8-21-19 WG#2 Meeting

- Present: Ben Velzen, Rose Roach, Rep. Lesch, Lenny Snellmen, Daniel Tikk, Mike Goodwin, Jennell Bilek, Eric Felker, Christie Keen

- J: represents generic pharmaceutical companies in litigation

- J: two types of new drug – 505b1 type of new drug with a new compound; and a 505b2 drug, which can be on the market for 25 years but only as an oral tablet and now they market it as a drug

- The b1 takes a long time and development; only 30-35% get through to phase two

- J: if you have a new compound, you have four years before you can file an ANDA

- J: FDA's "Orange Book" is the publishing of patent's relating to drugs and whether there is an AB rated generics

- The A rating means the FDA has certified there would be no safety or efficacy differences

- Patents are property rights and are 20 years, generally

- When an ANDA is filed the manufacturer looks at the Orange Book and must certify that they are not infringing or current patents for the same drug or that the patents are invalid for some reason

- If a branded manufacturer sues, they get an automatic 2.5 years of exclusivity before the FDA will approve the ANDA

- If this 2.5 years expires and you launch but then lose the lawsuit, that is dramatic for the generic manufacturer in turns of losing the lawsuit later the related damages associated with launch a drug that infringes another drug, etc.

- J: challenges to a "compound" are the most difficult to win, while challenges "method of use" and

- J: even if you have a weak patent, you put in in the Orange Book and even though it is weak it will give you some ability to sell the drug while the litigation against your weak patent is pending

- J: it used to be just 'one first filer' to enter the branded market first because you get six months of generic exclusivity, but sometime in the last ten years there are now a flood of 'first filers' to that results in 10 or 15 companies coming in to the market at the same

- Dr. S: what about patent reform, even just for drugs?

- Rep. L: what about competition from China and/or India

- J: usually the patent comes far before FDA approval, which are two different things

- S: for small molecule, figure out why 10 players are coming in now instead of one because if it is only one that gives more incentive; (2) look at specialty drugs, because there is no definition and everything is being lumped into being a "specialty" drug, which means it can only be distributed by certain distributors that, in turn, drives up its price; (3) evaluate the biosimilar and the 12 years of exclusivity

- Rep. L left at 6:00

- J: wraps up at 6:05

- E: started walking through his slide show slide by slide; review these

- E: even under current law, gaining access to pharmacy networks can go a long way to lowering drug prices and other good outcomes

- E: autoimmune area is aggressively monitored by payers because the costs are so high

- Dr. S: what do you mean by competitors? E: it acts an oligopolistic market even though it should be a competitive market

- Slide 8 all reflect "specialty" drugs

- There are two federal antitrust cases (Phizer v. J&J and __) that are challenging "typing arrangements" that are or should be illegal

- E: one recommendation for Minnesota to lower drug prices is to have educational types of programs on when low income persons should be applying for drug manufacturer's patient assistance programs

- E: high drug prices are largely supported by larger employer groups

- Dr. S: large employers get stuck with the branded drugs because PBMs favor branded drugs because PBM gets both rebates and an administrative fee that is percent of the drug cost

- E: increase in volume of drugs used is often correlated with population increases in particular drug market classes, so increase in spend in the same market class is generally attributed to price increases

- E: maintaining innovation in the distribution channel, which large health plans do, is a good thing; the leaders in innovation in distribution channel are big companies like UnitedHealth and Aetna, including "value based payment" where the drug price is rolled into the cost of the treatment

- Rose: value based payments warp incentives for providers to provide good care because they are trying to stay under the "per condition capitated cap" to make money

- Dr. S: how you define what is "value" has a huge effect on this

- E: CMS is also trying to implement VBP, but it is doing it in a complicated manner

- E's Word document with recommended ideas:

- State pharmacy laws – better use pharmacies as triage patients by liberalizing laws

- Alliance with pharmacy networks to distribute low priced generics, etc.

- Explore the use of compounding pharmacies, which bypasses the FDA because they pre-date statutes

- Fund and expand educational programs focusing on underserved populations to gain access to care and apply for assistance, etc.

- Drug compliance programs integrating providers with generic products to raise generic use

- Community health workers – current 1115 Medicaid waiver is not helping to sustain workforce, but take a look at Medicaid waiver program

- Value based payments and reimbursement for therapeutic classes

- Risk sharing partnerships with drug manufacturers

- Restructure PBM rebate agreements and increase transparency into rebates

- Re-aligning PBM rebates to benefit Minnesota residents

- last meeting on September 4; 5-7

- Meeting ended at 7:00