ASSEMBLY CONCURRENT RESOLUTION No. 119

STATE OF NEW JERSEY

219th LEGISLATURE

INTRODUCED FEBRUARY 20. 2020

Sponsored by:
Assemblyman GARY S. SCHAER
District 36 (Bergen and Passaic)

SYNOPSIS

Urges federal government to induce pharmaceutical manufacturers to review and extend pharmaceutical product expiration dates.

CURRENT VERSION OF TEXT

As introduced.

A CONCURRENT RESOLUTION urging the federal government to induce pharmaceutical manufacturers to review and extend pharmaceutical product expiration dates.

WHEREAS, The federal Food and Drug Administration (FDA) requires that all pharmaceutical products include an expiration date, which is intended to reflect the maximum period of time for which the manufacturer guarantees the product will remain at least 90 percent effective; and

WHEREAS, Manufacturers determine pharmaceutical expiration dates using stability testing, which involves exposing the product to extreme heat and moisture to determine how it degrades under stress and over time; and

WHEREAS, Manufacturers submit a proposed expiration date to the FDA, which will approve the date after confirming that it is supported by the available data. Expiration dates are typically set at one to five years after the date of manufacture; and

WHEREAS, Even after a pharmaceutical product is launched, manufacturers continue to test the product to confirm that the approved expiration date reflects a period during which the medication continues to be at least 90 percent effective. However, they do not currently evaluate whether the expiration date can be extended; and

WHEREAS, Generally, federal law requires pharmacies, government agencies, and other entities that maintain stockpiles of pharmaceutical products to dispose of products that have reached the labeled expiration date; and

WHEREAS, In 1986, as a cost-saving measure, the FDA and the Department of Defense (DOD) created the Shelf Life Extension Program to determine whether the expiration dates for various drugs could be extended. At least one study conducted under the program determined that approximately two-thirds of the 122 drugs tested remained stable past the approved expiration date, and, on average, these drugs remained at least 90 percent effective for more than four years after the expiration date; and

WHEREAS, As a result of the study, a number of federal entities, including the federal Centers for Disease Control and Prevention, the Department of Veterans Affairs, and the military, are permitted to retain stockpiles of certain medications beyond the approved expiration date; and

WHEREAS, According to one estimate, retaining pharmaceutical products beyond their expiration dates saves the federal government between $600 million and $800 million per year. Moreover, one DOD official reported that the Shelf Life Extension Program cost the DOD approximately $3.1 million to run in 2016, while netting cost savings of $2.1 billion, representing $677 in savings for each $1 spent; and

WHEREAS, Notwithstanding the findings of the Shelf Life Extension Program, pharmaceutical manufacturers have not opted to extend expiration dates for their products, and the FDA has not authorized entities outside the federal government to retain pharmaceutical products beyond their expiration date; and

WHEREAS, Requiring pharmacies and other entities to dispose of pharmaceutical supplies according to the labeled expiration date results in wasted product, drives up the cost of doing business for pharmacies, increases operational costs for law enforcement agencies, emergency medical services providers, and local and county health departments, and results in inflated prices that adversely affect health insurers and consumers alike; and

WHEREAS, It is therefore appropriate for the federal government to induce pharmaceutical manufacturers to review, evaluate, and extend the expiration dates for their products to reflect the true shelf life of those products; now, therefore,

BE IT RESOLVED *by the General Assembly of the State of New Jersey (the Senate concurring):*

1. The New Jersey Legislature respectfully urges the federal Food and Drug Administration, the Congress of the United States, and the President of the United States to take appropriate measures, including, but not limited to, enacting legislation, adopting regulations, and implementing executive actions, as may be necessary to induce pharmaceutical manufacturers to review, evaluate, and extend the expiration dates for their products to reflect the true shelf life of those products.

2. Copies of this resolution, as filed with the Secretary of State, shall be transmitted by the Clerk of the General Assembly or the Secretary of the Senate to the President and Vice President of the United States, the Commissioner of Food and Drugs, the Majority and Minority Leaders of the United States Senate, the Speaker and Majority and Minority Leaders of the United States House of Representatives, and each member of the United States Congress elected from New Jersey.

STATEMENT

This concurrent resolution respectfully urges the federal Food and Drug Administration (FDA) and the Congress and President of the United States to take appropriate measures to induce pharmaceutical manufacturers to review, evaluate, and extend the expiration dates for their products to reflect the true shelf life of those products.

Currently, pharmaceutical manufacturers propose expiration dates to the FDA that are intended to reflect the time period during which the product will remain at least 90 percent effective; the FDA approves these dates upon confirming they are supported by the available data. Pharmacies, government agencies, emergency medical response squads, county and local health departments, and other entities that stockpile pharmaceutical products are required to dispose of any products that have reached their expiration date.

In 1986, the FDA and the Department of Defense began the Shelf Life Extension Program, which found that many pharmaceutical products remain at least 90 percent effective for several years past the labeled effective date. In light of this, the federal government has allowed certain federal entities, including the federal Centers for Disease Control and Prevention, the Department of Veterans Affairs, and the military, to retain pharmaceutical products beyond the labeled expiration date, resulting in significant cost savings. However, this approval has not been extended to entities outside the federal government, which are still required to dispose of any pharmaceutical product that has reached its expiration date. This results in safe and effective products being wasted and increases costs for pharmacies, consumers, insurers, and the various entities that maintain pharmaceutical stockpiles.

Requiring pharmaceutical manufacturers to review and extend expiration dates for their products to accurately reflect the true shelf life of those products would be a significant step in helping realize cost savings in the pharmaceutical market, both within New Jersey and throughout the nation.