
***Ed Note: While this article pertains to human use, info is applicable to veterinary use as well.**

DO MEDICATIONS REALLY EXPIRE ?

By Richard Altschuler

© September 9, 2002

Try An Experiment With Your Mother-In-Law

Does the expiration date on a bottle of a medication mean anything? If a bottle of Tylenol, for example, says something like "Do not use after June 1998," and it is August 2002, should you take the Tylenol? Should you discard it? Can you get hurt if you take it? Will it simply have lost its potency and do you no good?

In other words, are drug manufacturers being honest with us when they put an expiration date on their medications, or is the practice of dating just another drug industry scam, to get us to buy new medications when the old ones that purportedly have "expired" are still perfectly good?

These are the pressing questions I investigated after my mother-in-law recently said to me, "It doesn't mean anything," when I pointed out that the Tylenol she was about to take had "expired" 4 years and a few months ago. I was a bit mocking in my pronouncement - feeling superior that I had noticed the chemical corpse in her cabinet - but she was equally adamant in her reply, and is generally very sage about medical issues.

So I gave her a glass of water with the purportedly "dead" drug, of which she took 2 capsules for a pain in the upper back. About a half hour later she reported the pain seemed to have eased up a bit. I said "You could be having a placebo effect," not wanting to simply concede she was right about the drug, and also not actually knowing what I was talking about...

Upon my return to NYC and high-speed connection, I immediately scoured the medical databases and general literature for the answer to my question about drug expiration labeling. And voila, no sooner than I could say "Screwed again by the pharmaceutical industry," I had my answer. Here are the simple facts:

Expiration Date

First, the expiration date, required by law in the United States, beginning in 1979, specifies only the date the manufacturer guarantees the full potency and safety of the drug - it does not mean how long the drug is actually "good" or safe to use.

Second, medical authorities uniformly say it is safe to take drugs past their expiration date -- no matter how "expired" the drugs purportedly are. Except for possibly the rarest of exceptions, you won't get hurt and you certainly won't get killed. A contested example of a rare exception is a case of renal tubular damage purportedly caused by expired tetracycline (reported by G. W. Frimpter and colleagues in JAMA, 1963;184:111). This outcome (disputed by other scientists) was supposedly caused by a chemical transformation of the active ingredient.

Third, studies show that expired drugs may lose some of their potency over time, from as little as 5% or less to 50% or more (though usually much less than the latter). Even 10 years after the "expiration date," most drugs have a good deal of their original potency. So wisdom dictates that if your life does depend on an expired drug, and you must have 100% or so of its original strength, you should probably toss it and get a refill, in accordance with the cliché, "better safe than sorry." If your life does not depend on an expired drug - such as that for headache, hay fever, or menstrual cramps - take it and see what happens.

One of the largest studies ever conducted that supports the above points about "expired drug" labeling was done by the US military 15 years ago, according to a feature story in the Wall Street Journal (March 29, 2000), reported by Laurie P. Cohen. The military was sitting on a \$1 billion stockpile of drugs and facing the daunting process of destroying and replacing its supply every 2 to 3

years, so it began a testing program to see if it could extend the life of its inventory. The testing, conducted by the US Food and Drug Administration (FDA), ultimately covered more than 100 drugs, prescription and over-the-counter. The results showed that about 90% of them were safe and effective as far as 15 years past their original expiration date.

In light of these results, a former director of the testing program, Francis Flaherty, said he concluded that expiration dates put on by manufacturers typically have no bearing on whether a drug is usable for longer. Mr. Flaherty noted 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," said Mr. Flaherty, a pharmacist at the FDA until his retirement in 1999. "It's not profitable for them to have products on a shelf for 10 years. They want turnover."

The FDA cautioned there isn't enough evidence from the program, which is weighted toward drugs used during combat, to conclude most drugs in consumers' medicine cabinets are potent beyond the expiration date. Joel Davis, however, a former FDA expiration-date compliance chief, said 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 said. "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."

Consider aspirin. Bayer AG puts 2-year or 3-year dates on aspirin and says that it should be discarded after that. However, Chris Allen, a vice president at the Bayer unit that makes aspirin, said the dating is "pretty conservative;" when Bayer has tested 4-year-old aspirin, it remained 100% effective, he said. So why doesn't Bayer set a 4-year expiration date? Because the company often changes packaging, and it undertakes "continuous improvement programs," Mr. Allen said. Each change triggers a need for more expiration-date testing, and testing each time for a 4-year life would be impractical. Bayer has never tested aspirin beyond 4 years, Mr. Allen said. But Jens Carstensen has. Dr. Carstensen, professor emeritus at the University of Wisconsin's pharmacy school, who wrote what is considered the main text on drug stability, said, "I did a study of different aspirins, and after 5 years, Bayer was still excellent. Aspirin, if made correctly, is very stable."

Okay, I concede. My mother-in-law was right, once again. And I was wrong, once again, and with a wiseacre attitude to boot. Sorry mom. Now I think I'll take a swig of the 10-year dead package of Alka Seltzer in my medicine chest - to ease the nausea I'm feeling from calculating how many billions of dollars the pharmaceutical industry bilks out of unknowing consumers every year who discard perfectly good drugs and buy new ones because they trust the industry's "expiration date labeling."

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2003

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