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## **Non-Profit Advocacy Groups - Part IV Tracking the American Epidemic of Mental Illness**

*By Evelyn Pringle*

As a main component of the Psychopharmaceutical Industrial Complex, the so-called "patient advocacy" organizations have become the leading force behind the American epidemic of mental illness over the past two decades.

Drug makers, and their foundations, funnel millions of dollars to these non-profits every year. In return, the leaders recruit their members as foot soldiers to carry out the latest marketing campaigns and to provide a fire-wall so that no money trail can be tracked back to the drug companies.

### **Gigantic Pyramid**

The psychiatric front groups form a gigantic pyramid and once pharmaceutical money enters the system through a major organization, it gets channeled into a huge spider-web that weaves through many groups, making it nearly impossible to keep track of where it came from or where it all went. Often, when the grant reports of the drug companies list a large donation to one organization, the annual reports of the other groups will show smaller gifts from that same organization.

The "charity" groups are exempt from income tax and the "contributions" funneled through them are tax deductible. The money is used for disease mongering campaigns to both market disorders and pressure public health care programs and private insurers to pay for expensive treatments.

"Presenting themselves as patient advocacy groups is highly disingenuous not only to their membership, many of which may have a sincere desire to help a loved one or a family member with mental problems, but to legislators, the press and the American public -- for they have consistently lobbied for legislation that benefits the mental health and pharmaceutical industries which fund them, and not patients they claim to represent," according to Citizens Commission on Human Rights International, a mental health watchdog group.

In a June 2, 2010, commentary titled, "Psychiatric Fads and Overdiagnosis," on the Psychology Today website, Dr Allen Frances points out that it "is too bad that there is no advocacy group for normality that could effectively push back against all the forces aligned to expand the reach of mental disorders."

The leaders of the supposedly "non-profits" earn outrageously high salaries, along with excellent benefit packages, while many of the patients they claim to represent are encouraged to seek federal disability payments of under \$700 a month, and apply for public housing, food stamps, and Medicaid, to make ends meet. The top officials will often move from a leadership role in one organization to a higher position in another.

The drug makers rely on the front groups to do their bidding any time profits are threatened. For instance, if the FDA is considering adding a black box warning about a deadly side effect to a drug's label, which may result in a drop in sales, representatives of front groups will show up at the FDA advisory panel hearings to testify against adding the warning.

They will also lobby FDA panels whenever there is a chance to increase profits, such as enlarging the drug customer base. In June 2009, the Psychopharmacologic Drugs Advisory Committee was set to meet to evaluate AstraZeneca's Seroquel, Pfizer's Geodon and Eli Lilly's Zyprexa for use with 13 to 17 year-olds diagnosed with schizophrenia, and 10 to 17 year-olds diagnosed with pediatric bipolar disorder.

On June 8, 2009, nine front groups issued a joint statement urging the panel to vote to approve all three drugs for kids. The groups signing the letter included the American Academy of Child and Adolescent Psychiatry, American Foundation for Suicide Prevention, American Psychiatric Association, Child and Adolescent Bipolar Foundation, Children and Adults with Attention-Deficit/Hyperactivity Disorder, Families for Depression Awareness, Mental Health America, National Alliance on Mental Illness, and the National Council for Community Behavioral Healthcare.

"As advocates for people living with mental illnesses, we strongly urge the FDA to carefully consider the importance of viable treatment options for bipolar disorder and schizophrenia in pediatric and adolescent populations," they wrote. "Access to safe and effective treatments, including more information about all treatment options, is crucial to treating these serious and complex conditions in children and adolescents."

In an obvious attempt to downplay the serious side effects of the antipsychotics, the groups stated: "Other treatments for grave

childhood illnesses such as cancer can cause hair loss, nausea, compromised immune systems and even death. However, few people question the necessity of these aggressive forms of treatment."

"Like cancer," they wrote, "aggressive treatment may be needed for some patients with bipolar disorder and schizophrenia, diseases with a higher risk of death than some forms of cancer."

The National Council for Community Behavioral Healthcare only recently began showing up in public pharma campaigns with the other front groups. Last year it was listed as a supporter of one of the most evil customer recruitment schemes ever devised, targeting the roughly four million pregnant women who give birth in the US each year, through passage of federal legislation known as the "Mothers Act."

On its website, the Council is described as "a non-profit association representing 1,300 mental health and addictions treatment and rehabilitation organizations." But a review of the few grant reports available on drug companies found this non-profit received over a half a million dollars since 2008, from Eli Lilly and Wyeth alone.

Lilly's grant reports shows a \$440,000 donation in 2008, and another \$25,000 grant in 2009. The Council also received \$20,000 in 2008, and \$10,000 in 2009, from Wyeth (now owned by Pfizer). For the first quarter of 2010, Lilly's lists two grants to the Council totaling \$90,000.

