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**Federal Trade Commission**

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**The First Wealth is Health: Protecting Competition in Healthcare Markets**

*Remarks at the 2017 ABA Fall Forum*

**Maureen K. Ohlhausen<sup>1</sup>**  
**Acting Chairman, U.S. Federal Trade Commission**

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Good afternoon. I'd like to talk to you today about protecting competition in health care markets. I will highlight some of the key initiatives we have undertaken and some of the more critical policy issues we have engaged with during my tenure as the Acting Chairman. Although the focus of today's talk is health care, some of the approaches we have used here may well have broader application in other sectors of the economy where free market competition and government regulation both play significant roles.

As antitrust enforcers, there are probably few markets we touch that are more important to both consumers and the economic health of the country than health care markets. As Ralph Waldo Emerson said, "The first wealth is health" and healthcare certainly implicates a lot of this country's wealth. Total health care spending in the U.S. accounts for just under 18% of total

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<sup>1</sup> 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.

GDP<sup>2</sup> and these markets frequently involve some of the most vital products and services consumers will ever need. Notably, the President recently issued an executive order to foster greater competition in the health care markets, an order that specifically requires HHS to consult with the FTC<sup>3</sup>. So to say there is a lot of pressure on us to make sure we get the competition issues right in these markets is something of an understatement.

During my time at the helm of the FTC, we have taken a multi-faceted approach to the health care space. These markets often raise complex, nuanced questions that require careful, tailored interventions to protect consumers from anticompetitive conduct. Nor is our work limited to the direct enforcement of the antitrust laws. As I'll discuss in a moment, health care markets are frequently subjected to extensive regulatory intervention, which raises a constellation of issues that lay outside the realm of traditional law enforcement. In these regulated markets, protecting competition requires a willingness to embrace a variety of less conventional tools. Through things like our active and substantial advocacy program, our independent research, and the facilitation of constructive dialogue among various stakeholders, I have pursued every avenue to encourage and safeguard the beneficial forces of competition. It is not enough to be just a cop on the beat in the health care space, we also must be tireless advocates for the underlying principles the antitrust laws were created to protect.

This is not to denigrate the crucial role of antitrust enforcement, however, and so I will start with a brief discussion of our recent efforts. Last year we successfully blocked two major hospital mergers, winning victories in cases involving healthcare systems in the suburbs of

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<sup>2</sup> Centers for Medicare & Medicaid Services, *NHE Fact Sheet*, <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.html> (last visited Nov. 14, 2017).

<sup>3</sup> Presidential Executive Order Promoting Healthcare Choice and Competition Across the United States, THE WHITE HOUSE (Oct. 12, 2017), <https://www.whitehouse.gov/the-press-office/2017/10/12/presidential-executive-order-promoting-healthcare-choice-and-competition>.

Chicago and the Harrisburg area of Pennsylvania.<sup>4</sup> Together, these two cases moved an important area of the law into a much more settled place and will likely serve both the agency and the public for many years to come. We have already started building on that very sound foundation. This year, the Commission moved to challenge the acquisition of Mid-Dakota Clinic by Sanford Health, together with the State of North Dakota. The Commission complaint alleges that the transaction would combine the two largest providers of primary care services, as well as pediatric and OB/GYN services in areas around Bismarck, North Dakota.<sup>5</sup>

Anticompetitive behavior in markets for patented pharmaceuticals also continues to be a significant focus for the agency during my tenure. Pay-for-delay issues remain an important piece of the puzzle, but it may be that we have finally started to turn the corner on this issue. As you may know, under the Medicare Modernization Act of 2003, firms are required to report to the FTC and the Department of Justice when they enter into these settlements. In our most recent staff report summarizing these reports, we noted that the frequency of potentially problematic pay-for-delay deals has finally started to decline in the wake of the *Actavis* decision.<sup>6</sup> There is plainly more work to do on this front, and still some unsettled subsidiary questions to resolve as the lower courts continue to apply the lessons of *Actavis*. Indeed, we currently have several matters in active litigation involving alleged pay for delay issues.

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<sup>4</sup> Advocate Health Care Network, FTC File No. 141 0231 (2017), <https://www.ftc.gov/enforcement/cases-proceedings/141-0231/advocate-health-care-network-advocate-health-hospitals>; Penn State Hershey Medical Center, FTC File No. 141 0191 (2016), <https://www.ftc.gov/enforcement/cases-proceedings/141-0191-d09368/penn-state-hershey-medical-center-ftc-commonwealth>.

