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**Covid-19 has supercharged innovation in the status quo**

**Ramalingam & Prabhu 20** [Ben Ramalingam- Overseas Development Institute, United Kingdom. Jaideep Prabhu University of Cambridge, United Kingdom. “Innovation, development and COVID-19: Challenges, opportunities and ways forward.” OECD. 1 December 2020. Link: <https://www.oecd.org/coronavirus/policy-responses/innovation-development-and-covid-19-challenges-opportunities-and-ways-forward-0c976158/>] JV

Coronavirus (COVID-19) innovation: what is happening? A global perspective At the same time as causing a huge impact on health and livelihoods around the world, COVID-19 has a created fertile breeding ground for novel solutions and approaches (OECD Observatory of Public Sector Innovation, n.d.[2]). The most comprehensive survey of global research and development (R&D) funding commitments for COVID-19, undertaken by the US-based Policy Cures programme, shows that investment in health-related innovation has been unprecedented (Policy Cures, 2020[3]). The scale of innovation resources mobilised globally is remarkable: USD 9 billion in seven months. By comparison, the total global funding disbursed for Ebola R&D between 2014 and 2018 was USD1.9 billion. The nature of the innovation processes that have been deployed is also notable. In the six months since the outbreak began, the US Food and Drug Administration (FDA) has approved almost 100 COVID-19 tests, in contrast to the three months the FDA took to approve the first Ebola test during the 2014 West Africa outbreak. The first COVID-19 vaccine entered into human trials within a record-breaking 69 days of identifying the causative agent of the outbreak[1](https://www.oecd.org/coronavirus/policy-responses/innovation-development-and-covid-19-challenges-opportunities-and-ways-forward-0c976158/#endnotea0z2) – a remarkable achievement, considering that it took 25 months for the first vaccine to reach the human trial stage during the previous global coronavirus outbreak (SARS in 2002–04).

**Waiving patent on COVID-19 vaccine would hurt innovation needed to combat future pandemics**

**Okutsu & Sharma 21** [Akane Okutsu: Japan based reporter. Kiran Sharma: India based reporter. “Vaccine patent waiver: COVID stopper or innovation killer?” Nikkei Asia. 14 May 2021. Link: <https://asia.nikkei.com/Spotlight/Coronavirus/COVID-vaccines/Vaccine-patent-waiver-COVID-stopper-or-innovation-killer>] JV

One major concern is a loss of incentives for costly research and development. Pharmaceutical research has a low success rate and requires enormous sums of money. Without the profits generated from intellectual property rights, "there would be no new drugs," as companies would have no hope of recouping their investments, a JPMA spokesperson said. Ito said this raises "concerns about how to respond to future pandemics." Speedy vaccine development, he said, is driven in part by the chance to corner the market. If the patents are to be waived, Ito suggested other steps to spur innovation will be needed, such as establishing a fund to buy such knowledge. But setting prices and deciding how to deal with the technical secrets would be no easy task. Ito said a quicker solution might be for Group of Seven countries to "consider policies to expand production capacity and strengthen the [World Health Organization's] COVAX initiative to purchase and distribute vaccines to developing countries."

**Medical innovation is crucial to prevent pandemics and mitigate economic harms during shut downs**

**Mulligan 21** [Casey B. Mulligan– American economist and author. He is a Professor in Economics at the University of Chicago. “Economic activity and the value of medical innovation during a pandemic” Cambridge University Press. 9 June 2021. Link: <https://www.cambridge.org/core/journals/journal-of-benefit-cost-analysis/article/economic-activity-and-the-value-of-medical-innovation-during-a-pandemic/864F8042F794D4417E64C643999C9280>] JV

Medical innovation can reduce the duration and severity of pandemics. In doing so, innovation reduces the duration and severity of the direct health costs as well as the costs of economic shutdowns intended to mitigate the health costs. As long as it remains a major barrier to medical innovation, regulation will unnecessarily add to the economic and health costs of the current pandemic (Peltzman, 1973; Philipson & Sun, 2008). Innovation is not finished when scientists discover a new medicine, device, or technique and demonstrate its safety. Pandemic medicines and equipment need to be manufactured and distributed on a massive scale. Personnel need to be trained to administer new treatments. These processes can be slowed by regulatory barriers ranging from federal inspections of facilities manufacturing drugs and devices to state occupational licensure. Although not new, disease testing and contact tracing are essential techniques that are scalable in principle, but early in the pandemic were unavailable in the USA in more than small quantities. Regulatory barriers slow both the manufacturing of these devices and techniques as well as the development of more scalable methods for distributing them.

**Pandemics are a non-linear, existential risk---encompasses AND outweighs other threats. Empirically proven by historic epidemics such as the Black Death and Spanish flu**

**Pamlin and Armstrong 15**, Dennis Pamlin, Executive Project Manager Global Risks, Global Challenges Foundation, and Stuart Armstrong, James Martin Research Fellow, Future of Humanity Institute, Oxford Martin School, University of Oxford, February 2015, “Global Challenges: 12 Risks that threaten human civilization: The case for a new risk category,” Global Challenges Foundation, p.30-93, <https://api.globalchallenges.org/static/wp-content/uploads/12-Risks-with-infinite-impact.pdf> //Re DE EK

4 Global A pandemic (from Greek πᾶν, pan, “all”, and δῆμος demos, “people”) is an epidemic of infectious disease that has spread through human populations across a **large region**; for instance **several continents**, or even **worldwide**. Here only worldwide events are included. A widespread endemic disease that is stable in terms of how many people become sick from it is not a pandemic. 260 84 Global Challenges – Twelve risks that threaten human civilisation – The case for a new category of risks 3.1 Current risks 3.1.4.1 Expected impact disaggregation 3.1.4.2 Probability Influenza subtypes266 Infectious diseases have been one of the **greatest causes of mortality in history**. Unlike many other global challenges pandemics have happened recently, as we can see where reasonably good data exist. Plotting historic epidemic fatalities on a log scale reveals that these tend to follow a **power law with a small exponent**: many plagues have been found to follow a power law with exponent 0.26.261 These kinds of power laws are heavy-tailed262 to a significant degree.263 In consequence most of the fatalities are accounted for by the top few events.264 If this law holds for future pandemics as well,265 then the majority of people who will die from epidemics will likely die from the **single largest pandemic**. **Most epidemic fatalities follow a power law, with some extreme events – such as the Black Death and Spanish Flu – being even more deadly.**267 There are other grounds for suspecting that such a highimpact epidemic will have a ***greater probability*** *than* ***usually assumed****.* All the features of an extremely devastating disease **already exist in nature**: essentially **incurable** (Ebola268), nearly always **fatal** (rabies269), **extremely infectious** (common cold270), and **long incubation periods** (HIV271). If a pathogen were to emerge that somehow **combined these features** (and influenza has demonstrated **antigenic shift**, the ability to combine features from different viruses272), its death toll would be extreme. Many relevant features of the world have changed considerably, making past comparisons problematic. The modern world has better sanitation and medical research, as well as national and supra-national institutions dedicated to combating diseases. Private insurers are also interested in modelling pandemic risks.273 Set against this is the fact that **modern transport** and **dense human population** allow infections to spread much more rapidly, and there is the potential for urban slums to serve as breeding grounds for disease.275 Unlike events such as nuclear wars, pandemics would not damage the world’s infrastructure, and initial survivors would likely be resistant to the infection. And there would probably be survivors, if only in isolated locations. Hence the risk of a civilisation collapse would come from the **ripple effect** of the fatalities and the policy responses. These would include **political and agricultural disruption** as well as **economic dislocation** and damage to the world’s **trade network** (including the food trade). **Extinction risk** is only **possible** if the aftermath of the epidemic **fragments and diminishes human society** to the extent that recovery becomes impossible277 before humanity succumbs to **other risks** (such as **climate change** or **further pandemics**). Five important factors in estimating the probabilities and impacts of the challenge: 1. What the true probability distribution for pandemics is, especially at the tail. 2. The capacity of modern international health systems to deal with an extreme pandemic. 3. How fast medical research can proceed in an emergency. 4. How mobility of goods and people, as well as population density, will affect pandemic transmission. 5. Whether humans can develop novel and effective anti-pandemic solutions.

