

Writing May Be on Wall for Ritalin

By Kelly Patricia O'Meara

A lawsuit challenging the validity of the science behind mental illness and psychotropic drugs will have repercussions for drug makers as well as for the mental-health establishment.

Hardly a mention was made in the national media concerning the class-action lawsuit filed in May by the Dallas law firm of Waters and Kraus. It named the Novartis Pharmaceutical Co. (the maker of the drug Ritalin), the American Psychiatric Association (APA) and Children and Adults with Attention Deficit/Hyperactivity Disorder as defendants for conspiring, colluding and cooperating in promoting the diagnosis of attention-deficit disorder (ADD) and attention-deficit/hyperactivity disorder (ADHD).

Last week, however, a second lawsuit made a bang when even bigger guns were rolled out in California and New Jersey to take aim at an industry that has enjoyed a special relationship with the Clinton/Gore administration. Indeed it is a relationship which, based on numerous speeches by the vice president and his wife — who has been the president's White House mental-health guru — would continue if Al and Tipper Gore are allowed to make the White House their new residence on Inauguration Day.

And if the beating the tobacco industry took at the hands of these attorneys is any indication of what the defendants should anticipate, the psychiatric community, pharmaceutical industry and mental-health advocacy groups finally may be called upon to put their science where their mouths are. Putting aside the legal jargon, what appears to be in question is the ever-increasing influence of pharmaceutical companies over public and private mental-health organizations and, ultimately, whether that influence is responsible for the growing number of



Mental-health adviser: *Tipper Gore has served the administration as an advocate of mass medication.*

“mental illnesses” and the subsequent increased use of psychotropic drugs.

The class-action lawsuit that was filed last week in California and New Jersey names Novartis and the APA as defendants for conspiring to create a market for Ritalin by targeting millions of children and misdiagnosing them with ADD/ADHD for the strategic purpose of expanding use of the drug.

Both the APA and Novartis have a great deal at stake professionally and financially. To fight the claim that chil-

dren have been and still are being misdiagnosed with ADD/ADHD, the APA — the nation's leading psychiatric professional group — will be required to cough up its medical and scientific data to support the ADD/ADHD diagnosis. This may be difficult given the growing number of physicians, scientists and even psychiatrists who long have argued that the diagnosis of ADD/ADHD is not based in science — that the diagnosis is a fraud based on subjective assessments.

Furthermore, should the APA fail to provide the necessary scientific data, Novartis could be forced by the courts to return to consumers hundreds of millions, if not billions, of dollars made from the sale of Ritalin. Even more devastating to Novartis, should it be exposed that the diagnosis of ADD/ADHD is scientifically baseless, would be an end to the prescribing of the drug. This type of judgment could open the industry to additional lawsuits requiring proof of thousands of alleged mental illnesses. The reverberations through the pharmaceutical industry could be devastating.

Considering that Ritalin has been in use since the mid-1950s, one has to wonder how tens of millions of children and adults could be prescribed a highly addictive drug for more than 40 years without concrete scientific data to support the diagnosis. According to psychiatrist Loren Mosher, it isn't that tough. Mosher is the former chief of the Center for Studies for Schizophrenia at the National Institute of Mental Health (NIMH) and author of the definitive book *Community Mental Health, A Practical Guide*. Mosher explains that the Ritalin phenomenon comes down to a very simple theory: “If you tell a lie long enough, it becomes the truth.” Long aware of infiltration by the pharmaceutical companies into professional psychiatric organizations, Mosher resigned his membership in the APA with a stinging 1998 letter in which he wrote:

“The major reason for this action is my belief that I am actually resigning from the American Psychopharmacological Association. Luckily, the organization's true identity requires no change in the acronym. ... At this point in history, in my view, psychiatry has been almost completely bought out by the drug companies.”

