Pennsylvania Pharmacists Association
Testimony on Prescription Drug Costs
Insurance Committee Hearing
February 8, 2017

Good Morning Honorable Members of the Pennsylvania House of Representatives Insurance Committee. My name is Pat Epple and I am the CEO of the Pennsylvania Pharmacists Association (PPA). I am accompanied today by PJ Ortmann, a Lancaster County pharmacist with almost 40 years of varied pharmacy experience in Military, Hospital, Managed Care, the Pharmaceutical Industry and Community Practice. He is also president of MedVisors, an independent advisor helping employers identify and eliminate unnecessary high-cost prescription claims.

We appreciate the opportunity to participate in this hearing and understand your concern in light of news stories of the last several months for increased transparency in drug pricing. It is our understanding that we were specifically to address the issue of coupons and in a short amount of time. However addressing simply that issue is difficult given the complexity of the current drug pricing model and I would be remiss without mentioning a few things:

1. The drug pricing model is unlike any typical retail model and is quite complex in the flow of money, product, and the many variables. (Please see our attached chart and brief description in the addendum.)

2. There is not one entity that you can simply point the finger at and say "fix that" and the issue will be solved. There is not a quick and easy fix and any changes need to be explored in the context of other ramifications.

3. Along the way there is plenty of money taken out of the system from the drug manufacturer, the drug wholesaler, the third party payer, the insurer, and particularly the pharmacy benefit manager. All have a slice of the pie, some larger than others.

4. Of all the entities, the community pharmacy is the one with the least amount of net profit and frequently the one that is squeezed the hardest and/or viewed as the one establishing pricing.

With that said, let's talk about manufacturer coupons. A manufacturer's coupon is a physical coupon given out by a drug manufacturer to help reduce expensive copays set by insurers/Pharmacy Benefit Managers (PBM) on brand name medications. Sounds like a good thing – a way to get your prescription medications at a lower cost.

But first remember this -- drug companies typically give these coupons out as a way to encourage patients to use a brand name medication instead of a less expensive generic. Most brands are considerably more expensive than generics so to what degree using a coupon is a savings is highly questionable. This is especially true since the coupons are, in effect, undoing what the insurer or PBM set out to do by structuring lower copays for generics to contain costs.

Additionally, manufacturer's coupons typically only allow a patient a limited number of refills for a particular drug. So while at first, a patient may seem to get a great discount for using the manufacturer's drug; once they have used up the coupon's maximum amount of refills, they are usually stuck paying the regular full price, non-discounted prices going forward. This is bad news for those with chronic health conditions and may affect adherence, which ultimately could have many ill-advised consequences including higher healthcare costs.

It is also important to realize that not everyone is allowed to use these coupons. For example, anyone who is on Medicare, Medicaid, or any other form of state/federal insurance cannot use a manufacturer's coupon. Copayment coupons do not help the uninsured because they only cover a small amount of the total drug cost.

With coupons, keep in mind that someone is still paying the full regular cost. By driving patients to more expensive brand name drugs, insurers are paying that full price, which ultimately is going to get passed on to patients in the form of higher

premiums. In short coupons generally incentivize costly and potentially poor behavior.

We believe the reasons for the rise in prescription drug costs are complex, with many overlapping and interconnected moving parts. Middlemen growth and influence is emerging nationally as a root cause for pricing dysfunction and cost inequities for the consumer. However, gimmicks such as coupons, along with rebates, and others certainly add to the general cost confusion. We would be remiss if we did not also mention Direct to Consumer (DTC) advertising. There is no question that over the years this has grown and the $6 billion dollars spent is a factor in any manufacturer's pricing. DTC advertising also tends to focus consumers towards branded drugs that they might "want" rather than generic versions which also do the job.

There is no easy or single fix to the entire problem; as there are many factors that go into prescription drug prices. Fixing prescription drug pricing and reimbursement will require comprehensive efforts and give and take, not only by federal, state, and local governments but by manufacturers, insurers, employers, unions, physicians, pharmacists, other health care providers, and patient advocacy groups.

We look forward to continuing to be of some help as you move forward with looking at the issue of drug pricing transparency.

