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PROMOTING COMPETITION IN PHARMACEUTICAL MARKETS: IS THE BIDEN EXECUTIVE ORDER DELIVERING ON THE PROMISE?

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In 2021, the Biden administration issued a landmark Executive Order (EO) on competition. A major focus of the EO is the pharmaceutical sector in the U.S., where consumers pay prices for prescription drugs that are significantly higher than in other countries. In deploying a number of policy tools, the sector is a proving ground for the EO's signature "whole-of-government" approach to promoting competition. However, the approach largely overlooks the critical role of merger control by the Federal Trade Commission (FTC) in the pharmaceutical sector. Merger control is the first line of defense in preventing harmful increases in market concentration that can enhance market power and reduce consumer welfare through higher drug prices, lower quality, and less innovation. In excluding merger control from the policy toolkit, the Biden administration has also missed an important opportunity to revisit the FTC's longstanding, controversial policy for pharmaceutical mergers. That policy has been to approve virtually all mergers subject to divestitures, which has fostered higher concentration in critical drug markets. This analysis makes the case for why it is time for the Biden administration to take stock and consider a mid-course policy correction in implementing the EO in the pharmaceutical sector.

I. TAKING STOCK OF THE BIDEN ADMINISTRATION'S EXECUTIVE ORDER ON COMPETITION

The availability and affordability of prescription drugs are an essential part of promoting the health, stability, and productivity of the U.S. population. Competition in pharmaceutical R&D that produces new branded drugs, and the entry of generic and biosimilar drugs, plays a leading role in ensuring that medications are accessible and affordable. But anticompetitive strategies can limit competition and reduce consumer welfare through higher drug prices, lower quality, and less innovation. These include "product-hopping" schemes and "pay-for-delay" agreements involving branded drugs coming off-patent, that stifle competition from generics and biosimilars.[1] Pharmaceutical mergers involving generic drug manufacturers that significantly increase market concentration can also lead to outcomes that reduce consumer welfare.

Early on, the Biden administration recognized the challenges of promoting competition in the pharmaceutical sector. For example, the July 2021 Executive Order (EO), *Competition in the American Economy,*" sets forth a "whole-of-government" approach that is "necessary to address

[1] *See, e.g., FTC v. Actavis, Inc.*, 570 U.S. 136 (2013), and *In re Suboxone Antitrust Litigation*, 64 F. Supp. 3d. 665(E.D. Pa., 2014).

overconcentration, monopolization, and unfair competition in the American economy."[2] The EO shines a light on the pharmaceutical sector, noting that Americans pay "too much" for prescription drugs, and that they pay far more for drugs than in other countries.

Concerns over competition and drug pricing and access, of course, pre-date the Biden administration. Federal legislative proposals to protect competition and consumers target harmful conduct ranging from anticompetitive agreements that pay generic firms to stay out of a market, to excessive drug pricing. They include, for example, the CREATES Act of 2019, Protecting Consumer Access to Generic Drugs Act of 2019, and Prescription Drug Price Relief Act of 2019.[3] California has also led state efforts to promote competition through legislation that makes pay-for-delay agreements illegal.[4]

The Biden EO frames an ambitious suite of initiatives to address pharmaceutical competition by looking at domestic supply chains, prices paid by the government, generic and biosimilar competition, patent policy, and payment models. An array of executive agencies are tasked with implementation: Health and Human Services and Centers for Medicare & Medicaid Services, the Food and Drug Administration, and the U.S. Patent and Trademark Office. The Federal Trade Commission (FTC) is also charged with using its rulemaking authority to enforce methods of unfair competition or anticompetitive agreements involving prescription drugs.

The scope of the EO's approach to pharmaceutical competition appears consistent with "whole-of-government." Antitrust enforcement is clearly a major policy tool. However, the Biden administration omits a vital prong of antitrust enforcement — merger control — as a first line of defense in addressing pharmaceutical competition and drug pricing concerns. In doing so, the EO also misses an important opportunity to revisit the FTC's longstanding, troubled policy for reviewing and remedying pharmaceutical mergers.

