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Expired Medicines Still Work, Study Says

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Do drugs really stop working after the date stamped on the bottle?

Fifteen years ago, the United States military decided to find out. Sitting on a \$1 billion stockpile of drugs and facing the daunting process of destroying and replacing its supply every two to three years, the military began a testing program to see if it could extend the life of its inventory.

The testing, conducted by the Food and Drug Administration, ultimately covered more than 100 drugs, prescription and over-the-counter. The results, never before reported, show that about 90 percent of them were safe and effective far past their original expiration date, at least one for 15 years past it.

In light of these results, a former director of the testing program, Francis Flaherty, says he has concluded that expiration dates put on by manufacturers typically have no bearing on whether a drug is usable for longer.

Flaherty notes that a drug maker is required to prove only that a drug is still good on whatever expiration date the company chooses to set. The expiration date doesn't mean, or even suggest, that the drug will stop being effective after that, nor that it will become harmful.

"Manufacturers put expiration dates on for marketing, rather than scientific, reasons," says Flaherty, a pharmacist at the FDA until his retirement last year. "It's not profitable for them to have products on a shelf for 10 years. They want turnover."

The FDA cautions that there isn't enough evidence from the program, which is weighted toward drugs needed during combat and which tests only individual manufacturing batches, to conclude that most drugs in people's medicine cabinets are potent beyond the expiration date. Still, Joel Davis, a former FDA expiration date compliance chief, says that with a handful of exceptions -- notably nitroglycerin, insulin and some liquid antibiotics -- most drugs are probably as durable as those the agency has tested for the military.

"Most drugs degrade very slowly," he says. "In all likelihood, you can take a product you have at home and keep it for many years, especially if it's in the refrigerator."

Drug-industry officials don't dispute the results of the FDA's testing, within what is called the Shelf Life Extension Program. And they acknowledge that expiration dates have a commercial dimension. But they say relatively short shelf lives make sense from a public-safety standpoint, as well.

New, more-beneficial drugs can be brought on the market more easily if the old ones are discarded within a couple of years, they say. Label redesigns work better when consumers don't have earlier versions on hand to create confusion. From the companies' perspective, any liability or safety risk is diminished by limiting the period during which a consumer might misuse or improperly store a drug.

"Two to three years is a very comfortable point of commercial convenience," says Mark van Arandonk, senior director for pharmaceutical development at Pharmacia & Upjohn Inc. "It gives us enough time to put the inventory in warehouses, ship it and ensure it will stay on shelves long enough to get used." But companies uniformly deny any effort to spur sales through planned obsolescence.

Now that the FDA has found that many drugs are still good long after they have supposedly expired, why doesn't it advocate later expiration dates for consumer drugs? One reason is that the consumer market lacks the military's logistical reasons to keep drugs around longer.

Frank Holcombe, associate director of the FDA's office of generic drugs, says that in many cases a manufacturer could extend expiration periods again and again, but to support those extensions, it would have to keep doing stability studies, and keep more in storage than it would like.

Davis adds: "It's not the job of the FDA to be concerned about a consumer's economic interest." It would be up to Congress to impose changes, he says.

"People think that, upon expiration, drugs suddenly turn toxic or lose all their potency," says Philip Alper, professor of medicine at the University of California San Francisco. In his own practice, Alper says, "I frequently hear -- from patients who can't afford medicine -- that they have thrown away expired drugs." He says companies should be required to test drugs for longer periods and set later expiration dates when results warrant.

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