According to Mosher, “The APA receives a huge amount of money from the pharmaceutical companies through grants, but the most obvious and obnoxious examples are the two meetings the APA has each year. At both, the drug houses basically lease 90 percent of the

exhibition space and spend huge sums in giveaway items. They have nearly completely squeezed out the little guys, and the symposiums that once were dedicated to scientific reports now have been replaced by the pharmaceutical-industry-sponsored speakers."

The National Alliance for the Mentally Ill (NAMI), explains Mosher, "gets the pharmaceutical money and then says they spend it on their 'anti-stigma' campaign. They say that mental illness is a brain disease. And it works well for the people who suffer from this to use their drugs. This is why NAMI is pushing for forced medication. It is an amazing selling job on the part of NAMI."

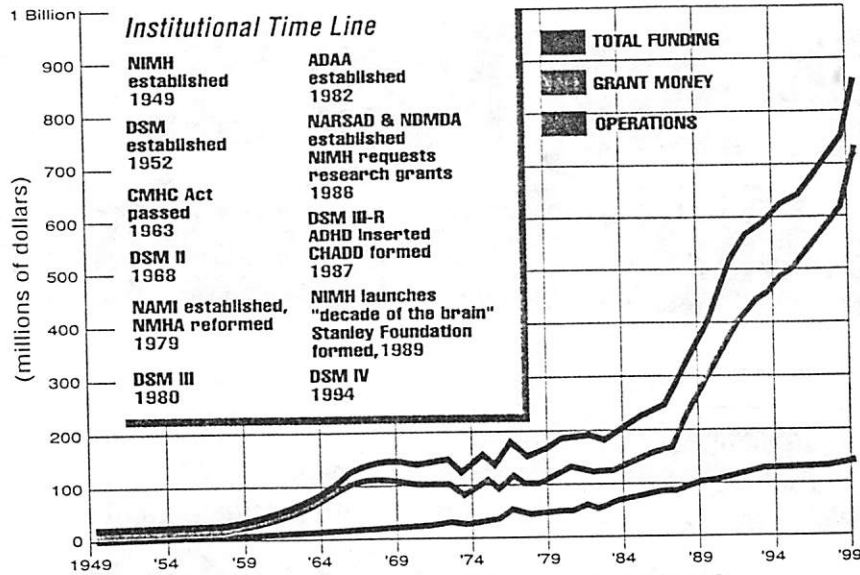
A nonprofit, grass-roots, self-help support and advocacy organization for people with severe mental illness, NAMI was featured in a November/December 1999 *Mother Jones* article, "An Influential Mental Health Non-profit Finds Its 'Grassroots' Watered by Pharmaceutical Millions," by Ken Silverstein. The article focused on the enormous amount of funding which NAMI receives from pharmaceutical companies, with Eli Lilly and Co. taking the lead by donating nearly \$3 million to NAMI between 1996 and 1999. In fact, according to Silverstein, NAMI took in a little more than \$11 million from 18 drug companies for that period. Nonetheless, NAMI, Eli Lilly and the others deny any conflict of interest.

While Eli Lilly, manufacturer of Prozac, admits making substantial contributions to NAMI and the National Mental Health Association (NMHA), it claims that for "proprietary reasons" it is unable to provide a list of specific contributions. According to Jeff Newton and Blair Austin, spokesmen for the company, "The key issue here is that these are unrestricted grants. The groups can use the money any way they want. Lilly's support of these initiatives presents no conflict of interest since they represent efforts to raise public awareness around issues that Lilly publicly supports."