The front groups all have "experts" serving on advisory or scientific boards and committees from major universities and government agencies, who have financial relationships with drug makers of one kind or another. Some organizations even have drug company officials, often from marketing and sales departments, sitting on boards and committees. Many of the same people will serve in multiple groups within the pyramid.

For example, Dr Herbert Pardes, a former director of the NIMH, is president of the scientific board of the National Alliance for Research on Schizophrenia and Depression (NARSAD). He is also a past president of the American Psychiatric Association, and served as chairman of the APA's Council on Research for several years. A bio on the internet says he is a regular advisor to the National Alliance for the Mentally Ill (NAMI), the Anxiety Disorders Association of American, and Mental Health America. He has also served on the board of TeenScreen and is a charter associate member of the Depression and Bipolar Support Alliance.

### **Collapse of the Pyramid?**

For several years, with Iowa's Republican Senator, Charles Grassley, leading the charge, the US Senate Finance Committee has been investigating pharmaceutical industry funding, as it relates to marketing practices, involving Continuing Medical Education, consulting arrangements, publications in medical journals, the non-profit professional and patient advocacy organizations, and the conflicts of interest among academics who receive federal funding from the National Institutes of Health through research grants to major universities.

The Committee oversees spending in public health care programs, such as Medicaid and Medicare, for coverage of more than 100 million Americans, including mental health treatment and prescription drugs.

The "drug industry's most powerful means of boosting the bottom line is funding research, which allows companies to control, or at least influence, a great deal of what gets published in the medical journals, effectively turning supposedly objective science into a marketing tool," Shannon Brownlee explained in an April, 2004, Washington Monthly report titled, "Doctors Without Borders."

"By penetrating the wall that once existed around academic researchers," she says, "drug companies have gained access to the "thought leaders" in medicine, the big names whose good opinion of an idea or a product carries enormous weight with other physicians."

"Companies target academic KOLs, or Key Opinion Leaders, in the lexicon of marketing, and woo them with invitations to sit on scientific advisory committees, or to serve as members of speakers' bureaus, which offer hefty fees for lending their prestige to a company and touting its products at scientific meetings and continuing medical education conferences," she reports.

Grassley's investigations at major universities turned up more conflicted academics in the field of psychiatry than in any other specialty. His chief investigator, Paul Thacker, developed a system where he would request conflict-of-interest records on psychiatrists from their universities and simultaneously ask drug companies to provide reports on what they paid the same researchers.

Some of the biggest names in the field appear on the list of psychiatrists who failed to disclose all their financial benefits from drug companies, which thus far includes three from Harvard, Joseph Biederman, Thomas Spencer and Timothy Wilens; Charles Nemeroff and Zachery Stowe from Emory; Melissa DelBello at the University of Cincinnati; Alan Schatzberg, outgoing president of the American Psychiatric Association, and chair of psychiatry at Stanford; Martin Keller, a former chair of psychiatry at Brown; Karen Wagner and Augustus John Rush from the University of Texas; and Fredrick

Goodwin, of George Washington University, and also the host of a radio show called "Infinite Minds," that was broadcast for years by National Public Radio.

All of the above "KOLs" have served as officials, or on boards and committees, of major front groups, and many have received awards, consulting and speakers fees, and research funding from various organizations.

### **Ensuing Outrage**

The revelation that millions of dollars have been flowing from drug makers to academics in psychiatry, undetected for a decade, has drawn outrage and demands for more accountability in the entire field.

"Financial transparency and full disclosure is not just an advocacy position anymore," says anti-drugging proponent, Vince Boehm. "This is rapidly becoming the order of the day."

"While the efforts of advocates were crucial in precipitating this amazing shift in public policy," he says, "our efforts were unwittingly helped by the massive greed of our opponents and the public furor that ensued."

"Events such as the Biederman scandal at Harvard and other equally disgusting problems of the same proportions have provoked public outrage," he points out.

Back on June 18, 2008, Dr Bruce Levine, author of, "Surviving America's Depression Epidemic," issued a warning in an Alternet commentary. "If those physicians who are not drug-company shills want to save their profession they might want to start taking aggressive actions against their colleagues who are on the take," he said.

"Perhaps it will help motivate clean physicians to be reminded that history shows that *any* institution -- no matter how large and powerful -- can arrogantly cross those lines leading to its demise," he advised.

On the Health Care Renewal website, Dr Bernard Carroll, former head of Duke's psychiatry department, says the leaders of the major professional and scientific organizations, like the American Psychiatric Association, the American College of Psychiatrists, the American College of Neuropsychopharmacology, and the Society of Biological Psychiatry, may not be stepping up to the plate publicly because "perhaps they are confounded by the awkward fact" that some of the exposed individuals "are current and past presidents of these very organizations."

