CONSUMERS F1RST

The Alliance to Make the Health Care System Work for Everyone

January 6, 2020

The Honorable Nancy Pelosi
Speaker
U.S. House of Representatives
Washington, DC 20515

The Honorable Mitch McConnell
Majority Leader
United States Senate
Washington, DC 20510

The Honorable Kevin McCarthy
Minority Leader
U.S. House of Representatives
Washington, DC 20515

The Honorable Chuck Schumer
Minority Leader
United States Senate
Washington, DC 20510

Dear Speaker Pelosi, Leader McConnell, Leader McCarthy, and Leader Schumer:

Consumers First is a new alliance that brings together interests from consumers, children, employers, labor unions, and primary care providers working to change the fundamental economic incentives and design of the health care system. Our work is to realign the incentives and design of health care so that the system truly delivers the health and high quality care that all families across our nation deserve. Together, we are working to ensure that the nation's health care system finally fulfills its obligation to the people it serves by providing affordable, high-quality, cost-effective care to everyone.

High and rising prices of prescription drugs impact consumer's access to the medicines they need and even impact their ability to afford other health services and basic necessities. Families, employers, health care providers and labor unions are eager for Congress to enact reforms that will rein in high drug costs that put undue burden on families and purchasers. We were pleased with last year's passage of the Creating and Restoring Equal Access to Equivalent Samples Act (CREATES Act), legislation that will prevent brand-name pharmaceutical companies from blocking biosimilar or generic drug manufacturers from obtaining the samples needed to bring generic drugs to market faster; however, more action is needed. *Consumers First* is very supportive of and encouraged by the bipartisan efforts in Congress to pass prescription drug reform legislation. Although *Consumers First* has not endorsed a specific proposal, we do support various provisions from across several proposals in the Senate and House, including provisions within:

- S.1895, "Lower Health Care Cost Act"
- S.2543, "The Prescription Drug Pricing Reduction Act of 2019"
- S.64, "The Preserve Access to Affordable Generics and Biosimilars Act"
- H.R.3, "The Lower Drug Costs Act Now"
- H.R.1499, "Protecting Consumer Access to Generic Drugs Act of 2019"
- H.R. 1520, "The Purple Book Continuity Act of 2019"
- H.R. 1503, "Orange Book Transparency Act of 2019"

While these bills take a broad approach to addressing the underlying drivers of high prescription drug costs, they do not address these costs for specific vulnerable populations such as children, people with disabilities or those with rare conditions. We urge you to consider the provisions below, which we

believe bring down prescription drug costs and improve access to life-saving prescription drugs for consumers and purchasers. And, we urge you to consider approaches to bring down prescription drug costs for vulnerable populations including children.

Consumers First believes that we cannot significantly reduce the escalating cost of drugs without overarching reforms that will lower list prices, increase transparency and promote competition. Prescription drug reforms must directly target these prices, which drive high costs throughout the drug supply chain and health care system, keeping needed medicines out of reach for families. To that end, ***Consumers First* urges Congress to include the following provisions to lower prescription drug prices and protect consumers:**

- Restructure the Medicare Part D benefit to significantly lower the out-of-pocket maximum that beneficiaries will pay, and that reduce federal reinsurance payments for catastrophic coverage. Such provisions are included in H.R. 3 and S.2543.

- Limit price increases for Part D drugs and for single source drugs in Medicare Part B to the Consumer Price Index for All Urban Consumers (CPI-U). Manufacturers who raise prices on single source Part B drugs and brand name Part D drugs above the rate of inflation must rebate the difference to Medicare. Such provisions are included in H.R. 3 and S.2543.
    - If an inflation rebate mechanism is enacted, such as described above, protections should be included to prohibit drug companies from cost-shifting to employer plans.

- Require drug manufacturers to report to the Secretary of Health and Human Services information and supporting documentation to justify price increases for drugs and biological products. Require the Secretary to publicly post those price justifications. Such provisions are included in H.R. 3 and S.2543.

