COST DRIVERS IN THE DRUG SUPPLY CHAIN AND THEIR IMPLICATIONS

BACKGROUND

- Over the years, the pharmaceutical industry has made enormous strides to improve, extend and save our lives. The medicines they produce have also reduced hospital admissions and lengths of stay by better managing the chronic conditions that are the cause of death of most Americans.
- These advances were made possible through decades of research which produced decades of cutting edge and blockbuster drugs. Most recently, these efforts led to the development of expensive, but highly effective biologics and biosimilars which tend to be more narrowly tailored drugs with a smaller potential market than many of the drugs developed in the past.
- These drugs are produced in state-of-the-art facilities built by America's skilled union tradesmen and women who benefit from good jobs and are customers for their products through their health benefit plans that provide comprehensive prescription benefits and whose pension plans are source of investment capital.
- Since 1960, national spending on retail prescription drugs has risen from approximately $2.7 to $328.6 billion, with the percentage of overall healthcare spending dedicated to retail drugs over the same period falling from 10% to nearly 4% in the early 1980s before rising back and stabilizing near 10% since the early 2000s. As a percentage of GDP, however, retail drug spending has risen from approximately 0.5% in 1960 to 1.7% by the end of 2015.
- Sources of payment have evolved as well; whereas, in 1960, before the expansion of employer sponsored plans and the creation of Medicare and Medicaid, patients paid over 90% of retail drug costs out-of-pocket, that portion had shrunken to approximately 14% by 2016, with the involvement of third-party payers (insurers, self-funded employee/employer benefit plans and trusts) and government programs each paying approximately 43%.

THE SUPPLY CHAIN

- Similarly, the "Supply Chain" that moves the product from the manufacturer to the patient has become larger and more complex. In addition to the manufacturers, the links in this chain include: wholesalers, Pharmacy Benefit Managers (or "PBMs), specialty facilities (free standing and hospitals), and pharmacies. Each receives a portion of the costs, but not necessarily in relation to the value they add.
- High drug costs are a source of concern by patients, payers, lawmakers, regulators and the industry itself. While the pharmaceutical industry is quite profitable, the media and less informed advocates and policy makers typically characterize the manufacturers as solely responsible for high drug prices.
- Contrary to basic economic principles, however, in health care price is not necessarily a function of supply and demand. In fact, there are at least eleven different ways of expressing "price" and those who determine demand are often neither the doctors who prescribe the drugs, nor the patients for whom they are prescribed.
- Price is most often determined by others in the supply chain; principally, PBMs who determine which classes of drugs are available as well as which drugs within any class will be covered by establishing drug "formularies." Often, these are determined as much by the levels of rebates and discounts which can be negotiated with the manufacturers as by their clinical efficacy. In addition, they will negotiate with pharmacies to determine which will be listed on a plan's

participating list. The ability to negotiate these items and terms will often dictate a drug or pharmacy's profitability.

PRICE VARIABILITY

- In addition to PBMs, facilities that sell specialty drugs (those which require clinical administration or supervision), both free-standing and institutional (outpatient), were estimated to account for 50% of retail drug costs in the U.S. in 2018. In addition, the average price mark-up on hospital administered specialty drugs was 479% in 2016, with 17% reporting mark-ups of 700%, and 8% reporting mark-ups of over 1000%.
- Price variability, is another problem. Last year *Consumer Reports* published the results of their study of how a "basket" of five drugs was priced at 150 pharmacies in 6 cities. Prices ranged from a low of $66 at an online pharmacy, to $105 at Costco to a high of nearly $900 for the same basket. Same drugs – but wildly varying prices.

REGULATORY RESPONSE

- Such variability has been the subject of extensive analysis and litigation among state Medicaid programs. In the case of a generic version of the oral chemotherapy drug Gleevec whose price had fallen by 89% to $33.46 from the price of the brand name drug, state Medicaid programs were charged anywhere from $108.60 in the Washington, to $267.80 in Kentucky and $273.50 in Indiana, to a high of $295.70 in Illinois. Such pricing has prompted litigation and revised pricing structures for such programs with more to come.
- Other, more creative responses to reducing costs include New Jersey's reverse auction which changed the reimbursement structure away from rebates and is projected to save the 750,000 member state employee health benefit plan $1.6 billion over three years without changing the benefit structure or increasing costs to participants.
- At the federal level, the Trump Administration has targeted reducing drug pricing as a major policy objective. In its first policy pronouncement on the topic "*American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*" they identified three policy concerns that are to be addressed: high list prices; lack of negotiating tools; and foreign governments "free-riding" on American investments. In their first hundred days, negotiations with the major manufacturers resulted in 60% fewer brand name price increases and 54% more generic and brand name drug decreases than in the prior year. Year-to-year inflation price changes in just five state Medicaid programs produced reductions from $26 million to $8.5 million last year.
- The Administration and Congress who share a desire to address drug pricing, if little to nothing else, are both working on additional regulatory and legislative proposals as are many state governments, all of whose efforts we will continue to monitor.

NEED FOR GREATER TRANSPARENCY AND PRICING ALTERNATIVES

- Given the magnitude of the costs being imposed on the system by PBMs (estimated at as much as 30%) and concern over the lack of transparency of negotiated rebates and other discounts, it is apparent that the traditional pricing model for PBMs in particular will need to be voluntarily changed to adopt creative alternatives, or risk involuntary changes being imposed by both the market and direct government intervention.