THE SUBCOMMITTEE ON HEALTH OF THE COMMITTEE ON ENERGY AND COMMERCE

Negotiating a Better Deal: Legislation to Lower the Cost of Prescription Drugs

Tuesday, May 4, 2021 at 11:30 a.m. via Cisco WebEx

PURPOSE

The purpose of this legislative hearing was to discuss the policies of key drug pricing reform proposals, including the major bills presented by Democrats and Republicans, as well as legislation that would introduce new guardrails in drug development to enhance competition in the generics and biosimilars market.

KEY TAKEAWAYS

- Lowering drug prices remains a key bipartisan priority, but the proposed approaches diverge significantly. While legislators agree that Americans are often paying too much for prescription drugs, they differ on the extent to which the federal government should be involved.
- Republicans and Democrats remain divided over authorizing the Secretary of Health and Human Services to negotiate Part D drug prices and tying rebates to inflation. While Democrats see this as essential to lower costs, Republican characterize it as bureaucratic overreach that will hinder competition and impede drug development.
- The biologics and biosimilar development industry, which focuses largely on cancers, as well as rare and complex diseases, is a frontier of significant innovation. However, these drugs tend to present some of the highest out-of-pocket costs to patients.
- Proponents of minimizing government intervention and promoting competition and innovation pointed to the success of Operation Warp Speed and the authorization of three COVID-19 vaccines in a year.
- However, Part D price negotiation could lower prices on some of the most widely used drugs, resulting in system-wide savings as people are able to avoid acute care episodes and better manage chronic disease.
  Reforms to intellectual property policies that are used to preserve market exclusivity for brand name drugs and biologics could enhance competition and create a stronger generics market

LEGISLATION

- **H.R. 3** – Elijah E. Cummings Lower Drug Costs Now Act
- **H.R. 19** – Lower Costs, More Cures Act of 2021
- **H.R. 153** – Protecting Consumer Access to Generic Drugs Act of 2021

- **H.R. 2815** – Bolstering Innovative Options to Save Immediately on Medicines Act **(**BIOSIM Act)
- **H.R. 2831** – Prompt Approval of Safe Generic Drugs Act
- **H.R. 2843** – Stop The Overuse of Petitions and Get Affordable Medicines to Enter Soon Act of 2021 (STOP GAMES Act)
- **H.R. 2846** – to amend title XVIII of the Social Security Act to require PDP sponsors of a prescription drug plan under part D of the Medicare program that use a formulary to include certain generic drugs and biosimilar biological products on such formulary, and for other purposes
- **H.R. 2853** – Bringing Low-cost Options and Competition while Keeping Incentives for New Generics Act of 2021 **(**BLOCKING Act)

WITNESSES

Therese Ball
Patient

Michael A. Carrier
Distinguished Professor of Law
Rutgers Law School

Rachel Sachs
Associate Professor of Law
Washington University in St. Louis, School of Law

Gaurav Gupta, M.D., M.S.E.
Founder
Ascendant BioCapital

Khrystal K. Davis, J.D.
Rare Disease Caregiver & Patient Advocate
Texas Rare Alliance Founding President

OPENING STATEMENTS

Chairwoman Eshoo (D-CA) stated that U.S. law prohibits Medicare from negotiating drug prices. The U.S. is the only developed country in the world where this is the case, and Americans pay three or four times more than citizens of other nations. Chairwoman Eshoo stated that this can be changed, and lives can be saved through policy action. Year after year pharmaceutical drug company profits have gone up 20% on average, while patients are left to choose between paying rent, buying food or paying for their prescription drugs. One in four diabetics ration their insulin and many skip doses. 1.1 million Americans will die prematurely due to high drug costs. Chairwoman Eshoo stated that we can help them by moving H.R. 3 forward. This bill caps out of pocket costs to $2000. Currently, seniors can pay up to $15,000 a year for one drug. This bill would stop drug price hikes, seen in the case of EpiPen's increase and Martin Shkrelli. If prices for drugs, including generics, increase above the rate of inflation, pharmaceutical drug companies must pay back this sum to the Treasury. Non-partisan analysis state that this bill will reduce price by 40% to 55% on average. This would save $500 billion dollars over 10 years. The bill would kick start innovative research coming out the National Institutes of Health (NIH), Food and Drug Administration (FDA), and the Advanced Research Projects Agency for Health (ARPA-H) announced by President Biden last week.

