



March 29, 2019

TO: Republican Members, Committee on Energy and Commerce

FROM: Committee Minority Staff

RE: Hearing entitled “Priced Out of a Lifesaving Drug: The Human Impact of Rising Insulin Costs.”

---

The Subcommittee on Oversight and Investigations will hold a hearing on Tuesday, April 2, 2019, at 10:30 a.m. in 2322 Rayburn House Office Building entitled “Priced Out of a Lifesaving Drug: The Human Impact of Rising Insulin Costs.”

## I. WITNESSES

- Gail DeVore, Patient Advocate;
- William T. Cefalu, MD, Chief Scientific, Medical, and Mission Officer, American Diabetes Association (ADA);
- Alvin C. Powers, MD, Endocrine Society Representative; Director, Vanderbilt Diabetes Center; Director, Division of Diabetes, Endocrinology, and Metabolism, Vanderbilt University Medical Center;
- Kasia J. Lipska, MD, Clinical Investigator, Yale-New Haven Hospital Center for Outcomes Research and Evaluation, Yale University Medical Center;
- Christel Marchand Aprigliano, MS, Chief Executive Officer, Diabetes Patient Advocacy Coalition (DPAC); and
- Aaron J. Kowalski, PhD, Chief Mission Officer, JDRF.

## II. BACKGROUND

### A. Diabetes in the United States

The Centers for Disease Control and Prevention (CDC) estimates that more than 30 million individuals—or 9.4 percent of the population—in the United States have diabetes.<sup>1</sup> Of these 30 million Americans, about 23.1 million individuals are diagnosed with diabetes, which

---

<sup>1</sup> Centers for Disease Control and Prevention, *National Diabetes Statistics Report, 2017: Estimates of Diabetes and Its Burden in the United States* (2017), available at <https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf>.

includes about 132,000 children and adolescents younger than 18 years of age, and about 7.2 million individuals are undiagnosed.<sup>2</sup> These individuals have either type 1 diabetes or type 2 diabetes; the bodies of type 1 diabetics do not produce insulin, and the bodies of type 2 diabetics have insulin resistance and do not use insulin properly.<sup>3</sup> Most individuals with diabetes have type 2 diabetes—about five percent of individuals with diabetes have type 1 diabetes while 90 to 95 percent of individuals with diabetes have type 2 diabetes.

**Adults with Diabetes in Select States<sup>4</sup>**

State	Number of individuals with diabetes in 2016
Indiana	586,112
Kentucky	449,044
Oklahoma	355,508
Oregon	306,344
South Carolina	504,185
Texas	2,333,065
Virginia	687,972
West Virginia	218,960

A 2018 American Diabetes Association (ADA) report found that diabetes is the most expensive chronic disease in the United States.<sup>5</sup> According to this analysis, the economic cost of diagnosed diabetes in the United States in 2017 was about \$327 billion.<sup>6</sup> Moreover, out of the cost categories analyzed for the ADA’s report, care for individuals with diabetes accounted for approximately 24 percent of the health care dollars spent in the United States in 2017, and more than half of those expenditures were directly attributable to diabetes.<sup>7</sup>

## **B. Medications for Diabetics in the United States**

Individuals with type 1 diabetes must use insulin to stay alive and treat their diabetes while individuals with type 2 diabetes may use oral medications and/or insulin to help manage their diabetes.<sup>8</sup> According to the ADA, “[i]nsulin cannot be taken as a pill because it would be broken down during digestion just like the protein in food” and instead “[i]t must be injected into the fat under your skin for it to get into your blood.”<sup>9</sup> The CDC estimates that, in 2016, about

---

<sup>2</sup> *Id.*

<sup>3</sup> American Diabetes Association, *Type 1 Diabetes* (last visited Mar. 26, 2019), available at <http://www.diabetes.org/diabetes-basics/type-1/>; American Diabetes Association, *Type 2 Diabetes* (last visited Mar. 26, 2019), available at <http://www.diabetes.org/diabetes-basics/type-2/>.

<sup>4</sup> Centers for Disease Control and Prevention, *Diagnosed Diabetes* (last visited Mar. 26, 2019), available at <https://gis.cdc.gov/grasp/diabetes/DiabetesAtlas.html>.

<sup>5</sup> Krista Maier and Meghan Riley, *Improving Insulin Access and Affordability*, American Diabetes Association (May 2018), available at <http://www.diabetes.org/assets/pdfs/advocacy/improving-insulin-access-and.pdf>.

<sup>6</sup> American Diabetes Association, *Economic Costs of Diabetes in the U.S. in 2017*, DIABETES CARE, at 8 (Mar. 2018), available at <http://care.diabetesjournals.org/content/early/2018/03/20/dci18-0007>.

<sup>7</sup> American Diabetes Association, *Economic Costs of Diabetes in the U.S. in 2017*, DIABETES CARE, at 8 (Mar. 2018), available at <http://care.diabetesjournals.org/content/early/2018/03/20/dci18-0007>.

<sup>8</sup> American Diabetes Association, *Medication* (last visited Mar. 26, 2019), available at <http://www.diabetes.org/living-with-diabetes/treatment-and-care/medication/>.

<sup>9</sup> American Diabetes Association, *Insulin Basics* (last visited Mar. 26, 2019), available at <http://www.diabetes.org/living-with-diabetes/treatment-and-care/medication/insulin/insulin-basics.html>.

6.7 million Americans aged 18 and older used insulin—2.9 million of these 6.7 million Americans took insulin only and 3.8 million took both insulin and oral medications.<sup>10</sup> Three manufacturers serve nearly all of the United States insulin market; these manufacturers include Sanofi, Novo Nordisk, and Eli Lilly.<sup>11</sup>

There are two types of insulin products: basal insulins (intermediate or long-acting insulin) and mealtime insulins (short or rapid-acting insulin).<sup>12</sup> As shown in the chart below, some insulin products mix different types of insulin.<sup>13</sup>

