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November 14, 2011

The Honorable John Seeba
Inspector General
Federal Trade Commission
Office of the Inspector General
Room 1110
600 Pennsylvania Ave., N.W.
Washington, DC 20580

Via email to: oig@ftc.gov
Hard Copy Via U.S. Mail

RE: Investigation of Prohibited Lobbying

Dear General Seeba:

I write today to bring to your attention a matter requiring further investigation. This matter involves the officers and consultants of the Federal Trade Commission's (FTC) lobbying Congress in apparent violation of 18 U.S.C. § 1913.

Relevant Authority

The U.S. Code at 18 U.S.C. § 1913 states as follows:

> No part of the money appropriated by any enactment of Congress shall, in the absence of express authorization by Congress, be used directly or indirectly to pay for any personal service, advertisement, telegram, telephone, letter, printed or written matter, or other device, intended or designed to influence in any manner a Member of Congress, a jurisdiction, or an official of any government, to favor, adopt, or oppose, by vote or otherwise, any legislation, law, ratification, policy, or appropriation, whether before or after the introduction of any bill, measure, or resolution proposing such legislation, law, ratification, policy, or appropriation; but this shall not prevent officers or employees of the United States or of its departments or agencies from communicating to any such Member or official, at his request, or to Congress or such official, through the proper official channels, requests for any legislation, law, ratification, policy, or appropriations which they deem necessary for the efficient conduct of the public business, or from making any communication whose prohibition by this section might, in the opinion of the Attorney General, violate the Constitution or interfere with the conduct of foreign policy, counter-intelligence, intelligence, or national security activities. Violations of this section shall constitute violations of section 1352(a) of title 31.

While there are some exceptions, the general rule as set forth in this section is clear: appropriations made by Congress shall not be disbursed for the purpose of lobbying Congress.

Facts

The following examples show clearly that the FTC's Chairman, Jon Leibowitz, has been actively lobbying Congress seeking legislation to prohibit payments from branded drug companies to generic companies in settlements during patent litigation. Further, at least one "consultant" of the FTC, Professor C. Scott Hemphill has actively used his position to advocate for these changes as well. Consider the following examples.

On June 26, 2006, the Supreme Court refused to consider the FTC's appeal to reinstate its charges that Schering-Plough entered into an illegal patent settlement with generic competitors. In response, Leibowitz said that the FTC would hold out hope that the high court would agree to hear a similar appeal or that Congress would move to ban the practice outright.

> "The U.S. Supreme Court on Monday dealt a setback to U.S. antitrust authorities, refusing to consider their appeal to reinstate charges that drug maker Schering-Plough illegally paid generic competitors to stay out of the market...'Obviously, we're disappointed that the Supreme Court chose not to accept (the appeal),' FTC commissioner Jon Leibowitz said in a statement. Leibowitz held out hope that the high court would agree to hear a similar appeal by the FTC in future, or that Congress would move to ban the practice outright." (June 26, 2006 Reuters News.)

On July 20, 2006, FTC Commissioner Jon Leibowitz spoke before the U.S. Senate's Special Committee on Aging. In his testimony, Leibowitz said, despite Congress's success in working to ensure access to generic drugs, "there have been, and continue to be, competitive problems in pharmaceutical markets."

> "Testifying today on behalf of the Federal Trade Commission before the U.S. Senate's Special Committee on Aging, Commissioner Jon Leibowitz described the FTC's work in the area of branded and generic pharmaceutical competition and discussed barriers that can lead to the delay of generic entry into the U.S. marketplace. Despite the Congress's 'remarkable record of success' in working to ensure that consumers gain access to generic drugs as quickly as possible, he said 'there have been, and continue to be, competitive problems in pharmaceutical markets.'" (July 20, 2006 US Fed News.)

> "The economic implications of the agreements are 'staggering,' FTC Commissioner Jon Leibowitz told a hearing by the Senate Special Committee on Aging. Leibowitz noted that consumers and health plans spend over $100 billion a year on prescription drugs, and that generics can shave up to 80 percent off the cost of a prescription drug — if they can get on the market." (July 20, 2006 CQ Healthbeat.)

> "The testimony next addressed how patent litigation settlements can delay generic drug entry. It discussed the types of patent settlements that the Commission believes are anticompetitive - presenting possible legislative solutions to this problem - as well as how

> brand-name pharmaceutical manufacturers have used the 180-day marketing exclusivity period granted by Hatch-Waxman for generic first-filers to block generic entry. It also discussed how recent Court of Appeals rulings may have led to companies entering into more of such settlements. "In the current fiscal year, we have seen significantly more settlements with payments and restriction of entry - seven of ten agreements between brand-name and generic companies included a payment from the brand-name to the generic company and an agreement to defer generic entry," the testimony stated, citing the most recent information on such settlements provided to the Commission. Continuing, the testimony reviewed the antitrust implications of agreements entered outside the context of patent litigation, discussing the FTC's ongoing litigation against Warner-Chilcott and Barr Laboratories regarding the Ovcon oral contraceptive, and its enforcement actions against agreements between generic companies that delay generic entry and competition." (July 20, 2006 US Fed News.)

