# 1NC

## Framing

#### The standard should be preserving human life

#### Epistemic modesty breaks any tie and answers all AC pre-empts.

#### Bostrom 12 (Nick Bostrom, Existential Risk Prevention as a Global Priority, 2012. NS)

These reflections on moral uncertainty suggest an alternative, complementary way of looking at existential risk. Let me elaborate. Our present understanding of axiology might well be confused. We may not now know—at least not in concrete detail—what outcomes would count as a big win for humanity; we might not even yet be able to imagine the best ends of our journey. If we are indeed profoundly uncertain about our ultimate aims, then we should recognize that there is a great option value in preserving—and ideally improving—our ability to recognize value and to steer the future accordingly. Ensuring that there will be a future version of humanity with great powers and a propensity to use them wisely is plausibly the best way available to us to increase the probability that the future will contain a lot of value.

#### Extinction justifies moral loopholes

Bok, 1988 (Sissela Bok, Professor of Philosophy, Brandeis, Applied Ethics and Ethical Theory, Ed. David Rosenthal and Fudlou Shehadi, 1988)

The same argument can be made for Kant’s other formulations of the Categorical Imperative: “So act as to use humanity, both in your own person and in the person of every other, always at the same time as an end, never simply as a means”; and “So act as if you were always through actions a law-making member in a universal Kingdom of Ends.” No one with a concern for humanity could consistently will to risk eliminating humanity in the person of himself and every other or to risk the death of all members in a universal Kingdom of Ends for the sake of justice. To risk their collective death for the sake of following one’s conscience would be, as Rawls said, “irrational, crazy.” And to say that one did not intend such a catastrophe, but that one merely failed to stop other persons from bringing it about would be beside the point when the end of the world was at stake.For although it is true that we cannot be held responsible for most of the wrongs that others commit, the Latin maxim presents a case where we would have to take such a responsibility seriously—perhaps to the point of deceiving, bribing, even killing an innocent person, in order that the world not perish.

## Off-Case

### Innovation DA

**Pharma profits are up from COVID vaccines, patent waivers threaten this**

**Buchholz 5-17-21**

(Katharina, https://www.statista.com/chart/24829/net-income-profit-pharma-companies/)

The profitability of coronavirus vaccines has been in the spotlight since U.S. President Joe Biden come out in support of temporarily lifting vaccine patents to make the production of the life-saving inoculations more financially feasible for poorer countries. EU leaders meanwhile remain divided over such a move. Company financial reports show that COVID-19 vaccine makers and developers like Johnson & Johnson, Pfizer, Moderna, AstraZeneca and BioNTech have seen their profits increase since the vaccine rollout, at times majorly. In early May, stocks of several companies that benefit from COVID-19 vaccine sales **took a nosedive on the news of Biden’s reversal**. Moderna stocks, for example, were still down more than 6 percent at close on May 5, the day of the announcement. Stocks recovered somewhat as German chancellor Angela Merkel came out against patent waivers the following day. While fluctuations in the stock market price have hurt drug makers in the **short term**, patent waivers would diminish the bottom line of companies involved with the development and production of COVID-19 **vaccines in the long term**. Pharma giants like Johnson & Johnson and Pfizer bring in billions of dollars of income every quarter from diverse sources, so the COVID bump was smaller for them. In the case of Pfizer, which has been a bigger producer than J&J, the year-over-year profit increase was a handsome 44 percent, however. For smaller AstraZeneca, the COVID year meant that its profits doubled. In the case of Moderna, the past year has turned a Q1 loss into a profit. The case is similar for German company BioNTech, which collaborated with Pfizer on its COVID vaccine. While Q1 2021 brought in a profit of $1.1 billion, the company ran a deficit since its founding in 2008 up until Q4 2020, when it posted a profit for the first time. The $446 million earned stood in contrast to losses of almost $428 million accrued in the first nine months of the year.

**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.

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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.