<sup>5</sup> Sanford Health, FTC File No. 171 0019 (2017), <https://www.ftc.gov/enforcement/cases-proceedings/171-0019/sanford-healthsanford-bismarckmid-dakota-clinic>.

<sup>6</sup> FED. TRADE COMM’N, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: OVERVIEW OF AGREEMENTS FILED IN FISCAL YEAR 2015 (2017), [https://www.ftc.gov/system/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-modernization/overview\\_of\\_fy\\_2015\\_mma\\_agreements\\_0.pdf](https://www.ftc.gov/system/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-modernization/overview_of_fy_2015_mma_agreements_0.pdf).

Although I cannot comment on any of our active matters, what I can say is that I take the recent report that these deals are in decline as an encouraging sign. It would not be wise to put too much weight on a single data point, but perhaps firms are starting to get the message that fending off legitimate patent challenges by paying generics to delay entry will not be tolerated by either the enforcement agencies or the courts. In aggregate, these cases have consumed a lot of agency resources over the last few decades, and it would be nice to see fewer of them in the years ahead, as the law becomes clearer in the wake of the agency's victory in *Actavis*.

But pay-for-delay is not the only issue of great concern in the pharmaceutical space. In February of this year, in the very first case under my leadership, the Commission voted to initiate litigation against Shire Viropharma Inc.<sup>7</sup> In this matter, the FTC alleged that, to maintain its monopoly in Vancocin, ViroPharma waged a campaign of serial, repetitive, and unsupported filings with the U.S. Food and Drug Administration and the courts to delay the FDA's approval of generic Vancocin Capsules and exclude competition. According to the complaint, ViroPharma submitted 43 filings with the FDA and filed three lawsuits against the FDA between 2006 and 2012. The number and frequency of ViroPharma's petitioning at the FDA are many multiples beyond that by any drug company related to any other drug. The Commission complaint also alleges that ViroPharma knew that it was the FDA's practice to refrain from approving any generic applications until it resolved any pending relevant citizen petition filings, and that Viropharma intended for its serial filings to delay the approval of generics, restricting competition and maintaining higher prices for consumers.

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<sup>7</sup> FTC Press Release, "FTC Charges that Shire ViroPharma Inc. Abused Gov't Processes Through Serial, Sham Petitioning to Delay Generics and Maintain its Monopoly over Vancocin HCl Capsules," (Feb. 7, 2017), <https://www.ftc.gov/news-events/press-releases/2017/02/ftc-charges-shire-viropharma-inc-abused-government-processes>.

This case represents the culmination of many years of work for me personally. Not only have I long focused on abuse of government process as a competition problem, I headed the FTC's work to clarify the *Noerr-Pennington* doctrine, which resulted in a scholarly report in 2006.<sup>8</sup> The report recommended that the doctrine should not protect repetitive petitioning filed without regard to merit, petitioning that uses government process itself to harm competitors and suppress competition. I hope my investment in narrowing this doctrine will pay off for consumers and competition.

Not everything we are doing in the pharmaceutical space involves active enforcement matters, however. As most of you know, the Hatch-Waxman Act framework is designed to balance the needs of innovators to invest appropriately in new innovative therapies and the needs of the public to obtain low-cost generic medicines once patents have run their course.

Competition is key to containing prescription drug costs. During the last ten years, generic drugs have saved Americans more than \$1.67 trillion. For many drugs, the Act has successfully lowered generic barriers to entry, spurring additional competition that has led to lower drug prices. Still, there are concerns about rising drug prices and generic competition. When these concerns arise, it is critical that we identify barriers that may prevent drugs from entering the market, even after applicable patent protections have expired. Consequently, I have directed staff to take a closer look at what is happening in some of these markets for drugs that are no longer covered by patents, markets where we would typically expect to see vigorous and effective generic competition lowering prices for consumers.

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<sup>8</sup> FED. TRADE COMM'N, ENFORCEMENT PERSPECTIVES ON THE NOERR-PENNINGTON DOCTRINE (2006), <https://www.ftc.gov/sites/default/files/documents/reports/ftc-staff-report-concerning-enforcement-perspectives-noerr-pennington-doctrine/p013518enfperspectnoerr-penningtondoctrine.pdf>.

