

**Testimony**  
of the  
**American  
Pharmacists  
Association**

**Freedom of Conscience for Small  
Pharmacies**

**Submitted to the  
House Small Business Committee**

**July 25, 2005**



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**Testimony of the American Pharmacists Association**

**Linda Garrelts MacLean, RPh, CDE**

**Before the Small Business Committee  
United States House of Representatives**

**Hearing on  
Freedom of Conscience for Small Pharmacies**

**July 25, 2005**

Good morning. Thank you for the opportunity to appear before you today and present the views of the American Pharmacists Association (APhA). I am Linda Garrelts MacLean, a pharmacist and active member of APhA. I have been in practice for 27 years and am the former co-owner of two community pharmacies in Spokane and Deer Park, Washington. Founded in 1852 as the American Pharmaceutical Association, APhA is the first-established and largest national pharmacist organization in the United States, representing more than 53,000 practicing pharmacists, pharmaceutical scientists, student pharmacists and pharmacy technicians. APhA members practice in virtually every area of pharmacy practice, including independent and chain community pharmacy, hospital pharmacy, nuclear pharmacy, long term care pharmacy, home health care and hospice.

Let me first commend the Committee for holding today's hearing to address the effects that the Governor of Illinois' emergency order requiring pharmacies to provide contraceptives based on a valid, legal prescription 'without delay' will have on small pharmacies. We greatly appreciate the opportunity to provide the pharmacist's perspective on this important topic. As you can see from the chart provided as Attachment A, pharmacists are the most accessible health care providers on the health care team. Pharmacists fulfill a vital role in rural communities and other communities suffering from a shortage of health care providers. This role must be taken into account when considering proposals that may affect pharmacists in rural areas. For some of these patients, the pharmacist may be the only access point into our health care system.

Recent activity at the state and federal level on the issue of pharmacist conscience clauses has had and will have a direct impact on the ability of pharmacists and pharmacies to provide care to their patients. This activity has also magnified the issue to a degree which does not accurately reflect the scope of the issue. The vast majority of pharmacists dispense the vast majority of

prescriptions. Regardless, pharmacists want to retain the ability to opt out of providing services to which they personally object. My testimony will focus on the actual professional side, the provision of pharmacist services. Pharmacist services are a business. Intruding on how and what I choose to provide my patients is an intrusion into how I run my small business. To that end, I appreciate the Committee recognizing the business aspect of a health care issue.

My comments today will discuss the pharmacist conscience clause, pharmacists' activities to increase appropriate access to emergency contraceptives, the impact of 'duty to fill' legislation has on the pharmacist's clinical role, the scope of the problem, and potential next steps. Whether expanding the pharmacist's role in improving medication use, working to successfully implement the Medicare prescription drug benefit, seeking adequate reimbursement in the Medicaid program, or enacting laws to allow pharmacists to immunize patients, pharmacists are stepping up to the plate to help ensure patients have access to medications and know how to make the best use of those medications.

### **Pharmacist Conscience Clause**

The ability of health professionals to opt out of providing services they find personally objectionable is an important component of our health care system. The pharmacy profession officially addressed this situation in 1998 through the APhA's policy-making process, our House of Delegates. Stimulated in part by the legalization of physician assisted suicide in Oregon, the policy applies to any situation where a pharmacist objects to dispensing a medication for personal (religious or moral) reasons. APhA's policy states:

APhA recognizes the individual pharmacist's right to exercise conscientious refusal and supports the establishment of systems to ensure [the] patient's access to legally prescribed therapy without compromising the pharmacist's right of conscientious refusal.

APhA's policy supports the ability of a pharmacist to opt out of dispensing a prescription or providing a service for personal reasons and also supports the establishment of systems so that the patient's access to appropriate health care is not disrupted. In sum, our policy supports a pharmacist 'stepping away' from participating but not 'stepping in the way' of the patient accessing the therapy.

Pharmacists, like physicians and nurses, should not be forced to participate in procedures to which they have moral objections. However, recognizing pharmacists' unique role in the health care system, there should also be systems in place to make sure that the patient's health care needs are served. It is possible to address the rights of patients and the ability of pharmacists to step away from an activity to which they object. Real world experience has proven this to be true. And it does **not** require a confrontation with the patient.

