given the historically unprecedented speed with which the US pharmaceutical industry has developed COVID-19 vaccines—3 of the 4 first products likely to be approved for marketing are almost certainly from US firms—it would seem appropriate for a renewed sense of confidence, support and even acclaim for the economic model that lies behind this success. Instead, the sector remains under pressure to lower prices and protections for its patented products, both in the United States and globally. It is worth noting that the entire world benefits from the new medical advances in treating the worst pandemic in at least 50 years. Instead, President Trump has continued to criticize the industry for its pricing model for newly developed drugs, while countries such as India, Pakistan, and Brazil call for breaching of the patent shield for the new vaccines (and recent treatments such as those for HIV and Hepatitis C), and developed countries in Europe, East Asia, as well as Canada, persist in questioning the medical value of the new medicines to their citizens.¹

To add to the current uncertainty about US leadership, there is ever-increasing competition from China in terms of basic science and pharmaceutical products. The Chinese national goal of self-sufficiency in these two fields has resulted in a huge increase in research and development funding and purchases of leading biotechnology firms in the United States and Europe. At the same time, China’s global market share in generic drugs and active pharmaceutical ingredients (APIs) is steadily growing. Chinese government funding for research in these fields has grown by 20 percent annually since 2008.
The incoming Biden administration is calling for new pricing models and the use of compulsory licensing for some new products, especially those related to the new virus pandemics. Compulsory licensing allows a government to license entities other than the patent holder to produce and sell patented products without the patent holder’s permission.

If the economic and scientific model which promotes constant advances in medicines and new treatments is to survive, the current domestic ecosystem for research and development ought to be strengthened, instead of being undermined by reducing private sector incentives and weakening the protection of intellectual property (IP). Additionally, ways to address the problem with other countries enjoying a “free ride” at the expense of US consumers and public health systems, need to be considered.

The United States as Global Leader in Innovation

The United States is now the undisputed world leader in both medical science and the innovative products and treatments which are needed to meet the challenges of improving healthcare in a globalized world. This has not always been the case. The US is now the home for half of the global pharmaceutical companies which account for half of global sales for this sector. US firms now account for over 60 percent of innovative new drugs, up from 41 percent in the 1980s. In the 1980s, countries apart from the United States and the European nations, accounted for 41 percent of the top new innovative medicines (the most prominent players being Japan, Korea, Canada, and Australia), but by the late 1990s that proportion fell to 17 percent.

Underpinning the improved US performance is its investment in basic research and development. In recent years, US public investment in medical science has been twice the level of all other industrialized countries (except China) combined. The United States accounts for half of global medical research.

About 75 percent of global venture capital (VC) investment in bio-medical science and product development goes to US firms. And private industry firms in the United States devote around 20 percent of their revenues to R&D. The US has raised its share of private sector research among developed countries from 43 to 57 percent since 1995.

While China is committed to becoming a world-class competitor in this increasingly important industry, European and some East Asian countries have lagged behind in both basic science funding and product development. European public and private investment was almost 50 percent higher than that of the United States in the 1980s, but the situation has reversed since then. The relative slowdown in Europe occasioned a decrease in its share of innovative new drugs. In 1992, six of the top ten medicines sold worldwide were of European origin, but by 2002, that figure dropped to only two out of ten. By 2005, Günter Verheugen, then the Vice-President of the European Commission for Enterprise and Industry, was lamenting that “…we are confronted with a move of research and production of innovative drugs outside Europe.”

The shift in relative competitiveness in this sector is a result of both push and pull. Europe, and similarly Japan, Canada, Australia, and other developed countries with national health care systems, decades ago began to emphasize price controls and limitations on approvals for new drugs as a means to keep their national health care costs within budget. Doing so, however, limits the ability of private sector firms to invest in new product research. In the United States, the basis of leadership in innovation is a combination of favorable tax treatment, regulatory actions to speed the approval process for new medicines, and massive support for academic research and lab-based medical science. A culture that favors saving lives over reducing costs also encourages and facilitates private sector investment in new product development. Additionally, national legislation in the 1980s prevented the US Medicare system from negotiating directly
with private sector firms on pricing decisions for medicines. This reality is in stark contrast to most of the rest of the world which invariably drives down prices with monopsonist purchasing models and is reluctant to approve new products and new uses for the already existing medicines.

As the US Council of Economic Advisers demonstrated in a February 2020 study, the cost-cutting measures in Europe and elsewhere, along with the market-based US approach, resulted in a growing disparity in the domestic pricing of new drugs. In 2003, the US prices for similar drugs were about 50 percent higher than their German and Canadian counterparts. By the time of the Obama and Trump administrations, US prices ranged from two to three times those in other developed countries.

Academic and public policy research consistently correlates the US dominance of new drug discovery to the attractiveness of US markets in terms of prices and a better climate for approval of innovative new products. In the United States, consequently, patients have quicker and broader access to new treatments. In areas like oncology and the treatment of rare diseases like cystic fibrosis, new advances have been approved more rapidly and better patient outcomes are observed. Most other countries have far fewer choices of new treatments than those available in the United States.

However, patients in other advanced economies do benefit from the US advances without contributing a commensurate share of the costly R&D required for new drug discovery, development and approval. As long as their national health care systems continue to approve the new products and the innovative firms in the United States agree to a lower pricing structure for bulk purchases, other countries will continue to enjoy this benefit. Some analysts refer to this as “free-riding” on the part of European countries as well as Canada, Japan, Korea, among others. Many developing countries such as India, South Africa, Indonesia, Brazil and Pakistan try to double down on this sort of free-riding by imposing high tariffs, resisting giving patent protection for new treatments and trying to impose compulsory licensing on innovative American, Swiss, UK, and EU-based firms. The new COVID-19 vaccines and treatments are, in effect, ground zero for compulsory licensing efforts.