They may also be confounded by the "awkward fact," that all the medical journals, textbooks and other literature put out by the so-called "professional" groups in the field of psychiatry are filled with ghostwritten infomercials, fraudulently crediting the skills on Grassley's list as authors, with major universities following their names, and nothing short of a mass book burning event will erase all the false advertising.

About a year ago, Grassley asked eight leading medical journals to describe their policies and practices regarding ghostwriting as part of a "broader effort to establish transparency with regard to financial relationships between the pharmaceutical industry and medical professionals," according to his July 2, 2009 press release.

In a June 16, 2010, letter to the editor of the Miami Herald, Dr John Nardo, a former faculty member in Emory's Department of Psychiatry, alluded to this problem while complaining about the fact that the University of Miami has "hired a chairman for the Department of Psychiatry, Dr. Charles Nemeroff, who has become the poster child for what's wrong with academic medicine in our country."

"Nemeroff was relieved of his chairmanship at Emory University in Atlanta for failing to disclose conflicts of interest in his publications and presentations," he said. "That means that he was a well-paid frontman for a number of drug manufacturers."

"Now it has been revealed that many of his articles were ghost-written by the drug companies and that he recommended a drug, Paxil, as safe for pregnant women when, in fact, it can cause congenital heart defects in newborns," Nardo wrote.

"One has to wonder what the people at UM are thinking?" he said. "Or if they're thinking at all?"

Nardo's letter is related to the latest scandal, in the seemingly never-ending Charles Nemeroff saga, which now involves the Director of the National Institute of Mental Health, Thomas Insel, who apparently worked behind the scenes to help Nemeroff get hired at the University of Miami, after he was kicked off the chair of psychiatry thrown at Emory, according to a June 6, 2010, article by Paul Basken in the "Chronicle of Higher Education."

Bernard Carroll, who was Nemeroff's boss for over 6 years while Nemeroff was a professor at Duke, says Nemeroff probably called in some markers. Because back in 1994, Nemeroff found Insel a position at Emory when Insel was facing nonrenewal of a research job at NIMH. And, in addition to being Insel's boss at Emory, Nemeroff also lobbied for Insel's appointment as NIMH director, and soon after Insel

moved to the NIMH, he appointed Nemeroff as an advisor, Carroll says.

In a November 5, 2009, press release, UM announced Nemeroff's hiring and described him as "one of the world's leading experts in the field of psychiatry."

Although not a peep was said about his fall from grace or the problems Nemeroff caused at Emory, the release stated: "He moved to Emory in 1991 as chairman of psychiatry. There he took an average department to become one of the top ten in the country."

On January 4, 2010, Ed Silverman posted a Pharmalot blog under the title, "Charles Nemeroff and the House That Glaxo Built," with a link to a December 30, 2009, headline for a story by BlockShopper, in South Florida, that read: "Psychiatrist spends \$1.91M on Miami 6BD."

"Dr. Charles B. Nemeroff and Gayle Nemeroff bought a six-bedroom, seven-bath home at 1780 Espanola Dr. in Miami from David and Carolyn Shulevitz for \$1.91 million on Dec. 4, " BlockShopper reported.

In addition to pointing out that Nemeroff had taken a new job at UM, Silverman wrote, "the new home appears big enough to house plenty of consulting materials."

The next day, he informed readers that the first house that Glaxo built for Nemeroff in Atlanta was up for sale at a price of \$1.25 million. "This one sports just five bedrooms, but still plenty of room for storing consulting materials," he wrote.

The Emory investigation found Nemeroff was paid more than \$960,000 by Glaxo, from 2000 through 2006, but he listed less than \$35,000 on disclosure forms. All totaled, he had earnings of \$2.8 million from drug companies between 2000 and 2007, but failed to disclose at least \$1.2 million, according to Grassley's reports.

The real outrage toward Insel stems from the reporting that Pascal Goldschmidt, dean of the UM's medical school, told Baskin that Insel guaranteed him Nemeroff would be allowed to apply for NIH research grants, even though Emory had suspended Nemeroff's work on an NIH grant, and in December 2008, placed a 2-year ban on Nemeroff applying for NIH funding. Goldschmidt claimed Emory's ban "was an immediate reaction to the political pressure that the university was under."

Further fanning the flames, was the Chronicle's revelations that

Nemeroff is serving on the NIH expert panels that help decide "which grant applications win federal financing," at a time when there is still an ongoing investigation into the NIH's lack of oversight of Emory and conflicts of interest involving Nemeroff, by the Department of Health and Human Services Office of Inspector General.

After reading Baskin's article, Grassley fired off a letter to Daniel Levinson, the Inspector General, on June 7, 2010. "I was extremely disturbed to read a story today in *The Chronicle of Higher Education*," he told the IG.

