroads of development, government, science, businesses and philanthropy; (September 2013) Promoting access to medical innovation; WIPO Magazine;** <https://www.wipo.int/wipo_magazine/en/2013/05/article_0002.html>**; CKD)**

Striking an appropriate balance between encouraging medical innovation and enabling access to it has been a major preoccupation of policymakers, health activists and the private sector, since the 1990s when concerns about access came to the fore in relation to the treatment of HIV/AIDS in many African countries. The WTO′s Doha Declaration on the TRIPs Agreement and Public Health of 2001, clarified a number of rules specific to IP and helped reassure the global community that **IP should not prevent access to the medicines needed in developing countries**. Medical technologies are usually very expensive to develop but relatively cheap to reproduce. **Without the protection conferred by a patent it would not be financially viable for companies to continue investing in research, product development and regulatory approval**. If competitors could “free ride” on the cost of developing a product and were able to immediately introduce their own versions, the inventor would not get the expected financial returns thereby **weakening any incentive to develop new products.**

**DA**

**1NC – Disease**

**Pharma industry innovation is up but profit margins are razor thin**

**Young 9-14-21**

(Peter, CEO and President of Young & Partners, and a member of Pharm Exec’s Editorial Advisory Board. https://www.pharmexec.com/view/fishawack-health-appoints-new-ceo-jonathan-koch)

Business. The business outlook for pharma manufacturers is positive with regard to drug development and the **volume and quality of promising drugs in the pipeline**. The industry’s innovations in drug development and productivity **have improved**. Combined with indirect R&D pursuits through the biotech industry, overall development activity has been **strong and should continue to be strong**. There has been a shift in emphasis toward orphan drugs, oncology therapies, new innovations such as mRNA, gene therapy, CAR-T, immune system solutions, CRISPR, etc. The current pandemic has been a plus for the reputation of the industry, but a negative with regard to the ability to execute clinical trials and to maintain industry supply chains. Generic pharma companies are **under severe profit pressures** and will continue to consolidate, cut costs, and try to push selectively into higher value and more protected product areas. They are under intense pricing and competitive pressure.

**Strong IP protection spurs innovation by encouraging risk-taking and incentivizing knowledge sharing -- prefer statistical analysis of multiple studies**

**Ezell and Cory 19** [Stephen Ezell, vice president & global innovation policy @ ITIF, BS Georgetown School of Foreign Service. Nigel Cory, associate director covering trade policy @ ITIF, MA public policy @ Georgetown. "The Way Forward for Intellectual Property Internationally," Information Technology & Innovation Foundation, 4-25-2019, accessed 8-25-2021, https://itif.org/publications/2019/04/25/way-forward-intellectual-property-internationally] HWIC

IPRs Strengthen Innovation

Intellectual property rights power innovation. For instance, analyzing the level of intellectual property protections (via the World Economic Forum’s Global Competitiveness reports) and creative outputs (via the Global Innovation Index) shows that counties with stronger IP protection have more creative outputs (in terms of intangible assets and creative goods and services in a nation’s media, printing and publishing, and entertainment industries, including online), even at varying levels of development.46

IPR reforms also introduce strong incentives for domestic innovation. Sherwood, using case studies from 18 developing countries, concluded that poor provision of intellectual property rights deters local innovation and risk-taking.47 In contrast, IPR reform has been associated with increased innovative activity, as measured by domestic patent filings, albeit with some variation across countries and sectors.48 For example, Ryan, in a study of biomedical innovations and patent reform in Brazil, found that patents provided incentives for innovation investments and facilitated the functioning of technology markets.49 Park and Lippoldt also observed that the provision of adequate protection for IPRs can help to stimulate local innovation, in some cases building on the transfer of technologies that provide inputs and spillovers.50 In other words, local innovators are introduced to technologies first through the technology transfer that takes place in an environment wherein protection of IPRs is assured; then, they may build on those ideas to create an evolved product or develop alternate approaches (i.e., to innovate). Related research finds that trade in technology—through channels including imports, foreign direct investment, and technology licensing—improves the quality of developing-country innovation by increasing the pool of ideas and efficiency of innovation by encouraging the division of innovative labor and specialization.51 However, Maskus notes that **without protection from potential abuse of their newly developed technologies, foreign enterprises may be less willing to reveal technical information associated with their innovations**.52 The protection of patents and trade secrets provides necessary legal assurances for firms wishing to reveal proprietary characteristics of technologies to subsidiaries and licensees via contracts. Counties with stronger IP protection have more creative outputs (in terms of intangible assets and creative goods and services in a nation’s media, printing and publishing, and entertainment industries, including online), even at varying levels of development. The relationship between IPR rights and innovation can also be seen in studies of how the introduction of stronger IPR laws, with regard to patents, copyrights, and trademarks, affect R&D activity in an economy. Studies by Varsakelis and by Kanwar and Evenson found that **R&D to GDP ratios are positively related to the strength of patent rights**, and are conditional on other factors.53 Cavazos Cepeda et al. found a positive influence of IPRs on the level of R&D in an economy, with each 1 percent increase in the level of protection of IPRs in an economy (as measured by improvements to a country’s score in the Patent Rights Index) equating to, on average, a 0.7 percent increase in the domestic level of R&D.54 Likewise, a 1 percent increase in copyright protection was associated with a 3.3 percent increase in domestic R&D. Similarly, when trademark protection increased by 1 percent, there was an associated R&D increase of 1.4 percent. As the authors concluded, “Increases in the protection of the IPRs carried economic benefits in the form of higher inflows of FDI, and increases in the levels of both domestically conducted R&D and service imports as measured by licensing fees.”55 As Jackson summarized, regarding the relationship between IPR reform and both innovation and R&D, and FDI, “In addition to spurring domestic innovation, strong intellectual property rights can increase incentives for foreign direct investment which in turn also leads to economic growth.”56

**Biopharmaceutical innovation is key to prevent future pandemics and bioterror**

**Marjanovic and Feijao 20** [Sonja Marjanovic Ph.D., Judge Business School, University of Cambridge. Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitative biology, Imperial College London; B.Sc. in biology, University of Lisbon. "How to Best Enable Pharma Innovation Beyond the COVID-19 Crisis," RAND Corporation, 05-2020, accessed 8-8-2021, https://www.rand.org/pubs/perspectives/PEA407-1.html] HWIC

As key actors in the healthcare innovation landscape, pharmaceutical and life sciences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a bioterrorism context.1 The general threat to public health that is posed by antimicrobial resistance is also well-recognised as an area in need of pharmaceutical innovation. Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and competition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an indispensable partner in the search for solutions that save lives. This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceutical innovation in response to infectious disease threats to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic. In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is essential for socially responsible companies in the sector. 2 It is therefore unsurprising that we are seeing industry-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing compounds to assess their utility in the fight against COVID19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating trials for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accelerate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions.3,5,6 The primary purpose of such innovation is to benefit patients and wider population health. Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be relatively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pressure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in developing products that would be affordable in the world’s poorest countries.7 Similarly, in the United States AbbVie has waived intellectual property rights for an existing combination product that is being tested for therapeutic potential against COVID-19, which would support affordability and allow for a supply of generics.8,9 Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.10 Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other infectious diseases, bioterrorism agents and antimicrobial resistance) are urgently in need of pharmaceutical innovation, even if their impacts are not as visible to society as COVID-19 is in the immediate term. The pharmaceutical industry has responded to previous public health emergencies associated with infectious disease in recent times – for example those associated with Ebola and Zika outbreaks.11 However, it has done so to a lesser scale than for COVID-19 and with contributions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still low.12 There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innovation conditions.

