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MARKUP OF H.R. 965, THE CREATES ACT;

H.R. 2375, THE PRESERVE ACCESS TO AFFORDABLE GENERICS AND BIOSIMILARS ACT;

H.R. 2374, THE STOP SIGNIFICANT AND TIME-WASTING ABUSE LIMITING LEGITIMATE INNOVATION OF NEW GENERICS ACT; AND

H.R. 2376, THE PRESCRIPTION PRICING FOR PEOPLE ACT OF 2019.

Tuesday, April 30, 2019

House of Representatives

Committee on the Judiciary

Washington, D.C.

The committee met, pursuant to call, at 2:22 p.m., in Room 2141, Rayburn Office Building, Hon. Jerrold Nadler [chairman of the committee] presiding.

Present: Representatives Nadler, Lofgren, Jackson Lee, Cohen, Jeffries, Cicilline, Lieu, Raskin, Demings, Correa, Scanlon, Garcia, Neguse, Stanton, Dean, Murcarsel-Powell, Collins, Sensenbrenner, Chabot, Gohmert, Jordan, Buck, Roby,

Johnson of Louisiana, Biggs, McClintock, Reschenthaler, Cline, Armstrong, and Steube.

Staff present: David Greengrass, Senior Counsel; Senior Advisor; Lisette Morton, Director of Policy, Planning, and Member Services; Madeline Strasser, Chief Clerk; Moh Sharma, Member Services and Outreach Advisor; Susan Jensen, Parliamentarian/Senior Counsel; Amanda Lewis, ACAL Counsel; Joseph Van Wye, Professional Staff Member, ACAL; Lina Khan, Counsel, ACAL Subcommittee; Slade Bond, Chief Counsel, ACAL; Brendan Belair, Minority Chief of Staff; Robert Parmiter, Minority Deputy Chief of Staff; Jon Ferro, Minority Parliamentarian; Tom Stoll, Minority Chief Counsel, Intellectual Property Subcommittee; Daniel Flores, Minority Chief Counsel, Antitrust Subcommittee; Erica Barker, Minority Chief Clerk; and Andrea Woodard, Minority Professional Staff Member.

Chairman Nadler. The Judiciary Committee will please come to order, a quorum being present. Without objection, the chair is authorized to declare a recess at any time.

Pursuant to Committee Rule II and House Rule XI, Clause 2, the chair may postpone further proceedings today on the question of approving any measure or matter or adopting any amendment for which a recorded vote for the yeas and nays are ordered.

Pursuant to notice, I now call up H.R. 2375, the Preserve Access to Affordable Generics and Biosimilars Act, for purposes of markup and move that the committee report the bill favorably to the House.

The clerk will report the bill.

Ms. Strasser. H.R. 2375, to prohibit prescription drug companies from compensating other prescription drug companies to delay the entry of a generic drug, biosimilar, biological product, or interchangeable biological product into the market.

Chairman Nadler. Without objection, the bill is considered as read and open for amendment at any point.

[The bill follows:]

Chairman Nadler. I will begin by recognizing myself for an opening statement.

H.R. 2375, the Preserve Access to Affordable Generics and Biosimilars Act, is one of a series of bipartisan measures that we are considering today to address the critical need to lower the soaring costs of prescription drugs, which is jeopardizing the health and wellbeing of millions of Americans. Too many Americans simply cannot afford lifesaving medicines. Others find their budgets strained to the limit because of the high cost of prescription drugs. Some patients delay essential care, cut their pills in half, or skip drug treatment all together, all because of unaffordable drug prices, and their health suffers as a result.

Several of the bills we are considering today address in different ways one of the leading drivers of high prescription drug costs, efforts by branded drug companies to preserve their monopolies by preventing or delaying competition from lower-priced generic and biosimilar drugs. The Preserve Access to Affordable Generics and Biosimilars Act prohibits one of these outrageous delay tactics, so-called pay-for-delay settlement agreements. These agreements occur when a generic drug maker seeks to enter the market and compete with a brand-name drug product. If the drug patent has not yet expired, patent litigation ensues, and the

branded drug firm may seek a settlement agreement as a vehicle to pay the potential generic competitor to delay entering the market with a lower-cost generic product. These agreements result in a financial windfall for both drug companies. The brand-name drug company gets to keep its monopoly, and the generic gets paid off with a portion of the monopoly profits, but consumers inevitably lose.

According to a Federal Trade Commission study, pay-for-delay agreements are estimated to cost American consumers $3-and-a-half billion per year, $35 billion over the decade from 2010 to 2020. And despite a clear holding by the Supreme Court in the *Actavis* case nearly 6 years ago that such agreements may be significantly anticompetitive and illegal under the antitrust laws -- I almost feel like saying "you think" -- they still persist today.

In 2015 alone, there were 14 settlements between branded and generic drug companies that contained potential pay-for-delay provisions, covering 11 branded drugs totaling $4.6 billion in sales. And the FTC continues to investigate and challenge potential pay-for-delay agreements that keep affordable generic drugs off the market. That is why these anticompetitive practices must be prohibited all together.

The significance of generic competition on drug prices cannot be overstated. According to the FTC, the first generic competitor's product is typically offered at a 20 to

30 percent discount from the branded product's price. Subsequent generic entry creates massive price discounts with additional competition reducing the cost of prescription drugs by as much as 85 percent or more off the branded price.

To help ensure that these generic alternatives can enter the market, this bill would establish that certain pay-for-delay agreements are presumptively anticompetitive, and would authorize the FTC to initiate an enforcement proceeding against parties to such an agreement involving the sale of a drug or biological product. Importantly, the Preserve Access to Generics and Biosimilars Act also includes safe harbors that preserve the incentives of generic and biosimilar competitors to challenge weak patents and enter the market as early as possible.

