

August 9, 2021

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independent Avenue, Southwest
Washington, D.C. 20201

Dear Secretary Becerra:

We write to you as a broad coalition of groups with the common goal of taking on the concentration and anticompetitive conduct in the health care industry that has harmed patients and worsened health outcomes in our country.

We applaud your outstanding work and leadership as Secretary of the Department of Health and Human Services (HHS) and are excited to see HHS included in President Biden's Executive Order on Competition Policy.¹ The Executive Order represents a shift in thinking and practice, moving democratic institutions to disperse economic power centered on patients, working people, and communities, while moving away from decades of consolidation and unfair conduct by health care monopolies.

With this in mind, we write to propose several policies HHS may enact to lower drug prices, strengthen domestic manufacturing, and reduce government spending on prescription drugs in accordance with Section 5(p)(iv) of the Executive Order.

As explained herein, we believe HHS has authority to act on multiple fronts to address the drug supply chain and affordability crisis by: (I) using compulsory patent licensing provided by 28 U.S.C. § 1498(a) to bring new insulin manufacturers to market to increase competition and break the historic cartel; (II) restoring fair markets for independent pharmacies and purchasers by eliminating predatory DIR fees, unfair patients steering, and anti-kickback exemptions for group purchasing organizations (GPOs); (III) aggressively enforcing laws against pharmaceutical companies who have repeatedly engaged in illegal conduct to harm competition; and (IV) using participation in the Part D and Medicaid programs to encourage competition.

I. Insulin Policy

The most urgent competition issue in the U.S. is the high price of insulin because of the historically dominant insulin cartel consisting of Eli Lilly, Novo Nordisk, and Sanofi-Aventis.² The Colorado Attorney General recently reported that approximately 40% of insulin users are forced to ration their insulin at least once a year.³ Additionally, there have been widespread media reports of injuries and deaths because of insulin rationing. Americans, many of whom have insurance, are dying of insulin scarcity in the richest country in the world even though insulin was invented 100 years ago, and the most popular brands of insulin were first approved by the FDA more than 20 years ago.⁴

¹ Executive Order 14036 of July 9, 2021, *Promoting Competition in the American Economy*, 88 Fed. Reg. 36,987 (July 14, 2021).

² See American Economic Liberties Project, *Letter to the FTC Requesting Investigation of Insulin Market* (Nov. 10, 2020), <https://drive.google.com/file/d/138710kssVYxPm0OuRNKKgfuJVluNRbRr/view>.

³ Colorado Dept. of Law, *Prescription Insulin Drug Pricing Report*, at 16 (Nov. 2020), <https://coag.gov/app/uploads/2020/11/Insulin-Report-102020.pdf>.

⁴ Some of the top insulins include: NovoLog (2000); Humalog (1996); Lantus (2000); Levemir (2005).

The insulin cartel is not the result of legal competition. Eli Lilly, Novo Nordisk, and Sanofi-Aventis, along with their Pharmaceutical Benefit Manager (PBM) co-conspirators, have consistently violated antitrust and related laws to illegally maintain their individual and collective monopolies by:

- (1) illegally listing injector device patents in the Orange Book;⁵
- (2) using PBM rebates as kickbacks to secure market share away from lower cost competition and inflate patients' out of pocket costs;⁶
- (3) obtaining obvious or otherwise invalid patents;⁷
- (4) entering anticompetitive licensing agreements with potential competitors;⁸
- (5) product hopping and/or evergreening;⁹

Despite years of controversy and these widespread illegal practices, Medicare and Medicaid continue to spend billions each year on illegally price-fixed insulin while Americans die because of artificial scarcity in a life-sustaining market. People living with diabetes cannot wait any longer for long-term policy solutions. They need immediate action to protect them from the predatory insulin cartel.

Accordingly, HHS should use the compulsory licensing authority provided in 28 U.S.C. § 1498(a) to immediately force licensure of all relevant patents on all older generations of insulin products. Compulsory licensing would allow the U.S. government to “seize” the relevant patent monopolies and contract with other manufacturers to directly produce and distribute insulin to increase competition in the major product markets to break the historic insulin cartel.¹⁰

The statute, 28 U.S.C. 1498(a), specifically allows for the government to hire companies to manufacture items on its behalf. While insulin manufacturers will certainly object, they will be entitled to fair compensation for use of their patents as determined by the United States Court of Federal Claims if any of the relevant patents are eventually found to be valid and enforceable.¹¹ Compulsory licensing and manufacturing of the major brand insulin products, along with enforcement actions described below, appears to be the most direct method that HHS could use to increase competition in the insulin market in the immediate future.

