

Title: Drug Expiration Date Testing Lengthening and Transparency

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Referred to: Reference Committee D

House Action:

Whereas, consumers are frequently and dangerously confronted with whether it is safe to take expired medications due to financial constraints and convenience, and many consumers end up taking such drugs^{1,2,3}, and

Whereas, the risks and benefits of such behavior are poorly understood because there is a general lack of public knowledge and transparency about the process of stability testing and the significance of drug expiration dates¹, and the FDA's directions for "reliable, meaningful, and specific" stability testing methods designed to determine expiration dates⁴ are poorly defined, and

Whereas, the AMA recognizes that studies examining the clinical and fiscal impact of expiration dates and especially of lengthening expiration dates are extremely limited to nonexistent⁵, and

Whereas, there is evidence that manufacturers significantly underestimate expiration dates, i.e., the Department of Defense/U.S. Food and Drug Administration Shelf Life Extension Program (SLEP) studied the safety and efficacy of drugs past their labeled expiration dates and extended expiration dates of 88 percent of 122 stockpiled drug products an average of 66 months^{7,8}, and

Whereas, other common civilian medications have been considered efficacious and safe well beyond labeled expiration dates^{3,12,14}, though the clinical significance of SLEP's results for civilian drugs, while suggestive, remains uncertain due to different storage conditions in military stockpiles versus civilian storage, and

Whereas, more accurate expiration date labeling could significantly reduce waste in the US's over \$230 billion¹⁰ annual drug expenditures: the military spent \$3.9 million on SLEP but saved \$263.4 million between 1993 and 1998³ out of an estimated \$1.2 billion annual drug costs⁹ by using drugs beyond their originally labeled expiration date deemed safe and effective by the FDA that would have otherwise been wastefully discarded and replaced, and

49 Whereas, patients, for whom rising costs are often prohibitive to filling
50 necessary prescriptions¹¹, may benefit from such cost savings if similar savings
51 would apply to the civilian world, and

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53 Whereas, offices, clinics, and hospitals statewide currently discard
54 significant amounts of ‘expired’ but potentially safe and effective medicines with
55 resultant monetary waste, and potentially overly conservative expiration dates
56 may waste needed resources and thus impede the alleviation of human suffering
57 in domestic and international relief efforts^{3,13}, and

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59 Whereas, pharmaceutical manufacturers are not required to perform
60 stability testing beyond labeled expiration dates to test for efficacy or toxicity
61 because extension of expiration dates is entirely voluntary by drug companies⁵,
62 the result being highly conservative dates⁶; therefore be it

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64 **RESOLVED:** That MSMS incorporate AMA’s support for more rigorous,
65 scientifically based stability testing for prescription drugs into its policies; and
66 be it further

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68 **RESOLVED:** That the Michigan Delegation to the AMA ask the AMA to
69 encourage the U.S. Food and Drug Administration and the federal government to
70 more rigorously define and make transparent the process of scientifically based
71 stability testing used to determine prescription drug expiration dates; and be it
72 further

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74 **RESOLVED:** That our AMA directs the FDA to replicate the military model
75 of the Shelf Life Extension Program for non-military drug use so labeled dates
76 can more accurately reflect drug stability.

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79 **WAYS AND MEANS COMMITTEE FISCAL NOTE: NONE**

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- 1 Springen, Karen (Oct 27, 2010). “Do you take expired medications? Lots of people do. Here’s what you need to know.” MSNBC Web Exclusive. Available at <http://www.msnbc.msn.com/id/15445260/site/newsweek/>.
 - 2 Singer, Natasha (Aug 24, 2010). “Poll: Americans Skimp on Medicines.” New York Times. Available at <http://prescriptions.blogs.nytimes.com/2010/08/24/poll-americans-skimp-on-medicines/>.
 - 3 Cohen, Laurie P. (Mar 28, 2000) "Many Medicines Prove Potent for Years Past Their Expiration Dates". *The Wall Street Journal* 235 (62): pp. A1. Available at http://www.endtimesreport.com/Prescription_longevity.html.
 - 4 “Title 21—Food and Drugs. Chapter 1—Food and Drug Administration. Department of Health and Human Services. Subchapter C—Drugs: General. Part 211: Current Good Manufacturing Practice for Finished Pharmaceuticals. Sec 211.166a3.” See also Sec 211.137 “Expiration dating,” 211.165 “Testing and release for distribution,” and the rest of 211.166 “Stability Testing.” (Apr 1, 2009) Food and Drug Administration. Available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=211>.
 - 5 “Report 1 of the Council on Scientific Affairs (A-01) Full Text: Pharmaceutical Expiration Dates.” (Jun 6, 2001) American Medical Association. Available at <http://www.ama-assn.org/ama/no-index/about-ama/13652.shtml>.

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- 6 "Johns Hopkins Health Alert: Ask the Doctor About Your Prescriptions." (Mar 2010) Johns Hopkins Health Alerts. Available at http://www.johnshopkinshealthalerts.com/alerts/prescription_drugs/JohnsHopkinsPrescripti onDrugsHealthAlert_677-1.html.
 - 7 Lyon CR et al (2006) Stability Profiles of Drug Products Extended beyond Labeled Expiration Dates. *J Pharm Sci* 95(7):1549-1560.
 - 8 "SLEP Info Paper: Extending The Shelf Life of Critical Chemical Biological, Nuclear, and Radiological (CBRN) Medical Materiel Using the FDA/DoD Shelf Life Extension Program." (Oct 1, 2009) Defense Medical Standardization Board, SLEP-The DoD/FDA Shelf Life Extension Program. Available at https://slep.dmsbfda.army.mil/portal/page/portal/SLEP_PAGE_GRP/SLEP_HOME_NEW.
 - 9 "National News Brief; Military Stockpiles Drugs After Expiration Date." (Mar 30, 2000) New York Times. Available at <http://www.nytimes.com/2000/03/30/us/national-news-briefs- military-stockpiles-drugs-after-expiration- date.html?scp=1&sq=drug%20expiration%20dates&st=cse>.
 - 10 "Prescription Drug Trends." (May 2010) Kaiser Family Foundation. Available at <http://www.kff.org/rxdrugs/upload/3057-08.pdf>.
 - 11 Kennedy J and Erb C. (2002) Prescription noncompliance due to cost among Americans with disabilities in the United States. *Am J Pub Health* 92(7):1120-1124.
 - 12 "Stockpiled antivirals at or nearing expiration." (Jun 22, 2010) Food and Drug Administration. Available at <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm154962.htm>.
 - 13 "Guidelines for Drug Donation." (1999) World Health Organization. Available at http://www.who.int/selection_medicines/emergencies/guidelines_medicine_donations/en/
 - 14 December 14/28 2009, Volume 51, *The Medical Letter*, published by The Medical Letter, Inc.