Contact: Pennsylvania Pharmacists Association
508 North Third Street, Harrisburg, PA 17101
(717) 234-6151 ext. 106 www.papharmacists.com

Patricia A. Epple, CAE | CEO | Email: pepple@papharmacists.com
Jeff Stuby | Government Relations Manager | Email: jstuby@papharmacists.com

PJ Ortmann, RPh, MBA | MedvisoRx, LLC, Box 284, 590 Centerville Rd, Lancaster, PA 17601| 717-572-5524 (cell)

Addendum 1

Prescription Drug Costs and Pricing

To illustrate and provide some understanding, the chart attached to our testimony, titled *"The U.S. Pharmacy Distribution and Reimbursement System for Patient-Administered, Outpatient Drugs"* illustrates the flow for patient-administered, outpatient drugs. Please note that the chart is purely illustrative and is not intended to be a complete representation of every type of financial, product flow, or contractual relationship in the marketplace.

Focus on the blue lines and the center/left of the illustration with the blue and gray boxes, which are the movement of product – the drugs. The manufacturers make and sell their product to Drug Wholesalers, who in turn sell those drugs to pharmacies, who then dispense the prescription to the patient. Additionally, as to be expected those are done through contracts (the red lines) and payment is made accordingly through the green lines.

The pharmacy at the bottom of the chart does not, set the price at which they "sell" the drug to patients.

Now turn your attention to the right and the green boxes. There is something called Pharmacy Benefit Managers. These are the middlemen who manage prescription drug benefits for insurers and other third party payers (see other green boxes). They generally do not actually buy or physically distribute drugs. However, they do have contracts with manufacturers for rebates and formulary arrangements which provide significant financial compensation. But their most significant role is contracting with pharmacies, unfortunately sometimes in restricted, limited, or preferred networks, for the reimbursements they will provide to pharmacies for dispensing the drugs they "allow," less the co-payment amounts those pharmacies receive from patients at the point of service. In the simplest of terms, the PBMs set the prices at which the pharmacies "sell" the drugs which is completely different from typical retain operations. It is also important to note that some PBMs also own pharmacies, both mail order and retail ones, which are competitors. So it hardly seems fair that they can set prices for their competition.

As you are well aware, there have been many recent instances when the cost of medications increases drastically. In some cases, these have been explained and reasonable shortages but other cases have left all of us, understandably perplexed. EpiPens, which are used to prevent anaphylaxis related to severe allergic reactions, is one of the most recent notable examples. We also recently heard about insulin. Several federal Congressional committees have held investigative hearings to examine the cause of these extreme fluctuations and its impact on patient care.

A recent report issued by the U.S. Government Accountability Office (GAO) examined prices of generic medications and revealed that more than 20% of the drugs studied (315 out of 1,441) experienced a price hike of at least 100% over the course of a year between 2010 and 2015. During this time frame, 35 drugs experienced multiple price hikes of 100% or more. While GAO stated in most cases prices increased between 100-200%, it discovered that in 63 instances they rose more than 500%, with 15 of these rising more than 1000%. The study further found that these price increases generally persisted for more than a year, and most experienced no price decrease after the initial price spike.

The report goes further to show that on average generic drugs do help lower prices, which is why community pharmacists have promoted their use for years. Additionally, through multiple surveys, the National Community Pharmacists Association has received numerous examples of price spikes for generic medications, as well as information about the effects these price spikes have had on both patients and pharmacies. For patients, these price increases may make medications unaffordable, particularly for those with limited or no insurance coverage or with increased cost sharing levels. Moreover, those on Medicare Part D may be forced into the coverage gap prematurely due to these increases.

While plan sponsors, patients, and pharmacies are paying more for prescription drugs, pharmacies are facing an additional challenge: the uncertainty of whether reimbursements for prescription drugs will cover the higher costs of purchasing them. Typically, reimbursement increases lag significantly behind the immediate increases pharmacies see on the purchasing end. So there are times when the spread between what is charged a plan sponsor and what is paid to the pharmacy can be quite significant. That spread is pocketed by the PBM.

Addendum 2

Pennsylvania - Pharmaceutical Pricing Transparency

Similar to the majority of traditional consumerism (e.g. Food, Automobiles, Clothing, Homes) occurring directly between a supplier and paying purchaser, Healthcare and particularly Prescription medications pass from the Pharmaceutical manufacturer to wholesalers to the Pharmacy for distribution, but are paid for by someone other than the end user. From initiation by a prescriber, however, that prescription PAYMENT is controlled by the undisclosed contract arrangements between and among the Pharmaceutical Industry, Health Plans, and PBMs before a prescription is ever dispensed to a PATIENT by a Pharmacist.

It is impractical to discuss the escalating cost of prescription pricing without acknowledging what ultimately contributes to the (High) price of Branded medications.