II. Policies to Protect Independent Pharmacies and Rebuild a Resilient Pharmaceutical Supply Chain

⁵ See e.g., *In re Lantus Direct Purchaser Antitrust Litigation (César Castillo, Inc. v. Sanofi-Aventis U.S., LLC)*, 950 F.3d 1, 10 (1st Cir. 2020).

⁶ *In re Direct Purchaser Insulin Pricing Litigation*, 3:20-cv-3426 (BRM) (LHG) (D.N.J. July 9, 2021). See also, Xcenda, *White Paper: Skyrocketing Growth in PBM Formulary Exclusions Raises Concerns About Patient Access* (Sept. 2020), (finding 2 out of 3 PBMs excluded lower cost authorized generic versions of insulin and hepatitis C drugs in favor of brand drugs that come with PBM rebates), https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/xcenda_pbm_exclusion_whitepaper_9-20.pdf?la=en&hash=B59B51A73075D62E561C94D85CC769FAD039D6BA.

⁷ See e.g., *Mylan Invalidates Sanofi's Lantus SoloSTAR Device Patents in IPR Proceedings* (May 29, 2020), <https://www.prnewswire.com/news-releases/mylan-invalidates-sanofis-lantus-solostar-device-patents-in-ipr-proceedings-301067927.html>.

⁸ Robin C. Feldman & Prianka Misra, *The Fatal Attraction of Pay-for-Delay*, 18 Chicago-Kent Journal of Intellectual Property 1, 274, available at <https://scholarship.kentlaw.iit.edu/cgi/viewcontent.cgi?article=1225&context=ckjip> (describing how Lilly agreed not to compete against Sanofi's Lantus in the U.S.).

⁹ See Connor Christensen, *The Evergreen Forests of Insulin Patents* (Sept. 14, 2020), <https://awakenwfu.com/2020/09/14/the-evergreen-forests-of-insulin-patents/>.

¹⁰ See Amy Kapczynski and Aaron Kesselheim, *Government Patent Use: A Legal Approach to Reducing Drug Spending*, Health Affairs 35 (2016), 791-97, <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2015.1120> (arguing for compulsory licensing of hepatitis C drugs).

¹¹ 28 U.S.C. § 1498(a).

The White House recently released a 100-Day Report that addressed vulnerabilities in the U.S. supply chain of prescription drugs among other critical materials.¹² While the Report correctly identified supply chain vulnerabilities arising from foreign drug manufacturing, it failed to address anticompetitive practices that are threatening the thousands of independent pharmacies that form the critical, distributed last mile of the prescription drug supply chain.

A. Eliminate Pharmacy DIR Fees

The easiest thing HHS could do to strengthen the pharmaceutical supply chain is to complete the Trump’s administration’s previous rulemaking that would have eliminated pharmacy Direct and Indirect Remuneration (DIR) Fees within Medicare Part D.¹³

DIR fees are most prominent in Part D and essentially allow plans to retroactively change the amount they reimburse pharmacies for prescriptions months after those prescriptions have been filled based on complicated, opaque performance metrics. In short, DIR fees threaten independent pharmacies, harm patients, and drive-up Medicare costs, all while enriching Part D plans with little or no accountability. CMS first publicly recognized the unsustainable and unfair nature of DIR fees in January 2017.¹⁴ Since then, Pharmacy DIR Fees in Medicare Part D more than doubled and reached \$9.1 billion per year in 2019.¹⁵

Accordingly, CMS should rapidly enact the previous administration’s proposed rule (83 Fed. Reg. 62,152 (Nov. 30, 2018)), which would eliminate retroactive DIR fees by changing the definition of “negotiated prices” to require that all pharmacy price concessions be included at the point of sale. This would simply close the pharmacy DIR loophole and ensure that the Part D program no longer allows plans to extract predatory fees from independent pharmacies.

B. Prohibit Plans Favoring Affiliated Pharmacies and Patients

Another practice that threatens independent pharmacies is when PBMs and plans steer independent pharmacies’ patients to their own mail-order and specialty pharmacies. In this way, PBMs and insurers are using their dominance in one market (PBM services) to gain power in another market (retail pharmacy). It has been widely documented that vertical consolidation has led to a variety of anticompetitive harms including “spread pricing” in the Medicaid program,¹⁶ PBMs profiting from driving patients to expensive specialty drugs to retain rebates,¹⁷ and other ways PBMs have been accused of favoring affiliated pharmacies over arms-length independent pharmacy competitors often in violation

¹² White House, *Building Resilient Supply Chains, Revitalizing American Manufacturing, and Fostering Broad-Based Growth* (June 2021), https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf?utm_source=sfmc%E2%80%8B&utm_medium=email%E2%80%8B&utm_campaign=20210610_Global_Manufacturing_Economic_Update_June_Members

¹³ See National Community Pharmacists Association, *Letter to Secretary Becerra* (July 19, 2021), available at <https://ncpa.org/sites/default/files/2021-07/NCPA%20LTR%20Becerra%20RE%2045%20Day%20Report%20EO%20FINAL.pdf>

¹⁴ CMS.gov, *Medicare Part D – Direct and Indirect Remuneration (DIR)* (Jan. 19, 2017), <https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir>.