**COVID incentivizes engineered bioterror.**

**Walsh, 20** -- Axios Future correspondent [Bryan Walsh, "The coronavirus pandemic reawakens bioweapon fears," Axios, 5-14-2020, https://www.axios.com/coronavirus-pandemic-pathogen-bioweapon-45417c86-52aa-41b1-8a99-44a6e597d3a8.html, accessed 9-7-2020]

The coronavirus pandemic reawakens bioweapon fears

The immense human and economic toll of the COVID-19 pandemic only underscores the threat posed by pathogens that could be deliberately engineered and released.

Why it matters: **New tech**nology like **gene editing** and **DNA synthesis** has made the creation of more virulent pathogens easier. Yet security and regulation efforts haven't kept pace with the science.

What's happening: Despite some claims by the White House, overwhelming scientific evidence indicates that the novel coronavirus was not accidentally released from a lab or deliberately engineered, but naturally spilled over from an animal source.

That doesn't mean the threat from bioweapons isn't dire. Along with AI, **engineered pandemics** are widely considered the **biggest existential risk facing humanity**.

That's in part because a pathogen could be **engineered** in a lab **for maximum contagiousness and virulence**, well beyond what would arise through natural selection.

Case in point: a 2018 pandemic simulation put on by the Johns Hopkins Center for Health Security featured a fictional engineered virus called Clade X that combined the contagiousness of the common cold with the virulence of the real-life Nipah virus, which has a mortality rate of 40-75%. The resulting simulated global outbreak killed 150 million people.

COVID-19 isn't anywhere near that fatal, but the pandemic has shown the vulnerability of the U.S. and the world to biological threats both natural and manmade.

"Potential adversaries are of course seeing the same things we’re seeing," says Richard Pilch of the Middlebury Institute of International Studies. "Anyone looking for a radical leveling approach — whether a state actor like North Korea or a motivated terrorist organization — may be influenced by COVID-19 to consider pursuing a biological weapons capability."

Background: Bioweapons were officially banned by the Biological Weapons Convention in 1975, though North Korea is suspected of maintaining an offensive bioweapons program.

A particular concern about biowarfare and bioterror, though, is that many of the tools and methods that could be used to create a weaponized virus are largely indistinguishable from those used in the course of legitimate scientific research. This makes biotechnology "dual-use" — and that much more difficult to safely regulate without cutting off research that could be vitally important.

While earlier bioweapons fears focused on the possibility that a state or terror group could try to weaponize a known dangerous agent like smallpox — which would require somehow obtaining restricted pathogens — new technology means that someone could obtain the genetic sequence of a germ online and synthesize it in the lab.

"If you've been trained in a relevant technical discipline, that means you can make almost any potentially harmful agent that you're aware of," says Kevin Esvelt, a biologist at the MIT Media Lab and a member of the CDC's Biological Agent Containment Working Group. That would include the novel coronavirus that causes COVID-19, which was recently synthesized from its genetic sequence in a study published in Nature.

How it works: Currently, synthetic DNA is ordered through commercial suppliers. But while most suppliers screen DNA orders for the sequences of dangerous pathogens, they're not required to — and not all do, which means safety efforts are "incomplete, inaccurate, and insecure," says Esvelt.

Screening efforts that look for the genetic sequences of known pathogens also wouldn't necessarily be able to detect when synthetic DNA was being used to make something entirely novel and dangerous.

In the near future, desktop DNA synthesizers may be able to generate synthetic DNA in the lab, cutting out the need for commercial suppliers — and potential security screenings.

The **democratization of biotech**nology could unleash a **wave of** creativity and **innovation**, just as the democratization of personal computing did. But it also increases the number of people who could potentially make a dangerous engineered virus, whether deliberately or by accident.

**That causes extinction, which outweighs.**

**Millett & Snyder-Beattie ‘17**. Millett, Ph.D., Senior Research Fellow, Future of Humanity Institute, University of Oxford; and Snyder-Beattie, M.S., Director of Research, Future of Humanity Institute, University of Oxford. 08-01-2017. “Existential Risk and Cost-Effective Biosecurity,” Health Security, 15(4), PubMed

In the decades to come, advanced bioweapons could **threaten human existence**. Although the **probability** of human extinction from bioweapons **may** be low, the **expected value** of **reducing** the risk could **still** be **large**, since such risks jeopardize the existence of **all future generations**. We provide an overview of biotechnological extinction risk, make some rough initial estimates for how severe the risks might be, and compare the cost-effectiveness of reducing these extinction-level risks with existing biosecurity work. We find that reducing human extinction risk can be more cost-effective than reducing smaller-scale risks, even when using conservative estimates. This suggests that the risks are not low enough to ignore and that more ought to be done to prevent the worst-case scenarios. How worthwhile is it spending resources to study and mitigate the chance of human extinction from biological risks? The risks of such a catastrophe are presumably low, so a skeptic might argue that addressing such risks would be a waste of scarce resources. In this article, we investigate this position using a cost-effectiveness approach and ultimately conclude that the expected value of reducing these risks is large, especially since such risks jeopardize the existence of all future human lives. **Historically, disease events have been responsible for the greatest death tolls** on humanity. The 1918 flu was responsible for more than 50 million deaths,1 while smallpox killed perhaps 10 times that many in the 20th century alone.2 The Black Death was responsible for killing over 25% of the European population,3 while other pandemics, such as the plague of Justinian, are thought to have killed 25 million in the 6th century—constituting over 10% of the world's population at the time.4 It is an open question whether a future pandemic could result in outright human extinction or the irreversible collapse of civilization. A skeptic would have many good reasons to think that existential risk from disease is unlikely. Such a disease would need to spread worldwide to **remote populations**, overcome **rare genetic resistances**, and **evade detection**, cures, and **countermeasures**. Even evolution itself may work in humanity's favor: **Virulence and transmission is often a trade-off**, and so **evolutionary pressures** could push against maximally lethal wild-type pathogens.5,6 While these arguments point to a very small risk of human extinction, they **do not rule** the possibility **out** entirely. Although rare, there are recorded instances of **species going extinct due to disease**—primarily in amphibians, but also in 1 mammalian species of rat on Christmas Island.7,8 There are also **historical examples of large human populations being almost entirely wiped out** by disease, especially when multiple diseases were simultaneously introduced into a population without immunity. The most striking examples of total population collapse include **native American tribes** exposed to European diseases, such as the Massachusett (86% loss of population), Quiripi-Unquachog (95% loss of population), and the Western Abenaki (which suffered a staggering 98% loss of population).9 In the modern context, no single disease currently exists that combines the worst-case levels of transmissibility, lethality, resistance to countermeasures, and global reach. But **many diseases are proof** of principle that **each worst-case attribute can be realized independently**. For example, some diseases exhibit nearly a 100% case fatality ratio in the absence of treatment, such as rabies or septicemic plague. Other diseases have a track record of spreading to virtually every human community worldwide, such as the 1918 flu,10 and seroprevalence studies indicate that other pathogens, such as chickenpox and HSV-1, can successfully reach over 95% of a population.11,12 Under optimal virulence theory, **natural evolution** would be an **unlikely** source for pathogens with the **highest possible levels of transmissibility, virulence, and global reach**. But **advances in biotech**nology might allow the creation of diseases that **combine such traits**. Recent controversy has **already emerged** over a number of **scientific experiments** that resulted in viruses with enhanced **transmissibility**, **lethality**, and/or the ability to overcome **therapeutics**.13-17 Other experiments demonstrated that mousepox could be modified to have a 100% case fatality rate and render a vaccine ineffective.18 In addition to transmissibility and lethality, studies have shown that other disease traits, such as incubation time, environmental survival, and available vectors, could be modified as well.19-21 Although these experiments had scientific merit and were not conducted with malicious intent, their implications are still worrying. This is especially true given that there is also a **long historical track record** of**state-run bioweapon research** applying cutting-edge science and technology to design agents not previously seen in nature. The Soviet bioweapons program developed agents with traits such as enhanced virulence, resistance to therapies, greater environmental resilience, increased difficulty to diagnose or treat, and which caused unexpected disease presentations and outcomes.22 Delivery capabilities have also been subject to the cutting edge of technical development, with Canadian, US, and UK bioweapon efforts playing a critical role in developing the discipline of aerobiology.23,24 While there is no evidence of state-run bioweapons programs directly attempting to develop or deploy bioweapons that would pose an existential risk, the logic of deterrence and **m**utually **a**ssured **d**estruction could create such incentives in more unstable political environments or following a breakdown of the Biological Weapons Convention.25 The **possibility of a war** between great powers could also increase the pressure to use such weapons—during the World Wars, bioweapons were used across multiple continents, with Germany targeting animals in WWI,26 and Japan using plague to cause an epidemic in China during WWII.27