Innovative cures would be made available and affordable to all Americans through this bill. Associations like the American Association of Retired Persons (AARP) and the American Medical Association (AMA) support the bill.

Ranking Member Guthrie (R-KY) said that H.R. 3 is a partisan bill. He stated that there is no doubt that something needs to be done regarding the rising cost of drugs. He said that H.R. 19 would lower prescription drug costs. He stated that the American people do not want increased premiums subverted for liberal programs. H.R. 3 would bring the American system one step closer to a single payer system - a dangerous idea, stated by Ranking Member Guthrie. America has developed the market's most innovative drugs and employed brilliant scientists. To address this issue, access is the key term. Estimates state that H.R. 3 could result in up to 100 fewer drugs introduced onto the market in the next 10 years. This could have largely affected the development of COVID-19 vaccines. He stated that thanks to President Trump, America took a different approach than its European allies, with Operation Warp Speed. The results showed as three effective and safe vaccines were developed in record time. H.R. 3 disincentivizes drug development and we could have seen this significant effect in preventing the development of the COVID-19 vaccines. Just last week, President Biden stated that there is desire to pass something that is bipartisan. H.R. 19 is an all bipartisan bill. He stated that he strongly supports proposals targeting Part D reform and value-based agreements.

Representative Burgess (R-TX) said that in this Committee, there is a history of working together in a bipartisan manner. The list of legislative proposals includes bipartisan bills. H.R. 3 did not get signed into law, because it is a partisan bill. Parts of H.R. 19 did become law, because it is a law both sides can agree on. Representative Burgess urged the Congress to act on what President Biden advised and work together to pass bipartisan drug pricing policy.

Chairman Pallone (D-NJ) said health care is still the number one priority. Lowering the price of drugs is the biggest priority. H.R. 3 and other legislation would make the way for lower prices for patients in this country. Today, Americans are forced to ration the drugs that they need. They pay much more for the same drugs than other countries pay. H.R. 3 would allow the Secretary of Health and Human Services (HHS) to negotiate on behalf of Medicare. Chairman Pallone stated that these prices would be available to all Americans. The bill would require drug companies pay a rebate for price increases above that of inflation. The out of pocket cap would ensure that the elderly pay no more than $2000 per year for prescription drugs. Chairman Pallone stated that we need to reinvest savings to find the next breakthrough and improve Food and Drug Administration (FDA) drug evaluations. The additional savings would improve outcomes, and H.R. 3 would lower prices, resulting in more take home pay for workers. Beneficiaries will be healthier as they are able to take drugs as prescribed. Americans should not have to choose between their health and food or rent. Long past time to address the issue of high drug pr. Competition is key to bringing down prices.

Representative Schrader (D-OR) introduced the BIOSIM Act. He stated that this is a common sense act to increasing competition in the drug market. This bill targets pay for delay tactics, in which some generic manufacturers park their drug applications when they gain exclusivity to block competitors from entering the market, in exchange for payments from branded name drug manufacturers. These industry practices deeply affect Americans.

Representative McMorris-Rodgers (R-WA) said the story of American innovation is one that should be celebrated. Rep. McMorris-Rodgers stated that this should be approached the American way, with Alzheimer's as an example of an area in need of innovation. New cures and treatments are real if private investment is protected. It's a false choice to jeopardize cures in the name of saving money. H.R. 3 would result in dozens of fewer cures- up to 100 fewer drugs in the next decade. This policy would make the U.S. more reliant on China, and more reliant on the federal bureaucrat. Rep. McMorris-Rodgers should focus on areas for bipartisan work to develop uniquely American solutions.

TESTIMONY

Therese Ball said that she is a multiple sclerosis patient as well as a registered nurse (RN). She stated that she had a front row seat to the lack of access to treatment due to high drug prices. The price for Copaxone is 5 times higher in the U.S. than the price in other comparable nations. When the grant from the independent charity assisted with funding, there was a fear that she would lose this aid. When the Foundation did not renew grant, costs soared to $6000 a month. Subsequently, she suffered from severe progressive health problems. This is not a unique problem, and patients have waited long enough.

