Commentary

Holiday Every Day for Pharma under the Bush Administration

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Abstract

A December 21, 2004 report by the watchdog group Public Citizen provides information that explains why it's been a holiday every day for the pharmaceutical industry, since George W. Bush took office.

Thirteen pharmaceutical industry executives or lobbyists rank among Bush's "Rangers" and "Pioneers," the honorary titles given to those who have raised at least $200,000 or $100,000, respectively, for one of Bush's presidential campaigns, according to Public Citizen, "Together, these pharmaceutical industry super-fundraisers have raised at least $2.2 million for Bush."

This report also provides details concerning TeenScreen, the Texas Medication Algorithm Project (TMAP), and other programs, including Medicaid, the National Institute of Health (NIH), and Food and Drug Administration (FDA) riddled with conflicts of interest.

Keywords: Pharmaceutical industry profits, TeenScreen, government conflicts of interest

Bush Administration and Pharma Industry: A revolving door

A December 21, 2004 report by the watchdog group Public Citizen provides information that explains why it's been a holiday every day for the pharmaceutical industry, since George W. Bush took office.

For its December 2004 report, Public Citizen conducted an analysis of lobbying disclosure forms filed with the Secretary of the Senate and Clerk of the House, and the report provides relevant information about the pharma-connected fundraisers.

Pharmaceutical Research & Manufacturers of America (PhRMA) itself, the industry's trade group, spent more than $16 million for lobbying lawmakers in 2003, a 12.5% increase from 2002. In 2003 it hired 136 lobbyists, 24 more than in 2002, according to a June 2004 report by Public Citizen.

Since Bush took office, he's done much to enact policies to enrich his top contributors. By the end of the 2004 reelection campaign, Bush campaign headquarters must have resembled a PhRMA annual reunion.

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Campaign rainmakers, include top executives such as Pfizer CEO, Ranger Hank McKinnell. Until last year, McKinnell served as chairman of the board for PhRMA. His company produces 14 drugs that are the top sellers in their respective categories. Public Citizen reports that Pfizer ranks second among all drug companies in terms of lobbying expenditures – spending $5.3 million in 2003.

Retired Bristol-Myers Squibb Vice Chairman, Pioneer Bruce Gelb, is now a senior consultant to the company. Gelb has long-standing ties to the Bush family. He was appointed chief of the US Information Agency, and ambassador to Belgium by the first president Bush.

Before the 2000 election, Bristol-Myers executives reportedly were pressured to make maximum donations to the Bush campaign. Reluctant donors were warned that CEO Charles Heimbold, Jr. – whom Bush later named ambassador to Sweden – would be informed if they failed to give, according to the September 5, 2003 *New York Times* article, *Industry Fights to Put Imprint on Drug Bill*.

Lobbyist Tom Loeffler is a former Congressman himself. In 2000, he served as finance co-chair for the Bush-Cheney campaign, and for Bush's first gubernatorial race in Texas, according to the January 13, 2003 *New York Sun*. He is currently a self-employed lobbyist with his own firm, Loeffler Jonas & Tuggey, whose client list includes Bristol-Myers and Purdue Pharma. Loeffler was a Pioneer in 2000 and a Super-Ranger in 2004 raising more than $300,000. Loeffler took in $580,000 in 2003 from Bristol-Myers, Purdue Pharma, and PacifiCare.

In May 2000, Loeffler set up his own firm and business has increased fivefold since Bush took office. His website boasts of "strong ties to the current administration, having worked directly with the President, Vice President, the White House Chief of Staff, Cabinet secretaries and their aides," according to Public Citizen.

Bill Paxon is a lobbyist for Akin Gump and was a Bush Pioneer in 2000 and 2004. In 2003, Akin Gump had total revenues from the pharmaceutical industry of $2,020,000, including $600,000 from PhRMA, $420,000 each from Pfizer and Abbot, $240,000 from Johnson & Johnson, $120,000 from Wyeth, $80,000 from Merck, and $140,000 from Human Genome Science, reported Public Citizen.

A review of lobbyist registration forms on the issue of drug importation alone revealed that seven former members of the Bush administration are listed, six of whom lobbied their former agency. But these seven are not the only people who have

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passed through the revolving door between the Bush administration and the pharmaceutical industry. At least 14 senior officials have left to work or lobby for drug companies or PhRMA.

Federal law prohibits officials from lobbying their former employing agency for a period of one year, but the ban only applies to the specific sub-office where an official used to work. This enables officials to openly exploit the connections they gained in the course of their public employment, which is evidenced by the large number of officials who are registered to lobby their former agency. This practice allows special interests to corrupt the federal decision-making process by promising officials high-paying jobs offered only because of their position of power in the government decision-making process.

One of the most blatant examples of the revolving door practice is Tom Scully, who was the chief administrator for the Centers for Medicare and Medicaid Services and Bush's lead negotiator with Congress on the prescription drug bill, while he was discussing employment opportunities with a half dozen health-care-sector employers.

In December 2003, less than one month after the bill was signed, Scully accepted jobs from both the lobbying firm of Alston & Bird and the private equity investment firm Welsh, Carson, Anderson & Stowe. Since Scully came on board, Alston & Bird has signed up at least a dozen drug company clients, including Abbott and Aventis Pharmaceuticals.

Just three days after the Medicare bill was signed, another one of the lead senate negotiators, Colin Roskey, left his job as health policy adviser and counsel for the Senate Finance Committee for a position with Alston & Bird, one of the same firms that hired Scully.

Robert Wood, who was the chief of staff for HHS Secretary, Tommy Thompson, accepted employment with Barbour, Griffith & Rogers in June 2003. From there, he has lobbied on behalf of Bristol-Myers, GlaxoSmithKline, Pfizer, and PhRMA. In 2004, Wood even lobbied the HHS and the White House for Pfizer and GlaxoSmithKline.

Public Citizen also lists two former pharma executives who have been placed in influential positions within the administration, where they can push their former, and potentially future, employers' interests:

Doug Badger became Bush's top health policy adviser in October 2002, after helping to bring in more than $1 million for Washington Council Ernst & Young in 2002 from clients like Aventis Pharmaceuticals, Eli Lilly, Johnson & Johnson and Pfizer.

Ann-Marie Lynch, was positioned as the principal assistant deputy secretary for planning and evaluation at HHS, after Lynch had lobbied HHS and the FDA, on behalf of PhRMA in 2001, according to Public Citizen's analysis of lobbying disclosure forms.

Many top staffers have also left the administration to lobby for pharma. Dirksen Lehman was a special assistant to the president for legislative affairs, and served as the chief White House liaison to the Senate for Medicare, Medicaid and health care regulations. In May 2003, Lehman became a lobbyist for Clark & Weinstock, and during the Medicare debate, he lobbied on behalf of clients such as Aventis, Novartis and PhRMA.

Overall, lobbying hit an all-time high in 2003. Nearly $2 billion was spent on efforts to pass the industry-friendly version of the prescription drug bill alone. A little over $1 billion was spent during the 6 months immediately prior to the vote on the bill. This was the first time Washington lobbying reached a billion dollar mark in a 6 month period, according to a study by the nonpartisan Political Money Line campaign tracking service.

In the end, the Medicare bill that passed does very little for seniors, but represents a windfall for pharma. The average senior will have about $3,160 in total drug costs in 2006, when the program kicks in, according to a November 20, 2003 letter from the Congressional Budget Office to Senator Don Nichols (R-OK).

Under the new law, the average senior will have to pay 66% of that $3,160, or $2,080. Most will have to pay a $420 annual premium, a yearly deductible of $250, and co-payments on drugs. Co-payments are 25% on the first $2,250, and then rise to 100% of the cost between $2,251 to $5,100, referred to as the "doughnut hole," according to a March 2004 Kaiser Family Foundation Medicare Fact Sheet.