**Types of Insulin<sup>14</sup>**

Category	Products	
Short-acting	<ul style="list-style-type: none"> <li>• Humulin R</li> <li>• Humulin R Pen</li> </ul>	<ul style="list-style-type: none"> <li>• Novolin R</li> </ul>
Rapid-acting	<ul style="list-style-type: none"> <li>• Humalog</li> <li>• Humalog Pen</li> <li>• Humalog Kwikpen</li> <li>• Apidra</li> <li>• Apidra Solostar</li> <li>• NovoLog</li> </ul>	<ul style="list-style-type: none"> <li>• Admelog (Humalog follow-on biologic)</li> <li>• Afrezza</li> <li>• Fiasp</li> <li>• Fiasp Flextouch</li> </ul>
Intermediate-acting	<ul style="list-style-type: none"> <li>• Humulin N (NPH)</li> <li>• Novolin N (NPH)</li> </ul>	
Long-acting	<ul style="list-style-type: none"> <li>• Lantus</li> <li>• Lantus Solostar</li> <li>• Levemir</li> <li>• Toujeo</li> </ul>	<ul style="list-style-type: none"> <li>• Toujeo Max</li> <li>• Tresiba FlexTouch</li> <li>• Basaglar KwikPen (Lantus follow-on biologic)</li> </ul>
Pre-mixed (Intermediate- and Rapid-acting)	<ul style="list-style-type: none"> <li>• Humalog Mix 75/25</li> <li>• Humalog Mix 75/25 KwikPen</li> <li>• Humalog 70/30</li> <li>• Humalog Mix 50/50 KwikPen</li> </ul>	<ul style="list-style-type: none"> <li>• Humalog Mix 50/50</li> <li>• NovoLog Mix 70/30</li> <li>• NovoLog Mix 70/30 FlexPen</li> </ul>
Pre-mixed (Long-and Rapid-acting)	<ul style="list-style-type: none"> <li>• Ryzodeg 70/30 Flex Touch</li> </ul>	
Pre-Mixed (Intermediate- and Short-acting)	<ul style="list-style-type: none"> <li>• Humulin 70/30</li> <li>• Humulin 70/30 KwikPen</li> </ul>	<ul style="list-style-type: none"> <li>• Novolin 70/30</li> </ul>

According to the ADA, “almost everything has changed over the past 50 years for Americans with diabetes,” including how long a diabetic can expect to live.<sup>15</sup> Insulin has changed dramatically over this period as well. Nearly 100 years ago, the only treatment for type

<sup>10</sup> Centers for Disease Control and Prevention, *Diagnosed Diabetes* (last visited Mar. 26, 2019), available at <https://gis.cdc.gov/grasp/diabetes/DiabetesAtlas.html#>.

<sup>11</sup> William T. Cefalu, et al., *Insulin Access and Affordability Working Group: Conclusions and Recommendations*, DIABETES CARE, at 2 (May 2018), available at <http://care.diabetesjournals.org/content/early/2018/05/03/dci18-0019>.

<sup>12</sup> U.S. Food and Drug Administration, *Insulin* (last updated Feb. 5, 2019), available at <https://www.fda.gov/forconsumers/byaudience/forwomen/womenshealthtopics/ucm216233.htm>.

<sup>13</sup> *Id.*

<sup>14</sup> *Id.*

<sup>15</sup> American Diabetes Association, *50 Years of Diabetes Research and Treatment* (June 6, 2015), available at <http://www.diabetes.org/newsroom/press-releases/2015/50-years-of-diabetes-research-and-treatment.html>.

1 diabetic was to inject animal insulin from cows or pigs.<sup>16</sup> The first commercially available insulin product—introduced in 1923—was manufactured by Eli Lilly and was derived from animal insulin.<sup>17</sup> In 1982, Eli Lilly introduced the first recombinant DNA human insulin to the market—Humulin.<sup>18</sup> In 1996, Eli Lilly received Food and Drug Administration (FDA) approval for the first commercial human insulin analog in the United States—Humalog.<sup>19</sup> Insulin has continued to evolve with the development of rapid-acting analogs, analog mixtures, basal analogs, and other human insulin products and formulations, including Sanofi’s development of its long-acting insulin glargine, Lantus.<sup>20</sup>

### C. List and Net Price of Insulin

Recent discussions regarding the increasing price of insulin have typically focused on the list price of the medicine—the initial price for the medicine set by the manufacturer. The list price of insulin has increased significantly over the past decade. According to a 2016 study, the average list price of insulin nearly tripled between 2002 and 2013.<sup>21</sup> Similarly, a January 2019 report by the Health Care Cost Institute on “Spending on Individuals with Type 1 Diabetes and the Role of Rapidly Increasing Insulin Prices,” showed that the point-of-sale prices for insulin also have been increasing rapidly. Point-of-sale prices are the prices charged by a pharmacy to certain customers and, while not the “list price,” these prices also do not account for all manufacturer rebates, discounts, and other price concessions. The study found that the point-of-sale price of all insulin products increased between 2012 and 2016, and that the average point-of-sale price nearly doubled during this period.<sup>22</sup> As a result, an individual using an average amount of insulin went from spending about \$7.80 per day for their insulin to spending about \$15 a day for their insulin.<sup>23</sup>

#### Point-of-Sale Prices for Common Insulin Products, 2012 to 2016<sup>24</sup>

---

<sup>16</sup> Joseph M Tibaldi, MD, *Evolution of Insulin: From Human to Analog*, THE AMERICAN JOURNAL OF MEDICINE (Oct. 2014), available at [https://www.amjmed.com/article/S0002-9343\(14\)00585-3/pdf](https://www.amjmed.com/article/S0002-9343(14)00585-3/pdf).

<sup>17</sup> Nicholas Florko, ‘Everyone is at fault’: With insulin prices skyrocketing, there’s plenty of blame to go around, STAT NEWS (Feb. 19, 2019), available at <https://www.statnews.com/2019/02/19/no-generic-insulin-who-is-to-blame/>.

<sup>18</sup> New England Healthcare Institute, *Insulin Analogs: Innovation in Biotechnology* (2006), available at [https://www.nehi.net/writable/publication\\_files/file/analog\\_one\\_pager.pdf](https://www.nehi.net/writable/publication_files/file/analog_one_pager.pdf).

<sup>19</sup> *Id.*

<sup>20</sup> See *supra* note 15; Eli Lilly, *Lilly To Discontinue Four Insulin Products* (July 6, 2005), available at <https://investor.lilly.com/news-releases/news-release-details/lilly-discontinue-four-insulin-products>; and *Drug Pricing in America: A Prescription for Change, Part II: Hearing Before S. Comm. on Finance*, 116<sup>th</sup> Cong. (Feb. 26, 2019), Testimony of Olivier Brandicourt, M.D., Chief Executive Officer, Sanofi.