Also in his July 20, 2006 testimony, Leibowitz said legislation "could provide a swifter, and a more comprehensive" approach to ending brand and generic settlements and that the FTC would "continue to be vigilant in looking for ways to challenge anticompetitive settlements."

> "Leibowitz said legislation 'could provide a swifter, and a more comprehensive' approach to ending the payoffs than waiting for another chance to obtain Supreme Court review. FTC strongly supports the intent of Kohl's bill, S 3582, but added that 'drafting such a measure is challenging, so we're happy to work with you as the bill moves forward.'" (July 20, 2006 CQ Healthbeat.)

> "The FTC is trying to bring a case that will split circuit court opinion and force the Supreme Court to address the issue of "reverse payment" settlements between brand and generic drugmakers, FTC Commissioner Jon Leibowitz said at a hearing on Capitol Hill July 20. However, Leibowitz acknowledged during the hearing held by the Senate Special Committee on Aging that legislation would be a much quicker way to address the problem...In reverse payment agreements, a brand drugmaker pays a generic drugmaker to delay marketing its generic version of a brand drug (DID, June 27). Now, the FTC is 'looking to find cases so we can create, for example, a split in the courts' to push the Supreme Court to consider the issue, Leibowitz said. 'We'll continue to be vigilant in looking for ways to challenge anticompetitive settlements, and I hope the Supreme Court will eventually weigh in on this problem,' Leibowitz said, but added that legislation could provide a swifter and more comprehensive approach. 'Litigating another case to conclusion will take years and provide little relief for those consumers harmed in the interim,' he said." (July 24, 2006 Drug Industry Daily.)

On January 17, 2007, Senator Herb Kohl reintroduced the "Preserve Access to Affordable Generics Act" to outlaw pay-for-delay settlements. On the same day, Leibowitz testified before the Senate Judiciary Committee panel called, "Paying Off Generics to Prevent Competition with Brand Name Drugs: Should it Be Prohibited?"

> "In the meantime Congress has stepped in. On Jan. 17, Senator Herb Kohl (D-Wisconsin) proposed a bill that would make it "unlawful" for a settlement between a drug patent holder

> and a generic challenger to "include an exchange of anything of value." Expect major pushback from both generic companies and the notoriously powerful Big Pharma lobby." (February 5, 2007 Fortune.)
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> "The FTC is lobbying for the proposal as it seeks to challenge such settlements in court, either through its own lawsuits or in support of private suits. Leibowitz today told the panel that Congress may act more quickly than the courts." (January 17, 2007 Susan Decker Bloomberg.)
>
> "Commissioner Jon Leibowitz, once a lawyer on the staff of the Senate Judiciary Committee, is scheduled to testify before that panel Wednesday as the senators consider the topic 'Paying Off Generics to Prevent Competition with Brand Name Drugs: Should it Be Prohibited?'" (January 15, 2007 TheDeal.com.)
>
> "The Supreme Court denied the FTC's writ of certiorari last summer after the DOJ recommended against it. In response, a handful of senators introduced legislation that would ban the practice of reverse payments (DID, June 27, 2006). The bill was reintroduced this year as S. 316 and H.R. 1432, the Preserve Access to Affordable Generics Act. In addition to the Preserve Access to Affordable Generics Act, Rep. Bobby Rush (D-Ill.) has introduced the Protecting Consumer Access to Generic Drugs Act of 2007, H.R.1902. At a House subcommittee hearing last month, Leibowitz called the bill a 'fundamentally sound approach to eliminate the pay-for-delay settlement tactics'" (June 25, 2007 Drug Industry Daily.)

In his testimony, Leibowitz said, "it is critical to eliminate" pay-for-delay settlements. He also said that legislation banning pay-for-delay settlements would be a "swifter, more certain and more comprehensive solution," than allowing the lawfulness of settlements to be determined in court.

> "But the FTC's Leibowitz said it's better for Congress to draw a bright line on what's allowed because that would be a 'swifter, more certain and more comprehensive solution," than allowing the settlements to be hashed out in the legal system'." (February 8, 2007 Indianapolis Star.)
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> "'It is critical to eliminate the pay-for-delay settlement tactics employed by the pharmaceutical industry,' FTC Commissioner Jon Leibowitz recently told the Senate Judiciary Committee. 'Companies should not be able to play 'deal or no deal' at the expense of American consumers'." (February 8, 2007 Maureen Groppe Indianapolis Star.)

On May 2, 2007, Leibowitz told members of the House Subcommittee on Commerce, Trade and Consumer Protection that the FTC is firmly behind a bill aimed at stopping reverse patent settlements calling it "fundamentally sound." Leibowitz also said that the FTC will "look forward to continuing to work with [congress] to ensure that the legislation effectively bars anticompetitve agreements."