Never-Ending Money Trail

When Bush signed the Medicare prescription drug bill in 2003, he praised three supposedly non-profit organizations which are actually front groups financed by pharma. Bush said in part:

"Jim Martin, the president of 60 Plus Association, worked hard. Charlie Jarvis, the chairman and CEO of United Seniors Association, worked hard," he said. "Mary Martin, the chairman of the board of the Seniors Coalition, worked hard."

These three groups, plus the new group, America 21, which arrived on the scene in 2002, all claim to be advocacy groups for seniors or evangelical Christians.

In 2002, the groups sponsored broadcasts and direct mailings that mirrored one another's – and focused heavily on the prescription drug bill, which was the top legislative concern for PhRMA, according to a September 2004 report, Big PhRMA's Stealth PACs, by Public Citizen.

In 2002, PhRMA appears to have channeled as much as $41 million to its four Stealth PACs, according to records filed with the IRS. Money from the drug industry's association enabled USA, 60 Plus, the Seniors Coalition, and America 21 to broadcast ads and send direct mailings in 39 US Senate and House contests that year. The ads consistently supported candidates friendly to PhRMA's agenda and criticized those considered unfriendly, the Citizen's report said.

In 2002, USA reported nearly $18.6 million in radio and television ads on its 990 tax form. The Wisconsin Advertising Project, the academic research program assessing the political content of ads, concluded that 72.9% of the group's television activity was intended to influence the outcome of elections, as opposed to issue-advocacy work. Based on these two figures, Public Citizen estimates that USA spent $13.6 million on ads intended to influence elections in 2002.

Voters had no way of knowing that the ads and mailings were underwritten with industry money. PhRMA was able to stay hidden in the background while exerting substantial influence through the 501(c) groups that acted as PhRMA's Stealth PACs.

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Time for Bush to Pay Up

The government-backed mental health screening programs sprouting up all over the country represent another gift from Bush to the pharmaceutical industry.

On April 29, 2002, Bush established The New Freedom Commission (NFC) by executive order. On that day, while speaking in New Mexico, Bush said mental health centers and hospitals, homeless shelters, the justice and school systems have contact with individuals suffering from mental disorders, but that too many Americans fall through the cracks of the current system, and so he created the Commission to ensure "that the cracks are closed."

On July 22, 2003, a NFC Report recommended redesigning the mental health systems in all 50 states, and its press release stated, "Achieving this goal will require greater engagement and education of first line health care providers—primary care practitioners—and a greater focus on mental health care in institutions such as schools, child welfare programs, and the criminal and juvenile justice systems. The goal is integrated care that can screen, identify, and respond to problems early."

On February 5, 2003, a subcommittee report titled, *Promoting, Preserving and Restoring Children's Mental Health*, stated in part, "The extent, severity, and far-reaching consequences of mental health problems in children and adolescents make it imperative that our nation adopt a comprehensive, systematic, public health approach to improving the mental health status of children."

The NFC's final report calls for mental health screening for every child in America, including preschool children, and states that "schools are in a key position to identify mental health problems early and to provide a link to appropriate services."

Children who are hooked into government programs, often through no fault of their own, will automatically be screened due to the NFC recommendation that, "Screening should be implemented upon entry into, and periodically thereafter in, the juvenile justice and child welfare systems, as well as in other settings and populations with known high risk, such as the Medicaid population. When mental health problems are identified, youth should be linked with appropriate services and supports."

To that end, the NFC recommends that a program known as TeenScreen be set up in all 50 states. The program is billed as a suicide prevention tool when in actuality, it is just another component in a government-backed marketing scheme to recruit kids as prescription drug customers for pharma.

First of all, pharma does not need more customers. Dr. Marcia Angell, former editor of the *New England Journal of Medicine*, lists the industry's annual drug sales at $200 billion in the US and $400 billion worldwide in her book, *The Truth About the Drug Companies: How they Deceive us and What To Do About It*, Random House (2004).

And we don't need more people hooked on psychiatric drugs. According to Dr. Barry Duncan, PSYD, author of *What's Right With You* (2005), "in 2003 more than 150 million prescriptions were written for antidepressants, and more than $14 billion was spent on them." Yet as Dr. Duncan points out, "rates of depression have not changed for thirty years," and "suicide rates, despite the millions taking antidepressants, have not reduced."

Critics from all walks of life are outraged about the plan to screen the nation's school population for various reasons. "The New Freedom Commission is blatantly promoting the coercive and manipulative tactics that have led to millions of children being falsely labeled with mental disorders in our public schools," according to Peter Dockx, of the Citizen's Commission on Human Rights.

"The goal is to promote the patently false idea that we have a nation of children with undiagnosed mental disorders crying out for treatment," says Congressman Ron Paul (R-TX), who is also a physician, in *Forcing Kids Into a Mental Health Ghetto*.

"How in the world have we allowed government to become so powerful and arrogant that it assumes it can force children to accept psychiatric treatment whether parents object or not?" asks Congressman Paul, "What kind of free people would turn their children's most intimate health matters over to government strangers?"

In an October 31, 2004 letter to the editor of the Washington Times, pediatrician Dr. Karen Effrem points out: "Whatever good may come from the other recommendations (of the NFC), is completely overshadowed by the loss of freedom and damage that would come from labeling and drugging potentially millions of children based on these unsupportable screening and treatment programs."

Dr. Jane Orient, Executive Director of the Association of American Physicians and Surgeons (AAPS), is perturbed about the government's invasion of privacy involved in this money-making scheme. "Teams of experts are awaiting an infusion of cash," she says, "They'll be ensconced in your child's school before you even know it."

To parents of children undergoing screening, Dr. Orient notes that an added "bonus is that your little darlings will probably give them quite a bit of information about you also, and then you can receive therapy you didn't know you needed."

According to Orient, kids will be asked nosey questions like whether their parents raise their voice, or "Ever spank them? Have politically incorrect attitudes? Use forbidden words? Own a gun? Smoke cigarettes, especially indoors? Read extremist literature? Refuse to recycle?"

"Prepare for a knock at the door," she warns, "The answers to these questions could lead to a home visit."

School screening programs are clearly a part of an overall marketing scheme aimed at mining as many children as humanly possible and converting them into life-long prescription drug customers before they even graduate from high school. "One obvious beneficiary of the proposal is the pharmaceutical industry," warns Congressman Paul, "which is eager to sell the psychotropic drugs that undoubtedly will be prescribed to millions of American school children under the new screening program."

The NFC also recommends screening for all pregnant women which will no doubt lead to the use of selective-serotonin re-uptake inhibitors (SSRIs) antidepressants, even after the results of a study published in the *American Journal of Pediatrics*, and reported in the February 2, 2004 *News Telegraph*, showed that pregnant women who use SSRIs "to combat depression could be damaging the brains of their unborn babies."

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According to the study, the direct evidence of a link between fetal exposure and disrupted neurological development became apparent in a study of American mothers and their babies. "Abnormal sleeping patterns, heart rhythms and levels of alertness were linked by researchers to drugs called selective-serotonin re-uptake inhibitors (SSRIs)," it noted.

Philip Zeskind, a developmental psychologist and research professor of pediatrics at the University of North Carolina, who led the investigation, told the *Telegraph*, "What we've found is that SSRIs disrupt the neurological systems of children, and that this is more than just a possibility, and we're talking about hundreds of thousands of babies being exposed to these drugs during pregnancy."

"These babies are bathed in serotonin during a key period of their development and we really don't know what it's doing to them or what the long-term effects might be," he warned. "We're not saying that pregnant women should not take the drugs, because depression is itself a big problem," the Professor said, "But these drugs are being given away like smarties, and this is a big problem."

TeenScreen is a Fraud

TeenScreen claims that it can assess a variety of mental disorders in 10 minutes. On March 2, 2004, the program's Executive Director, Laurie Flynn, testified at a congressional hearing and said that in the screening process, "youth complete a 10-minute self-administered questionnaire that screens for social phobia, panic disorder, generalized anxiety disorder, major depression, alcohol and drug abuse, and suicidality."