Michael A. Carrier said prices for drugs are too high. Brand companies play games with pay for delay and citizen petition tactics. These tactics inhibit generic competition and harm patients. Settlement legislation is important to fix some of these issues. Mr. Carrier stated that he is a supporter of bills H.R. 153 and H.R. 19. Pay for delay settlements prevent patients from gaining access to generic and biosimilar drugs. Additionally, the FDA faces barriers to addressing citizen petitions that harm patients.

Dr. Gaurav Gupta stated a cap and eliminating cost through health exchanges would be high impact to increasing access. This would dramatically undermine biopharmaceutical companies' ability to treat and cure drugs in the future. This would undermine American competitiveness in an industry where the country has been a leader. China touts that they are able to take a drug to the market faster than the U.S. and this continues to be a factor in global competition. In order to protect American patients, the nation has to protect the ability to nurture competition domestically.

Khrystal K. Davis stated that she is a rare disease parent and patient advocate. She said that she seeks to improve access to care in rare disease groups. She stated that her son lost all movement as a baby. He was diagnosed with Spinal Muscular Atrophy (SMA). SMA is the number one genetic cause of death in infants. Witness and family were told at the time that there was no hope. They travelled to Mexico to enroll in a clinical trial, and her son was the first to receive the lifesaving treatment of Spinraza. Upon FDA approval and coverage determinations of the drug in the U.S., her son qualified to receive the drug. ICER estimated that the cost was not affected with a value assessment, yet adopting a reference price with discriminatory QALYs would inhibit all patient advocacy efforts. The witness stated that she opposes H.R. 3. She stated that families of patients become caretakers and health care experts. Other nations that adopt reference pricing are innovation deserts. Research and development are what dreams are made of, witness stated. At the current rate, it would take thousands of years for the discovery of life-saving treatments for all rare diseases when innovation should and could move as quickly as COVID-19 drug development has. Advocacy groups cannot afford to stop opposing H.R. 3 or QALYs as measures that do not account for patients' lives.

Rachel Sachs stated that she focuses on the topics of innovation and access to new pharmaceutical drugs. She said that the U.S. has high drug prices and this Committee has the ability to help and solve this issue. Comprehensive drug reform should include the following: (1) lowering patient out of pocket costs for patients, (2) fixing misaligned incentives, and (3) addressing the underlying issue of high drug prices. There is no single method of addressing the issue of rising drug costs, and other nations have adopted multiple ways to doing so. H.R. 3 pulls all three levers. Not only are drug costs rising, individual drug prices are rising as well with list prices of Part D drugs rising above the rate of inflation.

QUESTIONS AND ANSWERS

Chairwoman Eshoo thanked Therese Ball for her testimony. She restated that the price of Copaxone, an MS drug increased from $800 to $6,000 a month from 2003 to 2017. She asked the witness whether there was any innovation in the drug during that time period. **Ms. Ball** stated that there had not been any improvements or innovations and that the drug company had raised the price of the drug 27 times. **Chairwoman Eshoo** asked whether other countries see comparable price hikes. **Ms. Ball** stated in some cases yes, but the drug price is initially much higher in the U.S. to begin with. **Chairwoman Eshoo** posed the question to Dr. Gupta of what he can say to a patient like Ms. Ball. **Dr. Gupta** stated that as a physician who moved over to the biopharmaceutical industry, he assures that patients are at the center of what they do. He said that he understood the frustration when patients don't have access to treatment. He agreed and acknowledged that out of pocket costs are a barrier for patients, addressing Ms. Ball directly. He stated that there are ways to find common ground and improve access to all patients. Chairwoman Eshoo asked whether H.R. 3 would limit patient access to care. **Ms. Sachs** stated that H.R. 3 would not disrupt Medicare coverage requirements, especially those within the protected classes.

