## ELIZABETH WARREN MASSACHUSETTS

COMMITTEES:
BANKING, HOUSING, AND URBAN AFFAIRS
ARMED SERVICES

# United States Senate

UNITED STATES SENATE WASHINGTON, DC 20510-2105 P: 202-224-4543

2400 JFK FEDERAL BUILDING 15 NEW SUDBURY STREET BOSTON, MA 02203 P: 617-565-3170

1550 MAIN STREET SUITE 406 SPRINGFIELD, MA 01103 P: 413–788–2690

www.warren.senate.gov

FINANCE
SPECIAL COMMITTEE ON AGING

January 25, 2023

The Honorable Lina Khan Chair Federal Trade Commission 600 Pennsylvania Avenue, NW Washington, DC 20580

The Honorable Alvaro Bedoya Commissioner Federal Trade Commission 600 Pennsylvania Avenue, NW Washington, DC 20580 The Honorable Rebecca Kelly Slaughter Commissioner Federal Trade Commission 600 Pennsylvania Avenue, NW Washington, DC 20580

Dear Chair Khan, Commissioner Slaughter, and Commissioner Bedoya:

I am writing to express my concerns regarding rampant consolidation in the pharmaceutical industry and its impact on drug affordability and access in this country. I am particularly concerned about two pending pharmaceutical transactions: Amgen and Horizon Therapeutics, and Indivior and Opiant. Given these companies' records of anti-competitive business practices, these acquisitions could cause further price increases on lifesaving drugs and prevent affordable alternatives from entering the market. The Federal Trade Commission (FTC) should carefully scrutinize these deals and oppose any Big Pharma acquisition that will threaten competition, reduce innovation, or increase costs for American families.

There has been extensive consolidation in the pharmaceutical industry in recent decades, with the 60 most dominant pharmaceutical companies consolidating to a mere 10 firms between 1995 and 2015, leading to higher prices for American patients<sup>1</sup> and decreased innovation.<sup>2</sup> These corporate deals are bad for patients: prices for drugs sold by acquired companies increase at a faster rate than those sold by their non-acquired counterparts.<sup>3</sup> *The Inflation Reduction Act* contained a number of provisions that will help control drug prices and help American families with the cost of prescription drugs. This law – signed into law by President Biden in August 2022 – caps insulin copays for Medicare patients at \$35.<sup>4</sup> It ensures seniors will never pay more

<sup>&</sup>lt;sup>1</sup> Washington Post, "Drug companies keep merging. Why that's bad for consumers and innovation," Robin Feldman, April 6, 2021, <a href="https://www.washingtonpost.com/outlook/2021/04/06/drug-companies-keep-merging-why-thats-bad-consumers-innovation/">https://www.washingtonpost.com/outlook/2021/04/06/drug-companies-keep-merging-why-thats-bad-consumers-innovation/</a>.

<sup>&</sup>lt;sup>2</sup> Harvard Business Review, "Research: Innovation Suffers When Drug Companies Merge," Justus Haucap and Joel Stiebale, August 3, 2016, https://hbr.org/2016/08/research-innovation-suffers-when-drug-companies-merge.

<sup>&</sup>lt;sup>3</sup> SSRN, "Mergers, Product Prices, and Innovation: Evidence from the Pharmaceutical Industry," Alice Bonaime and Ye Wang, March 15, 2019, <a href="https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=3445753">https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=3445753</a>.

<sup>&</sup>lt;sup>4</sup> CNBC, "The Inflation Reduction Act caps costs for medicare patients on insulin. Where the push for broader relief stands," Lorie Konish, August 16, 2022, <a href="https://www.cnbc.com/2022/08/16/inflation-reduction-act-to-cap-costs-for-medicare-patients-on-insulin.html">https://www.cnbc.com/2022/08/16/inflation-reduction-act-to-cap-costs-for-medicare-patients-on-insulin.html</a>.

than \$2,000 each year in out-of-pocket drug costs. And, for the first time, it allows Medicare to negotiate lower prices for prescription drugs.<sup>5</sup>

This new law will make a profound difference for millions of Americans struggling with high drug costs. But beyond the passage of this law, there are additional actions that the administration can take to reduce the cost of prescription drugs and ensure competition in the pharmaceutical market. In particular, robust FTC enforcement of antitrust law can help slow the pace of drug company consolidation.