**Case**

**Theory**

**Yes 1AR theory but no pre-determined paradigm issues, you don't give the death penalty for shoplifting – punishment should fit the crime**

**Reject multiple 1AR shells – if there was abuse they could j win on one – time skew – substance crowdout**

**Framing**

**Structural violence framing devolves to util – conceding that pain and suffering are bad can only logically mean we should reduce it in all instances – war and disease may not be structures they still causes massive suffering and death which is a disad to their framing mechanism**

**Focus on large scale catastrophes is good and they outweigh – appeals to social costs, moral rules, and securitization play into cognitive biases and flawed risk calculus – 2020 is living proof**

**Weber 20** (ELKE U. WEBER is Gerhard R. Andlinger Professor in Energy and the Environment and Professor of Psychology and Public Affairs at Princeton University.), November-December 2020 Issue, "Heads in the Sand," Foreign Affairs, <https://www.foreignaffairs.com/articles/2020-10-13/heads-sand> mvp

We are living in a time of crisis. From the immediate challenge of the COVID-19 pandemic to the looming existential threat of climate change, the world is grappling with massive global dangers—to say nothing of countless problems within countries, such as inequality, cyberattacks, unemployment, systemic racism, and obesity. In any given crisis, the right response is often clear. Wear a mask and keep away from other people. Burn less fossil fuel. Redistribute income. Protect digital infrastructure. The answers are out there. What’s lacking are governments that can translate them into actual policy. As a result, the crises continue. The death toll from the pandemic skyrockets, and the world makes dangerously slow progress on climate change, and so on.

It’s no secret how governments should react in times of crisis. First, they need to be nimble. Nimble means moving quickly, because problems often grow at exponential rates: a contagious virus, for example, or greenhouse gas emissions. That makes early action crucial and procrastination disastrous. Nimble also means adaptive. Policymakers need to continuously adjust their responses to crises as they learn from their own experience and from the work of scientists. Second, governments need to act wisely. That means incorporating the full range of scientific knowledge available about the problem at hand. It means **embracing uncertainty,** rather than willfully ignoring it. And it means thinking in terms of a long time horizon, rather than merely until the next election. But so often, policymakers are anything but nimble and wise. They are slow, inflexible, uninformed, overconfident, and myopic.

Why is everyone doing so badly? Part of the explanation lies in the inherent qualities of crises. Crises typically require navigating between risks. In the COVID-19 pandemic, policymakers want to save lives and jobs. With climate change, they seek a balance between avoiding extreme weather and allowing economic growth. Such tradeoffs are hard as it is, and they are further complicated by the fact that costs and benefits are not evenly distributed among stakeholders, making conflict a seemingly unavoidable part of any policy choice. Vested interests attempt to forestall needed action, using their money to influence decision-makers and the media. To make matters worse, policymakers must pay sustained attention to multiple issues and multiple constituencies over time. They must accept large amounts of uncertainty. Often, then, the easiest response is to stick with the status quo. But that can be a singularly dangerous response to many new hazards. After all, with the pandemic, business as usual would mean no social distancing. With climate change, it would mean continuing to burn fossil fuels.

But the explanation for humanity’s woeful response to crises goes beyond politics and incentives. To truly understand the failure to act, one must turn to human psychology. It is there that one can grasp the full impediments to proper decision-making—the cognitive biases, emotional reactions, and suboptimal shortcuts that hold policymakers back—and the tools to overcome them.

AVOIDING THE UNCOMFORTABLE

People are singularly bad at predicting and preparing for catastrophes. Many of these events are “black swans,” rare and unpredictable occurrences that most people find difficult to imagine, seemingly falling into the realm of science fiction. Others are “gray rhinos,” large and not uncommon threats that are still neglected until they stare you in the face (such as a coronavirus outbreak). Then there are “invisible gorillas,” threats in full view that should be noticed but aren’t—so named for a psychological experiment in which subjects watching a clip of a basketball game were so fixated on the players that they missed a person in a gorilla costume walking through the frame. Even professional forecasters, including security analysts, have a poor track record when it comes to accurately anticipating events. The COVID-19 crisis, in which a dystopic science-fiction narrative came to life and took everyone by surprise, serves as a cautionary tale about humans’ inability to foresee important events.

Not only do humans fail to anticipate crises; they also fail to respond rationally to them. At best, people display “bounded rationality,” the idea that instead of carefully considering their options and making perfectly rational decisions that optimize their preferences, humans in the real world act quickly and imperfectly, limited as they are by time and cognitive capacity. Add in the stress generated by crises, and their performance gets even worse.

Because humans don’t have enough time, information, or processing power to deliberate rationally, they have evolved easier ways of making decisions. They rely on their emotions, which serve as an early warning system of sorts: alerting people that they are in a positive context that can be explored and exploited or in a negative context where fight or flight is the appropriate response. They also rely on rules. To simplify decision-making, they might follow standard operating procedures or abide by some sort of moral code. They might decide to imitate the action taken by other people whom they trust or admire. They might follow what they perceive to be widespread norms. Out of habit, they might continue to do what they have been doing unless there is overwhelming evidence against it.

Not only do humans fail to anticipate crises; they also fail to respond rationally to them.

Humans evolved these shortcuts because they require little effort and work well in a broad range of situations. Without access to a real-time map of prey in different hunting grounds, for example, a prehistoric hunter might have resorted to a simple rule of thumb: look for animals where his fellow tribesmen found them yesterday. But in times of crisis, emotions and rules are not always helpful drivers of decision-making. High stakes, uncertainty, tradeoffs, and conflict—all elicit negative emotions, which can impede wise responses. Uncertainty is scary, as it signals an inability to predict what will happen, and what cannot be predicted might be deadly. The vast majority of people are already risk averse under normal circumstances. Under stress, they become even more so, and they retreat to the familiar comfort of the status quo. From gun laws to fossil fuel subsidies, once a piece of legislation is in place, it is hard to dislodge it, even when cost-benefit analysis argues for change.