Representative McKinley (R-WV) said that all stakeholders know that there in a need for drug pricing reform. He stated that no side is arguing against that; however H.R. 3 is a clear overreach. Press states that H.R. 3 will not pass the Senate, and he questioned why there is action on this highly partisan bill, H.R. 3. He emphasized a desire to work on legislation that can be passed into law and supported in a bipartisan manner. He stated that America deserves better. He stated that H.R. 19 proposes to pass rebates to patients and make it unlawful for pay for delay among manufacturers. He said that generics are the best way to lower prices and asked whether Part D design and formulary placement for generics address the issue of lowering prices. Ms. Sachs stated that current incentives lead manufacturers, PBMs, and plans to increase prices over time rather than to reduce them. Competition only works in cases where there is generic and biosimilar competition available. Many of the highest drug spend cases do not face competition. Top 10 selling drugs in Part D, including Humira does not face competition. **Rep. McKinley** asked about whether H.R. 3 would affect the market for non-addictive pain medications and medically assisted treatments during a time of increasing drug overdoses. **Dr. Gupta** stated that the need for non-opiate and non-addictive pain medications is great, and the entire pharmaceutical industry is working to tackle this issue. Price controls would only inhibit the work of several drugs that are currently in development. Price controls do not ensure savings to patients.

Chairman Pallone (D-NJ) stated that the task to lower drug prices is urgent. He said that H.R. 3 would lower the drug prices and set a Medicare Part D cap at $2,000 per year. It is important to acknowledge that not all proposals are the same. **Ms. Sachs** said that a cap, though helpful, would only move money around in the system. This could even increase premiums and increase spending. The cap needs to be coupled with other reforms. Inflationary rebates apply to Medicaid, and this has worked, but even this does not address the underlying issue. **Chairman Pallone** stated that the Republican bill would not allow for Medicare negotiation. He asked whether this would be effective to decrease prices. **Ms. Sachs** says that the Part D cap would help seniors with out of pocket costs, while potentially long-term increasing premiums.

Ranking Member Guthrie said that there is valuable work that all can agree on. He stated that he agrees that there are long existing therapeutics whose prices increase faster than inflation. The market requires competition. Congress should focus on patent processes. Price setting is a major concern, and though 93% of respondents support lower drug prices, fewer support this at the expense of innovation and access to these drugs. He stated that a nation cannot change the way it pays for drugs without changing what the nation receives. Europe decided to negotiate with the COVID-19 drugs and unfortunately, Europe is still in a lock down. In Kentucky, vaccines are accessible to those who want one. He posed the question of whether importing a European style of drug pricing would change the innovation America gets. **Dr. Gupta** stated that those other countries that negotiate are willing to deny the access to innovative treatments, namely cancer medications among others. There are significant delays that border on years. The risk to H.R. 3 is significant. **Rep. Guthrie** stated that incentives are necessary for

developing therapies. He asked about the potential for value-based agreements to address the larger issue. **Dr. Gupta** stated that this is a promising avenue that makes sense for companies to put together those voluntary price proposals and could potential impact and improve access. **Ranking Member Guthrie** stated that out of pocket caps are favorable, though it only does move money around. He stated that patent reform and proposals that enhance competition are strong proposals.

Representative Butterfield (D-NC) said the time for action is here. He stated that policies could be passed if Republican colleagues would cooperate. Patients today have to choose between food and medicine. **Ms. Sachs** stated that H.R. 3 recognized that reducing patient out of pocket costs is critical, though it covers up the main issue and makes it harder to see price increases. **Rep. Butterfield** asked whether this would affect rare disease drug development. **Ms. Sachs** said that most rare disease drugs would not qualify among the top selling drugs subject to negotiation.

Representative McMorris-Rodgers stated a dedication to working on rare disease drug development. She stated she is anxious to work in a bipartisan manner to deliver on drug pricing. She shared a concern regarding the big picture impacts of H.R. 3. **Dr. Gupta** stated that we are living at the dawn of the golden age of innovation. Many biological targets that have been "undruggable" are now understood with therapeutics in development. **Rep. McMorris-Rodgers** stated that a concern is that H.R. 3 would disrupt innovation for drugs that treat rare diseases like SMA. She asked the question what quicker entry into the market means for a child with SMA. **Ms. Davis** stated that every day matters for a child with SMA and innovation and access to these drugs should be a priority. QALY metrics represent a discriminatory measure preventing patients who need the treatments from getting them.