The omission of important policy tools, or lack of inter-agency coordination, has marked implementation of the whole-of-government approach in other sectors. For example, the U.S. Department of Transportation has not moved to redesign the airport takeoff and landing slot system, or to revisit its approval criteria for airline joint ventures.[5] Both policies are central to promoting competition. The Federal Energy Regulatory Commission has given incumbent natural monopolies in electricity and natural gas precedence in expanding critical infrastructure, a policy that limits competition from other important market players.[6]

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[2] *Executive Order on Promoting Competition in the American Economy*, The White House (Jul. 9, 2021), at § 1, https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/.

[3] S. 340, 116th Cong. (2019) (incorporated into H.R. 1865, 116th Cong. (2019); H.R. 1499, 116th Cong. (2019); and S. 102, 116th Cong. (2019).

[4] A.B. 824, 2019–20 Sess. (Cal. 2019).

[5] Diana L. Moss, *Revisiting Antitrust Immunity for International Airline Alliances*, Am. Antitrust Inst. (Mar. 28, 2018), https://www.antitrustinstitute.org/wp-content/uploads/2018/03/AAI_Revisiting-Antitrust-Immunity_R-2.28.19.pdf.

[6] Diana L. Moss, *FERC v. the Biden Executive Order: Reversing Course on Competition in the Energy Sector?* Am. Antitrust Inst. (Sept. 6, 2022), https://www.antitrustinstitute.org/work-product/ferc-v-the-biden-executive-order-reversing-course-on-competition-in-the-energy-sector/.

This analysis unpacks why a lack of focus on merger control in the pharmaceutical sector is likely to limit the effectiveness of the whole-of-government approach under the Biden administration's EO. It discusses why a focus on consumer welfare should be a critical policy "lens" through which to view important competition issues; the importance of revisiting merger control in pharmaceutical markets based on past enforcement failures; and the need for a mid-course policy correction.

II. COMPETITION, CONSUMER WELFARE, AND DRUG PRICES

Drug prices are affected by a number of factors, including the cost of R&D, powerful pharmacy benefit managers, which take a significant cut of final drug prices, and the intensity of competition in branded and generic drug markets.[7] These factors play centrally into the question of why U.S. prescription drug prices are significantly higher than in other countries. For example, in 2018, prices for all drugs were more than 2.5 times higher in the U.S., relative to a 32-country sample. Prices for branded drugs in the U.S. were 3.4 times higher.[8]

Economic, legal, and policy experts assess the source and impact of drug pricing through different policy lenses. Trends in aggregate metrics such as price inflation may factor into broader macroeconomic policies.[9] However, such measures are neither the standard, nor the motivating force, for antitrust enforcement. Enforcement is triggered by harmful consolidation and strategic conduct that reduces consumer welfare through higher prices, lower quality, or less innovation.

Antitrust concerns arise in specific drug markets that are the subject of challenged mergers and conduct that is expressly designed to limit competition. The former includes, in particular, generic drug mergers that harmfully eliminate head-to-head competition and raise prices to consumers. The latter includes efforts by branded drug manufacturers to delay generic or biosimilar entry through pay-for-delay agreements or product hopping schemes that limit generic entry by moving patients to a minimally reformulated, and re-patented, drug.

Anticompetitive strategies can disproportionately affect prices for certain drugs. For example, in 2021, 80% of prescriptions filled in the U.S. were for generics, but branded drugs accounted for 80% of total prescription drug spending.[10] Further, the top 10% of drugs, by price, accounted for less than 1% of all prescriptions but 15% of retail spending.[11] Of the approximately 5,860 drug

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[7] Matej Mikulic, *Flow of Payments for a 100 Dollar Blood Pressure Medication if the Patient Pays a Copayment in the U.S. as of 2017*, Statistia (May 23, 2018), https://www.statista.com/ statistics/829418/payment-flow-for-100-usd-blood-pressure-medication-with-patient-copayment/.

