The Pharmacist Activist

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Editorial

The *20/20* Report on Pharmacy Errors – An Indictment of Some Chain Pharmacies: Part 1

It was sensationalistic "journalism," complete with hidden cameras. It was highly critical and one-sided. Other than several brief observations about pharmacists doing the right things, it ignored the positive, and sometimes life-saving, interventions that pharmacists initiate. HOWEVER, every pharmacist and pharmacy student should see the *20/20* report that was seen by a television audience of millions on the evening of Friday, March 30.

Every one of us has made mistakes. It is not an overstatement to indicate that dispensing a prescription involves "life or death" decisions and actions. These are among the reasons for which pharmacists and their employers must demonstrate a commitment to provide the time, expertise, and personal attention needed to reduce errors to the lowest number possible. Many pharmacy errors are preventable. In many places in which our profession is practiced, not nearly enough is being done to prevent errors and an excessively busy and stressful workplace environment increases the likelihood of errors. This situation must change!

The *20/20* report described two very serious errors involving prescriptions dispensed by Walgreens pharmacies. In one situation, phenobarbital was prescribed for a baby, Alexandra. An antidiabetic medication was dispensed in error and Alexandra experienced seizures and brain damage. She is now 8 years old and can not talk, walk, or feed herself. These consequences were clearly evident during the interview with her mother in the family's home. The lawsuit that was filed went to trial and resulted in a verdict in the amount of $21 million.

The victim of the second error was Beth, a mother of several school-age children. She was prescribed Coumadin in a dosage of 1 mg a day. The prescription that was dispensed contained Coumadin tablets in a 10 mg-potency. Beth experienced a massive stroke and major disabilities.

The *20/20* report addressed the fast-paced and stressful working conditions that exist in some chain pharmacies and interviewed an attorney for one of the error victims who alleged that Walgreens wants pharmacists to dispense 350 prescriptions per shift. It interviewed a retired Walgreens pharmacist who noted that he had received poor evaluations for being "too slow" in dispensing prescriptions.

The two pharmacists and a pharmacy technician who were involved in the dispensing errors were publicly identified in the *20/20* report, with the additional observation that "these pharmacists are still working at Walgreens." It is noteworthy that no Walgreens supervisor or executive was identified. These are the individuals who are responsible for determining the prescription "quotas" and the staffing levels in their pharmacies, and for determining how many new Walgreens will be opened at a time when many of their current pharmacies are not adequately staffed.

Other issues addressed in the *20/20* report included the failure of pharmacy staff to identify and prevent potential drug interactions, requesting patients to sign a log without informing them that they were waiving their right to counseling, and questioning the credentials of some of the individuals involved in dispensing prescriptions. It was noted that, in some states, individuals as young as 16 years of age can participate in such responsibilities. The prior job of the technician who was involved with one of the prescription errors was identified as "cleaning a movie theatre and serving popcorn."

Viewers of this *20/20* report will not quickly forget Alexandra and Beth, and the consequences they experienced from prescription errors. Their faces and their disabilities were painful to observe and are

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etched in my memory. It was also painful to watch my profession being attacked. However, any disservice experienced by our profession pales in comparison with what Alexandra and Beth experienced. In fact, the *20/20* report accurately identifies concerns that we pharmacists already recognize, but have not done nearly enough to address. We have now been publicly exposed and we must take appropriate actions. Some have suggested that the report is a "wake-up call" or alarm for our profession. I would suggest that it should have the impact of an explosion for the profession in general and for some chain pharmacies in particular.

Responses

Some have responded to the *20/20* report by noting that the two serious dispensing errors that were reported are rare experiences and that one of the errors occurred eight years ago. Fortunately, such errors are rare. However, they occur more often that we think, but the resulting litigation is settled out of court with the agreements including confidentiality restrictions. The two errors described in the *20/20* report went or are going to trial and detailed information became available. The most important perspective is that errors must not be viewed as statistics, but must be recognized as harming people. The errors that had such tragic results for Alexandra and Beth should not have occurred.

Some have responded that, because every pharmacist, pharmacy student, and pharmacy technician has committed or will commit errors at some point, it was unfair to single out Walgreens and its two pharmacists and technician for criticism on national television. It is true that others have also made very serious and even fatal errors that have received no publicity, and I sympathize with the pharmacists and technician who are identified in the *20/20* report, as well as the many highly capable and dedicated Walgreens pharmacists and technicians who are linked through their employer to these unfortunate incidents. Presumably, Walgreens had opportunities to settle these situations out of court and avoid some of the negative publicity, but doing so sometimes does little more than delay the recognition of serious problems that require intervention.

