Responses of Federal Trade Commission Chairwoman Edith Ramirez
To Questions Submitted for the Record
Senate Judiciary Committee Subcommittee on Antitrust, Competition Policy, and Consumer Rights Hearing: "Oversight of the Enforcement of the Antitrust Laws"
March 9, 2016

Questions from Subcommittee Chairman Mike Lee

In January last year, the FTC required Albertsons to sell 168 supermarkets as a condition of approval for its merger with Safeway. 146 of these went to Washington-based Haggen. But just 8 months later, Haggen filed for bankruptcy. As part of its bankruptcy proceedings, Haggen agreed to sell 33 of the stores it acquired from Albertsons…back to Albertsons.

- **In light of these events, do you believe the Commission should revisit its approach to merger remedies?**

  I believe that the Commission's approach to merger remedies is sound. To resolve most merger challenges, the Commission relies on divestitures to maintain competition. In each of those situations, the Commission has determined that a divestiture can address the aspects of the transaction that are likely to result in competitive harm while allowing the beneficial aspects of the deal to go forward.

  Before authorizing a divestiture, the FTC thoroughly evaluates whether a proposed buyer of divested assets has the financial resources, incentives, and skills to replace the competition that would otherwise have been lost because of the merger. This detailed review includes consideration of the proposed buyer's commitment to remain in the market, its past operations, and its plans for the divested assets going forward. In the vast majority of cases, the FTC-approved divestiture buyers have successfully preserved competition.

  While we always endeavor to make the best possible decisions with the information that is available to us, there are rare occasions when our merger remedies do not fully achieve their remedial objectives due to unanticipated developments. We recognize that we have to regularly assess the effectiveness of our remedies as we seek to achieve the best outcomes for competition and consumers. To that end, as noted in the Commission's prepared testimony, the Commission is currently conducting a study of the agency's prior merger remedies in an effort to ensure that our remedies continue to achieve their primary goal of maintaining competition in affected markets.

  Specifically with respect to the Albertson's matter, some of the Albertson's stores that Haggen had acquired pursuant to the Commission's divestiture order continue to operate with independent owners. However, certain divested stores were ultimately reacquired by Albertson's through the bankruptcy process. That occurred only in instances where Albertson's was the sole interested and qualified bidder. Had Albertson's not reacquired those stores, the stores would likely have been closed.

One of my ongoing concerns relates to competition in high tech markets with evolving business models, such as online video distribution. In situations like these, it is not uncommon to see market incumbents attempt to thwart disruptive innovation that may benefit consumers, but threatens their legacy business model.

- **What is your agency doing to protect competition in these cutting edge industries?**

Another cutting edge market in which it is important to promote and protect competition is the much-discussed "sharing economy."

- **What is your agency doing to adapt your antitrust analysis to these young and evolving markets to ensure that incumbents and legacy competitors don't stifle innovation?**

  The emergence of new and disruptive business models is not a new phenomenon. In recent years, we have seen e-Commerce and technology facilitate the development of new products and services and new ways of doing business. The antitrust laws are sufficiently flexible to address anticompetitive conduct in these new and dynamic markets, and effective enforcement of the antitrust laws can ensure that market incumbents compete on the merits.

  In addition to examining existing forms of competition, the FTC considers future competition and innovation when conducting merger and conduct investigations. We also work to better understand changing markets and the way new technologies affect consumers and the competitive dynamics within markets. This frequently entails having attorneys and economists work side-by-side with the agency's technologists.

  We also engage regularly with market participants and outside experts, both informally and in the context of FTC workshops. For instance, last June, we hosted a workshop that brought together academics, practitioners, policymakers, and consumer advocates to explore competition, consumer protection, and economic issues relating to the "sharing" economy. The aim of the workshop was to promote more informed analysis of the competitive dynamics of the sharing economy as well as the benefits and risks to consumers. In particular, the workshop examined whether, and to what extent, existing regulatory frameworks can be responsive to legitimate health, safety, and other consumer protection issues raised by sharing economy business models without undermining the benefits of competition.

  This in-depth examination of the sharing economy complements the FTC's advocacy work in this area. Over the last several years, the FTC has submitted various advocacy letters urging cities and taxicab authorities to carefully consider the competitive effects of regulations on new ride-sharing platforms such as Uber and Lyft. The FTC's key message is that, where regulation is needed, policymakers should narrowly tailor those regulations to serve legitimate policy goals without unduly restricting new forms of competition.

