### Innovation DA

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#### Pharma innovation is high now – profit incentive is the biggest factor.

**Swagel 21** Phillip L. Swagel, Director of the Congressional budget office 4-xx-2021, "Research and Development in the Pharmaceutical Industry," Congressional Budget Office, <https://www.cbo.goc/publication/57126#_idTextAnchor020> SJ//DA

**Every year, the U.S. pharmaceutical industry develops a variety of new drugs that provide valuable medical benefits. Many of those drugs are expensive and contribute to rising health care costs for the private sector and the federal government. Policymakers have considered policies that would lower drug prices and reduce federal drug expenditures. Such policies would probably reduce the industry’s incentive to develop new drugs.** In this report, the Congressional Budget Office assesses trends in spending for drug research and development (R&D) and the introduction of new drugs. CBO also examines factors that determine how much drug companies spend on R&D: expected global revenues from a new drug; cost to develop a new drug; and federal policies that affect the demand for drug therapies, the supply of new drugs, or both. What Are Recent Trends in Pharmaceutical R&D and New Drug Approvals? T**he pharmaceutical industry devoted $83 billion to R&D expenditures in 2019. Those expenditures covered a variety of activities, including discovering and testing new drugs, developing incremental innovations such as product extensions**, and clinical testing for **safety-monitoring or marketing purposes. That amount is about 10 times what the industry spent per year in the 1980s, after adjusting for the effects of inflation.** The share of revenues that drug companies devote to R&D has also grown: **On average, pharmaceutical companies spent about one-quarter of their revenues (net of expenses and buyer rebates) on R&D expenses** in 2019, which is **almost twice as large a share of revenues as they spent in 2000.** That revenue share is larger than that for other knowledge-based industries, such as semiconductors, technology hardware, and software. The number of new drugs approved each year has also grown over the past decade. On averace, the Food and Drug Administration (FDA) approved 38 new drugs per year from 2010 through 2019 (with a peak of 59 in 2018), which is 60 percent more than the yearly average over the previous decade. **Many of the drugs that have been approved in recent years are “specialty drugs.” Specialty drugs generally treat chronic, complex, or rare conditions, and they may also require special handling or monitoring of patients**. Many specialty drugs are biologics (large-molecule drugs based on living cell lines), **which are costly to develop, hard to imitate, and frequently have high prices.** Previously, most drugs were small-molecule drugs based on chemical compounds. Even while they were under patent, those drugs had lower prices than recent specialty drugs have. Information about the kinds of drugs in current clinical trials indicates that much of the industry’s innovative activity is focused on specialty drugs that would provide new cancer therapies and treatments for nervous-system disorders, such as Alzheimer’s disease and Parkinson’s disease. **What Factors Influence Spending for R&D?** Drug companies’ R&D spending decisions depend on three main factors: Anticipated lifetime global revenues from a new drug, **Expected costs to develop a new drug**, and Policies and programs that influence the supply of and demand for prescription drugs. Various considerations inform companies’ expectations about a drug’s revenue stream, including the anticipated prices it could command in different markets around the world and the expected global sales volume at those prices (given the number of people who might use the drug). The prices and sales volumes of existing drugs provide information about consumers’ and insurance plans’ willingness to pay for drug treatments. Importantly, when drug companies set the prices of a new drug, they do so to maximize future revenues net of manufacturing and distribution costs. A drug’s sunk R&D costs—that is, the costs already incurred in developing that drug—do not influence its price. **Developing new drugs is a costly and uncertain process, and many potential drugs never make it to market. Only about 12 percent of drugs entering clinical trials are ultimately approved for introduction by the FDA. In recent studies, estimates of the average R&D cost per new drug range from less than $1 billion to more than $2 billion per drug**. Those estimates include the costs of both laboratory research and clinical trials of successful new drugs as well as expenditures on drugs that do not make it past the laboratory-development stage, that enter clinical trials but fail in those trials or are withdrawn by the drugmaker for business