April 2018

Antitrust Health Care
Chronicle

Vol. 32 / No. 3

EDITOR'S REPORT

Welcome to the third issue of the *Chronicle* for the ABA 2017-18 term. In this issue, we are pleased to present an interview with Alexis Gilman, former Assistant Director for Mergers IV at the Federal Trade Commission and current Partner at Crowell & Moring LLP. *Chronicle* editor Amanda Hamilton interviewed Gilman about best practices for advocating before the FTC on health care deals. Our second article discusses the implications of increased government focus on branded drug companies' refusals to sell samples of drugs subject to REMS programs to generic firms and other forms of alleged REMS abuse. The third article provides a summary of recent congressional hearing activity related to antitrust issues in the health care sector.

If there is a topic that you would like to see covered in a Committee program or if you have any other suggestions, please contact the Committee Co-Chairs, Seth Silber (ssilber@wsgr.com) or Leigh Oliver (leigh.oliver@hoganlovells.com).

If you would like to submit an article for the *Chronicle*, please contact Amanda Lewis (alewis1@ftc.gov) or Anthony Swisher (Anthony.Swisher@squirepb.com).

In This Issue

A Publication of the Health Care and Pharmaceuticals Committee of the Antitrust Section of the American Bar Association, Co-Chaired by Seth Silber of Wilson Sonsini and Leigh Oliver of Hogan Lovells.

EFFECTIVE ADVOCACY BEFORE FTC ON HEALTH CARE DEALS

Alexis Gilman, a partner at Crowell & Moring LLP and former Assistant Director (AD) at the Federal Trade Commission, was interviewed by Amanda Hamilton, *Chronicle* editor and Associate at Haug Partners, LLP. From 2014 to 2017, Mr. Gilman served as the AD of the Mergers IV Division (Mergers IV) in the Bureau of Competition of the Federal Trade Commission. As AD, Mr. Gilman oversaw merger investigations and litigations across various industries, including hospitals and other health care providers, distribution services, supermarkets, funeral homes, casinos and online gaming, retail, and consumer goods. In the interview, Mr. Gilman provides insights into Mergers IV's review process for health care mergers, the types of claims and evidence that the agency finds persuasive, and other tips for effective advocacy before the agency.

Alexis Gilman
Crowell & Moring LLP

The Chronicle: *What should one expect in terms of process when Mergers IV reviews a health care deal?*

Mr. Gilman: For mergers that raise potential concerns, the staff will typically send each of the merging parties a voluntary access letter. Access letters in a health care provider deal typically ask for, among other things, contact information for the parties' top health plans (based on reimbursement); strategic and business plans; documents discussing competition and market shares; information about the parties' service areas; annual discharge and revenue data; and information about the parties' efficiencies claims and post-merger plans. Third-party health plans and competing providers can expect a request by Mergers IV staff for an interview so that the staff can learn more about the merging parties, the services they and their competitors provide, and the geographic area they serve; understand the health plan's contract negotiations with the merging parties and its provider network in the area; and solicit views about the merger.

The Chronicle: *Generally, what are some best practices for advocating before Mergers IV in support of health care mergers?*

Mr. Gilman: The most obvious best practice is to maintain your credibility with the agency. Another best practice is to deal with difficult facts up front, putting your best arguments forward to the staff as early as possible. Rather than leaving the staff to form conclusions about unhelpful facts, it's often better to provide the staff with context, the parties' views on those facts, and the reason why those facts aren't fatal for your deal. At the very least, doing so could let you know sooner rather than later what the staff thinks of those facts, your arguments, and the deal overall. Finally, and relatedly, I think another best practice is to engage with the staff frequently and ask lots of questions about where they are in their analysis, what unresolved questions or concerns they have, and what information would be helpful to answer those questions and concerns.

The Chronicle: *Does your advice differ based on the type of merger?*

Mr. Gilman: Each deal is different, so each deal could call for a different approach, but as a general rule, I don't think it matters significantly if it's a horizontal merger or a vertical merger. If a deal raises concerns, the best practices for advocating for your client and working with the staff in a horizontal deal are likely to apply equally in a vertical deal.

The Chronicle: *Alternatively, what are some bad, unhelpful, or unproductive practices that you recommend against engaging in?*

Mr. Gilman: These are really the opposite of the best practices. Exaggerating or withholding

information is usually not a successful strategy because the staff almost always gets to the bottom of the facts. So taking that kind of approach may diminish your credibility, lose your client the benefit of the doubt on the margin, and perhaps even slow down the staff's review if they have to triple check all the representations that counsel is making. Additionally, not engaging with the staff for long stretches, either generally or with respect to the unhelpful facts in your case, is usually not a productive practice. Again, the staff will work to figure things out and they might reach conclusions that are less favorable to the client, so counsel should take their best shot at taking on bad facts and engaging with staff on a regular basis.

The Chronicle: *Are there any misconceptions about practicing in front of Mergers IV or the FTC that you would like to correct?*

Mr. Gilman: One potential misconception is that agency lawyers are always looking to go to court to block a merger. While the FTC, and Mergers IV in particular, has been in court a lot in the past several years, what's harder to see and track are all the investigations that the staff closes—including some mergers that are very close calls. I also think people might be surprised by the number of investigations closed, at least in part, because of efficiencies, failing-firm, and/or flailing-firm defenses—although it is certainly true that there is a very high bar for those claims in investigations.

The Chronicle: *What are some important issues in a health care deal that the private bar should be ready to address during the early stages of an investigation?*

Mr. Gilman: Parties to a merger that could trigger a preliminary investigation should be prepared to provide the information that the staff will likely request in an access letter, particularly on substantive issues that are likely to be key in the staff's analysis, whether it be geographic market, competitive effects, failing firm, etc. The staff will certainly want to try to get at least a rough cut of market shares and try to do diversion-ratio analysis, so the parties should be prepared to provide or address that type of data analysis. Even if counsel decide not to affirmatively present some of this information, counsel should at least know what those documents and data say. If the staff determines that they need to conduct a more in-depth review, they may want to get detailed discharge data (patient-level information, including age, gender, diagnosis, and length of stay, for each inpatient discharged from a hospital). If the parties have these data available to provide to the staff upon request, that can expedite the process because, otherwise, the staff may need to get these data from the state, which can take time.

The Chronicle: *Are there any publicly available sources of information that provide insight into how Mergers IV or the FTC evaluates health care deals?*

Mr. Gilman: The Horizontal Merger Guidelines are the foundation for the staff's general analytical approach, so that's a good place to start. More specific to health care deals, there are a lot of court decisions from the last few years in the FTC's favor, so those will largely reflect, and be key sources of information about, the FTC's approach. For example, for product market issues, the Commission's decision in the *ProMedica/St. Luke's* merger may be the most important case to understand how the FTC defines product markets in provider mergers. Additionally, the Sixth Circuit's opinion in the *ProMedica/St. Luke's* case addressed the flailing-firm defense, and I would also point to an FTC Competition Matters blog post in March 2015 that Debbie Feinstein and I wrote about the requirement to search for an alternative purchaser when making a failing-firm defense. For geographic market, the best sources for how the FTC looks at geographic market definition are the *Advocate/NorthShore* and *Penn State Hershey/Pinnacle* opinions and the FTC's briefs in those cases. For efficiencies, the district court's decision in *St. Luke's/Saltzer* is notable because it recognized, even commended, the parties' efforts to move from fee-for-service to value-based care and achieve other efficiencies, but ultimately said those arguments didn't save the merger. Unfortunately for health care providers looking to merge (at least with a close competitor), those cases can seem pretty grim. So I would point to the Statements of Antitrust Enforcement Policy in Health Care and the Enforcement Policy Statement Regarding Accountable Care Organizations as agency guidance that speaks to certain mergers, collaborations, and arrangements that raise relatively little antitrust risk and that provide antitrust safe harbors. Finally, I would note that over the last decade, only about 1% of hospital mergers have been challenged—and the agency hasn't challenged any purely vertical provider mergers to date—so odds are still in your favor if you are a health care provider looking to merge.

The Chronicle: *What is the role of the Bureau of Economics in Merger IV's health care investigations?*

Mr. Gilman: Bureau of Economics (BE) staff plays an important and integral role in investigations. BE economists are usually involved from day one in crafting the information requests in access letters; interviewing the parties and third parties; analyzing state discharge data and trying to calculate market shares and diversion ratios; drafting Second Requests, Civil Investigative Demands, and subpoena specifications; reviewing all

the data that comes in during an investigation; and helping attorneys prepare for, and then actually attending, investigational hearings. If there are Front Office or Commissioner briefings, BE managers and staff are involved in those as well. At the end of a full-phase investigation, BE will make its own recommendation to the Front Office and the Commission. And if there is going to be a complaint recommendation, BE will have participated in identifying, interviewing, and working with the outside economic experts. So BE is a very important audience when advocating for a deal before the agency.

The Chronicle: *What if you have a deal that is unlikely to be problematic, what do you recommend?*

Mr. Gilman: If it's really unlikely that a deal is going to be problematic or even undergo a preliminary investigation, there's probably not much outside counsel should do at the agency, at least not much that would be cost-effective for the client. If early termination of the HSR waiting period is critical, however, you can call the staff to try to explain the urgency to them, but there's only so much that can be done in that respect. But counsel have to consider this "hands off" approach carefully, because the risk of sitting back is that a staff concern could arise late in the process, which could delay the parties' ability to close.

The Chronicle: *If you have a health care deal that is likely to be problematic, what do you recommend?*

Mr. Gilman: As I mentioned earlier in terms of best practices, I think it's best for the parties and their counsel to be prepared with all (or as much) of the information that you know the staff will want to see early on, then come in to meet the staff to present the deal and your best arguments about any problematic facts and the key issues in the case. It's often helpful to bring business people to those meetings to explain the deal rationale and help the staff get up to speed quickly. But counsel need to make sure that their business people (and counsel themselves) are well-prepared to go into those meetings and not say something, unintentionally, that will raise even more concern.