I understand the Commission has been investigating Herbalife's business practices for over 24 months. I have heard some concerns that this length is due to the Commission considering novel theories of consumer harm with respect to multilevel marketing.

- **Is 24 months a typical length for this sort of investigation, and is the Commission considering changing its approach to these businesses?**

  Because the company has publicly acknowledged it, I can confirm that an investigation is ongoing. Commission rules regarding non-public investigations prevent me from commenting any further. As a general matter, I can assure you that the FTC strives to conduct thorough investigations as expeditiously as possible.

There are increasing tensions and concerns internationally with regard to how antitrust laws are being enforced. Some suggest that there are poor transparency, flawed analytical frameworks, and questionable remedies.

- **What are you doing to address these concerns?**

  Our international engagement occurs through participation in multilateral forums, like the International Competition Network (ICN) and the Organisation for Economic Co-operation and Development (OECD), as well as through bilateral engagement and cooperation with counterpart competition agencies around the world. With more than 130 competition agencies globally, one of the Commission's top priorities is to promote the application of sound antitrust enforcement principles and policies grounded in economics. As part of our messaging, we also emphasize the importance of procedural fairness in antitrust investigations and proceedings.

  Working through the ICN we have made great strides in developing international consensus around sound substantive rules governing the core areas of antitrust – mergers, unilateral conduct, and anti-cartel enforcement. Recently, the FTC co-chaired an ICN initiative that resulted in the ICN's Recommended Practices on the Assessment of Dominance, which provide an analytical framework grounded in economic principles for assessing whether market power exists. In addition, the FTC has been actively engaged in a multi-year ICN project to develop a Merger Remedies Guide addressing how agencies can design and implement appropriate remedies. We expect that the ICN will approve this guide later this month.

  The FTC has also been a leader in the area of procedural due process. A multi-year ICN project initiated and co-led by the FTC resulted in the adoption of consensus guidance on process issues in investigations. This guidance lays out international best practice standards for procedural fairness in antitrust investigations and serves as a benchmark to promote convergence in this important area. We are now working to promote implementation of the guidance.

  FTC case cooperation also contributes to promoting sound substantive and procedural approaches and helps to ensure effective and efficient remedies and outcomes. We routinely engage with foreign competition agencies on key substantive and procedural issues in matters undergoing review in multiple jurisdictions. In fiscal year 2015, we had significant cooperation in 35 investigations with counterpart agencies around the world,

leading to compatible outcomes in all of the cases completed within the fiscal year, including coordinated remedies.

We also engage with counterpart agencies on enforcement and policy matters through regular bilateral interactions. Last fall, for example, we held our second formal bilateral consultation with the Chairman and other senior officials of the Korea Fair Trade Commission, which provided an opportunity to discuss key issues of common interest, including antitrust enforcement involving intellectual property and due process. At that meeting, the FTC and the Department of Justice's Antitrust Division ("DOJ") signed a memorandum of understanding with the KFTC to promote increased cooperation and communication. This week we will be holding this year's Joint Dialogue with the leadership of the three Chinese anti-monopoly agencies.

In appropriate cases, we are able to use our strong bilateral relationships if we become aware of concerns about, for example, the adequacy of due process provided. In our experience, foreign competition agencies can be highly responsive when we engage with them as colleagues in a sensitive manner about concerns. The FTC also may work with U.S. embassies and other U.S. government agencies through the interagency process to determine the most effective strategy to address due process concerns.

The FTC also shares its experience and expertise with a broad array of young competition agencies. During the past year, the FTC conducted 30 competition training missions, including on merger remedies in Brazil and programs in India and China. Additionally, the FTC hosts "International Fellows" from foreign competition agencies who work directly with FTC staff to gain first-hand appreciation of the practices and approaches that the FTC uses in its enforcement, in the expectation that they will bring this learning back to their agencies.

In some countries, it appears that antitrust enforcement is a tool of native interests used to target foreign firms, force tech transfer, and extract other concessions to the benefit of domestic competitors.

