



**United States of America  
Federal Trade Commission**

# **The FTC's Ongoing Efforts to Promote Competition and Choice in Our Health Care System**

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\* The views expressed in these remarks are my own and do not necessarily reflect the views of the Federal Trade Commission or any other Commissioner. Many thanks to my Attorney Advisor, Keith Klovers, for assisting in the preparation of these remarks.

## I. INTRODUCTION

Good morning! Many thanks to the Council for Affordable Health Coverage (CAHC) for inviting me to speak here today. As always, I must begin by giving the standard disclaimer: The views I express today are my own, and do not necessarily reflect the views of the U.S. Federal Trade Commission or any other Commissioner.

With that out of the way, I'm pleased to join you here today to speak about a topic – health care – that is near and dear to my heart. It is also a perennial focus of the FTC. This is now my third tour of duty at the agency. During my first stint, as a law school student in the 1990s, the agency was busy sifting through mergers in the PBM supply chain, like Lilly-PCS, a merger I worked on then.<sup>1</sup> During my second stint, in the early 2000s, the agency revamped its hospital merger efforts,<sup>2</sup> expanded its already significant work in the pharmaceutical industry,<sup>3</sup> and brought dozens of cases challenging physician efforts to fix prices.<sup>4</sup> And, as I will describe more fully in a few minutes, the industry remains a core focus of the agency today.

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<sup>1</sup> *Eli Lilly & Co.*, 130 F.T.C. 243 (1995) (Decision and Order).

<sup>2</sup> *See, e.g.*, Press Release, Federal Trade Commission Announces Formation of Merger Litigation Task Force, Aug. 28, 2002, <https://www.ftc.gov/news-events/press-releases/2002/08/federal-trade-commission-announces-formation-merger-litigation> (last visited Jan. 14, 2020) (“The Task Force will be responsible for reinvigorating the Commission's hospital merger program, which includes a review of, and potential challenge to, consummated transactions that may have resulted in anticompetitive price increases.”).

<sup>3</sup> *See, e.g.*, Prepared Statement of the Federal Trade Commission before the Committee on Commerce, Science, and Transportation, U.S. Senate, Washington, D.C., Apr. 23, 2002, *available at* [https://www.ftc.gov/sites/default/files/documents/public\\_statements/prepared-statement-federal-trade-commission-pharmaceutical-industry/pharmtestimony.pdf](https://www.ftc.gov/sites/default/files/documents/public_statements/prepared-statement-federal-trade-commission-pharmaceutical-industry/pharmtestimony.pdf) (“This testimony addresses the Commission's efforts to ensure efficient operation of the Hatch-Waxman process directly through vigorous enforcement of the antitrust laws. To date, these efforts principally have entailed litigation relating to settlements between brands and generics alleged to be anticompetitive; this testimony refers to those as ‘first generation litigation.’ More recently, the Commission has progressed to ‘second generation litigation,’ involving issues such as allegedly improper Orange Book listings. We are also examining potentially anticompetitive settlements between generics themselves.”); *see also* FED. TRADE COMM’N & DEP’T OF JUSTICE, IMPROVING HEALTH CARE: A DOSE OF COMPETITION (July 2004), *available at* <https://www.ftc.gov/sites/default/files/documents/reports/improving-health-care-dose-competition-report-federal-trade-commission-and-department-justice/040723healthcarerpt.pdf>.

<sup>4</sup> *See, e.g.*, Press Release, FTC Settles Price-Fixing Charges Against Physician-Hospital Network in Northeast Maine, July 18, 2003, <https://www.ftc.gov/news-events/press-releases/2003/07/ftc-settles-price-fixing-charges-against-physician-hospital> (last visited Jan. 14, 2020).

As many here can attest, health care is also a significant priority for our citizens and their elected officials. For example, a 2019 poll by RealClear Opinion Research found that more respondents (36 percent) identified health care as the “top issue facing America today” than any other issue, and a majority of respondents (52 percent) ranked it as either their first or second most-pressing issue.<sup>5</sup> Similarly, a Gallup poll found that 24 percent of respondents were “very worried” about paying “medical costs for normal healthcare” and only 17 percent of respondents were “very satisfied” with the quality of medical care.<sup>6</sup> In fact, studies show that even as health care costs are increasing, the quality of outcomes is falling.<sup>7</sup>

In the aggregate, the health care industry also accounts for a large chunk of our economy. The Centers for Medicare and Medicaid Services (CMS) estimate that health care spending accounted for 17.9 percent of U.S. GDP in 2017, the most recent available year.<sup>8</sup> CMS also projects that health care will continue to grow almost 1 percentage point faster than the economy as a whole.<sup>9</sup> By 2027, CMS projects that health care spending will account for \$6 trillion dollars, or 19.4 percent of U.S. GDP.<sup>10</sup>

