Durbin joins milestone effort to bring down prescription drug prices

March 30 2017 10:07 AM

Landmark Proposal Introduced by Key Senate Democrats to Improve the Affordable Care Act by Addressing Skyrocketing Drug Prices

WASHINGTON - In the wake of Congressional Republicans' failed attempt to rip health coverage away from millions of Americans, Senator Dick Durbin (D-IL) joined Senator Al Franken (D-MN) in launching a major push to improve the Affordable Care Act (ACA) by bringing down the skyrocketing price of prescription drugs, one of the main reasons why health care costs are rising.

An overwhelming majority of Americans agree that prescription drug prices are too high and that we need action to lower prices. The *Improving Access to Affordable Prescription Drugs Act*would help ensure that drug companies put patients before

profits and bring some much-needed relief to families and seniors, including many who have had to make the impossible choice between paying for a life-saving drug and putting food on the table.

This important legislative package was introduced today by Senators Franken and Durbin, Bernie Sanders (I-VT), Sheldon Whitehouse (D-RI), Sherrod Brown (D-OH), Amy Klobuchar (D-MN), Elizabeth Warren (D-MA), Tammy Baldwin (D-WI), Jack Reed (D-RI), Kirsten Gillibrand (D-NY), Maggie Hassan (D-NH), Chris Van Hollen (D-MD), Jeff Merkley (OR), Tom Udall (D-NM), Richard Blumenthal (D-CT), and Cory Booker (D-NJ).

The landmark proposal, which the senators said they want to see included in upcoming legislative debates, seeks to tackle prescription drug costs by increasing transparency and accountability, boosting access and affordability of key drugs, spurring innovation, and increasing choice and competition.

"Too many Americans are forced to choose between paying for life-saving medicine and providing for their families, even as pharmaceutical companies continue raking in record profits," said Senator Durbin. "It's long past time for Congress to put people over profits. This legislation would help curb price hikes and bring much-needed transparency to price setting in the prescription drug industry."

"We need to bring down prescription drug prices. No American should have to skip meals or turn off their heat in order to afford needed medications," said Senator Franken. "But right now, that's exactly what's happening. Companies are putting profits before people and setting prices far beyond the reach of Minnesotans, which is driving up costs. Our comprehensive legislation will bring down prescription drug prices. We are working on real solutions to address real problems facing Americans. I strongly urge Congress, and the President-who has committed to addressing drug prices-to make this legislative package a top priority.

The senators' legislation is supported by the American Medical Student Association (AMSA), AFSCME, Housing Works, MoveOn, National Committee to Preserve Social Security & Medicare. National Physicians Alliance, Other98, People of Faith for Access to Medicines (PFAM), Public Citizen, Social Security Works, Universities Allied for Essential Medicines (UAEM), AFT, Doctors for America, Center for Medicare Advocacy, and Alliance for Retired Americans.

A companion bill was introduced in the House of Representatives by Reps. Jan Schakowsky (D-IL), Elijah Cummings (D-MD), Rosa DeLauro (D-CT), and Peter Welch (D-VT).

You can read more about the legislation here or below:

Improving Access to Affordable Prescription Drugs Act

Title I: Transparency

Section 101: Drug manufacturer reporting.

To better understand how research and development costs, manufacturing and marketing costs, acquisitions, federal investments, revenues and sales, and other factors influence drug prices, this section requires drug manufacturers to disclose this information, by product, to the Secretary of the Department of Health and Human Services (HHS), who, in turn, will make it publicly available in a searchable format.

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

To better understand how patient assistance programs affect drug prices and the extent to which drug makers are using independent charity assistance programs to drive up profits, this section requires independent charity assistance programs to disclose to the IRS the total amount of patient assistance provided to patients who are prescribed drugs manufactured by any contributor to the independent charity assistance program. It also requires a GAO study on the impact of patient assistance programs on prescription drug pricing and expenditures.

Title II: Access and Affordability

Section 201: Negotiating fair prices for Medicare prescription drugs.

