SENATE JUDICIARY SUBCOMMITTEE ON COMPETITION POLICY, ANTITRUST, AND CONSUMER RIGHTS

"A PRESCRIPTION FOR CHANGE: CRACKING DOWN ON ANTICOMPETITIVE CONDUCT IN PRESCRIPTION DRUG MARKETS"

JULY 13, 2021 – 2:30 PM

OVERVIEW

On Tuesday, July 13 the Senate Judiciary Subcommittee on Competition Policy, Antitrust, and Consumer Rights held a hearing with medical and industry experts and patient advocates to examine competition in the prescription drug market.

Members asked about practices that impact the cost of drugs; patient access; ways to lower drug costs; patents; antitrust enforcement; pharmaceutical innovation; direct-to-consumer pharmaceutical advertising; pay-for-delay; patent thickets; rebate walls; citizen petitions; pharmacy benefit managers; monopolies; government mandated price controls; cross subsidization; product hopping; biosimilars; generics; bundling rebates over multiple products; the Biden Administration's support for the TRIPS waiver for COVID-19 vaccines; intellectual property rights of drug companies; and non-interference clause, among other things.

The witnesses all agreed that greater transparency should be required for pharmacy benefit managers (PBMs) in terms of pricing and the ability to pass rebates and discounts through to patients at the pharmacy counter.

Mr. Levitt, appearing on behalf of PhRMA, and Mr. Abbott indicated that Congress should not legislate in the area of the U.S. intellectual property system, except in cases of clear abuse. They both defended the current patent system saying it enables drug companies to innovate, develop new medications, and save lives, while ensuring appropriate competition. Mr. Abbott added that while current antitrust enforcement is robust and effective, additional market-oriented legal reform would be helpful. He also spoke out against the imposition of price controls saying they create drug shortages, reduce investment, and reduce innovation. Mr. Levitt also voiced opposition to President Biden's support for the TRIPS waiver for COVID-19 vaccines. Additionally, he stated that PBMs should be reformed and their power should be diminished.

Mr. Mitchell advocated for elimination of the tax deduction for consumer advertising by drug companies; increased transparency for pharmacy benefit managers (PBMs); address anticompetitive practices of PBMs; and remove the non-interference clause for both Medicare Parts B and D. He also agreed with Ranking Member Lee that PBMs should be required to have a fiduciary obligation to their beneficiary.

Mr. Kades recommended scrutinizing all of the actors in the prescription drug marketplace; allowing Medicare to negotiate under Part D; reforming the patent system; a combined approach of broad based reforms as well as pay-for-delay and addressing patent thickets; and allowing the safe importation of drugs to spur competition in our system. He also expressed concern about the loss of disgorgement and restitution authority at the Federal Trade Commission (FTC).

Dr. Moodie spoke about the problem of patent thickets that shields branded drugs from scrutiny. She suggested that product hopping should be addressed by limiting direct-to-consumer advertising and strengthening the FTC and Department of Justice's (DOJ) ability to bring cases against branded drug companies who are engaging in the practice. Dr. Moodie also recommended getting biosimilars to the market at a more appropriate time as the best way to bring down drug prices and simultaneously eliminate reference pricing. Additionally, she noted that we need legislation that targets anti-competitive settlements while preserving pro-competitive settlements.

OPENING STATEMENTS

- Chairwoman Amy Klobuchar (D-MN)

WITNESS PANEL

- Michael Kades – Director, Markets and Competition Policy, Washington Center for Equitable Growth
- Alden Abbott – Senior Research Fellow, The Mercatus Center at George Mason University
- Geoffrey Levitt – Of Counsel DLA Piper, Appearing on behalf of PhRMA
- Rachel Moodie – Vice President, Head of Legal and Intellectual Property, Biosimilars, Fresenius Kabi
- David Mitchell – President and Founder, Patients for Affordable Drugs

QUESTION AND ANSWER SUMMARY

Sen. Dick Durbin (D-IL) – What value does direct-to-consumer pharmaceutical advertising on television provide to the consumer?

