## CP - UHC Insulin

#### The member nations of the World Trade Organization ought to implement a universal healthcare system including free insulin

#### IP isn’t the problem stopping insulin access or the bad innovation discussed in Hanson, it’s long standing corruption that forces any entering companies to have extremely long and expensive trials

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 a UHC system 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, likely 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.

**CP - Abolish WTO**

#### Text: The World Trade Organization ought to be abolished. The following 164 countries listed in the speech doc ought to independently and without influence from international government reduce intellectual property protections for diabetes medicines.

Afghanistan

Albania

Angola

Antigua and Barbuda

Argentina

Armenia

Australia

Austria

Bahrain, Kingdom of

Bangladesh

Barbados

Belgium

Belize

Benin

Bolivia, Plurinational State of

Botswana

Brazil

Brunei Darussalam

Bulgaria

Burkina Faso

Burundi

Cabo Verde

Cambodia

Cameroon

Canada

Central African Republic

Chad

Chile

China

Colombia

Congo

Costa Rica

Côte d’Ivoire

Croatia

Cuba

Cyprus

Czech Republic

Democratic Republic of the Congo

Denmark

Djibouti

Dominica

Dominican Republic

Ecuador

Egypt

El Salvador

Estonia

Eswatini

European Union (formerly EC)

Fiji

Finland

France

Gabon

Gambia

Georgia

Germany

Ghana

Greece

Grenada

Guatemala

Guinea

Guinea-Bissau

Guyana

Haiti

Honduras

Hong Kong, China

Hungary

Iceland

India

Indonesia

Ireland

Israel

Italy

Jamaica

Japan

Jordan

Kazakhstan

Kenya

Korea, Republic of

Kuwait, the State of

Kyrgyz Republic

Lao People’s Democratic Republic

Latvia

Lesotho

Liberia

Liechtenstein

Lithuania

Luxembourg

Macao, China

Madagascar

Malawi

Malaysia

Maldives

Mali

Malta

Mauritania

Mauritius

Mexico

Moldova, Republic of

Mongolia

Montenegro

Morocco

Mozambique

Myanmar

Namibia

Nepal

Netherlands

New Zealand

Nicaragua

Niger

Nigeria

North Macedonia

Norway

Oman

Pakistan

Panama

Papua New Guinea

Paraguay

Peru

Philippines

Poland

Portugal

Qatar

Romania

Russian Federation

Rwanda

Saint Kitts and Nevis

Saint Lucia

Saint Vincent and the Grenadines

Samoa

Saudi Arabia, Kingdom of

Senegal

Seychelles

Sierra Leone

Singapore

Slovak Republic

Slovenia

Solomon Islands

South Africa

Spain

Sri Lanka

Suriname

Sweden

Switzerland

Chinese Taipei

Tajikistan

Tanzania

Thailand

Togo

Tonga

Trinidad and Tobago

Tunisia

Turkey

Uganda

Ukraine

United Arab Emirates

United Kingdom

United States

Uruguay

Vanuatu

Venezuela, Bolivarian Republic of

Viet Nam

Yemen

Zambia

Zimbabwe

**Hawley, senator, JD Yale, 20**

(Josh, 5-5, https://www.nytimes.com/2020/05/05/opinion/hawley-abolish-wto-china.html)

The coronavirus emergency is not only a public health crisis. With [30 million Americans unemployed](https://www.cnbc.com/2020/04/30/us-weekly-jobless-claims.html), it is also an economic crisis. And it has exposed a hard truth about the modern global economy: it weakens American workers and has empowered China’s rise. That must change. The global economic system as we know it is a relic; it requires reform, top to bottom. We should begin with one of its leading institutions, **the World Trade Organization. We should abolish it.**

**The WTO as an institution is unethical and perpetuates colonialism**

**Godrej 20**

(Dinyar, Co-editor @ New Internationalist, 4-20, https://newint.org/features/2020/02/10/brief-history-impoverishment)

