We are pleased to respond to the request for comments to help inform the work of the Multilateral Pharmaceutical Merger Task Force as it seeks to review and update the analysis of pharmaceutical mergers. We trust that the views we express herein may prove helpful to the task force as it undertakes this commendable and important initiative.

The Competition Project at the Mercatus Center at George Mason University is dedicated to advancing knowledge about the effects of regulation on society. Conducting careful and independent analysis that employs contemporary economic scholarship is part of the Competition Project’s mission. This comment, therefore, does not represent any particular interest group.

We begin with a brief overview of general and pharmaceutical-specific merger enforcement, centered primarily on the record of the Federal Trade Commission (FTC). We find that current federal merger enforcement is sound and highly effective and that legislative changes are not needed. Next, we address, in order, the seven specific questions posed by the task force related to the evaluation of pharmaceutical mergers. We then finish with some concluding thoughts.

A BRIEF COMMENT ON FTC MERGER ENFORCEMENT ACTIONS
The FTC has a long and successful history overseeing mergers and acquisitions in the pharmaceutical sector. Between 1994 and 2020, the FTC challenged 67 pharmaceutical mergers,

---

2. See id.
deciding in all but one instance to settle subject to divestitures. In all these cases, the FTC has pursued an evidenced-based approach and has employed analysis consistent with the 2010 Horizontal Merger Guidelines and the newly issued 2020 Vertical Merger Guidelines. Evidence shows that these divestitures have been successful in maintaining premerger levels of competition in the market.

Courts require that securing convictions under section 7 of the Clayton Antitrust Act of 1914 requires sound, empirically based economic analysis supporting the proposition that the merger at issue would be likely to substantially harm competition. In the healthcare merger cases that the FTC has litigated, the courts have been convinced by the FTC’s fact-specific arguments a majority of the time. This trend demonstrates thorough and reasoned analysis in the cases that the FTC decides to bring forward. Had the FTC filed more unsupported cases, it would have suffered significantly more losses, wasting valuable resources and diminishing its reputation before the courts.

In short, current federal merger enforcement is highly effective and reflects sound legal and economic policy. Therefore, recent calls for legislation to revise section 7 standards to allow more merger challenges are unnecessary. Moreover, proposed legislative changes would tend to harm consumer welfare and thus undermine the paramount goal of antitrust. Particularly problematic is the suggestion to alter the burden of persuasion to require a company to prove that a proposed merger is procompetitive—a concept that stands in opposition to Supreme Court precedent and rules of civil procedure. Adoption of such a major change would discourage many potentially welfare-enhancing mergers, harming consumers.

Additionally, and inconsistent with the reform proposals, the theory of the firm teaches that mergers may be motivated by the underutilization or misallocation of assets or the opportunity to create welfare-enhancing synergies. In the pharmaceutical industry, these synergies may come from joining complementary research and development programs, combining diverse and specialized expertise that may be leveraged for better, faster drug development and more innovation.

6. FED. TRADE COMM’N, OVERVIEW OF FTC ACTIONS IN PHARMACEUTICAL PRODUCTS AND DISTRIBUTION (Apr. 2021); FED. TRADE COMM’N, OVERVIEW OF FTC ACTIONS IN HEALTH CARE SERVICES AND PRODUCTS (Apr. 2021). The FTC has won 17 of the 24 merger challenges in the healthcare, hospital, and pharmaceutical sectors it has brought before federal courts from 1994 to the present, amounting to an approximately 70 percent win rate.
8. For a discussion of Supreme Court precedent and rules of civil procedure regarding the burden of proof in antitrust cases, see Edward Brunet & David J. Sweeney, Integrating Antitrust Procedure and Substance after Northwest Wholesale Stationers: Evolving Antitrust Approaches to Pleadings, Burden of Proof, and Boycotts, 72 Va. L. Rev. 1015, 1057–63 (1986). In addition, requiring a firm to “prove” a future state of competition would require it to engage in speculation about possible changes in market conditions based on information it likely does not possess.
10. Id. at 28 (“[C]onsolidation can increase demand for externally-sourced innovation and, ultimately, strengthen aggregate drug innovation.”).
Finally, leading antitrust scholars, including Justice Stephen Breyer and Judge Frank Easterbrook, among others, have noted that antitrust is an administrative system with inevitable error. Agencies should seek to maximize the value of expected enforcement-related benefits minus administrative costs, including aggregate error costs. A more aggressive, non-evidence-based, non-economics-based approach to pharmaceutical mergers would be at odds with this framework. It would render the FTC a less effective enforcer, an agency whose actions would yield significantly smaller welfare gains than they do at present.

