

Fox in the Henhouse: **How Eli Lilly's Drug Prices and Criminal Marketing Activities Disqualify Alex Azar for the Cabinet**

Executive Summary: **Alex Azar is the Wrong Choice for HHS Secretary**

Time and again, when asked to list their number one public policy priority, Americans choose healthcare.¹ For many, their own health and the health of their families is an existential issue. Of the issues plaguing our health care system, soaring prescription drug costs are among the most financially devastating for working Americans. These crippling prices are protected by one of the world's most powerful special interests: the lobbying power of the pharmaceutical industry.²

President Trump has spoken repeatedly about the need to bring drug prices “way down.”³ When he said drug companies were “getting away with murder,”⁴ he voiced a widely-held belief: seventy-three percent of Americans say they think drug companies make too much profit, and 77% say the cost of prescription drugs is unreasonable.⁵

This makes all the more disturbing the reports that former Eli Lilly executive Alex Azar will be nominated as Secretary of the U.S. Department of Health and Human Services (HHS).⁶ Mr. Azar's appointment would “put a pharmaceutical fox in charge of the health care hen house.”⁷ The appointment would contradict the President's pledge to “drain the swamp” and change Washington's pay-to-play atmosphere, where a lucrative revolving door moves former federal regulators into jobs at huge corporations – and back again into government.⁸

Mr. Azar served as Deputy Director of HHS under President George W. Bush before moving to Eli Lilly. Between June 2007 and January 2017, Mr. Azar held various senior roles at Lilly USA, LLC, the final five years of which he served as President. During this period, Eli Lilly and Company:

- Boosted the price of a vial of its best-selling insulin product to \$255, a 1,214%, increase from 1996;
- Became the subject of several legal proceedings and law enforcement investigations related to the company's pricing of insulin products;
- Allegedly bribed officials in multiple foreign countries;
- Conducted illegal off-label marketing, resulting in “the largest criminal fine for an individual corporation ever imposed in a United States criminal prosecution of any kind”;⁹ and
- Spent millions in federal and state lobbying to thwart efforts at price transparency, and placed Mr. Azar as a senior executive in BIO, the powerful prescription drug lobby trade association.

Mr. Azar risks replicating the troubled tenure of his predecessor, Tom Price. Price was drummed from office after his repeated use of taxpayer money to fund trips on private planes was revealed,¹⁰ but his short stint as HHS Secretary was marred throughout by questions of conflict of interest. As a Congressman, Price had introduced legislation that would have directly benefited drug companies in which he held stock,¹¹ and during his confirmation he failed to fully explain his legislative efforts on behalf of the drug industry.^{12,13 14}

Alex Azar's conflicts are clearer and more troubling than Mr. Price's. Eli Lilly's involvement in drug price gouging, in crimes that drew the largest corporate fines in U.S. history, and in the unleashing of a gusher of lobbying cash during his tenure at Lilly USA make Alex Azar uniquely unsuited to any cabinet post, let alone one with oversight of America's struggling health care system. Congress must stop the Azar nomination and put the health care needs of the American people ahead of corporate interests.

Alex Azar is the wrong choice for Secretary of HHS.

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Background

Eli Lilly and Company is a Fortune 500 corporation¹⁵ that had \$21.2 billion in 2016 revenues,¹⁶ making it the 14th largest pharmaceutical company in world.¹⁷ As of September 30, 2017, Lilly had 41,224 employees, 55% (22,710) of whom are outside of the U.S.¹⁸

The company owns manufacturing and distribution facilities in the U.S. (including in Indiana, New Jersey, and Puerto Rico) and in 14 other countries,¹⁹ and its products are marketed in about 125 countries.²⁰ Lilly USA, LLC, is Eli Lilly and Company's largest affiliate, responsible for approximately half of the Company's global revenue.²¹