<sup>21</sup> William T. Cefalu, et al., *Insulin Access and Affordability Working Group: Conclusions and Recommendations*, DIABETES CARE, at 2-3 & 11 (May 2018); Xinyang Hua, MSc, Natalie Carvalho, PhD, Michelle Tew, MPH, et al., *Expenditures and Prices of Antihyperglycemic Medications in the United States: 2002-2013*, THE JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION (2016).

<sup>22</sup> Jean Fuglesten Biniek and William Johnson, *Spending on Individuals with Type 1 Diabetes and the Role of Rapidly Increasing Insulin Prices*, HEALTH CARE COST INSTITUTE (Jan. 21, 2019).

<sup>23</sup> *Id.*

<sup>24</sup> The Health Care Cost Institute used point-of-sale prices that are reported on a claim for a prescription drug and did not have data on rebates or coupons. *Id.*

	Product	Delivery	Description	Average Price per Product (\$)					5-yr Chg. (%)
				2012	2013	2014	2015	2016	
Basal	Humulin N	Vial	10mL, 100 units/mL	68	79	95	116	131	93%
		Pen	5 pens, 3mL each, 100 units/mL	219	257	290			
		KwikPen	5 pens, 3mL each, 100 units/mL			314	370	415	
	Novolin N	Vial	10mL, 100 units/mL	67	75	89	108		
	Lantus	Vial	10mL, 100 units/mL	123	152	211	244	243	98%
		SoloStar Pen	5 pens, 3mL each, 100 units/mL	217	258	325	368	367	69%
	Levemir	Vial	10mL, 100 units/mL	124	152	216	252	264	113%
		FlexPen	5 pens, 3mL each, 100 units/mL	217	253	315			
		FlexTouch	5 pens, 3mL each, 100 units/mL			353	380	398	
		Toujeo	SoloStar Pen	3 pens, 1.5mL each, 300 units/mL				333	328
	Tresiba	U-100 Pen	5 pens, 3mL each, 100 units/mL					440	
		U-200 Pen	3 pens, 3mL each, 200 units/mL					524	
Meatime	Humulin R	Vial	10mL, 100 units/mL	68	80	96	116	132	94%
		U-500 Vial	20mL, 500 units/mL	563	804	961	1152	1319	134%
		U-500 KwikPen	2 pens, 3mL each, 500 units/mL					513	
	Novolin R	Vial	10mL, 100 units/mL	68	79	93			
	Apidra	Vial	10mL, 100 units/mL	97	124	169	209	240	147%
		SoloStar Pen	5 pens, 3mL each, 100 units/mL	196	244	332	408	466	138%
	Humalog	Vial	10mL, 100 units/mL	127	147	178	213	241	90%
		Cartridge	5 cart., 3mL each, 100 units/mL	235	271	334	398	449	91%
		Pen	5 pens, 3mL each, 100 units/mL	247	285	346	415	469	90%
		KwikPen	2 pens, 3mL each, 200 units/mL					381	
	Novolog	Vial	10mL, 100 units/mL	127	146	176	209	237	87%
		Cartridge	5 cart., 3mL each, 100 units/mL	242	275	333	397	443	83%
		FlexPen	5 pens, 3mL each, 100 units/mL	247	286	344	409	461	87%

These pre-rebate prices, such as the list price, oftentimes are not the amount of money the manufacturer ultimately receives for the product nor are they typically the amount that pharmacy benefit managers (PBMs) and health plans pay for the medicine. Instead, as Matt Eyles, Senior Executive Vice President and Chief Operating Officer for Policy and Regulatory Affairs at America’s Health Insurance Plans testified before the Committee on Energy and Commerce in December 2017, the list price is the “starting point for plans and PBMs to negotiate lower prices for consumers.”<sup>25</sup> Indeed, there is not a single, consistent price for any insulin formulation. The ultimate price paid for each product depends on confidential negotiations between stakeholders.<sup>26</sup>

Typically, wholesalers purchase products directly from the drug manufacturers for an amount at or close to the list price and receive a handling fee that generally is a fixed percentage of the list price.<sup>27</sup> Pharmacies and providers then purchase the product from the wholesale distributors at an amount close to the list price and dispense the medicine to patients.<sup>28</sup> Pharmacies and wholesale distributors may negotiate minimal volume and/or prompt pay

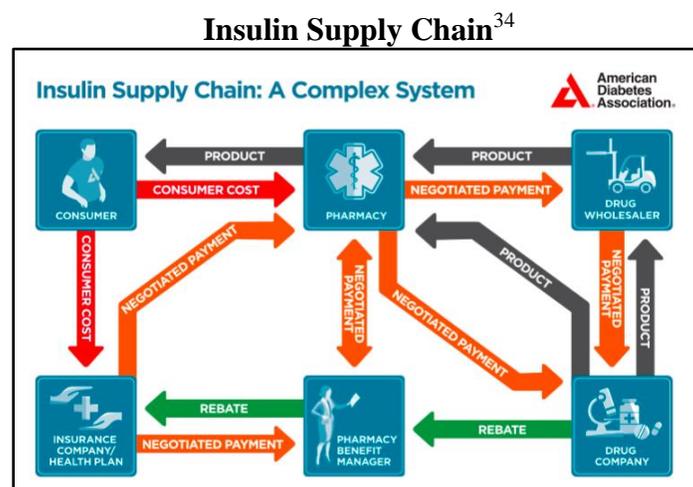
<sup>25</sup> *Examining the Drug Supply Chain: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 115<sup>th</sup> Cong., Preliminary Transcript, 15 (Dec. 13, 2017).

<sup>26</sup> William T. Cefalu, et al., *Insulin Access and Affordability Working Group: Conclusions and Recommendations*, DIABETES CARE, at 2 (May 2018).

<sup>27</sup> *Id.*

<sup>28</sup> *Examining the Drug Supply Chain: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 115<sup>th</sup> Cong., Testimony of Matt Eyles, Senior Executive Vice President and Chief Operating Officer, America’s Health Insurance Plans (Dec. 13, 2017).

discounts with the manufacturer.<sup>29</sup> When dispensing the medicine, pharmacies collect any cost-sharing required by the patient's health insurance plan and submit an invoice to the patient's health insurance plan, if there is one, for the cost of the medicine less any cost sharing collected from the patient, plus a dispensing fee.<sup>30</sup> The pharmacies negotiate their reimbursement rates with PBMs and health plans.<sup>31</sup> Sometimes, the manufacturer provides a discount to a specific pharmacy and/or provider, and in those instances, the wholesaler will bill the manufacturer for the difference between the amount the wholesaler paid the manufacturer for the medicine and the amount the provider and/or pharmacy paid the wholesaler.<sup>32</sup> PBMs and health plans also typically negotiate additional rebates and fees with manufacturers for preferred formulary placement on lower cost-sharing tiers.<sup>33</sup> The flow of dollars in the supply chain can substantially differ depending on the specific actors in each transaction.



Although it is clear that the list price of insulin is increasing, there is limited publicly available information about how the net price has changed in recent years since information about rebates and other price concessions is considered confidential and proprietary information.<sup>35</sup> Both the Congressional Budget Office and the Federal Trade Commission (FTC) have expressed concerns that disclosure of rebate information could inhibit competition.<sup>36</sup> For example, in discussing price transparency in the health care industry generally, the FTC noted

<sup>29</sup> *Id.*

<sup>30</sup> William T. Cefalu, et al., *Insulin Access and Affordability Working Group: Conclusions and Recommendations*, DIABETES CARE, at 2 (May 2018).

<sup>31</sup> See *supra* note 28.

<sup>32</sup> The Health Strategies Consulting, LLC, *Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain*, Prepared for The Kaiser Family Foundation (Mar. 2005).

<sup>33</sup> *Examining the Drug Supply Chain: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 115<sup>th</sup> Cong., Testimony of Lori M. Reilly, Executive Vice President, Policy, Research, and Membership, Pharmaceutical Research and Manufacturers of America (Dec. 13, 2017).

<sup>34</sup> William T. Cefalu, et al., *Insulin Access and Affordability Working Group: Conclusions and Recommendations*, DIABETES CARE (May 2018).

<sup>35</sup> See, e.g., Jean Fuglesten Biniek, William Johnson, *Spending on Individuals with Type 1 Diabetes and the Role of Rapidly Increasing Insulin Prices*, HEALTH CARE COST INSTITUTE (Jan. 21, 2019).

<sup>36</sup> Congressional Budget Office, *Prices for and Spending on Specialty Drugs in Medicare Part D and Medicaid* (Mar. 2007), available at <https://www.cbo.gov/system/files?file=2018-10/03-12-drug-rebates.pdf>.

that transparency may harm competition and consumers if it goes too far.<sup>37</sup> More specifically, in a different letter, the FTC raised concerns about a New York proposal requiring PBMs to disclose their rebate agreements with drug manufacturers, explaining that disclosure of this information could harm competition and consumers.<sup>38</sup>

While these concerns about the effect of transparency on competition have resulted in there being limited public information available about net price for each insulin product, there is some evidence available showing that the net price of insulin has not increased nearly as rapidly as the list price. Indeed, some reports have shown that the net price paid to insulin manufacturers for some insulin products has declined in recent years. For example, in 2016, the *Wall Street Journal* reported that, while the list price of insulin more than doubled since 2011, the net price had remained almost flat during that same period.<sup>39</sup> In addition, a 2018 report by the ADA's Insulin Access and Affordability Working Group found that there have been greater increases in the list prices than the net prices for insulin. More specifically, the report stated:

The Working Group found a number of examples from public sources showing that the net price to the insulin manufacturers has grown at a slower rate, or has gone down, compared to list prices. For example, the net price of the insulin formulation Lantus (glargine) increased more or less in parallel with the list price from 2007 to 2013. However, the net price has decreased in recent years. As a result, the net price increased by 57% between 2007 and 2016, increasing 23% as fast as the list price reported as a 252% increase of the same period.

Reports on other insulin products also illustrate the difference between the rapid increase in list price as compared with the slower increase in net price to manufacturer, a trend that may have started earlier for some insulin formulations. Bloomberg News reported an estimate by independent market research firm that the list price of Eli Lilly's human insulin analog, Humalog, increased by 138% between 2009 and 2015, while the net price to the manufacturer increased by 6%.

Novo Nordisk also published data for two of their insulin products, NovoLog and NovoLog FlexPen. Since the early 2000s, the [compound annual growth rates (CAGRS)] for the list prices for NovoLog and NovoLog FlexPen have been in the range of 9.8-9.9%. This translated into large total increases in the list prices: 353% (2001-2016) for a NovoLog vial and 270% (2003-2016) for a FlexPen. In contrast,

---

<sup>37</sup> Tara Isa Koslov and Elizabeth Jex, Office of Policy Planning, Federal Trade Commission, *Price transparency of TMI?* (July 2, 2015), available at <https://www.ftc.gov/news-events/blogs/competition-matters/2015/07/price-transparency-or-tmi>.

<sup>38</sup> Letter from James Cooper, Acting Director, Office of Policy Planning, Pauline M. Ippolito, Acting Director, Bureau of Economics, and David P. Wales, Acting Director, Bureau of Competition, Federal Trade Commission to The Hon. James L. Seward (Mar. 31, 2009), available at [https://www.ftc.gov/sites/default/files/documents/advocacy\\_documents/ftc-staff-comment-honorable-james-l.seward-concerning-new-york-senate-bill-58-pharmacy-benefit-managers-pbms/v090006newyorkpbm.pdf](https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-honorable-james-l.seward-concerning-new-york-senate-bill-58-pharmacy-benefit-managers-pbms/v090006newyorkpbm.pdf).

<sup>39</sup> Denise Roland and Peter Loftus, *Insulin Prices Soar While Drugmakers' Share Stays Flat*, THE WALL STREET JOURNAL (Oct. 7, 2016), available at <https://www.wsj.com/articles/insulin-prices-soar-while-drugmakers-share-stays-flat-1475876764>.

net prices received by the manufacturer increased at a more modest rate with CAGRs of 3-36%--more in line with the rate of inflation for the overall economy.<sup>40</sup>

Similarly, as part of Sanofi's Prescription Medicine Pricing Principles, Sanofi released information showing that for their entire insulin portfolio, the average net price is 25 percent lower today than it was in 2012.