**Solvency**

**Patents are not the limiting factor – 95% of insulin patents expired in 2016**

**Kaplan MA 16**

Warren A. Kaplan, (MA works in Department of Global Health), 7-19-2016, "The global intellectual property ecosystem for insulin and its public health implications: an observational study," Journal of Pharmaceutical Policy and Practice, [https://joppp.biomedcentral.com/articles/10.1186/s40545-016-0072-8 //](https://joppp.biomedcentral.com/articles/10.1186/s40545-016-0072-8%20//) AW

Global insulin patents Most patents on insulin products in the world have already expired by 2015 yet many markets continue to be dominated by the brand-name versions marketed by original patent-holders. Figure [1](https://joppp.biomedcentral.com/articles/10.1186/s40545-016-0072-8#Fig1) plots the percentage of all OB/HC granted patents on insulin remaining in force in any given year (based on a 20 year-from-filing patent life (black markers), and shows how relatively quickly the Eli Lilly, Novo and Pfizer insulin OB/HC patents are expiring compared to Sanofi. We confirm that after 2016, between about 5–20% of Pfizer, Eli Lilly and Novo Nordisk patents listed in the OB/HC remain un-expired and these percentages rapidly dimish, except for those of Sanofi who appears to have listed OB/HC patents whose expirations would extend well into 2030 and beyond (i.e., derived from a patent application filed in 2010).

**It is not IP that is limiting Insulin’s availability, it is corrupt trial processes**

**Peccoud 18**

Jean Peccoud (professor at colorado state), 9-13-2018, "After a century, insulin is still expensive – could DIYers change that?," Conversation, [https://theconversation.com/after-a-century-insulin-is-still-expensive-could-diyers-change-that-99822 //](https://theconversation.com/after-a-century-insulin-is-still-expensive-could-diyers-change-that-99822%20//) AW

Patents don’t make insulin expensive [Discovering and developing drugs is expensive](https://www.scientificamerican.com/article/cost-to-develop-new-pharmaceutical-drug-now-exceeds-2-5b/). Patents help drug companies recoup the costs from their investments by granting them a monopoly for a limited time. Once the patent expires, competing companies can begin producing generics: off-brand versions of a patented drug. This healthy competition drives [prices down](https://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/GenericDrugs/UCM609808.pdf). So why, with the original patent long-expired, is there still no affordable generic insulin? Don’t let yourself be misled. The insulin for purchase today is not the same insulin used to treat diabetic patients nearly 100 years ago. That insulin came primarily from animals. Today, insulin is brewed up by microbes that have been [genetically engineered](https://www.fda.gov/downloads/AboutFDA/WhatWeDo/History/ProductRegulation/UCM593496.pdf) with the gene for human insulin. Insulin pumps are one of the newer ways to administer the drug to diabetic patients. [AP Photo/Mark Zaleski](http://www.apimages.com/metadata/Index/Insulin-Legislation/75bd28fc8ed840c3802727306873cce0/1/0) And insulin is seldom injected with an old-fashioned syringe and needle anymore. Now there are insulin pens, pumps, test strips and other devices that improve the quality of life for diabetic patients. Pharmaceutical companies have also modified the chemical formula to produce faster-acting or longer-lasting insulins. With each of these inventions came a new patent. But the benefits of these “improved” insulins [are debatable](https://doi.org/10.2337/dc13-2915), and there’s nothing preventing competing companies from selling older, long off-patent versions of insulin. So [what’s the holdup](https://doi.org/10.1016/j.tibtech.2018.07.009)? Regulations keep insulin expensive Insulin is a [biologic drug](https://theconversation.com/biologics-the-pricey-drugs-transforming-medicine-80258), which means it’s produced by a living organism, not a chemical reaction. This process, called biomanufacturing, is [more inconsistent](https://doi.org/10.1177/1932296813516958) than chemical synthesis of non-biologic drugs like aspirin. Making reliable biologic drugs is a little like winemaking. Even though the winemaker carefully follows a well-established process, minute differences will affect the final product. It’s always wine, but some vintages are better than others and tasting the wine is the only way to evaluate the final product. So if a new company wants to make insulin, that insulin has to be tested on patients in expensive clinical trials. Bringing a biologic drug to market can cost as much as [$250 million](https://doi.org/10.4161/mabs.3.2.15005). No company can afford that lump if it can’t file for a patent to recoup the investments. That’s why there’s only [one “generic” insulin](https://www.businessinsider.com/insulin-cheaper-generic-2016-12) available so far. It’s [made by a company](https://www.basaglar.com/en/) that was already a major player in the insulin market, and it’s only 15 percent cheaper than the patented version. By comparison, most non-biologic generic drugs cost [80 percent less](https://doi.org/10.1056/NEJMms1411398) than the original. Obviously, regulations are important for keeping insulin safe, but at what cost? [Ten percent of people](https://doi.org/10.2337/dc12-0257) living with diabetes in the U.S. are uninsured, and there are nearly 10,000 crowdfunding campaigns related to insulin on the site GoFundMe alone. Stories about diabetic patients ending up hospitalized or worse because they [tried to ration their insulin](https://www.cbsnews.com/news/the-rising-cost-of-insulin-horror-stories-every-day/) are all-too common. Could big pharma eventually be cut out of the process by home brewers cooking up their own medications? [Sanofi Pasteur](https://www.flickr.com/photos/sanofi-pasteur/5283263633), [CC BY-NC-ND](http://creativecommons.org/licenses/by-nc-nd/4.0/) Democratizing insulin production Some people are taking matters [into their own hands](https://doi.org/10.1016/j.tibtech.2018.07.009), tinkering to meet their medical needs. In 2015, patients and hobby scientists launched an initiative known as the [Open Insulin Project](http://openinsulin.org/about-the-project/). As in winemaking, the specific know-how required for insulin production is a guarded secret. The goal of the Open Insulin Project is to figure out a patent-free method and release the information, so that competing companies can manufacture “generic” insulin. Given the cost of regulatory approval, it is more likely that the project could enable patients to “home brew” their own diabetic treatments. There is currently no structure for regulating drugs that are not produced commercially. One report estimates that as many as [2,000 patients have already reverse engineered](https://www.bloomberg.com/news/features/2018-08-08/the-250-biohack-that-s-revolutionizing-life-with-diabetes) their own insulin pumps and electronic monitoring systems. The insulin itself could be next. Is it possible to make biologic drugs like insulin more affordable without compromising safety? One suggestion that has been gaining steam is to [scale down biomanufacturing](https://doi.org/10.1038/nbt.3888). Right now, biologic medicines like insulin are cooked up in giant batches. Ensuring that those batches are consistent and free of contamination is a major challenge. Think about the meat department in your grocery store. Many big-box stores stock hamburger that was ground in a central processing plant and then distributed. If an E. coli outbreak occurs in the plant, it’s going to spread to all of the stores downstream, potentially infecting hundreds or thousands of people. The meat is also exposed to more potential contamination events through storage and transport. And, if contaminated meat is identified in one store, it won’t be immediately clear whether or not all the others are safe. Industrial-scale production – whether of hamburger or drugs – makes it harder to zero in on the source of problems when they occur. [David Tadevosian/Shutterstock.com](https://www.shutterstock.com/image-photo/meat-grinder-industry-775823329) Now, consider a small local butcher who grinds meat in-house. Any safety risk is going to be isolated to the customers of that one store and the source will be obvious. Similarly, producing medications in smaller batches reduces the potential impact of any one safety event. Pharmacy compounding provides [an example](https://doi.org/10.1038/nbt.3888). In compounding, drugs are specially mixed or produced for a very small number of patients. Compounded medications are not subject to clinical trials. If insulin were made in smaller batches, manufacturers might be able to forego clinical trials and use simpler and [less expensive tests](https://doi.org/10.1208/s12248-016-9908-z) to confirm that each batch of insulin produced is safe and comparable to previously approved insulins. It would be like using chemical tests to identify important flavor compounds in two vintages of wine instead of organizing taste tests. [This model](https://doi.org/10.1016/j.tibtech.2018.07.009) could also apply to other expensive biologic drugs such as those that treat cancer, HIV and rheumatoid arthritis. The technology necessary for small-batch insulin production [already exists](http://news.mit.edu/2016/portable-device-produces-biopharmaceuticals-on-demand-0729). [Future research](http://peccoud.org/insulin/) could help automate and streamline small batch medicine production in order to minimize safety risks. The authors describe how biohacking insulin and other biologic drugs have important implications for the future of pharmaceutical drug regulation. The future of medicine The pharmaceutical industry is [ripe for disruption](https://doi.org/10.1016/j.tibtech.2018.07.009). In the coming decades, drugs might be produced in very different settings. Hospitals have already begun [plans to make their own medicines](http://www.latimes.com/business/la-fi-generic-drugs-hospitals-20180906-story.html). DIY biologists could provide patients with the knowledge needed to produce for themselves the drugs their lives depend on. As the industry and regulatory agencies gain more experience with biologic drugs, it is also possible regulations will ease up, lowering the cost of approval. This would enable the emergence of small-scale drug manufacturers that could provide off-brand drugs at a lower cost. One thing is certain, the future of medicine will not be “business as usual.” Biomanufacturing technologies will continue to evolve. These changes could enable [decentralized production of life-saving drugs](https://doi.org/10.1016/j.tibtech.2018.07.009). How the regulatory system and pharmaceutical industry will adjust to that future is yet to be determined.