### **Types of Systems**

Because APhA's policy supports the establishment of systems to ensure patients receive access to their care, it is worthwhile to take a moment to discuss these various types of systems. The first of several potential systems begins when a pharmacist chooses where to practice. A pharmacist who objects to physician assisted suicide would choose a practice outside the State of Oregon, or outside a practice that participates. A pharmacist with personal objections to dispensing hormonal contraceptives would avoid practicing in a Title X clinic. Even when a pharmacist makes a thoughtful decision about where to practice, the pharmacist may be faced with a prescription to which they have moral or religious objections. Common systems that are used to balance a pharmacist's moral or religious objections and a patient's needs include staffing the pharmacy so that another pharmacist in the same pharmacy can dispense the prescription, and referring a new prescription or transferring a refill prescription to a different pharmacy.

An active communication plan can also help navigate these situations. When prescribers and patients are directed proactively to pharmacies that carry certain drugs, such as emergency contraceptives, patients can be directed to those pharmacies. The Association of Reproductive Health Professionals operates a national hotline (1-888-not-2-late) that allows patients to find a listing of providers who provide emergency contraception services. The same group, in collaboration with Princeton University's Office of Population Research, also operates a website (<http://not-2-late.com>) that can help patients identify a provider of emergency contraceptives in their area. This concept can be applied more informally at the local level by proactive communications between pharmacists and prescribers.

Enacting pharmacist prescriptive authority for emergency contraceptives is another system that I will discuss in greater length. Where these programs are in place, patients are directed to the pharmacists who prescribe and dispense emergency contraceptives and away from those who do not. For example, in rural Washington State, potential patients are directed to pharmacists who

participate in the emergency contraceptive care program, streamlining the process for the patient. Finally, in areas where no pharmacist will dispense a medication it may be the prescriber who chooses to dispense the product. What each of these systems has in common is better communication between pharmacists and prescribers — a concept with broader benefits than navigating these rare situations.

An important underlying concept of our proposed systems is that they are established proactively — before a pharmacist is presented with a prescription to which they object. The system should be seamless, with a pharmacist – patient interaction that is very similar to the interaction that occurs with any other prescription. Similar to the situation where a medication is simply out of stock on any given day, if the pharmacist is unable to dispense the prescription, then the patient must be made aware of the options available to them to fulfill his or her medication needs. The pharmacist should not use their position of power to berate the patient, to share their own personal beliefs, or obstruct patient access to therapy—such as refusing to return a patient’s legally valid, clinically appropriate prescription. In most states this activity is prohibited by law. When alternative systems are established proactively, the patient is unaware of the pharmacist’s actions and both the patient’s right to care and the pharmacist’s need to step away from certain activity are accommodated.

### **Ongoing Activities; Opportunities for the Future**

As professionals, pharmacists continually strive to provide the best patient care possible, including continuous review of practices and taking steps to improve medication use and advance patient care. Unfortunately, the press has highlighted a few negative situations rather than focusing on the more broad reality of a significant number of pharmacists working to increase access to therapy such as emergency contraception.

Because of the short timeframe involved in effective use of emergency contraceptives, the opportunities for pharmacist involvement in expanding patient access are many. APhA supports the voluntary involvement of pharmacists, in collaboration with other health care providers, in emergency contraceptive care programs that include patient evaluation, patient education, and direct provision of emergency contraceptive medications.<sup>1</sup>

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<sup>1</sup> APhA policy adopted in 2000. (*JAPhA NS40(5)Suppl.1:S8. September/October, 2000*) (*JAPhA NS43(5) Suppl. 1:S58. September/October 2003*)

Pharmacists in Alaska, California, Hawaii, Maine, New Hampshire, New Mexico and Washington have legal authority to prescribe and dispense emergency contraceptives under collaborative agreements with doctors and other prescribers. Legislation to establish similar programs was introduced this year in Illinois, Kentucky, Maryland, Massachusetts, New Jersey, New York (it is waiting for the Governor's signature), Oregon, Texas, and Vermont.

In the states where pharmacists have this authority, patients do not need to go to their physician first — something that could be difficult to accomplish in the short time period of effectiveness. Instead, patients may go directly to a participating pharmacist to receive their prescription for emergency contraceptives. Participating pharmacists receive training and work in collaboration with physicians and other prescribers through a pre-established protocol detailing the situations where emergency contraception should be used. Patients are first interviewed and counseled by the pharmacist. If the pharmacist agrees that the patient meets the clinical criteria for the medication, then the pharmacist will write the prescription and dispense the medication. Patients who need additional clinical care are referred to their physician.

