A Discussion With FTC Commissioner Maureen K. Ohlhausen

Introduction

Commissioner Ohlhausen has a long history of distinguished public service at the Federal Trade Commission and in the federal court system. She spent five years as a law clerk for Judge David Sentelle and staff attorney at the U.S. Court of Appeals for the D.C. Circuit before she first joined the FTC in 1997. At the Commission, she has held a number of different positions, including attorney advisor to Commissioner Orson Swindle and Director of the Office of Policy and Planning from 2004 – 2008. She was sworn in as an FTC Commissioner in April 2012 for a term that expires in September 2018.

The interview below was conducted by the editors of the Chronicle and covers various aspects of antitrust and the health care and pharmaceutical industries.

***The Chronicle*:** To start, could you describe your top priorities as a Commissioner at the FTC and where health care and pharmaceuticals enforcement ranks among those priorities?

***Commissioner Ohlhausen*:** Sure. My top priority is for the agency to focus its enforcement and policy efforts on conduct or transactions that have the most significant adverse impact on consumers. For example, we should prioritize conduct or a transaction that has caused significant consumer harm or would cause such harm now, rather than one that is merely suspected to create harm in the future. Not surprisingly, given the prominence of health care, including pharmaceuticals, in the economy, I think it is appropriate that the FTC has focused a lot of its attention in the health care area—on both the enforcement side and the policy side. Our law enforcement, research, advocacy, and economic resources should be focused on problems that present the greatest harms to consumers today—whether we're talking about health care or any other sector of the economy.

***The Chronicle*:** And you have spent a lot of time at the FTC, in the past as the Director of the Office of Policy Planning and as an attorney adviser to former Commissioner Orson Swindle. Could you describe the most significant changes that you have seen in health care and pharmaceutical enforcement over the years?

***Commissioner Ohlhausen*:** One of the most significant changes that I have seen is that we started to win our hospital merger challenges. Whether we actually win in court or we challenge a transaction and it is abandoned by the parties, I think we have really managed to turn around a losing streak that we had in the 1990s and early 2000s. We are pursuing and prevailing against hospital mergers that are likely to lead to a substantial lessening of competition and, by laying down clear precedent, hopefully preventing other problematic deals before they get out of the planning stages. I was here for a good part of that turnaround, and it has been an encouraging development for our agency in the health care space.

***The Chronicle*:** Do you think that's attributable to anything in particular? Are there things that the Commission may be doing better?

***Commissioner Ohlhausen*:** I think our recent successes are attributable in large part to former Chairman Muris. He really sent a message that we're not winning these cases, we're not convincing the courts to accept our predictions of anticompetitive effects from these mergers. So, he ordered the Bureau of Economics in 2002 to undertake a study of consummated hospital mergers to see if the kinds of effects that we had forecast had actually taken place. And, our retrospective analysis showed those effects. I think that was really a turning point. I also think it was a matter of not giving up—continuing to press ahead and then eventually to make inroads with our arguments. We have been able to do that in the hospital merger context and in areas like pay-for-delay agreements.

This actually leads me to another key priority for me as a Commissioner: greater transparency through more careful and deliberate articulation of our actions as a Commission. We ought to be as transparent as possible about what we are doing as an agency and why we are doing it. It would certainly help participants in the market to have a better idea of where we see problems occurring or where we are going to draw the line between lawful and unlawful conduct. I think that type of transparency will also help us in our enforcement efforts. This is a type of preventative care that we can pursue. It's a good thing in enforcement as well as in health care.

***The Chronicle*:** The Affordable Care Act has gotten a lot of press recently and there have been some commentators out there that have said that the FTC's enforcement actions against provider consolidations may be inconsistent with the goals of the ACA to improve efficiency and quality of care. Do you have reaction to those comments?

***Commissioner Ohlhausen*:** I think that really misunderstands what the FTC is trying to do and what the Affordable Care Act is trying to do. In my view, the ACA is trying, among other things, to achieve efficiencies for patients, to give them higher quality of care at a lower cost, through increased coordination of care. The challenge in any consolidation of hospitals or providers is to protect competition because that helps create efficiencies whose benefits can flow to consumers. I also think that antitrust enforcement should not be viewed as a barrier to collaboration among competing providers. If they want to integrate in a way that improves the quality of care, and they can show that the integration will improve quality and without having a significant competitive downside, I think that generally should be acceptable under the antitrust laws. One of the areas that we can improve on at the FTC is to perhaps address this area more vocally—again to be even better about transparency and articulating our enforcement philosophy. I think the onus is on us as an agency to explain why the perceived tension between our enforcement efforts and the ACA does not actually exist. Further, in individual cases, we need to explain why it is that we think a particular integration will or will not achieve quality improvements and whether on balance the integration will be anticompetitive.