"For almost a year," he wrote, "Dr. Charles Nemeroff has been under investigation by your office for failing to fully disclose his conflicts of interest regarding his grants from the National Institute of Mental Health (NIMH)."

"During this same time, *The Chronicle of Higher Education* reports that the Director of the NIMH was assisting Dr. Nemeroff in obtaining a new job and made assurances that Dr. Nemeroff would be able to apply for new NIMH grants," he said. "I ask that you look into this matter and proceed as you deem appropriate."

On June 7, 2010, Grassley sent a letter to UM president, Donna Shalala, basically stating the same thing except he told her: "I was also troubled by Dr. Goldschmidt's comments that a ban against Dr. Nemeroff from receiving NIH grants was 'an immediate reaction to the political pressure that the university was under.'"

"President Shalala," he wrote, "I hope that you would agree--contrary to Dr. Goldschmidt's views that disciplining researchers for failing to disclose conflicts of interest is merely a political issue--that enforcing federal conflict of interest policy involves ethical and legal issues that ensure taxpayer trust."

In response to the letter, Grassley asked her to provide "all emails and communications by Dr. Goldschmidt," regarding Nemeroff's conflicts of interest and Nemeroff's work and/or grants with the NIH, and "all emails and communications by Dr. Nemeroff," regarding the same, along with all conflict of interest forms filed by Nemeroff with UM.

## **Money Laundering Operation**

Dr Daniel Carlat, author of the Carlat Psychiatry Blog, and the new book, "Unhinged: the Trouble With Psychiatry," explains that "much of the continuing medical education (CME) industry in the United States is a legalized money laundering operation," in a June 10, 2008 blog.

"Rather than paying doctors directly to give accredited CME courses (which is illegal), drug companies pay third party companies to create the courses," he says. "The checks are actually written by the education company, but the ultimate source is clearly the sponsoring pharmaceutical company."

The Harvard scandal represents the "perfect storm" of the CME industry money laundering operation, Carlat reported on his blog.

It's clear that "the majority of money received by these doctors did not come directly from drug companies, but indirectly from various third party companies," he says. "And this is likely the key to the mystery of why the doctors assumed they could ethically hide these payments."

After going through the list of payments posted in the Congressional Record, Carlat found it appeared that "the vast majority of the money eventually reported by the Harvard Trio, a combined \$4.2 million over 7 years, was drug company money that was laundered and processed to seem like it wasn't drug company money."

"The most glaring example," he says, "comes from Dr. Wilens disclosures."

Grassley posted slightly more than a third of Wilens' payments (\$612,303 out of a total of \$1.6 million). Only \$69,915 of this (11%) came directly from drug companies. Most of the money (\$542,388) came from various third party companies, many, possibly all of which, are CME companies, Carlat reports.

"The biggest tool the industry has for off-label promotion is continuing education," says Adriane Fugh-Berman, an associate professor at Georgetown University Medical Center, involved with a program called PharmedOut, created to educate doctors about the prescribing influences of big drug companies, in the Star-Ledger on June 6, 2010.

"Physicians have freedom of speech and aren't under the same constraints as industry employees," she explained.

When drugs are prescribed for off-label or unnecessary uses, public health care programs not only have to pay for the drugs, they must also pay the prescribing doctors' fees and the cost of medical care for any injuries caused by the drugs.

Government spending tied to psychiatric drugs has gone through the roof in the past two decades due to the bilking of public programs.

And no doubt as a result, pharma CEOs are earning over the top pay packages. In 2008, the head of J&J pulled in \$29.1 million, Abbott Labs' CEO took home \$28.3 million, the top dog at Bristol-Myers earned over \$23 million, Lilly's CEO pulled down close to \$13 million, Pfizer's took home over \$15.5 million, Wyeth's CEO earned nearly \$26 million, and Forest Labs' top official was paid more than \$6.5 million, according to the AFL-CIO's "Executive Pay Watch" website.

### **American Psychiatric Association**

Early on in his investigation, Grassley asked the "American Psychiatric Association," for an accounting of money received from drug companies and foundations created by drug companies. In 2006, the industry accounted for about 30% of the Association's \$62.5 million in financing, or about \$18.75 million, according to the New York Times.

The 38,000 member APA describes itself as "a national medical specialty society whose physician members specialize in the diagnosis, treatment, prevention and research of mental illnesses."

The outgoing president of the APA is Alan Schatzberg, the same guy whose name appears on the Grassley list.

The "American Psychiatric Foundation," is the charitable and public educational arm of the APA, according to its website. In 2009, the Foundation's 15 member board of directors included four Vice Presidents from the drug companies Pfizer, Eli Lilly, and J&J's Janssen Pharmaceutica division.