This legislation builds on the committee's strong tradition of bipartisan work to lower the cost of prescription drugs through the full benefits of competition. This committee has been and will continue to be active in stopping drug companies from reaping monopoly profits at the expense of the health of American consumers.

I am proud of this work to provide meaningful relief to Americans who struggle every day with the high cost of prescription medicine along with other outrageous healthcare costs. I thank Ranking Member Collins for his leadership on this issue, and I urge my colleagues to support this

legislation. And speaking of Ranking Member Collins, I now recognize the ranking member of the Judiciary Committee, the gentleman from Georgia, Mr. Collins, for his opening statement.

Mr. Collins. Thank you, Mr. Chairman, and I will be brief on this. But thank you for your leadership and introducing the Preserve Access to Affordable Generics and Biosimilars Act, and I am proud to be the lead co-sponsor on the Republican side for this important bill.

Years ago when the Congress passed the Hatch-Waxman Act, the hope was that it would dramatically help speed the introduction of low-cost generic alternatives to high-cost brand-name prescription drugs. At the same time, it was also hoped that the legislation had struck the right balance to preserve healthy incentives for the innovation of new drugs branded by manufacturers. To a degree these hopes have been realized, but unfortunately too often those hopes have been stymied by the use of pay-for-delay settlements.

In these often anticompetitive settlements, the generic manufacturer has filed for FDA approval to produce a generic alternative. The branded manufacturer raises patent litigation in response, and the pay-for-delay settlement buys the peace. The generic manufacturer agrees to delay for a certain time, and the branded manufacturer agrees to pay the generic manufacturer for that delay.

There is just one catch. While the situation looks rosy for the two manufacturers, consumers who would benefit from the lower cost of a new generic drug get stuck still paying the high cost of the branded drug. That is true even if the threatened patent litigation is not justified. However long the delay endures, higher costs prevail. That is not right, and it is part of the reason that American consumers still pay too much for prescription drugs.

The Preserve Access to Affordable Generics and Biosimilars Act would solve this problem and accelerate the lowering of prescription drug prices in America. It doesn't prevent litigants from entering into bona fide pro-competitive settlements that would help consumers, but it does prevent the anticompetitive settlements that just line drug company's pockets while consumers pay the bill, and I would urge my colleagues to support this bill. Mr. Chairman, I yield back.

Chairman Nadler. Thank you, Mr. Collins. I now recognize the chair of the Subcommittee on Antitrust, Commercial, and Administrative Law, the gentleman from Rhode Island, Mr. Cicilline, for his opening statement.

Mr. Cicilline. Thank you, Mr. Chairman, and thank you for holding today's important markup of bold legislation to address the skyrocketing costs of prescription drugs.

The average American spends roughly $1,200 on

prescription drugs every year, more than people in any other country. And over the past decade, prescription drug costs have grown by 200 percent, resulting in higher insurance premiums, larger hospital bills, and billions of taxpayer dollars ending up in the pockets of giant prescription drug companies, drug companies that are able to extract monopoly profits for off-patent drugs at the expense of American patients. That is hard-earned taxpayer dollars that could go to fixing our Nation's crumbling infrastructure, making higher education more affordable, and improving access to healthcare.

H.R. 2375, the Preserve Access to Affordable Generics and Biosimilars Act, would prohibit anticompetitive settlements, also called pay-for-delay agreements, that block access to affordable prescription drugs. These settlements literally involve a high-cost branded drug company paying off a generic competitor to stay out of the market. In response to this problem, the Preserve Access to Affordable Generics and Biosimilars Act would establish that these agreements are presumptively illegal under the antitrust laws, and authorize the Federal Trade Commission to impose significant penalties on companies that engage in these pay-for-delay schemes.

Mr. Michael Kades of the Washington Center for Equitable Growth, an antitrust attorney with over 2 decades of experience in pay-for-delay litigation at the FTC, testified

before the Antitrust Subcommittee in March that this practice is still a problem today. As he noted, and I quote, "Despite the U.S. Supreme Court's clear signal in the *Actavis* case that pay-for-delay can be anticompetitive, the FTC continues to spend substantial resources and time challenging clear violations. Tougher laws, such as the Preserve Access to Affordable Generics Act, would deter such conduct and free up limited resources to attack other anticompetitive conduct."

According to the Congressional Budget Office, ending pay-for-delay agreements will save the government hundreds of millions of dollars in Medicare savings. Moreover, by lowering the FTC's burden to prove the obvious point of paying a competitor not to compete as anticompetitive, this legislation would free up FTC resources, resources that can be put to work for American patients in other healthcare markets.

I thank the chairman for his introduction of this great piece of legislation. I strongly support it and urge my colleagues to do the same. And with that, I yield back.

Chairman Nadler. Thank you. I now recognize the ranking member of the Antitrust Subcommittee, the gentleman from Wisconsin, Mr. Sensenbrenner, for his opening statement.

Mr. Sensenbrenner. Well, I thank the gentleman, and I want to commend both the chairman and the ranking member, Mr. Collins, for introducing this legislation. They have fully

described why it is necessary. I support it, and yield back the balance of my time.

Chairman Nadler. Wow.

[Laughter.]

Chairman Nadler. Thank you, Mr. Sensenbrenner. Without objection, all other opening statements will be included in the record. Are there any amendments to H.R. 2375? The gentleman from Pennsylvania, Mr. Reschenthaler.

Mr. Reschenthaler. Mr. Chairman, I move to strike the last word.

