



# The High Cost of Insulin in the United States: An Urgent Call to Action

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**A**lec Smith was 23 when he was diagnosed with type 1 diabetes. He worked as a restaurant manager in Minnesota. At age 26, he could no longer stay on his mother's health care insurance plan and needed to find his own coverage. On June 1, 2017, he was on his own. The insurance available to him came with a \$7600 deductible and a monthly premium of approximately \$440.<sup>1</sup> Because he could not afford this, Alec decided to temporarily forego insurance coverage and purchase insulin with cash. Unfortunately for him, the cash price of insulin was far beyond his means.<sup>2</sup> He decided to try and ration the amount of insulin he took till he had enough savings to purchase insurance. Sadly, on June 27, 2017, he was found dead in his apartment of diabetic ketoacidosis.

The most commonly used forms of analog insulin cost 10 times more in the United States than in any other developed country.<sup>3</sup> There have been many other recent reports of deaths in patients with type 1 diabetes because of lack of affordable insulin.<sup>4,5</sup> The high prevalence of diabetes, the chronic lifelong nature of the disease, and the fact that patients with type 1 diabetes will die without access to insulin make this an urgent problem that must be solved expeditiously. The price of insulin is also a stark and troubling example of the rising cost of prescription drugs in the United States and highlights a systemic problem with how drugs are priced compared with every other commodity.<sup>6,7</sup> This commentary will address the reasons for the high cost of insulin and examine possible solutions. By understanding and solving this problem, we can create a roadmap that brings much needed reform and fairness to the existing system and helps make all prescription drugs more affordable.

The 3 main reasons cited by pharmaceutical companies for the high cost of new prescription drugs do not apply to insulin. First, the "high cost of development" is not relevant for a drug that is more than 100 years old; even the latest and most commonly used analog insulin products are all over 20 years old.<sup>8</sup> Second, the pricing is not the product of a free market economy. Free market forces are clearly not operational; there is limited competition on price, the person who needs the product is not in a position to negotiate the price, and there is no relationship of price increases over time compared with overall market inflation. The price of insulin has risen inexplicably over the past 20 years at a rate far higher than the rate of inflation.<sup>9</sup> One vial of Humalog (insulin lispro), which used to cost \$21 in 1999, costs \$332 in 2019, reflecting a price increase of more than 1000%.<sup>10-12</sup> In contrast, insulin prices in other developed countries, including neighboring Canada, have stayed the same. *Insulin pricing in the United States is the consequence of the exact opposite of a free market: extended monopoly on a lifesaving product in which prices can be increased at will, taking advantage of regulatory and legal restrictions on market entry and importation.* Third, the arguments that high costs are needed for continued innovation and that attempts to lower or regulate the prices will hamper innovation are not a valid excuse.<sup>13</sup> There is limited innovation when it comes to insulin; the more pressing need is affordability.

## Reasons for the High Cost of Insulin

The number 1 reason for the high cost of insulin is the presence of a vulnerable population that needs insulin to survive (Table 1).

**TABLE 1. High Cost of Insulin: Reasons and Possible Solutions**

Reasons for the high cost of insulin
<ul style="list-style-type: none"> <li>• Vulnerable population who is willing to pay high costs to have access to a lifesaving drug</li> <li>• Virtual monopoly/oligopoly</li> <li>• Patent abuse and evergreening</li> <li>• Barriers to biosimilar entry</li> <li>• Pharmacy benefit managers and other middlemen who benefit from a high list price</li> <li>• Lobbying power of insulin manufacturers</li> </ul>
Possible policy level solutions
<ul style="list-style-type: none"> <li>• Value-based reimbursement and pricing, and laws and regulations governing price increases</li> <li>• Easier path for biosimilar entry, including reciprocal approval of biosimilars</li> <li>• Patent reform</li> <li>• Governmental or nongovernmental agency to oversee pricing</li> <li>• Transparency on rebates</li> <li>• Nonprofit manufacturing</li> <li>• Emergency access laws</li> <li>• Increased advocacy</li> </ul>
Solutions that can be implemented by physicians and institutions
<ul style="list-style-type: none"> <li>• Discussion with patients about affordability</li> <li>• Awareness about sources of information on prices</li> <li>• Practice guidelines that take cost into account</li> <li>• Preference of lower-cost biosimilars in formularies</li> <li>• Advocacy</li> </ul>

This population, which numbers in the millions,<sup>14</sup> is willing to pay anything to have access to a lifesaving drug. The desperate need for a lifesaving product allows insulin to be priced at high levels because it is not a luxury item that one can forego. The manufacturers of insulin know that patients who need it will spend whatever it takes to acquire it, regardless of price. It is a matter of life and death.