> "FTC commissioner Jon Leibowitz told lawmakers Wednesday that the Federal Trade Commission is firmly behind a bill aimed at cracking down on payments made by brand-

name pharmaceutical companies to generic drug makers to stay out of a particular market. Calling the bill 'fundamentally sound,' Leibowitz said that a legislative approach to resolving the issue would be the 'quickest and cleanest' way to outlawing many of these types of payments. The Democratic commissioner was testifying before a hearing of the House Subcommittee on Commerce, Trade and Consumer Protection looking at the merits of the Protecting Consumer Access to Generic Drugs Act. 'These developments threaten substantial harm to consumers and others who pay for prescription drugs,' said Leibowitz in his opening statement. 'For that reason, the commission commends your efforts to prohibit these anticompetitive settlements.'...Leibowitz was asked by Rush what would happen if the legislation failed. He responded that the FTC would continue to pursue enforcement action, but that 'there will be more and more of these deals, and they're going to push out the entry of the first generic drug maker into the market.' The commissioner said that he thought a legislative change was the best approach, rather than for the courts to make a precedent ruling in the area." (May 2, 2007 Dow Jones News Service.)

"During the hearing, FTC Commissioner Jon Leibowitz testified that HR 1902 'represents a fundamentally sound approach to eliminating the exclusion payment problem- We look forward to continuing to work with you to ensure that the legislation effectively bars anticompetitive agreements but allows exceptions for those agreements that do not harm competition'" (May 07, 2007 The Pink Sheet.)

Scott Hemphill is Professor of Law at Columbia Law School. In May 2007, Hemphill testified before the House Commerce, Trade, and Consumer Protection Subcommittee in favor of the patent settlements bill along with Leibowitz.

"SPONSOR: House Energy and Commerce Committee AGENDA: Commerce, Trade, and Consumer Protection Subcommittee hearing on H.R.1902, the "Protecting Consumer Access to Generic Drugs Act of 2007." WHO: Jon Leibowitz, commissioner of the Federal Trade Commission; Scott Hemphill, associate professor of law at the Columbia University Law School; Barry Sherman, CEO of Apotex, Inc.; Michael Wroblewski, project director at the Consumer Education and Outreach Consumers Union; Phillip Proger, partner at Jones Day; and Theodore Whitehouse, partner at Willkie Farr and Gallagher, testify DATE: May 2, 2007 LOCATION: 2123 Rayburn House Office Building" (May 2, 2007 Washington Daybook.)

"Mr. Scott – C. Scott Hemphill, J.D., is an associate professor of law at the Columbia University Law School. Professor Hemphill has devoted considerable academic work to the issue of exclusion payments and agreements and will testify in favor of the bill." (Source: May 2, 2007, Transcript, Hearing on H.R. 1902, Protecting Consumer Access to Generic Drug Act of 2007.)

"The pay-for-delay settlement problem appears to be worsening, as courts continue to decline to prohibit the settlements and as settlements evolve in a direction that makes effective judicial intervention increasingly unlikely. Congress has a vital role to play in establishing a broad prohibition of anticompetitive settlements, while maintaining agency flexibility to recognize exceptions where they are practically justified." (Source: May 2, 2007, Testimony

of C. Scott Hemphill before the House Committee on Energy and Commerce Subcommittee on Commerce, Trade, and Consumer Protection.)

At a Pharmaceutical Care Management Association Symposium on June 19, 2007, Michael Kades, attorney advisor to FTC Commissioner Leibowitz, said the FTC is engaged in a two-front assault against reverse payment settlements by pushing the Supreme Court to hear a reverse-payment case and supporting legislation to ban patent settlements.

> "The FTC is engaged in a two-front assault against reverse-payment agreements: pushing the Supreme Court to hear a reverse-payment case and supporting legislation to ban reverse payments, Michael Kades, attorney adviser to FTC Commissioner Jon Leibowitz, said. He spoke at the Pharmaceutical Care Management Association's Pharmacy Benefit Management & Generic Pharmaceutical Issues Symposium June 19...Reverse-payment deals, 'the single most important antitrust issue in the last 50 years,' are becoming more common, Kades said. There were zero such agreements in 2004, three in 2005 and 14 last year. These settlements are meant to evade generic patent challenges, which the generic companies win roughly 70 percent of the time, Kades said. Instead of undergoing patent litigation, the brand company simply pays the generic company not to launch. 'The brand and the generic can always make each other better off,' he said." (June 25, 2007 Drug Industry Daily.)

On February 25, 2008, *The Washington Post* printed an opinion piece by Jon Leibowitz entitled, "This Pill Not To Be Taken With Competition; How Collusion Is Keeping Generic Drugs Off the Shelves." Leibowitz's wife, Ruth Marcus, serves as a member of the editorial board of *The Washington Post*.

> "This Pill Not To Be Taken With Competition; How Collusion Is Keeping Generic Drugs Off the Shelves...Jon Leibowitz...The Federal Trade Commission's approach to stopping these pay-for-delay settlements is twofold. We support the bipartisan legislation to ban such agreements that is moving through both houses of Congress. And until that law is enacted, we are doing everything in our power to end these unconscionable deals. The writer is one of the five members of the Federal Trade Commission." (February 25, 2008 The Washington Post.)