EXPLORING SEVEN KEY ASPECTS OF CURRENT PRACTICES FOR THE EVALUATION OF PHARMACEUTICAL MERGERS

In the following subsections, we explore questions from the task force regarding seven key aspects of the evaluation of pharmaceutical mergers.

THEORIES OF HARM

When considering theories of harm, investigators should weigh potential efficiencies that may benefit consumers and producers against the harm that may come from reduced competition. The basic theory of harm should continue to be the loss of direct competition between products in horizontal mergers through unilateral or coordinated effects. Both situations have the probability to raise prices, reduce output, or both, but investigators must perform evidence-based analysis to estimate the magnitude of such harm.

Potential competitive harm may also occur where a product or products in the regulatory pipeline of one of the merging firms would, when approved, compete directly with a product of the other firm. In such cases, firms may have an incentive to shutter one product to create or maintain a competitive advantage in the specific product space. Mere speculation about future diminution in innovation, including reduced R&D, when there may be future competition between existing and forthcoming products, however, should not in and of itself support a merger challenge.

In the case of vertical mergers, investigators should consider foreclosure and raising rivals’ costs theories, but blocking of a merger must only proceed if hard facts support those theories and with due consideration given to efficiencies of vertical integration. Such efficiencies involve reduction of costs not related to competitive harm and avoidance of double marginalization. Given the existence of research that suggests that mergers may enhance the efficiency of R&D and innovative efforts, enforcement agencies should heavily weight innovation efficiencies and not readily assume that a merger-related reduction in R&D spending represents harm; such a reduction may represent welfare gains owing to more efficient use of R&D.

---

11. Global Antitrust Institute, The United States Department of Justice Antitrust Division Roundtable Series on Competition and Deregulation, First Roundtable on State Action, Statutory Exemptions and Implied Immunities, Comment of the Global Antitrust Institute, Antonin Scalia Law School, George Mason University (Mar. 13, 2018), at 3–9, https://www.justice.gov/atr/page/file/1043131/download (discussing the Court and Breyer’s jurisprudence developing an error-cost framework for antitrust and noting in particular that “[t]he potential social benefits and costs of the application of antitrust law and remedies in the context of an existing regulatory framework include not only administrative costs, but also those arising from changes in deterrence levels. This benefit-cost approach is thus necessarily predicated upon the error-cost framework the Court has adopted in many antitrust actions, including Brooke Group, Trinko, Weyerhauser, Leegin, linkLine, and Twombly” [citations omitted]); see generally Frank H. Easterbrook, The Limits of Antitrust, 63 Tex. L. Rev. 1 (1984); Isaac Ehrlich & Richard A. Posner, An Economic Analysis of Legal Rulemaking, 3 J. Legal Stud. 257 (1974); Richard A. Posner, An Economic Approach to Legal Procedure and Judicial Administration, 2 J. Legal Stud. 399 (1973).

EFFECTS ON INNOVATION

Using theoretical harms to innovation as a justification to block a merger is not the correct approach. This approach has the potential to disincentivize innovative efforts; reduce efficiency in the R&D process; and decrease viability of small, research-focused firms.

Although some observers claim that mergers reduce innovation in the pharmaceutical sector, these claims are based on an outdated understanding of the R&D process. Until the 1980s, R&D was conducted largely in house, with the bulk of the risk being taken by a single pharmaceutical company. Along with this R&D, the pharmaceutical company also carried out trials and marketed the drug. Although the evidence is largely neutral, some studies find a slight negative correlation between mergers and in-house R&D.

Currently, however, much of the R&D for large pharmaceutical companies is achieved through partnerships or investment in small biotechnology and research firms specializing in a single type of therapy. Whereas large pharmaceutical companies have expertise in marketing, navigating regulation, and undertaking trials of new drugs, small, research-focused firms can achieve greater advancements in medicine with smaller budgets.

