



AMERICAN ACADEMY OF
FAMILY PHYSICIANS
STRONG MEDICINE FOR AMERICA

November 28, 2007

Andrew C. von Eschenbach, MD
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Dr. von Eschenbach:

On behalf of the 93,800 members of the American Academy of Family Physicians (AAFP), I am writing in response to your proposal about the public health benefit of permitting some prescription drugs to be behind-the-counter (BTC) with the requirement that they be dispensed by a pharmacist but without consultation with a physician. The Academy strongly opposes this proposal. Following are our reasons for our opposition.

The information in support of this proposal contained in the *Federal Register* is incomplete. The background materials posit a potential increase in patient access to drugs; describe the use of a BTC class in many Western countries (if drugs are "suitable for self-medication, including self-diagnosis, with the intervention of a pharmacist and low potential for side effects);" and emphasize the training and knowledge of pharmacists.

Unfortunately, the background information is focused narrowly on the purported goal of allowing patients simpler access to drugs via pharmacists and does not include a broader perspective on the effect this proposal would have on the already fragmented American health system and patient care. Specifically, the crucial role that physicians play in diagnosis and prescribing drugs to their patients is not mentioned and more broadly, whether or not BTC drugs are a logical step toward the goal of an integrated, coordinated system of quality patient care. Our question is what problem this proposal is trying to solve and is this plan the best way to solve it? In our view, this plan is yet another symptom of a dysfunctional health care system, i.e., the perceived inability of patients to get medications, and should be addressed by overarching reform. With that perspective in mind, following are our responses to questions posed by FDA that are relevant to physicians.

Answers to Questions Posed by FDA That Are Relevant to Physicians

2. What might the impact of BTC be on patient access?

We believe that BTC drugs will not improve patient access to medications. The lack of access to drugs is tied to our fragmented, poorly-coordinated and costly health care system. Access will be improved with a patient-centered medical home directed by a primary care physician (see further description below), and an appropriate history, examination and diagnosis performed by a physician. In addition, access will be improved if we can achieve health care coverage for all.

www.aafp.org

President
James D. King, MD
Selmer, TN

Board Chair
Rick D. Kellerman, MD
Wichita, KS

Vice Speaker
Leah Raye Mabry, MD
San Antonio, TX

Directors
Brad Fedderly, MD, Fox Point, WI
Lori Heim, MD, Vass, NC
Robert Palkay, MD, Savannah, GA
David W. Avery, MD, Vienna, WV
James Dearing, DO, Phoenix, AZ
Roland A. Goertz, MD, Waco, TX

Kenneth R. Bertka, MD, Holland, OH
David A. Ellington, MD, Lexington, VA
Glen R. Stream, MD, Spokane, WA
Jason Marker, MD (New Physician Member), Mishawaka, IN
Tobie-Lynn Smith, MD (Resident Member), San Antonio, TX
Beth Lawson Loney (Student Member), Eudora, KS

President-elect
Ted Epperly, MD
Boise, ID

Speaker
Thomas J. Weida, MD
Lritz, PA

Executive Vice President
Douglas E. Henley, MD
Leawood, KS

3. What might be the impact of BTC be on patient compliance with drug therapy?

Compliance with drug therapy will not be improved with a new class of BTC drugs. Patient compliance with drugs involves a complex mix of an understanding of one's disease, appropriate follow-up with the diagnosing physician and ongoing monitoring by the physician of the appropriate medication(s) for side effects or reduced efficacy.

5. Please comment on the following criteria for what roles a pharmacist or other health professional might play, which are included below for discussion purposes. For example, a pharmacist or other practitioner licensed by law to dispense prescription drugs prior to sale might (A) Review or conduct an initial screening for clinical laboratory test results, contraindications, or drug interactions; (B) Counsel the patient on safe use; (C) Monitor for continued or safe or effective use.

We agree that pharmacists are trained to be experts on drugs and drug interactions. We strongly oppose pharmacists performing the remainder of the suggested roles. These activities are the purview of the physician and not of the pharmacist. Further, the examples do not take into account patients with multiple chronic conditions who may take numerous medications and need a physician to treat them as a "whole person" and not by individual disease state. Finally, in the event of a serious drug interaction, patients should call their primary care physician and not a pharmacist.

Logistics, Question 5. Should reimbursement be available to pharmacists for providing services associated with BTC dispensing? What type? What type of billing procedures could be utilized and how would third part companies facilitate such reimbursement?

The AAFP is strongly opposed to reimbursement for pharmacists for providing BTC drugs. Currently, physicians are not paid appropriately for prescribing medications done in the context of diagnosis and treatment. Payment for dispensing of BTC drugs by individuals lacking physician knowledge and training would be an inappropriate use of scarce medical dollars.

14. In general, what are the benefits and costs to the healthcare system as a whole related to BTC availability?

As stated in our introductory paragraph, the Academy believes that a new class of BTC is under discussion due to overarching problems in the entire American health care system. We believe that the entire system should be transformed so that issues such as access to the appropriate medications are handled within a broader framework, i.e., the patient-centered medical home. Following is information on this concept.

