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For Immediate Release
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Grassley seeks thorough review of nursing home use of anti-psychotic drugs

WASHINGTON — Sen. Chuck Grassley has asked for a review by the Inspector General for the Department of Health and Human Services into how anti-psychotic drugs are being used in nursing homes given questions of patient safety and taxpayer liability for the prescriptions, including off-label use of the drugs.

“Along with overall quality of care provided to a nursing home resident, it’s of tremendous concern that federal programs are paying for prescription drugs that could be unnecessary or potentially harmful for people living in nursing homes,” Grassley said. “Independent scrutiny needs to be given to the prescribing practices going on with this very vulnerable population and what’s motivating those practices.”

Grassley has also asked the federal agency that oversees nursing home quality to report on its response to nursing homes that misuse prescription drugs, and he has asked the manufacturers of three of the leading anti-psychotic drugs for information about their marketing efforts with regard to nursing home residents.

The text of Grassley’s five letters, sent this week following a front page news story in the Wall Street Journal, is below this news release.

Grassley has long worked to improve the quality of care provided in nursing homes. As Chairman of the Senate Special Committee on Aging during the late 1990s, he conducted an oversight effort that resulted in the launch of the “Nursing Home Initiative” by the federal agency then known as the Health Care Financing Administration. The goal of the initiative was strong regulations and steadfast enforcement by federal and state officials. Since the launch of the Nursing Home Initiative, Grassley has frequently asked the GAO to provide status reports on the progress made in holding homes accountable for the quality of care provided to vulnerable residents.

Today, Grassley is Ranking Member of the Senate Committee on Finance, which is responsible for Medicare and Medicaid oversight and legislation. Nearly 1.7 million elderly and disabled Americans live in 17,000 nursing home facilities across the country. Combined

Medicare and Medicaid payments for nursing home services total an estimated \$70 billion annually.

December 4, 2007

The Honorable Daniel R. Levinson
Inspector General
U.S. Department of Health and Human Services
Office of Inspector General
330 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Inspector General Levinson,

The United States Senate Committee on Finance (Committee) has jurisdiction over, among other things, the Medicare and Medicaid programs. As Ranking Member of the Committee, I have a responsibility to protect both the Medicare and Medicaid programs

There are nearly 1.7 million elderly and disabled individuals in about 17,000 nursing home facilities in the United States today. Over the last decade, I have been a champion in the fight to insure that nursing home residents receive high quality care on a consistent basis.

As I have said repeatedly that the vast majority of nursing homes provide quality care on a consistent basis. They provide valuable services to those who can no longer care for themselves. However, and as the old saying goes; "a few bad apples can spoil the whole bunch."

I was troubled by the attached article, which appeared today in the Wall Street Journal regarding prescription abuse of antipsychotic drugs in nursing homes. Specifically, the Wall Street Journal reported that nearly 21% of nursing home residents are receiving antipsychotic drugs "off-label." That means that nursing home residents who are not diagnosed as psychotic can receive these drugs for dementia, a condition prevalent among many elderly nursing home residents. This is disturbing and alarming on several levels.

The first issue that comes to mind is that nursing home residents are receiving powerful drugs that are not intended for their underlying condition. Indeed some of these drugs have "black box" warnings because of their serious side effects. So the question in turn that arises is whether or not nursing home residents are receiving the quality of care that they should be receiving.

The next issue of concern is whether or not the Medicare and Medicaid programs are paying for drugs that may not be in the best interest of the patient but may also be unnecessary. The amount of money expended in the United States on drugs such as Risperdal, Seroquel and Zyprexa is substantial-exceeding \$11 billion in worldwide sales in 2006 alone.

Over the past year, I have also been examining payments made to physicians by pharmaceutical companies. There have been numerous reports that some physicians are

influenced by drug companies to prescribe drugs that may not necessarily be in the best interest of the patient and to also prescribe these drugs “off-label.” I am concerned that this practice may have spread beyond physicians in the nursing home environment to now include nurses, certified nursing assistants and others involved in the day-to-day, hands-on care of nursing home residents.