¹⁵ Adam Fein, *Drug Channels, Pharmacy DIR Fees Hit a Record \$9 Billion in 2019—That’s 18% of Total Medicare Part D Rebates* (Feb. 13, 2020), <https://www.drugchannels.net/2020/02/pharmacy-dir-fees-hit-record-9-billion.html>.

¹⁶ 3 Axis Advisor, *Sunshine in the Black Box of Pharmacy Benefits Management: Florida Medicaid Pharmacy Claims Analysis* (Jan. 30, 2020), <https://www.3axisadvisors.com/projects/2020/1/29/sunshine-in-the-black-box-of-pharmacy-benefits-management>.

¹⁷ 46Brooklyn, *New Pricing Data Reveals Where PBMs and Pharmacies Make Their Money* (April 21, 2019), <https://www.46brooklyn.com/research/2019/4/21/new-pricing-data-reveals-where-pbms-and-pharmacies-make-their-money>.

of Part D’s ‘any willing provider’ rule.¹⁸ Medicare allows these practices to exist even though they harm independent pharmacies that are much safer and more secure.¹⁹

Accordingly, HHS should crack down on all forms of favoritism and patient steering in Part D and Medicaid and pass regulations to prohibit conflicts of interest within these programs and specifically target practices that allow PBMs and insurance companies to dominate U.S. pharmacy markets.

C. Re-Implement Anti-Kickback Rules for Group Purchasing Organizations

Drug shortages are far too common, with hundreds of drugs or medical supplies—everything from saline to epinephrine to chemotherapeutic agents to antibiotics and sterile water—regularly in short supply or outright shortage. Drug shortages were rare, however, until the 1990s because drug manufacturing supply chains were domestic, resilient, and world-class. Back then, increased demand led to higher prices and rapidly more supply, as intended. Since the early 2000s however, these market signals stopped working—more demand didn’t lead to more supply, but instead, to shortages. In addition, much of the domestic generic manufacturing capacity moved abroad. These trends are related and have to do with the consolidation of the GPO industry and its exemption from the Anti-Kickback Statute.²⁰ There is even evidence that PPE shortages, notably masks, were the result of these distorted market structures.²¹

GPOs are bulk buyers of supplies for hospitals. Originally formed to help hospitals secure better prices for supplies and medicine, GPOs now increase prices and encourage less resiliency in supply chains. The reason for this shift is twofold. First, Congress passed a law in 1987 exempting GPOs from the Anti-Kickback statutes. In 1991, HHS enacted regulations to implement that statutory exemption. Shortly thereafter, GPOs went on a significant merger spree. Today, 90% of the market for medical supplies is controlled by four firms.²²

GPOs effectively sell access to the suppliers who provide the biggest rebates to the GPOs. Hospitals get rebates to use certain GPOs, which has effectively created a cartel within the medical supply market. The consolidation and corruption are so extreme that hospital executives are given a cut of fees directly from GPOs.²³ With complete control of the market, GPOs use a variety of contracting methods to constrain the manufacturers’ ability to raise prices, which in turn thins the supply chain to the absolute lowest cost manufacturers, discourages investment in future capacity, and limits diversification of supply. These practices include contracting with manufacturers who are willing to pay to be sole suppliers and adding

¹⁸ See 46Brooklyn, *The Flawed Design of Medicare Part D: A Copaxone Case Study* (Aug. 12, 2020), <https://www.46brooklyn.com/research/2020/8/12/copaxone> (discussing strategies around the any willing provider rule). See also, <http://www.medpac.gov/docs/default-source/default-document-library/pbms-and-specialty-pharmacies---final.pdf?sfvrsn=0> (“PBMs may get around this rule by instituting fees that discourage pharmacy participation.”).

¹⁹ Ohio Pharmacist Workload Advisory Committee, *Pharmacist Workload Survey* (April 2021), available at <https://www.pharmacy.ohio.gov/Documents/Pubs/Reports/PharmacistWorkloadSurvey/2020%20Pharmacist%20Workload%20Survey.pdf>.

²⁰ Matt Stoller, *On Antitrust Enforcement*, American Compass, June 11, 2020, <https://americancompass.org/essays/on-antitrust-enforcement/>.