Given these figures, it is not surprising that the topic attracts significant attention up and down Pennsylvania Avenue. Just over one year ago, the Trump Administration released a report

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<sup>5</sup> Carl M. Cannon, New Poll Shows Health Care Is Voters’ Top Concern, May 15, 2019, [https://www.realclearpolitics.com/real\\_clear\\_opinion\\_research/new\\_poll\\_shows\\_health\\_care\\_is\\_voters\\_top\\_concern.html](https://www.realclearpolitics.com/real_clear_opinion_research/new_poll_shows_health_care_is_voters_top_concern.html).

<sup>6</sup> Gallup, In Depth: Healthcare System, <https://news.gallup.com/poll/4708/healthcare-system.aspx> (infographic #4, April 2019 data (most recent available observation); infographic #8, 2019 data (most recent available observation)).

<sup>7</sup> CHARLES SILVER & DAVID A. HYMAN, OVERCHARGED: WHY AMERICANS PAY TOO MUCH FOR HEALTH CARE 245-260 (2018).

<sup>8</sup> Centers for Medicare and Medicaid Services, National Health Expenditure Projections 2018-2027: Forecast Summary, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ForecastSummary.pdf> (last accessed Jan. 15, 2020) (“Health spending is projected to grow 0.8 percentage point faster than Gross Domestic Product (GDP) per year over the 2018-27 period; as a result, the health share of GDP is expected to rise from 17.9 percent in 2017 to 19.4 percent by 2027.”).

<sup>9</sup> *Id.*

<sup>10</sup> *Id.* (“Under current law, national health spending is projected to grow at an average rate of 5.5 percent per year for 2018-27 and to reach nearly \$6.0 trillion by 2027. . . [A]s a result, the health share of GDP is expected to rise from 17.9 percent in 2017 to 19.4 percent by 2027.”).

called “Reforming America’s Healthcare System Through Choice and Competition”<sup>11</sup> (the “Administration Report”), which provides a detailed blueprint for rebuilding and reforming our health care system. Given our extensive efforts to promote competition in this industry, the FTC was closely involved in this effort and the resulting document. I believe the Administration Report provides us with an excellent blueprint. So, for that matter, do my hosts; when the Administration Report was released, CAHC President Joel White applauded the Administration for “taking an honest look at the[] festering problems” in our health care system “and offering worthy solutions for reform.”<sup>12</sup>

So, with all of that in mind, I will cover three topics today: one past, one present, and one future. First, and looking backward, I will recap the FTC’s excellent work promoting health care and explain how those efforts factored into the Trump Administration’s plan. Second, in the present, I will summarize some of the key recommendations in the Administration Report, and particularly those addressed to the FTC. And third, looking forward, I will map out my vision for how the FTC can implement these important recommendations. As one of several agencies responsible for setting health care policy, this discussion necessarily recognizes the limits of our legal authority, and therefore identifies several competitive distortions – like excessive state regulation – that lie beyond our bailiwick. It is my hope that other policymakers will step forward to address the issues outside our jurisdiction.

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<sup>11</sup> U.S. DEP’T OF HEALTH AND HUMAN SERVICES, U.S. DEP’T OF THE TREASURY, & U.S. DEP’T OF LABOR, REFORMING AMERICA’S HEALTHCARE SYSTEM THROUGH CHOICE AND COMPETITION (Dec. 3, 2018) [hereinafter ADMINISTRATION REPORT], available at <https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf>.

<sup>12</sup> Press Release, Council for Affordable Health Coverage, CAHC Supports Key Recommendations in Trump Administration’s Report on Healthcare Choice & Competition, Dec. 3, 2018, <https://www.cahc.net/newsroom/2018/12/3/cahc-supports-key-recommendations-in-trump-administrations-report-on-healthcare-choice-amp-competition> (last visited Jan. 14, 2020).