1) **Pharmaceutical Industry pricing** - Many factors are considered in the cost of a new-to-market medication: raw materials, special manufacturing processes (e.g. sterilization), unique delivery devices, marketing, etc. More often, however, much of a selling price determination includes (lack of) competition, PBM / Heath Plan rebate considerations, government "Best price", patent expiration (Life-cycle), patient copay assistance, obligation to stockholders, marketing and promotion (including Direct-to-Consumer ads and Physician influence*), liability (Bad Drug.com) investment in research of New Molecules, and ultimately profit.

   The attached report* articulates the example of the increase in the PRICE of Novo-Nordisk insulin compared to the increase in Manufacturer PROFIT over 10 years. This is by no means a justification, but illustrates "where the money goes". As much as Pharmaceutical costs, especially the newer Specialty Medications, have increased dramatically, these abnormal costs are being driven by the very HIGHLY PROFITABLE middle managers who claim to be reducing drug costs! The PBM industry is a $250Billion business which essentially processes Rx claims with no risk, no transparency nor accountability.

2) **Epi-Pen** – Several points must be made to fully understand the Mylan Epi-pen scenario:

a. Regardless of why Mylan increased the price of Epi-Pen many multiples of just a few years ago, the $600 price tag only became an issue when high deductible Rx plans caused situations where insurance required 100% copay for some. The product cost did not suddenly rise to $600/Rx in late 2016, but as long as traditional copays of $10-25 allowed patients to obtain this lifesaving medication, it was not newsworthy. High deductible Prescription plans clearly brought this to public attention
b. Mylan's post-news focus offer to help patients with up-to $300 copay assistance DID NOT LOWER THE COST for Employers who offered low-deductible plans.
c. Generic approval of Patent protected Brand prescriptions usually takes several years. If Mylan was able to offer a half-price generic version in just a few months (Dec 2016 release), Mylan must have already obtained the generic approval, but delayed release until forced to do so. "Pay-for-delay" is the process of Brand Pharmaceutical companies paying generic companies NOT to release a generic version, allowing the continued sale and profit of an unchallenged Branded medication.
d. Pharmaceutical Industry "Life-cycle" management is a highly sophisticated process, maximizing the duration and therefore profitability of a Brand medication. It is neither unreasonable, nor unprecedented, that the entire Mylan Epi-Pen episode was internally predicted with a planned and executed response including the $300 copay offer, generic launch, and accommodation for financial penalties.

3) **Generic Prescription Medications**

Generic medications are traditionally considered the "cheap" or low cost versions of Brand prescriptions which have lost patent protection. This is somewhat true, but not entirely.

a. Once a drug patent has expired, only one generic company has exclusive rights to sell the generic version for the first 6 months, so the price typically does not drop significantly until after the exclusivity period. During that time, the original Brand manufacturer

is frequently also the "owner" of that protected generic position, and so continues to profit, but under the generic label.

b. Pricing generics at whatever the market will bear. Generic drug manufacturers are not obligated to maintain low prices. We have seen many examples of medications that have been priced very low for many years after patent expiration suddenly increase in cost without cause. Daraprim increased from $13.50 a tablet to $750, Overnight* and other examples in attached article.

4) **FDA Approvals** – to a lesser but important degree, the FDA has approved several high cost medications of questionable advantage over less expensive alternatives.
   a. **Vimovo – ($800/mo)** Naproxen and Esomeprazole (Aleve and Nexium OTC) - $20
   b. **Duexis** – ($900/mo) Ibuprofen 800mg and Famotidine/Motrin - Pepcid OTC - $20
   c. **Niaspan/Niacin ($150/month)** – Niacin OTC $8
   d. **Metformin ER (Glutmetza) $1500/month** – Metformin ER (Glucophage) $5/mo

http://www.drugchannels.net/2016/12/novo-nordisk-sheds-new-light-on-pbm.html
http://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html?_r=0

December 19, 2016

Pharma Companies Paid 618,000 Physicians $2 Billion in 2015

ProPublica recently released updated statistics for their Dollars for Docs database on pharmaceutical industry payments to US physicians. Here are some key findings from the report:

- From 2013-2015, companies paid $600 million a year to teaching hospitals.
- Companies made $2 billion in general payments to 618,000 physicians each year

- 1 in 4 doctors who received a payment in 2015 didn't receive one in 2014.
- Blood thinner Xarelto ($28.4 million) was the top payer to physicians in 2015.
- Arthritis drug Humira made $24.9 million in payments to physicians in 2015.
- Diabetes drug Invokana made $20.9 million in payments to physicians in 2015

