DBSA-CA NEWS

Depression and Bipolar Support Alliance–California
(formerly California Depressive and Manic-Depressive Association)

Volume 13, No 4 Fall 2008

ARE OUR LEADING PEDIATRICIANS DRUG INDUSTRY SHILLS?

BY LAWRENCE DILLER

Most parents have never heard of him, but Joseph Biederman of Harvard may be the United States' most influential doctor when it comes to determining whether their children are normal or mentally ill.

In 1996, for example, Biederman suggested that drugs like Ritalin might serve 10 percent of American kids for Attention Deficit Hyperactivity Disorder. By 2004, one in nine 11-year-old boys was taking the drug. Biederman and his team also are more responsible than anyone for a child bipolar epidemic sweeping America (and no other country) that has 2-year-olds on three or four psychiatric drugs.

The science of children's psychiatric medications is so primitive and Biederman's influence so great that when he merely mentions a drug during a presentation, tens of thousands of children within a year or two will end up taking that drug, or combination of drugs. This happens in the absence of a drug trial of any kind - instead, the decision is based upon word of mouth among the 7,000 child psychiatrists in America.

That's why Iowa Sen. Charles Grassley's recent revelation that Biederman did not declare $1.6 miffion in drug company consulting fees is so important, scarey and tragic. If true, this scandal is yet one more stake in the heart of American academic medicine's credibility with frontline doctors like me - and more importantly, with the parents of the patients I deal with every day.

American medicine, with psychiatry the most culpable, has fallen back to a time more than 100 years ago when doctor credibility was tantamount to the promotion of patent medicine. Subsequent reforms severed ties between medical school doctors and the drug industry - and for decades there was a much more ethical balance between the industry and physicians.

Now once again, drug company money is corrupting medical practice and the maintenance of our country's health. In a market economy, both doctors and the companies are motivated by profit. However, doctors' Hippocratic oath and their personal/professional relationships with their patients attenuate the most crass aspects of a fee-for-service system.

In contrast, drug companies owe primary responsibility to their shareholders. Of course these companies must operate within legal business and Food and Drug Administration restraints, but the drive to push such rules to the limit is implicit in any business.

Such a strategy isn't always beneficial when our children's health is affected.

The Fortune 500 drug companies, by their sheer economic cloout, have become the single most doinant influence in our health carre system. The ambiguities of

*Continued on page 2 (**Pediatricians**)*

PEDIATRICIANS *(Cont'd from pg 1)*

children's mental health and illness make chld psychiatry the most vulberable branch of medicine open to such influence.

In this climate, drug company research money, professional medical education and direct advertisements to parents tilt familites and doctors to biologically brain-based solutions, rather tan nondrug (e.g., parenting and education) approaches.

That's why we're seeing famous (or infamous) Neewsweek cover boys like Max, a 10'year'old woh has taken 38 psychiatric medications in his short, unhappy life.

Research funding must be directed to the needs of patients and their doctors - not to the bottom line of stockholders. Drug companies can still make money, but it's ethically immoral when stockholder profits trump children's health needs (as in the cover-up of negative studies of antidepressants in children).

More money must be directed toward head-to-head competition between existing generics and the new products, and toward more studies comparing nondrug or combination approaches to drug-only interventions for children's problems.

Drag company funding of medical research is not going to end - nor should it entirely stop. Yet a new set of federal rules dictating the transparency and direction of such funding is desperately needed to redress a dangerously corrupt system. It's not enough to simply have doctors more explicitly report their incomes from drug companies, though it is a very useful first step.

I remember about six years ago when I read a major article by the Biederman team on the advantages of a non-Ritalin drug pathway for ADHD. On the same day, much to my dismay, I also heard him give a speech - for a Wall Street audience - promoting a new drug by Eli Lilly called Strattera.

Although Strattera turned out to be a bust both clinically and commercially for ADHD, I was still shaken that such a prominent researcher could be so brazen with his potential conflict of interest appearance.

The $1.6 million that Biedennan didn't declare is only a small fraction of the full amount of research funding that his clinic receives from nearly a dozen companies that pay for not only the cost of running studies but also the salaries of the doctors involved. Virtually all doctors who receive drug company money say they are not influenced, but every independent study examining the effects of such money says they are.