## II. PAST FTC EFFORTS

During recent decades, the FTC has developed a laudable track record of protecting health care consumers and promoting competition in the industry. For example, under Chairman Muris we revamped the way we analyze hospital mergers, an approach that remains effective today. During the past 15 years, we have successfully sued to block several problematic hospital mergers, including recent transactions in Illinois and Pennsylvania.<sup>13</sup> We have also used the approach to block significant mergers involving physician practices, including recent victories in Idaho and North Dakota.<sup>14</sup>

Similarly, the Commission has long battled anticompetitive patent litigation settlements in the pharmaceutical industry. Chairman Leibowitz in particular championed this effort, filing a number of new cases. These efforts culminated in the Commission's landmark Supreme Court victory in the *Actavis* case, which held that patent litigation settlements can violate the antitrust laws and must be evaluated under traditional antitrust rules.<sup>15</sup>

Since then, the use of so-called reverse payments has plummeted, from an estimated 40 to 50 percent of all pharmaceutical patent litigation settlements in fiscal years 2006 and 2007 to less than 1 percent – one settlement out of 232 – in fiscal year 2016.<sup>16</sup> Although problematic new

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<sup>13</sup> See *FTC v. Advocate Health Care Network*, 841 F.3d 460 (7th Cir. 2016); *FTC v. Penn State Hershey Med. Ctr.*, 838 F.3d 327 (3d Cir. 2016).

<sup>14</sup> *FTC v. Sanford Health*, 926 F.3d 959 (8th Cir. 2019); *Saint Alphonsus Med. Ctr.-Nampa Inc. v. St. Luke's Health Sys., Ltd.*, 778 F.3d 775 (9th Cir. 2015).

<sup>15</sup> *FTC v. Actavis, Inc.*, 570 U.S. 136, 158 (2013) (“In sum, a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects; one who makes such a payment may be unable to explain and to justify it; such a firm or individual may well possess market power derived from the patent; a court, by examining the size of the payment, may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the patent; and parties may well find ways to settle patent disputes without the use of reverse payments. In our view, these considerations, taken together, outweigh the single strong consideration—the desirability of settlements—that led the Eleventh Circuit to provide near-automatic antitrust immunity to reverse payment settlements.”).

<sup>16</sup> Jamie Towie & Brad Albert, FTC Bureau of Competition, Then, Now, and Down the Road: Trends in Pharmaceutical Patent Settlements after *FTC v. Actavis*, May 28, 2019, <https://www.ftc.gov/news-events/blogs/competition-matters/2019/05/then-now-down-road-trends-pharmaceutical-patent> (“After some courts largely inoculated most reverse payments from antitrust review in 2005, the use of reverse payments skyrocketed. In

agreements are now rare, the Commission continues to litigate older settlements and clarify the law. To that end, our recent *Impax* case was the first opportunity since *Actavis* for the Commission to clarify and operationalize that ruling.<sup>17</sup>

Of course, the Commission has brought many cases in other segments of the health care industry.<sup>18</sup> We were particularly active last year, my first as a Commissioner. Among the many cases, I'll mention four, two involving anticompetitive conduct and two involving anticompetitive mergers.

I'll start with the conduct cases. In April 2019, the Commission brought a monopolization case against Surescripts, the dominant provider in two electronic prescription markets.<sup>19</sup> That litigation continues. In July 2019, the Commission settled allegations that the pharmaceutical company Reckitt Benckiser maintained a monopoly in the market for certain opioid addiction treatments. Reckitt did so both by abusing the FDA citizens' petition process and by engaging in a broader "product hopping" strategy that allowed it to thwart the entry of

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2004, none of the final settlements included reverse payments. In FY 2006 and FY 2007, 40-50% of all final settlements filed with the FTC contained reverse payments."); *id.* ("Parties can—and do—settle patent litigation without the brand company paying its potential generic competitor. Of the 232 final settlements received in FY 2016, only one contained ... the most commonly challenged forms of reverse payments.").

<sup>17</sup> *Impax Labs., Inc.*, No. 9373, Mar. 28, 2019, available at [https://www.ftc.gov/system/files/documents/cases/d09373\\_impax\\_laboratories\\_opinion\\_of\\_the\\_commission\\_-\\_public\\_redacted\\_version\\_redacted\\_0.pdf](https://www.ftc.gov/system/files/documents/cases/d09373_impax_laboratories_opinion_of_the_commission_-_public_redacted_version_redacted_0.pdf)

<sup>18</sup> Indeed, this paragraph covers only a few of the Commission's recent cases. *See also, e.g.*, Press Release, FTC Requires Divestitures and Imposes Conditions on Boston Scientific Corp.'s Acquisition of BTG plc, Aug. 7, 2019, <https://www.ftc.gov/news-events/press-releases/2019/08/ftc-requires-divestitures-imposes-conditions-boston-scientific>; Press Release, FTC Requires Fresenius Medical Care AG & KGaA and NxStage Medical, Inc. to Divest Bloodline Tubing Assets to B. Braun Medical, Inc. as a Condition of Merger, Feb. 19, 2019, <https://www.ftc.gov/news-events/press-releases/2019/02/ftc-requires-fresenius-medical-care-ag-kgaa-nxstage-medical-inc>; Press Release, FTC, Last Remaining Defendant Settles FTC Suit that Led to Landmark Supreme Court Ruling on Drug Company "Reverse Payments," Feb. 28, 2019, <https://www.ftc.gov/news-events/press-releases/2019/02/last-remaining-defendant-settles-ftc-suit-led-landmark-supreme>; Press Release, FTC Enters Global Settlement to Resolve Reverse-Payment Charges against Teva, Feb. 19, 2019, <https://www.ftc.gov/news-events/press-releases/2019/02/ftc-enters-global-settlement-resolve-reverse-payment-charges>.