#### **Recent Consolidation**

Recent deals in the pharmaceutical industry highlight the pernicious effects of consolidation on drug prices and innovation. Just this month, Merck completed<sup>6</sup> its acquisition of Imago BioSciences for \$1.35 billion, which will give the company ownership of Imago's highlycoveted blood cancer treatment, Bomedemstat. 8 Merck's acquisition illustrates how in the face of lagging research productivity<sup>9</sup> and the loss of patent protections on key drugs<sup>10</sup>, larger companies are shifting their focus from innovation towards acquisitions – a strategy that will likely reduce the number of life-saving drugs on the market and raise costs for patients. In addition to this anti-competitive tactic, Merck has an extensive track record of price gouging, as well as a history of abusing the U.S. patent system to block generic competition and rake in record profits. 11

In June 2019, AbbVie acquired Allergan for a staggering \$63 billion. This megamerger came as AbbVie was set to lose patent protections on its most profitable drug, Humira, in 2023, after the company successfully blocked generic competition in the U.S. from 2002 to 2023. AbbVie was able to bring in nearly \$20 billion in revenue 12 from Humira in 2020 due to rapacious price hikes unsupported by clinical evidence<sup>13</sup>, which added almost \$1.4 billion dollars to costs for U.S. patients between 2019 and 2020. 14 But instead of focusing on innovation to compensate for the predicted loss of revenue from Humira, they decided to purchase a company

2

<sup>&</sup>lt;sup>5</sup> *Id*.

<sup>&</sup>lt;sup>6</sup> Merck, "Merck Completes Tender Offer to Acquire Imago BioSciences, Inc.," January 11, 2023, https://www.merck.com/news/merck-completes-tender-offer-to-acquire-imago-biosciences-inc/.

<sup>&</sup>lt;sup>8</sup> Wall Street Journal, "Merck Strikes \$1.35 Billion Deal for Bone-Marrow Disease Drug Developer," Jonathan Rockoff, November 21, 2022, https://www.wsj.com/articles/merck-strikes-1-35-billion-deal-for-bone-marrowdisease-drug-developer-11669033105.

<sup>&</sup>lt;sup>9</sup> Sustainalytics, "Implications of Consolidation in the Pharma and Biotech Sector," Anna Bonomi and Oana Pop, December 12, 2018, https://www.sustainalytics.com/esg-research/resource/investors-esg-blog/implications-ofconsolidation-in-the-pharma-and-biotech-sector.

<sup>&</sup>lt;sup>10</sup> Wall Street Journal, "Behind Spate of Drug Deals, the Need for Short-Term Growth," Jared Hopkins, June 25, 2019, https://www.wsj.com/articles/behind-spate-of-drug-deals-the-need-for-short-term-growth-11561494972?tesla=y&mod=article\_inline.

11 I-Mak, "Keytruda's Patent Wall," May 2021, https://www.i-mak.org/keytruda/.

<sup>&</sup>lt;sup>12</sup> Statista, "Revenue of AbbVie's Humira 2011-2021, Matej Mikulic, July 27, 2022, https://www.statista.com/statistics/318206/revenue-of-humira/.

<sup>&</sup>lt;sup>13</sup>Reuters, "Report says drugmakers impose unjustified U.S. price increases; spending on AbbVie drug rises \$1.4 billion, https://www.fiercepharma.com/pharma/abbvie-s-humira-leads-icer-s-list-unjustified-drug-price-increases-u-

 $<sup>\</sup>frac{S.}{14}Id.$ 

with an already profitable line of products, including the anti-wrinkle treatment, Botox. <sup>15</sup> This transaction highlights AbbVie's focus on acquisitions in lieu of innovation. Of 20 large pharmaceutical companies, AbbVie had the lowest spending on research and development as a percentage of revenue in 2021, <sup>16</sup> and upon announcement of the deal, AbbVie's Chairman and CEO indicated that there were plans to slash Allergan's research and development spending by \$1 billion. <sup>17</sup>

