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Prescription Abuse Seen In U.S. Nursing Homes

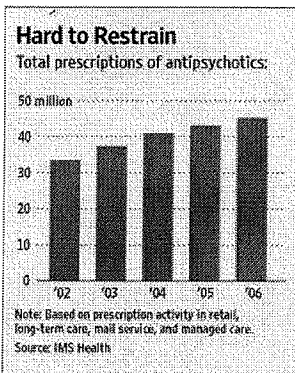
Powerful Antipsychotics Used to Subdue Elderly; Huge Medicaid Expense

By LUCETTE LAGNADO
December 4, 2007; Page A1

In recent years, Medicaid has spent more money on antipsychotic drugs for Americans than on any other class of pharmaceuticals -- including antibiotics, AIDS drugs or medicine to treat high-blood pressure.

One reason: Nursing homes across the U.S. are giving these drugs to elderly patients to quiet symptoms of Alzheimer's disease and other forms of dementia.

Nearly 30% of the total nursing-home population is receiving antipsychotic drugs, according to the Centers for Medicare & Medicaid Services, known as CMS. In a practice known as "off label" use of prescription drugs, patients can get these powerful medicines whether they are psychotic or not. CMS says nearly 21% of nursing-home patients who don't have a psychosis diagnosis are on antipsychotic drugs.



That is what happened to a woman listed in New York state health department inspection records as Resident #18. The 84-year-old Alzheimer's patient, who lives at the Orchard Manor nursing home in Medina, N. Y., likes to wander and roll her wheelchair around her unit, according to a report filed earlier this year, and sometimes she nervously taps her foot.

To address her behavior, which was considered disruptive, Resident #18 was given a powerful antipsychotic drug called Seroquel, a drug approved for schizophrenia and bipolar disorder. Resident #18 is not psychotic and Seroquel -- like other atypical antipsychotics -- carries a "black box" warning that elderly dementia patients using it face a higher risk of death.

"She is a handful," says Thomas Morien, administrator of Orchard Manor. "Other residents complain about her because often at night, she will get up and go to their rooms." The patient has since been taken off the drugs.

The growing off-label use of antipsychotic medicines in the elderly is coming under fire from regulators, academics, patient advocates and even some in the nursing-home industry.

"You walk into facilities where you see residents slumped over in their wheelchairs, their heads are hanging, and they're out of it, and that is unacceptable," says Christie Teigland, director of informatics research for the New York Association of Homes and Services for the Aging, a not-for-profit industry group. Her research, which she believes reflects national trends, shows that about one-third of dementia patients in New York's nursing homes are on antipsychotics; some facilities have rates as high as 60% to 70%. "These drugs are being given way too much to this frail elderly population," Dr. Teigland says.

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Federal and some state regulators are pushing back, questioning the use of antipsychotic drugs and citing nursing homes for using them in ways that violate federal rules. New York has increased its focus on antipsychotics in nursing homes, training inspectors to spot signs of medication abuse. Last month, the Arkansas attorney general filed suit against Johnson & Johnson and two of its units, claiming, among other things, that they "engaged in a false and misleading campaign" to promote its antipsychotic drug Risperdal to geriatric patients.

A spokesman for Janssen LP, one of the Johnson & Johnson units that manufactures Risperdal, says, "We are prepared to vigorously defend ourselves against these claims."

Setting Limits

The \$122 billion-a-year nursing-home industry's use of drugs raises complex issues in an aging society. Revulsion against practices such as tying down and sedating disruptive elderly patients led in 1987 to a landmark federal law, signed by President Reagan, that set limits on how and when nursing homes can physically, or chemically, restrain a patient. Since then, a rising population of elderly people suffering dementia has entered nursing facilities, many of which have overburdened staff.

The vast majority of antipsychotic medicines paid for by Medicaid are atypical antipsychotic drugs, thought to have fewer of the side effects typical of older drugs. Many were introduced in the 1990s to treat schizophrenia, and have become huge sellers for pharmaceutical companies. Nursing homes turned to the drugs to try to calm dementia patients and to maintain safety and order in their facilities.

The newer antipsychotics are more expensive than older ones. A dose of Seroquel, for instance, can cost more than \$4 at retail, while Risperdal can cost more than \$5 a pill retail; older antipsychotics can cost less than a dollar per dose.

In all, atypical antipsychotics rang up U.S. sales of \$11.7 billion last year, up from \$6.6 billion in 2002, according to IMS Health, a health-care information company. Doctors last year filled 45.4 million prescriptions for atypical antipsychotics, compared with 33.6 million five years ago, IMS Health says.