Source: ProPublica, December 13, 2016

The U.S. Pharmacy Distribution and Reimbursement System for Patient-Administered, Outpatient Prescription Drugs

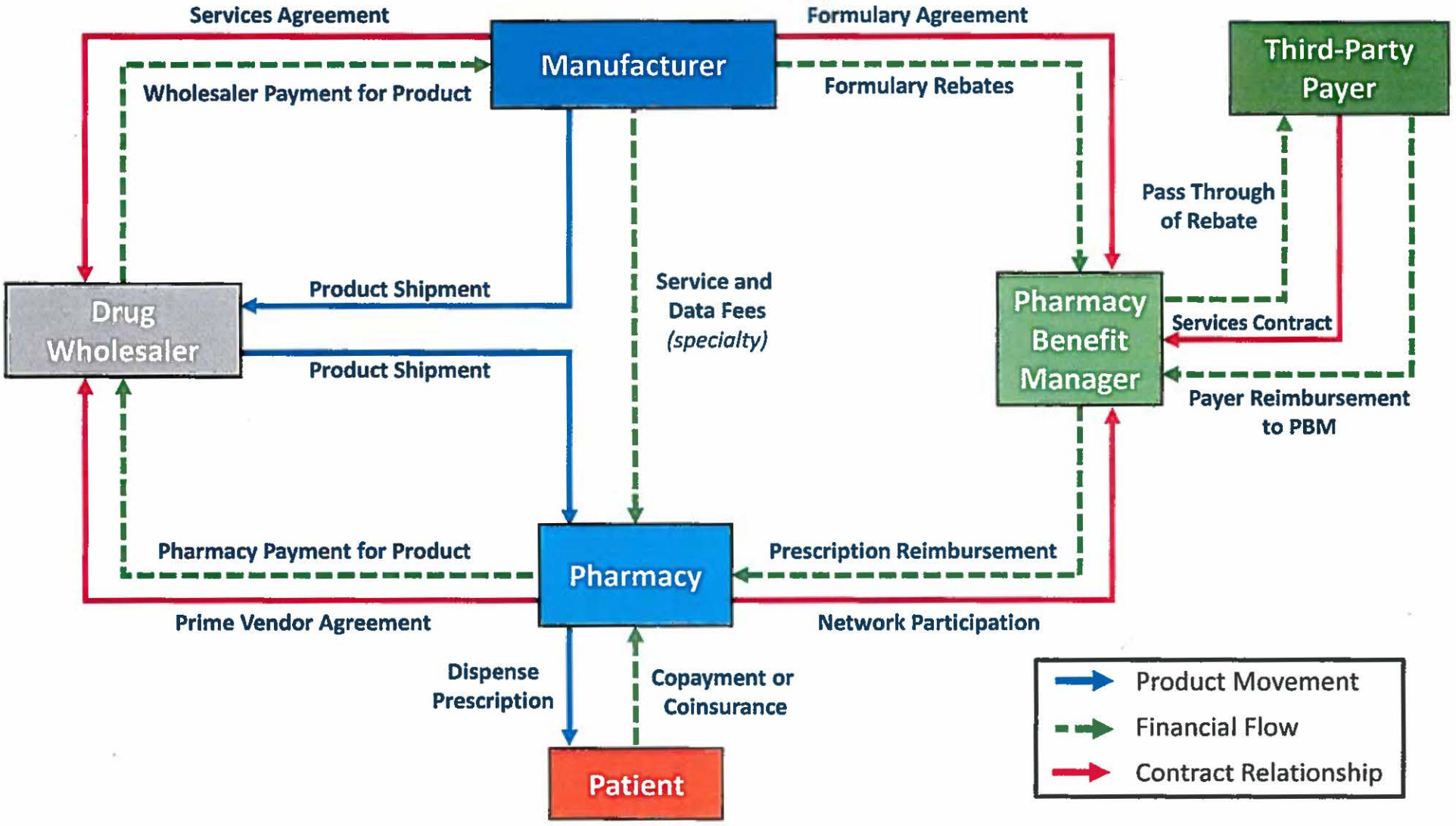

Chart illustrates flows for patient-administered, outpatient drugs. Please note that this chart is illustrative. It is not intended to be a complete representation of every type of financial, product flow, or contractual relationship in the marketplace.

Source: Source: Fein, Adam. J., *The 2016 Economic Report on Retail, Mail and Specialty Pharmacies*, Drug Channels Institute, January 2016. (Available at http://drugchannelsinstitute.com/products/industry_report/pharmacy/)

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