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Improving Access to Affordable Prescription Drugs Act
Section-by-Section Summaries and Context

At a time when Americans are being forced to choose between filling prescriptions and putting groceries on the table and demanding government action to lower prices, measures included in the Improving Access to Affordable Prescription Drugs Act are vitally important. This document presents brief summaries and corresponding background context of the 18 sections included in the Act.

TITLE I—TRANSPARENCY

Sec.101.Drug manufacturer reporting.

This section would require prescription drug corporations to disclose a variety of information, ranging from research and development expenditures, marketing and advertising, and acquisitions, to profits, pricing information, and executive compensation, among other factors. It would require reported information to be made available online, and noncompliant corporations would face a civil penalty.

Sec.101 Context

Currently, prescription drug corporations only disclose aggregated research and development (R&D) data, which makes it impossible for outside researchers to independently verify claims from prescription drug corporations and from industry-funded academic studies that do not disclose the data upon which analysis is based, such as the infamous $2.6 billion estimate from Tufts.[1] Granular and disaggregated data will allow independent researchers to assess the validity of industry funded studies, develop independent assessments of the costs of pharmaceutical R&D, and allow for better-informed debate regarding R&D-based justifications for exorbitantly high drug prices.

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

This section would require 501(c)(3) organizations to disclose to the Internal Revenue Service 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 report for Congress on the impact of copayment coupons and other patient assistance programs on prescription drug pricing and expenditures, including adherence to Office of Inspector General (OIG) of HHS guidance on the avoidance of waste, fraud and abuse, among other factors.

[1] http://keionline.org/node/2464

Sec.102 Context

While for some patients, use of copayment coupons can help defray out-of-pocket costs for medicines priced out of reach, the overall impact of such coupons on our healthcare system may lead to patients footing higher bills overall. In 2016, ProPublica reported, "Drug coupons are a clever marketing tactic increasingly used by pharmaceutical companies for a counterintuitive purpose: to keep drug prices high. By forgoing or reducing patients' payments for pricier brand-name drugs, they ensure more sales for which insurers foot the bulk of the bill."[2] The study required in this section would allow government investigators to get to the bottom of this problem and help inform legislative action to prevent prescription drug corporations from using coupons to game the system.

TITLE II—ACCESS AND AFFORDABILITY

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

This section 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. In the event of a failure of negotiations, the Secretary could establish a price that is the lower of the price paid by the Department of Veterans Affairs or the 'Big Four'. The negotiated or established price would provide a ceiling for how much Part D plan sponsors may be charged.

It would require the Secretary to submit regular reports to Congress and the public on the impacts of such negotiations. It would further require the Comptroller General to conduct a study on the negotiations, including recommendations on how to improve the negotiations. Lastly, it would mandate the Center for Medicare and Medicaid Innovation to conduct testing of at least three models to improve the value provided through drug and biologic prices.

Sec.201 Context

Medicare Part D represents seven percent of total global prescription drug spending, but rather than using its purchasing power to attain lower prices, the Secretary of HHS is explicitly forbidden from negotiating with drug companies.[3] If the secretary were able to attain drug price levels of the Department of Veterans Affairs, it would save taxpayers $16 billion annually.[4] Reaching price levels attained in other industrialized countries could result in even greater savings.[5]

Sec.202.Prescription drug price spikes.

This section would impose a tax on prescription drug companies that raise drug prices beyond the rate of medical inflation over one year or between two and five years. They would be required to submit sales information to the HHS OIG for the purposes of determining applicable fines. Noncompliant

[2] https://www.propublica.org/article/are-copay-coupons-actually-making-drugs-more-expensive
[3] http://www.citizen.org/documents/2269a.pdf.
[4] Ibid.
[5] Ibid.

companies would be penalized by a percentage of the product's gross revenues. Collected revenues would be appropriated to the HHS Secretary for the purposes of funding or conducting research on economic and policy implications of price patterns of prescription drugs; or increasing funding to the National Institutes of Health (NIH) for drug research and development.