Thus, just last week, I convened a full-day workshop bringing together academic experts, regulators, and industry stakeholders to examine generic drug entry in markets where the branded drug is off-patent, and to explore the supply chain from manufacturer to consumer.<sup>9</sup> We worked together on this program with the FDA, the principal sector regulator in this space. During the exploration of generic drug entry, panelists focused on small patient populations, consolidation, drug shortages, and gaming strategies as potential contributors to insufficient competition in generic drug markets. The FTC will continue to collect public comments on this important issues through December 8, 2017.<sup>10</sup>

In his remarks at our workshop, FDA Commissioner Scott Gottlieb emphasized the importance of generic entry after patent expiration as a key pillar of the regulatory framework. He particularly singled out efforts to keep generic companies from obtaining the samples they need to establish bioequivalence. I think it is fair to say that Dr. Gottlieb and I are very much on the same page in terms of the importance of allowing generics access to markets no longer protected by intellectual property rights.

When we see problems like the inability of generics to purchase the samples they need to obtain regulatory approval through REMS abuse, or sham petitioning activities that seek to twist the regulatory process into a tool to maintain market dominance, we should consider whether the antitrust laws may be brought to bear in appropriate circumstances. As always, however, we must make that decision on the basis of specific facts and actual market effects, using the familiar methods and processes of antitrust law.

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<sup>9</sup> FTC Workshop, Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics (Nov. 8, 2017), <https://www.ftc.gov/news-events/events-calendar/2017/11/understanding-competition-prescription-drug-markets-entry-supply>.

<sup>10</sup> Comments may be submitted to <https://ftcpublic.commentworks.com/ftc/pharmaworkshop> until December 8, 2017.

Competition advocacy on specific regulations is also a vital tool in ensuring competitive healthcare markets. In fact, about 40% of the advocacies the Commission has filed so far in 2017 address health care issues. For example, we have filed advocacies recommending that lawmakers loosen restrictions on telehealth services for rural consumers and pressed to liberalize access to dental therapists to provide basic dental care. My Economic Liberty taskforce, aimed at reducing regulatory barriers to employment, has focused on license portability issues and state reciprocity issues of particular interest to many healthcare providers. But the two single health care issues that have consumed the most of our advocacy activity in the last year are Certificates of Need (CON) and Certificates of Public Advantage (COPA).

As I discussed in a 2015 article in the ABA Antitrust magazine, certificate of need laws are an unfortunate legacy of a failed, mid-20<sup>th</sup> century effort to control healthcare costs.<sup>11</sup> At the time, health care services were typically billed on a cost-plus basis, and it was thought that providers had no check on excessive expenditures. The idea was that the government would step into these markets directly, requiring providers to establish that a community really needed a new MRI machine or even a new hospital, before the government would permit the expenditure to take place.

These days, health care is no longer billed on a cost-plus basis, and most people now understand that establishing a government-created shortage of things tends not to reduce their cost. Also, perhaps not surprisingly, these laws really never provided any meaningful cost savings.

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<sup>11</sup> Maureen K. Ohlhausen, *Certificate of Need Laws: A Prescription for Higher Costs*, 30 ANTITRUST MAG. 50 (Fall 2015), <https://www.ftc.gov/public-statements/2015/12/certificate-need-laws-prescription-higher-costs>.

CON laws are an excellent example of what I call the “Brother May I”<sup>12</sup> problem, where a potential new entrant must first obtain permission from the very companies with which it hopes to compete. It is hardly surprising that when you ask most incumbents if it would be a good idea for them to face more competition that might pressure them to improve quality or lower their prices, the answer is frequently a resounding no. Normally, firms don’t need a permission slip from the government, endorsed by their future competitors, to enter a market. Yet perversely, that is exactly what CON laws provide.

Fortunately, the federal government abolished its efforts to require states to adopt CON laws in 1984, and a number of these state CON laws were subsequently repealed. Unfortunately, these laws remain on the books in 35 states today.<sup>13</sup> Why do these pernicious laws persist? In my view, the current landscape reflects a combination of legislative inertia and the fact that incumbent providers benefit when the state protects them from competition. Today, CON laws insulate politically powerful incumbents from market forces, and those providers naturally are loathe to give up the special government preferences that CON laws bestow.

