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Summary of "Improving Access to Affordable Prescription Drugs Act"

TITLE I—TRANSPARENCY

Sec.101.Drug manufacturer reporting.

Section 101 would require disclosure of a variety of information from prescription drug corporations, including, by product, expenditures on research and development (delineated by clinical trial phase and other factors), non-clinical studies, acquisitions (including patents and licensing), carrying out post-market requirements, marketing and advertising, and other factors.

Section 101 also would require disclosure of revenues, profits, levels of sales, pricing information, contributions to patient assistance programs (and details relating to such programs), federal benefits received by the manufacturer, executive compensation, and other factors. The section would require reported information to be made available online in searchable format. Corporations that fail to report the required information would face a civil penalty.

Sec.102.Determining the public and private benefit of copayment coupons and other patient assistance programs.

Section 102 would amend the law relating to information disclosures to the Internal Revenue Service (IRS) from 501(c)(3) organizations, adding the requirement for such organizations to disclose the total amount of patient assistance provided to patients who are prescribed drugs manufactured by any contributor to that 501(c)(3) organization.

It would also require the Government Accountability Office (GAO) to conduct a study and draft a report for Congress on the impact of copayment coupons and other patient assistance programs on prescription drug pricing and expenditures, including as it relates to government health programs and private markets; tax benefits of manufacturers offering such programs, and adherence to Office of Inspector General (OIG) of HHS guidance regarding the avoidance of waste, fraud and abuse.

TITLE II—ACCESS AND AFFORDABILITY

Sec.201.Negotiating fair prices for Medicare prescription drugs.

Section 201 would allow the Secretary of HHS to negotiate Medicare Part D prescription drug prices with prescription drug companies through use of techniques the Secretary deems appropriate, including potentially through use of formularies, reference pricing, discounts, rebates, other price concessions and coverage determinations.

In the event of a failure of negotiations, the Secretary may establish a price that is the lower of the price paid by the Secretary of Veterans Affairs (VA) or established for the 'Big Four' (VA, Indian Health Service, Coast Guard, Department of Defense).

The price achieved through such negotiations or through establishment of the VA or Big Four price would provide a ceiling for how much drug companies may charge Part D Plan (PDP) sponsors.

Section 201 would also require the Secretary of HHS to submit regularly to Congress and make publicly available reports on the impacts of such negotiations, data on Part D spending on covered Part D drugs, a list of covered drugs with no therapeutic substitute and spending related to such drugs, access to covered drugs, compliance rates and related health outcomes, and appeals by enrollees with respect to drugs not included in PDP formularies.

Section 201 also required the Comptroller General to conduct a study on the negotiations described in this section, including pricing impacts for Part D, other federal and state government programs, the private market, and specifically who is accruing the benefits of lower prices. The Comptroller General would be required to submit the report no later than the beginning of 2021 along with recommendations on how to improve the negotiations.

Lastly, section 201 would mandate the Center for Medicare and Medicaid Innovation (CMMI) to conduct testing of at least three models to improve the value provided through drug and biologic prices from a list of possible frameworks including indications-based pricing, reference pricing, and pricing based on comparative effectiveness research, among others.

Sec.202.Prescription drug price spikes.

Section 202 would impose a tax on prescription drug companies that raise the prices of their drugs (according to average manufacturer price (AMP), or if the AMP is not available, according to average sales price (ASP)) beyond the rate of medical inflation over an annual period or over a period between two and five years.

Prescription drug corporations would be required to submit, on a quarterly basis, sales information to the OIG of HHS for the purposes of determining applicable fines. Companies that fail to disclose required information would be penalized based on a percentage (ranging from 0.5% to 1.0%) of gross revenues of the prescription drug product for which requisite information was not disclosed.

Revenues from annual price spikes beyond the level of medical inflation but less than 15% would be fined at a level of 50%. Those equal to or greater than 15% but less than 20% would be fined at a level of 75%. Revenues from price spikes equal to or greater than 20% would be fined at 100%.

