



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

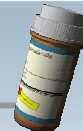


- ▶ HJ 699 -2007 (Patron: Delegate James M. Scott)
 - ▶ Directed JCHC to study the accuracy of discard dates on prescription drugs & evaluate the feasibility of extending discard dates
 - ▶ HJ 699 was left in the House Committee on Rules
 - ▶ VPhA Statement: “The Virginia Pharmacists Association expresses 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.”



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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



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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



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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



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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



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