On its website, the Foundation identifies drug companies that donate but does not give the exact amount. For example, AstraZeneca, Bristol-Myers, Lilly, Forest, Janssen, and Wyeth are listed as giving "\$40,000 and above." However, the few grant reports publicly available show drug companies may be giving more than ten times that amount. Lilly donated \$450,000 to the Foundation in 2007, in addition to the \$400,000 given to the American Psychiatric Association.

The Foundation also received one grant from Lilly for \$241,915 in 2009, and another \$20,000 donation to fund the Foundation's Newsletter. The Foundation received \$102,961 from Pfizer, and \$205,400 from Wyeth, in 2009, as well.

In the first quarter of 2010, the Foundation received grants from Lilly of \$36,000, \$10,000 and \$18,000. Pfizer gave the Foundation \$20,000 in the first quarter of 2010.

Pfizer's 2008 grant report shows donations of more than \$700,000 to the American Psychiatric Association. Lilly gave the APA grants totaling more than \$600,000 in both the first and second quarter of 2008. Wyeth donated \$43,831 in 2008.

Lilly's 2009 report shows the APA received four grants of \$154,575, \$142,575, \$142,575, and \$154,575. Pfizer gave the group \$250,000 in 2009.

The American Psychiatric Institute for Research and Education (APIRE), is another philanthropic arm of the APA, established in 1998 "to establish the leadership role of the APA in contributing to the scientific base of psychiatric practice and policy," with a stated mission to "improve the quality of psychiatric care through research, education, health policy analysis, and dissemination."

For the March 6, 2010, paper, "Pharmaceutical Philanthropic Shell Games," in *Psychiatric Times*, Lisa Cosgrove, PhD and Harold J. Bursztajn, MD, investigated the financial relationships of the APIRE board members with pharmaceutical companies that manufacture psychiatric drugs and found 9 of the 16 board members have industry ties.

"The fact that over half of APIRE's board has financial ties to industry is problematic, and it is noteworthy that this percentage is a highly conservative estimate," they wrote.

"Current disclosure policies do not require reporting of pooled industry monies (eg, when companies give large sums of money to academic departments, units, hospitals, and medical schools)--even when direct benefit, such as salary, may be derived from pooled funds," they point out.

In addition, one board member who reported "no disclosure" in an APA publication "was found to be on the speakers' bureau of multiple pharmaceutical companies," they note.

The APA is currently revising psychiatry's billing bible, the DSM-V. "Approximately 68% of the members of the *DSM-V* task force reported having industry ties, which represents a relative increase of 20% over the proportion of *DSM-IV* task force members with such ties," Cosgrove and Bursztajn report.

"Also, of the 137 *DSM-V* panel members who have posted disclosure statements, 77 (56%) have reported having industry ties, such as holding stock in pharmaceutical companies, serving as consultants to industry, or serving on company boards--no improvement over the

56% of *DSM-IV* members who were found to have such industry relationships," they point out.

The APA also issues "Clinical Practice Guidelines," with recommendations for the use of specific drugs for mental disorders. "Ninety percent of the authors of 3 major clinical practice guidelines in psychiatry had financial ties to companies that manufacture drugs explicitly or implicitly identified in the guidelines as recommended therapies for the respective mental illnesses," according Cosgrove and Bursztain.

They also found the corporate advisory council of the Foundation "is made up of pharmaceutical companies that contribute significant funding to APF and that manufacture medications recommended in the APA's CPG."

On June 11, 2010, the Wall Street Journal reported that the APA "has seen a \$7.5 million decrease in pharmaceutical industry dollars over the past year a more than 10% cut in revenue, which funds its research and education activities."

"The biggest changes at the APA have come at its money making annual meeting," the Journal said. "Over the past three years it has been phasing out industry sponsored symposia dinners and talks." This translated to a loss of \$1.8 million to \$1.9 million in industry funding between 2008 and 2009, an APA official told the Journal.

However, according to Martha Rosenberg's coverage of the group's annual meeting in a May 31, 2010, Scoop article, although 200 protestors were chanting "no drugging kids for money," and "no conflicts of interest," at the convention hall, "polarizing figures" were still present at this year's event.

For instance, she writes: "Sitting next to outgoing APA president Alan F. Schatzberg, MD, even as protestors chanted outside, was Charles Nemeroff, MD, former psychiatry chairman at Emory University who was investigated by Congress."

"And a paper presented about attention deficit hyperactivity disorder (ADHD) was co-written by Harvard's Joseph Biederman, MD, also investigated by Congress for pharma financial links and considered the father of the pediatric bipolar disorder craze," she reports.