The AbbVie/Allergan deal was announced just months after Bristol-Meyers Squibb (BMS) acquired Celgene Corp. for \$74 billion in one of the largest pharmaceutical deals in history. <sup>18</sup> After the deal was completed, the new partnership created a combined portfolio of nine drugs making over a billion dollars each in annual sales <sup>19</sup>, giving BMS ample opportunity to continue its price gouging strategy that saw the company raise prices more frequently per drug than any other pharmaceutical company between 2015 and 2019. <sup>20</sup> Celgene, for its part, has raised prices on its top-selling product, Revlimid, 22 times since 2005, even though the price increases were not substantiated by research and development expenses. <sup>21</sup> Unsurprisingly, the day the deal was completed, BMS announced it would increase the price of Revlimid to \$763 per pill – a more than 300% increase from its \$215 price tag in 2005. <sup>22</sup> And aside from price increases on the drug, both BMS and Celgene have been embroiled in legal trouble over their efforts to shield Revlimid from competition. <sup>23</sup>

These are only a handful of examples of Big Pharma deals that have happened in the last few years. In light of the anti-competitive effects that appear to have been exacerbated by recent consolidation, the FTC should be cautious about greenlighting future deals that could lead to similar harms. In particular, the FTC should heavily scrutinize the Amgen-Horizon and Indivior-Opiant proposed acquisitions, as the companies have shown time and time again that they would rather squash competition and hike prices than deliver for U.S. patients.

<sup>&</sup>lt;sup>15</sup>Wall Street Journal, "Behind Spate of Drug Deals, the Need for Short-Term Growth," Jared Hopkins, June 25, 2019, <a href="https://www.wsj.com/articles/behind-spate-of-drug-deals-the-need-for-short-term-growth-11561494972?tesla=y&mod=article">https://www.wsj.com/articles/behind-spate-of-drug-deals-the-need-for-short-term-growth-11561494972?tesla=y&mod=article</a> inline.

<sup>&</sup>lt;sup>16</sup> Drug Discovery & Development, "Pharma's top 20 R&D spenders in 2021," Brian Buntz, March 30, 2022, <a href="https://www.drugdiscoverytrends.com/pharmas-top-20-rd-spenders-in-2021/">https://www.drugdiscoverytrends.com/pharmas-top-20-rd-spenders-in-2021/</a>.

<sup>&</sup>lt;sup>17</sup> Stat, "How Brent Saunders' Allergan experiment failed," Matthew Herper, June 26, 2019, https://www.statnews.com/2019/06/26/how-brent-saunders-allergan-experiment-failed/.

<sup>&</sup>lt;sup>18</sup> Reuters, "Bristol-Myers to buy Celgene for \$74 billion in largest biopharma deal," Michael Erman and Anjur Banerjee, January 3, 2019, <a href="https://www.reuters.com/article/us-celgene-m-a-bristol-myers/bristol-myers-to-buy-celgene-for-74-billion-in-largest-biopharma-deal-idUSKCN1OX0VM">https://www.reuters.com/article/us-celgene-m-a-bristol-myers/bristol-myers-to-buy-celgene-for-74-billion-in-largest-biopharma-deal-idUSKCN1OX0VM</a>.

<sup>&</sup>lt;sup>19</sup> Wall Street Journal, "Bristol-Myers Squibb to Acquire Celgene for About \$74 Billion," Jared Hopkins and Aisha Al-Muslim, January 3, 2019, <a href="https://www.wsj.com/articles/bristol-myers-squibb-to-acquire-celgene-11546517754">https://www.wsj.com/articles/bristol-myers-squibb-to-acquire-celgene-11546517754</a>.

<sup>20</sup> Axios, "Drug makers still raising prices, but seeking fewer hikes," Bob Herman, January 22, 2019, <a href="https://www.axios.com/2019/01/22/brand-name-drug-price-increases-46brooklyn">https://www.axios.com/2019/01/22/brand-name-drug-price-increases-46brooklyn</a>.

<sup>&</sup>lt;sup>21</sup> U.S. House of Representatives Committee on Oversight and Reform, "Drug Pricing Investigation: Celgene and Bristol Myers Squibb—Revlimid," September 2020, p. 1,

 $<sup>\</sup>underline{https://oversight democrats.house.gov/sites/democrats.oversight.house.gov/files/Celgene \% 20BMS\% 20Staff\% 20Report\% 2009-30-2020.pdf.\ .}$ 

<sup>&</sup>lt;sup>22</sup> *Id*.