- **What are you doing to coordinate with the broader US government, particularly with USTR and Commerce, to confront these protectionist practices?**

  The FTC has long advocated internationally that competition law should be used to maximize consumer welfare and that it should be applied in a non-discriminatory manner. We advocate for these principles through speeches,[1] directly with our foreign agency counterparts, and in multilateral bodies such as the ICN and the OECD. Using competition law for protectionist purposes undermines the consumer benefits from

[1] *See, e.g.*, Edith Ramirez, Chairwoman, Fed. Trade Comm'n, Core Competition Agency Principles: Lessons Learned from the FTC, Keynote Address at the Antitrust in Asia Conference, Beijing, China (May 22, 2014), https://www.ftc.gov/system/files/documents/public_statements/314151/140522abachinakeynote.pdf; Edith Ramirez, Chairwoman, Fed. Trade Comm'n, Keynote Address, Seventh Annual Global Antitrust Enforcement Symposium (Sept. 25, 2013), https://www.ftc.gov/sites/default/files/documents/public_statements/7th-annual-global-antitrust-enforcement-symposium/130925georgetownantitrustspeech.pdf.

competition law enforcement as well as the legitimacy of the international competition law system.

Although it can often be difficult to determine whether particular enforcement actions are, in fact, motivated by protectionist concerns as opposed to legitimate competition policies, we seek to assess patterns of discriminatory enforcement. If it appears that enforcement may be based on protectionism, the FTC raises, where appropriate, the issue directly with the relevant agency. In addition, the FTC, along with DOJ, coordinates with other U.S. agencies through the interagency process to address these issues, including through appropriate government-to-government dialogue.

Questions from Chairman Grassley

I've heard concerns that certain brand name drug companies are misusing their Risk Evaluation and Mitigation Strategies (known as REMS) to withhold access to drug samples for bioequivalence testing and generic drug development in violation of FDA regulations and the Hatch Waxman Act. There also are concerns that certain brand companies are misusing REMS to deny access to the REMS single shared system mandates under FDA regulations.

- **Is there a problem with how certain companies are using REMS?**

  The FTC continues to be very concerned about potential abuses by branded pharmaceutical companies of REMS or other closed distribution systems to impede generic competition. As we have explained in amicus briefs in two private lawsuits, this conduct undermines the careful balance Congress struck in the Hatch-Waxman Act to encourage competition from lower-cost generic drugs, and may violate federal antitrust laws.[2] We are closely monitoring pharmaceutical markets to guard against unlawful conduct and will take action where necessary.

- **What kind of data has the FTC collected on this issue?**

  The FTC undertakes a wide variety of activities designed to collect information about REMS and other restrictions on pharmaceutical distribution that may affect competition. These include: (1) monitoring public sources of information, such as media and trade press reports; (2) reviewing information and complaints from generic pharmaceutical companies; (3) monitoring private litigation; and (4) reviewing information from the FDA regarding generic companies that have submitted REMS-compliant bioequivalence testing protocols for the FDA's approval or reported difficulty accessing branded drug samples for bioequivalence testing.

- **How is the FTC working with the FDA to address anti-competitive practices in the REMS program and to ensure that our health, safety and competition goals are being appropriately balanced?**

  As noted above, the FTC periodically requests information from the FDA regarding generic companies that have reported difficulty accessing branded drug samples or have submitted REMS-compliant bioequivalence testing protocols for the FDA's approval. Additionally, FTC staff has periodic conversations with FDA staff about issues of mutual concern to the agencies. Given the FTC's and the FDA's respective mandates, the FTC focuses on the competition aspects of branded and generic pharmaceutical companies' behavior, while deferring to the FDA for determinations concerning public health and safety.

[2] FTC Brief as Amicus Curiae, Mylan Inc. v. Celgene Corp., Case No. 2:14-CV-2094 (D.N.J. June 17, 2014), https://www.ftc.gov/system/files/documents/amicus_briefs/mylan-pharmaceuticals-inc.v.celgene-corporation/140617celgeneamicusbrief.pdf; FTC Brief as Amicus Curiae, Actelion Pharms Ltd. v. Apotex Inc., Case No. 1:12-cv-05743 (D.N.J. Mar. 11, 2013), https://www.ftc.gov/policy/advocacy/amicus-briefs/2013/03/actelion-pharmaceuticals-ltd-et-al-v-apotex-inc.