The survey is already being administered to students all over the country even after an investigation by the US Preventive Services Task Force found no evidence that any screening reduces suicide attempts or mortality, and warned that there is only limited evidence on the accuracy of screening tools used to identify suicide risk.

While appearing before Congress, Executive Director, Flynn, had the nerve to ask lawmakers to redirect funding allocated for alcohol and drug abuse treatment programs to set up TeenScreen programs in public schools.

In other words, she is asking Congress to take tax dollars earmarked for alcohol and drug treatment and allow the money to be used to implement a nationwide marketing scheme for the most profitable industry on the planet, which will without a doubt, propel millions of normal children straight into drug addiction.

TeenScreen was developed in large part, by psychiatrist David Shaffer, of Columbia University. Shaffer has many known financial ties to pharma. He has served as an expert witness on behalf of drug companies in several trials, and has worked as a consultant for pharma on various psychotropic drugs.

In 2003, when British regulators were set to recommend against the use of SSRI antidepressants in the treatment of children because the drugs had been linked to suicidal thoughts and self-harm, Shaffer, at the request of a drug maker, attempted to block the recommendation by sending a letter to the British regulatory agency claiming there was insufficient data to restrict the use of the drugs in adolescents, according to the December 11, 2003 *New York Times*.

The truth is, the TeenScreen survey cannot possibly diagnose mental illness in kids, for reasons cited by the US Surgeon General in 1999, "The normally developing child hardly stays the same long enough to make stable measurements ... the signs and symptoms of mental disorders are often also the characteristics of normal development."

Dr. Effrem explains that psychiatric diagnoses are inherently subjective and warns that "America's children should not be medicated by expensive, ineffective, and dangerous medications based on vague and dubious diagnoses."

"There's no doubt that there are kids who are bored, who are frustrated, who are anxious, there's no doubt that some kids don't fit into our schools and some aren't doing well in their families," Dr Peter Breggin advises. "But there's no evidence whatsoever that it's a disease or a medical disorder, it's a child in conflict, it has to be dealt with in a conflict situation," he said.

The screening programs implemented in many schools have already caused grave injuries to children. For example, while in the 7th grade, Aliah Gleason became a victim of mental health screening at school, which led to five months in the hospital, during which time her parents were not allowed to see or speak to her.

During her hospitalization, Aliah was placed in restraints more than 26 times and given at least 12 different psychiatric drugs, many simultaneously, including antidepressants Zoloft, Celexa, Lexapro and Desyrel; Ativan, an antianxiety drug; and two of the newer, very expensive atypical antipsychotics - Geodon and Abilify. (See Waters R, *Medicating Aliah*; *Mother Jones*, May 2005.)

After the hospital stay, Aliah spent four more months in a residential facility—getting even more drugs, according to *Dangers of Mental Health Screening*, by Nathaniel Lehrman, MD, September 23, 2005.

Another victim of a school screening is 15-year-old Chelsea Rhoades of Indiana. In December 2004, in accordance with her school's TeenScreen program, Chelsea was given a ten minute yes-or-no test without her parent's knowledge or consent.

Shortly after the test, an employee from the Madison Mental Health Treatment Center informed Chelsea that she was diagnosed with an obsessive compulsive disorder and a social anxiety disorder and advised Chelsea that her mother should bring her to the Madison Center for treatment if her condition worsened.

Chelsea's parents were livid, not only about the testing without their consent, but over the school labeling their daughter mentally ill. The family has since filed a law suit, with the assistance of the Rutherford Institute against the school district and the Madison treatment center.

The TMAP Component

The New Freedom Commission specifically recommends the, "Texas Medication Algorithm Project (TMAP)," as a model medication treatment plan which it claims "illustrates an evidence based practice that results in better consumer outcomes."

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An algorithm is a flow chart of guidelines that doctors use to identify and medicate a certain illness. It's a formulary of specific drugs that a doctor must prescribe. If a drug is not on the list, it cannot be used as a first or second line of treatment for an illness.

The true motive behind the development of the original TMAP, was to recruit new customers from the Texas juvenile justice system, foster care program, mental health hospitals, and prison systems to generate high volume sales of pharma's newest and most expensive drugs. Once in place, the TMAP gave pharma unlimited access to Texas institutions to expand its customer base.

TMAP provided a direct funnel for tax dollars to pharma, a process that was further enhanced when Texas lawmakers passed legislation to increase Medicaid coverage for prescription drugs to persons who did not ordinarily qualify, and increased the state budget to pay for the cost of psychiatric drugs for people in public institutions. In addition, as governor, Bush supported legislation that required private industry to provide increased insurance coverage for psychiatric drugs.

The guidelines for the TMAP were established in the 1990s, while Bush was governor of Texas, by an "expert consensus," based not on scientific research, but on the opinions of handpicked members of an "expert" panel. Panel members were drawn from pools of candidates who were already known to be supportive of the drugs pharma wanted on the lists. In most instances, the "experts" chosen had easily traceable financial ties to pharma.

For example, one "expert" with a host of financial ties to drug companies is Dr. Karen Wagner. According to the *Journal of the American Medical Association*, Wagner conducted a Pfizer-funded study and reported that Pfizer's SSRI Zoloft was safe, effective and well-tolerated in children, at an extremely convenient time when both the British Committee on Safety in Medicines and the FDA had announced that they were re-examining the data from clinical trials and studies on all SSRIs.

Over the years, Wagner has received research funding from Abbott, Bristol-Myers, Eli Lilly, Forest Laboratories, GlaxoSmithKline, Organon, Pfizer, and Wyeth-Ayerst. She has served as a National Institute of Mental Health consultant to Abbott, Bristol-Myers, Cyberonics, Eli Lilly, Forest Laboratories, Glaxo, Novartis, Otsuka, Janssen, Pfizer, and UCB Pharma, and she has participated in speaker's bureaus for Abbott, Eli Lilly, Glaxo, Forest, Pfizer, and Novartis, as reported by *Drug News* on September 3, 2003.

The website http://www.cspinet.org/integrity/index.html lists connections between drug companies and researchers, and lists expert panel member, Graham Emslie, MD as: Consultant to GlaxoSmithKline, Forest, and Pfizer. Receives research support from Eli Lilly, Organon, Religion, and Wyeth-Ayerst. Member of the speaker's bureau for McNeil.

Many other "experts" on the panel had financial ties to Pharma. Dr. Jack Gorman of the New York Psychiatric Institute had received over $140,000 between April 1, 1997 and March 31, 1998, in speaking fees, travel accommodations, board memberships, and consulting fees from Janssen, Eli Lilly, Pfizer, and other drug companies.

In fact, twelve panel members were from the New York Psychiatric Institute, and each was found to have profited from drug company money.

Nearly all of the major drug companies were involved in funding the TMAP component of scheme, including Eli Lilly, Janssen Pharmaceutica, Johnson & Johnson, AstraZeneca, Novartis, Janssen-Ortho-McNeil, GlaxoSmithKline, Abbott, Pfizer, Bristol Myers Squibb, Wyeth-Ayerst and Forrest Laboratories.

The TMAP mandates the use of the most expensive drugs on the market for the first and second line of treatment for schizophrenia, bipolar disorder and depression. The drugs chosen by the "experts" were predictably manufactured by the same companies that funded the scheme and include, Zyprexa, Paxil, Zoloft, Allerall, Risperdal, Seroqual, Depakote, Prozac, Celexa, Wellbutrin, Zyban, Remeron, Serzone, Effexor, and Buspar.

A couple of years after the original TMAP was in place in Texas, another "expert" panel was chosen to formulate the TCMAP, a list of drugs to be used on children. The panel basically decided that the drugs on the adult list should be used on children for the first and second line of treatment for bipolar disorder, depression and schizophrenia.