²¹ Diana Falzone, *The Costco Model on Steroids’: Massive Corporate Deals Are Making Hospitals’ PPE Shortages Worse*, Vanity Fair (May 21, 2020), <https://www.vanityfair.com/news/2020/05/corporate-deals-making-hospitals-ppe-shortages-worse>; Marion Mass, *COVID-19 unmasks GPO middlemen, shortages of medical supplies*, The Intelligencer (August 13, 2020), <https://www.theintell.com/story/opinion/columns/more-voices/2020/08/13/guest-opinion-covid-19-unmasks-gpo-middlemen-shortages-of-medical-supplies/113142224/>.

²² *Building Resilient Supply Chains, Revitalizing American Manufacturing, and Fostering Broad-Based Growth*. (June 19, 2020) <https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf>.

²³ Phillip L. Zweig and Frederick C. Blum, *Where Does the Law Against Kickbacks Not Apply? Your Hospital*, Wall Street Journal (May 7, 2018), <https://www.wsj.com/articles/where-does-the-law-against-kickbacks-not-apply-your-hospital-1525731707>.

administrative fees that detract from further investment in quality manufacturing capacity.²⁴ As Phillip L. Zweig and Frederick C. Blum noted in 2018:

The results of this anticompetitive system are higher costs and inevitable supply breakdowns. For example, the GPOs would have the public believe that Hurricane Maria triggered shortages of sterile IV solutions by damaging Baxter International's Puerto Rican plants. In fact, shortages of saline and other solutions have existed for years, forcing the U.S. to import them from several countries. The deeper reason is that GPOs have relied almost exclusively on Baxter for these products, concentrating production and discouraging potential competitors. Although information on contract terms is confidential, a Baxter press release touting a 2007 deal with Novation (now Vizient) describes the terms as "an extended single source award for IV solutions."²⁵

Congress should repeal the exemption from anti-kickback laws for GPOs. Until then, HHS should narrow the scope of GPOs exemption from anti-kickback prohibitions as much as possible under the existing statute and oppose any further consolidation of GPOs.

III. Policies to Address Conduct to Delay Generic and Biosimilar Competition

A. The FDA Should Immediately Remove All Device and REMS from the Orange Book as False Statements in Drug Applications.

There has been a huge, underappreciated problem of drug manufacturers illegally listing certain categories of patents in the FDA's Orange Book despite those patents being banned under statute and FDA regulation.

The Orange Book is the FDA's official list of drug patents that is used to determine when all patents and regulatory exclusivities have expired so the FDA and potential generic manufacturers can determine when the FDA is legally allowed to approve generic products. Crucially, the mere act of listing a patent in the Orange Book regarding a brand drug statutorily prohibits the FDA from approving any generic product for 30 months to give the parties time to litigate patent infringement claims. Unfortunately, the FDA failed to monitor what patents are listed in the Orange Book and has allowed manufacturers to illegally list certain types of patents in the Orange Book merely to obtain this 30-month generic delay, even when these types of patents are prohibited by the relevant statute, as recently recognized by the First Circuit Court of Appeals in *In re Lantus Antitrust Litigation*.²⁶

Drug companies that manufacture drug-device combination products, including the major brands of insulin injectors, COPD/asthma inhalers, and epinephrine autoinjectors, have illegally extracted tens of billions of dollars from federal programs in recent years by delaying generic competition through this illegal patent listing strategy.²⁷ In addition to device patents, REMS patents (related to the FDA's Risk

²⁴ FDA, *Drug Shortages: Root Causes and Potential Solutions* (2020), at 41, available at <https://www.fda.gov/media/131130/download>.

²⁵ Phillip L. Zweig and Frederick C. Blum, *Where Does the Law Against Kickbacks Not Apply? Your Hospital*, Wall Street Journal (May 7, 2018), <https://www.wsj.com/articles/where-does-the-law-against-kickbacks-not-apply-your-hospital-1525731707>.

²⁶ *In re Lantus Direct Purchaser Antitrust Litig. (César Castillo, Inc. v. Sanofi-Aventis U.S., LLC)*, 950 F.3d 1, 10 (1st Cir. 2020) (interpreting 21 U.S.C. § 355(b)(1) and 21 C.F.R. § 314.53(b)(1)) ("The statute and regulations clearly require that only patents that claim the drug for which the NDA is submitted should be listed in the Orange Book. The '864 patent, which neither claims nor even mentions insulin glargine or the Lantus SoloSTAR, does not fit the bill.")

²⁷ Reed F. Beall et al., "Is Patent 'Evergreening' Restricting Access to Medicine/Device Combination Products?," *PLoS One* (Feb. 24, 2016), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4766186/>.