[8] Andrew W. Mulcahy, et al., *International Prescription Drug Price Comparisons Current Empirical Estimates and Comparisons with Previous Studies* (2021), Rand Corporation, https://www.rand.org/pubs/research_reports/RR2956.html.

[9] Drug price inflation lagged overall inflation from 2018-2022, reversing a six-year trend from 2013-2017. *Consumer Price Index*, U.S. Bureau of Labor Statistics, https://www.bls.gov/cpi/.

[10] *Trends in Prescription Drug Spending, 2016-2021*, U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation (Sept. 2022), at p. 1, https://aspe.hhs.gov/sites/default/files/documents/a3849b001cb2b9b961a3b8399ddbfe23/sdp-trends-prescription-drug-spending.pdf.

[11] *Id.*

products surveyed by HHS in 2022 that experienced changes in list prices, 73% showed list price increases.[12] About 46% of those medications had list price increases that were higher than the rate of inflation, with an average increase of about 15%.[13]

High-profile price hikes for life-saving medications illustrate the gravity of the foregoing issue. For example, Mylan increased the price for a pack of two Epi-Pen (epinephrine) auto-injectors by 400% between 2011-2016, a price that remains high even with generic entry by Teva.[14] And after the toxoplasmosis medication, Daraprim, was acquired by Turing Pharmaceuticals in 2015, the price increased by more than 5500%.[15] The pricing of both drugs has been the subject of antitrust scrutiny.[16]

Moreover, there is strong economic evidence that competition from generics is a major factor in driving down drug prices. For example, as the number of generic competitors in a drug market increases, generic prices fall increasingly below those of branded prices.[17] This, and other competition issues, highlight the importance of antitrust enforcement in pharmaceutical markets, particularly the vital role of merger control in preserving competition and protecting consumers.

III. MERGER CONTROL IN THE PHARMACEUTICAL SECTOR IS AN ESSENTIAL POLICY TOOL

To get a sense of how other policy tools for addressing pharmaceutical competition stack up against merger control, take the White House's recent announcement that drug manufacturers agreed to negotiate prices with the Centers for Medicare & Medicaid Services for 10 major drugs under Medicare Part D.[18] There is a good deal of uncertainty around how the drug price negotiation program will unfold. Among other issues, the program is the subject of numerous

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[12] *Changes in the List Prices of Prescription Drugs, 2017-2023*, U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation (Oct. 6, 2023), https://aspe.hhs.gov/sites/default/files/documents/0cdd88059165eef3bed1fc587a0fd68a/aspe-drug-price-tracking-brief.pdf.

[13] There is little visible impact of the pandemic on prescription drug spending. See, HHS (2016-2021), *supra* note 10, at 1.

[14] Committee on Oversight and Gov't Reform, Hearing on Reviewing the Rising Price of EpiPens, 114th Cong. 3 (2016) https://www.govinfo.gov/content/pkg/CHRG-114hhrg24914/ pdf/CHRG-114hhrg24914.pdf.

[15] Andrew Pollack, *Once a Neglected Treatment, Now an Expensive Specialty Drug*, N.Y. Times (Sept. 20, 2015).

[16] *See, e.g.*, In Re EpiPen Marketing, Sales Practices and Antitrust Litigation, No. 2:17-md-02785-DDC-TJJ (MDL No: 2785) (D. Kan., Oct. 17, 2017), https://www.epipenclassaction.com/documents/October%2017,%202017%20Consolidated%20Class%20Action%2; *See also* Eric Sagonowsky, *Shkreli hit with $64.6M verdict, lifetime pharma ban in antitrust case* (Jan. 14, 2022), Fierce Pharma, https://www.fiercepharma.com/pharma/shrekli-hit-64-6m-verdict-lifetime-pharma-ban-antitrust-case.

[17] Ryan Conrad and Randall Lutter, *Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices*, U.S. Food & Drug Administration, at p. 2, https://www.fda.gov/media/133509/download?attachment.