Some have chosen to focus on the $21 million award in Alexandra's case as an example of how our court system is not working properly. But can a monetary value be placed on one's good health? I am certain that, if Alexandra and her family could have a choice between her being able to enjoy good health and their having $21 million, it would not be the money they would choose.

Some have suggested that it is the shortage of pharmacists that results in the very busy and stressful workplace environments that increases the likelihood of prescription errors. It is true that there is a shortage of pharmacists in many parts of the country. However, to a large extent, the shortages experienced by some chain pharmacies is self-inflicted because of stressful working conditions and low job satisfaction that result in a high turnover rate. These situations will be addressed further in "Part 2" of this editorial that will be published in the May issue of *The Pharmacist Activist*.

My response was to show the *20/20* report to the students in my courses and to discuss its implications. It was of concern to hear how many of the students were already aware of errors made in the pharmacies in which they are employed. I voiced my hope that none of them would ever be in a situation in which they were responsible for a serious error. I urged them to not accept, or to leave, employment situations in which they were too busy and/or stressed to have confidence that they and their colleagues were observing the appropriate safeguards to avoid dispensing errors.

Walgreens' Response

The *20/20* report included a statement that Walgreens had provided to the effect that "it deeply regrets the few errors that occur out of the 500,000,000 prescriptions they fill every year."

Reflecting on the consequences of the error on Alexandra's prescription, the concluding comment in the report is, "Eight years after it (the error) happened, the family says it has yet to receive an apology from Walgreens."

This response, or lack thereof, is inadequate. I urge that the following actions be taken:

1. Walgreens should apologize to Alexandra and her family.
2. Walgreens should apologize to the spokeswoman for the National Association of Chain Drug Stores (NACDS) who had the impossible task of trying to explain and defend the errors and other shortcomings of Walgreens and other chain pharmacies.
3. Walgreens states that they dispense 500,000,000 prescriptions a year in an attempt to create the impression that errors are rare occurrences. Because they identify the number of prescriptions they dispense, they should also identify the number of errors rather than refer to a "few" errors. They should disclose the specific number of errors that occurred during the period in which 500,000,000 prescriptions were dispensed.
4. Walgreens should revise its policies regarding the number of pharmacists and other professional staff in its pharmacies, and assure that pharmacists have adequate time to fulfill their expected responsibilities in dispensing prescriptions and counseling patients.
5. Walgreens should not open new pharmacies until adequate staffing of its existing pharmacies is assured.

Pharmacists who have concerns that their workplace situation places them at risk of making errors should communicate this concern in writing to their manager/supervisor and request that appropriate changes be made. If appropriate changes are not made promptly, these pharmacists should seek employment elsewhere.

To be continued

Daniel A. Hussar

The Right Way to PRACTICE PHARMACY

On the afternoon of March 30, I was returning from a meeting and decided to visit Longenecker Pharmacy in Gap, PA (pharmacist Noreen Tracy) and Longenecker Pharmacy in Parkesburg, PA. Both are owned by pharmacist Dick Brown and the pharmacy in Parkesburg has a very high prescription volume. As I observed in the prescription department, I was very impressed by the fact that there were five pharmacists on duty (Dick, his daughter Michele Brown, Andy Irons, Niall Sheridan, and Laura Boarts), as well as a senior pharmacy student Melissa DeVere and several certified pharmacy technicians. The competent and professional manner in which they, and Noreen and her colleagues at the pharmacy in Gap, served their patients was exemplary.

These visits were very encouraging and demonstrated that our profession can be practiced the right way, even in a very busy pharmacy. This positive experience was also very timely as it helped cushion the blow of the *20/20* report that I watched later that night.

Daniel A. Hussar

New Drug Review

Lisdexamfetamine dimesylate (Vyvanse – Shire)

Agent for Attention Deficit Hyperactivity Disorder

New Drug Comparison Rating (NDCR) = 3
(no or minor advantages/ disadvantages)
in a scale of 1 to 5, with 5 being the highest rating

Indication:

Treatment of attention deficit hyperactivity disorder (ADHD); effectiveness has been demonstrated in studies in children aged 6 to 12; indicated as part of a total treatment program for ADHD that may include other measures (e.g., psychological, educational, social).