Ending CON laws in the United States is not going to be an easy lift. Nevertheless, we continue to press for further repeal or liberalization of these laws whenever the opportunity arises. Under my watch, we have also started to file advocacies recommending CON boards allow new entry or expansion where it would increase competition and benefit consumers.<sup>14</sup>

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<sup>12</sup> See Maureen K. Ohlhausen & Gregory P. Luib, *Brother, May I?: The Challenge of Competitor Control over Market Entry*, 4 J. ANTITRUST ENFORCEMENT 111 (2015), [https://www.ftc.gov/system/files/documents/public\\_statements/801861/150917brothermayi.pdf](https://www.ftc.gov/system/files/documents/public_statements/801861/150917brothermayi.pdf).

<sup>13</sup> National Conference of State Legislatures, *Certificate of Need State Laws* (Aug. 2016), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx>; see also Mercatus Center, George Mason University, *Certificate-Of-Need Laws: How CON Laws Affect Spending, Access, and Quality across the States*, <https://www.mercatus.org/conlaws> (last visited Nov. 14, 2017).

<sup>14</sup> See FED. TRADE COMM’N, *FTC Staff Comment Before the Georgia Department of Community Health Regarding the Certificate of Need Application Filed by Lee County Medical Center* (Oct. 16, 2017),



Although it is not within our power to repeal these laws ourselves, we are going to continue the important work of educating policymakers and the public about their negative impacts. In a time when healthcare costs concern many Americans, states need to be doing all they can to unleash the beneficial forces of competition, which are extraordinarily effective at reducing prices and improving quality.

Finally, let me say a few words about Certificates of Public Advantage. Beginning in the 1990s, several states passed COPA laws and regulations intended to allow healthcare providers to enter into cooperative agreements that might otherwise be subject to antitrust scrutiny. Historically, the stated purpose of these laws has been to reduce “unnecessary” duplication of healthcare resources and control healthcare costs. These laws purport to immunize certain activities and transactions under the state action doctrine. COPA laws have covered various forms of provider collaboration and also have shielded provider mergers that are anticompetitive.

In recent years, we have observed a resurgence in the passage and use of COPA laws to immunize provider transactions from antitrust scrutiny. In some situations, we have seen state legislatures passing COPA legislation with the intent to exempt specific proposed hospital mergers from anticipated antitrust challenges. In these and other situations, hospitals have claimed that they need an antitrust exemption because consolidation is the only way to achieve the size, scale, and degree of clinical integration necessary to participate in new delivery and payment models, such as population health initiatives and value-based payment models. Because procompetitive health care collaborations are already permissible under the antitrust laws, however, there is considerable concern that the main effect of these laws is to immunize

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<https://www.ftc.gov/policy/advocacy/advocacy-filings/2017/10/ftc-staff-comment-georgia-department-community-health>.

conduct that would *not* generate efficiencies and therefore would *not* pass muster under the antitrust laws.

On my watch, we have tried push back against both these laws and their specific application to problematic transactions through our advocacy program. The Bureau of Economics also recently announced a call for more scholarship on the impact of these laws, and our Office of Policy Planning is currently in the early stages of organizing a 2018 workshop that will take an even deeper dive on the COPA issue.

Finally, a few concluding observations. I have played many roles at the FTC, culminating in leading the agency as the Acting Chairman this year. My varied experience instilled in me the importance of a coordinated approach to big, complex competition issues. The FTC is primarily a law enforcement agency, and, on the competition side of the house, that means we spend most of our time prosecuting specific cases with discrete impacts on competition. But we are not just a law enforcement agency, and, in markets where existing regulatory frameworks and market forces jostle endlessly for position, it is crucial that the strong belief in competition that underlies our enforcement docket has a voice in the public square and the halls of government.

This work is often difficult and unglamorous, with long lead times before effort leads to tangible results. For example, my early work on the State Action doctrine didn't come to full fruition until over a decade later in two Supreme Court victories. But the difficulty of this work doesn't make it any less important. During my time leading the FTC, I have taken an integrated approach to the health care space, prosecuting specific cases where the facts warrant, and pursuing policy initiatives addressed to some of the most important competition concerns we have encountered.

What I would most like you to take away from these remarks is that while protecting competition in the health care space is neither easy nor straightforward, it remains a critical focus for me personally and for the FTC as a whole. Consumers always deserve markets that work *for* them. But that need is perhaps never more acute than when they depend on the operation of those markets to provide health care for themselves and their families. I am proud to have carried these efforts forward during my time as Acting Chairman.

Thank you all very much.