Questions from Senator Orrin G. Hatch

Questions for Assistant Attorney General Baer & Chairwoman Ramirez

1. **I'd like to begin with a question about foreign antitrust enforcement. In some instances, antitrust enforcement in other countries is shaped by considerations apart from promoting competition. In fact, one could argue that some countries use antitrust enforcement as a tool to target foreign firms, force foreign competitors to transfer technology, and extract other concessions to benefit domestic businesses. What are you doing to coordinate with other U.S. agencies, particularly USTR and the Commerce Department, to confront protectionism by foreign antitrust authorities? Will you make this issue a priority?**

   The FTC has long advocated internationally that competition law should be used to maximize consumer welfare and that it should be applied in a non-discriminatory manner. We advocate for these principles through speeches,[3] directly with our foreign agency counterparts, and in multilateral bodies such as the ICN and the OECD. Using competition law for protectionist purposes undermines the consumer benefits from competition law enforcement as well as the legitimacy of the international competition law system.

   Although it can often be difficult to determine whether particular enforcement actions are, in fact, motivated by protectionist concerns as opposed to legitimate competition policies, we seek to assess patterns of discriminatory enforcement. If it appears that enforcement may be based on protectionism, the FTC raises, where appropriate, the issue directly with the relevant agency. In addition, the FTC, along with DOJ, coordinates with other U.S. agencies through the interagency process to address these issues, including through appropriate government-to-government dialogue.

2. **The Department and the Commission frequently use divestitures as a way to reduce the anticompetitive effects of a merger. There's been criticism in some quarters recently about the efficacy of divestitures, with some groups suggesting that divestitures aren't effective because they don't account for changing market conditions two or three years down the line. I'm not sure I agree with these criticisms, but I wanted to give you an opportunity to comment. Do you believe that divestitures are effective means for reducing the potential anticompetitive effects of a merger? Why or why not?**

   Merger review is by its nature a forward-looking enterprise, and the goal of any merger remedy is to maintain (or restore) the pre-transaction competitive dynamics in the relevant market. When a proposed transaction raises competitive concerns, we are often able to resolve them by requiring the divestiture of selected assets. A divestiture allows the Commission to address the aspects of the transaction likely to result in competitive harm while allowing the beneficial aspects of the deal to go forward. When the Commission orders a divestiture, it does so to prevent the merger from causing harm in the future, whether through higher prices, lower quality, less innovation, or fewer choices.

[3] *See, e.g.*, Ramirez, *supra* note 1.

When determining whether a transaction may substantially lessen competition in violation of Section 7 of the Clayton Act, the Commission engages in a thorough investigation of market conditions, including the potential for existing firms to expand, new firms to enter, or other developments that may affect the way firms compete in the future. The information gathered during the investigation, including the possibility of changing industry dynamics, is central to the Commission's determination of whether a divestiture is appropriate and, if so, the form it should take.

To provide greater insight regarding the effectiveness of our merger remedies, the Commission is currently conducting a study of prior FTC merger remedies to ensure that they achieve their primary objective – preserving the competition that would have been lost as a result of a merger.

Questions for Chairwoman Ramirez

1. **In the Commission's January 2013 statement closing its investigation into Google's alleged manipulation of search results, the Commission said it would "remain vigilant and continue to monitor Google for conduct that may harm competition and consumers." As I mentioned at the hearing, various actors, including state attorneys general, have raised concerns that Google continues to engage in anti-competitive behavior. What has the Commission done since closing its investigation of Google to monitor Google with regard to conduct that may harm competition and consumers?**

   As you know, Google made certain commitments in a letter dated December 27, 2012 to then FTC Chairman Jon Leibowitz regarding its display of content from third-party websites and its AdWords API terms and conditions for a period of five years. Google also agreed to submit annual compliance reports describing the steps it has taken related to those commitments. To date, Google has filed four such annual reports, most recently on February 25, 2016, as well as one additional report outlining changes it made to give website owners the option to prevent crawled content from their websites from being displayed on certain Google pages. These compliance reports are similar to those filed by parties who are under Commission orders and are reviewed by staff in both the Compliance and Anticompetitive Practices Divisions of the Bureau of Competition. In addition to the Commission's own monitoring, we regularly engage with market participants. Parties that may have concerns about Google's conduct are likely to bring them to the FTC's attention. Here and elsewhere, the Commission will not hesitate to take action if we have reason to believe there is a violation of the antitrust laws.

2. **In April 2015, the European Commission (EC) announced it was launching an investigation of Google with respect to Android smartphones and mobile devices. In its statement announcing the investigation, the EC said the investigation "will focus on whether Google has entered into anti-competitive agreements or abused a possible dominant position in the field of operating systems, applications, and services for smart mobile devices." Similar allegations have been raised against Google in the U.S., including the allegation that Google has required device manufacturers to pre-load Google applications in order to gain access to the proprietary version of the Android operating system, which is owned by Google and is the world's most popular mobile device operating system. Is the FTC considering launching its own investigation of this issue?**

   While I cannot discuss the existence of non-public investigations, I can assure you that I am aware of these concerns.

