



NEW DRUGS

Fusion Inhibitor for HIV

The Food and Drug Administration (FDA) has announced the accelerated approval of enfuvirtide (Fuzeon™, Roche) for use with other anti-HIV medications in adults and children ages six years and older with advanced human immunodeficiency virus (HIV) infection. Enfuvirtide is the first in a new class of medications called fusion inhibitors, which interfere with the fusion of viral and cellular membranes, thus hindering the entry of HIV-1 into cells.

The FDA's approval was based on six months of data from two ongoing clinical studies involving approximately 1,000 patients. Adding enfuvirtide to other anti-HIV drugs reduced the level of infection more than the anti-HIV drugs did alone. Because HIV is treated with a combination of medications, enfuvirtide can be used in patients with limited treatment options. However, the drug is expected to cost about \$20,500 a year, or nearly three times the price of the next most expensive drug used to treat acquired immunodeficiency syndrome (AIDS). The cost, the manufacturer explains, is attributable in part to the complexity of the drug.

The manufacturing process is the most complicated ever instituted on a large scale. It takes 106 steps, not the five or six that are needed to make most other AIDS drugs, and 45,000 kilograms of expensive raw materials are needed to make 1,000 kilograms of enfuvirtide.

The drug, administered as a subcutaneous injection, should be used only in patients who have taken other anti-HIV drugs and in whom viral replication has persisted.

The long-term effects are being evaluated. Although bacterial pneumonia was uncommon in study participants, bacterial infection developed in more patients receiving enfuvirtide than in

patients not treated with this drug.

Enfuvirtide can also cause serious systemic allergic reactions. Patients should be advised to contact their health care providers right away if they have difficulty in breathing or if they experience fever, skin rash, chills, vomiting, or dizziness.

Local skin reactions at the site of injection are common and can be painful. Patients should be cautioned about signs and symptoms of infection at the site.

(Sources: *FDA News*, March 13, 2003; www.medscape.com/viewarticle/451067.)

Moxifloxacin for Eye Infections

Alcon has received FDA approval of its newest antibiotic product, moxifloxacin ophthalmic solution (Vigamox™) 0.5%, after a six-month review. This potent fourth-generation fluoroquinolone antibiotic is safe and effective for adults and children as young as one year old.

The solution, which is administered only three times a day for seven days, is used to treat bacterial conjunctivitis. Moxifloxacin is highly soluble, which allows it to be formulated at a higher concentration (0.5%) than other fourth-generation fluoroquinolones.

It is effective against many types of harmful bacteria that infect the surface of the eye. The solution covers difficult-to-treat gram-positive bacteria, including *Staphylococcus* and *Streptococcus* organisms, which account for an estimated 80% of eye infections. It is also highly active against chlamydial infections and other emerging bacterial threats.

Vigamox™ solution is robust enough to be formulated without the preservative benzalkonium chloride. It results in a low incidence of stinging when applied in the eye—an especially important consideration for children.

(Source: PR Newswire; Alcon news release, April 16, 2003; www.alconinc.com.)

Gatifloxacin Ophthalmic Solution for Bacterial Conjunctivitis

The FDA has approved gatifloxacin ophthalmic solution (Zymar™, Allergan), 0.3%, an anti-infective and the first fourth-generation fluoroquinolone to enter the market for the treatment of bacterial conjunctivitis caused by susceptible strains of bacteria. The drug is expected to be available by June 2003.

The most frequently reported adverse events associated with this drug have been conjunctival irritation, increased secretion of tears, inflammation of the cornea, and papillary conjunctivitis in approximately 5% to 10% of patients. Other reactions occurring in 1% to 4% of patients were swelling of the tissue surrounding the cornea, conjunctival hemorrhage, dry eye, eye discharge, eye irritation, eye pain, swelling of the eyelid, headache, red eye, reduced visual acuity, and taste disturbance.

(Source: Allergan news release, March 31, 2003.)

New Vaginal Estrogen Ring for Menopausal Women

Approximately 75% of menopausal women experience such symptoms as vaginal dryness and temperature fluctuations ("hot flashes"). Many women who have taken estrogen tablets or patches still experience vaginal symptoms. The FDA has approved an estradiol acetate vaginal ring (Femring™, Galen), the first vaginal estrogen product that is indicated to treat both the hot flashes and the vaginal symptoms associated with menopause. Galen plans to introduce the drug into the U.S. market in June 2003.