Chairman Nadler. The gentleman is recognized.

Mr. Reschenthaler. Thank you, Mr. Chairman. I applaud the bipartisan work the committee is undertaking today to the lower the cost of prescription drugs. Like the chairman and the ranking member, I believe that pay-for-delay agreements should be strictly prohibited, and I thank them for addressing this important issue. I do, however, have some concerns with this bill, and while I am not offering an amendment as I had originally planned to do today, I hope that we can work together on the issue moving forward.

My concern is with the provision in the underlying bill that treats certain patent settlements as presumptively anticompetitive. The burden is on the generic or the biosimilar developer to prove their agreement is above board and complies with the law. We know that in many instances,

patent settlements actually speed up market entry of generics and biosimilars. They protect generic manufacturers from unpredictable and costly litigation. In fact, studies have shown that the ability to settle patent litigation is a key factor in determining investment decisions about bringing medicines to market.

Additionally, since the Supreme Court's 2013 decision in *FTC v. Actavis*, the total number of patent settlements has increased while the number of potential anticompetitive settlement agreements has, in fact, decreased. For example, in Fiscal Year 2016, the FTC flagged just one settlement as anticompetitive. This shows the success of the *Actavis* decision in the FTC's effort to combat anticompetitive deals.

Again, I support the chairman and the ranking member's efforts on this bill, and I wholeheartedly agree that we must prevent pay-for-delay settlements. I do, however, feel that if the government alleges anticompetitive conduct, they have to be the ones to prove it. The government should carry that burden. And I remain concerned that while well intentioned, the bill as it is currently drafted may make it harder to bring generics and biosimilars to market.

So, again, I thank the chairman and the ranking member for introducing this legislation, which I do plan to support. I just ask that we continue this important conversation as we prepare this bill for floor consideration. I now would yield

the remainder of my time to Ranking Member Collins.

Mr. Collins. Thank you, and I thank my friend from Pennsylvania for his comments. And they are well founded, and I think they raise a legitimate point. The bill is strongly-needed medicine to prevent anticompetitive pay-for-delay settlements, and I support it. But at the same time, I acknowledge that the standard of proof drug manufacturers must meet under the bill to show that their settlements are pro-competitive, not anticompetitive, is high.

I share the gentleman's concern that this aspect of the bill may need some more work so that we strike the right balance. I would be happy to work with the gentleman on this issue as the legislative process continues, and it is my hope that we will be able to reach a complete consensus on where to draw the line on the burden of that proof. With that, I yield back.

Chairman Nadler. Thank you. I recognize myself. I thank the gentleman from Pennsylvania, and I understand your concerns. And I agree that patent settlements can be helpful to ensuring timely market entry of affordable generic and biosimilar medicines. That is why we worked extensively with stakeholders and the Federal Trade Commission to address these concerns through the inclusion of safe harbors in H.R. 2375 that are tailored for certain pro-competitive settlement provisions, such as an acceleration clause to allow for early

entry by generic drug companies.

These safe harbors are tailored to encourage, rather than discourage, settlement provisions that facilitate early generic entry and the associated cost savings for taxpayers from generic competition. Additionally, H.R. 2375 is narrowly drafted only to target anticompetitive settlements where branded drug companies literally paying or transferring value to a low-cost generic drug company to stay off the market. And even in those instances, the companies can overcome the bill's presumption that this behavior is illegal by showing that the pre-competitive effects of the settlement clearly and convincingly outweigh its anticompetitive effects.

Nonetheless, I look forward to continuing our bipartisan work to improve the bill, and I will commit to working with the gentleman and with the ranking member to try and address the concerns expressed by the gentleman before the bill gets to the House floor. Are there any other -- the gentleman California, Mr. Correa.

Mr. Correa. Thank you, Mr. Chairman. I move to strike the last word.

Chairman Nadler. The gentleman is recognized.

Mr. Correa. Chairman Nadler and Ranking Member Collins, thank you very much for holding this most important markup. I fully support this legislation. Medical device and

pharmaceutical companies are very important to my district in Orange County. Many of my constituents have found good-paying, rewarding jobs that have opened the pathway for the middle class for them and their families.

These companies have created miracle drugs that have revolutionized cancer treatment and have invented lifesaving medical devices, such as heart valves. The work done in California is the envy of the world. This research has extended lives and created better lives for many people. Yet all of this research is worth nothing if it is only the wealthy that have access and only the wealthy that can afford it. We must ensure that everyone has access and can afford these miracle cures. We as policymakers must achieve that balance, namely meaningful access to miracle cures, while assuring investment in tomorrow's cures. I yield the remainder of my time.

Chairman Nadler. I thank the gentleman. Does anyone else seek recognition?

[No response.]

Chairman Nadler. If not, a reporting quorum being present, the question is on the motion to report the bill, H.R. 2375, favorably to the House.

Those in favor, say aye.

Opposed?

The ayes have it, and the bill is ordered reported

favorably to the House.

Members will have 2 days to submit views.

Pursuant to notice, I now call up H.R. 965, the CREATES Act, for purposes of markup and move that the committee report the bill favorably to the House.

The clerk will report the bill.

Ms. Strasser. H.R. 965, to promote competition in the market for drugs and biological products by facilitating the timely entry of lower-cost generic and biosimilar versions of those drugs and biological products.

Chairman Nadler. Without objection, the bill is considered as read and open for amendment at any point.

[The bill follows:]

Chairman Nadler. I will begin by recognizing myself for an opening statement.

H.R. 965, the Creating and Restoring Equal Access to Equivalent Samples Act of 2019, or the CREATES Act, is bipartisan legislation that would substantially lower drug prices by making it easier for generic pharmaceutical companies to obtain drug samples from branded companies, samples which they require in order to perform testing necessary to enter the market.