Revenues from cumulative price spikes over a period of two-to-five years would be levied according to similar calculations, but compounded over the applicable period of time. The cumulate price spike tax would be levied at levels based on compounding the rates applicable to the annual brackets over the applicable period of time, and the fines levied for each cumulative price spike bracket would be at the same rate as in the comparable brackets in the annual tax (i.e. greater than inflation but less than 15% compounded at 50%, equal to or greater than 15% compounded but less than 20% compounded at 75%, and equal to or greater than 20% compounded at 100%). Only the greater of this cumulative price spikes tax or annual price spikes tax shall be imposed.

Any fines calculated shall be adjusted downward when the OIG of HHS finds that any of the price spike revenue is due solely to an increase of the cost of goods sold (e.g. an increase in the cost of the active pharmaceutical ingredient procured from another company).

Revenues collected under this section would be appropriated to the Secretary of HHS for the purposes of funding or conducting research on economic and policy implications of price patterns of prescription drugs; or increasing the amount available to the National Institutes of

Health (NIH) for research and development of drugs.

Sec.203.Acceleration of the closing of the Medicare Part D coverage gap.

Section 203 would accelerate the closing of the Part D coverage gap, aka "donut hole". Generic drug coinsurance in the coverage gap would be reduced to 25% in 2018 (rather than 2020, as under current law).

For brand-name drugs, coinsurance for beneficiaries would be reduced to 25% in 2018, and the level of manufacturer discount would be increased from 50% to 75% from 2018 onward.

Sec.204.Importing affordable and safe drugs.

Section 204 replicates language of The Affordable and Safe Prescription Drug Importation Act, which would instruct the Secretary of HHS to issue regulations allowing for the import of qualifying prescription drugs manufactured at FDA-inspected facilities from licensed Canadian sellers. After two years, it would allow, with the Secretary's permission, import from other Organisation for Economic Co-operation and Development (OECD) countries that meet statutory or regulatory standards comparable to those in the U.S.

In order to qualify to sell drugs under section 204, the seller must be a wholesale distributor or licensed foreign pharmacy that is current with applicable registration fees and sell only qualifying prescription drugs. Certification criteria include that the seller is located in Canada, engaged in distribution of drugs offered for import under this section, has existed for at least five years and has a purpose other than for this import program, only sells to individuals with valid prescriptions, certifies compliance with Canadian laws and regulations, conducts quality assurance programs, agrees that laboratories approved by the Secretary shall be used to test product samples, agrees to notify the Secretary and importers of product recalls, has a process for resolving grievances and will be held accountable for rule violations, does not sell to U.S. customers who would not qualify for sale in Canada, and meets any other conditions established by the Secretary.

The administration and enforcement of the program is paid through fees on foreign sellers.

Importing individuals shall only be allowed to procure drugs from pharmacies licensed to practice and dispense in Canada, and only for personal use and in quantities less than a 90-day supply.

Importing companies are required to submit biannual reports to the Secretary containing an array of information detailing the products imported, when they were imported, and from whom they were imported.

The Secretary would be given the authority to suspend importation of a product or products if there is an importation involving counterfeit drugs, drugs that have been recalled or withdrawn, or drugs in violation of a requirement of this section until the Secretary determines that the importer has not endangered public health. Such suspensions of imports from a seller would be required if there is a pattern of violations.

Section 204 would prohibit drug manufacturers from restricting, prohibiting or delaying importation of qualifying drugs except in cases of shortage. It would also put in place penalties of up to 10 years imprisonment or a fine up to $250,000 for persons selling counterfeit products with intent to defraud or mislead, with reckless disregard for public safety, or that knowing dispense drugs without a valid prescription.