Insulin: The Irony of Monopoly Prices

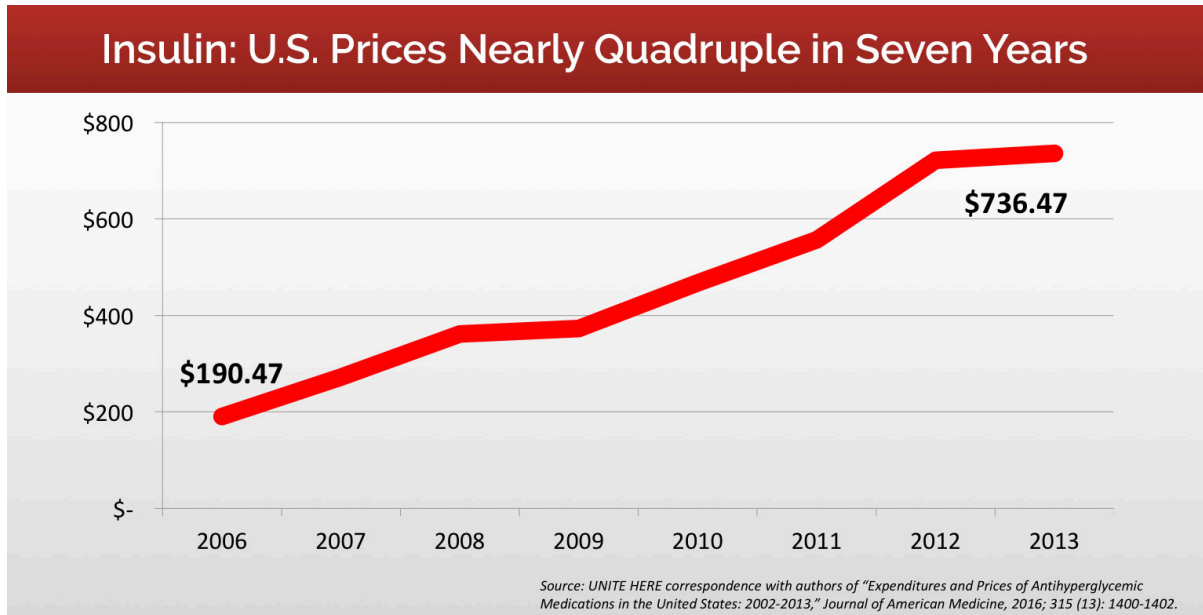
Insulin is a hormone necessary for human life that helps the body use glucose for energy. In the bodies of Type 1 diabetics, the pancreas does not produce insulin, and Type 2 diabetics do not respond well to insulin. Diabetics must thus inject or pump insulin.²² About 6 million diabetics in the U.S. use insulin.²³

Insulin was initially discovered by researchers at the University of Toronto in 1921. According to a recent article in the *New England Journal of Medicine* that describes the origins of the medication, "When the [research] team [that discovered the insulin] applied for a U.S. patent in January 1923 (which they later sold to the university for \$1), they stated that their goal was not profit, but ensuring the speedy and safe availability of their discovery to the public."²⁴ These scientists wanted to be sure that "no one could secure a profitable monopoly" on the production of the drug.²⁵

Today, insulin manufacturers in the U.S. "exercise monopoly power over pricing," in the words of Dr. Rena Conti, Ph.D., a Harvard-trained health economist and Assistant Professor in the Departments of Pediatrics & Public Health Sciences (Health Services Research) at the University of Chicago.²⁶ The cost of insulin per patient rose 387% between 2006 and 2013 in the U.S., climbing from \$190 per year to \$736 per year.²⁷ Eli Lilly, Novo Nordisk and Sanofi dominate the global insulin market in terms of revenue.²⁸

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Figure 1 - Rise of Insulin Prices in the U.S., 2006-2013



Scrutiny of Lilly's Insulin Pricing

During Azar's tenure at Lilly USA, LLC, and into this year, Eli Lilly and Company has faced public and political scrutiny – and the attention of law enforcement agencies in the U.S. and abroad – for the pricing of its insulin products.²⁹ The list price for a vial of Lilly's top-selling product, the insulin Humalog, increased 1,214%, from \$21 to \$255 between 1996 and 2016.³⁰

On November 3, 2016, Senator Bernie Sanders and Congressman Elijah Cummings wrote Attorney General Loretta Lynch and Federal Trade Commission Chairwoman Edith Ramirez "to ask the Department of Justice and the Federal Trade Commission to investigate whether pharmaceutical companies manufacturing insulin products have colluded or engaged in anticompetitive behavior in setting their drug prices."³¹ The letter names Eli Lilly repeatedly, and notes that in 2010, Mexico's antitrust enforcement agency fined Eli Lilly in Mexico for colluding with other insulin manufacturers in a scheme that involved "eliminating competition and ensuring artificially high prices."³²