Mr. Mitchell – The more information you give to consumers, the better. It will help them understand the choices they are being called upon to make. I'm not sure that including prices in advertisements will lower prices but I do believe it will help consumers better understand what's happening to them. We support eliminating the tax deduction for consumer advertising by drug companies in order to discuss their use because it's only used to sell drugs at higher prices.

Sen. Durbin – In your testimony, you cite the $83 billion investment in research and development by pharmaceutical companies in 2019. You state, "due to uncertainty around research and development endeavors, investors require higher returns to compensate for higher risk." How do you square the fact that the 14 largest drugmakers spent more on stock buybacks than on research and development during the past five years?

Mr. Levitt – These are individual economic decisions by pharmaceutical companies. I can assure you that biopharmaceutical companies do not invent lifesaving medicines in order to make them inaccessible to patients. There is a balance between innovation and access. Research and development spend is very high and has increased significantly over the past several years. It's at a peak now and the U.S. accounts for the vast majority of that spending. Companies also put their money into making patients aware of the benefits and potential uses of their products through direct-to-consumer advertising, which is an important means of conveying information to patients about drugs. Prescribers then have the choice of whether to prescribe the drug.

Sen. Durbin – We're putting billions into the NIH each year. We want to make sure consumers can afford the products that these pharmaceutical companies generate from that research. Do you think we're getting that kind of return?

Mr. Levitt – I would say that the research ecosystem is a complete whole of which basic research funded by NIH is an important part, but NIH does not bring drugs into clinical development and marketing approval. That can only be done by pharmaceutical companies. If we look at statements of NIH itself, they will acknowledge that without the efforts of the pharmaceutical industry to develop and bring drugs to market, their basic research would not produce patient-accessible innovation.

Sen. Durbin – If you listened to Dr. Moodie's testimony, the thickets that we've created in patent law cannot serve the purpose of research, innovation, or benefits to the consumers. It's all about monopoly control of some of these drugs so you can have profits for a longer period of time. Isn't that right?

Mr. Levitt – I would take issue with a couple of comments made by Dr. Moodie. It's not that easy to get a patent in the first place. To get a patent you have to show that the invention has novelty, utility, and other features that entitle it to get a patent. I would also point out that innovation does not stop upon approval of a product. There are many very important innovations in product development post approval that benefit patients tremendously such as changing the dosage form of a product from an injectable to an oral, reducing dosage frequency, or allowing for a fixed drug combination instead of having patients take multiple drugs for conditions such as HIV.

Dr. Moodie – We see the U.S. patent system as an outlier now compared to other systems around the world. In the U.S., there are of course rules for examining patents that are working well but it's also easy to circumvent those rules in order to do numbers gaming where you can build up different patents having claims of incrementally different wording to make an army of continuation patents all derived from one original patent filing. This ends up building a patent thicket that's both protracted and multi-layered. Overall, we do believe the root cause of the problem is the examination procedures and the rules that the USPTO is using and that by tightening up those rules, it can help provide a more balanced patent system that can provide the benefits to both incentivizing innovation as well as allowing more affordable medications to come onto the market at a more appropriate time.

Sen. Michael Lee (R-UT) – In 2019, OIG found that the rebate model used by pharmacy benefit managers (PBMs) was a significant contributor to high drug prices. What reforms should we consider to address this? Some experts believe that PBMs should be required to have a fiduciary obligation to their beneficiary? Would this help solve the problem?

Mr. Levitt – We believe that the major need and necessity in this area in terms of reform is greater transparency in terms of pricing and the ability to pass rebates and discounts through to the patients at the point of filling their prescriptions. We have a growing disparity between list prices, which are then subject to rebates and discounts that are discounted between a manufacturer and a PBM. Those rebates and discounts do not then reliably find their way to a patient. We strongly believe in greater transparency. Your point about fiduciary duty on the part of PBMs is interesting. We don't have a position on that yet but we will look at it closely.