reasons, or that are not approved by the FDA. Those estimates also include the company’s capital costs—the value of other forgone investments—incurred during the R&D process. Such costs can make up a substantial share of the average total cost of developing a new drug. The development process often takes a decade or more, and during that time the company does not receive a financial return on its investment in developing that drug. The federal government affects R&D decisions in three ways. First, it increases demand for prescription drugs, which encourages new drug development, by fully or partially subsidizing the purchase of prescription drugs through a variety of federal programs (including Medicare and Medicaid) and by providing tax preferences for employment-based health insurance. Second, the federal government increases the supply of new drugs. It funds basic biomedical research that provides a scientific foundation for the development of new drugs by private industry. Additionally, tax credits—both those available to all types of companies and those available to drug companies for developing treatmentscof uncommon diseases—provide incentives to invest in R&D. Similarly, deductions for R&D investment can be used to reduce tax liabilities immediately rather than over the life of that investment. Finally, the patent system and certain statutory provisions that delay FDA approval of generic drugs provide pharmaceutical companies with a period of market exclusivity, when competition is legally restricted. During that time, they can maintain higher prices on a patented product than they otherwise could, which makes new drugs more profitable and thereby increases drug companies’ incentives to invest in R&D. Third, some federal policies affect the number of new drugs by influencing both demand and supply. For example, federal recommendations for specific vaccines increase the demand for those vaccines and provide an incentive for drug companies to develop new ones. Additionally, federal regulatory policies that influence returns on drug R&D can bring about increases or decreases in both the supply of and demand for new drugs. Trends in R&D Spending and New Drug Development Private spending on pharmaceutical R&D and the approval of new drugs have both increased markedly in recent years, resuming a decades-long trend that was interrupted in 2008 as generic versions of some top-selling drugs became available and as the 2007–2009 recession occurred. **In particular, spending on drug R&D increased by nearly 50 percent between 2015 and 2019.** Many of the drugs approved in recent years are high-priced specialty drugs for relatively small numbers of potential patients. By contrast, the top-selling drugs of the 1990s were lower-cost drugs with large patient populations. R&D Spending R&D spending in the pharmaceutical industry covers a variety of activities, including the following: Invention, or research and discovery of new drugs; Development, or clinical testing, preparation and submission of applications for FDA approval, and design of production processes for new drugs; Incremental innovation, including the development of new dosages and delivery mechanisms for existing drugs and the testing of those drugs for additional indications; Product differentiation, or the clinical testing of a new drug against an existing rival drug to show that the new drug is superior; and Safety monitoring, or clinical trials (conducted after a drug has reached the market) that the FDA may require to detect side effects that may not have been observed in shorter trials when the drug was in development. In real terms, private investment in drug R&D among member firms of the Pharmaceutical Research and Manufacturers of America (PhRMA), an industry trade association, was about $83 billion in 2019, up from about $5 billion in 1980 and $38 billion in 2000.1 Although those spending totals do not include spending by many smaller drug companies that do not belong to PhRMA, the trend is broadly representative of R&D spending by the industry as a whole.2 A survey of all U.S. pharmaceutical R&D spending (including that of smaller firms) by the National Science Foundation (NSF) reveals similar trends.3 Although total R&D spending by all drug companies has trended upward, small and large firms generally focus on different R&D activities. **Small companies not in PhRMA devote a greater share of their research to developing and testing new drugs,** many of which are ultimately sold to larger firms (see Box 1). By contrast, a greater portion of the R&D spending of larger drug companies (including those in PhRMA) is devoted to conducting clinical trials, developing incremental “line extension” improvements (such as new dosages or delivery systems, or new combinations of two or more existing drugs), and conducting postapproval testing for safety-monitoring or marketing purposes.