According to Bob Carolla, director of Media Relations for NAMI, "We represent a constituency that uses their [pharmaceutical] products. Why shouldn't they give us money? They're making money off of our members and some of it has to go back into the community to help us get better mental-health programs to help people. Much of what we do has nothing to do with the pharmaceutical industry. We do not advocate or endorse any specific medications or products, but we also are not going to back off from saying that mil-

National Institute of Mental Health Funding

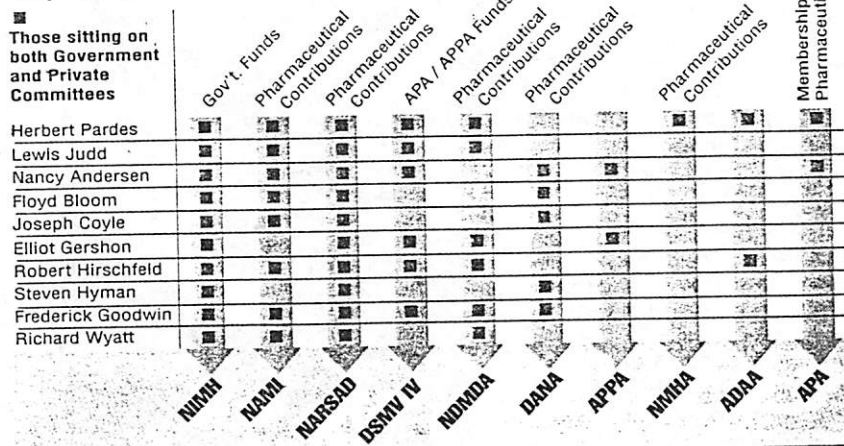
NIMH funding has skyrocketed with the establishment of patients-rights groups and foundations.



1949: Number of mental illnesses proved to be brain disorders: 0
1999: Number of mental illnesses proved to be brain disorders: 0

Who Funds Whom?

A sampling of NIMH researchers, and the groups and foundations they serve.



NIMH - National Institute of Mental Health
NAMI - National Alliance for the Mentally Ill
NARSAD - National Alliance for Research on Schizophrenia and Depression
DSM-IV - Diagnostic and Statistical Manual-IV
NDMDA - National Depressive and Manic-Depressive Association
DANA - DANA "Alliance for Brain Initiatives"
APPA - American Psychopathological Association
NMHA - National Mental Health Association
ADAA - Anxiety Disorders Associations of America
APA - American Psychiatric Association

lions of Americans lead productive lives because of the medications they are prescribed."

Meanwhile, NAMI has no problem stating that "mental illnesses are disorders of the brain." In fact, according to Carolla, NAMI "has been trying to educate people that mental illnesses are a result of brain disorders and they are treatable. Stigmas still exist and stigmas need to be overcome." Asked to

provide scientific data that mental illness is a disease of the brain, Carolla deferred to a higher authority explaining that "this [question] reminds me that one small interest group denies that mental illness even exists."

Carolla added, "Mental illnesses are biological brain disorders. Go read the dominant body of medical information out there. It is a function of biochem-

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istry. I encourage you and recommend you talk to the surgeon-general's office."

Carolla was referring to the Report on Mental Health released by the U.S. surgeon general in December 1999, which he says "stands as the national baseline." This enormous document goes into great detail about mental health in the United States. But it does not provide a single piece of scientific data supporting the claim that even one mental illness is caused by a brain disease. In fact, what it says is "the body of this report is a summary of an extensive review of the scientific literature, and of consultations with mental-health-care providers and consumers. Contributors guided by the Office of the Surgeon General examined more than 3,000 research articles and other materials...."

According to the report, "The review of research supports two main findings: 1) the efficacy of mental-health treatments is well documented, and 2) a range of treatments exists for most mental disorders."

Voilà! The review of research came up with findings about treatments, not with scientific causes of mental disorders. And there even appears to be some question about the validity of the treatments.

The surgeon general nonetheless places Ritalin in a category where the "efficacy of mental-health treatments is well-documented," when in Chapter 3 of his report he writes that "because the symptoms of ADHD respond well to treatment with stimulants," and because stimulants increase the availability of the neurotransmitter dopamine, the "dopamine hypothesis" has "gained a wide following."