Sec.202 Context

There is nothing in current law to prevent a company from pricing a medicine at whatever level they believe the market will bear, and prescription drug corporations price medicines to maximize profits.[6] In the wake of recent high-profile price increases from the likes of Martin Shkreli, Valeant, Retrophin, Rodelis, Mylan, Kaleo and Hospira, Americans have become aware of the need to take action to stop steep price hikes.[7,8,9] This section would limit price increases and penalize companies that sharply raise medicine prices.

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

This section 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). Starting in 2018, for brand-name drugs, beneficiaries' coinsurance would be reduced to 25%, and the level of manufacturer discount would be increased from 50% to 75%.

Sec.203 Context

Currently, once Medicare beneficiaries and their plan have spent enough money to reach the initial coverage limit ($3,700 in 2017) on covered prescription drugs, beneficiaries enter the coverage gap, also known as the "donut hole", wherein beneficiaries are required to pay a higher share of prescription drug costs (40% coinsurance for covered brand-name drugs in 2017) until they reach the catastrophic limit ($4,950 in 2017).[10,11] While the Affordable Care Act included measures to ease the financial burden on Part D beneficiaries in the donut hole, this section goes further by accelerating the reduction of the financial burden and increasing required discounts from prescription drug corporations. This would reduce out-of-pocket costs for seniors, which are linked to cost related non-adherence.[12]

Sec.204.Importing affordable and safe drugs.

This section 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.

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[6] https://delauro.house.gov/sites/delauro.house.gov/files/Prescription-Drugs-Innovation-Spending-and-Patient-Access-12-07-16.pdf.
[7] https://www.aging.senate.gov/imo/media/doc/Drug%20Pricing%20Report.pdf
[8] https://www.statnews.com/2016/08/25/mylan-antitrust-epipen-schools/
[9] http://www.vox.com/2017/2/3/14490804/kaleo-evzio-price-hike-opioid-epidemic
[10] https://www.medicare.gov/part-d/costs/coverage-gap/part-d-coverage-gap.html
[11] https://www.medicare.gov/part-d/costs/catastrophic-coverage/drug-plan-catastrophic-coverage.html
[12] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4265885/.

After two years it would allow imports from other select countries that meet comparable U.S. statutory or regulatory standards. The Secretary would be given the authority to suspend importation of a product that is in violation of this section, and impose penalties for persons selling counterfeit products. In order for foreign distributors or pharmacies to export to the U.S. under this section they would be required to meet an extensive series of certification requirements.

This section would require 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 final 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.204 Context

Currently, the United States generally pays more for prescription drugs that other 'developed' countries, including Canada, even after accounting for rebates and discounts.[13] Proponents of parallel importation[14] argue that allowing the purchase of drugs from Canada would help bring down drug prices to Canadian levels.[15] While this section includes measures intended to limit safety risks of importing drugs that have not gone through the FDA approval process, critics generally are concerned with the safety implications of such an approach.[16]

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

This section would amend Medicare Part D by requiring drug manufacturers to grant drug rebates to HHS for low-income individuals at the level provided in Medicaid. Drugs or biologics by a manufacturer that fails to enter into a rebate agreement would be excluded from Part D coverage. It would exclude rebates from Medicaid's calculation of best and average manufacturer price.

Sec.205 Context

Prior to the creation of Medicare Part D, low-income Medicare beneficiaries who were also eligible for Medicaid (dual-eligible beneficiaries) received prescription drug coverage through Medicaid, including the Medicaid statutory discount of 23.1 percent and rebates for price increases exceeding inflation. After Part D became law, low-income beneficiaries received subsidies, but drug manufacturers no longer were required to provide Medicaid-level discounts. This section would restore those discounts and help bring down Part D costs.

[13] https://www.bloomberg.com/graphics/2015-drug-prices/
[14] http://www.wipo.int/export/sites/www/about-ip/en/studies/pdf/ssa_maskus_pi.pdf
[15] http://www.vox.com/policy-and-politics/2017/1/17/14295932/pharmaceuticals-canada-cheaper-not-dangerous
[16] http://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1094&context=hlp

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

This section would amend the essential health benefit requirements of the Affordable Care Act by specifying that requirements relating to cost-sharing apply to prescription drugs offered by insurance plans. For plan years beginning in 2019 or later, prescription drug cost sharing would be capped at $250 for individuals or $500 for families. The caps would be adjusted in subsequent years in accordance with the medical care component of the consumer price index.

