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< [Back to Regular Story Page](#)

Drugs might breed violence

Attacks on staff rise at Western State Hospital

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Violence has been a growing problem at Western State Hospital for years.

If present trends continue, one in four of the Lakewood mental hospital's more than 1,700 workers can expect to be assaulted by a patient in 2007, according to the state Department of Labor and Industries.

For years, hospital administrators have blamed the violence on familiar causes: not enough staff members, not enough money and increased societal violence that leads to the admission of more-violent patients. But they don't have the data to back up those assertions.

A News Tribune analysis of drug-prescribing trends at Western since 1999 finds another possible factor: Western is giving more patients psychiatric drugs with side effects that can include extreme agitation and aggression.

The drugs include newer antidepressants and newer anti-psychotics dubbed atypical anti-psychotics.

The newer drugs, which are expensive compared with older, generic alternatives, have been heavily promoted at the hospital by the pharmaceutical companies that make them. Sales representatives for those companies have logged about 1,200 visits to Western since late 2003, when administrators began tracking their activity.

Concerned about their influence on prescribing patterns, the hospital in March banned all drug company representatives from visiting the campus to meet with doctors.

Randy Burkholder, an associate vice president for Pharmaceutical Research and Manufacturers of America, the Washington, D.C.-based drug industry lobby group, acknowledged The News Tribune analysis, saying it's a "great idea" to discover more about the impact of pharmaceuticals through original investigation.

"There may be something there, there may not be," he said about the findings. But he cautioned that the analysis doesn't prove cause and effect. Instead, it just hints at a possible association. Only additional research can make that determination, Burkholder said.

The link between changes in drug use at Western and recent increases in violence "is very plausible," said Dr. Stefan Kruszewski, a Harvard-trained psychiatrist and an expert on the side effects of anti-psychotic drugs who is on the faculty at Eastern University, outside Philadelphia.

"There is a significant relationship between restlessness and agitation induced by medicine and the propensity for violence," Kruszewski said.

Western has never studied the idea that changes in drug use could contribute to increased violence, said Dr. Roger Jackson, the hospital's acting medical director and an employee there since 1993.

Western is not alone in that regard.

"This has not been adequately studied" at any psychiatric hospital, Kruszewski said. "Most studies done on (psychiatric) violence assume violence is secondary to the illness or the surroundings, or because of lack of staff, money or social structures."

Those assumptions, which have dominated internal and state agency violence studies at Western for more than a decade, do

not hold up under analysis.

Since 1999, the staffing ratio of ward workers to patients has improved from 1.18 workers for every patient to 1.34 workers per patient in 2006.

Funding has increased about 50 percent overall – going from \$106 million in 1999 to \$156 million in 2007 – and has kept pace with medical inflation.

Hospital administrators don't offer statistical evidence that society has become more violent, leading to a more violent patient population. Meanwhile, violent crime in the areas from which Western draws its patients has dropped significantly, according to U.S. Department of Justice statistics.

What does correspond with the increase in violence is the roughly 35 percent increase since 1999 in the use of drugs that a hospital pharmacy handbook and drug experts say are more likely than similar medications to induce agitation and aggression, The News Tribune analysis indicates.

By the end of 2006, there was roughly one order for these drugs for every patient at Western.

NEW DRUGS, MORE DRUGS

Drug therapy has been the mainstay of psychiatric treatment for decades, and it long has been known that while some medications can make patients drowsy, others can cause extreme agitation and a tendency to lash out.

This restlessness can be physical, mental or both, and is known as akathisia.

"It's almost like having too many cups of coffee in the morning," said Dr. Neil Kaye, a psychiatrist and an authority on the condition, as well as a professor at Jefferson Medical College in Philadelphia. "It's extremely uncomfortable and makes people have a shorter fuse."

Akathisia "is horrendous," said Lori Yates, a Western social worker who once was a mental patient in a Texas hospital before her illness was brought under control.

She knows the side effect well, because she had to try several drugs before the right ones were found to help her.

"There's agitation, hyperarousal, sleeplessness – your psychosis gets worse," Yates said.

Starting in the mid-1990s, new atypical anti-psychotics came onto the market to treat schizophrenia and related disorders, the most common diagnoses at Western. Currently, there are seven atypical anti-psychotic drugs, three of them new since 2001.

They are expensive, some more than \$15 per pill, compared with less than a dollar per pill for the older medications. In 2006, the hospital spent more than \$5 million on atypical anti-psychotics, according to Western's pharmacy.

