The Pharmacist Activist

Volume 11, No. 5 • May 2016

Editorial

OUTRAGES! – But Some With Opportunities!

There are more serious issues facing the profession of pharmacy than I have time and space to address in *The Pharmacist Activist*. It seems to me that more than the usual number of these situations have received extensive media publicity in the last several months, and certain of these are briefly considered in the discussion that follows.

Deaths from medical errors

A recent study has generated headlines indicating that medical errors are the third leading cause of death in the United States. Although there are some questions regarding the study's methodology and conclusions, the fact remains that medical errors, including medication errors, occur very frequently. Whether they are the third leading cause of death, or the thirtieth, most of these errors are preventable and demand the highest priority attention. The Institute for Safe Medication Practices (ISMP) has provided exceptional programs and services that have kept the numbers of errors and deaths from being even larger than they are. However, much more needs to be done.

A commentary in the May 17 issue of *The Wall Street Journal* written by James B. Lieber, carries the title, "How to Make Hospitals Less Deadly." One of the reforms recommended by the author is, "Bring in the pharmacists."

Deaths from opioid overdosage

As with medical errors, even one death that results from overdosage of an opioid is a tragedy. The total number of these deaths is absolutely shocking! It is too easy to attribute much of the blame for this problem to irresponsible behaviors and the actions of criminals who smuggle and sell these products. Although these are important components of the challenge that must be addressed, many overdosage deaths have resulted from opioids that have been prescribed by physicians and dispensed by pharmacists. Pharmacists and

physicians must communicate and collaborate much more closely in assuring the most appropriate use of opioids and other medications/strategies in managing pain in a manner that is as effective and as safe as possible.

Even when the collaboration of physicians and pharmacists is much closer and more effective, there will still be a small minority of physicians and pharmacists who betray the public and our professions by selling prescriptions and drugs that they know will be abused. These situations must not be tolerated and, when they are recognized by responsible health professionals, they should be reported to the appropriate authorities (e.g., state licensure boards, Drug Enforcement Administration [DEA]) and severe penalties should be imposed.

Unused prescription medications

The DEA National Prescription Drug Take-Back Day program has had remarkable results. On the take-back day in early May, approximately 447 TONS of unused prescription drugs were collected. Although this is a very positive initiative that reduces risk by getting potentially dangerous products out of homes, the numbers tell a story of ineffectiveness, inefficiency, and waste with respect to the prescribing, dispensing, and use of prescription medications.

Prescribers and pharmacists must accept and address our responsibilities regarding this waste and its accompanying risks if the products were left in the home. The take-back program might be the source of data that would provide helpful clarification of causative factors. I expect that many of the tons of unused medications would be found to be automatic refills of prescriptions from many chain and mail-order pharmacies that have not been specifically requested by patients.

Drug prices

The outrageous price increases enacted by Turing, Valeant, and some other drug companies, as well as the deceptions of the Valeant – Philidor working relationship, have been discussed in previous issues of *The Pharmacist Activist*. However, as Dan Hoffman points out in a recent commentary, "…these companies have caused a far smaller problem for the affordability of health care than the annual 10%-12% price increases by mainstream … pharmas." Many of the medications for which these price increases are imposed are used for chronic conditions by millions of individuals for many years and, sometimes decades. Yet even in the face of increasing concerns about the unaffordability and/or unsustainability of the current pricing models, many pharmaceutical companies appear determined to test the limits of the public's willingness to tolerate their pricing excesses. When the budgets and patience of the public and our legislators reach the breaking point, price controls will be established. The pharmaceutical companies will have only themselves to blame as the price controls will have been self-inflicted.

PBM and health insurance company profits – for doing what?

Yes, individuals and our society need health insurance and prescription benefit programs. But at what cost? In my opinion, the companies providing these programs contribute nothing to the quality and scope of health care and the appropriate use of medications. However, they extract tens of billions of dollars from the healthcare system. If there is any question about the costs and profits associated with these programs, consider the recent action in which Anthem, the second largest health insurer, is suing Express Scripts, the largest PBM, for $15 BILLION. A primary basis for this action and the alleged damages is that Express Scripts has negotiated better prices for drugs from the pharmaceutical companies but has not passed on to Anthem what it considers to be its share of the savings. Another example is the recent announcement that OptumRx, the pharmacy benefits business of United Health, the largest health insurer, has been awarded a 5-year contract for $4.9 billion for the prescription program for California public employees. Additional insight pertaining to the financial strategies and battles of corporate giants is provided in a recent article in *The Washington Post* (May 12, 2016; Carolyn Johnson) titled, "Secret rebates, coupons and exclusions: how the battle over high drug prices is really being fought."

The ways in which the PBMs increase their own profits are at the expense of pharmacy services (e.g., counseling) for patients and equitable compensation for pharmacists. The

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New Drug Review

Lesinurad (Zurampic – AstraZeneca; Ironwood)

Agent for Gout

New Drug Comparison Rating (NDCR) = 4
(significant advantages)
in a scale of 1 to 5 with 5 being the highest rating

Indication:
In combination with a xanthine oxidase inhibitor for the treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric acid concentrations with a xanthine oxidase inhibitor alone.

Comparable drugs:
Xanthine oxidase inhibitors: allopurinol, febuxostat (Uloric).

Advantages:
- Has a unique mechanism of action (inhibits uric acid transporter 1 [URAT1] and organic anion transporter 4 [OAT4]);
- Provides additional reduction in serum uric acid concentrations.

Disadvantages:
- Is not a first-line treatment;
- Labeled indications are more limited (compared with allopurinol that is also indicated for patients receiving cancer treatments that cause increased uric acid concentrations, and for the management of patients with recurrent calcium oxalate calculi);
- Is more likely to cause acute renal failure and other renal adverse events;
- May reduce the reliability of hormonal contraceptives.