The patient-centered medical home is a proven model in health care delivery that the AAFP has proposed along with the American College of Physicians, the American Academy of Pediatrics and the American Osteopathic Association. In this new model, the traditional doctor's office is transformed into the central point for Americans to organize and coordinate their health care, including prescription drugs, based on their needs and priorities.

At its core, the patient-centered medical home model is an ongoing partnership between each person and a primary care physician. This new model provides improved access through email communication and same-day appointments and secure online tools to help consumers manage their health information, review the latest medical findings and make informed decisions. Patients receive reminders about necessary appointments and screenings, as well as other

support to help them and their families manage chronic conditions such as diabetes or heart disease, including the use of prescription medications.

The primary care physician's practice that serves as a medical home includes a team of specialists and other health care providers such as nutritionists and physical trainers. The primary care physician makes sure that the team works together to meet all of the patient's needs in an integrated, "whole person" fashion. In our view, pharmacists would be incorporated into a team of providers who would be responsible for a patient's care. The FDA's proposal to detach pharmacists from this team and allow them to deliver drugs independently would be a step away from this goal.

The patient-centered medical home will be recognized by an independent organization so that payers can be assured that their investment in this model of care delivery will result in a higher standard of care.

Conclusion

We understand the FDA's concern about increasing access to medications, particularly to those who are uninsured. The solution proposed does not address the complexities involved in today's pharmaceutical world. More importantly, with its narrow focus on the role of the pharmacist, the plan ignores the larger health care system, and, in particular, the crucial role that is played by a physician whose goal is to coordinate patient care. For your information, I am attaching our 2006 policy on Pharmacists, which describes our views in detail.

We invite you to work with us to pursue development of the patient-centered medical home in which the pharmacist is a valued team member and part of a model whose goal is to provide appropriate and quality care.

Sincerely,

A handwritten signature in cursive script that reads "Rick Kellerman MD".

Rick Kellerman, MD, FAAFP
Board Chair

AAFP Policy (2006)

Pharmacists (Position Paper)

Introduction

The Academy recognizes the evolving complexity and proliferation of pharmaceutical agents and the important role of pharmacists participating in the provision of high quality health care. The pharmacy professional and physician can and should work in a collaborative environment where their combined expertise is used to optimize the therapeutic effect of pharmaceutical agents in patient care. It is the intent of this document to define the nature of that relationship.

Environment

The pharmaceutical armamentarium is one of the most rapidly evolving elements of the clinical continuum. The pharmaceutical industry has produced in recent years a large number of effective medications with an ever-expanding range of applications. Additionally, the industry has greatly impacted both patients and physicians by their decision to market directly to the public. Illustrative of the dynamics compounding the complexity is that many of the largest selling drugs in the country have, or will soon lose patent protection. Patients are already being pressured to switch to generic medications as insurance companies attempt to regain some control over pharmaceutical costs. Pharmaceutical costs as a percent of total costs for a typical managed care plan has increased 85% in the past decade.¹ While the Academy is aware of the need and supports initiatives to reduce health care costs, pressure to reduce costs should not take precedence over patient needs.

Role of the Pharmaceutical Professional

Definition and Education

The increased complexity of pharmaceutical applications is at least partially reflected in the profession's decision to upgrade its educational standards. Until July 1, 2000, an individual who wished to become a pharmacist could enroll in a program of study that would lead to either a Bachelor of Science degree or a Doctor of Pharmacy degree. As of July 1, 2000, the doctor of pharmacy became the only degree accredited by the American Council on Pharmaceutical Education (ACPE). Pharm. D. programs take six years to complete and usually involve two years of preprofessional coursework and four years of professional education.² For the purposes of this document the terms pharmacist(s), Pharm. D., and pharmacy professional are interchangeable.

Role & Scope of Practice

Pharmacists, like other health professionals, are seeking to expand their influence and scope of practice. This is consistent with the overall expansion in the level of medical complexity and mirrors the subspecialization of other medical professions.

Expanded roles for pharmacists have legislative and regulatory support. Currently, 32 states have collaborative drug therapy management (CDTM) legislation or regulations.³ These laws allow physicians and pharmacists to enter into voluntary written agreements to manage the drug therapy of a patient or group of patients. Forty states have legislation requiring insurance plans to cover self-management education for patients with diabetes and some of these states list pharmacists among the health professionals who may provide and receive payment for diabetes education and self management services.³ Pharmacists have the authority to immunize patients in 32 states.³ The significance of the pharmacy professional is even greater since an estimated 250 million people walk into a pharmacy every week.⁴ Pharmacists may represent the most accessible professional in the health care system.⁴

It would be within the parameters established by current policy that the issues of pharmacy professionals taking an independent role in medical management situations or managing medications in disease state management (DSM) programs would be defined. The Academy's policy, Disease State Management, specifically lists outpatient drug management as a component present in most effective disease state management programs.⁵ A report from the University of Arizona Center for Pharmaceutical Economics states that the annual costs of medication-related mortality and morbidity is \$76.6 billion with a potential reduction of \$45.6 billion through the application of pharmaceutical care services.⁶ Where disease state management programs have been developed to address specific high-cost and/or high volume diagnosis, and when such programs have a pharmaceutical element that is an essential element of the overall program, there is a critically important role for the pharmacist.

