

A Return To Republican Antitrust Policies For Pharma

By **Seth Silber, Jeff Bank and Brendan Coffman, Wilson Sonsini Goodrich & Rosati PC**

Law360, New York (January 24, 2017, 1:09 PM EST) --

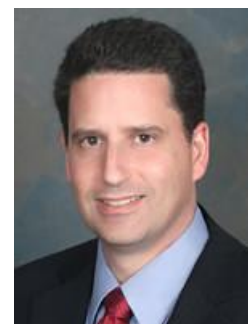
Every four or eight years, seasoned attorneys break out their tarot cards and tea leaves and offer predictions about the enforcement and policy intentions of a new regime. This time is no different — except, perhaps, for the fact that most of these opinion pieces are ending with an emphatic “who knows?” And until we know who President Trump selects to put at the helm of the U.S. Department of Justice’s Antitrust Division and the Federal Trade Commission, many articles focusing on the future of antitrust enforcement are concluding with a similarly cloudy forecast.

However, when it comes to antitrust policies regarding pharmaceuticals, we see a bit more clarity as to the administration’s plans. While a rollback to past Republican agendas appears to already be in the works in some areas, on certain issues — notably, pharmaceutical pricing — Trump may bend a bit more toward populism and increase the growing pressure on both branded and generic companies.

The role of antitrust law in the pharmaceutical industry has significantly increased over the last eight years. Mergers and acquisitions have been subject to closer scrutiny, the FTC and state attorneys general have strategically targeted certain practices by brands and generics alike, and civil plaintiffs have extracted billions of dollars in litigations following government investigations.

In many respects, a return to past Republican policies might give pharmaceutical companies a bit of relief. For example, former Republican FTC Commissioner Joshua Wright[1] and former Bush Deputy Assistant Attorney General for Antitrust David Hight[2] have been key players on the transition team on antitrust. Both have pro-market reputations, and have long counseled restraint when it comes to merger enforcement. The FTC will lose its chairwoman on Feb. 10 when Edith Ramirez (a Democrat) steps down, leaving current Republican Commissioner Maureen Ohlhausen as the most likely candidate for chairwoman, at least temporarily, and perhaps permanently. Commissioner Ohlhausen’s position on disgorgement, which she has called an “extraordinary remedy” that is “a significant departure from the agency’s traditional reliance on its cease-and-desist authority in antitrust cases,”[2] may be one indication of future enforcement priorities.

However, the picture is not altogether rosy for pharmaceutical companies. DOJ cartel



Seth Silber



Jeff Bank



Brendan Coffman

enforcement across the board has ramped up in the past decade, and the DOJ's investigation of the generic pharmaceutical industry has certainly gained attention over the last two years. This ongoing investigation is unlikely to stop, even with new management coming to the DOJ. And it may be that the administration will support the agencies' continued focus on certain other practices raising competition concerns, given the pressure to reduce pharmaceutical prices. If the current climate remains, conduct that can cause price increases, such as "risk evaluation and mitigation strategy"[3] abuse, product-hopping, and sham patent listings, will still be carefully scrutinized. Trump himself has specifically called out this area, accusing pharmaceutical companies of "getting away with murder"[4] with their pricing and expressing a commitment to "bring down drug prices,"[5] suggesting aggressive enforcement.

As tempting as it is to begin and end this article with a noncommittal shrug, we instead believe real guidance can be offered to the pharmaceutical industry. This article begins by reviewing past changes in administration and how antitrust enforcement has been impacted. We then discuss the significance of leadership appointments for antitrust jurisprudence, using the Bush administration as an example in which overall enforcement decreased, but particular areas of interest — including pharmaceuticals — continued to see significant attention. Finally, we review several current issues in pharmaceutical antitrust, and offer projections as to Trump's enforcement priorities.

Historical Differences Between Democratic and Republican Administrations

It is typical to expect a seismic shift upon an administration change, but the data suggests this assumption is somewhat misguided. The "federal budget for antitrust enforcement has increased steadily and substantially since the first Bush administration,"[6] indicating a steady commitment to enforcement despite administration changes. Consistency at the staff level at the DOJ and FTC also lends stability to the agencies that is never completely undone by the politically appointed management. However, steady budgets and staff are not the end of the story; overall enforcement does tend to dip under Republican presidents and rise again under Democrats.