Dr. Moodie – When it comes to rebates and passive monopolies, the problem with these extended monopolies is that the rebates can increase for a longer period of time. This grows the patients out of pocket cost.

Sen. Lee – Do you think our patent system encourages or enables some of the anticompetitive conduct by pharmaceutical companies? If so, what can we do to change that?

Dr. Moodie – The way that the patent system is working right now, it's easy to circumvent certain rules that allow you to repeatedly claim a similar invention over and over again. This means that by building the number of patents by similar applicants, we can't economically clear the path through that many patents. Then you can create an inappropriate monopoly because you're shielding your patents from being scrutinized by the checks and balances that were built into the system. The processes that we use to challenge patents – IPRs and PGRs – have been weakened over the years. What would be really beneficial for third parties like ourselves to really scrutinize the patents and put the checks and balances back into the system would be to strengthen the IPRs tool as well.

Sen. Lee - Do you think the PTO is rubber stamping weak patent applications?

Dr. Moodie – There are of course good secondary patents. Evidence shows that over half of the patents that are granted are of questionable quality. We do need to raise the bar of patentability at the USPTO. We also need to tighten up the rules that make it possible to game the system to create lots of patents. We also need to give third parties better tools to challenge the patents to put back the checks and balances into the system.

Sen. Lee – Once a drug goes off patent, you see some generic competition and prices go down. Then, in many instances, you see the price for the same molecule, that's now off patent, skyrocket. Do you have any theories as to why that's happening?

Dr. Moodie – It could be that the generics are dropping out for various reasons such as not being able to make a profit whatsoever. That's not only a patent issue.

Sen. Lee – Do you think government mandated price controls would work in response to rising prescription drug costs?

Mr. Abbott – I don't think so. As a general matter, history shows price controls as tort markets. They create shortages, reduce investment, and reduce innovation. That would mean fewer drug improvements and new drugs, many patients being denied opportunities for cures, and cures for treatment of diseases. The U.S. leads the world in pharmaceutical innovation and research and development and would surrender it if it adopted price controls. Canada directly regulates drug prices which has led to widespread drug shortages that are getting worse. Pharmaceutical research and development in Canada fell significantly between 2001 and 2017 while U.S. pharmaceutical research and development more than doubled to $56 billion during that time period. Importing drugs from Canada with the aim of reducing prices could also import the problems of reduced availability and investment.

Sen. Lee – What role might cross subsidization be playing here?

Mr. Abbott – The cross subsidization problem you have in many countries is of a one buyer national system where drug companies face a monopoly buyer and they're threatened by a lack of access to markets or lack of protection of intellectual property. That's one of the reasons why prices are a lot lower. In fact, you have anticompetitive buyer activity going on.

Sen. Richard Blumenthal (D-CT) – How are biosimilar alternatives hindered by the practice of product hopping?

Dr. Moodie – Product hopping is a tactic used by branded drug companies to shift market just before biosimilars come to market in order to thwart the competition. This tactic can also be used to increase the price. We feel that advertisements for the new presentations of these product hops often minimize the risks and exaggerate the effectiveness, as well as include unsubstantiated claims of superiority over the biosimilars. Product hops can be addressed by limiting the promotional material, including the direct-to-consumer advertising that would influence patients and providers to switch to the product hop unless the branded drug company has conducted a clinical trial to show clinical superiority. Another mechanism to address product hopping is to strengthen the Department of Justice (DOJ) and the Federal Trade Commission's (FTC) ability to bring cases against branded drug companies who are engaging in product hopping.

Sen. Blumenthal – How are patients affected by product hopping by branded pharmaceutical companies?

