



Pa Chapter ENewsletter

SEPTEMBER 24, 2008

VOLUME 1, NUMBER 4



[Registration is now open for Geriatrics' 08](#)



[Have you joined ASCP's MTM provider partners? Click here for details](#)

[Are you a student or recent graduate? Find out how to get started in consultant or senior care pharmacy>](#)



[Not a member but would like to join? Look at the benefits of membership>](#)

PA-ASCP NEWSLETTER

FDA Publishes List Of Potential Problem Drugs

Posted on: Monday, 8 September 2008, 14:10 CDT

In an effort to better inform doctors and patients of certain risks, the government on Friday began posting a list of prescription drugs under investigation for potential safety problems.

The first list names 20 medications and the potential issue for each, but provides no indication of how widespread or serious the problems might be, leading some consumer advocates to question its usefulness, and prompting industry worries that skittish patients might stop taking a useful medication if they see it listed.

Officials at the Food and Drug Administration said they are trying to walk a fine line in being more open to the public while avoiding needless scares. Congress, in a drug safety bill passed last year, ordered the agency to post quarterly listings of medications under investigation.

Five of the drugs on the list had previously publicized problems. These included the blood thinner heparin, recalled earlier this year, and immune-suppressing medications being studied for a link to cancer in youngsters.

"It's a good thing to get started but it needs to have much more detail if it's to have significant safety value," said Thomas J. Moore, a senior scientist with the Institute for Safe Medication Practices. "A table with just a few words of description is quite limited." "It's just the most basic warning system," said Diana Zuckerman, president of the National Research Center for Women and Families. "It's not going to say how many reports there were. It's not going to say how many died and how many were hospitalized."

It is also still unclear how drugs suspected of a problem will be removed from the list if later exonerated.

[Potential Signals of Serious Risks/New Safety Information Identified by the Adverse Event Reporting System \(AERS\) January - March 2008](#)

New Antipsychotics No Better Than Older Drugs

Monday, Sep 15 A new study has discovered two newer atypical antipsychotic medications were no more effective than an older conventional antipsychotic in treating child and adolescent schizophrenia and may lead to more metabolic side effects.

The study was funded by the National Institutes of Health's National Institute of Mental Health (NIMH) and is published online ahead of print in the *American Journal of Psychiatry*.

"Schizophrenia and schizophrenia-related disorders are rare in childhood. But

FDA Alerts

[Ammonul \(sodium phenylacetate and sodium benzoate\) Injection 10%/10%](#)

[Tarceva \(erlotinib\)](#)

[Phosphocol P 32 \(Chromic Phosphate P 32 Suspension\)](#)

Officers

President

Stan Spoon

consultpharm@netscape.net

Immediate Past President

Robert Dura

Robert.Dura@omnicare.com

President Elect

Eric Donley

edonley@alertpharmacy.com

Regional Directors

Western Regional Director

Kristina Wenslovas

kris.wenslovas@omnicare.com

Central Regional Director

Eric Donley

edonley@alertpharmacy.com

North-East Regional Director

Nicole Kruszek

nxk7001@pharmerica.com

South East Regional Director

Jeff Kruk

jkruk@ccrx.org

when they do occur, those afflicted generally have more severe symptoms and a worse prognosis than those who develop the disorder in adulthood," said NIMH Director Thomas R. Insel, M.D.

"The newer atypical antipsychotics are often used to treat these children, but until now, it has been unclear how effective and safe they really are in children. The side effects of the newer medications should be factored into making treatment decisions."

The six-year, multisite Treatment of Early Onset Schizophrenia Study (TEOSS) included 116 youth between 8 and 19 years old, diagnosed with early onset schizophrenia spectrum disorder (EOSS).

The TEOSS team randomly assigned the children to eight weeks of either olanzapine (Zyprexa) or risperidone (Risperdal)—both new generation atypical antipsychotics—or to the older conventional antipsychotic molindone (Moban) plus benztropine, a medication often used to reduce side effects like uncontrolled shaking or tremor that can be associated with molindone.

The children were monitored throughout the study by an NIMH oversight board to ensure their safety.

Response rates after eight weeks of treatment were comparable among the three medications—50 percent of the children taking molindone improved, 46 percent taking risperidone improved, and 34 percent taking olanzapine improved.

Children taking olanzapine or risperidone improved within the first two weeks, while the children on molindone improved within three weeks.

The treatment groups did differ in side effects. The children taking olanzapine gained about 13 pounds (6 kilograms) during the trial on average, while children taking risperidone gained about 8 pounds (3.6 kilograms), and those taking molindone did not gain weight.

The olanzapine group also showed increases in cholesterol levels and other metabolic disruptions that may have become dangerous. The outcome prompted the safety review board to end the olanzapine arm of the study in 2006.

