

INSULIN PRICING SCHEME LITIGATION



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ATTORNEYS AT LAW



Clay Lewis Jenkins | David Brown | Ted Lyon

800 -285-HURT (4878)

IS YOUR ENTITY — SELF INSURED? — DO YOU HAVE MEMBERS WHO ARE — INSULIN DEPENDENT? —

Your self insurance plan may have been affected by a massive overcharging scheme for insulin. You could be entitled to recover sizable compensation from overcharging.

CALL 800 -285-HURT (4878)

Our team is here to help with a no cost review of your insulin overcharge claims.
You only pay if we recover money for you.



Troy Rafferty

Troy Rafferty is a shareholder at Levin Papantonio Rafferty. He litigates mass tort, pharmaceutical, and major personal injury cases throughout the country. Mr. Rafferty has been appointed to handle some of the nation's largest pharmaceutical and mass tort cases. He has been appointed to serve on many Plaintiffs' Steering Committees including the national Vioxx Litigation which resulted in a \$4.7 billion settlement and the national Zyprexa Litigation which resulted in a \$700 million settlement. Mr. Rafferty was also one of the leading attorneys in the national Rezulin Litigation. He and his partner obtained a \$40 million judgement for a woman who took this diabetes drug. Mr. Rafferty has successfully tried numerous complex pharmaceutical cases throughout the country.

A DALLAS BASED LAW FIRM

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DIABETES IS AN EPIDEMIC

Over 34.2 million people (10.5% of the U.S. population) have diabetes and over 88 million people have prediabetes.

Diabetes is the seventh leading cause of death in the country, despite the availability of effective treatment.

Diabetes is the underlying cause of death of approximately 275,000 Americans per year.

INSULIN IS A NECESSITY

Due to the prevalence and severity of diabetes, insulin is a necessary, life-saving medicine.

More than **7 million** people per day require insulin.

PRICES OF INSULIN ARE ARTIFICIALLY & EXCESSIVELY HIGH

Insulin manufacturers and pharmacy benefit managers (PBMs) have artificially inflated the price of insulin at the expense of self-funded health plans and their members and beneficiaries.

INSULIN & ITS RISING COST

Insulin was discovered in 1921 and was harvested from animals until 1978 when the first biosynthetic human insulin was developed. Humulin, the first biosynthetic human insulin product, was reviewed and approved by the FDA on October 28, 1982. Additionally, very few scientific advances in insulin have occurred since the 1980s.

Despite the prominence of the disease and the long-understood treatment with insulin, the costs associated with diabetes treatment in the United States are exceedingly high. A 2022 Yale study found that 14% of insulin users, approximately 1.2 million people, in the United States face “catastrophic” levels of spending on insulin, meaning they spent at least 40% of their post-subsistence income on insulin.

The over-pricing of insulin has led to countless articles, exposés, documentaries, and even congressional investigations all highlighting the gravity of the problem and its causes. The insulin manufacturers and PBMs’ pricing scheme has exacerbated this epidemic, costing millions of dollars to organizations just like you.

