POSITION STATEMENT

DRUG SHORTAGES AND THE USE OF OUTDATED MEDICATIONS

POSITION

ASCP advocates for research to be conducted to determine the safety of medications extended past their documented expiration date, in an effort to reduce waste and allow for use when there is a shortage of medications.

PREAMBLE / BACKGROUND

The Federal Food, Drug and Cosmetic Act (FD&C Act) defines a “drug shortage” as a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug. The total number of new shortages in 2021 was 114. Over 60% of these products were injectables and 24% of medicines were sole source products. Common classes of drugs in short supply included: central nervous system agents, electrolytes, antibiotics, cardiovascular drugs, hormone therapies, gastrointestinal agents, and chemotherapy medicines.

Drug shortages can lead to inadequate medical care, medical mistakes, and increase possibility of fraudulent drug sales.

The three main causes of shortages include:

1. Lack of incentives to produce less profitable drugs,
2. Failure of the market to recognize and reward manufacturers for mature quality management systems, and
3. Logistical and regulatory challenges that make recovery after a supply disruption difficult.

Other causes of drug shortages include manufacturing issues, raw material shortages, increased demand, drug discontinuation, lack of financial incentive, and natural disasters.

ARGUMENTS

The expiration date of a medication is the final date that the manufacturer guarantees the full potency and safety of the medication. It is an estimated date using stability testing under good manufacturing practices as determined by the Food and Drug Administration (FDA).

The US Air Force started the Shelf Life Extension Program (SLEP) study in 1985 and later extended it to other military services in the early 1990s. The military had gathered a stockpile of medications worth more than a billion dollars that were close to or past their expiration dates. No one wanted to throw away expensive medications that might still be safe and effective. So, the drugs were extensively tested with oversight by the FDA. Most medications were still good nearly three years past their expiration dates.
Senate bill S.3493 was introduced on January 12, 2022, titled “Drug Shortages Shelf Life Extension Act”. This bill requires the FDA to issue or revise guidance to address issues relating to extending drug expiration dates. Specifically, the guidance must address recommendations to drug companies relating to (1) submitting stability testing data in applications for market approval for drugs or biological products; and (2) establishing on drug labels the longest feasible expiration date supported by such data, taking into consideration how extended expiration dates may help prevent or mitigate drug shortages.

The FDA must also periodically report to Congress certain information about requests to change the expiration date on a drug label, including the number of such requests from the FDA to the manufacturer and the rationale for each request.7

**SUMMATION**

Billions of dollars of medications are discarded each year based on expiration dates stamped on stock bottles.8 Additionally, repackaged medications, such as those dispensed in hospitals and nursing homes, are assigned expiration dates that prevent use after the designated period per US Pharmacopeia (USP) guidelines.9

Expiration dating may underestimate the shelf life of medications, and at least some medications are extremely stable over long periods of time. If shown by evaluation such as the SLEP, that some medications retain adequate potency, they should be used in the US during periods of critical drug shortages and/or donated to developing countries in which the usual commercial product is prohibitively expensive or not readily available. When medications are circulated that do not have specific potency data, an acceptable date limit should be identified.

More research should be conducted to determine a medication's potential for extended stability beyond the expiration date.

**REFERENCES**


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