[18] *Biden-Harris Administration Takes Major Step Forward in Lowering Health Care Costs; Announces Manufacturers Participating in Drug Price Negotiation Program*, The White House (Oct. 3, 2023), https://www.whitehouse.gov/briefing-room/statements-releases/2023/10/03/biden-harris-administration-takes-major-step-forward-in-lowering-health-care-costs-announces-manufacturers-participating-in-drug-price-negotiation-program/.

legal challenges and patents for half the drugs are slated in the next three years, raising questions around how it will impact competition from generics and biosimilars.[19] But the major limitation of the drug price negotiation policy is that it targets the outcome, not the source, of the drug pricing problem.

A major source of higher drug prices is consolidation that significantly increases concentration and enhances market power, leading to higher drug prices. But the EO overlooks the most effective policy tool, merger control, in combatting this problem. In the process, the EO *also* misses the opportunity to motivate the FTC to revisit its longstanding and controversial approach to merger control. Indeed, there is compelling evidence that the FTC's approach to evaluating and remedying drug mergers has fostered rising market concentration in critical drug markets.

A recent study revealed that between 1994-2020, the FTC challenged 67 pharmaceutical mergers worth almost $1 trillion dollars. Of those mergers, however, the Commission moved to block only one, and settled virtually all others with narrowly tailored packages of asset divestitures.[20] The vast majority of these mergers eliminated significant competition, reducing the number of rivals in markets from four-to-three, three-to-two, and two-to-one.[21] Highly concentrative mergers are especially harmful to consumers. And it is well-known that the more concentrative a merger, the more difficult it is for a remedy to restore competition and protect consumers.

The FTC's policy of approving challenged pharmaceutical mergers subject to divestitures has promoted ownership of critical assets by a shrinking number of firms. A number of key observations highlight this problem. First, only a small number of firms that were particularly acquisitive between 1994-2020 accounted for the "churn" in a relatively large proportion of pharmaceutical assets.[22] Second, the majority of pharmaceutical firms that were party to mergers and purchased divestiture assets in other challenged mergers were also "serial" purchasers. Finally, about one-third of all buyers of divestiture assets were merged into, or acquired by, a top pharmaceutical company within two years after purchase.

These outcomes highlight that the FTC's policy has promoted a pattern of pharmaceutical assets changing hands among a smaller number of pharmaceutical firms over time, contributing to higher market concentration. For example, a study of generic drugs between 2004-2016 indicates that about 40% of generic drug molecule dosage forms were supplied by a single firm and about 50% were supplied by no more than two competitors.[23]

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[19] Alexandra Lu and Matt Wetzel, *The Drug Price Negotiation Program and Pending Legal Challenges*, Big Molecule Watch (Aug. 25, 2023), https://www.bigmoleculewatch.com/2023/08/25/first-drugs-selected-for-price-negotiations-under-the-inflation-reduction-act-to-be-announced-next-week-a-recap-of-what-that-means-the-drug-price-negotiation-program-and-pending-legal-challenges/.
[20] Diana L. Moss, *From Competition to Conspiracy: Assessing the Federal Trade Commission's Merger Policy in the Pharmaceutical Sector*, Am. Antitrust Inst. (Sept. 3, 2020), https://www.antitrustinstitute.org/wp-content/uploads/2020/09/AAI_PharmaReport2020_9-11-20.pdf.
[21] *Id.*, at 13.
[22] Moss, *supra* note 21, at p. 16.
[23] Ernst R. Berndt, Rena M. Conti, & Stephen J. Murphy, *The Landscape of the U.S. Generic Prescription Drug Markets, 2004-2016*, NBER Working Paper #W23640, at Table 15 (July2017), http://www.nber.org/papers/w23640.

Another outgrowth of the FTC's merger policy in pharmaceutical markets is non-merger antitrust violations. For example, many of the firms that were the most engaged in M&A, and as purchasers of divestiture assets, are named defendants in private, state, and federal non-merger antitrust litigations. These include, importantly, price-fixing indictments among generic drug manufacturers that have particularly egregious effects on consumers.[24] Indeed, about 55% of the pharmaceutical companies that were involved in drug mergers and purchases of divestiture assets have been, or are currently, involved in antitrust litigations.