Most important risks/adverse events:
Acute renal failure (boxed warning; risk is greater when lesinurad is used alone, and should be used in combination with a xanthine oxidase inhibitor; renal function should be monitored when initiating and during therapy, and particularly in patients with an estimated creatinine clearance below 60 mL/minute; treatment should not be initiated in patients with an estimated creatinine clearance below 45 mL/minute; patients should be evaluated for symptoms of acute uric acid nephropathy); contraindicated in patients with severe renal impairment, end-stage renal disease, in recipients of kidney transplants, patients on dialysis, or patients with tumor lysis syndrome or Lesch-Nyhan syndrome; major cardiovascular adverse events (a causal relationship has not been established); not recommended in patients with severe hepatic impairment; is a CYP2C9 substrate and activity may be increased in patients who are poor CYP2C9 metabolizers and in those also being treated with a CYP2C9 inhibitor (e.g., fluconazole, amiodarone); activity may be reduced in patients treated with a CYP2C9 inducer (e.g., carbamazepine); concurrent use with inhibitors of epoxide hydrolase (e.g., valproic acid) should be avoided; effectiveness may be reduced by aspirin in doses higher than 325 mg a day; may reduce the concentrations of CYP3A substrates (e.g., sildenafil, amlodipine); may reduce the reliability of hormonal contraceptives and women should be advised to use additional methods of contraception.

Most common adverse events:
Headache (5%), influenza (5%), gastroesophageal reflux disease (3%), increased serum creatinine concentrations (4%).

Usual dosage:
200 mg once a day in the morning with food and water; if treatment with the xanthine oxidase inhibitor is interrupted, the use of lesinurad should also be interrupted; patients should be instructed to stay well hydrated (e.g., 2 liters [68 ounces] of liquid each day); gout flare prophylaxis (e.g., colchicine, nonsteroidal anti-inflammatory drugs) is recommended when starting treatment; treatment should be discontinued if estimated creatinine clearance is reduced and is persistently less than 45 mL/minute.

Products:
Tablets – 200 mg.

Comments:
Lesinurad inhibits uric acid transporter 1 (URAT1) and organic anion transporter 4 (OAT4). URAT1 is responsible for the majority of the reabsorption of filtered uric acid from the renal tubular lumen, and OAT4 is a uric acid transporter associated with diuretic-induced hyperuricemia. By inhibiting the action of these transporters, lesinurad increases renal clearance and excretion of uric acid, and reduces serum uric acid concentrations. Its effectiveness was demonstrated in studies in which lesinurad or placebo was used with allopurinol or febuxostat. The combination of lesinurad with the xanthine oxidase inhibitor reduced serum uric acid concentrations to the target in approximately twice as many patients (55%) as in patients receiving placebo.

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PBM abuses with respect to compensation for pharmacists include many situations in which the compensation provided by a PBM for drug product costs is less than the invoice cost for the drugs paid by the pharmacists. This abuse has reached such an extreme that legislation has been passed or is being considered in some states that would permit pharmacists to decline to dispense prescriptions for which the compensation they would receive is less than their cost.

Other PBM abuses include, but are not limited to, unfair audits, the exclusion of pharmacies from networks, and failure to process drug price increases on a timely basis. Individual pharmacists and our associations must give a very high priority and greater support for efforts to revise and establish prescription benefit plans that meet patient needs and provide appropriate compensation for pharmacists.

Working conditions in many chain pharmacies

The stressful workplace environment in many chain pharmacies is deplorable. Understaffing and lengthy workdays greatly increase the risk of errors. The disagreement between CVS and its unionized pharmacists in the Chicago area has received considerable media coverage. The pharmacists warn of safety risks. The CVS spokesperson responds that the union's claims are "negotiation posturing" and that customer safety is the company's number one priority. This statement from CVS, and similar responses from some other chain pharmacies is blatantly false! It is recognized that metrics and profit are their real number one priority.

The executives of these pharmacies will not listen to the concerns of pharmacists and make the necessary changes. Pharmacists are increasingly hesitant to even voice concerns about important issues because of fear of retaliation and even the loss of their position at a time when other employment opportunities are difficult to identify. These pharmacists need and must be provided the support from our professional associations and entire profession to obtain the workplace changes that are necessary to address patient safety concerns, and provide professionally fulfilling responsibilities for pharmacists.

Sale of tobacco products in pharmacies

In spite of the fact that most independent pharmacies, CVS, Target, Wegmans, and other pharmacies have discontinued the sale of tobacco products, Rite Aid, Walgreens, Walmart, and most other chain/grocery/big box stores still sell tobacco products. These latter companies want to be perceived as caring about and promoting the health of their customers. As examples, recent articles carry titles such as "Walgreens to expand mental health services" and "Walmart aims to be the 'front door' of U.S. health care." The sale of tobacco products exposes the hypocrisy of these companies. They know the deadly consequences of smoking but their motivation is more profits and not concerns for the health of their customers.

The public should no longer tolerate this hypocrisy and should no longer patronize these stores. State boards of pharmacy have a mission to safeguard the health care of citizens with respect to the licensing and operations of pharmacies. State boards should discontinue issuing new licenses and renewing previous licenses of pharmacies that sell tobacco products or are in facilities that sell tobacco products.

It can be discouraging to recognize that the topics considered above represent only the beginning of a much longer list of outrages. However, the issues are so important that we must not give up in our efforts to achieve positive resolutions.

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The opinions and recommendations are those of the author and do not necessarily represent those of his full-time employer or the publisher.

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