#### The aff crushes drug innovation.

Glassman 21 [Amanda; 5/6/21; Executive vice president and a senior fellow at the Center for Global Development, a nonpartisan, nonprofit think tank in Washington and London; “*Big Pharma Is Not the Tobacco Industry*,” Barron, <https://www.barrons.com/articles/big-pharma-is-not-the-tobacco-industry-51620315693>] Justin

But here is the crux of the problem: The pharmaceutical industry is not the tobacco industry. They are not merchants of death. The companies are amoral and exist to make money, but their business is not fundamentally immoral. Big Pharma (mostly) develops and sells products that people need to survive and thrive. Their products improve health and welfare. Fights over access to medicines are possible because medicines exist in the first place—medicines that were usually developed by Big Pharma. And yes, the pharmaceutical industry benefits from public subsidy and publicly financed foundational research. But the companies also put their own capital at risk to develop new products, some of which offer enormous public benefits. In fact, several of them did just that in the pandemic: invested their own money to develop patented manufacturing technologies in record time. Those technologies are literally saving the world right now. Public funding supported research and development, but companies also brought their own proprietary ingenuity and private investments to bear toward solving the world’s singular, collective challenge. Their reward should be astronomical given the insane scale of the health and economic benefits these highly efficacious vaccines produce every day. Market incentives sent a clear signal that further needed innovation—greater efficacy, single doses, more-rapid manufacturing, updated formulations, fast boosters, and others—would be richly rewarded. Market incentives could also have been used to lubricate supply lines and buy vaccines on behalf of the entire world; with enough money, incredible things can happen. But activist lobbying to waive patents—a move the Biden administration endorsed yesterday—sends exactly the opposite signal. It says that the most important, valuable innovations will be penalized, not rewarded. It tells innovators, don’t bother attacking the most important global problems; instead, throw your investment dollars at the next treatment for erectile disfunction, which will surely earn you a steady return with far less agita. It is worth going back to first principles. What problem are we trying to solve? We have highly efficacious vaccines that we would like to get out to the entire world as quickly as possible to minimize, preventable disease and deaths address atrocious inequities, and enable the reopening of society, trade, and commerce. Hundreds of millions of people have been plunged into poverty over the past year; in the developing world, the pandemic is just getting started. What is the quickest way to get this done? Vaccine manufacturing is not just a recipe; if you attack and undermine the companies that have the know-how, do you really expect they’ll be eager to help you set up manufacturing elsewhere? Is the plan to march into Pfizer and force its staff to redeploy to Costa Rica to build a new factory? Do the U.S. administration or activists care that this decision could take years to negotiate at the World Trade Organization, and will likely be litigated for years thereafter? Does it make sense to eliminate the incentive for private companies to invest in vaccine R&D or in the response to the next health emergency? And if the patent waiver is only temporary and building a factory takes months or years, will anyone bother to do so, even if they could? No, none of it makes sense. Worse still, we could solve the policy problem more easily by harnessing market incentives for the global good by ponying up cash to vaccinate the entire world. No confiscation necessary.

#### Pharma Innovation prevents Extinction – checks new diseases.

Engelhardt 8, H. Tristram. Innovation and the pharmaceutical industry: critical reflections on the virtues of profit. M & M Scrivener Press, 2008 (doctorate in philosophy (University of Texas at Austin), M.D. (Tulane University), professor of philosophy (Rice University), and professor emeritus at Baylor College of Medicine)

Many are suspicious of, or indeed jealous of, the good fortune of others. Even when profit is gained in the market without fraud and with the consent of all buying and selling goods and services, there is a sense on the part of some that something is wrong if considerable profit is secured. There is even a sense that good fortune in the market, especially if it is very good fortune, is unfair. One might think of such rhetorically disparaging terms as "wind-fall profits". There is also a suspicion of the pursuit of profit because it is often embraced not just because of the material benefits it sought, but because of the hierarchical satisfaction of being more affluent than others. The pursuit of profit in the pharmaceutical and medical-device industries is tor many in particular morally dubious because it is acquired from those who have the bad fortune to be diseased or disabled. Although the suspicion of profit is not well-founded, this suspicion is a major moral and public-policy challenge. Profit in the market for the pharmaceutical and medical-device industries is to be celebrated. This is the case, in that if one is of the view (1) that the presence of additional resources for research and development spurs innovation in the development of pharmaceuticals and med-ical devices (i.e., if one is of the view that the allure of **profit is one of the most effective ways not only to acquire resources but productively to direct human energies** in their use), (2) that given the limits of altruism and of the willingness of persons to be taxed, the possibility of profits is necessary to secure such resources, (3) that the allure of profits also tends to enhance the creative use of available resources in the pursuit of phar-maceutical and medical-device innovation, and (4) if one judges it to be the case that such innovation is both necessary to maintain the human species in an ever-changing and always dangerous environment in which new microbial and other threats may at any time emerge to threaten human well-being, if not survival (i.e., that such innovation is necessary to prevent increases in morbidity and mortality risks), as well as (5) in order generally to decrease morbidity and mortality risks in the future, it then follows (6) that one should be concerned regarding any policies that decrease the amount of resources and energies available to encourage such innovation. One should indeed be of the view that the possibilities for profit, all things being equal, should be highest in the pharmaceutical and medical-device industries. Yet, there is a suspicion regarding the pursuit of profit in medicine and especially in the pharmaceutical and medical-device industry.

