AMCP Academy of Managed Care Pharmacy

1957 '02 JUN 25 A9:37

President
C.E. (Gene) Reeder, RPh, PhD
University of South Carolina, College of Pharmacy
Columbia, SC

President-Elect
Michael E. Bailey, RPh
MedImpact Healthcare Systems, Inc.
San Diego, CA

Past President
Cynthia J. Pigg, RPh, MHA
CIGNA HealthCare
Richmond, VA

Treasurer
Peter M. Penna, PharmD
Formulary Resources, LLC
University Place, WA

Director
Michael J. Dillon, MS, RPh, FAMCP
NMHCRx
Latham, NY

Director
Rusty Hailey, DPh, MBA
Coventry Health Care, Inc.
Franklin, TN

Director
Lydia Nesemann, PharmD
Midwestern University College of Pharmacy
Glendale, AZ

Director
Craig S. Stern, PharmD, MBA, FAMCP
ProPharma Pharmaceutical Consultants, Inc.
Northridge, CA

Director
Debbie Stern, RPh
Rxperts
Irvine, CA

Executive Director
Judith A. Cahill, CEBS
AMCP
Alexandria, VA

June 21, 2002

Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket number 02N-0115

Thank you for the opportunity to reply to your request for comments on the Food and Drug Administration's approach to risk management of prescription drugs. (Federal Register, April 15, 2002).

The Academy of Managed Care Pharmacy (AMCP) is a professional association of pharmacists and associates who serve patients and the public through the promotion of wellness and rational drug therapy through the application of managed care principles. Its sole purpose is to represent the views and interests of managed care pharmacy. The Academy has more than 4,800 members nationally who provide comprehensive coverage and services to the over 200 million Americans served by managed care.

The mission of AMCP is to provide a means by which the membership may pursue its common goals; provide leadership and support for its members; represent its members before private and public agencies and professional health care organizations; and advance pharmacy practice in managed health care systems.

AMCP and its members recognize, support, and promote the role of pharmaceutical care in the provision of quality, cost-effective health care. AMCP members are intimately involved in the care and course of pharmaceutical treatment for patients and are dedicated to achieving optimal patient outcomes, improving the patient's quality of life, and containing health care resources.

The comments in this letter will focus on three areas of concern: Risk Communication; Tools for Risk Management; and Evaluation of Risk

02N-0115 C3

100 North Pitt Street
Suite 400
Alexandria, VA 22314

703 683 8416
800 827 2627
Fax 703 683 8417

Management Strategies and Interventions. These areas of focus must be explored for the most effective and appropriate initiatives that minimize negative effects and unintended consequences on patients and the health care system.

I. Risk Communication

Improvements that may enhance communication to prescribers and pharmacists about safety issues for drugs

When the FDA becomes aware of a patient-threatening situation, the FDA may request that "Dear Health Professional" letters be sent by mail to prescribers, pharmacies, and hospitals. The letters are usually not easy to retrieve for further reference and in many cases have not been appropriately filed for future use. Delivery of this material by e-mail or fax would increase the speed of transfer of material to health care personnel in the hopes that adverse consequences could be avoided by a quicker dissemination of information. E-mail would also improve ease of storage for such medication alerts.

In addition, "Dear Health Professional" letters should be sent to other health care personnel who do not currently receive them: e.g. network pharmacy administrators, health plan administrators, nurses, and patient advocacy groups.

Take for example, the utility of sending the alert to a network pharmacy administrator. These administrators are employees of health plans or pharmacy benefit management companies that have responsibility for alerting pharmacies under contract to potential safety hazards to patients. This is usually done on an electronic basis when a prescription claim is sent for adjudication. If network pharmacy administrators were alerted to a problem, they could build an electronic alert in their messages to their pharmacies. If a drug has been recalled or a new drug warning has been issued, a network pharmacy administrator could introduce "stops" into the on-line prescription adjudication system. The prescription drug claim entered for a recalled drug would therefore not adjudicate. When a claim does not adjudicate, the pharmacist may be reminded that the drug was recalled or the pharmacist may call the "help desk" and be informed of the recall. A similar situation can occur when new drug warnings are issued. A network pharmacy administrator can request specific information before a prescription would be adjudicated and paid (prior authorization requested). A drug message could also be returned from a chain, a processor, or the plan to a pharmacist attempting to adjudicate a prescription claim.

Nursing and patient advocacy groups strive to increase patient safety and can help extend the alert among health care personnel and patients.

AMCP also suggests that the FDA require that all drug labeling,
and television and printed advertising include a toll-free number for reporting of adverse drug events by prescribers, pharmacists, other health care personnel and patients.

