SB-35

Reducing high-prescription drug prices and unsafe overprescription by regulating direct-to-consumer advertising and requiring increased pricing transparency for pharmaceutical companies.

IN THE SENATE OF THE AMERICAN LEGION BOYS NATION

Mr. Gautam of Georgia introduced the following bill;

A BILL

Reducing high-prescription drug prices and unsafe overprescription by regulating direct-to-consumer advertising and requiring increased pricing transparency for pharmaceutical companies.

Be it enacted by The American Legion Boys Nation Senate assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Pharmaceutical Pricing Regulation and Transparency Act of 2023".

SECTION 2. THE ISSUE

a. Direct-to-consumer advertising is only legal in two countries: the United States and New Zealand.

b. According to the CIDSA, over the next decade, more than 1.1 million seniors alone could die due to high prescription drug pricing, costing Medicare 475.9 billion dollars.

c. According to the Centre for Economic Policy Research, DTCA or Direct-to-Consumer Advertising increases prescription drug prices by 5%.

d. Though state laws exist to increase drug pricing transparency, any pharmaceutical company can set a drug price without justifying it to a federal agency.

e. A RAND corporation report finds that the U.S spends twice as much on pharmaceutical spending per capita than any other country combined.

f. DTC advertising also contributes to overprescription and misinformed use of drugs, while also increasing out-of-pocket costs by falsely portraying generic pharmaceutical drugs as inferior to brand-name drugs.

g. To remediate these problems, Section 3 and Section 4 outline regulations targeting drug pricing transparency and direct-to-consumer advertising.

SECTION 3. REGULATION OF DTCA

(a)The Federal Trade Commission, no more than a year after the passing of this bill, shall be required to regulate advertisements for prescription drugs before a consumer is exposed to the advertisement, the processes for regulation being outlined under subsection (b).

(b) Process of regulation:

1. The FTC will collaborate with the Food and Drug Administration to ensure that each statement made by the advertisement is an accurate representation of the clinical trials mentioned in the package insert/label for the drug.

2. The FTC will ensure that no statement in the advertisement can be perceived as promoting the brand name of the drug over the generic version of the drug unless robust clinical data supports that statement.

3. The FTC will require manufacturers to include, on all promotional materials including but not limited to websites and TV adverts, a clear depiction of adverse reactions spoken at a pace of no more than 200 words per minute or written above size 12 pt. font.

4. If, by section 3c, the advertisement is deemed misleading or in breach of regulations, the company will have no more than forty-five (45) days to revise their advertisement before they are

blocked from advertising that drug directly to consumers.

SECTION 4. FAIR PRICING JUSTIFICATION

I: For new drug manufacturers:

a. Before entering a market, a drug manufacturer must create a transparency report justifying their prices, including what percent of revenue will be used as profit, invested into research and development (RND), and used to recoup advertising costs.

b. The FDA and the U.S Department of Health and Human Services will be tasked with reviewing the transparency report. If pricing is deemed unreasonable, as outlined in section 4c, the HHS will reject the pricing application, and the drug manufacturer must adjust prices.

c. Regulations for pricing reasonability:

1. A pharmaceutical company is free to make profit; however, they must meet a 5% spending requirement on research and development if their price is above 100$.

II: For existing drug manufacturers with reference prices:

a. After the passing of this act, existing drug manufacturers have 1 year to create a transparency report justifying their prices.

b. These prices must be referenced to the next top 4 pharmaceutical markets, namely, China, Japan, Germany, and France.

c. If prices are more than twice their reference pricing ranges, drug manufacturers have 180 days to reduce their prices to less than twice the average price of the reference drug between the four outlined countries.

d. All pricing reasonability regulations outlined in 4.I.C.1 shall be applicable.