

# Preschoolers on Prozac

## Off-label psychiatric prescriptions uncovered

February 22, 2000

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Fox News

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**NEW YORK** — Doctors are prescribing Ritalin and antidepressants to preschool children as young as 2 years old, a new study reports in this week's *Journal of the American Medical Association*, even though there is no evidence the drugs are safe for the toddlers' developing minds.

"If you thought that because a doctor puts a child on these medications then it's safe, that's a false assumption," said lead study author Dr. Julie Magno Zito, of the University of Maryland.

Examining data from two state Medicaid programs and a health maintenance organization, Magno Zito and her team found widespread psychiatric prescriptions to 2- to 4-year-old children:

- 1.2 percent of children got stimulants, mostly the generic form of Ritalin;
- 0.3 percent received antidepressants, including the new selective serotonin re-uptake inhibitors (SSRIs) like Prozac and Paxil;
- 0.2 percent were given clonidine, a blood pressure medication also used as a sedative;
- 1 to 1.5 percent of these children were receiving stimulants, antidepressants or antipsychotic drugs.

The drugs could be affecting children at a vulnerable time. "Early childhood is a time of tremendous change for the human brain," according to an accompanying *JAMA* editorial, and there are "legitimate concerns" that psychotropic drugs, as they are called, "could have deleterious effects on the developing brain."

### Off-Label Off-Kilter?

The new research, published in this week's *JAMA*, puts the spotlight on "off-label" prescriptions.

Physicians are allowed by law to prescribe drugs in ways not specifically approved by the Food and Drug Administration. The drugs listed in the study are not approved for use in such young children, and there have been no studies confirming they are safe or effective for that age group.

Off-label prescriptions for children are "unknown and uncharted," said Magno Zito. "We never know the long-term consequences ... and regulations should be tightened."

"There's an enormous hazard over the lack of regulation over how doctors prescribe drugs to their patients," said Dr. Peter Breggin, author of *Talking Back to Ritalin* and *Reclaiming Our Children*, and a longtime critic of the pharmaceutical industry. "As long as it doesn't offend the narcotics control authorities, doctors are pretty much home free."

"I don't think the FDA is being careful enough," said Dr. Alan Sager of the Boston University School of Public Health. "It's a laissez-faire, caveat emptor mode, and we need to start speaking English rather than French or Latin — let's get some trustworthy evidence on benefits and risks."

### Attention Deficit Bandwagon

The study shows psychotropic, or mind-altering, drug prescriptions to preschoolers rose up to three-fold between 1991 and 1995, and attributes part of the increase to "greater acceptance of biological treatments for a behavioral disorder."

Before the heightened awareness of attention deficit/hyperactivity disorder in older children, Magno Zito said, "it never occurred to anybody to think of ADHD as a condition that's appropriate for a 2-year-old or a 3-year-old, and the same with depression." She surmised the clonidine was being prescribed as a sedative to counteract the insomnia often caused by Ritalin and other stimulants.

Critics say the study confirms their worst fears about the dangers of psychopharmacology.

"Psychiatry and the drug companies have convinced the public that the problems children have are biological and genetic, and this has opened the road to medicating soon after birth," said Breggin. "Soon they'll be giving drugs to pregnant women if the baby's overactive in the womb."

### **The Quick Fix**

"It appears that behaviorally disturbed children are now increasingly subjected to quick and unexpected pharmacologic fixes," said Dr. Joseph Coyle, chair of the department of psychiatry at Harvard Medical School, in the accompanying editorial. In an interview with FOXNews.com, he blamed cutbacks in mental health services for much of the shift.

"I strongly suspect what we're seeing is increasing prescriptions by primary care physicians and even nurses" rather than psychiatric specialists, he said, as HMOs and Medicaid programs have tightened access to often-expensive mental health providers.

"If managed care is restricting access for children with significant emotional and behavioral problems," he said, "then that problem needs to be addressed."

"Pediatric use of medication should be our highest of level of certainly of effectiveness and safety," said Magno Zito. "The standard should be 'we can't do without it' instead of 'let's try this and see.'"