Pharmacists have an important role in providing direction to patients seeking advice on over-the-counter medications. Even if desirable, it is not practical to assume that a physician will be consulted in most instances where nonprescribed medication is involved. In the absence of direction from a physician and in instances where a patient is seeking information, the pharmacy professional is the logical source to provide that information. For the patient seeking nonprescription medication, the pharmacist is positioned to determine the presence of allergies, as well as additional medications being taken which could adversely react with the over-the-counter medicine.

Relationship With Physicians

With increased emphasis on the use of prescription medication, the expanding role of the pharmacy professional directly affects family physicians. In a collaborative environment the pharmacist is a logical member of a team and qualified to deal with issues of drug usage, medication efficacy, and medication use patterns.

As indicated, 32 states allow physicians and pharmacists to enter into voluntary written arrangements to manage the drug therapy of patients. The Academy's policy on Integrated Practice Arrangements states, however, while the Academy supports health professionals working together, "...interests of patients are best served when their care is provided by a physician or through an integrated practice supervised directly by a physician."⁵ The policy defines the central issue of positioning the family physician as "coordinator" and defining the pharmacy professional. As stated previously, Academy policy clearly states that in all instances supervision by a physician is a paramount concern.

The expansion of the pharmacist's professional role has made certain aspects of current Academy policy on non-physician providers (NPPs) applicable. The policy states that, "The central principle underlying physician supervision of NPPs is that the physician retains ultimate responsibility for the patient care rendered. Physician supervision means that the NPP only performs medical acts and procedures that have been specifically authorized and directed by the supervising physician (emphasis added)."⁵ This aspect of the policy would certainly be applicable in those instances where a collaborative (or integrated) approach is being utilized to optimize drug therapy.

At issue is the nature of the appropriate relationship between family physicians and pharmacy professionals. Although evolving, the basic aspect of the relationship is the fact that the pharmacist dispenses the medication prescribed by the physician or the physician's designated surrogate who is under the appropriate level of supervision by the physician.

After an examination and determination of what is in the best interests of the patient the family physician is best positioned to prescribe medications. As indicated by the Academy's recently revised policy, Drugs, Prescribing, " The AAFP believes that only licensed doctors of medicine, osteopathy, dentistry, and podiatry should have the statutory authority to prescribe drugs..."⁵ The pharmacy professional is in the position to dispense the prescription written by the physician.

Given the ever-expanding number and complexity of pharmaceutical agents, family physicians' relationship with pharmacists is not dissimilar to that with specialist and subspecialist physicians. Obviously the level of autonomy accorded other specialist physicians is not appropriate when dealing with pharmacy professionals, but in terms of acknowledging and utilizing expertise the process is similar.

Benefits of Collaborative Arrangements

There is a growing body of research indicating that physicians and pharmacy professionals working in a collaborative environment can make positive contributions to patient health. Certain areas have been identified which seem amenable to the presence of a pharmacy professional. Patients treated in a pharmacist-managed clinic had better anticoagulation control, fewer bleeding and thrombotic complications, fewer hospitalizations and emergency room visits, and lower health care costs compared to newly anticoagulated patients treated in the standard manner.⁷ Collaborative programs have demonstrated success in other areas, including hyperlipidemia, asthma, diabetes, and hypertension.⁸ The program basics are similar in each instance. Pharmacist participation entails monitoring compliance, reviewing drug therapy, recommending changes in drug regimens, and education in behavior modification.

References

1. Dickman D F, et al, Medscape, "Consumerism and Escalating Drug Costs: A Volatile Mix," [Drug Benefit Trends 13(1): 48-52, 2001].
2. The Council on Credentialing in Pharmacy, "Credentialing in Pharmacy," September 2000.
3. American Pharmaceutical Association, "Pharmacists Finding Solutions Through Collaboration," www.aphanet.org.
4. Madhavan S S, et al, "Pharmacists and Immunizations: A National Survey," Journal of the American Pharmaceutical Association, Vol. 41, No. 1, January/February 2001.
5. The American Academy of Family Physicians, "AAFP Policies on Health Issues, 2001."
6. Joint Commission of Pharmacy Practitioners, "Prescribing Medications: Changing the Paradigm for a Changing Health Care System."
7. Chiquette E, et al, "Comparison of an Anticoagulation Clinic With Usual Medical Care. Anticoagulation Control, Patient Outcomes, and Health Care Costs," Archives of Internal Medicine 1998, 153.
8. Munroe W P, et al, "Economic Evaluation of Pharmacist Involvement in Disease Management In a Community Pharmacy Setting," Clinical Therapeutics, Vol. 19, No. 1. (2002) (August 2006)