Virginia Joint Commission on Health Care

Staff Report: Accuracy of Discard Dates on Prescription Drugs

HJ 699 (Patron: Delegate James M. Scott)

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Introduction

- The High Cost of Prescription Drugs
  - Prescription drug costs are rising at 19% per year
  - Americans spend $200 billion per year
- Department of Defense (DoD) Shelf Life Extension Program (SLEP)
  - 1986-present. Most extensive source of pharmaceutical stability data.
  - Administered by FDA
  - Tests 122 drug products (3005 lots)
  - 88% of lots extended at least 1 year beyond expiration date
  - Average extension = 66 months
  - 10.4% extended beyond 4 years

Introduction

- HJ 699 -2007 (Patron: Delegate James M. Scott)
  - Directed JCHC to study the accuracy of discard dates on prescription drugs & evaluate the feasibility of extending discard dates
  - HJ 699 was left in the House Committee on Rules
  - VPhA Statement: "The Virginia Pharmacists Association expresses concerns regarding House Joint Resolution No. 699... The current responsibilities of the U.S. Food and Drug Administration are to ensure the safety and efficacy of drugs, as well as to ensure that drug products are represented accurately, honestly, and informatively to the public… Since a study on the accuracy of current drug discard dates and the feasibility of extension of such dates involves ensuring both drug safety and efficacy, it is the position of VPhA that the FDA rather than the Joint Commission on Health Care should be encouraged to investigate and reevaluate current discard dates and requirements."

Expiration Dates vs. Discard Dates

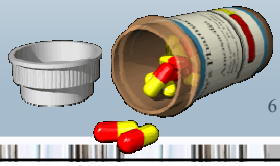
- Expiration Dates
  - Determined by stability testing of manufacturer
  - Only applies when drug is stored in original unopened container, under defined conditions
- Discard Dates ('Beyond Use' Dates)
  - Applies to repackaged drugs
  - Discard date "shall be no later than a) the expiration date on the manufacturer's container, or b) one year from the date the drug is dispensed, whichever is earlier" (AMA, 2001).
  - Pharmacy Repackaging
    - 17 states require 'Discard Dates' by law (not Virginia)
    - All other states voluntarily follow the discard date guideline

Accuracy of Drug Dating

- Accuracy of Expiration Dating:
  - Applying SLEP Findings to a Consumer Environment
    - Applies only to stability testing of unopened stockpiled drugs
    - Requires controlled storage conditions
    - Does not address repackaging laws
- Accuracy of Discard Dating:
  - Discard date based on pharmacists' professional judgment
  - Not based on stability testing data

Conclusion

- Feasibility of Extending Expiration Dates on Prescription Drugs
  - More stability testing required → Increased Cost
  - Pharmaceutical companies prefer shorter expiration dates because product labeling/information inserts may change over time.
  - VPhA statement: "…the FDA rather than the Joint Commission on Health Care should be encouraged to investigate and reevaluate current discard dates and requirements."
  - Most likely a federal policy issue



Conclusion

- Feasibility of Changing Discard Date Policies
  - Discard the "Discard Date"
    - Florida precedent
      - May, 2005: Florida State Board of Pharmacy repealed provision that pharmacists put a "discard after" date on prescriptions
    - **Potential Option**: Repeal Virginia's "Discard Date" provision
  - Use of Blister Packs
    - Protects medicine from environmental conditions
    - **Potential Option**: Repeal Virginia's "Discard Date" provision for blister packs only
    - Require manufacturers to package medicines in blister packs
      - Federal policy issue

List of Sources

- Abramowicz, Mark (Editor). 2002. "Drugs Past Their Expiration Date." The Medical Letter. Vol. 44, October 28.
- Angell, Marcia. 2004. The Truth About the Drug Companies: How they deceive us and what to do about it. New York, NY: Random House.
- Angell, M. and Arnold Relman. 2001. "Prescription for Profit," Washington Post. June 20.
- Altschuler, Richard. 2002. "Do Medications Really Expire? Try an Experiment with Your Mother-In-Law." Medscape Psychopharmacology Today. September.
- American Medical Association. 2001. "Report 1 of the Council on Scientific Affairs: Pharmaceutical Expiration Dates." June.
- American Pharmacists Association. 2006. "Re-Distribution of Medications: APhA Policy Committee Background Information." November.

List of Sources (cont'd)

- Cohen, Laurie P. 2000. "Many Medicines Are Potent Years Past Expiration Dates." End Times Report. April.
- Ette, Ene I. 2004. "Conscience, the Law, and Donation of Expired Drugs." The Annals of Pharmacotherapy. Editorial. Vol. 38, July/August.
- Freeman, Liz. 2006. "Ex-Pharmacist Campaigns Against Prescription Drug 'Discard' Dates." BonitaNews.com. July 29.
- Garey, Devin W. et al. 2004. "Economic Consequences of Unused Medications in Houston, Texas." The Annals of Pharmacotherapy. Vol. 38, July/August.
- Huang, Josie. 2006. "Do Expired Drugs Still Work?" Portland Press Herald. July 31.
- Internet Broadcasting Systems. 2006. "Expiration Dates on Medicines Questioned." Local6.com. November 24, 26. Orlando, Florida.

List of Sources (cont'd)

- Internet Broadcasting Systems. 2003. "The Investigators: Expired Medicine." Local10.com. May 7. Miami, Florida.
- Jones, Maggie. 2006. "Big Idea! New Life for Old Pills." AARP: The Magazine. September/October Issue.
- Lohiya, S. 1996. "Expiry Date Display on Drug Packages." Western Journal of Medicine. Vol. 164, No. 4, April: 365-366.
- Lyon, Robbe C et al. 2006. "Stability Profiles of Drug Products Extended Beyond Labeled Expiration Dates." Journal of Pharmaceutical Sciences. Vol. 95, No. 7, July
- MacDonnell, Celia P. et al. 2002. "Drug Product Expiration Dates: Practice Implications." Medicine and Health, Rhode Island. Vol. 85, No. 4, April.

List of Sources (cont'd)

- Murhammer, Joan et al. (Editors). 2005. "Revised Policy on Drug Expiration Dating." Rx Update. October. University of Iowa Hospitals and Clinics, Department of Pharmaceutical Care.
- Musselman, Tim. 2007. Virginia Pharmacist Association. Position Statement on HJ 699. Phone Interview. March 28.
- Okeke, Claudia C. and V. Srini Srinivasan. 1998. "Expiration and Beyond Use Dates." American Journal of Health-System Pharmacy Vol. 55, Issue 5, March: 433-434.
- Okeke, Claudia C. et al. 2000. "Revised USP Standards for Product Dating, Packaging, and Temperature Monitoring." American Journal of Health-System Pharmacy. Vol. 57, Issue 15, August: 1441-1145.

List of Sources (cont'd)

- United States Army Medical Materiel Agency. 2003. "Labeling Requirements for Pharmaceuticals Managed Under the DoD/FDA Shelf-Life Extension Program." www.usamma.army.mil
- Woods, Michael. 2005. "Drugs May Outlast Label Date." Pittsburgh Post-Gazette. May 30.
- 2005. "Expiration Dating of Unit-Dose Repackaged Drugs: Compliance Policy Guide." Draft. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research. May.
- 2003. "Drug Expiration Dates: Do They Mean Anything?" The Family Health Guide. November. Harvard Medical School Publication.

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