The Chronicle: *What if you have a deal that is unlikely to be problematic, but presents complex and new issues that may take the staff more time than the statutory 30-day waiting period provides for?*

Mr. Gilman: If timing is tight and the parties want to close quickly, this is probably another scenario where it may make sense for outside counsel and perhaps the business people to come in early to meet with the staff to explain why the complexity or new issues still don't make this a deal that the staff needs to worry about. If timing is tight, it's probably also best to have information to send to the staff readily at hand in case they request it, even if you don't ultimately need it. This scenario is also one where outside counsel should prepare their clients for the possibility that you may need to pull-and-refile, not because there is ultimately going to be a problem, but simply because the staff might need more time to complete their review.

The Chronicle: *What sort of information is particularly helpful to the agency's analysis of the relevant geographic market?*

Mr. Gilman: During an investigation, the staff tries to take in as much qualitative and quantitative information as they can from different sources about the geographic market. For example, the staff will look at the parties' primary service area; ordinary course documents about which area the parties serve; how (in what area) the parties calculate market shares and which providers they consider to be their primary competitors; and maps for any state lines or other natural barriers that might affect patient travel patterns. The staff will talk to health plans about the providers that their members turn to today and where they think they (the health plans) and their members would go if the parties' facilities were no longer available. A key question that the staff asks commercial insurers is whether they could offer a marketable health plan in a candidate geographic market if it did not include any of the providers in that candidate geographic market. This is a qualitative way to try to get at the hypothetical monopolist test, and testimony responsive to this question featured prominently in recent cases. Finally, while the FTC clearly states that it doesn't conduct a formal Elzinga-Hogarty inflow/outflow test to define a geographic market, they certainly will take a look at patient-flow information. I don't think inflow information—the number or percentage of patients coming into a candidate geographic market from outside that area—is compelling to the staff, but outflow information could be a lot more relevant because it may suggest that patients see providers outside a candidate market as viable alternatives.

The Chronicle: *What are the types of product markets Mergers IV may identify and assess in health-system mergers?*

Mr. Gilman: In a merger involving general acute care (GAC) hospitals, the product market is virtually certain to be the market for inpatient GAC services sold to commercial health plans. What specifically is included in the GAC market will vary by deal because it usually consists of the overlapping primary and secondary GAC services offered by the merging parties. Whether tertiary services are included in the GAC market has varied by case—they weren't in *ProMedica/St. Luke's*, but were in *Advocate/NorthShore* and

Penn State Hershey/Pinnacle. The FTC may also look at individual service lines—as it did with obstetrical services in *ProMedica/St. Luke's*—to see if the merger would have an even greater effect in a particular service line. In a health-system merger, the FTC will also assess, on a service-line-by-service-line basis, whether the merger raises concerns in any outpatient or physician service lines (e.g., outpatient surgical services or primary care physician services).

The Chronicle: *Does Mergers IV generally view the relevant product market in health-system mergers as a bundle or cluster market?*

Mr. Gilman: Mergers IV has generally taken the view that the product market is a cluster market. Because individual health care services are generally not substitutable for one another, the FTC's view (which courts have accepted) is that each service could be its own relevant product market. But because you're often dealing with dozens, if not hundreds, of services offered by merging health care providers, courts have said it's appropriate to aggregate hospital services into the inpatient GAC services cluster market where the competitive conditions for the clustered services are similar.

The Chronicle: *What sort of information does the agency consider in its competitive-effects analysis of health care mergers?*

Mr. Gilman: The agency considers a range of evidence, including documents, data, and testimony (interviews, declarations, and investigational hearings). Obviously, if the parties' documents talk about the merger enabling them to raise prices or obtain leverage in health-plan negotiations, that's pretty damaging, although that type of document is pretty rare. The more common evidence that will get factored into the effects analysis is information about the structure of the market (e.g., the parties' post-merger market share, market concentration measured by the Herfindahl-Hirschman index (HHIs), and number of remaining competitors of similar size and quality); diversion ratios between the parties and other evidence indicating how closely the merging parties compete with each other; evidence that health plans have used one party as leverage to negotiate lower rates with the other party; and evidence that one party agreed to a lower reimbursement rate if an insurer excluded the other party (i.e., the merger partner) from its provider network and a higher rate if the insurer included the merger partner in the network. Again, a key factor for the staff is whether health insurers say either that they could not offer a marketable network in a particular geographic area if both merging parties were out of their network, or that they (the health insurers) would be willing to pay higher rates to the merged firm than try to market a health plan that excluded the merged firm. Notably, the FTC's effects analysis has not found contracts negotiated between the merging providers and commercial insurers that freeze rates for a period of years to be persuasive about a merger's potential effects.

The Chronicle: *What type of claims does the FTC consider in evaluating an efficiencies defense?*

Mr. Gilman: The staff considers a range of potential efficiencies, including cost savings, ability to offer new services, and an improved ability to engage in population health management, engage in risk-based contracts, invest in technology and physician recruiting, and so forth. Ultimately, quality-related efficiencies are probably the most important and persuasive efficiency claim that merging parties can make.

The Chronicle: *Does that vary from what a court considers?*

Mr. Gilman: I don't think *what* a court considers differs meaningfully from what the staff considers. But while the FTC staff has closed investigations based, at least in part, on efficiency claims, no court has ever denied an injunction based on an efficiencies defense. The bar has been too high for anyone to get over in court.

The Chronicle: *How early in the investigation should the parties raise efficiencies arguments?*

Mr. Gilman: The first time they talk to the staff. From day one, the staff will investigate the potential for a merger to result in efficiencies, and the burden of bringing a case is technically on the agency, but as a practical matter, the burden ends up falling on the parties to marshal the evidence on efficiencies—because it's in their possession—and to try to convince the staff that they should not be concerned about a deal, because of the efficiencies or otherwise. If the parties wait to present their efficiencies claims, that could suggest that the efficiencies weren't a key driver of the deal and the staff may begin to suspect that the claims were generated to defend the merger in response to FTC concerns.

The Chronicle: *How early in the review process should merging parties retain an efficiencies expert?*

Mr. Gilman: Of course, if you suspect you are going to face agency resistance and the parties want to move forward, sooner rather than later is better. But experts are expensive, and many provider mergers are relatively small (in terms of deal value), are between non-profits, and involve parties with smaller balance sheets and income statements—which may make it hard to incur big efficiencies-expert expenses too early. Early on, I would primarily focus on the competitive

effects analysis, so retaining an economic consultant is more valuable in the early stages.

But given my answer to the prior question—about when the parties should raise efficiencies claims—there can also be significant value in hiring an efficiencies expert very early in the process. This question also highlights another challenge that merging parties face. On the one hand, agency staff wants to see that efficiencies were a driving force for a deal, not an afterthought, but it's extremely difficult, if not near impossible, for the parties to have a perfectly polished and detailed efficiencies plan on signing a letter of intent or even by the time they sign a definitive agreement. On the other hand, the more that the parties can refine their efficiencies analysis as they continue to conduct diligence and explore opportunities, the more confident they can be in what they present to the staff. But as the deal progresses through an investigation, the staff can become skeptical about revised and evolving claims, worried that they may be "made-for-litigation."

The Chronicle: *What if the hospital is having financial problems? Will Mergers IV consider a failing- or flailing-firm defense?*

Mr. Gilman: Yes, Mergers IV staff will consider failing- and flailing-firm defenses. While the FTC defeated this type of argument in the *ProMedica* case, financial-condition arguments have resulted in the agency closing several non-public investigations. Unfortunately for the hospital involved, the most persuasive arguments are those where the hospital can show that its key financial and operational metrics are all pointing and trending significantly downward—declining revenues, profits, admissions, patient days, and days cash on hand; increasing debt and accounts payable; violation of debt covenants; physician and staff layoffs; facility and service line closures; etc.—and that its quality is, or is at risk of, suffering.

In fact, quality-based *efficiency* arguments are often most persuasive when the hospital is in poor financial condition and quality is likely to suffer absent the merger, but likely to be maintained or improved with the merger. Of course, as the Merger Guidelines and the FTC Competition Matters blog post makes clear, the staff will test whether there are alternatives to the merger—such as an acquisition by an alternative purchaser that poses a less severe danger to competition. So counsel need to understand the acquired hospital's sale process and whether there were any alternative bidders.

The Chronicle: *Any other advice or tips relating to effective advocacy before the FTC on health care deals?*

Mr. Gilman: One thing that we will all have to see is whether there are any changes in how the new Commission approaches health care merger analysis, either substantively or procedurally. For example, we'll have to see if there are any changes in the types of economic analyses that the new commissioners find persuasive, are more accepting of efficiencies arguments, and whether there is any change in document and data requests to reduce the burden on merging parties. Any such changes could affect advocacy before the FTC, although I suspect we're going to see largely consistent, aggressive health care merger enforcement.

THE FDA'S AND FTC'S INCREASED FOCUS ON GENERIC DRUG COMPETITION SIGNALS ENHANCED ATTENTION TO REMS ISSUES

To obtain approval from the U.S. Food and Drug Administration ("FDA") for generic drugs, the generic manufacturers must prove, not surprisingly, that the drugs are bioequivalent to the reference branded drug. To perform the required bioequivalence testing required for an Abbreviated New Drug Application ("ANDA"), the generic applicant generally needs to have access to a sufficient quantity of the brand name drug the generic is meant to imitate. If a generic cannot demonstrate bioequivalence in the ANDA, it cannot use this abbreviated pathway to obtain FDA approval for its drugs that would ultimately compete with—and in most instances, due to state substitution laws, replace—the respective branded drugs. Over the past decade, disputes regarding access to samples for bioequivalence testing have increased between generic and brand manufacturers. Specifically, some generics have argued that brand manufacturers misuse risk-management programs known as Risk Evaluation and Mitigation Strategies ("REMS")—FDA programs created to help ensure the safe use of certain potentially dangerous drugs—to thwart competition from generic manufacturers by delaying or blocking their access to the samples necessary for testing their products. Brand drug companies, on the other hand, argue that providing samples of drugs subject to REMS could threaten patient safety, leave the brand companies vulnerable to liability, and they have no duty to deal with their generic competitors under the antitrust laws anyway.