The surgeon general may want to review the Drug Enforcement Administration's (DEA) 1995 report on methylphenidate, which makes clear that Ritalin has the same effect on children and adults with ADHD as it does upon those not diagnosed with ADHD. According to the report:

"There is a considerable body of literature on the short-term efficacy of stimulant pharmacotherapy on the symptoms of ADHD. From 60 to 90 percent of children have been judged as positive drug responders to methylphenidate medication. However, contrary to popular belief, stimulants like methylphenidate will affect normal children and adults in the same manner they affect ADHD children. Behavioral or attentional improvements with methylphenidate treatment therefore are not diagnostic criteria of ADHD."

NAMI, however, is not the only group apparently being misled by the surgeon general's report. Take, for instance, the Mental Health Early Intervention, Treatment, and Prevention Act (S2639), a broad piece of federal mental-health legislation sponsored by Sens. Pete Domenici, R-N.M., Ted Kennedy, D-Mass., and Paul Wellstone, D-Minn. According to one staffer familiar with the legislation, Domenici's staff took the lead in writing it. The first of Congress' "findings" states that "almost 3 percent of the adult population, or 5 million individuals in the United States, suffer from a severe and persistent mental illness." When asked where Domenici got these figures, the same source explained that "the numbers come from various federal agencies, various studies that have been conducted and the surgeon general's report. The senator takes into consid-

If the APA's data is invalidated, the Novartis Co. could be forced to return hundreds of millions, if not billions, of dollars made from selling Ritalin.

eration that there are those who argue there is no such thing as a medically diagnosable mental illness but, when someone like Dr. Steven Hyman [director of NIMH] shows a brain with schizophrenia and one without, then the senator takes it seriously. Hyman is well-respected."

While it appears that Hyman's "brain" slide show has wowed a great many people, the fact is that even Hyman has contradicted his own presentation. For instance, as Hyman explained in a Feb. 28, 1999, *New York Times Magazine* article, "indiscriminate use of MRI and PET scans ... as a high-tech form of phrenology ... are pretty but inconsequential pictures of the brain." While Domenici may place a great deal of trust in the "science" presented by doctors such as Hyman, he also has a more personal interest much closer to home: His wife served on NAMI's board for nearly three years. Domenici's office did not respond to inquiries about whether the senator

had received campaign contributions from pharmaceutical companies.

NAMI's Carolla openly admits that NAMI worked with the sponsors of the legislation, and one doesn't have to look too hard to see the similarities between the Senate bill and NAMI's proposed Omnibus Mental Illness Recovery Act, which Eli Lilly paid to print.

NAMI fully supports the Senate bill, which features such programs and expenditures as Section 581 in which \$75 million would be appropriated to fund an anti-stigma advertising campaign — which many argue is a promotion for the pharmaceutical industry and should not be funded with taxpayer dollars. In question also is why taxpayers should be burdened with funding an anti-stigma campaign which many believe was created by the mental-health community when it first began labeling individuals as defective.

Section 582 would provide \$50 million in training grants for teachers and emergency-services personnel to recognize (read: diagnose) symptoms of childhood and adolescent mental disorders. This would allow service personnel such as firefighters, police officers and teachers to make referrals for mental-health treatment — a difficult task given that each of these categories of personnel appears to have its hands full with jobs for which they already are trained.

Section 583 would provide another \$50 million for emergency mental-health centers within which mobile crisis-intervention teams would be established. This would allow for the designation of a central receiving point in the community for individuals who may be cited by, say, a firefighter, to be in need of emergency mental-health services. And this is just the beginning of the programs proposed under the Mental Health Early Intervention, Treatment, and Prevention Act, now pending in Congress.

Larry Sasich, a pharmacologist who handles Food and Drug Administration drug-safety issues for the Washington-based Public Citizen's Health Research Group, tells *Insight* that "conflicts of interest are kind of a fact of life in the scientific community. At some point groups like NAMI are going to have to pay the piper — they're going to have to answer for what they are promoting. But it's hard to tell how much influence the pharmaceutical companies have. It could be subtle or overt influence depending on what they want."

One thing that is certain, concludes Sasich: "The group that is paying the money wields the big stick." ●