The ring includes a steady three-month supply of estradiol in just one dose. In clinical trials, women reported that they found the ring convenient, effective, and easy to use. The women had few problems inserting or removing the ring, and the most of them reported



they were comfortable and not aware of wearing it. Most of the women expressed the desire that health care professionals offer the ring when discussing hormone therapy options with their patients.

The drug will be available in two strengths, 0.05 mg/day or 0.1 mg/day.

The most frequently reported adverse events in clinical trials were headache, bleeding between menstrual periods, vaginal candidiasis, and breast tenderness. These events are commonly observed with all estrogen products.

Estrogens should not be used in any of the following situations:

- undiagnosed abnormal genital bleeding
- known or suspected cancer of the breast or a history of the disease
- known or suspected estrogen-dependent neoplasia
- active deep vein thrombosis, pulmonary embolism, or a history of these conditions
- active or recent arterial thromboembolic disease
- known hypersensitivity to any of the drug's compounds

Estrogens, with or without progestins, should not be used to prevent cardiovascular disease. Estrogens have been reported to increase the risk of endometrial carcinoma.

(Source: www.galenplc.com.)

Generic Version of Oral Contraceptive Available

Norethindrone acetate and ethinyl estradiol tablets (Microgestin®, Watson), a generic version of the oral contraceptive Loestrin® (Pfizer), will be available in strengths of 1 mg/20 mcg, and 1.5 mg/30 mcg.

(Source: PR Newswire, April 8, 2003.)

Gemifloxacin for Community-Acquired Pneumonia

The FDA has approved gemifloxacin (Factive®, GeneSoft) for the treatment of mild to moderate community-acquired pneumonia and acute bacterial exacerbation of chronic bronchitis.

The manufacturer anticipates that Factive® will provide physicians with a powerful treatment option at a time when up to 40% of the strains of *Streptococcus pneumoniae* might be resistant to both penicillin and erythromycin.

As many as 13 million people experience acute exacerbation of chronic bronchitis in the U.S. with mortality rates in hospitalized patients as high as 30%. There are as many as four million cases of community-acquired pneumonia, which causes 64,000 deaths every year. It is the leading cause of death resulting from infections.

Like other antibiotics, Factive® should be used only to treat infections that have been strongly suspected or confirmed to be caused by bacteria, not viruses. The most common side effects include diarrhea, rash, nausea, and headache. Rash is generally mild to moderate in nature and is more likely to occur if taken for longer than the recommended course.

(Source: PR Newswire, April 4, 2003.)

Generic Capsules Approved for Severe Acne

Barr Laboratories has announced that the FDA has approved its application to manufacture and market a generic version of Accutane® (isotretinoin, Roche) capsules, in strengths of 10, 20, and 40 mg. The company plans to market Claravis™ as a generic brand and to launch it in May 2003.

Claravis™ is indicated for the treatment of severe recalcitrant nodular acne. Because of the significant adverse effects associated with its use, this drug should

be reserved for those patients who have not responded to conventional therapy, including systemic antibiotics. The drug is indicated only for women who are not pregnant and will not become pregnant.

(Source: PR Newswire/First Call, April 11, 2003.)

NEW INDICATIONS

Labeling Changes Planned for Simvastatin

The FDA has announced labeling changes for simvastatin (Zocor®, Merck), a cholesterol-lowering drug, as a result of The Heart Protection Study (HPS) findings. The new labeling will indicate that simvastatin is effective in reducing the risk of fatal and nonfatal heart attacks and strokes and in reducing the need for bypass surgery and angioplasty.

In the study, the risk of death from coronary heart disease was reduced by 18% in the patients receiving simvastatin, and their risk of their having a nonfatal heart attack was reduced by 38%. Simvastatin also reduced the risk of stroke by 25% and the need for coronary or non-coronary revascularization procedures to unblock clogged arteries by 30% and 16%, respectively. Patients who had diabetes, peripheral vessel disease, and cerebrovascular disease but no evidence of heart disease also appeared to benefit from taking simvastatin.

As with other statins, simvastatin should be used in conjunction with a standard cholesterol-lowering diet. The dosage range is 5 to 80 mg/day.

Patients should be aware of any muscle pain, which may indicate an adverse reaction called rhabdomyolysis, a muscle breakdown disorder. Symptoms can include fatigue, fever, nausea and vomiting, severe muscle pain, weakness, and tenderness. Rhabdomyolysis can cause electrolyte imbalances that can result in heart rhythm problems, cardiac arrest, or heart attack.