***The Chronicle*:** So would you say that there has been any change to the FTC's approach or analysis in provider consolidation? To what extent are the goals of the Affordable Care Act taken into account?

***Commissioner Ohlhausen*:** I don't think there has been a change in our approach for assessing provider consolidation post-ACA. There has obviously been a significant recent trend toward

consolidation. For example, the percentage of physicians that are independent is down significantly since 2000. There have been many hospital mergers in the past five or so years. But I do not think our fundamental analysis has changed since the Affordable Care Act. We still consider the potential for competitive harm in a given product or service market, then we balance the possibility of any competitive harm against the cognizable efficiencies attributed to the merger, including, for example, improvements in quality of care. In that sense, I think we are doing the same thing that we have always done.

The ACA emphasizes provider integration, and we understand that that can yield efficiencies and other benefits for consumers. But efficiencies have always been part of modern merger review—that's nothing new. One of the things that we do try to do when a party makes efficiencies arguments to us is to look at the ordinary course of business documents and the deal analysis and ask: Will the merger change the incentive that the parties already have to improve quality of care? In previous consolidations, acquisitions, or integrations, did the promised quality improvements occur? We also ask the merging parties why the merger is necessary to achieve the quality improvements that they are claiming, and how they will take place—that is, how they will actually be obtained. One of the things we fear most is that parties will offer these potential efficiencies and then we go back and look at previous acquisitions or integrations and the promised quality failed to materialize. So, we have to closely evaluate efficiencies arguments and then consider whether the benefits can be achieved without the possible anticompetitive effects of the proposed transaction.

***The Chronicle*:** Is there a way that parties can better present their efficiencies story? What is the best way parties can demonstrate that their proposed efficiencies are going to be achieved and quality improvements are real, tangible, and likely to occur?

***Commissioner Ohlhausen*:** I think parties can do that by taking us through the analysis on a step-by-step basis and not just saying, "We plan to employ electronic health records," or "We plan to adopt best practices." Parties should also explain why they have not adopted those best practices already and why they have to consolidate to achieve those best practices, or why they have not already implemented an electronic health records system and why an EHR system is going to make their provision of care so much better. We also look at the parties' plans for integration and how necessary the integration is to actually achieving all the proposed benefits. Explaining these benefits in a step-by-step approach can be more helpful than just providing a very general description of the potential efficiencies.

***The Chronicle*:** The Affordable Care Act requires providers to take certain actions on electronic health records, and we have seen smaller providers say they need to do a deal in order to meet the ACA requirements. To what extent is that argument persuasive to the FTC, or do you consider that almost like a failing firm defense—not a failing firm defense *per se*, but is that something that the FTC is likely to consider?

***Commissioner Ohlhausen*:** We do hear that from time to time. I think we have to really take a hard look at the numbers and ask whether the firm is really struggling or really not cutting it, and then we also look at the likely anticompetitive effect of the consolidation. Things always have to be balanced and we of course need to consider whether the consolidation involves particularly close competitors or whether there is another

alternative that does not reduce competition. Maybe there is a better way to achieve what the parties want to achieve without having the anticompetitive effects.

***The Chronicle*:** At the beginning of this year, FTC Staff issued an advisory opinion relating to the Norman Physician Hospital Organization. To what extent does that matter provide the model or a roadmap to parties in terms of what the FTC is looking for in achieving appropriate clinical integration?

***Commissioner Ohlhausen*:** To be clear, this was an FTC Staff advisory opinion, and so it doesn't necessarily represent the Commission's views. I do think, however, that it offered meaningful guidance on how providers can stay on the right side of the antitrust laws in their integration efforts. There are a variety of factors that I think went into the Norman Physician Hospital Organization that made it acceptable to staff. First, it was developed with serious input from the community. Second, it included a mentor committee, and real consideration was given to quality improvement planning, including a specialty advisor group to determine performance benchmarks to ensure compliance. Third, I think it was important that the network was not exclusive. Finally, there were no vertical arrangements between the hospitals and physicians involved in the PHO.

As I said earlier, you asked how people can present things better: with more specifics. I think the Norman PHO presented a lot of specifics about how it will achieve quality improvements and how its integration facilitates and serves the envisioned quality benefits. So, those two concepts were well integrated, with one explaining the other really well. That helps mitigate any concern about a loss of competition. So, I think the PHO told a very good story about why this integration was going to be beneficial on balance to patients.

