# 1NC

### Framework

#### I negate Resolved: The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines.

#### I value morality, per the use of ought in the resolution, asking us to evaluate the moral obligations for both sides.

#### Since the resolution asks nations to take an action, our frameworks in this debate should focus on government action.

#### Governmental actors must be utilitarian, acknowledging that some policies will inevitably benefit some and harm others.

**Professor Woller in 1997**, - (Gary [Professor of Public Management, Brigham Young University] “An Overview by Gary Woller” A Forum on the Role of Environmental Ethics, pg. 10) GHS//GB

Appeals to **a priori moral principles, such as environmental preservation**, also often **fail to acknowledge that** public **policies** inevitably **entail trade-offs** **among competing values.** Thus since policymakers cannot justify inherent value conflicts to the public in any philosophical sense, and since public only general guidance to ethical dilemmas in public affairs and do not themselves suggest appropriate public policies, and at worst**, they create a regimen of regulatory unreasonableness while failing to adequately address the problem or actually making it worse**. For example**, a moral obligation to preserve the environment by no means implies the best way**, or any way for that matter**, to do so,** just as there is no a priori reason to believe that any policy that claims to preserve the environment will actually do so. **Any number of policies might work, and others, although** seemingly **consistent with the moral principle, will fail** utterly. That **deontological principles are an inadequate basis for environmental policy** is evident in the rather significant irony that most forms of **deontologically based environmental laws and regulations tend to be implemented in a very utilitarian manner** by street-level enforcement officials. Moreover, **ignoring the relevant costs and benefits of environmental policy** and their attendant incentive structures can, as alluded to above, **actually work at cross purposes to environmental preservation.** (There exists an extensive literature on this aspect of regulatory enforcement and the often perverse out- comes of regulatory policy. See, for example, Ackerman, 1981; Bartrip and Fenn, 1983; Hawkins, 1983, 1984; Hawkins and Thomas, 1984.) Even the most die-hard preservationist/deontologist would, I believe, be troubled by this outcome. The above points are perhaps best expressed by Richard Flathman, The number of values typically involved in public policy decisions, the broad categories which must be employed and above all, the scope and complexity of the consequences to be anticipated militate against reasoning so conclusively that they generate an imperative to institute a specific policy. It is seldom the case that only one policy will meet the criteria of the public interest (1958, p. 12). It therefore follows that **in a democracy, policymakers have an ethical duty to establish a plausible link between policy alternatives and the problems they address,** and the public must be reasonably assured that a policy will actually do something about an existing problem; this requires the means-end language and methodology of utilitarian ethics**. Good intentions, lofty rhetoric, and moral piety are an insufficient**, though perhaps at times a necessary, **basis for public policy in a democracy**

#### Additionally, policy makers face moral uncertainty when making decisions since they are unsure of the ethical implications that their policy will have on each individual – as a result, they must make decisions that benefit the most people.

#### Thus, my value criterion is maximizing expected well-being.

## SO21 – DA – Counterfeit Drugs

#### Healthcare counterfeiting is on the rise, but national regulations in the status quo combat the problem for the WTO – IP is the goldilocks enabler for sustained cooperation.

**Author Diana Bentley in 2021**, (“The insidious problem of counterfeiting in healthcare," Raconteur, <https://www.raconteur.net/legal/intellectual-property/counterfeiting-healthcare/>) KD

**Criminal activity in healthcare has also intensified with the coronavirus pandemic**. Under Interpol’s Operation Pangea XIII, conducted last March, police, customs and **health authorities in 90 countries seized counterfeit** face masks, self-testing kits, anti-viral medication and other products worth more than $14 million, leading to 121 arrests and the closure of 2,500 weblinks and websites.

National and regional regulation, and the **work of healthcare producers and law enforcement agencies** including the police and customs officials, all **provide the front-line defence against healthcare counterfeiting**. Healthcare producers use a plethora of measures to combat the problem, notably barcodes, holograms and anti-tampering devices as well as a range of fieldwork.

