

TABLE 1.—MEDICATION ERROR RATES REPORTED IN VARIOUS STUDIES—Continued

Study	Definition of Medication Error Used	Medication Error Rate
Matched case-control study of all patients admitted to a hospital in a 3-year period by Classen et al. (Ref. A-6).	"Adverse drug event" defined as an event that is "noxious and unintended and occurs at doses used in humans for prophylaxis, diagnosis, therapy, or modification of physiologic functions" but excludes therapeutic failures, poisonings, and intentional overdoses.	1% of all adverse drug events, but the authors also state that almost 50% of all adverse drug events are potentially preventable.
Review of 10,778 medication orders at 2 urban teaching hospitals by Kaushal et al. (Ref. A-3).	"Medication errors" defined as errors in drug ordering, transcribing, dispensing, administering, or monitoring.	5.7%, with adult patients cared for in a pediatric setting experiencing the most medication errors.
Prospective cohort study in 36 institutions by Barker et al. (Ref. A-10).	"Medication error" defined as a dose administered differently than as ordered on the patient's medical records.	19%, or nearly 2 errors every day for a typical patient receiving 10 doses per day, or, for a facility with 300 patients, almost 40 potential adverse drug events in a facility. The percentage of potentially harmful errors was 7% or more than 40 per day per 300 inpatients.

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Study	Definition of Medication Error Used	Medication Error Rate
Examination of all U.S. death certificates between 1983 and 1993 by Phillips et al. (Ref. A-14).	"Medication errors are "accidental poisonings by drugs, medicaments, and biologicals" and have resulted from "acknowledged errors, by patients or medical personnel.	Medication error rate rose from 1 out of every 439 outpatient deaths and 1 out of every 1,622 inpatient deaths in 1983 to 1 out of every 131 outpatient deaths and 1 out of every 854 inpatient deaths in 1993. The authors suggest the increase may be due to an increasing willingness to attribute error deaths that were previously ascribed to natural causes.

III. References in the Appendix

The following references have been placed on display in the Dockets Management Branch (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

A-1. Folli, H. L., R. L. Poole, W. E. Benitz, et al., "Medication Error Prevention by Clinical Pharmacists in Two Children's Hospitals," *Pediatrics*, 79:718-722, 1987.

A-2. Leape, L. L. et al., "The Nature of Adverse Events in Hospitalized Patients," *New England Journal of Medicine*, 324:377-384, 1991.

A-3. Kaushal, R. et al., "Medication Errors and Adverse Drug Events in Pediatric Inpatients," *Journal of the American Medical Association* 285:2114-2120, 2001.

A-4. Lesar, T. S. et al., "Medication Prescribing Errors in a Teaching Hospital," *Journal of the American Medical Association* 263:2329-2334, 1990.

A-5. McCarthy, A. M., M. W. Kelly, and D. Reed, "Medication Administration Practices

of School Nurses," *Journal of School Health*, 70:371-376, 2000.

A-6. Classen, D.C. et al., "Adverse Drug Events in Hospitalized Patients," *Journal of the American Medical Association*, 277:301-306, 1997.

A-7. Thur, M. P., "Medication Errors in a Nurse-Controlled Parenteral Admixture Program," *Journal of Hospital Pharmacy*, 29:298-304, 1972.

A-8. Tisdale, J. E., "Justifying a Pediatric Critical-Care Satellite Pharmacy by Medication-Error Reporting," *American Journal of Hospital Pharmacy*, 43:368-371, 1986.

A-9. Bates, D.W., D. L. Boyle, M. B. Vander Vliet, et al., "Relationship Between Medication Errors and Adverse Drug Events," *Journal of General Internal Medicine*, 10:199-205, 1995.

A-10. Barker, K. N. et al., "Medication Errors Observed in 36 Health Care Facilities," *Archives of Internal Medicine*, 162:1897-1903, 2002.

A-11. Porter, J., and H. Jick, "Drug-Related Deaths Among Medical Inpatients," *Journal of the American Medical Association*, 237:879-881, 1977.

A-12. West, D. W., S. Levine, G. Magram, et al., "Pediatric Medication Order Error Rates Related to the Mode of Order Transmission," *Archives of Pediatric and Adolescent Medicine*, 148:1322-1326, 1994.

A-13. Bates, D. W., D. J. Cullen, N. Laird, et al., "Incidence of Adverse Drug Events and Potential Adverse Drug Events," *Journal of the American Medical Association* 274:29-34, 1995.

A-14. Phillips, D. P., N. Christenfeld, and L. M. Glynn, "Increase in US Medication-Error Deaths Between 1983 and 1993," *Lancet*, 351: 643-644, 1998.

List of Subjects

21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 606

Blood, Labeling, Laboratories, Reporting and recordkeeping requirements.

21 CFR Part 610

Biologics, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that parts 201, 606, and 610 be amended as follows:

PART 201—LABELING

1. The authority citation for 21 CFR Part 201 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg-360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

2. Section 201.25 is added to read as follows: