



**MEMORANDUM**

**April 5, 2019**

**To: Subcommittee on Oversight and Investigations Members and Staff**

**Fr: Committee on Energy and Commerce Staff**

**Re: Hearing on “Priced Out of a Lifesaving Drug: Getting Answers on the Rising Cost of Insulin”**

On Wednesday, April 10, 2019 at 10:30 a.m. in room 2322 of the Rayburn House Office Building, the Subcommittee on Oversight and Investigations will hold a hearing entitled, “Priced Out of a Lifesaving Drug: Getting Answers on the Rising Cost of Insulin.” This is the second part of a hearing examining insulin affordability and the ensuing financial and health challenges and effects on patients’ lives. Below is an updated version of the original memo that was circulated.

**I. OVERVIEW: DIABETES AND INSULIN**

Approximately 30 million people are living with diabetes in the United States, and 1.5 million people receive new diagnoses in the country each year.<sup>1</sup> Over the last 20 years, the number of adults diagnosed with diabetes has more than tripled, and it is estimated that roughly one in four living with diabetes in the United States are undiagnosed.<sup>2</sup> According to the Centers for Disease Control and Prevention, diabetes is the seventh leading cause of death in the United States, and is the number one cause of kidney failure, lower-limb amputations, and adult blindness.<sup>3</sup> Diagnosed diabetes is associated with \$327 billion in direct medical costs and reduced productivity costs each year.<sup>4</sup>

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<sup>1</sup> American Diabetes Association, *Statistics About Diabetes* ([www.diabetes.org/diabetes-basics/statistics/](http://www.diabetes.org/diabetes-basics/statistics/)) (accessed Mar. 26, 2019).

<sup>2</sup> Centers for Disease Control and Prevention, *About Diabetes* ([www.cdc.gov/diabetes/basics/diabetes.html](http://www.cdc.gov/diabetes/basics/diabetes.html)) (accessed Mar. 26, 2019).

<sup>3</sup> *Id.*

<sup>4</sup> Wenya Yang, et al, *Economic Costs of Diabetes in the U.S. in 2017*, American Diabetes Association (Mar. 22, 2018) (<http://care.diabetesjournals.org/content/41/5/917>).

Type 1 diabetes is an autoimmune disease that occurs when an individual does not produce enough insulin to enable blood sugar to enter cells for energy.<sup>5</sup> Usually diagnosed in children and young adults, there is no known way to prevent Type 1 diabetes.<sup>6</sup> In the United States, approximately 1.25 million adults and children have Type 1 diabetes, which comprises five percent of all diabetes diagnoses.<sup>7</sup> About 90 percent of diabetes diagnoses in the United States are for Type 2 diabetes, when one's body does not use insulin well or keep blood sugar at normal levels.<sup>8</sup> Unlike Type 1 diabetes, Type 2 diabetes can be prevented through lifestyle changes including losing weight, diet, and exercise.<sup>9</sup>

Insulin, which was discovered nearly 100 years ago, is a critical part of treatment for diabetes.<sup>10</sup> Approximately 7.4 million Americans rely on one or more formulations of insulin.<sup>11</sup> Due to dramatic price increases for insulin in recent years, some people with diabetes are going without insulin or rationing their doses, risking their health and even suffering death.<sup>12</sup>

## II. RISING INSULIN PRICES

When the discovery of insulin was made in 1923, the co-inventors wanted everyone who needed the medication to be able to afford it. Accordingly, they sold the insulin patent to the University of Toronto for a single dollar.<sup>13</sup> Approaching a century later, while the estimated manufacturing cost of most insulins, human and analog, range from \$2.28 to \$6.34 per vial,<sup>14</sup> patients can pay beyond \$400 per month for the lifesaving drug.<sup>15</sup>

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<sup>5</sup> Centers for Disease Control and Prevention, *About Diabetes* ([www.cdc.gov/diabetes/basics/diabetes.html](http://www.cdc.gov/diabetes/basics/diabetes.html)) (accessed Mar. 26, 2019).

