

2006 marked the 40th year of publication for *The Annals*. Throughout its history, *The Annals* has provided important contributions to the development of clinical pharmacy. In 2007, we are continuing to publish articles reflecting on the history of clinical pharmacy through the eyes of practitioners, including those pioneering clinical pharmacy, as well as those who have more recently entered the profession and a well-established specialty. In addition, we are presenting articles and editorials from the early history of *The Annals* that have given direction and shape to the practice of clinical pharmacy (see page 1887).

Prescribing Authority for Pharmacists, Florida Style: A Home Run or a Swing and a Miss?

Paul L Doering

About the time that *The Annals* (*Drug Intelligence* at that time) was publishing its inaugural issue, a high school student from Miami was about to begin his pharmacy education. Little did I know that this would be the start of a long and fulfilling career as a pharmacy educator. But I digress.

By the time I began my professional courses in 1969, the enthusiasm for the changes taking place in pharmacy practice was electric. In each of our courses, professors managed to incorporate the words “clinical pharmacy” into their lectures. To be sure, some of their comments were unflattering, and at times downright inflammatory. By and large, however, this was a time of great optimism and great hope for the future of our practice. In fact, this emotionally charged atmosphere prompted me to pursue graduate studies in the fledgling field called clinical pharmacy.

Naturally, my parents were not immediately thrilled that I would need additional finances to continue my studies. They had no idea of the changes taking place in our profession. Try as I might, I could not put into words this vision for the future that pharmacists were embracing. Finally, I figured out a way to explain the excitement I was feeling. “Mom,” I said, “it won’t be long before the doctor makes the diagnosis and the pharmacist will write the pre-

scription.” Well, that seemed to make sense at the time and I was allowed to continue my studies and, as they say, the rest is history.

In 1984, Florida became the first state to allow pharmacists to independently prescribe certain medications. With this, we thought that we were on the right road to gaining important patient care responsibilities. History has shown that, although we were headed in the right direction, perhaps we were on the wrong road. In the full light of day, we discovered that we were on a dirt road instead of a superhighway. In Florida we came oh, so close, but somehow the concept of pharmacist prescribing fell short. I do not wish to minimize the historic significance of the Florida law; indeed, it was the courage and insight shown by the architects of this law that set the stage for the prescribing laws to follow in other states.

Historical Background

For years, pharmacists have tried to establish a third class of drugs, while the Food and Drug Administration (FDA) has steadfastly opposed such action, continuing instead to recognize only the traditional prescription-only and over-the-counter (OTC) categories. By the FDA’s definition, an OTC preparation is one that the average consumer could use safely simply by reading and following the instructions printed on the label. Prescription drugs are those that cannot be used in this way and hence require

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Author information provided at the end of the text.

some input from a qualified professional. Despite many attempts over the years, organized pharmacy had been unable to get the FDA to budge from this position. Ironically, today the FDA seems ready to seriously consider this concept.

Florida was not the first state to pursue prescribing privileges for its pharmacists. In 1979, Washington granted pharmacists the right to initiate or modify drug therapy in accordance with written guidelines or protocols. In 1981, California pharmacists were given authority to modify drug therapy, perform physical assessment, order necessary laboratory tests, and administer drugs by injection under protocol in the inpatient setting. In 1983, the authority to initiate drug therapy was added, but pharmacists' prescribing activities were still limited to the inpatient environment. In Oregon, prescribing privileges for pharmacists were granted, not by changes in the law, but rather after a favorable interpretation from the attorney general of language already in the pharmacy practice act was received. The prescribing authority in Oregon is considered to be collaborative prescribing authority whereby physicians delegate to individual pharmacists the right to prescribe.

Florida was the first state to grant outright statutory authority for pharmacists to independently prescribe drugs. The actual wording of the law can be found in Chapter 465.186 of Florida Statutes. The official name given this law is "Pharmacist's order for medicinal drugs; dispensing procedure; development of formulary." But it quickly took on a more descriptive, informal name: The Florida Self-Care Consultant Law. In a sense, this law is a workaround for the federal restrictions that prevent pharmacists from prescribing. Remember, the federal government has always left it up to the individual states to decide which persons will be granted prescribing privileges. The FDA will tell you that it regulates drugs and not the practice of the professions.

