Date: **December 13, 2017**
Topic: **Energy and Commerce Committee Health Subcommittee Hearing Examining the Drug Supply Chain**

On December 13, 2017, WSW staff monitored the Energy and Commerce Committee Health Subcommittee hearing on the drug supply chain. With ten witnesses from up and down the drug supply chain there was plenty of disagreement as to who was to blame for high drug prices. There appeared to be bipartisan agreement that the high cost of drugs is an issue and that something needs to be done. Very few specific legislative proposals were mentioned, instead members from both parties tended to focus on broad concepts such as transparency and value-based pricing. The Chairman urged the witnesses to develop solutions to these problems, warning them that if they did not, the Committee would take action and they may not like the results.

Witnesses

Chip Davis
President & CEO
Association for Accessible Medicines

Tom DiLenge
President, Advocacy, Law and Public Policy
Biotechnology Innovation Organization

Matt Eyles
Senior Executive Vice President & Chief Operating Officer for Policy and Regulatory Affairs
America's Health Insurance Plans

Elizabeth Gallenagh
Senior Vice President, Government Affairs and General Counsel

B. Douglas Hoey
CEO
National Community Pharmacists Association

Mark Merrit
President & CEO
Pharmaceutical Care Management Association

David Mitchell
Founder and President
Patients for Affordable Drugs

Tom Nickles
Executive Vice President for Government Relations and Public Policy
American Hospital Association

Healthcare Distribution Alliance

Gerald Harmon, M.D.
Chair, Board of Trustees
American Medical Association

Lori Reilly
Executive Vice President for Policy, Research and Membership
Pharmaceutical Research and Manufacturers of America

Opening Statement Highlights

Ms. Reilly, PhRMA

- Prescription drug spending is growing slowly
- Drug spending is projected to stay at 14% of health care spending over the next several years
- PBMs exert significant cost pressure to keep costs in check
- Insurance companies and PBMs need to push rebates to patients

Mr. DiLenge, BIO

- Industry is growing jobs at twice the rate of the national average
- Advances such as gene therapy and immunotherapy
- 90% of clinical programs fail
- Need to reward value over volume

Mr. Davis, AAM

- Patient access side of Hatch-Waxman is in jeopardy due to increase in anti-competitive business practices
- Generic medicines are currently experiencing unprecedented price deflation
- AAM has provided the Committee with recommendations that can be taken today

Ms. Gallenagh, HDA

- Industry margin is just over 1% on average
- Distributors sell drugs to downstream customers based on wholesale acquisition cost (WAC) price which is set my manufacturers

Mr. Merrit, PCMA

- Drugmakers are shifting to making much more expensive drugs
- Insurers are shifting costs to keep premiums down
- Pricing decisions not driven by supply chain
- Mylan blamed supply chain for price increases – this is wrong
- 90% of rebates are passed through to consumers
- Open to alternatives to rebates

Mr. Eyles, AHIP

- Consequences of "out of control" launch prices and big price increases
- Conversation must begin at list price which is set by manufacturers
- Drug companies are taking advantage of market skewed in their favor
- Recommendations: real competition, greater transparency in drug pricing, expanding efforts to link drug prices to clinical value

Mr. Nickles, AHA

- Starting negotiating price for hospitals is WAC price
- Hospitals face resource constraints as drug prices increase
- 340B stretches scare federal resources

Dr. Harmon, AMA

- Prior authorization, changing formularies, step therapy are barriers to treatment and take time away from patient care
- Series of forms that have to be filled out if a patient's drug is not on formulary
- When patients can't afford the co-pay, physicians have to pay for the medicines up front

Mr. Hoey, NCPA

- PBMs are increasing pricing complexity and contributing to higher costs
- PBMs not subject to regulation
- DIR fees assessed on pharmacies months after a prescription is filled

Mr. Mitchell, Patients for Affordable Drugs

- Drugs don't work if people can't afford them
- Drug manufacturers are at the center of the problem
- Should allow Medicare to negotiate drug prices
- Need increased transparency throughout the supply chain
- Patient assistance programs are "phony charities"

Committee Member Opening Statements

Chairman Michael Burgess (R-TX)

- The drug supply chain and factors around cost are complicated
- Patient access is a key health care issue for Americans
- Expects disagreement on this topic

Ranking Member Gene Green (D-TX)

- Innovative drugs are important, but we have to ensure patients can afford them
- Transparency and value-based approaches are good market based solutions
- Must ensure that patient safety is not diminished
- This challenge requires a bipartisan solution

Chairman Greg Walden (R-OR)

- Important that we hear from entire sector
- We've taken important steps passing 21st Century Cures and the user fee agreements
- Drug supply chain is very complex – need to understand the impact of each stakeholder in the supply chain on the ultimate price patients pay

Ranking Member Frank Pallone (D-NJ)