The expert consensus process has become the standard device used for approving drugs for the formularies and it has been employed repeatedly between 1996 and 2003.

Drugs are Dangerous and Ineffective

For years, the studies that have shown atypicals and SSRIs to be ineffective and dangerous have been intentionally excluded from the promotional materials released by drug makers, and the literature sent to doctors portrayed a totally false appraisal of the drugs.

The worst part of this tragedy is that in the end, the new generation of "miracle drugs," have not only proven to be extremely harmful, they are no more effective then the older, cheaper drugs, and the drug companies and the regulatory officials knew it.

As far back as December 2000, a review of 52 studies involving 12,649 patients published in the *British Journal of Psychiatry* reported: "There is no clear evidence that the atypical antipsychotics are more effective or better tolerated than conventional antipsychotics."

In November 2003, the *Journal of the American Medical Association* reported the results of a study that tracked 309 schizophrenic patients at seventeen VA hospitals for 12 months. Of those 309 patients, 159 received Lilly's Zyprexa, and 150 took the generic antipsychotic, Haldol. The study monitored symptom reduction and adverse effects, along with quality of life, patient satisfaction, and costs.

In the end, the study found no significant advantage to patients on Zyprexa in measures of compliance, symptoms, or overall quality of life. It determined that neither Zyprexa nor Haldol was superior to the other and the only major difference was the cost. Zyprexa prices were between $3,000 to $9,000 more per patient each year than Haldol.

According to Dr. Stefan Kruszewski, the entire new generation of antipsychotics are extremely harmful and substantially increase the risk of obesity, diabetes type II, hypertension, cardiovascular complications, heart attacks and stroke. "The drug makers had this information and simply ignored the problem,"

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he said.

In September 2003, the FDA directed the makers of all atypicals to add a warning to their labels that the drugs can cause hyperglycemia, diabetes, and even death. Janssen was also instructed to send a letter to health care providers acknowledging that the company had misled providers by representing that Risperdal did not increase the risk of diabetes.

In fact, Janssen had to admit that the drug probably does increase the risk. On July 24, 2004, the *Miami Herald* reported that the "maker of a billion-dollar antipsychotic medication has acknowledged misleading doctors and other healthcare providers about the safety of its product, minimizing potentially deadly side effects."

"Risperdal is the leading drug used to combat schizophrenia ... earning Janssen about $2.1 billion in annual sales," the *Herald* noted. "The drug was first marketed about eight years ago, and is prescribed to more than 10 million people worldwide."

Another side effect of atypicals was discovered in a government study released in June 2005, which revealed that patients taking the drug Risperdal had a higher incidence of benign tumors in the pituitary gland. The FDA study was presented on June 18, 2005 at a University of Pittsburgh conference. The following information describes the methodology and findings of this FDA study:

The researchers analyzed 2.5 million adverse events reported by doctors, patients, and individuals since 1968. Of the 307 reports of pituitary tumors, 64, or 21%, occurred in patients taking antipsychotics. Forty-eight reports of pituitary tumors were reported in patients taking Risperdal according to the June 17, 2005 *Wall Street Journa*l. A lead author of the study, Ana Szarfman, noted that this kind of study cannot accurately determine how common "the pituitary tumor side effect may be for users of Risperdal and the other atypical antipsychotics because, unfortunately, it is well-known that doctors do not report all suspected adverse drug reactions to the FDA's MedWatch program," the *WSJ* wrote.

As of April 2005, the FDA now requires Black Box warnings about the increased risk of death on the labels of atypical drugs such as Zyprexa (Eli Lilly), Risperdal (Janssen), Abilify (Bristol-Myers Squibb), Clozril (Novartis), and Geodon (Pfizer).

As for the effectiveness of SSRIs, in June 2005, the *Washington Post* reported that "Despite a dramatic increase in treatment of psychiatric disorders during the past 10 years, there has been no decrease in the rate of suicidal thoughts and behavior among adults, according to a federal study primarily funded by the National Institute of Mental Health."

"The study found that although people who attempt suicide were far more likely to be treated, especially with antidepressants in 2001-03 compared to 1990-92, the rates of suicidal ideation, gestures and attempts remained basically unchanged, according to researchers from Harvard Medical School and elsewhere, in their published findings in the *Journal of the American Medical Association*," the *Post* wrote.

During the February 2004 FDA hearings on SSRIs, researchers presented evidence that showed that with children, SSRI's were little or no more effective than placebos. Psychologist David Antonuccio, from the University of Nevada Medical School, was part of a team that analyzed 12 studies and told the committee, "Our conclusions were that the advantages of the antidepressants in children were so small and so trivial as to be clinically insignificant."

"In order to evaluate the cost effectiveness of antidepressant use in children, the committee must consider the benefits, as well as the risks," Dr. Antonuccio testified. "Clinically meaningful benefits have not been adequately demonstrated in depressed children, therefore, no extra risk is warranted."

"An increased risk of suicidal behavior is certainly not justified by these minimal benefits," he said. "Neither are the established increased risks of other commonly reported side effects, which include agitation, insomnia, and gastrointestinal problems," he added.

The FDA committee heard from 65 speakers during the hearing, many of whom were grieving parents of children who had committed or attempted suicide or homicide after being placed on SSRIs which led to dramatic behavioral changes.

Probably the most damning comments regarding SSRIs come from one of their inventors, Dr Candace Pert. She worked at the NIH for 13 years and was one of the two scientists who discovered the serotonin binding process that made SSRIS possible, according to DrugAwareness.org.

"I am alarmed at the monster that Johns Hopkins neuroscientist Solomon Snyder and I created when we discovered the simple binding assay for drug receptors 25 years ago," Dr. Pert said, "Prozac and other antidepressant serotonin-receptor-active compounds may also cause cardiovascular problems in some susceptible people after long-term use, which has become common practice despite the lack of safety studies."

"The public is being misinformed about the precision of these selective serotonin-uptake inhibitors when the medical profession oversimplifies their action in the brain and ignores the body as if it exists merely to carry the head around!" she advised. "In short, these molecules of emotion regulate every aspect of our physiology. A new paradigm has evolved, with implications that life-style changes such as diet and exercise can offer profound, safe and natural mood elevation."

During an interview with Street Spirit in August 2005, investigative author Robert Whitaker described the dangers of psychiatric drugs. "When you look at the research literature, you find a clear pattern of outcomes with all these drugs," he said, "you see it with the antipsychotics, the antidepressants, the anti-anxiety drugs and the stimulants like Ritalin used to treat ADHD."

"All these drugs may curb a target symptom slightly more effectively than a placebo does for a short period of time, say six weeks," Whitaker said. However, what "you find with every class of these psychiatric drugs is a worsening of the target symptom of depression or psychosis or anxiety, over the long term, compared to placebo-treated patients."

"So even on the target symptoms, there's greater chronicity and greater severity of symptoms," he reports, "And you see a fairly significant percentage of patients where new and more severe psychiatric symptoms are triggered by the drug itself."

But what Whitaker is saying now is nothing new. Uncorrupted medical professionals have tried to warn the public about this problem for years. For more than a decade, Dr. Peter Breggin said, "I have documented in books and scientific reports how this stimulation or activation profile can lead to out-of-

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control behavior, including violence."

"Evidence from many sources confirms that selective serotonin reuptake inhibitors commonly cause or exacerbate a wide range of abnormal mental and behavioral conditions," Dr. Breggin reported in the *International Journal of Risk & Safety in Medicine* 16 (2003/2004). "These adverse drug reactions include the following overlapping clinical phenomena: a stimulant profile that ranges from mild agitation to manic psychoses, agitated depression, obsessive preoccupations that are alien or uncharacteristic of the individual, and akathisia," he said.

"Each of these reactions can worsen the individual's mental condition and can result in suicidality, violence, and other forms of extreme abnormal behavior," Dr. Breggin warns.