Most important risks/adverse events:

Potential for dependence and misuse/abuse (boxed warning; classified in Schedule II of the Controlled Substances Act); sudden death and serious cardiovascular adverse events (boxed warning with respect to the greater risk associated with misuse/abuse); psychiatric adverse events (e.g., hearing voices, becoming suspicious for no reason, becoming manic); exacerbation of motor and phonic tics and Tourette's syndrome; long-term suppression of growth; contraindicated in patients with advanced arteriosclerosis, symptomatic cardiovascular disease, moderate to severe hypertension, hyperthyroidism, or glaucoma, in patients in an agitated state or with a history of drug abuse, or during or within 14 days following the administration of a monoamine oxidase inhibitor; action may be increased by urinary alkalinizing agents, and decreased by urinary acidifying agents; may reduce the action of antihypertensive agents.

Most common adverse events:

Decreased appetite (39%), insomnia (19%), upper abdominal pain (12%), irritability (10%), vomiting (9%), decreased weight (9%), nausea (6%), dizziness (5%), dry mouth (5%).

Usual dosage:

30 mg once a day in the morning; if needed, dosage may be increased in increments of 20 mg/day and at approximately weekly intervals to the maximum recommended dosage of 70 mg/day; afternoon doses should be avoided because of the increased likelihood of insomnia; capsules may be swallowed whole or the contents of a capsule may be dissolved in a glass of water.

Products:

Capsules – 30 mg, 50 mg, 70 mg

Comparable drugs:

Dextroamphetamine (e.g., Dexedrine), amphetamine/dextroamphetamine mixed salts (e.g., Adderall, Adderall XR).

Advantages:

- Formulation may have a lesser potential for abuse;
- May be administered in water for children who have difficulty swallowing capsules (compared with dextroamphetamine);
- Has a longer duration of action that permits once-daily administration (compared with Adderall).

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New Drug Review (cont.)

Disadvantages:

- Has not been directly compared in clinical studies with other amphetamine/dextroamphetamine products;
- Has not been studied in patients younger than 6 or older than 12 years of age (compared with dextroamphetamine and Adderall that have been studied in children as young as 3 years of age, and with dextroamphetamine and Adderall XR that have been studied in patients older than 12 years);
- Labeled indications are more limited (compared with dextroamphetamine and Adderall XR that are also indicated for the treatment of narcolepsy).

Comments:

Lisdexamfetamine is a prodrug of dextroamphetamine in which the amino acid l-lysine is linked to dextroamphetamine. Following oral administration lisdexamfetamine is rapidly absorbed and converted to dextroamphetamine, which is responsible for its activity. Dextroamphetamine is a sympathomimetic amine with central nervous system (CNS) stimulant activity, and is thought to block the reuptake of norepinephrine and dopamine.

Lisdexamfetamine was evaluated in two placebo-controlled studies in children aged 6-12, and significant improvements in behavior were reported in patients receiving the new drug compared to those receiving placebo. It has not been directly compared with other amphetamine and/or dextroamphetamine products although one of the placebo-controlled studies included a group of patients who were treated with Adderall XR.

The risks and adverse events associated with the use of lisdexamfetamine are similar to those for comparable drugs. The FDA has directed the manufacturers of all drug products approved for the treatment of ADHD to develop patient medication guides to warn patients regarding cardiovascular risks and the potential for adverse psychiatric symptoms. The amphetamines and other CNS stimulants such as methylphenidate (e.g., Ritalin) may cause modest increases in blood pressure and heart rate.

Because lisdexamfetamine itself is inactive and its conversion to dextroamphetamine occurs gradually, it has been suggested that it has a lesser potential for misuse/abuse and that abuse via inhalation or intravenous use will be limited. However, it has not been demonstrated to have a lesser abuse liability and, like the related products, it is classified in Schedule II.

The gradual conversion of lisdexamfetamine to dextroamphetamine is associated with a longer duration of action that permits once-daily administration of a conventional (i.e., not extended-release) capsule formulation. The capsules may be swallowed whole, or the contents of a capsule may be dissolved in a glass of water to facilitate administration in children who have difficulty swallowing capsules.

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