DEFENDANTS & THEIR LIABILITY

MANUFACTURERS

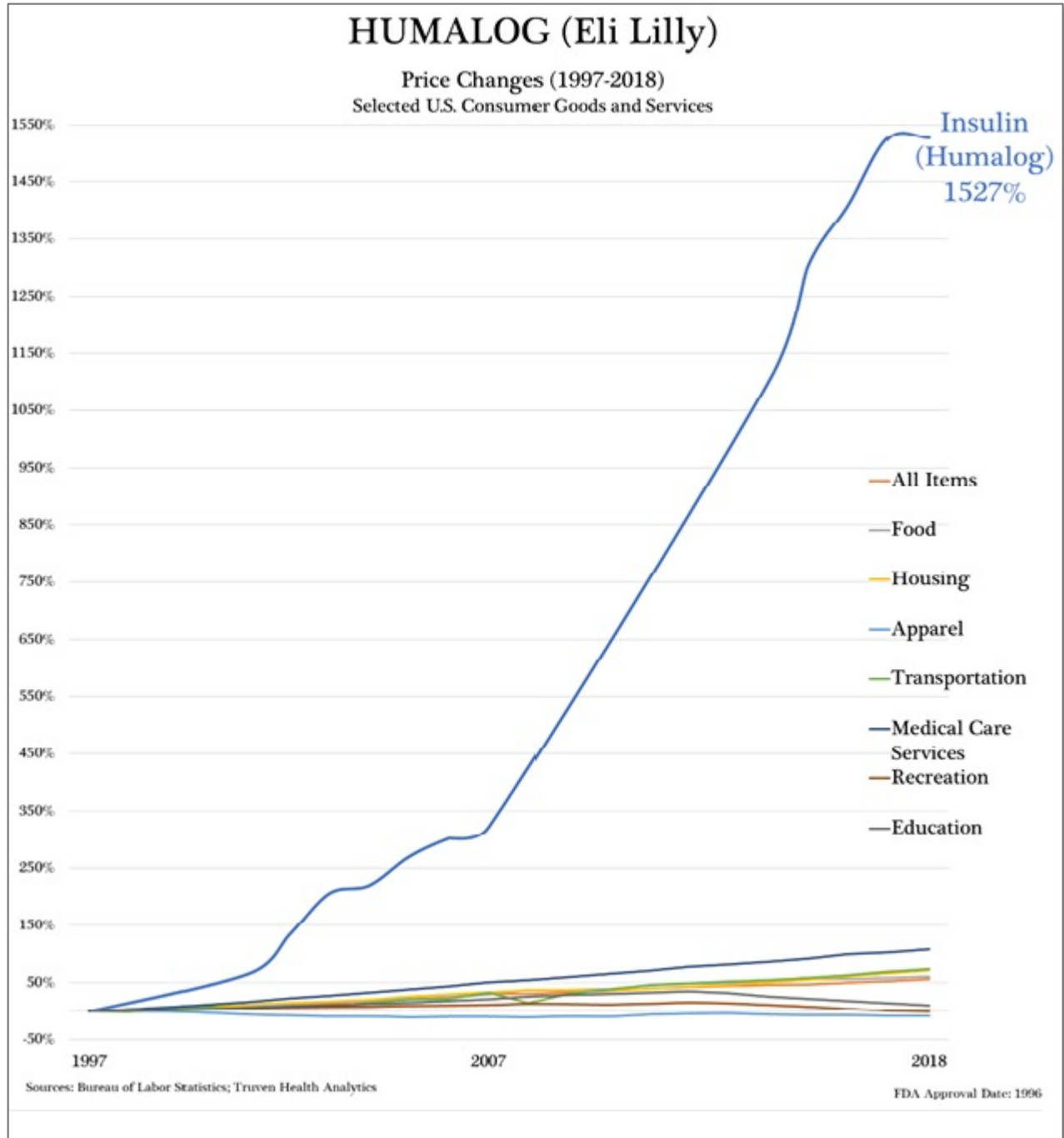
- Eli Lilly
- Novo Nordisk
- Sanofi

PBM_s

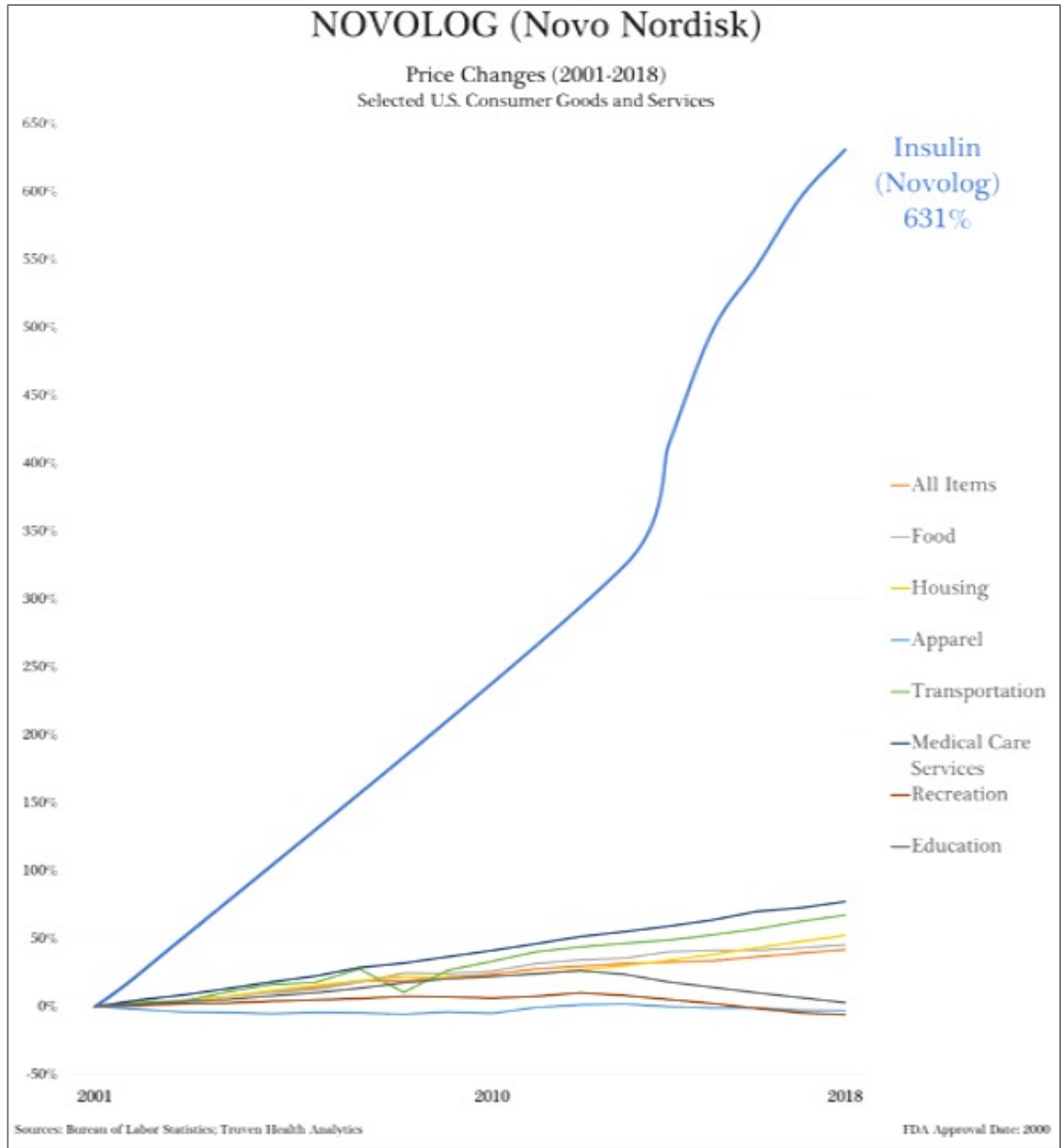
- Express Scripts
- CVS Caremark
- OptumRx

Insulin prices have skyrocketed over the past 20 years, despite the drug being over 100 years old, decreased manufacturing costs, and minimal innovations regarding the drug since its initial formulation. Since 2003, the list price of certain insulins has increased by more than 1000%, greatly outpacing the inflation rate for consumer goods and services.

