Advisory Task Force on Lowering Pharmaceutical Drug Prices
Past and Current Legislative Regulatory and Law Enforcement Strategies Group
July 18th, 2019

Members attending: Chair Dr. Cody Wiberg (CW) via conference call, Shilynn LaChapelle (SL), Nicole Smith-Holt (NSH)

Also attending: Joe Sellwood from Association for Accessible Medicines, Trisha Stachowski, Willow Fortunoff, Ben Velzen, Michaela Muza for Sen. Matt Little (ML), Harriet Washington via conference call

Speaker presentation: Harriet Washington (she said everything unless noted otherwise)
-African Americans and Hispanics have reduced access to medications
-Primarily based on financial inequalities
-She is wary of economic solutions that reify racial differences
-Much of the pharmaceutical/medical industry treats race as existing entity rather than social construction

-Bidil: 2 drugs combined (hydralazine and isosorbide dinitrate) that was first tested on white population yet wasn't approved by FDA
-Manufacturer claimed that it was more efficacious on African American population than white; this allowed for FDA approval
-Trial granted on the basis of political capital, not success of drug
-Trial only included African Americans
-First drug to be approved for use of African Americans only
-People who were prescribed Bidil had to take additional medications as well, leading to more costly treatments

-Patent abuse is a major problem, other countries don't allow for 20 year patents or other manipulative tactics
-CW: This is another example of drug companies combining existing medications into a new medication and marketing it as a new drug

-There is a demonstrated beneficial effect of removing caps on the number of reimbursable Medicare prescriptions per month (drug caps)
-Removing drug caps narrowed gaps drug access between racial groups

-11% of African Americans and 19% of Hispanic Americans are uninsured (Kaiser Family)

-Pain control: multiple studies show that African Americans and Hispanics get inadequate pain control at hospitals and pharmacies
-Racial methodology: practitioners believe people of color are more likely to abuse painkillers
-Suggests legislation that addresses this directly; the studies/proof exist and we now need to address it

-National phenomenon, pharmacies located in traditionally African American and Hispanic neighborhoods have inadequate medications

-CW: Discriminating counts as misconduct, if we can demonstrate that pharmacies are refusing to dispense painkillers than we can push the matter farther/start asking questions

-CW: We don't have laws to require pharmacies to stock certain painkillers

-CW: If we look at national pharmacy chains, we could examine their geographical medication stocking policies across the country to see if they're implementing disproportionate stocking

-Practices separate African Americans from medications they need due to lobbying

-Lobbyists are encouraging officials to pass laws that favor corporations over individuals

-African Americans have higher rates of serious illness, therefore are disproportionately affected

-Suggests national ban on lobbyists

-$10 million spent on lobbyists last year by pharmaceutical companies (Center of Responsive Politics)

-Difficulty in ascertaining efficacy of numerous legislative efforts due to the pervasive influence of lobbyists

-SL: Problems that Harriet addressed affect everyone, yet disproportionately affect people of color

-Drug innovation is plummeting, long patents result in copycat drugs

-SL: How can we release patented drugs that aren't available? (Held by companies to wait for best price)

-Patent march-in right allows government to step in, pay patent owner a fee, and then reassign drug to a manufacturer who will make it available

-US doesn't choose to take advantage of this law

Group discussion (speaker is Cody Wiberg unless noted otherwise)

-Several states have tried to enact price controls

-Maine law in 2003 mandated that pharmaceutical companies lower prices for everyone or be taken off Medicaid formulary

-Manufacturers took Maine to court, Maine won

-Medicaid has had national drug rebate program

-State could collect rebates as long as they were at least as good as federal rebate

-Florida developed supplemental rebate program

-Federal government regulates drug products while state regulates practice

-State Boards of Pharmacy regulate wholesalers

-Opportunity for states to take responsibility and regulate drug prices

-State action spurs political pressure and change, even when it's in direct violation of federal laws

-Drug manufacturers respond to nationwide pressure (to a certain extent)

-Vermont has a law on the books that says if the FDA could certify that the importation could be done safely, then it could occur, but both the Clinton and Bush FDAs refused to so certify

-Vermont supposedly re-requested approval from the federal government to certify importation as safe; the feds said they would get back to Vermont soon

-Mid-level management at FDA considered it; shut down by upper level

-Violates federal law

-SL: Are there any initiatives to put this on ballots?

-Joe Sellwood has a recent report on the status of this law, will send to AGO

-State programs that have a medical marijuana program (at least 35) violate Controlled Substance Act

-Example of states bypassing federal law

-Nevada's PBM transparency law

-Some argue that this could result in price increases, CW believes that manufacturers already know prices and that consumers (patients) are the only stakeholders who lack price transparency

-Individual pharmacies are losing money/going out of business across the country

-Manufacturers and PBMs appear to be making the most money in the supply chain

-BV, CW: Many drugs in US are paid for by health plans, except for patients on insurance plans with high deductibles

-Price transparency would help health plans choose most affordable drugs

-CMS negotiates contracts with manufacturers

-Best price: best rebate price given to private insurers

-Not even the insurers understand if PBM is passing along rebates and keeping costs down

-SL: We continue to do the same dance with the same players, it's time to change the rules

-NSH: Pharma is now pointing finger at PBM

-Every other single industrial country has figured this out

-Pharma argues that we need these prices to drive innovation, yet American patent laws don't incentivize real innovation

-Drug examples for report:

-Wellbutrin came out with 3x/day dosage - then when patent expired, they put out patent with 2x/day dosage and then again with 1x/day.

-Manufacturer could likely have produced final version from the start, yet obtained a patent 3x longer

-Prilosec and Nexium are essentially the same drug (mirror images)

-UK evaluates the cost-effectiveness of drugs based on quality-adjusted life years (QALY)

-We should look into failed state action to inform future recommendations

-SL: We need to go directly to the people and encourage them to put pressure on politicians; circumvent power of lobbyists
    -public events, petitions, social media

-Potential future speakers:
    -NCSL pharmaceutical researcher who can speak to current political climate
    -National Governors' Association might also have pharmaceutical researcher
    -Representative from PMPRB

-Designated Survivor: Season 3, Episode 3 focuses on march-in rights and features Nicole
-Next meeting: August 21st 5-7
-CW is on vacation from August 26th-September 16th