<sup>&</sup>lt;sup>23</sup> Fierce Pharma, "'Monopoly' allowed Bristol Myers and generics makers to steal' from Revlimid purchasers, lawsuit says," Kevin Dunleavy, November 22, 2022, <a href="https://www.fiercepharma.com/pharma/new-antitrust-lawsuit-says-monoploy-allowed-bristol-myers-and-generics-makers-steal-30b">https://www.fiercepharma.com/pharma/new-antitrust-lawsuit-says-monoploy-allowed-bristol-myers-and-generics-makers-steal-30b</a>.

#### **Amgen-Horizon**

Amgen's \$28.7 billion proposed acquisition of Horizon Therapeutics would be among the largest healthcare deals of recent years. <sup>24</sup> This acquisition presents numerous antitrust and price gouging concerns. Both Amgen and Horizon have engaged in brazen price increases on drugs that face little or no competition, <sup>25</sup> <sup>26</sup> while Amgen has abused the patent process, creating patent thickets to "evergreen" their products, prevent generic competition, and maintain market dominance. <sup>27</sup>

Amgen's most egregious price hikes have involved its most profitable drug, Enbrel. After acquiring Enbrel's rights in 2002, Amgen has enacted 27 price hikes on the drug, raising its initial price of \$996 per month in 2002 to \$5,556 per month in 2020 – a 457% increase. Amgen's price hikes reveal a concerted effort by executives to pad their profits at the expense of American patients. Internal documents released by the U.S. House Committee on Oversight and Reform revealed that the drug's frequent price increases were "driven primarily by the need to meet increasingly aggressive revenue targets," resulting in rising profits for the company and generous executive compensation. Meanwhile, Medicare recipients taking Enbrel saw their annual out-of-pocket costs increase nearly \$600 between 2016 and 2019, forcing patients to choose between shelling out hundreds of dollars or foregoing treatment they desperately needed. Moreover, Amgen was able to meet aggressive revenue benchmarks due in part to its success with patent thickets, which effectively shielded their most profitable drug from generic competition for over 30 years. In the property of the drug from generic competition for over 30 years.

<sup>&</sup>lt;sup>24</sup> Wall Street Journal, "Amgen Agrees to Acquire Horizon Therapeutics for \$27.8 Billion," Ben Dummett, Dana Cimilluca, and Laura Cooper, December 12, 2022, <a href="https://www.wsj.com/articles/amgen-in-advanced-talks-to-buy-horizon-therapeutics-11670785882">https://www.wsj.com/articles/amgen-in-advanced-talks-to-buy-horizon-therapeutics-11670785882</a>.

<sup>&</sup>lt;sup>25</sup> U.S. Committee on Oversight and Reform U.S. House of Representatives, "Drug Pricing Investigation: Amgen—Enbrel and Sensipar," October 2020, pp. 1-3,

 $<sup>\</sup>frac{https://web.archive.org/web/20201003064007/https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Amgen%20Staff%20Report%2010-1-20.pdf.}$ 

<sup>&</sup>lt;sup>26</sup> Fierce Pharma, "Horizon's faced repeated price-hike criticism, but Vimovo just got its 11<sup>th</sup> raise—to almost \$3,000," Eric Sagonowsky, February 15, 2018, <a href="https://www.fiercepharma.com/pharma/horizon-s-vimovo-gets-a-february-price-hike-its-11th-recent-years-">https://www.fiercepharma.com/pharma/horizon-s-vimovo-gets-a-february-price-hike-its-11th-recent-years-</a>

report#:~:text=A%20Horizon%20spokesperson%20confirmed%20the,or%20less%20out%20of%20pocket.

27 Biopharma Dive, "A three-decade monopoly: How Amgen built a patent thicket around its top-selling drug," Jonathan Gardner, November 1, 2021, <a href="https://www.biopharmadive.com/news/amgen-enbrel-patent-thicket-monopoly-biosimilar/609042/">https://www.biopharmadive.com/news/amgen-enbrel-patent-thicket-monopoly-biosimilar/609042/</a>.

