HYPERACTIVITY
Should schools decide the remedy?

JULIAN HIRSHOWITZ—CORBIS STOCK MARKET

NEW RITALIN AD BLITZ MAKES PARENTS JUMPY

More families and legislators are revolting against the push to consume antihyperactivity medications

By VIVECA NOVAK WASHINGTON

IN SHEILA MATTHEWS' VIEW, IT WAS A heartening event for the back-to-school season: the signing of a law in Connecticut that she and others hope will relieve the growing pressure on parents to put their kids on drugs to control attention-deficit/hyperactivity disorder (ADHD). The New Canaan homemaker helped gather support for the bill and was understandably proud to be in the Governor's office last week for the ceremony. But she and her fellow lobbyists for the legislation, most of them parents, also got a surprise kick in the teeth.

Picking up the September issues of a number of women's and parenting magazines, they saw the very first ads promoting these same medications. Considered Schedule II controlled substances by the Drug Enforcement Administration, they are among the most addictive and abused drugs that are still legal. Says Patricia Weathers, a Millbrook, N.Y., mother pushing for a law like Connecticut's: "It seems like every time we take a step forward, they come back and hit us harder."

Connecticut's law is the first to bar school officials from recommending psychotropic drugs for kids on the theory that such matters should be left to families and their doctors. The law comes on the heels of legislation enacted by Minnesota earlier this year preventing schools from forcing parents to medicate ADHD children. Utah and New Jersey have similar bills pending, and lawmakers in many other states have shown interest in such action.

But the legislative trend is at odds with a new—and unprecedented—marketing push by the makers of ADHD drugs. Until now, drugmakers have heeded a 30-year-old international treaty meant to discourage consumer advertising of psychotropic substances. No more. In one ad, drugmaker Celltech shows a smiling boy and his mom with the message: "One dose covers his ADHD for the whole school day," plus the drug's name, Metadate CD. The ad is running in a dozen magazines, including *Ladies' Home Journal,* which has two more ADHD drug ads in the same issue—from Shire Pharmaceuticals (maker of Adderall) and McNeil Consumer HealthCare (Concerta). These ads don't name any medications, but they do give toll-free numbers for more information. McNeil also has a similar ad on cable TV.

In light of what appears to be an epidemic of ADHD—some 3 million U.S. youngsters are believed to be afflicted with it and related behavior problems—pharmaceutical companies are locked in a fierce battle for what will soon be a $1 billion-a-year market for drugs treating the problem. New prescriptions for ADHD treatments have gone up more than 38% over the past five years, with 20 million prescriptions written in the past year. No longer do Ritalin and its generic knockoffs rule. Now there are more than half a dozen treatments, some of which last a whole school day, sparing kids the stigma of lining up at the nurse's office.

Last year pharmaceutical manufacturers spent $2.5 billion marketing drugs of all kinds to consumers. A spokeswoman for the Pharmaceutical Researchers and Manufacturers Association says such ads "empower" patients by informing them of treatment options. But, as doctors will tell you, they are a double-edged sword because they drive up demand for drugs. And that's particularly dicey in the case of drugs like those used for ADHD, which the DEA puts in the same category with morphine, cocaine, Demerol and Oxycontin.

Alarmed as it is by the trend, the government's hands may be tied. Under a 1971 United Nations convention, signatory nations agreed to prohibit the advertisement of psychotropic substances to the public. But the U.S. never passed such a law. So when the DEA recently complained to Celltech about its ad, it could only express strong concern—not threaten legal action.

The Food and Drug Administration is

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MARKETING A flurry of new ads promoting ADHD medications in consumer magazines breaks an old moratorium

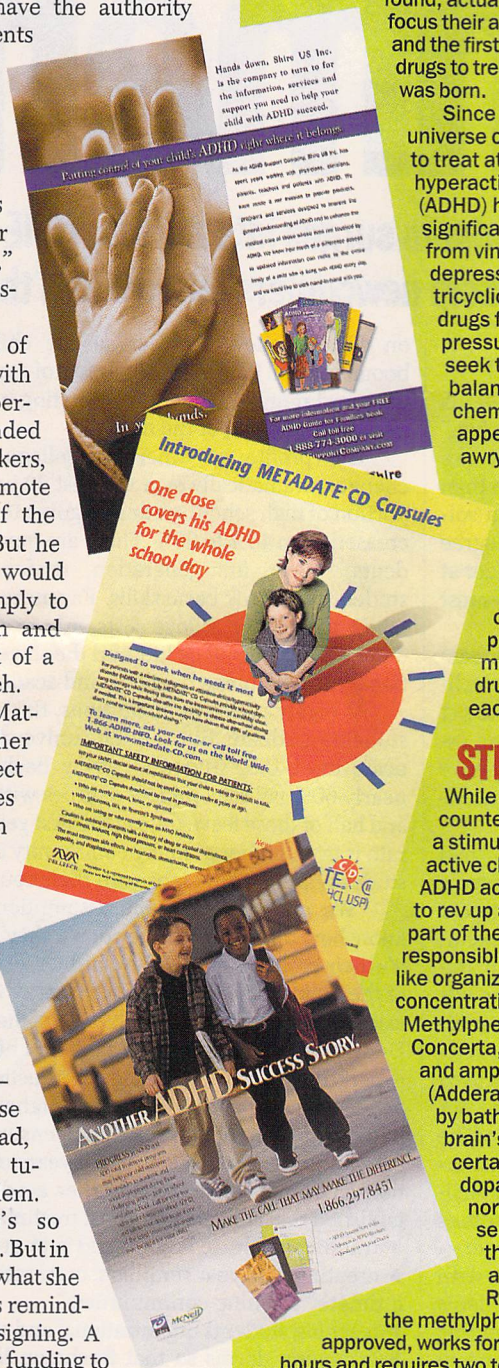
also handcuffed. Most of the ADHD ads are not within its jurisdiction because they neither name the drug nor describe it. (Exception: Celltech's ad for Metadate CD, which the FDA is reviewing.) And even if they were, says FDA official Nancy Ostrove, the agency doesn't have the authority "to treat advertisements for controlled substances any differently" from those for other drugs. As for the drug companies, they insist their ads "are within the letter and spirit of all laws," in the words of a spokesman for McNeil.