## CP

**CP Text: The member nations of the World Trade Organization should decrease tariffs and export restrictions.**

**Exports are necessary for access to vaccines.**

**Peters and Prabhakar 6-11** Ralf Peters is the chief of UNCTAD's trade information section. Divya Praghakar is a trade and development policy specialist working in the same section. , 6-11-2021, "Export restrictions do not help fight COVID-19," Unctad, <https://unctad.org/news/export-restrictions-do-not-help-fight-covid-19>, accessed 8/20/2021 EH

Brazil, India, Laos, Nepal, Peru, Thailand: **new** and **even more catastrophic waves of COVID**-19 have **hit the developing world**. On top of this, the world is also witnessing another phenomenon – vaccine nationalism. Come summer, wealthy nations are beginning to return to normal, while the rest of the world continues the struggle to vaccinate its population. Many are eyeing the G7 countries, who are set to meet in June, to lead the way to vaccine equity. But two questions persist: **why are vaccines not reaching everyone**? And what can we do about it? As the pharmaceutical powerhouse of the world and a key supplier of the COVAX initiative, **India** was poised to help a great number of developing and least developed countries by supplying COVID vaccines. However, facing a catastrophic second wave itself, it has not only **stopped exporting vaccines, but is now beginning to import them**. The **implications** of this could be **severe**, particularly for poorer countries that were depending on India. The ripple effects would **hit the most vulnerable countries the hardest**, leaving them behind in the respective vaccination drives. 60% of vaccines for 20% of the population The WHO has already warned of a new wave in Africa, where vaccine imports have slowed down since India stopped exporting. But it is **not just India**. **Other vaccine producing countries** like the **US** and the **E**uropean **U**nion have **imposed restrictions on exports of vaccines and critical raw materials needed for its production**. This is **despite having already hoarded over 60% of the world’s vaccines before** they were **even approved for use**. These developed countries comprise no more than 20% of world’s population. The **production** of vaccines is **highly concentrated**, mainly in a small number of higher and middle-income countries. The **necessary raw materials**, too, are **imported** from only a **handful** of countries. The two top exporters of key ingredients, for instance, are the US and the EU – which account for half of total exports – followed by the UK, Japan and China, with significantly smaller shares. This implies that **restrictions on exports of vaccines or other critical raw material and equipment by even one or two countries** can **easily send shockwaves through the rest of the world, derailing the entire vaccine production and distribution effort,** as we see at present. **Export restrictions are not exclusive to vaccines**. Over 80 countries had resorted to **banning exports of medical** and personal protective **goods** in the early phases of the pandemic. This too **had severe supply chain implications**. Nearly **60% of these curbs are still in place**. Ultimately, these export restrictions may come back to bite the countries who imposed them. As the virus continues to mutate, it may render vaccines ineffective and the already vaccinated less immune. The global economy, too, will not revive until everyone is vaccinated, since lockdowns and social distancing norms in key manufacturing locations continue to curtail global trade. Besides, this is a huge moral failure on the part of the global community. A turning point? The subject of export restrictions should be tackled at the WTO. The pandemic should serve as both a reference and a turning point. Reviving the debate around emergency export bans should form a key part of the WTO reform agenda. The current rules allow for temporary export restrictions or prohibitions to prevent or relieve critical shortages of essential products, provided all measures are communicated, have phase out timelines and are proportionate to the scale of the problem at hand. But who decides what constitutes proportionate, and what timeline is reasonable? **Export restrictions are sometimes seen as a necessary instrument to ensure popular acceptance of multilateral trade agreements.** The latter is important. **However, open markets do not fit with sudden export restrictions during a pandemic**. It is perhaps **time for stricter rules on essential goods**, which can ensure transparency through more effective monitoring and review of members states’ trade policies during emergencies. Some sort of “compulsory” provisions to ensure that dependent countries’ interests are accounted for in emergency situations should be agreed upon. The declaration of a pandemic by the WHO could be one objective trigger for the state of emergency, a declaration by the FAO of a food shortage another. A recent UN policy brief calls for an agreement not to impose export restrictions on essential foodstuffs destined for food-deficit developing countries during an emergency situation. Achieving full transparency through strengthened notifications is a relatively low hanging fruit, but already **an important measure**. Special and differential treatment provisions, without much wriggle room for major exporters, should be emphasised. **The global community needs to present a united front now so that everyone is equally prepared in future crises**. Outside the WTO, national governments and the private sector will have to reduce their over-reliance on a small number of manufacturing sites for vaccines or other pharmaceutical goods, which, as the pandemic has shown, can be quite costly.

**Waivers do nothing—exports solve**

**Meyer 21** David Meyer, 6-18-2021, "The WTO’s survival hinges on the COVID-19 vaccine patent debate, waiver advocates warn – Fortune," Fortune, https://fortune.com/2021/06/18/wto-covid-vaccines-patents-waiver-south-africa-trips/amp/, accessed 7/18/2021 EH

Big Pharma’s stance on the issue is that **WTO** members **can help the effort without backing a waiver, but instead by pushing for the lifting of export restrictions on medical goods. “The WTO still has much concrete work to do to remove trade barriers that are hurting manufacture and distribution of vaccines, therapeutics and diagnostics globally,”** says Thomas Cueni, director general of the Geneva-based International Federation of Pharmaceutical Manufacturers & Associations (IFPMA). “**The call for waiving patents is driven by a political agenda playing to the gallery and not bringing a single more vaccine short term but could jeopardize the very framework which has helped us to respond so fast to the COVID-19 pandemic.”** Mercurio also says Mlumbi-Peter and Wallach’s suggestions are agenda-driven. “I think the **comments that the WTO’s credibility rests on the outcome of a TRIPS waiver** (which I am against and have written on) **are overstated, in the extreme**,” he says. “**People with an interest in every topic say it**—environmentalists say the credibility rests on the outcome of fishery subsidies, tech people say the same on the e-commerce and services negotiations, and industrialists say the same regarding subsidies.” However, Wallach insists that **nothing about the waiver would change the system, because the system already provides for such temporary suspensions of intellectual-property protections**. “This doesn’t change a comma in the actual TRIPS agreement,” she says. “The WTO is the relevant forum, and it has the relevant policy tools to respond to the current pandemic by addressing IP barriers so as to ramp-up and diversify production across the world,” says Mlumbi-Peter. IFPMA’s Cueni says “**taking away the patent won’t do anything short term for the current pandemic” as the real problems are trade barriers and scarcity of raw materials**. There is also a clear need for technology transfers if new COVID-19 vaccine-making facilities are to come online—though it should be noted that the vaccine companies have all failed to contribute to the World Health Organization’s COVID-19 Technology Access Pool (C-TAP), which was set up last year as a way for them to voluntarily help other manufacturers join the effort.

