DEPARTMENT OF JUSTICE

A Prescription for Competition

BERNARD (BARRY) A. NIGRO, JR.
Deputy Assistant Attorney General
Antitrust Division
U.S. Department of Justice

Remarks as Prepared for the
Antitrust in Healthcare Conference

Arlington, VA

May 17, 2018

Thank you, Christi, for that kind introduction. I also want to thank Doug Ross and Jeff Brennan, who, along with Christi Braun, organized this important conference.

I am delighted to be here this morning to discuss competition in the healthcare industry, and in particular, some of the healthcare-related issues on which the Antitrust Division is focused.

Healthcare is a large and critical part of our nation's economy. In 2016, healthcare spending by households, businesses, and the government accounted for approximately 18% of Gross Domestic Product, and totaled $3.3 trillion, or $10,348 per person.[1] Imagine a reduction in competition that causes prices to rise by 5% throughout this industry—that equates to $165 billion in annual consumer harm. But, it is not just a question of money: reduce the quality or accessibility of healthcare by 5%, and you potentially cut short millions of lives. Competition in healthcare means being able to afford life-saving surgery, or critical medicines, or an infant's first checkup. It's important. That's why few, if any, segments of our economy merit higher priority when it comes to antitrust enforcement, and healthcare has long been an enforcement priority for the Antitrust Division and our friends at the Federal Trade Commission.[2]

I. Criminal Enforcement

I will start with the area about which we are most concerned—criminal enforcement. Criminal violations are pernicious antitrust offenses. Price fixing and naked market allocation agreements are effectively agreements to steal from consumers (whether in the form of higher prices, lower quality, or fewer choices) and have no procompetitive justification.

But, before I discuss our criminal antitrust enforcement as it relates to healthcare, I am pleased to share that the Division last week welcomed Richard Powers as our new Acting Deputy Assistant Attorney General for criminal enforcement. A West Point graduate, Richard

---

[1] *National Health Expenditure Data: NHE Fact Sheet*, CENTERS FOR MEDICARE AND MEDICAID SERVICES, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet.html.

[2] For example, the FTC supports increased generic drug competition through its litigation and competition advocacy regarding reverse payments. *See, e.g.*, Brief of Federal Trade Commission as Amicus Curiae in Support of No Party, In re Wellbutrin XL Antitrust Litig., No. 15-3559 (3d Cir. Mar. 11, 2016), https://www.ftc.gov/system/files/documents/amicus_briefs/re-wellbutrin-antitrust-litigation/160311wellbutrinbrief.pdf.

served in the Army and received a Bronze Star for his service in Iraq, after which he attended law school at the University of Alabama. Richard has spent most of his career at the Antitrust Division, working on cartel and fraud matters.

Richard also has a keen interest in promoting antitrust enforcement in the healthcare industry. Since 2016, he had been serving in the Criminal Division Fraud Section's Healthcare Fraud Unit in the Eastern District of New York. From there, Richard is stepping in to lead our criminal antitrust enforcement section, which are quite active in the healthcare space.

For example, the Division's focus on detecting and deterring collusion in crucial industries for U.S. consumers includes an investigation into price fixing, bid rigging, and market allocation agreements in the generic pharmaceuticals industry. Millions of Americans purchase prescription drugs every year to treat acute and chronic health conditions. In 2017, for example, nearly 3.9 billion generic prescriptions were dispensed, accounting for 89% of all prescriptions filled in the United States, but only 26% of drug spend.[3] Because so many Americans rely on access to these generic drugs as a more affordable alternative to brand-name drugs, it is critical that those markets remain competitive.

In recent years, however, there have been large price spikes for certain generic drugs — and the Division's investigation into this market has revealed that some corporations and executives have sought to enrich themselves at the expense of consumers who rely on these critical medications. It is hard to imagine a more brazen antitrust crime than colluding to take money out of the pockets of seniors and others whose health depends on prescription drugs.