Mr. Mitchell – When a drug is about to come off patent and small changes are made to try and move people to this new and more expensive drug, they're stuck if it's a hard switch. If it's a soft switch, sometimes they can be misled, without evidence, that the new drug is superior. Sometimes the branded drug company disparages their old version of the drug. Patients are often misled into taking the hopped product when the old product would do just fine. Product hops reduce choice and push people towards more expensive drugs that they don't necessarily need.

Sen. Chuck Grassley (R-IA) – Has there been too much concentration leading to very few companies with too much power? Should PBMs be required to provide more transparency on how prescription drugs are priced?

Mr. Levitt – We completely agree with you that the current situation with respect to PBMs and the market power and negotiating power that they have needs to be scrutinized very carefully. What is often perceived as an increase in prescription drug costs on the part of patients is actually a result of these PBMs, who control three quarters of the market for prescription drug benefits, to be transparent, share, or pass through the rebates and discounts to the patients at the point of prescription. This is why when you look at net prices – the price of pharmaceuticals after rebates and discounts – those prices are stable or declining. However, patients are perceiving an increase in cost and that's because the cost has been shifted onto the patient. We believe that is a problem that needs to be examined closely.

Mr. Kades – There clearly has been substantial consolidation in the PBM market. You would expect if that consolidation leads to market power, you would see that in the PBMs taking a larger and larger share of the rebates. That's a really important question. One of the things that can be problematic in this debate is that various actors like to finger point so we should be looking at all actors. We should also remember that rebates are a tool used by branded companies to prevent generic entry or competition, which is something that the Finance Committee report made a finding about on insulin.

Mr. Mitchell - It is wrong that a patient like myself cannot know if a preferred drug is on a formulary because it's the best drug for me, it's the least expensive drug among equally effective options, or if it's just there because the PBM got a big kickback, which we call a rebate. We believe there must be more transparency in the way PBMs operate. We need to know how much of the rebate is going to lower my premium, lower my out of pocket cost, and the profit of the PBM and/or the insurer. Transparency is key. The headwater of the problem of high drug prices is list prices set by the drug companies. These downstream anticompetitive practices by PBMs need to be addressed and we need to make sure they're working on behalf of patients. Sen. Lee mentioned maybe they should have a fiduciary responsibility. That would be just fine.

Sen. Grassley – Do you believe the action of companies engaged in bundling rebates over multiple products can be harmful to patients access to quality, lower cost drugs? If you believe this kind of action is anticompetitive, what kind of action would you think would help address the issue?

Mr. Mitchell – I do believe these things are hurting patients. I think it's very important to recognize that rebate traps and rebate walls are deals entered into voluntarily to the benefit of both the drugmaker and the PBM. However, they are not increasing patient choice or lowering patient price. That's why we need you to take a closer look and have the ability through transparency to examine how these deals are working and how PBMs are doing their business.

Mr. Levitt – If a company uses its market power coercively to exert anticompetitive effects and bar competitors from the market, that is anticompetitive behavior and it should be scrutinized. However, not all exclusive contracts are necessarily anticompetitive. It all depends on the terms and conditions, the duration, and the market power of the parties that can be used to reduce prices in principle. Again, when they're used in a coercive and anticompetitive way, they're definitely wrong.

Mr. Kades – It's absolutely true that dominant companies use rebate traps to stall entry. That is almost entirely to the benefit of the dominant company. While in theory, that action should be illegal under the antitrust laws, we know it's pervasive. It's part of the reason costs are high in insulin markets, it's why costs are high in the EpiPen market. It's why Remicade biosimilar competition has not developed. Part of the reason is why when courts look at this, they're getting it wrong. They're defining markets too broadly or a court looks at the case at summary judgment before you go to trial and says the rebate increased so there can't be an antitrust problem. That's why when you have laws that are so deferential to dominant firm conduct, you get this kind of activity that we're all paying for.