Second, there is virtual monopoly on insulin that has been sustained for decades. Three companies, Novo Nordisk, Sanofi-Aventis, and Eli Lilly control most of the market.<sup>2</sup> Until recently, almost every insulin product sold in the United States was made by these 3 companies. They still continue to have a monopolistic hold on an essential product, with limited competition, and no regulations in effect to cap or control prices.<sup>11</sup>

**TABLE 2. Timeline of Insulin Products**

1921: Discovery of insulin (Banting, Best, Macleod)
1923: First insulin patented (patent sold for \$3)
1946: Neutral protamine Hagedorn insulin (improved long-acting)
1950s: Lente insulin (zinc containing, with no protamine)
1970s: Improved purified (“monopeak”) insulins
1984: Recombinant human insulin
1996: Analog insulin
2000: Long-acting analog insulin
2014-present: Introduction of biosimilar insulins

Third, there is the problem of patent evergreening.<sup>15</sup> For a drug that was first made in 1921, it is hard to imagine that insulin is still under patent protection. However, as Table 2 points, from 1921 to early 2000s, there has been a continued improvement in insulin formulations. Each new formulation provided more reliable control of diabetes, provided more convenience, but also came with new patents. Newer formulations have prolonged the patent life and extended the monopoly on these products to the present day. In addition to prolonging patent life, with the introduction of improved analog versions of insulin, pharmaceutical companies have resorted to filing and securing multiple patents on the same drug.<sup>15</sup> For example, 70 patents have been filed for Lantus since the drug was first introduced, which can technically provide more than 30 additional years of monopoly protection. Even more worrisome are lawsuits filed to prevent new competition alleging patent violation<sup>16</sup> and possible “pay-for-delay” schemes in which competitors are paid money to delay market entry.<sup>17</sup>

Fourth, there are barriers to the entry of biosimilars. Because insulin is a biological product, similar products that are almost identical to the parent drug are technically referred to as *biosimilars* and not as *generics*. Although the Food and Drug Administration has been receptive to biosimilar entry, the process is still long and cumbersome.<sup>8,17</sup> As a result, there are few biosimilar insulins on the market in the United States. The first

biosimilar Basaglar, a biosimilar insulin glargine, was introduced in the United States in December 2016, almost 2 years after the first biosimilar was approved in Europe. Since then, 1 additional biosimilar has been introduced in April 2018: Admelog (biosimilar insulin lispro). Biosimilar entry in the United States has also been hampered by lawsuits that effectively delay market entry even if they are without merit.<sup>16,17</sup> The 2 biosimilars that have finally managed to make it through are insufficient competition to have an effect on prices. Furthermore, both face barriers to enter formularies and to become the preferred alternatives for the established brand-name insulin products, despite an advantage of cost.<sup>17</sup> As a result of insufficient competition and the problem of rebates and middlemen described below, Basaglar and Admelog are priced only about 15% to 20% less than their respective competitors Lantus and Humalog.<sup>11</sup>

Fifth, there are middlemen who exercise considerable control over market share and stand to gain from a high price.<sup>18,19</sup> Insulin, like other drugs, moves from the pharmaceutical company manufacturing the drug to a wholesaler and then to the retail pharmacy. At each step there is a markup in the price, roughly proportional to the list price set by the manufacturer. Thus, absent regulations, both the wholesaler and the retail pharmacy stand to gain more if the list price is higher. From the payment side, the cost of insulin paid to the retail pharmacy is borne by the patient (in the form of deductibles, co-pay, or coinsurance) and the insurance company. Payments from the insurance company go through a pharmacy benefit manager (PBM) who negotiates the price of insulin with the retail pharmacy (negotiated price) as well as with the pharmaceutical company (in the form of rebates). Rebates paid by the manufacturer to the PBM lower the net price of insulin, but unfortunately, although most of the rebates are passed back to the insurance company, they have also become a major source of income for PBMs.<sup>17,19</sup> The higher the list price, the bigger the rebate can be, resulting in more revenue for a PBM. Together, the