Sellers may only purchase drugs intended for import into the U.S. from FDA-registered manufacturers or other certified foreign sellers, and shall disclose to importers an array of information relating to the purchase, including relating to their seller, the drugs purchased and a certification that the seller did not knowingly ship an illegitimate product. The section calls for the Secretary to seek to enter into a memorandum of understanding with Canada (or other permitted country) to ensure compliance with subchapter H of chapter V of the FDCA.

Finally, this section would require for the Secretary to issue a report to Congress and the public within one year of finalizing of all rules called for in this section, and for the GAO to conduct a study within 18 months of the finale rule to analyze the implementation of this section and review its impacts on drug safety and cost savings as well as its importation shipment and tracing processes.

Sec.205.Requiring drug manufacturers to provide drug rebates for drugs dispensed to low-income individuals.

Section 205 reflects language included in the Medicare Drug Savings Act of 2015 (S. 1083) of the 114th Congress. The section would amend Medicare Part D by requiring drug manufacturers to grant drug rebates to HHS for low-income (dual-eligible) individuals at the level provided in Medicaid, and exclude Medicare Part D coverage of drugs or biologics manufactured by a manufacturer that fails to enter into such a rebate agreement with the Secretary of HHS.

The section would also amend the Social Security Act to exclude such rebates from the calculation of best price and average manufacturer price under Medicaid.

Sec.206.Cap on prescription drug cost-sharing.

Section 206 would amend the essential health benefit requirements of the Affordable Care Act (ACA) by specifying that requirements relating to cost-sharing apply to prescription drugs offered by insurance plans. The section would require that for plan years beginning in 2019 or later, prescription drug cost sharing would be capped at $250 for individuals or $500 for families. The level of said caps would be adjusted in subsequent years by multiplying those amounts by the level of the medical care component of the consumer price index.

Section 206 would also require that group health plans meet the above requirements relating to prescription drug cost-sharing caps.

TITLE III—INNOVATION

Sec.301.Prize fund for new and more effective treatments of bacterial infections.

Section 301 would establish in the Treasury of the United States an Antibiotics Prize Fund of two billion dollars in fiscal year 2018. During a ten-year period following enactment of this bill, the bill would require the Director of the NIH to award up to three prizes for products that provide added benefit, demonstrated through superiority in clinical trials, to patients over existing antibiotic treatments, and award open source dividend prizes for contributions that advance antibiotic research with openly sourced materials, technology, data and knowledge.

No more than five percent of the prize payments would be available for open source dividend prizes.

Section 301 would require the Director of NIH to establish criteria to qualify for the award of prizes, with consideration of the number of patients in the United States and in other countries

who would benefit from the treatment; whether the product treats or has the potential to treat a serious condition for which there is no other treatment or for which there is a high chance of resistance to existing treatments; the incremental therapeutic benefit provided, the transmissibility of the bacterial infection the product treats; the extent to which openly sourced knowledge, data, materials and technology have contributed to the development of the product; and other criteria as the Director of NIH sees fit to ensure the prizes provide appropriate incentive.

The open source dividend prizes would be awarded to persons that openly share on a royalty-free, not-for-profit, and non-discriminatory basis, materials, technology, data and knowledge that contribute in a significant way to the successful development of a qualifying product or significantly advance research in the field.

The Director of NIH would also establish goals that qualifying products or contributions must show in order to establish the contribution to the advancement of research in the field. These goals would help determine eligibility of persons for receiving a prize.

The section goes on to establish various conditions on the receipt of prize, including reasonable pricing, public disclosure of clinical trial data, submissions of marketing materials to government authorities to ensure good stewardship, waiving of patent rights and FDA-granted exclusivities, and other conditions determined by the Director of NIH. These conditions would also apply to subsequent owners, licensees, producers, manufactures and assignees of the product or any of its chemical components for which the prize was awarded.

A product would be considered to have a reasonable price if it openly licenses all necessary rights needed to make and sell the product to manufacturers of a generic version of the product, sells the product at no more than twice the price approved antibiotics with similar manufacturing costs, or sells the product at a price not higher than the median price in seven countries determined by the secretary under criteria outlined in the section.