Humalog Price Increase 1997 – 2018

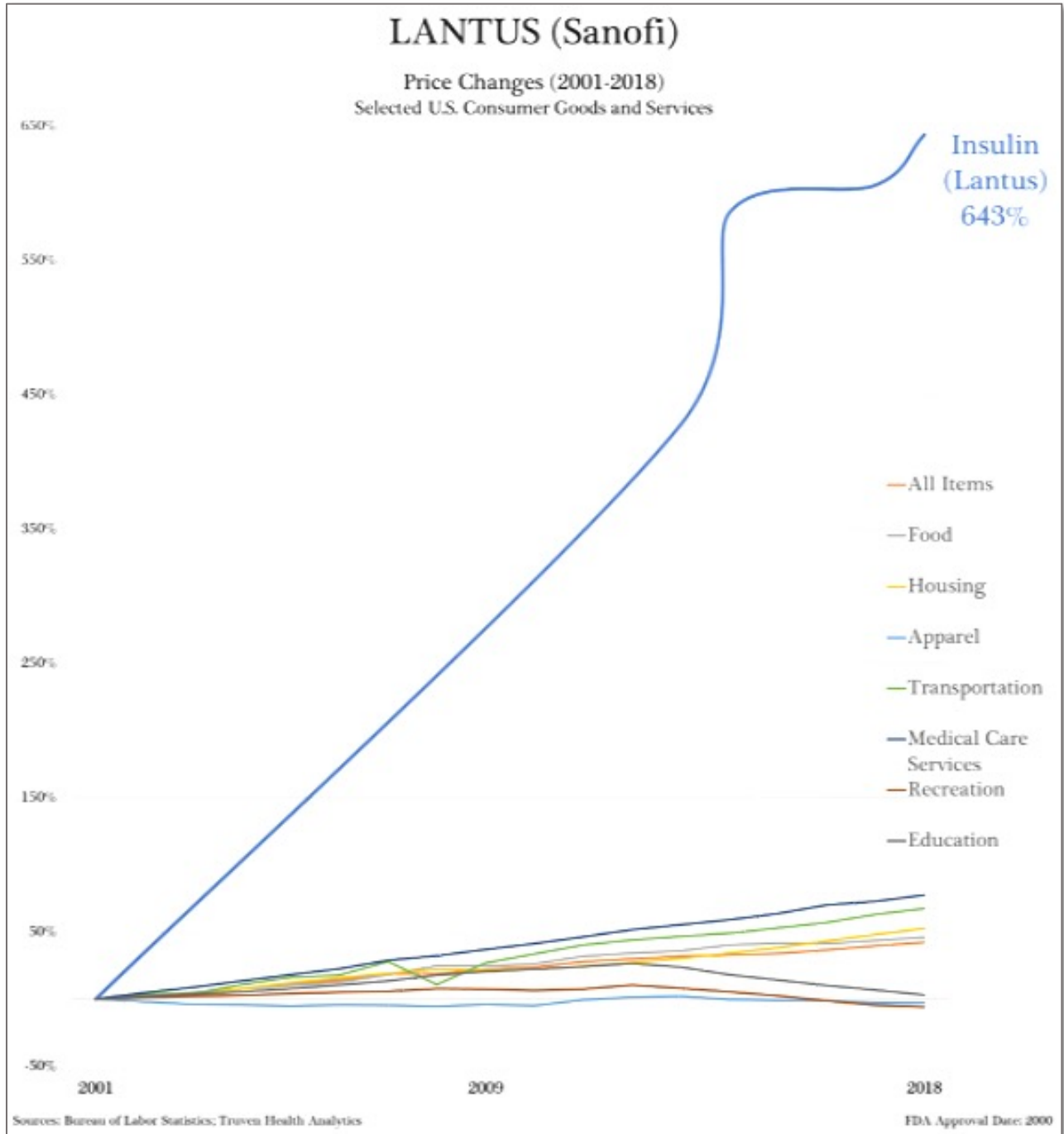


Novolog Price Increase 2001 – 2018



Lantus Price Increase

2001 – 2018



WHY THE SKYROCKETING PRICES?