Questions from Senator Al Franken

1. **I am increasingly concerned about the need for a meaningful Do Not Track standard that empowers consumers to decide whether companies can collect information about their online behavior. Unfortunately, the World Wide Web Consortium has proposed a standard that permits the largest Internet companies – such as Google, Comcast, and Amazon – to actually ignore explicit requests from users who tell them not to track. Not only does this standard not respect consumers' privacy, but it also gives the Internet giants an unfair advantage over companies that are trying to protect consumer rights and expectations.**

   Chairwoman Ramirez, back in 2010, the FTC was instrumental in calling for a meaningful Do Not Track mechanism. Can you tell me what the FTC is doing now to remedy the shortcomings of the World Wide Web Consortium's proposal? And further, what is the FTC doing to regain control of the process and put forward meaningful protections for consumers?

   I share your concern about online tracking. While tracking can provide benefits to consumers, it also raises privacy concerns. Entities collect vast amounts of consumer data and use that data in ways largely invisible to consumers. For that reason, the Commission has long called for improved transparency and choice in this area. Indeed, studies have shown that consumers have more trust in companies that provide transparency and choice.

   Although we have followed the efforts of W3C, the Commission's call for transparency and choice has not been dependent on any particular forum or initiative. Rather, we have called on industry to improve consumers' ability to exercise choices in this area. There have been some positive steps. In 2013, Axciom, one of the largest data brokers in the world, released a consumer choice tool.[4] And the Digital Advertising Alliance has made important improvements to its self-regulatory program.[5]

   Our recommendation to industry is clear: provide simple, universal choice mechanisms that are effective, persistent, and enforceable. When consumers exercise choices, companies should make sure to address collection, not just use, and make sure they do not circumvent those choices by using alternative technologies to track consumers. We continue to hold industry accountable on this issue. For example, we have brought law enforcement actions against companies that have tried to circumvent consumer choices by using different technologies to track consumers.[6] The Commission also recently hosted a workshop to

[4] *See* https://www.aboutthedata.com/.

[5] *See generally* http://www.aboutads.info/.

[6] *See, e.g.*, Epic Marketplace, Inc., No. C-4389 (F.T.C. Mar. 13, 2013), http://www.ftc.gov/enforcement/cases-proceedings/112-3182/epic-marketplace-inc; ScanScout, Inc., No. C-4344 (F.T.C. Dec. 21, 2011), http://www.ftc.gov/enforcement/cases-proceedings/102-3185/scanscout-inc-matter.

examine privacy issues raised by advertising based on cross-device tracking.[7] The message from that workshop is that consumer choices should be respected across devices.

There is more work to be done, and through continued enforcement, policy, and education, we are encouraging more progress in this area. However, the FTC cannot do this alone. For instance, as a general matter under current law, the FTC cannot require companies to provide transparency and choices over online tracking. We need industry to develop and implement effective choice mechanisms for consumers and provide meaningful oversight of these programs. The FTC also needs additional tools, which is why I continue to recommend that Congress enact baseline privacy legislation that would address these and other important privacy issues.

2. **(Chairwoman Ramirez) I have a number of concerns about Pfizer's proposed deal with Allergan. U.S. companies should not be permitted to dodge taxes by moving their address offshore. I'm concerned about how this deal might impact research and development into new innovative drugs and treatments. I'm also concerned that the deal's approval could result in higher drug prices. The pharmaceutical industry has been on a dangerous path for years – drug price hikes are not new, and they definitely aren't losing any steam. In fact, since January 1, 2016, Pfizer has raised prices on more than 100 of its prescription drugs. And despite the media's renewed attention to the issue in recent months, Pfizer has not reduced the price of any of its prescriptions.**

   Chairwoman Ramirez, my question is two-fold. First, what factors – in addition to the impact on individual drug and treatment markets – does the FTC consider when evaluating pharmaceutical deals like Pfizer's proposal? And second, what is the FTC doing to ensure that Americans have affordable access to necessary medicines and treatments?