#### Innovation is key to stopping bioterror

**Marjanovic and Fejiao ‘20** Marjanovic, Sonja, and Carolina Feijao. Sonja Marjanovic, Ph.D., Judge Business School, University of Cambridge. Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitive biology, Imperial College London; B.Sc. in biology, University of Lisbon. "Pharmaceutical Innovation for Infectious Disease Management: From Troubleshooting to Sustainable Models of Engagement." https://www.rand.org/pubs/perspectives/PEA407-1.html (2020). [Quality Control]

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

#### State-created bioweapons uniquely risk extinction in the hands of bioterrorists

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

In the decades to come, advanced bioweapons could threaten human existence. Although the probability of human extinction from bioweapons may be low, the expected value of reducing the risk could still be large, since such risks jeopardize the existence of all future generations. We provide an overview of biotechnological extinction risk, make some rough initial estimates for how severe the risks might be, and compare the cost-effectiveness of reducing these extinction-level risks with existing biosecurity work. We find that reducing human extinction risk can be more cost-effective than reducing smaller-scale risks, even when using conservative estimates. This suggests that the risks are not low enough to ignore and that more ought to be done to prevent the worst-case scenarios. How worthwhile is it spending resources to study and mitigate the chance of human extinction from biological risks? The risks of such a catastrophe are presumably low, so a skeptic might argue that addressing such risks would be a waste of scarce resources. In this article, we investigate this position using a cost-effectiveness approach and ultimately conclude that the expected value of reducing these risks is large, especially since such risks jeopardize the existence of all future human lives. Historically, disease events have been responsible for the greatest death tolls on humanity. The 1918 flu was responsible for more than 50 million deaths,1 while smallpox killed perhaps 10 times that many in the 20th century alone.2 The Black Death was responsible for killing over 25% of the European population,3 while other pandemics, such as the plague of Justinian, are thought to have killed 25 million in the 6th century—constituting over 10% of the world's population at the time.4 It is an open question whether a future pandemic could result in outright human extinction or the irreversible collapse of civilization. A skeptic would have many good reasons to think that existential risk from disease is unlikely. Such a disease would need to spread worldwide to remote populations, overcome rare genetic resistances, and evade detection, cures, and countermeasures. Even evolution itself may work in humanity's favor: Virulence and transmission is often a trade-off, and so evolutionary pressures could push against maximally lethal wild-type pathogens.5,6 While these arguments point to a very small risk of human extinction, they do not rule the possibility out entirely. Although rare, there are recorded instances of species going extinct due to disease—primarily in amphibians, but also in 1 mammalian species of rat on Christmas Island.7,8 There are also historical examples of large human populations being almost entirely wiped out by disease, especially when multiple diseases were simultaneously introduced into a population without immunity. The most striking examples of total population collapse include native American tribes exposed to European diseases, such as the Massachusett (86% loss of population), Quiripi-Unquachog (95% loss of population), and the Western Abenaki (which suffered a staggering 98% loss of population).9 In the modern context, no single disease currently exists that combines the worst-case levels of transmissibility, lethality, resistance to countermeasures, and global reach. But many diseases are proof of principle that each worst-case attribute can be realized independently. For example, some diseases exhibit nearly a 100% case fatality ratio in the absence of treatment, such as rabies or septicemic plague. Other diseases have a track record of spreading to virtually every human community worldwide, such as the 1918 flu,10 and seroprevalence studies indicate that other pathogens, such as chickenpox and HSV-1, can successfully reach over 95% of a population.11,12 Under optimal virulence theory, natural evolution would be an unlikely source for pathogens with the highest possible levels of transmissibility, virulence, and global reach. But advances in biotechnology might allow the creation of diseases that combine such traits. Recent controversy has already emerged over a number of scientific experiments that resulted in viruses with enhanced transmissibility, lethality, and/or the ability to overcome therapeutics.13-17 Other experiments demonstrated that mousepox could be modified to have a 100% case fatality rate and render a vaccine ineffective.18 In addition to transmissibility and lethality, studies have shown that other disease traits, such as incubation time, environmental survival, and available vectors, could be modified as well.19-21 Although these experiments had scientific merit and were not conducted with malicious intent, their implications are still worrying. This is especially true given that there is also a long historical track record of state-run bioweapon research applying cutting-edge science and technology to design agents not previously seen in nature. The Soviet bioweapons program developed agents with traits such as enhanced virulence, resistance to therapies, greater environmental resilience, increased difficulty to diagnose or treat, and which caused unexpected disease presentations and outcomes.22 Delivery capabilities have also been subject to the cutting edge of technical development, with Canadian, US, and UK bioweapon efforts playing a critical role in developing the discipline of aerobiology.23,24 While there is no evidence of state-run bioweapons programs directly attempting to develop or deploy bioweapons that would pose an existential risk, the logic of deterrence and mutually assured destruction could create such incentives in more unstable political environments or following a breakdown of the Biological Weapons Convention.25 The possibility of a war between great powers could also increase the pressure to use such weapons—during the World Wars, bioweapons were used across multiple continents, with Germany targeting animals in WWI,26 and Japan using plague to cause an epidemic in China during WWII.27 Non-state actors may also pose a risk, especially those with explicitly omnicidal aims. While rare, there are examples. The Aum Shinrikyo cult in Japan sought biological weapons **for the express purpose of causing extinction**.28 Environmental groups, such as the Gaia Liberation Front, have argued that “we can ensure Gaia's survival only through the extinction of the Humans as a species … we now have the specific technology for doing the job … several different [genetically engineered] viruses could be released”(quoted in ref. 29). Groups such as R.I.S.E. also sought to protect nature by destroying most of humanity with bioweapons.30 Fortunately, to date, non-state actors have lacked the capabilities needed to pose a catastrophic bioweapons threat, but this could change in future decades as biotechnology becomes more accessible and the pool of experienced users grows.31,32 What is the appropriate response to these speculative extinction threats? A balanced biosecurity portfolio might include investments that reduce a mix of proven and speculative risks, but striking this balance is still difficult given the massive uncertainties around the low-probability, high-consequence risks. In this article, we examine the traditional spectrum of biosecurity risks (ie, biocrimes, bioterrorism, and biowarfare) to categorize biothreats by likelihood and impact, expanding the historical analysis to consider even lower-probability, higher-consequence events (catastrophic risks and existential risks). In order to produce reasoned estimates of the likelihood of different categories of biothreats, we bring together relevant data and theory and produce some first-guess estimates of the likelihood of different categories of biothreat, and we use these initial estimates to compare the cost-effectiveness of reducing existential risks with more traditional biosecurity measures. We emphasize that these models are highly uncertain, and their utility lies more in enabling order-of-magnitude comparisons rather than as a precise measure of the true risk. However, even with the most conservative models, we find that reduction of low-probability, high-consequence risks can be more cost-effective, as measured by quality-adjusted life year per dollar, especially when we account for the lives of future generations. This suggests that despite the low probability of such events, society still ought to invest more in preventing the most extreme possible biosecurity catastrophes.