<sup>&</sup>lt;sup>28</sup> U.S. Committee on Oversight and Reform U.S. House of Representatives, "Drug Pricing Investigation: Amgen—Enbrel and Sensipar," October 2020, pp. 1-3,

 $<sup>\</sup>frac{\text{https://web.archive.org/web/20201003064007/https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Amgen%20Staff%20Report%2010-1-20.pdf.}$ 

<sup>&</sup>lt;sup>29</sup> U.S. House Committee on Oversight and Reform U.S. House of Representatives, "Drug Pricing Investigation: Amgen—Enbrel and Sensipar," October 2020, pp. i-ii,

 $<sup>\</sup>frac{https://web.archive.org/web/20201003064007/https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Amgen%20Staff%20Report%2010-1-20.pdf.}{}$ 

<sup>&</sup>lt;sup>30</sup> *Id*, p. 14.

<sup>&</sup>lt;sup>31</sup> Biopharma Dive, "A three-decade monopoly: How Amgen built a patent thicket around its top-selling drug," Jonathan Gardner, November 1, 2021, <a href="https://www.biopharmadive.com/news/amgen-enbrel-patent-thicket-monopoly-biosimilar/609042/">https://www.biopharmadive.com/news/amgen-enbrel-patent-thicket-monopoly-biosimilar/609042/</a>.

Horizon Therapeutics also has a history of price gouging themselves. A 2021 report published by the ICER highlighted ten drugs with the highest net price increases over the 12-month period. Horizon's Krystexxa, a gout medication, topped the list of drugs whose price increases were unsupported by new clinical evidence with a nearly 12% annual price increase acquiring Medicare patients to pay up to \$3,210 more per year on average. Medicare patients to pay up to \$3,210 more per year on average. Similarly, since acquiring the rights of Vimovo – a prescription painkiller that combines Aleve and Nexium, both of which can be purchased over the counter for under \$40 – the price of a 60-pill bottle increased from \$138 in 2014 to nearly \$3,000 in 2018. Horizon also priced Duexis, another two-in-one painkiller, at nearly \$3,000 for a 90-pill bottle, despite the fact that its two underlying drugs cost as little as \$15.

Amgen's proposed acquisition of Horizon is especially alarming given Horizon's ownership of a number of orphan drugs, which often garner high price tags due to the willingness of insurance companies to cover their costs. Horizon's Raviciti, a treatment for urea cycle disorders, now costs nearly \$700,000 annually, and has undergone a three-fold price increase since Horizon acquired the drug in 2015.<sup>37</sup> Horizon's Tepezza, the only FDA-approved medication to treat a rare thyroid eye disease, <sup>38</sup> costs nearly \$433,000 per course.<sup>39</sup>

Price gouging and evergreening in the pharmaceutical market is already squeezing American patients and forcing them to make tough financial decisions about their health. This megamerger between two companies that have abused these tactics and put profit over people could make matters even worse.

#### **Indivior-Opiant**

Indivior's proposed acquisition of Opiant<sup>40</sup> – the original owner of the opioid reversal treatment Narcan – comes at the height of the opioid epidemic, which according to the Centers for Disease Control and Prevention (CDC) took an estimated 75,673 lives in 2021 – a nearly

<sup>35</sup> Fierce Pharma, "Horizon's faced repeated price-hike criticism, but Vimovo just got its 11<sup>th</sup> raise—to almost \$3,000," Eric Sagonowsky, February 15, 2018, <a href="https://www.fiercepharma.com/pharma/horizon-s-vimovo-gets-a-february-price-hike-its-11th-recent-years-">https://www.fiercepharma.com/pharma/horizon-s-vimovo-gets-a-february-price-hike-its-11th-recent-years-</a>

report#:~:text=A%20Horizon%20spokesperson%20confirmed%20the,or%20less%20out%20of%20pocket.

<sup>&</sup>lt;sup>32</sup> Institute for Clinical and Economic Review, "Unsupported Price Increase Report: 2022 Assessment," December 6, 2022, <a href="https://icer.org/assessment/upi-2022/">https://icer.org/assessment/upi-2022/</a>.