Promoted by drug companies as safer and more effective, atypicals are widely used at Western and most psychiatric hospitals.

Their growing use, coupled with the continued use of some of the older drugs, has resulted in an increase since 1999 of about 30 percent in the amount of anti-psychotic medication being given to patients at Western, The News Tribune found.

Many patients now receive two or more anti-psychotic drugs at once, a doubling of medication unheard of just eight years ago, when the older drugs were more prevalent.

Jackson, the acting medical director, attributed the increased use of anti-psychotics to several factors. In some cases, he said, disappointing results with one drug led physicians to add a second drug.

And compared with 1999, he said, a greater proportion of patients at Western have schizophrenia and require anti-psychotic drugs.

But there also has "been a very hard sell on the (newer drugs), and a very clever hard sell" to psychiatrists and other

doctors worldwide, said Dr. David Healy, a professor of psychiatry at the University of Wales and an internationally recognized authority on psychiatric drug side effects.

Recently, several major medical studies have cast doubt on claims that the newer anti-psychotic drugs are more effective and safer than the typicals.

A British study published last fall by the American Medical Association found that patients did as well or better on the older drugs. Another suggested patients who take the newer drugs could be more likely to develop diabetes and die at an earlier age.

The sales pitches, Healy said, have led the medical community to “assume the evidence is there” to back up the advertising claims.

But the evidence, he said, “just is not there.”

Medical staff at Western said they are aware of the situation, and are rethinking their use of atypicals.

“It is not yet clear to me what will eventually happen with regard to prescribing practices,” said Jackson, “because the newer drugs are still believed to have some benefits, despite the recent findings.

“The jury is still out.”

Burkholder, the drug industry executive, acknowledged the recent findings concerning atypicals, and said the studies should “help doctors tailor treatment to the individual patient.”

ASSUMPTIONS QUESTIONED

Akathisia once was thought to be an uncommon side effect with the newer anti-psychotics, but for three of the atypicals in common use at Western, that’s now in doubt.

Bristol-Myer Squibb’s atypical drug is called Abilify, which hit the market in 2002. Data from the company suggested up to 15 percent of people who took the drug developed akathisia.

Recent studies suggest a higher percentage. Possibly the highest estimate to date came from a small study published in March. Researchers found that five of 12 patients, or 42 percent, developed akathisia after taking Abilify.

At the beginning of December, about one in 10 Western patients received Abilify, according to The News Tribune analysis.

Bristol-Myer Squibb spokesman David Rosen defended his company’s product by pointing out that the small number of patients in the recent Abilify study might have skewed the results.

Despite recent findings, many doctors still assume that atypicals are not likely to cause akathisia, Jackson said, “so their index of suspicion is not as high.”

That could be part of the reason, he said, for a roughly 50 percent drop at Western over the past eight years in the use of drugs – such as tranquilizers and propranolol, a beta blocker drug also used for heart problems – used to control drug-induced anxiety and agitation.

The pharmacy periodically prints out lists of drug orders, giving a snapshot of drug trends at Western.

A printout on Nov. 24, 1998, showed 1,736 orders for drugs often used to calm patients experiencing akathisia, among about 913 patients at the hospital. On Dec. 6, 2006, the most recent day for which data were available, there were 792 orders for those drugs among 860 patients.

FDA ORDERS LABEL WARNINGS

Western State Hospital also has switched to newer types of antidepressants, including Prozac and similar drugs, that are linked to akathisia.

Research by the University of Wales' Healy and others suggests the drugs sometimes cause such extreme agitation that people commit suicide to escape it or lash out in murderous rage.

The Food and Drug Administration in 2004 required manufacturers to update the drugs' labels to warn of the possibility of "anxiety, agitation ... hostility (aggressiveness), impulsivity, akathisia" and other problems, including suicidal behavior.

Pfizer Pharmaceuticals' Zoloft was one of the antidepressants whose label was updated. There were 74 orders for the drug at Western State Hospital on a single day, Dec. 6, 2006.

POSSIBILITY, NOT PROOF

Like Burkholder, the psychiatrists interviewed for this story said The News Tribune's analysis only suggests that changes in drug use might contribute to violence at Western. Proving such a link would require an analysis of patient data not available to the public.

It would be important to analyze incidents of violence to see what drugs patients were on at the time, as well as their histories of violence while not medicated, said Kaye, the Philadelphia psychiatrist and professor.