In addition to mandatory features required by regulators for packaging, including serialisation, **pharmaceuticals giant Novartis uses overt and covert security features so country verifiers can identify falsified products**. Mobile laboratories are used by its forensic teams to analyse suspected samples in the field. A new cloud-based, mobile-enabled solution, which will accelerate the testing, detecting and reporting of false medicines to national authorities and WHO, is now being piloted.

**Technology is a critical enabler in the fight against pharmaceutical crime**, says Stanislas Barro, Novartis global head of anti-counterfeiting. “Detecting falsified medicines requires state-of-the-art technology to test packaging and products in the field. We use online monitoring, like webcrawlers with customised parameters, to monitor the internet 24/7 to detect illicit sales of suspected falsified medicines using our brands,” he says.

The company has also built a data analytics and visualisation dashboard to support its risk-analysis effort, he adds.

**Although counterfeiters are prosecuted by law enforcement agencies, the actions of IP holders remain vital.**

“We file trademarks to clearly identify our products and record our IP rights with customs authorities globally to empower them to identify suspected falsified goods,” says Myrtha Hurtado Rivas, Novartis global head of legal brand protection.

“But companies like ours cannot fully shift responsibility to reduce patient risk to national law enforcers. Taking action based on IP rights is necessary, for instance to ensure rogue online pharmacies are taken down swiftly. In the majority of legal actions, **having an IP right increases the chances of success against counterfeiters**.” Legitimate pharmaceutical companies also have a duty to report confirmed incidents of falsified versions of their products to local health authorities, Novartis points out, and it has voluntarily committed to reporting these to WHO within seven days of discovery following WHO’s recommendations.

#### IP is the key tool to prevent the spread of counterfeit medicines – the 1AC removes insurance measures for companies to have the necessary standards for developing high-quality medications.

**FIFARMA in 2021**, Latin American Federation of Pharma Industry, represent 16 research-based biopharmaceutical companies and 11 local associations dedicated to discovering and developing innovative, quality and safe health products and services that improve the lives of patients in Latin America and the Caribbean and advocate for patient-centric, sustainable health systems characterized by high regulatory standards and ethical principles ("This is how we fight counterfeit medicines with Intellectual Property," https://fifarma.org/en/this-is-how-we-fight-counterfeit-medicines-with-intellectual-property/) KD

**The role of IP**

In addition to functioning as a tool to maintain constant innovation in the industry, **IP helps reducing counterfeit medicines because medicines have better technologies and ingredients are more difficult to copy**. This means that, **through market incentives**, **the industry manages to have high quality infrastructure**, new technology and trained personnel, to **create specialized and specific medicines** and therapies, which is why they are difficult to replicate.

On the other hand, political will functions as another important axis, as it must prosecute those who are making counterfeit medicines. This is achieved through a constant conversation between industry and governments. Therefore, it will be absolutely clear how to identify the authenticity of medicines.

In short, **IP** **allows quality standards to be clearer and stricter, and regulators to have greater knowledge and traceability of each product that enters the market.** Through IP, you can establish a record of all products globally, which makes it easier to find possible counterfeit medicines.

Consequently, the **best way to fight counterfeit medicines is through accessing the best quality medicines** and for this to happen, an ecosystem between countries, regulators and industry is needed. This ecosystem shall take into account the structural deficiencies of each country and addresses them in a holistic manner, to provide the best quality medicines.

In the end, with the Intellectual Property associated with the creation of the product, there are also associated standards of transparency and detailed information that every regulatory agency can access. Moreover, the value chains will receive all this information in order to be aware of the appearance of products that are not registered with the standards of a product protected by IP.

Also, **IP helps to combat counterfeit medicines internationally, since there are laws that cover all member countries of the United Nations and punish more severely those who commit this crime.** Likewise, these laws provide countries with the necessary mechanisms to take concrete action once a counterfeit medicine is discovered. This, of course, must go hand in hand with the political will of each country, because only with collaboration between different actors will it be possible to prosecute the entire chain of counterfeit medicines.

