The Pharmacist Activist

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Editorial

Our Professional Autonomy and the Health of our Patients are at Risk!

We Need More Independence in our Practice Responsibilities and More Independent Pharmacies

Our profession of pharmacy has made some notable advances in recent years and we should be encouraged by what has been accomplished. However, we must also be prepared to identify and challenge the situations and influences that compromise our efforts and restrict the extent to which we can use our knowledge and skills regarding drug therapy for the benefit of our patients and society.

At the same time that our authority and autonomy for making decisions that influence drug therapy is growing in some areas, it is declining in other areas. Although most pharmacists might claim that they have the freedom to exercise their best professional judgment in making decisions regarding drug therapy, is this really the case? I would contend that the situations in which pharmacists have decision-making authority in their practice environment are declining rather than increasing.

Most Americans have insurance coverage and/or a prescription benefit plan that covers a large part of the cost of prescription medications. The government agencies, insurance companies, and PBMs dictate the policies and terms of the prescription programs, including the formulary of medications that are covered, situations requiring prior authorization, and the compensation to be provided for professional services and reimbursement of the cost of the drug product.

Most prescriptions provided to ambulatory patients are dispensed by employee pharmacists in chain pharmacies and other large retail stores, and in mail-order pharmacies. The policies and procedures of these pharmacies are typically developed by executives and managers who are not pharmacists and who are motivated more by the economics of the business and pleasing shareholders rather than the scope and quality of professional services for patients. Many chain pharmacists voice repeated concerns about inadequate staffing that results in their not having the time to contact a physician to verify the validity of a prescription for a narcotic or to seek clarification for a drug interaction alert for which an override is an easy option. Mail-order pharmacists do not see or speak with their "patients," and the nature of the mail-order system results in many individuals not receiving their medications on a timely basis. Do these pharmacists actually have the autonomy and opportunity to practice in a manner that will best serve and protect the health care interests of their patients? The answer is, "No!"

Even in hospitals, in which a commitment to the provision of the most comprehensive

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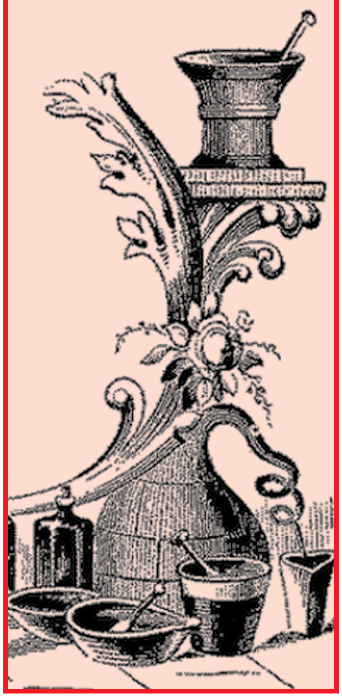

and intensive patient care is expected, pharmacists often do not have the authority and autonomy to practice in a manner in which there is optimum use of their expertise and skills. Although some hospital pharmacists have assumed expanded responsibilities in hospital administration, they often encounter economic and political realities that require higher-priority attention than their desire to provide additional pharmacy services. Hospital pharmacists often have important positions in Pharmacy and Therapeutics Committees and other forums within the hospital. However, they are usually not successful in "competing" with medicine, nursing, etc. for scarce institutional resources that could be used to extend the scope of the services provided by pharmacists. Some will respond that I am understating the accomplishments of pharmacists in the hospital setting. My response is that, if the scope and quality of pharmacy services in the hospital were where they should be, we would have seen a dramatic reduction in the occurrence of medication errors. As in the community setting, the autonomy of pharmacists is also very limited in the hospital setting.

Physicians

It is noteworthy that the profession of medicine and individual physicians are facing many of the same challenges that pharmacy is. The number of physicians in individual private practices has sharply declined as group practices of physicians have been established. Although the authority and autonomy of an individual physician are reduced when compared to a private practice, the authority still rests with the group of physicians. However, with increasing frequency, hospitals are acquiring physician practice groups with the result that the physicians relinquish most of the decision-making authority they had previously. There are also situations in which insurance companies are acquiring hospitals.