### Covid CP

#### Counterplan: The World Trade Organization ought to

#### -Increase covax support

#### -prioritize trade facilitation

#### -commit to aid for LDC’s

#### -invest in pandemic preparedness

[**Violeta Gonzalez**](https://www.devex.com/news/authors/1581504)8-1-20**21**, "Opinion: 4 ways to promote vaccine equity through trade," Devex, https://www.devex.com/news/opinion-4-ways-to-promote-vaccine-equity-through-trade-100457

### As of Monday, only [1.1 % of people in low-income countries](https://ourworldindata.org/covid-vaccinations) had received at least one COVID-19 vaccine dose. This is making it harder to battle a third wave of infections, as the highly transmissible [delta variant](https://news.un.org/en/story/2021/07/1095152) spreads across many nations. In the [World Health Organization](https://www.devex.com/organizations/world-health-organization-who-30562)’s Africa region — where a [high number](https://www.uneca.org/sites/default/files/com/2021/E2100045-English-CoM21-Progress-in-the-implementation-of-the-priority-areas-of-the-Programme-of-Action-for-the-Least-Developed-Countries-for-the-Decade-2011-2020_Istanbul-Programme-of-Action.pdf) of LDCs are located — COVID-19 fatalities [surged 44.2%](https://apps.who.int/iris/bitstream/handle/10665/342715/OEW28-0511072021.pdf) over one week in July. The coronavirus is [devastating](https://www.un.org/development/desa/dpad/2021/major-study-on-covid-19-impact-on-ldcs-released/) many LDCs’ already fragile economies and causing poverty and inequality to rise. Without equitable access to vaccines, [global economic recovery cannot be sustained](https://www.wto.org/english/news_e/news21_e/gc_05may21_e.htm) and progress toward the Sustainable Development Goals will be derailed. While trade alone cannot eradicate vaccine unequity or its negative consequences for the [economy](https://news.un.org/en/story/2021/05/1091732) and [vulnerable groups](https://observatoryihr.org/news/covid-19-vaccine-distribution-highlights-social-inequality/), it has a powerful contribution to make. Here are four actions that would make an impact: 1. Increase COVAX support Vaccine equity can only be achieved if the global community eschews vaccine nationalism. High-resource countries should [ramp up donations](https://www.devex.com/news/wto-chief-to-g-20-donate-2-3b-more-covid-19-vaccine-doses-100306) through the vaccine-sharing initiative COVAX and commit to securing a swift, workable resolution to ongoing debates around [technology transfers and intellectual property waivers](https://www.devex.com/news/wto-council-offers-hope-for-trips-vaccine-proposal-100125). While countries in the G-7 group of nations have [pledged to increase their support](https://www.who.int/news/item/13-06-2021-g7-announces-pledges-of-870-million-covid-19-vaccine-doses-of-which-at-least-half-to-be-delivered-by-the-end-of-2021) for COVAX, the initiative has faced hurdles in the form of [supply bottlenecks](https://www.devex.com/news/india-crisis-puts-covax-150-million-doses-behind-schedule-99860), [export restrictions](https://unctad.org/news/export-restrictions-do-not-help-fight-covid-19), and [logistical weaknesses](https://www.devex.com/news/the-cold-chain-storage-challenge-99869). Many currently available COVID-19 vaccines have short shelf lives and must be stored at low temperatures. LDCs can only benefit from donated doses if they have fast and efficient processing at their borders, modern transportation systems, and access to cold chain infrastructure. 2. Prioritize trade facilitation Accelerating implementation of the [World Trade Organization](https://www.devex.com/organizations/world-trade-organization-wto-44694)’s 2017 [Trade Facilitation Agreement](https://www.wto.org/english/tratop_e/tradfa_e/tradfa_e.htm) is critical for helping LDCs overcome these challenges. A total of [154 WTO members](https://www.tfafacility.org/ratifications) now support the agreement, which pledges investment in the simplification and modernization of the movement, release, and customs clearance of goods globally. It also aims to help low-income countries overcome these same barriers through technical assistance and capacity building. The [Global Alliance for