So in plain language, this means that rather than correcting the illusive "chemical imbalance," these widely prescribed drugs themselves disrupt the brain's chemistry.

Whitaker told Street Spirit that the rate of Americans being diagnosed disabled due to mental illness has skyrocketed since use of SSRIs began. He reports:

(1) the number of mentally disabled people in the US has been increasing at a rate of 150,000 people per year since 1987;

(2) that represents an increase of 410 new people per day being disabled by mental illness.

(3) the disability rate has continued to increase and today, one in every 50 Americans is disabled by mental illness;

The statistics above beg the question of how could this happen when all the so-called "wonder drugs" flooded the market during the same time frame. The truth is, the "wonder drugs" are the cause of many of the bizarre behaviors listed by doctors to warrant a diagnosis of mental illness disability.

Whitaker says SSRIs play a dual role in transforming healthy people into disabled individuals because an SSRI patient often suffers a manic or psychotic episode as a side effect of taking the drug; but instead of viewing the adverse reaction for what it is, the patient's diagnosis gets changed to bipolar disorder or schizophrenia, after which the patient is prescribed an antipsychotic, along with the SSRI, in what Whitaker refers to as a "drug cocktail."

The prescribing of a drug cocktail places the patient on a fast track to permanent disability and converts the patient into a lifelong customer of the pharmaceutical-psychiatric-complex. Since the first SSRI, Prozac, came on the market in 1987, the number of people diagnosed disabled by mental illness in the US has gone from 3.3 million to 5.7 million, according to Whitaker R, *Anatomy of an Epidemic: Psychiatric Drugs and the Astonishing Rise of Mental Illness in America*; *Ethical Human Psychol and Psychiatry* 2005; 7:23-33.

In addition to all the other problems with SSRIs, the drugs are addictive. In June 2003, Glaxo-SmithKline removed labels that said their drug Seroxat was not habit-forming after thousands of patients claimed they had become addicted to it.

In October 2004, the FDA ordered Black Box warnings on SSRIs for children, and drug makers were instructed to include the following in package inserts: "Clinical Worsening and Suicide Risk: Patients and their families should be encouraged to be alert to the emergence of anxiety, agitation, panic attacks, insomnia, irritability, hostility, impulsivity, akathisia, hypomania, mania, other unusual changes in behavior, worsening of depression, and suicidal ideation, especially early during antidepressant treatment and when the dose is adjusted up or down. Families and caregivers of patients should be advised to observe for the emergence of such symptoms on a day-to-day basis, since changes may be abrupt."

In June 2005, the FDA issued a Public Health Advisory on "Suicidality in Adults Being Treated with Antidepressant Medications," and said adult patients "should be watched closely for worsening of depression and for increased suicidal thinking or behavior. Close watching may be especially important early in treatment, or when the dose is changed, either increased or decreased."

But the FDA should do more than merely warn the public when hidden reports surface involving dangerous drugs. The FDA should investigate each and every case and punish the drug company officials responsible for causing injury and death by allowing dangerous drugs to be sold for the sole purpose of increasing profits.

In September 2005, British regulatory officials instructed doctors to never prescribe SSRIs to children without providing psychotherapy as well. They were also told to never prescribe the medications without trying other alternative drugs first, and to not prescribe Effexor or Paxil to children under any condition.

Tim Kendall, a British psychiatrist, led a 2-year analysis of both the published and hidden studies on SSRIs and the results of the analysis is what motivated UK officials to ban the use of Paxil and Effexor by children altogether and to severely restrict the use all other SSRIs. The long-term effects of these drugs still remain virtually unknown.

Yard Sale—State Officials Cheap

Over the last several years, with groups and programs like the NFC, TMAP, and TeenScreen, all working together, pharma has managed to compromise a whole network of government officials all across the US.

According to Pennsylvania investigator turned whistleblower, Allen Jones, "the pharmaceutical industry has systematically infiltrated the mental health service delivery system of this nation." Jones was an Investigator in the Office of Inspector General (OIG), Bureau of Special Investigations, when a TMAP model was being implemented in PA.

Jones says TMAP is "part of a large pharmaceutical marketing scheme designed to infiltrate public institutions and influence treatment practices." A state's adoption of the program requires that all patients coming in contact with state systems are to be treated with the listed drugs only, regardless of a patient's history of success with other drugs.

Once the TMAP was set up in Texas, the Johnson & Johnson foundation provided a $300,000 grant for the sole purpose of convincing other states to adopt a TMAP model. To that end, Johnson, and many other drug makers, paid for meetings to be set up with key state officials, who controlled funding for mental health services in their respective states, to sell officials on adopting a TMAP model.

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As the marketing scheme spread to other states, it was only mentioned briefly in the mainstream press. In May 2004, the *New York Times* reported that drug companies were using new strategies to capture the Medicaid and Medicare markets that involved a "focus on a much smaller group of customers: state officials who oversee treatment for many people with serious mental illness."

"Those patients—in mental hospitals, at mental health clinics and on Medicaid" the *Times* wrote, "make states among the largest buyers of anti-psychotic drugs."

On June 27, 2004 another *NYT* article reported: "In the mid-1990s, Pharma developed a new set of marketing techniques for dealing with local government officials. A group of drug company giants, led by Johnson & Johnson, has worked to convince state officials that a new generation of antipsychotic drugs, like Risperdal, Zyprexa and Seroquel are superior to older and cheaper drugs like Haldol."

"The marketing campaign has led a growing number of states to adopt prescribing guidelines for treating schizophrenia, bi-polar and other disorders that make it difficult for doctors to prescribe anything other than these very expensive drugs," the *Times* wrote.

The Pennsylvania Medication Algorithm Project (PennMap), was adopted by the Department of Public Welfare (DPW), Office of Mental Health and Substance Abuse Services (OMHSAS) in 2002, and was fully implemented in January 2003. In response to a request for an interview, Allen Jones provided the details of his investigation into pharma's influence on Pennsylvania officials which lead to state's adoption of PennMap.

The shady aspects of program emerged quickly Jones said: (1) The recommended drugs were exclusively new, patented and expensive; (2) The drugs were selected by expert consensus of persons with financial ties to Pharma; and (3) The claims of increased efficacy and safety made by the drug companies, and State employees getting perks from the companies, was contradicted by the available science.

Jones discovered that the drugs mandated by PennMap were neither safe nor effective. "The pervasive manipulation of clinical trials, the non-reporting of negative trials and the cover-up of debilitating and deadly side effects, render meaningful informed consent impossible by persons being treated with these drugs," Jones found.

Though his investigation, Jones determined that the same state officials responsible for writing the PennMap guidelines, were receiving money from drug companies with a financial stake in the outcome.

When charged with examining the receipt of drug company funds by state employees, he "began to look at the overall issue of Pharma marketing and immediately became alarmed that tactics used in marketing to the private sector were being replicated with public employees," he said.

Jones discovered a hidden slush fund account, "into which pharmaceutical companies were paying money that was being accessed by state employees," Jones said. "They were given unrestricted educational grants that were deposited into an off-the-books account, unregistered, unmonitored, literally operated out of a drawer," he added.

Jones also "found that various pharmaceutical companies were paying state employees directly and also giving them perks such as lavish trips, meals, transportation, and honorariums of up to $2,000 for speaking in their official capacities at drug company events," he said.

"It is illegal for a public employee to accept honorariums and to consult with industry without permission, yet it was happening openly," he explained.

Charles Currie, the Deputy Secretary of the Office of Mental Health and Substance Abuse Services, in the relevant time frame, was appointed by then Governor, Tom Ridge, to a key position even though he lacked medical credentials. It was Currie who approved the off-the-books account that became the basis of the initial OIG investigation, and the receipt of "educational grants" intended to promote the TMAP agenda.

The OIG received reports that pharma sales representatives were frequently and openly making gifts of meals and sporting event tickets to state officials and state hospitals during Currie's tenure.