The Division filed its first charges in this investigation in late 2016.[4] Two executives, the former CEO and former president of a generic pharmaceutical company, were charged with price fixing, bid rigging and customer allocation for an antibiotic and a drug used to treat

[3] Association for Accessible Medicines, "2017 Generic Drug Access and Savings in the U.S.," *available at* https://accessiblemeds.org/resources/blog/2017-generic-drug-access-and-savings-us-report.
[4] Former Top Generic Pharmaceutical Executives Charged with Price-Fixing, Bid-Rigging, and Customer Allocation Conspiracies (Dec. 14, 2016), https://www.justice.gov/opa/pr/former-top-generic-pharmaceutical-executives-charged-price-fixing-bid-rigging-and-customer.

diabetes. Both have pleaded guilty and both have agreed to cooperate in the Antitrust Division's investigation, which is ongoing.

Combatting rising healthcare prices has been, and under the new Administration will continue to be, a priority for the Division. We are investigating other potential criminal antitrust violations in this industry, including market allocation agreements among healthcare providers and no-poach agreements restricting competition for employees.[5] We believe it is important that we use our criminal enforcement authority to police these markets, and to promote competition for all Americans seeking the benefits of a competitive healthcare marketplace.

II. Civil Enforcement

We also have been active in healthcare on the civil side. Last year, the Division won a major victory for American consumers in two major health insurance merger trials. The resulting district court orders enjoined both Anthem's proposed acquisition of Cigna, a $54 billion transaction which would have been the largest proposed transaction in the history of the healthcare industry, and Aetna's proposed acquisition of Humana, a $37 billion deal that would have combined two of the five largest insurers in the United States.[6] Had they been allowed to proceed, the Division believed the proposed transactions would have "increase[d] concentration and harm[ed] competition" among health insurers.[7] According to the Division's complaint in the Anthem case, consumers would have borne the consequences, in the form of "higher prices and reduced benefits."[8] In addition, the proposed transaction "would [have] deprive[d] consumers and healthcare providers of the innovation and collaboration necessary to improve care outcomes." The Division successfully defended the *Anthem* decision on appeal before the

[5] An explanation of the circumstances in which no-poach agreements will be prosecuted criminally can be found in the Competitive Impact Statement filed last month in connection with the Division's civil case against two railroad brake manufacturers. *See* Competitive Impact Statement, United States v. Knorr-Bremse AG and Westinghouse Air Brake Technologies Corporation, No. 1:18-cv-00747 (D.D.C. Apr. 3, 2018), *available at* https://www.justice.gov/atr/case-document/file/1048891/download.

[6] *See* United States v. Aetna Inc., 240 F.Supp. 3d 1 (D.D.C. 2017); United States v. Anthem, Inc., 236 F.Supp. 3d 171 (D.D.C. 2017).

[7] Justice Department and State Attorneys General Sue to Block Anthem's Acquisition of Cigna, Aetna's Acquisition of Humana (July 21, 2016), https://www.justice.gov/opa/pr/justice-department-and-state-attorneys-general-sue-block-anthem-s-acquisition-cigna-aetna-s.

[8] Complaint, United State v. Anthem, Inc. and Cigna Corp., No. 1:16-cv-01493 (D.D.C. July 21, 2016), *available at* https://www.justice.gov/atr/file/903111/download.

United States Court of Appeals for the D.C. Circuit.[9] All four insurers ultimately abandoned their proposed transactions.

We remain busy in this area as healthcare deals seem to travel in pairs—our Healthcare and Consumer Products Section is currently investigating two new proposed transactions in the healthcare space, CVS's proposed acquisition of Aetna, and Cigna's proposed acquisition of Express Scripts.[10]

In addition to mergers, we are actively challenging anticompetitive conduct by healthcare providers. The Division is currently in litigation against Carolinas HealthCare System, which recently changed its name to Atrium Health.[11] In that case, the Division has challenged Atrium's practice of including so-called anti-steering restrictions in its contracts with major health insurers. Without these provisions, insurers could promote competition by "steering" patients to medical providers that offer lower priced, but comparable or higher-quality services. Importantly, that practice benefits consumers, but the anti-steering restrictions prevented it. We alleged that Atrium used these restrictions on steering to protect itself from price competition, and consumers lost the benefit of that competition. The Atrium case is currently scheduled for trial in May 2019.