#### Counterfeits inflate prices for market introductions and strengthen anti-microbial resistance – that’s the key internal link to pandemics

**Buckley and Gostin 13,** Senior Program Officer at National Academies of Sciences, Engineering, and Medicine; Highest Academic Rank at Georgetown Law, American law professor who specializes in public health law. He was a Fulbright Fellow and is best known as the author of the Model State Emergency Health Powers Act and as a significant contributor to journals on medicine and law ("The Effects of Falsified and Substandard Drugs," <https://www.ncbi.nlm.nih.gov/books/NBK202526/>) KD

**Individual patients have much to lose from substandard and falsified medicines**. These products also **encourage drug resistance** and thereby **threaten population health today and for future generations**. This is a particular concern with substandard products where the dose of active ingredient is low and variable and with **falsified products diluted by criminals in an effort to pass screening assays**. Drug resistance is common in pathogens with short life cycles: viruses, bacteria, and protozoa. Poor-quality antimicrobial medications, taken frequently and, **in poor countries**, generally taken without professional supervision, **contribute to drug resistance.**

Antimicrobial Resistance

Antibiotics should be used only when indicated, in the appropriate dose, and for the correct length of time. Ensuring the proper treatment with the right combination of drugs is the underlying principle of Directly Observed Treatment—Short Course (DOTS), the internationally accepted method of tuberculosis surveillance and treatment ([WHO SEARO, 2006](https://www.ncbi.nlm.nih.gov/books/NBK202526/)). DOTS also depends on a safe and reliable drug supply. **Poor-quality drugs have been cited as a causal factor for the rise of multidrug-resistant tuberculosis** ([Kelland, 2012](https://www.ncbi.nlm.nih.gov/books/NBK202526/)). Over time, the bacteria causing tuberculosis have become increasingly drug resistant. Multidrug-resistant tuberculosis precedes extensively drug-resistant tuberculosis, and finally, sometimes, totally drug-resistant tuberculosis ([Udwadia, 2012](https://www.ncbi.nlm.nih.gov/books/NBK202526/)**). Extensively drug-resistant strains of tuberculosis account for about** **6 percent of incident infections worldwide**, but much more in China, India, and the former Soviet Union ([Jain and Mondal, 2008](https://www.ncbi.nlm.nih.gov/books/NBK202526/)). [Figure 2-1](https://www.ncbi.nlm.nih.gov/books/NBK202526/figure/fig_2_1/?report=objectonly) shows the increasing incidence of multidrug-resistant tuberculosis around the world.

**Drug-resistant bacteria often surface in hospitals, causing infections that are difficult to treat and are an important killer of adults in low-and middle-income countries** ([Okeke et al., 2005b](https://www.ncbi.nlm.nih.gov/books/NBK202526/); [WHO, 2012a](https://www.ncbi.nlm.nih.gov/books/NBK202526/)). It is difficult to estimate the burden of antimicrobial resistance in low- and middle-income countries, in part because of the dearth of data, especially from francophone Africa, the Asian Pacific, and the former Soviet Union ([Okeke et al., 2005a](https://www.ncbi.nlm.nih.gov/books/NBK202526/)). The data that do exist are grim. **Multidrug-resistant staph**ylococcus, an emerging problem in India and sub-Saharan Africa ([Parasa et al., 2010](https://www.ncbi.nlm.nih.gov/books/NBK202526/); [Vincent et al., 2009](https://www.ncbi.nlm.nih.gov/books/NBK202526/)), accounts for more than half of all nosocomial infections in parts of Latin America ([Guzmán-Blanco et al., 2009](https://www.ncbi.nlm.nih.gov/books/NBK202526/)). (See [Figure 2-2](https://www.ncbi.nlm.nih.gov/books/NBK202526/figure/fig_2_2/?report=objectonly).)

In a qualitative study in Orissa, India, **doctors, veterinarians, and pharmacists cited poor-quality antibiotics as a cause of drug resistance,** but mentioned it only in passing, focusing more on patient and provider behaviors([Sahoo et al., 2010](https://www.ncbi.nlm.nih.gov/books/NBK202526/)). This is consistent with most public health literature, which gives great deal of attention to the overuse of antibiotics as contributing to the rise of antimicrobial resistance in general ([Byarugaba, 2010](https://www.ncbi.nlm.nih.gov/books/NBK202526/); [Okeke et al., 2005b](https://www.ncbi.nlm.nih.gov/books/NBK202526/)) and **drug-resistant pneumonia in particular** ([Unicef and WHO, 2006](https://www.ncbi.nlm.nih.gov/books/NBK202526/)). Comparatively little work, however, **discusses the role of drug quality in encouraging bacterial resistance**. Antibiotics that contain low doses of active ingredient cause low circulating levels of the drug in the patient. This contributes to treatment failure and selectively favors the growth of drug-resistant organisms ([Okeke et al., 2005b](https://www.ncbi.nlm.nih.gov/books/NBK202526/)). Resistance is most common among the oldest and least expensive families of antibiotics ([Okeke et al., 2005b](https://www.ncbi.nlm.nih.gov/books/NBK202526/)).