Big Spenders

Medicaid outlays on atypical antipsychotic drugs in the U.S. have grown consistently.

| Year | Medicaid spending on atypical antipsychotic drugs in billions | Percentage of total* |
|------|---|----------------------|
| 2005 | \$5.40 | 13.7% |
| 2003 | 4.10 | 12.6 |
| 2000 | 2.14 | 10.7 |

* Drug spending by Medicaid program
 Note: Doesn't include Tennessee and Washington state excludes rebates the government obtains for drug purchases

Source: Centers for Medicare & Medicaid Services, tabulation of Medicaid Drug Rebate data

Schizophrenic patients, for whom the drugs were originally intended, make up 1.1% of the U.S. population, or 2.4 million people over 18, according to the National Institute for Mental Health. It says 2.6% of Americans suffer from bipolar disorder, for which the drugs were later also approved.

Marketing atypical antipsychotic drugs for use in treating dementia is banned, since the drugs aren't approved for such use. Still, drug companies have reached out to those who take care of incapacitated patients. For instance, the March 2007 issue of *Annals of Long-Term Care*, a publication of the American Geriatrics Society that caters to doctors and long-term care specialists, carries a multipage ad for Seroquel. The ad says in large type that the drug has been approved for treatment of bipolar depression.

A spokesman for AstraZeneca Pharmaceuticals, the maker of Seroquel, says "bipolar depression afflicts adults of all ages, including seniors." He noted that the warning of dangers to elderly patients was prominently featured in the ad.

Seroquel had global sales of \$3.4 billion last year, making it one of the industry's blockbusters. U.S. sales were \$2.5 billion. For the past two years, Seroquel has been the No. 1 drug purchased by Medicaid.

AstraZeneca says it "does not recommend Seroquel for uses other than its approved indications in schizophrenia and bipolar disorder." The company noted the warning on the labels "of all drugs of this class" regarding use in dementia patients. "Decisions about medical treatment are made by physicians," the company says.

Nursing homes often find it difficult to balance the demands of caring for certain patients against the pressure to keep staff costs down. The economics of elderly care can work in favor of drugs, because federal insurance programs reimburse more readily for pills than people.

The use of antipsychotic drugs comes amid a wider debate about how to care for the rising numbers of seniors, many of whom have behavior problems stemming from dementia. They can be difficult to manage, at home or in an institution. They can cry, lash out, wander or even be violent, to themselves or others. There aren't many effective methods to calm them, doctors say.

A big question is whether to use a medical model -- administering antipsychotics as the way to alleviate distressing symptoms of dementia -- or trying to find other ways to help these patients.

The Centers for Medicare & Medicaid -- the federal agency that oversees the two huge tax-funded insurance programs that cover the elderly and the poor -- has "initiated a more rigorous process to oversee appropriate use of medicine," says Chief Medical Officer Barry Straube. He says the number of nursing-home inspections that result in citations for violating drug-misuse rules has jumped by nearly 50% between 2004 and this year. Action is being taken and the increased vigilance is

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working, CMS says.

Dr. Straube says CMS -- which both funds and oversees nursing homes -- "is very concerned about the quality of care in nursing homes and has taken steps within its authority to discourage inappropriate use of all drugs, including psychotropic medications."

In 2005, the most recent year for which total expenditure figures are available, Medicaid spent \$5.4 billion on atypical antipsychotic drugs. It spent less on AIDS drugs (\$1.58 billion) and medications to lower cholesterol (\$2.1 billion). These figures don't include rebates the government receives.

High use of antipsychotics in a nursing home can be an indicator of inadequate staffing, says Bruce Pollock, president-elect of the American Association of Geriatric Psychiatry. "We know the more staffing there is and the higher quality of care, the less the antipsychotic usage," he says.

Neurological Disease

Psychosis is a severe psychiatric illness which frequently includes delusions or hallucinations. Alzheimer's is a neurological disease that can be accompanied by either psychosis or severe behavioral symptoms, such as aggression or agitation. Dr. Pollock, a professor of neuropsychiatry at the University of Toronto, says one problem is that the psychosis in Alzheimer's disease is not the same as psychosis in younger patients with schizophrenia.

America is facing a public health crisis over the care of those with dementia, Dr. Pollock says. "We are left with the atypicals because we have nothing else," he says. These drugs have a role to play, he says, but "nonpharmacologic treatments" should be tried first.