One of the anticompetitive tactics that many branded drug companies employ to keep lower-cost generics off the shelf is to refuse to provide samples of their drugs to generic and biosimilar competitors. The branded companies argue that FDA-imposed safety measures prevent them from giving samples to generic companies, claiming that the generics cannot follow the required safety protocols. But in many cases this appears to be nothing more than gamesmanship designed to prolong the branded companies' monopoly power.

The plainly-anticompetitive behavior perpetuates the branded company's monopoly over the drug, enabling it to charge excessive prices. These higher prices cost patients and taxpayers billions of dollars in unnecessary spending, and, perhaps most importantly, they lead some patients who cannot afford such high prices to forego the use of prescription drugs all together, placing their health in

greater jeopardy.

The CREATES Act ends this abusive delay tactic by providing generic and biosimilar competitors with tailored relief to obtain samples necessary to enter the market. Furthermore, in cases where the brand-name drug company has no legitimate business justification for withholding samples from a generic competitor, the bill also includes a civil penalty.

The Subcommittee on Antitrust, Commercial, and Administrative Law held a hearing in March on competition in the healthcare marketplace. During this hearing, several bipartisan witnesses testified in strong support for the CREATES Act, noting that it would significantly reduce drug prices and create competition where there is none today. For example, minority witness, Dr. Craig Garthwaite of Northwestern University, testified that the CREATES Act is "an attractive piece of legislation that should be passed at the earliest opportunity." Michael Kades, a leading antitrust practitioner with the Washington Center for Equitable Growth, similarly testified that the CREATES Act "would stop both sample blockades and safety protocol filibusters, which delay competition with no countervailing benefit."

This legislation would preserve important safety measures while ensuring that lower-price generic competition

that benefits consumers is not unreasonably delayed from entering the market. Accordingly, I thank the gentleman from Rhode Island, Subcommittee Chairman Cicilline, and the gentleman from Wisconsin, Subcommittee Ranking Member Sensenbrenner, for their leadership on this critical issue, and I urge my colleagues to support this important bipartisan legislation.

I now recognize the ranking member of the Judiciary Committee, the gentleman from Georgia, Mr. Collins, for his opening Statement.

Mr. Collins. Thank you, Mr. Chairman. I would like to thank Subcommittee Chairman Cicilline and the ranking member of the subcommittee, Mr. Sensenbrenner, for introducing this important bill.

Competition from generic and biosimilar prescription drugs is one of the key ways to obtain lower prescription drug prices, but if before generic or biosimilar can enter the market its manufacturer has to gain FDA approval to do that, the manufacturer has to obtain samples from the branded drug with which it intends to compete so it can perform tests to show FDA that its product also should be allowed to gain entry into the market. And therein lies the rub. If the branded manufacturer denies the provision of samples, it can delay the competitors' approval and prop up its own high drug cost.

This should not be happening. Our laws are written to allow generic and biosimilars to compete and lower drug prices for the benefit of consumers. True, they also are written to protect the legitimate rights of innovative branded manufacturers, but that does not include rights to game the system to keep the competition wrongfully out or consumer drug prices artificially high.

The CREATES Act will prevent this kind of gaming and make sure that the generic and the biosimilar manufacturers can gain samples to complete testing and win FDA approval. It does so in a very simple and straightforward way. It allows generic and biosimilars manufacturers to bring antitrust suits against branded manufacturers who wrongfully hold up their samples.

In these suits, courts can order branded manufacturers to provide the samples. If justified, the Court can also award the generic and biosimilar manufacturers damages based on the revenues that branded manufacturers reap while wrongfully withholding samples. These are the consequences that should make clear to the branded manufacturers from the get-go that there is no benefit to be had from trying to game the system or denying samples. As a result, this legislation should bring this anticompetitive behavior to a grinding halt.

The CBO has estimated that the CREATES Act will save the

Federal government $3.9 billion in prescription spending. It should lower prescription drug costs even more when non-government spending is taken into account. This is strong relief for Americans suffering from the burden of excessively-high prescription drug costs. I'm a co-sponsor of this legislation and would urge all of my colleagues to support the bill, and I will yield back the remainder of my time.

Chairman Nadler. I thank the gentleman. I now recognize the chair of the Subcommittee on Antitrust, Commercial, and Administrative Law and the chief sponsor of this bill, the gentleman from Rhode Island, Mr. Cicilline, for his opening statement.

Mr. Cicilline. Thank you, Mr. Chairman. Across the country, the outrageous cost of prescription drugs are destroying lives. According to Kaiser Health, a quarter of Americans cannot afford their medicine while many cancer patients are delaying care, cutting their pills in half, or skipping drug treatment entirely as an example.

It is a dark reality that for far too many Americans, the life of a loved depends on whether they can raise enough money on a crowd-funding platform to pay for treatment before time runs out. Faced with no other option, Americans are left to beg strangers for help to keep their loved ones alive. Prices are skyrocketing, and people are dying or

going bankrupt because they can't afford their prescription medicines. And despite decades of rising costs, the United States ranks dead last in health outcomes among similarly-developed countries.

Ending this crisis is a top priority of mine as chairman of the Antitrust Subcommittee and a top priority for House Democrats to keep our promise to work for the people by taking on drug profiteering and other barriers to affordable healthcare. H.R. 965, the CREATES Act, would lower the costs of prescription drugs by billions of dollars by putting a stop to abusive delay tactics that prevent generic competitors from offering lower-cost alternatives to costly brand-name drugs.