There are sharp differences of opinion regarding recent changes pertaining to health care (e.g., Medicare coverage of prescription drugs for outpatients, Obamacare). However, if there is one situation in which there is almost complete agreement, it is that there is now or soon will be a huge shortage of primary care physicians that will continue well into the future. I recently became aware of the following situation that has very important implications with respect to the supply of primary care physicians and other health professionals, including pharmacists. A group medical practice comprised of approximately 10 primary care physicians plus physician assistants and nurse practitioners is owned by the local hospital. The group practice has two practice sites and most of the patients at one of the practice sites receive health care services that are funded by the Medicaid program. The hospital reaches a conclusion that it is losing too much money at this practice site and makes a decision to reorganize the group practice. The result is that several primary care physician positions are eliminated and replaced with positions for lower-salaried physician assistants and nurse practitioners. Although the physicians who were affected by this reorganization of the group practice identified other positions, there was a challenging transition in their responsibilities. In addition, there was a disruption in the continuity of care for hundreds of patients who now had either a different primary care practitioner, or a different practice group to which they transferred to stay under the care of the same physician.

I understand the importance of the economic concerns that have dominated the recent consideration of health care issues. These concerns must be effectively addressed but that is beyond the scope of this editorial. Rather, my focus is on the question of *who* is making the most important decisions regarding health care or, more specifically, who is *not* making these decisions. In most situations it is *not* physicians, pharmacists, or other health professionals who are making the decisions that will have the greatest influence on the scope and quality of health care. Health professionals have lost much of our autonomy and decision-making authority, and are at risk of losing more.

Consequences

To a large extent the challenges and problems experienced by the health professions are self-inflicted. We have not been accountable, we have not been transparent, we have not been willing enough to communicate and collaborate both within the individual health professions and between the professions. However, those at greatest risk are our PATIENTS, who so often are the victims of our haste, negligence, errors, and lack of sufficient caring. Is there really any excuse for the extent that medication errors and drug-related problems such as drug interactions and noncompliance continue to occur?

The September 22-23, 2012 issue of *The Wall Street Journal* includes a feature article (page C1) titled, "How to Stop Hospitals from Killing Us." Written by a surgeon, Marty Makary, the article includes experiences and statistics that all would agree are unacceptable. The author also identifies an "unspoken rule"—"to overlook the mistakes of our colleagues." Dr. Makary has written a book that I plan to read – *Unaccountable: What Hospitals Won't Tell You and How Transparency Can Revolutionize Health Care.*

Far too many of our patients are at risk. My expectation is that an even larger number of patients will be at risk if there is a continuation of the erosion of autonomy and decision-making authority of pharmacists and physicians.

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New Drug Review

Peginesatide acetate (Omontys – Affymax; Takeda)

Erythropoiesis-stimulating Agent

New Drug Comparison Rating (NDCR) = 4

(significant advantage[s]) in a scale of 1 to 5 with 5 being the highest rating

Indication:

Administered intravenously or subcutaneously for the treatment of anemia due to chronic kidney disease in adult patients on dialysis.

Comparable drugs:

Other erythropoiesis-stimulating agents (ESAs): Epoetin alfa (Epogen, Procrit), darbepoetin alfa (Aranesp).

Advantages:

- Is administered less frequently (once a month, compared with 3 times a week with epoetin alfa and once every 1-2 weeks with darbepoetin alfa);
- Is less likely to cause neutralizing antibodies (may be less likely to cause pure red cell aplasia).

Disadvantages:

- Labeled indications are more limited (comparable drugs are also indicated for the treatment of anemia due to chronic kidney disease in patients not on dialysis, and for the treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy; epoetin alfa also has additional indications);
- Effectiveness and safety have not been established in pediatric patients.

Most important risks/adverse events:

Risk of death, myocardial infarction, stroke, venous thromboembolism, and thrombosis of vascular access (boxed warning; caution must be exercised in patients with cardiovascular disease and stroke); tumor progression or recurrence in patients with cancer (boxed warning); contraindicated in patients with uncontrolled hypertension (blood pressure must be monitored); targeting a hemoglobin concentration greater than 11 grams/dL increases the risk of adverse events and has not been shown to provide additional benefits (hemoglobin concentrations should be monitored at least every 2 weeks until stable and then at least monthly; the lowest dosage sufficient to reduce the need for red blood cell transfusions should be used); adjustment in dialysis prescription may be required; increased anticoagulation with heparin may be needed to prevent clotting of the extracorporeal circuit during hemodialysis; supplemental iron may be required (transferrin saturation and serum ferritin should be evaluated prior to and during treatment).