DRUG NEWS

Generic Tiazac® Approved for Hypertension

Andrx Corporation has announced that the FDA has approved the marketing of its Abbreviated New Drug Application for Taztia™ (diltiazem HCl). The extended-release capsules are bioequivalent to Tiazac® (Biovail). This product, a calcium-channel blocker, is indicated to treat hypertension and chronic stable angina. The capsules will be available in strengths of 120, 180, 240, 300, and 360 mg.

(Source: Business Wire, April 10, 2003.)

Metformin Extended-Release Tablets Approved for Diabetes

The FDA has approved metformin HCl extended-release tablets (Glucophage® XR, Bristol-Myers Squibb) in a new dosage strength of 750 mg for the treatment of type-2 diabetes. The 750-mg tablet was developed to provide physicians with an additional option to make titration to higher doses more convenient when necessary. Glucophage® XR is already available as a 500-mg tablet and is approved together with diet and exercise for use as initial drug therapy to improve glycemic control for diabetic adults 17 years and older when diet and exercise are not enough. In addition to initial therapy, this drug may be used in combination with a sulfonylurea or insulin to improve glycemic control.

In rare cases, Glucophage® XR can cause lactic acidosis, a serious condition resulting from a buildup of lactic acid in the blood. Lactic acidosis occurs mainly in people with kidney impairment, and it can be fatal in up to 50% of cases. Patients should advise their physicians about alcohol consumption. They should not take the drug if they have kidney problems, if they are 80 years of age or older (unless the kidneys have been tested), if they are taking medication for heart failure, or

if they have or had liver disease. The most common side effect is diarrhea.

(Source: PR Newswire/First Call, April 14, 2003.)

Hydrocodone Bitartrate for Acute Pain

The FDA has approved an Abbreviated New Drug Application for hydrocodone bitartrate and ibuprofen tablets (Teva), which are bioequivalent to Vicoprofen® (Abbott) to treat severe pain. The approved dosages are 7.5 mg/200 mg.

(Sources: FDA Update; Teva Pharmaceutical Industries Ltd., April 14, 2003; www.tevapharm.com.)

Antibiotics after Acute Myocardial Infarction

Giving antibiotics to help prevent inflammation in patients with coronary disease is an attractive idea to clinical researchers for a number of reasons. Many studies have focused on whether antibiotics can help change the course of coronary artery syndromes. Results have been mixed, with smaller studies tending to show benefits but larger trials showing no advantages.

One large study, Antibiotic Therapy after an Acute Myocardial Infarction (ANTIBIO), monitored 868 patients for 12 months. Patients who were given roxithromycin (e.g., Rulid®, Aventis) 300 mg/day for six weeks fared no better and no worse than patients given placebo. Of 431 patients in the drug group, 28 died (6.5%); of 437 placebo patients, 26 died (6%).

The ANTIBIO researchers noted that the type of macrolide (roxithromycin or azithromycin [Zithromax®, Pfizer]), the type coronary artery disease (unstable or stable), the duration of therapy, and whether or not patients had *C. pneumoniae* infection did not seem to have a major impact on the effect of antibiotic treatment. Because smaller trials have

Although the beneficial effects of simvastatin in the study were observed with the 40-mg dose, lower doses are recommended for those taking certain medications (e.g., cyclosporine, verapamil, amiodarone, and other cholesterol-lowering drugs) and in patients with kidney problems.

(Sources: FDA Talk Paper, April 16, 2003; www.fda.gov.)

Infliximab Reduces Fistulas in Crohn's Disease

The FDA has granted marketing approval for infliximab (Remicade®, Centocor) to state that it can reduce the number of draining enterocutaneous and rectovaginal fistulas and to maintain fistula closure in patients with fistulizing Crohn's disease (CD). Up to 30% of the estimated half-million Americans with CD have associated fistulas—openings that extend through the bowel wall into nearby organs or through the surface of the skin.

The new maintenance indication requires treatment every eight weeks, following an induction regimen in which patients receive doses at weeks zero, two, and six.

Remicade® is the only biological drug indicated for the treatment of both CD and rheumatoid arthritis (RA). In June 2002, the FDA approved Remicade® to induce and maintain clinical remission in patients with moderate to severe CD with maintenance dosing every eight weeks.