The decision to adopt PennMap was made during Currie's reign, and shortly after PennMap was implemented, Bush appointed Currie to head the Substance Abuse and Mental Health Services Agency (SAMHSA), where he worked to further expand TMAP. In 2002-2003, SAMHSA had a $500,000 budget for the express purpose of aiding TMAP development, Jones said. Currie was also appointed to serve on Bush's New Freedom Commission.

Steven Fiorello was the Director of the Pharmacy Services Office of Mental Health and Substance Abuse Services in Pennsylvania and quickly became the main target of the Jones investigation.

Fiorello was the Chairman of the Formulary Committee that approves or disapproves drugs for the state formulary and describes himself as the "Point Man" for any company wishing to have their product added to the state formulary.

In an April 2002 Janssen Drug Company publication, under "Faculty Bio," Janssen describes Fiorello as being "responsible for the formulation of policies and procedures for drug use for ten state hospitals and facilities including the development and implementation of the PENNMAP project."

According to Jones, over time, Fiorello solicited educational grants from pharmaceutical companies totaling at least $13,765. Part of the money was used to bring Texas official and TMAP promoter, Steven Shon, to Pennsylvania to sell the TMAP model, and part was spent on trips to New Orleans for Fiorello, and OMHSAS Psychiatric Services Manager, Dr. Robert Davis, to meet with TMAP promoters and marketing representatives from Janssen.

In late 2001, at Janssen's request, Fiorello traveled to Philadelphia to promote PennMap to a group of community based managed care providers, and he also went to Philadelphia another time as a pharmacy consultant to Janssen.

On April 17, 2002, Fiorello and Dr. Fredrick Maue, Chief of the Clinical Services Division, for the Pennsylvania Department of Corrections, gave a presentation on PennMap at a Janssen-sponsored event in Hershey, PA.

Fiorello was paid $2,000 for the presentation, delivered in his official state capacity.

A Janssen sub-contractor, Comprehensive NeuroSciences (CNS), arranged the Hershey event for Janssen and a Janssen

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sales representative attended.

Documents unearthed by Jones in his investigation showed that CNS and Janssen personnel actually prepared and reviewed Fiorello's materials for the presentation. CNS sent Fiorello slides from the previous year to use as a template.

According to Jones, "The presentation materials gave formularies, dates, and numbers of state hospital patients involved, and clearly tied the Pennsylvania Program to the identical program in Texas." This involvement was in direct violation of AMA regulations and FDA Guidelines for Industry, Jones said.

As another favor to Janssen, Fiorello conducted "retrospective analysis" of patient records from the state hospital system. He essentially mined the records for information favorable to Janssen and compiled a report. He then went to New Orleans to present the report to a meeting of pharmacists from all over the country with all expenses paid by Janssen.

During the implementation phase of PennMap, Fiorello also gathered data regarding off-label experiments with dosages of atypical medications that were higher and/or lower than the FDA approved dose listed in the Physician's Desk Reference. In addition, he gathered data on the off-label use of medications for illnesses which were not FDA approved.

Fiorello then entered this information into a computerized data collection system that was provided, at least in part, by pharmaceutical companies, and he later relayed the results drawn from patient's records to the drug companies.

During his investigation, Jones discovered that Pfizer also had Fiorello on its payroll. On Pfizer's behalf, Fiorello traveled as a consulting pharmacist to Maryland with Pfizer representatives, where he met with his counterpart in the Maryland Department of Mental Health to discuss the implementation of a TMAP model in Maryland.

Fiorello also traveled to Pfizer's world headquarters in Manhattan 3 times to participate on an "advisory council" with all expenses paid for by Pfizer, including lodging at Manhattan's Millennium Hotel. Fiorello was paid an honorarium of $1,000 for attending each advisory council meeting.

Another key official, Robert Davis, MD, was the Psychiatric Physician Manager of the Pennsylvania Medical Services Division of the OMHSAS. Janssen paid all expenses for Davis to attend two functions in New Orleans with Fiorello.

Davis also attended dinner meetings with Fiorello and Janssen representative and participated in Fiorello's analysis of patient data, the formulation of the "study report," and the dissemination of information to drug companies.

Information Jones provided to his superior in the OIG clearly established that state employees were experimenting on mental health patients and reporting the results to drug companies, yet Jones was not permitted to question Davis about his pharma affiliations or his role in data gathering and its transmission to drug companies.

Another key official, Steven Karp, was the Medical Director for the Office of Mental Health and Substance Abuse Services within the Pennsylvania Department of Public Welfare. Karp was recruited from private industry by Charles Currie and was a supervisory level above Fiorello.

According to Jones, Karp knew about Fiorello's association with Janssen, his gathering of patient information, and the dissemination of that information to drug companies.

While in the private sector, Karp often gave presentations for drug companies for which he received honorariums and paid expenses. In 2000, he was appointed to an advisory board for the publication known as *Mental Health Issues Today* (MHIT).

The Parexel International Corporation is a pharma front group and has a contract with Janssen to produce the MHIT publication, which means Janssen funnels money to the corporation and Parexel writes the checks, Jones discovered.

As an advisory board member, Karp was invited, at Parexel's expense, to attend periodic board meetings. On June 23-25, 2001 he attended a meeting at the Mayflower Park Hotel in Seattle, Washington and using Parexel as a funnel, Janssen provided airfare, lodging and sustenance as well as reimbursing Karp for his expenses in getting to the airport.

On November 17-19, 2002, Karp attended a meeting at the Hyatt Regency in Tampa, Florida, again with Janssen covering his expenses via Parexel, and in June or July of 2002, Karp attended a meeting in Chicago with all expenses paid by Janssen, via Parexel.

A list of attendees at these events reveals a membership comprised almost exclusively of state mental health directors, Jones reports.

As a result of his participation in these meetings, Karp was quoted in articles published in *Mental Health Issues Today*, and achieved a degree of notoriety in his profession. Janssen, via Parexel, funded the publication and the distribution of the articles.

Karp belongs to the National Association of State Mental Health Program Directors (NASMHPD) along with Steven Shon, and NFC chairman Michael Hogan. The growth of this organization coincides with the development of TMAP, and it has been heavily subsidized by pharma.

The NASMHPD sought and accepted grants from pharma to fund its conferences and publications, and its membership includes directors from all states that have adopted a TMAP model.

His superiors in the OIG severely restricted the scope of questions that Jones was permitted to ask Karp. He was forbidden to ask Karp about his knowledge of drug treatment in the corrections system or pharma's involvement with state employees, other than Fiorello.

The same went for the Chief of the Clinical Services Division for the Department of Corrections, Fredrick Maue, who was Karp's counterpart in the Department of Corrections.

In April of 2002, Maue made three presentations at Janssen-funded events sponsored by Janssen's contractor CNS, including one with Fiorello, and two more in Sacramento, California and Orlando, Florida. According to CNS, Maue received a $2,000 honorarium plus all expenses for each of the presentations.

After receiving Fiorello's presentation materials, Jones knew that he could obtain similar materials to document pharma ties to Maue's presentations.

He advised his superiors, "that the Maue presentation materials would give us a clear picture of the scope of the drug project within the state prison system" and that he could obtain the materials from the same source that provided the Fiorello materials.

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Jones was ordered not to investigate the pharma money trail to Maue. In fact, despite the evidence of corruption involving many state officials, the OIG limited Jones' investigation to Fiorello, the lowest ranking employee involved in the scheme.

When his superiors ordered him to back off, Jones took the results of his investigation to the *New York Times*, after which he was subsequently fired. Jones has since filed a whistleblower lawsuit against the state of Pennsylvania and various drug companies.

Two other key state officials heavily involved in the overall pharma marketing scheme are the Ohio Mental Health Director, Michael Hogan, and California Director, Stephen Mayberg. Both men are members of the NFC, both control mental health services in their respective states, and both are members of a Janssen-funded Parexel advisory board.

