



**Clinical Update**

**January/February 2004**

## **Psychopharmacology – and Kids**

Child and adolescent psychiatrist Jud Staller MD, who is seeking patients for a clinical study of the metabolic and endocrine effects of antipsychotic drugs on children and adolescents, has also documented a dramatic increase in CNY's use of psychopharmacology for treating young patients.

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## **IBS at its Most Severe**

Women who suffer from disabling, diarrhea-predominant Irritable Bowel Syndrome may be candidates for a new multicenter clinical trial led by gastroenterologist Philip Holtzapple MD.

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## **Building Blocks For a CNY Children's Hospital**

Paper bricks are plastering the walls of local pediatrician's waiting rooms and sending a clear message: pediatric patients and their parents enthusiastically support the plan to build the CNY Children's Hospital at University Hospital.

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## Taking a Closer Look



Jud Staller MD  
Assistant Professor  
of Child & Adolescent Psychiatry  
SUNY Upstate Medical University

SUNY Upstate's Jud Staller MD studies the long-term safety of antipsychotic drugs for children – and tracks the growing trend toward psychopharmacology for young patients.

During two decades as a child and adolescent psychiatrist, Jud Staller MD has kept a keen eye on patterns of prescribing psychopharmacologic drugs for children – and witnessed a dramatic increase in their use. Young patients today are routinely prescribed stimulants, antidepressants and antipsychotic drugs – often in combination.

While these drugs often alleviate symptoms, Dr. Staller is concerned about the lack of research on their long-term safety. He is currently seeking patients for a clinical study of 5- to 17- year olds who have been on antipsychotic drugs for six months or longer. The patients may also be taking antidepressants and/or stimulants.

The focus of the trial is on the endocrine and metabolic effects of these drugs. "We are not studying the efficacy of these drugs in treating psychiatric conditions," he empha-

sizes. "We are exploring the safety of these drugs during long-term use in children."

Patients who enroll in the study (see notice, page A3) commit to an initial interview with Dr. Staller, who will gather basic medical information and discuss any side effects of the drugs. There are also two follow-up clinical pathology visits where blood is drawn.

### **Troubling Side Effects**

Potential side effects of antipsychotic drugs include weight gain (which can sometimes be dramatic); Parkinson's-like symptoms (and other neurological symptoms); and a rise in levels of prolactin, a brain chemical which can prompt breast development, lactation or changes in bone density.

Dr. Staller is focusing on antipsychotic drugs because of a dramatic increase in prescribing them for



children, most of whom have no diagnosis of a psychotic condition.

The drugs are prescribed because they are often effective in treating severely aggressive and dysregulated behaviors. "Perhaps they should be called multi-purpose drugs, because they work so well with many of these disorders," Dr. Staller says.

### **Nearly Tripled, Nationally**

"In Central New York, about 27 percent of children and adolescent in care as psychiatric outpatients are prescribed antipsychotic drugs," he reports. Nationally, the use of antipsychotic drugs in children nearly tripled between 1987 and 1996.

While improvements in behavior suggest the drugs are effective, "The question remains: are they safe for long-term use?" Dr. Staller asks. "Existing research has focused on short-term use of these drugs – six to eight weeks at the most. There is very little data on long-term use.

"When I was a SUNY Upstate resident in psychiatry," Dr. Staller recalls, "Professor Seymour Fischer always stressed the importance of an evidence-based practice. This study will help fill a gap in existing research, providing evidence about these drugs for long-term use in children."

### **Often in Tandem**

In another clinical trial, Dr. Staller attempted to study the long-term metabolic effects of antipsychotic drugs in patients on no other psychopharmacologic drugs. "In one year, we were able to enroll only six patients," he reports. "It's difficult to find children who are not taking other drugs as well. It's more typical for them to take an antipsychotic plus an antidepressant or an antipsychotic plus a stimulant. And it's not uncommon for a patient to be on all three."

### **The Larger Picture**

While studying endocrine and metabolic side effects of antipsychotic drugs, Dr. Staller has also been documenting patterns of psychopharmacological treatment of children in Central New York.

"When I entered practice in the early 1980s, only a handful of children were prescribed these drugs," he reports. "Today, almost 75 percent of children in ongoing treatment (after full evaluation) are on medication, and 37 percent are on more than one medication."

In the largest chart study of its kind, Dr. Staller and his research team recently reviewed the charts of 1,292

patients in three private practices (27 percent of sample) and five clinics (73 percent of sample) in Central New York.

### **Personal Insights**

Outside the realm of his carefully documented research, Dr. Staller makes some personal observations about the rise in frequency – and severity – of psychiatric conditions in children.