Heather S. Choi[1]
Baker Botts LLP

William C. Lavery
Baker Botts LLP

Michael J. Perry
Baker Botts LLP

Jana I. Seidl
Baker Botts LLP

While both the FDA and the Federal Trade Commission ("FTC") have kept an eye on these developments and issued some guidance, including FTC amicus briefs, neither agency has taken enforcement actions to address this issue. Likewise, while there have been some cases challenging this conduct, not a single REMS abuse allegation has been fully litigated on the merits. However, recently there has been an increased government focus—including by both Congress and federal agencies—on the antitrust implications of some branded companies' refusals to sell samples of drugs that are subject to REMS programs to generic firms. The FDA is clear that it is prioritizing a response to address these disputes; the FTC is working closely with the FDA in its efforts, signaling potential investigations. Congress is considering enacting new legislation aimed at providing a "fix." And the first slew of private litigations is moving towards the merits stage, including class actions. These developments will impact the dynamic in the pharmaceutical industry and should cause any interested party to take note.

REMS Background

In 1984, Congress passed the Hatch-Waxman Act, which created a streamlined process of generic drug approvals and provided additional incentives to invest in pharmaceutical research and development.[2] The Act made it easier for generic drug companies to demonstrate the safety of their drugs while also containing provisions to protect the innovator companies' patent rights, recognizing the lengthy development timeline for new drugs. In this manner, Congress spurred accelerated entry of lower priced generic alternatives, while at the same time maintaining incentives for continued research and development by branded drug manufacturers. Under the Hatch-Waxman Act, the generic drug companies can take advantage of an ANDA to gain FDA approval of a competing generic drug. ANDAs are much less costly and time consuming

[1] Heather Choi, William Lavery, and Michael Perry are Partners, and Jana Seidl is an Associate, in the Antitrust Group of the Washington, D.C. office of Baker Botts L.L.P. The views are those of the authors and do not necessarily reflect the views of Baker Botts L.L.P. or any client.

[2] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 (2012)).

than New Drug Applications ("NDAs") required for approval of the initial brand drug. Under an ANDA, a generic must demonstrate bioequivalence to the brand drug, or Reference Listed Drug ("RLD"), meaning that the "generic version must deliver the same amount of active ingredients into a patient's bloodstream in the same amount of time" as the RLD.[3] In addition, the generic drug must be "comparable to an innovator [i.e., branded] drug product in dosage form, strength, route of administration, quality, performance characteristics, and intended use."[4] To demonstrate bioequivalence, generic drug companies require access to samples of the branded drugs for tests.

Twenty three years later, in 2007, Congress passed the Food and Drug Administration Amendments Act ("FDAAA") in an effort to help enhance drug safety.[5] One of the FDAAA's provisions requires the sponsor of a NDA to implement a REMS if "necessary to ensure that the benefits of the drug outweigh the risks of the drug[,]" such as injury or death.[6] The FDA defines REMS as "required risk management plans that use risk minimization strategies beyond the professional labeling to ensure that the benefits of certain prescription drugs outweigh their risks."[7] The specific REMS program can take many forms and varies greatly from drug to drug. REMS programs may, for example, take the form of a medication guide, a patient package insert, a communication plan, and, for particularly risky drugs, elements to assure safe use ("ETASU").[8] ETASU basically comprise actions to mitigate the drug's risks that physicians must perform before providing the patient access to the drug subject to the REMS program. These actions can include liver function monitoring or negative pregnancy tests for drugs that carry the risk of significant birth defects.[9]

Given these parameters, in implementing a REMS to address certain potential safety concerns, an innovator firm may be required to restrict how the drug is distributed to patients. Additionally, REMS may include distribution restrictions which limit the types of entities to which the brand manufacturer can sell its product (e.g., only to hospitals or pharmacies). REMS may also require that a manufacturer closely monitor the distribution and use of the product. Generic firms have argued that these restricted distribution programs have made it difficult or impossible to obtain samples of the RLD from the usual sources.

Notably, the FDAAA includes language stating that REMS provisions may not be used to "block or delay" approval of an ANDA.[10] Nevertheless, the FDAAA does not explicitly require brand companies to provide samples for bioequivalence testing and does not provide for an enforcement mechanism or a private right of action to address anticompetitive blocking of generic competition. An early House draft of the FDAAA did include a provision mandating that branded manufacturers would have to sell to generics a quantity of its branded drug sufficient for bioequivalence testing, but this language was not included in the final bill.[11] As recently as 2012, Congress again considered, but did not enact, certain proposals that would give the FDA additional authority to address competitive issues raised by REMS programs.[12]

Additionally, under the FDAAA an ANDA for a generic equivalent of a listed drug that is subject to REMS requires that the brand and generic work together to implement a single, shared system REMS ("SSRS"), unless the FDA waives that requirement, which would allow the generic to use a separate, but still comparable, REMS to that required of the brand drug. This type of collaboration can obviously create antitrust questions in and of itself. The dispute to date centers around the fact that while the law requires collaboration, it does not set a time limit for implementing shared REMS programs. So, like the dispute relating to the delay of brand drug sample access, generics are also accusing brand manufacturers of abusing the cooperation process by prolonging negotiations or refusing to agree to a shared system to block generic entry. Brand manufacturers argue that these SSRS negotiations take time as it requires developing complex business arrangements. The disputes surrounding REMS are showing no sign of slowing down as a 2014 study explained that at the time roughly 40% of all new FDA approvals were subject to REMS,

---

[3] *Id*.

[4] FDA, Abbreviated New Drug Application (ANDA), *available at* https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/default.htm.

[5] 21 U.S.C. § 355-1; FDA, FDA Basics Webinar: A Brief Overview of Risk Evaluation and Mitigation Strategies (REMS) (Dec. 30, 2017), *available at* https://www.fda.gov/AboutFDA/Transparency/Basics/ucm325201.htm.

[6] 21 U.S.C. § 355-1.

[7] *Id.* at 2.

[8] *Id.* at 7.

[9] *Id*. at 3, 12-13.

[10] 21 U.S.C. § 355-1(f)(8) ("No holder of an approved covered application shall use any element to assure safe use required by the Secretary under this subsection to block or delay approval of an application under section 355 (b)(2) or (j) of this title or to prevent application of such element under subsection (i)(1)(B) to a drug that is the subject of an abbreviated new drug application.").

[11] David Rodi & Zach Hughes, *Life Sciences Update: Are Branded Manufacturers Obligated to Sell Their Drugs to Generic Manufactures So They Can Make Copies?*, Baker Botts LLP (Feb. 28, 2012), https://s3.amazonaws.com/documents.lexology.com/106332e6-2cb0-41a6-a203-ca1907fa1576.pdf.

[12] Henry N. Butler, *REMS-Restricted Drug Distribution Programs and the Antitrust Economics of Refusals to Deal with Potential General Competitors*, 67 Fla. L. Rev. 977, 984 n.36 (2016).

that include distribution restrictions has been increasing.[13] Currently, the FDA website lists 72 active Individual REMS programs, 8 of which are SSRS programs.[14] About 45 of these REMS programs have some sort of restricted access requirement.[15] And at least one report notes that the FDA received 150 complaints from generic drug manufacturers last year regarding alleged REMS abuse by brand manufacturers.[16]

FDA and FTC Response to Allegations of REMS Abuse

Allegations of REMS and SSRS abuse started almost immediately following the passage of the FDAAA.[17] Some commentators have argued that the FDA is the appropriate agency to take action to address these concerns. This is because the FDA already has adequate regulatory overview, and therefore allegations of REMS abuse issues should not also be subject to the federal antitrust laws. Emphasizing that firms are generally free to choose with whom to deal, these commentators argue that antitrust liability should be cautiously applied given the high error cost of false positives.[18]

For its part, the FDA has generally referred generic manufacturers' complaints of alleged anticompetitive conduct on the part of branded drug manufacturers to the FTC, taking the position that these issues are beyond the scope of the FDA's regulatory mission.[19] In addition, the FDA has issued draft guidance outlining how generic manufacturers can obtain a letter from the FDA stating that their proposed bioequivalence protocols contain adequate safety protections.[20] Notably, the process for obtaining such a letter has become a significant issue in at least one of the antitrust cases involving alleged REMS abuse.

In public statements, the FTC has shown an interest in using the antitrust laws to address perceived REMS abuse. For example, then FTC Chairman Jon Leibowitz stated at the 2012 ABA Spring Antitrust Meeting that "under the pretext of concern for patient safety, it seems that some of the branded drug companies may be systematically denying potential generic competitors samples of their drugs by claiming that they cannot provide it to the generic drug manufacturer because the generic does not have adequate protection."[21] He foreshadowed that "[t]his is going to be an issue that we [the FTC] are going to be looking at in the future."

His successor, former FTC Chairwoman Edith Ramirez stated in April 2013, that pursuing alleged REMS abuse would be an enforcement priority.[22] In fact, just a month prior, the FTC had voted 4-0 to file an amicus curiae brief in the pending REMS case, *Actelion Pharms Ltd. v. Apotex Inc.* (Case No. 1:12-cv-05743) in the U.S. District Court for the District of New Jersey.[23] And a few months later the FTC filed a second, very similar, amicus curiae brief regarding potential REMS abuse in *Mylan Pharms., Inc. v. Celgene Corp.* (Case No. 2:14-cv-2094) pending in the same district court. This time, the Commission vote approving filing of the brief was 4-1, with Commissioner Joshua Wright voting no.[24] In both briefs the FTC was careful not to opine on the merits but merely stated that it believed there were cognizable antitrust claims at issue. To date, however, the FTC has not brought any law enforcement actions in this area.