In many states, only osteopaths, veterinarians, dentists, and physicians can prescribe within the realm of their practices, while in other states advanced registered nurse practitioners, physicians' assistants, and other professionals have also been granted this right. While there has never been a prohibition against including pharmacists in this group, no state had ever before specifically granted pharmacists the right to prescribe. In that respect, the new law was a break with tradition.

In essence, this law created the long-awaited third class of drugs by default. Certainly, it is a limited group of drugs that pose little risk to the patient, drugs that many, including myself, feel should probably have carried an OTC status to begin with.

The Legislative Hurdle

This legislation hardly sailed through the law-making process. The bill did not pass on the first and second attempts; it did finally pass on the third try because it had a

lot of public appeal. It promised consumers greater access to more effective medications without the cost and inconvenience of having to go to a physician for every simple, self-limiting illness.

Benefits to the Consumer

The legislation made good sense from an economic standpoint. Take, for example, medicinal drug shampoos containing lindane. At the time, it was the only truly effective lice treatment on the market. Previously, when a child was sent home from school with a note saying that he or she had head lice, the parent would have to go to the physician to get a prescription for a lindane shampoo. And if the family has just moved to town and did not have a physician, this might mean an expensive trip to the hospital emergency department to have the diagnosis confirmed and obtain a prescription for a lindane-containing shampoo. Only then could the consumer go to the pharmacy and buy the medication.

Under the new law, the pharmacist can confirm that the child has head lice and dispense the prescription-only product at a fraction of the previous total cost, in much less time, and with greater convenience for the consumer.

The Drugs

Several things happened during the implementation of the law and in the years shortly thereafter. First, the FDA was expanding its switch philosophy from prescription-only to OTC. Overnight, the need for a drug like nystatin, a mediocre but safe topical antifungal, was supplanted by the movement of clotrimazole (AF) to the OTC counter. Why would a pharmacist want to go through the trouble of prescribing nystatin ointment for a topical fungal infection when clotrimazole, a more effective and equally safe antifungal agent, was available as an OTC drug? One by one, the unique treatment options created by the Florida Self-Care Consultant Law were eroded by the switch of drugs from prescription to OTC status or by approval of a new OTC drug.

A few more examples are presented here.

As stated above, lindane (Kwell) shampoo was a prescription drug at the time of the passage of the Pharmacist Prescribing Law. Shortly after the law went into effect, Burroughs Wellcome began marketing its head lice remedy, Nix, as an OTC rinse. Now there was a product that was just as good (if not better) as Kwell that could be sold without the need for a prescription. Nix was easier to use and arguably a safer medication than Kwell. Who wouldn't opt for the newer product available without prescription?

Addition of terfenadine (Seldane) to the original prescribing formulary in 1990 created a unique opportunity for pharmacists to provide this nonsedating antihistamine to patients who found that OTC antihistamines made them

too drowsy. As bad fortune would have it, only a short while after its addition, new information about terfenadine's potential for life-threatening cardiac arrhythmias appeared in the pharmacy and medical literature. While once previously considered a very safe medication, terfenadine was now being viewed by physicians, pharmacists, and patients in a totally new light. If ever pharmacists had reason to be fearful about the safety of a drug on the prescribing formulary and the liability created by prescribing it, it was with terfenadine.

Among the second group of medications to be added to the prescribing formulary was nicotine polacrilex, sold under the brand name of Nicorette Gum. Keeping in mind that this was added before marketing of the OTC nicotine patches, its addition offered pharmacists the potential to help people quit smoking, thus greatly reducing their health risks. However, the committee that approves drugs for the formulary and designates conditions under which pharmacists may prescribe them effectively handcuffed the pharmacist. The law stipulates that the pharmacist must obtain a letter from the physician authorizing the pharmacist to prescribe the drug. What is the difference between this letter of authorization and a prescription itself? In effect, pharmacists were given no prescriptive authority regarding nicotine chewing gum.