entire supply chain benefits from a high price—except the patient. To make matters worse, there is a near monopoly among wholesalers and PBMs. Three PBMs—Optum, Express Scripts, and CVS—control approximately 75% of the market,<sup>20</sup> whereas 3 wholesalers control approximately 90% of the market.<sup>21</sup> Manufacturers run the risk that their product may not be the preferred insulin in formularies if they do not work with PBMs on rebates. All of this results in the bizarre phenomenon of almost synchronized price increases of insulin that have occurred over the past 20 years. Thus, price increases of NovoLog and Humalog have occurred in lockstep for the past 20 years<sup>22</sup> and so have price increases of Lantus and Levemir. Every time the price of one goes up, the price of the other one also goes up, often almost the same day. Manufacturers argue that because of rebates, the price of insulin is not as high as the list price would suggest. But there are problems with this. Patients who have coinsurance payments pay a proportion of the list price and are therefore affected by rising prices and the absolute magnitude of the list price. Furthermore, during the deductible phase, they end up needing to spend a considerable portion of income on insulin and most of the population does not have adequate savings to afford this. More importantly, people without insurance (cash-paying patients) including people who cannot afford insurance (but are not poor enough to qualify for Medicaid or patient assistance programs) bear the full brunt of the list price, which in the case of insulin can have deadly consequences.<sup>1,2,4,9</sup> Despite these problems, it appears that middlemen on the whole contribute only to one-third of the increased cost.<sup>23</sup>

Finally, there is the lobbying power of pharmaceutical companies.<sup>24</sup> The vast amount of money spent by this powerful group on lobbying and advertising has been able to prevent changes to the current system, specifically the solutions presented below (Table 1). Many proposals to lower insulin costs as a result have unfortunately not been successful.

## Possible Solutions

**Solutions at the State and Federal Policy Level.** First, we need protection against monopoly, both for new drugs and for existing drugs. Regulations should protect against unreasonable launch prices for new drugs by using value-based pricing approaches used in other developed countries.<sup>6,25</sup> For lifesaving established drugs such as insulin where there is a barrier to entry for competing products, we need regulations to prevent price increases. Capping the maximum price increases to the rate of inflation is needed and can happen only through state and/or federal legislation.<sup>26</sup> Such laws will need to be broad and cover not just insulin but also all other drugs of which there are only a small number of manufacturers who control the market.

Second, we need to reform the regulatory and legal processes such that there is an easier path for generics and biosimilars to enter the market. Currently the process is cumbersome, and this has delayed the arrival of insulin biosimilars. We need legislation to prevent lawsuits that are filed by manufacturers to delay biosimilar entry into the market. Moreover, the current system has allowed brand-name pharmaceutical companies to nonsensically relabel their own drugs as “authorized generics.” Eli Lilly and Novo Nordisk have introduced cheaper “authorized generics” for Humalog (insulin lispro) and NovoLog (insulin aspart), respectively. Unfortunately, these moves deter competition and allow these companies to further consolidate market share.<sup>12,27</sup> The fact that identical products made by the same manufacturer can be sold for vastly different prices is a clear reflection of our broken pricing system.

A reciprocal approval process such that biosimilars that are approved in Canada or western Europe are automatically granted regulatory approval in the United States will greatly simplify the regulatory process.<sup>28</sup> This requires trust and cooperation with regulatory agencies from selected countries, analogous to the process by which countries mutually allow visa-free travel and trusted traveler programs.

Third, we need to reform the patent system to prevent overpatenting and patent abuse.<sup>15</sup> Patent life should be capped at 7 to 10 years from the date of first entry into the market, and additional patents as a way of prolonging market exclusivity must be prohibited. Fourth, we need a governmental or a nongovernmental agency to oversee pricing and make recommendations to Medicare and insurers on the maximum price of new and existing drugs including insulin. The Institute for Clinical and Economic Review has done excellent work, and we need more formal support of their work through Medicare regulation or legislation. For drugs such as insulin that have already been on the market for many years, the Institute for Clinical and Economic Review can be a watchdog that recommends the maximum price increase, if any, that is allowed. Until this is possible, the alternative solution is to cap prices of lifesaving drugs such as insulin to an international reference price.