"Atypical antipsychotics are commonly used to treat kids with EOSS, but these results question the wisdom of that approach," said lead author Linmarie Sikich, M.D., of the University of North Carolina at Chapel Hill.

"They also remind us that we need to develop safer, more effective medications to treat these children, given the limited effectiveness of both the atypical and the conventional medications."

Study coauthor Jeffery Lieberman, M.D., of Columbia University Medical Center, noted that TEOSS is the first documented evidence of how newer antipsychotics compare to older ones when treating children and adolescents with schizophrenia.

"Doctors need to educate families about the potentially serious side effects these drugs can have so that strategies can be put into place to address them," he reiterated.

The TEOSS results are similar to those found in the NIMH-funded Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE), for which Lieberman was the principal investigator. CATIE found that the newer antipsychotics were no more effective than an older antipsychotic in treating adults with schizophrenia.

To submit material or items of interest for this newsletter please contact

Stan Spoon
consultpharm@netscape.net

ASCP- We're on the Web!

www.ascp.com

Have You Considered ASCP?

An E-Student Membership in ASCP Can Provide You With... Ways to help you find a job!

- ASCP will provide you with a list of names and addresses of our regional directors and key contact members who may be able to assist you.
- ASCP will provide you with a list of companies that have reported they hire new graduates.
- ASCP's MyRxCareer.com lists ads from employers and allows you to post your resume.

ASCP's [Consider a Career in Consultant Pharmacy](#) flyer

Quick Updates

[FDA bans dozens of Ranbaxy-made generic drugs](#)

Medications

[Sancuso](#)

Sancuso (granisetron transdermal system) is an anti-emetic transdermal delivery system indicated for the control of nausea and vomiting in patients receiving moderately and/or highly nausea-inducing chemotherapy.

[Nplate](#)

Nplate (romiplostim) is a thrombopoietin mimetic peptibody for the treatment of thrombocytopenia in adult patients with chronic immune (idiopathic) thrombocytopenic purpura (ITP).

[Xenazine](#)

Xenazine (tetrabenazine) is a selective and reversible centrally-acting dopamine depleting drug indicated for the treatment of chorea associated with Huntington's disease.

[Cleviprex](#)

Cleviprex is an intravenous, ultrashort-acting calcium channel blocker under development for the treatment of severely elevated blood pressure in the hospital setting when oral therapy is not feasible or desirable.

[Stavzor](#)

Stavzor is delayed-release valproic acid formulated in the EnteriCare enteric soft gelatin capsule delivery system designed to minimize GI adverse events. Stavzor is indicated for the treatment of manic episodes associated with bipolar disorder, adjunctive therapy in multiple seizure types (including epilepsy), and prophylaxis of migraine headaches.

[Navstel](#)

Navstel is a balanced salt ophthalmic solution for use as an intraocular irrigation during surgical procedures involving perfusion of the eye.

[Eovist](#)

Eovist (gadoxetate disodium) is a gadolinium-based contrast agent for intravenous use in T1-weighted magnetic resonance imaging (MRI) of the liver to detect and characterize lesions in adults with known or suspected focal liver disease.

[Evolence](#)

Evolence is a collagen-based structural dermal filler for the correction of moderate to deep facial wrinkles and folds, such as nasolabial folds.

[Kinrix](#)

Kinrix [Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine] is a combination vaccine for protection

against diphtheria, tetanus, pertussis and polio diseases in children.

[Durezol](#)

Durezol (difluprednate ophthalmic emulsion) is a topical steroid for the treatment of postoperative ocular inflammation and pain.

[PrandiMet](#)

PrandiMet (repaglinide and metformin HCl) is a fixed-dose combination of the fast-acting secretagogue repaglinide (also known as Prandin) and insulin sensitizer, metformin, indicated for the treatment of type 2 diabetes.

[Pentacel](#)

Pentacel is a combination vaccine indicated for active immunization against diphtheria, tetanus, pertussis, poliomyelitis and invasive disease due to Haemophilus influenzae type b in children 6 weeks through 4 years of age.

[Trivaris](#)

Trivaris (triamcinolone acetonide) is a glucocorticoid corticosteroid delivered via intravitreal injection for the treatment of sympathetic ophthalmia, temporal arteritis, uveitis, and ocular inflammatory conditions unresponsive to topical corticosteroids.

[Entereg](#)

Entereg (alvimopan) is a peripherally-acting mu opioid receptor antagonist used to help patients regain gastrointestinal (GI) function earlier following bowel resection surgery.

[OraVerse](#)

OraVerse is a dental anesthetic reversal agent that accelerates the return to normal sensation and function following dental procedures