***The Chronicle*:** Do you think the Health Care Antitrust Statements are ripe for revision at this point given that a lot of time has passed since they were written and health care markets and services have evolved since that time?

***Commissioner Ohlhausen*:** I think that the Health Care Statements are still very useful; they remain applicable and we rely on them to a great extent. With that being said, I think that it is important for the agency to always try to keep our guidance up-to-date and reflective of current market conditions. So, I think it would a good idea for us to at least consider whether updating the Statements would be appropriate.

***The Chronicle*:** The FTC also had a number of notable victories this year…

***Commissioner Ohlhausen*:** Yes, we have.

***The Chronicle*:** What do you think the impact will be of the Supreme Court's decision in *Phoebe Putney*, in terms of the FTC's enforcement activities and future cases that involve state action issues?

***Commissioner Ohlhausen*:** Well, as exciting as the *Phoebe Putney* victory was—a nine-to-zero Supreme Court decision, after all—we put a lot of efforts into reshaping the state action doctrine over the decade that led up to that decision. I worked on the State Action Task Force Report, published in 2003. Following the issuance of that report, we looked for cases and areas in which to improve the state of the law on state action immunity.

I do not think our enforcement is going to change post-*Phoebe* because we were not shying away from many fights in this area. I do think, however, that this victory really shows the value of investing in the policy work and research efforts at the FTC as a way to improve the state of the antitrust laws. It is a great example of where we identified a problem more than a decade ago, and we used all of our tools

to address the competitive issue. We conducted research, we issued a report, and we looked for suitable cases to move the law. In addition to being a state action case, *Phoebe Putney* also involved a hospital merger, and we found that the two efforts came together very nicely in this one matter.

I expect that we will continue to focus on the state action area. We obtained a favorable decision from the Fourth Circuit in the *North Carolina Dental* case. That was a situation where competition was being reduced as a result of purported state action. I think we should continue to focus on state action issues, and as it turns out, many of these arise in the health care area.

***The Chronicle*:** Moving on to the recent decision in the *Actavis* litigation, what do you think the impact will be in terms of FTC enforcement in the pay-for-delay area? Do you think it will lead to more enforcement actions? What will be the impact on the market?

***Commissioner Ohlhausen*:** I think it is hard to predict this soon after the *Actavis* decision either what the market behavior will be or what the FTC's response will be. Clearly, I think the lower courts will be feeling their way around in this area for a while. Also, pursuing a pay-for-delay case under a full-blown rule of reason analysis likely will be a much more resource-intensive effort, and so the agency will have to make some hard decisions about how to allocate our resources in this area.

***The Chronicle*:** Pushing on that a bit more—can you anticipate any emerging practices or have you seen, in the context of current investigations, any practices of brand or generic manufacturers that may give rise to the next area of enforcement action in pharmaceuticals?

***Commissioner Ohlhausen*:** There is one area that creates some concerns for me and that I would like to explore further. That is the abuse of the restrictive distribution systems to sell certain types of pharmaceuticals. We filed an amicus brief in the *Actelion Pharmaceuticals* case earlier this year, which I supported and in which we argued that the refusal to sell restricted distribution drugs to potential generic manufacturers can constitute exclusionary conduct under Section 2 of the Sherman Act. I think that is an area for us to take a hard look at.

We also filed an amicus brief last year in the *Mylan v. Warner Chilcott* litigation on the issue of pharmaceutical product hopping. That is another area I think we should spend some time looking into. I personally think we should tread very lightly in the area of product design, but I think it is important to at least counter the premise that a change in a product's design could never constitute exclusionary conduct under Section 2. I think that the D.C. Circuit decision in *Microsoft* gives us the guidance that we should be following in that area.

***The Chronicle*:** Is product hopping less of a concern because the patent system is there to protect it or is there some other reason? Could you expand on this?

***Commissioner Ohlhausen*:** Well, I think that product design raises the issue of what benefit to consumers results from making a change to the design of the product. And, when the older product is withdrawn from the market, it raises the question of how to evaluate what those benefits are and which version consumers may prefer. That said, I do think it is important that we proceed with caution in this area and that we are cognizant of possibly interfering with innovation in product design, as the D.C. Circuit has pointed out. Incidentally, I am very fond of the D.C. Circuit because I worked there for five years.

***The Chronicle*:** In an address you gave in March 2013 at the National Policy Forum of

America's Health Insurance Plans, you talked about efforts to encourage state legislatures to loosen restrictions on advance practice registered nurses in order to allow them to prescribe certain medications, therefore arguably to advance competition in that area. How successful has this advocacy effort been since last spring?