"Nemeroff was signing the Textbook of Psychopharmacology which he co-edited with Schatzberg, also investigated by Congress. Schatzberg, psychiatry chairman at Stanford, consults to seven drug companies, owns stock and patents with others and is on Sanofi-Aventis' Speakers Bureau according to the meeting's Daily Bulletin,"

she wrote.

### **National Alliance on Mental Illness**

Last year, the National Alliance on Mental Illness became the first patient advocacy group to come under investigation by Grassley's Committee. In a letter to Michael Fitzpatrick, Executive Director of NAMI, in April 2009, Grassley asked for "an accounting of industry funding that pharmaceutical companies or foundations established by these companies have provided," to NAMI since January 2005.

"Based upon reporting in the New York Times," Grassley said, "I have come to understand that money from the pharmaceutical industry shapes the practices of non-profit organizations which purport to be independent in their viewpoints and actions."

"Specifically, it is alleged that pharmaceutical companies give money to non-profits in an attempt to garner favor in ways that increase sales of their products," he explained.

The disclosures provided to Grassley revealed that the National NAMI group receives nearly two-thirds of its funding from the pharmaceutical industry. Between 2006 and 2008, drug companies, and their foundations, gave the group almost \$23 million.

After receiving Grassley's letter, NAMI's executive director sent out an email to many NAMI supporters and stated in part: "NAMI does not engage in product promotion, endorsement, licensure or certification of any product, service or program owned by a corporate sponsor."

However, Philip Dawdy pointed out the falsity of that claim on his Furious Seasons website. "Fitzpatrick has certainly engaged in product pimping for J&J/Janssen," he wrote in his daily blog. To substantiate the "pimping" charge, Dawdy provided a link to a blog he wrote on December 21, 2006, in response to a J&J press release put out to promote its Risperdal's me-too drug, Invega, with Fitzpatrick praising the drug using his official title of "Executive Director, National Alliance on Mental Illness."

"New and efficacious treatment options, like INVEGA, provide significant opportunities for more people with schizophrenia to manage their disease as they work with their treatment teams to live more fulfilling and productive lives," Fitzpatrick stated in the press release.

In her book, *Side Effects*, Alison Bass tells a story of how James

McNulty, NAMI president from 2002 to 2004, failed to disclose that he was being paid thousands of dollars by drug companies to promote their products to NAMI members, and others, at speaking engagements. "In a particularly intriguing twist," she notes on her website, "McNulty laundered this drug company money through a state chapter of NAMI." Bass further explains how the scheme worked for funneling the cash to McNulty:

"He would be paid thousands of dollars to speak about the benefits of various antidepressants -- McNulty himself suffered from depression -- and rather than pay him directly, companies such as Eli Lilly, the maker of Prozac, Pfizer, the maker of Zoloft, and GlaxoSmithKline, which made Paxil, would give his speaking fees to the Rhode Island chapter of NAMI, which would then cut McNulty a check."

On May 8, 2008, when the APA announced the members of the work groups who would develop the DSM5, James McNulty was listed as a task force member with an expert qualification of "President Emeritus," of NAMI.

Each year, NAMI gives awards to "Exemplary Psychiatrists," at its annual banquet. In 2008, a May 5, press release reported that "support for the awards" is provided by Eli Lilly and Janssen, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc.

NAMI was named as a defendant, right along with Pfizer, in a Medicaid fraud lawsuit filed by whistleblower, Mark Westlock, involving the illegal promotion of Geodon. Pfizer "conspired" with NAMI to act as a front organization in the off-label promotion of Geodon, the complaint says. Pfizer turned "NAMI into a Trojan Horse for the illegal marketing scheme to promote Geodon," for use with children on the NAMI website.

Laurie Flynn, the former executive director of NAMI, and current leader of Columbia University's TeenScreen, even went so far as to claim that with the advent of atypical antipsychotic medicines "the long-term disability of schizophrenia can come to an end," the complaint alleges.

In addition to Geodon, the drugs currently marketed by Pfizer, through NAMI and the pyramid of front groups, include the antidepressants Zoloft, Nardil, Sinequan, Effexor and Pristiq, Xanax for anxiety, the anticonvulsants, Neurontin and Lyrica, and the anti-smoking drug, Chantix, and the ED drug, Viagra.

In September 2009, the US Department of Justice announced that Pfizer would pay the largest single criminal fine, and largest combined federal and state health care fraud settlement in the history of the DOJ.

The company agreed to pay \$2.3 billion, with \$1.3 billion in criminal fines, "to resolve criminal and civil health care liability relating to fraudulent marketing and the payment of kickbacks," according to the government's "Stop Medicare Fraud Website."

The charges included paying kickbacks to health care providers to "induce them to prescribe," or "in connection with marketing," for a list of thirteen drugs that included Geodon, Zoloft, Lyrica and Viagra. The six whistleblowers received a combined total of roughly \$100 million for helping the government.