---

[13] Alex Brill, Lost Prescription Drug Savings from Use of REMS Programs to Delay Generic Market Entry, Matrix Global Advisors (July 2014) at 1, *available at* http://www.gphaonline.org/media/cms/REMS_Studyfinal_July2014.pdf.

[14] FDA, Approved Risk Evaluation and Mitigation Strategies (REMS), https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm (last accessed Jan. 29, 2017).

[15] Id.

[16] FDA, FTC take aim at abuse of restricted drug programs, FTC Watch, Aug. 4, 2017 (Issue 922), *available at* http://ftcwatch.com/?cat=28.

[17] The generic manufacturer Lannett Co. sued brand manufacturer Celgene Corp. in 2008 alleging that Celgene was refusing it access to the sample of the drug Thalomid (thalidomide) necessary to conduct the bioequivalence testing for Lannett's proposed ANDA. *See Lannett Co. v. Celgene Corp.*, No. 08-3920, 2011 WL 1193912 at *1 (E.D. Pa. Mar. 29, 2011).

[18] *See, e.g.*, Butler, *supra* note 12; Jan Rybnicek, *When Does Sharing Make Sense?: Antitrust & Risk Evaluation and Mitigation Strategies*, CPI Antitrust Chronicle (Apr. 2014).

[19] *See Butler*, *supra* note 12, at 984.

[20] FDA, Draft Guidance: How to Obtain a Letter from FDA Stating that Bioequivalence Study Protocols Contain Safety Protections Comparable to Applicable REMS for RLD (Dec. 2014), *available at* https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm425662.pdf.

[21] Jon Leibowitz, American Bar Association Section of Antitrust Law Spring Meeting: Roundtable Conference with Enforcement Officials (March 30, 2012), https://www.americanbar.org/content/dam/aba/publishing/antitrust_source/jun12_full_source.authcheckdam.pdf.

[22] Prepared Statement of the Federal Trade Commission, Before the Unites States Senate Committee on the Judiciary, Subcommittee on Antitrust, Competition Policy and Consumer Rights, *Oversight of the Enforcement of the Antitrust Laws* (Apr. 16, 2013), at 7, *available at* https://www.ftc.gov/sites/default/files/documents/public_statements/prepared-statement-federal-trade-commission-entitled-oversight-enforcement-antitrust-laws/130416antitrustenforcement.pdf. Republican Commissioners have also suggested that the FTC may pursue allegations of REMS abuse. *See* Antitrust Health Care Chronicle, "A Discussion With FTC Commissioner Maureen K. Ohlhausen" (Nov. 1, 2013), at 6.

[23] Press Release, *FTC Amicus Brief: Improper Use of Restricted Drug Distribution Programs May Impede Generic Competition* (March 12, 2013), https://www.ftc.gov/news-events/press-releases/2013/03/ftc-amicus-brief-improper-use-restricted-drug-distribution. Michael Perry was the staff contact for this matter.

[24] Press Release, *FTC Amicus Brief: Improper Use of Restricted Drug Distribution Programs May Impede Generic Competition* (June 19, 2014), https://www.ftc.gov/news-events/press-releases/2014/06/ftc-amicus-brief-improper-use-restricted-drug-distribution.

Private Antitrust Actions Involving REMS

Private plaintiffs have been more aggressive in pursuing antitrust suits based on alleged REMS abuse, although none of these cases have progressed to an adjudication on the merits. In fact, there have been eight private antitrust lawsuits brought, including the *Actelion* and *Mylan* matters noted above, alleging refusals by branded drug companies to sell product samples to their generic competitors.[25] The first class action lawsuit involving a refusal to deal of REMS-restricted drugs was filed in 2014, with two more brought just last year. The cases where generics have sued branded companies for denying samples (or other similar violations) typically allege monopolization claims under Section 2 of the Sherman Act for exclusionary conduct—specifically, unlawful refusals-to-deal with rivals.[26] But the issue as applied to REMS has never been litigated through trial and no appellate court has addressed the issue.

Antitrust Jurisprudence Regarding Refusals-to-Deal

It is well-settled in antitrust jurisprudence that generally, a monopolist is free to do business or to not do business with anyone it pleases. There are exceptions—albeit limited ones—to this general rule that "[e]ven monopolists are almost never required to assist their competitors."[27] The exceptions can be summarized as follows below.

The Supreme Court in *Otter Tail Power Co. v. United States*,[28] first established what is now mainly dead letter—the essential facilities doctrine. In this case, Otter Tail Power Co. refused to cooperate with several localities wishing to establish their own electrical systems, thus replacing Otter Tail.[29] However, the operation of these new systems would rely on Otter Tail's existing transmission infrastructure.[30] Otter Tail refused the localities access and the Supreme Court affirmed the lower court's holding that Otter Tail had "used its monopoly power . . . to foreclose competition or gain a competitive advantage, or to destroy a competitor, all in violation of the antitrust laws"[31]—and this despite a lack of a prior course of dealing between the parties. The *Otter Tail* decision, however, in practice remains extremely limited to the facts at issue where the company was a natural monopoly in a highly regulated business and where its refusal-to-deal made little economic sense since the costs it would incur were practically nil.

The next time the Supreme Court addressed the issue was twelve years later in *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*[32] Aspen Skiing Co. ("Aspen") and Aspen Highlands Skiing Corp. ("Highlands") had been providing a single pass for all four of the ski areas owned by both companies. Aspen, which owned three of the four major ski resorts, then terminated the pass and refused to sell tickets to Highlands' resort or honor vouchers Highland issued as part of its own pass.[33] The Supreme Court affirmed the lower court's holding that Aspen had a duty to deal with its competitor because, in part, the profitable prior course of dealing between the two companies demonstrated its conduct made no economic sense—it was not supported by any valid business justification.[34] This holding of an affirmative duty to deal represents the high-water mark in Section 2 cases. But the Supreme Court's next decision on the topic leaves no doubt that a theory based solely on a prior course of dealing cannot support liability.

In 2004, in *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*,[35] the Supreme Court found that Verizon did not have a duty to deal with its rivals. Verizon, which held an exclusive franchise within a particular service area, competed with local carriers but also had a regulatory obligation to complete orders for service through its own ordering system. Verizon's competitors alleged that Verizon breached its duty to deal (i.e., share its network) by approaching its obligation in a discriminatory

[25] *See New England Carpenters Health Benefits Fund v. Celgene Corp.*, No. 2:17-cv-07637-MCA-MAH (D.N.J. Sep. 28, 2017) (class action alleging refusal to sell samples of Thalomid and Revlimid to generics among other claims); *Int'l Union of Operating Engineers Stationary Engineers Local 39 Health and Welfare Trust Fund v. Celgene Corp.*, No. 2:17-cv-04319-MCA-LDW (D.N.J. June 14, 2017) (class action alleging abuse of REMS distribution systems and refusal to sell Thalomid and Revlimid samples to generics for bioequivalence testing among other claims); *Int'l Union of Bricklayers and Allied Craft Workers Local 1 Health Fund v. Celgene Corp.*, No. 2:14-cv-06997-KSH-CLW (D.N.J. Nov. 7, 2014) (class action alleging abuse of REMS distribution systems and refusal to sell Thalomid and Revlimid samples to generics among other claims); *Natco Pharma Ltd. v. Gilead Sciences, Inc. and Express Scripts Holding Co.*, No. 14-cv-3247-DWF-JSM (D. Minn. Aug. 22, 2014) (alleged refusal of brand to sell samples of Letairis for bioequivalence testing of generic ambrisentan); *Mylan Pharms., Inc. v. Celgene Corp.*, Case No. 2:14-cv-2094-ES-MAH (D.N.J. Apr. 3, 2014) (alleged refusal to sell samples of Thalomid and Revlimid to generic); *Accord Healthcare v. Acorda*, No. 13-cv-60742-RNS (S.D. Fla. Apr. 1, 2013) (alleged refusal of brand to sell samples of Amypra to generic for bioequivalence testing); *Actelion Pharms. Ltd. v. Apotex, Inc.*, No. 12-cv-5743-NLH-AMD (D.N.J. Sept. 14, 2012) (seeking declaratory judgment that brand manufacturer has no duty to supply generics with samples of REMS-restricted drugs); *Lannett Co., Inc. v. Celgene Corp.*, No. 08-cv-3920-TJS (E.D. Pa. Aug. 15, 2008) (alleged refusal to sell samples of Thalomid to generic). *Mylan v. Celgene* and the class action cases, which have been consolidated, are the only cases still active.

[26] In the two instances where the FTC has weighed in, the FTC argued that the branded companies' conduct may also violate Section 5 of the FTC Act, although the FTC did not outline a "standalone" Section 5 theory.

[27] *Authenticom v. CDK Global, LLC*, 874 F.3d 1019, 1025 (7th Cir. Nov. 6, 2017) (Wood. J.).

[28] 410 U.S. 366 (1973).

[29] *Id.* at 370-73.

[30] *Id*.

[31] *Id*. at 377.

[32] 472 U.S. 585 (1985).

[33] *Id*. at 593-94.

[34] *Id*. at 608-609, 611.