While serving as President and President-elect for the Washington State Pharmacist's Association, I was instrumental in helping enact emergency contraceptive prescriptive authority in my home State of Washington, which was the first state to enact this type of law. Pharmacists began providing emergency contraception services in 1997. Since then, hundreds of pharmacists and student pharmacists have been trained annually. Approximately 1,200 emergency contraception interventions are done quarterly by pharmacists in local, Washington chain pharmacies in forty-three locations. Clearly the system is working well in Washington.

The states that have more recently adopted pharmacist emergency contraception prescriptive authority laws appear to have strong support from their pharmacists as well. Two to three times more pharmacists than expected have attended emergency contraception prescriptive authority training programs. These numbers and the experience of Washington State reflect the growing movement in pharmacy to make better use of pharmacists' clinical expertise while also helping to improve access to medications, including emergency contraceptives. It is a reality that negates the perception the media has created of pharmacists as obstructionists.

### **Pharmacists' Clinical Role**

Another consequence of ‘duty to fill’ legislation is its impact on the clinical role of pharmacists. (‘Duty to fill’ legislation would require *pharmacies* or *pharmacists* to dispense ‘legal’ prescriptions. When poorly crafted, such a requirement conflicts with the pharmacist’s legal responsibility to assess the clinical safety and appropriateness of the prescription.) Much of the media coverage and the discussion around some of the legislative proposals portray pharmacists as simply robots—transforming individuals from thinking health care professionals into automatons forbidden from having personal beliefs, and from exercising their considerable professional judgment gained during years of education and practice. Serving our patients and helping them make the best use of their medication is our priority.

If the pharmacist’s role were merely to dispense lawfully prescribed medicines, that robot or automaton would fit the bill. But pharmacists are professionals whose role on the health care team is to collaborate with physicians and patients to help medications do what they should—and nothing they shouldn’t. The profession exists to help patients access medications that will help them, and that means going beyond a ‘lawful’ prescription.

- A prescription calling for a 10-fold overdose is ‘lawful’, but likely fatal to the patient.
- A prescription calling for the antibiotic amoxicillin for a patient allergic to penicillin is ‘lawful’, but again, potentially fatal to the patient.
- A prescription calling for an oral contraceptive for a patient with a history of thromboembolic disease is ‘lawful’, but may result in patient harm.

‘Duty to fill’ legislation can cause problems for pharmacists and our patients. Under Illinois Governor Blagojevich’s original April 1<sup>st</sup> order, for example, pharmacies that sell contraceptives are required to fill valid, legal prescriptions for these medications without delay. As written, the rule did not appear to permit pharmacists to protect patients from medications contraindicated because of allergy or drug-related interactions or to correct potential dosing errors. Nor did the rule permit pharmacists to transfer prescriptions if they had any objections to filling the prescriptions. According to the Governor, he was prompted to issue the order by reports to state health authorities that two women were unable to have prescriptions filled for emergency contraceptives at a chain pharmacy in Chicago.

Pharmacy’s reaction to Governor Blagojevich highlighted the reality that the emergency order, as originally written, would conflict with provisions in the Illinois Pharmacy Practice Act that

require pharmacists to conduct prospective drug utilization review. The profession stated, “The requirement to dispense a valid, lawful prescription ‘without delay’ could require a pharmacist to dispense a valid, lawful-but clinically inappropriate-medication ‘without delay.’”<sup>2</sup>

In response, on April 11<sup>th</sup>, the Illinois Department of Financial and Professional Regulation published an open letter to Illinois pharmacists in which it clarified that the April 1<sup>st</sup> emergency rule was not intended to “interfere in any way with a pharmacist’s responsibility to conduct prospective drug utilization review.” Governor Blagojevich and the Department have pursued a permanent rule through the regulatory process to replace the emergency amendment. Patients in Illinois will be well served if the Illinois Pharmacist Association’s efforts to include pharmacist prescriptive authority for emergency contraception is successful as it is one of the mechanisms to expand access.

As stated previously, pharmacists are professionals whose role on the health care team is to collaborate with physicians and patients to help medications do what they should – and nothing they shouldn’t. To take away their clinical judgment is a draconian step backwards in an era when we are seeking to reduce the number of medication-related errors.