> "Members of the Editorial Board...Ruth Marcus...Editorial Writer, Columnist." (Source: The Washington Post http://www.washingtonpost.com/wp-srv/opinions/writers/editorialboard/index.html) (Accessed: November 14, 2011.)

In his editorial, Leibowitz said that the FTC supports bipartisan legislation to ban pay-for-delay settlements and until the law is enacted, the FTC will do "everything in its power" to end the deals.

> "Jon Leibowitz...The Federal Trade Commission's approach to stopping these pay-for-delay settlements is twofold. We support the bipartisan legislation to ban such agreements that is moving through both houses of Congress. And until that law is enacted, we are doing everything in our power to end these unconscionable deals. The writer is one of the five members of the Federal Trade Commission." (February 25, 2008 The Washington Post.)

> "Jon Leibowitz, Chairman...He lives in Bethesda with his wife, Ruth Marcus, and his two daughters, Emma and Julia." (Source: FTC http://www.ftc.gov/commissioners/leibowitz/index.shtml) (Accessed: November, 14, 2011.)

On March 31, 2009, Columbia Professor Hemphill again appeared before the House Commerce, Trade, and Consumer Protection Subcommittee, voicing opposition to settlements and urging Congress to pass legislation.

> "The following information was released by the U.S. House of Representatives Committee on Energy and Commerce: The Subcommittee on Commerce, Trade, and Consumer Protection will hold a legislative hearing at 11:00 a.m. on H.R. 1706, Protecting Consumer Access to Generic Drugs Act of 2009, on Tuesday, March 31, 2009, in 2123 Rayburn House Office Building...Witness List...The Honorable J. Thomas Rosch, Commissioner, Federal Trade Commission Scott Hemphill, Associate Professor of Law, Columbia University Joanne Handy, Board Member, AARP Diane Beiri, General Counsel, Pharmaceutical Research and Manufacturers of America Dr. Barry Sherman, Chief Executive Officer, Apotex, Inc. Ted Whitehouse, Willkie Farr and Gallagher, On behalf of Teva Pharmaceuticals" (March 27, 2009 States News Service.)

> "I wish to make three points. First, the pay-for-delay settlement problem is large and longstanding. Second, the problem is becoming more difficult, as the forms of settlement continue to evolve. And third, Congress can play a useful role in this area by passing legislation that prohibits settlements that combine payment with delay." (Source: March 31, 2009, Testimony of C. Scott Hemphill Associate Professor, Columbia Law School, Hearing on H.R. 1706, Protecting Consumer Access to Generic Drugs Act of 2009.)

In May 2009 the Columbia Law Review published an article by C. Scott Hemphill that disclosed "The author has consulted with the Federal Trade Commission on the antitrust issues raised by brand-generic patent settlements."

> "C. Scott Hemphill's Scholarly Papers...An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition... Columbia Law Review, 2009, Columbia Law and Economics Working Paper No. 347...C. Scott Hemphill Columbia University - Law School...Posted: 11 Mar 09 Last Revised: 25 Aug 09.." (Source: http://papers.ssrn.com/sol3/cf_dev/AbsByAuth.cfm?per_id=663359) (Accessed: November 14, 2011.)

> "C. Scott Hemphill*...This Article examines the "aggregation deficit" in antitrust:...* Associate Professor and Milton Handler Fellow...and Sannu Shrestha provided outstanding research assistance. The author has consulted with the Federal Trade Commission on the antitrust issues raised by brand-generic patent settlements. Views or errors in this Article are the author's alone." (Source: May 2009, C. Scott Hemphill, Columbia Law Review, An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition)

During a speech at the Center for American Progress in June, Leibowitz told an audience that he saw "encouraging signs in the administration, in the courts, and in congress" that there is growing recognition that pay-for-delay deals should be stopped.

> "'I see encouraging signs in the administration, in the courts, and in Congress. As the evidence mounts, there appears to be growing recognition that pay-for-delay deals should be stopped,' Leibowitz told an audience at the Center for American Progress, a left-leaning think tank." (June 23, 2009 Associated Press.)

On July 31, 2009, the House Energy and Commerce Committee passed its version of healthcare reform by a 31-28 vote after adopting several amendments, including legislation introduced by Representative Bobby Rush that would ban pay-for-delay patent settlements.

> "Last Friday, the House Energy and Commerce Committee favorably reported its version of 'America's Affordable Health Choices Act' (H.R. 3200) by a 31-28 vote after adopting several amendments. A copy of the bill and amendments are available here. Importantly, the committee agreed to amendments sponsored by Representatives Anna Eshoo (D-CA) (by a 47-11 vote) and Bobby Rush (D-IL) (by voice vote) that would create a Follow-On Biologics ("FOB") approval pathway and that would prohibit so-called 'pay-for-delay' or 'reverse payment' settlements between generic and brand-name drug companies, respectively." (August 2, 2009 Kurt R. Karst FDA Law Blog.)