Sec.206 Context

While the Affordable Care Act placed annual caps on out-of-pocket costs for health plans offered through the Obamacare exchanges and employer-sponsored plans ($7,150 for individual plans and $14,300 for family plans in 2017)[17], out-of-pocket costs for prescription drugs, and for specialty drugs in particular, can weigh heavily on beneficiaries.[18] As noted above[19], higher levels of cost-sharing are linked to higher levels of cost related non-adherence.[20] By capping prescription drug cost sharing amounts at $250 per month for individuals and $500 per month for families, this section would curtail the financial strain of prescription drugs on patients and reduce cost related non-adherence.

TITLE III—INNOVATION

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

This section would establish in the U.S. Treasury an Antibiotics Prize Fund of two billion dollars in FY2018. The Director of NIH would establish public criteria and goals that contribute to the advancement of research in the field in order to qualify for the prizes, in addition to reasonable pricing, waiving of patent rights, and government authority to clawback the prize from noncompliant awardees. The Director would enter into an agreement with the National Academies of Sciences, Engineering, and Medicine to conduct a study on the efficacy of prize funds and models of delinking the costs of research and development from drug prices.

Sec.301 Context

The Antibiotic Resistance Coalition, an international collection of civil society groups, in its declaration states, "Antibiotic resistance threatens to undermine the effectiveness of modern medicine … lack of effective antibiotics is a global concern with the potential to affect all humans and domesticated animals," and "the policy frameworks for research and development are further fueling resistance without advancing innovation." [21] The prize fund provided under this section provides an alternative to the monopoly-based framework that has failed to provide the world with "a truly new

[17] https://www.healthcare.gov/glossary/out-of-pocket-maximum-limit/
[18] https://cdn.americanprogress.org/wp-content/uploads/2015/09/15131852/DrugPricingReforms-report1.pdf
[19] See discussion of section 203 above.
[20] https://cdn.americanprogress.org/wp-content/uploads/2015/09/15131852/DrugPricingReforms-report1.pdf
[21] http://abrdeclaration.org/wp-content/uploads/2014/11/ARC-Declaration-22-May.pdf

class of antibiotics for decades."[22] The prize fund is a market-based approach that has been endorsed by experts[23] and lauded by proponents of delinking the costs of R&D from the prices of medicines.[24,25]

Sec.302.Public funding for clinical trials.

This section would establish at the NIH a Center for Clinical Research, for the purpose of conducting clinical trials on drugs. The Director of the Center would establish and publish criteria for acquiring patent rights and selecting drugs to ensure they address an existing or emerging need. When said drug receives FDA approval, the Director would 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 publically available.

Sec.302 Context

The monopoly-based system of using patent monopolies and other exclusivities to provide incentive for biomedical innovation and R&D leads directly to high drug prices.[26] One approach supported by proponents of delinkage[27] is to provide direct public funding of clinical trials.[28] The U.S. government is already the largest funder of biomedical R&D[29]. Economist Dean Baker argues that the increased burden on the government shouldering the costs of trials would easily be recouped by lower medicine prices.[30] This section would provide a limited space in which to further explore an important alternative system of innovation to reliance on monopolies and the prices imbedded in such an approach.

Sec.303.Rewarding innovative drug development.