Lastly, there have been numerous law suits filed against the makers of some of the most popular antipsychotic drugs by among others, Pennsylvania, Louisiana, Montana and South Carolina. These suits often question whether or not drug makers are fraudulently marketing antipsychotic drugs and in turn, owe money back to the government.

Today's Wall Street Journal article is eye opening and concerning. Accordingly, we would like to request that the Office of Inspector General (OIG) examine the matters set forth above and report back to the Committee. In that regard, I request that the OIG identify and examine a number of nursing homes, including but not limited to the number of antipsychotic drugs used, payments or other items of value provided to the prescribing physician and/or others in the nursing home facility from sponsoring companies, the indicated use for the antipsychotic drug used and the payments made by Medicare and Medicaid.

As always I am happy to meet with you to discuss this request further. Thank you in advance for your assistance.

Sincerely,
Charles E. Grassley
Ranking Member

December 5, 2007

Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Acting Administrator Weems:

The United States Senate Committee on Finance (Committee) has jurisdiction over, among other things, the Medicare and Medicaid programs. As Ranking Member of the Committee, I have a responsibility to protect both the Medicare and Medicaid programs.

There are nearly 1.7 million elderly and disabled individuals in about 17,000 nursing home facilities in the United States today. Over the last decade, I have been a champion in the fight to ensure that nursing home residents receive high quality care on a consistent basis.

I was troubled by the attached article which appeared in yesterday's Wall Street Journal regarding prescription abuse of antipsychotic drugs in nursing homes. Specifically, the Wall Street Journal reported that nearly 21% of nursing home residents are receiving antipsychotic drugs "off-label." That means that nursing home residents who are not diagnosed as psychotic can receive these drugs for dementia, a condition prevalent among many elderly nursing home residents.

According to the article, the Chief Medical Officer for the Centers for Medicare and Medicaid Services (CMS), Dr. Barry Straube, stated that CMS has "initiated a more rigorous process to oversee appropriate use of medicine." Dr. Straube also said that the number of nursing home inspections resulting in citations for violating drug-misuse rules jumped by nearly 50%. I would greatly appreciate receiving information regarding the changes in processes that have been made by CMS. In addition, I would appreciate receiving clarification and supporting documentation about the 50% jump in citations, including the nature of the citation, the date of the citation, and the amount collected by CMS. Please provide this information for the period of January 1, 2005 to the present.

The Wall Street Journal article also reported on a matter involving Resident Number 2, who is described as a 96 year-old Alzheimer's patient. It was reported that Resident Number 2 received 90 doses of Haldol in a 6 month period. That would amount to a dose every few days. The article went on to say that the facility responsible for Resident Number 2 paid a \$2000 fine for medication misuse. That fine seems very low and does not appear to fit the violation. Accordingly, I would appreciate detailed information regarding that matter, including the circumstances and events that led to the fine, how the fine was calculated, and whether or not it is CMS's view that the \$2000 fine was appropriate for the violation.

Please respond to these requests stated above by December 19, 2007.

Finally, I would appreciate a response to my August 14, 2007 letter in which I requested information regarding federal expenditures for Risperdal, Zyprexa and Seroquel. I have attached my original letter to you as it is months late.

Thank you in advance for your assistance.

Sincerely,
Charles E. Grassley
Ranking Member

August 14, 2007

Herb B. Kuhn
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Acting Administrator Kuhn:

I request that the Centers for Medicare and Medicaid Services provide the available data showing total Medicare and Medicaid reimbursements for calendar year 2003 to the present for the following drugs: Seroquel, Zyprexa, Risperdal, Avandia, Actos, Celebrex, Lexapro, Aranesp, Epogen, and Procrit.

Please be sure to provide the Medicaid payment data by state. Thank you in advance for your assistance on this matter. I would appreciate receiving this information as soon as possible but in no event later than August 28, 2007.

Sincerely,
Charles E. Grassley
Ranking Member

December 5, 2007

Mr. Tony Zook
President and Chief Executive Officer
AstraZeneca Pharmaceuticals LP
P.O. Box 15427
Wilmington, DE 19850- 5437

Dear Mr. Zook:

The United States Senate Committee on Finance (Committee) has jurisdiction over the Medicare and Medicaid programs. Accordingly, the Committee has a responsibility to the more than 80 million Americans who receive health care coverage under those programs to oversee the proper administration of the programs and ensure that beneficiaries receive drugs that are both safe and effective.