   Section 7 of the Clayton Act prohibits combinations that are likely to substantially lessen competition in any line of commerce in any part of the country.[8] Traditionally, this requires that the Commission assess a merger's likely competitive effects in a relevant product and geographic market, including an examination of whether the merging parties are close competitors such that the transaction is likely to have anticompetitive effects, such as higher prices or reduced innovation. In most instances, relevant markets consist of products or services that are functional substitutes for each other, such that they compete closely. In pharmaceutical mergers, drugs that are therapeutic alternatives approved for use in the United States might be considered substitutes for the treatment of a medical condition or disease. This determination is fact-specific, and in many cases is limited to a specific drug, or possibly even a specific dosage or method of delivery, if doctors are unlikely to substitute other products in response to a price increase. We also consider the likelihood that one or

[7] FTC, Press Release, FTC to Host Workshop on Cross-Device Tracking (Mar. 17, 2015), https://www.ftc.gov/news-events/press-releases/2015/03/ftc-host-workshop-cross-device-tracking-nov-16.

[8] Pfizer and Allergan called off their proposed merger last week following actions announced by the U.S. Department of the Treasury regarding inversions. *See* Press Release, Pfizer Pharmaceutical, Pfizer Announces Termination of Proposed Combination with Allergan (Apr. 6, 2016), http://www.pfizer.com/news/press-release/press-release-detail/pfizer_announces_termination_of_proposed_combination_with_allergan.

both of the merging parties are developing products that may compete in the future when they receive FDA approval. In many pharmaceutical mergers, this product level analysis reveals overlaps that raise competitive concerns. To remedy concerns that a merger will reduce the number of suppliers for a specific formulation, the Commission often requires divestiture of the intellectual property and other assets needed to manufacture that formulation.

In addition to product-level overlaps, we evaluate whether there are broader competitive implications from a proposed merger. The FTC's 2009 investigation of Pfizer's acquisition of Wyeth illustrates how the Commission has considered these broader issues in the pharmaceutical sector. There, the Commission investigated whether the transaction would adversely affect competition in a broader market of treatments for Alzheimer's disease, whether the combination would affect the pace of pharmaceutical innovation generally, either by changing incentives to innovate or by eliminating a competitively important source of innovation, and the competitive impact of combining the merging parties' patent or pharmaceutical portfolios.[9] By investigating the individual product overlaps as well as the broader aspect of pharmaceutical combinations, the Commission is able to comprehensively assess whether the transaction is likely to have an adverse impact on competition in any potential relevant market.

The Commission is also attentive to special circumstances affecting competition in specific pharmaceutical markets. For example, we have considered whether the markets at issue are susceptible to supply disruptions. In the Commission's 2013 investigation of the merger between Mylan and Agila, our remedy specifically accounted for the fact that the generic products at issue were highly susceptible to supply disruptions because of the difficulties of producing sterile liquid drugs.[10] We have also considered whether, because of buying practices for certain categories of pharmaceuticals, competitors with a large portfolio of those types of pharmaceuticals may have an advantage. In Pfizer/Wyeth, which also included significant overlaps in animal health products, we found that because veterinarians tend to purchase all their vaccines from a single supplier, a firm must sell a large portfolio of vaccines in order to be a significant competitor.[11] The Commission took this into account and ordered Wyeth to divest its entire animal health subsidiary whose assets included not just those related to 21 specific animal vaccines that both companies sold, but all assets related to broad categories of vaccines.

Regarding your second question, promoting competition in pharmaceutical markets has been a top priority for the Commission for many years. The Commission's prepared testimony outlines the FTC's most recent efforts to stop both anticompetitive mergers and conduct in drug markets. The latter includes efforts to stop pay-for-delay agreements and to curb other attempts by branded pharmaceutical companies to prevent generic competition. In late

[9] Statement of the Federal Trade Commission Concerning Pfizer/Wyeth, FTC File No. 091-0053 (Oct. 14, 2009), https://www.ftc.gov/sites/default/files/documents/cases/2009/10/091014pwyethstmt.pdf.

[10] Complaint, In re Mylan, Inc., Dkt. C-4413 (Sept. 26, 2013), https://www.ftc.gov/sites/default/files/documents/cases/130926mylancmpt.pdf.

[11] Analysis to Aid Public Comment, In re Pfizer Inc., Dkt. No. C-4267 (Oct. 14, 2009), https://www.ftc.gov/sites/default/files/documents/cases/2009/10/091014pwyethanal.pdf.