## Case

### HIV/AIDS

#### Removing patents won’t do much to solve the HIV/AIDS problem

**Gillespie-White 2000** [Lee Gillespie-White, Venus Griffith, Albena Petrova and Stetson Sanders of the IIPI staff, and Paul Salmon of the World Intellectual Property Organization. “Patent protection and access to HIV/AIDS pharmaceuticals in Sub-Saharan Africa.” The world intellectual property organization. December 2000. Link: <https://www.wipo.int/export/sites/www/about-ip/en/studies/pdf/iipi_hiv.pdf>] JV

The patent issue, likewise, is dramatically overplayed in the discussions on access to HIV/AIDS medicines. The perception that patents are blocking access to HIV/AIDS drugs is also overly simplistic and incorrect. As discussed in Chapter 3 of this report, our patent surveys shows that most antiretroviral medications are not widely patented in Africa. In the majority of countries of sub-Saharan Africa where no patents exist, there is still a dramatic lack of access to drugs. Similarly, there are tremendous access problems with medicines long ago off patent. Where patents do exist, the TRIPS Agreement permits a great deal of flexibility to seek compulsory licenses or parallel imports of drugs under patent. The United States and European Union have indicated that they will not oppose such practices consistent with the TRIPS Agreement. While it may be easy to use the drug industry as a scapegoat, patents are not blocking access to HIV/AIDS medications in sub-Saharan Africa. Even if antiretroviral HIV/AIDS drugs were made available free tomorrow, there is a lack of health care infrastructure to conduct testing, store and distribute medications, and monitor patient compliance with what are often very complicated regimens. Nils Daulaire, President of the Global Health Council, is among a growing chorus acknowledging that the challenge is much deeper than cheaper medications. “Even if AIDS drugs were free, no more than 10 to 20 percent of Africans would benefit as the health infrastructures do not exist to manage infections in each individual”, he said.79 Compounding the problem is the fact that in some countries, governments lack the political will to direct needed attention and resources to the problem of HIV/AIDS.

#### Alternative causes to lack of access to HIV/AIDS drugs

**Gillespie-White 2000** [Lee Gillespie-White, Venus Griffith, Albena Petrova and Stetson Sanders of the IIPI staff, and Paul Salmon of the World Intellectual Property Organization. “Patent protection and access to HIV/AIDS pharmaceuticals in Sub-Saharan Africa.” The world intellectual property organization. December 2000. Link: <https://www.wipo.int/export/sites/www/about-ip/en/studies/pdf/iipi_hiv.pdf>] JV

It is increasingly widely accepted that the lack of availability of HIV/AIDS medicines is the result of a wide and complex range of causes, primary amongst which is a lack of financial resources to fund the health care system in general. Per capita incomes, and hence the availability of private resources for expenditures on medicines (whether generic or branded), are among the lowest in the world in subSaharan Africa. Governments also lack the resources to adequately fund health care infrastructure given their high debt burdens and the vast number of competing spending needs. According to the WHO, public spending on drugs in over three dozen countries, many in sub-Saharan Africa, is less than $2 per capita per year. “In such countries, inadequate and misdirected financing is arguably the greatest barrier to access to lifesaving essential drugs.”80 Further complicating the problem is the lack of insurance. Only 10.3% of the population of sub-Saharan Africa are covered by health insurance, requiring out-of-pocket expenditure that accounts for up to 80% of total health expenditures in some countries.81 According to the WHO, “Affordability of drugs could be increased substantially however, by eliminating or reducing import duties, distribution costs and dispensing fees. These can account for up to 80% of the total price paid for drugs. In particular, import duty can be as high as 30%, while value-added and other national and local taxes can amount to 20% of a drug cost.82 Current levels of foreign assistance are completely inadequate to support the needed costs to build the needed infrastructure and support drug purchase costs. This is true whether the purchase of generic drugs or patented drugs is involved. As noted recently in the newsletter of the AIDS advocacy organization Project Inform: “The cost of drugs is only a small part of the problem. Building the necessary medical infrastructure will also be costly, as will be meeting the most fundamental needs for food and clean water. … President Clinton has declared the spread of AIDS in developing nations an urgent matter of US national security. If we believe this, then he and other western heads of state must begin to treat it as such. Just as they met to discuss intervention in Bosnia or to launch warfare against Iraq, they must now meet to plot out national and international strategy against this threat. They must begin negotiations and planning efforts with the heads of the affected nations, as well as grass roots representatives of the people in those nations. And they must begin to adjust their thinking in terms of dollars. Current efforts amount to a few hundred million dollars here and there, this from a country that spends roughly one and a half billion each time the space shuttle makes a supply run into orbit.”83

## COVID VACCINE

#### Waiving covid patents will start a scramble for resources that will actually slow vaccine production

**Breuninger 21** [Kevin Breuninger: CUNY Graduate School of Journalism. “Pfizer CEO opposes U.S. call to waive Covid vaccine patents, cites manufacturing and safety issues.” CNBC. 7 May 2021. Link: <https://www.cnbc.com/2021/05/07/pfizer-ceo-biden-backed-covid-vaccine-patent-waiver-will-cause-problems.html>] JV

[Pfizer](https://www.cnbc.com/quotes/PFE) CEO Albert Bourla warned Friday that waiving patent protections for Covid vaccines — [a proposal President Joe Biden just endorsed](https://www.cnbc.com/2021/05/05/us-backs-covid-vaccine-intellectual-property-waivers-to-expand-access-to-shots-worldwide.html) — would set off a worldwide race for raw materials that threatens the safe and efficient manufacturing of Covid shots. The Biden administration said Wednesday it supports the limited waiver of intellectual property rules in service of expanding vaccine distribution to the lower-income nations currently being battered by [the pandemic](https://www.cnbc.com/coronavirus/). But Bourla, whose company produces one of three vaccines approved for emergency use in the U.S., said that he believes “categorically” that the waiver proposal will “create more problems.” “Currently, infrastructure is not the bottleneck for us manufacturing faster,” Bourla wrote in a dear colleague [letter posted on LinkedIn](https://www.linkedin.com/pulse/today-i-sent-letter-have-candid-conversation-our-drivers-bourla/?trackingId=d3cDOlWvR4SUfMQpxVeLbw%3D%3D). “The restriction is the scarcity of highly specialized raw materials needed to produce our vaccine.” Pfizer’s vaccine requires 280 different materials and components that are sourced from 19 countries around the world, Bourla said. He contended that without patent protections, entities with much less experienced than Pfizer at manufacturing vaccines will start competing for the same ingredients. “Right now, virtually every single gram of raw material produced is shipped immediately into our manufacturing facilities and is converted immediately and reliably to vaccines that are shipped immediately around the world,” Bourla wrote. He predicted that the proposed waiver “threatens to disrupt the flow of raw materials.” “It will unleash a scramble for the critical inputs we require in order to make a safe and effective vaccine,” Bourla wrote. “Entities with little or no experience in manufacturing vaccines are likely to chase the very raw materials we require to scale our production, putting the safety and security of all at risk,” the CEO wrote.The White House referred CNBC’s outreach on Bourla’s post to the Office of U.S. Trade Representative, which did not immediately respond to a request for comment. World Trade Organization leaders have recently urged member nations to come to an agreement on the potential vaccine patent waivers. But even with the U.S. backing, a deal is hardly guaranteed, since the WTO’s rulings are based on consensus, requiring approval from all 164 members. Germany, a WTO member and the largest economy in Europe, came out against the waiver proposal on Thursday. [BioNTech](https://www.cnbc.com/quotes/BNTX), which partnered with Pfizer in developing the vaccine, is based in Germany. Bourla on LinkedIn also expressed concern that the possible vaccine waivers “will disincentivize anyone else from taking a big risk.” “The recent rhetoric will not discourage us from continuing investing in science. But I am not sure if the same is true for the thousands of small biotech innovators that are totally dependent on accessing capital from investors who invest only on the premise that their intellectual property will be protected,” the CEO wrote.