<sup>19</sup> *See* Press Release, FTC Charges Surescripts with Illegal Monopolization of E-Prescription Markets, Apr. 24, 2019, <https://www.ftc.gov/news-events/press-releases/2019/04/ftc-charges-surescripts-illegal-monopolization-e-prescription>.

lower-cost generic drugs.<sup>20</sup> Reckitt Benckiser agreed to pay \$50 million, to be used for consumer redress, as part of the settlement.<sup>21</sup>

On the merger side, I'll likewise limit myself to two cases. First, in June 2019, the Commission required the divestiture of assets in Nevada as part of a consent agreement allowing health insurer UnitedHealth Group to acquire DaVita Medical Group, a network of physician practice groups.<sup>22</sup> Second, in December, the Commission challenged the merger of two manufacturers of DNA sequencing machines, Illumina and Pacific Biosciences.<sup>23</sup> In the face of this challenge, the parties abandoned the transaction.<sup>24</sup>

The bottom line is that the Commission's enforcement efforts in the health care industry save consumers billions of dollars annually. I'm proud to have played a small role in these efforts over the years.

### **III. THE TRUMP ADMINISTRATION'S BLUEPRINT**

Let us now return to the present. Given its importance to the economy and our citizens, President Trump rightly has prioritized efforts to increase competition in the health care industry. This effort is most visible in Executive Order 13813, which President Trump issued during his first year in office. Among other things, the Order directs the Administration to "re-inject

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<sup>20</sup> See Press Release, Reckitt Benckiser Group plc to Pay \$50 Million to Consumers, Settling FTC Charges that the Company Illegally Maintained a Monopoly over the Opioid Addiction Treatment Suboxone, July 11, 2019, <https://www.ftc.gov/news-events/press-releases/2019/07/reckitt-benckiser-group-plc-pay-50-million-consumers-settling-ftc>. Note that I did not participate in this matter.

<sup>21</sup> *Id.*

<sup>22</sup> See Press Release, FTC Imposes Conditions on UnitedHealth Group's Proposed Acquisition of DaVita Medical Group, June 19, 2019, <https://www.ftc.gov/news-events/press-releases/2019/06/ftc-imposes-conditions-unitedhealth-groups-proposed-acquisition>.

<sup>23</sup> Press Release, FTC Challenges Illumina's Proposed Acquisition of PacBio, Dec. 17, 2019, <https://www.ftc.gov/news-events/press-releases/2019/12/ftc-challenges-illuminas-proposed-acquisition-pacbio> (last visited Jan. 14, 2020).

<sup>24</sup> Press Release, FTC, Statement of Gail Levine, Deputy Director of FTC Bureau of Competition, Regarding the Announcement that Illumina, Inc. Has Abandoned Its Proposed Acquisition of Pacific Biosciences of California, Jan. 2, 2020, <https://www.ftc.gov/news-events/press-releases/2020/01/statement-gail-levine-deputy-director-ftc-bureau-competition> (last visited Jan. 14, 2020).

competition into health care markets by lowering barriers to entry, limiting excessive concentration, and preventing abuses of market power.”<sup>25</sup>

Pursuant to that Executive Order, in 2018 the Department of Health and Human Services (HHS), in collaboration with the Department of the Treasury, the Department of Labor, and the FTC, issued the Administration Report that I mentioned at the beginning of my remarks.<sup>26</sup> The report is packed with recommendations for increasing competition in the sector, including numerous proposals to expand competition among health care providers,<sup>27</sup> pare back state policies that restrict entry into provider markets,<sup>28</sup> reform insurance markets in ways that lower barriers to entry,<sup>29</sup> and arm consumers with better information about their health care options.<sup>30</sup> I agree with these recommendations, and I believe implementing them will empower consumers, reduce costs, and improve health care outcomes.

#### **IV. THE FTC WILL CONTINUE TO PLAY A KEY ROLE**

Finally, looking ahead, I believe the FTC has a key role to play in executing the vision set out in the Administration Report. To succeed in this role, we will need to double down on existing efforts and expand our work to address new practices and new markets.