March 2016, the FTC sued drug makers Endo, its partner Teikoku, Impax, and Allergan for entering into two pay-for-delay agreements to keep generic versions of opioid drug Opana ER and lidocaine patch Lidoderm off the market. The settlements, which we contend cost consumers hundreds of millions of dollars, both included payments in the form of agreements by the brand not to launch an authorized generic, among other compensation. Those agreements are particularly harmful for consumers because they not only serve as compensation to the generic for delaying entry, but they also reduce competition once the first-filing generic launches, resulting in higher generic prices as well. The Commission's record in this area demonstrates that we are committed to using our authority under the antitrust laws to ensure a competitive marketplace in the pharmaceutical industry.

5. (Chairwoman Ramirez and Assistant Attorney General Baer) Three years ago, as the Supreme Court was preparing their ruling in the *American Express v. Italian Colors* case, I asked you both about the importance of private antitrust enforcement. The decision in that case has since made it much harder for small businesses to file private antitrust enforcement actions and instead they are forced to arbitrate their claims. Can you explain how antitrust enforcement has changed since that decision? Do you continue to have concerns about business' ability to bring antitrust claims to court?

Private antitrust enforcement complements government antitrust enforcement efforts. As a result, I am concerned when private litigants are limited in their ability to vindicate their rights under the antitrust laws. Jointly with DOJ, the FTC filed an amicus brief with the Supreme Court in *American Express Co. v. Italian Colors Restaurant* expressing concerns that companies could use a combination of class action and joinder prohibitions, confidentiality requirements, and other procedural restrictions to deter potential plaintiffs from filing antitrust suits. Although the Commission has not studied the impact of the Supreme Court's decision in that case, I continue to have concerns that the Court's ruling could reduce the intended deterrent and compensatory effect of federal antitrust laws.

Questions from Senator Richard Blumenthal

Chairwoman Ramirez, one important and ongoing competition issue in the health care sector is the effect of hospital group purchasing organizations ("GPO's").

GPO's contract to buy medical equipment and supplies on behalf of hospitals, and are paid by the hospital suppliers. Virtually all hospitals in the United States belong to at least one GPO and a relatively small number of GPO's are responsible for the vast majority of products purchased by hospitals through GPO contracts. GPO's were created to provide volume discounts for hospitals, and are intended to reduce the costs of health care, a laudable goal.

However, allegations have also been raised regarding GPO's engaging in anticompetitive conduct. Critics allege that in some circumstances, GPO's have prevented innovative medical device technologies from accessing the market. GPO's argue that hospitals have a choice on whether or not to use GPO's, and that hospitals enjoy volume discounts by participating.

The joint FTC/Justice Department Healthcare Guidelines provide an "antitrust safety zone" that provides GPO's with wide latitude in their operations with limited governmental antitrust scrutiny. This antitrust safety zone was first promulgated more than two decades ago.

Since then there have been significant changes in the marketplace, including major consolidation among GPO's.

a. Chairwoman Ramirez, do you think these guidelines need to be reexamined, or do you believe the market is working as it should? Do you have suggestions on how to increase competition in the medical supply chain?

Because the antitrust safety zone laid out in the 1996 Statements of Antitrust Enforcement in Health Care applies only to the formation of joint purchasing arrangements among healthcare providers, they would not shield GPOs that engage in any anticompetitive conduct such as exclusionary contracting practices.

The FTC is aware of the concerns raised about the conduct of GPOs and has on a number of occasions examined complaints about GPO conduct. Determining whether any specific conduct is anticompetitive is a fact-specific inquiry requiring a careful examination of market circumstances. Evaluating claims that a particular GPO has market power involves more than just an assessment of the sales volume made through GPOs. Moreover, possession of market power alone is not an antitrust violation. Rather, the key question is whether market power has been obtained, or is being maintained, through improper means. To date, the Commission has not charged a GPO with a violation of the antitrust laws. Nonetheless, we will continue to monitor competition among GPOs as well as the markets for the products that hospitals purchase through them.

What do DOJ and FTC do to encourage regulations in service of competition by other federal agencies?

Both of your agencies have a set of tools for encouraging and facilitating competition. I see it as part of our job to ensure you use those tools fully. That means you must block mergers where appropriate, prosecute criminal conduct when it occurs, and when all else fails break up companies that have grown too large and dominant.