This evidence supports the notion that any merger policy that fosters rising market concentration and spurs stronger incentives to engage in harmful conduct should be a major focus of reform under the Biden administration's EO. The FTC itself recognizes the failings of its longstanding policy to approve virtually all drug mergers subject to divestitures, rather than moving to block harmful deals outright. The Commission's own study of on-market generics found, for example, that 25% of firms that purchased divestiture assets between 2006-2012 *stopped* selling the drug post-divestiture.[25] When such remedies fail to restore the competition lost by harmful drug mergers, consumers directly bear the burden of higher drug prices.[26]

Finally, it is important to note that the federal antitrust agencies' recently issued revised merger guidelines will not provide the needed review and invigoration of the FTC's enforcement policy for pharmaceutical mergers.[27] The proposed guidelines do not resolve basic questions around how the FTC reviews pharmaceutical mergers, nor do they address merger remedies, which are a major concern.

IV. THE NEED FOR A MID-COURSE CORRECTION

Drug pricing will remain a high-profile public policy issue. The level of drug prices can determine whether consumers buy medicines or pay their energy or food bills. As the first line of defense against rising concentration and higher drug prices, merger control is the major and most effective policy tool. It will also be especially important in light of the looming patent "cliff," or a cluster of major drug patent expirations in the 2020s. For example, upcoming patent

[24] *Id.*, at pp. 17-20.
[25] Fed. Trade Comm'n Bureaus of Competition and Econ., FTC's merger remedies 2006-2012 (2017), https://www.ftc.gov/system/files/documents/reports/ftcs-merger-remedies-2006-2012-report-bureaus-competition-economics/p143100_ftc_merger_remedies_2006-2012.pdf. The highest failure rate was observed for complex generics, followed by oral solid generics.
[26] Since 2020, the FTC has required divestitures in the generic drug merger of ANI Pharmaceuticals and Notivium Pharma. *See, FTC Approves Final Order Requiring Generic Drug Marketers ANI Pharmaceuticals, Inc. and Novitium Pharma LLC to Divest Rights and Assets to Generic Sulfamethoxazole-Trimethoprim Oral Suspension and Generic Dexamethasone Tablets*, Fed. Trade Comm'n. (Jan. 12, 2022), https://www.ftc.gov/news-events/news/press-releases/2022/01/ftc-approves-final-order-requiring-generic-drug-marketers-ani-pharmaceuticals-inc-novitium-pharma.
[27] *FACT SHEET: White House Competition Council Announces New Actions to Lower Costs and Marks Second Anniversary of President Biden's Executive Order on Competition*, The White House (Jul. 19. 2023), https://www.whitehouse.gov/briefing-room/statements-releases/2023/07/19/fact-sheet-white-house-competition-council-announces-new-actions-to-lower-costs-and-marks-second-anniversary-of-president-bidens-executive-order-on-competition/. *See also*, U.S. Dep't. of Justice and Fed. Trade Comm'n., *Merger Guidelines* (July 2023), https://www.justice.gov/d9/2023-07/2023-draft-merger-guidelines_0.pdf.

expirations will put about $200 billion in drug revenue at risk through 2030 as generic entry diverts market share and revenue from the branded drug.[28] As in the past, branded drug manufacturers will look for replacement revenue streams, which could come from number of sources, including strategic M&A that is designed to solidify or extend drug portfolios.

Merger control, coupled with rethinking the FTC's troubled approach to pharmaceutical merger review, should be a central component of the EO's whole-of-government approach to promoting competition and controlling drug prices. But despite considerable attention to the FTC's pharmaceutical merger, no substantive reforms are in play. The time has come, therefore, for the Biden administration to assess its progress under the EO and make a mid-course correction to conform competition policy in the pharmaceutical sector to a genuine, whole-of-government approach.

[28] Jonathan Gardener, *Big pharma's looming threat: a patent cliff of 'tectonic magnitude',* BioPharma Dive (Feb. 21, 2023), https://www.biopharmadive.com/news/pharma-patent-cliff-biologic-drugs-humira-keytruda/642660/.