<sup>&</sup>lt;sup>33</sup> *Id*, p. ESR

<sup>&</sup>lt;sup>34</sup> *Id*, p. 34

<sup>&</sup>lt;sup>36</sup> Financial Times, "Irish drugmaker Horizon Pharma raises painkiller price to \$3,000 in US," David Crow, February 15, 2018, https://www.ft.com/content/1922e424-11d4-11e8-940e-08320fc2a277.

<sup>&</sup>lt;sup>37</sup> Stat, "The parents hoped an existing drug might keep their kids from having seizurs. Then they saw the price," Erika Check Hayden, June 3, 2021, <a href="https://www.statnews.com/2021/06/03/parents-hoped-an-existing-drug-might-keep-their-kids-from-having-seizures-then-they-saw-the-">https://www.statnews.com/2021/06/03/parents-hoped-an-existing-drug-might-keep-their-kids-from-having-seizures-then-they-saw-the-</a>

price/#:~:text=Horizon%20then%20tripled%20Ravicti's%20price,130%2C000%20per%20year%20to%20%24243%2C000.

<sup>&</sup>lt;sup>38</sup> U.S. Food & Drug Administration, "FDA approves first treatment for thyroid eye disease," press release, January 21, 2020, <a href="https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-thyroid-eye-disease">https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-thyroid-eye-disease</a>.

<sup>&</sup>lt;sup>39</sup> Bio Stock, "Amgen targets rare diseases with acquisition," December 15, 2022, <a href="https://www.biostock.se/en/2022/12/amgen-targets-rare-diseases-with-acquisition/">https://www.biostock.se/en/2022/12/amgen-targets-rare-diseases-with-acquisition/</a>.

<sup>&</sup>lt;sup>40</sup> Wall Street Journal, Narcan Owner Opiant to Be Acquired by Indivior for \$145 Million," Julie Wernau, November 14, 2022, <a href="https://www.wsj.com/articles/narcan-opiant-merge-indivior-11668352543">https://www.wsj.com/articles/narcan-opiant-merge-indivior-11668352543</a>.

20,000 increase from the 12 months prior.<sup>41</sup> The unimaginable spike in overdose deaths coincides with a shortage in opioid reversal treatments, which are necessary to get the crisis under control.<sup>42</sup>

Indivior and its former parent company, Reckitt Benckiser Group, have also been mired in legal trouble over monopolistic behavior towards their opioid addiction treatment, Suboxone. Introduced in 2002, Suboxone, initially taken in pill form, was set to lose its patent protection in 2009.<sup>43</sup> However, in an attempt to shield the drug from generic competition and keep prices high, Indivior developed a dissolvable film version of the drug, which it then deceptively marketed as safer than the tablet form in an attempt to shift prescriptions to the newly patented protected drug. 44 Ultimately, the FTC settled with both Indivior and Reckitt Benckiser Group for a total of \$60 million after the agency found that the companies "illegally maintained a monopoly over the opioid addiction treatment Suboxone."<sup>45</sup> In separate cases with the Department of Justice (DOJ), Indivior and Reckitt Benckiser were found guilty of falsely marketing Suboxone's film version as a safer treatment alternative to the tablet version, as well as using a telephone and internet program where doctors prescribed Suboxone in quantities that violated federal regulations. <sup>46</sup> All in all, the resolution required the two companies to pay roughly \$2 billion in fines – the largest ever opioid-related resolution the DOJ has ever brought forward.<sup>47</sup> The FTC should strongly consider Indivior's history of anti-competitive and deceptive practices when evaluating how Indivior might behave after this potential transaction is completed.

Opiant – the original owner of Narcan, which made over \$400 million in sales in 2021<sup>48</sup> before generic competition was introduced<sup>49</sup> – is also developing a nasal spray formulation of nalmefene, an opioid antagonist found to be more effective than naloxone medicines like Narcan.<sup>50</sup> The drug was fast-tracked by the in November of 2021,<sup>51</sup> and it is scheduled to

<sup>&</sup>lt;sup>41</sup> Centers for Disease Controll and Prevention, "Drug overdose Deaths in the U.S. Top 100,000 Annually," November 17, 2021, https://www.cdc.gov/nchs/pressroom/nchs press releases/2021/20211117.htm.