The Federal Trade Commission reports that generic drugs can reduce the price of branded drugs by more than 85 percent. Even the presence of just one generic competitor can decrease prescription drug prices by 20 to 30 percent. But over the past decade, some branded drug companies have abused safety protocols of the Food and Drug Administration in order to keep prices high and affordable drugs out of reach for hardworking Americans.

Congress never intended these safety programs, called risk evaluation mitigation strategies, to allow a branded drug company to block or delay generic competitors from getting FDA approval to enter the market. And yet some drug

companies have exploited the FDA safety protocols to delay generic competition, if only by days and months, to prolong their ability to charge monopoly prices. For some Americans, days or months could mean life or death. To these companies, months of delay could be worth hundreds of millions of dollars in additional monopoly revenues as the generic sits on the sidelines as patent law expert, Professor Robin Feldman, has noted.

Although this abusive behavior often violates antitrust law, as the FTC testified last Congress, fighting this conduct in court often takes too long to provide effective relief for the American people. The CREATES Act is a powerful solution to this abusive conduct by pharmaceutical companies. The bill will stop these delays by creating a tailored path for generic drug manufacturers to obtain the samples they need to bring low-cost drugs to market. By lowering the cost of prescription drugs, the CREATES Act would save American taxpayers $3.8 billion over 10 years through savings through Medicare and Medicaid, according to the nonpartisan Congressional Budget Office. Furthermore, private estimates found that the bill would save American consumers an additional $5.4 billion.

This bipartisan, bicameral legislation is supported by a broad group of U.S. senators, including Senators Patrick Leahy, Chuck Grassley, Amy Klobuchar, and Mike Lee. It is

also backed by a diverse coalition of healthcare providers, patient groups, and public interest organizations across the political spectrum, including AARP, Freedom Works, and Public Citizen, among more than 90 others.

I want to particularly thank Ranking Member Sensenbrenner for his support and co-sponsorship and leadership on this legislation, and thank the members of the committee and ask that you support this legislation as well. And with that, I yield back.

Chairman Nadler. Thank you, Mr. Cicilline. I now recognize the ranking member of the Antitrust Subcommittee, the gentleman from Wisconsin, Mr. Sensenbrenner, for his opening statement.

Mr. Sensenbrenner. Thank you, Mr. Chairman. Let me begin by saying that the desire to lower prescription drug prices is not the exclusive prerogative of one of our great political parties. It is a Republican priority, and that is, I think, one of the reasons by being bipartisan we are going to have a much better chance of seeing this go all the way into law. And I certainly am thankful to both the chairman and the ranking member of the full committee and Chairman Cicilline for their efforts in this matter. I think we are all on board with this, and I think that this is an example where we can go back and tell our constituents we are actually doing something good for them. Sometimes they do

have their doubts about that.

According to the Centers for Medicare and Medicaid Services, Americans' spending on healthcare now accounts for 17.8 percent of the U.S. GDP. That is over $3.6 trillion, or over $10,000 a person. These astronomical costs are the result of many factors. Front and center among them are obstacles to patients' access to low-cost generic drugs. Subcommittee Chair Cicilline and I addressed this problem head on during the first weeks of this Congress by reintroducing the CREATES Act.

This strong bipartisan legislation will deter branded pharmaceutical companies from manipulating test sample availability to block cheaper generic alternatives from obtaining FDA approval and entering the marketplace. The CREATES Act will lead to lower costs for patients by ensuring that they have faster access to safe and effective FDA-approved generic drugs.

The Congressional Budget Office has estimated that our bill would produce a multibillionaire decrease in the Federal deficit. Savings to consumers and private insurers will likely be much greater. I urge all my colleagues to support the bill and yield back the balance of my time.

Chairman Nadler. Thank you, Mr. Sensenbrenner. Without objection, all other opening statements will be included in the record.

Are there any other amendments to H.R. 965?

[No response.]

Chairman Nadler. In that case, a reporting quorum being present, the question is on the motion to report the bill, H.R. 965, favorably to the House.

Those in favor, say aye?

Opposed, no?

The ayes have it, and the bill is ordered reported favorably to the House. Members will have 2 days to submit views.

Pursuant to notice, I now call up H.R. 2374, the Stop Stalling Act, for purposes of markup and move that the committee report the bill favorably to the House.

The clerk will report the bill.

Ms. Strasser. H.R. 2374, to enable the Federal Trade Commission to deter filing of sham citizen petitions to cover an attempt to interfere with approval of a competing generic drug or biosimilar, to foster competition, and facilitate the efficient review of petitions filed in good faith to raise legitimate public health concerns, and for other purposes.

Chairman Nadler. Without objection, the bill is considered as read and open for amendment at any point.

[The bill follows:]

Chairman Nadler. I will begin by recognizing myself for an opening statement.

H.R. 2374, the Stop Stalling Act, takes an important step toward lowering drug prices and increasing competition in healthcare markets. It does this by addressing sham citizen petitions, a delay tactic that some brand-name companies use to keep low-cost generic competitors off the market. Sham petitions result in higher drug prices, potentially causing higher mortality among those who can least afford such higher costs.

The citizen petition process provides an avenue for the public to raise legitimate scientific and health concerns about drugs under review by the Food and Drug Administration. But instead of serving this important function, this process has often been misused by brand-name drug manufacturers to stifle competition from generics and biosimilars. These companies flood the FDA with sham petitions, lacking any scientific or health-related basis, in order to bog the agency down in paperwork and grind the approval process to a halt.