<sup>6</sup> *Id.*

<sup>7</sup> *Id.*

<sup>8</sup> *Id.*

<sup>9</sup> *Id.*

<sup>10</sup> William T. Cefalu, et al., *Insulin Access and Affordability Working Group: Conclusions and Recommendations*, American Diabetes Association (Jun. 2018) (<http://care.diabetesjournals.org/content/41/6/1299>).

<sup>11</sup> *Id.*

<sup>12</sup> *Insulin's Steep Price Leads To Deadly Rationing*, Kaiser Health News (Sept. 7, 2018).

<sup>13</sup> Vox, *Insulin price hikes tell us a lot about what's wrong with drug pricing in America* (May 12, 2017) ([www.vox.com/science-and-health/2017/5/12/15621952/insulin-price-increases](http://www.vox.com/science-and-health/2017/5/12/15621952/insulin-price-increases)).

<sup>14</sup> Dzintars Gotharn, et al., *Production costs and potential prices for biosimilars of human insulin and insulin analogues*, BMJ Global Health (Sept. 25, 2018) (<https://gh.bmj.com/content/3/5/e000850>). See supplementary appendix page 10.

<sup>15</sup> Vox, *Insulin price hikes tell us a lot about what's wrong with drug pricing in America* (May 12, 2017) ([www.vox.com/science-and-health/2017/5/12/15621952/insulin-price-increases](http://www.vox.com/science-and-health/2017/5/12/15621952/insulin-price-increases)).

There have been dramatic price increases for insulin in recent years, with the price tripling between 2002 and 2013.<sup>16</sup> The prices continued to climb, nearly doubling between 2012 and 2016.<sup>17</sup> Over that same period, the average list price of the four insulin categories—short-acting insulin, long-acting insulin, rapid-acting insulin vials, and rapid-acting insulin pens—increased between 15–17 percent per year.<sup>18</sup> During the same four years the price that pharmacies paid and Medicare Part D spending on insulin also increased at similar rates.<sup>19</sup> People with diabetes with employer-sponsored insurance saw the average price for a 40-day supply of insulin rise from \$344 to \$666 over the course of those same years.<sup>20</sup>

In the past two decades, prices for the most commonly prescribed insulins have increased from about \$20 per vial to over \$250 per vial—a more than 700 percent increase after adjusting for inflation.<sup>21</sup> This steep price increase has made insulin unaffordable even for some high-income individuals.<sup>22</sup>

### III. IMPACT OF RISING INSULIN PRICES ON PEOPLE WITH DIABETES

When people with diabetes go without insulin, or ration their doses, there can be tragic consequences, including death.<sup>23</sup> People with Type 1 diabetes need to take insulin every day to survive.<sup>24</sup> The 7.4 million people who rely on insulin to treat their diabetes use at least one vial of insulin each month, though some patients require multiple vials or multiple types of insulins

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<sup>16</sup> William T. Cefalu, et al., *Insulin Access and Affordability Working Group: Conclusions and Recommendations*, American Diabetes Association (Jun. 2018) (<http://care.diabetesjournals.org/content/41/6/1299>).

<sup>17</sup> Health Care Cost Institute, *Price of Insulin Prescription Doubled Between 2012 and 2016*, (Nov. 29, 2017).

<sup>18</sup> William T. Cefalu, et al., *Insulin Access and Affordability Working Group: Conclusions and Recommendations*, American Diabetes Association (Jun. 2018).

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

<sup>20</sup> Health Care Cost Institute, *Price of Insulin Prescription Doubled Between 2012 and 2016*, (Nov. 29, 2017) ([www.healthcostinstitute.org/blog/entry/price-of-insulin-prescription-doubled-between-2012-and-2016?highlight=WyJpbN1bGluIl0=](http://www.healthcostinstitute.org/blog/entry/price-of-insulin-prescription-doubled-between-2012-and-2016?highlight=WyJpbN1bGluIl0=)). Average prices were calculated from the actual amounts paid at either in-person or mail order pharmacies, and may not reflect any discounts, rebates or coupons.