**IP is the single effective preventative measure against counterfeit medicine, removal would explode the counterfeit drug market hurting diabetes prevention globally**

**Konski 08**

**Antoinette Konski, 2008, “Ip Strategies to combat distribution of counterfeit drugs”, Foley and Lardner LLP,** [https://www.foley.com/-/media/files/insights/publications/2008/04/ip-strategies-to-combat-distribution-of-counterfei/files/ip-strategies-to-combat-distribution-of-counterfei/fileattachment/combatcounterfeitdrugs\_a-konski.pdf //](https://www.foley.com/-/media/files/insights/publications/2008/04/ip-strategies-to-combat-distribution-of-counterfei/files/ip-strategies-to-combat-distribution-of-counterfei/fileattachment/combatcounterfeitdrugs_a-konski.pdf%20//) **AW**

A number of international government initiatives have been established to combat the growing problem of counterfeits. The World Health Organization (WHO) and the U.S. Food and Drug Administration have specific programs to make it more difficult to manufacture and distribute counterfeit pharmaceuticals.7 Criminal actions by governmental entities also help impede counterfeiting and can provide a powerful deterrent. For example, on August 31, 2007, Johnson & Johnson, Inc. announced that a Shanghi Court fined and sentenced Su Zhiyong, Chinese business man, to 3 ½ years in prison for selling approximately 1 million counterfeit OneTouch™ test trips. The counterfeit strips were found in 35 U.S. States, Canada, Greece, India, Pakistan, the Philippines, Saudi Arabia and Turkey.8 Such governmental efforts reduce the public health threat of counterfeit drugs but will not provide economic redress to those whose products are being copied. Enforcement of privately held intellectual property rights can however, address economic harm while at the same time, remove the copies from the market. Proactive procurement of intellectual property is the first step toward seeking private redress for economic harm. Patents, trademarks and copyrights, collectively referred to as intellectual property (IP), vary in scope, duration, geographical reach, as well as the investment of time and money required to obtain and enforce.9 It is useful at the outset for businesses to assess which form of IP protection is appropriate for a product and anticipate how illicit copying of their products and/or packaging may occur. Important considerations in this initial assessment include the type of product, the nature of the likely copying, the geographical scope of intended distribution and the duration of the exclusivity period needed to protect against copiers.10 Patents A patent allows the patentee to exclude third parties from making, using, importing, selling, or offering for sale patented products or methods of manufacture or use for a finite period of time, typically no more than 20 years from the date of initial patent filing. Patent protection must be obtained on a country-by-country basis. It is used to prevent others, for that geographical area and without the consent of the patent holder, from manufacturing and/or selling exact and close copies of the patented technology. Pharmaceutical patents are usually considered the first line of defense in protecting intellectual capital because patents can prevent others from manufacturing, using, selling and/or importing products that have the same or equivalent active ingredient or formulation. However, as compared to other intellectual property, patent rights are expensive to enforce and a final, enforceable judgment may only be obtained years after a lawsuit is filed. Patent holders must prove in civil litigation that the alleged copier is making or selling a product that is described in the patent. This requires a detailed review of the patent document and correspondence between the patent applicant and the patent office. Frequently, technical experts are retained to opine on technical terminology and the meaning of phrases or terms during this phase of the lawsuit. Only after this initial review is the alleged infringing technology compared to the property right defined during the initial phase of the proceeding. Thus, the patent can only prevent others from manufacturing, using, selling or importing products that are exact or close copies of the patented technology. Rarely, however, are counterfeit medicines close copies of the original. For example, counterfeit medicines often do not contain the same, or perhaps the same amount of the genuine, patented formulation. Therefore, a patent will not prevent the making or selling of a look-alike counterfeit drug that does not contain the same or similar active compound or formulation. In addition, a patent is granted to an “innovator” and therefore manufacturers of generic drugs, frequently manufactured after drugs have gone off-patent, cannot use patents to prevent distribution of counterfeited generics. 9 Under appropriate circumstances, misappropriation of trade secrets can provide economic redress. For a general discussion of trade secret protection, and its comparison to other forms of intellectual property, see Medd and Konski, Workplace Programs to Protect Trade Secrets, Nature Biotechnology (2003) Vol. 21:201-203. 10 Id. ©2008 Foley & Lardner LLP 4 Copyrights Copyrights prevent others from copying and claiming authorship of original works. Copyright protection is granted to original works of authorship that have been fixed in a tangible form of expression. Works of authorship include literary, musical, dramatic, pictorial, graphic, sculptural, cinematic, and architectural works. Titles, names, and short phrases are generally not copyrightable. Ownership of a copyright is secured from the time of creation and the work need not ever be published. Similar to patent protection, copyright protection is available on a countryby-country basis and requires a registration process to enforce the right against third parties. In terms of the use of copyrights to secure protection from counterfeiters, copyrights on package inserts may be useful but is of limited effectiveness in preventing the counterfeit from reaching the public or providing redress for economic harm. Trademarks Because trademarks seek to prevent exactly what counterfeiters seek to obtain, i.e. the economic benefit and investment in product integrity

of the manufacturer, a strong trademark is the most valuable type of intellectual property that can be used to combat counterfeiting. Similar to patents, trademarks are enforceable on a country-by-country basis, and therefore trademark protection must be obtained in each country where the product is made or distributed.11 However, in contrast to patents, trademarks are not limited to a finite period of time but can extend as long as the trademark is used in commerce in connection with the product. Trademarks are used to identify the source of goods or services. Words, names, numbers, symbols, devices, designs, sounds, and colors that function as brands to distinguish the source of goods and their packaging may be registered as trademarks. The colors of pills as well as their shape may be trademarked. In contrast to patents, a trademark cannot be obtained on the process of making the product or medicine and does not protect the innovation of the underlying product. However, trademarks are available to generic manufacturers who identify their products with a unique logo or other identifying mark or property. Misappropriated trademarks mislead consumers by copying the unique name, logo, product packaging, shape and/or color used by the manufacturer on the genuine product or packaging, thus confusing consumers as to the actual source, and quality, of the product. Therefore, all unique aspects of the product and packaging should be considered as worthy of trademark protection and the company’s trademark should be applied as frequently as possible, e.g., on the pill itself, on both inner and outer packaging, etc. All modifications of the label, such as the product logo or other unique identifying descriptive marks should be protected in the language of the country where the product is to be sold. 11 Unlike patents, some countries recognize a trademark right without a formal application and review process, although other procedural requirements typically must be met in such cases as demonstrating proof of sale of the product within the relevant jurisdiction. ©2008 Foley & Lardner LLP 5 As compared to patents, obtaining and enforcing trademark rights are typically less costly, and a final enforceable judgment is usually obtained faster than in a patent infringement action. Indeed, evaluation of whether a trademark is likely to be infringed can be limited to a visual inspection rather than a complicated analysis of the patented technology. Most significantly, however, in many countries trademark owners can have the counterfeit goods and accompanying documents, and even sometimes manufacturing equipment immediately seized at the outset of the lawsuit. Such powerful preliminary remedies are generally not available in patent lawsuits and can lead to swift resolution of the action. Conclusion The rise of counterfeit medicines is a threat to public health and the economic investment made by innovators and generic manufacturers in the pharmaceutical industry. All manufactures of medicines can limit their economic harm by proactively assessing their product and available intellectual property options and anticipating counterfeit designs and products. After this initial assessment, appropriate intellectual property protection can be pursued in the relevant markets and countries. Although patents and to a lesser extent copyrights can be useful in combating counterfeiting and addressing economic harm, a strong trademark is the strongest intellectual property tool for combating counterfeiting.