Furthermore, changes within firms brought about by a merger may increase innovation. With increases in intellectual property and proprietary data that come from the merging of two firms, research firms may have access to greater pools of information, enhancing the potential for innovation without increasing spending. This change not only raises the efficiency of the research being conducted in these small firms, but also increases the probability of a breakthrough without an increase in risk.

CONDUCT-RELATED RISKS

Conduct-related risks, such as price setting (unilateral or collusive) or anticompetitive reverse payments, should not hinder merger assessments. Although price setting is partly a function of market share, it is also a function of reimbursement rates and availability of viable alternative products. In addition, any anticompetitive result that might be achieved through a reverse payment could be handled appropriately through merger enforcement, and reverse payment issues do not provide additional complications for merger enforcers. The next two paragraphs explore these conduct-related risks and how the FTC may deal with them.

Anticompetitive Reverse Payments. The ability for reverse payments to disrupt competition has been handled effectively by the FTC, according to a recent analysis of pharmaceutical patent

15. See generally Carmine Ornaghi, Comm’c’n Submitted to the Toulouse School of Econ. for the Conf. The Economics of the Health Care and the Pharmaceutical Industry: Mergers and Innovation in Big Pharma (Jan. 25–26, 2008); Comanor & Scherer, supra note 13, at 31.
17. Shepherd, supra note 9, at 25.
Reverse payment investigations occur outside merger enforcement. Instead, they involve allegations of anticompetitive agreements between two separate firms whereby a branded drug patent holder seeks to pay off a potential generic producer to delay the entry of the generic producer into the market and thereby forestall competition. If in lieu of a reverse payment agreement the two separate firms were to seek to merge, the potential loss of competition between their products would be assessed by the investigating agency. Based on the investigation's findings, the merger could be challenged or subjected to a divestiture that maintains competition between the products. In short, a proposed merger would not in any way enable firms to evade the antitrust scrutiny and exposure they would receive under a reverse payment agreement.

**Price Setting.** Price setting is more a function of downstream negotiations and insurance company power than pharmaceutical company market share. Because of the complex negotiations over rebates, discounts, and list prices, end consumers rarely pay the full list price of drugs. However, list prices have been skyrocketing owing to increases in rebates taken by intermediaries between manufacturer and consumers. A detailed evaluation of these considerations is outside the scope of this comment. Suffice it to say that regardless of the market power a manufacturer may have after a merger, price setting is never unilateral in the pharmaceutical market. Without onerously complex analysis, the effect of market share on the end price of drugs after a merger may never be accurately estimated within the timeframe of a merger review.

We do not mean to suggest, of course, that reverse-payment and price-setting risks are immaterial. The FTC should conduct full investigation and analysis of companies accused of anticompetitive unilateral or collusive conduct in all cases, in line with agency best practices. The FTC has a long history of thorough analysis supported by economic reasoning and focused on promoting consumer welfare. A lack of primary focus on reverse payments and price setting during merger analysis will not prevent the FTC from looking into future conduct.

One conduct-related consideration that the FTC should account for during merger analysis is regulatory navigation by postmerger companies. It is well established that regulatory compliance places a large burden on companies in many sectors, and regulatory navigation is particularly challenging in the pharmaceutical sector. For many small firms, compliance with FDA and US Department of Health and Human Services regulations is a significant hurdle when bringing a new drug to market. Accordingly, a merger with a large firm that is established in the industry and has experience surmounting the regulatory hurdles may aid smaller companies in producing and