In one case, Shire ViroPharma, a major biopharmaceutical company, abused the citizen petition process in order to maintain a monopoly over Vancocin capsules, a drug used to treat potentially life-threatening gastrointestinal infections. For 6 years, ViroPharma inundated the FDA with

sham petitions to delay it from approving generic competitors to Vancocin. According to the Federal Trade Commission's antitrust complaint, ViroPharma's serial sham petitions "lacked any supporting clinical data," yet they succeeded in delaying generic entry at a cost of hundreds of millions of dollars to patients and other purchasers.

Another appalling example of the use of sham petitions -- I don't know what they are doing. Another appalling example of the use of sham petitions to extend monopolies resulted in dramatically increasing the cost of combatting opioid abuse, a serious nationwide public health crisis. In 2016, together with the attorneys general of 34 other States, the New York attorney general filed a lawsuit against Indivior alleging that the drug manufacturer engaged in citizen petition abuse and other anticompetitive business practices to maintain its monopoly over Suboxone, a treatment for patients who are addicted to prescription painkillers, heroin and other drugs.

According to the complaint, Indivior filed a series of sham petitions to prevent the generic competitor from entering the market with the same Suboxone tablets that it sold in the market for nearly 10 years at a profit of over $2 billion. By the time the FDA rejected the sham citizen petitions, Indivior had pulled the Suboxone tablet version from the market and converted the market to its newly-

patented Suboxone film. By abusing the citizen petition process, Indivior reaped monopoly profits from the sale of Suboxone film, and it deprived victims of opioid addiction and medical practitioners the benefits of generic competition.

The Stop Stalling Act will put an end to these abusive and anticompetitive practices. The bill provides the submission of a sham petition to prevent the delayed entry of a generic or biosimilar competitor is presumptively illegal under the antitrust laws. It also gives the FTC authority to seek a civil penalty and other appropriate relief in response to the filing of sham petitions by drug manufacturers. Importantly, this measure applies only to petitions that are used for anticompetitive purposes as a cover for an attempt to interfere with the approval of a competing drug. In doing so, the Stop Stalling Act carefully adheres to existing case law and constitutional principles.

This legislation strikes a reasonable balance that will help lower the cost of prescription drug prices by preventing unnecessary delays and the approval of lower-cost generic competitors while preserving the public's right to petition the government. I thank my colleagues, Congressman Jeffries and Subcommittee Ranking Member Sensenbrenner, for their leadership on this important legislation, and I urge my colleagues to support this potentially lifesaving measure.

I now recognize the ranking member of the Judiciary Committee, the gentleman from Georgia, Mr. Collins, for his opening statement.

Mr. Collins. Thank you, Mr. Chairman. I want to thank also Mr. Jeffries and Mr. Sensenbrenner for their bipartisan work on this legislation.

When used appropriately, citizen petitions filed with the FDA allow all Americans to raise legitimate health and safety concerns about prescription drugs proposed for FDA approval. But for too long, drug manufacturers have been allowed to game the system by submitting numerous or baseless, bogus petitions simply so the FDA would delay competing manufacturers' approvals. As long as the FDA is tied up in reviewing petitions, the original manufacturer is shielded from competition, and consumer drug prices stay high.

Recently, the Third Circuit's decision in *FTC v. Shire ViroPharma* made it harder for the FTC to use antitrust enforcement to stop this anticompetitive behavior. The Stop Stalling Act is sound bipartisan legislation to make sure that the FTC has effective authority to act against sham petitions, while preserving the rights of citizens to bring legitimate health and safety concerns to the FDA. It should stop in their tracks drug manufacturers who seek only to file baseless petitions to keep competitors off the market and

prevent consumers from accessing lower-cost alternative medications.

I am an original co-sponsor to this bill and would encourage all my colleagues to support it as well. With that, I yield back.

Chairman Nadler. I thank the gentleman. I now recognize the chair of the Subcommittee on Antitrust, Commercial, and Administrative Law, the gentleman from Rhode Island, Mr. Cicilline, for his opening statement.

Mr. Cicilline. Thank you, Mr. Chairman. I want to urge my colleagues to support H.R. 2374, the Stop Stalling Act, and I want to thank the lead sponsor, Congressman Jeffries, for this excellent bill. And I would like to yield the balance of my time to him so he can explain it to the committee.

Mr. Jeffries. I thank my good friend for yielding. I also want to thank Chairman Nadler, Ranking Member Collins, my good friend, Chairman Cicilline, as well as Ranking Member Sensenbrenner, the lead Republican on this issue, for their partnership in tackling the soaring cost of lifesaving prescription drugs.

Today we are offering another bipartisan solution, the Stop Stalling Act, to crack down on abusive behavior in the pharmaceutical industry as we endeavor to make prescription drugs more affordable for everyday Americans. Prescription

drug costs in the United States are skyrocketing. Four of the top 10 prescription drugs in the U.S. have increased in price by more than 100 percent since 2011.

Studies have shown that increased competition in the pharmaceutical arena, rather than monopoly-like behavior, lowers prescription drug costs. The entry of generic drugs into the market to compete with brand-name drugs can dramatically reduce prices for the American people. It is a simple economic principle that is as American as apple pie. Competition lowers prices.

In fact, the U.S. Food and Drug Administration said, "Generic medicines have the same therapeutic effect as their branded counterparts, but are typically sold for an estimated 80 to 85 percent less compared with the price of brand-name medicine." In order to artificially inflate the cost of prescription drugs, some companies are blocking generic competition into the market. In this regard, stalling tactics are sometimes used to delay the launch of generic products that can compete with brand-name drugs.