Trade Facilitation](https://www.devex.com/organizations/global-alliance-for-trade-facilitation-102992) has made good progress in identifying barriers to vaccine equity and introducing solutions. In [Mozambique](https://www.tradefacilitation.org/article/two-new-mozambique-projects-aim-to-ease-access-to-vaccines-medical-products/), for example, the alliance is working to digitalize pre-shipment authorization for vaccine imports — a process that can take as long as two weeks, during which vaccine doses must be kept in storage. This digitalization should help Mozambique decrease wait times, improve shipment traceability, and reduce storage and inventory management costs. Yet more work remains to help governments overcome [challenges associated with implementing](https://www.wto-ilibrary.org/trade-facilitation-and-customs-valuation/world-trade-report-2015_f2985d96-en) the Trade Facilitation Agreement, such as changing domestic legislation and involving the private sector. Lower-income countries and LDCs have flagged a need around human resources and training, legal assistance, and the acquisition of information and communication technologies. 3. Commit to Aid for Trade For LDCs to participate fairly in global vaccine supply chains — as importers or exporters of inputs and finished products — they need financial and technical assistance to strengthen their [productive capacity](https://www.devex.com/news/cepi-ceo-concerted-effort-needed-to-build-lmic-vaccine-manufacturing-100013), streamline their cross-border standards and processes, and improve their logistics infrastructure and [technological know-how](https://www.wto.org/english/news_e/news21_e/dgno_21may21_e.htm). The Aid for Trade initiative exists to provide that support — but can only deliver if donor countries maintain or increase their official development assistance, or ODA. Preliminary figures from the [Organisation for Economic Co-operation and Development](https://www.devex.com/organizations/organisation-for-economic-co-operation-and-development-oecd-29872) show that [Development Assistance Committee](https://www.devex.com/organizations/development-assistance-committee-dac-100607) members [expanded their ODA by $10 billion](https://www.devex.com/news/what-to-make-of-the-2020-dac-stats-99641) between 2019 and 2020, mostly as part of their COVID-19 response. However, with several government donors having reprogrammed their aid budgets to focus on immediate health priorities, [fears are growing](https://www.weforum.org/agenda/2021/01/helping-small-businesses-build-resilience/) that their overall ODA may also be slashed — and, with this, their support for Aid for Trade. The generosity of some countries provides hope. Norway, for example, recently stepped up to help plug such gaps with [45 million Norwegian kroner](https://www.wto.org/english/news_e/news21_e/if_22jun21_e.htm) of additional funding for the WTO-backed [Enhanced Integrated Framework](https://www.devex.com/organizations/enhanced-integrated-framework-eif-78046), a global Aid for Trade program that aims to reduce poverty. 4. Invest in preparedness In 2019, only [$374 million](http://www.healthdata.org/sites/default/files/files/policy_report/FGH/2020/FGH_2019_Interior_Final_Online_2020.09.18.pdf) — or less than 1% — of the world’s total development assistance for health was spent on pandemic preparedness. Within months, the consequences of that underinvestment became clear. Integrating lower-income countries and LDCs into global and regional [pharmaceutical value chains](https://unctad.org/news/unctad-report-says-least-developed-countries-position-improve-access-medicines-through-local-0) is vital for ensuring the world is better prepared next time. Directing increased aid to help these countries become [producers and exporters](https://www.bloomberg.com/news/articles/2021-07-26/africa-must-build-vaccine-production-capacity-wto-chief-says) of medical equipment and vaccines has never been more needed. LDCs would not only receive more of the [vaccines and therapeutics they need now](https://trade4devnews.enhancedif.org/en/op-ed/access-denied-ensuring-vaccines-worlds-poorest-countries) but could actively contribute to the global response when th