**Sanofi's Insulin Cost Over Time<sup>41</sup>**



Likewise, Eli Lilly recently released a shareholder report indicating that the “net price” patients pay for Eli Lilly’s most commonly prescribed version of Humalog—Humalog U-100—decreased by 8.1 percent from \$147 a patient per month in 2014 to \$135 in 2018 while the list price increased 51.9 percent during the same period.<sup>42</sup>

The pharmaceutical industry has argued that one reason manufacturers increase their list price is because of the growing pressure for them provide PBMs and insurers with larger rebates so their medicine will be placed on the formulary.<sup>43</sup> According to the Pharmaceutical Care Management Association (PCMA), however, there is no correlation between increasing insulin list prices and the average rebate levels that the manufacturers negotiate with PBMs for those products. For example, PCMA issued a chart indicating that top insulins with lower average

<sup>40</sup> William T. Cefalu, et al., *Insulin Access and Affordability Working Group: Conclusions and Recommendations*, DIABETES CARE, at 2-3 & 11 (May 2018), available at <http://care.diabetesjournals.org/content/early/2018/05/03/dci18-0019> (Citations omitted).

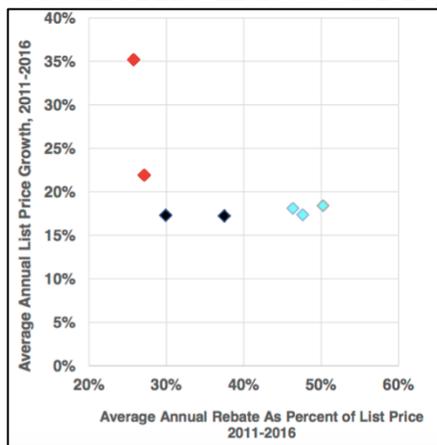
<sup>41</sup> Sanofi, *Prescription Medicine Pricing: Our Principles and Perspectives* (May 2017), available at [https://www.sanofi.us/-/media/Project/One-Sanofi-Web/websites/north-america/sanofi-us/home/corporateresponsibility/Prescription\\_medicine\\_pricing\\_2019.pdf](https://www.sanofi.us/-/media/Project/One-Sanofi-Web/websites/north-america/sanofi-us/home/corporateresponsibility/Prescription_medicine_pricing_2019.pdf).

<sup>42</sup> Lillypad, *Solutions to Bring Down Consumers' Prices* (Mar. 25, 2019), available at <https://lillypad.lilly.com/entry.php?e=11317>; Eli Lilly and Company, *2018 Integrated Summary Report* (2019), available at [https://assets.ctfassets.net/hadumfdtzsru/d6mQkK4sswwM4j4ZoHGrA/af9e78215e6c2c5c4dac1e3c6596fcff/2018\\_I\\_SR\\_03062019\\_Final-WithCover.pdf](https://assets.ctfassets.net/hadumfdtzsru/d6mQkK4sswwM4j4ZoHGrA/af9e78215e6c2c5c4dac1e3c6596fcff/2018_I_SR_03062019_Final-WithCover.pdf).

<sup>43</sup> *Drug Pricing in America: A Prescription for Change, Part II: Hearing Before S. Comm. on Finance*, 116<sup>th</sup> Cong. (Feb. 26, 2019).

rebates had higher annual price increases between 2011 and 2016 while top insulins with higher average rebates had only average price increases.<sup>44</sup>

#### Average Rebates and Price Increases for Top Insulin Brands<sup>45</sup>



PBMs emphasize that they use tools such as generics (when available), prior authorization and step therapy, and formulary placement to help lower prescription drug costs for their clients. For example, CVS Health recently described how they used formulary management to remove Lantus from their standard formulary in favor of the new follow-on biologic, Basaglar, resulting in 20,000 of the 27,000 Lantus users in CVS’ client base to more cost-effective therapies.<sup>46</sup> As a result, CVS Health said that moving all users to Basaglar would save more than \$30 million per year.<sup>47</sup> Similarly, in their 2018 Drug Trend Report, Express Scripts highlighted that commercial plans enrolled in their clinical solutions saw a 1.5 percent decline in unit costs for insulin, despite an increase in the average list price of insulin products during the same period.<sup>48</sup> In the report, Express Scripts noted that they reduced the unit costs of medicines by “guiding plan members to effective, lower-cost therapies and by securing deeper discounts from manufacturers and pharmacies.”<sup>49</sup>

#### D. Out-of-Pocket Costs for Patients

While it remains unclear which entities in the supply chain, if any, benefit from list price increases, it is clear that list price increases oftentimes directly harm patients by increasing their

<sup>44</sup> PCMA, *Insulins: Prices, Rebates, and Other Factors Influencing Costs* (May 2018), available at <https://www.pcmanet.org/wp-content/uploads/2018/05/Insulins-Prices-Rebates-Costs.pdf>.

<sup>45</sup> *Id.*

<sup>46</sup> CVS Health, *Current and New Approaches to Making Drugs More Affordable* (Aug. 2018), available at <https://cvshealth.com/sites/default/files/cvs-health-current-and-new-approaches-to-making-drugs-more-affordable.pdf>.

<sup>47</sup> *Id.*

<sup>48</sup> Express Scripts, *2018 Drug Trend Report* (last visited Mar. 27, 2019), available at <https://my.express-scripts.com/rs/809-VGG-836/images/Express%20Scripts%202018%20Drug%20Trend%20Report.pdf>.

<sup>49</sup> *Id.*

out-of-pocket costs. An uninsured patient that purchases insulin at the pharmacy is likely to pay the list price of the medicine unless they have access to a patient assistance program.<sup>50</sup>

The out-of-pocket costs for an individual with insurance also may be impacted by the list price depending on a variety of different factors such as the benefit design of the patient's health plan (*e.g.*, whether the patient is in the deductible phase of his or her plan, the formulary tier structure, the type of cost sharing such as a flat fee or a coinsurance, etc.), whether the plan passes manufacturer rebates through to the patient or uses them to lower premiums, and the reimbursement amount negotiated between the health plan and the pharmacy. For example, during the Committee's December 2017 hearing entitled "Examining the Drug Supply Chain," the Executive Vice President of the Pharmaceutical Research and Manufacturers of America (PhRMA), Ms. Lori M. Reilly, explained how a patient's insurance plan may require them to pay the full undiscounted price in some instances.<sup>51</sup> Ms. Reilly, testified:

Due to the growing gap between list and net prices, patients' cost sharing for medicines is increasingly based on prices that do not reflect plan sponsors' actual costs. For example, market analysts report that negotiated discounts and rebates can lower the net price of insulin by up to 50% to 70%, yet health plans require patients with deductibles to pay the full undiscounted price. As a result, a patient in a high-deductible health plan who pays the list price each month for insulin may be paying hundreds—or even thousands—more annually than their insurer.<sup>52</sup>

Similarly, in response to the August 30, 2018 letter that the Committee sent to PBMs, the Committee heard that lower list prices would likely result in immediate savings for patients. For example, when asked how a lower list price for a medicine would impact beneficiaries, one PBM said:

If the patient has a high deductible health plan, the lower price would pass directly to the patient. If a patient pays a coinsurance, (percentage of the drug cost) amount the savings would also be included proportionately in the patient pay amount. If the patient has a flat copay, the savings would only be realized if the price of the drug were below the set copay.<sup>53</sup>

Sanofi recently testified that the net price of their insulin product Lantus has decreased by over 30 percent since 2012 while the average out-of-pocket costs for patients with commercial

---

<sup>50</sup> William T. Cefalu, et al., *Insulin Access and Affordability Working Group: Conclusions and Recommendations*, DIABETES CARE (May 2018).