According to a recent Tufts University estimate, it costs more than $1.3 billion to bring a new drug to market ([Kaitin, 2010](https://www.ncbi.nlm.nih.gov/books/NBK202526/)). Antibiotics in particular offer pharmaceutical companies a low return on investment; patients take them for only a week or two, in contrast to lifetime regimes of maintenance drugs. There would be even less monetary incentive to develop antibiotic for only the poorest parts of the world. Preserving antibiotics is imperative and depends on maintaining drug quality as much as on encouraging rational use.

#### AMR is the key internal link to sustained pandemics and causes biowarfare

* AMR -> no herd immunity -> longer-lasting and stronger pandemics

**MacIntyre et al 18,** Principal Research Fellow, School of Public Health and Community Medicine, UNSW Medicine, University of New South Wales, Sydney, NSW 2052 Australia ("Converging and emerging threats to health security," PubMed Central (PMC), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7104605/>) KD

There is growing recognition of the **costs and significance of AMR**. Multi-resistant organisms are emerging at much higher rates than seen previously, with **urgent attention needed to mitigate a risk which is predicted in one report to be the greatest global burden of disease** (Review on Antimicrobial Resistance [2016](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7104605/#CR65)). One recent estimate indicates that **by 2050, infections from resistant bacteria may overtake cancer as the leading cause of death in the world and cost US$100 trillion.** This estimate has been questioned and likely an overestimate, but AMR nonetheless causes a significant burden of disease (De Kraker et al. [2016](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7104605/#CR18)). The world is in urgent need of **new strategies** in the human, animal, agricultural and food industries. This includes **reviewing how we price/value antimicrobials, incentives for new antimicrobial development and judicious use, and restrictions around use across sectors**. In addition, **serious AMR could be engineered and released as an act of bioterrorism**, **given** the availability of **technology such as CRISP Cas9** (MacIntyre and Bui [2017](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7104605/#CR42)). A longer-term model of population risk (versus immediate individual risk of often minor infection) is required to guide everyday use and mitigate this global threat. **Whether a bioterrorist attack, pandemic or infections complicated by AMR**, the risk is increasing as outlined above. Infectious diseases do not respect international borders and can spread rapidly around the world. The continued growth in large urban areas, and megacities in particular, in which high population densities represent optimum conditions for spread of infection merits significant attention in biosecurity. This **risk is** **heightened** for megacities **in developing countries in which serious gaps exist in public health surveillance for early detection of epidemic threats**, together with **inadequate critical infrastructure** and other preparedness resources. Prevention, mitigation and control of these threats, therefore, require efforts at local, national and global levels. Despite the call for a One Health approach (Rabinowitz et al. [2013](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7104605/#CR63)), there is **no suitable system for governing use of antimicrobials across human health, animal health and food production, and often no coordination of efforts across these sectors.** **Global legal and governance frameworks for pandemics and bioterrorism are critical**, but there are **gaps in some relevant regulations**—the International Health Regulations (IHR) (World Health Organization [2017c](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7104605/#CR95)), the Biological Weapons Convention (BWC) (United Nations Office for Disarmament Affairs [2016](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7104605/#CR85)) and the Cartagena Protocol (Convention on Biological Diversity [2012](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7104605/#CR15)). The IHR provides a framework for epidemic preparedness, **but many countries do not have the resources to comply with them**, and the IHR has not been fully revised since 2005 (World Health Organization [2008](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7104605/#CR90)). The BWC was revised in 2016, but widely regarded as unenforceable and inadequate in **considering new technologies** such as CRISPR Cas9 (Bulletin of the Atomic Scientists [2016](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7104605/#CR9)). The Cartagena protocol was developed to address regulation of movements of living modified organisms (LMOs) resulting from biotechnology from one country to another, but has focused on ecology and biodiversity and has not been utilised for human biosecurity. The TAPIC framework (Trump [2017](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7104605/#CR81)) is a good starting point for considering how existing regulations can be improved and enforced and how new ones could be developed globally.

