For the Record, my name is Dennis Linthicum - Senator District 28

I'll be the first to admit that **Pharmaceutical drug manufacturers have a tough job**. They face a plethora of product development issues:

- Biologics
- Business strategy in drug development
- Clinical trials
- Diagnostics
- Drug delivery
- Drug regulation
- Drug safety and screening
- Medicinal chemistry
- Pharmaceutics
- Pharmacology
- Target identification
- Target validation
- Toxicology

And, all of this while trying to focus on **the FDA's rigorous test and validation regimen, patient safety, commercial potential,** and, at the end of the day, the hope of some **profitability**.



The federal healthcare system is a giant spaghetti ball of legislation, myriads of Alphabet soup agencies and 50 years of "re-DO's", "Take-overs" and fixes The end result is an overly complex and extremely messy bundle of rules, regulations and unintended consequences.

And, we're stuck in the middle...

Much of the discussion about drug prices focuses on whether brand-name drug manufacturers, PBMs, wholesalers, or large-scale insurers are the primary drivers drug price increases.

Unfortunately, the consumer, patient, or beneficiary often does not reap any tangible benefits from rebates and discounts that happen deep within the pharmaceutical supply chain **because they don't impact the consumer directly like in a free market**.

This graph illustrates the lack of competition across products that should be competitive marketplace. What transpired over this time-frame to allow these two products to advance in lock-step with each other?

If there were justifiable price hikes the would most likely **reflect supply chain issues or disruptions, underlying plant and equipment improvements, failures or natural disasters.** However, we would not see a uniform pattern of lock stepincreases over a twenty-year period.

This graphic tells us something is wrong.

I confess, I have a dog in this fight.

The timeline displayed here illustrates the cost curve of my life as **a Type I**, Juvenile Onset, Insulin Dependent Diabetic.

Actually, it represents the timeline of my daughter, Dani, because she has been a **a Type I**, **Juvenile Onset**, **Insulin Dependent Diabetic for nearly 20 years**, **but my life would require twenty additional years from the '70's through the start of this graphic...**

On the left side of the graphic (For the twenty years earlier) Insulin was \$5 - \$6 a vial.

I remember distinctly paying \$12 - \$15 for a vial for bovine, equestrian or porcine insulin. I also remember prices jumping to \$30/vial as human recombinant DNA Insulin became prevalent in the marketplace.

I believe in free, open and voluntary markets where competitive pricing sponsors patient responsibility but today's Prescription drug market–it is broken.

I am not keen on exposing any industry to invasive government inquiries, but, something is wrong. **Please allow the implications of this graphic to soak-in.**

During my lifetime, Insulin prices doubled from 6 to 12, from 12 to 24, from 24 to fifty, from 50 to 100, from 100 to 200, and today insulin routinely cost \$330 per vial.

Please tell me what a new, Insulin Dependent, 10-year-old child can expect to see in her lifetime?

Will she and her parents be forced to endure the same endless doubling of prescription prices as everyone is follows the menagerie of pricing rules created by the federal government?

This is why Transparency is sorely needed.

The current system stifles true competition and has created perverse incentives by legislative fiat.

It is also hard to see but the pricing increases shown are for two Insulin products.

Obviously, even when alternatives exist, there is little competition **and prices do not go down.** In fact, the opposite occurs—prices increase, in tandem with one another.

This, for a large part has been the result of federal legislation... As can be seen in these trend-lines... [Hidden graphics in the PowerPoint slideshows.

Here is a graphic of prices outside the US? **HB 4005** is **designed as a precise and narrowly crafted requirement for pharmaceutical manufacturers to shed some light on drug pricing** – only when annual increases exceed 10% and the monthly cost of the drug exceeds \$100.

It is time form some visibility with regard to pricing.

However, not only is it hideously complicated, it is mainly driven by factors other than consumer price-consciousness. As can be seen with this graphic...



And... Unfortunately, pharmaceutical manufactures may not even be responsible for the current price increases, but they are the first step, if you will, the No. 1 pin in the lane.

EAC: Estimated Acquisition

programs to set payment for

by many state Medicaid

drug ingredient costs

Cost; EAC is a benchmark used



- **AWP: Stands for "Average Wholesale Price**," but is more akin to a sticker price; AWP is one benchmark used to calculate EAC
- WAC: Wholesale Acquisition Cost; WAC is one benchmark used to calculate EAC
- AAC: Actual Acquisition Cost
- NADAC: National Average Drug Acquisition Cost; NADAC can be used to calculate AAC
- **FUL: Federal Upper Limit**; FUL sets a reimbursement limit for some generic drugs
- MAC: Maximum Allowable Cost; MACs are reimbursement limits set by states in addition to the FUL
- **AMP: Average Manufacturer Price**; AMP is used to calculate drug rebates. The ACA also established that it would replace list prices as the basis for FULs, but this has not yet been implemented

When it comes to prices, we know that buyers and sellers can usually negotiate some degree of transparency. For example, pharmacy benefit managers (PBMs), play a crucial role in reining in healthcare costs by negotiating drug price discounts with manufacturers for employers and insurance firms.

However, PBMs keep their prices strictly confidential. Some PBM clients want to know the details about wholesale drug price cuts, but most only care about how much they end up paying for the drugs they use. Therefore, HB 4005 is aimed at the No. 1 pin in the lane.

If the diagram looks like a skittle table, it is. The No. 1 pin, the one that starts the chain reaction going, is, unfortunately, the prescription drug manufacturers.

HB 4005 is an attempt at transparency for price increases with manufacturers.

Thank you for your time...

I'll be happy to answer any questions...