Earlier this year, the Division reached a settlement with Henry Ford Allegiance Health, a hospital in Michigan, to terminate its agreements with a rival hospital to limit outreach and marketing in the rival's county, and thereby avoid soliciting the rival's customers.[12] The Division had previously settled similar claims against three other hospitals in the area.[13] As a result of the hospitals' agreements, consumers were denied the benefits of competition,

---

[9] United States v. Anthem, Inc. 855 F.3d 345 (D.C. Cir. 2017).
[10] CVS Health Corporation Form 8-K (Feb. 1, 2018), *available at* https://www.sec.gov/Archives/edgar/data/64803/000119312518029474/d533300d8k.htm; Cigna Corporation Form 8-K (Apr. 23, 2018), *available at* https://www.sec.gov/Archives/edgar/data/701221/000095015918000160/cigna8k.htm.
[11] Complaint, United States and North Carolina v. The Charlotte-Mecklenburg Hospital Authority, d/b/a Carolinas HealthCare System, No. 3:16-cv-00311 (W.D.N.C. June 9, 2016), *available at* https://www.justice.gov/atr/file/867111/download.
[12] Justice Department Reaches Settlement with Henry Ford Allegiance Health on Antitrust Charges (Feb. 9, 2018), https://www.justice.gov/opa/pr/justice-department-reaches-settlement-henry-ford-allegiance-health-antitrust-charges.
[13] Justice Department Sues Four Michigan Hospital Systems for Unlawfully Agreeing to Limit Marketing for Competing Healthcare Services (June 25, 2015), https://www.justice.gov/opa/pr/justice-department-sues-four-michigan-hospital-systems-unlawfully-agreeing-limit-marketing.

including free screenings and other services, as well as valuable information that informs healthcare choices and opportunities for higher quality care. Thanks to the Division's action, consumers will benefit from this type of competition among Michigan hospitals going forward.

III. Protecting Taxpayers

Let me shift to a third topic—protecting taxpayers. As the cases I have just discussed illustrate, consumers and other market participants suffer considerable harm as a result of anticompetitive practices in the healthcare sector. The federal government spends a significant part of its budget on healthcare-related fees, so it too (really taxpayers) is harmed by anticompetitive conduct in the healthcare industry.

As Assistant Attorney General Makan Delrahim previously announced, when the government has been the victim of conduct in violation of the antitrust laws, where appropriate, the Division intends to consider bringing actions for damages to recover on behalf of the taxpayers.[14] Section 4 of the Clayton Act enables civil litigants who have been harmed "by reason of" an antitrust violation to recover treble damages; Section 4A does the same for the government.

Pursuing treble damages under Section 4A has two important benefits. First, it deters cartels and other anticompetitive conduct. Second, it compensates taxpayers for the harms the government suffers due to antitrust violations. We intend to exercise the authority Congress has provided and are actively considering cases in this industry to bring. We hope that by doing so, healthcare providers will have even greater incentive to invest in vigorous and effective antitrust compliance.

IV. Limiting Exemptions and Immunities

Another component of the Division's work related to healthcare is competition advocacy. Through competition advocacy, the Division—both individually and jointly in coordination with the Federal Trade Commission—has raised awareness regarding the importance of antitrust enforcement in the healthcare industry, and encouraged federal, state and

[14] "U.S. DOJ Looks to Recover Damages for Price-Fixing," Global Competition Review (Jan. 22, 2018), https://globalcompetitionreview.com/article/1152948/us-doj-looks-to-recover-damages-for-price-fixing.

local governments to consider the competitive impact of various healthcare-related legislative and regulatory proposals.[15]

Exemptions and immunities from the antitrust laws have been for many years a focus of the Division's competition advocacy efforts. Earlier this spring, the Division hosted a public roundtable regarding exemptions and immunities. The roundtable discussion reflected a broad consensus that exemptions and immunities should be limited. Often, when an industry is bestowed with an exemption or immunity, competition is displaced, or cabined, by government regulation. As Justice Robert Jackson, who had previously served as the Assistant Attorney General of the Antitrust Division, explained, "Every step to weaken [the] antitrust laws or to suspend them in any field . . . is a certain, even if unknowing, step to government control."[16] Similarly, as the Antitrust Modernization Commission found, exemptions and immunities allow firms to avoid "the tough discipline of competition." When an industry is given an exemption or immunity, "the beneficiaries of [the] exemption likely appreciate reduced market pressures, [but] consumers … and the U.S. economy generally bear the harm from the loss of competitive forces."[17]