### **Impact on the Business of Pharmacy**

‘Duty to fill’ legislation can also affect the business side of pharmacy. As noted previously, it is a reality that health care is a business, and pharmacy practice a component of that business. ‘Duty to fill’ legislation affects business—and specifically small businesses—by dictating how a business must accommodate its staff, in this situation, its pharmacists.<sup>3</sup> For example, some proposals have defined the type of system a pharmacy must implement in order to assure patients may access necessary medications, such as requiring a pharmacy to order a product if the medication is not in stock. With more than 10,000 medications on the market today, it is

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<sup>2</sup> April 5, 2005 letter to the Honorable Rod R. Blagojevich, Governor, State of Illinois, from the American Pharmacists Association, the Illinois Pharmacists Association and the American Society of Health-System Pharmacists. Accessed at [http://www.aphanet.org/AM/Template.cfm?Section=Federal\\_Government\\_Affairs&CONTENTID=3201&TEMPLATE=/CM/ContentDisplay.cfm](http://www.aphanet.org/AM/Template.cfm?Section=Federal_Government_Affairs&CONTENTID=3201&TEMPLATE=/CM/ContentDisplay.cfm)

<sup>3</sup> Some of the ‘duty to fill’ proposals have attempted to accommodate the individual pharmacist’s ability to opt-out of objectionable activity by placing the requirement on the ‘pharmacy’—the business—rather than the individual, the pharmacist. But for a small business like an independent pharmacy operated by a single pharmacist, the distinction between the two is minimal. Even in larger operations, a ‘pharmacy’ does not exist without a ‘pharmacist’, and rigid requirements regarding dispensing certain products compromise the individual pharmacist’s activities.

impossible for a typical pharmacy to carry all medications—and unnecessary as well. Decisions about which drugs to stock are based on the patient population served, the health plans in which the pharmacy participates, and the prescribing patterns of the physicians and other prescribers in the community. Medications that are widely used in some geographic areas may be used only infrequently in others. In some cases, a pharmacy may be willing to order a drug that is typically not available at the practice. But depending on the patient's needs, how quickly the pharmacy can receive the drug, and how much more the drug may cost the pharmacy (special orders may cost the pharmacy more — and the pharmacy may not receive any payment to cover those additional costs), special-ordering the drug may not be a viable option. In these situations, patients would typically be referred to other pharmacy practices or alternative arrangements would be made.

In trying to address an issue that to some may be a legitimate access issue and to others may be an issue of convenience, 'duty to fill' proposals would compel health care providers and businesses to provide certain services. Decisions about what services to provide and by whom should be left up to individual health care providers. Decisions about which systems to implement and how to implement them should be left up to pharmacy managers and pharmacists. Patients will choose the pharmacy and pharmacists who best serve their needs, and market forces will dictate what services the pharmacies provide.

### **Is Legislation Necessary?**

As with any policy discussion, it is critical to examine the situation in context and to carefully review the potential impact — positive and negative — of a legislative or regulatory proposal. With most, if not all, 'duty to fill' proposals, both health care and small businesses are negatively impacted.

The first challenge with such proposals is that they use a broad approach to a statistically minor problem. While any instance of a pharmacist obstructing access to medications must be addressed, such situations are very rare. Nearly 3.3 billion prescriptions are dispensed each year in the outpatient setting<sup>4</sup>, averaging about 9 million prescriptions per day. Proponents of 'duty to fill' laws document approximately twelve examples of refusals to fill since 1996. One must

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<sup>4</sup> 2004 data for retail pharmacy prescriptions (including mail-service), prepared by National Association of Chain Drug Stores' Economic Department using data from IMS Health. Accessed at [http://www.nacds.org/user-assets/PDF\\_files/2004results.PDF](http://www.nacds.org/user-assets/PDF_files/2004results.PDF)

question the need for new laws or regulations to address a handful of situations that may have been avoided through better communication and alternative systems.

Additionally, APhA strongly objects to creating federal oversight of the practice of pharmacy. The practice of pharmacy, both the profession and the business, are regulated at the state level, just as all other health care providers. We would oppose federal legislation to regulate the practice of pharmacy at the federal level. Health care should be regulated at the local level to reflect local needs. State Boards of Pharmacy should remain the leader in regulating the practice, not state or federal legislators who may not understand or appreciate a proposal's impact on local patient care, local health care, or local pharmacies and physician offices.

It is not unusual for a good policy to have unintended consequences. Some of the proposals that would create a 'duty to fill' could result in a pharmacy choosing not to stock a certain product to avoid the situation of forcing their pharmacists to dispense. Other pharmacies could decide to rescind the conscience clause protections they had had in place, and which were working well, because they do not believe that they can allow pharmacists to 'step away' and still meet the law's requirements. And a seemingly simple law, depending on how it is written, could compel pharmacists to participate in current 'opt-in' programs such as Oregon's physician assisted suicide program.