"One thing that's clear is that we are increasingly substituting chemical control for residential treatment," he says. "Psychiatric hospitals and residential treatment facilities are now few and far between, and they are usually full.

"The yeoman's work is now being done through outpatient care," Dr. Staller reports. "We are seeing very tough cases as outpatients. That's a big change from 20 years ago."

Dr. Staller believes that the media, especially television, have "a very severe impact on our culture and on our kids' aggressive, narcissistic, risk-taking and promiscuous behaviors.

"There are also significant family issues, specifically, who's taking care of the kids?" he says. "In today's  
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families, consistency and discipline are often pushed aside, and peer pressure, alcohol and marijuana fill the gap.”

### **Multi-modal**

In his own practice, Dr. Staller often combines psychotherapy, family therapy and medication – if indicated.

“Today’s parents are very interested in medication,” he reports. “This is very different from 20 years ago, when parents were resistant to medication.

“Psychiatry today runs the risk of becoming the specialty of psychopharmacology,” he concludes. “At Upstate, we remain true to our psychodynamic underpinnings. We have a very sought-after residency program, because of its continued focus on psychotherapy, in addition to biological treatments. Residency applicants tell us it’s difficult today to find this balance – to train in a place where you still know the names of the patient’s family.” ●

## **Dr. Staller’s CNY Chart Review**

Among the findings:

- 50 percent of patients have more than one diagnosis
- more males than females are prescribed medication
- largest age group in treatment: 10 to 14 years
- more boys in treatment at lower end of age spectrum
- female preponderance increases with age
- 76 percent of patients prescribed antipsychotics have no psychotic diagnosis
- most common diagnosis: ADHD, followed by disruptive disorders, depressive disorders and anxiety disorders
- ADHD highly comorbid
- significant pattern of externalizing/internalizing comorbidity – i.e., externalizing behavior with depression or anxiety
- most CNY findings in keeping with national trends
- one significant difference: fewer CNY preschoolers in psychiatric treatment

## Seeking Subjects: Child & Adolescent Psychiatry Study

Dr. Jud Staller, assistant professor in the Child and Adolescent Psychiatry Division of SUNY Upstate Medical University, is seeking subjects for an important clinical research study. This study will evaluate certain side effects of long-term treatment with certain antipsychotic medications – Risperdal (risperidone), Zyprexa (ziprasidone), and Seroquel (quetiapine). Specifically, this study will assess blood sugar, cholesterol, triglycerides, liver function, thyroid function, body weight, and a brain hormone called prolactin. Subjects must be between the ages of 5 and 17, and be currently taking only one of the above-mentioned antipsychotic medications for at least six months.

Subjects do not receive any medication from the study. The study only requires three visits – a first interview along with height and weight measurements, and two subsequent visits to a clinical laboratory to obtain blood samples (about 2 teaspoons). A copy of results will be sent to the child’s doctor. There is no cost to subjects, and they will receive \$25 for each laboratory visit. This study may be of significant benefit to the child as well as to other children who receive these medications, through an enhanced awareness and understanding of safety and risks. If you know a child who may qualify, please call Anne at 315-464-9089.



## Seeking Patients for Clinical Research Study: Irritable Bowel Syndrome

Women with severe diarrhea-predominant Irritable Bowel Syndrome are being sought for a study on the efficacy and safety of medication for disabling forms of this condition.

Principal investigator for the local site of this multicenter trial is Philip Holtzapple MD, professor of Medicine at SUNY Upstate Medical University and of the Division of Gastroenterology at SUNY Upstate Medical University.

Duration of the study may be up to 19 weeks, including a two-week screening period, a seven-day window for any necessary procedures after screening, a 12-week treatment phase and four-week follow-up period.

Candidates for the study must be women at least 18 years old, must have suffered from severe diarrhea-predominant type of IBS for at least six months and must have failed conventional therapy.

Volunteers meeting these and other criteria will be asked to undergo a two-week screening period. Participants will also be asked to use an automated phone reporting system throughout the study.