<sup>21</sup> Harvard Political Review, *How Insulin Became Unaffordable* (Jan. 22, 2018) (<http://harvardpolitics.com/united-states/how-insulin-became-unaffordable/>).

<sup>22</sup> *Id.*

<sup>23</sup> *Insulin's Steep Price Leads To Deadly Rationing*, Kaiser Health News (Sept. 7, 2018).

<sup>24</sup> Centers for Disease Control and Prevention, *About Diabetes* ([www.cdc.gov/diabetes/basics/diabetes.html](http://www.cdc.gov/diabetes/basics/diabetes.html)) (accessed Mar. 26, 2019).

each month.<sup>25</sup> Adherence to an individualized medication regimen is critical for someone living with diabetes to avoid complications such as diabetic ketoacidosis which can develop within 24 hours and cause severe dehydration, kidney damage, brain swelling and damage, stroke, and respiratory failure.<sup>26</sup>

A 2018 Yale University survey of patients with Type 1 or Type 2 diabetes who use insulin found that one in four patients were rationing their insulin due to cost.<sup>27</sup> The patients who indicated insulin underuse were three times more likely to have poor glycemic control—an indicator of ineffective diabetes management—than other surveyed patients.<sup>28</sup> Among patients surveyed by the American Diabetes Association in 2018, 27 percent reported that insulin costs affected their past year’s purchase or use of insulin and these patients were more likely to experience adverse health effects.<sup>29</sup> In addition to being more likely to ration their insulin, these patients also reported having to forego other needs such as transportation, utilities, housing, doctor’s visits, or other medications.<sup>30</sup>

#### **IV. ROLES OF MANUFACTURERS AND PHARMACY BENEFIT MANAGERS**

While the price a consumer ultimately pays for a drug is driven by many factors, it begins with the list price set by the manufacturer. Some experts attribute the rapidly increasing price of insulin to several factors, including a lack of competition in the insulin market that includes just one follow-on biologic and an authorized generic across all types of insulin.<sup>31</sup> Experts also say

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<sup>25</sup> Endocrine Society, *Increasing Insulin Affordability: An Endocrine Society Position Statement* (Nov. 2018) ([www.endocrine.org/advocacy/priorities-and-positions/increasing-insulin-affordability](http://www.endocrine.org/advocacy/priorities-and-positions/increasing-insulin-affordability)).

<sup>26</sup> OnTrack Diabetes, *Insulin Rationing: What It Is and Why It’s So Dangerous* (Jan. 17, 2019) ([www.ontrackdiabetes.com/live-well/diabetes-management/insulin-rationing-what-it-why-its-so-dangerous](http://www.ontrackdiabetes.com/live-well/diabetes-management/insulin-rationing-what-it-why-its-so-dangerous)).

<sup>27</sup> Darby Herkert, et al., *Cost-Related Insulin Underuse Among Patients With Diabetes*, *Journal of the American Medical Association* (Jan. 2019) (<https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2717499>).

<sup>28</sup> *Id.*

<sup>29</sup> American Diabetes Association, *Insulin Affordability Survey, 2018* (May 22, 2018) ([www.diabetes.org/assets/pdfs/advocacy/insulin-affordability-survey.pdf](http://www.diabetes.org/assets/pdfs/advocacy/insulin-affordability-survey.pdf)).

<sup>30</sup> *Id.*

<sup>31</sup> William T. Cefalu, et al., *Insulin Access and Affordability Working Group: Conclusions and Recommendations*, American Diabetes Association (Jun. 2018) (<http://care.diabetesjournals.org/content/41/6/1299>); CNN, *Amid uproar over high drug prices, Eli Lilly introduces generic insulin at half price of brand-name Humalog* (Mar. 4, 2019) ([www.cnn.com/2019/03/04/health/insulin-price-humalog-generic-eli-lilly-bn/index.html](http://www.cnn.com/2019/03/04/health/insulin-price-humalog-generic-eli-lilly-bn/index.html)).