The simple exercise of looking at the number of cases filed, or mergers blocked, or the amount of monetary penalties obtained may not be an effective tool in assessing the strength or weakness of an administration's antitrust platform.[7] Rather, an analytical deep dive is necessary to parse out which areas might be ripe for increased enforcement, especially in the new Trump regime. It may well be the case that the volume of antitrust cases decreases, but the FTC and DOJ nonetheless impact the pharmaceutical industry through policy initiatives and targeted enforcement on certain issues.

Leadership Decisions Are Signals of Enforcement Priorities

In 2000, after eight years of economic growth under President Clinton, experts braced for the incoming President George W. Bush and predicted diminished antitrust enforcement. Opinions ranged from the relatively benign ("[what] big companies hope for is a change in antitrust policy"[8]) to the alarmist ("[Bush's nominees for antitrust leadership] herald a radical shift in the enforcement of America's antitrust laws: Under the Bush administration, there may not be any.")[9] While everyone correctly forecasted a lower volume of cases brought by the government, few anticipated that Bush-era antitrust initiatives would have a substantial impact on particular areas of anti-competitive concern, but that is what happened. President Bush's selection for head of the FTC, Tim Muris, epitomized this surgical approach, and presents a playbook that we may see unfold under the Trump administration.

Pharmaceutical Antitrust Enforcement Under George W. Bush

Chairman Muris placed renewed emphasis on the intersection of antitrust and intellectual property, dramatically increased the FTC's attention to competition in the health care sector, and increased the agency's use of administrative litigation.

Muris championed aggressive enforcement and the modernization of antitrust policies despite bringing fewer cases.[10] In testimony before the Senate Committee on Commerce, Science and Transportation in April 2002, he characterized the FTC's agenda as "efforts to ensure efficient operation of the Hatch-Waxman process directly through vigorous enforcement of the antitrust laws." [11] The following are some examples of where the FTC's enforcement and leadership strategies changed that were both unanticipated and contrary to speculated underenforcement:

- **Pay-for-Delay** — The FTC began investigating pay-for-delay cases during the Clinton administration, and enforcement increased dramatically during Muris' reign, leading to the U.S. Supreme Court's *Actavis* decision in 2013.
- **Regulatory Abuse** — Chairman Muris coined the phrase "second generation litigation" as a catch-all for the FTC's efforts to curb unilateral strategies to abuse the Hatch-Waxman process. In particular, the FTC focused on improper Orange Book listings that delayed generic entry by triggering an automatic 30-month stay. The FTC filed an amicus brief in civil litigation[12] challenging this conduct, providing the FTC a platform to shape policy without enduring the expense of litigation. The FTC also investigated and settled an action against Biovail relating to its acquisition and subsequent wrongful listing of a patent in the Orange Book.[13]
- **Noerr-Pennington and State Action Doctrines** — Shortly after becoming chair, Muris conducted internal studies of both Noerr-Pennington cases as well as state-action cases to ensure that the FTC had a comprehensive understanding of the state of the law,[14] including a Noerr-Pennington Task Force in June 2001.[15] This approach allowed the FTC to respond when opportunities arose to influence the relevant doctrines, including statements to state legislatures on pending bills,[16] amicus briefs in pending cases in other jurisdictions,[17] and, when necessary, the filing of FTC complaints.[18]
- **Non-Pay-for-Delay Agreements** — In addition to pay-for-delay agreements, the FTC also investigated other potentially anti-competitive agreements between drug companies. For instance, the FTC scrutinized an agreement between the only two generic over-the-counter children's ibuprofen manufacturers, Perrigo Co. PLC and Alpharma Inc. The FTC found that Alpharma agreed not to compete with Perrigo in exchange for a payment and royalties on Perrigo's sales.[19] The parties eventually settled the FTC's charges, agreeing to disgorge \$6.25 million in illegally obtained profits. Notably, this was the FTC's first application of its 2003 policy statement on monetary equitable remedies in competition cases, which identified the circumstances under which the commission could appropriately seek disgorgement.[20]
- **FTC Policy Studies** — Chairman Muris expended significant efforts on the FTC's role as an educational and research-focused agency and directed the agency "to hold public hearings, conduct studies, and issue reports to Congress and the public." [21] Muris undertook an "industry-wide study of generic drug competition" that examined the potential for companies to exploit the 180-day exclusivity and 30-month stay provisions of Hatch-Waxman.[22] Published in 2002, the study led to the U.S. Food and Drug Administration enacting a rule in 2003 that permitted only one automatic 30-month stay per abbreviated new drug application.[23] Under

Muris, the FTC “endeavor[ed] to ensure that the careful Hatch-Waxman balance — between promoting innovation and speeding generic entry — [was] scrupulously maintained.”[24]

Likely Pharmaceutical Antitrust Agenda in the Trump Administration

On balance, we expect the change in pharmaceutical antitrust enforcement from the Obama administration to the Trump administration will most likely resemble that of the Bush administration vis-a-vis the Clinton administration — a continued focus on enforcing antitrust laws, but a decrease in volume in exchange for enhanced attention on specific regulatory objectives. The following are several areas where we may observe changes in current antitrust enforcement priorities.