#### Bioterrorism and future pandemics cause extinction.

Hamish De Bretton-Gordon, CBRN Expert @ British Army, 20 [Director @ DBG Defense, Consultant on CBRN and Biosecurity], “Biosecurity in the Wake of COVID-19: The Urgent Action Needed,” Combatting Terrorism Center Sentinel, November/December 2020, Volume 13, Issue 11, <https://ctc.usma.edu/biosecurity-in-the-wake-of-covid-19-the-urgent-action-needed/>

Policymakers around the world did not grasp just how large the impact of a bio threat could be. Beyond the enormous human and economic impact, the current pandemic has exposed the weakness, lack of preparedness, and poor responsiveness of healthcare systems of even highly developed countries like the United States and the United Kingdom. And the virus has inflicted carnage, even though SARS-CoV-2 (the virus that causes COVID-19) is not especially virulent. The world may be confronted with other viruses in the future whose combination of virulence (the harm a pathogen does to its host), transmissibility, and other characteristics pose much greater danger.

While overwhelming evidence points to SARS-CoV-2 spontaneously spreading to humans, the advances in synthetic biology and the growth in the number of Level 3 and 4 biocontainment facilities around the world storing deadly viruses1 mean there is also the very real possibility that in the future, bad actors will try to engineer or steal/obtain a highly transmissible and highly virulent virus and unleash it onto the world. Another risk is accidental releases from such biocontainment facilities.

COVID-19, a highly transmissible but not very virulent pathogen, has had a devastating global impact, a fact that will not have gone unnoticed by rogue states and terror organizations. Advances in synthetic biology have created tools that could be put to malevolent use. In the last two decades, scientists synthesized the poliovirus from its genetic sequence,2 recreated the 1918 Spanish flu virus,3 and succeeded in modifying the H5N1 avian flu virus so that it resulted (in a research laboratory) in airborne transmission among mammals.4 In the future, we should think of weaponized biology as no less of an existential threat to the planet than weaponized atomic science. It should also be noted that the fear and panic that even a medium-scale bioterror attack could create could have dangerous implications that may rival or even surpass the immediate loss of life.

The Need to Rethink Likelihood

Given the fact that in late 2019 when, as far as is known, COVID-19 cases first started emerging in China, it had been more than a century since the previous catastrophic outbreak (the 1918-1919 “Spanish flu” pandemic),d it was unsurprising that many thought of such pandemics as a one-in-a-100-year event. Such assumptions should no longer hold. The encroachment of human settlements into areas that had previously been sanctuaries for wildlife5 and the popularity in some parts of the world of markets where people and wild animals are brought into proximity have made it more likely viruses will make the species leap to human beings.e And when they do, as the COVID-19 pandemic illustrated, the interconnectedness of a world in which millions of people fly each day6 means they can spread very rapidly.

There is also growing concern about engineered viruses. Not only have advances in synthetic biology (SynBio) created growing capacity for extremely dangerous viruses to be engineered in a laboratory, but the number of people with access to potentially dangerous ‘dual use’ technology has greatly expanded and continues to expand, making malevolent use of such technology ever more likely.

In the August 2020 issue of this publication, scientists at the U.S. Military Academy at West Point warned that:

The wide availability of the protocols, procedures, and techniques necessary to produce and modify living organisms combined with an exponential increase in the availability of genetic data is leading to a revolution in science affecting the threat landscape that can be rivaled only by the development of the atomic bomb. As the technology improves, the level of education and skills necessary to engineer biological agents decreases. Whereas only state actors historically had the resources to develop and employ biological weapons, SynBio is changing the threat paradigm.