***Commissioner Ohlhausen*:** To provide some context, this is part of our competition advocacy program at the FTC. I headed up that program for four years, and I continue to be a big supporter of it. I think it is one of the areas in which the FTC is able to very effectively use its non-enforcement tools. Our advocacy efforts are an important part of the long-term effort by the agency to engage in a dialogue about how to get cost-effective health care to people, particularly to rural and other underserved populations. So, this advocacy effort has shined a spotlight on that issue. However, there have not been any developments since our last advocacy in this area. We have not been able to change the law we were concerned about or get a better law enacted, but it has drawn attention to this issue, and I think our concerns are starting to resonate with people.

I also think it is important to focus other policy makers on whether evidence actually exists to support the safety concerns cited by proponents of these bills. States should certainly consider safety issues when evaluating the possibility of expanding the scope of APRNs' and other providers' practices. However, it is not uncommon for these kinds of very basic safety concerns to be put forward when there is little evidence of an actual safety issue. We saw this, for example, in regulations that were adopted to restrict teeth whitening to dentists. Policy makers should be looking closely at studies and other evidence to see if there really are safety risks associated with certain practices because they may be drawing the line in a certain way that restricts what may be lower-cost alternatives or may make certain types of health services less available.

***The Chronicle*:** Can you talk a little bit about what the FTC has done either in conducting its own studies or compiling research on price and quality issues and how they evaluate these types of concerns and then how this information is disseminated to state policy makers? Is this ever an issue?

***Commissioner Ohlhausen*:** We have not conducted our own studies; rather, we have pointed other policy makers to studies conducted by other entities, including a recent Institute of Medicine study that reviewed the safety issues often cited by opponents of expanding the scope of medical practice, as well as a National Governors Association study that speaks to APRNs filling the gap between supply and demand of health care services. We are trying to point state-level policy makers toward the available resources. It, of course, is up to each state to make decisions for its own citizens, but the FTC's role is to put more information into the states' hands and direct their attention to relevant information. I think that is a very appropriate role for the FTC. That is how advocacy works: you can only persuade, you cannot force. But our advocacy program has actually been very successful over the long term in focusing attention on many of these issues in health care and many other professional services areas.

Let me also mention one of the things I was able to do with our advocacy program when I was head of the Office of Policy Planning that I believe has helped make it successful. I implemented a system whereby each advocacy effort was followed up a few months later with a letter to the relevant policy makers to see how effective our advocacy was and to get some idea

of what factors went into its success or failure. In this way, we measure how effective our efforts were and learn how to make our advocacy more effective.

***The Chronicle*:** You have twice raised the importance of looking backwards and evaluating the impact of a policy or the impact of a merger. I'm curious to know your position on doing further retrospective studies, especially in the health care space.

***Commissioner Ohlhausen*:** I think retrospectives can be extremely valuable. Obviously, we have to acknowledge our resource constraints. This means having to allocate our resources to challenging either a merger or an emerging competition problem, on the one hand, or looking back on our past efforts, on the other. But I think that we have to at least do some of that retrospective analysis. One of the things that I did in my previous role in OPP was head up the "FTC at 100" project under former Chairman Kovacic. Some of the questions we focused on there were how to measure effectiveness as an agency: How do we know whether we are doing a good job or not? On what basis should we judge our performance? How can we improve our performance?

Measuring an agency's success is truly important and that is something that we need to keep in mind. I think retrospectives can help us measure success or failure and figure out how we improve our analysis the next time. If we aren't forecasting correctly, maybe our tools are off, maybe our assumptions are off, and that is how we need to adjust things. We can't measure success simply by the number of cases that we bring. That is one factor, but that is not the only factor. We have to ask: Did we win those cases? And, if we did win, are consumers better off? Did we draw the line in the right place or did we miss something? One thing I would be interested in looking at is a merger we did not challenge, particularly where we were getting a lot of external pressure to bring a challenge. I would like to look back and examine whether the merger adversely affected competition or whether we predicted things correctly. It seems as though a good candidate for such a retrospective would be the Express Scripts/Medco transaction that the FTC closed without a challenge just prior to my arrival at the Commission in April 2012.

***The Chronicle*:** And what is the availability of resources in order to do that?

***Commissioner Ohlhausen*:** We have our Bureau of Economics, which is well equipped to conduct merger retrospectives. But again it is a resource balancing issue. I think retrospective work should be part of what we do, but it has to be balanced appropriately with our enforcement and other policy work.