A victory for pharmacists was won when scopolamine patches for motion sickness were added to the prescribing formulary. Now, pharmacists in coastal areas could provide this effective and safe medication for their patients who were going fishing for the day or taking a cruise for a week. Despite concerns among physician members of the formulary committee, the drug was added with few restrictions.

Products containing hydrocortisone 0.5% were permitted for prescription by the pharmacist. At the time of passage of the law and the rules adding this drug, most products containing 0.5% hydrocortisone were already available OTC. When the maximum concentration allowed for OTC sale of hydrocortisone products was increased to 1%, there was no longer any justification for prescribing a product with half the amount of hydrocortisone, an amount thought by most dermatologists to be subtherapeutic.

Loperamide was originally restricted to prescription-only status. As the pharmacist prescribing bill was being formulated, this drug was targeted as one that could improve the treatment of self-limiting diarrheal disease without the need for a visit to the physician. Once again, before the law was fully implemented, this agent was moved to OTC status and there was no longer any advantage to prescribing it.

In an audit of prescribing by pharmacists reported by Eng and McCormick¹ in 1990, pharmacist prescribing appeared to be limited to 3 primary drug categories: topical pediculicides (lindane shampoo), oral analgesics, and otic analgesics; these comprised 82% of all pharmacist-generated prescriptions. One by one, the drugs permitted under the law were rendered obsolete or unsafe. To be effective, such laws must create real opportunities to help patients.

But are Pharmacists Trained to Diagnose Disease?

What would happen if the pharmacist prescribed a cough medication when, in fact, the patient had lung cancer? This is one of the extreme arguments put forth by those who opposed the legislation. One must remember that the medications that pharmacists are allowed to prescribe are for the symptomatic treatment of short-term and, in most cases, self-limiting conditions. If a man tells the pharmacist that he needs something for a cough, the pharmacist would naturally inquire as to the symptoms. If told that the patient had been coughing for more than 4 or 5 days, the prudent pharmacist would refer the patient to a physician rather than recommend a product. That is simply sound practice.

For serious, long-term illnesses, there is no question that only the physician is qualified to diagnose and manage the condition. But in terms of the prescribing privileges outlined in the law, the pharmacist would not be doing anything he has not done previously when recommending OTC products. The difference is that now the pharmacist can recommend more products than before and will have to commit to writing a brief patient history and the recommendation made.

Key Benefits to Participating Pharmacists

First, in terms of professional fulfillment, there is no question that this new legislation represented a long overdue vote of confidence in the pharmacist's valued role within the American healthcare picture. To me, the new law was a welcome, positive expansion of responsibility.

Another benefit will be the developing relationship between pharmacist and patient. An increased sense of trust and loyalty is bound to result from this expanded role. Florida residents would now choose their pharmacist with the same care exercised in selecting a physician. Conceivably, the trend would have favored the independently owned pharmacy, taking away some of the appeal of the larger chains. On the other hand, the large chain that can adapt and provide such personal service is sure to benefit.

The Fear of Liability

Many pharmacists expressed concern about being sued if they misprescribed a drug. Liability did not come into being with this new law. Munger et al.² reminded us that having a statutory basis for pharmacists' prescribing may turn the floodlights on this area of pharmacy practice. However, pharmacists are open to liability every time they turn the key to unlock the pharmacy's front door. What could be more devastating than human error in the process of filling and dispensing a prescription written by a physician? And yet, pharmacists fulfill this responsible role every day of their professional lives, without undue fear of liability. The same

now applied to recommending medication: competence is the individual pharmacist's best insurance.

But What Will the Physicians Think?

Traditionally, there has been an unspoken understanding between pharmacists and physicians: you send us customers and we send you patients. As difficult as it is for us to hear these words (after all, patients are patients), there were some who were wary of rocking the boat. In fact, Eng et al.² showed that physicians were, indeed, concerned about the economic impact that pharmacists' prescribing would have on their income.