### CP- FDA Reg (Prices)

#### CP text: Denationalize drug approvals by establishing an international drug approval agency.

Henderson and Hooper 15, Henderson, David,( phd) and Charles Hooper (ms). To Increase Innovation and Make Drugs More Affordable, Deregulate, Journal of Clinical Pathways, Sept. 2015, www.hmpgloballearningnetwork.com/site/jcp/article/increase-innovation-and-make-drugs-more-affordable-deregulate.

The first, and, in our opinion, more effective means of reducing drug prices is to make it easier for drug companies to introduce new drugs to the market. Under current legislation, all drugs are essentially illegal until the FDA approves them. Drug companies cannot get approval simply by showing that a drug is safe; they also must show that it is efficacious when used at a particular dosage for a particular ailment. Moreover, in recent years the FDA has required larger and larger groups of patients to be tested. All of this is extremely costly. In 2003, DiMasi et al.1 estimated that the total cost of a successful new drug was $802 million. Christopher P. Adams and Van V. Brantner2, an economist and a research analyst, respectively, at the US Federal Trade Commission, tried to replicate this figure in 2003, using different data, and found the cost to be slightly higher—$868 million. More recently, DiMasi et al.3 estimated that the cost to bring a drug successfully to market is $2.558 billion, a number that seems reasonable given the previous estimates and the methodology used. Why is this number so high? It is because so much of research and development is spent on drugs that do not make it to market. In reaching their conclusion, DiMasi et al.3 take account of the probability that a drug will actually make it to market. That way, they include all the “dry holes”: the drugs that didn’t work at all, the drugs that were too unsafe, and the drugs that were not efficacious enough. We argue that the cost of bringing a new drug to market would fall substantially if drug companies did not have to depend on FDA approval. There are two simple changes that could be made, while still retaining the FDA. The first is to denationalize drug approvals by granting international drug approval authority to a dozen or so respected government regulatory bodies around the world, such as the European Medicines Agency and the Health Products and Food Branch of Health Canada. The FDA and Health Canada approve drugs using similar methods and with similar objectives; why should residents in Bellingham, WA, be given access to new drugs potentially years after their neighbors in Vancouver? As Daniel B. Klein explained in an article for the Library of Economics and Liberty: “Under the proposal, the FDA would have to compete in giving permission” (italics in original).4 Safety and efficacy would still be paramount, but regulatory agencies would compete on cost, efficiency, and reasonableness. Government agencies are non-profit institutions, but they often charge pharmaceutical companies a fee for considering their drugs for approval. For instance, in the United States, the FDA’s Prescription Drug User Fee Act (PDUFA) fees can total $2-3 million per approval.5 Such fees may be lower in other countries. Additionally, delays and unneccessary clinical trials result in even greater costs to pharmaceutical companies. For a drug that will have sales of $365 million per year, for example, every day of delay costs the producer of that drug $1 million. Additionally, the cost of conducting clinical trials can total tens or hundreds of millions of dollars. Therefore, the cost of bringing a drug to market would be greatly reduced with a speedier approval process and reduced clinical trials requirements. One may reasonably inquire about the incentives for these regulatory agencies to compete for the opportunity to grant drug approvals. In addition to competeing on the basis of revenues from fees, such as the PDUFA fees, agencies would also compete for reasons of status and organizational power. The latter motivation has been supported by research on the concept of public choice, which proposes that even those who work in government agencies are motivated chiefly by their own self-interests.6 The second change we propose is to allow drug companies to sell drugs that are not FDA-approved as long as the drug company states clearly, in large letters, in the package insert and on the container in which the drug is sold, “This drug has NOT been certified by the FDA.” Pharmacists could help disseminate this caution. This second reform sounds radical; but it can actually make all patients either better off, or at least not worse off, by their own standards. Patients can be divided into two categories: (1) those who insist on FDA certification of any drug they take, and (2) those who are willing to take drugs that are certified by non-FDA certifiers. These non-FDA certifiers could include: U.S. Pharmacopeia, U.C. Berkeley Wellness Letter, Consumer Reports, Drug Facts and Comparisons, medical journals, the multitude of guideline-setting