For countries that were undergoing economic ravishment by structural adjustment, the 1990s brought new **torments in the form of the World Trade Organization** (WTO), a club dominated by rich nations. In the name of creating a ‘level playing field’, the WTO required poorer countries to sign up to an all-or-nothing, binding set of rules, which removed protections for domestic industries and allowed foreign capital unhindered access. This **was strongly prejudicial to the interests of local industries**, which were not in a position to withstand foreign competition. Influence within the WTO is weighted by the size of a nation’s economy – thus **even if all poorer nations joined forces** to demand policy changes **they would still not have a chance** against wealthy nations. This trade injustice has drawn widespread protests and pressure for the WTO to reform. Meanwhile, wealthy nations are increasingly going down the route of bilateral Free Trade Agreements (FTAs). Usually negotiated in secret, the interests of their corporations are paramount in FTAs and include the ability to sue states for eye-watering sums (should they, for example, want to terminate a contract or nationalize an industry) with no provision for states to do the same. Such instruments are working to create a utopia for transnational corporations, creating a business-friendly climate, which translates as the **demolition of labour protection, tax cuts for the wealthiest and a supine regulatory environment**. Tax havens operated by the richest countries are home to huge sums of illicit wealth draining out of some of the poorest. Today, due to how the global economy has been engineered, **for every dollar of aid sent to poorer countries, they lose 10 times as much in outflows** – **and that’s before one counts their losses through unfair trade rules and underpaid labour**. Foreign investors take nearly $500 billion a year in profits from the Global South, and trade-power imbalances cost poorer nations $700 billion a year in lost export revenue. 7 CONCENTRATION In the 21st century wealth increasingly flows through corporate hands towards a small super-elite. In a trend that began in the 1990s, the lion’s share of equity value is being realized through squeezing workers: the classification ‘working poor’ so familiar in the Global South is now increasingly also being used in the wealthy North, where neoliberal capitalism is leading inevitably to wage erosion and work precarity, coupled with the withdrawal of state support. Inequality is rising dramatically. In 2018 the richest 26 people owned wealth equivalent to the poorest half of the world’s population. And their wealth was increasing at the rate of $2.5 billion a day. Meanwhile 3.4 billion people – nearly half the world – were living on less than $5.50 a day.

## Trademark/Counterfeits DA

#### Counterfeit medicines related to insulin are prevalent in the squo and disproportionately affect oppressed peoples – the agrees in Konrad 17

Cheng 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

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.

#### Trademark 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.

**Case**

### Framing:

#### The role of the judge is to decide who wins the debate and the roll of the ballot is to tell tabroom this decision – the ballot should go to whoever wins more offense. Their framework is arbitrary and self-serving – vagueness and lack of a coherent weighing mechanism means the aff wins every time.

#### Uncertainty and social contract require governments use util

Gooden, 1995 **(**Robert, philsopher at the Research School of the Social Sciences, Utilitarianism as Public Philosophy. P. 62-63)

Consider, first, the argument from necessity. Public officials are obliged to make their choices under uncertainty, and uncertainty of a very special sort at that. All choices—public and private alike—are made under some degree of uncertainty, of course. But in the nature of things, private individuals will usually have more complete information on the peculiarities of their own circumstances and on the ramifications that alternative possible choices might have on them. Public officials, in contrast, are relatively poorly informed as to the effects that their choices will have on individuals, one by one. What they typically do know are generalities: averages and aggregates. They know what will happen most often to most people as a result of their various possible choices. But that is all. That is enough to allow public policy-makers to use the utilitarian calculus—if they want to use it at all—to choose general rules of conduct. Knowing aggregates and averages, they can proceed to calculate the utility payoffs from adopting each alternative possible general rules.

#### Disregarding foreseeable harm reifies structures of domination

**McCluskey 12** – JSD @ Columbia, Professor of Law @ SUNY-Buffalo

(Martha, “How the "Unintended Consequences" Story Promotes Unjust Intent and Impact,” Berkeley La Raza, doi: dx.doi.org/doi:10.15779/Z381664)