Evaluation and Mitigation Strategies program), have also been illegally listed in the Orange Book to delay generic competition.²⁸

The Trump administration launched a FDA rulemaking to address this issue in 2020,²⁹ which drew comments from several state attorneys general who recognized that illegal device patent listing has been a major contributor to the insulin affordability crisis.³⁰ The FDA re-opened comments on this issue in March 2021, when in response to the passage of the Orange Book Transparency Act of 2020, signed by President Trump on January 5, 2021, which required the FDA to solicit public comment and report to Congress on this issue and reaffirmed the FDA's previous regulation about which patents could be listed.³¹

Despite the new statute, the First Circuit's decision in *In re Lantus Antitrust Litigation*, FDA regulation, and the recently passed federal statute to further clarify the law, drug industry lawyers are still advising their clients to continue illegally listing device patents in the Orange Book.³²

The FDA should finally resolve this issue and immediately issue regulations that squarely prohibit all device and REMS patents from being listed in the Orange Book. Additionally, the FDA should immediately pursue enforcement actions against the sponsors of NDAs containing illegal patent listing. Additionally, the FDA should also use its fundamental authority to punish and reject drug applications that contain false statements of material fact, which includes every NDA that references an illegally listed patent.³³ Accordingly, the FDA should immediately pursue enforcement of all illegally listed patents to allow generic competition in these important markets.

B. The FDA Should Stop Approving Nearly Identical Drug Products That Are Intended to Delay Competition.

Another practice that allows drug companies to extract anticompetitive profits is “product hopping” or “evergreening,” which describes drug companies’ strategy of slightly modifying existing brand drugs in a way that impedes generic competition.³⁴ Drug companies commonly modify the dose or dosage form of an existing brand product just enough to thwart legally mandated substitution of generic version of the original brand product. In this way, drug companies can perpetually force patients to “new” nearly identical drug products and perpetually avoid generic competition. Professor Robin Feldman recently surveyed the practice of ever-greening across drugs in the Orange Book and concluded that 78% of

²⁸ Michael A. Carrier & Brenna Sooy, *Five Solutions to the REMS Patent Problem*, 97 B.U. L. Rev. 1661, 1671 (2017) (explaining the REMS patent listing problem); Comment from Prof. Michael Carrier, *Why REMS Patents Should Not Be Listed in the Orange Book*, FDA-2020-N-1127-0002, <https://www.regulations.gov/comment/FDA-2020-N-1127-0002>.

²⁹ *Listing of Patent Information in the Orange Book, Establishment of a Public Docket*; Request for Comments, FDA-2020-N-1127-0001, <https://www.federalregister.gov/documents/2020/06/01/2020-11684/listing-of-patent-information-in-the-orange-book-establishment-of-a-public-docket-request-for>.

³⁰ Karl Racine et al., *Listing of Patent Information in the Orange Book*, FDA-2020-N-1127-0013, <https://www.regulations.gov/comment/FDA-2020-N-1127-0013> (referencing *In re Lantus Antitrust Litigation*). Illegal device patent listing no longer helps maintain insulin exclusivity after the major insulin brands became regulated as biologic products for the first time. Biologic products do have patent listings or 30-months stays.

³¹ H.R.1503 - Orange Book Transparency Act of 2020.

³² Polsinelli, *President Signs Orange Book Transparency Act of 2020* (Jan. 11, 2021), <https://www.polsinelli.com/intelligence/president-signs-orange-book-transparency-act> (“Accordingly, NDA applicants are likely to continue to exercise their own discretion on whether to submit device patents for listing in the Orange Book...”).

³³ 21 U.S.C. § 355(e)

³⁴ See Michael A. Carrier and Steve Shadowen, *A Non-Coercive Approach to Product Hopping*, 33 Antitrust 102 (2018).

patents pertain to brand drug companies' existing drug products, instead of new drug products, as is commonly assumed.³⁵

For example, product hopping was at issue in *In re Asacol Antitrust Litigation* where the Court found evidence that AbbVie (then Warner Chilcott) removed its ulcerative colitis medicine, Asacol, from the market right before generics would have entered the market to switch patients over to a new drug, Delzicol.³⁶ Delzicol was literally an Asacol tablet wrapped in an inert cellulose capsule (<https://www.youtube.com/watch?v=eNtahEEygHI>).³⁷ There have also been similar product hopping schemes alleged regarding Namenda,³⁸ Nexium,³⁹ Suboxone,⁴⁰ and Lo Loestrin⁴¹ among other major brand drug products. These schemes greatly increase costs for patients because they force patients to continue paying co-pays and deductibles for high-price brand drugs years after cheaper generic versions of the original product were supposed to come to market.

While the FTC and DOJ can address product hopping under traditional antitrust laws, the FDA could also develop policies and regulations to ensure it is not facilitating anticompetitive product hopping schemes. Specifically, FDA should refuse to approve nearly identical drug products, or withdrawal any drug products from FDA databases, when these actions appear to thwart upcoming generic competition as contemplated by the Hatch-Waxman system. The FDA should prohibit minor changes to existing dose, dosage form, multi-drug combinations, and dispensing devices on existing products in a period before expected generic entry in addition to all other product changes that are intended to delay or thwart generic competition.