***The Chronicle*:** One area that you have really spent a lot of time working on is privacy and consumer protection laws. What do you see as the most important issues today at the intersection of privacy and consumer protection and the health care and pharmaceutical industries?

***Commissioner Ohlhausen*:** Starting with privacy first, although many health privacy issues are covered by HIPAA, which we do not enforce, the FTC still has a significant role in protecting the privacy of health-related information. For example, we brought a case against Eli Lilly for exposing e-mail addresses of people who were taking a particular antidepressant. We have also brought cases against pharmacies that took prescription records and threw them out in the dumpster behind the store, thereby exposing sensitive patient information. We also do consumer protection work in the advertising area. We

look to make sure that advertisers have adequate substantiation of health-related claims.

We also pay attention to possible fraud in the health care area. We have brought cases against several entities offering bogus health insurance coverage—the Health Care One case and United States Benefit cases. In addition, we are monitoring the marketplace and providing consumer education to make sure that, as the health exchanges come online under the ACA, consumers are protected against bogus offers or scams related to those exchanges. We see that every time there is a new government program there are perpetrators of fraud that use the launch of these programs to scam consumers. So, we are paying attention and trying to address any scams that may arise but also giving consumers tools to help protect themselves.

***The Chronicle*:** Do you think that there is a greater prevalence of this type of behavior in the health care area?

***Commissioner Ohlhausen*:** Yes, there are always purveyors of diet pills and lotions and creams that make health benefit claims that are not substantiated. There is a constant supply of these advertisements that we challenge. As I said earlier, when there is a new government program, scams develop around it. So, now that there are going to be new health insurance exchanges, I would expect to see an uptick in fraud related to those exchanges.

***The Chronicle*:** A little earlier you mentioned the FTC's use of non-enforcement tools in combination with its enforcement tools. Do you feel like the FTC today is using everything at its disposal? Can you discuss how you are using the various tools in terms of enforcement in the health care/pharmaceutical space?

***Commissioner Ohlhausen*:** Sure. I think the FTC has been using all of its tools and it is something that I always keep in mind. As issues come up to me, I will ask: Is there an advocacy that should be done on this? Should we be conducting a study? Is there a need for consumer education or business education to make sure that we are leveraging all of our expertise as effectively as possible? Obviously, we spend a lot of enforcement resources in the health care area, especially with our hospital merger reviews. We are also paying more attention to physician acquisitions. We persevered in the pay-for-delay area and eventually got a favorable decision from the Supreme Court. We do a lot with advocacy in the medical practice area in an effort to reduce barriers for alternative medical providers. We have also advocated against the abuse or expansion of antitrust immunities. In the policy area, we tried to improve the state action doctrine through *Phoebe Putney*, *North Carolina Dental*, and other cases. We hold workshops on emerging competition and consumer protection issues in health care. In 2008, we issued a report on follow-on biologics that has been very useful. I think transparency is really important as well. We are transparent about what we are doing, which provides guidance to practitioners about where the lines will be drawn. I think that is really important. We also coordinate with other agencies in our health care efforts, including DOJ, HHS, CMS, and FDA. We have many different constituencies, and throughout everything we do, I think it is important that we explain to them what we are doing and why we are doing it.

***The Chronicle*:** What do you see as the hottest topic in antitrust in the next few years, especially in health care and pharmaceuticals, but maybe even beyond that? What are the things that you see coming down the road as being particularly interesting to you?

***Commissioner Ohlhausen*:** Important issues raised in hospital mergers and physician acquisitions are not going away. Our work in the pharmaceuticals area will continue as well. I don't think any of that is going away. Some of the issues that are interesting to me, given my experience as head of the FTC's Internet Access Task Force back in 2007 and from when I was in private practice at a firm with a lot of telecommunications and technology clients, is the impact of new technologies on the market and the availability of various services to consumers. For example, I think some of the things that are being developed around remote medical diagnosis and care could be very, very interesting. These technologies impact our competitive effects analysis. We have to start putting that into our market analysis. There are the state licensing issues—if somebody diagnosed you from five states away—we need to consider in our market analysis. The continuing effort to have alternative providers is a very important issue, particularly for underserved areas. I think another issue that is going to be very interesting and may raise more issues on the consumer protection side than for competition is technology that enables you to use your handset or phone as a medical device. I think this raises potential privacy and security issues that we need to pay close attention to. There is a lot of innovation going on out there that is very interesting to me—both as a consumer and a Commissioner at a competition and consumer protection authority.

***The Chronicle*:** Thank you so much for your time today.