> "FTC Chairman Jon Leibowitz, a long-time critic of the settlements, praised the Committee's actions in a July 31 statement. 'If enacted into law, this measure will put an end to the sweetheart deals between brand and generic pharmaceutical companies that force consumers to wait — sometimes years — for more affordable generic drugs. We estimate that this critical provision will save consumers about $3.5 billion per year.'" (August 4, 2009 Drug Industry Daily.)

Regarding a draft bill that would allow patent settlements between brand and generic drug firms if they are proved to be pro-competitive. Leibowitz said the FTC supports the draft bill stating: "Courts are all over the map, and that's why we want Congress to step in."

> "The U.S. Senate Judiciary Committee is backing off a proposed ban on deals that delay cheaper, generic drugs from reaching the market and is instead floating legislation aimed at appeasing the pharmaceutical industry...A draft bill introduced Thursday at a Judiciary Committee hearing would allow brand-name drug makers to pay generic pharmaceutical companies to delay cheaper, generic copies of their medicines from reaching patients if they can prove such deals are 'pro-competitive.'" (September 10, 2009 Jared A. Favole Dow Jones Newswires.)

> "FTC Chairman Jon Leibowitz said he supports the draft bill. He said the deals are blatantly anti-competitive and need to be stopped. 'Courts are all over the map, and that's why we want Congress to step in,' he said. Drug makers say the deals aren't anti-competitive and oppose moves to stop the agreements. Pharmaceutical representatives said they don't support the draft bill." (September 10, 2009 Jared A. Favole Dow Jones Newswires.)

On October 15, 2009, a Senate panel voted 12 to 7 to bar pay-for-delay settlements. FTC Chairman Leibowitz responded, "By taking this action, the Committee clearly recognizes the very real danger that these sweetheart deals pose to Americans struggling to pay their medical bills."

> "A Senate panel voted on Thursday to bar drug companies from paying generic drugmakers to delay bringing their cheaper medicines to market. The Judiciary Committee voted 12 to 7 to forbid such deals." (October 15, 2009 Reuters Health.)

> "'By taking this action, the Committee clearly recognizes the very real danger that these sweetheart deals pose to Americans struggling to pay their medical bills,' says FTC chairman Jon Leibowitz, in a statement. 'Consumers must wait – sometimes years – for far less expensive generic drugs when branded pharmaceutical companies pay off their generic competitors to stay out of the market.'" (October 15, 2009 Ed Silverman Pharmalot.)

On January 13, 2010, Leibowitz and Members of Congress, including Representative Chris Van Hollen, Chairman Bobby Rush, and Representative Mary Jo Kilroy, held a press conference to renew their call for legislation that would end pay-for-delay settlements.

> "Federal Trade Commission Chairman Jon Leibowitz and key members of Congress, including Representative Chris Van Hollen, Chairman Bobby Rush, and Representative Mary Jo Kilroy, today renewed their call for legislation that would put an end to anticompetitive patent settlements, which drug manufacturers have been using to keep less-expensive medicines off the market and charge consumers billions of dollars a year in higher drug prices." (January 13, 2010 FTC Press Release.)

Also at the press conference, the FTC announced the release of its report on pay-for-delay settlements. In his remarks, Leibowitz said, "Pay-for-delay deals are a bad prescription for America. When drug companies agree not to compete, consumers lose."

> "Now it is the Federal Trade Commission's ("FTC's") turn to put on the pressure. On January 12, 2010, the FTC announced that it will hold a press conference at the Rayburn House Office Building on January 13, 2010 "to announce an FTC staff analysis showing that pay-for-delay deals between brand and generic drug companies are costing American consumers billions a year, and to encourage inclusion of the House-passed pay-for-delay provision in the final version of the health care reform bill." The FTC – and FTC Chairman Jon Leibowitz in particular – has made no bones about its opposition to pay-for-delay settlements. In June 2009, Chairman Leibowitz said in a speech that eliminating 'pay-for-delay' settlements could save consumers $3.5 billion annually." (January 12, 2010 Kurt R. Karst FDA Law Blog.)

> "The Federal Trade Commission is using the full armamentarium of public relations techniques to press for inclusion of a ban on 'pay for delay' settlements in the health care reform legislation. A Jan. 13 event on Capitol Hill featured a pack of politicians, a report

with footnotes, and a personal story from a citizen." (January 13, 2010 The Pink Sheet Daily.)

"'Pay-for-delay deals are a bad prescription for America. When drug companies agree not to compete, consumers lose,' FTC Chairman Jon Leibowitz said at a press conference. 'Ending this practice as part of health care reform is one simple, effective and straightforward way for Congress to help control drug costs,' Leibowitz said.." (January 13, 2010 Richard Vanderford IP Law360.)

In response to a April 29, 2010 U.S. Court of Appeals decision, FTC Chairman Jon Leibowitz said, "Hopefully the courts will put an end to these deals. In the meantime the FTC will continue to explain, in court and in the halls of Congress, why these sweetheart deals for drug companies are such a bad deal for American consumers and taxpayers."