Representative Matsui (D-CA) said that there is a lot of conversation surrounding the out of pocket cap in Medicare Part D. **Representative Matsui** asked what a $2,000 annual cap would mean for the witness. **Ms. Ball** stated that this would allow her to know exactly how to plan in a way that her $6,000 cost does not. This would help a great deal. **Rep. Matsui** stated that the role of inflationary rebates is attractive, though it may be limited in their ability to lower prices. She posed the question about what leverage does Medicare have. **Ms. Sachs** stated that Medicare has little to no leverage today and that inflationary rebates will be helpful.

Representative Upton (R-MI) said that the 21st Century Cures Act was a major milestone, and he is working on a second version of the bill. He reiterated that all want cures for rare diseases. One major issue at the time of passage was exit of venture capital to overseas investment. This is still a factor to consider today. **Rep. Upton** stated that H.R. 3 compromises U.S. leadership potentially leading to longer delays in market access and compromised quality due to manufacturing standards that are set overseas compared to FDA standards. H.R. 19 packaged proposals that are bipartisan, while allowing for a future for innovative precision medicine.

Representative Castor (D-FL) stated that prices for drugs are soaring. RAND Corporation estimated that the U.S. pays 256% more for prescription drugs than the average of 32 countries. This takes a toll on families, neighborhoods, and communities. She stated that this prohibition on negotiation is illogical. She called for the lift of Medicare negotiation prohibition. **Ms. Sachs** said that it is common for drug companies to state that they price drugs at the level the "market will bear". This exceeds the profit levels that would recoup research and development investment. Medicare has very little leverage. Medicaid, though required to cover all drugs, can limit increases in above inflationary increases. She stated that though generic competition is important, it is reactive, whereas negotiation would curtail industry practices regarding high initial prices.

Representative Burgess (R-TX) said that the NIH is a national treasure, but it is not designed to bring new medicine to market. **Dr. Gupta** stated that there is no national formulary. **Rep. Burgess** stated that Operation Warp Speed is a case where private sector involvement resulted in unprecedented outcomes. He asked whether negotiation in addition to an excise tax looks like typical market negotiation. **Dr. Gupta** stated that investment capital is not courageous when challenged. The laws of economics state that a policy like H.R. 3 would put capital at risk. **Ms. Ball** said that QALY criteria are discriminatory in determining who deserves access to treatments.

Representative Sarbanes (D-MD) said that high prices of drugs force them to make sacrifices and compromises. List prices went up 129% for top selling drugs. At the same time OOP spending increased. This specific toll of giving Medicare the ability to negotiate is the center of the toolkit. **Ms. Sachs** stated that the issue of drug pricing is so complex that there is no one fix.

Representative Griffiths (R-VA) said the problem with this bill does not include negotiations. This committee has a role to determine whether bills passed are constitutional. There is a constitutionality concern here. **Rep. Griffiths** stated that he doesn't believe this bill is constitutional.

Representative Welch (D-VT) said the pharmaceutical industry has record profits. Pharma is not opposed to governmental action that provides patent protection and the exclusive right to use the product. Pharma is not opposed to governmental action with taxpayer money that is monetized. It is not against governmental action in Medicare and Medicaid. Pharma has a pretty good arrangement with a guaranteed market and the model allows them to make billions of dollars. Pharma spends more on advertising than research and development. All of these things add up to price gouging impacts. The biggest threat to access to healthcare is the cost of healthcare. Unless we face this, we are going to allow the erosion of access to healthcare for all Americans. The argument is that it will impact innovation. **Ms. Sachs** said that innovation will be harmed no matter what the reform is.

Representative Bilirakis (R-FL) said there is an access issue and the VA negotiates drug prices. He stated he is concerned about the impacts of H.R. 3 on rare diseases. The

bulk is from biopharma industry, and there is a need to invest in rare diseases. He worries that direct investment in rare diseases will make companies make only safe bets, meaning people with rare diseases are suffering. Policies like reference pricing will keep companies thinking inside of the box. He asked how H.R. 3 will impact complex rare diseases due to the economic incentives. **Dr. Gupta** said that small biopharma companies are the long striving innovation and primarily serve rare disease patient populations. Because of that phenomenon, price controls will disproportionately impact them. He said that H.R. 3 would significantly negatively impact rare disease patients. **Representative Bilirakis** asked if H.R. 3 will increase Chinese influence over companies. **Dr. Gupta** said he does not think it will influence companies.