Not all antitrust exemptions were created by Congress:[18] some have been created by judicial doctrine. For example, the Supreme Court created the implied immunity doctrine to address circumstances when it is necessary to reconcile federal antitrust laws and federal regulatory statutes.[19] The Court noted that implied antitrust immunity "is not favored," and "can be justified only by a convincing showing of clear repugnancy between the antitrust laws and the regulatory system."[20]

In several recent investigations, parties have made arguments that the Division should decline to pursue an antitrust enforcement action because the business is subject to regulation.

---

[15] The Division's activities related to competition in healthcare are catalogued at: https://www.justice.gov/atr/health-care; the FTC's activities are catalogued at: https://www.ftc.gov/tips-advice/competition-guidance/industry-guidance/health-care.
[16] Robert H. Jackson, Should the Antitrust Laws Be Revised? 71 U.S. L. Rev. 575, 577 (1937), *available at* https://www.roberthjackson.org/speech-and-writing/should-the-antitrust-laws-be-revised/.
[17] ANTITRUST MODERNIZATION COMMISSION: REPORT AND RECOMMENDATIONS 334-35 (2007).
[18] There are several federal statutory exemptions in the health space, such as the McCarron-Ferguson Act, 15 U.S.C. § 1011 *et seq.*, which exempts certain aspects of the business of insurance from antitrust liability.
[19] Cantor v. Detroit Edison, 428 U.S. 579, 597 (1976).
[20] *Id*. at 597 n.37 (*quoting* United States v. Nat'l Assn. of Securities Dealers, 422 U.S. 694 (1975).

Even where parties do not claim that regulation has completely displaced the antitrust laws, they sometimes argue that regulation does such a good job that antitrust enforcement and competition add little value.

The Division saw a version of this argument in the successful effort to block the merger between Aetna and Humana. There is no question, government regulations affect how insurers compete in the Medicare market. Regulations administered by the Center for Medicare and Medicaid Services (or CMS) set many requirements for Medicare Advantage plans. Pointing to these regulations, the merging insurers argued that "federal regulation of Medicare Advantage leaves 'no opening for the anticompetitive effects that the Government posits.'"[21]

The district court analyzed the claim that these regulatory tools adequately protected competition, and ultimately rejected this defense.[22] Because there was sufficient room for private companies to choose premium levels and aspects of plan quality within the constraints established by regulation, the court concluded that competition provided meaningful pressure that kept premiums down and quality up, and the merger threatened harm to that competitive dynamic.[23] To be clear, the Division is skeptical of any claim that government regulation prevents competitors from exercising market power or that consumers do not benefit from the forces of competition to protect their interests.

A second type of judicially created exemption, the state action doctrine, exempts certain anticompetitive state laws—or conduct allowed by those laws—from antitrust enforcement. State occupational licensing requirements are a common example of state regulations that may harm competition by raising barriers to entry, and thus the state action doctrine is often raised as a defense in cases challenging such regulations as antitrust violations.[24] First articulated in *Parker v. Brown*,[25] the doctrine provides that these state law restraints must be taken pursuant to

[21] United States v. Aetna Inc., 240 F. Supp. 3d 1, 48 (D.D.C. 2017) (quoting Defs.' Proposed Findings & Conclusions at 129).
[22] *Id*.
[23] *Id*. at 49.
[24] *See, .e.g.*, North Carolina State Bd. Of Dental Examiners v. FTC, 135 S.Ct. 1101 (2015).
[25] 317 U.S. 341 (1943).

a "clearly articulated and affirmatively expressed . . . state policy" to displace competition, and be "actively supervised by the state itself."[26]