Medicare is one of the largest purchasers of prescription drugs in the country but, unlike Medicaid and the Department of Veterans Affairs (VA), it is not allowed to leverage its purchasing power to negotiate lower drug prices and bring down costs. This section would allow the Secretary of HHS to negotiate with drug companies to lower prescription drug prices, and directs the Secretary to prioritize negotiations on specialty and other high-priced drugs.

Section 202: Prescription drug price spikes.

Prescription drugs are priced in the United States according to whatever the market will bear and are sometimes subject to drastic and frequent price increases without apparent justification. This makes drugs increasingly unaffordable and creates significant uncertainty for patients' and insurers' budgets. This section requires the HHS Office of

the Inspector General (HHS OIG) to monitor changes in drug prices and take steps to prevent drug manufacturers from engaging in price gouging.

Section 203: Acceleration of the closing of the Medicare Part D coverage gap.

This section closes the Medicare Part D prescription coverage gap in 2018, two years earlier than under current law, providing faster financial relief to seniors, and requires drug manufacturers to pay a larger share of the costs during the coverage gap.

Section 204: Importing affordable and safe drugs.

This section allows wholesalers, licensed U.S. pharmacies, and individuals to import qualifying prescription drugs manufactured at FDA-inspected facilities from licensed Canadian sellers and, after two years, from OECD countries that meet standards comparable to U.S. standards.

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

This section restores prescription drug rebates for seniors who are dually eligible for Medicare and Medicaid and extends these rebates to other Medicare patients in Medicare low-income-subsidy plans.

Section 206: Cap on prescription drug cost-sharing.

For plan years beginning in 2019 and later, this section caps prescription drug cost sharing at $250 per month for individuals and $500 a month for families enrolled in Qualified Health Plans and employer-based plans.

Title III: Innovation

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

This section creates a $2 billion prize fund at the National Institutes of Health to fund entities that develop superior antibiotics that treat serious and life-threatening bacterial infections and to fund research that advances such treatments and is made publicly available. In order to receive prize funds, recipients must commit to offering their products at a reasonable price, share clinical data, and take steps to promote antibiotic stewardship.

Section 302: Public funding for clinical trials.

This section creates a Center for Clinical Research within the NIH to conduct all stages of clinical trials on drugs that may address an existing or emerging health need.

Section 303: Rewarding innovative drug development.

This section amends various exclusivity periods awarded by the FDA to brand-name pharmaceutical companies in an effort to accelerate competition in the generic and biologics market. First, the bill modifies the New Chemical Entity (NCE) exclusivity period to allow FDA to accept a generic drug application for the branded product after three years rather than five. Second, this section would add in a requirement that products awarded the 3-year New Clinical Investigation Exclusivity must show significant clinical benefit over existing therapies manufactured by the applicant in the 5-year period preceding the submission of the application. Third, this section reduces the biological product exclusivity from 12 years to 7 years.

Section 304: Improving program integrity.

This section would terminate any remaining market exclusivity periods on any product found to be in violation of criminal or civil law through a federal or state fraud conviction or settlement in which the company admits fault.

Title IV: Choice and Competition

Section 401: Preserving access to affordable generics.

This legislation would make it illegal for brand-name and generic drug manufacturers to enter into anti-competitive agreements in which the brand-name drug manufacturer pays the generic manufacturer to keep more affordable generic equivalents off the market.

Section 402 and 403: 180-Day exclusivity period amendments regarding first applicant status and agreements to defer commercial marketing.

This section enables FDA to take away the 180-day generic drug exclusivity period from any generic company that enters into anti-competitive pay-for-delay settlements with brand-name drug manufacturers.

Section 404: Increasing generic drug competition.

This section introduces new reporting requirements and financial incentives to promote and sustain competitive generic markets.

Section 405: Disallowance of deduction for advertising for prescription drugs.

This section eliminates the tax breaks drug companies receive from the federal government for expenses related to direct-to-consumer advertising.

Section 406: Product hopping.

This section establishes a definition for the term "product hopping" and instructs the FTC to submit a report to Congress on the extent to which companies engage in these anti-competitive practices and their effects on company profits, consumer access, physician prescribing behavior, and broader economic impacts.