#### The plan can’t solve manufacturing expertise and reduces international distribution.

**Pooley 21** [James Pooley, 5-25-2021, "The Big Secret Behind the Proposed TRIPS Waiver," IPWatchdog, <https://www.ipwatchdog.com/2021/05/25/big-secret-behind-proposed-trips-waiver/id=133905/>] //DD PT

So, this is why a temporary waiver of TRIPS—which would suspend national obligations to enforce IP rights—can’t possibly help countries like India get more vaccines to its citizens. The know-how required to manufacture at scale is owned by the companies like Pfizer and Moderna that are producing doses in record volumes. To effect the demanded “technology transfer,” governments would have to secure the agreement of those companies not just to hand over their entire “cookbook” but also to send qualified scientists and technicians to spend time at the foreign facilities, basically consulting on how to implement the secret processes to produce a safe vaccine. And even if that transfer happened tomorrow, getting to the point of actually manufacturing in volume would take more than a year. Not only would the TRIPS waiver not produce the results the proponents want, it would likely reduce the current level of international distribution of vaccines, by interfering with access to the limited supplies of required ingredients. In fact, this supply chain disruption was recently cited by none other than the government of India in pushing back against popular demands for a compulsory license on Gilead’s Remdesivir and other COVID-19 treatments, noting that the “main constraint” was not intellectual property rights but preventing competition for scarce “raw materials and other essential inputs.”

#### The plan doesn’t do anything – most pharmaceutical companies are already mass manufacturing vaccines.

Wright 21 [Elizabeth Wright, 5-10-2021, "Biden Trips Badly on Intellectual Property in TRIPS," Citizens Against Government Waste, <https://www.cagw.org/thewastewatcher/biden-trips-badly-intellectual-property-trips>] //DD PT

The waiver is not only dangerous, it is also superfluous, because Johnson & Johnson, Moderna, and Pfizer are already producing tens of millions of doses of vaccines and gearing up to produce more, and all have plans to distribute them around the world without any need for the WTO to intervene or allow their IP to be stolen. Moderna [stated](https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-agreement-sanofi-fillfinish-manufacturing) on April 26 that it was working with Sanofi to produce 200 million doses by September 2021 and [announced](https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-supply-agreement-gavi-500-million-doses-covid) on May 3 a supply agreement with Gavi (the Vaccine Alliance that supplies vaccines to the COVAX Facility) to make up to 500 million doses to help end the pandemic in the lowest income countries. Moderna is [also](https://www.expresspharma.in/covid19-updates/who-issues-emergency-use-listing-for-modernas-covid-19-vaccine/) working with the World Health Organization for the emergency use of their vaccine and UNICEF to help with distribution of vaccines. Pfizer is in the [process](https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-supply-us-100-million-additional-doses) of delivering 200 million doses in the U.S. by July 31, 2021 and [stated](https://news.yahoo.com/pfizer-supply-4-5-million-174132337.html) on May 2 it would be shipping 4.5 million doses of its COVID-19 vaccine to South Africa by June. While the company is still [waiting](https://www.msn.com/en-us/news/politics/pfizer-ceo-discussing-expedited-vaccine-approval-with-india/ar-BB1gk2qO) for India to register its COVID-19 vaccine (making it highly suspicious that the waiver is simply an attempt to steal the patents since it would be faster to finalize approval), Pfizer is already [sending](https://www.msn.com/en-us/news/politics/pfizer-ceo-discussing-expedited-vaccine-approval-with-india/ar-BB1gk2qO) other free medicines to assist their public hospitals in fighting COVID-19. Johnson & Johnson, in spite of some setbacks, resumed production on April 23 and had administered [6.8 million](https://www.baltimoresun.com/coronavirus/bs-hs-jj-returns-in-maryland-20210430-zabqvbxhwrb3dpswdtthehl3be-story.html) single-shot doses.

#### Limiting IP protections lead to a laundry list of problems—less research and drugs, employees, decline in US leadership

Kennedy 19 Joe Kennedy [senior fellow at the Information Technology and Innovation Foundation. He focuses on economic policy.], September 9, 2019, “The Link Between Drug Prices and Research on the Next Generation of Cures”, Information Technology and Innovation Foundation, https://itif.org/publications/2019/09/09/link-between-drug-prices-and-research-next-generation-cures. EH