This section would reduce the periods and applicability of certain FDA-granted exclusivities. New Chemical Entity data exclusivity would be reduced from five to three years, while new drug application marketing exclusivity would be maintained for five years after approval. Biologic exclusivity would be reduced from 12 to seven years. 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 during a certain timeframe. This section would also require the GAO to conduct a study and submit to Congress a report on orphan drugs, including Medicare and

[22] https://amr-review.org/sites/default/files/160525_Final%20paper_with%20cover.pdf
[23] Ibid.
[24] http://keionline.org/node/848
[25] https://www.chathamhouse.org/sites/files/chathamhouse/field/field_document/20151009NewBusinessModelAntibioticsCliftGopinathanMorelOuttersonRottingenSo.pdf
[26] https://www.theguardian.com/commentisfree/cifamerica/2011/may/31/healthcare-pharmaceuticals-industry
[27] http://delinkage.org/
[28] http://delinkage.org/mechanics/direct-funding/
[29] Ibid.
[30] http://cepr.net/documents/publications/clinicaltrials_2008_03.pdf

Medicaid expenditures on such products and more in-depth pricing and usage information for a sample of products.

Sec.303 Context

FDA-granted exclusivities enable companies to prevent cost-lowering generic competition, even in the absence of unexpired patent protections on the product. Reducing data exclusivity for new chemical entities from five to three years would expedite generic competition by allowing the FDA to consider generic drug applications earlier in the process, enabling generics to immediately enter the market at the expiration of the five-year market protection provided to the brand-name drug company.

Reducing biologics exclusivity from 12 to seven years would allow earlier biosimilar competition. HHS estimates it would provide nearly seven billion dollars in savings to the federal government over ten years.[31]

Restricting an applicant's exclusivities to supplements that show a significant clinical benefit over its existing therapies would help to curb a practice known as "product hopping" – when companies develop and shift patients to newer therapies that show no greater clinical benefit than the original therapy, in order to maintain its monopoly protection. This section would limit this popular tactic employed by prescription drug corporations to maintain high revenues on older therapies.

The United States currently grants an exclusivity period of seven years for 'orphan indications', or uses of a medicine for the treatment of a disease for which fewer than 200,000 patients are indicated in the U.S., as well as an orphan drug tax credit wherein the government subsidizes up to 50% of clinical trial costs. These lucrative benefits provided for orphan drugs and recent reports of apparent abuses have led to congressional calls for investigation, which this section would mandate.[32] Since the drafting of this bill, the Government Accountability Office has already announced that it will be conducting a study on potential abuses of the Orphan Drug Act, but is still determining the scope of its investigation.[33]

Sec.304.Improving program integrity.

This section would rescind FDA granted exclusivities to a person who is found to have committed a violation under this section with respect to that drug. Violations range from the misbranding of a drug, to defrauding the federal or state government, among other areas. Failure to report violations would result in a fine of $200,000 per day so long as the violation persists.

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[31] https://schakowsky.house.gov/press-releases/schakowsky-brown-mccain-introduce-bipartisan-legislation-to-lower-costs-of-lifesaving-drugs/

[32] http://www.npr.org/sections/health-shots/2017/03/22/521081742/gao-will-investigate-skyrocketing-prices-for-orphan-drugs

[33] Ibid.

Sec.304 Context

Currently, even when a prescription drug corporation is found guilty of a crime relating to a drug, the U.S. government still provides market protections to the offending company for that very same product. A Public Citizen study found that from 1991 through 2015, prescription drug corporations entered into 373 settlements totaling $35.7 billion in criminal penalties.[34] This section would deter the pharmaceutical industry from committing abuses by terminating market exclusivities for the related product.

TITLE IV—CHOICE AND COMPETITION

Sec.401.Preserving access to affordable generics.

This 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 in violation of this section if the abbreviated new drug application (ANDA) filer agrees to delay development or sale of the implicated generic drug in exchange for anything of value, with some exclusions. Entities subject to FTC enforcement may petition the order to be reviewed in federal court within 30 days of the order's issuance. Violations of this section would result in civil penalties no greater than three times the value given to the responsible party.

Sec.401 Context

Brand name prescription drug corporations and generic firms sometimes enter into patent settlements wherein brand-name companies pay generic firms not to bring low-cost generic versions of their brand-name prescription drug product on the market for a certain period of time, also known as "pay-for-delay".[35] The FTC estimates that this practice costs U.S. consumers $3.5 billion in higher drug costs each year.[36] While in recent years the FTC has been stepping up actions to stop these anticompetitive deals, the commission rightly supports legislation to end these deals.[37] This section would provide the FTC with the legal tools it needs to curtail this anti-consumer, anticompetitive practice.