Sen. Amy Klobuchar (D-MN) – Why are U.S. drug costs so much higher than they are anywhere else in the world? Does a lack of competition play a role?

Mr. Kades – Yes. The lack of competition plays a significant role but there are other causes that might be improved by your bill to increase negotiations, allowing Medicare to negotiate under Part D or other payment processes that could help control drug prices. Patent system reform would also help.

Mr. Abbott – Yes. Prices are high but there are also institutional factors. The expansion of rebates may have also contributed to the raising of list prices. Also remember that drug companies have to cover the 90% of failed efforts involved in bringing forth a new drug. We are cross subsidizing other parts of the world.

Mr. Levitt – Other developed countries tend to have very different healthcare systems with a much greater degree of government involvement and price controls that Americans would not be willing to tolerate. They pay for that degree of government control with less access and less innovation for patients. Yes, we spend somewhat more for prescription medications in this country. However, we also spend more on all aspects of healthcare in this country. Administrative costs in our country are four times what they are in Canada. We have to put this in context. Prescription drug costs have remained flat at 15% of overall healthcare expenditure in this country for the past several years.

Dr. Moodie – We are seeing biosimilars hit foreign markets years before they hit the U.S. That trend is going to continue and get worse. The patent thickets that we're seeing growing up around the newer biological drugs are growing so much faster and bigger than the famous thickets that people are talking about today. The branded companies are getting better at this gaming of the numbers of patent thickets. Getting biosimilars to the market at a more appropriate time is the best way to bring down those prices and then you don't need reference pricing either.

Mr. Mitchell – We're paying almost four times what other wealthy nations pay for the same brand drugs. No other country allows brand drugmakers to dictate the prices of drugs as we do in this country. They negotiate, we don't. The outcome is that prices range as high as everyone here knows.

Sen. Klobuchar – In your written testimony, you compared the competition problems in prescription drug markets to the canary in the coalmine of U.S. competition law. Are you saying these problems in our drug market should have been an early warning sign? Do you think broad based reforms would be most helpful?

Mr. Kades – Absolutely, I do. If there are two products that treat a disease, they have to be in the same market. Getting rid of that competition has to be bad. Somehow the court got that wrong. Time and again the government is spending massive resources proving essentially what is obvious. When we look at the antitrust enforcement in pharmaceutical industries, it's a sign that things are working. We need to look at what the conduct is that is occurring. Companies putting a tablet inside a capsule to prevent generic entry is not innovation. The fact that the system allows that tells us that the antitrust laws are too weak.

Sen. Klobuchar – So, would you suggest broad based support as well as doing these specific things such as pay for delay, addressing patent thickets, etc.?

Mr. Kades – Yes. It's a combined approach.

Sen. Klobuchar – Are you also concerned about the loss of disgorgement and restitution authority at the FTC?

Mr. Kades – Yes.

Sen. Klobuchar – Do you think that needs to be fixed?

Mr. Kades – Absolutely. Taking away the FTC's ability to deprive people of the illegal profits just says go ahead and violate the antitrust laws because the most the federal enforcers can do is go forth and send no more.

Sen. Klobuchar – In your testimony, you wrote that for both generics and biosimilars our laws are intended to "strike a balance between providing access to medicines and preserving incentives for innovation." However, we're not seeing that balance. We're seeing deep patent thickets with sometimes more than 100 patents filed for a single drug, many of which are filed after the drugs are approved. Aren't these practices throwing off what you call the delicate balance between patient access and incentives for innovation?

Mr. Levitt – Product innovation does not stop upon approval of a product. Particularly with complex products like biologics, there can be many different kinds of inventions that can take place after approval that can improve the profile of that product in ways that matter to patients that make it easier to administer, extend the shelf life, or improve the stability. Each of these potentially qualifies for a patent. Patents are not so easy to get. You have to show the requisite requirements to get a patent in the first place. Once you get a patent, it is absolutely subject to challenge through either the inter partes review process or the PGR process. In a way, one could take the figure cited by Dr. Moodie that 56% of the IPRs succeed as evidence that the process works. If a patent is weak and is subject to challenge then it's going to go down. I can assure you that innovator companies are not in the business of getting weak patents so they can be struck down. They're getting patents for innovations that improve the product. We don't oppose properly targeted legislation on product hopping. I'm happy to discuss the specifics of that with the committee.