The biopharmaceutical industry is one of America’s leading sectors in terms of funding research and employing researchers. Public policy should try to encourage its growth and protect its competitiveness. Academic studies consistently show that a reduction in current drug revenues leads to a fall in future research and the number of new drug discoveries. Policymakers need to keep this cost in mind when setting any policies that affect drug revenues. Congress could lower drug prices by expanding access to affordable insurance, streamlining regulation, especially for the manufacture of approved drugs, encouraging other countries to pay their fair share of the cost of developing new drugs. INTRODUCTION Drug prices are once again a major focus of public policy in Washington D.C. President Trump has stated that reducing drug prices is one of his highest priorities.1 The administration recently issued new regulations requiring manufactures to list the price of their drugs in television ads.2 Congress has already passed the Know the Lowest Price Act and the Patient Right to Know Drug Prices Act, both of which try to promote transparency in prices.3 The Senate Special Committee on Aging recently conducted a series of hearings on drug pricing.4 And the Senate’s bipartisan Prescription Drug Pricing Reduction Act would reduce government spending on drugs by an estimated $100 billion over the next decade.5 This renewed attention is due to several factors. In a few cases, companies have dramatically raised the prices of specific drugs in order to generate more profits.6 Although these instances have been relatively rare, they have generated a great deal of publicity and comment. In other cases, new drugs have been introduced with large price tags. For instance, Novartis recently announced its new drug Zolgensma, which treats spinal muscular atrophy, will be priced at $2.1 million for a one-time therapy.7 A large reason for the high cost is that relatively few people suffer from the disease and thus the cost of development must be spread over fewer patients. Finally, the rising cost of health care, including drugs, is placing greater pressure on individuals, insurers, and public budgets. A recent report by Accenture revealed a $30 billion gap between the expected profits of drug companies from new drug launches and the projected drug spending of the public health programs in developed countries.8 Public policy demands a constant array of trade-offs whose difficulty only makes them more important. For prescription drugs these trade-offs occur on at least three levels. At the first level, policymakers must weigh the benefits of devoting more resources to health care as opposed to other important social needs such as infrastructure, education, and income support. Second, within health care they must balance spending on pharmaceuticals against other forms of health care, the prices of which have also been rising. These trade-offs may not be so stark, however, as in many cases the use of prescription drugs reduces the cost of other forms of health care.9 There is also the difficult question of whether to devote extensive resources to help a few people with severe conditions at the expense of slightly better care for the majority. Attempts to evaluate the worth of different treatments require that we assign a cost to human life. But this cost is extremely subjective and cannot be determined by economic considerations alone.10 Finally, policymakers must choose between the respective demands of current and future patients. Government price controls and other measures to reduce drug prices, such as weakened intellectual property protection will undoubtedly help current patients. But this will come at a cost. Money not consumed today can be invested for tomorrow. For the issue of pharmaceutical drugs, an overwhelming body of academic research shows that price controls will significantly restrict the number of new drugs in the future. The pharmaceutical industry is the epitome of a dynamic high-tech industry, wherein the profits from one generation of products go to pay the high development costs for the next generation. Artificially reducing drug revenues today will not only cause companies to cut back on their future research—meaning the next generation will benefit less from new drug discoveries—it will jeopardize U.S. leadership in an industry that punches above its weight in funding research and employing scientists.11 An overwhelming body of academic research shows that price controls will significantly restrict the number of new drugs in the future. All of these trade-offs are inevitable. Because there is no one right answer, many of these decisions should be subject to the political process, wherein policymakers can weigh the views and interests of different groups. This report does not presume to make these decisions for society. However, it is critical that when making these decisions, policymakers clearly understand the benefits and costs of each option. The purpose of this report is threefold. First, it reviews some of the data regarding drug spending. Second, it reviews the pharmaceutical industry’s strong record in funding research and employing scientists. Finally, it summarizes the academic research showing a strong causal link between current drug prices and revenues on the one hand and future research and discoveries on the other. ARE DRUG PRICES TOO HIGH? In order to maximize social welfare with limited resources, policymakers need to appreciate the costs and benefits of each decision they make. In the context of drug prices, they need to clearly understand the strong link between current revenues (which may or may not be the same as consumer prices) and the generation of future drugs. Put simply, drug companies must make significant profits on their best-selling drugs in one generation in order to reinvest in the next generation. A large portion of these “profits” goes to three sources before they are available for distribution to shareholders. First, the revenues must cover the costs of the high number of failed research efforts, most of which generate no revenues. Second, they must pay for the long delays between initial research and product sales. These capital expenditures account for roughly half of the total costs of developing new drugs. Finally, a large portion of the remainder goes into new research on the next generation of drugs. Market investors quickly notice whenever companies do not have a group of promising drugs in their pipelines. As figure 1 points out, change in total spending on retail pharmaceuticals varied dramatically between 2000 and 2017. Although spending rose in later years, the increases were mostly modest. The total number of pharmaceutical doses sold (the volume of drugs) also increased, in part because of the increase in the U.S. population (up an average of 0.84 percent per year since 2000) and the increase in the elderly population which on average consumes more drugs (the population of Americans older than 65 years of old has increased an average of 2.27 percent per year since 2000).12 Figure 2, on the other hand, shows that the source of spending has changed dramatically. In 1960, fully 96 percent of all prescription drugs were paid for out of pocket. By 1980, this had fallen to 71.3 percent, and by 2000, it was 27.8 percent. In 2017, only 14 percent of prescription drugs were paid for out of pocket. Private insurance and Medicare/Medicaid paid for 42.0 percent and 40.2 percent, respectively. By 2027, the Centers for Medicare and Medicaid Services (CMS) expects the portion to decline to 12.8 percent. This trend has made many patients less sensitive to the cost of their medications. Figure 3 shows retail pharmaceutical sales as a percent of total health care spending. Although the fraction rose from 1980 to 2000, it has declined slightly since 2002 and is slightly lower than where it was in 1960. It is also projected to be relatively flat for the next decade. It should be no surprise that total health care spending is increasing, since the nation is getting richer and its population has grown. Nevertheless, total retail spending on drugs has increased almost sixfold, even after correcting for the Bureau of Labor Statistics’ consumer price index for prescription drugs (see figure 4). However, so has gross domestic product (GDP). Figure 5 shows that, as a percentage of GDP, the rise was far less dramatic—with 2017 levels below 2009 levels—and only a small portion of total income. Much of the increase has been driven by increased demand, in part as drugs have become more effective medical treatments. And much of the demand has been driven by those over the age of 65. Between 2002 and 2014, total retail spending on prescription drugs rose by $140 billion. Spending on those over the age of 65 accounted for $54 billion, or 38 percent of this rise. Yet the proportion of those over 65 in the population only rose from 12.3 percent to 14.3 percent of the total population. Figure 6 again shows total spending on retail prescription drugs, adjusted for inflation. It then adjusts this spending by the growth in the number of people ages 65 or older, revealing that when controlling for the growth of the elderly, real spending has declined 10.4 percent since 2007. The Cost of Drug Development Drug development is extremely costly for three main reasons. The first is the heavily regulated nature of the drug markets. Second, and partly due to this regulation, drug-development time is very lengthy, taking an average of 10 to 20 years. Because future revenues are worth less than those received today, a dollar of revenue in ten years will not come close to offsetting a dollar of research paid for today. Finally, drug development pushes at the boundaries of biological and chemical science, causing roughly 90 percent of all drug projects to fail.19 In order to survive, companies must recoup the costs of these failures in the revenues from the relatively rare successes. A recent study by the Congressional Budget Office (CBO) estimates pharmaceutical companies need to make a margin of 62.2 percent on their successful products in order to average a 4.8 percent rate of return on all of their assets. Based on past studies, the report assumes that 90 percent of all research spending results in no revenues, and that the approval process takes 12 years 20 A recent CBO study estimates pharmaceutical companies need to make a margin of 62.2 percent on their successful products in order to average a 4.8 percent rate of return on all of their assets. The most commonly accepted estimate of the cost of developing a new drug comes from the Tufts Center for the Study of Drug Development. Looking at drugs that began human testing between 1995 and 2007, it estimated that the average cost of developing and bringing to market a new compound had been $2.6 billion (in 2013 dollars). Post-approval costs added another $300 million. Out-of-pocket costs were $1.4 billion. The rest was the cost of capital, using a discount rate of 10.5 percent. Costs had risen over the last decade due to a decline in clinical success rates and a rise in average research costs.21 The study also found that, although tax provisions such as the research and development (R&D) and the orphan-drug tax credits reduce the cost of development, their effect is relatively small compared to the total costs. While this study has been criticized, other estimates have produced comparable results.22 The problem of rising drug costs is made worse by the fact that Americans must pay a large share of the costs of drug