Even though prices have increased dramatically, the production costs of insulin have **decreased** with efficiency and optimized processes. A September 2018 study found that a reasonable price of a year's supply of human insulin, based on production costs, should be \$48 to \$71 per person, which would still deliver generous profits to manufacturers. Another study found that manufacturers could be profitable charging less than \$2 per vial for insulin. However, the average diabetic spent \$5,705 on insulin in 2016.

What about research? There have been minimal innovations to insulin since the 1990s. Manufacturers have invested only a small fraction of their outsized profits on research and development and the investments they have made have largely been on delivery devices rather than drug formulations. For example, Eli Lilly spent \$395 million on R&D between 2014 and 2018. During that time, Eli Lilly spent \$1.5 billion on sales and marketing for insulin and generated \$22.4 billion in revenue from its insulin line. Similarly, Sanofi reported net sales of nearly \$37 billion for its insulin products while only investing \$902 million on insulin R&D.

All of this begs the question: why have insulin prices increased so much? The answer is simple: greed.

HOW DOES THIS PRICING SCHEME WORK?

The insulin pricing scheme is based on two separate but related illegal activities:

- PBMs demand large, secret, and ever-growing “rebates” and other payments for preferred formulary placement, leading to increased prices for payors and plan members.
- Manufacturers increase their insulin prices in lockstep to accommodate larger rebates and maintain access to lucrative placement on PBMs’ standard formularies.

