

House Energy and Commerce Committee

Markup of H.R. 3, the "Lower Drug Costs Now Act of 2019", H.R. 4665, the "Medicare Vision Act of 2019", H.R. 4671, the "Help Seniors Afford Health Care Act", H.R. 4618, the "Medicare Hearing Act of 2019", H.R. 4650, the "Medicare Dental Act of 2019". October 17, 2019 10:00AM, 2123 Rayburn House Office Building

Purpose:

The purpose of the proceedings was to markup five bills: H.R. 3, the "Lower Drug Costs Now Act of 2019", H.R. 4665, the "Medicare Vision Act of 2019", H.R. 4671, the "Help Seniors Afford Health Care Act", H.R. 4618, the "Medicare Hearing Act of 2019", H.R. 4650, the "Medicare Dental Act of 2019".

Opening Statements:

During his opening statement, **Chairman Pallone** said that the committee is continuing its important work of lowering prescription drug prices by stopping drug companies from ripping off Americans. It is time to give Medicare the power to negotiate a better deal for the American people. The committee has made some key changes to H.R. 3 since its legislative hearing: first, a phased in increase of the minimum number of drugs the Secretary of Health and Human Services (HHS) must negotiate prices for; second, a guarantee that a negotiated price will remain in place until there are at least two generics available; third, a new provision to negotiate prices for newly launched drugs; and fourth, a new title on drug transparency that is based on the FAIR Drug Pricing Act. The Congressional Budget Offices (CBO) recently found that this transformative legislation would have Americans \$345 billion in Part D spending. The committee is also considering four bills that will strengthen Medicare by reinvesting some of the savings in expanding benefits to include hearing, vision, and dental. Taken together, these bills will make great strides in containing the soaring costs of prescription drugs.

During his opening statement, **Ranking Member Walden** said that the committee should be working in a bipartisan effort to lower the cost of prescription drugs. Instead, the Speaker's office has seized control and produced a pre-baked bill. It did not have to be that way. CBO found that the Speaker's bill would prevent the development of up to 15 new medicines. None of us know which medicine or cure will not be invented as a result. One cure prevented is one too many. The other bills being considered have faced no hearings. The Parties could have worked together, but that is not what will happen today.

Rep. Eshoo also gave an opening statement. She said the H.R. 3 would give Medicare the power to negotiate a better deal for Americans. Doing so will save lives and prevent Americans from going bankrupt in order to pay for their drugs. According to a recent poll, 89 percent of Americans favor Medicare negotiation.

Rep. Burgess also gave an opening statement. He said that he is disappointed that the committee has not tried to work in a bipartisan way. This bill is not going to become law. There is bipartisan consensus on several policy proposals to lower drug costs, including capping out-of-pocket costs for seniors. The Senate Finance Committee has also put together a bipartisan proposal to

restructure Part D. If the House wanted to work in a bipartisan, bicameral way, they could produce something that the President would sign. But that is not the case.

Bill Consideration:

H.R. 3, the "Lower Drug Costs Now Act of 2019":

Chairman Pallone offered an amendment in the nature of a substitute (AINS). He said the amendment makes technical changes to the bill, raises the minimum number of drugs the Secretary can negotiate prices for, allows the Secretary to negotiate the price of new drugs more quickly, and guarantees that a negotiated price will stay in place until at least two generics are available. It also includes a new Title IV, which will improve Part D access for low-income seniors, and a new Title V, which includes critical transparency provisions that will give the public access to important pricing information. Rep. Bucshon asked Counsel if the language in the bill places the sole power to determine whether a drug is "essential" for a patient's treatment in the HHS Secretary. Counsel said yes. Rep. Bucshon asked if the bill requires consultation with the patient or the physician to determine what treatment is essential. Counsel said no. Rep. Shimkus asked Counsel if the inflationary rebate penalty would apply to a company that spent resources to get a new drug indication approved by the Food and Drug Administration (FDA), and increased the price of the drug above the rate of inflation to recoup those costs. Counsel said yes. Rep. Rush said that the out-of-pocket cap should be \$1,500, rather than \$2,000. Rep. Guthrie asked Counsel if the negotiate price of a drug could become the Medicaid Best Price. Counsel said that the legislation does not change the definition of Medicaid Best Price, but the negotiated price would factor into average price calculations. Several Democrats spoke in favor of the amendment, emphasizing the need to give Medicare the power to negotiate in order to lower drug prices. Several Republicans spoke in opposition to the amendment, voicing concern that price negotiation would significantly hamper innovation and expressing disappointment that the committee is not working in a bipartisan way. Ranking Member Walden said that the no one is arguing that drug prices are too high for consumers. The committee has done a lot of good, bipartisan work to address that issue. Republicans support expanding access to generics and biosimilars, and restructuring Part D to help seniors. But Republicans feel shut out of this process. They will be offering an amendment that includes many consensus provisions, and he hopes Democrats will support it.