Hogan is also a member of TeenScreen's Advisory Board and he is the guy Bush chose for Chairman of the New Freedom Commission.

Hogan has proven himself to be so valuable to Eli Lilly's marketing schemes that the company awarded him a "Lifetime Achievement Award." In granting the award it was noted that Hogan had given over 75 presentations at conferences since he became chairman of the NFC.

Every event that records researcher Sue Weibert was able to track down where Hogan made a presentation was sponsored by pharma. In addition, each group that organized an event received money from pharma to pay the key note speaker.

A key Florida official heavily involved in the overall grand marketing scheme is Jim McDonough, Director of the Florida Office of Drug Control, which has received a ton of pharma money. McDonough is also a member of TeenScreen's Advisory Board.

Drugging for Profit

On October 2, 2004, Melissa Carr reporting for Independent Media TV, said, "One might have been able to write off Allen Jones' stunning report as a conspiracy theory, if it weren't for the lawsuits of Dr. David Franklin and Dr. Stefan Kruszewski."

According to Carr, "Franklin, a former Warner-Lambert (now part of Pfizer) employee, was "paid to lie to doctors" about prescribing the drug Neurontin in cases where it was neither clinically safe nor effective. Pfizer pleaded guilty to criminal fraud and agreed to pay $430 million in fines. That amount pales in comparison to the $2.9 billion in annual Neurontin sales," Carr wrote.

With the adoption of PennMap, Dr. Stefan Kruszewski, a Harvard-trained psychiatrist working for the Pennsylvania DPW, discovered that people were being drugged for profit after he was assigned to review psychiatric care provided by state-funded agencies to identify waste, fraud, and abuse.

Kruszewski said in response to a request for an interview, that in the summer of 2001, he began documenting examples of what he refers to as "insane polypharmacy," meaning the widespread off-label use of drugs for conditions not approved by the FDA.

He found that the Neurontin, the drug listed in Franklin's lawsuit, "was being massively prescribed for anxiety, social phobia, PTSD, social anxiety, mood instability, sleep, oppositional defiant behavior, attention deficit disorder," even though "there's almost no evidence to support these uses in adults and no evidence for kids whatsoever," he said.

Kruszewski found "cases where children were placed in state-funded residential treatment facilities, sometimes for years, and were heavily drugged with the new antipsychotics and anticonvulsants."

"These kids were on multiple medications without the clinical diagnoses to support the medications," Kruszewski said. During his investigation, Kruszewski discovered that four children and one adult had died while under state care, after being prescribed lethal combinations of drugs off-label.

He reported the prescribing abuse to his supervisors and advised them of the danger to patients, as well as the potential liability risks to the state. His supervisors told him it was none of his business after which he was fired for his continued investigation of the matter.

Kruszewski was denied access to the autopsy records and was therefore unable to investigate the deaths any further, which prompted him to go public with the results of his investigation. He too has a lawsuit pending against the state.

Pharma Invades Nation's Health Care System

In addition to corrupting state officials, pharma has infiltrated the nation's health care systems to convince prescribing physicians to routinely over-medicate patients and send the bills to government programs such as Medicaid and Medicare.

A bribery scheme involving Janssen was uncovered in Massachusetts when doctors were found to have changed the medication of four patients for non-medical reasons. The November 10, 2003 *Boston Globe* reported that the patients were switched to Janssen's atypical Risperdal, without consent or medical necessity, to make them eligible for a drug trial sponsored by Janssen.

When other staff members complained, the matter was investigated and the trial was stopped. As a result of the investigation, all state hospital doctors were required to undergo recertification in the ethics of medical research and facility's director, Dr. Douglas Hughes, resigned after it was revealed that he had received $30,000 in speaker's fees from Janssen in 2003.

Another bribery scheme to turn doctors into more aggressive prescribers was described in the June 27, 2005, *New York Times*, which stated in part: "The check for $10,000 arrived in the mail unsolicited. The doctor who received it from Schering-Plough said it was made out to him personally in exchange for an attached "consulting" agreement that required nothing other than his commitment to prescribe the company's medicines." See *As Doctors Write Prescriptions, Drug Companies Write Checks*, by Gardiner Harris.

Pharma has also found ways to influence prescribers in nursing homes to funnel tax dollars through senior citizens. In one study, researchers found that 75% of long-term care elderly residents were receiving psychotropic medications. (D Fisk et al., *Archives of Internal Medicine*, 2003; 163:2716–24).

Another study released in August 2004, noted that 41% of prescriptions, for 765,423 people over age 65, were for psychotropic medications. (L Curtis et al., *Archives of Internal Medicine*, 2003; 164:1621–5).

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A more recent June 13, 2005, study in the *Archives of Internal Medicine* examined the quality of antipsychotic prescriptions in approximately 2.5 million Medicaid beneficiaries in nursing homes and found that "over half (58.2%)," received antipsychotic drugs that exceeded the maximum recommended dosage, received duplicate therapy, or under the guidelines, had inappropriate indications for the medications to begin with.

The study determined that more than 200,000 nursing home residents received antipsychotic therapy but had "no appropriate indications for use."

Pharma has found way to influence doctors within the VA hospital system to get them to prescribe the new expensive drugs over the older cheaper and equally effective generics.

Dr. Robert Rosenheck, a director with the Department of Veterans Affairs, found that more than 80% of schizophrenics in the VA system are now on the new antipsychotics, and 38% take Zyprexa. The VA spent more than $208 million on psychotropic drugs in 2003, with over $106 million going for Zyprexa alone.

Drug companies go to great lengths to influence doctors in general. In a May 2005 interview with Jeanne Lenzer, Kathleen Slattery-Moschkau, gave an insider's view of drug marketing from her experience as a drug company representative. One of the techniques used by drug companies was to buy doctors' prescribing records so drug representatives knew what drugs doctors were prescribing and could tailor their marketing to them, she said. *See What Can We Learn from Medical Whistleblowers?* PLoS Med 2(7): e209

Drug representatives developed "personality profiles" on doctors and were taught to pitch their sales to specific personality types, and representatives were compensated, Kathleen said, by "how many prescriptions we could encourage." Lenzer Jeanne (May 2005).

Pharma Corrupts Scientists

Pharma also maintains financial relationships with scientific researchers. Dr. Marcia Angell is a nationally recognized authority on medical ethics and she was named one of the twenty-five most influential people in the nation by *Time Magazine*. Dr. Angell had this to say in a 2000 *New England Journal of Medicine* article about the financial ties that bind pharma and researchers:

"The ties between clinical researchers and industry include not only grant supports, but also a host of other financial arrangements. Researchers also serve as consultants to companies whose products they are studying, join advisory boards and speakers bureaus, enter into patent and royalty arrangements, agree to be the listed authors of articles ghostwritten by interested companies, promote drugs and devices at company sponsored symposiums, and allow themselves to be plied with expensive gifts and trips to luxurious settings"

According to Shane Ellison, "Today, drug companies utilize a large majority of their profits to pay for and design their own studies." Additionally, "ghost writers" are hired to write favorable reviews of drugs despite their known dangers. These reviews are published in peer reviewed medical journals, which are used by medical doctors to get information on FDA approved drugs. Ultimately, doctors are hoodwinked into thinking that a given drug is safe and effective when, in reality, it poses great risk without benefit, Ellison charges.

Dr. Lawrence Diller MD, author of "Should I Medicate My Child?" was one of several physicians and researchers who testified at the February 2004 FDA hearings. He voiced concern that too many scientific studies are conducted by medical professionals with financial ties to the drug companies, and as a direct result the adverse effects of drugs have either been suppressed or misinterpreted.

Diller testified about his "loss of faith in my academic colleagues to generate accurate information and opinions that I feel I can trust because of the extremely intimate link between researchers and the drug industry."