But even if DOJ and the FTC do everything under the antitrust laws, we are not left with perfect markets. Competition is not like a light switch that is either on or off. Even when companies are not strict monopolies, they may lack adequate incentives to serve consumers. If consumers do not have the tools they need to pick the best product, market forces will not fully maximize consumer wellbeing.

It is my view that other federal agencies routinely promulgate regulations that have important implications for competition. DOJ and the FTC can help build high-functioning markets by working with other agencies to ensure that rulemaking is done with an eye to competition.

a. What do your respective agencies do to encourage other federal agencies to encourage competition?

b. In your view, can rulemaking by agencies play an important role in building competitive markets?

The FTC's jurisdiction over both competition and consumer protection, and our advocacy, consumer education, and research, enable the Commission to promote the proper functioning of competitive markets by contributing to a range of rulemakings and policy proposals from other federal agencies. The FTC's contributions to other agencies are both formal, through comments filed in rulemaking proceedings, and informal, through regular engagement with another agencies.

Comments provided to agencies by the FTC's antitrust experts are intended to ensure that those agencies consider the impact of their rules and policies on competition. We emphasize that, depending on the context, agency rules can both facilitate or harm competition, and we consistently advocate for policies that promote competition. In recent years, for example, FTC staff have filed numerous competition advocacy comments with other federal agencies, including the FDA regarding its draft guidance addressing nonproprietary names for biological products (October 2015),[12] and, jointly with DOJ, the U.S. Patent and Trademark Office regarding its initiative to increase patent quality (May 2015).[13]

[12] Comment of the Staff of the Federal Trade Commission Submitted to the Food and Drug Administration In Response to a Request for Comments on Its Guidance for Industry on the Nonproprietary Naming of Biological Products; Draft Guidance for Industry; Availability (Oct. 27, 2015), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-submitted-food-drug-administration-response-fdas-request-comments-its-guidance/151028fdabiosimilar.pdf.

[13] Comments of the United States Federal Trade Commission and the United States Department of Justice Before the Department of Commerce Patent and Trademark Office In the Matter of Request for Comments on Enhancing Patent Quality (May 6, 2015), https://www.ftc.gov/system/files/documents/advocacy_documents/comment-united-states-federal-trade-commission-united-states-department-justice-united-states/150507ptocomment.pdf.

Comments provided to other agencies by our consumer protection staff also support competition and well-functioning markets by seeking to ensure that consumers have access to truthful, non-deceptive information upon which to base their choices in the marketplace. For example, FTC staff recently recommended that the FDA reconsider the framework it uses to regulate homeopathic medicines because it may appear to conflict with the FTC's advertising substantiation doctrine in ways that could harm consumers and cause confusion.[14]

In addition to our formal engagement, the FTC works to cultivate and deepen our relationships with sister agencies to generate opportunities for informal competition advocacy. Staff at other agencies often consult with FTC staff when new regulations and policies are being developed to solicit our competition expertise and input at early stages. As a result, when proposed regulations are formally promulgated, they may already reflect our competition advice.

One notable example of this effort was the creation of Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs) under the Affordable Care Act. The FTC, together with our counterparts from DOJ, worked closely with HHS and other agencies as they formulated the MSSP ACO implementing regulations to ensure that certain regulatory choices were consistent with longstanding FTC enforcement policies regarding clinically integrated health care organizations. On the same day HHS announced its proposed regulations, the antitrust agencies jointly issued a proposed antitrust enforcement policy statement regarding commercial conduct by ACOs participating in the MSSP program.[15]

Occasionally, we also arrange staff "details" to and from our sister agencies, which help the FTC to promote greater understanding of competition policy and principles. Details to the Centers for Medicare and Medicaid Services and from the Office of the National Coordinator for Health Information Technology have been particularly useful in recent years.

[14] FTC Staff Comment Before the Food and Drug Administration Regarding the Current Use of Human Drug and Biological Products Labeled As Homeopathic, and the FDA's Regulatory Framework For Such Products, 80 Fed. Reg. 16327 (Mar. 27, 2015), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-food-drug-administration-regarding-current-use-human-drug-biological-products/150821fdahomeopathic.pdf.

[15] Statement of Antitrust Enforcement Policy Statement Regarding Accountable Care Organizations Participating In the Medicare Shared Savings Program, 76 Fed. Reg. 67026 (Oct. 2011), https://www.ftc.gov/policy/federal-register-notices/ftc-doj-enforcement-policy-statement-regarding-accountable-care.