Rep. Burgess offered an amendment to the AINS. The amendment would require that 100 percent of the rebate on insulin be passed through to the patient at the pharmacy counter. **Rep. DeGette** asked Counsel which patients the amendment would apply to. **Counsel** said that it would apply to Part D or Medicare Advantage Part D plan recipients. **Rep. Eshoo** said that Congress will not know the full amount of rebates, given that pharmacy benefit manager (PBM) negotiations are secret. **Ranking Member Walden** said that the plans and manufactures know what the full rebate is, and they will be compelled by law to pass 100 percent along to patients. **Chairman Pallone** said that he opposes the amendment because H.R. 3 already mandates that the Secretary negotiate the price of insulin, and an additional mandate that rebates are passed along to patients could result in higher premiums.

Rep. Burgess's amendment to the AINS was defeated by a vote of 30 to 23.

Rep. Schrader offered an amendment to the AINS. The amendment would encourage increased utilization of biosimilars by temporarily increasing reimbursement for biosimilars. **Rep. Gianforte** spoke in favor of the amendment.

Rep. Schrader's amendment to the AINS was agreed to by a voice vote.

Rep. Carter offered an amendment to the AINS. The amendment would exempt Alzheimer's drugs from government price negotiation. **Chairman Pallone** spoke in opposition to the amendment. He said that science and medicine are evolving fields. Congress is not in the best position to decide which diseases should or should not be exempt. The big picture is that drugs need to be more affordable. **Rep. Doyle** spoke in opposition to the amendment. He said that research would not stop just because the government negotiates a lower price for a drug. Several other Democrats spoke in opposition to the amendment as well. Several Republicans spoke in favor of the amendment, saying that researchers and pharmaceutical companies need funding in order to pursue cures. **Ranking Member Walden** said that in countries that have government negotiation, it often takes several months longer for a new treatment to become available.

Rep. Carter's amendment to the AINS was defeated by a vote of 27-24.

Rep. Tonko offered an amendment to the AINS. The amendment would require HHS to incorporate a measure of biosimilar access into the existing star rating for Part D and Medicare Advantage plans. He asked if Chairman Pallone would commit to work on this issue. **Rep. Pallone** said he would. **Ranking Member Walden** said that he is willing to continue work on the issue as well.

Rep. Tonko withdrew his amendment.

Ranking Member Walden offered an amendment to the AINS. He said that the goal of the amendment is to work towards a bipartisan process to address drug costs. The amendment is a package that could become law. It is made up of bipartisan provisions including the CREATES Act, the BLOCKING Act, pay-for-delay, stopping spread pricing, and a full modernization of Medicare Part D, including a cap on out-of-pocket costs. He noted that Republicans oppose the 95 percent penalty on drug companies that do not agree to government price setting, but he included it in the amendment in order for the amendment to be germane. **Chairman Pallone** spoke in opposition to the amendment. He noted that President Trump has supported Medicare price negotiation in the past. Several Republicans spoke in favor of the amendment and working in a bipartisan way, and several Democrats spoke in opposition.

Rep. Walden's amendment to the AINS was defeated by a vote of 30-22.

Rep. Welch offered an amendment to the AINS. The amendment would prohibit Part D plan sponsors from using DIR fees to retroactively apply claims fees to pharmacies. **Chairman Pallone** said he is happy to continue work on that issue. **Ranking Member Walden** said that he is prepared to continue work on that issue as well. Several members of both Parties spoke in favor of the amendment.

