Prevalence of Compounding in Independent Community Pharmacy Practice

Timothy B. McPherson, Patrick E. Fontane, Kelsey D. Jackson, Kathleen S. Martin, Tricia Berry, Rasma Chereson, and Rhonda Bilger

ABSTRACT

Objectives: To determine the extent of prescription compounding in independent community pharmacies and identify factors that influence the decision of independent pharmacists whether to provide compounding services.

Design: Cross-sectional survey.

Setting: Illinois, Missouri, Kansas, and Iowa.

Participants: 370 pharmacists in charge.

Intervention: Anonymous questionnaire mailed in January 2005.

Main Outcome Measures: Percentage of pharmacies that provide compounding; percentage of dispensed prescriptions that require compounding; factors contributing to decisions whether to provide compounding service.

Results: Overall, 94% of respondent pharmacies provided compounding services at the time of this survey. Prescriptions that required compounding represented less than 1% of total prescriptions for the majority (58.3%) of respondents. The main reasons for the decision to provide compounding service were wanting to provide full pharmaceutical care to patients (73.8% of compounders) and responding to requests by prescribers (48.7%). Pharmacies that did not provide compounding service cited the main reason as not receiving prescriptions that required compounding (63.6% of noncompounders).

Conclusion: Compounding remains a component of pharmacy practice in the independent community setting. Prescriptions that required compounding represented 2.3% of all prescriptions dispensed by compounding pharmacies.

Keywords: Compounding, community and ambulatory pharmacies, survey.

J Am Pharm Assoc. 2006;46:568–573.

Received September 12, 2005, and in revised form January 6, 2006. Accepted for publication March 4, 2006.

Timothy B. McPherson, PhD, is Associate Professor, School of Pharmacy, Southern Illinois University Edwardsville, Edwardsville, Ill.; at the time the study was conducted he was Associate Professor of Pharmaceutics, St. Louis College of Pharmacy, St. Louis, Mo. Patrick E. Fontane, PhD, is Professor of Sociology; Kelsey D. Jackson is student research assistant; Tricia Berry, PharmD, BCPS, is Associate Professor of Pharmacy Practice; Rasma Chereson, PhD, is Professor of Biopharmaceutics; and Rhonda Bilger, BS, BPharm, is Assistant Professor of Pharmacy, St. Louis College of Pharmacy, St. Louis, Mo. Kathleen S. Martin, PhD, is Assistant Professor of Pharmaceutics, University of the Incarnate Word School of Pharmacy, San Antonio, Tex.; at the time the study was conducted she was Assistant Professor of Pharmaceutics, St. Louis College of Pharmacy, St. Louis, Mo.

Correspondence: Timothy B. McPherson, PhD, SIUE School of Pharmacy, Campus Box 2000, Edwardsville, IL 62026-2000. Fax: 618-650-5163. E-mail: tmcpher@siue.edu

Disclosure: The authors declare no conflicts of interest or financial interests in any product or service mentioned in this article, including grants, employment, gifts, stock holdings, or honoraria.

Funding: Research Incentive Fund, St. Louis College of Pharmacy.

Acknowledgments: Jon C. Schommer, PhD, for providing data from a 1990 Wisconsin survey; and to Gireesh Gupchup, BPharm, PhD, Kenneth W. Kirk, PhD, and Peter D. Hurd, PhD, for valuable comments on an earlier version of the manuscript.

Pharmaceutical compounding, "the preparation of components into a drug product…as the result of a practitioner's prescription drug order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice,"[1] has always been a part of community pharmacy practice. Before the availability of manufactured drug products, virtually all prescriptions were compounded. Compounded prescriptions as a fraction of total prescription volume decreased during the 20th century, to an apparent low of less than 1% during the 1970s.[2–6]

Data on the current status of compounding in community pharmacy practice are lacking. The annual prescription surveys by DeNuzzo,[6] which apparently ceased after 1982, were predominantly limited to pharmacies in New York State and focused on manufactured drug products rather than compounded prescriptions. Schommer et al.[7] studied compounding by Wisconsin pharmacists in a variety of practice settings. The most commonly reported prevalence of compounding was 0.25% of total prescriptions dispensed.[7] However, this statistic also represents only a single state a decade and half ago. An estimate by the Food and Drug Administration (FDA) that 1%–10% of all prescriptions require compounding was unsupported by data, according to the U.S. Government Accounting Office.[8]

The contemporary prevalence of compounding is represented by two indicators: (1) the International Academy of Compounding Pharmacists, founded in 1991 to promote pharmaceutical compounding, currently has approximately 1,800 members,[9] and (2) the *International Journal of Pharmaceutical Compounding*, a journal devoted entirely to various aspects of pharmaceutical compounding, began publication in 1997 and currently has a readership of approximately 13,000 (Susanne Johnson, written communication, June 5, 2005).

An apparent increase in compounding practice has become a justification for increased efforts to regulate the practice. Compounded prescriptions, unlike manufactured drug products, do not require quality control testing (potency, purity, stability). Many compounding pharmacists perform or contract for these tests, but it is done voluntarily. FDA has cited[10] widely publicized cases of problems with compounded products[11–13] to illustrate dangers associated with an increase in compounding practice.

The focus on problem cases calls attention to compounded products from independent community pharmacies, and regulatory proposals implicitly focus on the independent community practice. For example, the Missouri Board of Pharmacy recently defined a new classification, "Class D: Non-sterile Compounding," for pharmacies that compound 5% or more of their prescriptions.[14] Chain pharmacies may provide compounding services, but they are not often mentioned in association with compounding. Hospital pharmacies, where compounding, especially of sterile products, is extensively practiced, are regulated by the Joint Commission on Accreditation of Healthcare Organizations.

Thus, efforts at increased regulation of pharmaceutical compounding are apparently based on assumptions that the practice represents a significant, and increasing, fraction of pharmaceutical services and that the quality of compounded products cannot be assured. Independent community pharmacies are the putative source of compounding services, and they are the focus of current regulatory scrutiny. Data to support these assumptions are clearly lacking. An understanding of the contemporary prevalence of compounding in community pharmacy practice is needed.

Objectives

The primary objectives of this inquiry were to determine the extent of prescription compounding in independent community pharmacies in several states and identify factors that influence the decision of independent pharmacists whether to provide compounding services.

AT A GLANCE

Synopsis: Compounding services were being provided in nearly all independent community pharmacies in Illinois, Missouri, Kansas, and Iowa during January 2005, according to this survey of 370 pharmacists in charge. But the bulk of the compounding was performed in a minority of pharmacies. Compounded prescriptions accounted for more than 5% of dispensed medications in 12.3% of pharmacies with such services, but this group of pharmacies dispensed two thirds of the compounded prescriptions dispensed in a typical week.

Analysis: *Compounding practice is assumed to have increased in frequency since a 1990 article reported that 0.25% of total prescriptions involved compounding. The increasing prevalence is inferred on the basis of growing membership numbers for the International Academy of Compounding Pharmacists and the readership of the* International Journal of Pharmaceutical Compounding. *The assumed increase in compounding prevalence has been accompanied by efforts to broaden regulation of compounding practice in view of widely publicized problems with compounded products. Regulations that cover compounding services must take into account the low prevalence of compounding in the large majority of independent community pharmacies. Required licensing or certification may curb patient access if a pharmacy's prescription volume cannot justify expensive or time-consuming compliance with regulatory requirements.*