Pharmaceutical Expiration Dating Advice Given By Retail Pharmacists

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Abstract: ***Background:*** **There is presently no uniform legislation requiring or standardizing the expiration labeling of prescription drug containers dispensed to patients by retail pharmacies, and most communities in the United States do not require such labeling. Expired medications can suffer changes in toxicity, potency, or palatability. Inadvertent use because of incomplete labeling can impact negatively on good patient care.**

Methods: **A telephone survey of 124 retail pharmacists in a community suburban to New York City was conducted using a prepared script.**

Results: **When a caller requested "do not use later than" advice for 10-mg propranolol tablets said to have been purchased 6 months earlier, responses ranged from 3 to 60 months. Most pharmacists recommended discarding medications 1 year (31 percent) or 2 years (27 percent) following purchase, but fewer than one-fourth of those responding attempted to verify expiration dates before answering.**

Conclusions: **Physicians counseling patients to use prescription medicines within 1 year of purchase are giving advice consistent with that offered by 85 percent of the responding pharmacists, but physicians should be aware of the limitations of this recommendation. In the absence of uniform expiration-dating policies, physicians can minimize potential risks to patients by printing the instruction "label expiration date" on prescription blanks. (J Am Board Fam Pract 1991; 4:407-10.)**

Pharmaceuticals inadvertently used after their assigned expiration dates can develop undesirable properties that negatively influence patient care.[1] A prescription label that records the date of purchase but not the date advising "do not use later than" provides incomplete information to the patient and to the physician. It is current practice for pharmaceutical manufacturers to record suggested expiration dates on nonprescription medications intended for retail sale to consumers and on the stock bottles of prescription medications supplied to pharmacists,[2,3] but there is presently no uniform legislation requiring or standardizing the labeling of "do not use later than" dates on prescription drug containers dispensed to patients by retail pharmacists. Only seven states (Georgia, Hawaii, Maryland, Massachusetts, Nevada, Oregon, and Washington) require such labeling.[4] In other states, prescription drug containers are labeled only at the discretion of the dispensing pharmacist. Patients frequently ask physicians whether a previously prescribed medication has remained suitable for use to treat a current condition. Awareness of the "do not use later than" advice given to patients by retail pharmacists might, therefore, be of value when such recommendations are offered.

Methods

A New York State community that has no legislation requiring expiration labeling for prescription medicines dispensed at retail level was chosen for study. One hundred twenty-four pharmacies located in areas suburban to New York City (lower Westchester County) were chosen at random from commercial telephone listings and called. "Do not use later than" information was requested for 10-mg propranolol tablets that were said to have been purchased at that pharmacy 6 months earlier. The caller (N.B.) asked to speak with the pharmacist, introduced himself by name, described the medication, gave the date of purchase, and asked whether "this medicine is still good" (question 1). When there was an affirmative answer, the caller asked, "How many more months will it be all right to use this medicine?" (question 2). The pharmacists' advice and their

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Table 1. Retail Pharmacists' Responses to "Can Previously *Dispensed* 10-mg Propranolol Tablets Be Used by the Patient for at Least Six Months?"

Response	Number (n=124)	Respondents Attempting to Verify
	No. (%)	No. (%)
Declined	13 (10.7)	9 (69.2)
Yes	110 (88.7)	3 (2.7)
No	1 (0.8)	0 (0.0)

attempts to confirm expiration dates were recorded and tabulated.

Results

Responses to question 1 are listed in Table 1. Only 1 of the 124 responding pharmacists advised the patient to discard his 6-month-old medication. Nine of the 13 pharmacists who declined to give advice declined when they were unable to verify information regarding the caller, the prescription, or the medication. Table 2 summarizes the longest "do not use later than" advice given by the pharmacists. A respondent answering yes to question 1, but who declined to answer question 2 was recorded as having given an answer of 6 months. Responses varied from 3 to 60 months. Pharmacists most commonly answered 1 year (31 percent) or 2 years (27 percent). Of the 105 pharmacists (85 percent) recommending use 1 year or longer following purchase, 19 percent checked records before responding. Thirteen percent of the 53 pharmacists recommending use 2 or more years following purchase verified records, and 22 percent of the 18 pharmacists recommending use 3 or more years following purchase did so after checking stock or records.

Table 2. Retail Pharmacists' "Do Not Use Later Than" Advice to Patients for 10-mg Propranolol Tablets.

Time to Expiration (months)	Pharmacists Responding (n=124) No. (%)	Respondents Attempting to Verify No. (%)
Declined	13 (10.7)	9 (69.2)
< 6	1 (0.8)	0 (0.0)
6	5 (4.0)	1 (20.0)
12	39 (31.4)	7 (17.9)
18	13 (10.5)	6 (46.2)
24	33 (26.6)	2 (6.1)
30	2 (1.6)	1 (50.0)
36	10 (8.1)	1 (10.0)
48	7 (5.6)	3 (42.9)
60	1 (0.8)	0 (0.0)
Totals		
Declined	13 (10.7)	9 (69.2)
< 12	6 (4.8)	1 (16.7)
≥ 12	105 (84.7)	20 (19.0)
≥ 24	53 (42.7)	7 (13.2)
≥ 36	18 (14.5)	4 (22.2)