Monopolization

Over the past eight years, the antitrust agencies (and the FTC in particular) have pursued or supported monopolization cases against branded pharmaceutical companies. These efforts include two amicus briefs in support of a private product-hopping case;[25] an amicus brief in support of a generic pharmaceutical plaintiff alleging REMS;[26] and an amicus brief expressing the opinion that a brand pharmaceutical manufacturer’s conduct before a private standard-setting organization is not protected First Amendment speech under the Noerr-Pennington doctrine.[27]

The new administration likely will continue to focus on monopolization cases that pertain to abuse of regulatory processes (e.g., REMS and SSOs), but may be less likely to investigate or bring cases where the brand’s primary defense is a harm to innovation through over-regulation (e.g., product hopping). For instance, Commissioner Ohlhausen voted against the FTC’s product-hopping amicus brief, perhaps foreshadowing a Republican-led FTC’s reluctance to pursue this issue. On the other hand, former Commissioner and Trump transition team member Joshua Wright voted against the FTC’s REMS-abuse amicus brief, while Commissioner Ohlhausen voted in favor of this brief. Thus, while there may be some rollback on pharmaceutical monopolization cases, we will have to wait for Trump to select the new leader of the FTC (and fill the other two commissioner vacancies at the FTC) to see what the FTC will do in the future.

Pay-for-Delay

Pay-for-delay enforcement has remained vigorous during the Obama presidency, culminating with the FTC obtaining a disgorgement of \$1.2 billion from Teva Pharmaceuticals Inc. (formerly Cephalon) in April 2015. Less than a year ago, the FTC filed another high-profile pay-for-delay case against Endo Pharmaceuticals Inc. alleging that it conspired with Impax Laboratories Inc., Teikoku Seiyaku Co. Ltd. and Watson Laboratories Inc. to delay generic competition for two different drugs (Lidoderm and Opana). The FTC is seeking disgorgement from all companies. The FTC has also played an active role in private litigation. Over the last eight years, the FTC has submitted amicus briefs in seven pay-for-delay cases and has opined on issues including whether Actavis applies to noncash payments.[28]

Pay-for-delay enforcement will likely remain a priority of the FTC in the Trump administration, but the scope of enforcement may narrow, and the FTC is almost certainly going to back away from pursuing disgorgement. Indeed, shortly after Actavis was announced, then-Commissioner Joshua Wright stated that “[t]he Commission will continue to protect consumers from anticompetitive drug settlements that result in higher drug costs.”[29] Moreover, it may be the case that the FTC adopts a bright-line approach that condemns only a narrow subset of issues currently being raised in pay-for-delay cases. In his

September 2013 remarks, Commissioner Wright hinted at a narrower approach to enforcement in the pay-for-delay area: “For instance, [the FTC] may be able to deduce that reverse payment settlements for a particular class of drug or with particular contractual features are more likely to be anticompetitive than others. This is an area where I believe the Commission should and will continue to put its institutional advantages in research and reporting to good use.”[30] Thus, we may see more limited enforcement, but perhaps continued strategic amicus filings to influence the development of the law in this area.

Although disgorgement has made for big headlines under the Obama-led FTC, it is not expected to play as much of a role in the new administration. Despite Commissioner Ohlhausen’s comments that have significantly critiqued the use of disgorgement, it should not be assumed that the remedy will be completely off the table. Commissioners Ohlhausen and Wright issued a joint statement on the FTC’s decision to pursue disgorgement in Cephalon to explain why they believed disgorgement was appropriate in that limited circumstance — namely, (1) the violation was clear, (2) there was a reasonable basis for calculating the disgorgement, and (3) the value of seeking monetary relief was present or, at the very worst, balanced by the overwhelming nature of the evidence.[31]