- Modify the transparency tool established under the 21st Century Cures Act of 2015 to require comparable information for services that can also be furnished in a physician office to ensure beneficiaries are not responsible for coinsurance generated from site of service payment differentials for Medicare Part B services. Such a provision is included in S.2543.

- Disclosure to plan sponsors of drug discounts established between insurers and Pharmacy Benefit Managers (PBMs), and between PBMs and specialty, mail order and retail pharmacies. Such provisions are included in S.1895.

- Require HHS to make public information on aggregate price concessions including rebates and discounts, and the aggregate amount of the different between what insurers pay a PBM and what a PBM pays retail and mail order pharmacies. Ensure the Secretary displays the information in a manner that prevents the disclosure of price concessions with respect to an individual drug or an individual plan in order to preserve competition for lower drug prices. Such a provision is included in S. 2543.

- Prohibit PBMs from engaging in spread pricing, or charging a plan sponsor, health insurance plan or patient more for a drug that what the PBM paid to acquire the drug. Require PBMs to pass on any rebates or discounts to the plan sponsor. Such a provision is included in S.1865.

Consumers First also supports measures that bring generics to market faster, providing lower cost alternatives to costly, monopolistic brand-name drugs. Specifically, we support provisions that will provide greater transparency on patents for biologics, including on exclusivity periods and when they are expired, so that generic manufacturers have the timely and accurate information they need to come to market. We also support provisions which include important measures to prevent gaming that can delay the availability of generics.

***Consumers First* urges Congress to include the following provisions in prescription drug legislation:**

- Prohibit certain "pay-for-delay" agreements used to settle claims of patent infringement between sponsors of brand-name, generic, or biosimilar drugs relating to the sale of a drug or biological product. Such a provision is included in H.R.1499 and S.64.

- Prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market; and prohibit biological product manufacturers from compensating biosimilar and interchangeable companies to delay the entry of biosimilar biological products and interchangeable biological products. Such provisions are included in S.64.

- Increase transparency of patent information for biological products by requiring information to be submitted to the Food and Drug Administration and published in the "Purple Book", and that codifies the "Purple Book" as a single, searchable list of information about licensed biological products. Such a provision is included in S.1895 and H.R. 1520.

- Requires the Secretary, in consultation with the Director of the U.S. Patent and Trademark Office, to publish a list of any holders of biological product licenses that failed to submit such information; and require FDA to remove patents and patent claim information from the Orange Book when the U.S. Patent and Trademark Office determines a patent or patent claim is invalid or inoperative to encourage drug development in the area no longer patented. Such provisions are included in S.1895 and H.R. 1503.

- Maintain the use of citizen petitions to allow interested stakeholders, including drug companies, to notify FDA of concerns with pending generic and other follow-on drug applications; Address the abuse of the citizen petition process, which can be used to unnecessarily delay the approval of a drug application. Such a provision is included in S.1895.

- Prevent first-to-file generic drug applicants from blocking, beyond a 180-day exclusivity period, the entrance of subsequent generic drugs to market. Such a provision is included S.1895 and H.R. 938.

- Ensures that drug manufacturers cannot receive new chemical entity (NCE) exclusivity for making small tweaks to old drugs, and that only the most innovative or novel drugs quality for exclusivity. Such a provision is included in S.1895.

Thank you for considering the above provisions. Please contact Shawn Gremminger, Senior Director of Federal Relations at Families USA (Sgremminger@familiesusa.org) for further information.

Sincerely,

Consumers First Steering Committee

American Academy of Family Physicians
American Benefits Council
American Federation of State, County, and Municipal Employees
American Federation of Teachers
Families USA
First Focus
Pacific Business Group on Health

Cc: The Honorable Frank Pallone, House Energy and Commerce Committee
The Honorable Greg Walden, House Energy and Commerce Committee
The Honorable Richard Neal, House Ways and Means Committee
The Honorable Kevin Brady, House Ways and Means Committee
The Honorable Bobby Scott, House Education and Labor Committee
The Honorable Virginia Foxx, House Education and Labor Committee
The Honorable Jerrold Nadler, House Judiciary Committee
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