I’ll start with the easier task, doubling down on existing FTC efforts. I am proud to say that several of the recommendations included in the Administration Report build upon longstanding FTC initiatives. In the interests of time, I’ll limit myself to two.

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<sup>25</sup> Exec. Order No. 13,813 § I(c)(2), 82 Fed. Reg. 48,385, 48,385-86 (Oct. 12, 2017).

<sup>26</sup> ADMINISTRATION REPORT, *supra* note 11.

<sup>27</sup> *Id.* at 30-41 (for example, recommending that state governments reduce scope-of-practice requirements and increase licensure reciprocity).

<sup>28</sup> *Id.* at 50-63 (for example, recommending the repeal of “certificate of need” laws).

<sup>29</sup> *Id.* at 63-93 (for example, recommending the repeal of “any-willing-provider” laws).

<sup>30</sup> *Id.* at 94-105.

First, the Administration Report recommends that state governments take action “to repeal or scale back Certificate of Need [CON] laws.”<sup>31</sup> As set out in a 2015 analysis by then-FTC Commissioner Maureen Ohlhausen, the FTC has advocated for the repeal of CON laws since at least 1987,<sup>32</sup> sometimes alone<sup>33</sup> and sometimes in conjunction with our counterparts at the Antitrust Division of the U.S. Department of Justice.<sup>34</sup> Most recently, in March 2019 FTC staff submitted testimony to the State of Alaska regarding a proposal to repeal that state’s CON laws.<sup>35</sup>

Second, the Administration Report “recommends policies that will broaden providers’ scope of practice while improving workforce mobility . . . to encourage innovation and to allow providers more easily to meet patients’ needs.”<sup>36</sup> The Commission has long advocated for rules that do not unduly restrict a licensed doctor or nurse’s ability to provide medical care that they are medically trained and certified to provide. For example, the Commission has issued 17 letters to state actors over the past 10 years addressing state laws that artificially restrict the kinds

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<sup>31</sup> *Id.*, cover letter, at 3.

<sup>32</sup> Maureen K. Ohlhausen, *Certificate of Need Laws: A Prescription for Higher Costs*, ANTITRUST, Fall 2015, at 50, 54 & n.14 (“The FTC has tirelessly advocated for the repeal of these laws for many years, with strong support from Commissioners of both parties.” (citing, *inter alia*, Federal Trade Commission, FTC Staff Comment Before the Virginia Commission on Medical Care Facilities, Certificate of Public Need, Concerning Reform of Certificate of Public Need Regulation or Health Facilities (Aug. 6, 1987), available at [https://www.ftc.gov/sites/default/files/documents/advocacy\\_documents/ftc-staff-comment-virginia-commission-medical-care-facilities-certificate-public-need-concerning/af-35.pdf](https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-virginia-commission-medical-care-facilities-certificate-public-need-concerning/af-35.pdf))).

<sup>33</sup> *See id.* (citing the 1987 FTC staff comment to Virginia).

<sup>34</sup> *See id.* (also citing Joint Statement of the Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice to the Virginia Certificate of Public Need Work Group (Oct. 26, 2015), available at [https://www.ftc.gov/system/files/documents/advocacy\\_documents/joint-statement-federal-trade-commission-antitrust-division-u.s.department-justice-virginia-certificate-public-need-work-group/151026ftc-dojstmtva\\_copn-1.pdf](https://www.ftc.gov/system/files/documents/advocacy_documents/joint-statement-federal-trade-commission-antitrust-division-u.s.department-justice-virginia-certificate-public-need-work-group/151026ftc-dojstmtva_copn-1.pdf)).

<sup>35</sup> *See* Statement of the Federal Trade Commission to the Alaska Senate Committee on Health & Social Services on Certificate of Need Laws and SB 1, Mar. 27, 2019, available at [https://www.ftc.gov/system/files/documents/advocacy\\_documents/statement-federal-trade-commission-alaska-senate-committee-health-social-services-certificate-need/v0800007\\_commission\\_testimony\\_re\\_alaska\\_senate\\_committee\\_032719.pdf](https://www.ftc.gov/system/files/documents/advocacy_documents/statement-federal-trade-commission-alaska-senate-committee-health-social-services-certificate-need/v0800007_commission_testimony_re_alaska_senate_committee_032719.pdf).