Pharmaceutical Price Increases

Pharmaceutical pricing has been a hot topic since Martin Shkreli raised the price of Daraprim and invited Congress to focus its sights on pharmaceutical pricing. In addition to its obvious importance to American consumers, interest in pharmaceutical prices is unique in that it spans both sides of the aisle. President Trump has stated that pharmaceutical companies are “getting away with murder.” Bernie Sanders called for drug companies to report information affecting drug pricing,[32] and two senators introduced a bipartisan bill that would require companies to provide manufacturing and research and development costs, net profits, and marketing and advertising spending for any drug undergoing a 10 percent price increase.[33]

At the urging of Congress, the FTC is investigating drug pricing practices,[34] and the DOJ currently is investigating allegations of collusion within the pharmaceutical industry.[35] However, collusion charges aside, there are significant doubts by antitrust experts as to whether a company’s unilateral decisions to raise prices (no matter how large the increase) should be scrutinized under antitrust law. While the right to make unilateral pricing decisions has long been a foundation of conservative antitrust enforcement, Trump has already shown a willingness to bypass typical conservative economic positions and regulatory norms to negotiate directly with companies, either explicitly or via social media. If political capital or public approval ratings can be gained, Trump may try to directly (or through his antitrust appointees) pressure pharmaceutical companies to reduce prices.

Mergers and Acquisitions

M&A enforcement varies across administrations, but pharmaceutical M&A enforcement typically remains consistent. The nature of pharmaceutical M&A (both for brands and generics) lends itself to somewhat predictable enforcement outcomes, given the often narrow market definitions, the significant lead time required for entry into any market, the important role of intellectual property, and the ability of the FTC to remedy concerns with divestitures.

Take Teva’s recent acquisition of Allergan PLC.[36] The FTC stated that it considered three other potential areas of harm “beyond individual product overlaps,” which is the typical sole analysis in generic mergers. These additional three areas were: (1) whether the combined entity would be likely to

bundle products anti-competitively; (2) whether the combined entity would have a decreased incentive to challenge patents held by brands in Hatch-Waxman patent litigation; and (3) whether the merger “might dampen incentives to develop new generic products.” Notwithstanding this expansive probe, the FTC found the merger unlikely to harm competition, and permitted the transaction to proceed following the divestiture of 75 overlapping products.

M&A policy under President Trump is likely to be permissive, potentially including pharmaceutical deals. However, given Trump’s statements regarding concerns over pharmaceutical pricing and his proclivity to offer his views on specific transactions (e.g., AT&T/Time Warner), he could surprise us with a more populist approach on pharmaceutical mergers.

Conclusion

Pharmaceutical companies will likely view a potential rollback in enforcement under Republican leadership as a welcome change after eight years of increased scrutiny under President Obama. However, certain aspects of Trump’s positions make it more likely that the antitrust agencies will continue to focus on practices that can lower drug prices. Ultimately, while we expect some decrease in enforcement under Trump, history suggests that this decrease will come with a policy-driven agenda that may exchange volume for precision. Furthermore, the possibility remains very real that Trump’s antitrust agency leadership drives enforcement priorities in an unusual and even anti-doctrinal way. Thus, the pharmaceutical industry should watch carefully Trump’s appointments in this area, and then follow the agencies’ actions carefully to see if the change in administration results in modest changes or potentially more dramatic shifts in response to public demand.

Seth Silber is a partner in the Washington, D.C., office of Wilson Sonsini Goodrich & Rosati PC and former adviser to former FTC Chairman Jon Leibowitz. Jeff Bank is of counsel in the firm's New York office and previously practiced at the FTC's Health Care Division. Brendan Coffman is an associate in the firm's Washington office.

The opinions expressed are those of the author(s) and do not necessarily reflect the views of the firm, its clients, or Portfolio Media Inc., or any of its or their respective affiliates. This article is for general information purposes and is not intended to be and should not be taken as legal advice.

[1] Josh Wright is currently of counsel in the Washington, D.C., office of Wilson Sonsini Goodrich & Rosati and is affiliated with the authors of this article.

[2] Separate Statement of Commissioners Maureen K. Ohlhausen and Joshua D. Wright, Fed. Trade Comm'n v. Cephalon, Inc., File No. 061-0182 (F.T.C. May 28, 2015), available at https://www.ftc.gov/system/files/documents/public_statements/637781/150420cardinalhealthcomstmt.pdf.