development. Since the United States accounts for roughly half of the global market (in terms of the amount of drugs consumed), one might normally expect it to pay for only about half of subsequent rounds of innovation.23 But many countries, including high-income ones, pursue policies that keep the prices of their patented drugs artificially low.24 Because manufacturers cannot recover much of their fixed costs overseas, they must charge higher prices in the United States in order to achieve a given rate of return. Somewhat surprisingly, some also raise the price of generic drugs in order to protect domestic manufacturers of those drugs. As a result, U.S. consumers pay approximately 70 percent of all global patented biopharmaceutical profits.25 Many countries, including high-income ones, pursue policies that keep the prices of their patented drugs artificially low. As a result, U.S. consumers pay approximately 70 percent of all global patented biopharmaceutical profits. This makes sense from the point of view of each country, particularly low-income countries. Because of their relatively small market size compared with the United States, raising drug prices would have little effect on either the amount or direction of global research. Collectively, however, price restrictions harm the global community.26 They result in significantly less research, and fewer drugs. Everyone, including Americans, would benefit if all nations contributed their fair share to drug research. Solving this collective action problem has proven difficult, however. It is interesting to note that efforts to fight climate change share the same dynamic. For most countries, especially smaller ones, the rational action would be to not pay the price premium required for clean energy because the cost of not doing so would be widely diffused to all nations, while the benefit of a higher living standard from cheaper energy would be accrued by the individual nation. Yet, most nations have decided that, when it comes to clean energy innovation and adoption, they will put the interests of the globe ahead of their own interest. Nations such as Canada, Japan, and much of Europe that prioritize fighting climate change think nothing of free-riding on U.S. expenditures when it comes to fighting global diseases, thereby slowing rates of new drug innovation. Measuring Prices and Profits Measurement problems complicate any analysis of the pharmaceutical industry. First, there are problems measuring drug prices. For one thing, it can be very difficult to determine the correct price of a given drug. Pharmaceutical pricing involves a number of different players and several levels of discounts. Very few buyers pay list price, discounts vary significantly depending upon the buyer, and manufacturers have become more reliant on rebates in order to sell products. A recent Accenture report found that 4 of 11 drug companies studied had issued rebates totaling more than half of their gross U.S. sales.27 Two pills with identical ingredients but different names can vary in price by a factor of five.28 Moreover, middlemen play an important role in drug distribution and pricing. Even when a common price definition is used, price indexes of the real cost of pharmaceuticals tend to overestimate the amount of inflation.29 First, The U.S. Bureau of Labor Statistics (BLS) infrequently changes the market basket of drugs whose prices it monitors, so new generics are often not included in the sample for several years even though their entrance into the market quickly lowers prices. And when they are included, they are measured as new products, not as cheaper versions of the branded drugs.30 According to an estimate from 1993, this resulted in an upward bias in the measured price of drugs of 1.2 percentage points a year.31 Making this adjustment would mean actual prices fell in 3 of the last 9 years (see figure 1). Second, price increases tend to be more rapid for mature branded pharmaceuticals that have proven their worth, while the prices of new products increase more slowly and can even decline. However, because new products are not included in the index until several years after their market entry, this declining-price experience is underrepresented. Finally, BLS does not measure improvements in consumer benefits associated with new drugs. If a new version of a drug costs the same as an existing one but delivers better results, its real cost has fallen, although the index would not capture that. In contrast, the government does include quality improvements in its measures of inflation for most other products, such as cars and computers. Although the government has tried to address some of these problems, the indexes likely still overstate the rate of inflation. A second problem concerns how profits are measured, and particularly the accounting treatment of research costs and marketing expenses. Because both of these costs have a useful life of more than one year, standard accounting practice would include them as assets and amortize them over a period of years (perhaps five to eight) beyond which they cease to have value. For example, the Bureau of Economic Analysis now counts research as an asset and depreciates the value of biopharmaceutical research by 10 percent each year.32 However, the convention in the pharmaceutical industry is to deduct research and marketing costs from revenues in the first year. Although expensing for tax purposes makes sense in order to reduce the after-tax cost of research, and to reflect actual cash flow within the company, the measurement of return on assets should reflect traditional accounting principles. The deduction of research costs temporarily lowers measured profits because it raises the amount of costs that are deducted from revenues. However, by ignoring the continued value of research assets, it significantly understates a company’s assets and therefore overstates the rate of return on assets.33 CBO has reported that, after properly adjusting for the asset value of research, the industry’s profitability remains “somewhat” higher than the average for all industries, but not twice as large, as standard measures show.34 When research was properly accounted for, the return on equities fell to 8.3 percent for pharmaceuticals and rose to 0.9 percent for biotechnology. The market average was 14.1 percent. In recent years, industry returns have been even lower. New York University professor Aswath Damodaran calculated estimated returns on equity (ROE) for different industries going back several years. His calculations include estimates that treat research as both a standard expense and a capital expenditure. For 2018, the return on equity for pharmaceuticals and biotechnology was 12.6 percent and -1.6 percent, respectively, compared with an economy average of 15.6 percent.35 However, when research was properly accounted for, the ROEs fell to 8.3 percent for pharmaceuticals and rose to 0.9 percent for biotechnology. The market average was 14.1 percent. This relative performance is reflected in stock prices. Over the past five years, the NYSE ARCA Pharmaceutical Index experienced an annual return of 2.0 percent, compared to 7.6 percent for the broader S&P 50036 Finally, even a significant reduction in margins would not transform drug pricing. The Government Accountability Office estimated that pharmaceutical and biotechnology revenues were $775 billion in 2015, with an industry profit margin of 17.1 percent (not taking into account capitalization of research).37 Reducing this margin to 6.7 percent (the average for Fortune 500 companies) and assuming all savings were used to lower prices would have lowered prices by only 10 percent. Measuring the Benefits Any analysis of the cost of drugs needs to also consider the benefits from their use. There is ample evidence that the benefits substantially exceed the costs. Policies that restrict the flow of future drugs are therefore likely to harm society, particularly if the savings are consumed, rather than invested. A 2008 study by CBO found that average returns to society from past drug R&D appeared to have been large.38 A study of the use of other medical services and whether advances in pharmaceutical treatments had any effect on days lost to sickness found that conditions that had larger increases in post-1990 drugs per affected person also had larger declines in disability days and the use of almost all non-drug medical devices.39 The total benefit was $95 per person, or twice the cost of the additional drugs. All of this social benefit went to patients and health care providers. In another study, improved medication adherence in patients with four chronic diseases resulted in benefit-to-cost ratios of between 3.1:1 and 10.1:1 depending on the condition. Annual savings per patient varied from $1,258 to $7,823.40 The creation of net benefits also extends to future drugs. Reduced biomedical innovation would increase future health care costs and slow improvements in health and longevity.41 The Alzheimer’s Association recently evaluated the current cost of treating the disease.42 By 2050, 16 percent of Americans 65 or older will suffer from some stage of Alzheimer’s, with 6.5 million individuals in the severe stage of needing round-the-clock care. The cost of treating Alzheimer’s that year will be $1.2 trillion in 2019 dollars. The report estimates that discovering a drug in 2025 that would delay the onset of Alzheimer’s by 5 years would reduce the cost of treatment in 2050 by one-third. Savings in the first 10 years alone would total $935 billion. The high cost of mental illness (roughly $1.5 trillion annually) also offers a great opportunity for cost reduction through better drugs.43 However, the presence of large social benefits is not enough. Companies must still be able to realize a profit on their drugs. A recent news article reports on the difficulty biotech firms face in developing new antibiotics.44 Despite a growing need, a decline in market returns has caused larger firms to shift research over to other areas. For example, only three companies are currently conducting clinical research on antibiotics. The article speculates that part of the problem is few doctors know about the new antibiotics, which may be the result of a lack of marketing. Another problem is new drugs, due to their high costs, are only used when other treatments do not work, meaning their overall sales are likely not enough to pay for new-drug development. PHARMA’S ROLE IN PROMOTING RESEARCH The pharmaceutical and biotechnology industries combined account for a large percentage of U.S. research, both as a fraction of their profits and as a fraction of total U.S. R&D. Figure 7 shows total business expenditures on pharmaceutical R&D in 2014 (the latest year for which data is available), with private research developing new drugs in the United States at a significantly higher percentage of GDP than in the rest of the world. Although Japan comes close in percentage terms, total private R&D spending was $56.6 billion in the United States, compared with $14.6 billion in Japan. This high level of investment also applies to the total value of the pharmaceutical industry. Figure 8 shows R&D intensity by industry, measured as business R&D spending as a percentage of the gross value added of an industry. Once again, the U.S. pharmaceutical industry conducts far more pharma research than other countries, and more research overall than other U.S. industries. U.S. pharmaceutical companies devoted 43.8 percent of their total value added in 2014 back into R&D, ahead of both air and spacecraft, and electronic and optical products. Because of this research, Americans enjoy earlier access to new drugs. The European Federation of Pharmaceutical Industries and Associations recently found that, although the North American market accounted for only 48.9 percent of worldwide pharmaceutical sales, 65.2 percent of sales of new medicines launched between 2013 and 2018 were in the United States.47 It also determined that, although the growth of drug research had stagnated from 2009 to 2013 (a period in which significant reforms to health care were being discussed), it grew at an 8.6-percent rate between 2014 and 2018. The European rate was only 3.8 percent.48 Worldwide, the pharmaceuticals and biotechnology industry spent almost $112 billion on R&D in 2013 (the latest year for which data is available).49 The National Science Foundation regularly collects data on business research. According to its latest data, companies producing pharmaceuticals and medicines paid for $65.8 billion of research in 2016.50 This was almost 17 percent of all research funded by manufacturing companies in the United States. Biotechnology firms contributed another $6.1 billion. Over 85 percent of this pharmaceutical research was conducted in the United States. Over 64 percent of this funding was devoted to development, while another 21 percent was spent on applied research.51 Companies devoted 16.5 percent of sales to domestic R&D.52 The only industries with higher ratios that year were semiconductor machinery and scientific R&D services (which include biotechnology). Biopharmaceutical companies accounted for 687,000 domestic employees, of which 144,000, or 21 percent worked in R&D.53 This is over 9 percent of all R&D workers funded by industry. THE EFFECT OF DRUG PRICES ON INNOVATION The previous section discussed the strong contribution the pharmaceutical industry makes to U.S. research. The U.S. lead in life-sciences research delivers large benefits to the economy in the form of faster, more numerous breakthrough drugs and continued advances in existing therapies, as well as tens of thousands of high-paying jobs across the nation.54 This section reviews the academic literature on the strong link between drug prices and the future introduction of new drugs. Like any industry, pharmaceutical manufacturers need to earn an adequate rate of return on their assets in order to remain in business. However, the special nature of the pharmaceutical industry, in particular the heavy upfront investment in drug research and testing, and the long and uncertain delay between initial investments and drug revenues, means government price controls or other policies to reduce revenue (such as weakened intellectual property protection) will reduce drug innovation. Numerous studies have shown a firm link between prices and profits on the one hand and higher levels of research and drug innovation on the other. Although this report will not attempt to define the proper balance in detail, policymakers need to be aware this link is well established. Lowering prices now will result in less future research and fewer new drugs. The decline in future drugs will in turn reduce patient welfare over the longer term. This is not to say the federal government should sit on the sidelines regarding the affordability of drugs, but rather that price controls will come at a cost to innovation and long-term patient well-being. The Trade-Off Between Short-Term Affordability and Long-Term Innovation The unique nature of the pharmaceutical industry complicates the task of setting prices. In many traditional industries with a competitive market, firms often set prices only slightly higher than the marginal cost of producing an additional unit. This is because in most traditional industries fixed costs (e.g., capital equipment, R&D, and other overhead) are relatively low compared with total costs of production. However, setting prices close to marginal cost won’t work for innovation industries—including biopharmaceuticals—wherein the marginal cost of producing another unit (e.g., a pill or dose) is usually relatively small in comparison with the overall fixed costs, especially research, development, and testing. As innovation companies, drug companies must be able to recover these high up-front costs. Like some other industries such as movies, wherein there is a risk of the product being a bust, biopharmaceutical companies must be able to price drugs to cover not just the fixed and marginal costs of the successful drug, but also the costs of the failures. High fixed costs (from both successes and failures) ensure companies will need to price drugs significantly above the marginal cost. Although short-term affordability of drugs may be increased if drug revenues are based on marginal cost, drug companies will not be able to recover their costs, which will make them stop investing in future research, lose money, and go out of business. Ensuring prices remain high enough to allow drug manufacturers to recover their high fixed costs requires government intervention. In the United States, this is done mainly by giving drug companies patent protection for new discoveries. These policies give companies the ability to raise prices above marginal—and even average—cost, at least as long as there are few close substitutes to a particular treatment. Without patent protection, other companies would swoop into markets, thereby avoiding the hard and expensive work of developing and testing a drug and bearing only production and marketing costs. This is in fact what happens once the patent on a popular drug expires. 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 “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.” Previous Literature Reviews Previous government reports have summarized the link between biopharmaceutical profits and innovation within the drug industry. CBO pointed to two underlying reasons why this link might be so strong.64 First, as in most industries, the introduction of successful new drugs often leads to higher profits as companies are able to capture some of the social value created by their products. The profitability of current drugs also serves as a proxy for the profitability of future drugs. If biopharmaceutical firms are allowed to make reasonably large profits from their current products, they are likely to conclude that the same will be true in the future. This may cause them to increase both the speed and amount of their research activities. Conversely, they may view current attempts to hold down prices as likely to continue into the future, in which case they may decrease research funding. The second reason CBO identified is adequate profits generate significant cash flow, which allows companies to finance the next round of innovation.65 The availability of cash flow is important because raising significant amounts of money in the stock or bond markets is more costly. Biopharma companies have a much more detailed knowledge of disease models, the status of their current research, and the probabilities of success. Because investors cannot adequately assess these risks for themselves, they demand higher returns for investing. Assuming firms invest in R&D until their cost of capital exceeds the rate of return, financing through cash flow should allow them to justify more projects than if they have to raise the money from outside investors. The Organization for Economic Cooperation and Development (OECD) conducted a detailed study of this issue in the pharmaceutical industry. It found that “[p]harmaceutical pricing and reimbursement policies stand to affect innovation through multiple channels, influencing both the incentives to invest in private R&D and the costs of investment. The main channel of prospective influence is the impact of pricing and reimbursement policies on the expected return on investment in R&D.”66 In fact the generation of large revenues is closely related to the amount of research an individual company does. Figure 9 shows R&D expenditures and sales of the 151 largest pharmaceutical firms in the world in 2006. There was clearly a very strong correlation (0.97). Pricing policies affect not only the amount of research conducted (leading-edge or marginal improvements) but also the type and the decision of whether and when to introduce a new product to the market. The Government Accountability Office recently completed its own review of trends in pharmaceutical profits and R&D.68 It found that both experts and academic research has concluded that high revenue potential associated with a large number of patients, or the ability to charge a high price, is an important incentive for R&D investment.69 Exclusivity periods and patent protection, tax incentives, and expedited review programs were also cited as influencing R&D. Of course, while biopharmaceutical companies, like other firms, would like to charge as high a price as possible, their ability to do so is limited by both buyers not being willing to pay more for a drug than the benefits it delivers in terms of longer, healthier lives, and the presence of at least some competition in the marketplace. Experts and academic research have concluded that high revenue potential associated with a large number of patients, or the ability to charge a high price, is an important incentive for R&D investment. Academic studies that explore the causal link between drug revenues and research face a common difficulty in finding good data. They also take different approaches to choosing the inputs, outputs, and econometric model to measure the relationship between prices and profits, and research and innovation. So it is somewhat remarkable that, collectively, they arrive at the common answer that high prices for today’s treatments are closely associated with more research and a larger number of future drugs. There appear to be no scholarly studies that show no relationship between current prices and future innovation. Given their common conclusion that short-term price declines will endanger future drug innovation, it is worthwhile to discuss some of the major studies individually. Grabowski and Vernon (2000) Two studies by Duke University’s Henry Grabowski and John A. Vernon from the University of North Carolina at Chapel Hill looked at the relationship between expected returns and cash flows on the one hand, and company research on the other. The first study covered the period from 1962 to 1975.70 This followed passage of the Kefauver-Harris Amendment to the Food, Drug, and Cosmetic Act, which required a showing of efficacy as well as safety in order to get FDA approval. This increased development times by several years and R&D costs per new drug by several-fold. The authors found that research productivity, defined as sales of recent new drug introductions divided by lagged R&D spending, declined rapidly during the period. This eventually influenced cash flows, the decline of which along with the fall in research productivity together had the effect of reducing R&D. A later study looked at research spending between 1974 and 1994 in 11 firms specializing in prescription drugs.71 Together, these firms represented just over 40 percent of the U.S. market and half of the innovative output (defined as the first 3 years’ sales of all new chemical entities introduced in a period of time). Unlike the previous period, research productivity rose over 50 percent. Grabowski and Vernon found that both expected productivity of R&D and available cash flow positively affect R&D spending. Again, the link between cash flow and research is due to the fact that internally generated