Unlike other anticompetitive schemes, product hopping requires the FDA's participation to approve what are essentially sham drug products that are often based on false statements. The FDA should enact policies and procedures regarding the approval of nearly identical drug products to ensure that the agency is not unwillingly participating in product hopping schemes.

C. FDA Should Request the PTO Develop Policies to Fight “Patent Thickets,” Patent Extensions, and Double Patenting

The Competition EO also directs the FDA to notify the Under Secretary of Commerce for IP and the Director of the U.S. PTO regarding concerns that drug companies unfairly game the patent system to prevent biosimilar and generic competition.⁴² The FDA should encourage those agencies to fight back

³⁵ Robin Feldman, *May your drug price be evergreen*, Journal of Law and the Biosciences, (Dec. 2018), Pages 590–647, <https://doi.org/10.1093/jlb/lxy022>; Related database here - <https://sites.uchastings.edu/evergreensearch/#.YP2ga5NKiL4> (“Rather than creating new medicines, pharmaceutical companies are largely recycling and repurposing old ones. Specifically, 78% of the drugs associated with new patents were not new drugs, but existing ones, and extending protection is particularly pronounced among blockbuster drugs.”).

³⁶ See *In re Asacol Antitrust Litigation*, No. 15-cv-12730 (Nov. 9, 2017), available at <https://www.leagle.com/decision/infdco20171113b48>.

³⁷ The Bend Bulletin, *Delzicol: How new is it?*, (Jul. 28, 2013), <https://www.youtube.com/watch?v=eNtahEEygHI>.

³⁸ *In re Namenda Antitrust Litigation (New York ex rel. Schneiderman v. Actavis PLC)*, 787 F.3d 638 (2d Cir. 2015) (Actavis caught attempting to force patients from Namenda to Namenda XR before generic entry).

³⁹ 2Axis Advisors, *Purple Haze: How a little purple pill called Nexium exposes big problems in the U.S. drug supply chain*, (Nov. 7, 2019), available at https://static1.squarespace.com/static/5c326d5596e76f58ee234632/t/5def9d6dc4c5ef230178e095/1575984501347/PurpleHaze_3AxisAdvisors_110719.pdf

⁴⁰ *In re Suboxone (Buprenorphine Hydrochlorine & Naloxone) Antitrust Litig.*, 967 F.3d 264, 268 (3d Cir. 2020)

⁴¹ *In re Loestrin Antitrust Litigation*, 13-md-02472, Consolidated Class Action Complaint, ECF 40, at 38-40 (describing Warner Chilcott's scheme to forcibly shift patients away from Loestrin 24 Fe and towards Lo Loestrin and Minastrin 24 before generic entry).

⁴² The Competition Order, § 5(p)(vi).

against several patent strategies commonly used to prevent biosimilar competition, which will ultimately determine the future of U.S. drug spending.

First, the FDA should request the PTO combat “patent thickening” in which brand drug companies file and receive dozens or hundreds of related patents on brand drugs.⁴³ For example, the PTO may have failed to ensure every patent was novel and non-obvious when it granted 257 patents on Humira and 222 patents on Avastin, as reported by I-MAK.⁴⁴

Second, the FDA should request the PTO reduce the issuance of new drug patents long after drugs are first approved by the FDA. Besides the extreme number of patents on Humira, AbbVie’s monopoly was specifically extended because 89% of the patents issued on Humira were filed after the drug first came on the market.⁴⁵ It seems nearly impossible that hundreds of new, non-obvious methods of using Humira were invented since the drug’s introduction.

Third, the FDA should direct those agencies to combat the practice of double patenting, which is the practice of obtaining multiple rounds of patents for essentially the same invention, sometimes by dividing patent rights between legal entities. This occurred regarding the blockbuster drug Enbrel, where the patent owner recently avoided a finding of non-obviousness because of a licensing agreement that technically divided patent rights between two entities.⁴⁶ The Federal Circuit’s recent decision upholding this loophole may extend the patent monopoly on Enbrel through 2029, which would give the drug 39 years of total exclusivity after it was first patented in 1990.⁴⁷

Finally, the FDA should direct those agencies to investigate and punish to the maximum extent permitted by law all attorneys and patent applicants who have committed fraud before the PTO to illegally extend their drug patent monopolies including the fraudulent schemes delayed generic competition for Apriso,⁴⁸ Namenda/Namzaric,⁴⁹ Zytiga,⁵⁰ and Restasis.⁵¹

IV. Policies to Encourage Competition in Part D and Medicaid

A. FDA Should Require Drug Companies to Comply with Industry-Specific Competition Standards as a Condition of Participation in Federal Health Programs.

