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3 **AMENDED RESOLUTION 64-10A**  
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5 **Title: Use of Expired Drugs by Charitable Clinics**  
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7 **Introduced by: Gail A. Cookingham, MD, for the MI Allergy & Asthma Society**  
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9 **Original Author: Clyde R. Flory, MD**  
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11 **Referred to: Reference Committee C**  
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13 **House Action: Referred to the Board for Study**  
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16 **Whereas, economic hardships now force many people to choose between**  
17 **food and medicine, and**

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19 **Whereas, consumers are frequently confronted with whether it is safe to take**  
20 **expired medications<sup>1,2,3</sup>; and**

21  
22 **Whereas, the December 14/28 2009, Volume 51, *The Medical Letter*, published**  
23 **by The Medical Letter, Inc. a non-profit organization, has identified data evaluating**  
24 **the safety and effectiveness of expired drugs, and**

25  
26 **Whereas, the Department of Defense/U.S. Food and Drug Administration Shelf**  
27 **Life Extension Program has studied 122 drugs beyond their expiration dates and**  
28 **found that 88 percent of the lots tested remained stable for an average of 66 months**  
29 **beyond their expiration dates, and**

30  
31 **Whereas, the FDA extended expiration dates of 88 percent of 122 stockpiled**  
32 **drug products an average of 66 months for the US Department of Defense's Shelf**  
33 **Life Extension Program (SLEP)<sup>7, 8</sup>; and**

34  
35 **Whereas, the military spent \$3.9 million on SLEP but saved \$263.4 million**  
36 **between 1993 and 1998<sup>3</sup> out of an estimated \$1.2 billion annual drug costs<sup>9</sup> by using**  
37 **drugs deemed safe and effective beyond their originally labeled expiration date by**  
38 **the FDA that would have otherwise been discarded and replaced; and**

39  
40 **Whereas, soaring annual prescription drug spending, doubling between 1997**  
41 **and 2001 to \$154 billion<sup>10</sup>, is the fastest growing component of rising US health care**  
42 **expenditures and may be contained by a civilian effort similar to SLEP; and**

43  
44 **Whereas, there is a general lack of public knowledge and transparency about**  
45 **the process of stability testing and the significance of drug expiration dates<sup>1</sup>; and**

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47 **Whereas, the FDA's directions for "reliable, meaningful, and specific" stability**  
48 **testing methods designed to determine expiration dates<sup>4</sup> are poorly defined and**  
49 **nonspecific; and**

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51           Whereas, pharmaceutical manufacturers are not required to perform stability  
52 testing beyond labeled expiration dates to test for efficacy or toxicity because  
53 extension of expiration dates is entirely voluntary by drug companies<sup>5</sup>, the result  
54 being highly conservative dates<sup>6</sup>; and  
55

56           Whereas, medical staffs in offices, clinics, and hospitals statewide currently  
57 discard significant amounts of outdated medicines with resultant monetary waste;  
58 and  
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60           Whereas, rising costs often prohibit patients from filling and refilling  
61 necessary prescriptions<sup>11</sup>; and  
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63           Whereas, other common civilian medications have been considered  
64 efficacious and safe well beyond labeled expiration dates<sup>3,12</sup>; and  
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66           Whereas, the AMA recognizes that studies examining the clinical and fiscal  
67 impact of expiration dates and especially of lengthening expiration dates are  
68 extremely limited to nonexistent<sup>5</sup>; and  
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70           Whereas, adherence to potentially overly conservative expiration dates may  
71 waste resources and thus impede the alleviation of human suffering in domestic and  
72 international relief efforts<sup>3,13</sup>; therefore be it  
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74           **RESOLVED:** That MSMS reaffirm AMA's support for longer scientifically  
75 based stability testing for prescription drugs; and be it further  
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77           **RESOLVED:** That The Michigan Delegation to the AMA ask the AMA to  
78 encourage the U.S. Food and Drug Administration and the federal government to  
79 more rigorously define and make transparent the definition and process of  
80 scientifically based stability testing used to determine prescription drug expiration  
81 dates; and be it further  
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83           **RESOLVED:** That the Michigan Delegation to the AMA ask the AMA to join with  
84 the U.S. Food and Drug Administration, the U.S. Pharmacopeia, and pharmaceutical  
85 companies to increase awareness and educate the public, doctors, and hospitals  
86 regarding the significance of expiration dates and beyond-expiration date usage of  
87 prescription drugs and over-the-counter medications in terms of potency and  
88 toxicity; and be it further  
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90           **RESOLVED:** That the Michigan Delegation to the AMA ask the AMA to  
91 encourage the U.S. Food and Drug Administration to study the fiscal and clinical  
92 impact of expiration date extensions for both civilian medications and essential  
93 medicines commonly used in domestic and international relief efforts.  
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96 **WAYS AND MEANS COMMITTEE FISCAL NOTE: NONE**  
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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](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/cfcr/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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10. "Prescription Drug Expenditures in 2001: Another Year of Escalating Costs". (May 6, 2002) National Institute for Health Care Management Research and Educational Foundation.
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>.
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### **H-115.983 Expiration Dates and Beyond-Use Dates of Prescription Drug Products.**

*Our AMA: (1) supports the inclusion of expiration dates on the containers/labels of prescription drug products and recommends that expiration dates be determined by pharmaceutical manufacturers using scientifically based stability testing with subsequent approval by the Food and Drug Administration (FDA); (2) urges the pharmaceutical industry, in collaboration with purchasers, the FDA, and the United States Pharmacopeia*

*(USP), to determine whether lengthening of expiration dates will provide clinical and/or economic benefits or risks for patients and, if this is the case, to conduct longer stability testing on their drug products; (3) recommends that pharmacists place a beyond-use date on the labeling of all prescription medications dispensed to patients, and that the beyond-use date be based on the recommendations in the most recent edition of the United States Pharmacopeia and National Formulary (currently USP 24-NF 19) (official January 1, 2000); and (4) encourages the USP, in collaboration with pharmaceutical manufacturers, pharmacy organizations, and the FDA, to continue to explore the development of appropriate stability tests for the determination of scientifically sound beyond-use dates for repackaged products. (BOT Rep. O, I-90; BOT Rep. 1, A-95; Appended: Res. 527 and Reaffirmed: Res. 520, A-00; Modified: CSA Rep. 1, A-01; Reaffirmed: Res. 515, A-02; Reaffirmation A-07).*