China employs all the tactics highlighted above but also is a leading counterfeiter of the existing pharmacopeia. It has the ambition of building on the successes of others and its own progress in producing generic drugs and active pharmaceutical ingredients to create an innovative, science-based drug industry. This sector is one of the ten target industries of the program called “Made in China 2025.” Some of the salient features of this program are exploiting the open educational systems in the United States and other advanced countries to acquire and bring home new science capabilities, buying, often through opaque company structures, foreign biotechnology firms, and outright theft of intellectual property. The program also restricts access to its own market by foreign manufacturers to give advantage to its domestic aspirants. Since Chinese quality standards are often inadequate and dangerous to patients, China is not yet a peer competitor to the United States but it is advancing rapidly. Like China, India is a growing producer of generics and APIs, though it also suffers from suspect quality oversight and counterfeiting.

The Challenge for the Biden Team
In looking ahead to the Biden administration, it is unclear whether it will continue many of the policies which have strengthened the competitive position of the US pharmaceutical sector over the last twenty or more years. Biden and his team have signaled strong support for domestic manufacturing and for additional funding for basic science research in key technologies, including biopharmaceuticals. Bipartisan support for these policies has been growing in the Congress, especially in the wake of the pandemic. The
Biden team has also articulated a need to work on fairness and reciprocity in US trade relations, especially with regard to China. Presumably this emphasis includes vigorous support for defending IP rights, combating unfair trade practices such as compulsory licensing and counterfeiting, and lack of equal access to markets. In this case, access to markets would encompass pushing back on practices which limit new product patenting or inclusion in the list of products for which national health care systems would reimburse producers.

In contrast, some elements of the Biden platform and the records of incoming cabinet officials such as Xavier Becerra, the designated head the Department of Health and Human Services, are cause for concern. The Biden “Plan to Rebuild US Supply Chains” and comments by Becerra suggest that use of US government purchasing power to drive down drug pricing, a policy that could be supercharged if some version of a “Medicare for All” program were adopted. Both the Biden platform and Becerra’s record show an openness to compulsory licensing of pharmaceuticals in some circumstances. In his capacity as the Attorney General of California, Becerra vigorously supported measures to limit the duration of patents for medicines. All of these factors would limit the overall revenues of innovative, research-based pharmaceutical firms, without implementing associated compensating policies (some of the international components of such a policy are mentioned below). These ideas, if implemented, could set the United States on a path to a European-style medical product ecosystem which has reduced new drug development and broader adoption of new medicines and treatments.

The Biden platform also calls for raising US corporate taxes. One factor in the move of pharmaceutical manufacturing abroad has for decades been lower taxes in countries like Ireland and Switzerland, as well as in Puerto Rico prior to that. This factor has encouraged US firms to move production to lower tax locations. The United States already has a huge pharmaceutical trade deficit with low tax countries, approximately $39 billion with Ireland as well as $14 billion with Switzerland in 2019. One can observe that at least in the case of Ireland there is little reason for such a trade deficit in advanced technology other than the tax regime available to highly profitable firms. It is difficult to discern how higher domestic corporate taxes could help bring manufacturing, as well as associated R&D, back to the United States.

China and India represent the largest untapped markets for advanced medicines but the two countries will continue to restrict access as they struggle to become competitors to industries in the developed world and to build their own national health care systems. In the Phase 1 trade deal with Trump, China committed itself to improving protections for IP, stamping out counterfeiting, and reducing barriers to introduction of new medicines from non-Chinese firms. China should be held to its commitments by the Biden administration. The United States, along with allies, should also broaden their capabilities in terms of inspecting Chinese and Indian manufacturing facilities of generics and APIs for quality and safety assurance. In recent years, there have been numerous reports of quality and safety violations, and substitution of untested and sometimes dangerous components in the drug manufacturing industries of the two countries has been observed.

The toughest issue for the Biden team will be fulfilling the commitment to achieving lower domestic prices for patented medicines, while still promoting the extent of R&D needed for the United States to remain a global leader in this sector. The US industry is clearly a “global good” in the sense that it helps produce the breakthroughs required to meet modern health challenges like HIV and COVID-19. Convincing other advanced economies (not to mention China, India and other large developing economies) to participate more fully in funding the basic sciences and product development through more public funding for research and more balanced reimbursement
patterns for finished products is not an easy task, no matter how much allies like the European nations and Canada hasten to repair trade relations with the United States during the Biden term.

Europe enjoys a trade surplus in pharmaceutical products with the United States of over $50 billion annually, partly due to the disparity in reimbursements for the same drugs in the United States. In effect, the US consumers and public health providers help support both US and European (along with Japanese, Korean and other) firms by paying higher prices for new products and approving more new drugs and new applications than their competitors. European and Japanese companies are also significant innovators in new medicines but they have seen their share of new products steadily eroded as their national health care systems squeeze prices and make obtaining approval for new products more complicated.

One path to start addressing this global problem could be commissioning the Organization for Economic Cooperation and Development to do a study highlighting the value of new medicines in combatting pandemics and endemic diseases, focusing on the new drug development process and how it is supported around the world today. There are precedents in trade law, especially in anti-dumping and countervailing duty law, as it applies to semiconductor and steel industries, for consideration of research and development costs as major components of determining fair prices in global markets. If other countries continue to pay less than fair value for US products while their own companies benefit from a better pricing environment in the United States, this may constitute a violation of the spirit, if not the letter, of the established WTO principle of reciprocal access. As with the debate over sharing the burden in NATO, or in addressing climate change, the United States should aim to convince its allies to increase their contributions to resolving the global health problems.

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Endnotes


4 Pham and Donovan, “Biopharmaceutical R&D”


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