Representative Schrader (D-OR) inquired if H.R. 3 passes, how it would impact the start-up sector. **Dr. Gupta** said the impacts would be far reaching and would be generally negative. If there are sectors that would seek out safer returns, they may see a diminishment in risk in biotech. **Representative Schrader** asked if instead of benchmarking, they allowed negotiations, would that be different. **Dr. Gupta** said it doesn't address the core issue of access, and price controls of any sort will not ensure the payers will pass those on to patients. He stated he hesitates to suggest any amount of negotiation without focusing on larger problems. **Representative Schrader** asked fi there are policies that Congress should be prioritizing. **Ms. Sachs** said that it is important to look at roles of insurers, pharmacy benefit managers, and physician/provider groups to drive prices. **Representative Schrader** said linking clinical value paid for by governmental entities and asked if it would be beneficial. **Ms. Sachs** said the idea of value assessment means that they want to pay more for the drug that works better. But different models are voluntary to engage in, and companies are not required to enter into these deals.

Representative Long (R-MO) said ensuring prescription drugs are affordable is necessary and hopes bipartisan opportunity can be achieved. He asked for elaboration on capping OOP costs for beneficiaries in part D. **Dr. Gupta** said that capping OOPS costs is necessary to ensure access to healthcare. **Representative Long** asked how H.R. 3 may impact the biotech job sector and if these jobs may move overseas if H.R. 3 is enacted. **Dr. Gupta** said most of the workers are highly mobile, and if H.R. 3 and price controls are set in, there may be impacts on the job sector across the country. **Representative Long** asked about China's strategy if H.R. 3 becomes law. **Dr. Gupta** said the only way china will ever catch up is if we do it to ourselves. He commented that they would lean in trying to catch up to syphon as much of the talent as they can in a defined way. **Representative Long** asked if H.R. 3 becomes law, would it immediately change the biotech industry. **Dr. Gupta** said we have a tremendous advantage and it would not be an immediate change.

Representative Cárdenas (D-CA) aid that lowering prescription drug costs is a priority. The current economic reality has made it worse and the prices are unjust, resulting in matter of life or death. He said it is important to ensure research and development of new drugs to ensure higher quality of life. He asked how it felt like to know about rationing of care from patients due to prices. **Ms. Ball** said that not only did she have difficulties

mentally and physically, but everyone is past the point of what they can do for their disease. She said that they must look at this from getting the bill passed to save the people of the US. **Representative Cárdenas** said biosimilars play a role in lowering drug costs and has introduced a bill to prescribe biosmilars to improve patient access. He asked about thoughts on biosimilars to improve affordability of drugs. **Ms. Sachs** said that biosimilar are a key part of the social bargain, and at some point competition will improve affordability. The US has yet to realize the full promise of biosimilars and it is important to consider bills to increase biosimilar competition.

Representative Mullin (R-OK) said that he has concerns on H.R. 3 because it is government takeover of drugs. Drug companies are entrepreneurs and governments affect what they do and what they are willing to invest in. He said they should be looking at what is impacting consolidation of pharma companies. He asked if innovation is the best way to control pricing. **Dr. Gupta** said that yes, and there are a couple aspects of that. These drugs keep people out of the hospital and improves overall healthcare costs. When these drugs go generic, society saves billions of dollars a year. **Representative Mullin** asked if modernizing drugs will control prices better. **Dr. Gupta** said yes, it would also stimulate biopharma companies to develop new drugs.

Representative Ruiz (D-CA) said that it is important to recognize why they are having this debate in the first place, which is to ensure patient access to healthcare and drugs. The average American can usually not afford their coverage even if they have healthcare or Medicare. Individuals and their doctors should choose drugs based on the effectiveness, not based on cost. Healthcare is a right for everyone and access to medications is not a privilege. He inquired if negotiating drugs would be the most effective way to deliver the largest about of savings and if H.R. 3 allows the most bang for our buck. **Ms. Sachs** said that yes that seems to be the case for H.R. 3. She said that phasing in the program to deliver the most savings makes the most sense. **Representative Ruiz** said that savings can be achieved and asked what impacts this would have on OOP costs. **Ms. Sachs** said that if patients are more easily get their dugs, they will more likely to take the drugs and lower overall healthcare costs.