Remicade® is a monoclonal antibody that specifically targets and irreversibly binds to tumor necrosis factor (TNF)-alpha on the cell membrane and in the blood. Overproduction of TNF-alpha is believed to play a role in CD, RA, and many immune-mediated inflammatory disorders.

(Source: Internet Wire, April 3, 2003.)



been more likely to show benefits, the researchers suggest that the effect of antibiotics, when added to standard therapy, might be very small and perhaps limited to certain patient subgroups, such as patients with high antibody titers. They add that their findings challenge the hypothesis that *C. pneumoniae* plays a major role in the pathogenesis of arteriosclerosis.

(Source: *Circulation* 2003;107:1253–1259.)

Hormones for Women: The Debate Continues

Although a large government study, the Women's Health Initiative, has suggested that hormone therapy shows no benefit in terms of the quality of life for postmenopausal women, many women disagree with the results.

For years, physicians—and a number of women—believed that hormones enhanced daily life after menopause. It was thought that estrogens and progestin could improve mood, memory, insomnia, vitality, and sexual activity. Although the hormones can relieve temperature fluctuations and vaginal dryness, the study concluded that women who do not have these problems after menopause will not feel better in the long run than women who take placebo.

The estrogen–progestin part of the study was stopped early because women taking the hormones were experiencing a somewhat higher incidence of breast cancer, stroke, heart attacks, and pulmonary blood clots than the women who were taking placebo.

Since the study ended, some women have decided to risk taking hormones because they say that they feel better. In the end, these quality-of-life factors are quite subjective and difficult to measure.

(Sources: *The Philadelphia Inquirer*, March 18, 2003; *N Engl J Med* electronic version, March 17, 2003.)

Does Flu Vaccine Prevent Stroke and Heart Disease?

Flu shots appear to do more for older people than once thought; they might also protect against heart disease and stroke.

A large study of more than 286,000 people over age 65 revealed that hospital stays for patients with heart disease or stroke during two influenza seasons were substantially reduced among those patients who received flu shots.

Influenza contributes to an average 36,000 deaths in the U.S. each year. Flu shots are now recommended for all adults 50 years of age and older. In 2001, about 63% of people over age 65 were vaccinated in the U.S.

The flu vaccine reduces deaths overall and prevents pneumonia in the elderly, and some small studies have suggested that they help ward off heart disease and strokes.

Researchers have observed that flu vaccination cut hospitalizations for heart disease by 19% during the two flu seasons (1998–1999 and 1999–2000). Hospital stays for stroke were reduced by 16% in the first season and by 23% in the second.

The connection between the flu and heart disease and stroke was not clear, according to the lead researcher, but the virus could have been affecting blood vessels and the development of clots in the brain and heart. Some have argued for a national program to offer flu shots.

(Sources: Associated Press, April 3, 2003; *N Engl J Med* 2003;348:1322–1332).

Can Monthly Migraines Be Prevented?

Neurologists at Thomas Jefferson University Hospital in Philadelphia, Pennsylvania, may have found a long-acting drug to stop monthly migraines that occur in some women around the time of their menstrual periods—before the headaches start.

Frovatriptan succinate (Frova®, Elan), was found in a nationwide study to prevent migraines associated with menstruation in as many as 50% of the women evaluated. Frovatriptan is in a class of drugs called triptans, which reduce inflammation of certain blood vessels in the brain that are thought to cause pain.

Participants had an average 12-year history of migraine, which affects more than five million American women. In the U.S. alone, approximately nine million women suffer from migraines; about 60% of them, or 5.4 million, report an increased number of headaches in association with their menstrual periods.

For the women in the study, the migraines typically began between two days before and one day after the start of menstruation. The average duration of these migraines in women who received placebo was 29 hours, and more than 75% of the patients reported moderate or severe headache pain.

In the trial, 545 women were treated two days before and four days during their menstrual periods with placebo, a once-daily dose of frovatriptan, or a twice-daily dose of the drug for three months. The study, based at Jefferson, was conducted at 36 centers nationwide.

Fifty percent of patients treated in the six-day period with 2.5 mg of frovatriptan twice daily had no headache. In addition, 39% of the patients taking 2.5 mg of frovatriptan once daily had no headache, compared with 26% taking placebo. Depending on the dose given, frovatriptan reduced the severity and duration of menstruation-associated migraines and decreased the degree and duration of functional impairment and the need for rescue medications.