The leadership of Harvard's psychiatry department is strangely silent or even defends Biederman. These are good men with solid reputations both in drug and nondrug aspects of treatment. Yet they know that their psychiatry department would not exist were it not for drug company money - considering the withdrawal of federal research dollars over the past nine years and the meager reimbursements that psychiatrists receive for their services from insurance companies and Medi-Cal.

Seas. Grassley, a Republican, and Herbert Kohl, a Wisconsin Democrat, have introduced the Physician Payments Sunshine Act, which will require more vigorous reporting and enforcement on payments (anything more than $500) received by doctors from drug companies.

Continued on page 3 (*Pediatricians*)

JOIN DBSA-California TODAY!

Please fill out form and return to:

DBSA-California
16280 Whispering Spur
Riverside, CA 92504

___ I wish to support the Depression and Bipolar Support Alliance of California by becoming a member.

Individual $20.00 per year ___
Contribution for Annual Conference $30.00 ___
(This does not mean chapter membership)
Lifetime membership $100.00 ___
Additional Contributions Welcome

___ Our organization is willing to let DBSA-Cal use our group's name for fundraising.

Group's Name_____

_____ _____
Name date

_____
Address

_____ _____ _____
City, State, Zip

_____
Phone

_____
eMail

SPONSORSHIP

We are looking for sponsorship of our quarterly DBSA-Cal Newsletter.

Any person, business, or organization that would like to help, please call (951)780-3366 and leave a message.

Thank You

Cognition-Enhancing Drugs Common Among Academics

NEW YORK (Reuters Health) - A survey of individuals who read the journal Nature, a technical bioscience publication, reveals that roughly one in five use prescription drugs to improve their focus, concentration, or memory.

A total of 1,400 people from 60 countries responded to the online survey. The subjects were asked specifically about the use of three drugs: methyiphenidate (Ritalin), which is used to treat attention deficit hyperactivity disorder (ADHD), but is considered on college campuses as a "study aid"; modafinil (Provigil), which is prescribed for sleep disorders, but is used by some to fight general fatigue or jet lag; beta-blockers, cardiovascular drugs prescribed for heart failure and high blood pressure, which are also known for their anti-anxiety effect.

Brendan Maher, a feature and commentary editor with Nature, analyzed the results and found that among those "who choose to use," methylphenidate was the most popular agent: 62 percent of users reported taking it. Modafinil was taken by 44 percent of users and beta blockers by 15 percent. Thus, many of the subjects were using more than one drug

When asked about use of other drugs, many of the subjects reported taking Adderall, a drug prescnbed for ADHD containing a mixture of amphetamines. Other drugs used included centrophenoxine, piracetam, dextroamphetarnine sulfate, and alternative medicines, such as ginkgo and omega-3 fatty acids.

The use of cognition-enhancing drugs did not vary by age group, the report indicates. Maher said this may be surprising to some people since prior research has suggested increased usage in 18- to 25-years-olds.

Improving concentration was the main reason cited for using these drugs with enhancing focus on a specific task being a close second.

Usage patterns were evenly split between daily, weekly, monthly or no more than once a year. Unpleasant side effects, induding headache and jitteriness, among others, were reported by roughly half of the users. The emergence of side effects did not correlate with decreased frequency of use, however.

Four fifths of respondents believed that healthy adults should be permitted to take cognition-enhancing agents if they want to and 69 percent said they would risk mild adverse effects to take the drugs themselves.

Eighty-six percent of respondents said that children under 16 years should be restricted from using these drugs, yet one third of respondents said they would feel pressured to give their child these agents if other children were taking them.

In a related commentary, Dr. Barbara Sahakian and Dr. Sharon Morein-Zamir, UK researchers whose 2007 study of cognition-enhancing drug use prompted the current survey, caution that "although the appeal of pharmaceutical cognitive enhancers...is understandable, potential users, both healthy and diseased, must consider the pros and cons of their choices."

Sahakian and Morein-Zamir, neuroscientists with the University of Cambridge, add that "scientists, doctors, and policymakers should provide easy access to information about the advantages and dangers of using cognitive-enhancing drugs and set out clear guidelines for their future use."