---

20. According to a December 2020 FTC staff report analyzing pharmaceutical patent settlement agreements, very few agreements involved reverse payments that are likely to be anticompetitive. Commenting on this report, then-FTC Chair Joseph Simons states that “[t]he report shows, following the [Supreme Court’s] Actavis decision [submitting reverse payments to antitrust scrutiny] and subsequent case law applying it, a continued decline in use of the types of reverse-payment agreements that are most likely to harm consumers.” Press Release, Fed. Trade Comm’n, FTC Staff Issues FY 2017 Report on Branded Drug Firms’ Patent Settlements with Generic Competitors (Dec. 3, 2020).
22. Id.
23. DELOITE CENTER FOR HEALTH SOLUTIONS, THE CHALLENGE OF COMPLIANCE IN LIFE SCIENCES: MOVING FROM COST TO VALUE (2015). For a discussion of the regulatory pathway and potential challenges related to FDA compliance, see LISA L. MICHAELS & SUSAN J. SCHNIEPP, REGULATORY COMPLIANCE ASSOC. INC., U.S. FOOD AND DRUG ADMINISTRATION (FDA) REGULATORY PATHWAYS FOR MEDICAL DEVICES (2019) (“Obtaining regulatory clearance or approval for new medical device products and technologies has historically been a complex and challenging process for many manufacturers.”).
marketing a new drug. Decreasing the time to market for a new drug may increase competition, reduce prices, and allow more options for end consumers.\textsuperscript{24}

MARKET DEFINITION
At present, there is no reason to rework the market definition framework for pharmaceutical merger analysis. Admittedly, there may be problems in applying the paradigmatic hypothetical monopolist SSNIP (small but significant and nontransitory increase in price) test of the \textit{Horizontal Merger Guidelines} to pharmaceutical products.\textsuperscript{25} The guidelines’ treatment of market definition, however, is not wedded to a narrow, inflexible version of SSNIP methodology: “The [antitrust] Agencies implement these principles of market definition flexibly when evaluating different possible candidate markets.”\textsuperscript{26}

In cases where market information is incomplete, consumer spending patterns are distorted,\textsuperscript{27} or the relevant product market does not yet exist, different forms of analysis may be needed to determine the nature of competitive harm. As advised in the merger guidelines, the FTC may use previous consumer behavior in similar markets and market event studies as natural experiments to reach this end.\textsuperscript{28} Although these methods are imperfect, they give a best estimation framework for future market conditions based on estimated market concentrations after a merger and allow error costs to be minimized.\textsuperscript{29}

EXPANDED THEORIES OF HARM
It is not clear that expanded theories of harm are needed. Evidence is required for propositions that a merger would likely diminish competition in a particular pharmaceutical market consistent with the application of both horizontal and vertical merger guidelines.\textsuperscript{30} Although direct evidence of harm is rare, given the fact that one is dealing with future competitive interactions, the merger guidelines provide methods of estimating the competitive effects based on current market conditions. Relying on market definition in future-looking mergers usefully cabin error costs.

---

\textsuperscript{24} See generally \textsc{Anna Chorniy et al., Mercatus Center at George Mason University, Regulatory Review Time and Pharmaceutical R\&D (2019) ["W]e find a substantial and statistically negative relation between drug development and the time the FDA takes to process [new drug applications]. . . . If review time is prolonged by about three months, there is, on average, one fewer drug in development in each drug category."]).

\textsuperscript{25} See U.S. \textsc{Dept. of Just. \& Fed. Trade Comm’n, Horizontal Merger Guidelines, supra note 4, § 4.1.2, at 10–11; Stephanie Demperio & Jennifer Cascone Fauer, Defining the Relevant Market in Pharmaceutical Antitrust Cases, 32 \textit{Antitrust Health Care Chronicle} 2, 2–3 (2017) ["T]he results generated by a SSNIP test in pharmaceutical cases may not be informative of economic substitution . . . [because] the true prices that would be relevant for a demand analysis of a candidate market for prescription drugs are typically not observable."]).

\textsuperscript{26} U.S. \textsc{Dept. of Just. \& Fed. Trade Comm’n, Horizontal Merger Guidelines, supra note 4, § 4, at 7–14.}

\textsuperscript{27} Distortion in the pharmaceutical context may come from insurance markets. Because consumers who have access to insurance are not internalizing the full cost of the product and may not pay the same price as others in the market, the effect of an increase in price may not be uniform across relative elasticities. See Mark V. Pauly, \textit{Taxation, Health Insurance, and Market Failure in the Medical Economy}, 24 \textit{J. of Econ. Lit.} 629 (1986).