"The words of the appeals court are 'further evidence that courts are rethinking their approach to pay-for-delay settlements,' Leibowitz said in a statement today. 'Hopefully, the courts will put an end to these deals,' he said. 'In the meantime, the FTC will continue to explain, in court and in the halls of Congress, why these sweetheart deals for drug companies are such a bad deal for American consumers and taxpayers.'" (April 29, 2010 Susan Decker Bloomberg.)

On June 9, 2010, FTC Chairman Jon Leibowitz told a Senate Judiciary subcommittee that ending pay-for-delay deals is one of the FTC's most significant efforts to promote competition and enforce antitrust laws. Leibowitz also said that "Since a few misguided court decisions in 2005," the problem of pay-for-delay settlements "has only gotten worse."

"FTC Chairman Jon Leibowitz told a Senate Judiciary subcommittee Wednesday that ending pay-for-delay deals is one of FTC's most significant efforts to promote competition and enforce antitrust laws. FTC believes the settlements are a violation of antitrust law because brand-name drug makers pay would-be generic competitors to refrain from selling their products until an agreed-upon date. FTC has suffered several setbacks trying to block pay-for-delay settlements through the courts, though Leibowitz said there is 'reason to believe that the tide may be turning' in light of an appeals court ruling last month. He also reiterated FTC's support for a legislative ban on the agreements." (June 9, 2010 The Vitals: A Health Policy Blog.)

"JONATHAN LEIBOWITZ...Since a few misguided court decisions in 2005, the problem has only gotten worse." (June 9, 2010 Testimony of FTC Chairman Jon Leibowitz Senate Judiciary Committee.)

Also on June 9, 2010, Senators Herb Kohl, Charles Grassley, and Susan Collins proposed an amendment to the Tax Extenders Act that would ban patent settlement agreements.

"On the same day that the Senate Judiciary Committee held a hearing on 'Oversight of the Enforcement of the Antitrust Laws,' at which Federal Trade Commission ("FTC") Chairman Jon Leibowitz and U.S. Department of Justice ("DOJ") Assistant Attorney General for the

> Antitrust Division Christine Varney testified (here and here) on, among other things, patent settlement agreements (what opponents call 'pay-for-delay' agreements), Senators Herb Kohl (D-WI), Charles Grassley (R-IA), and Susan Collins (R-ME) proposed an amendment – SA 4332 – during the Senate's consideration of the Tax Extenders Act (H.R. 4213) that could significantly curtail patent settlement agreements." (June 10, 2010 Kurt R. Karst FDA Law Blog.)

On July 27, 2010, Leibowitz testified about the FTC's performance under the new administration and named settlements as its top competition priority.

> "Hearing of the Courts and Competition Policy Subcommittee of the House Judiciary Committee Subject: Federal Trade Commission's Bureau of Competition and the U.s. Department of Justice's Antitrust Division...MR. LEIBOWITZ:..Chairman Johnson, Chairman Conyers, Mr. Coble, members of the subcommittee, thank you so much for inviting me to testify here today...Right now our top competition priority at the commission is to stop pay-for-delay agreements between brand-name and generic drug makers." (Source: July 27, 2010, Federal News Service Hearing Transcript, House Judiciary Committee.)

On July 29, 2010, the Senate Appropriations Committee approved a measure seeking to ban pay-for-delay settlements. The provision was attached to the "Financial Services and General Government Appropriations" bill. Jon Leibowitz said the passage of the Senate measure put consumers "one step closer to saving billions on their prescription drugs."

> "The Senate Appropriations Committee Thursday approved a measure seeking to ban so-called pay-for-delay deals...The provision, sponsored by Sen. Her Kohl (D-Wis.), squeaked through as part of the Financial Services and General Government Appropriations bill...The passage of the Senate measure last week, Leibowitz said Thursday, puts consumers 'one step closer to saving billions on their prescription drugs.'" (August 2, 2010 BioWorld Today.)

On October 28, 2010, *Pharmalot* published an interview with Jon Leibowitz in which he said that the FTC has a "two-pronged approach" to gets patent settlements banned: legislation and litigation. He affirmed, "we're going to get this done."

> "Pharmalot: Yet, you haven't had much luck. A recent federal appeals court upheld the practice and Republicans are threatening to block legislation. It seems you're tilting at windmiYour odds don't seem so good. Leibowitz: We've had a two-pronged approach. One is to get a case to the Supreme Court and that's the litigation prong. And the other is the legislative prong that would restrict these deals. And it's pretty modest legislation. What are the chances (either will work)? We've made steady progress, although sometimes it's two steps forward and one step back. But there was no legislation in 2006 or late 2005 and, on a bipartisan basis, (legislation we want) has passed the House twice. It's (recently) passed the Senate Committee with bi-partisan support and it's in the appropriations bill with bipartisan support. So I think our chances are pretty darned good… Pharmalot: It seems, though, that you're tilting at windmills. Liebowitz: We're not tilting at windmills. We're going to get this done…" (October 28, 2010 Pharmalot.)