Dr. Moodie – Due to the numbers gaming of the patent system, we can't economically use IPRs and PGRs to clear the path through hundreds of patents. The system would work better if you could get one patent per secondary or follow on invention. However, now they're creating these families of patents around each invention to circumvent and shield the patent through economic means.

Sen. Tom Cotton (R-AR) – If the Biden Administration succeeds in pushing through an expropriation of American companies' intellectual property, will this increase the production of vaccines worldwide?

Mr. Levitt – No. Biopharmaceutical companies share the goal of vaccinating as many people as possible, as quickly as possible around the world. However, punitive transfers of patents will not help increase production capacity, nor will they accelerate access to COVID-19 vaccines. In fact, they also risk putting production in the hands of parties who lack the technical and quality know how to accomplish this. The concern that apparently lies behind this unfortunate move of transferring and seizing patent rights is misdirected. If there are any issues about getting product and vaccine out, it's in the supply chain, not in the intellectual property rights that have enabled companies to develop vaccines in an incredibly short amount of time.

Sen. Cotton – This supply chain and manufacturing process for the coronavirus vaccines is incredibly complicated. Is that correct?

Mr. Levitt – It absolutely is.

Sen. Cotton – It depends on incredibly customized equipment as well as highly specialized knowledge. Is that correct?

Mr. Levitt – Vaccine production is among the most complicated manufacturing processes in the world. There are more than dozens of separate steps, each of which has to be very carefully controlled under stringent quality requirements.

Sen. Cotton - It's not the patent rights that these companies have that is the bottleneck for vaccine production around the world but rather the supply chain and manufacturing process itself. Is that correct?

Mr. Levitt – Absolutely correct.

Sen. Cotton – Who might benefit from this waiver or what might better be called an expropriation of American companies' intellectual property?

Mr. Levitt – It certainly won't be the patients. It will be foreign economic competitors who really don't play by the rules in the first place.

Sen. Cotton – Would most or many of these competitors be located in China?

Mr. Levitt – It has been said that is one of the countries in that category.

Sen. Cotton – Why does it matter to all Americans that we protect the intellectual property rights of companies to include the patent rights of these vaccine manufacturers?

Mr. Levitt- It matters because taking this kind of drastic action to seize intellectual property and violate intellectual property rights is going to endanger future production and innovation by creating confusion and uncertainty among vaccine manufacturers at a time when they're working around the clock to bring vaccines to patients. The damage will be less access to needed medicines and economic harm to a vibrant industry that provides high quality jobs to hundreds of thousands of Americans.

Sen. Cotton – All in return for which we don't get any acceleration in the effective production of coronavirus vaccines. Is that correct?

Mr. Levitt – Precisely.

Sen. Josh Hawley (R-MO) – Should we limit the ability of PBMs to apply DIR fees retroactively?

[no audio]

Sen. Hawley – If we can agree that the life of a patent should be limited, I'm trying to figure out why it is that some of the companies in the organization that you represent have gone to such lengths to stretch things out in a way that seems almost indefinite. Can you help me out with that?

Mr. Levitt – Innovations continue after the approval of a product and those innovations can come in many areas, which can then be subject to patenting. If those innovations are truly beneficial to patients, they will get out on the market and get uptake in the market. If they're not, then they won't.

Sen. Hawley – If your clients aren't trying to behave in an anticompetitive way, then why aren't all the relevant patent applications for a particular drug filed at once when a product first comes to market as opposed to being staggered over time and continue to lengthen the protections?

