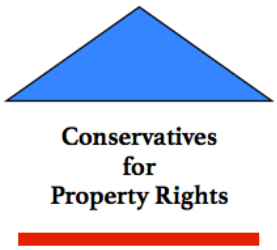

June 25, 2021

Federal Trade Commission
Office of the Secretary
Room H-113 (Annex X)
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

RE: Pharmaceutical Task Force, Project No. P212900

Dear Commissioners and Task Force members:

Conservatives for Property Rights (CPR), a coalition of public policy organizations concerned with preserving and protecting private property rights with respect to all forms of property, provides these comments to help inform efforts of the Multilateral Pharmaceutical Merger Task Force (Pharmaceutical Task Force, Project No. P212900).

CPR appreciates the opportunity to provide input on the Federal Trade Commission's (FTC) undertaking to consider the best approach to mergers and acquisitions specifically in the pharmaceutical sector. Fundamentally, antitrust serves the overall purpose of ensuring consumer welfare. As then-Assistant Attorney General for Antitrust Makan Delrahim has observed, "for over 40 years, the consumer welfare standard has served as a neutral principle for the administration of the antitrust laws. It focuses enforcers and courts on harm to competition and requires them to evaluate competitive effects. The consumer welfare standard is agnostic to considerations other than the actual competitive process."[1]

We believe this important standard has served consumers and businesses in the United States extremely well. By applying uniform principles, objective economic criteria, and consistent legal standards in antitrust matters, U.S. consumers have benefited from the resulting competition, innovation, consumer choice, quality, and value. Businesses, both incumbent corporations and startups, have benefited from the resulting rule of law, fairness, due process, predictability, and objectivity. Thus, a top priority for CPR is to ensure the preservation of the consumer welfare standard in antitrust.

[1] "The Future of Antitrust: New Challenges to the Consumer Welfare Paradigm and Legislative Proposals," Assistant Attorney General Makan Delrahim Delivers Remarks at the Federalist Society National Lawyers Convention, Washington, DC, November 14, 2019.

We emphasize that U.S. competition agencies do not have industry-specific guidelines or rules for mergers and acquisitions (M&A) reviews. This is most appropriate. It is vital to U.S. interests and to the interest of property rights that M&A reviews, antitrust enforcement, and legal adjudication continue to use general rules agnostic to economic sector in any given case. This sound approach serves the rule of law.

Further, the system we presently have works well as structured. The FTC (or the Department of Justice (DOJ) for reviews within its purview) receives data and information on pharmaceutical mergers and acquisitions. The agency already has the ability to challenge transactions thought to be anticompetitive in administrative or judicial proceedings. In fact, the FTC has brought challenges from time to time. The FTC has required divestiture of products where the agency perceived potential issues to exist. The present system works just fine regarding pharmaceutical industry M&A transactions. CPR sees no need for interposing special treatment of such transactions; indeed, an industry-specific approach would run counter to the American understanding of the rule of law, impartiality, and due process.

Further, we observe that the consumer welfare standard's central importance to sound antitrust policy may not be shared among other participants of the task force. Their continental and foreign antitrust policies differ in important ways from those of the United States. Notably, U.S. innovator companies in many economic sectors repay America in spades for constructive, solid antitrust policies such as the consumer welfare standard. Considering the U.S. global lead in pharmaceutical, biotech, wireless, advanced manufacturing, and other fields and technologies they provide, our current antitrust M&A review approach does us well. They also produce an outsized share of good jobs paying above-average salaries with a derivative job-creation effect in supporting businesses. These include good blue- and white-collar jobs.

Moreover, it must be factored in that some task force members come from nations that are comfortable with a significantly heavier role of government in their economies and societies, including government-run health systems, centralization at odds with our federalist framework, and a heavily intrusive regulatory regime. Allowing such perspectives to influence U.S. antitrust policies very well could inject a far heavier hand than necessary and cause adverse effects in excessive merger assessments. Causing greater uncertainty over, costs for, and barriers to economically reasonable private actions are dangers we urge the FTC and the task force to take special care to avoid and prevent.

Another hazard we raise as a potential outcome to be forestalled is that this exercise focuses on the pharmaceutical sector, but whatever is developed is eventually likely to be applied to other economic sectors. We reiterate how such a dangerous precedent and ill-advised approach would set back American innovation, consumer choice, competition (including dynamic competition from the introduction of innovation that creates new markets, enables new market entrants, and sparks new applications of the novel technology), and economic growth. A tighter grip would sap an American competitive edge just as we face a tremendous competitive challenge. An aggressive China seeks to displace the United States as the global leader in innovation in emerging technologies. The FTC and the task force must not ignore this imminent threat and the associated consequences of a radical departure from general antitrust rules to industrial sector-specific ones. The big picture really matters here.