Rep. Welch withdrew his amendment.

Rep. Walberg offered an amendment to the AINS. The amendment would exclude orphan drugs from the list of drugs eligible for price negotiation. **Rep. Matsui** spoke in opposition to the amendment. She said that the committee has a long history of supporting the development of orphan drugs. Orphan drugs are often significantly more expensive than other drugs. That is exactly why they should be subject to negotiation. Several Republicans spoke in favor of the amendment.

Rep. Walberg's amendment to the AINS was defeated by a vote of 29-24.

Rep. Schrader offered an amendment to the AINS. The amendment would add an advisory committee to the Secretary's drug selection process. He said that there should be a panel of experts to help determine which drugs should be subject to negotiation.

Rep. Schrader withdrew his amendment.

Rep. Latta offered an amendment to the AINS. The amendment would prevent titles I, II, and III from taking effect until the Secretary determines that enacting them would not affect the development of, or access to, mental health and substance use treatment. **Ranking Member Walden** spoke in favor of the amendment. **Rep. Welch** said that there must be mental health parity. This amendment would again lead to a bifurcated system.

Rep. Latta's amendment to the AINS was defeated by a vote of 29-24.

Rep. Kennedy offered an amendment to the AINS. The amendment would require all individual ACA and ERISA plans to cover all drugs related to depression without cost-sharing for one year post-partum. **Rep. Carter** spoke in favor of the amendment. **Rep. Burgess** said that he supports holding a hearing on this issue.

Rep. Kennedy withdrew his amendment.

Rep. Bucshon offered an amendment to the AINS. The amendment would remove reference pricing provisions from H.R. 3. **Chairman Pallone** spoke in opposition to the amendment. He said it is unacceptable that Americans pay so much more than those in other countries for the same drugs.

Rep. Bucshon's amendment to the AINS was defeated by a vote of 29-24.

Rep. O'Halleran offered an amendment to the AINS. The amendment would instruct the Secretary to establish a grant program for critical access hospitals that have GME programs and host students on rotation. He asked for the committee to continue working on the issue. **Chairman Pallone** said they would.

Rep. O'Halleran withdrew his amendment.

Rep. Walden offered an amendment to the AINS. The amendment would extend the international reference price model in H.R. 3 to reimbursement for hospitals, medical providers, and insurance companies. He said that it represents a total government takeover of health care, which it seems like the majority wants.

Rep. Walden withdrew his amendment.

Rep. Carter offered an amendment to the AINS. The amendment would strike the provision of the bill imposing an inflationary cap. He said inflation caps only serve to distort the market. His amendment also includes a \$3,100 out-of-pocket cap for Part D beneficiaries, and would require 80 percent of all rebates and discounts negotiated in Part D to be passed on to patients at the point of sale. **Chairman Pallone** and other Democrats spoke in opposition to the amendment. Several Republicans spoke in favor of the amendment. Members agreed that low-income beneficiaries need equal access to drugs.

Rep. Carter's amendment to the AINS was defeated by a vote of 29-24.

Rep. Schakowsky offered an amendment to the AINS. The amendment would amend the Medicare statute to provide coverage for compression garments used to treat lymphedema. **Rep. Carter** spoke in favor of the amendment. **Rep. Schakowsky** said that she hopes the committee will consider the proposal in the future.

Rep. Schakowsky withdrew her amendment.

Rep. Burgess offered an amendment to the AINS. The amendment would clarify the purpose of the 340B program and require that 75 percent of the 340B discount go directly to patients. He said that Congress did not clearly identify the intent of the 340B program and did not define many of the parameters. Congress should restate that the intent of the program is to help low-income patients directly with their drug costs. **Rep. Matsui** spoke in opposition to the amendment. She said that the purpose of the program is clear: it was created to allow hospitals to stretch scarce federal resources to expand services for low-income patients. **Rep. Bucshon** spoke in favor of the amendment. He asked if H.R. 3 allows 340B eligible drugs to have their prices negotiated by the Secretary. **Chairman Pallone** said yes. **Rep. Carter** asked Counsel how the 340B price and the Medicaid rebate program would interact with the negotiated price. **Counsel** said that the AINS does not change the 340B formula.