<sup>&</sup>lt;sup>42</sup> Wall Street Journal, "Fentanyl Kills So Fast That Aid Groups Are Rethinking How to Fight Overdoses," Julie Wernau, April 27, 2022, <a href="https://www.wsj.com/articles/fentanyls-deadly-speed-is-changing-strategy-on-overdose-reversal-drugs-11651064400?mod=article">https://www.wsj.com/articles/fentanyls-deadly-speed-is-changing-strategy-on-overdose-reversal-drugs-11651064400?mod=article</a> inline.

<sup>&</sup>lt;sup>43</sup> Federal Trade Commission, "Indivior, Inc. to Pay \$10 Million to Consumers, Settling FTC Charges that the Company Illegally Maintained a Monopoly over the Opioid Addiction Treatment Suboxone," July 24, 2020, <a href="https://www.ftc.gov/news-events/news/press-releases/2020/07/indivior-inc-pay-10-million-consumers-settling-ftc-charges-company-illegally-maintained-monopoly.">https://www.ftc.gov/news-events/news/press-releases/2020/07/indivior-inc-pay-10-million-consumers-settling-ftc-charges-company-illegally-maintained-monopoly.</a>

<sup>&</sup>lt;sup>44</sup> *Id*.

<sup>&</sup>lt;sup>45</sup> *Id*.

<sup>&</sup>lt;sup>46</sup> The Hill, Drugmaker agrees to pay \$1.4 billion in largest opioid settlement in US history," Jessie Hellmann, July 12, 2019, <a href="https://thehill.com/policy/healthcare/452771-drugmaker-agrees-to-pay-14-billion-in-largest-opioid-settlement-in-us/">https://thehill.com/policy/healthcare/452771-drugmaker-agrees-to-pay-14-billion-in-largest-opioid-settlement-in-us/</a>.

<sup>&</sup>lt;sup>47</sup> *Id*.

<sup>&</sup>lt;sup>48</sup> Opiant, "Opiant Pharmaceuticals Announces Fourth Quarter and Full-Year 2021 Financial Results and Provides Corporate Update," March 15, 2022, <a href="https://ir.opiant.com/news-releases/news-release-details/opiant-pharmaceuticals-announces-fourth-quarter-and-full-year">https://ir.opiant.com/news-releases/news-release-details/opiant-pharmaceuticals-announces-fourth-quarter-and-full-year</a>.

<sup>&</sup>lt;sup>49</sup> Fierce Pharma, "Teva, Sandoz have launched Narcan generics, but Emergent's branded option should still thrive: analysts," Kevin Dunleavy, January 6, 2022, <a href="https://www.fiercepharma.com/pharma/teva-and-sandoz-s-generics-have-launched-but-emergent-s-narcan-still-likely-to-">https://www.fiercepharma.com/pharma/teva-and-sandoz-s-generics-have-launched-but-emergent-s-narcan-still-likely-to-</a>

thrive#:~:text=Through%20the%20first%20three%20quarters,of%2050%25%20year%20over%20year.

<sup>&</sup>lt;sup>50</sup> Wall Street Journal, Narcan Owner Opiant to Be Acquired by Indivior for \$145 Million," Julie Wernau, November 14, 2022, <a href="https://www.wsj.com/articles/narcan-opiant-merge-indivior-11668352543">https://www.wsj.com/articles/narcan-opiant-merge-indivior-11668352543</a>.

<sup>&</sup>lt;sup>51</sup> *Id*.

receive approval later this year. <sup>52</sup> Indivior's history of engaging in illegal monopolistic behavior raises questions about whether and how consumers would benefit from allowing the company to acquire Opiant's new form of nalmefene, along with its other advanced treatments for opioid use disorder. <sup>54</sup>

### FTC Should Carefully Scrutinize Drug Company Mergers

Given the clear anti-competitive concerns associated with pharmaceutical company mergers, and the specific records of the companies in question, these proposed transactions may threaten competition in pharmaceutical markets and result in reduced innovation and increased costs for American patients. The FTC should carefully scrutinize Big Pharma mergers under Section 7 of the *Clayton Act*, which prohibits any acquisition whose effect "may be to substantially lessen competition, or to tend to create a monopoly." If the FTC determines any of these deals would violate antitrust law, I urge you to aggressively oppose them.