Brian Kenney and Tavy Deming of the Pennsylvania firm of Kenney Egan McCafferty & Young, represented the Geodon whistleblowers. The off-label marketing allegations were first made in a lawsuit filed on behalf of Harrisburg psychiatrist, Dr Stefan Kruszewski.

The antipsychotic was approved only for adults with schizophrenia or acute manic or mixed episodes of bipolar disorder, but Pfizer illegally promoted it for off-label conditions that included depression, bipolar maintenance, mood disorder, anxiety, aggression, dementia, ADHD, obsessive compulsive disorder, autism, PTSD, and for pediatric, adolescent and geriatric patients, according to the complaint.

Less than "5% of the United States population is diagnosed with schizophrenia or bipolar disorder, yet in 2008 Geodon surpassed the blockbuster benchmark of \$1 billion in sales," Attorney Deming reported in a September 2, 2009 press release.

As part of its marketing campaign, Pfizer claimed that Geodon had a safe metabolic profile when compared to other antipsychotics, such as Zyprexa, Seroquel and Risperdal, and urged doctors to switch patients to Geodon. The switching campaign "endangered patients by ignoring or materially understating Geodon's serious, and even life threatening, side effects," Attorney Kenney said in the press release.

On September 3, 2009, Kruszewski told the Philadelphia Inquirer that Pfizer sales representatives pushed him to prescribe Geodon to children for such symptoms as anxiety and agitation.

"Pfizer targeted pediatrics and adolescents to expand off-label use and maintained on its payroll an army of more than 250 child psychiatrists nationwide," Kenney reported in the press release.

"Pfizer regularly paid generous speaking fees to these child psychiatrists to give what were basically promotional lectures about the benefits of Geodon to their peers, who were naturally also child psychiatrists," he said.

Apparently, NAMI will continue on with business as usual, except now it will disclose the amounts of Pharma gifts. In 2009, NAMI received 84 payments over \$5,000 from different sources, according to an April 2010, analysis by John Mack, on his popular Pharma Marketing Blog. Of payments totaling \$4,737,610, Mack found \$3,836,750, or 81%, came from major drug companies, with the largest amounts coming from antipsychotic makers, including \$1,255,000 from AstraZeneca, followed by Lilly with \$750,500, and Bristol-Myers giving 506,250. Wyeth's 2009 grant report shows donations to all NAMI groups totaling \$268,000.

In October 2009, Grassley sent letters to all fifty state NAMI chapters asking them to disclose income from pharmaceutical companies and their foundations. On April 26, 2010, Grassley sent a letter to the leaders of NAMI National and included a chart showing the top 10 state chapters receiving the most money from January 2005 to October 2009, totaling \$3.84 million.

Also in October 2009, NAMI CEO Fitzpatrick told the New York Times: "For at least the years of '07, '08 and '09, the percentage of money from pharma has been higher than we have wanted it to be," and promised the industry's share of NAMI fund raising would drop "significantly" in 2010.

However, NAMI's grant report for the first quarter of 2010, shows the group received \$1,247,128 from drug companies and foundations, or only \$2,212 less than the \$1,249,340 it received in the first quarter of 2009. So far this year, Lilly gave NAMI groups over \$84,000, and Pfizer's report shows \$78,000 went to NAMI groups.

Conspicuously missing from NAMI's 2010 first quarter report is AstraZeneca, being the Seroquel maker gave the National group \$905,000 in the last quarter of 2009. It may be that Astra was too busy rounding up the more than \$520 million it agreed to pay the Federal government and State Medicaid programs in April 2010, to resolve fraud allegations related to the off-label marketing of Seroquel.

"Illegal acts by pharmaceutical companies and false claims against Medicare and Medicaid can put the public health at risk, corrupt medical decisions by health care providers, and take billions of dollars directly out of taxpayers' pockets," said Attorney General, Eric Holder, in an April 27, 2010, DOJ press release.

But Astra can't be hurting financially because in 2008, even though it makes up only about 5% of the world population, the US accounted for over \$3 billion of the roughly \$4.45 billion in world-wide Seroquel sales. It was Astra's second-best selling drug that year, behind the heartburn drug Nexium, and the fifth top selling drug in sales overall in the US. The price of Seroquel at DrugStore.com that year was \$839

for hundred middle dose tablets in December 2008. By August 23, 2009, the price had increased by \$50 to \$890 for the same number of pills.

"A half a billion dollar one-time settlement is just a small cost of doing business for a company that sold \$17 billion worth of the offending drug in the last five years," Dr Roy Poses points out on the Health Care Renewal website.

"This was a well thought out marketing campaign that operated on many levels," said Brian Kenney, one of the attorneys who again represented, Dr Kruszewski, one of two whistleblowers in this case as well, in an April 28, 2010 press release.