Hospital administrators and state regulators should pursue such an analysis, said Dr. David Antinuco, a University of Nevada psychiatrist and an authority on psychiatric drugs. That could lead to a new way to combat violence not only at Western, but also at psychiatric hospitals across the nation, he said.

"This should have been done years ago," said Eastern University's Kruszewski. "There is little information in the psychiatric and neuropsychiatric literature" analyzing drug use and violence at mental hospitals.

Proof that drug choice influences violence at Western would be "very important for everyone to know," Kaye agreed, adding that it could lead to better training for doctors on how to recognize, observe and treat akathisia.

After reviewing the findings of The News Tribune analysis, Western State Hospital chief executive officer Andy Phillips said he would be "very interested" in studying the matter further, but said the stumbling block would be finding funding to back such research.

REVOLVING DOOR CLOSES

What stands out in Western's pharmacy data is that doctors, who can prescribe virtually any anti-psychotic or antidepressant drug they want, rapidly adopt the newest and most expensive drugs from the pharmaceutical industry.

Jackson, the hospital's acting medical director, said one likely reason is that by the time patients come through Western's door, some already have failed on the older drugs.

But until they were banned from visiting campus in March, pharmaceutical industry salespeople were a fact of life at Western, as they are in virtually every hospital and doctor's office in the country.

Western is a huge market for the drug industry, said Phillips.

Since December 2003, sales reps made hundreds of visits a year to Western to brief doctors about their latest products, according to pharmacy logs analyzed by The News Tribune.

About 50 sales representatives from 13 companies, many visiting several times a week, accounted for those visits. Typically, representatives from a given company visited in pairs or small groups, according to pharmacy logs.

For many doctors, there was "no appreciation that what they hear from drug reps (was) a sales pitch," said Jackson, who refuses to see drug sellers.

From October until the March ban, drug representatives were required to state how much time they spent on campus. Records show visits lasting from 15 minutes to more than three hours.

The vast majority of the visits were by representatives from companies with new antidepressants and atypicals on the

market. More than half of the visits were from companies that make atypicals and antidepressants linked to higher rates of akathisia, records show.

Representatives often visited the same doctors repeatedly.

Asked why Pfizer representatives has made almost 200 visits to Western since December 2003, company spokesman Bryant Haskins said, "That's where our customers are." Pfizer makes the atypical drug Geodon, one of those linked to agitation.

"At hospitals, we have a number of Pfizer products being used," he said, "so our sales reps check in regularly to make sure (staff) have new information, samples, and any questions answered."

Western's ban on drug representatives' visits with doctors comes after years of increasing restrictions on pharmaceutical promotions. Several years ago, administrators banned representatives from helping doctors select drugs for specific patients. And physicians may not accept gifts from representatives beyond small items such as pens and note pads.

The ban resulted from doctors feeling pressured by sales pitches, said Dr. Margaret Dean, Western's medical director until May. At weekly medical review meetings, she said, there sometimes were so many drug sellers that doctors had hard a time finding chairs.

She and others said sales representatives hung out after the meetings to pigeonhole doctors.

"That kind of pushy interaction can't happen anymore," Dean said.

Drug companies, however, still buy lunches and dinners and host lectures at local restaurants for Western doctors and nurses, according to one physician, who did not want his name in the paper for fear of losing his job.

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SOME DRUGS WITH AGITATIVE SIDE EFFECTS

Here are some anti-psychotic and antidepressant drugs more likely than others in their class to cause agitating side effects such as restlessness, anxiety and insomnia. Taken as a group, there has been about a 35 percent increase in orders for these drugs at Western State Hospital since 1999. There's also been a steady increase in assaults on workers over that time. Western averages about 900 patients a day.

Atypical anti-psychotics		
Drug	Manufacturer	Orders on Dec. 6, 2006
Risperdal	Janssen	307
Geodon	Pfizer	118
Abilify	Bristol-Myers Squibb	82
Typical anti-psychotics		
Haldol	Ortho-McNeil, generic makers	98
Prolixin	Bristol-Myers Squibb, generic makers	26
Navane	Pfizer, generic makers	6
Antidepressants		
Zoloft	Pfizer, generic makers	74
Effexor	Wyeth, generic makers	38
Prozac	Eli Lilly, generic makers	37

Wellbutrin	GlaxoSmithKline, generic makers	22
Cymbalta	Eli Lilly	20

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