[35] 540 U.S. 398 (2004).

manner thereby creating barriers to entry. The Supreme Court flatly rejected this claim, holding that "Verizon's alleged insufficient assistance in the provision of service to rivals is not a recognized antitrust claim under this Court's existing refusal-to-deal precedents."[36] The Court went on to explain that it did "not believe that traditional antitrust principles justify adding the present case to the few existing exceptions from the proposition that there is no duty to aid competitors."[37] Importantly, in this case, the Supreme Court's decision was partially informed by the fact that there already existed regulatory schemes in place. In recognizing this, the Court also warned that "[m]istaken inferences and the resulting false condemnations 'are especially costly, because they chill the very conduct the antitrust laws are designed to protect.'"[38]

Application to REMS Abuse Claims

To date, some of the cases involving REMS claims were dispensed on a motion to dismiss, and still others settled while a motion to dismiss was pending or after surviving the motion to dismiss stage, so there are very few decisions applying the refusal-to-deal jurisprudence to REMS claims.[39] As such, *Mylan Pharmaceuticals, Inc. v. Celgene Corp.* remains one of the few decisions to address refusals to deal in the REMS context.[40] The dispute in this matter goes back as far as 2004, when Mylan initially requested samples of Thalomid (thalidomide) from Celgene for bioequivalence testing. Thalomid is subject to a strict REMS program.[41] Celgene has several FDA requirements under the Thalomid REMS program to ensure safe use of the drug.[42] In 2013, Mylan also requested samples of Celgene's Revlimid (lenalidomide) for bioequivalence testing. Revlimid is also subject to REMS restrictions.[43] Celgene initially refused Mylan's requests, seeking assurances that Mylan's testing protocols for thalidomide and lenalidomide testing were acceptable under the drug's REMS restrictions. In late 2007, the FDA signed off on Mylan's testing protocols for Thalomid and in mid-2013, found that Mylan's protocols for Revlimid were adequate to ensure patient safety. At no point did the FDA affirmatively require Celgene to provide samples to Mylan. Celgene issued additional information requests related to safe use and requested agreements providing for indemnification to protect Celgene in the event of misuse of its REMS-restricted drugs. Celgene did not provide the requested samples. Mylan filed suit in 2014, alleging that Celgene improperly withheld both Thalomid and Revlimid drug samples. Judge Esther Salas of the U.S. District Court for the District of New Jersey upheld Mylan's complaint based on an alleged Section 2 violation of the Sherman Act. In doing so, Judge Salas rejected Celgene's argument that a duty to deal would only arise where there was a prior course of dealing and the alleged monopolist irrationally abandons short-term profits for long-term gains.[44] Instead, Judge Salas remarked that "there remains valid Supreme Court law imposing an affirmative duty to deal when no prior course of dealing was alleged" and "Mylan has pled that there is no legitimate business reason for Celgene's actions, which it argues are solely motivated by its goal to obtain long-term anticompetitive gain."[45] Because Mylan's complaint was sufficiently detailed, the court concluded that the complaint "may give rise to a plausible § 2 claim."[46] Celgene sought interlocutory appeal but the Third Circuit refused the opportunity to address the certified question of "whether a prior, voluntary course of dealing is required to allege an actionable refusal to deal under Section Two of the Sherman Act."[47] The parties have argued a motion for summary judgment and are currently awaiting a decision.[48]

Recent Actions Signal A Likelihood of Increased Enforcement By The FDA and FTC

Over the past several years, generic manufacturers and members of Congress have advocated for more aggressive action to address allegations of REMS abuse. More

[36] *Id. at 410.*

[37] *Id.* at 407-408.

[38] *Id. at 414 (internal quotation omitted).*

[39] *See Lannett v. Celgene*, No. 08-cv-3920 (E.D. Pa. 2011) (parties settled after Lannett's allegations that Celgene improperly withheld samples of Thalomid – characterized as an essential facility by Lannett – survived a motion to dismiss); *Actelion Pharms. Ltd. v. Apotex, Inc.*, No. 12-cv-5743-NLH-AMD (D.N.J. 2013) (parties settled after the court denied Actelion's motion for judgment on the pleadings and allowed discovery to proceed on Actelion's request for declaratory judgment that it had no duty to supply generic competitors with samples of REMS-restricted drugs); *In re Suboxone (Buprenorphine Hydrochloride and Naxolone) Antitrust Litig.*, No. 13-md-2445 (E.D. Pa. 2014) (motion to dismiss granted on REMS claims because generic was able to obtain a sample and the brand manufacturer had no duty "to aid Generics in obtaining expeditious approval of an ANDA."); *Natco Pharma Ltd. v. Gilead Sciences, Inc. and Express Scripts Holding Co.*, No. 14-cv-3247-DWF-JSM (D. Minn. 2015) (motion to dismiss granted on REMS claims because brand manufacturer had a valid business reason to refuse supplying generic outside of REMS program).

[40] Transcript of Oral Opinion, *Mylan Pharms. Inc. v. Celgene Corp.*, No. 2:14-cv-02094-ES-MAH (D.N.J. Dec. 22, 2014).

[41] FDA, Thalomid Risk Evaluation and Mitigation Strategy (June 2017), available at https://www.accessdata.fda.gov/drugsatfda_docs/rems/Thalomid_2017-06-27_REMS_Document.pdf.

[42] *Id*.

[43] FDA, *Revlimid Risk Evaluation and Mitigation Strategy* (June 2017), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/rems/Revlimid_2017-06-27_REMS_Document.pdf.

[44] Transcript of Oral Opinion, *Mylan Pharms. Inc. v. Celgene Corp.*, No. 2:14-cv-02094-ES-MAH, at 10 (D.N.J. Dec. 22, 2014).

[45] *Id*. at 16-18.

[46] *Id*. at 17.

[47] *See* Celgene Petition for Leave to File Interlocutory Appeal, *Mylan Pharms., Inc. v. Celgene Corp.*, Case No. 15-8017 (Feb. 9, 2015); Order Denying Petition for Permission to Appeal, *Mylan Pharmaceuticals, Inc. v. Celgene Corp.*, Case No. 15-8017 (March 5, 2015).

[48] The court's ruling on summary judgment was deferred for a period of time while the parties pursued mediation, but these efforts ultimately proved to be unsuccessful. Minutes of Proceedings, Dkt. 273, *Mylan Pharmaceuticals, Inc. v. Celgene Corp.*, Case No. 2:14-cv-02094-ES-MAH (D.N.J. Dec. 13, 2017).

recently, these calls appear to have resulted in renewed attention from Congress and the FDA. For example, a 2016 report from the Senate Special Committee on Aging concluded that REMS may be abused to delay generic entry into the market place and characterized the abuses as "serious"—reportedly resulting in an estimated increased cost to consumers of $5.4 billion per year.[49] More notably, the newly appointed FDA Commissioner, Scott Gottlieb, has pushed for enhanced scrutiny of potential REMS abuse, noting that while the FDA "doesn't have a direct role in drug pricing" it could likely address some of the issues raised by the tension between bioequivalence requirements and REMS restrictions "by using [its] own authorities more forcefully."[50] For example, Commissioner Gottlieb has testified regarding SSRS programs that the FDA "through our current policy can help address a potential stall tactic. . . . if we put in place a policy signifying that we were willing to step in [after a delay in negotiations] and . . . allow the generic company to move on their own, companies might reach agreement quicker than they are today."[51]

On June 21, 2017, the FDA announced a renewed focus on removing some of the "scientific and regulatory obstacles to generic competition" that can delay and deny patient access to more affordable versions of FDA-approved drugs.[52] As part of this effort, the FDA is launching a Drug Competition Action Plan aimed at eliminating obstacles to generic drug access, including the misuse of REMS. According to Scott Gottlieb, "we know that branded companies are using [FDA] rules that are intended to protect consumers… and taking advantage of these rules in order to deliberately forestall the entry of expected generic drug competition."[53]

At this point, the FDA is also explicitly inviting the FTC to the table. Commissioner Gottlieb remarked that the FDA would be "looking hard at how best to coordinate with the Federal Trade Commission in identifying and publicizing practices that the FTC finds to be anti-competitive. FDA is not the FTC. It is the FTC's responsibility to prevent anticompetitive business practices."[54] Commissioner Gottlieb's statement signals that he does not believe the FDA has sufficient authority to regulate the potential anticompetitive effects of REMS. Instead, he issued an express call for involvement from the FTC in implementing the FDA's goals of improved patient access to generic versions of FDA-approved drugs, opening the door to increased regulatory enforcement activity.

Commissioner Gottlieb's statement is in line with a series of recent calls for antitrust enforcement to fill the gap in combating rising drug prices due to the lack of generic substitutes. Some of the loudest voices for additional reform come from sponsors of the Creating and Restoring Equal Access to Equivalent Samples Act of 2017 ("CREATES Act") (discussed further below). For example, Senator Mike Lee lamented the "complex regulatory environment[] … rife with opportunities for manipulation and abuse to avoid competition."[55] Senator Chuck Grassley (R-Iowa), in a recent letter to Commissioner Gottlieb, stated that he shared the FDA's concerns about "abuses within the REMS program."[56] Senator Grassley followed up with a joint letter, alongside Senators Patrick Leahy (D-Vt.), Mike Lee (R-Utah), and Amy Klobuchar (D-Minn.), promoting the CREATES Act as "an essential part of the solution to ending these [REMS] abuses."[57] The CREATES Act would provide a mechanism for a private right of action and expedited review for lawsuits by a potential generic entrant based on a claim that a branded manufacturer is withholding access to a RLD sample necessary for bioequivalence testing under an ANDA.[58] Additionally, the CREATES Act would provide the FDA with the authority to allow generics to create their own REMS system to combat any potential anticompetitive conduct related to SSRS programs.[59] Addressing a concern for brand manufacturers, the CREATES Act also includes a limitation on liability, absolving brand manufacturers of claims

[49] United States Senate Special Committee on Aging, *Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System*, at 114 (Dec. 2016), *available at* https://www.aging.senate.gov/imo/media/doc/Drug%20Pricing%20Report.pdf.