When the state action doctrine puts a potentially anticompetitive state regulation (or action pursuant to that regulation) beyond the reach of federal antitrust law, the Division has urged state legislatures to consider the negative effects on competition. State certificate of need laws, for example, have been a frequent subject of competition advocacy. In April 2017, the Division and the FTC urged the Alaska state legislature to approve legislation that would repeal the state's certificate of need laws. These laws prohibit entry unless a potential entrant demonstrates, to the satisfaction of regulators, that there is an unmet need for the medical services it intends to provide. The decision to invest many millions of dollars, say in a new hospital, reflects an assessment of business risk and a judgment that the investment is expected to be profitable. Certificate of need laws allow regulators to second guess that business judgment. The new hospital may be profitable at the expense of incumbent competitors, but that is the essence of competition. Incumbent firms thus are the primary beneficiaries of certificate of need laws, and they can take advantage of these laws to thwart or delay entry or expansion by their competitors. Who suffers the consequences? Consumers. Rather than being treated in a new hospital nearby, they may have to travel further, or go to an older facility, or have fewer choices for treatment. And, reduced competition between facilities may lead to higher prices and innovation in health care markets than otherwise might have existed.

V. Group Conduct: "Danger, Will Robinson!"

Another particularly important subject of competition advocacy, and antitrust enforcement, is where competitors band together to set standards for professional licensing or certification. Sometimes such groups act on behalf of a state, and other times they act as private self-regulatory bodies. But in either case they involve the same risk—the risk that rivals will act in ways to limit competition.

[26] Calif. Retail Liquor Dealers Ass'n v. Midcal Aluminum, 445 U.S. 97, 105 (1980).

a. Occupational Licensing

Licensing requirements define the minimum standards or qualifications to practice in an area. Physicians must obtain a medical license, and lawyers must be members of the bar, to practice their professions. These types of legal requirements ensure that professionals are minimally capable to provide the services for which they are licensed. They also, however, restrict who can provide such services and thus serve as entry barriers.

Occupational licensing requirements have been an important subject of the Division's competition advocacy. Jointly with the FTC, we have urged state legislatures to carefully consider laws that impose occupational licensing requirements, and insure that any health or safety benefit from such requirements is balanced against the harms to competition such requirements may create.

One such statute proposed to regulate telehealth services in Michigan. We noted that lowering and avoiding unnecessary barriers to the delivery of innovative health services can benefit consumers by improving access and reducing cost.[27] At the same time, we recognized the importance of protecting patient safety. We thus urged the legislature to limit regulations only to those needed, for example, to protect patient safety, improve public health, or protect against fraud.

The Division and the FTC also urged the Massachusetts and Puerto Rico legislatures to consider the competitive implications of two proposed laws regarding optometrists and ophthalmologists.[28] The proposed legislation in Massachusetts allowed optometrists to treat glaucoma patients under some circumstances. Without it, only ophthalmologists could do so. Puerto Rico's proposed law expanded the scope of practice for optometrists to allow them to use and prescribe medications to diagnose and treat eye diseases. Both Massachusetts and

---

[27] Letter from Robert Potter, Chief, Legal Policy Section, Antitrust Division, to Senator Peter MacGregor, 28th District, Michigan State Senate (Nov. 29, 2016), *available at* https://www.justice.gov/atr/page/file/913876/download.

[28] Joint Statement of the Antitrust Division and the FTC to the Puerto Rico House of Representatives on S.B. 8991, Regarding Pharmacological Care by Optometrists (May 18, 2016), *available at* https://www.justice.gov/atr/file/861721/download; Joint Statement of the Antitrust Division and the FTC to the Massachusetts House of Representatives on H.B. 1973, Regarding Glaucoma Care by Optometrists (February 18, 2016), *available at* https://www.justice.gov/opa/file/826371/download.

Puerto Rico were outliers among states and territories in not allowing optometrists to provide those services. In each case, we recognized the critical need for patient health and safety, while urging state legislators to avoid unnecessarily restrictive laws that deny consumers the benefits of competition or create entry barriers without corresponding health or patient safety justifications.