Fifth, we need to ensure that any rebates that are paid by a manufacturer to a PBM are transparent and are passed on to the patient. Transparency is critical to ensure that the public and the government are aware of the arrangements between manufacturers and PBMs. The existence of rebates disproportionately affects uninsured cash paying patients who pay the full list price. Pharmacy benefit managers should not have a business model in which they benefit more when the list price is higher. In the present system, a product that is lower priced than its competitor can end up being not the preferred drug on the formulary because a PBM stands to gain more by choosing the more expensive product.<sup>29-31</sup> This leads to a never-ending game of rising prices as manufacturers try to increase prices synchronously with their competitors to provide PBMs with higher rebates.

Sixth, we need nonprofit generic manufacturing, an idea we proposed in 2012.<sup>6</sup> For example, Mayo Clinic has partnered with Intermountain Healthcare and a number of other organizations in becoming governing members of Civica Rx, a nonprofit generic company. This effort will initially

target drugs that are commonly used but are in short supply. Expansion of this effort to cover biologics such as insulin will go a long way in controlling prices, because the cost to manufacture insulin is a fraction of the list price, and a not-for-profit manufacturer can provide affordable insulin.

Seventh, we need measures and laws that provide access to affordable and safe insulin in emergency circumstances, particularly for patients with type 1 diabetes who find themselves uninsured or unable to afford insulin. Several measures are being discussed and adopted in state legislatures to implement this with the help of insulin manufacturers. Action in this regard at the federal level will provide a more comprehensive safety net. We cannot afford to lose a single additional life because of the high cost of insulin.

Finally, we need greater advocacy from professional and patient organizations. At present, groups such as T1International have been advocating strongly for more affordable access to insulin in the United States and worldwide.<sup>32</sup> We need more.

**Physician and Institutional Levels.** At the physician and institutional levels, we need to commit to helping our patients get the drugs they need at affordable prices. To do this, we need to become better educated on drug prices and be more willing to discuss prices and affordability with patients. A recent study found that physicians brought up the cost of drugs infrequently in conversations with patients. Even when patients raised the issue, they were met with inadequate responses or silence.<sup>33</sup> An investigation by Consumer Reports<sup>34</sup> found that for common drugs, the price difference across pharmacies can be astonishing. For example, for clopidogrel, the cost was \$10 per month at HealthWarehouse vs \$141 at CVS. Such striking price differences almost never occur with any product other than prescription drugs in the United States. Similarly, insulin prices vary widely among the 23 commonly used brands.<sup>11</sup> As physicians, we need to become familiar with

resources such as [goodrx.com](http://goodrx.com) and [blinkhealth.com](http://blinkhealth.com) that provide information on the cost of drugs as well as the pharmacies that offer the drug at the lowest price. This is particularly important for patients who have high deductibles or who are uninsured and are paying cash for their prescription drugs, including insulin.

Institutional formularies should prefer products with the lowest price rather than a competing product that is more financially beneficial as a result of rebates or some other negotiated arrangement. Practice guidelines should be strict, take cost considerations into account, and support insulin biosimilars. Finally, we need to collectively advocate for lower prescription insulin prices and policies that can achieve that goal with state and federal lawmakers, similar to the effort by oncologists to highlight the problem of high cancer drug prices.<sup>35</sup> In this regard, Cefalu et al<sup>14</sup> are to be applauded for drawing attention to the cost of insulin and a number of legislative initiatives are currently underway that actively address salient aspects of this issue and appear promising. Advocacy in recent times has also become more effective through active participation in social media. Our individual and collective advocacy gives voice to the needs of our patients.

The tragedy of insulin prices and the rationing that follows is not something that happens in other developed countries, but it is common in the United States.<sup>36</sup> A study conducted at Yale University found that 25% of patients with diabetes ration insulin because of the high cost.<sup>13,37</sup> There are 30 million patients with diabetes in the United States, and approximately 25% (7.4 million Americans) need insulin.<sup>14</sup> For the 1.3 million patients with type 1 diabetes, insulin is as vital as air and water. We cannot wait to act.

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