[50] Remarks by Commissioner Scott Gottlieb, Opening Remarks for Part 15 Public Meeting on Generic Drug Competition (July 18, 2017), *available at* https://www.fda.gov/NewsEvents/Speeches/ucm567323.htm.

[51] C-SPAN, Commissioner Gottlieb, Testimony before a Senate Appropriations subcommittee on President Trump's fiscal year 2018 Food and Drug Administration budget request (June 20, 2017), *available at* https://www.c-span.org/video/?430216-1/fda-administrator-testifies-fy-2018-budget&start=1590.

[52] Commissioner Scott Gottlieb, FDA Working to Lift Barriers to Generic Drug Competition (June 21, 2017), *available at* https://blogs.fda.gov/fdavoice/index.php/2017/06/fda-working-to-lift-barriers-to-generic-drug-competition/.

[53] Remarks by Commissioner Scott Gottlieb, Opening Remarks for Part 15 Public Meeting on Generic Drug Competition (July 18, 2017), *available at* https://www.fda.gov/NewsEvents/Speeches/ucm567323.htm.

[54] *Id.*

[55] Senator Mike Lee, Opening Statement on the CREATES Act (June 21, 2016), *available at* https://www.lee.senate.gov/public/index.cfm/speeches?ID=D038B585-B5F0-47F9-BF8B-59B2600BCCB5.

[56] Senator Charles Grassley, Ltr. to Dr. Scott Gottlieb, Commissioner, FDA (June 19, 2017), *available at* https://www.grassley.senate.gov/sites/default/files/constituents/2017-06-19%20CEG%20to%20FDA%20-%20Affordable%20Prescription%20Medication.pdf.

[57] Senators Charles Grassley et al., Ltr. to Dr. Scott Gottlieb, Commissioner, FDA (July 20, 2017), *available at* https://www.grassley.senate.gov/sites/default/files/constituents/CREATES_FDA_07.20.17.pdf.

[58] S.974 - CREATES Act of 2017, *available at* https://www.congress.gov/115/bills/s974/BILLS-115s974is.pdf.

[59] *Id*.

arising from a situation in which the generic manufacturer failed to follow adequate safeguards during development and bioequivalence testing.[60]

And the FTC appears willing to take up the cause, though with some reservations about the scope of their purview. Already in March 2016, the FTC stated that it was still "concerned about potential abuses by branded pharmaceutical companies of [FDA] safety protocols known as REMS…."[61] A little over a year later, in recent testimony before the U.S. House of Representatives' Judiciary Committee Subcommittee on Regulatory Reform, Commercial and Antitrust Law, the FTC's Acting Director of the Bureau of Competition, Markus H. Meier, testified that branded manufacturers have used restricted distribution programs to delay generic entry.[62] This is because "drug manufacturers have exploited certain features of the existing regulatory framework created by the Hatch-Waxman Act to extend exclusive rights well beyond the periods Congress provided to spur investments in innovation."[63]

Consistent with the FDA's view of the potentially problematic conduct, Acting Director Meier testified that brand companies abuse REMS, attempting to distort competition in two main ways: by refusing to provide samples to the generic firm, leaving it unable to perform the required bioequivalence testing to obtain FDA approval, or by preventing the generic from joining the existing REMS distribution system so the FDA cannot approve the generic firm's ANDA.[64] He acknowledged that "some of these methods will be difficult to reach effectively under the antitrust laws today."[65] While Acting Director Meier noted that the FTC believes REMS abuse "an appropriate area for Congressional focus and concern," he also added that the FTC has pursued and will continue to engage in efforts to combat anticompetitive conduct by both branded and generic firms to "keep prices artificially high."[66] Additionally, he made clear that the FTC supports the CREATES Act "to protect the competitive process by eliminating incentives and opportunities for branded manufacturers to engage in manipulation of the REMS process to delay generic entry."[67]

The most recent statements from the agencies on REMS issues come from a November 2017 workshop on "Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics" held at the FTC. Acting Chairman Maureen Ohlhausen opened the workshop announcing that "when a law enforcement agency like the FTC identifies an area of concern, many people assume that this is a prelude to a raft of new enforcement actions," cautioning to audience to be careful about such assumptions. She then went on to note that "the anti-trust [sic] laws are not a panacea for every economic concern" and that any decision "that there is a need for greater anti-trust [sic] enforcement in pharmaceutical markets, . . . will be made on the basis of specific facts and actual market effects, using the familiar methods and processes of anti-trust [sic] law."[68] Commissioner Gottlieb participated in the workshop and called on companies to "end the shenanigans."[69] He also foreshadowed potential for increased regulatory focus noting that he "look[ed] forward to building on enhancing our [FDA's] partnership with the FTC in order to achieve our shared goal of increasing competition, expanding access to quality generic drugs, and protecting consumers."[70]

Conclusion

Ultimately, developments currently underway related to regulatory enforcement by the FDA and FTC, the proposed CREATES Act, and the currently active litigations demonstrate an increased focus on the competitive dynamic between brand and generic manufacturers in the pharmaceuticals industry. Any additional investigations the agencies launch could also invite further private challenges. If the CREATES Act were to become law, it could spur additional litigation as it would provide generic manufacturers with a legal avenue to force branded manufacturers to provide samples for bioequivalence testing and monetary damages for alleged REMS abuses, without having to prove the elements of an antitrust violation under the refusal-to-deal

[60] *Id*.

[61] Chairwoman Edith Ramirez, Prepared Statement of the Federal Trade Commission Before the United States Senate Committee on the Judiciary Subcommittee on Antitrust, Competition Policy and Consumer Rights "Oversight of the Enforcement of the Antitrust Laws" (March 9, 2016), at 10, https://www.ftc.gov/system/files/documents/public_statements/934563/160309enforcementantitrustlawstest.pdf.

[62] The FTC approved Acting Director Meier's testimony and its inclusion in the formal record by a vote of 2-0. Press Release, FTC Testifies before House Judiciary Committee's Subcommittee on Regulatory Reform, Commercial and Antitrust Law about Antitrust Concerns and the FDA Approval Process, Fed. Trade Comm'n (July 27, 2017), *available at* https://www.ftc.gov/news-events/press-releases/2017/07/ftc-testifies-house-judiciary-committees-subcommittee-regulatory.

[63] Prepared Statement of Markus H. Meier, Acting Director, Bureau of Competition, U.S. Federal Trade Commission Before the United States House of Representatives Judiciary Committee Subcommittee on Regulatory Reform, Commercial and Antitrust Law on *Antitrust Concerns and the FDA Approval Process* (July 27, 2017), at 3, *available at* https://judiciary.house.gov/wp-content/uploads/2017/07/Meier-FTC-Testimony.pdf.

[64] *Id*. at 7-8.

[65] *Id*. at 4.

[66] *Id*. at 3-4.

[67] *Id*. at 14.

[68] FTC, FTC Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics Workshop (Nov. 8, 2017), at 5, *available at* https://www.ftc.gov/system/files/documents/videos/understanding-competition-prescription-drug-markets-intro-keynote-remarks/ftc_understanding_competition_in_prescription_drug_markets_-_transcript_segment_1.pdf.

[69] *Id*. at 5.

[70] *Id*.

case law. And legal decisions in the pending REMS cases could reshape refusal-to-deal jurisprudence going forward. Given all these variables, pharmaceutical companies and other industry stakeholders should continue to pay attention to how these legal and regulatory developments unfold.

COMPETITION IN HEALTH CARE: SUMMARY OF RECENT CONGRESSIONAL HEARINGS

Recently, on the same day, Congress held hearings in both the House and Senate that addressed topical trends in the health care and life sciences industries. The hearings demonstrated that Congress remains keenly interested in looking into a wide array of health care-related issues. The Senate hearing to consider President Trump's nominees to the Federal Trade Commission ("Nomination Hearing") covered a broad range of issues.[2] The Senate Commerce Committee approved the four nominations by voice vote on Wednesday, February 28, 2018, and a final confirmation vote by the full Senate remains. The House of Representatives hearing was titled, "Examining the Impact of Health Care Consolidation" ("House Hearing"), and featured a panel of health care experts who addressed a range of health care-specific issues and policy proposals.[3] This article provides a summary of both hearings.

Liam E. Phibbs[1]
Hogan Lovells US LLP

Keynote Remarks From the FTC and FDA

President Trump has now nominated individuals for all five FTC Commissioner seats, but the Nomination Hearing only considered four of the five nominees.[4] The Nomination Hearing began with opening remarks from Senators Thune (R-SD) and Nelson (D-FL). The senators touched on several industries that the FTC has shown interest in over the past few decades, including the health care industry. Specifically, Senator Nelson noted several consumer protection actions that he viewed as positive steps by the FTC in this space. Senator Nelson commended the FTC for its efforts to combat cigarette ads aimed at children and false ads that claimed certain sports equipment was safer than it actually was. He also noted, however, how long the FTC took to respond to the opioid epidemic. The senator asked the nominees to reflect on what the FTC could have done differently when large pharmaceutical companies first marketed these products, but he did not put forward any specific policy proposals.

After the senators' opening statements, the nominees were introduced and each read their own opening statements. None of the nominees' opening statements specifically touched on health care issues. The senators then questioned the nominees on a range of issues relevant to the health-care industry, including pharmacy benefit managers ("PBMs"), the possibility of a merger retrospective, drug prices, and merger challenges.

PBMs and a Proposed Merger Retrospective

Mr. Simons indicated in the questionnaire he submitted to the Senate committee and again in his testimony that, if confirmed, he would like to implement a merger review retrospective program.[5] The goal of the program would be to identify whether the FTC's merger enforcement efforts have been effective. Mr. Simons would ideally like to identify areas where the FTC has been efficient in bringing enforcement actions, as well as where the FTC has been too lax in its

[1] Liam E. Phibbs is a Law Clerk at Hogan Lovells.