On November 17, 2010, with Senator Kohl's pay-for-delay provision still pending in the Senate, FTC Commissioner Thomas Rosch spoke out against Jon Leibowitz's strategy of inserting the measure into a funding bill. Rosch said, "In my view, pay-for-delay legislation should rise and fall on its own merits...We should not be tacking this kind of legislation onto a funding bill."

> "FTC Chairman Jon Leibowitz has urged Congress to pass limits on pay-for-delay settlements, but lawmakers on both sides of the aisle have said drug patent settlement language should not be incorporated in funding bills...FTC Commissioner Thomas Rosch criticized the commission's strategy... 'In my view, pay-for-delay legislation should rise and fall on its own merits,' Rosch said at a generic drug conference. 'We should not be tacking this kind of legislation onto a funding bill.'" (November 19, 2010 FDA Week.)

Professor Hemphill authored another settlements paper in December 2010, "Collusive and Exclusive Settlements of Intellectual Property Litigation," in which he discloses that he "has consulted with the Federal Trade Commission on the antitrust issues raised by patent settlements in the pharmaceutical industry..."

> "Collusive and Exclusive Settlements of Intellectual Property Litigation...C. Scott Hemphill*...* Professor of Law, Columbia Law School. This paper is adapted from remarks made on April 7, 2010, as the Milton Handler Lecture before the Antitrust Section of the New York City Bar Association...The author has consulted with the Federal Trade Commission on the antitrust issues raised by patent settlements in the pharmaceutical industry. Views or errors are the author's alone." (Source: Working Paper 2010, C. Scott Hemphill, Professor of Law, Columbia Law School, Collusive and Exclusive Settlements of Intellectual Property Litigation.)

> "Collusive and Exclusive Settlements of Intellectual Property Litigation...Columbia Law and Economics Working Paper No. 384...C. Scott Hemphill Columbia University - Law School...Posted: 02 Dec 10 Last Revised: 06 Dec 10..." (Source: http://papers.ssrn.com/sol3/cf_dev/AbsByAuth.cfm?per_id=663359.) (Accessed: November 14, 2011.)

In January 2011, Professor Hemphill posted up a working paper on generic drug incentives which is to be published in the *Antitrust Law Journal* in 2011. The paper discloses that he "has served as a consultant to the FTC on antitrust issues..."

> "C. Scott Hemphill's Scholarly Papers...Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act...Antitrust Law Journal, 2011, Stanford Law and Economics Olin Working Paper...Posted 10 Jan 11...Last Revised 04 Jul 11..." (Source: http://papers.ssrn.com/sol3/cf_dev/AbsByAuth.cfm?per_id=663359) (Accessed: November 14, 2011.)

> "Hemphill has served as a consultant to the FTC on antitrust issues in the pharmaceutical industry, and Lemley represented Impax, an antitrust plaintiff in Abbott Labs. v. Impax Labs., a case discussed infra." (Source: C. Scott Hemphill, Columbia University Law School, Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act, Antitrust Law

Journal, 2011, Stanford Law and Economics Olin Working Paper.)

On January 21, 2011, Jon Leibowitz gave an interview to *Bloomberg News*. In the interview, he spoke about the FTC's efforts to eliminate pay-for-delay settlements stating, "I think everyone other than the pharmaceutical industry and its paid supporters, in industry...recognize that this is anti-competitive." He went on to say that 2011 is "going to be a year of belt-tightening for everybody" and that government will be looking for "pay-forwards." Leibowitz called legislation against patent settlements "a really good pay-forward."

> "So I think everyone other than the pharmaceutical industry and its paid supporters, in industry - I'm talking about sort of putting aside Congress, recognize that this is anti-competitive. And then as Congress struggles for funds this year, because obviously it's a year of austerity for government agencies, it's a year of belt-tightening for government. It's going to be in the next proration cycle, budget cycle. It's going to be a year of belt-tightening for everybody. They're going to be looking for pay-forwards. And this is a really good pay-forward. And so, I think we still have a very good chance of getting it done." (January 21, 2011 Bloomberg News.)

In February 2011, the Obama administration's proposed 2012 budget included a proposal allowing the FTC to stop patent settlements. Jon Leibowitz said in a statement, "At a time when the government is making tough choices on spending, it is a matter of simple common sense to stop these sweetheart deals between pharmaceutical companies that needlessly increase government spending on prescription drugs by billions of dollars."

> "The Obama administration's 2012 budget blueprint released Monday...would allow the U.S. Federal Trade Commission to stop controversial settlements in which brand-name drug companies pay their generic competitors to drop patent challenges that could lead to early entry of generic drugs...'At a time when the government is making tough choices on spending, it is a matter of simple common sense to stop these sweetheart deals between pharmaceutical companies that needlessly increase government spending on prescription drugs by billions of dollars,' FTC Chairman Jon Leibowitz said in a statement." (February 14, 2011 Dow Jones Newswires.)

On May 3, 2011, the FTC released a report on patent settlements. In its release, Leibowitz said, "the increasing number of these deals is a win-win proposition for the pharmaceutical industry, but a lose-lose for everyone else."