If a prize recipient or subsequent owner or licensee does not fulfil the conditions for receipt of the prize, the Secretary and Attorney General shall take all necessary actions to clawback the prize.

The Director of NIH would be required to make public methodology and criteria used in determining the award of prizes as well as an analysis of how prize recipients fulfilled award conditions. Finally, the section would require the Director to seek an agreement with the National Academies of Sciences, Engineering, and Medicine to conduct a study to examine the use of innovation inducement prize funds for biomedical research, models of delinking the costs of research and development from drug prices, and the size and effectiveness of awards in this section.

Sec.302.Public funding for clinical trials.

Section 302 would establish at the NIH a Center for Clinical Research, for the purpose of conducting clinical trials on drugs.

Each year, the Director of the Center would select two molecules, compounds, drugs or biological products on which to conduct clinical trials at the Center, or enter into contracts with other entities to conduct such trials.

The Director of the Center would establish and make public criteria for acquiring patent rights

for and selecting drugs to ensure they address an existing or emerging need, and are not solely drugs that private sector researchers with access to all available information on such drugs chose not to develop. The Director would secure patent rights to selected drugs and perform clinical trials at NIH or subcontract their performance to another entity. When a drug for which trials were conducted by the Center that receives FDA approval, the Director shall execute non-exclusive license for manufacturers to manufacture the drug or enter into purchasing contracts.

Data and findings from the Center's studies would be made available (subject to privacy protections) through submission to a peer-reviewed journal, and if not accepted for publication or after publication of an accepted study, all de-identified data would be made available online.

Costs of studies conducted by the Center and with subcontract agreements under this section would be made public. $1,000,000,000 would be appropriated each fiscal year 2017 through 2026 to carry out this section.

Sec.303.Rewarding innovative drug development.

Section 303 would reduce the periods and limit the applicability of certain exclusivities provided through the FDA.

New Chemical Entity (NCE) exclusivity would be amended to allow FDA consideration of an abbreviated new drug application (ANDA) relying on an approved new drug application (NDA) submission after three years and allow marketing of such a generic five years after the approval of the NDA.

The award of exclusivity for a new clinical study would be restricted to supplements of applications that show a significant clinical benefit over existing therapies manufactured by the applicant in the five-year period preceding the submission of the application.

Biologic exclusivity would be reduced from 12 to seven years.

The extension of 30-month exclusivity provided to a brand-name company when such a company commences an action for patent infringement after the fourth year since FDA approval against a generic drug applicant that has certified that the brand-name company has filed no patent information, that there is no unexpired patent, or that any existing patents of the originator are not infringed in its ANDA would be reduce to extend to six-and-one-half years since NDA approval (if necessary) rather than seven-and-one-half years since NDA approval.

Pediatric study exclusivity periods provided through the FDA are amended to provide an additional six months to existing exclusivity periods as amended by this section.

Additionally, section 303 would require the Government Accountability Office (GAO) to conduct a study and submit to Congress a report that includes a list of drugs for which the Secretary of HHS received a request for rare disease designation, the number of such designations granted, the number denied and the number pending; a list of drugs for which orphan drug exclusivity was granted, including the date of approval and indication for which orphan designation was granted; a list of drugs for which orphan drug designation has been revoked or denied during the applicable period; for each drug with an orphan designation, over a certain period, total Medicare and Medicaid expenditures, the number of Medicare and Medicaid beneficiaries who used the drug each year in the time period and changes in unit prices over that time period. Additionally, the report would include, for a sample orphan drugs selected by the Comptroller General, with respect to each drug, gross revenues of manufacturers, manufacturer

spending on marketing and patient assistance programs, the average price per drug and how those prices change over time, and the indications for which the drugs received orphan designation as well as the indications for which each drug has been most commonly used, including off-label indications.

Sec.304.Improving program integrity.