Representative Carter (R-TX) stated that as a pharmacist for over 30 years, the problem is the vertical integration of insurance companies and PBMs. Three PBMs are owned by insurance companies. Prescription drug prices are only a small percentage of costs. Three PBMs cover 70% of the market. Rep. Carter stated that this needs to be broken up.

Representative Dingell (D-MI) asked how H.R. 3 would incentivize innovation. **Mr. Carrier** and **Ms. Sachs** state that the drugs that would be subject to negotiation are in need of competition and represent the highest spend drugs on the market.

Representative Dunn (R-FL) stated Americans have access to more cures than European counterparts. Americans should have access and lower prices. H.R. 19 represents bipartisan reforms that target transparency. COVID vaccines show a

case study where investment from the private sector assists with innovation. **Dr. Gupta** stated that innovation will be impacted from H.R. 3 for the negative.

Representative Kuster (D-NH) stated prices are unsustainable and H.R. 3 would include billions of dollars of savings. **Rep. Kuster** said that automatic coverage of lower cost generic drugs could be a significant help. **Ms. Sachs** stated that giving generic prices would be helpful. She stated that CBO can generate savings estimates in support of this.

Representative Curtis (R-UT) said that biotech companies are developing cures for cancer and COVID. H.R. 3 would result in the loss of 20,000 jobs. He asked witness to comment. **Dr. Gupta** said that the overall cost to small businesses and biotech employees would be significantly high.

Representative Barragan (D-CA) stated that allowing the market to do its work is not working. Communities of color have high rates of risk factors. **Ms. Sachs** stated that high prices exacerbate health disparities.

Representative Joyce (R-OH) stated that the availabilities of cancer treatments have saved lives, particularly within oncology. H.R. 3 would cause the loss of access to innovative treatments. **Dr. Gupta** stated that this is exactly right and the other systems within other nations block innovation. Rep. Joyce asked whether this would limit access to life saving therapies. **Dr. Gupta** stated that this is a potential possibility.

Representative Fletcher (D-TX) said the current system is not sustainable. She stated that the cost has gone up substantially for witness present. **Ms. Ball** stated that the increasing price represented a price increase for no innovation. **Rep. Fletcher** stated that the inflationary rebate would assist with the access issue for drugs. **Ms. Sachs** stated the cost of drugs would be significantly improved by H.R. 3.

Representative Crenshaw (R-TX) said that there are many concerns regarding innovation. He asked whether it is fair to call H.R. 3 negotiation. **Ms. Sachs** stated it is a fair characterization. **Rep. Crenshaw** stated that this can be called price setting.

Representative Rush (D-IL) asked whether there has been an example where pay for delay has hurt American consumers. **Mr. Carrier** stated that pay for delay prevents generic competitors from entering the market, delaying access to the drug for years.

Representative DeGette (D-CO) stated that diabetes drugs are the clearest textbook example of what has happened in America. Prices have increased over 700% while the drug has remained the same. **Ms. Ball** stated that an out of pocket cap would make drugs much easier to pay for. **Rep. DeGette** stated that H.R. 3 would address this issue and urged Members to pursue a true solution to the critical issue rather than a band aid fix.

Representative Soto (D-FL) said that Medicaid is able to negotiate prices, and Medicare should be able to as well. He stated opposition to scare tactics employed today. He stated

that in a country where patients must ration their drugs, policy has to move forward. **Mr. Carrier** stated that current standards deem citizen petitions difficult to stop. The FDA has to prove primary purpose is to delay generic entry and the raise a clear valid issue. The FDA has never used this power to curb petitions.

Representative Schrier (D-WA) stated that though the immediate need of the last year was addressing the pandemic, the issue of drug pricing has not gone away. Insulin is a poster child for price gouging. **Ms. Sachs** stated that though many drug prices are overpriced, there are specific drugs and drug therapies that are potentially under rewarded. These therapies include oncology treatments that extend quality of life. **Rep. Schrier** stated that comparative analyses should be incorporated into drug evaluation.