Rep. Burgess' amendment to the AINS was defeated by a voice vote.

Rep. Kuster offered an amendment to the AINS. The amendment would ensure that generics and biosimilars are covered upon launch and create a new formulary tier for generics and biosimilars. **Rep. McKinley** spoke in favor of the amendment.

Rep. Kuster withdrew her amendment.

Rep. Burgess offered an amendment to the AINS. The amendment would exclude drugs used for sickle cell treatment from price negotiation. **Rep. Butterfield** spoke in opposition to the amendment. He said that Congress should not exempt specific diseases from drug price negotiation. Several other Democrats spoke in opposition to the amendment.

Rep. Burgess' amendment to the AINS was defeated by a vote of 28-22.

Rep. Griffith offered an amendment to the AINS. The amendment added a non-severability clause to the bill. **Chairman Pallone** spoke in opposition to the amendment. He said that there is

no question about the constitutionality of H.R. 3. **Ranking Member Walden** said that if there is no constitutional question, Democrats should support this amendment.

Rep. Griffith's amendment to the AINS was defeated by a voice vote.

Rep. Shimkus offered an amendment to the AINS. The amendment would establish guardrails for CMS Innovation Center demonstration programs. Several Republicans spoke in favor of the amendment.

Rep. Clarke insisted on a point of order that the amendment is not germane. Chairman Pallone ruled that the amendment is not germane because it implicates Rules Committee jurisdiction.

Rep. Mullin offered an amendment to the AINS. The amendment would create a value-based payment model for innovative drugs coming to market. **Rep. Schrader** said that he is a proponent of value-based pricing for innovative drugs and hopes the committee will continue work on this issue. Several members spoke in favor of the amendment.

Rep. Mullins withdrew his amendment.

Rep. Flores offered an amendment to the AINS. The amendment would require the Secretary to certify that enacting the bill will not result in research or manufacturing jobs being shipped overseas. **Rep. Hudson** spoke in favor of the amendment. **Rep. Eshoo** said that protecting intellectual property from being taken overseas is an important issue.

Rep. Flores' amendment to the AINS was defeated by a vote of 30-22.

The amendment in the nature of a substitute to H.R. 3, as amended, was agreed to by a voice vote.

H.R. 3, the Lower Drug Costs Now Act of 2019, as amended, was reported favorably to the full House by a vote of 30-22.

H.R. 4665, the "Medicare Vision Act of 2019":

Rep. O'Halleran spoke in favor of the bill. He said that vision care is essential for seniors, and it is time for it to be covered by Medicare. **Ranking Member Walden** said that the coverage expansion bills being considered are being rushed though the committee process without having had a legislative hearing. Medicare is also facing shortfalls. Medicare Advantage plans already offer supplemental vision, hearing, and dental coverage.

H.R. 4665, the Medicare Vision Act of 2019 was reported favorably to the full House by a voice vote.

H.R. 4671, the "Help Seniors Afford Health Care Act":

Rep. Schrader said that these coverage expansion bills are well-intentioned, but it will be important to understand what they will cost before the full House votes on them. **Rep. Blunt**

Rochester said that many seniors who are eligible for Medicare Shared Savings Program (MSP) coverage are not enrolled. This bill will expand access to the MSP.

H.R. 4671, the Help Seniors Afford Health Care Act was reported favorably to the full House by a voice vote.

H.R. 4618, the "Medicare Hearing Act of 2019":

Rep. Dingell spoke in favor of the bill. She said that hearing loss is one of the most common health issues facing seniors today. Many seniors cannot afford treatment, and this must change. **Rep. Soto** said that the savings generated by H.R. 3 should be used to strengthen Medicare and expand coverage.

H.R. 4618, the Medicare Hearing Act of 2019 was reported favorably to the full House by a voice vote.

H.R. 4650, the "Medicare Dental Act of 2019":

Rep. Kelly said that the bill will allow millions of seniors to gain access to dental care. **Rep. Barragan** spoke in favor of the bill.

H.R. 4650, the Medicare Dental Act of 2019 was reported favorably to the full House by a voice vote.