\textsuperscript{28} U.S. \textsc{Dept. of Just. \& Fed. Trade Comm’n, Horizontal Merger Guidelines, supra note 4, § 4.1.3; see generally Demperio & Cascone Fauer, supra note 25.}

\textsuperscript{29} For an analysis of Easterbrook’s error-cost framework and implications for modern antitrust enforcement, see Thomas A. Lambert, \textit{The Limits of Antitrust in the 21st Century}, 43 \textit{Regulation} 20 (2020).

\textsuperscript{30} U.S. \textsc{Dept. of Just. \& Fed. Trade Comm’n, Horizontal Merger Guidelines, supra note 4; U.S. \textsc{Dept. of Just. \& Fed. Trade Comm’n, Vertical Merger Guidelines, supra note 4.}
As noted previously, there have been 67 mergers reviewed by the FTC in the pharmaceutical space between 1994 and 2020, and in 66 of those cases it was determined that a divestiture was required. The FTC conducted a study in 1999 to analyze the effectiveness of divestitures and long-term competitive viability of divested assets. Of the 37 divestitures that were studied, 28 resulted in viable competitors in the relevant market.31

Of note are two insights found in the original report. First, divestiture of whole lines of business, not partial assets or divisions of a larger product line, is critical for the success and competitiveness of the divested assets. Second, firms looking to acquire divested assets should have a clear understanding of the market in which divested assets will compete.32

The next section presents a more encompassing view of the efficiency ramifications of divestitures, but in the specific case of divesting partial product lines there is the potential for losses of both competition and efficiency. Without inclusion of all aspects of product line support (proprietary data, support staff, technical knowledge, patents, etc.), there will be efficiency losses. These aspects of the product line are not only vital to the development and distribution of drugs, but also fundamental to the operation of businesses. Reengineering all of these different aspects from the ground up will expend substantial resources and will put pressure on the profitability of products.33

Without these assets there will be a fundamental lack of competitive pressure from the divested product line. Every dollar spent on reengineering the vital assets required to operate a business is a dollar not spent competing with rivals. In the case of divestitures from merging parties to maintain competition in a particular product line, the brand retained by the merging parties will not have a problem with efficiency. Divesting without a complete business line will allow the merged parties to almost certainly eliminate one competitor through superior efficiency.

Furthermore, without an encompassing understanding of the lines of business in which the assets compete, acquiring firms will have no hope of success. Following a similar argument as with partial divestitures, an incomplete understanding of the competitive and regulatory environment that acquiring firms are about to enter will lead to decreased efficiency and competition. The time spent learning about and hiring experts to navigate the industry is time spent not competing. If a divestiture is so critical to maintaining a competitive balance in the market, then any losses owing to imperfect information must be minimized.

When one discusses vertical mergers, different remedies may be applicable. Separation of business divisions to prevent anticompetitive information exchanges, and other possible vertical remedies, may warrant consideration.34

However, in both horizontal and vertical merger cases, behavioral remedies present serious risks associated with costly and imperfect oversight, and incentives to act efficiently may also be

32. Id. at 37–38.
33. In this case, the divestment of partial assets is equivalent to a one-time increase in the marginal cost of production.
34. U.S. DEPT. OF JUST. & FED. TRADE COMM’N, VERTICAL MERGER GUIDELINES, supra note 4.
skewed. In cases of behavioral modification, so-called regulatory capture may occur, and resources will be spent lobbying for favorable oversight as opposed to vigorously competing. 35

DIVESTITURES TO RESOLVE COMPETITIVE CONCERNS

Divestitures have been a key method for maintaining competition in pharmaceutical markets when mergers have been shown to pose an anticompetitive risk. According to the aforementioned FTC divestiture study, divesting product lines has an estimated 75 percent success rate, 36 significantly higher than the 70 to 90 percent failure rate for mergers throughout the economy. 37 However, this high success rate of divested assets will not necessarily hold for divestitures in the future unless the FTC follows appropriate policies. Because every line of business and every company is different, the FTC should follow different divestiture strategies.

Only lines of business where mergers that take place without divestiture have the potential to decrease competition should be subject to divestiture. This limitation is critical to the viability of both the divested assets and the merging companies. If merging firms are forced to divest assets despite a competitive concern not being present, those assets may become less innovative. Furthermore, if investigators do not identify a competitive concern with a merger but the FTC nevertheless requires merging firms to divest certain assets, such a requirement may reduce efficiency and increase the cost of bringing drugs to market.