**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

### OWS CP

#### CP Text: The governments of the member nations of the World Trade Organization ought to buy medicines and distribute it for free as per Adler et al.

#### Solves COVID without reducing IP protections- Operation Warp Speed proves. Time frame is now and the CP is totally feasible and can be conducted through coordination from the WTO and its member nations

Adler et al. 8-4-21 [David Adler is author of the monograph The New Economics of Liquidity and Financial Frictions, coeditor of the forthcoming anthology The Productivity Puzzle, and an adviser on industrial strategy at the Common Good Foundation (UK). Reda Cherif is a Senior Economist at the International Monetary Fund (IMF). He joined the IMF in 2008 and worked in several departments on fiscal issues and macroeconomic analysis of emerging and developing countries. His research focuses on development economics, natural resources, fiscal policy, and growth and innovation. Reda holds a PhD in economics from the University of Chicago. Fuad Hasanov is a Senior Economist at the International Monetary Fund (IMF) and an Adjunct Professor of Economics at Georgetown University. Before joining the IMF, Fuad was an Assistant Professor of Economics at Oakland University in Rochester, Michigan in 2004-2007. Fuad received a PhD in economics from the University of Texas at Austin. “How to deliver 10 billion COVID-19 vaccines at Warp Speed.” World Economic Forum. August 4, 2021. <https://www.weforum.org/agenda/2021/08/how-to-deliver-10-billion-covid-19-vaccines-at-warp-speed/>] HW Alex Lee