<sup>36</sup> ADMINISTRATION REPORT, *supra* note 11, cover letter, at 3.

of care that nurse practitioners can provide.<sup>37</sup> Our staff issued the most recent of these letters, to state legislators in Kansas and Ohio, just this week.<sup>38</sup> We have also encouraged state actors to loosen, when appropriate, restrictions on physicians. Most recently, in November 2019 our staff supported an effort to eliminate a Massachusetts state law that prohibited podiatrists from treating ankle injuries, even though their medical training and certifications covered that joint.<sup>39</sup>

Because I believe that the most durable barriers to competition are those erected by governments, I believe our work in seeking to have those barriers lowered is incredibly important. Therefore, although the FTC has long devoted staff time and resources to its competition advocacy efforts, I believe we can and should do more, starting by increasing the resources we devote to the program.

Now let me turn to new practices and new markets. Although the Commission remains very active in the health care space, it takes serious effort to keep up with the pace of innovation in the industry. And I don't just mean the good kind of innovation – with billions of dollars at stake, savvy health care executives often face very strong financial incentives to develop new business practices that weaken the competitive pressure they face from rivals. For this reason, we carefully monitor industry trends and are receptive to concerns from industry participants and consumers.

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<sup>37</sup> See, e.g., Letter from Susan DeSanti, Joseph Farrell, and Richard A. Feinstein, Fed. Trade Comm'n, to the Hon. Daphne Campbell, Florida House of Representatives, regarding Florida House Bill 4103, Mar. 22, 2011, *available at* [https://www.ftc.gov/sites/default/files/documents/advocacy\\_documents/ftc-staff-letter-honorable-daphne-campbell-florida-house-representatives-concerning-florida-house/v110004campbell-florida.pdf](https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-letter-honorable-daphne-campbell-florida-house-representatives-concerning-florida-house/v110004campbell-florida.pdf).

<sup>38</sup> See Press Release, FTC Comments to State Legislatures in Kansas and Ohio Encourage Granting Advanced Practice Registered Nurses Full Practice Authority, Jan. 13, 2020, <https://www.ftc.gov/news-events/press-releases/2020/01/ftc-comments-state-legislatures-kansas-ohio-encourage-granting> (last visited Jan. 14, 2020).

<sup>39</sup> See Letter from FTC Staff to the Hon. Paul J. Donato, Massachusetts State Representative, regarding House Bill 1869 / Senate Bill 1329, Nov. 13, 2019, *available at* [https://www.ftc.gov/system/files/documents/advocacy\\_documents/comment-staff-federal-trade-commission-massachusetts-rep-paul-j-donato-regarding-hb1869-sb1329/v200002\\_staff\\_comment\\_letter\\_re\\_ma\\_house\\_1869\\_senate\\_1329\\_signed.pdf](https://www.ftc.gov/system/files/documents/advocacy_documents/comment-staff-federal-trade-commission-massachusetts-rep-paul-j-donato-regarding-hb1869-sb1329/v200002_staff_comment_letter_re_ma_house_1869_senate_1329_signed.pdf).

One troubling trend is the growing use of anticompetitive strategies by branded biologic drug manufacturers to forestall competition from generic “biosimilar” products.<sup>40</sup> This trend parallels similar trends in more traditional small molecule pharmaceuticals. Former Food and Drug Administration head Scott Gottlieb sounded the alarm about the biologics issue last August in an op-ed in *The Wall Street Journal*.<sup>41</sup> As he has noted elsewhere, fewer than 2 percent of Americans use biologic drugs, yet they account for 40 percent of total spending on prescription medications.<sup>42</sup> He worries that branded biologic firms are working overtime “to squelch competition from biosimilars,”<sup>43</sup> and recommends a number of steps to preserve competition in this space.<sup>44</sup>

Although the Commission was already looking into these practices,<sup>45</sup> former Commissioner Gottlieb’s comments underscore how important it is for us to nip these pernicious

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<sup>40</sup> The FTC first studied the industry in 2009 and continues to follow it closely. *See, e.g.*, FED. TRADE COMM’N, EMERGING HEALTH CARE ISSUES: FOLLOW-ON BIOLOGIC DRUG COMPETITION (2009), available at <https://www.ftc.gov/sites/default/files/documents/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report/p083901biologicsreport.pdf>.

<sup>41</sup> Scott Gottlieb, *Don’t Give Up on Biosimilars—Congress Can Give Them a Boost*, WALL ST. J., Aug. 25, 2019, available at <https://www.wsj.com/articles/dont-give-up-on-biosimilarscongress-can-give-them-a-boost-11566755042>.