Source: Nature
April 10, 2008

Lucrative $15 Billion Antidepressant Market

IntelGenx Announces Positive Results From First Pilot Pharmacokinetic Study on Anti-Depressant CPI-300

SAINT LAURENT, QUEBEC—(Marketwire - May 29, 2008) - IntelGenx Corp. today announced that the pilot clinical trial of the antidepressant CPI-300 shows strong positive results. The preliminary results of the fasted and fed studies show that CPI-300 is equivalent to the reference product. The product uses lntelGenx's proprietary Versatab oral delivery technology and will address the largest market within the company's current pipeline; the lucrative $15 billion antidepressant market. IntelGenx is on track with its development timeline and project commercialization by the second half of 2009.

Source: Marketwire Canada (English) - May 29, 2008

PEDIATRICIANS *(Cont'd from pg 2)*

But in addition, we need laws to have the federal government, along with the major academic research centers, coordinate and direct the use of drug company money in medical research. This is not pie-in-the sky wishing. Such reform was precisely what the doctors of 100 years ago accomplished in this country.

Source: Lawrence Diller, M.D., practices behavioral-developmental pediatrics in Walnut Creek and is on the clinical faculty of UCSF. He is the author of "The Last Normal Child" (Praeger, 2006). Contact us at ***insight@sfchronicle.com.***

This article appears on page G - 2 of the San Francisco Chronicle Sunday, July 13, 2008.

Study: Anti-psychotic drugs no better than placebo in treating aggression

BY BENEDICT CAREY
NEW YORK TiMES NEWS SERVICE

The drugs most widely used to manage aggressive outbursts in intellectually disabled people are no more effective than dummy pills for most patients and may be less so, researchers say.

The finding, being published today, sharply challenges standard medical practice in mental health clinics and nursing homes in the United States and around the world.

In recent years, many doctors have begun to use the so-called anti-psychotic drugs, which were developed to treat schizophrenia, as all-purpose tran-quilizers to settle threatening behavior — in children with attention-deficit problems, college students with depression, older people with Alzheimer's disease and intellectually handicapped people.

The new study tracked 8 adults with low IQs in community housing in England, Wales and Australia over more than a month of treatment. It found a 79 percent reduction in aggressive behavior among those taking placebo pills, compared with a reduction of 65 percent or less in those taking anti-psychotic drugs.

The researchers focused on two drugs, Risperdal by Janssen, and an older generic drug, Haldol, but said the findings almost certainly applied to all similar medications.

Experts said the findings were almost certain to inflame a continuing debate over the widening use of anti-psychotic drugs.

Patient advocates and some psychiatrists say the medications are overused.

Previous studies of the drugs' effect on aggressive outbursts have been mixed, with some showing little benefit and others a strong calming influence.

But the drugs have serious side effects, including rapid weight gain and tremors.

While it's unclear how much the study will alter prescribing habits, "the message to doctors should be, think twice about prescribing, go with lower doses and monitor side effects," said Johnny L. Matson a professor of psychology at Louisiana State University, co-author of an editorial with the study in the journal Lancet, adding: "Or just don't do it. We know that behavioral treatments can work very well with many patients."

Source: Riverside Press-Enterprise
January 4, 2008

Doctors say placebo use common

By Julie Steenhuysen

CHICAGO (Reuters) - Placebos are a surprisingly common prescription, according to a U.S. study in which nearly half of the doctors surveyed said they had doled out a dummy pill at some point.

Researchers at the University of Chicago said on Thursday the study raises ethical questions and suggests a need for greater recognition and understanding of placebo use.

"It illustrates that doctors believe expectation and belief have therapeutic potential," said Rachel Sherman, a medical student at the University of Chicago, whose study was published in the Journal of General Internal Medicine.

The idea behind placebos is that when patients think they are getting an effective treatment, they sometimes feel better, even though the pill has no proven benefit.

They are often used in clinical trials to compare the benefits of drugs, and many times patients taking placebos show some improvement. But few studies have shown how doctors use placebos in routine practice.

Sherman and Dr. John Hickner, a family medicine professor at the University of Chicago, sent surveys to 466 internists at three Chicago-area academic medical centers. About half, or 231, responded.

Of those, 45 percent said they had used a placebo during their clinical practice, a number that surprised the researchers. But 12 percent of those surveyed said placebos should never be used.

"1 think this shows that it strikes a chord among physicians. We may underestimate the body's natural healing potential," Sherman said in a telephone interview. "This shows that doctors may think that, too."

But Sherman said the practice brings up ethical issues, induding whether a doctor has an obligation to provide patients with informed consent.

Of respondents who reported using a placebo in clinical practice, 34 percent said they told the patients the substance was something that "may help and will not hurt."

About a third gave other information to patients including, "this may help you but I am not sure how it works."

Nineteen percent said it was a "medication," and 9 percent called it "a medicine with no specific effect." Only 4 percent of the doctors said, "it is a placebo."

Part of the reason doctors are not forthcoming about giving a placebo is that in order for it to work, patients need to believe it can help, Sherman said.

One way around this dilemma is to ask all new patients for their consent in advance. "The patient could say no. Then you avoid any of these ethical questions," Sherman said.

Source: Reuters
January 3, 2008

Experts troubled by at-home tests for bipolar

Many such products sold online with almost no government oversight

SAN DIEGO - Dr. John Kelsoe has spent his career trying to identify the biological roots of bipolar disorder. In December, he announced he had discovered several gene mutations closely tied to the disease, also known as manic depression.

Then Kelsoe, a prominent psychiatric geneticist at the University of California, San Diego, did something provocative for the buttoned-down world of academic medical research: He began selling bipolar genetic tests straight to the public over the Internet last month for $399.

His company, La Jolla-based Psynomics, joins a legion of startups racing to exploit the boom in research connecting genetic variations to a host of health conditions. More than 1,000 at-home gene tests have burst onto the market in the past few years.

The proliferation of these tests troubles many public health officials, medical ethicists and doctors. The tests receive almost no government oversight, even though many of them are being sold as tools for making serious medical decisions.

Health experts worry that many of these products are built on thin data and are preying on individuals' deepest anxieties.

"People are always rushing to the market on the basis of one or two studies," said Dr. Mum Khoury, director of the National Office of Public Health Genomics at the Centers for Disease Control and Prevention. "We have very little evidence that telling people their genetic information is going to make any difference."

Tests have become available claiming to help predict and diagnose everything from serious illnesses like cancer and Alzheimer's to athletic ability and a person's ideal diet. Psynomics' offering is one of the first psychiatric gene tests on the market

FIndings far from complete

Kelsoe, 52, acknowledges that bipolar disorder probably results from a combination of genetic factors and life experiences, and that the presence of these gene variations does not at all mean that someone will, in fact, develop the disease. He admits, too, that his findings about the genetic basis of the illness are far from complete.

But he said his test is a vital starting point toward moving away from the notoriously tricky practice of diagnosing bipolar disorder based purely on a person's behavior.

'The goal of this is to try and help doctors make an accurate diagnosis more quickly so the patient can be treated appropriately," Kelsoe said. "Anything is going to help, even if it just helps a little bit."

Bipolar sufferers experience intense The disease is often misdiagnosed as other forms of depression, which delays treatment and can result in the prescribing of antidepressants that make some patients' symptoms worse.

mail a plastic cup that they spit into, seal and send back to Psynomics. The company analyzes DNA in the saliva.

Psynomics will send patients' test results only to their doctors to avoid the risk of self-diagnosis.

The report that accompanies those results instructs doctors that a positive test means patients are two to three times more likely to have bipolar disorder. But the studies from which those figures come also show the gene variations themselves are rare even among those with bipolar.

The report also points out that for now, the test is valid only for whites of Northern European ancestry who show some behavioral symptoms and have at least one other bipolar family member.

Patients taking Psynomics' bipolar test may feel branded by a positive result, even if they are not ultimately diagnosed with the disorder, said Hank Greely, a professor of law and genetics with the Stanford Center for Biomedical Ethics. Or they may feel false hope from a negative result, despite the company's disclaimers.

Spur poor decisions?

Likewise, doctors have little training beyond what companies tell them when it comes to applying the test results. "They may make a foolish decision that backfires to put you on meds," Greely said. "Or they may make a decision that backfires not to put you on meds."

Unlike many tests for other conditions on the market, Psynomics does not claim its bipolar test can predict a person's risk of developing the disorder later in life. It is meant to be used as a purely diagnostic tool for patients already showing symptoms.

That is an important distinction that makes the Psynomics test more responsible than others that promise a glimpse into the genetic crystal ball, according to Dr. Greg Feero, head of genomic health care at the National Human Genome Research Institute.

"Now you're talking about an individual who has symptoms or signs that already put them in a very different risk category than someone who has no symptoms or signs," Feero said.

Among hundreds of families Kelsoe has studied, one of the gene variations in the Psynomics test showed up in 1 percent of those unaffected by the disorder versus 3 percent who are affected. The other variation appeared in 7 percent of those without bipolar compared to 15 percent who have the disease.

Many other genes interacting with a patient's environment contribute to the development of bipolar disorder, Kelsoe and other researchers believe, meaning no single genetic variation

*Continued on page 6 (***At-Home Tests)**

AT-HOME TESTS *(Cont'd from pg 5)*

ultimately causes the disease. Researchers in Kelsoe's lab are working to track down more genes.

"Why are we starting before it's finished? You've got to start somewhere," Kelsoe said. "Even if we knew everything about the genes, which we certainly don't, it's never going to be 100 percent predictive."

Psynomics has sold only a few tests so far but is projecting sales of 1,800 tests in 2008 and 30,000 in the next five years.

In coming months, at least two other startups led by genetic researchers are set to release their own psychiatric genetic tests. One test claims to predict the risk of developing schizophrenia. The other is designed to forecast the likelihood that some medications for major depression could heighten suicidal thoughts in patients.

The American Psychiatric Association has yet to create an official policy on genetic testing. A fact sheet issued by the Federal Trade Commission advises consumers to be wary of assertions made by at-home genetic testing companies.

The Food and Drug Administration does not evaluate the tests for accuracy, though a panel is working on a set of standards for the growing industry.

For now, worry persists that with the proliferation of tests, there is too little understanding of what to do with the results, or what they mean.

"We just don't know how people will use the information," said Dr. Jinger Hoop, a professor of psychiatric genetics and medical ethics at the Medical College of Wisconsin in Milwaukee. "We don't know whether it will be helpful to them in the long run."

Source: The Associated Press
March 23, 2008

Study Suggests Greater Risk of Suicide

December 1, 2007, NEW YORK, NY--People with a depression-prone subtype of bipolar disorder are at significanly greater risk of suicide attempts, new research suggest.

Resarchers from the New York State Psychiatric Institute and Columbia University studied 113 patients with a diagnosis of bipolar and examined whether their first reported episode was either manic/hypmanic or depressed. Their study found those in the depressed group were eight times more likely to have had a past suicide attempt. The manic/hypomanic patients had more alcoholism and psychosis, but a lower suicide risk.

The researchers said more study of these subtypes is needed.

The study, which appeared in the *Journal of Affective Disorder*s in Decembr, was called "Does first episode polarity predict risk for suicide attempt in bipolar disorder?"

Source: bp Magazine
Winter 2008

Caution Urged on BP Alternative Treatments

September 1, 2008, PITTSBURGH, PA--Although growing numbers of people with mood disorders are turnig to alternative and complementary medicines, a new study warns that those treatments aren't without riskes.

Pittsburgh researchers revewed the published scientific evidence of the benefits and risks of alternative treatments. Because so few studies of alternative treatments involving people with bipolar have been carried out, they had to look at studies involving major depressive disorder.

They reviewed research into omega-3 fatty acids, St. John's wort, acupuncture, and the dietary supplement SAMe.

While there is eveidence that St. John's wort may help treat mild to moderate depression , and that SAMe may be effective for depression, the researchers cautioned that both supplements have the potential to induce mania, and that St. John's wort can interact with a variety of medications.

The said people need to be informed of the possible risks of alternative treatments.

The study, which appeared in the *Journal of Affective Disorders*, was titled "Complementary and alternative medicine in the tratment of bipolar disorder -- a review of the evidence."

Source: bp Magazine
Fall 2008

Two Genes May Play a Key Role

August 17, 2008, WAHINGTON, DC -- Two genes that influence the activity of nerve cells in the brain may play a key role in a person's risk for bipolar disorder, an international team of scientists say.

The study involved looking at the genomes of more than 10,000 people, mostly from the United States and Britain. The researchers found those with biploar were more likely to have certain variants of the genes ANK3 and CACNAIC. Proteins made y the two genes help govern the flow of sodium and calcium ions into and out of neurons in the brain, influencing the activity of these nerve cells.