- Prescription drug prices are higher than ever
- Urge Committee to examine specific proposals to address high prices of drugs
- All of the witnesses have a role to play in solutions

Areas of Interest Covered

Rebates

- There was extensive discussion about how rebates work and their impact on drug costs
- Concern that rebates were not getting back to consumers
- Potential for perverse incentives in current system

Transparency

- Calls for transparency in drug pricing, PBM and insurer practices
- Patients unable to make informed decisions because they don't have access to necessary information
- Unclear what role each stakeholder plays in pricing

List Price

- Several panelists argued that the drug manufacturer sets the list price and is not influenced by the rest of the supply chain
- The PhRMA and BIO witnesses disagreed saying that there are many things that factor into their pricing decisions
- List price vs. net price. vs. what patient pays

PBMs & Pharmacies

- Impact of DIR fees and clawbacks
- PBM contracts with gag clauses that prevent pharmacists from telling patients that they could get drug cheaper if they pay cash

Committee Questions

- **Chairman Walden (R-OR)** –asked for PhRMA's response to Mr. Mitchell's testimony, insurers response to increase in high deductible plans and beneficiaries paying more out of pocket

- **Ranking Member Green (D-TX)** – importance of policies to encourage a workable pathway for biosimilars and encouraging uptake by physicians and patients, importance of disclosure of intended list price and greater transparency in price increases

- **Rep. Guthrie (R-KY)** – explanation for dramatic increase in price of insulin, impact of rebates on list price, whether rebates get passed on to the consumer

- **Rep. Pallone (D-NJ)** – importance of robust generic marketplace, differences in business model between generics and branded drugs, role of rebates in negotiations between generic manufacturers and payors

- **Rep. Blackburn (R-TN)** – what change would each panelist like to see to increase patient access and lower cost (patent abuse, value based pricing, greater competition, transparency)

- **Rep. Matsui (D-CA)** – do manufacturers make available information on how they determine list price, do doctors know cost of drug when they prescribe it for a patient, examples of biologics are innovating but also keeping prices low, policy solutions that encourage innovation and close loopholes

- **Rep. Barton (R-TX)** – pricing and development challenges of biosimilars, need for different incentives for biosimilars marketplace

- **Rep. Schrader (D-OR)** –pharmaceuticals are not the highest cost in our health care system, need for effort to address REMS issue, ways to increase transparency in PBM practices without jeopardizing proprietary information

- **Rep. Shimkus (R-IL)** – issue with insurers and PBMs clawing back money from pharmacies months after prescription filled by patient

- **Rep. DeGette (D-CO)** – need for more transparency in drug supply chain, need for PCMA, PhRMA and AHIP to work together and with committee to address increases in price of insulin, ways that PBMs make money

- **Rep. Latta (R-OH**) – working on legislation to modernize FDA's OTC monograph system, how can Congress modernize FDA and help speed process of getting drugs to market

- **Rep. Eshoo (D-CA)** – Committee will be taking action to reform the current system, value of REMS in protecting patient safety

- **Rep. Lance (R-NJ)** – how should rebates function in Part D program, who should be responsible for overseeing rebates and is a statutory change necessary

- **Rep. Schakowsky (D-IL)** – does insurance industry have input or insight into manufacturers list price, problems with business model of Gilead drug Sovaldi and others to significantly increase prices, tax breaks on patient assistance programs

- **Rep. Griffith (R-VA)** – need for transparency in PBM practices, bill to end pharmacy clawbacks, impact of DIR fees on community pharmacies, situation in which it is cheaper for a patient to pay cash for drugs instead of using insurance

- **Rep. Sarbanes (D-MD)** – what type of transparency is needed from PBMs

- **Rep. Bilirakis (R-FL)** – is it safe to import drugs from Canada, CMS proposed Part D rule on pharmacy lock-in

- **Rep. Long (R-MO)** – ExpressScripts is only PBM to have implemented an opioid abuse plan, challenges with patient survey and opioid abuse, negotiations in Part D program and how that has helped to bring down prices

- **Rep. Buschon (R-IN)** – concerns with expansion of 340B, value of and potential for AHA support for reporting requirements for 340B hospitals

- **Rep. Hudson (R-NC)** – what are stakeholders doing to educate patients to lower their drug costs before they meet their deductible

- **Rep. Carter (R-GA)** – instances where pharmacists are being threatened by PBMs for mailing drugs to patients, use of gag clauses in PBM contracts with pharmacies

preventing pharmacists from telling patients that they could get their drug cheaper without going through insurance, growth in DIR fees

- **Rep. Welch (D-VT)** – pharmaceutical company efforts to extend the life of the patent (ex: Allergan)

- **Rep. Burgess (R-TX)** – encouraged panelists to come up with solutions to this issue because otherwise the Committee may act and stakeholders may not like it, value of life-saving products such as Keytruda, role of PBMs in prescription drug monitoring – identifying patients that are at risk