### **Next Steps**

One individual's rights should not outweigh another's. Our policy balances the needs of the patient and the individual needs of the pharmacist, as well as the pharmacist's professional responsibility. Implemented well, patients will receive care and pharmacists will not be forced to ignore their personal moral beliefs. With planning, there are no winners or losers – both persons are accommodated. Rather than designating a profession as robots or automatons that ascribe to one set of beliefs, a different approach is available. And it works. It takes more time, and proactive implementation, but then, many of the best solutions do.

As a portion of the recently adopted American Medical Association (AMA) pharmacist conscience clause resolution indicates, pharmacists and physicians agree. Patients should receive their medications without harassment and interference, but pharmacists should not be compelled to participate in activity they find objectionable. The resolution directs the AMA to have a dialogue with APhA on this issue. We welcome a dialogue that will ensure this continued

recognition of the need to serve patients and recognize the individual beliefs of pharmacists and physicians. Just like physicians, pharmacists abide by a Code of Ethics for the delivery of health care. Just as physicians are not required to provide all medical services, pharmacists should not be required to provide all pharmacy services.

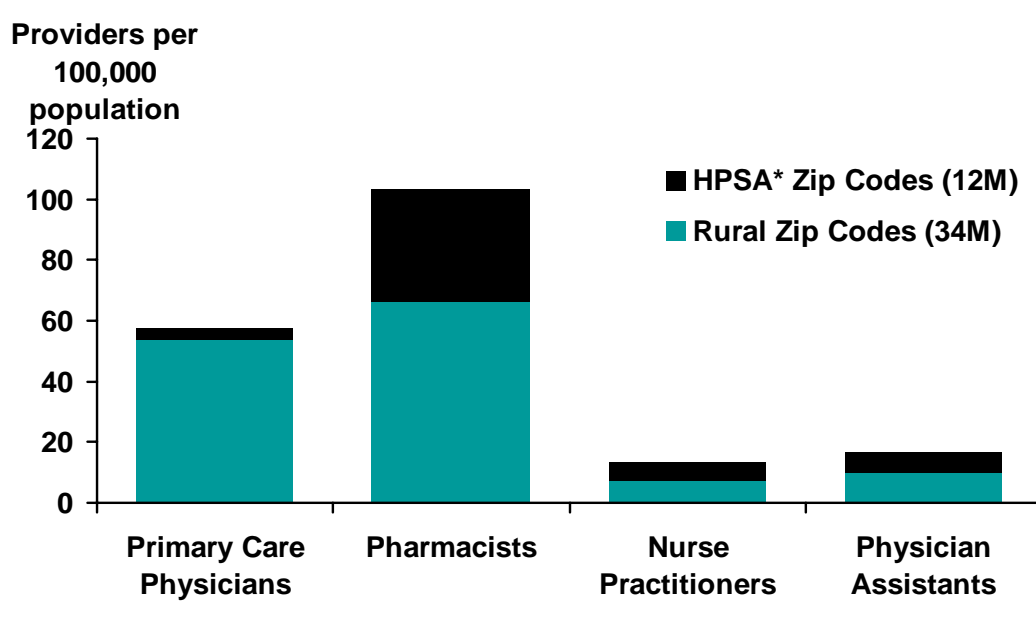
Physicians and pharmacists collaborate every day to improve medication use and advance patient care—including navigating issues of conscience. We look forward to working with the AMA on this issue, much as our individual members are working together with physicians today and everyday in your districts. It is a great opportunity for the profession to lead the efforts to address an issue facing health care professionals and patients.

Additionally, APhA will continue to help state pharmacy associations enact legislation that would provide pharmacists the legal authority to increase access to emergency contraception. These programs support the clinical role of pharmacists in counseling and educating patients and also increase the awareness among consumers and prescribers about these drug products. Lack of patient and prescriber awareness is a significant barrier to care.

Thank you for the opportunity to provide pharmacists' perspective on this important issue. APhA offers our assistance to the Committee as you continue your valuable work on this important issue and would welcome the opportunity to facilitate communications with state pharmacy associations so that Members of Congress can better assess the situation in their districts.

Attachment A

## Distribution of U.S. Provider Groups



Source: JAPhA 1999; 39:127-35.

\* HPSA: Health Provider Shortage Area