In what might seem to be reverse logic, the prescribing guidelines might have served to increase physician referrals. The wise pharmacist would send any patient with questionable symptoms to a physician. It would be important that those physicians be made aware of where the referral came from.

When this law was being rolled out, I suggested that pharmacists, particularly in smaller communities, meet with the local physicians and tell them to expect referrals of patients who should be evaluated and managed by a physician. Such a meeting would also allow for discussion of what the law does and does not permit. These measures should allay the fears on both sides of the healthcare fence.

In drafting the law, there were several assumptions that had to be made, many of which proved to be false.

Assumption 1

The types of drugs that pharmacists could prescribe would make available unique drugs that could be safely and effectively used without the patient needing to visit a physician.

REALITY 1

As it turns out, most of the drugs on the prescribing formulary were OTC products masquerading as prescription drugs.

Assumption 2

All pharmacists would embrace the prescribing function and would see it as a way of elevating the profession.

REALITY 2

Shortly after passage of the legislation, rumblings among rank-and-file pharmacists hinted that a group of them thought it was a mistake to allow pharmacists to prescribe drugs. These rumblings grew into outright contention by a sizeable number of pharmacists. They were heard to say things like, "Doctors should prescribe drugs; pharmacists should fill prescriptions. That's the way it has

always been and that's the way it always should be. And besides, we don't get paid for prescribing." Incidentally, there is wording in the law that specifically allows for pharmacists to charge a fee for the prescribing function, above and beyond the charge for the drug itself.

Turf issues are bound to arise whenever new roles are proposed for a particular group of health professionals. Ophthalmologists opposed giving optometrists prescribing privileges. It took several years and much lobbying to finally secure prescribing prerogatives for physician assistants. Not all physicians support the prescribing role of nurse practitioners. Turf battles are argued publicly on the basis of whether the practitioner has sufficient qualifications to perform a certain task. If the truth were known, behind most turf arguments lies a perceived threat to one's livelihood. This is addressed in more detail later in this article.

Hospital pharmacists felt somewhat disaffected by this legislation. Since it was to be performed primarily in the community pharmacy setting, hospital pharmacists really did not take the time to learn much about the law. Overall, their attitude about the prescribing role ranged anywhere from ambivalence to contentiousness.

Assumption 3

All pharmacists are equally prepared to prescribe drugs.

REALITY 3

Pharmacy education has changed dramatically over the past 40 years. A certain percentage of the 23,672 pharmacists licensed in Florida graduated before the emphasis in pharmacy education was patient-oriented rather than product-oriented. Some may lack the in-depth drug knowledge base and patient assessment skills necessary to prescribe drugs. True, many of the drugs on the pharmacist prescribing list require minimal patient assessment, but that very fact may have severely limited the breadth of drugs that otherwise might have been included.

Assumption 4

Other health professionals, especially physicians, would support the prescribing role for the pharmacist or, at a minimum, would not oppose it.

REALITY 4

From the start, there was considerable opposition from the medical community regarding a pharmacist's right to prescribe medications. Some of the opposition was vocal, with editorials written and statements made in the press questioning the wisdom of the legislation. Although the content of these statements showed that physicians did not understand the limited scope and the built-in safeguard of

the law, nonetheless it did not foster a good working relationship between the 2 professions.

At one of the hearings during which nicotine chewing gum (available OTC since 1996) was being considered for addition to the prescribing formulary, vigorous opposition was heard from the physicians on the formulary committee and from those in the audience. Horror story after horror story was recounted about how people were going to die if pharmacists were given the right to prescribe nicotine gum. It was laughable to think that these healthcare professionals would rather see people continue to smoke cigarettes than have a shot at quitting by using nicotine gum.

When the hearing was over, pharmacists had won the right to prescribe nicotine gum, as long as the prescriber wrote a letter to the pharmacist authorizing the prescribing. Getting a physician to do this would be difficult; it would be easier to simply call the physician and receive a prescription over the phone. I would guess that no more than a handful of prescriptions for nicotine chewing gum were written by pharmacists in the 10 years the law has been in effect.