With respect to the biopharmaceutical sector, the FTC and the task force should be relieved to learn that this sector is demonstrably not highly concentrated or consolidated, remains especially innovative (as seen by American firms Pfizer, Moderna, and Johnson & Johnson each having developed highly effective, safe vaccines for COVID-19 in under a year's time), and that any M&A in this sector has not especially affected product prices.

Pharmaceutical sector concentration/consolidation

The Information Technology & Innovation Foundation (ITIF) recently produced a report that makes these points and backs them up with reliable sources and data. In rebuttal of a claim of intense pharmaceutical consolidation, ITIF reports:

> ". . . [I]n 2006, the top 10 drug producers accounted for 56 percent of global industry sales, while the top 60 accounted for 92 percent. But by 2019, the top 10 accounted for 43 percent, and the top 60 86 percent.
>
> "Moreover, looking at combined output for firms in the United States (not imports), the sales for the top four in each industry (C4 ratio) in the Pharmaceutical Preparation Manufacturing and Biological Product Manufacturing industries (NAICS codes 325412 and 325414) increased only modestly from 2002 to 2017, from 36 percent to 43 percent, while the C8 ratio increased from 54 to 58 percent, and the C20 ratio fell slightly from 77 percent to 76 percent.
>
> "Given that drugs are sold internationally, a more accurate measure of market concentration takes into account all drug firms. In 2019, the top 4 firms globally had just 21 percent of the market, with the top 8 having 37 percent, and the top 20 64 percent. While the C4 and C8 ratios were up slightly from 2006, when they were 18 percent and 31 percent, respectively, the C20 ratio actually fell to 64 percent.
>
> "Finally, [regarding] claims that mergers increase prices[,] . . . when the Government Accountability Office (GAO) examined this issue, it found that this was only the case with respect to generic drug company mergers."[2] (internal footnote numbers omitted)

Moderna, the creator of one of the first U.S. COVID-19 vaccines to gain FDA approval, illustrates the biopharma innovation ecosystem. Moderna was founded in 2010 and has worked on its messenger RNA platform on various drug candidates for a variety of viruses and diseases. Yet, it was not until May 2021, after the COVID vaccine had cleared the FDA for emergency use, was purchased in quantity, disseminated, and its administration to the public well underway that the company reported its first profitable quarter.[3]

Pfizer's partner on its COVID vaccine, German biotech BioNTech, further helps illustrate the roles of financing, collaborations, and exit strategies in the biopharma innovation ecosystem.[4] Founded in 2008, BioNTech has conducted mRNA technology research and development (R&D), such as on cancer immunotherapies, work the company founders began entrepreneurially years earlier. It partnered with Pfizer on R&D in 2018, and this timely relationship was in place when the COVID pandemic broke out. The company had its IPO on Nasdaq in October 2019. BioNTech has had a strong year on account of its successful vaccine collaboration in the pandemic.

Law Professor Joanna Shepherd has shed light on the state of biopharma M&A and the appropriate way to approach these matters, given today's pharmaceutical and biotech innovation ecosystem. She writes that "concerns about consolidation's impact on drug innovation are largely based on an outdated understanding of the innovation ecosystem in the

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[2] Robert D. Atkinson and Stephen Ezell, "Five Fatal Flaws in Rep. Katie Porter's Indictment of the U.S. Drug Industry," Information Technology & Innovation Foundation, May 20, 2021, p. 2.

[3] Peter Loftus and Matt Grossman, "Moderna Turns First Profit, Boosted by Its Covid-19 Vaccine," Wall Street Journal, May 6, 2021.

[4] For background on BioNTech, see the Motley Fool and CNBC.

pharmaceutical industry. Today, most drug innovation originates not in traditional pharmaceutical companies but in biotech companies and smaller firms, where a culture of nimble decisionmaking and risktaking facilitates discovery and innovation. In fact, about two-thirds of New Molecular Entities approved by the FDA [Food and Drug Administration] originate in biotech and small pharmaceutical companies, and these companies account for almost 70 percent of the current global pipeline of drugs under development."[5]

Many biopharma startups and early-stage companies remain prerevenue for years, and many eventually go out of business.[6] Pressures come from clinical failures, investors, cash-flow challenges, regulators, coverage and reimbursement decisionmakers, and changed market conditions. Yet, there is nothing to sniff at regarding the quality of most firms' research and drug development. Small-entity survival and thriving often relies on mergers, acquisitions, and strategic alliances with larger pharmaceutical research and manufacturing firms. Initial public offerings (IPOs) happen for some, but that is hardly the only exit strategy for early-stage biopharma companies. This dynamic must not be underestimated or underappreciated.