> "FTC Staff Report Finds 60 Percent Increase in Pharmaceutical Industry Deals That Delay Consumers' Access to Lower-Cost Generic Drugs...'Collusive deals to keep generics off the market are already costing consumers and taxpayers $3.5 billion a year in higher drug prices,' said FTC Chairman Jon Leibowitz. 'The increasing number of these deals is a win-win proposition for the pharmaceutical industry, but a lose-lose for everyone else.'" (May 3, 2011 FTC Press Release.)

Also on May 3, 2011, Leibowitz told *Bloomberg* that "either the courts or Congress needs to stop [patent settlements]."

> "Some of these settlements 'are outrageous, and they harm consumers,' Leibowitz said on May 3 in an interview at the Bloomberg News office in New York. 'Either the courts or Congress needs to stop them.'" (May 10, 2011 Bloomberg.)

On July 21, 2011, the Senate Judiciary Committee reported out legislation to ban patent settlements with a 10-8 vote. In response to the vote, Leibowitz released a statement that said, "In the midst of all the congressional work to reduce the nation's deficits, I think it's especially commendable that the Senate Judiciary Committee passed legislation that would put an end to the collusive pay-for-delay deals to keep generics off the market."

> "A Senate panel for the third time in five years has approved a bill that will severely hamstring drug patent settlements, but as before, the legislation will likely face difficulty moving any further. The Senate Judiciary Committee reported out the Preserve Access to Affordable Generics Act in a 10-8 vote largely along party lines Thursday." (July 22, 2011 Drug Industry Daily.)

> "For its part, the FTC applauded the bill's advance, pointing to its recent studies showing a 60 percent increase in the number of questionable patent settlements from 2009 to 2010. "In the midst of all the congressional work to reduce the nation's deficits, I think it's especially commendable that the Senate Judiciary Committee passed legislation that would put an end to the collusive pay-for-delay deals to keep generics off the market," FTC Chairman Jon Leibowitz said Thursday." (July 21, 2011, IP Law360.)

On September 12, 2011, Leibowitz sent a letter to the 12-member Joint Select Committee on Deficit Reduction asking it to restrict patent settlements.

> "The FTC is asking a special Congressional committee on the federal deficit to restrict reverse settlements, continuing its quest to stop such deals between brand and generic-drug companies. FTC Chairman Jon Leibowitz sang a tune familiar to drugmakers in his Monday letter to the 12 members of the Joint Select Committee on Deficit Reduction. The longtime opponent of pay-for-delay deals urged committee members to limit patent settlements. The FTC deems those deals anticompetitive, saying they retard the entry of generic drugs, thus keeping drug prices higher." (September 14, 2011 Drug Industry Daily.)

On October 24, 2011, *The Washington Post* published its fourth and latest editorial against patent settlements entitled, "Ending Drug Companies' Pay-for-Delay Deals." In it, the writers referenced "[a]n upcoming report by the Federal Trade Commission," a copy of which had been "obtained by the editorial board."

> "Ending Drug Companies' Pay-for-Delay Deals October 24, 2011 The Washington Post...AN UPCOMING REPORT by the Federal Trade Commission shows that brand-name pharmaceutical makers continue to cut questionable deals with generic manufacturers that delay the introduction of cheaper drugs onto the market...The legislation should appeal to the deficit-reduction 'supercommittee,' which has been tasked with identifying ways to cut the federal deficit." (October 24, 2011 The Washington Post.)

The next day on October 25, 2011, the FTC released the report on patent settlements referenced in *The Washington Post's* editorial and called again for the Supercommittee to restrict patent settlements. In a statement, Leibowitz said, "Fortunately, Congress has the opportunity to fix this problem through the Joint Select Committee on Deficit Reduction."

> "The FTC staff report found that drug companies entered into 28 potential pay-for-delay deals in FY 2011 (October 1, 2010 through September 30, 2011). The figure nearly matches last year's record of 31 deals and is higher than any other previous year since the FTC began collecting data in 2003. Overall, the agreements reached in the latest fiscal year involved 25 different brand-name pharmaceutical products with combined annual U.S. sales of more than $9 billion. 'While a lot of companies don't engage in pay-for-delay settlements, the ones that do increase prescription drug costs for consumers and the government each year,' said FTC Chairman Jon Leibowitz. 'Fortunately, Congress has the opportunity to fix this problem through the Joint Select Committee on Deficit Reduction -- and save the government and American taxpayers billions of dollars.'" (October 25, 2011 Federal Trade Commission Press Release)

Conclusion

Chairman Leibowitz's actions clearly constitute lobbying and as such an investigation of these actions should occur to determine whether they violate the express prohibitions found in 18 U.S.C. § 1913. Further, the consultancy between the FTC and Professor Hemphill should be reviewed to determine whether any funds appropriated by Congress were used by Hemphill in an effort to lobby Congress. Additionally, an investigation should be conducted to see whether these actions are in compliance with any other legal and ethical standards that are applicable to FTC Commissioners and consultants.

Based on the forgoing I request that your office fully investigate these matters, report to the public on your findings, and make any appropriate referrals for further action.

Sincerely,

William Wilson
President