The cost threshold of engineering viruses is also lowering, with the West Point scientists warning that synthetic biology has “placed the ability to recreate some of the deadliest infectious diseases known well within the grasp of the state-sponsored terrorist and the talented non-state actor.”7

As already noted, another source of vulnerability is that deadly viruses could be stolen from or escape from a research laboratory. There are now around 50 Biosafety Level 4f facilities around the world, where the deadliest pathogens are stored and worked on, and this figure is set to increase in the next few years.g This is a large increase over the last 30 years, creating bigger risk of a breach. Of equal, if not greater concern are the thousands of Biosafety Level 3 labs globally,8 which handle deadly pathogens like COVID-19.9

Given what has been outlined above, the risk of a future destructive biological attack or another devastating global pandemic should no longer be seen as low. From this point forward, there should no higher priority for the international community than biosecurity.

## Innovation DA

#### Pharmaceutical R&D has skyrocketed after COVID – but sustained research relies on the strength of pharmaceutical plans.

**CBO 21,** Congressional Budget Office, Non-partisan Analysis for US Congress (Research and Development in the Pharmaceutical Industry," Congressional Budget Office, <https://www.cbo.gov/publication/57126>) KD

CBO relied on the PhRMA data because before 2008, the NSF survey did not include domestic firms’ R&D spending outside of the United States**.** (Both the NSF and PhRMA estimates reflect worldwide R&D spending by pharmaceutical companies with operations in the United States.) NSF’s **estimates of R&D spending** **since 2008** **suggest that PhRMA members’ worldwide R&D spending constitutes about 75 percent to 85 percent of the industry** total, depending on the year. In recent years, the **pharmaceutical industry’s R&D spending as a share of net revenues** (sales less expenses and rebates) **has increased:** Consumer spending on brand-name prescription drugs has risen, but R&D spending has risen more quickly. In the early 2000s, when drug industry revenues were rising sharply, the industry’s R&D intensity—that is, its R&D spending as a share of net revenues—averaged about 13 percent each year. Over the decade from 2005 to 2014, the industry’s R&D intensity averaged 18 percent to 20 percent each year. **That ratio has been trending upward since 2012, and it exceeded 25 percent in 2018 and 2019,** the highest R&D intensities recorded by the pharmaceutical industry as a whole since at least 2000. Data are limited for earlier years, but among PhRMA member companies, annual R&D intensities averaged 18 percent from 1980 through 2010 and never exceeded 22 percent.[4](https://www.cbo.gov/publication/57126#footnote-080) Since then, R&D intensity has increased among PhRMA firms just as it has for the industry as a whole, reaching 25 percent in 2017 before decreasing slightly in 2018. By comparison, **average R&D intensity across all industries typically ranges between 2 percent and 3 percent**.[5](https://www.cbo.gov/publication/57126#footnote-079) R&D intensity in the software and semiconductor industries, which are generally comparable to the drug industry in their reliance on research and development, has remained below 18 percent (see [Figure 1](https://www.cbo.gov/publication/57126#_idTextAnchor007)). There are several possible explanations for the increase in the industry’s R&D intensity over the past eight years. It could reflect the increased role of small drug companies, which have little revenue and, therefore, high ratios of R&D spending to net revenues. It could also indicate that the **expected returns from investments in R&D have increased (if market conditions have changed) or that opportunities to develop new drugs have increased** (if recent advances in science and technology have been particularly productive). Finally, it could reflect rising costs of R&D inputs, such as capital equipment and skilled labor. CBO has not evaluated the relative importance of those possibilities. New Drug Development Over the past decade, the **pharmaceutical industry has introduced growing numbers of new drugs annually** (see [Figure 2](https://www.cbo.gov/publication/57126#_idTextAnchor010)). Between 2010 and 2019, **38 new drugs were approved each** year, on average. That is about a **60 percent increase compared with the previous decade**. Drug approvals reached a new peak in 2018, surpassing the record number of approvals of the late 1990s. (Counts of new drug approvals are a readily available but imperfect measure of output from the drug industry’s R&D spending. The measure does not reflect differences in the effectiveness of the new drugs relative to alternative treatments, or the number of people who might benefit from the new drugs.)