that evergreening, the practice of manufacturers seeking extra patents on variations of an original drug, contributes to reduced competition on the insulin market.<sup>32</sup>

Three insulin manufacturers serve the U.S. market: Eli Lilly, Novo Nordisk, and Sanofi.<sup>33</sup> Last month, Eli Lilly announced that it would make an authorized generic version of its Humalog insulin available in the U.S. with a 50 percent reduced price.<sup>34</sup> While this new authorized generic offering may reduce the price some consumers pay at the point-of-sale, some critics have noted that authorized generics allow the price of the brand drug to remain high without necessarily passing savings on to consumers.<sup>35</sup>

All three of the insulin manufacturers provide a range of patient assistance programs and discount cards with varying eligibility requirements and enrollment processes. While these options may provide short-term financial relief for some patients, they can be restrictive, difficult for patients to navigate, and do not provide long-term solutions to insulin affordability.<sup>36</sup>

Regarding the role of pharmacy benefits managers (PBMs), three such companies cover about 70 percent of all prescription claims in the United States: CVS Health, Express Scripts, and UnitedHealth Group.<sup>37</sup> PBMs administer prescription drug programs for commercial health plans and set the list of drugs covered by those plans (known as formularies). In exchange for placing drugs on formularies, PBMs negotiate discounts off the list prices from the manufacturers.<sup>38</sup> However, some experts believe PBMs may create incentives that lead to increasing prices for insulin. For example, the pressure to offer discounts may lead to higher list prices.<sup>39</sup> Experts have also pointed to the lack of transparency in financial agreements between

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<sup>32</sup> T1 International, *8 Reasons Why Insulin is so Outrageously Expensive* (Jan. 20, 2019) ([www.t1international.com/blog/2019/01/20/why-insulin-so-expensive/](http://www.t1international.com/blog/2019/01/20/why-insulin-so-expensive/)).

<sup>33</sup> *Id.*

<sup>34</sup> Eli Lilly and Company, *Lilly to Introduce Lower-Priced Insulin* (Mar. 4, 2019) (press release).

<sup>35</sup> *Lilly unveils a 'generic' insulin and shows how broken our healthcare system really is*, Los Angeles Times (Mar. 6, 2019).

<sup>36</sup> Endocrine Society, *Increasing Insulin Affordability: An Endocrine Society Position Statement* (Nov. 2018) ([www.endocrine.org/advocacy/priorities-and-positions/increasing-insulin-affordability](http://www.endocrine.org/advocacy/priorities-and-positions/increasing-insulin-affordability)).

<sup>37</sup> *Id.*

<sup>38</sup> William T. Cefalu, et al., *Insulin Access and Affordability Working Group: Conclusions and Recommendations*, American Diabetes Association (Jun. 2018) (<http://care.diabetesjournals.org/content/41/6/1299>).

<sup>39</sup> *Id.*

stakeholders in the supply chain – including among manufacturers and PBMs – as a contributing factor making it difficult to decipher the overall cost to patients.<sup>40</sup>

## V. WITNESSES

The following witnesses have been invited to testify:

**Mike Mason**

Senior Vice President, Lilly Connected Care and Insulins Global Business Unit  
Eli Lilly and Company

**Doug Langa**

Executive Vice President, North America Operations, and President of Novo Nordisk Inc.  
Novo Nordisk

**Kathleen Tregoning**

Executive Vice President for External Affairs  
Sanofi

**Thomas Moriarty**

Executive Vice President, Chief Policy and External Affairs Officer, and General  
Counsel  
CVS Health

**Amy Bricker**

Senior Vice President, Supply Chain  
Express Scripts

**Sumit Dutta, MD**

Senior Vice President and Chief Medical Officer  
OptumRx

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<sup>40</sup> Endocrine Society, *Increasing Insulin Affordability: An Endocrine Society Position Statement* (Nov. 2018) ([www.endocrine.org/advocacy/priorities-and-positions/increasing-insulin-affordability](http://www.endocrine.org/advocacy/priorities-and-positions/increasing-insulin-affordability)).