The major problem with existing antitrust enforcement is that it often takes years of litigation and millions of dollars to prove a single antitrust violation under the prevailing “rule of reason” standard, which allows defendants to offer unlimited, creative pro-competitive justifications for what would otherwise be illegal, anticompetitive conduct. For example, the FTC’s enforcement action in *In the Matter*

⁴³ See I-MAK, *Overpatented, Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving Up Drug Prices*, <https://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf> (recognizing that the top 12 drug products had an average of 71 granted patents from an average of 125 patent applications). See also, Jeffrey Wu & Claire Wan-Chiung Chieng, *Into the Woods: A Biologic Patent Thicket Analysis*, 19 Chi.-Kent J. Intell. Prop. 93 (2019-20).

⁴⁴ See, I-MAK, *American’s Bestselling Drugs of 2019*, <https://www.i-mak.org/2019-bestselling/>.

⁴⁵ I-MAK, *Overpatented, Overpriced Special Edition: Humira* (Rev. Oct. 2020), <https://www.i-mak.org/wp-content/uploads/2020/10/i-mak.humira.report.3.final-REVISED-2020-10-06.pdf>.

⁴⁶ Jordan Engelhardt and Matthew Weiss, *Sandoz Petitions the Supreme Court for Review of Enbrel Patent License* (March 9, 2021), <https://www.jdsupra.com/legalnews/sandoz-petitions-the-supreme-court-for-9079555/>.

⁴⁷ I-Mak, *Overpatented, Overpriced: Enbrel* (December 2018), <https://www.i-mak.org/wp-content/uploads/2018/12/i-mak.enbrel.report-2018-11-30F.pdf>.

⁴⁸ *Silbersher v. Valeant Pharm. Int’l*, 445 F. Supp. 3d 393 (N.D. Cal. 2020) (Apriso).

⁴⁹ *Silbersher v. Allergan Inc.*, No. 18-cv-03018 JCS (N.D. Cal. Dec. 11, 2020) (Namenda and Namzaric).

⁵⁰ *KPH Healthcare Services, Inc. v. Janssen Biotech, Inc.*, No. 20-cv-05901 (D. N.J. May 14, 2020) (Zytiga).

⁵¹ *In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig.*, 333 F. Supp. 3d 135, 141 (E.D.N.Y. 2018) (Restasis).

of Impax Laboratories, Inc. lasted from January 2017 until April 2021 to establish a single pay-for-delay violation in 2010 regarding Opana ER.⁵²

HHS could improve competition within the entire industry by promulgating industry-specific competition standards and then requiring drug manufacturers to certify compliance with these standards in all federal contracts that are required to participate in federal health care programs including the Medicaid National Drug Rebate Agreement, the 340B program agreement, and the master agreement with the Secretary of Veterans Affairs, all required by Section 1927(a) of the Social Security Act. This would allow HHS to contractually define (or otherwise regulate under its authority to prevent fraud and misconduct) the specific competition standards that drug companies must adhere to participate in federal health care programs.

Such standards could make competition enforcement easier and less costly (and therefore more likely to deter violations) in several ways: First, it would be a way to implement specific competition standards as applied to known anticompetitive practices within the industry without the need for years of litigation. Such standards could prohibit exclusionary contracting for API, patent misconduct, pay-for-delay agreements, REMS abuse, and abuse of the Citizen Petition process. Second, requiring certifications of compliance with competition standards would make those who falsely certify compliance liable for health care fraud and therefore subject to fraud enforcement from HHS and OIG as well as liable under the False Claims Act. Anticompetitive conduct by drug companies and health care fraud are often related and both types of illegal conduct should therefore be subject to traditional HHS/OIG Medicare and Medicaid fraud enforcement.

B. The FDA Should Use Its Anti-Kickback Authority to Prohibit Plans from Accepting Rebates to Favor Expensive Brand Drugs Over Cheaper Alternatives.

One major driver of Medicare drug spending is the widespread practice of Part D plans accepting rebates from drug manufacturers to favor expensive brand drugs over alternatives that would be cheaper to patients on Part D formularies.

This has been observed in multiple contexts. For example, Part D plans frequently favor expensive “zombie” brand drugs (which should have already gone generic) such as Copaxone years after cheaper alternatives have come to market.⁵³ Part D plans are objectively slower than commercial plans to cover newly released generic and biosimilar drugs as the rebate of PBM rebates that discourage adoption of the affordable generics.⁵⁴ Similarly, Part D plan frequently cover expensive brand drugs, but exclude identical “authorized generic” products made by the same manufacturers because generic products do not come with significant rebates.⁵⁵

After years of discussion, the Trump administration issued a final rule on November 30, 2020 that would have amended the regulatory safe harbors under the Anti-Kickback Statute to prohibit rebates and other price reductions to Part D plans unless any such rebates qualified as point-of-sale price reductions under a

⁵² *Impax Labs., Inc. v. Fed. Trade Comm'n*, No. 19-60394, at *7 (5th Cir. Apr. 13, 2021). See also, *In the Matter of Impax Laboratories, Inc.*, Docket No. 9373 (collecting dozens of administrative filings), <https://www.ftc.gov/enforcement/cases-proceedings/141-0004/impax-laboratories-inc>.