<sup>42</sup> Scott Gottlieb, Remarks as prepared for delivery at the Brookings Institution on the release of the FDA’s Biosimilars Action Plan, July 18, 2018, <https://www.fda.gov/news-events/press-announcements/remarks-fda-commissioner-scott-gottlieb-md-prepared-delivery-brookings-institution-release-fdas> (“While less than 2 percent of Americans use biologics, they represent 40 percent of total spending on prescription drugs.”); *see* Wayne Winegarden, Pacific Research Institute, *Incenting Competition to Reduce Drug Spending: The Biosimilar Opportunity*, at 6, July 2019, available at [https://medecon.org/wp-content/uploads/2019/07/BiosimilarsCompetition\\_F.pdf](https://medecon.org/wp-content/uploads/2019/07/BiosimilarsCompetition_F.pdf) (“Annual average net spending on biologic medicines have grown 10.7 percent a year between 2014 and 2018, according to IQVIA, resulting in total spending increasing from \$83.6 billion in 2014 to \$125.5 billion in 2018.”).

<sup>43</sup> Gottlieb, *supra* note 41.

<sup>44</sup> *Id.* (“Congress can make straightforward changes to speed the development and use of cost-saving biosimilars. First, it can pass a law mandating that brand companies sell their biologic drugs at a fair market price to biosimilar manufacturers seeking to develop copies. . . . Second, Congress can stop branded drug companies from using “rebates” to squelch competition from biosimilars. . . . Third, the U.S. must invest more heavily in educating doctors about the safety and effectiveness of biosimilars and the value that they can deliver to patients and the health-care system.”).

<sup>45</sup> *See, e.g.*, Prepared Statement of the Federal Trade Commission on Antitrust Concerns and the FDA Approval Process, Before the Subcommittee on Regulatory Reform, Commercial and Antitrust Law of the Judiciary Committee, United States House of Representatives, at 12, July 27, 2017, available at <https://www.ftc.gov/public-statements/2017/07/prepared-statement-federal-trade-commission-antitrust-concerns-fda> [hereinafter 2017 FTC Testimony] (explaining that “[t]he FTC’s REMS Concerns Extend to Biologic and Biosimilar Competition”); Press

practices in the bud. A few years ago, the Commission advocated for the passage of the CREATES Act, which we said “seeks to reduce incentives for regulatory abuse[s]” that had allowed branded pharmaceutical manufacturers to inhibit competition from both generics and biosimilars.<sup>46</sup> I similarly advocated for its passage last May when I testified before a subcommittee of the House Energy and Commerce Committee.<sup>47</sup> So needless to say I was glad to see Congress pass, and President Trump sign, the CREATES Act as part of the Further Consolidated Appropriations Act, 2020.<sup>48</sup>

With all of that said, the health care system is so fundamentally broken that antitrust cannot fix all that ails it. I believe many of these problems come down to consumers’ ability and incentive to choose among different products and services. Because insurers pick up much of the tab, one set of consumers – patients – have very little incentive to compare the prices of various health care providers. Even if they were inclined to comparison shop, it’s not clear they could, given the opacity of most prices. And the ability to comparison shop based on quality – in other words, patient outcomes – is even more limited, given the dearth of data available to patients.

Of course, information asymmetries and weak or adverse incentives are endemic up and down the health care supply chain. Let me give you two examples.

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Release, Fed. Trade Comm’n, FTC Submits Comment on FDA Guidance Regarding Nonproprietary Naming of Biological Products, May 8, 2019, <https://www.ftc.gov/news-events/press-releases/2019/05/ftc-submits-comment-fda-guidance-regarding-nonproprietary-naming> (last visited Jan. 14, 2020) (describing FTC staff comments to the FDA aimed at avoiding “unnecessary barriers to entry for lower cost biologic products that are biosimilar to or interchangeable with existing FDA-approved biologic products”).

<sup>46</sup> 2017 FTC Testimony, *supra* note 45, at 12-13.

<sup>47</sup> Oral Statement of Commissioner Christine S. Wilson, FTC, Before the U.S. House Committee on Energy and Commerce, Subcommittee on Consumer Protection and Commerce, May 8, 2019, *available at* [https://www.ftc.gov/system/files/documents/public\\_statements/1519254/commissioner\\_wilson\\_may\\_2019\\_ec\\_opening.pdf](https://www.ftc.gov/system/files/documents/public_statements/1519254/commissioner_wilson_may_2019_ec_opening.pdf) (“The third area where I believe legislation would be beneficial concerns abuses of Risk Evaluation and Mitigation Strategies, or ‘REMS,’ in the pharmaceutical industry. Concerns arise when branded pharmaceutical manufacturers subvert laws and regulations designed to protect consumer health and safety and instead use them to protect themselves from competition. I am grateful that members of the Committee share these concerns and have approved legislation to preserve competition in this important area of our economy.”).