I read with great concern yesterday's Wall Street Journal article regarding the increasing off-label use of antipsychotic drugs to subdue the elderly in nursing home facilities. Specifically, the article reported that almost 21% of nursing home patients are on antipsychotic medications even though they do not have a psychosis diagnosis and that a majority of the antipsychotic drugs paid for by Medicaid are atypical antipsychotic drugs. The inappropriate use of antipsychotic drugs in nursing home patients is not only a financial concern to the Committee, but also a serious patient safety concern, especially in light of the black box warnings of a higher risk of death associated with the use of antipsychotic drugs in elderly dementia patients.

In addition, a growing number of states have been investigating allegations of improper and fraudulent marketing and promotion of such drugs. Over the last few years, the Committee also has been reviewing allegations of improper marketing practices of the pharmaceutical industry. Accordingly, I am requesting that AstraZeneca Pharmaceuticals LP provide the Committee with the following information:

1. A copy of all documents, including but not limited to presentations, pamphlets, literature, and training materials, provided to employees, agents, and/or consultants who market and/or promote the use of Seroquel in the nursing home population, for the period of January 2002 through December 2006.
2. A copy of all documents, including but not limited to presentations, reports, and literature, related to Seroquel, that were shown or provided to nursing home physicians, nurses, and certified nursing assistants and/or other nursing home staff for the period of January 2002 through December 2006.
3. A copy of all internal and external communications and documents, including but not limited to presentations, reports, and pamphlets, related to off-label use of Seroquel in the nursing home population for the period of January 2002 through December 2006.
4. A copy of all documents regarding payments or other transfers of value to nursing home physicians, nurses, and certified nursing assistants and/or other nursing home staff related to the use of Seroquel for calendar years 2005 and 2006.
5. The total amount of sales of Seroquel to nursing homes for calendar years 2005 and 2006. To the extent available, please specify the amounts covered by Medicare and by Medicaid.

In cooperating with the Committee's review, no documents, records, data or information related to these matters shall be destroyed, modified, removed or otherwise made inaccessible to the Committee.

I look forward to your cooperation and assistance on this important matter. Thank you in advance for providing the name and contact information, including an e-mail address, for a person who will act as the point of contact for AstraZeneca Pharmaceuticals LP during the Committee's review by no later than December 10, 2007.

Sincerely,
Charles E. Grassley
Ranking Member

December 5, 2007

Mr. Sidney Taurel
Chairman and Chief Executive Officer
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, IN 46285

Dear Mr. Taurel:

The United States Senate Committee on Finance (Committee) has jurisdiction over the Medicare and Medicaid programs. Accordingly, the Committee has a responsibility to the more than 80 million Americans who receive health care coverage under those programs to oversee the proper administration of the programs and ensure that beneficiaries receive drugs that are both safe and effective.

I read with great concern yesterday's Wall Street Journal article regarding the increasing off-label use of antipsychotic drugs to subdue the elderly in nursing home facilities. Specifically, the article reported that almost 21% of nursing home patients are on antipsychotic medications even though they do not have a psychosis diagnosis and that a majority of the antipsychotic drugs paid for by Medicaid are atypical antipsychotic drugs. The inappropriate use of antipsychotic drugs in nursing home patients is not only a financial concern to the Committee, but also a serious patient safety concern, especially in light of the black box warnings of a higher risk of death associated with the use of antipsychotic drugs in elderly dementia patients.

In addition, a growing number of states have been investigating allegations of improper and fraudulent marketing and promotion of such drugs. Over the last few years, the Committee also has been reviewing allegations of improper marketing practices of the pharmaceutical industry. Accordingly, I am requesting that Eli Lilly and Company provide the Committee with the following information:

1. A copy of all documents, including but not limited to presentations, pamphlets, literature, and training materials, provided to employees, agents, and/or consultants who market and/or promote the use of Zyprexa in the nursing home population, for the period of January 2002 through December 2006.
2. A copy of all documents, including but not limited to presentations, reports, and literature, related to Zyprexa, that were shown or provided to nursing physicians, nurses, and certified nursing assistants and/or other nursing home staff for the period of January 2002 through December 2006.
3. A copy of all internal and external communications and documents, including but not limited to reports, presentations, and pamphlets, related to off-label use of Zyprexa in the nursing home population for the period of January 2002 through December 2006.
4. A copy of all documents regarding payments or other transfers of value to nursing home physicians, nurses, and certified nursing assistants and/or other nursing home staff related to the use of Zyprexa for calendar years 2005 and 2006.
5. The total amount of sales of Zyprexa to nursing homes for calendar years 2005 and 2006. To the extent available, please specify the amounts covered by Medicare and by Medicaid.

In cooperating with the Committee's review, no documents, records, data or information related to these matters shall be destroyed, modified, removed or otherwise made inaccessible to the Committee.

I look forward to your cooperation and assistance on this important matter. Thank you in advance for providing the name and contact information, including an e-mail address, for a person who will act as the point of contact for Eli Lilly and Company during the Committee's review by no later than December 10, 2007.

Sincerely,
Charles E. Grassley
Ranking Member

December 5, 2007

Mr. William C. Weldon
Chairman and Chief Executive Officer
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933

Ms. Janet Vergis
President
Janssen LP
1125 Trenton-Harbourton road
Titusville, NJ 08560

Dear Mr. Weldon and Ms. Vergis:

The United States Senate Committee on Finance (Committee) has jurisdiction over the Medicare and Medicaid programs. Accordingly, the Committee has a responsibility to the more than 80 million Americans who receive health care coverage under those programs to oversee the proper administration of the programs and ensure that beneficiaries receive drugs that are both safe and effective.

I read with great concern yesterday's Wall Street Journal article regarding the increasing off-label use of antipsychotic drugs to subdue the elderly in nursing home facilities. Specifically, the article reported that almost 21% of nursing home patients are on antipsychotic medications even though they do not have a psychosis diagnosis and that a majority of the antipsychotic drugs paid for by Medicaid are atypical antipsychotic drugs. The inappropriate use of antipsychotic drugs in nursing home patients is not only a financial concern to the Committee, but also a serious patient safety concern, especially in light of the black box warnings of a higher risk of death associated with the use of antipsychotic drugs in elderly dementia patients.

In addition, a growing number of states have been investigating allegations of improper and fraudulent marketing and promotion of such drugs. Over the last few years, the Committee also has been reviewing allegations of improper marketing practices of the pharmaceutical industry. Accordingly, I am requesting that Johnson & Johnson and Janssen LP provide the Committee with the following information:

1. A copy of all documents, including but not limited to presentations, pamphlets, literature, and training materials, provided to employees, agents, and/or consultants who market and/or promote the use of Risperdal in the nursing home population, for the period of January 2002 through December 2006.
2. A copy of all documents, including but not limited to presentations, reports, and literature, related to Risperdal, that were shown or provided to nursing physicians, nurses, and certified nursing assistants and/or other nursing home staff for the period of January 2002 through December 2006.
3. A copy of all internal and external communications and documents, including but not limited to reports, presentations, and pamphlets, related to off-label use of Risperdal in the nursing home population for the period of January 2002 through December 2006.
4. A copy of all documents regarding payments or other transfers of value to nursing home physicians, nurses, and certified nursing assistants and/or other nursing home staff related to the use of Risperdal for calendar years 2005 and 2006.
5. The total amount of sales of Risperdal to nursing homes for calendar years 2005 and 2006. To the extent available, please specify the amounts covered by Medicare and by Medicaid.

In cooperating with the Committee's review, no documents, records, data or information related to these matters shall be destroyed, modified, removed or otherwise made inaccessible to the Committee.

I look forward to your cooperation and assistance on this important matter. Thank you in advance for providing the name and contact information, including an e-mail address, for a person who will act as the point of contact for Johnson & Johnson/Janssen LP during the Committee's review by no later than December 10, 2007.

Sincerely,
Charles E. Grassley
Ranking Member

Wall Street Journal
Prescription Abuse Seen In U.S. Nursing Homes
Tuesday, December 4
By Lucette Lagnado

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.

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 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."

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.

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 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.

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.

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.