In New York, the state Health Department is stepping up its focus on antipsychotic use in nursing homes. Two years ago, it issued 16 citations involving medication misuse; this fiscal year, there were 67. Records of a state inspector's visit to the Orchard Manor nursing home earlier this year offer a glimpse of the problem.

The report profiles an 84-year-old woman identified, to protect her privacy, only as "Resident #18." She was confined to a wheelchair with a "lap buddy" -- a restraining device that prevents her from getting up. Her "primary" behavior issues are that she "self propels in wheelchair and enters other rooms," the report said. Resident #18 "is usually understood and usually understands," the report said. She suffers from Alzheimer's disease, but isn't psychotic.

Still, she was placed on the antipsychotic drug Seroquel, along with Haldol, an older, less-expensive antipsychotic.

New York regulators found in that case, Orchard Manor violated the federal requirement to refrain from giving patients "unnecessary drugs." The facility was ordered to submit a new plan for treatment. There was no fine.

Mr. Morien, Orchard Manor's administrator, says the facility submitted a plan within 14 days. He says the small, rural home provides excellent care. The facility may not have adequately explained to state officials its reasons for putting Resident #18 on antipsychotics, he says. He says she is off the drugs now.

It comes down to staffing, he says. Taking care of patients such as Resident # 18 requires many more people able to watch them. Yet under the current reimbursement system, where the government spends billions on these drugs, he says it is hard for a facility such as his to make ends meet.

"We are a nonprofit; we have not made a penny in years," he says. Mr. Morien says there are certain patients with behavioral issues, and "no matter what you do, you can't control them, and physicians will try different medications for them." But he says his facility tries to use drugs only as a "last approach to a behavioral problem."

Most dementia patients who become agitated are trying to communicate a deep-felt need or want, says Jeffrey Nichols, vice president for medical services at New York's Cabrini Eldercare Consortium, a nonprofit group. When they cry out, are they simply being combative or are they delusional and in need of a tranquilizer? Maybe neither, says Dr. Nichols: "They may be in pain."

Dr. Nichols, who oversees a 240-bed nursing home, says that for dementia patients, antipsychotic drugs "don't work very well and they are significantly overused." The use of such drugs to care for agitated dementia patients is "like hitting a TV on the side," he says.

In a statement, the American Health Care Association, which represents for-profit, investor-owned and nonprofit nursing homes, says facilities "work closely with doctors to ensure that medications prescribed are meeting the individual needs of each patient." Nursing homes are "treating an older, more frail population of seniors with increasingly complex care needs," the group says.

The use of atypical antipsychotic drugs in nursing homes continues despite scientific papers that question the benefits of using them on dementia sufferers in light of the risks. Earlier this year, the federal Agency for Health Care Research and Quality reviewed existing research and noted the drugs can trigger strokes, induce body tremors, fuel weight gain and affect an elderly person's gait, increasing their chances of falling.

'Black Box' Warning

The Food and Drug Administration issued a "black box" warning on using the drugs for dementia patients in 2005. But the

FDA stopped short of banning such use; officials say they give physicians the leeway to prescribe the drugs if they think it will help this difficult-to-treat population.

Some doctors are now switching back to older, cheaper antipsychotics, such as Haldol, the FDA says. The older drugs had fallen into disuse, but don't have a black-box warning. Now, the FDA says it's weighing putting a black-box warning on those drugs, too.

In Massapequa, N.Y, a nursing home was recently fined by the state for injecting 90 doses of Haldol into a 96-year-old Alzheimer's patient. The woman, identified only as Resident #2, enjoyed listening to music and getting her nails polished, according to a state report. But when agitated, she banged her hand on the table and sometimes yelled.

One aide found it was possible to calm her by offering ice cream and chatting with her, the report said. But other staff gave her the drug Haldol. Between August 2006 to February of this year, she received 90 doses of injectable Haldol, the report said. The facility, Parkview Care and Rehabilitation Center, paid a \$2,000 fine for medication misuse.

"It is a unique situation," says Steve Seltzer, Parkview's administrator. "I know that this is not the nature of this facility." He described Resident #2 as an especially difficult case, who reverted to her native European language, making it hard to communicate. As a result of the state's action, "staffing changes were made," he says. The woman was later given a teddy bear as both a way to calm her down and to provide a cushion so she wouldn't hurt herself.

She passed away last Friday.

Write to Lucette Lagnado at lucette.lagnado@wsj.com

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