II. What are the Tools for Risk Management?

A. A list of methods the FDA could use to manage risk include:

1. Tighter restrictions on the distributors of drug products - This may be achieved by restricting prescribing to select physicians and dispensing to certified pharmacies and/or certified pharmacists.

a) Advantages:

- By reducing the number of available outlets and prescribers; e.g. a sole distributorship of the drug product - the drug and patients may be more closely monitored.
  - By requiring heightened monitoring of patients by limited prescribers and dispensers, knowledge of adverse events will become known sooner.
- In cases of medications that require specialized handling and/or reporting, distribution channels can be limited to allow only pharmacists that have received the required specialized training or certification, etc., further ensuring proper distribution and monitoring of the product.
- A limited prescriber network would result in tighter control of drug products. Physicians who prescribe such drugs should go through an educational program regarding treatment alternatives, indications, risks, and monitoring. These educational programs do not have to assume the format of a traditional continuing education. Web-based interactive educational programs could be used.

b) Disadvantages:

- Drug would only be available from a limited number of locations.
  - Patients may need to travel greater distances if the outlet is not a "regular" pharmacy.
  - If no local outlet is available, mail service may be the only option to obtain the drug. This may result in a delay in prescription delivery.
- Loss of continuity of care
  - A restricted outlet may not be familiar with the patient, or have access to the patient's concurrent therapies. This lack of knowledge will make screening for drug-drug interactions much more difficult.
- Patients may not receive the appropriate degree of continuity of care if they are required to visit a specialist to receive drug treatment therapies for restricted products.
  - Specialists will not have broader knowledge of patients; or will require a copy of records from the primary care practitioner; or will rely on verbal reports from patients.

- Administrative expenses with certification or training program.
  - How often would providers need to re-certify?
  - How can the effectiveness of the certification program be assessed?
  - How will the oversight organization determine that a particular provider is qualified?
- Additional costs to patient
  - Pharmacy may charge a premium for restricted drugs to offset the cost of certification, or due to lack of competition.
  - Additional office visit expenses may be incurred if a patient's primary care prescriber is not "certified." Due to the fact that the patient may be required to obtain a referral to see a specialist who is "certified." Additional time away from work may be required, and there may be added transportation costs.
  - If the prescriber is a specialist, office visit charges would generally be higher than for primary care physicians.
- Requiring that patients obtain referrals to visit specialists could complicate and/or delay treatment, increase health care costs, and may potentially put patients at risk due to such delays.

2. Withdrawal of the drug from the market

a) Advantages:

- Removes immediate risk, as drug is no longer available.

b) Disadvantages:

- Patients no longer have access to the drug.
- There may be no clinical alternative.

3. Increased post-market surveillance: A need for faster analysis and feedback Patients should be enrolled in a national patient registry where they can be tracked and monitored.

a) Advantages:

- Faster feedback and analysis would provide earlier warning of potential problems with products. Knowledge sooner could expand the options available to the FDA. The FDA may not have to remove the drug from the market. The FDA may be able to implement a less restrictive type of management of the drug. e.g. issuance of "black box warnings", restricted network of prescribers and dispensers.

b) Disadvantages:

- Patient privacy issues. More personal information will be exchanged and stored in databases between health care practitioners and the FDA.
- There would be an increased burden of reporting requirements placed on the prescriber.

B. New tools that can be created to better address specific drug risks

1. ***The FDA website tracks adverse drug events. The Academy suggests several ways to enhance the site.***
   - Drug recalls and food recalls could be listed in separate sections.
   - The portion of the FDA web site that deals with drugs, drug recalls, and drug alerts could have separate web pages for the health care professional and the patient.
   - The patient web page could be available in simple, easy-to-understand language discussing the risk/benefit ratio of the drug.
   - Each major search engine would be able to search for the terms such as "drug recall" and bring the FDA site up in response. Currently this does not always happen.

2. ***The Academy monitors the FDA website and receives drug alerts from the FDA list-serve. The Academy recommends:***
   - The FDA continue development of a database and central registry to contact all pharmacists, physicians and other prescribers, nurses, pharmacy network administrators, and health plan administrators regarding drug alerts and recalls.

3. ***The MedWatch voluntary system gathers adverse drug event data sent in by physicians, pharmacists, and other healthcare personnel. Since the MedWatch program depends on this voluntary data collection, we recommend the Agency:***

- Increase its presence at national and state pharmaceutical, medical, and nursing meetings.
- Use the presence of FDA representatives among health care personnel and in the programming at the meetings to increase recognition of the Adverse Drug Event reporting program and generate more involvement by health care personnel.
- Use this increased presence to promote an educational campaign regarding adverse event reporting.
- Consider advertising the FDA website.