One of these tactics is the filing of sham petitions with the FDA. Citizen petitions were never designed as an avenue for branded companies to artificially inflate drug costs by stalling the entry of generic brands into the market. Congress designed the citizen petition process to let ordinary Americans raise legitimate public health

concerns with drugs under review by the FDA. Brand-name drug companies have hijacked this process and started flooding the FDA with fake, meritless safety concerns about generic drugs.

The FDA is required under law to respond to each petition, thereby wasting time and taxpayer-funded resources on often frivolous claims. While the sham petitions are in review, the generic drugs being petitioned sit in limbo without approval and out of reach from everyday Americans.

Take, for example, a brand-name company called ViroPharma that inundated the FDA with 24 citizen petitions and 22 other filings with respect to a competing generic drug to treat gastrointestinal infections. In 2017, the current Administration and the Federal Trade Commission said in the court case, *FTC v. Shire ViroPharma*, that ViroPharma's campaign had succeeded in delaying generic entry at a cost of hundreds of millions of dollars.

The American people are indeed being played. We must end these abusive tactics. That is why are advancing the bipartisan Stop Stalling Act, and I urge all my colleagues to support this legislation as we endeavor to lower prescription drug prices on behalf of the American people. And I yield back.

Chairman Nadler. I thank the gentleman. I now recognize the ranking member of the Antitrust Subcommittee, the gentleman from Wisconsin, Mr. Sensenbrenner, for his

opening statement.

Mr. Sensenbrenner. I thank my colleague, the gentleman from New York, Mr. Jeffries, for partnering with me on the Stop Stalling Act, and I also thank the chair and ranking member for bringing the bill to markup. I sincerely hope we can achieve enactment of this bill during this term of Congress.

The Stop Stalling Act is yet another way in which drug manufacturers game government processes to shut new generic drug competition out of the market. No one will champion more than I the right of American citizens to petition their government for redress of grievances, but some incumbent drug manufacturers too often abuse this right by filing sham citizen petitions with the FDA. These sham petitions simply gum up the FDA's generic approval process, delaying approvals until the petitions can be looked at and disposed of by the FDA.

While they can be quick and cheap for incumbent manufacturers to gin up, they can keep drug prices high and out of patients' reach. This is wrong, and it should stop. With the Third Circuit's recent decision in *FTC v. Shiro ViroPharma*, it stands to make it harder for the FTC to police the behavior through antitrust enforcement. This strong bipartisan bill responds by establishing a specific statutory remedy against the filing of sham petitions.

The bill preserves every right of every citizen to bring legitimate health and safety concerns to the FDA. At the same time it makes sure that generic drug manufacturers can sue under the antitrust laws those who file sham petitions just to keep lower-cost generic drugs out of the market. I urge my colleagues to support this bill and yield back the balance of my time.

Chairman Nadler. Thank you, Mr. Sensenbrenner. Without objection, all other opening statements will be included in the record.

Are there any amendments to H.R. 2374?

[No response.]

Chairman Nadler. Well, a reporting quorum being present, the question is on the motion to report the bill, H.R. 2374, favorably to the House.

Those in favor, say aye?

Those opposed, no?

The ayes have it, and the bill is ordered reported favorably to the House. Members will have 2 days to submit views.

Pursuant to notice, I now call up H.R. 2376, the Prescription Pricing for the People Act of 2019, for purposes of markup and move that the committee report the bill favorably to the House.

The clerk will report the bill.

Ms. Strasser. H.R. 2376, to require the Federal Trade Commission to study the role of intermediaries in the pharmaceutical supply chain and provide Congress with appropriate policy recommendations, and for other purposes.

Chairman Nadler. Without objection, the bill is considered as read and open for amendment at any point.

[The bill follows:]

Chairman Nadler. I will begin by recognizing myself for an opening statement.

H.R. 2376, the Prescription Pricing for the People Act of 2019, would require the Federal Trade Commission to conduct a comprehensive report on the state of competition in the drug supply chain. In particular, this study would focus on whether pharmacy benefit managers, or PBMs, have engaged in certain behavior for anticompetitive purposes, such as steering patients to pharmacies in which a PBM has an ownership interest, giving such pharmacies more favorable rates than it offers to competing pharmacies, or using its market power to depress the use of lower-cost prescription drugs.

PBMs are responsible for administering prescription drug benefits through negotiations and contracts with drug manufacturers, health insurers, healthcare providers, and pharmacies. As leading economist, Fiona Scott Morton, testified in the hearing on competition in the healthcare marketplace held by the Subcommittee on Antitrust, Commercial, and Administrative Law earlier this year, PBMs play a dual role in the drug supply chain, facilitating price competition among branded and generic companies while negotiating for lower prices in competitive markets. This role, she explained, is "critical because it is one of the few agencies in our commercial pharmaceutical marketplace

that creates price competition."

However, the PBM marketplace is highly concentrated. In fact, only three companies control the vast majority of the market, and the biggest PBMs also own the Nation's largest retail pharmacy chains, so they are negotiating against themselves. As a result of this concentration of market power and inherent to conflict of interest, these firms have the incentive and the ability to leverage their dominance in the PBM marketplace to steer business to their own pharmacies and away from competitors or to raise their rivals' costs.

There is also growing concern that some PBMs engage in anticompetitive contracting practices that lead to higher drug prices. This concern is exacerbated by the lack of transparency in the PBM marketplace. It is difficult for the public to know whether the cost savings achieved by PBM negotiations are ultimately passed on to consumers when the drug pricing process is shrouded in secrecy.

The study required by this legislation will provide helpful guidance to Congress as it considers ways to lower drug prices, and I commend Ranking Member Collins for his leadership and for his commitment to promoting greater competition in the drug supply chain. I look forward to working with him on this issue, and I urge my colleagues to support this legislation.