"AstraZeneca orchestrated scientific studies, ghost written articles, and the payment of large fees to academic psychiatrists to act as 'thought leaders' to promote the drug off label," he noted.

"The success can be seen in the huge numbers the campaign generated with 4.9 billion in sales in 2009," Kenney pointed out.

"It's particularly disconcerting that AstraZeneca successfully co-opted large portions of psychiatric academic community," he added.

"The manipulation and misuse of Seroquel scientific data to support AstraZeneca's off-label marketing campaign was the most disturbing aspect of the case to me," Kruszewski said in the press release. "There were strong indications from AstraZeneca's earliest clinical trials that Seroquel increased the risk of diabetes and induced profound sedation out of proportion to its weak antipsychotic effects."

"In the elderly population, they basically marketed Seroquel as an expensive sleeping pill and put hundreds of thousands of patients at risk for serious medical complications, premature cardiovascular disease, pneumonias, and premature death," he reported.

In addition to paying \$520 million, Astra had to enter into a 5-year corporate integrity agreement that requires the company to post information about payments to doctors on its website, which no doubt will include payments funneled through front groups like NAMI, for Continuing Medical Education programs, speaker fees, research grants, and the various awards given out each years.

Because according to the DOJ press release, the government contends that Astra "promoted the unapproved uses by improperly and unduly influencing the content of, and speakers, in company-sponsored Continuing Medical Education programs."

"The company also engaged doctors to give promotional speaker programs on unapproved uses for Seroquel and to conduct studies on unapproved uses of Seroquel," it says. "In addition, the company recruited doctors to serve as authors of articles that were ghostwritten by medical literature companies and about studies the doctors in question did not conduct. AstraZeneca then used those studies and articles as the basis for promotional messages about unapproved uses of Seroquel."

According to a recent report by Jim Edwards on BNET, former NAMI policy director and board member, Jim Dailey, was a paid consultant for Astra's Seroquel marketing team, and was paid \$600, plus airfare and limousine service, to attend one Seroquel consultant meeting in December 2003.

A picture taken at the meeting shows Daily, along with current NAMI CEO, Fitzpatrick, and Chuck Harmon, NAMI director of corporate relations, meeting with several Astra sales executives. The agenda for the meeting was: Seroquel vision, Role of Advocacy Groups, Increasing role of State/Medicaid with MH issues and MAP initiatives, and Ensuring access for patients.

Edwards explains that "MAP" sometimes stands for "Medication Algorithm Project." NAMI, along with J&J's Robert Wood Johnson Foundation, is identified in a Medicaid fraud lawsuit filed against J&J by former federal fraud investigator, Allen Jones, and joined by the Texas attorney general, as participating in off-label marketing schemes to increase the sales of Risperdal, including the "Texas Medication Algorithm Project," and "Texas Children's Medication Algorithm Project."

### **Latest Plan of Attack**

On June 17, 2010, under the headline, "Psychotropic Drug Abuse in Foster Care Costs Government Billions," Politics Daily reported that the Senate Subcommittee on Federal Financial Management, has asked the Government Accountability Office to look into the drugging of foster care children, who are typically concurrently enrolled in Medicaid.

"The investigators will attempt to account for estimates in the hundreds of millions of dollars of possible fraud arising from prescriptions for drugs explicitly barred from Medicaid coverage," according to the report.

"Often young patients under state supervision are also prescribed three or four high-risk drugs at a time -- all paid for by Medicaid," it pointed out.

"The GAO is collecting data from Oregon, Massachusetts, Florida, Maryland, Minnesota and Texas, to search for patterns of abuse," Politics said. "This effort marks the first time suspicion of Medicaid fraud related to psychotropic drugs has been examined at the federal level."

Alaska attorney, and founder of the Law Project for Psychiatric Rights, Jim Gottstein, told Politics that the increase of antipsychotic use in foster care amounts to "drug companies sacrificing children's lives on the altar of corporate profits."

In attempt to put a stop to the rampant off-label psychiatric drugging of foster kids, and other children on Medicaid, in Alaska, Gottstein and PsychRights have filed a Medicaid fraud lawsuit against a number of prescribing doctors, drug companies, pharmacies, and insurance companies in that state.

After learning NAMI was pulling in two-thirds of its funding from Pharma, Grassley sent disclosure requests to over 30 more non-profits. The final part in this series will cover the psychiatric front groups contacted including the Depression and Bipolar Support Alliance, Mental Health America, the National Alliance for Research on Schizophrenia and Depression, Screening for Mental Health, Children and Adults with Attention Deficit/Hyperactivity Disorder, and the National Center for Mental Checkups at Columbia University, or better known as TeenScreen.

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[Back](#)