Each patient received the treatment regimens over the course of three menstrual periods. The incidence and type of side effects reported were similar to those caused by placebo, including nau-



sea, dizziness, headache, and fatigue.

In another study conducted by the same author, frovatriptan also helped to prevent cluster headaches during the "transitional period," the two or three weeks it takes for long-term preventive therapies (e.g., lithium or calcium-channel blockers) to begin working. Cluster headaches are characterized by intermittent, pulsing head pain that lasts as long as eight weeks and comes once or twice a year. Patients sometimes describe attacks as a stabbing pain around the eye. Cluster headaches are less common than migraines and can be very difficult to treat.

(Source: American Academy of Neurology, 55th annual meeting, Honolulu, Hawaii, April 1, 2003.)

Topiramate for Migraine

Results from the largest controlled clinical trials ever conducted for the prevention of migraine headaches demonstrate that topiramate (Topamax®, Ortho-McNeil), an antiseizure medication, can help prevent migraine attacks. Beneficial effects were observed as early as one month into treatment. These findings were presented on April 2, 2003, at the 55th annual meeting of the American Academy of Neurology in Honolulu, Hawaii.

The average number of migraines per month was, at the least, cut in half for 49% of patients who were given 100 mg of the drug, 47% of those who were given the 200-mg dose, and 39% of those who received the 50-mg dose. Topamax® was found to be safe and was generally well tolerated, with no unexpected adverse events attributed to treatment.

Additional information is available from the National Headache Foundation, www.headaches.org.

(Source: PR Newswire/First Call, April 2, 2003.)

Few Complications from Multidose Activated Charcoal

Activated charcoal, often used as an antidote for accidental poisonings, is a tasteless and odorless powder that neutralizes toxins, gases, and metals in the body. Contrary to some concerns, multiple-dose activated charcoal (e.g., Liqui-Char®, Jones; Actidose®, Paddock) is relatively free of serious complications, say researchers from the University of Calgary, Canada. Upon reviewing the charts of 878 patients at eight tertiary-care hospitals, they found that clinically significant pulmonary aspiration and gastrointestinal obstruction were rare.

Data have been limited mainly to case reports that warned of complications, say the researchers, adding that theirs is the first study to estimate the frequency of complications in a wide range of poisoned patients. The expert panelists who reviewed the cases judged that activated charcoal treatment was likely to have caused pulmonary aspiration in only five patients and gastrointestinal obstruction in none. None of the patients died as a result of pulmonary complications, and none experienced long-term sequelae. The researchers also found hypernatremia in 53 patients, hypermagnesemia in 27, and corneal abrasion in one.

"Multiple-dose" was defined as two or more doses, which might have captured patients at very low risk. Of the study patients, 297 were given at least four doses and 106 were given six or more. Four of the patients who experienced aspiration, however, did so after the first dose of activated charcoal.

(Source: *Ann Emerg Med* 2003;41:370-377.)

Sarcoidosis and Methotrexate Toxicity

Liver-function tests might not be all that helpful in determining which patients with sarcoidosis should discontinue tak-

ing methotrexate. Researchers from the University of Cincinnati performed 100 liver biopsies in 68 patients with chronic sarcoidosis who had been treated for up to eight years with methotrexate. (To their knowledge, this study represented the largest series of liver-biopsy results in this patient population.)

Toxic drug effects were observed in 14 cases. After examining all the abnormal liver-function test results during the year before the biopsy, however, the researchers found no pattern that might predict toxicity. Patients with hepatic sarcoidosis already had higher levels of various liver enzymes, which meant that the predictive value of the liver-function tests was lost; in addition, more than half of the patients in the methotrexate toxicity group did not have elevated aspartate transaminase levels in the year before biopsy.

Methotrexate has become a standard second-line agent for the treatment of sarcoidosis, and hepatotoxicity is a well-known side effect of the drug. Using a liver biopsy to look for a toxic reaction to methotrexate has been controversial, the researchers note, and they point out that rheumatologists have relied on serial liver-function tests to identify at-risk patients with rheumatoid arthritis, based on the relatively low rate of methotrexate-related liver damage. For patients with sarcoidosis, the policy at the researchers' institution is to perform a liver biopsy in patients who receive methotrexate for more than two years.

(Source: *Arch Intern Med* 2003;163:615-620.)