In February 2017, a class action complaint was filed in federal district court on behalf of eleven named diabetic patients and similarly situated patients. The Amended Complaint filed in March 2017 alleges Eli Lilly, Novo Nordisk and Sanofi have unlawfully conspired to raise the price of insulin products in violation of the Racketeer Influenced and Corrupt Organizations Act (RICO) and various state consumer protection and antitrust statutes.³³ The suit alleges Eli Lilly and the

other companies broke the law by “engaging in a scheme and enterprise whose purpose is to unlawfully inflate the benchmark prices of rapid- and long- acting analog insulin drugs to provide large pharmacy benefit managers (PBMs) with wider spreads between the benchmark prices and real prices.”³⁴ The Amended Complaint states, “This scheme directly and foreseeably causes consumers to overpay for these life-saving medications.”³⁵

In September 2017, the Honorable Judge Brian R. Martinotti of the U.S. District Court of New Jersey consolidated this case – together with two additional antitrust cases naming Lilly, Novo, Sanofi and multiple PBMs as defendants – into what Kaiser Health News called last week “one behemoth potential class-action suit.”³⁶

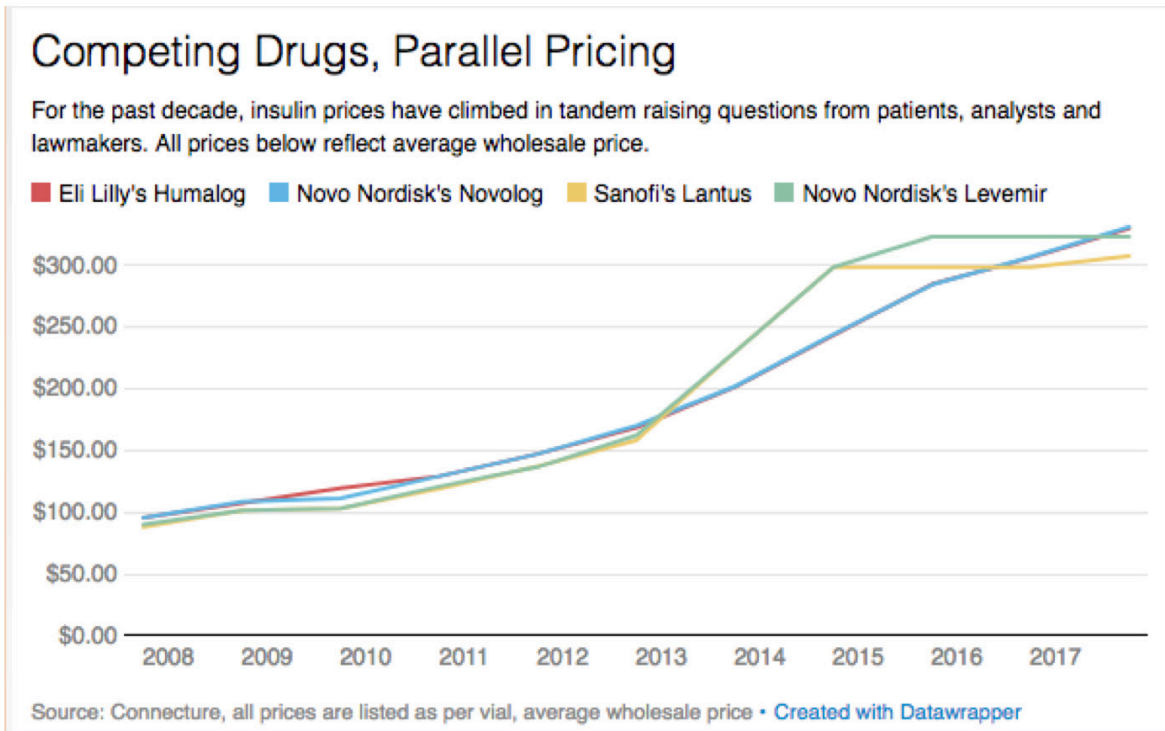
Throughout the past 18 months, a trickle of information has emerged in Eli Lilly’s filings with the Securities and Exchange Commission (SEC) that reveals ongoing law enforcement investigations into the company’s insulin product pricing.³⁷ Eli Lilly’s second quarter filing with the SEC in 2016 disclosed that the company had “received a civil investigative demand from the U.S. Attorney’s Office for the Southern District of New York requesting documents and information relating to our contracts with, services performed by and payments to pharmacy benefit managers.”³⁸

In its first quarter filing with the SEC in 2017, Eli Lilly divulged that it had “received a civil investigative demand from the State of Washington’s Office of the Attorney General relating to the pricing of our insulin products and our relationships with pharmacy benefit managers.”³⁹ In that same filing, Eli Lilly said it also had “received a civil investigative demand from the State of New Mexico’s Office of the Attorney General relating to the pricing of our insulin products.”⁴⁰