<sup>51</sup> *Examining the Drug Supply Chain: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 115<sup>th</sup> Cong., 15 (Dec. 13, 2017).

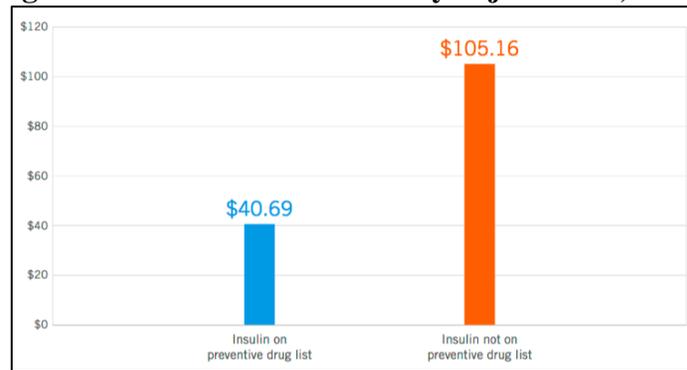
<sup>52</sup> *Examining the Drug Supply Chain: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 115<sup>th</sup> Cong., Testimony of Lori M. Reilly, Executive Vice President, Policy, Research, and Membership, Pharmaceutical Research and Manufacturers of America (Dec. 13, 2017).

<sup>53</sup> Letter to the Honorable Greg Walden, Chairman, H. Energy and Commerce Committee, et al., (Sept. 27, 2018) (on file with the Committee).

insurance and Medicare increased by approximately 60 percent over that same period.<sup>54</sup> Similarly, according to an analysis conducted by individuals from the University of Southern California (USC) Schaeffer Center for Health Policy & Economics, average out-of-pocket costs for all insulin types doubled between 2006 and 2013 for Medicare Part D beneficiaries.<sup>55</sup>

As enrollment in high deductible health plans has grown, patients have been increasingly exposed to higher out-of-pocket costs for medicines. Some PBMs have recommended that their clients include insulin on preventive drug lists, which would result in there being first-dollar coverage of insulin for beneficiaries in high deductible health plans. For example, Express Scripts noted that 64 percent of high deductible plans enrolled in their clinical solutions used the preventive drug list recommended by Express Scripts, and as a result, patients in those plans had substantially lower out-of-pocket costs for insulin.

**Express Scripts: Out-of-Pocket Costs for Patients in High-Deductible Plans Per 30 day adjusted Rx, 2018<sup>56</sup>**



An insured individual that wants to purchase an insulin product that is not on their insurer's formulary is likely to pay the list price of the medicine if they do not have access to a patient assistance program.<sup>57</sup> Indeed, the national formulary exclusion lists for one of the major PBMs includes language encouraging patients to “[t]ake action to avoid paying full price” by contacting their doctor to try and obtain a new prescription for one of the preferred alternatives if they are currently taking one of the excluded medications.<sup>58</sup>

<sup>54</sup> *Drug Pricing in America: A Prescription for Change, Part II: Hearing Before S. Comm. on Finance*, 116<sup>th</sup> Cong. (Feb. 26), Testimony of Olivier Brandicourt, M.D., Chief Executive Officer, Sanofi.

<sup>55</sup> William T. Cefalu, et al., *Insulin Access and Affordability Working Group: Conclusions and Recommendations*, DIABETES CARE, at 9 (May 2018).

<sup>56</sup> Express Scripts, *2018 Drug Trend Report* (last visited Mar. 27, 2019), available at <https://my.express-scripts.com/rs/809-VGG-836/images/Express%20Scripts%202018%20Drug%20Trend%20Report.pdf>; CVS Health, *Current and New Approaches to Making Drugs More Affordable* (Aug. 2018), available at <https://cvshhealth.com/sites/default/files/cvs-health-current-and-new-approaches-to-making-drugs-more-affordable.pdf>.

<sup>57</sup> See, e.g., Express Scripts, *2019 National Preferred Formulary Exclusions* (last visited Mar. 27, 2019), available at [https://www.express-scripts.com/art/pdf/Preferred\\_Drug\\_List\\_Exclusions2019.pdf](https://www.express-scripts.com/art/pdf/Preferred_Drug_List_Exclusions2019.pdf).

<sup>58</sup> *Id.*

The increased out-of-pocket costs for patients are negatively impacting patients, and many articles have highlighted instances where individuals with diabetes have stopped taking insulin, switched to less effective formulations, or started rationing the medicine.<sup>59</sup> A 2018 survey conducted on behalf of the ADA found that, in 2018, 39 percent of insulin users experienced an increase in the amount they personally paid for insulin over the past year and 27 percent of the respondents indicated that insulin cost had affected their purchase or use of insulin over the past year.<sup>60</sup> Similarly, the results of a survey conducted by the Yale Diabetes Center (YDC) and published in January 2019, showed that 25.5 percent of the survey respondents reported cost-related insulin underuse.<sup>61</sup>

### E. Patient Assistance Programs

There are a significant number of patient assistance programs available to help patients access insulin products.<sup>62</sup> All three major insulin manufacturers in the United States have patient assistance programs, including discount programs, savings cards, co-pay assistance programs, and other programs and information to help patients access insulin.<sup>63</sup> For example, Sanofi has an Insulins VALyou Savings Program that offers qualifying patients the ability to access all of Sanofi insulins for \$99 per 10mL vial or \$149 for a pack of SoloStar pens.<sup>64</sup> Similarly, Eli Lilly launched the Lilly Diabetes Solution Center (LDSC) that connects patients to resources such as the Lilly Cares Foundation which helps qualifying patients obtain certain Lilly medicines for free.<sup>65</sup> NovoNordisk has entered into partnerships to sell human insulin at Walmart for less than \$25 per vial and also has established the Novo Nordisk Patient Assistance Program.<sup>66</sup> This is not an exhaustive list of the programs offered by the manufacturers to help patients access insulin. Some of these programs have restrictions on program participation such as eligibility requirements.