funds, which are often the result of higher profits, cost less than either borrowed funds or new equity, and therefore lower the required rate of return for new research at the margin.72 U.S. Department of Commerce (2004) In 2004, Congress asked the U.S. Department of Commerce to study the effect of pharmaceutical price controls in OECD countries.73 The department concluded that most OECD countries use a variety of controls to limit the price of patent-protected drugs in their countries. These restrictions reduced the revenue of drug companies by $18 billion to $27 billion per year. The department estimated that lower revenues reduced global R&D by $5 billion to $8 billion, or 3 to 4 new drug entities annually. This latter effect was based on outside estimates regarding the cost of developing a new drug. Note that using a lower cost of development would imply that the reduction in research spending resulted in a higher number of new drugs not being discovered. Access to these new drugs would benefit U.S. consumers by $5 billion to $7 billion a year. In contrast, OECD countries also used price floors on generic drugs in order to protect their domestic manufacturers. Eliminating these floors would save Europeans $5 billion to $30 billion annually, potentially paying for restoring a competitive market to patent drugs. The study also found that significantly more new active substances were available in the United States than in other countries, which it attributed to companies’ increased ability to capture more of the social benefit from current drugs.74 Acemoglu and Linn (2004) One problem with modeling the relationship between prices and research is the causation may go both ways. It is possible that better research increases profits rather than the other way around. To get at this problem, economists Daron Acemoglu and Joshua Linn examined the pharmaceutical industry using the theory of induced innovation, which says that changes in the real prices of different goods or inputs should cause companies to change the direction of innovation.75 Their 2004 study looked at changes in demographic trends between 1970 and 1990. Demographic changes affect the potential market size for a drug but they do not depend on the amount of research being done. If research spending and the size of the market move together, causation should run from prices to research. Acemoglu and Linn divided specific drugs into categories depending on the age of the population that primarily used them. The results showed a strong relationship between market size and the entry of new drugs. As baby boomers aged over a 30-year period, the market for drugs mostly consumed by the young declined, while those used by older individuals increased. This produced a matching change in the number of new drugs in each category. A 1-percent increase in the potential market size led to a 6-percent increase in the number of new drugs entering that market. Although much of this increase came from generics, both the number of nongeneric drugs (those not identical or bioequivalent to an existing drug) and the number of new molecular compounds (drugs containing an active component that has never been approved by the FDA or marketed in the United States) increased by at least 4 percent. They also found that drug firms anticipated these demographic changes with a lead of 10 to 20 years. Giaccotto, Santerre, and Vernon (2005) A 10-percent increase in real prices caused firms to increase their R&D intensity by nearly 6 percent the following year. Another study, by Giaccotto, Santerre, and Vernon, found a strong link between real drug prices and firm R&D.76 Their 2005 study focused on R&D intensity (the ratio of R&D spending to product sales) rather than the level of research, and found that real drug prices, real GDP per capita, and the amount of foreign sales as a percentage of total sales all had a strong impact on R&D intensity the following year. Specifically, a 10-percent increase in real prices caused firms to increase their R&D intensity by nearly 6 percent the following year. Applying this result to the past, they estimated that if drug prices had not increased in real terms between 1980 and 2001, R&D spending would have been 30 percent below its actual level. The number of new drugs entering the market during this time would have fallen by between 330 and 365, or about one-third of the actual number. Abbott and Vernon (2005) Some studies have tried to estimate the impact of future price controls on research. In 2005, economists Thomas Abbott of Thomson-Medstat and John A. Vernon found a strong impact on future innovation.77 They used the history of specific firms to look at the impact of prices on the initial decision whether to start Phase I trials on a perspective drug. With data on actual development costs, drug revenues, and a measure of the uncertainty facing firms, they found that minor price changes would have relatively little effect. A price decline of 5 to 10 percent would reduce product development by about 5 percent. But larger price declines would have a more serious impact. For example, a price cut of 40 to 45 percent in real terms would reduce the number of new development projects by 50 to 60 percent. Lichtenberg (2006) A 2006 study by Frank Lichtenberg looks at relationships between expected market revenues on the one hand and both the number of chemotherapy regimens for treating a cancer site (i.e., skin, lungs) and the number of articles published in scientific journals pertaining to drug therapy for that cancer site.78 As the importation of drugs would decrease the U.S. price and therefore the expected revenues, Lichtenberg hypothesized that importation would cause both the number of regimens and the number of publications to fall. He started by assuming that the responsiveness of innovation to a change in revenues is at least as great as its responsiveness to the number of patients. To estimate the latter, he looked at both changes in the number of patents with particular types of cancer in Canada and the United States, and the number of regimens and research papers devoted to that type of cancer. The results showed the elasticity of the number of cancer patients to the number of chemotherapy regimens available to treat a specific type of cancer is 0.53. The elasticity of journal citations is 0.60. Therefore, a 10-percent fall in drug prices is likely to cause a 5- to 6-percent decline in both cancer regimens and research articles. A 10-percent fall in drug prices is likely to cause a 5- to 6-percent decline in both cancer regimens and research articles. The study also looked at the relationship between the number of innovations within a company (defined as FDA-approved active ingredients contained in products sold by the company that are not contained in any other company’s products) and the number of its employees. It finds an elasticity of 0.71 across 14 pharmaceutical companies; a 10-percent reduction in new approved active ingredients would cut the number of employees by 7 percent. Civan and Maloney (2009) In 2009, economists Abdulkadir Civan and Michael Maloney looked at both the existing drugs available to treat specific diseases and the number of new drugs in development for those same diseases.79 After correcting for the number of existing treatments available for a specific condition, they found a positive relationship between the average price of available drugs and the number of new drugs being developed. A 30-percent increase in drug prices for a given condition would increase the number of drugs in development for that condition by 25 percent. Of course, as generics enter the market in response to favorable market conditions, prices usually fall. Golec and Vernon (2010) Economists Joseph Golec of the University of Connecticut and John A. Vernon looked at the relationship between an index of drug prices in both the United States and Europe and the profitability, research spending, and stock price of U.S. and EU pharmaceutical firms, respectively.80 Between 1993 and 2004, European price controls prevented pharmaceutical prices from rising in inflation-adjusted terms, whereas real prices in the United States rose by 50 percent. However, the authors found a statistically significant positive correlation (0.64) between changes in the price increases and R&D spending.81 Market conditions not only affected the size of research spending, it also affected its location. Looking at other sets of data, they found biopharmaceutical research in the EU countries exceeded research conducted in the United States by 24 percent in 1986. But by 2004, U.S. levels were 15 percent greater than EU levels.82 This is mostly due to EU spending stalling between 1997 and 2001, roughly the same time the two price indexes diverged. Total U.S. biopharma research by foreign firms has been growing at a faster rate than foreign research by U.S. firms, largely because U.S. prices for on-patent drugs are higher than those in Europe. Higher prices have therefore caused foreign companies to divert their attention to the U.S. market, thereby strengthening the U.S. domestic industry. Golec and Vernon also looked at the real annual growth rate in research spending. U.S. research consistently grew about 3.4 percentage points more than EU research each year. However, both rates have been trending down in recent years. Using regression analysis, the study shows firms that were more sensitive to European prices spent less on R&D, while the opposite was true of sensitivity to U.S. prices. By assuming the annual real increase in R&D spending would have maintained its rate of 6.6 percent had the Europeans not introduced price controls, the report estimates the present value of reduced R&D from regulations has been almost $12 billion in current dollars and 1,680 R&D jobs.83 Using an average cost per drug of $260 million, this translates to 46 fewer medicines between 1986 and 2004. They noted that between 1987 and 1991, EU firms introduced 101 new medicines. This figure dropped to 57 new medicines between 2000 and 2004, the difference of which was roughly the number they attributed to the decline in R&D. Meanwhile, the number of U.S. new medicines increased from 54 to 70. Similar price controls in the United States would have reduced the present value of research by almost $31 billion, resulting in a loss of 117 new medicines and 4,368 jobs.84 Schwartz (2018) In 2018, researchers at Precision Health Economics used a model of the over-50 population to simulate the elimination of price controls in non-U.S. OECD countries.85 The study estimated that removing price controls would raise pharmaceutical revenues by 30 percent. The paper estimated that a 30-percent price increase in non-U.S. OECD countries would increase the size of the global pharmaceutical market by around 12 percent. This in turn would produce a 12 percent increase in research and 13 new drugs per year. The impact grows to 44 new molecules per year by 2060. Assuming these drugs would also be introduced into the United States, the expected longevity of American 45-year-olds would increase by 0.86 years, which the report values at $1.54 trillion, or $67,000 per individual. For 15-year-olds, the increase in longevity would be 1.6 years, worth $115,000 per person. Although the net benefits to non-U.S. individuals would be partially offset by higher drug prices in the near term, these benefits would still be significant. Life expectancy for a 45-year-old European would increase by 0.81 years, and welfare gains would exceed $80,000 per person.

19 even further out of reach.