

## Policy Tracker Archive

114<sup>th</sup> United States Congress (January 3<sup>rd</sup>, 2015 – January 3<sup>rd</sup>, 2017)

Purported Policy Intent	Policy Mechanisms	Proposals	Source
Accountability and Oversight	Limit influence of branded manufacturers on patient decision-making	[Responsibility in Drug Advertising Act of 2016; Introduced 02/12/2016] Amend the Federal Food, Drug, and Cosmetic Act to restrict direct-to-consumer drug advertising.	<a href="#">Rep. DeLauro (D-CT)</a>
Accountability and Oversight	Limit influence of branded manufacturers on patient decision-making	[Protecting Americans from Drug Marketing Act; Introduced 03/03/2016] Amend the Internal Revenue Code to deny a tax deduction for the cost of direct-to-consumer advertising of prescription drugs.	<a href="#">Sen. Franken (D-MN)</a>
Accountability and Oversight	Manufacturer Transparency	[Prescription Drug Affordability Act of 2015; Introduced 09/10/2015] Require drug companies to report not only the price information charged to federal payers, but also requires companies to submit prices, profits, and sale information in other countries in which those products are sold.	<a href="#">Sen. Sanders (I-VT)</a>
Accountability and Oversight	Manufacturer Transparency	[Prescription Drug Affordability Act of 2015; Introduced 09/10/2015] Require pharmaceutical companies to publicly report information that affects drug pricing, including the total costs incurred for research and development and clinical trials, as well as the portion of drug development expenses offset by tax credits or paid by federal grants.	<a href="#">Sen. Sanders (I-VT)</a>
Foster Competition	Drug importation for noncompetitive markets	[Pharmaceutical Supply and Value Enhancement Act; 09/28/2016] Allow for the expedited approval and temporary importation of generic prescription drugs in the case of noncompetitive drug markets (fewer than five holders of approved applications for brand or generic versions of the drug, drug has been approved for at least 10 years, or patents on the active ingredient of a drug have expired).	<a href="#">Sen. Klobuchar (D-MN)</a>
Foster Competition	Drug importation for noncompetitive markets	[Pharmaceutical Supply and Value Enhancement Act; Introduced 09/28/2016] Allow for importation of prescription drugs in the case of noncompetitive drug markets or drug shortages.	<a href="#">Sen. Klobuchar (D-MN)</a>
Foster Competition	Ensure competitive access to drug samples	[FAST Generics Act of 2015; Introduced 06/18/2015] Amend the Federal Food, Drug, and Cosmetic Act to ensure that eligible product developers have competitive access	<a href="#">Rep. Stivers (R-OH)</a>

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		to approved drugs and licensed biological products, so as to enable eligible product developers to develop and test new products, and for other purposes.	
Foster Competition	Incentivize generic and biosimilar entry	[SAVINGS Act; Introduced 09/22/2016] Require the FDA to expedite the review of second generics and make a final decision within 150 days of receiving these Priority Review Abbreviated New Drug Applications.	<a href="#">Sen. Cotton (R-AR)</a>
Foster Competition	Incentivize generic and biosimilar entry	[Pharmaceutical Supply and Value Enhancement Act; Introduced 09/28/2016] Allow for the expedited approval and temporary importation of generic prescription drugs in the case of noncompetitive drug markets (fewer than five holders of approved applications for brand or generic versions of the drug, drug has been approved for at least 10 years, or patents on the active ingredient of a drug have expired).	<a href="#">Sen. Klobuchar (D-MN)</a>
Foster Competition	Limit anticompetitive behaviors by manufacturers	[FAIR Generics Act; Introduced 01/08/2015] Disqualify from being a “first applicant” (which grants 180 days of market exclusivity) any ANDA applicant (for a generic drug) that has entered into a “pay for delay” agreement.	<a href="#">Sen. Vitter (R-LA)</a>
Foster Competition	Limit anticompetitive behaviors by manufacturers	[Prescription Drug Affordability Act of 2015; Introduced 09/10/2015] Prohibit anti-competitive arrangements between brand and generic drug makers where the brand name drug manufacturers pays the generic manufacturer to delay bringing their generic alternative to market.	<a href="#">Sen. Sanders (I-VT)</a>
Foster Competition	Limit anticompetitive behaviors by manufacturers	[EPI Act; Introduced 09/28/2016] Prohibit a company that holds the patent for a brand-name pharmaceutical product from also introducing an authorized generic.	<a href="#">Rep. Smith (D-WA)</a>
Foster Competition	Reduce market monopoly	[PRICED Act; Introduced 06/23/2016] Amend the Public Health Service Act to shorten the exclusivity period for brand name biological products from 12 to 7 years.	<a href="#">Sen. Brown (D-OH)</a>

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Limit Price Inflation	Impose a financial disincentive on manufacturers for drug prices that are increasing faster than inflation. Examples include excise taxes and rebates.	[Prescription Drug Affordability Act of 2015; Introduced 09/10/2015] Require generic drug manufacturers to pay an additional rebate to Medicaid if their drug prices rise faster than inflation, mirroring the current requirements for brand name drug makers.	<a href="#">Sen. Sanders (I-VT)</a>
Reduce costs and improve access for patients	Allow for the importation of FDA-approved drugs from other countries	[Prescription Drug Affordability Act of 2015; Introduced 09/10/2015] Allow individuals, pharmacists, and wholesalers to import prescription drugs from licensed Canadian pharmacies.	<a href="#">Sen. Sanders (I-VT)</a>
Reduce costs and improve access for patients	Lower out-of-pocket (OOP) costs	[Prescription Drug Affordability Act of 2015; Introduced 09/10/2015] Close the Medicare Part D donut hole for brand and generic drugs by 2017, three years earlier than under current law.	<a href="#">Sen. Grassley (R-IA)</a>
Reduce costs for government health programs	Allow the Medicare program to negotiate with manufacturers	[Prescription Drug Affordability Act of 2015; Introduced 09/10/2015] Instruct the Secretary of HHS to negotiate drug prices under the Medicare Part D prescription drug program.	<a href="#">Sen. Sanders (I-VT)</a>
Reduce costs for government health programs	Allow the Medicare program to negotiate with manufacturers	[Medicare Fair Drug Pricing Act of 2015; Introduced 12/09/2015] Require the Secretary of HHS to negotiate for the price of drugs covered by Medicare Part D that are either sole source drugs or biologics and are not manufactured by more than two drug manufacturers.	<a href="#">Rep. Schakowsky (D-IL)</a>
Reduce costs for government health programs	Increasing manufacturer rebates to government programs	[Medicare Drug Savings Act of 2015; Introduced 04/23/2015] Require drug makers to provide Medicare the same rebates as Medicaid for low-income individuals.	<a href="#">Sen. Nelson (D-FL)</a>
Reduce costs for government health programs	Increasing manufacturer rebates to government programs	[Prescription Drug Affordability Act of 2015; Introduced 09/10/2015] Restore minimum rebate on drugs covered under Medicare Part D for low income Medicare beneficiaries, previously eliminated in the creation of Part D.	<a href="#">Sen. Sanders (I-VT)</a>