I now recognize the ranking member of the Judiciary

Committee, the gentleman from Georgia, Mr. Collins, for his opening statement.

Mr. Collins. Thank you, Mr. Chairman, and I appreciate you partnering with me on this Prescription Pricing for the People Act. This is something that has been a passion of mine for the entire time I have been in Congress for the 6 years in dealing with this issue of PBMs. And I am glad to see this along with the Administration and others making moves to address this situation in our healthcare system.

Over the past decade, consolidation across the healthcare and prescription drug markets have rapidly increased. Nowhere is this more prevalent than the PBM, or pharmacy benefit manger, marketplace. Since 2008, the market has gone from more than 20 major players to three companies controlling 85 percent of the market. As these companies have consolidated horizontally, they have also merged vertically with major pharmacies and health insurers.

The resulting consolidation has enabled PBMs to maneuver in the shadows to block savings from reaching the patients who depend on them to afford their medications. PBMs consistently engage in anticompetitive behavior by targeting competing pharmacies with unfair audits and under reimbursements. PBMs are able to audit competing pharmacies, viewing data including the pharmacy's acquisition cost and patient data. PBMs then use the data to steer patients to

their own pharmacies and reimburse competing pharmacies at a much lower rate, retaining the spread along the way. In Ohio, CVS and OptumRx charge the State over $400 million more than they paid out to their pharmacies.

PBMs exert immense control over the patient formularies, allowing them to steer patients to high-cost medications because these medications give them higher rebates. By steering patients to high-cost medications, PBMs increase patient copays and incentive manufacturers to increase drug costs to pay the PBMs' higher rebate demands. PBMs' role as intermediaries also allow them to extract rebates and price concessions from competing pharmacies and manufacturers without passing them on to the patients. Due to the lack of transparency, these price concessions are often withheld from the patients and payers, increasing PBM profits while failing to decrease drug costs.

H.R. 2376, the Prescription Pricing for the People Act, directs the FTC to review and report on these anticompetitive behaviors of PBMs and other issues affecting the competition for the pharmaceutical supply chain as a whole. The FTC is on a short timeline to produce these reports so that we will be able to legislate upon the results during this term of Congress when the reports are in.

This is a bill that I appreciate the chairman partnering with me on. This long overdue. It is time to shine sunshine

in a very dark place and see if we can get this fixed. And I would all my colleagues to support this bill and yield back the remainder of my time.

Chairman Nadler. Thank you, Mr. Collins. I now recognize the chair of the Subcommittee on Antitrust, Commercial, and Administrative Law, the gentleman from Rhode Island, Mr. Cicilline, for his opening statement.

Mr. Cicilline. Thank you, Mr. Chairman. H.R. 2375, the Prescription Pricing for the People Act of 2019 would require the Federal Trade Commission to study the state of competition in the drug supply chain to ensure that all elements in the supply chain are aligned to reduce costs for consumers and healthcare payers. I strongly support promoting competition in every market, including within the pharmaceutical supply chain.

It is critical that consumers ultimately receive the benefit of lower drug prices, but as I have said before, I am deeply skeptical of claims that pharmacy benefit managers, PBMs, are a significant driver of high drug costs. PBMs are responsible for negotiating with branded drug companies to lower drug costs on behalf of health insurance payers and employees. Moreover, PBMs reduce costs and improve patient outcomes, as Professor Fiona Scott Morton recently testified before the Antitrust Subcommittee. Those cost savings come in addition to the billions of dollars saved by automatically

substituting generic drugs for branded drugs in retail pharmacies when available, as Professor Feldman and other leading experts have noted.

But make no mistake. Demonizing or scapegoating PBMs and retail pharmacies in the drug supply chain is a distraction from the leading causes of high drug prices. These include the lack of competition in the manufacturing of prescription drugs, regulatory abuse by branded drug companies to delay generic competitors, and barriers to generic competition, such as pay-for-delay settlements that keep drug prices at artificially high monopoly levels.

Addressing these issues head on is a critical first step for lowering the cost of prescription drugs, which is why moving today's package of legislation is so important. That said, it has been nearly 15 years since the Federal Trade Commission last issued a study on this market. It is important the public and this committee has the best data for informed policy discussions.

I thank Ranking Member Collins and his staff for their work on this legislation. It is a balanced inquiry into the subject, and, most importantly, does not come at the expense of serious reforms to high drug prices. I urge my colleagues to support this bill, and I yield back the balance of my time.

Chairman Nadler. I thank the gentleman and now

recognize the ranking member of the Antitrust Subcommittee, the gentleman from Wisconsin, Mr. Sensenbrenner, for his opening statement.

Mr. Sensenbrenner. Thank you very much, Mr. Chairman. I think that the previous speakers have said most of all, but I want to add one thing. I think one of the important things in this bill is that we will get the reports back from the FTC during this term in Congress. So this is something that will allow us to legislate either later on this year or next year to come up with something meaningful to address this part of the problem. I support this bill and urge my colleagues to vote for it. I yield back the balance of my time.

Chairman Nadler. I thank the gentleman. Without objection, all other opening statements will be included in the record.

Are there any amendments to H.R. 2376?

[No response.]

Chairman Nadler. A reporting quorum being present, the question is on the motion to report the bill, H.R. 2376, favorably to the House.

Those in favor, say aye?

Those opposed, no?

The ayes have it, and the bill is ordered reported favorably to the House. Members will have 2 days to submit

views.

This concludes our business for today. I thank all of our members for attending. The markup is adjourned.

[The information follows:]

[Whereupon, at 3:11 p.m., the committee was adjourned.]