⁵³ 46Brooklyn, *The Flawed Design of Medicare Part D: A Copaxone Case Study* (Aug. 12, 2020), <https://www.46brooklyn.com/research/2020/8/12/copaxone>.

⁵⁴ Association for Accessible Medicines, *New Generics Are Less Available in Medicare Than Commercial Plans* (July 2021) <https://accessiblemeds.org/sites/default/files/2021-07/AAM-New-Generics-Are-Less-Available-in-Medicare-2021.pdf>.

⁵⁵ Adam J. Fein, *Drug Channels, Why Part D Plans Prefer High List Price Drugs that Raise Costs for Seniors* (Jan. 22, 2020), <https://www.drugchannels.net/2020/01/why-part-d-plans-prefer-high-list-price.html>; Adam J. Fein, *Drug Channels, 2019 Express Scripts Formulary Exclusions: Hepatitis C Changes Show Why the Drug Channel Must Change, Too* (Aug. 16, 2018), <https://www.drugchannels.net/2018/08/2019-express-scripts-formulary.html>.

new safe harbor provision.⁵⁶ In March 2021, HHS announced it would delay the implementation of the final rebate rule until January 1, 2023.⁵⁷

HHS should now use its authority under the Anti-Kickback statute to specifically prohibit the types of rebates that increase prices for Part D and Medicaid patients, including (1) all instances where a plan receives a rebate in exchange for covering a brand over a generic or a significantly less expensive, similar brand; (2) all instances where a plan receives a rebate for covering a brand over an authorized generic version of that same drug; and (3) all instances where a plan receives a rebate to exclude coverage of a newly introduced drug product. These are the specific types of rebates that appear most harmful and most distorting to the Part D program.

Once again, we appreciate the administration's efforts in these areas, and we would be grateful for an opportunity to meet with you in coming weeks to discuss this letter further. We are available to answer any questions you might have on these matters in the meantime.

Sincerely,

American Economic Liberties Project

Beta Cell Foundation

Demand Progress Education Fund

Doctors For America

In the Public Interest

Revolving Door Project

T1International

Universities Allied for Essential Medicines

Physicians Against Drug Shortages (PADS)

Robert Campbell, M.D.
President, Central PA Anesthesia
Past President, Pennsylvania Society of Anesthesiologists
Lebanon, PA

James E Elbaor, M.D.
Co-chair
Orthopedist
Dallas, TX

Joanna G. Newton, MD, MSc
Hematologist/Oncologist, Aflac Cancer and Blood Disorders Center at Children's Healthcare of Atlanta

⁵⁶ HHS, *Fraud and Abuse; Removal of Safe Harbor Protection for Rebates*, RIN 0936-AA08 (March 22, 2021), available at <https://public-inspection.federalregister.gov/2021-05903.pdf>.

⁵⁷ *Id.*

Assistant Professor of Pediatrics
Emory University School of Medicine
Atlanta, GA

Mitchell Goldstein, M.D., M.B.A., C.M.L.
Professor of Pediatrics, Loma Linda University School of Medicine
Director, Neonatal ECMO Program
Loma Linda University Children's Hospital
Loma Linda, CA

Michael Levison, B.S.
Supply Chain Consultant
Toledo, OH

Mark Lopatin, M.D., FACP, FACR, FCPP
Co-chair
Jamison, PA

Norman D. Means, M.D., FCAP, DABFM
Co-chair
Physician
Goodland, KS

William J. Murphy, Ph.D.
Co-Chair
President, Good Government Now
Washington, DC

William "Bill" Price Esq.
Former United States Attorney
Western District of Oklahoma
Oklahoma City, OK

Marilyn M. Singleton, MD, JD
Redondo Beach, CA

Jim Thomas, M.D., M.B.A.
Co-Chair
Interventional Radiologist
Philadelphia, PA

Phillip L. Zweig, M.B.A.
Executive Director/Co-founder
New York, NY

Practicing Physicians of America (PPA)

Marion Mass, M.D.
Co-founder
Philadelphia area pediatrician

CC Brian Deese
Janet Woodcock, M.D.
Drew Hirshfeld
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David Cicilline
Lina Khan
Richard Powers
Tim Wu