Most common adverse events:

Diarrhea (18%), dyspnea (18%), nausea (17%), cough (16%), arteriovenous fistula site complication (16%).

Usual dosage:

Administered by subcutaneous or intravenous injection; treatment should be initiated when the hemoglobin concentration is less than 10 grams/dL; initial dosage in patients who are not currently treated with an ESA is 0.04 mg/kg once a month; product labeling should be consulted for guidelines for dosage adjustments and use in patients who have been treated with another ESA.

Products:

Single-use vials – 2 mg, 3 mg, 4 mg, 5 mg, 6 mg; single-use prefilled syringes – 1 mg, 2 mg, 3 mg, 4 mg, 5 mg, 6 mg; multiple-use vials – 10 mg/mL, 20 mg/2 mL (products should be stored in a refrigerator).

Comments:

ESAs are the standard of treatment for anemia due to chronic kidney disease. Epoetin alfa and darbepoetin alfa are produced using recombinant DNA technology. Peginesatide is a synthetic, pegylated dimeric peptide that has a longer duration of action than the other ESAs and can be administered once a month. It has been demonstrated to be as effective and safe as epoetin alfa in maintaining hemoglobin concentrations within the range of 10-12 grams/dL. With the use of epoetin alfa and darbepoetin alfa there have been reports of pure red cell aplasia and severe anemia that arise following the development of neutralizing antibodies to erythropoietin. Very few patients developed detectable concentrations of peginesatide-specific binding antibodies, and there were no reports of pure red cell aplasia in the clinical studies.

Daniel A. Hussar

Recapturing our autonomy

I am not suggesting that we have to return to the system in which almost all community pharmacies are owned by pharmacists and almost all medical practices are owned by physicians. However, in my opinion, the pendulum has swung too far to the other extreme in which a large majority of health professionals are employees of corporations, hospitals, etc., in which individuals who are not health professionals have the authority to make decisions that will influence the health care and safety of patients.

We must recapture our autonomy! The health of our patients is at risk! Our license to practice could be at risk if we do not take the time and provide the information and services that patients need to assure optimum outcomes from their drug therapy. I know that it is difficult to voice a concern to an employer or manager when you sense that there will not be receptiveness to your recommendation. But we must not tolerate situations that represent a disservice or risk to patients whose health we are committed by our license and conscience to protect and improve.

More independent pharmacies are needed

I am of the strong belief that the future progress and success of the entire profession of pharmacy is inextricably linked to the extent that independent pharmacies are able to survive and thrive. Independent pharmacists are the members of our profession who have the best opportunity to provide face-to-face personalized advice and services for patients. They are the "front-line," but all pharmacists are the beneficiaries of the reputation for integrity and ethics that our profession enjoys and for which independent pharmacists are primarily responsible. The challenges facing independent pharmacists are formidable but the issues are so important for both our patients and our profession that we must strongly support the efforts of our colleagues who are best positioned to promote and advance the services we are capable of providing. I recommend consideration and support for the following as part of a strategy to accomplish these goals:

1. The entire profession of pharmacy and our organizations must demonstrate a strong commitment to increase the number of independent pharmacies and to support and advance progressive models of practice in these pharmacies.

2. Independent pharmacists and the organizations in which they are participants must communicate more effectively and collaborate in addressing challenges and working toward professional goals. I recommend that the National Community Pharmacists Association (NCPA) convene a national meeting of the "stakeholders" (e.g., independent pharmacist leaders, wholesalers, buying groups of independent pharmacists) to start developing strategies and plans in this direction.

3. The required community pharmacy rotation in the Advanced Pharmacy Practice Experience (APPE) programs administered by the colleges of pharmacy should be provided in independent community pharmacies. Regrettably, many current students and recent graduates are hardly aware of the professional and entrepreneurial opportunities available in independent pharmacies because neither their employment experience nor college-directed experience programs have been in this setting.

4. Independent pharmacists should actively pursue collaborative working relationships with family practice physicians in their communities. Many family practice physicians have voiced concern regarding the establishment of "clinics" in some chain pharmacies that are typically staffed by nurse practitioners. As considered earlier, many physicians are experiencing challenges that are similar to the ones that pharmacists are facing. Opportunities exist for working relationships between independent pharmacists and family practice physicians that would be mutually beneficial and of value in improving the scope and quality of care for the patients served.

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