**Counterfeits for hormones like insulin have the wrong amount of API – literally killing patients who think they are being treated**

**Williams PharmD and MSPH 14**

Lakeisha Williams, Pharmd, Msph Drug Information Specialist Xavier University Of Louisiana College Of Pharmacy New Orleans, Louisiana Ellen Mcknight Pharmd Candidate, 2017 Xavier University Of Louisiana College Of Pharmacy New Orleans, Louisiana, 6-19-2014, "The Real Impact of Counterfeit Medications," No Publication, <https://www.uspharmacist.com/article/counterfeit-meds%20/> // AW

Counterfeit drugs have been defined as products deliberately and fraudulently produced and/or mislabeled with respect to identity and/or source to make it appear to be a genuine product.1-4 Counterfeit medications include drugs that contain no active pharmaceutical ingredient (API), an incorrect amount of API, an inferior-quality API, a wrong API, contaminants, or repackaged expired products.1,5 Some counterfeit medications may even be incorrectly formulated and produced in substandard conditions.5 Counterfeiting can apply to both branded pharmaceuticals and their less expensive generic counterparts.6 In fact, generic drugs are sometimes confused with counterfeit medications, which may pose an obstacle to the widespread use and acceptance of generic medications. This may create a particular challenge for pharmaceutical industries in places such as India, Europe, and Japan—countries in which generic drugs are manufactured. Moreover, any impact on generic-drug use is potentially far-reaching. It is estimated that half of all prescriptions in the United States, for example, are now filled with approved generic drugs, with expenditures estimated in the billions.6 Counterfeit Drugs: A Global Problem For years, the number of counterfeit medications that have made their way into trusted pharmacies and subsequently to patients’ medicine cabinets has been on the rise. Imagine the scenario in which a patient takes a medication for a life-threatening illness, only to become aware later that the doses contained no APIs. It is estimated that this misfortune has occurred with thousands of people worldwide and continues to happen. The growing issue of counterfeit medications is a concern not only for the patient, but also for pharmacists and pharmaceutical companies. Wertheimer et al state that the magnitude of the drug-counterfeiting problem is difficult to gauge.7 Since the crimes of producing and selling counterfeit drugs generally become known only when the perpetrators are caught, any accurate determination of prevalence is difficult.7 The World Health Organization (WHO) has estimated that 10% of global pharmaceutical commerce, or $21 billion worth, involves counterfeit drugs.7,12 Drug counterfeiting, although not a new phenomenon, has provoked greater concern because it has become so widespread in recent years.8,9 A WHO study revealed that nearly one-half (48.7%) of the documented cases of drug counterfeiting were reported in developing countries of the Western Pacific (China, the Philippines, and Vietnam), followed by developing countries grouped within WHO’s Regional Office for Africa, with 18.7%. The industrialized areas of WHO’s Regional Office for Europe came in third, with 13.6% of reported cases.10,11 It is estimated that approximately 1% of counterfeit medications are sold in the U.S, but the numbers are increasing annually.1 Most U.S. counterfeit medications are purchased online; however, others have infiltrated legitimate supply chains. Drugs Most Often Counterfeited High-demand, expensive medications such as various chemotherapeutic drugs, antibiotics, vaccines, erectile dysfunction drugs, weight loss aids, hormones, analgesics, steroids, antihistamines, antivirals, and antianxiety drugs are common counterfeiting targets.

1,3,4 Among those deceived into buying counterfeit drugs are consumers who use medicines inappropriately or who seek to purchase medications at discounted prices. In addition to being very cheap to make, counterfeit medicines often closely resemble actual medications, with nearly identical labels and tablets, thus duping unsuspecting pharmacists and patients. It has been reported that oftentimes drug counterfeiters use cheap and sometimes harmful materials such as brick dust, sheetrock, and flour to create their bogus tablets.13 Pfizer reported discovering 14 of its counterfeited pharmaceutical products in at least 36 countries, including the U.S., in the first 9 months of 2009 and reportedly seized more than 11 million counterfeit tablets, capsules, and vials that year.1,14,15 Also in 2009, a U.S. government crackdown uncovered some 800 packages of counterfeit medications, including Viagra (sildenafil citrate), Vicodin (hydrocodone bitartrate and acetaminophen), and Claritin (loratadine).16 Mui and Ylan state that some of the drugs had as much as three times the amount of API than is typically prescribed, while others contained no API at all or harmful substances.16 Internet Sites the Largest Suppliers Increasing access to the Internet coupled with new methods of manufacturing and distributing illegal pharmaceuticals have created new challenges to safeguarding the legitimate pharmaceutical supply chain.2 Thousands of websites openly sell unapproved and/or counterfeit drugs, as well as prescription drugs without requiring a valid prescription, all in violation of federal and state laws. Many of these sites are hosted by U.S. registrars, accept payment by U.S. payment processors, and ship their products via U.S.-based express courier companies or the U.S. Postal Service (USPS).2 Counterfeit Drugs: A Public Health Concern Counterfeiting drugs is not only illegal, but it is also a major public health concern. Counterfeit drugs often contain the correct ingredients in incorrect quantities; however, they may also contain either a wrong API—which may even be toxic—or no active substance at all.15 Treatment with ineffective counterfeit drugs such as antibiotics can lead to the emergence of resistant organisms and may have a deleterious effect on a wide section of the population. In extreme cases, counterfeit drugs may even cause death.3 For example, it has been estimated that between 60,000 and 80,000 children in Niger with fatal falciparum malaria were treated with a counterfeit vaccine containing only chloramphenicol, an antibiotic that is generally combined with another medication, which may have resulted in more than 100 fatal infections.17, 18 As a consequence of such damaging effects, counterfeit drugs may erode public confidence in healthcare systems, healthcare professionals, the suppliers and sellers of genuine drugs, the pharmaceutical industry, and national drug regulatory authorities.4 Taking Legal Action To disrupt and dismantle illicit networks trading these harmful counterfeit drugs in the U.S. and countries such as Africa and Asia, the White House’s Counterfeit Inter-Agency Working Group has collaborated with the FDA; the Departments of Justice, State, and Commerce; and the Agency for International Development as well as both foreign and domestic law enforcement partners such as U.S. Customs and Border Protection and U.S. Immigration and Customs Enforcement. In order to eliminate the distribution of counterfeit drugs, the combined efforts of these agencies have implemented strategies that include partnerships with the private sector to secure supply chains and share intelligence; identify, seize, forfeit, and destroy products that infringe trademarks and copyrights; and levy monetary penalties and enforce laws at the U.S. border.2 The FDA is working with law enforcement agencies and USPS inspectors to secure the global drug-supply chain by identifying drugs that are most likely to be counterfeited, contaminated, or adulterated and targeting shipments of these drugs for additional inspection.1 In addition, anticounterfeiting initiatives in other countries have been launched, including the Anti-Counterfeiting Trade Agreement—an initiative between the European Union, Japan, the U.S., and Switzerland. Other efforts to thwart counterfeiting include the World Customs Organization’s Provisional Standards Employed by Customs for Uniform Rights Enforcement, G-8 Countries’ Initiatives on Counterfeits, World Intellectual Property Organization’s Advisory Committee on Enforcement, and Security and Prosperity Partnership, an initiative between Canada, Mexico, and the U.S.6 Anticounterfeiting Technologies Many anticounterfeiting technologies are being utilized by pharmaceutical companies to ensure distribution of the authentic product from the manufacturing site to the pharmacy.1 Among these technologies used by pharmaceutical manufacturers are holograms, color-shifting inks, and embedded codes, images, and dyes.1 These anticounterfeiting features allow pharmacists to identify suspicious medications as possible counterfeits. Protecting Consumers According to the Pharmaceutical Research and Manufacturers of America, consumers who purchase medications online should avoid the following: sites that are located outside of the U.S. that do not indicate any physical address; sites that do not have a license by the relevant State Boards of Pharmacy; sites without a licensed pharmacist to answer questions; and websites that do not require a prescription.8,10 Consumers who wish to purchase drugs over the Internet should look for websites that have the Verified Internet Pharmacy Practice Sites seal. These sites, which are created by the National Association of Boards of Pharmacy, are licensed pharmacies selling FDA-approved medications to discourage the sale of counterfeit drugs from illegitimate online sources.5 Role of the Pharmacist Pharmacists are vital in ensuring the safety of medications used by patients. Furthermore, they are responsible for the integrity of the supply chain, ranging from manufacturer to distributor and, ultimately, to the patient. Specifics on how pharmacists, pharmacy students, and technicians can combat counterfeit medications are shown in TABLE 1.1,11 Conclusion Counterfeit medications may be detrimental to a patient’s health status. The use of substandard drugs may result in adverse side effects, treatment failure, resistance, toxicity, and even death. It is important that pharmaceutical companies, healthcare professionals, pharmacists, and patients be educated about counterfeit medications and the laws being enforced to prevent this crime. With increased awareness and the promotion of global health, the growing threat of counterfeit medications may begin to decline.

