

## Insulin Costs Are Skyrocketing. This Is Why.

Plus, what to do if you're a patient.

By Dr. Kevin Campbell, Contributor June 29, 2018

ACCORDING TO THE Centers for Disease Control and Prevention, more than 30 million Americans have diabetes – representing nearly 10 percent of our population. Those with Type 1 (insulin dependent) diabetes must inject daily insulin in order to survive. While Type 2 diabetes is far more common than Type 1, nearly one-third of those with Type 2 must also inject insulin on a daily basis. For some, the cost of diabetic supplies – particularly insulin – can lead to negative health consequences. In the last several decades, insulin prices have skyrocketed.

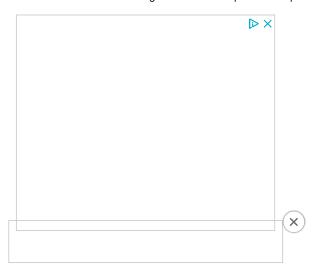
Insulin, discovered in 1921 has no generic competitors – only brand-name products are produced. A new study was presented in late June at the American Diabetes Association's annual scientific sessions showing that the cost of insulin results in nearly 25 percent of patients not taking insulin as they should. "Self-rationing" of insulin by patients can result in serious and potentially life-threatening complications such as blindness, loss of limbs, kidney failure and even death. Many patients are going to pharmacies only to find out that they must pay hundreds – if not thousands – of dollars for insulin.

## [Read: 8 Complications of Diabetes.]

### What Is Diabetes? A Quick Primer

Diabetes occurs when your body can no longer handle sugars as they're ingested as food or drink. In Type 1 diabetes, the pancreas (an organ which makes insulin) no longer functions properly, and the only solution is to use artificially produced insulin either from injections or from an insulin pump. In Type 2 diabetes, the body can no longer respond to insulin and becomes "resistant." In both types, blood sugar fluctuations can be harmful to multiple organs and create lifelong complications. While there's no cure for Type 1 diabetes, Type 2 can be reversed with diet, weight loss and exercise (in some cases). All patients with Type 1 diabetes must have daily insulin – some with Type 2 diabetes require insulin, while others can be treated with oral medications.





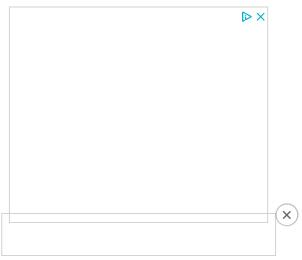
## Why Is Insulin So Expensive?

Insulin is a biologic compound that can be difficult and expensive to produce. There are several reasons it's become increasingly expensive – some are due to the biology and process involved in the manufacturing, and some are related to government regulations and the pharmaceutical industry's desire to continue to make a profit. From a biologic standpoint, insulin is created for human use by either "growing" an animal pancreas to produce insulin suitable for injection or by using recombinant DNA techniques that create bacteria that can produce large amounts of insulin for human use. Almost all insulin is created through the use of recombinant DNA techniques. Historically, pharmaceutical companies have simply made modifications to existing insulin types rather than work on the production of a "generic" or biosimilar product. While certainly possible, it's a bit more complicated to create a biosimilar form of insulin that would meet the standard for Food and Drug Administration approval. Moreover, the development of a generic or biosimilar insulin would be incredibly costly for the manufacturer but of a great benefit to patients.

### [Read: 6 Ways to Save Money on Your Diabetes Medications.]

From a regulatory perspective, insulin makers are protected from generic competitors under patent law. A patent allows a manufacturer to sell a product unchallenged for a certain number of years prior to approving a generic. In many cases, insulin makers continue to "tweak" current insulin products in order to extend their exclusivity rights. In addition, there's little incentive for pharmaceutical companies to spend millions of dollars to develop a cheaper alternative. Because insulin is considered a "biologic" drug, the FDA approval process is far more stringent and can take much longer than for other types of drugs. In addition, the FDA process is very costly for drug manufacturers. In the case of most generic alternatives, the generic can reduce costs by nearly 80 percent. In the case of insulin (because even a generic is expensive to produce), it's estimated that a generic form will only reduce costs by 20 percent. Unfortunately, it's my belief that the large manufacturers of insulin – Sanofi, Eli Lilly and Novo Nordisk – are working to make the development of generic insulins more difficult. In fact, Sanofi has filed lawsuits against both Merck and Mylan to prevent them from going to market with a generic lantus insulin (the Sanofi blockbuster drug).





### What Can Be Done? A Call to Action

The patents on the latest insulin analogues are expiring, and there's now a pathway for FDA approval. There are biosimilar forms of insulin that have been approved in Europe, and some are available in the U.S. A class action lawsuit has been filed against all three manufacturers of insulin, accusing them of setting artificially high prices in order to provide certain insurance providers with preferred discounts – most of which don't get passed on to the patient.

## [Read: 11 Ways to Save on Diabetes Supplies.]

For patients, it's important to take action:

- 1. Talk to your doctor about switching to a less expensive insulin. Make sure you're taking the type of insulin that's best for you at the best price point. And ensure your brand of insulin is on your insurance company's formulary.
- 2. Work with your local, state and U.S. representatives to effect legislative change to better regulate pharmaceutical companies and streamline FDA approval process for generic insulins.
- 3. Get involved with patient advocacy groups and work together to lower insulin prices. Patient-centered organizations are critical to effecting change.
- 4. Never attempt to save money by cutting your insulin dose. Take your medications as directed. If you're having trouble affording your medicine, talk to your doctor right away, and work to find a solution together.

### **Best Diabetes Diets**

#1

RANK

**Mediterranean Diet** 

DIET NAME

#2



#10 (tie)

RANK

**Ornish Diet** 

DIET NAME

DIET Ranking information as of June 27th, 2018

Dr. Kevin Campbell, Contributor



Tags: patients, patient advice, diabetes, diabetes type 2, diabetes type 1, American Diabetes Association

### **HEALTH DISCLAIMER »**

## **RECOMMENDED**

The HPV Vaccine for Men		×
BRANDFUSE ad content by Rakuten Would You Like to Get Cash E Shopping?	ack When Online	
LGBTQ Couples and Fertility	reatment	
Thumb Joint Replacement Surgery for Arthritis		
		×
11 Questions to Ask Your Card	ologist During Your First Visit	
Allergic Rashes in the Summ	r	



# DOCKET

# Explore Litigation Insights



Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

# **Real-Time Litigation Alerts**



Keep your litigation team up-to-date with **real-time** alerts and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## **Advanced Docket Research**



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## **Analytics At Your Fingertips**



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

### **LAW FIRMS**

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

### **FINANCIAL INSTITUTIONS**

Litigation and bankruptcy checks for companies and debtors.

## **E-DISCOVERY AND LEGAL VENDORS**

Sync your system to PACER to automate legal marketing.