The Academy in conjunction with the FDA and other organizations is leading an effort on medication error reduction with a particular emphasis on the on-line drug-drug interactions. The Steering Committee of the Initiative is composed of representatives from the Food and Drug Administration (FDA), United States Pharmacopeia (USP), the American Pharmaceutical Association (APhA), the American Society for Automation in Pharmacy (ASAP), the National Association of Chain Drug Stores (NACDS), the National Community Pharmacists Association (NCPA), and the Pharmaceutical Care Management Association (PCMA). The purpose of the on-line Drug/Drug Interaction Initiative is to increase patient safety and encourage pharmacists to concentrate on the

most severe drug-drug interactions at the point of dispensing. USP's Therapeutic Decision Making (TDM) Expert Committee is developing evidence-based criteria for drug-drug and drug-class interactions that pose the greatest risk of serious and/or life-threatening drug-induced illness for patients. Communications efforts seek buy-in from end-user pharmacists, pharmacies, vendors, prescription benefit managers, and employer groups. The project was initiated by professionals who believe it is in the best interest of the patient and the profession, and the product will therefore be made available at no cost. The objective of the task force is to make drug/drug interaction information more broadly accessible, simpler and more effective to use.

C. Risk interventions the FDA can initiate for pharmacists, physicians, patients, and drug manufacturers

The Academy suggests that the Agency engage in constructive endeavors to help patients receive as much education as possible regarding the medications that they will be using. Pharmacists have ongoing contact with their patients and are trained in medication management and counseling. In most cases, the pharmacist is the last point of contact for the patient who is beginning a new medication. Pharmacists managing medications should know what the specific risks are regarding those medications, and the specific questions that must be asked of the patient to be certain that the patient understands the risk/benefit of the medication.

In defining a role for the pharmacist in risk management, the pharmacist must focus on helping the patient to manage the risks of taking medication. Is the patient well informed by the pharmacist and prescriber? Risk communication and risk management efforts given by the prescriber and pharmacist must support the medication decision patients make.

Evaluation of Risk Management Strategies and Interventions

The Academy suggests the following actions:

A. Assess the effectiveness of risk management interventions that have been initiated in the past. e.g. Accutane-SMART Program, Thalomid -STEP Program. Are these programs effective?

B. Determine which criteria should be used to judge if a risk management intervention is effective.

Much of the criteria used in judging risk management interventions is well-defined and well-implemented in the acute care medical setting. It is defined to a lesser degree in skilled nursing and long term care, and to an even lesser degree in the community drug store setting. It is recommended that the risk management programs used in acute care settings or in the non-medical settings, e.g. air-traffic control, be evaluated to ascertain whether certain procedures can be used, modified,

or adapted to form a more effective FDA risk management program across the health care spectrum.

Pertinent questions include:

-Does the program eliminate or decrease fatal drug events?

-Do the adverse drug-drug interactions associated with the drug decrease? By how much?

-Does the physician explain the drug and risks of the drug to the patient?

-Does the pharmacist explain the drug and risks of the drug to the patient?

-Does the patient understand the risks of the drug?

-Did the patient receive verbal and written risk counseling information about the drug?

-Identification of criteria to determine when risk management tool should be used.

-Systems-based approach-Recommend a standardized process to work with medications demanding special attention. Develop patient, prescriber, and pharmacist education; specific laboratory monitoring tests for detection of adverse events, registration in database of patients using medication, special medication labeling.

-Documentation of prescriber and pharmacist interaction with patient-case management system for drugs with severe side effect profiles.

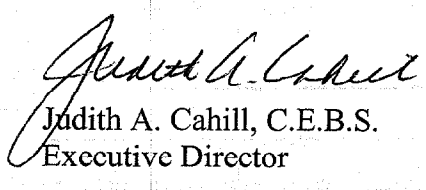
Medication use will improve only through the work of each pharmacist, in conjunction with each patient and with each prescriber.

Improving medication use requires education and collaboration, activities that go beyond regulatory jurisdiction.

Appropriate risk management strategies require three key areas of focus: communication; the evaluation and standards and establishment of appropriate tools; and evaluation of risk management strategies and interventions. We have outlined our recommendations and provided additional perspectives in each of these areas. No program can be successful unless all of the areas of focus are fully explored for the most effective and appropriate initiatives that minimize negative effects and unintended consequences on patients and the health care system. A strategy that ties them all together must be designed and implemented – each aspect of this program can only succeed if the FDA acts across the board to assess, implement and communicate a fully integrated risk management program.

The Academy looks forward to working with you on this important public safety issue.

Sincerely,



Judith A. Cahill, C.E.B.S.
Executive Director