The Biotechnology Innovation Organization reports 64 U.S. IPOs and 57 U.S. acquisitions in 2020 involving emerging therapeutic biotech firms. That was up from 41 of each in 2019.[7] Overall, the size of the biotech sector was 2,336 private companies and 447 publicly traded firms in the United States in 2015; thus, the vast majority of the sector is privately held.[8] The size of this vibrant sector indicates that, though the recent volume of exits through acquisition or IPO is not insignificant, these transactions hardly constitute market concentration or industry consolidation. Rather, the combinations represent a healthy, well-functioning sector whose commitment to innovation bodes well for patients and our economy.

Pharmaceutical sector innovation

Regarding the research-and-development intensity in the biopharma sector and thus indicating its high degree of innovation, ITIF finds:

> "Drug companies in America are incredibly R&D intensive and have become even more so, with their R&D-to-sales ratio increasing from 11 percent in 2006 to 20 percent in 2018. The ratio for the top 20 U.S. companies increased from 15 percent in 2006 to 23.6 percent. Further, while drug revenues increased 56 percent from 2006 to 2018 (in nominal dollars), R&D increased by 85 percent.
>
> "The [assertion] that small firms invest more in R&D and that big firms use their revenue for other purposes . . . [is belied by the fact that] in 2016, the top 20 firms globally accounted for 66.5 percent of global sales yet made 64 percent of R&D investment. In 2018, the R&D intensity of the largest 4 firms was 26 percent, of the top 8 was 25 percent, and of the top 20 was 22 percent, with the entire industry at 20 percent. In reality, it is the largest firms, not the smallest, that are the most R&D intensive.

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[5] Joanna Shepherd, "The Relationship Between Consolidation and Innovation in the Drug Industry," CLS Blue Sky Blog, April 24, 2017, citing her more extensive article, "Consolidation and Innovation in the Pharmaceutical Industry: The Role of Mergers and Acquisitions in the Current Innovation Ecosystem," in the Journal of Health Care Law & Policy.

[6] See Atkinson and Ezell, p. 4, "only for survivors, and do not include all the biopharma companies that went bankrupt because their discoveries did not pan out."

[7] BIO, "Emerging Therapeutic Company Investment and Deal Trends 2011-2021."

[8] Statista, "Number of biotechnology companies in the United States from 2012 to 2016."

". . . The U.S. biopharmaceutical industry is the world's most R&D-intensive industry, with firms in the United States investing over 21 percent of sales in R&D, while accounting for 23 percent of total domestic R&D funded by U.S. businesses—more than any other sector. Over the last decade, biopharmaceutical companies in the United States have invested over half a trillion dollars in R&D, while more than 350 new medicines have been approved by the FDA. The industry reinvested 43.8 percent of value added (value sales minus purchased inputs) into research in 2014, more than any other industry in any country. . . . In fact, companies' share of R&D classified as basic (14.3 percent) is higher than any other U.S. industry—and more than twice as high as the U.S. industry average (6.4 percent)."[9]

The beneficial result of U.S. biopharmaceutical firms' heavy investment in R&D shows up in rising novel drug discoveries. ITIF reports that, "in reality, new drug approvals have significantly accelerated. The FDA's Center for Drug Evaluation and Research's five-year rolling approval average stood at 44 new drugs per year in 2019, double the lowest five-year rolling average of 22 drugs approved, realized in 2009. . . . And the number of drugs in development globally increased from 5,995 in 2001 to 13,718 in 2016."[10]

Both blockbuster new medicines and follow-on drug products represent innovations that (at least in the United States, where our health system remains more market-based and so enables freer, more robust diffusion of innovation) offer wider consumer choice, greater competition, better quality, greater value, and superior clinical benefits from new and improved drug products.

ITIF elaborates: "[It is important to] recognize the significant clinical benefits of new drugs complementing existing drugs. Sometimes an existing drug does not perform as well as the new drug. Sometimes certain individuals have adverse reactions to an existing drug but not the new drug. In addition, follow-on drugs can be better in efficacy or methodology and convenience of use and administration. DiMasi and Faden found that 32 percent of follow-on drugs have received a priority rating from the U.S. FDA, indicating that these drugs are likely to provide an important improvement over the first-to-market drug. They concluded, 'Overall, these results indicate that new drug development is better characterized as a race to market among drugs in a new therapeutic class, rather than a lower risk imitation of a proven breakthrough.' Moreover, GAO found that the introduction of additional drugs lowers prices."[11]

In short, new medical innovation improves the welfare of consumers and of patients. This aspect of consumer welfare must be kept at the forefront of considerations regarding antitrust review of potential M&A and the task force's work.