Nick Craddock of Britain's Cardiff University said the study provides a clear idea of the sorts of chemicals and mechanisms in the brain that are involved in bipolar disorder, and that in time could pave the way to new kinds of treatments.

The study, which appeared in the journal Nature Genetics, was titled "Collaborative genome-wide association analysis supports a role for ANK3 and CACNAIC in biploar disorder.

Source: bp Magazine
Winter 2008

Disease

July 16, 2008, MIAMI, FL -- People suffering from major depression are at an incresed risk for cardiovasculaar disease, but treating these people with medication can greatly reduce the risk, according to new findings by researchers at the University of Miami Miller School of Medicine.

The researchers focused on what's known as the stress-hemoconcentration, which is a blood chemistry work-up. The stress-hemoconcentration increses during psychological stress and is considered a risk factor for heart disease.

The study consisted of 146 outpatients with depression who were studied and compared to people without depression. Patients underwent an eight-week study in which they were given antidepressants.

People with depression who received antidepressants experienced an improvement in depression symptoms and had better stress-hemoconcentration Measurements, which researchers said could reduce their risk of cardiovascular disease.

The study, which was published in *PLoS ONE*, was titled "Elevated stress-hemoconcentration in major depression is normalized by antidepressant treatment: Secondary analysis from a randomized, double-blind chlinical trial and relevance to cardiovascular disease risk."

Source: bp Magazine
Fall 2008

Clip and Keep!

Educational Resources

American Psychiatric Association
202 / 682-6220 • www.psych.org
American Psychological Association
800 / 374-2721 • www.apa.org
Advocacy Center
800 / 342-0823 • www.advocacycenter.com
Child & Adolescent Bipolar Foundation
847 / 256-8525 • www.bpkids.org
DBSA-California
(909) 780-3366
National Alliance for the Mentally Ill (NAMI)
800/ 950-6264 • www.nami.org
National Association for the Dually Diagnosed
800/ 331-5362
National Depression and Bipolar Support Alliance
800 / 826-3632 • DBSAlliance.org
National Family Caregivers Association
301 / 942-6430
National Foundation for Depressive Illnesses
800 / 248-4344
National Institute of Mental Health
800 / 421-4211 • www.nimh.nih.gov
Panic Disorder Line:
800 / 64PANIC (647-2642)
Anxiety Disorder Line:
888 / 826-9438
National Mental Health Association
800 / 989-6642 • www.nmha.org
Confidential depression screening:
www.depression-screening.org

Medi-Cal Mental Health Ombudsman's Office
1-800-896-4042
Help with Medi-Cal mental health services.

Health Rights Hotline
1-888-354-4474 TDD 916-551-2180
Local calls 916-551-2100 Fax 916-551-2158
http://www/hrh.org
Tells consumers in El Dorado, Placer, Sacramento and Yolo counties about their health care rights, and answers questions about health care coverage and managed care. HRH also has advocacy materials and referrals to other resources. HRH can help with HMOs, PPOs, Medicare, Medi-Cal, and CHAMPUS.

ADA Home Page — USDOJ
800-514-0301 800-514-0383 (TDD)
http://www.usdoj.gov/crt/ada/adahom1.htm
ADA technical assistance, information line, enforcement, settlement information, regulations, mediation, and more.

Rapid Cycling Has a Complex Clinical Course: Study

July 4, 2008 WASHINGTON, DC -- People with bipolar disorder who experience rapid mood switching have a complex clinical course, characterized by earlier onset, high rates of coexisting anxiety, and sensitivity to antidepressants, a study confirms.

Researchers from Howard Universitry and Johns Hopkins University found that among people with rapid cycling bipolar, the age of onset was earlier (age 18 versus 21 on average), they were nearly twice as likely to have coexisting anxiety, they were twice as likely to have violent behaior, they were more likely to be suicidal, and they were moare likely to have a substance abuse disorder.

The rapid cycling grtoup was also more likely to be hypersensitive to antidepressants.

The researchers said their findings support a clinical differentiation of bipolar disorder into subtypes.

The study, which appeared in an online version of the journal Bipolar Disorders ahead of print, was titled "Rapid switching of mood in families with familiral bipolar disorder."

Source: bp Magazine
Fall 2008

DBSA–California
16280 Whispering Spur
Riverside, CA 92504