Two months later, in its second quarter filing with the SEC, Eli Lilly revealed the company had “received a civil investigative demand from the State of Minnesota’s Office of the Attorney General relating to the pricing and sale of our insulin products.”⁴¹ The filing additionally states: “The Offices of Attorneys General in California and Florida have requested information relating to the pricing of our insulin products.”⁴²

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Figure 2- Rise of Insulin Product Prices in the U.S. (from Kaiser Health News)



Investigations of Bribery Under the Foreign Corrupt Practices Act

On December 20, 2012, the Securities and Exchange Commission (SEC) filed a complaint in U.S. District Court charging Eli Lilly with violating the Foreign Corrupt Practices Act (FCPA). The SEC alleged that between 1994 and 2009, Eli Lilly and Company made improper payments to government officials in Brazil, China, Russia and Poland to secure business in those countries.⁴³

The SEC complaint says Eli Lilly “paid bribes to government health officials in a Brazilian state in order to assure sales of a Lilly product to state government institutions.”⁴⁴ The complaint says that in Poland Eli Lilly made payments to a small charitable foundation dedicated to the “restor[ation of] the Chudow Castle in the town of Chudow and other historic sites in the Silesian region of Poland”;⁴⁵ this foundation “was founded and administered by the head of one of the regional government health authorities at the same time that the subsidiary was seeking the official’s support for placing Lilly drugs on the government reimbursement list.”⁴⁶

The SEC complaint says that in China, Eli Lilly’s sales representatives and sales managers submitted false expense reports in order “to purchase gifts, such as wine, specialty foods and a jade

bracelet, for government-employed physicians,” “to provide meals, visits to bath houses, and card games to government-employed physicians,” “to provide government-employed physicians with visits to bath houses and karaoke bars,” “to buy meals and cosmetics for government-employed physicians,” “to provide gifts and entertainment to government officials [including] spa treatments, meals, and cigarettes.”⁴⁷

The SEC complaint further alleges that Eli Lilly’s subsidiary in Russia “paid millions of dollars to off-shore entities for alleged ‘services’ [...] in order to induce pharmaceutical distributors and government entities to purchase Lilly’s drugs. In some instances, the off-shore entities appear to have been used to funnel money to government officials or others with influence in the government in order to obtain business for the subsidiary.”⁴⁸ In a press release the day it filed the complaint in U.S. District Court, the SEC said these payments included “approximately \$2 million to an offshore entity owned by a government official and approximately \$5.2 million to offshore entities owned by a person closely associated with an important member of Russia’s parliament.”⁴⁹

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Eli Lilly agreed to pay \$29.4 million to settle the charges, without admitting or denying any wrongdoing.⁵⁰

DOJ Guilty Plea and \$1.415 Billion Payment for Off Label Marketing

On January 15, 2009, the Department of Justice announced that Eli Lilly and Company “agreed to plead guilty and pay \$1.415 billion for promoting its drug Zyprexa for uses not approved by the Food and Drug Administration (FDA).”⁵¹

Zyprexa was originally approved by the FDA in 1996 for the treatment of various psychotic disorders. In 2000, the FDA expanded approval of Zyprexa for the short-term treatment of acute manic episodes associated with Bipolar I Disorder and the short-term treatment of schizophrenia.

The Department of Justice’s criminal information, filed in U.S. District Court, alleged that “Eli Lilly’s management created marketing materials promoting Zyprexa for off-label uses, trained its

sales force to disregard the law and directed its sales personnel to promote Zyprexa for off-label uses.” The criminal information said that “Eli Lilly expended significant resources to promote Zyprexa in nursing homes and assisted-living facilities.”⁵²

The criminal information further alleged that “building on its unlawful promotion and success in the long-term care market, Eli Lilly executives decided to market Zyprexa to primary-care physicians [...] even though the company knew that there was virtually no approved use for Zyprexa in the primary-care market.”⁵³

According to the Department of Justice, the \$1.415 billion figure paid by Eli Lilly “includes a criminal fine of \$515 million, the largest ever in a health care case, and the largest criminal fine for an individual corporation ever imposed in a United States criminal prosecution of any kind.”⁵⁴

Millions of Dollars of Lobbying Against Transparency

Between 2012 and 2016, Eli Lilly and Company spent, on average, \$8 million per year on lobbying the federal government.⁵⁵

Eli Lilly and Company is a leader of the pharmaceutical industry trade group the Biotechnology Innovation Organization (BIO). During Azar’s tenure as President of Lilly USA, LLC, he served on the Executive Committee of BIO’s Board of Directors and Chairman of BIO’s Reimbursement Committee,⁵⁶ which focuses on “health