Section 304 would rescind exclusivities granted by the FDA to a person or assigned to a person for a drug on or after the date of enactment of this section when the person is found to have committed a violation under this section with respect to that drug.

Exclusivities affected would include NCE exclusivities, new clinical investigation exclusivities, exclusivities provided due to successful paragraph IV certifications, exclusivities provided to NDA holders that commence an action for patent infringement during the fifth year after receiving FDA approval, exclusivities provided to NDA holders that conduct a pediatric study, exclusivities provided in the event of the approval of an antibacterial or antifungal intended to treat drug-resistant pathogens, exclusivities provided for orphan indications, biologic exclusivities, and any other exclusivities provided or extended with respect to a drug under the Federal Food, Drug & Cosmetic Act (FFDCA).

Violations of certain laws that would result in such exclusivity terminations include the criminal conviction of a person, civil judgment against a person, or settlement agreement in which a person admits to fault with respect to a drug for which that person has been assigned or granted exclusivity.

Laws for which violations pertain to the paragraph above include the adulteration or misbranding of a drug; making false statements to the Secretary or committing fraud; illegal marketing of the drug; violations of the False Claims Act; committing conspiracy to defraud the government with respect to claims; making false, fictitious or fraudulent claims; violating the Medicare and Medicaid 'anti-kickback statute'; violations of requirements related to Medicaid Rebate Agreements; or state laws against fraud comparable to those listed in this paragraph.

Exclusivity would be terminated, as applicable, when a final judgment is entered relating to criminal conviction or civil judgments described above; when a settlement described above becomes final or nonappealable; or, if there is no court order approving a settlement, when a court order dismisses the applicable case, issued after the settlement agreement, is or becomes final or nonappealable.

Persons who commit violations described in this section are required to report violations to the Secretary within 30 days of events described in the paragraph above. Failure to report violations would result in a fine of $200,000 per day so long as the violation persists.

The section would also authorize to be appropriated to the Federal Trade Commission such sums necessary for the purposes of addressing criminal activity and anticompetitive practices by pharmaceutical companies.

TITLE IV—CHOICE AND COMPETITION

Sec.401.Preserving access to affordable generics.

Section 401 reflects language included in S.124 of the 115th Congress. The section would amend the Federal Trade Commission Act to authorize the Federal Trade Commission (FTC) to initiate proceedings against parties to any agreement resolving or settling a patent infringement claim in

connection with the sale of a drug. Agreements would be considered anticompetitive and in violation of this section if the ANDA filer receives anything of value and agrees to limit or forego research, development, manufacturing, marketing, or sales of the generic drug implicated by the agreement.

Exclusions from violation include when the generic manufacturer is granted solely the right to market the drug prior to expiration of any exclusivity, payment of reasonable litigation expenses, or a covenant not to sue the generic firm for patent infringement.

Entities subject to FTC enforcement under this section may petition the order to be reviewed in federal court within 30 days of the issuance of the FTC order. Violations of this section would result in civil penalties no greater than three times the value given to the party that may reasonably be attributed to a violation of this section. If no value has been received by the NDA holder, then the penalty levied against it would be no greater than three-times the value of the value given to the ANDA filer.

These remedies are in addition to any existing remedies available under federal law.

Sec.402.180-Day exclusivity period amendments regarding first applicant status.

Sec.403.180-Day exclusivity period amendments regarding agreements to defer commercial marketing.

Sections 402 and 403 reflect language included in S. 131 of the 114th Congress. These sections amend the FFDCA by disqualifying a generic drug applicant from receiving "first applicant" 180-day exclusivity in the event that the applicant has entered into an agreement with the holder of the NDA or patent for the brand-name drug for which the generic applicant is seeking approval whereby the applicant agrees not to seek approval or begin marketing the generic drug until the expiration of the exclusivity period awarded to another applicant.