The US government's **Operation Warp Speed** (OWS) initiative **showed how successful public/private collaboration can be in rolling out a mass vaccination programme.** It provides a blueprint for how to build supply, regulate and distribute COVID-19 vaccines on a global scale. This kind of approach would focus on building capacity, supporting production in emerging or developing countries and encouraging rapid testing while vaccine production is underway. Operation Warp Speed (OWS), the US government initiative to accelerate the development, trials and production of COVID-19 vaccines, has been a **spectacular success. It showed that the state could work effectively with private firms to promote innovation and provide a powerful weapon against the virus.** It consisted of early and massive funding of R&D and investment in production of various vaccine candidates, as well as coordinating the value chain and addressing all regulatory and logistical hurdles. The result: several vaccines available within a year and widespread vaccination in most advanced countries. OWS showed that the state could effectively work with private firms to promote innovation and provide a powerful weapon against the virus. —Reda Cherif & Fuad Hasanov, IMF; David Adler, The Common Good Foundation (UK) However, **the pandemic** is far from over. It **is still raging in the developing world.** The official global death toll has passed 4 million people while The Economist has estimated 7-13 million excess deaths, most of which are outside advanced countries. New, more contagious variants are also affecting a younger population, implying that many poorer countries may not be protected by the youth of their populations anymore. **An OWS for the World is needed.** Given the many uncertainties and risks about vaccine production and supply, regulation, distribution, and virus variants, the market will most likely fail to provide the necessary volume of vaccines. This will lead to long delays in reaching global herd immunity. **OWS represents a blueprint of effective industrial policy in action. Speed is of the essence in the face of a pandemic** While the development of a vaccine has been an amazing feat, vaccination campaigns in many parts of the world have been dismal. By mid-June, about a billion people globally have had at least one dose of a vaccine (with more than 2.3 billion doses administered), and most of them reside in advanced countries. Africa has so far inoculated less than 30 million people, little more than 2% of its population. The US, in comparison, has vaccinated more than 170 million people, more than half of its population. The G7 leaders have committed to provide 1 billion vaccine doses by end-2022. The US has pledged to buy a total of 500 million doses from BioNTech/Pfizer to provide to poor countries by mid-2022 (with 200 million doses by end-2021). Although these initiatives show that the race against time to vaccinate the world has started, many campaigners argue **these commitments fall short of what is needed to end the pandemic as fast as possible. To vaccinate the world, another 10 billion doses are urgently required.** Waiting until end-2022 would still wreak havoc on many parts of the world. Delivering 10 billion vaccines in a year A recent IMF proposal to end the pandemic within a year called for donations of extra doses, financing of vaccines for poor countries, and investments to increase vaccine manufacturing capacity by 1 billion doses by early 2022. Moreover, many downside risks considered in the proposal, such as export restrictions and supply chain bottlenecks, have already materialized. The EU and others have called for scaling up and diversification of production as a result. This kind of risk-based approach calls for further global action along the lines of OWS to ensure the delivery of 10 billion doses within a year, accounting for extra capacity and redundancy. This would involve **three main steps**: Purchasing the required capacity from key vaccine manufacturers directly - essentially building capacity, if necessary - to send the needed doses to other countries; Facilitating building or expanding vaccine production in emerging and developing countries, including through partnerships such as that of Senegal’s Institut Pasteur and a Belgian biotech firm; and Producing and distributing rapid tests for widespread testing while vaccines are on the way. Building capacity, facilitating collaboration and rapid testing Creating extra production capacity to produce hundreds of millions of doses a month within a year is **feasible and would cost a fraction** of advanced countries’ foreign aid budget. Producing 8 billion doses of mRNA vaccines would cost between $10 billion (BioNTech/Pfizer) and $25 billion (Moderna) and could be done within a year, according to recent research from Imperial College London. Procurement alone is likely to take longer than desired. Buying or building capacity is what OWS did, and is what economists such as Nobel laureate Michael Kremer have advocated. Coordinating all stakeholders and clearing bottlenecks would be key to the success of OWS for the World. It could be done by the US Biomedical Advanced Research and Development Authority (BARDA), in coordination with an EU or UK vaccine taskforce and WHO, or **any other global task force**. As we argue in the context of industrial policy against pandemics and OWS as a model, this task force needs to set up relevant objectives, clear resulting hurdles - whether in supply chain, distribution, or communication - and coordinate across government agencies, manufacturers, and in this case, global users. The EU vaccine task force has already mapped, tracked, and cleared bottlenecks. It retrofitted a German dengue vaccine bottling factory for Johnson & Johnson’s vaccine, for example. At the same time, advanced countries need to help others build their own production facilities and supply chains to manufacture vaccines and rapid tests. Indeed, this would create a more resilient vaccine production system globally, mitigating against uncertainties and risks when providing booster shots and other vaccines in the future for developing countries. Since vaccine production may take longer, producing rapid tests, which could be easier and faster, is a hedge against delays in vaccine production. Finally, while awaiting vaccines, many countries need to conduct universal or widespread testing to prevent outbreaks. Creating extra production capacity to produce hundreds of millions of doses a month within a year is feasible and would cost a fraction of advanced countries’ foreign aid budget. —Reda Cherif & Fuad Hasanov, IMF; David Adler, The Common Good Foundation (UK) Last year, we argued that testing would end the pandemic within a few months, but only a few countries experimented with it. Rapid worldwide vaccination could do the same. Reducing the length of the pandemic, even by days, **would save lives and is worth the investment. It is not too late to act.**

### Counterfeit DA

#### Counterfeit medicines related to insulin are prevalent in the squo and disproportionately affect oppressed

Cheng BA LLB 09

May M. Cheng (BA LLB), Nov 2009, "Is the Drugstore Safe? Counterfeit Diabetes Products on the Shelves," PubMed Central (PMC), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2787054/#b12> // AW