---

<sup>59</sup> See, e.g., William T. Cefalu, et al., *Insulin Access and Affordability Working Group: Conclusions and Recommendations*, DIABETES CARE, at 8 (May 2018); Aimee Picchi, *The rising cost of insulin: "Horror stories every day,"* CBS NEWS (May 9, 2018), available at <https://www.cbsnews.com/news/the-rising-cost-of-insulin-horror-stories-every-day/>.

<sup>60</sup> Vault, *Insulin Affordability Survey, 2018* (May 22, 2018), available at

<http://www.diabetes.org/assets/pdfs/advocacy/insulin-affordability-survey.pdf>.

<sup>61</sup> Darby Herkert, BS, et al., *Cost-Related Insulin Underuse Among Patients with Diabetes*, JAMA (2018).

<sup>62</sup> American Diabetes Association, *Prescription Assistance* (last visited Mar. 27, 2019), available at

<http://www.diabetes.org/living-with-diabetes/health-insurance/prescription-assistance.html>.

<sup>63</sup> JDRF, *Help with Your Diabetes Prescription and Insulin Costs* (last visited Mar. 27, 2019), available at <https://www.jdrf.org/t1d-resources/living-with-t1d/insurance/help-with-your-diabetes-prescription-costs/>; Eli Lilly, *Insulin Affordability* (last visited Mar. 27, 2019), available at <https://www.insulinaffordability.com/>.

<sup>64</sup> Sanofi, *Insulins Valyou Savings Program* (last visited Mar. 27, 2019), available at [https://www.admelog.com/insulins-valyou-savings-program?utm\\_source=vanityurl&utm\\_medium=redirect&utm\\_campaign=valyou](https://www.admelog.com/insulins-valyou-savings-program?utm_source=vanityurl&utm_medium=redirect&utm_campaign=valyou).

<sup>65</sup> Lilly Cares, *The Lilly Cares Foundation Patient Assistance Program* (last visited Mar. 27, 2019), available at <http://www.lillycares.com/>; Eli Lilly, *Lilly Diabetes Solution Center* (last visited Mar. 27, 2019), available at <https://www.lilly.com/diabetessolutioncenter>.

<sup>66</sup> Walmart, *Novolin ReliOn Insulin N* (last visited Mar. 27, 2019), available at <https://www.walmart.com/ip/Novolin-ReliOn-Insulin-N/167672445>; Novo Nordisk, *Patient Assistance Programs* (last visited Mar. 27, 2019), available at <https://www.novonordisk-us.com/patients-and-providers/affording-your-medicines/patient-assistance-programs.html>.

The copayment coupons offered by manufacturers to reduce out-of-pocket costs for insured patients are controversial, and some health insurers and PBMs have expressed concerns with the use of co-pay coupons and similar programs, arguing that they “circumvent benefit design” and their use ultimately “results in higher premiums for everyone.”<sup>67</sup> As a result, some PBMs and health plans have taken steps to limit their effect. For example, in 2013, Express Scripts excluded 48 drugs from their formulary and their Chief Medical Officer (CMO) said that over 90 percent of the drugs they excluded in 2013 had coupons.<sup>68</sup> In an interview, the CMO elaborated:

Patient assistance programs help patients get the drugs they need, and we are very supportive of them. But coupons exist only when there are competing drugs in a marketplace and you’re trying to preserve your market share. The trouble with coupons is that they undermine the three-tiered benefit that plans put in place. The company doesn’t really want the 5% or 10% that the patient is contributing. They want the 90% that the plan sponsor is contributing.<sup>69</sup>

Likewise, more recently, some health plans and PBMs have started using copay accumulator and maximizer programs that prohibit manufacturer coupons from counting toward a patient’s deductibles and out-of-pocket maximum obligations.<sup>70</sup> Moreover, coupons are barred in federal health care programs under the anti-kickback statute.<sup>71</sup> Some states have also implemented laws prohibiting the use of coupons in certain circumstances when generic alternatives are available.<sup>72</sup>

### III. ADDITIONAL IMPORTANT ISSUES RELATING TO INSULIN PRICES

There are additional issues relating to insulin prices. These include:

- **340B Drug Discount Program:** To remain eligible for participation in the Medicaid program, drug manufacturers must provide certain outpatient drugs to covered entities in the 340B program at significant discounts, and, in certain circumstances, these manufacturers must sell their product to 340B covered entities for a penny. Some, but not all, 340B covered entities pass these savings on to patients.<sup>73</sup> For example,

---

<sup>67</sup> Karen Van Nuys, PhD, et al., *A Perspective on Prescription Drug Copayment Coupons*, USC Schaeffer (Feb. 2018).

<sup>68</sup> Peter Wehrwein, *A Conversation with Steve Miller, MD: Come in and Talk With Us, Pharma*, MANAGED CARE (Apr. 5, 2015), available at <https://www.managedcaremag.com/archives/2015/4/conversation-steve-miller-md-come-and-talk-us-pharma>.

<sup>69</sup> *Id.*

<sup>70</sup> Adam J. Fein, PhD, *Copay Accumulator Update: Widespread Adoption As Manufacturers and Maximizers Limit Patient Impact* (Sept., 18, 2018), available at <https://www.drugchannels.net/2018/09/copay-accumulator-update-widespread.html>.

<sup>71</sup> U.S. Dep’t of Health and Human Services, Office of Inspector General, *Special Advisory Bulletin: Pharmaceutical Manufacturer Copayment Coupons* (Sept. 2014).

<sup>72</sup> John S. Linehan, JD, *Assessing the Legal and Practical Implications of Copay Accumulator and Maximizer Programs*, MANAGED CARE (Feb. 13, 2019), <https://www.managedcaremag.com/archives/2019/2/assessing-legal-and-practical-implications-copay-accumulator-and-maximizer-programs>.