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Experience








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Chairman and Founder
 Seraphim Strategies, LLC
 Feb 2017 – Present • 10 mos
 Indianapolis, Indiana
 Seraphim Strategies, LLC, provides strategic consulting and counsel on the biopharmaceutical and health insurance industries, including biopharmaceutical sales, marketing, pricing, reimbursement, access, and distribution, as well as federal and state healthcare policy.
- 
Member Board of Directors
 HMS
 Oct 2016 – Present • 1 yr 2 mos
 Irving, Texas
- 
Member Board of Directors, Executive Committee, Co-Chair Reimbursement Committee
 Biotechnology Innovation Organization
 2013 – Jan 2017 • 4 yrs
- 
President, Lilly USA, LLC
 Eli Lilly and Company
 Jan 2012 – Jan 2017 • 5 yrs 1 mo
 Indianapolis, Indiana Area
- 
Vice President, Managed Healthcare Services and Puerto Rico, Lilly USA, LLC
 Eli Lilly and Company
 Apr 2009 – Dec 2011 • 2 yrs 9 mos
 Indianapolis, Indiana Area
- 
Senior Vice President Corporate Affairs and Communications
 Eli Lilly and Company
 Jun 2007 – Mar 2009 • 1 yr 10 mos
 Indianapolis, Indiana Area
- 
Deputy Secretary
 Department of Health and Human Services
 2005 – 2007 • 2 yrs

Figure 3 – The “Experience” Section of Alex Azar’s LinkedIn Profile as of November 6, 2017.

reform and reimbursement issues from a variety of perspectives, including legislative, regulatory, economic, marketing, and public relations. Members of the committee meet routinely with government officials regarding legislation and agency matters.”⁵⁷ In 2017, BIO has spent \$7.03 million lobbying the federal government.⁵⁸

Eli Lilly and Company is also a leader of the pharmaceutical industry trade group the Pharmaceutical Researchers and Manufacturers of America (PhRMA). From 2012-2013, Eli Lilly and Company President and CEO John Lechleiter chaired PhRMA’s Board of Directors.⁵⁹ Current Eli Lilly and Company President and CEO Dave Ricks serves on the Board, and he was one of six board members who accompanied PhRMA CEO Steven Uhl to an Oval Office meeting with President Trump earlier this year.⁶⁰ In 2017, PhRMA has spent \$19.8 million lobbying the federal government.⁶¹

On June 15, 2017, Nevada Governor Brian Sandoval signed the bipartisan Senate Bill 539, which provides for transparency on diabetes drug prices.⁶² During the legislative session, Lilly hired 5 lobbyists to work on its behalf, BIO hired 5 lobbyists, and PhRMA hired 7 lobbyists in Carson City.⁶³

Eli Lilly’s Billions in Unpaid Tax Avoidance

According to Citizens for Tax Justice research published in 2014, Eli Lilly appears to have amassed \$65.3 billion in un-repatriated profits between 2011 and 2013.⁷¹ Based on Eli Lilly’s own estimates in their securities filings, this means the company has successfully avoided paying at least \$8.3 billion in U.S. taxes.⁷²

Most Americans Disagree With Alex Azar’s Views on Drug Importation from Canada and Medicaid Funding

While 76% of people favor allowing Americans to buy prescription drugs imported from Canada,⁶⁶ when asked about this on Fox Business’ Varney & Co. on June 16, 2017 Mr. Azar said, “One of the best things in the American health care system is our closed distribution system. We have such tight control on product here in the United States [...] This thing about importing drugs from Canada is a canard [...] The U.S. distribution system is a crown jewel, let us not mess that up.”⁶⁷

While 87% of Americans want spending on Medicaid to stay about the same or to increase,⁶⁸ Mr. Azar has said, “I think there’s a lot to commend a block grant approach [to Medicaid] because the states are the laboratory for experimentation [...] It makes them better stewards of the money. It becomes their money again to make the choice.”⁶⁹ But experts agree that changing Medicaid to a block grant would reduce the program’s funding over time.⁷⁰

On October 9, 2017, after a two-year campaign, California Governor Jerry Brown signed the bipartisan Senate Bill 17, which provides for transparency on prescription drug prices.⁶⁴ In lobbying the California legislature between January 2015 and July 2017, Eli Lilly and Company spent \$306,244, BIO spent \$385,400 and PhRMA spent \$1,904,375.⁶⁵

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