#### IP protections creates market power and funding to maximize production of live-saving medicines to vulnerable populations

**Kennedy 19**, Joe Kennedy is a senior fellow at the Information Technology and Innovation Foundation. He focuses on economic policy. For almost three decades, he has provided legal and economic advice to senior officials in the public and private sector. Much of this advice has been directed at public policies involving technology, competitiveness, and the social contract. He also consults privately on these issues. Dr. Kennedy previously served as the chief economist for the U.S. Department of Commerce where he oversaw a staff of 15 economists and regularly briefed the secretary of commerce on economic issues including the financial crisis and immigration reform. He has held numerous other positions in government, serving on committees in both houses of Congress and in the executive branch. As senior counsel for the Senate Permanent Subcommittee on Investigations, he helped oversee investigations of the credit counseling industry, music downloading, and the United Nations Oil for Food Program. As senior economist for the Joint Economic Committee, he authored papers on telecommunications policy and nanotechnology. ("The Link Between Drug Prices and Research on the Next Generation of Cures," ITIF, https://itif.org/publications/2019/09/09/link-between-drug-prices-and-research-next-generation-cures) KD

**The granting of a monopoly through patents and other intellectual property protection has a positive effect on product development**—which in the case of drug companies, is **on research, development, and testing**. While market power from intellectual property protection may reduce short-term welfare, it **increases long-term welfare by encouraging more investment and innovation**. This is why the Founding Fathers included patent protection in the Constitution.55 Moreover, in many cases, a patent may not confer much effective pricing power. A company with a patent on a drug for a given disease may face strong competition from other drugs with similar effectiveness.56 In such cases, the patents may not translate into effective pricing power.57 In addition, the maker of a particular drug may face some limitations on market power from buyers, such as health care insurers and drug benefit plans, with their own market power. These restraints help ensure pharmaceutical prices will be roughly based on the value to patients and the broader health care system.58 For example, although Zolgensma is priced at $2.1 million for a one-time treatment, it treats spinal muscular atrophy (SMA). Infants born with SMA Type 1 typically die within 18 months or can only survive on life support. Roughly 30 new patients are born each month. The only existing therapy, Spinraza, costs $750,000 for the first treatment and $375,000 per year after that.59

But even when companies set prices high, society can still benefit. When companies decide how much money to invest in research, they typically invest until the benefits to them stop exceeding their costs. Because companies do not benefit from the spillover benefits to society (the benefit competitors and consumers get from their innovation), they do not take them into account. In fact, research levels would be maximized by letting these companies capture all the social benefits.60 A recent study by Tomas Philipson and Anupam Jena shows that drug companies typically capture only a small fraction of the total social benefit they produce.61 The study concentrated on therapies for HIV/AIDS introduced after the late 1980s. It estimated that these drugs increased social welfare by nearly $1.4 trillion. However, the companies that produced these drugs increased their profits by only $62.9 billion. They therefore captured less than 5 percent of the total welfare. The remainder went to the rest of society. Looking at over 200 previous studies of the cost efficiency of other drugs, the authors estimated that in 25 percent of the studies, companies captured less than 7 percent of the societal surplus. The appropriation of social welfare exceeded 25 percent in only one-quarter of the studies. Philipson and Jena also found that “dynamic efficiency only occurs when those undertaking the costs of R&D have incentives that are properly aligned with society, which is true when social surplus is entirely appropriated as profits.”62 Because firms capture only a small part of the total surplus, they do too little research. Although patent law, the R&D tax credit, and other policies can mitigate this effect, policymakers should remember that allowing firms to appropriate more of the surplus directly may promote dynamic efficiency (e.g., new drugs) and long-term societal benefits (e.g., health).

Drug pricing therefore requires a balance between short-term affordability and long-term innovation. Low prices (as well as public subsidies) allow more individuals to afford existing drugs now, but if they come at the expense of drug company revenues, they reduce the incentive to invest in new cures. Higher prices increase this incentive but can also make prices unaffordable for many patients. Subsidies for drugs, particularly for low- and moderate-income households, either through private insurance or government payments, is one way to balance this conflict. Unfortunately, there is no right answer for obtaining the proper balance, but those who try to strike it need to be aware of the trade-off.