The definition of "first applicant" is expanded to include applicants that did not submit an application on the first day that a substantially complete application was submitted, and have no patent infringement action pending against them. The expanded definition would also disqualify applicants that have entered into an agreement whereby the applicant agrees not to seek approval or begin marketing the generic drug until the expiration of the exclusivity period awarded to another applicant. If a "first applicant" described in the above paragraph has already begun marketing the drug, the "first applicant" described in this paragraph may not begin marketing the drug until 30 days after the former began marketing the drug.

A "first applicant" that has entered into a disqualifying agreement would be prohibited from beginning marketing until the earlier of 1) the latest date set forth in the agreement or 2) 180 days after a first day applicant begins marketing.

Sec.404.Increasing generic drug competition.

Section 404 would require the FDA commissioner to publish on the FDA website a complete list of all generic drugs, including the drug trade name, active pharmaceutical ingredient manufacturer, active finished dosage form manufacturer, any contract manufacturing organization, the date of the authorized generic drug entered the market and marketing status. The list would also designate whether a drug is a sole-source drug. The commissioner would also maintain a confidential list of the identity and address of each manufacturer and labeler reported under this section and report on the website only the city and state of the same. The

commissioner may choose to make exceptions to the reporting requirements above if in the interest of public health.

The section would also require entities engaged in the manufacture, preparation, propagation, compounding, or processing drugs or devices to register any contract with a contract manufacturer with regard to any drug the contractor manufacturers, distributes or compounds, including the start and end dates of the contract. Manufacturers of all drugs (rather than only drugs that are life-supporting, life-sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition) would be required to notify the Secretary of any discontinuance or interruption of the manufacturer of any drug that is likely to lead to a disruption of its supply in the United States.

If the Secretary determines that there are less than two manufacturers of an approved drug or biologic, the Secretary may waive applicable user fees, and expedite ANDA and biosimilar reviews until the number of manufacturers of the drug or biologic is at least four

Additionally, in such cases as described in the paragraph above, the Secretary may expedite and prioritize purchase contracts with manufacturers who hold approved applications but are not currently manufacturing the drug or biologic. The section also requires the Secretary to establish guidelines for such purchase contracts that provide that only drugs listed as an essential medicine by an external authority may be included in such a contract. If the manufacturer enters into such a purchase contract, the Secretary would be required to establish a limit on what retail price may be made available to U.S. consumers for the drug or biologic.

Sec.405.Disallowance of deduction for advertising for prescription drugs.

Section 405 reflects language included in S.2623 of the 114th Congress, but the section is slightly more expansive. The section would disallow tax deductions for expenses relating to direct-to-consumer advertising, including advertisements in regard to a prescription drug product primarily directed toward consumers in publications, broadcast media, over the internet and through patient assistance programs.

Sec.406.Product Hopping.

Section 406 would require the FTC to submit a report to Congress on the extent to which manufacturers of drug and biologic products engage in product hopping, commonly known as evergreening.

The section defines product hopping as a circumstance in which a drug or biologic manufacturer reformulates a drug or biologic product in such a way that allows it to submit a new NDA or biologics license application (BLA) with respect to the new formulation, that new formulation is intended for the treatment of the same medical condition as the product that was reformulated, and actions are taken to reduce or eliminate demand for the original product.

The report would include an analysis of the timing of the introduction of the reformulated product relative to the market entry of an approved ANDA or biosimilar product, the types of changes made in the new product, and the various forms of product hopping manufacturers employ. Additionally, the report would include the extent to which manufacturers asses profitability of a new product based on whether it launches before or after the entry of a generic competitor to the original product; the effect of product hopping on consumer behavior and costs; the effect of product hopping on insurance prices and availability; how product hopping affects manufacturer profits, revenues, unit sales and prices; and how product hopping affects

unit sales, manufacturer profits, and prices of generic versions of the original product.

Finally, section 406 would require the FTC to issue guidelines on circumstances in which product hopping raises anticompetitive concerns or should be considered a violation of antitrust laws.