Drug prices

Claims about drug costs imply that pharmaceutical consolidation must be rife and must be driving up drug prices for consumers. However, the facts do not support this assertion. The ITIF report addresses the evidence. The facts contradict the "conventional wisdom." The FTC and this task force should adhere to the evidence. "According to the Peterson Center on Healthcare and Kaiser Family Foundation, the percentage of total U.S. health care spending going toward retail prescription drugs was consistent from 2000 to 2017, at mostly under 10

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[9] Atkinson and Ezell, p. 3.

[10] Ibid., p. 5.

[11] Ibid., p. 6.

percent."[12] "When examining increases in prescription medicine costs from 2000 to 2019 compared with other facets of the U.S. health care system, such as 'hospital and related services' and 'medical care,' the increase in prescription medicine costs has been right in line with the increase in medical care, and just slightly above the increase in the urban consumer price index, considering all items."[13] Unstated in the report, but seen on a graph, the Consumer Price Index (CPI) of "hospital and related services" over the same 20-year timeframe as those categories named above outpaced their rates of inflation.

In regard to brand drugs and drug prices, it must be remembered that the vast majority of prescriptions are filled with generic drugs, which compete on price long after the market for a given drug has been established. The high-risk, high-reward level of investment in new drugs is illustrative. The vast majority of new drug candidates fail during testing for both efficacy and safety in human beings. Novel drugs initially compete on value or novelty, and on a range of factors (some related to the demands of payers and medical providers) in addition to price. Importantly, exclusivity of such novel medicines represents the fruit of the drug innovator's labor and up-front sunk costs. Drug exclusivity appropriately allows the innovator to proceed through regulatory and reimbursement processes, establish manufacturing and distribution, and create a market for something that has proven to be novel, effective, safe, and of sufficient improvement over the existing standard of care for a disease.

Further, many drug products do not recoup their costs. Most attract competitors prior to patent expiration. At that point, the first-in-class drug is compelled to compete more on price. Regarding pricing of new drugs, the GAO says, "We and others have reported that brand-name drug companies consider the availability and price of therapeutic alternatives along with potential market size, the perceived value of the drug relative to competitors, and other factors when determining the price for a new drug."[14] Notably, the GAO reports competitive effects for generic drugs, where competition on price is primary. GAO observes that "less competition—that is, a more highly concentrated market—is associated with higher drug prices, particularly for generic drugs."[15] Because generic medicines compete namely on price, such price sensitivity—or the lack thereof—is to be expected. These facts should inform antitrust considerations where antitrust and IP intersect. It is inappropriate to treat biopharma innovators as though they were competing primarily on price, and the novel vaccines, treatments, and cures, painstakingly developed and brought to market, as commodities.

It is hard to conclude that large incumbent biopharmaceutical firms' M&A appreciably consolidates the sector after examining the evidence. Nor does the evidence indicate that such acquisition activity causes drug prices to spike. For example, the GAO reports the M&A transactions involving 10 of the largest drug companies from 2006-2015.[16] Deals of at least $500 million in 2015 dollars by the firms studied in that timeframe numbered 53 total. Of those transactions, most (44) were below $10 billion. The highest priced deals among those reported were Pfizer's acquisition of Wyeth for $70.9 billion, Merck's purchase of Schering-Plough for $56.1 billion, and Roche's $48.5 billion acquisition of Genentech. Most M&A deals in the pharmaceuticals sector appear to align with Professor Shepherd's analysis, cited above.

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[12] Ibid., p. 7.

[13] Ibid., p. 8.

[14] Government Accountability Office, "Profits, Research and Development Spending, and Merger and Acquisition Deals," (GAO-18-40) Nov. 2017, p. 47.

[15] Ibid., pp. 47-48.

[16] Ibid., pp. 64-66.

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In conclusion, CPR urges the task force to tread lightly and not to unsettle the consumer welfare standard and U.S. antitrust with hazardous changes in policy and practice. Specifically, we urge retention of a uniform standard for antitrust reviews of potential mergers and acquisition, a set of rules that is sector-agnostic. A goal should be to ensure businesses predictability, both of process and of standards employed. Any M&A deal that warrants federal review involves millions or billions of dollars, represents significant outlays and efforts in negotiations and structuring contracts. Each one holds economic importance for which no government agency has a crystal ball. The possible harms to U.S. industrial competitiveness against China and other adversarial nations must be top of mind in the task force's proceedings and considerations. Finally, the potential for quashing innovation is especially high, notably in this instance with regard to the danger of denying Americans suffering from diseases of a cure, a treatment, or a vaccine. Unfortunately, the prospects of not getting this right are dangerously high.

Respectfully,

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