Fluoroquinolone Antibacterials Misused in Emergency Rooms

Roughly 80% of patients who are given fluoroquinolone antibiotics in emergency departments of academic medical centers are being treated improperly.

Researchers studied 100 patients at a

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tertiary-care hospital and at an urban community hospital. Of the 100 patients, 81 received a fluoroquinolone for an inappropriate indication. In more than half of these instances (43 patients, 53%), another agent had been considered first-line treatment (usually sulfamethoxazole-trimethoprim for urinary tract infection); in another third (27 patients, 33%), there was no evidence of infection based on the clinical evaluation or diagnostic studies; and in the rest (11 patients, 14%), evaluation was insufficient.

Even when the right drug was given, the dose and duration were often wrong. Of 19 instances in which the fluoroquinolone was given appropriately, only one patient received the right dose for the right duration. In general, when the dose and duration were incorrect, the dose was higher and the duration was longer than recommended by institutional guidelines. The most common example was an uncomplicated urinary tract infection that was treated for more than seven days or treated with levofloxacin injection (Levaquin™, Ortho-McNeil) 500 mg/day instead of 250 mg/day.

The researchers suggest that emergency department prescribers might be taking their patients' habits into account more than they should. For instance, knowing that many emergency-room patients don't have access to routine health care, some practitioners might be using broader-spectrum agents than necessary because of concerns that such patients will not follow up with their physicians for treatment. However, such assumptions can lead to other problems.

Multiple courses of fluoroquinolone antibiotics, for example, have been associated with resistance to these drugs. In addition, patients might be less likely to fill a prescription for the more expensive fluoroquinolone, increasing the chance that an infection will remain untreated.

Finally, higher doses and longer durations of fluoroquinolone therapy have been associated with a greater risk of adverse events.

(Source: *Arch Intern Med* 2003;163:601-605.)

Imatinib: The New "Gold Standard" for CML

Imatinib mesylate (Gleevec™, Novartis) is being touted as the new gold standard for the treatment of chronic myeloid leukemia (CML), displacing the previous holder of the title—interferon alfa therapy. Research has shown that imatinib produces high response rates in patients who have not benefited from interferon alfa.

The advent of imatinib already appears to have had an effect on the numbers of allografts being performed, note the researchers, emphasizing that "the choice between drug therapy and transplantation for newly diagnosed CML is becoming increasingly difficult."

On the basis of the high early mortality rate associated with bone marrow transplantation and the promising results with imatinib, the researchers say, early transplantation may be restricted to patients with the highest likelihood of success.

(Source: *N Engl J Med* 2003;348:994-1004.)

Risperidone and Stroke Risk

Johnson & Johnson plans to contact thousands of U.S. physicians advising them of a possible increased risk of stroke among elderly patients taking its well-known antipsychotic drug risperidone (Risperdal®). The company might also change the package insert label of the medication, which has annual global sales of \$2.1 billion, to note a possible risk of stroke.

In October 2002, the company had sent a similar warning letter to Canadian physicians and pharmacists citing 37

reports of stroke or related events such as blood clots and hemorrhages, including 16 deaths, among patients who had taken Risperdal®.

The company also cited two clinical trials in which a higher proportion of elderly patients with dementia taking Risperdal® experienced strokes or related events than patients who took placebo. J&J did note, however, that the elderly are generally at increased risk of stroke.

Although this drug has been approved only for schizophrenia, it is widely used to control behavioral disorders in elderly patients with dementia and Alzheimer's disease, such as delusions, aggression, and anxiety.

Risperdal® and rival schizophrenia drugs already include information in their labels about strokes that have been observed in patients taking them in either clinical trials or after the drugs reached the market. The labeling for Risperdal® will be changed, however, to include more specific information about strokes in the elderly.

Some think that physicians might be hurting patients by using Risperdal® to treat dementia, and they suggest that the incidence of stroke among elderly Alzheimer's patients should spur U.S. regulators to further examine whether younger schizophrenia patients are also prone to stroke.

Others feel that it would be impossible for many patients with dementia to live at home without this drug. Dr. Norman Sussman, a professor of psychiatry at New York University Medical Center, for instance, says that physicians must weigh the possibly higher stroke risk associated with Risperdal® against the higher quality of life it offers to patients with dementia.

(Source: Excerpted, in part, from *The Washington Post*, April 10, 2003; © 2003 Reuters.)