**The justification for high prices on any particular drug therefore depends on the assumption that they are needed to fund the subsequent round of innovation**. This link has been established by numerous empirical studies over the last several decades. A recent survey summarized the scholarly literature this way: “The preponderance of evidence suggests that **raising reimbursements for pharmaceuticals stimulates innovation, primarily because the expected rewards for innovation go up and secondarily because the cost of financing falls for cash-constrained pharmaceutical firms.”**63

#### COVID proves pharma innovation saves lives – prevents future pandemics.

**Roberts 6-3-**2021, senior director of the health and human services task force at the American Legislative Exchange Council; she previously served as campaign manager for Alabama Attorney General Luther Strange’s successful re-election campaign. She holds a Juris Doctorate from the University of Alabama ("Pandemic proves importance of pharmaceutical innovation," TheHill, <https://thehill.com/opinion/healthcare/556633-pandemic-proves-importance-of-pharmaceutical-innovation>) KD

If there is **one big lesson** learned **from** the **COVID** pandemic, it **is the importance of innovation** in this country. We have seen clothing manufacturers making face masks, alcohol producers making hand sanitizer and companies like GM manufacturing ventilators. All of which are examples of American ingenuity in the face of crisis. But there is another example that is undeserving of the bad rep it sometimes receives — pharmaceutical innovation.

The [vast majority](https://itif.org/publications/2020/07/16/ensuring-us-biopharmaceutical-competitiveness) of the world’s pharmaceutical innovation comes out of the U.S. We produce some of the most vital drugs for people around the globe. In the case of COVID, our pharmaceutical companies have risen to the challenge and have developed vaccines in less than a year. These vaccines will play a critical role in allowing life to get back to normal for most Americans.

In addition to the quick development of the vaccines, manufacturers were ready to go as soon as they had FDA approval. As a result, [more than half the population](https://thehill.com/policy/healthcare/556029-over-50-percent-of-total-us-population-has-received-at-least-one-dose-of) has gotten at least one dose of the vaccine in roughly four months. The incredible effort it took to accomplish that should not be overlooked.

Pharmaceutical companies have taken a beating in the media for the last several years over drug pricing and accessibility, and in response, state legislatures have supported bad policies like price controls and importing drugs from Canada. But the current pandemic shows us the importance of innovation in this area and why investment in pharmaceutical innovation is vital to the health and safety of Americans.

On average, taking a drug from a molecule to a marketable medicine costs $2.6 billion and is a [10-year process](https://www.sciencedirect.com/science/article/abs/pii/S0167629616000291). Companies that develop the drugs have a patent on their product for 20 years. The patent life starts to run while the company is developing the drug, often leaving a company only a handful of years to recoup their investment in that drug — and that is *if* the drug makes it through clinical trials and gets FDA approval. New drugs routinely fail during clinical trials, costing companies millions. Yet, these companies continue to develop and innovate.

That is why [President Biden](https://thehill.com/people/joe-biden)’s **recent decision to waive patents for the vaccine is so detrimental**. **The U.S. leads in pharmaceutical innovation due to our strong intellectual property protections and free market pricing system**. **Patents are a necessary part of innovation**. **Without them, companies would not take on the massive cost of developing new drugs.** By waiving the patents for the vaccine, President Biden is starting us down a slippery slope which could result in other patents being waived or challenged leading us to a much larger problem. It is a dangerous precedent to set.

Sen. [Richard Burr](https://thehill.com/people/richard-burr) (R-N.C.) [recently commented](https://thehill.com/homenews/senate/552956-gop-senator-urges-biden-to-withdraw-support-for-covid-vaccine-patent-waiver) on the patent waiver saying, “**Intellectual property protections are part of the reason we have these life-saving products. If these protections are not in place for innovators of life-saving medicines, we will not have them for the next pandemic.** It’s that simple,” and he’s right.

**Pharmaceutical innovation has saved countless lives and allows us to live longer and have a better quality of life.** Instead of treating drug manufacturers like the villain, [policymakers should be looking for ways](https://www.alec.org/publication/the-state-legislators-guide-to-prescription-drug-policy/) to support and encourage their work. The COVID pandemic has illustrated just how important it is to our everyday life.

## On Case