[3] REMS abuse is a catch-all phrase for the exploitation of procedures intended to ensure the safe distribution of certain prescription drugs by brand drug companies to thwart generic competition. See FTC Amicus Brief, Mylan Inc. v. Celgene Corp, June 17, 2014, Case No. 2:14-CV-2094 (D.N.J.), available at <https://www.ftc.gov/policy/advocacy/amicus-briefs/2014/06/mylan-pharmaceuticals-inc-v-celgene-corporation>.

[4] Caroline Humer & Rodrigo Campos, “Trump says pharma 'getting away with murder,' stocks slide,”

Reuters (Jan. 11, 2017) available at <http://www.reuters.com/article/us-usa-trump-drugpricing-idUSKBN14V24J>.

[5] Michael Scherer, “2016 Person of the Year Donald Trump,” Time (Dec. 7, 2011) available at <http://time.com/time-person-of-the-year-2016-donald-trump/>.

[6] Ronan P. Harty, Howard A. Shelanski, & Jesse Solomon, Merger Enforcement Across Political Administrations in the United States, *Competition Law Journal* (2012). Notably, co-author Howard Shelanski was the head of the Office of Information and Regulatory Affairs, the United States Government’s central authority for the review of Executive Branch regulations and approval of Government information collections, under President Obama.

[7] See generally, William Kovacic, Rating the Competition Agencies: What Constitutes Good Performance?, 16 *Geo. Mason L. Rev.* 903, 904 (2009).

[8] Tom Hamburger, Laurie McGinley, and David S. Cloud, Corporate Donors Seek Return on Investment in Bush Campaign, *The Wall Street Journal* (Mar. 6, 2001), <http://www.wsj.com/articles/SB983833353790355901>.

[9] John B. Judis, Trust Walk, *New Republic* (June 11, 2001).

[10] Thomas B. Leary, The Muris Legacy, *The Antitrust Source*, (Nov. 2004).

[11] Chairman Timothy Muris, Testimony before the Senate Committee on Commerce, Science, and Transportation, April 23, 2002, available at https://www.ftc.gov/sites/default/files/documents/public_statements/prepared-statement-federal-trade-commission-pharmaceutical-industry/pharmtestimony.pdf [hereinafter “Muris Senate Testimony”].

[12] *In re Buspirone Antitrust Litig.*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002).

[13] *In the Matter of Biovail Corporation*, Fed. Trade Comm’n, <https://www.ftc.gov/enforcement/cases-proceedings/011-0094/biovail-corporation>.

[14] Thomas B. Leary, “The Muris Legacy,” available at https://www.ftc.gov/sites/default/files/documents/public_statements/muris-legacy/041206murislegacy.pdf.

[15] Muris Senate Testimony at 5.

[16] See, e.g., FTC/DOJ Letter to the Standing Committee on the Unlicensed Practice of Law, State Bar of Georgia (Mar. 20, 2003), available at https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-and-department-justice-comment-georgia-state-bar-standing-committee-unlicensed-practice-law/v030007.pdf.

[17] See, e.g., FTC as amicus curiae, *Jackson, Tennessee Hospital Co. v. West Tennessee Healthcare, Inc.*, available at https://www.ftc.gov/sites/default/files/documents/amicus_briefs/jackson-tennessee-hospital-co.v.west-tennessee-healthcare-inc/040604jacksonhospitalamici.pdf.

[18] See, e.g., *Union Oil Company of California*, FTC Docket No. 9305 (Mar. 4, 2003) (complaint),

available

at <https://www.ftc.gov/sites/default/files/documents/cases/2003/03/030304unocaladmincmplt.pdf>.

[19] Complaint, FTC v. Perrigo Co. and Alpharma, Inc., No. 1: 04CV01397 (RMC), at 8-10 (D.D.C. Aug. 12, 2004), available

at <https://www.ftc.gov/sites/default/files/documents/cases/2004/08/040812comp0210197.pdf>.

[20] Press Release, F.T.C., Generic Drug Marketers Settle FTC Charges (Aug. 12, 2004), available

at <https://www.ftc.gov/news-events/press-releases/2004/08/generic-drug-marketers-settle-ftc-charges>.

[21] Testimony of Timothy J. Muris, Before the Subcomm. On Antitrust, Competition, and Business and Consumer Rights of the Senate Judiciary Comm., 107th Cong. 957 (2002); Thomas B. Leary, The Muris Legacy, The Antitrust Source, (Nov. 2004).

[22] Press Release, F.T.C., Muris Testifies on Competition in the Pharmaceutical Industry (Apr. 23, 2002), available at <https://www.ftc.gov/news-events/press-releases/2002/04/muris-testifies-competition-pharmaceutical-industry>.