<sup>73</sup> H. Comm. on Energy and Commerce, *Review of the 340B Drug Pricing Program*, 115<sup>th</sup> Cong. (2018).

during the Committee's investigation of the 340B program during the 115th Congress, one 340B entity told the Committee that they offer insulin at \$10 a vial to certain qualifying patients.<sup>74</sup>

- ***Insulin spending in federal programs:*** The federal government purchases a lot of insulin through federal programs such as the Medicare and Medicaid programs. According to CMS' 2018 Drug Dashboards, the 15 drugs with the highest total spending in Medicaid and Medicare Part D both included Lantus.<sup>75</sup> The information in the spending dashboards does not account for manufacturer rebates and discounts. Moreover, the list of drugs with the highest total spending does not account for the cost per beneficiary using the medication.
- ***Incentives throughout the prescription drug supply chain for a higher list price:*** As the Committee heard about during its hearing in December 2017 entitled "Examining the Drug Supply Chain," many of the fees collected throughout the supply chain are calculated as a percentage of the list price.<sup>76</sup> These types of arrangements, along with others, may create additional incentives for supply chain actors to favor higher list prices for medicines.
- ***Non-medical switching:*** Insurers and PBMs use tiered formulary designs to drive demand towards certain drugs and exclude some drugs from their formularies entirely. When a medicine is eliminated from the formulary entirely, a patient is often faced with either switching their medicine or paying the full list price for the medicine. "Non-medical switching" is a concern in the diabetes community—the Diabetes Patient Advocacy Coalition recently released a blog noting that "[f]or patients with diabetes, a change in medication can result in unmanageable fluctuations in insulin, increased out-of-pocket costs, and additional visits to [the] physician."<sup>77</sup>
- ***Consolidation throughout the prescription drug supply chain may impact supply chain negotiations:*** As the Committee heard during its February 2018 hearing entitled "Examining the Impact of Health Care Consolidation," there is consolidation occurring throughout the health care industry, and this consolidation may impact the bargaining position of different actors.<sup>78</sup>

---

<sup>74</sup> Letter from Northern Nevada HOPES to H. Comm. on Energy and Commerce, 340B Congressional Inquiry Responses, 115<sup>th</sup> Cong. (Sept. 26, 2017), available at <https://republicans-energycommerce.house.gov/wp-content/uploads/2017/09/Northern-Nevada-HOPES.pdf>.

<sup>75</sup> Centers for Medicare & Medicaid Services, *CMS Unveils Enhanced "Drug Dashboards" to Increase Transparency on Drug Prices* (May 15, 2018), available at <https://www.cms.gov/newsroom/press-releases/cms-unveils-enhanced-drug-dashboards-increase-transparency-drug-prices>.

<sup>76</sup> *Examining the Drug Supply Chain: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 115<sup>th</sup> Cong., 15 (Dec. 13, 2017).

<sup>77</sup> DPAC, *Non-Medical Switching and Diabetes* (Mar. 17, 2019), available at <http://diabetespac.org/non-medical-switching-and-diabetes/>.

<sup>78</sup> *Examining the Drug Supply Chain: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 115<sup>th</sup> Cong., 15 (Dec. 13, 2017).

- **Competition in the insulin market:** The FDA has approved two follow-on insulins—Basaglar and Admelog.<sup>79</sup> There are not, however, any substitutable generic forms of insulin available in the market. One reason that manufacturers have struggled to bring a substitutable generic insulin to market is because insulin has traditionally been regulated as a drug rather than a biologic and it is difficult to bring a substitutable generic insulin to market under the traditional drug pathway. Congress recognized this challenge when creating the new biosimilars pathway through the Biologics Price Competition and Innovation Act of 2009 (BPCIA) and included a provision in the law that will make it easier for manufacturers to bring substitutable generic insulins to market beginning in March 2020. Indeed, according to Dr. Gottlieb, March 2020 will be a “watershed moment for insulin products” because products that are biosimilar to, or interchangeable with, existing insulin will be able to come to market.<sup>80</sup>
- **Authorized generics and formulary access:** Recently, Eli Lilly released an authorized generic of its insulin product Humalog at a list price that is about 50 percent lower than the list price of Humalog.<sup>81</sup> One article noted that the launch price of the authorized generic is higher than the net price for the branded version of the product.<sup>82</sup> The same article questioned whether PBMs will give the authorized generic better formulary placement because of its lower list price.<sup>83</sup>
- **Patents on insulin products:** According to PCMA, one cost driver for insulin prices is manufacturers extending patents by delivering insulin product in pens. PCMA released information showing that the year a pen was launched for many of the top insulin products, the price of the product was increased by 29 to 96 percent.<sup>84</sup>
- **HHS OIG Rebate Proposal:** In January 2019, the Office of Inspector General (OIG) at the U.S. Department of Health and Human Services issued a proposed rule to exclude from safe harbor protection under the Anti-Kickback Statute rebates on prescription drugs paid by manufacturers to PBMs, Part D plans, and Medicaid managed care organizations.<sup>85</sup> The proposed rule creates a new safe harbor for prescription drug discounts offered directly to patients and for fixed fee service arrangements between drug manufacturers and PBMs.<sup>86</sup>

---

<sup>79</sup> John White, PA-C, PharmD, and Jennifer Goldman, PharmD, CDE, BC-ADM, FCCP, *Biosimilar and Follow-on Insulin: The Ins, Outs and Interchangeability*, THE JOURNAL OF PHARMACY TECHNOLOGY (2018).

<sup>80</sup> U.S. Food and Drug Administration, *Statement from FDA Commissioner Scott Gottlieb, M.D., on new actions advancing the agency’s biosimilars policy framework* (Dec. 11, 2018).

<sup>81</sup> Eli Lilly, *Lilly to Introduce Lower-Priced Insulin* (Mar. 4, 2019), available at <https://investor.lilly.com/news-releases/news-release-details/lilly-introduce-lower-priced-insulin>.

<sup>82</sup> John Wilkerson, *Humalog Authorized Generic May Help Brands or Corner Them*, INSIDE CMS (Mar. 5, 2019).

<sup>83</sup> *Id.*

<sup>84</sup> PCMA, *Insulins: Prices, Rebates, and Other Factors Influencing Costs* (May 2018), available at <https://www.pcmanet.org/wp-content/uploads/2018/05/Insulins-Prices-Rebates-Costs.pdf>.

<sup>85</sup> 84 Fed. Reg. 2340 (Feb. 6, 2019).

<sup>86</sup> *Id.*