Assumption 5

Patient care would be drastically improved if pharmacists could prescribe drugs.

REALITY 5

During consideration of this bill, legislators were reminded that pharmacists are some of the most accessible healthcare professionals, who can be seen without an appointment at almost any hour of the day. This appealed to both rural and urban lawmakers. The law made good sense. The benefits of having a qualified health professional who was able to treat minor illness without the hassle and expense of a physician's visit or a trip to the emergency department were readily apparent. But can we honestly say that measurable improvements in patient care actually came to pass?

Unfortunately, the examples that so vividly illustrated the benefits of the law never really materialized. The types of drugs that ultimately ended up on the list and the severe limitations placed upon them effectively gutted the law. The types of drugs that the average person might visualize the pharmacist prescribing were left off the list.

Every pharmacist has had patients in pain and in need of a medication beyond the strength of aspirin or acetaminophen. Certainly, with special training, motivated pharmacists could reasonably and dutifully evaluate a patient and prescribe codeine-containing medication to last until a physician can be seen. However, increased availability of controlled substances tends to raise the eyebrows of drug regulatory authorities in particular. It would take a major change of position for the Drug Enforcement Ad-

ministration to allow pharmacists to apply for and obtain a registration number allowing the prescribing of controlled substances.

Assumption 6

The extra time demands imposed by the patient assessment process and record-keeping requirements of the law could be accomplished without disrupting the normal work flow in the typical community pharmacy.

REALITY 6

Busy community pharmacists are already working at maximum output. Although it was estimated that the requirements of the law would add only about 10–15 minutes per prescription, this is an eternity in some pharmacy settings. Where productivity (and hence, rewards in the form of bonuses or promotions) is often tied to prescription volume, anything that would decrease prescription volume would be seen by both pharmacists and their management as counterproductive. Despite streamlining the paperwork and developing notebooks with set protocols, many pharmacists simply did not have the time to undertake the prescribing function.

Summary

Aside from the symbolic victory of winning the right to prescribe, we must honestly ask ourselves whether there is anything really to be gained by granting pharmacists prescribing privileges. We must think of patient care first and ourselves second. We must find answers to some very difficult questions:

1. Do all pharmacists want to prescribe drugs?
2. Are all pharmacists equally prepared to assume the prescribing role?
3. Should the prescribing function be done independent of other practitioners or should it be a collaborative arrangement?
4. What mechanisms should be in place to ensure the quality of the prescribing decisions made by pharmacists?
5. In what setting should the prescribing function take place?
6. What levels of review, if any, should be in place before pharmacist-initiated orders are instituted?
7. What educational or experience requirements should be met before prescribing privileges are granted?
8. What, if any, special incentives should be offered those pharmacists who choose to prescribe?
9. Should there be restrictions on the types of medications pharmacists prescribe and, if so, how should these be determined?

In the final analysis, was the law a home run or a swing and a miss? While it proved to be a disappointment to supporters, valuable lessons were learned. From these lessons pharmacists in other states and in other settings are the beneficiaries of the Florida experience. It is not likely that this model for pharmacist prescribing will ever succeed; I rarely hear pharmacists even mention this option. But the prescribing directive that had been a reality in Veteran's Administrations since 1995 serves as a shining example of pharmacist prescribing. In this model, clinical pharmacy specialists, advanced nurse practitioners, and physician assistants may prescribe through a credentialing process. The system seems to be working well.

All things considered, maybe it is not so important who puts pen to paper in generating the prescription. History has shown that pharmacists *are* having a positive impact on patient care and this progress has not come without some difficult and painful lessons to learn.

Paul L. Doering MS, Distinguished Service Professor of Pharmacy Practice, College of Pharmacy, University of Florida, Box 100486, Gainesville, FL 32610, fax 325/219-1091, doering@shands.ufl.edu

Reprints: Dr. Doering

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