<sup>48</sup> See *H.R. 1865: Further Consolidated Appropriations Act, 2020*, GOVTRACK.US, <https://www.govtrack.us/congress/bills/116/hr1865> (last visited Jan. 14, 2020) (finding that the Act incorporates 96 percent of the text of one of the CREATES Act bills, H.R. 965).

First, as Professors David Hyman and Charles Silver point out in a recently published book entitled *Overcharged*, the price that Medicare pays doctors to perform a given medical procedure is “set, in large part, according to estimates of the time required to perform procedures,”<sup>49</sup> which in turn are “prepared by a secretive American Medical Association (AMA) committee whose members know that higher estimates mean higher pay.”<sup>50</sup> Or, as they put it more succinctly, “what better way to send doctors lots of money than by letting them set their own rates?”<sup>51</sup>

Second, economists have found that health care providers charge wildly different prices for the same product or service. Recently a well-regarded econometric analysis published in the *Quarterly Journal of Economics* found, using insurer data covering a substantial proportion of the U.S. population,<sup>52</sup> that in some areas the highest-priced hospital charges more than twice as much as the lowest-priced hospital *for the same exact procedure*, even after adjusting for risk.<sup>53</sup> It also found that hospitals charge substantially different prices to different health insurance plans.<sup>54</sup> To the authors, these findings suggest that “the relative bargaining power of insurers with hospitals can strongly influence price levels.”<sup>55</sup>

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<sup>49</sup> OVERCHARGED, *supra* note 7, at 17.

<sup>50</sup> *Id.*

<sup>51</sup> *Id.*

<sup>52</sup> Zack Cooper, Stuart V. Craig, Martin Gaynor & John Van Reenen, *The Price Ain't Right? Hospital Prices and Health Spending on the Privately Insured*, 134 Q. J. ECON. 51, 52-53 (2019) (“Our data capture the claims from the health care services delivered to 27.6% of individuals in the United States with employer-sponsored coverage between 2007 and 2011. The data include more than 88 million unique individuals and capture over \$125 billion in health spending a year.”).

<sup>53</sup> *Id.* at 53-54 (“Hospital prices vary significantly across the country and across hospitals within HRRs. For example, hospitals with risk-adjusted knee replacement prices in the 90th percentile of the national distribution of hospitals are 2.3 times as expensive as hospitals in the 10th percentile. Likewise, in one representative HRR (Philadelphia, PA), the hospital in the 90th percentile of prices in the region is more than twice as expensive as the hospital in the 10th percentile. This variation is also present for plausibly undifferentiated services, such as lower-limb magnetic resonance imaging (MRI), which suggests that the dispersion we observe is not simply a function of differences in hospital quality or patient severity across providers.”).

<sup>54</sup> *Id.* at 54 (“We find that the variation in prices within hospitals for services ranging from joint replacement to lower-limb MRI is substantial. Over a fifth of the total price variation across cases in the average month-year occurs within hospitals for the same procedure, after controlling for hospital fixed effects, insurance plan characteristics, and patient characteristics. That there is such substantial variation in prices for plausibly undifferentiated procedures

Many of these problems lie beyond the reach of the antitrust agencies. Thankfully, the Trump Administration has focused minds throughout the Executive Branch on the need to improve competition in the health care space. But genuine improvements will require concentrated efforts on the part of state and federal actors, in both the executive and legislative branches. I, for one, plan to spend a great deal of time on this issue in 2020.

## V. CONCLUSION

In conclusion, I agree with the Administration that we must fight to further increase competition and choice in health care markets. The Administration Report recommends substantial reforms at every level of the industry, including branded and generic pharmaceutical manufacturers, insurers, medical device manufacturers, pharmacies, pharmacy benefits managers (PBMs), providers, and various health care software firms. The Commission has been fighting some of these battles – particularly in the pharmaceutical and hospital spaces – for many years.

Nonetheless, much work remains. As the Administration Report recognizes, the industry still “too often fails to deliver the value it should.”<sup>56</sup> Thankfully, we now have an excellent blueprint for further reforms. Although some of these reforms lie beyond our jurisdiction, like changes to state health regulations, others fall squarely within our bailiwick. I believe the FTC – and other governmental actors, at both the state and federal levels – are up to the challenge.

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such as lower-limb MRIs within hospitals suggests that the relative bargaining power of insurers with hospitals can strongly influence price levels.”).

<sup>55</sup> *Id.*

<sup>56</sup> ADMINISTRATION REPORT, *supra* note 11, cover letter, at 4.