Deaths caused by counterfeit medication often do not make the news in developing countries due to how commonplace such occurrences have become. Back in 1988, Dr. Dora Nkem Akunyili, a distinguished professor of pharmacology in Nigeria, witnessed the death of her 21-year-old sister due to hyperglycemia. However, it was not diabetes that killed her; it was the fake insulin supplied to her for treatment.[11](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2787054/#b11) A survey published in 2001 by the Nigerian Institute of Pharmaceutical Research indicated that some 80% of the drugs distributed in major pharmacies in Lagos, Nigeria, were counterfeit. Upon her appointment as head of the Nigerian National Agency for Food and Drug Administration and Control (NAFDAC) that same year, Dr. Akunyili became a crusader against counterfeit medicines, getting the police to raid premises, publicly burning mountains of fake drugs and putting suppliers behind bars. Her actions drew the wrath of the fake drug barons who firebombed NAFDAC's offices, and in a December 2003 ambush, six gunmen opened fire on her car. Undeterred, she has continued with a strong grassroots campaign that starts with educating consumers and involving all stakeholders, yielding impressive results. In 2006, the NAFDAC published a new survey showing a 90% decrease in the incidence of counterfeit drugs in circulation and a take of $100 million in counterfeit drugs seized and destroyed over a 5-year period.[11](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2787054/#b11) In February of 2009, it was reported that police in China had arrested four suspects on charges of selling fake diabetes drugs that killed two patients in the remote Northwest region of Xinjiang. The fatal drugs were falsely labeled with a known local brand name and contained illegal quantities of the chemical ingredient glibenclamide, which, while used in the treatment of diabetes, in excessive quantities can cause serious low blood glucose and consequent brain damage.[12](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2787054/#b12) Examples from developing countries are too numerous to recount. However, increasingly, the sale of counterfeit medical products in pharmacies is no longer isolated to developing countries. In recent years, there have been a number of incidents involving counterfeit blood glucose test strips for use with glucose meters being sold in licensed pharmacies in the United States. There are over 10 million Americans who measure blood glucose, many of whom rely on at-home diabetes tests to take sensitive measurements of blood sugar levels to monitor insulin requirements. OneTouch® Test Strips, manufactured by LifeScan, a Johnson & Johnson company, the world's largest consumer-health products maker, were the most successful of these products in the United States. In 2006, about one million phony OneTouch test strips turned up in at least 35 states and in a number of countries in Europe, the Middle East, and Asia. These counterfeit test strip kits, manufactured in China, were found to give incorrect readings, with the potential to cause patients to inject dangerous levels of insulin.[13](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2787054/#b13) The counterfeiters had accurately copied many elements of the test strip packaging, with the important exception of the lot number on the carton, which was incorrect, enabling the company to identify the fakes and issue public warnings.[13](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2787054/#b13) The Chinese businessman responsible for their distribution was apprehended and convicted in a Shanghai court in August 2007 and sentenced to 3.5 years in prison, among other penalties.[14](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2787054/#b14),[15](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2787054/#b15) Also in 2006, Johnson & Johnson and Lifescan successfully brought civil actions in a number of countries arising from these events [for example, Johnson & Johnson et al. v. Butt et al. (2007) 162 A.C.W.S. (3d) 232 (Ont. S.C.) and Johnson & Johnson et al. v. Alexander Vega et al. (2006) QCCS 5883 (Que. S.C.)]. The counterfeit test strips were sold via two Canadian companies to a number of U.S. distributors, which in turn ended up in over 700 U.S. pharmacies.[16](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2787054/#b16) The case underscores the burgeoning number of fake medical products entering the North American market and the danger of their infiltrating the legitimate supply chain through “gray market” channels that may act as a cover for dealing in illicit counterfeits.[16](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2787054/#b16) In another case involving defective blood glucose test strips in the United States, criminal charges led to a guilty plea in January 2009 by the president of a recycling company in Knox, Indiana.[17](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2787054/#b17) Bayer had discovered that Nor AmPlastics Recycling Inc. fraudulently sold previously recalled test strips on eBay for $3700 in profits, while Bayer was paying $8000 to recycle the diabetic glucose strips that were recalled by Bayer.[17](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2787054/#b17) Officials confirmed that over 100 people had purchased the bogus strips, but there were no reports of injuries.[17](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2787054/#b17)

#### 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

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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.

## Case

### AT: Insulin et. al

#### 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.