**By similarly making structures of inequality appear beyond the reach of law** reform, **the "unintended consequences" message helps update and reinforce the narrowing of protections against intentional racial harm. Justice is centrally a question of whose** interests and whose **harms should count**, in what context and in what form and to whom. **Power is centrally about being able to act without having to take harm to others into account**. **This power to gain by harming others is strongest when it operates through** systems and **structures that make disregarding that harm appear** routine, rational, and beneficial or at least **acceptable** or perhaps inevitable. By portraying law's unequal harms as the "side effects" of systems and structures with unquestionable "main effects," **the** "**unintended consequences" story helps affirm the resulting harm** even as it seems to offer sympathy and technical assistance. In considering solutions to the financial market problems, the policy puzzle is not that struggling homeowners' interests are overwhelmingly complex or uncertain. Instead, the bigger problem is that overwhelmingly powerful interests and ideologies are actively resisting systemic changes that would make those interests count. The failure to criminally prosecute or otherwise severely penalize high-level financial industry fraud is not primarily the result of uncertainty about the harmful effects of that fraudulent behavior, but because the political and justice systems are skewed to protect the gains and unaccountability of wealthy executives despite the clear harms to hosts of others. **The unequal effects of** the prevailing **policy** response to the crisis **are foreseeable and obvious, not accidental or surprising**. It would not take advanced knowledge of economics to readily predict that modest-income homeowners would tend to be far worse off than bank executives by a policy approach that failed to provide substantial mortgage forgiveness and foreclosure protections for modest-income homeowners but instead provided massive subsidized credit and other protections for Wall Street. Many policy actions likely to alleviate the unequal harm of the crisis similarly are impeded not because consumer advocates, low-income homeowners, or racial justice advocates hesitate to risk major changes in existing systems, or are divided about the technical design of alternative programs or more effective mechanisms for enforcing laws against fraud and racial discrimination. Instead, the problem is that these voices pressing for effective change are often excluded, drowned out or distorted in Congress and in federal agencies such as the Treasury Department and the Federal Reserve, or in the media, in the mainstream economics profession, and to a large extent in legal scholarship about financial markets. More generally, those diverse voices from the bottom have been largely absent or marginalized in the dominant theoretical framework that constructs widespread and severe inequality as unforeseeable and largely inevitable, or even beneficial. Moreover, **justice requires careful attention to both harmful intent and to complex harmful effects**. But **the concept of "unintended consequences" inverts justice by suggesting that the best way to care** for those at the bottom **is to not care to make law more attentive** to the bottom. "**Unintended consequences" arguments promote a simplistic moral message in the guise of sophisticated intellectual critique**-the message that those who lack power should not seek it because the desire for more power is what hurts most. Further, **like Ayn Rand's overt philosophy of selfishness, that message promotes the theme that those who have power to ignore** their **harmful effects on others need not-indeed should not-be induced by law to care about this harm**, because this caring is what is harmful. One right-wing think tank has recently made this moral message more explicit with an economic values campaign suggesting that the intentional pursuit of economic equality is a problem of the immoral envy of those whose economic success proves they are more deserving.169 **Legal scholars and advocates who intend to put intellectual rigor and justice ahead of service to** financial **elites should reject stories of "unintended consequences" and instead scrutinize the power and laws that have so effectively achieved the intention of making devastating losses to so many of us seem natural, inevitable, and beneficial**.

### Contention:

#### Offering a gender-neutral account of black health disparities turns the aff. This erases black women within federal health policy and research and means they are incapable of addressing the needs of black women

Ikemoto 06

(Lisa, Professor of Law, Loyola Law School; Visiting Professor, UC Davis School of Law., DECONSTRUCTING THE IMAGE REPERTOIRE OF WOMEN OF COLOR: In the Shadow of Race: Women of Color in Health Disparities Policy, 2006, 39 U.C. Davis L. Rev. 1023, JKS)

Black feminists, critical race feminists, and others have established that efforts to eliminate racism without specific attention to the experience of women of color do not fully address sociopolitically allocated risks to women of color. In some instances, race-only efforts exacerbate the risks. Patricia Hill Collins has shown that race and gender are constructed differently and that the experiences and identities formed at the matrices of these constructs are unique and nonderivative. n102 Race, then, is an inaccurate proxy for gender, even when applied to women of color. n103 For example, the 1999 Schulman study made headlines when it clearly demonstrated that racial and gender bias affect physician decision- [\*1052] making about treatment for chest pain. n104 The study showed that physicians would have provided different medical treatment to white men, white women, Black men, and Black women who were similarly situated in terms of socioeconomic status and health status. Physician decision-making showed the highest disregard for Black women, even compared with white women and Black men. An antiracist intervention that failed to take that phenomenon into account would fall short of addressing the health needs of Black women. The most obvious result of race-only efforts would be the disappearance of women of color from the federal health agenda. Without an explicit gender analysis, the androcentrism that has pervaded federal health and research programs would characterize its antiracism efforts as well. n105 This would further reduce the potential for convergence between race-based disparities efforts and women's health programs. Women of color would then remain statistical categories in most federal health initiatives. Two facile equations could mask the exclusion. The first is that between race and gender as applied to women of color. In other words, using race as a proxy for the health risks that women of color experience would not only cause but also mask their exclusion from the health agenda. The second arises from the fact that we take statistical categories so seriously that conflation between the statistical presence of women of color and substantive inclusion may not be noticed. Either equation would ensure that risks and issues significant to women of color would remain politically marginalized. A more subtle effect of using a race-only approach to health disparities is that acknowledging racism without addressing the interlocking aspects of patriarchy can reinforce the naturalization of gender. Biological essentialism is more central to constructions of gender than it [\*1053] is to racial construction. n106 As noted above, physical differences between biological females and biological males seem to give scientific credence to socially constructed gender essentialism. The centrality of biology to both sex and gender has made the feedback loop between them more difficult to challenge than biological race. n107 As a result, a race-only approach to health disparities will leave intact the ways in which gender allocates health risks among men and women. The apparently biological basis for gender would make disproportionate allocations of risk to women or men seem unavoidable. The naturalization of gender-based misallocations of health risk would then be more likely to remain unchallenged.

#### 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.