Mr. Levitt – That is because as the manufacturer gains further experience with the product and continues to examine the product for ways it can be improved upon, that's a process that naturally takes place over time. When you get the initial approval of a product, that is when it's ready for approval on the basis of safety and efficacy. That doesn't mean the product is perfected at that time or can't be improved upon in a whole variety of ways that can be beneficial to patient care, the quality of the product, and other attributes. It's naturally a process that takes place over time as providers and manufacturers gain more experience with the product and continue to perform scientific research on the product. It doesn't happen all at once.

Sen. Marsha Blackburn (R-TN) – How do you think incentives in the drug pricing supply chain are aligned? Are they there to drive out of pocket costs lower?

Mr. Levitt – In our view, that is one of the fundamental problems in the entire drug pricing system today. The incentives are misaligned and there is no incentive to pass on the savings to consumers that may exist upfront in the system between manufacturers and PBMs in the form of rebates or discounts. What we've seen is a growing trend for other entities in the healthcare system to realize those savings for themselves. Today, manufacturers only get a little bit over half of the actual cost of the drugs that they're providing. The rest is going to a variety of stakeholders including PBMs, government entities, payers, and others. The problem is that the patients are not seeing those savings at the pharmacy counter. We believe that is an issue that needs urgent attention.

Sen. Blackburn – Should the FTC do more to evaluate the anticompetitive behavior of the PBMs or should this be given to someone else?

Mr. Kades – Absolutely. The FTC should be looking at PBMs, considering whether there is anticompetitive conduct, and bringing cases where they can. I do think it's important to understand that part of the problem that we're seeing with PBMs and branded companies gaming the system is directly related to how we have abandoned antitrust law as a true regulator and promoter of competition.

Sen. Blackburn – How many of you think PBMs should be eliminated from the marketplace?

No one raised their hand.

Sen. Blackburn – How many of you think PBMs should be reformed and that their power should be diminished?

Mr. Levitt raised his hand.

Sen. Klobuchar – Can you talk about how it is beneficial for America, from a public health perspective and a humanitarian perspective, to get people in other countries vaccinated as soon as possible?

Mr. Mitchell – We don't have a position on international issues like the TRIPS waiver but I can speak for myself. A pandemic by definition is global and until we defeat a pandemic globally, we are all going to continue to be at risk from emerging variants. From a public health perspective and trying to look after ourselves in America and also being good citizens of the world, making sure people can get vaccinated all over the globe is in our best interest both as people who want to have good health and be good citizens.

Sen. Klobuchar – Did the stock ratings of pharmaceutical companies plummet when President Biden made the announcement that he supports the TRIPS waiver for COVID-19 vaccines?

Mr. Kades – My understanding is that they did not take a substantial hit.

Sen. Klobuchar – Can you elaborate on the harm to patients and competition caused by the filing of sham FDA petitions?

Mr. Kades – It's a tragic story. The government comes up with this idea that when the FDA makes decisions, average citizens and people involved should be able to petition the FDA. This improves participation. Nobody in their wildest dreams thought that virtually all the citizens petitions would be filed by their competitors and the branded companies saying this generic product should have special restrictions placed on it, should require more testing, etc. Even if the petition isn't successful, the FDA has to review it and make a decision within 180 days. By using the process of the FDA, branded companies can delay competition and force all of us to pay more for drugs without any innovation and without any advantage. Legislation to correct that problem would be excellent. Congress already tried to fix this once and branded companies found ways to nullify that. Congress should take another crack at it.

Sen. Klobuchar – In your written testimony, you talked about the need for greater resources for enforcers is particularly acute with regard to pharmaceutical enforcement given the great economic significance and complexity of pharmaceutical market issues. Given that you see this acute need, would you recommend that we get some additional resources for enforcement of the laws to the agencies?

Mr. Abbott – Yes.