INSULIN MARKET DOMINATION

3 PBMs

Control 89%
of the PBM Market



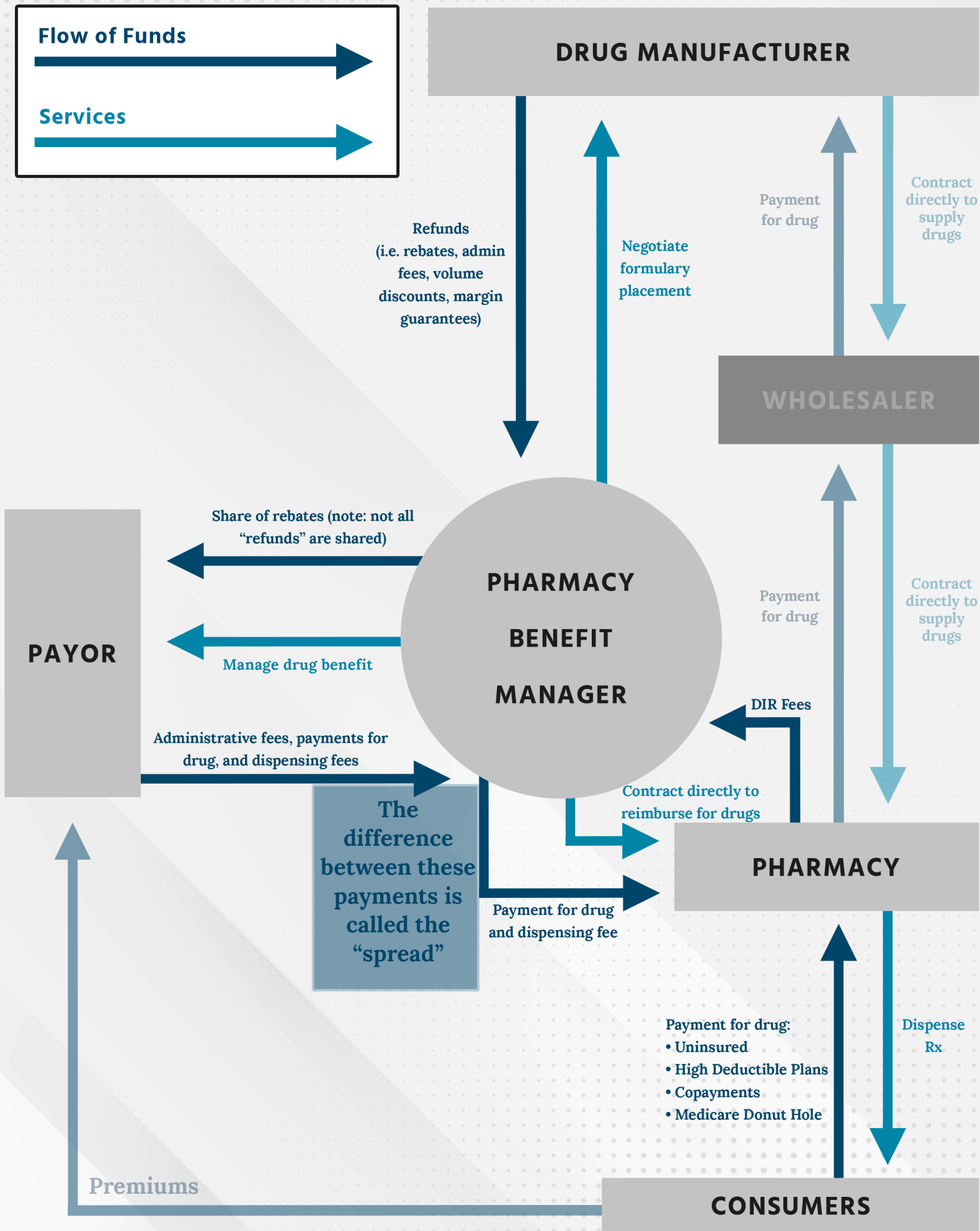
Source: NCPA, PBM Resources

3 Manufacturers

Control 99% of
the Insulin market
by value and 96%
by volume



Source: Research: Health Economics, A perspective on global access to insulin (2019)



EFFECT OF FRAUDULENT PRICING SCHEME

Community Impact

City Employee
Health Plan Impact

City Facilities/
Purchaser Impact

CAUSES OF ACTION

This misconduct by insulin manufacturers and PBMs gives rise to several legal claims. As we have done with existing clients, we would bring claims on your behalf for violations of RICO, deceptive and unfair trade practices, and for unjust enrichment. Through these claims, we will demand money damages and disgorgement for the excessive insulin prices you have paid in the past and we will seek to ensure that those rates are not charged to you in the future.

RICO (RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT)

Insulin manufacturers and PBMs have colluded in an effort to artificially increase insulin prices to achieve profits far exceeding the fair market value of the drugs and the services the PBMs provided. The federal RICO statute is an ideal vehicle to ensure they are collectively held accountable for the harm they have caused. The misconduct also supports a claim for civil conspiracy, which typically requires evidence similar to the evidence supporting a RICO claim.

UNFAIR AND/OR DECEPTIVE TRADE PRACTICES

In collaborating to artificially and excessively inflate the price of insulin, the insulin manufacturers and PBMs engaged in unfair and deceptive trade practices that are actionable in most States. PBMs misled payors regarding the fair market price for diabetes medications and concealed their agreements with insulin manufacturers and company-owned pharmacies while skimming profits that rightfully should have been passed along to payors.

UNJUST ENRICHMENT

This claim seeks reimbursement of monies paid over to the PBMs and manufacturers that rightfully should have remained in payors' pockets. The PBMs and manufacturers unjustly obtained monies through the insulin pricing scheme and they should not be permitted to retain them. Your overpayments should be returned to you.

POTENTIAL REMEDIES

The claims described above will seek significant equitable and monetary relief. Potential remedies include:

- Money wrongfully paid for artificially inflated insulin prices on behalf of your insured beneficiaries. For some claims, the damages awarded can be trebled – not only compensate you for the expenses you have wrongfully incurred, but also to deter similar future behavior from these defendants and others like them.
- Injunctive relief to stop the insulin pricing scheme. This would ensure that you and your members do not suffer monetary harm in the future.
- Disgorgement of ill-gotten gains on the part of the PBMs and manufacturers.
- Punitive damages designed to punish past misconduct and to deter future misconduct.