[2] Nomination Hearing to Consider Pending Nominations to the Federal Trade Commission: Hearing Before the S. Comm. on Commerce, Sci., & Transp., 115th Cong. 2nd sess. (2018). Video of the testimony is available at https://www.commerce.senate.gov/public/index.cfm/hearings?ID=EECF6964-F8DC-469E-AEB2-D7C16182A0E8.

[3] Examining the Impact of Health Care Consolidation: Hearing Before the H. Comm. on Energy & Commerce, 115th Cong. 2nd sess. (2018). Video of the testimony available at, https://energycommerce.house.gov/hearings/examining-impact-health-care-consolidation/.

[4] On March 26, 2018, President Trump nominated a second Democrat, Rebecca Slaughter, who is currently a top aide to Senator Charles Schumer. Dana Elfin, *Federal Trade Commission Will Be Back at Full Strength*, Bloomberg BNA (March 30, 2018), https://www.bna.com/federal-trade-commission-b57982090616/.

[5] *Completed Questionnaire from Joseph J. Simons for Nomination Hearing*, U.S. Senate Committee on Commerce, Science, & Transportation, https://dlbjbjzgnk95t.cloudfront.net/1010000/1010064/simons.pdf (last visited Feb. 23, 2018).

enforcement actions, as well as where the FTC has been too lax in its enforcement. One of the industries Mr. Simons specifically identified as a candidate for the retrospective program is the PBM industry.

Senator Capito (R-WV) asked the nominees about consolidation in the PBM industry and how the FTC should deal with it. Mr. Simons agreed that consolidation in this industry is a concern, and noted that reviewing the latest mergers under his retrospective program would help identify actions that the FTC should take moving forward, in response.

Senator Wicker (R-MS) brought up PBMs again, later in the hearing, and asked Ms. Wilson about the lack of transparency in the PBM industry.[6] Ms. Wilson indicated that transparency is often an effective agent to ensure competition in the marketplace, regardless of the industry. She went on to testify that she supported Mr. Simons' proposal to include the PBM industry in a retrospective analysis to determine whether the FTC should take any action in relation to the consolidation in that industry.

Based on Mr. Simons' testimony and the written statements he submitted, the proposed retrospective program appears similar to the retrospective program implemented by former Chairman Muris related to hospital merger challenges. The hospital merger retrospective analyzed consummated hospital mergers to determine whether prices increased after the merger.[7] As a result of the retrospective, the FTC found evidence that hospitals had substantially raised prices after some mergers that the FTC had not challenged. This evidence was not only used to challenge prospective hospital mergers, but already-consummated hospital mergers as well.[8]

Pharmaceutical Task Force

Several senators raised concerns about the price of prescription drugs. Senator Blumenthal (D-CT) indicated that, although this is not a new issue, it is a persistent one despite efforts taken by Congress. He stated that this indicates the FTC needs to undergo an enforcement "reinvention" with respect to prescription drug pricing. Senator Blumenthal also noted that he supports the creation of a task force to look into drug prices and that he was a co-sponsor of the Improving Access To Affordable Prescription Drugs Act, which seeks to create such a task force, but that such a measure is only an early effort that needs support from the FTC.[9]

Senator Blumenthal also asked the nominees if the FTC should engage in more vigorous enforcement regarding the pricing of drugs. Mr. Simons agreed that drug pricing is a significant concern. Mr. Simons also noted that consumers are often already at a difficult point when they have to consider large expenditures on drugs. Like Senator Blumenthal, Mr. Simons indicated that he would be interested in creating a drug-pricing task force with the goal of better identifying, in real time, when price increases occur and the likely causes of the price increases. If the reasons were likely anticompetitive in nature, he indicated that the FTC would get involved. If, however, it appears as though the increase were due to other causes, other steps would be appropriate. For example, if the causes of the price increase were regulatory in nature, the FTC staff could communicate their findings to the FDA. If the causes were something else, the FTC could coordinate with Congress. Mr. Simons also indicated that he would consider Senator Blumenthal's measure to address drug-pricing issues.

Rohit Chopra, also responded to Senator Blumenthal's question about drug prices and noted that the FTC "needed to anchor its work" by focusing on consumers' pocketbooks. Mr. Chopra views this issue as a "top priority" for the agency given the ever-increasing prices of prescription drugs.

Preliminary Injunctions for Mergers

The Committee also questioned the nominees on their views about differences in the FTC and DOJ standards for obtaining a preliminary injunction in merger challenges and the appropriate venue in which the FTC should seek preliminary injunctions. Senator Lee (R-UT) specifically asked the nominees about the "SMARTER Act,"[10] and whether the nominees knew of a reason why the FTC and DOJ should have different standards for merger reviews. He also asked the nominees whether they would consider seeking a preliminary injunction through an administrative proceeding in a Part

---

[6] As discussed below, one of the witnesses in the House Hearing echoed this sentiment when Dr. Gaynor expressed his opinion that the PBM industry is one of the least transparent in the health care space.

[7] Timothy J. Muris, *Everything Old Is New Again: Health Care and Competition in the 21st Century*, Remarks Before the 7th Annual Competition in Health Care Forum (Nov. 2002), http://www.ftc.gov/speeches/muris/murishealthcarespeech0211.pdf.

[8] *In re Evanston Nw. Healthcare Corp.*, 2007 WL 2286195, at *64 (F.T.C. Aug. 6, 2007).

[9] Improving Access To Affordable Prescription Drugs Act, S. 771, 115th Cong. 1st sess. (2017), https://www.congress.gov/bill/115th-congress/senate-bill/771.

[10] Standard Merger and Acquisition Reviews Through Equal Rules Act of 2015, H.R.2745, 114th Cong 2nd sess. (2015), https://www.congress.gov/bill/114th-congress/house-bill/2745. The SMARTER Act would amend the Clayton and Federal Trade Commission Acts to align the standards and processes for the DOJ's and FTC's review of proposed mergers and acquisitions. Id. In order to secure a preliminary injunction to block an unconsummated transaction, the DOJ must file an action in federal court. The FTC, however, can bring an administrative proceeding before pursuing an action in federal court. There is an ongoing debate about whether the current FTC standard is in fact easier to satisfy, thereby giving the FTC greater leverage. Jason M. Bussey, et al., *House Judiciary Committee Again Approves Legislation to Align FTC and DOJ Merger Reviews*, THE M&A Lawyer, 21 No. 5 M&A Law. NL 2 (May 2017).

III administrative court. All nominees acknowledged that both the FTC and DOJ should face the same burden in order to secure a preliminary injunction to block a transaction.

- **Mr. Simons** agreed that there should only be one standard, but went on to state that he was of the opinion that the two standards are functionally the same. Mr. Simons also indicated that merger challenges should occur in federal courts. According to Mr. Simons, there should only be one "bite at the apple," when seeking to block any merger.

- **Mr. Chopra** agreed that market participants should not have to worry about navigating two standards, but stated that he would need to consult with FTC staff to get more information on where it would be best to seek a preliminary injunction. Mr. Chopra also observed that there are certain efficiencies to seeking a preliminary injunction through an administrative procedure, but also acknowledged the due process concerns that weigh in favor of a preference for federal courts.

- **Mr. Phillips** agreed that there should only be one standard, but, like Mr. Chopra, he indicated that he would need to consult with FTC staff regarding the preliminary injunction issue.

- **Ms. Wilson** agreed that there should only be one standard and further noted it would be her preference to pursue a preliminary injunction for an unconsummated merger in federal court.

House Energy and Commerce Committee Hearing: Examining the Impact of Health Care Consolidation

On the same day as the Nomination Hearing, the House Energy and Commerce committee held a hearing titled "Examining the Impact of Health Care Consolidation." Three health care experts were called as witnesses to provide testimony regarding consolidation in the healthcare industry: Dr. Leemore S. Dafny[11]; Dr. Martin S. Gaynor[12]; and Dr. Kevin A. Schulman.[13] The committee members asked about a broad range of issues in the health care space, including consolidation at various levels of the industry and innovation.

Opening Statements

Three committee members gave opening statements.

- **Representative Gregg Harper** (R-MS 3rd) opened the hearing by highlighting that health care spending has been on the rise, and that this increased spending has been passed onto the American public. He explained that consolidation has contributed to these increased costs and that there needs to be a better understanding about the impact of consolidation, which is what prompted (at least in part) the hearing itself. Specifically of interest to Rep. Harper were hospital mergers—both horizontal mergers between hospitals and vertical consolidation of hospitals with physician services.

- **Representative Diana DeGette** (D-CO 1st) also provided an opening statement in which she observed that although consolidation in health care is not per se negative, there are still concerns when increased market power leads to increased costs for consumers. Rep. DeGette also expressed concerns about trends in the supply chain for prescription drugs—particularly issues involving PBMs.

- **Representative Greg Walden, Chairman** (R-OR 2nd) gave the final opening statement. He echoed concerns about the horizontal consolidation of hospitals, vertical consolidation of physician services with hospitals, and both the horizontal and vertical consolidation of PBMs. Rep. Walden emphasized the need to understand what these consolidation trends mean for patients.

The witnesses then provided their own opening statements.

Dr. Gaynor explained that there has been increasing consolidation in the health care industry and that consolidation trends like this can prevent markets from functioning as they should. This in turn can lead to higher prices for patients, without any accompanying improvement in the quality of care. Dr. Gaynor outlined several explanations as to what drives consolidation trends, namely: (1) attempts to protect market share; (2) "Newton's third law of consolidation," where one group sees consolidation occurring in the industry and decides to pursue consolidation efforts of its own; (3) to lower costs through increased scale; and (4) to help ensure continuity. Dr. Gaynor concluded by reiterating that consolidation can stifle competition and innovation,

[11] Bruce V. Rauner Professor of Business Administration, Harvard Business School.