When licensing requirements are not protected by the state action doctrine, assessing their antitrust implications requires evaluating the potential anticompetitive and procompetitive effects. On the one hand, such competitor collaboration is fraught with risk of collusion. As the Supreme Court recognized in *Allied Tube & Conduit Corp*., "members of such associations often have economic incentives to restrain competition and that the product standards set by such associations have a serious potential for anticompetitive harm."[29]

On the other hand, this is an area where some collaboration may be useful. As the Court acknowledged, "[w]hen . . . private associations promulgate safety standards based on the merits of objective expert judgments and through procedures that prevent the standard-setting process from being biased by members with economic interests in stifling product competition, those private standards can have significant procompetitive advantages."[30] Collaborators should always be vigilant to ensure that their efforts at collaboration are narrowly tailored such that they are focused on promoting the procompetitive aspects of the venture.

b. Professional Certification

In contrast to licensing requirements, the process of certifying professionals in various specialty fields can confirm that a practitioner has a particular skill or qualification. Certification can be in addition to, or independent of, a licensing requirement. Certification signals quality and promotes choice, because a consumer can choose between providers who offer lower prices and providers who charge higher prices but that do so because they believe they provide higher-quality care.

[29] *See* Allied Tube & Conduit Corp. v. Indian Head, Inc., 486 U.S. 492, 500 (1988).
[30] *Id*. at 501 (internal citation omitted).

Certification is used by many participants in the healthcare industry. Doctors and nurses can be certified in various medical specialties. Certification also exists for psychologists, dentists, pharmacists, physical therapists, occupational therapists, physician assistants, and other health professionals.

Private certification bodies raise interesting antitrust considerations. Certification may be procompetitive insofar as it promotes choice and signals quality. By receiving board certification, professionals in these fields can advertise to prospective patients that they have received extra training and thus, potentially, provide higher quality services. But, because certification sometimes becomes a de facto requirement for meaningful participation in a market for healthcare services, certification requirements can at times act as barriers to entry.

In addition, certification bodies sometimes impose continuing education requirements as part of the certification process. To the extent they do not have corresponding health or safety justifications, these requirements may raise prices and limit lower-priced options. On the other hand, in certain professions continuing education is a common requirement, and assessing the appropriate balance between patient safety and costs requires careful factual analysis and a significant degree of expertise.

c. Lessons from Standard Setting

Certification, and licensing when governed by a group of competitors, has important parallels to standard setting, which as many know is an area of interest to the Division. Both certification and standard setting set conditions for participating in the market, and both confer important economic advantages to those who qualify. In addition, both certification bodies and standard setting organizations often bring together competitors. It is well-understood by both courts and antitrust enforcers that SSOs "can be rife with opportunities for anticompetitive activity."[31] The FTC's case against the North Carolina State Board of Dental Examiners demonstrates that the concern is not limited to standard setting organizations, but extends to other types of certification bodies too. In that case, the FTC alleged that the Board, comprised largely of licensed dentists, was harming competition by blocking non-dentists from providing

[31] Am. Soc'y of Mech. Eng'rs, Inc. v. Hydrolevel Corp., 456 U.S. 556, 571 (1982).

teeth-whitening services in that state. The FTC found that teeth-whitening services are much less expensive when performed by non-dentists, and the Board's actions did not have sufficient benefits to justify their harmful effect on competition.[32]

In the certification context, if we had evidence that practicing professionals who control certification bodies increased certification requirements in a way that restricts competition, without a legitimate and sufficient health (or other procompetitive) purpose, that would raise antitrust concerns. Relatedly, if we learned that a certification body used market power to force hospitals or other companies not to do business with professionals certified by rival certification bodies, that too would raise antitrust concerns absent a plausible justification.

VI. Conclusion

Because competition benefits consumers in so many ways, antitrust enforcement will continue to play an outsized role in healthcare. Competition keeps healthcare costs down, which broadens access to health care products and services. Competition results in more choices for consumers. Non-price competition promotes higher-quality care and encourages innovation, which can lead to new, life-saving treatments. Protecting and fostering competition in this space is a responsibility that we at the Antitrust Division take very seriously, and, because of that, antitrust enforcement in healthcare will continue to be a high priority for the Division.

[32] Opinion of the Commission, In the Matter of the North Carolina Board of Dental Examiners, Docket No. 9343 (Dec. 7, 2011), *available at* https://www.ftc.gov/sites/default/files/documents/cases/2011/12/111207ncdentalopinion.pdf.