**Antibiotics**

**Alt cause—billions of livestock use more antibiotics than humans**

**No evidence post-plan innovations are aimed at AMR or quick enough to solve**

**Millett is just "disease" not abr-specific so prefer the DA for scenario specificity**

**Only vaccines can solve superbugs, NOT changing treatments- AC Sobti**

**Sobti 19** [Dr. Navjot Kaur Sobti is an internal medicine resident physician at Dartmouth-Hitchcock-Medical Center/Dartmouth School of Medicine and a member of the ABC News Medical Unit. May 1, 2019. “Amid superbug crisis, scientists urge innovation”. <https://abcnews.go.com/Health/amidst-superbug-crisis-scientists-urge-innovation/story?id=62763415>] DR 21

**Redfield emphasized the importance of vaccination** during the global superbug crisis, stating that “**the only way we have to eliminate an infection is vaccination**.” He added that investing in **innovation is key to solving the crisis.** While WHO continues to advocate for superbug awareness, they warn that AMR has reversed “a century of progress in health.” The WHO added that “the challenges of antimicrobial resistance” are “**not insurmountable**,” and that coordinated action will “help to save millions of lives, preserve antimicrobials for generations to come and **secure the future** from drug-resistant diseases.”

**New vaccine tech will be rapid and solve AMR**

* Lol says new vaccines in the next decade solve cancer too- hidden defense to the other advantage

**Rappuoli 2021** (Rino Rappuoli, Ennio De Gregorio, Giuseppe Del Giudice, Sanjay Phogat, Simone Pecetta, Mariagrazia Pizza, and Emmanuel Hanon. All authors work at the Research and Development Centre, GlaxoSmithKline in Italy. "Vaccinology in the post− COVID-19 era." *Proceedings of the National Academy of Sciences* 118, no. 3 2021 Graph omitted.)DR 21

**Reverse vaccinology**, **structure-based design, synthetic biology**, and **adjuvants** are the tools that we have today to design vaccines that can be delivered as purified antigens, or by RNA and viral vectors. The COVID-19 pandemic has accelerated the maturation of **RNA** and viral vectors by at least **a decade** and **made these new platforms available** not only for emerging infections but also for the other health priorities such as antimicrobial resistance (**AMR**), chronic infections, and **cancer** that our world will need to face with urgency as soon as the COVID-19 emergency is over. To analyze the new challenges for vaccines, in [Fig. 3](https://www.pnas.org/content/118/3/e2020368118#F3), we divided vaccines into four groups. On the opposite sides, there are vaccines that we already have or that can be made with existing technologies (group A; [Fig. 3A](https://www.pnas.org/content/118/3/e2020368118#F3)) and vaccines that we cannot yet approach with today’s knowledge (group D; [Fig. 3D](https://www.pnas.org/content/118/3/e2020368118#F3)). Vaccines in groups B and C ([Fig. 3 B and C](https://www.pnas.org/content/118/3/e2020368118#F3)) are intermediate. A closer look at these groups shows that we can divide vaccination into two big categories, depending on whether we vaccinate a naïve immune system or vaccinate an immune system that has already encountered the antigen (primed immune system).

Vaccines for a Naïve Immune System.

The vaccine against smallpox developed more than two centuries ago and the vaccines in development today against COVID-19 are based on a similar principle. They both introduce, into the body, antigens that had never been seen before by the immune system, aiming at stimulating a long-term protection for a future encounter with the virus. The large majority of the vaccines in use today are also based on antigens that had never been seen before by the naïve immune system (diphtheria toxin, tetanus toxin, measles, mumps, rubella, poliomyelitis, hepatitis B, papillomavirus, and infant vaccination against influenza, pneumococcus, and meningococcus) ([Fig. 3A](https://www.pnas.org/content/118/3/e2020368118#F3)). When these vaccines are used, the antigens are taken up by professional antigen-presenting cells and presented to naïve B and T cells which mount an adaptive immune response. An important step in this process is the formation of germinal centers where follicular T helper cells and B cells cooperate to increase the potency of the B cells specific for the new antigen, via affinity maturation of antigen-reactive antibodies. This is the textbook vaccination for which we have both mechanistic and animal models, and is the vaccinology that we study when we inject animals (mostly mice) with a variety of antigens that are new for their immune system. In most cases, we have sufficient technologies and knowledge to develop vaccines against pathogens for which the immune system is naïve. There are cases, however, where we are not yet able to make vaccines. Examples are HIV, where the virus changes so rapidly that vaccines are not effective, or malaria, where the antigenic profile is very complex, and we struggle to make effective vaccines.

Vaccines for a Primed Immune System.