[23] Application for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying that a Patent Claiming a Drug is Invalid or Will not be Infringed, 68 Fed. Reg. 36675 (2003); The FTC's Enforcement Initiative Against Improper "Orange Book" Listings in the Pharmaceutical Industry, F.T.C. Committee Newsletter, Fall 2003, at 4.

[24] Press Release, F.T.C., Muris Testifies on Competition in the Pharmaceutical Industry (Apr. 23, 2002), available at <https://www.ftc.gov/news-events/press-releases/2002/04/muris-testifies-competition-pharmaceutical-industry>.

[25] Federal Trade Commission as amicus curiae, Mylan Pharma. v. Warner Chilcott, 2012 WL 7649225 (E.D. Pa. Dec. 3, 2012) (No. 12-3824), available at https://www.ftc.gov/sites/default/files/documents/amicus_briefs/mylan-pharmaceuticals-inc-et-al.v.warner-chilcott-public-limited-company-et-al./121127doryxamicusbrief.pdf; Brief for Amicus Curiae Federal Trade Commission Supporting Plaintiff-Appellant, 2015 WL 6157989 (3rd Cir. Sep. 30, 2015) (No. 15-2236), available at https://www.ftc.gov/system/files/documents/amicus_briefs/mylan-pharmaceuticals-inc.v.warner-chilcott-plc-et-al./151001mylanamicusbrief.pdf.

[26] Federal Trade Commission's Brief as Amicus Curiae, Mylan v. Celgene, (D.N.J. Jun. 17, 2014) (No. 2:14-CV-2094-ES-MAH), available at https://www.ftc.gov/system/files/documents/amicus_briefs/mylan-pharmaceuticals-inc.v.celgene-corporation/140617celgeneamicusbrief.pdf.

[27] Brief of Amicus Curiae Federal Trade Commission in Support of Neither Party and in Favor of Reversal, Amphastar Pharma., Inc. v. Int'l Medication Sys., (1st Cir. Nov. 7, 2016) (No. 16-2113), available at https://www.ftc.gov/system/files/documents/amicus_briefs/amphastar-pharmaceuticals-inc-et-al-v-momenta-pharmaceuticals-inc-et-al/161108amphastar_v_momentaftc_amicus_brief_.pdf.

[28] Amicus Briefs, Federal Trade Commission, <https://www.ftc.gov/policy/advocacy/amicus-briefs>.

[29] Joshua D. Wright, Comm'r, Fed. Trade Comm'n, FTC v. Actavis and the Future of Reverse Payment Cases, Remarks at the Concurrences Journal Annual Dinner (Sept. 26, 2013), available

at http://www.ftc.gov/sites/default/files/documents/public_statements/ftc-v.actavis-future-reverse-payment-cases/130926actavis.pdf.

[30] Id.

[31] Separate Statement of Commissioners Maureen K. Ohlhausen and Joshua D. Wright, Fed. Trade Comm'n v. Cephalon, Inc., File No. 061-0182 (F.T.C. May 28, 2015), available at https://www.ftc.gov/system/files/documents/public_statements/637781/150420cardinalhealthcomstmt.pdf.

[32] Fighting to Lower Prescription Drug Prices, Bernie Sanders, <https://berniesanders.com/issues/fighting-to-lower-prescription-drug-prices/>.

[33] H.R.6043 - Fair Accountability and Innovative Research Drug Pricing Act of 2016, available at <https://www.congress.gov/bill/114th-congress/house-bill/6043>.

[34] Letter from Sen. Bernard Sanders and Sen. Elijah Cummings to Edith Ramirez, Chairwoman of the Fed. Trade Comm., Nov. 3, 2016, available at <http://www.sanders.senate.gov/download/sanders-cummings-letter-to-doj-ftc-on-insulin?inline=file>.

[35] Peter Loftus, Brent Kendall & Christopher M. Matthews, "Generic-Drug Firms Face Possible Collusion Charges," Wall Street Journal (Nov. 3, 2016), available at <http://www.wsj.com/articles/generic-drug-makers-shares-drop-on-report-of-possible-probe-1478209036>.

[36] Statement of the Fed. Trade Comm'n, In the matter of Teva Pharmaceuticals Industries Ltd. And Allergan plc, File No. 151-0196 (F.T.C. July 27, 2016), available at https://www.ftc.gov/system/files/documents/public_statements/973673/160727tevaallergan-statement.pdf.