Clarke Ross, head of Children and Adults with Attention-Deficit/Hyperactivity Disorder, funded in part by the drugmakers, agrees that the ads promote "public awareness of the existence of ADHD." But he thinks many families would prefer advertisers simply to discuss the condition and suggest drugs as part of a multipronged approach.

Certainly Sheila Matthews (who uses her maiden name to protect her son's privacy) does not believe medication is the answer—or even in ADHD's validity. Two years ago, school officials said her son fit an ADHD profile and warned that "if I didn't medicate him, he would self-medicate later"—meaning he would use drugs illegally. Instead, speech and language tutoring solved the problem.

That's why she's so pleased by the new law. But in case she had forgotten what she was up against, she was reminded at last Thursday's signing. A researcher lobbying for funding to test his new ADHD treatment technique was also there—as well as a representative from Novartis, the maker of Ritalin.

—With reporting by Amanda Bower/New York



More Drugs to Treat Hyperactivity

Back in the 1930s, a physician in Providence, R.I., trying to figure out what caused delinquent behavior in boys stumbled upon a relatively easy way to calm the boys' rowdy tendencies. Giving them stimulants like amphetamines, Dr. Charles Bradley found, actually helped them focus their attention in school, and the first generation of drugs to treat hyperactivity was born.

Since then, the universe of medications to treat attention-deficit/hyperactivity disorder (ADHD) has broadened significantly, ranging from vintage antidepressants known as tricyclics to various drugs for high blood pressure. Both groups seek to restore the balance of brain chemicals that appears to have gone awry in those with ADHD. Doctors generally start with stimulants like Ritalin; if these fail, as happens in about one-fifth of all patients, they move on to other drugs. Here's how each category works:

STIMULANTS

While it seems counterintuitive to give a stimulant to a hyperactive child, those with ADHD actually need to rev up activity in the part of their brain responsible for functions like organization and concentration. Methylphenidates (Ritalin, Concerta, Metadate) and amphetamines (Adderall) will do that by bathing the brain's nerve cells in certain chemicals—dopamine, norepinephrine or serotonin—that promote nerve activity.

Ritalin, the first of the methylphenidates to be approved, works for three to four hours and requires two to three doses a day. The newest generation of drugs in this class does better: Novartis, Ritalin's maker, is waiting to hear whether the FDA will approve its new version, Ritalin LA, which has double the current drug's effective time. Concerta, available since last summer, is effective for 12 hours; Metadate, approved in 1999, lasts about eight hours. A Concerta capsule acts as a minipump, gradually pushing methylphenidate out through tiny, laser-drilled holes in its coating. With Metadate, about one-third of each tablet consists of drug-filled beads that dissolve immediately after swallowing; the other two-thirds contain longer-lived beads that leak their contents over the next four to eight hours.

The required dosage of amphetamines is about half that of methylphenidates, but amphetamines still carry the risk of becoming habit forming. Doctors are hesitant to give them to patients, particularly teens, with a history of substance abuse or addictive behavior. But stimulants are usually well tolerated. The most common side effects are insomnia and loss of appetite.

ANTIDEPRESSANTS

For the 20% of ADHD patients who don't respond to stimulants, doctors prescribe an older class of antidepressants known as tricyclic amines such as Wellbutrin.

These keep levels of serotonin and norepinephrine high but are only about 60% effective in reducing ADHD symptoms. Tricyclics have also been associated with more troubling side effects, including fatal heart attacks in those with a history of heart-rhythm disturbances.

BLOOD-PRESSURE DRUGS

Alpha-adrenergic agents, originally used to treat high blood pressure, have been effective in reducing ADHD symptoms in some children. They work primarily by keeping up levels of norepinephrine and are particularly effective in treating ADHD youngsters who also show signs of impulse or anxiety disorders.

In the coming months, pharmaceutical companies will be releasing even more variations on the Ritalin theme. Novartis has received the FDA's preliminary approval to market another, more refined form of methylphenidate that requires a smaller dosage than the current formulation. Unlike Ritalin LA, however, this drug is not a long-acting medication but addresses the concerns some parents have about giving too much medication to their young children. Eli Lilly, on the other hand, is taking a cue from the blood-pressure medications with a new product called Atomoxetine that boosts norepinephrine. The drug is still being tested, but results so far are promising. The upshot of all these developments will be to make ADHD treatments more customized and ultimately more effective.

—By Alice Park