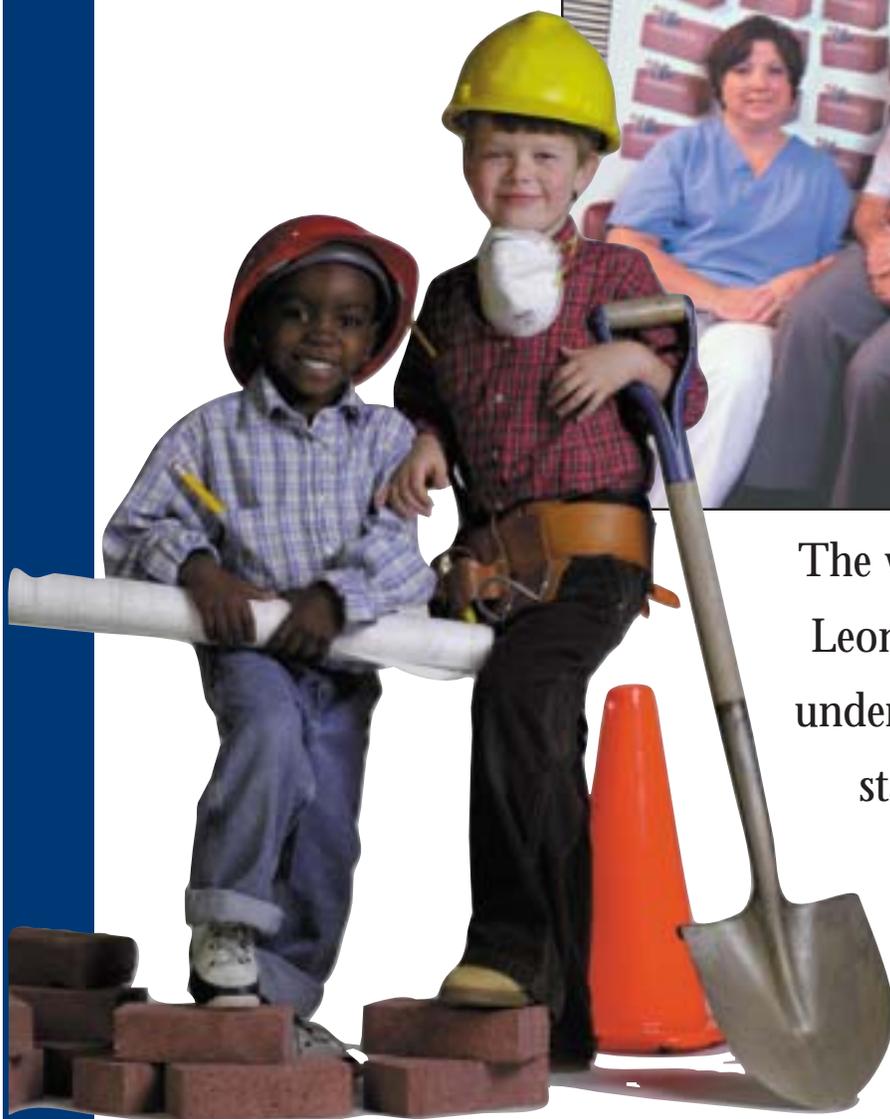
All office visits, medical evaluations and medications related to the study will be provided to patients at no cost.

For more information on this study, please call Health Connections at 315-464-8668/800-464-8668.



# Building Blocks For Better Pediatric Care

*Leonard Levy MD  
with nurse Sue Ashworth  
and office manager Karen Wiech  
in the brick-lined waiting room of  
his Fayetteville child and family  
medicine practice.*



The waiting room of pediatrician Leonard Levy MD looks as if it's under construction. The walls are stacked with paper bricks that will help change the way pediatric medical care is delivered in Central New York.



*Patient Jonathan Stenson with the brick he purchased to support the campaign for a Central New York Children's Hospital.*



More than 400 bricks have been purchased so far – primarily by Dr. Levy's patients and their families – to support the campaign for The Central New York Children's Hospital at University Hospital, scheduled to open in 2007.

The brick campaign, sponsored by the CNY Children's Miracle Network of the Upstate Medical University Foundation, was launched this fall in the offices of about 20 local pediatricians. The campaign continues to spread – to other physicians' offices, as well to daycare centers, nursery schools, health clubs and businesses. "The community has embraced the need for a children's hospital and has been very supportive," reports Toni Gary, director of the Children's Miracle Network. "We're rolling out the brick campaign in phases, but people are also calling and asking for bricks."

**For more information about the brick campaign, please call the CNY Children's Miracle Network at 315-464-KIDS (5437).**



For Dr. Levy, who is also chair of pediatrics at Community General Hospital, the brick campaign is the latest stage of a longstanding, professional commitment to building a children's hospital. "Those of us in private practice have been pushing for this for years," he reports. "Actually, this conversation began long before I came on the scene in 1965. My predecessors understood that sick children are best cared for in a dedicated children's hospital, and that pediatric subspecialists should be concentrated in one place. Through the years, this concept has had many supporters, and now it is finally coming to fruition.

"That's why I ask for support from everyone who comes through my door, including the FedEx guy and the mailman," reports Dr. Levy.