Sen. Klobuchar – Do you think that removing the non-interference clause is a good idea? What additional reforms do you think would be required for Medicare to get better price terms for the enormous quantity of drugs that it purchases?

Mr. Mitchell – Yes. We believe the non-interference clause should never have been inserted in 2003 and that it needs to be removed for both Medicare Part D and B drugs. The specialty drugs, many of which are Part B drugs, account for 0.4% of all prescriptions but 46% of all spending on drugs in this country. We would love to see the non-interference clause eliminated, negotiations extended to Parts D and B, and the prices negotiated by Medicare extended to the private sector to help employers who provide healthcare for 156 million Americans.

Sen. Klobuchar – What can the FTC do to better police pharmaceutical mergers under current law? Would reforming the laws enable the agencies to better police anticompetitive mergers?

Mr. Kades – Yes. Merger enforcement is going to be critical for the agencies. It's fair to say they need to be more risk seeking but under the current standards, the law is too lenient. I absolutely agree that it's time for Congress to reset that balance. Ideas of adopting new presumptions makes sense.

Sen. Klobuchar – Would allowing the safe importation of drugs inject some competition into our system?

Mr. Kades – I think that's an excellent idea and would improve competition. One of the problems on older drugs is to get approval, a company has to go through 18 months and spend money for that. When the price went sky high with Daraprim, there were all sorts of products in Europe that had been on the market for 20 years. Let's find a way to inject that competition back into the U.S. so that such price increases won't happen or won't last as long.

Sen. Lee - I introduced the TEAM Act along with Sen. Grassley. One of its provisions would require the courts to find that conduct is anticompetitive where there is clear evidence of intent to harm competition. In your view, would this make it easier for antitrust enforcers to stop anticompetitive conduct in the pharmaceutical industry?

Mr. Kades – Yes. One thing to think about is that once you make that law, companies will be more careful about what they put in their documents.

Sen. Lee – One of the provisions of the TEAM Act would limit the ability of courts to give credit to defendants for justifications that are speculative and out of market or that don't benefit consumers. Would this help some of the same problems faced in protecting competition in healthcare markets?

Mr. Kades – Absolutely. Once you get to litigation, companies magically have all sorts of justification that aren't in the record so tightening up those requirements would be very helpful.

Sen. Lee – I was excited to see that Walmart has recently broken into the insulin market and launched two low cost products. What can you tell me about why it has taken so long for a disruption like this to occur and why we haven't seen this kind of innovation from a traditional pharmaceutical company?

Mr. Abbott – It's interesting that discount retailers have been very important figures in healthcare. In fact, there was a recent study that bargaining costs for generics Medicare Part D were actually higher than the prices negotiated by Walmart. This suggests there should have been more companies doing this. The private sector is very good at bargaining and if you lift regulatory barriers to allow companies to enter into these markets, that's all to the good. One of the big problems here is if you have so many large entrenched actors, regulatory structure made a lot of large companies reluctant to enter.

Sen. Lee – What do you think we could do to make it easier so patients benefit from competitive markets? Is there anything we can do to limit the restrictions on entry?

Dr. Moodie – There has been a lot of talk about price controls. We don't think that is the solution. The solution is more competition. It does take up to 10 years to develop a biosimilar. By the time those biosimilars are ready to launch, we're seeing the patent thickets. We should also preserve pro-competitive settlements. It's important that we don't assume that all patent settlements are anti-competitive because pro-competitive settlements, which are those that do not include pay for delay. Those are one of the few tools we have to address a patent thicket as a whole. Those pro-competitive settlements act as a compromise that strike the right balance. Because we can't litigate so many patents, if we were to not have any settlements, you would often see the biosimilars coming to the market much later at the end of the expiry of the last patent thickets. A pro-competitive settlement brings the launch date earlier as a kind of a compromise. We have to be careful that any legislation targets those anti-competitive settlements while carving out the pro-competitive settlements.

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