Divested assets need full lines of business to be viable in a competitive market. 38 During the divestiture process, this stipulation necessitates that all relevant assets, data, and support systems must be in place to give the newly divested product line the greatest likelihood of success. However, if investigators do not find a competitive concern but the FTC nevertheless requires divestiture, the product line will become less innovatively efficient. Companies have synergies, allowing multiple product lines to share common assets. These common assets are specialized in nature, designed to perform their function within the company at an extremely high level. 39 During the divestiture process the main firm has an incentive to keep the most productive and efficient divisions, tying the divested products to less productive and efficient divisions.

Where a need to maintain competition through divestitures exists, a company that is acquiring divested assets has an incentive to invest in maintaining the efficient deployment of the assets, because there is proven demand for the product that the divested assets may produce. In these cases, the groundwork for competitive success has already been established, and investment in efficient operations will promote success. However, when no competitive concern exists, the change in hands of assets puts the acquiring company at a distinct disadvantage. The acquiring firm not only has to get up to speed quickly to compete, but also has less incentive to rigorously compete because of the increased risk of a low return. 40

---

35. For an overview of regulatory capture, see Adam Thierer, Regulatory Capture: What the Experts Have Found, TECHNOLOGY LIBERATION FRONT (Dec. 19, 2010), https://techliberation.com/2010/12/19/regulatory-capture-what-the-experts-have-found/.
40. This increased burden of divesting into an already highly competitive market will put strain on the competitiveness of the company. The newly divested company will not have the incentive to invest in efficiency-increasing means of business because of the probability of a low return on investment, and it will not be able to cut costs sufficiently to maintain profitability. See
Additionally, owing to the synergies found among complementary lines of business, the inability to pool risk and economize scales by forcing unnecessary divestitures will reduce efficiency and increase the cost of bringing drugs to market, leading to an increase in prices for consumers.

Just as the reduction in efficiency from an inappropriately designed divestiture harms the firm acquiring assets, it will also harm merging firms. Merging firms have an incentive to keep the most productive personnel, data, and assets, but they will invariably lose some of these at the margin. If merging parties lose valuable labor or data, they will have to hire and train more individuals and recreate the data for use in their other projects, which will take time and resources away from development, regulatory approval, and other necessary functions of a pharmaceutical business.

Divestitures, when formulated correctly, should have a neutral effect on efficiency and a positive effect on competitiveness. When regulators force merging firms to divest assets without providing a competitive justification, both efficiency and competitiveness will diminish. Forcing divestitures decreases competition and increases prices, leading to the outcome that regulators seek to avoid.

CONCLUSION
Federal merger enforcement in general and FTC pharmaceutical merger enforcement in particular have been effective in promoting competition and consumer welfare. Proposed statutory amendments to strengthen merger enforcement not only are unnecessary, but also would, if enacted, tend to undermine welfare and would thus be poor public policy. A brief analysis of seven questions propounded by the Multilateral Pharmaceutical Merger Task Force suggests that (a) significant changes in enforcement policies are not warranted and (b) investigators should employ sound legal and economic analysis, taking full account of merger-related efficiencies, when evaluating pharmaceutical mergers.

Klaus M. Schmidt, *Managerial Incentives and Product Market Competition*, 64 Rev. of Econ. Studies 191 (1997) (“The basic impact of increased competition is that it reduces the profits of a firm . . . [i]f a firm has high costs, then the reduction of profits may be sufficient to render the firm unprofitable . . . [and] the reduction in profits may affect the profitability of a cost-reduction.”).

41 For a discussion of the positive market effects of divestitures, see Helder Vasconcelos, CTR. FOR ECON. AND POL’Y RSCH., EFFICIENCY GAINS AND STRUCTURAL REMEDIES IN MERGER CONTROL 23 (2007) (“[W]henever partial mergers are part of the equilibrium path, the [enforcement agency] goes beyond recreating the level of competition that existed prior to the proposed transaction. The [enforcement agency] tends to demand divestitures to clear the merger proposal that will make the market more competitive than in the status quo industry structure.”).