Comment

Commercial expiration dating of medications has been established to ensure that each active ingredient maintains its chemical integrity and potency and that there are no changes in the physical properties of the medicine relating to its appearance, palatability, uniformity, and dissolution at the time of use. In addition, there should be no increase in toxicity or decrease in therapeutic efficacy, and there should be no adverse effect on sterility or resistance to bacterial growth.[1] Effective expiration dating of pharmaceuticals presupposes appropriate medicine storage, as the medication's stability can be adversely affected by extremes of temperature, humidity, and light.[1,5] It is the pharmacist's responsibility to educate the patient-consumer about proper storage of medications and to ensure appropriate conditions in pharmacy storage areas.[1]

Despite recommendations made by the American Pharmaceutical Association (APhA) in 1968 and 1989 that "beyond use" dates should be printed on the prescription labels of all time-dated drugs,[6,7] at present there are no uniform requirements to ensure compliance with this recommendation, and most states have not adopted such legislation. The hazards of noncompliance are obvious: patients inadvertently using outdated medicines can experience a suboptimal therapeutic effect because of a change in potency, and the resultant byproducts of drug degradation can, on occasion, be toxic.[1,5,8] Patients using long-term daily medications may be at special risk because they may commingle or simultaneously use tablets with varying expirations that had been dispensed at different times, thus creating an inconsistent therapeutic effect. Also, financial expense and inconvenience may be experienced if medicines are discarded sooner than necessary. One might speculate that there is a probable underreporting of adverse effects caused by the inadvertent use of expired medications; without such labeling, neither the patient nor the physician

would know that an outdated medicine had been used and was responsible for the untoward effect.

If the pharmacist no longer has access to the actual stock bottle from which the prescription was dispensed or does not have an accounting system that notes "beyond use" dates, it may be impossible to learn the manufacturer's expiration date for a specific previously prescribed medication. Those pharmacists who made no attempt to determine actual expiration dates before offering advice may have done so because of an awareness that pertinent information could not be retrieved. Many pharmacists (9 of 30) who did try to learn the expiration date subsequently declined to give "do not use later than" information to the caller.

Eighty-five percent of the respondents recommended use of the medication 1 or more years after purchase, and 43 percent suggested that the medicine could be used for 2 years or longer. One popular brand of propranolol (Inderal™, Wyeth-Ayerst Laboratories) is reported to have a suggested manufacturer's expiration date of approximately 5 years and a shelf life of approximately 3 years (personal communication, Wyeth-Ayerst Laboratories, Philadelphia, 19 April 1990). Assuming a reasonable turnover of stock and similar recommendations from other manufacturers, it is likely that most of the respondents' estimates were accurate and responsible. But 15 percent of the pharmacists recommended use of the prescribed medication 3 or more years following purchase, usually without first attempting to verify their recommendations, and these estimates might be subject to a greater degree of inaccuracy.

Propranolol was chosen as the medication for study because it is used to treat relatively benign illnesses, such as essential tremor, as well as more serious conditions.[9] Decreases in potency might create morbidity that could include the worsening of angina, hypertension, cardiac arrhythmias, migraine, or anxiety, depending on the reason for which the drug had been prescribed. Few of the pharmacists studied, however, asked why the medicine was being taken. None asked questions regarding storage conditions that might adversely influence effectiveness, presumably because proper storage was assumed to have been discussed at the time of purchase.

Confirming the accuracy of advice was beyond the scope of study, and no attempt was made to determine whether such variables as part-time pharmacist employment, pharmacy location, or sales volume influenced the advice given. It should also be noted that although propranolol is believed to be a representative prescription drug, the responses given by the dispensing pharmacists might have been different had another medication been chosen for study.

The 1989 APhA resolution that pharmacists place a "beyond use date" on the labels of all medications dispensed to patients suggests the following guidelines: the "beyond use date" should represent the manufacturer's expiration date on the original packaging, or 1 year from the date the product is dispensed, whichever is earlier; or a date determined by the pharmacist using his or her professional judgment.[7] This flexibility is necessary but can lead to great variability in expiration dating. A 1984 survey of hospital pharmacists reported that diverse criteria were being used to label expiration dates for hospital pharmaceuticals.[10] Our data suggest a similar lack of consistency in the verbal advice given by retail pharmacists. On the other hand, it may be of greater concern that in the absence of expiration dating, these decisions are left entirely to the patient's judgment when professional advice is not sought. Also, patients who are accustomed to verifying the expiration dates on nonprescription medicines might interpret their absence on prescription drug labels as an indication that indefinite use is acceptable. To avoid this possibility, physicians practicing in communities that have no "beyond use" labeling regulations may wish to print a "label expiration date" instruction on their blank prescription forms, and they may verbally request that pharmacists label containers with "beyond use" dates when they give telephone orders for prescription medications.

Conclusion

Physicians and patients should be aware that most communities have no legislated policy requiring the labeling of expiration dates on prescription medicines dispensed at retail level. Furthermore, when regulations are present, they are inconsistent from one community to another. In the absence of a legislated policy, the method for "beyond use" labeling is chosen by the pharmacist, or no dating may be used at all. The "do not use later than" advice for previously dispensed prescriptions given to patients verbally by retail pharma-

cists appears to be variable and is usually made without first attempting to verify the manufacturer's expiration date. Physicians who presently advise patients to use prescription medications within 1 year of purchase are offering advice consistent with that given by 85 percent of the retail pharmacists studied. This recommendation, however, should be made only with an understanding of its potential limitations. Inadvertent use of expired prescription medicines can have an adverse effect on a patient's treatment, and this potential cause of toxicity or decreased efficacy might go undetected when "beyond use" labeling is not being used. Physicians practicing in communities that do not have mandatory expiration labeling of prescription medicines may wish to print the instruction "label expiration date" on their blank prescription forms to minimize potential risk to patients and to monitor this potential cause of adverse therapeutic outcome.

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