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

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

These sections would amend the Federal Food, Drug and Cosmetic Act by disqualifying a generic drug applicant from receiving "first applicant" 180-day exclusivity under certain circumstances that would

[34] http://www.citizen.org/hrg2311
[35] https://www.ftc.gov/news-events/media-resources/mergers-competition/pay-delay
[36] Ibid.
[37] Ibid.

delay marketing of the generic drug, also known as "pay for delay". It would expand the definition of "first applicant" to certain subsequent applicants. A "first applicant" that has entered into a disqualifying agreement would be prohibited from beginning marketing for a specified period of time.

Sec.402&403 Context

Under current law, when a generic drug applicant is the first to file an ANDA and the application includes certification that the drug for which the firm is seeking approval does not violate any patent of the brand-name company, the U.S. government grants that generic firm a 180-day period excluding additional generic competitors.[38] Even if found to have entered into a pay-for-delay deal, under current law, the generics firm would still be granted this exclusivity. These sections would close this loophole and prohibit generic firms that enter into pay-for-delay deals from being granted 180-day exclusivity.

Sec.404.Increasing generic drug competition.

This section would require the FDA commissioner to publish on the FDA website a complete list of all generic drugs and related pertinent information to increase generic drug competition. It would also require entities engaged in the production of drugs or devices to register any contract. Manufacturers of all drugs would be required to notify the Secretary of any discontinuance or interruption of the production of any drug that is likely to lead to a disruption of its U.S. supply. If the Secretary determines that there are less than two manufacturers of an approved drug or biologic, the Secretary may take specific measures intended to increase the number of manufacturers and establish related guidelines.

Sec.404 Context

This section would help to identify more quickly drugs that are at risk of shortage or that have a limited number of competitors by requiring HHS to maintain an up-to-date public list of generic drugs and their manufacturers. Requiring public transparency as well as other measures in the section, such as waiving application fees under certain circumstances, may help increase generic competition.

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

This section would disallow tax deductions for expenses relating to direct-to-consumer (DTC) 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.

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38 https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm147166.htm

Sec.405 Context

The U.S. is one of two developed countries to allow prescription drug corporations to advertise their products directly to consumers on television and other media[39], with industry spending more than four billion dollars on such advertisements annually.[40] Even further, the U.S. government provides corporations with tax deductions for these advertisements. One negative consequence of DTC advertisements is the resulting higher costs paid by patients and taxpayers as drug corporations steer consumers to more expensive treatment options.[41] The American Medical Association has called for an outright ban on DTC advertising.[42] While first amendment rules make an outright ban difficult, this section would help to curtail the practice by removing the related tax benefits given to drug corporations.

Sec.406.Product Hopping.

This section 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, a form of evergreening in which a manufacturer reformulates an existing product to attain a new FDA approval for a product that treats the same condition, and takes action to shift patients to the new product. It would also require the FTC to issue guidelines on circumstances in which product hopping raises anticompetitive concerns or is considered a violation of antitrust laws.

Sec.406 Context

Prescription drug corporations engage in product hopping to maintain high profits from medicines that will soon lose monopoly protections.[43] MSF, rightly, has labeled such evergreening tactics as "an attack on access to medicines."[44] While strong legislation is needed to stop this expensive and anti-consumer practice, the FTC study and report required by this section would provide an important step towards more robust legislative action.

[39] https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm107170.htm
[40] http://www.fiercepharma.com/dtc-advertising/pharma-s-ad-spend-vaults-to-4-5b-big-spender-pfizer-leading-way
[41] http://www.who.int/bulletin/volumes/87/8/09-040809/en/
[42] https://www.ama-assn.org/content/ama-calls-ban-direct-consumer-advertising-prescription-drugs-and-medical-devices
[43] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3680578/
[44] https://www.msfaccess.org/content/evergreening-drugs-attack-access-medicines-0