I was encouraged by the FTC's 2021 resolution prioritizing investigations involving pharmaceutical companies, <sup>56</sup> and I hope you will use these tools to remedy the FTC's historically lax approach to enforcement in this area. To better understand the FTC's current approach to pharmaceutical deals, I request answers to the following questions by February 22, 2023:

- 1. Does the FTC scrutinize less vigorously tender offers such as Merck's recent acquisition of Imago Biosciences?
- 2. Section 6.4 of the Horizontal Merger Guidelines states that the FTC "may consider whether a merger is likely to diminish innovation competition by encouraging the merged firm to curtail its innovative efforts below the level that would prevail in the absence of the merger." Given the evidence noted above that Big Pharma firms have planned R&D cuts following blockbuster deals, how does the FTC factor such history or plans into its reviews of relevant pharmaceutical transactions?
- 3. Instead of innovating and competing, many Big Pharma firms simply acquire new companies. These dominant firms then have the resources to reduce competition and raise prices for the drugs of those acquired companies <sup>58</sup>, or they may even "discontinue"

<sup>&</sup>lt;sup>52</sup> Opiant, "Opiant Pharmacueticals Announces FDA Acceotance and Priority Review of NDA for OPNT003, Nasal Nalmefene, for Opiod Overdoes," January 19, 2023, <a href="https://ir.opiant.com/news-releases/news-release-details/opiant-pharmaceuticals-announces-fda-acceptance-and-priority">https://ir.opiant.com/news-releases/news-release-details/opiant-pharmaceuticals-announces-fda-acceptance-and-priority</a>.

<sup>&</sup>lt;sup>54</sup> *Id*. <sup>55</sup> 15 U.S.C. 18.

<sup>&</sup>lt;sup>56</sup> Federal Trade Commission, "FTC Authorizes Investigations into Key Enforcement Priorities," press release, July 1, 2021, <a href="https://www.ftc.gov/news-events/news/press-releases/2021/07/ftc-authorizes-investigations-key-enforcement-priorities">https://www.ftc.gov/news-events/news/press-releases/2021/07/ftc-authorizes-investigations-key-enforcement-priorities</a>.

<sup>&</sup>lt;sup>57</sup> Department of Justice and Federal Trade Commission, "Horizontal Merger Guidelines," August 19, 2010, <a href="https://www.justice.gov/atr/horizontal-merger-guidelines-08192010">https://www.justice.gov/atr/horizontal-merger-guidelines-08192010</a>.

<sup>&</sup>lt;sup>58</sup> Washington Post, "Drug companies keep merging. Why that's bad for consumers and innovation," Robin Feldman, April 6, 2021, <a href="https://www.washingtonpost.com/outlook/2021/04/06/drug-companies-keep-merging-why-thats-bad-consumers-innovation/">https://www.washingtonpost.com/outlook/2021/04/06/drug-companies-keep-merging-why-thats-bad-consumers-innovation/</a>.

innovation projects" to "preempt future competition." <sup>59</sup> How does the FTC factor these tactics into its reviews of relevant pharmaceutical transactions?

- 4. How does the FTC factor evergreening strategies (such as patent thickets and product hopping) into its reviews of relevant pharmaceutical transactions?
- 5. How does the FTC factor histories of price gouging, collusion, or settlements with the Justice Department regarding alleged criminal behavior into its reviews of relevant pharmaceutical transactions?
- 6. Under what circumstances would the FTC investigate whether a consummated pharmaceutical transaction violates antitrust law?
- 7. Under what circumstances would the FTC bring a lawsuit to unwind a consummated pharmaceutical transaction?

Sincerely,

Elizabeth Warren United States Senator

CC:

Kathi Vidal, Director, United States Patent and Trademark Office Jonathan Kanter, Assistant Attorney General – Antitrust Division, Department of Justice

<sup>&</sup>lt;sup>59</sup> Journal of Political Economy, "Killer acquisitions," Colleen Cunningham, Florian Ederer, and Song Ma, March 1, 2021, <a href="https://economics.sas.upenn.edu/system/files/2019-07/SSRN-id3241707.pdf">https://economics.sas.upenn.edu/system/files/2019-07/SSRN-id3241707.pdf</a>.