bodies (e.g., American Academy of Pediatrics, American Thoracic Society, National Comprehensive Cancer Network, National Kidney Foundation, and American Heart Association), the Agency for Healthcare Research and Quality, and even HMOs, hospitals, health insurers, or patients’ doctors. These organizations review the available evidence and, using a variety of criteria, make recommendations about which drugs are safe and efficacious for various conditions and which ones aren’t. Indeed, many of these organizations are more knowledgeable about diseases and their treatments than FDA employees. Drugs that are approved by any of these other certifiers, but not by the FDA, will not be taken by patients in the previously described first category; therefore, they will be neither better nor worse off under the new proposed system. But consider patients in the previously described second category. These patients will not have to wait for a drug to be approved by the FDA before they can take it. Therefore, some drugs will be available to them more quickly. Therefore, these patients, by their own standards, will be better off. One might argue that people should not be allowed to take drugs that have not been approved by the FDA. But a large majority of Americans now take drugs that the FDA has not certified; we refer to off-label uses of drugs. An off-label use is a use of a drug that the FDA has not approved for that particular use. Off-label prescribing is legal,7 widely practiced, and actively encouraged by Congress,8 the National Institutes of Health,9,10 Medicare,8 the Veterans Administration,11 and the National Cancer Institute.12 Indeed, a large percentage of the uses of drugs are off-label.8 Consider gastroparesis, a poorly understood upper gastrointestinal disorder in which the contents of the stomach do not move efficiently into the small intestine. Diabetics are particularly susceptible to this condition,13 for which there is only one FDA-approved drug: metoclopramide. Physicians have discovered that another drug, erythromycin, an antibiotic, helps reduce nausea, vomiting, and abdominal pain for some patients. Although erythromycin is not FDA-approved for gastroparesis, it unquestionably helps patients with this condition.14 Off-label uses in oncology can reach 90% of all treatments.12,15 There are some diseases for which there are no approved therapies; in those cases, 100% of the uses are off-label. For example, amyloid light-chain amyloidosis, for which there are no approved medicines, is often treated with medicines approved for related diseases, such as multiple myeloma.16 If it makes sense to allow people to use drugs for off-label uses, then it also makes sense for them to use drugs that the FDA has not approved for any use. Concerns about the potential toxicity of drugs not approved by the FDA could be addressed by instituting a requirement that all drugs at least complete a Phase I clinical trial before being brought to market. That makes our suggested reform what economists call a Pareto improvement: an action that harms no one and helps at least one person.17 Few potential reforms would make some people better off while making no one worse off; we should implement those few. How would these reforms accomplish the goal we began with: encouraging innovation while keeping drugs affordable? With the possibility of marketing and selling drugs without FDA approval, drug companies would face a lower upfront cost of bringing drugs to market. In turn, there would be more innovation. A lower cost required to move drugs through the research pipeline would mean that more drugs would make it to the market and, thus, would be available to patients. A drug that otherwise would not have been available at all, or would have been available later, could make an enormous difference to patients and even potentially save lives. As for the goal of making drugs more affordable, lowering the costs of research and development alone would not necessarily cause drugs to be cheaper. From the perspective of a profit-maximizing company, these costs are sunk and will be regarded as irrelevant in setting prices. The company will set the price of a drug based on what the market will bear. But now consider another positive effect of our reform: increased competition. With a lower cost of research and development, some new drugs that would otherwise not have existed or would have come later will compete with existing drugs. Some of these drugs would be cheaper than the existing drugs with which they compete. With more available products on the market, some companies, in an effort to gain market share, will price their drugs lower than existing competitors. Additionally, drug companies could justify higher prices for approved drugs that underwent the FDA drug approval process. As a result, those drugs that are not FDA approved might be priced lower in an attempt to compete better with drugs that are FDA approved. This competition will put pressure on sellers of FDA-approved drugs to lower prices, or at least not raise them as much.