[12] E.J. Barone University Professor of Economics and Health Policy, Heinz College, Carnegie Mellon University.

[13] Visiting Scholar, Harvard Business School, Associate Director, Duke Clinical Research Institute.

which in turn negatively impacts consumers.

Dr. Dafny was the next to speak, echoing some of Dr. Gaynor's statements. Dr. Dafny explained that her research has found that consolidation in the health care industry generally leads to higher prices, but that the quality of care does not improve accordingly. Like Dr. Gaynor, Dr. Dafny provided explanations as to what is driving parties to consolidate in the health care industry, in particular that the parties are seeking to: (1) increase their bargaining leverage with industry players at other levels of the supply chain; (2) reach scale economies to realize cost savings; (3) take better advantage of government program reimbursement rules; and (4) create integrated systems of care that will produce synergies. To better ensure that consolidation creates value for consumers, Dr. Dafny advocated for the creation of publicly available industry pricing databases and for increased funding for antitrust enforcement agencies.

Dr. Schulman's statement emphasized the need for organizational and disruptive innovation in health care. He noted that there is little evidence that hospitals are planning for major changes to their business architecture, demonstrating that little effort is being made to make health care more flexible. Dr. Schulman stressed the importance of hiring and properly funding Chief Innovation Officers and innovation efforts in order to better equip health care organizations to drive and react to change.

These opening statements introduced many of the issues and trends that were addressed throughout the remainder of the hearing, namely: hospital consolidation, the vertical consolidation of hospitals acquiring physician groups, horizontal consolidation in the PBM industry, and general vertical trends in the industry (e.g., CVS's potential acquisition of Aetna).

Hospital Consolidation

Representative Harper asked the witnesses whether the trend towards consolidation among hospitals has increased patient costs and whether this trend should be viewed as a concern. Dr. Gaynor noted that the combination of closely competing hospitals generally leads to increased prices for consumers, and that the evidence is mixed as to whether the quality of care increases. Dr. Dafny offered a somewhat stronger perspective, stating that the available data gives the public good reasons to be concerned about the impact of consolidation on patients and went so far as to say that she has not been able to identify a hospital merger that she would consider "good."[14]

Later in the hearing, Representative Tonko (D-NY 20th) asked the witnesses how a hospital merger could lead to increased prices for consumers. Dr. Dafny responded that this occurs because merged hospitals have increased bargaining power vis-à-vis insurers. When there are fewer hospitals in a region, an insurer is more likely to be beholden to whatever rate the post-merger hospitals request.

Representative Collins (R-NY 27th) acknowledged the concerns regarding hospital consolidation, but expressed concern regarding failing rural hospitals. He asked whether an example of a beneficial consolidation may be scenarios where a hospital in a rural area is failing, and the only way for the hospital to survive is for the hospital to be bought by a larger system. Dr. Dafny stated that a merger along those lines could be beneficial, but that simply keeping a hospital open, without more, does not automatically make a merger "good," because it could enable the newly merged hospital to raise prices for consumers. Representative Collins stressed that access to care in rural areas is a very difficult issue that needs to be addressed. Dr. Schulman agreed with Representative Collins and noted that his home state of North Carolina was working through these same issues.

Finally, Representative Costello (R-PA 6th) questioned the witnesses regarding the FTC's traditional approach to analyzing hospital mergers, and, specifically, on how the FTC conducted the merger retrospective under Chairman Muris. Dr. Gaynor explained that after having lost a series of hospital merger challenges in the 1990s, the FTC decided to review these mergers to see what impact they had on consumers. The evidence gathered as part of this effort indicated that the consummated mergers often led to price increases. This evidence of price increases post-merger was then used by the FTC to successfully challenge future unconsummated hospital mergers.[16]

Vertical Consolidation of Physician Groups

In the context of this broader discussion on how mergers can lead to increased prices for consumers,

[14] Dr. Dafny published an article outlining how she would define a "good" merger. Leemore Dafny, The Good Merger, THE NEW ENGLAND JOURNAL OF MEDICINE, 372 New England Journal of Medicine 1804-1806 (2015), http://www.nejm.org/doi/full/10.1056/NEJMp1502338.

[15] *See generally* FTC & DOJ, *Improving Health Care: A Dose of Competition, Ch. 4 Competition Law: Hospitals* (2004), https://www.ftc.gov/sites/default/files/documents/reports/improving-health-care-dose-competition-report-federal-trade-commission-and-department-justice/040723healthcarerpt.pdf.

[16] *See supra Sec. I.a.i.*

Representative Tonko raised the issue of vertical consolidation of physician services. Dr. Dafny explained that when hospitals acquire physician groups, the same services may cost consumers more. Additionally, there may be a referral issue where the physician will be more likely to refer patients to the hospital for other health care issues, which may be more expensive than receiving care outside of the hospital system.

In his opening statement Representative Walden acknowledged that the 340B Drug Pricing Program had been cited as a major factor that has caused hospitals to acquire oncology physician groups. Representative Barton (R-TX 6th) expressed similar views. Later in the hearing, Representative Castor (D-FL 14th) sought to clarify for the record, that the 340B program has been generally effective and asked the witnesses their opinions on the issue. Dr. Gaynor agreed that the program has been helpful, but echoed the comments from Representatives Walden and Barton in explaining that studies have shown that the program is a major factor behind hospital acquisitions of oncology and hematology physician groups. As a result, patients have to go hospitals for oncology and hematology treatments, which can be more expensive.

PBM Consolidation

Representative DeGette asked whether PBM consolidation could result in increased prices for important drugs like insulin. Dr. Dafny stated that she had not seen statistical research indicating that prices have increased as a result of PBM consolidation. However, she went on to advocate for a merger retrospective to examine recent PBM mergers, which (as discussed above) is something the now-confirmed Chair of the FTC indicated interest in pursuing. Dr. Gaynor agreed that there should be a retrospective assessing concentration levels in the PBM market.

Representative Carter (R-TX 31st) also inquired about whether the discounts PBMs negotiate with drug manufacturers are actually passed on to consumers. Dr. Schulman stated that PBM operations are not transparent and there is no way of knowing how much of the discount goes back to consumers or the employers who pay for insurance plans. Dr. Dafny indicated that this is another issue that could be studied in the context of a PBM merger retrospective.

General Vertical Consolidation Trends

Several Representatives questioned the panel regarding recent announcements about vertical consolidation in the health care industry, highlighting, in particular, the proposed merger between CVS and Aetna.[17]

Representative Brooks (R-IN 5th) asked the witnesses what antitrust enforcement of vertical transactions will look like in the future and what tools would be helpful when challenging vertical transactions. Dr. Dafny remarked that antitrust enforcers have narrow laws to enforce and that they enforce them narrowly. Because defining vertical markets is difficult, they are less likely to be challenged. Dr. Dafny recommended that there should be more enforcement-focused research on vertical transactions. Dr. Gaynor recommended that the vertical merger guidelines be amended to better address current trends.

Representative Costello asked the witnesses if there will be more consolidation in the future and whether it would likely be horizontal or vertical. Dr. Dafny noted that the incentives for consolidation have not changed so it would likely continue, and that it would likely be vertical because parties may think a vertical merger is less likely to be challenged.

Innovations in the Industry

Several representatives remarked on the need for more innovation in health care. One of the examples frequently cited by committee members was the announcement from Amazon, JP Morgan, and Berkshire Hathaway that they would be looking into ways to provide more effective healthcare for their employees.[18] The committee members citing this example acknowledged that little is known publicly so far regarding the initiative, but wanted to know the witnesses' opinions regarding the announcement. Dr. Gaynor stated that he did not have enough information to evaluate whether the effort will be successful, but viewed it as a positive step to see executives of large companies focusing on healthcare.

Outlook

The concerns raised during these hearings demonstrate that Congress, as a whole, remains focused on the state of health care in America, and that this focus encompasses a broad

[17] *See* Press Release, *CVS Health to Acquire Aetna; Combination to Provide Consumers with a Better Experience, Reduced Costs and Improved Access to Health Care Experts in Homes and Communities Across the Country* (Dec. 3, 2017), https://cvshealth.com/newsroom/press-releases/cvs-health-acquire-aetna-combination-provide-consumers-better-experience.

[18] Nick Wingfield, et al., *Amazon, Berkshire Hathaway and JPMorgan Team Up to Try to Disrupt Health Care*, N.Y. Times, Jan. 30, 2018, https://www.nytimes.com/2018/01/30/technology/amazon-berkshire-hathaway-jpmorgan-health-care.html.

range of topics and issues. While none of the issues were novel, they are persistent and echo ongoing conversations already occurring at the agencies. For example, in November 2017, the FTC held a workshop on the prescription drug supply chain, where issues related to PBMs were a major topic of discussion. The workshop discussed, among other topics, the impact of PBM consolidation, concerns regarding transparency, and the potential that a lack of transparency can lead to misaligned incentives for PBMs vis-à-vis their health plan customers and patients.[19] Assuming that the FTC commissioner nominees are ultimately confirmed by the full Senate, it appears that, although there is unlikely to be a sea change with respect to how the FTC will analyze and prioritize health care and life sciences issues, the future may hold some interesting insights from new initiatives, including the proposed merger retrospective.

[19] FTC, *Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics, Panel 2: Understanding Intermediaries: Pharmacy Benefit Managers*, slides 73-130, https://www.ftc.gov/system/files/documents/public_events/1255653/understanding_competition_in_prescription_drug_markets_workshop_slides_11-8-17.pdf.

ANTITRUST HEALTH CARE CHRONICLE EDITORIAL BOARD

HEALTH CARE AND PHARMACEUTICALS COMMITTEE LEADERSHIP

Please contact the Executive Editors if you have any comments or suggestions regarding the Chronicle.
For past issues, visit: http://apps.americanbar.org/dch/committee.cfm?com=AT301000