Some of the vaccines described above, when delivered to adolescents, adults, or the elderly, may find an immune system that has already been exposed to the antigen, following natural infection or by other microorganisms carrying cross-reacting antigens ([Fig. 3B](https://www.pnas.org/content/118/3/e2020368118#F3)). In this case, the immune system is not naïve any longer, and the vaccines are required to modify the preexisting immunity of antigen-experienced people. Seasonal influenza is probably the best example. In this case, we deliver a vaccine specific for a new influenza virus strain to an immune system that has already gone through the process of developing the response to the same antigen and has already generated specific memory B and T cells. The new vaccine quickly expands the preexisting memory B cells and, at the same time, triggers the expansion and affinity maturation of naïve B cells ([38](https://www.pnas.org/content/118/3/e2020368118#ref-38)). However, it is clear that the first exposure to the antigen has already shaped forever the way the immune system reacts to subsequent encounters with the same antigen. This phenomenon is known as “antigenic sin” ([39](https://www.pnas.org/content/118/3/e2020368118#ref-39)). Another recent example is vaccination against dengue virus. In this case, a vector-based vaccine was effective in boosting a preexisting immunity in seropositive people, while it was unable to effectively prime the naïve immune system of naïve children where it induced antibody-dependent disease enhancement, which increased the risk of hospitalization ([40](https://www.pnas.org/content/118/3/e2020368118#ref-40)). Meningococcal and pneumococcal conjugate vaccines are another example ([41](https://www.pnas.org/content/118/3/e2020368118#ref-41)). When they are given to naïve infants, they prime the immune system to the new antigen, and it takes at least two immunizations to have a good immune response. However, when the same vaccine is given to adolescents or the elderly, who have already been exposed to these pathogens, one dose of vaccine is sufficient to get an excellent immune response. Although there are no definitive studies in humans describing the germinal center response in this context, it is likely that the single vaccination elicits an immediate antibody response—probably by an extrafollicular transformation of memory B cells into plasma cells—and then the immune system becomes refractory to any booster immunization for a long period (as long as 2 y). In this period, more affinity maturation happens, and new memory B cells are generated. Only after that, the immune system is ready to respond to a booster immunization with a massive level of antibodies which can be as high as 10 times the response to the first immunization ([41](https://www.pnas.org/content/118/3/e2020368118#ref-41)). Unfortunately, we do not have animal models able to reproduce what is described in the examples above, and we do not have a mechanistic understanding of what it takes to vaccinate an “experienced” immune system. The absence of animal models and the lack of knowledge are serious limitations for the development of new vaccines that target pathogens to which most people have already been exposed by natural infection.

A big and urgent example in this category is bacteria resistant to antibiotics and responsible for recurrent infections. AMR is a slowly evolving pandemic, with predicted catastrophic consequences for health and economy during the next 10 to 20 y ([42](https://www.pnas.org/content/118/3/e2020368118#ref-42)). **Vaccines can help to tackle AMR** ([43](https://www.pnas.org/content/118/3/e2020368118#ref-43)). We urgently need vaccines for pathogenic Escherichia coli, Staphylococcus aureus, Clostridium difficile, Klebsiella pneumoniae, Pseudomonas aeruginosa, Neisseria gonorrhoeae, Salmonella typhi, Shigella, Acinetobacter baumannii, Enterococcus faecium, and Campylobacter ([Fig. 3B](https://www.pnas.org/content/118/3/e2020368118#F3)). Experimental vaccines against some of these pathogens are based on proteins or polysaccharides which induce normal or low response to the first vaccination when tested in naïve mice, followed by a better response to the second and third vaccinations. However, when adult volunteers were immunized with the same vaccines, a strong response was observed already after the first immunization, with no increased response to the second vaccination (at least in the short term). The main reason for this is that adult volunteers have already been colonized by these bacteria or by their relatives, and they already have memory B and T cells that recognize them and respond to vaccination. In this setting, adjuvants failed to increase the antibody response. The consequence is that, during vaccine development, in most cases, we make the choice to make a one-dose vaccine without adjuvant ([44](https://www.pnas.org/content/118/3/e2020368118#ref-44)). However, we are not sure whether this is the right choice for long-term protection, and some of the vaccines failed even the primary efficacy endpoint ([45](https://www.pnas.org/content/118/3/e2020368118#ref-45)). While we do not yet fully understand the mechanistics of immunizing a primed immune system, or the lack of a protective immune response that allows reinfection, we have enough **tech**nologies and **empirical knowledge** to **develop new vaccines for AMR**

. Similarly, we have enough knowledge to develop vaccines for some viral diseases such as respiratory syncytial virus, dengue, and Zika viruses even in adults and the elderly, where the immune system has been usually primed by natural infection.

Vaccines for an Immune System Primed by Controlled Chronic Infections.

The difficulty of making vaccines increases when the immune system not only has already been primed by the exposure to the pathogen but somehow has already been defeated by it. The immune system has not been able to clear the pathogen, which has established a lifelong chronic infection. In some cases, once chronic infections are established, the immune system is still able to keep at bay the pathogen for most of the time. This is the case for herpes viruses (zoster, HSV1 and HSV2, EBV, and CMV) and for bacteria such as Mycobacterium tuberculosis ([Fig. 3C](https://www.pnas.org/content/118/3/e2020368118#F3)). The pathogen establishes a latent infection and persists quietly in the body without causing disease. However, due to concomitant infections, immunosuppressive pharmacological treatments, or aging, the immune system becomes weak, and the pathogen takes over, causing disease.

Up to a few years ago, we had not a single example of a successful vaccine against chronic infections. It took us 20 y of research to start conquering some of them. The first step in this direction was the licensure of the live attenuated vaccine against herpes zoster in 2006 ([46](https://www.pnas.org/content/118/3/e2020368118#ref-46)). Although this vaccine was not able to eliminate the chronic infection, it was able to keep the chronic virus silent and avoid reactivation in 60% of the cases. Recently, a new vaccine composed of a protein antigen and the potent AS01 adjuvant (a liposome containing a TLR4 agonist and a saponin) showed an efficacy of 97% against herpes zoster ([47](https://www.pnas.org/content/118/3/e2020368118#ref-47)). This was followed by encouraging results against tuberculosis, where the combination of a protein antigen and the AS01 adjuvant was able to prevent reactivation and disease in 50% of the chronically infected people ([48](https://www.pnas.org/content/118/3/e2020368118#ref-48)). The successful vaccines against herpes zoster and the encouraging results against tuberculosis represent an incredible milestone in the history of vaccination, because, for the first time, we have been able to make effective vaccines against chronic infections.

Vaccines for a Primed and Failed Immune System.

There are cases in which the immune system has been exposed to pathogens and has been completely defeated. Examples are chronic infections, such as HIV, papillomavirus, hepatitis C virus (HCV), hepatitis B virus (HBV), and cancer, where the immune system is not able to control the pathogen or the cancer cells, which continue to replicate forever ([Fig. 3D](https://www.pnas.org/content/118/3/e2020368118#F3)). So far, we have not been able to make successful vaccines against these diseases, and we do not have the scientific knowledge to make them. However, even this area is not without hope, because the progress made by immunotherapy in the area of cancer has shown that the defeated immune system is characterized by dormant regulatory T cells that can be activated using antibodies against the checkpoint inhibitors, removing the constrains imposed on the immune system ([49](https://www.pnas.org/content/118/3/e2020368118#ref-49)). The success of immunotherapy in the field of cancer and the increased understanding of mechanistic features of the defeated immune system suggest that, in the near future, vaccination may also be able to conquer cancer and chronic diseases.

**Conclusions**

The urgent need for COVID-19 vaccines has **accelerated** **the time required to develop vaccines** and the **availability of powerful technologies**. It is possible that evolution of the new technologies fast-tracked for COVID-19 (RNA vaccines, viral vectors, and protein-based vaccines with potent adjuvants) combined with the learning coming from immunotherapy will be the answer for some of the new challenges of modern society such as emerging infections, **AMR**, chronic infections, **and cancer**. For instance, RNA vaccines and viral vectors may be designed to encode not only antigens but also molecules able to reactivate the dormant immune system.