In 2005, the assertions of these experts were proven true. An internal National Institutes of Health (NIH) review shows that dozens of government employed scientists have done work for drug companies in violation of ethics rules, indicating the agency's ethical woes are far greater than previously known, according to Representative Joe Barton's (R-TX) website on July 14, 2005.

The findings came in response to a March 10, 2005 letter sent by the Chairman of the House Energy and Commerce Committee, Joe Barton, (R-TX), and ranking member John Dingell (D-MI) to NIH Director, Elias Zerhouni, concerning the status of the agency's internal review of the unreported and undisclosed consulting agreements between drug companies and NIH scientists.

Chickens Come Home to Roost

On April 14, 2005, the Associated Press reported that Pennsylvania's Steven Fiorello, the state Department of Public Welfare's chief pharmacist repeatedly violated state ethics law by using his position to earn extra income from sources that included drug makers, the State Ethics Commission said in a report.

The commission's report cited 20 violations with repeated conflicts of interests between Fiorello's official duties and unofficial activities, and included serving on a panel that decides which medications may be given to patients at the nine state mental hospitals. It also cited his repeated failures to disclose income from drug makers Pfizer and Janssen.

The commission fined Fiorello more than $27,000 and referred the case to the attorney general's office for possible criminal prosecution.

The way things are shaping up, its likely that Fiorello won't be the only state official to go down in flames. Over the past summer, Congress began looking into the collusion between state officials, health care providers, and pharma in getting the TMAP adopted all over the nation.

On June 10, 2005, Senators Charles Grassley and Max Baucus issued a press release saying that they were asking a number of drug makers to explain the practice of giving financial grants to state governments and other organizations. The senators say they are concerned that the dollars are more focused on product promotion than education.

Grassley is chairman and Baucus is ranking member of the Senate Committee on Finance, which has legislative and oversight responsibility for Medicare and Medicaid. Their investiga-

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tion is based on reports that companies awarded educational grants to health care providers as inducement to prescribe certain drugs, and that grants to state agencies have prompted the agencies to develop drug programs that have resulted in the overmedicating of patients at an unwarranted expense to taxpayers.

The senators' press release said "they want to know more about the practice to ensure that it's not just a backdoor way to funnel money to doctors and other individuals who can influence prescribing and purchasing of particular prescription medicines, including off-label prescriptions."

"We need to know how this behind-the-scenes funneling of money is influencing decision makers," Senator Grassley said, "The decisions result in the government spending billions of dollars on drugs. The tactics look aggressive, and the response on behalf of the public needs to be just as vigorous."

In the press release, Senator Baucus said, "I support drug companies giving back to the community through grants for educational programs used to educate state governments and health organizations ... However, I am concerned that some grants may be for purposes other than education. These grants need to be driven by good intentions instead of motivation for larger profits," he stated.

On June 9, 2005, the senators sent a letter with questions about the grants to: Pfizer, Glaxo, Johnson & Johnson, Merck, AstraZeneca, Bristol-Myers, Novartis, Amgen, Wyeth, Eli Lilly, Sanofi Aventis, Eisai, Boehringer Ingelheim Pharmaceuticals, Schering-Plough, Hoffman-LaRoche, Forest Pharmaceuticals, Abbott, Genentech, Biogen Idec, Genzyme Corporation, Chiron Corporation, Serono, and TAP Pharmaceutical Products.

"The Committee has identified the use of grants, particularly educational grants, as a practice with potential for abuse," the senators wrote, "it appears that some manufacturers may be using educational grants to fund activities primarily to promote their products."

The letter ended with a request for answers to a lengthy list of specific questions about the grants and instructed the drug companies to provide copies of a ream of documents related to the grants.

In addition to investigations by lawmakers, on August 3, 2005, Reuters reported a continuing investigation by the US attorney for the Eastern District of Pennsylvania into the Eli Lilly's marketing and promotion of Zyprexa and Prozac in that state. That investigation was initiated in March 2004, Reuters wrote.

Reuters also reported that Lilly had received a subpoena from the Florida attorney general's office seeking documents on Medicaid-related sales of the drug Zyprexa, and Lilly's marketing of the drug in that state.

In a regulatory filing, Lilly said it had received the subpoena in June 2005, from the Medicaid Fraud Control Unit, and said it was possible that other Lilly products could become subject to the investigation, and that the investigation could lead to criminal charges, fines, or penalties against the company, according to Reuters.

In another legal battle that ended in June 2005, Lilly agreed to pay about $690 million to settle lawsuits filed by approximately 8000 Zyprexa customers who alleged they had not been warned the drug might increase the risk of diabetes. But then what is $690 million to a company that raked in $4.4 billion in sales of Zyprexa in 2004, reported by CBS.marketwatch.com on February 7, 2005.

However, "More than 2,500 other claimants refused to participate in the settlement, presumably in the belief that the amount received by each claimant, $62,500 on average, was insufficient compensation for the pain and suffering Zyprexa caused them," according to Leonard Roy Frank, in *Zyprexa: A Prescription for Diabetes, Disease and Early Death*, August 2005 issue of Street Spirit.

As more and more secret documents and studies surface in each lawsuit, many more lawsuits will no doubt be filed against these drug makers.

Joe Citizen Foots the Bill

Pharma needs to be put on notice that their government funded gravy train is about ready to be shut down. In their June 9, 2005 letter, Senators Grassley and Baucus said in part, "In recent years, the cost to Medicaid of reimbursement for prescription drugs has grown faster than any other area of the program."

"Marketing practices that increase the rates at which drugs are prescribed, particularly for off-label uses, are of concern because they have the potential to increase program costs and may encourage the use of typically newer, more expensive drugs that have not been proven superior to existing treatments," the senators wrote.

On another front, in the June 16, 2005, *Washington Post*, House Energy and Commerce Committee Chair Joe Barton (R-Texas) said, "We have reached a point where there just are not enough taxes or taxpayer money to keep Medicaid going," adding, "Medicaid eventually will bankrupt every state in the nation."

Medicaid is the primary funding source for mental health services. Public funds currently account for 63% of all mental health spending. States are looking for ways to reduce Medicaid spending. Since 2000, it has risen more than 50% to more than $300 billion per year, according to the June 22, 2005 Report, *Parity-Plus: A Third Way Approach to Fix Americ's Mental Health System*, by the Progressive Policy Institute.

The October 23, 2005 *San Francisco Chronicle* reports, that "Nationwide, Medicaid programs purchase an estimated 60 to 75 percent of antipsychotic drugs." For instance, the highest expenditure for Medi-Cal, California's version of Medicaid, was Zyprexa at close to $250 million in the year ending in June 2005. Two other atypicals, Risperdal and Seroquel, ranked 2nd and 4th in the list of highest cost drugs funded by Medi-Cal.

The difference in prices for generics and brand-name antipsychotics is enormous. The costliest atypical is Lilly's, Zyprexa, for which Medi-Cal paid an average of $399.26 per prescription, according to the state Department of Health Services. Perphenazine, the generic, cost just $65.14 on average, according to *Chronicle*, and yet Zyprexa is prescribed 35 times more often than the generic.

Collectively, the brand-name antipsychotics accounted for four of the top 10 drugs that Medi-Cal spent the most money on in the 12 months prior to June 30, 2005. All total, California spent over $620 million on the drugs.

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As a direct result of PennMap, "Pennsylvania is paying tens of millions of dollars for patented drugs that have no proven advantage over cheaper generic drugs," Jones reports. In 2003, the state spent a combined total of $139 million for SSRIs and atypical antipsychotics alone, he said.

According to Jones' best estimate, there are approximately 9,000 schizophrenics in PA prisons and mental hospitals at any given time. Based on the average length of stay, Jones says that an additional 4,000 patients move through the system each year resulting in the potential recruitment of 13,000 customers, worth about $6,000 each per year.

Jones also points out that mental hospitals and prisons have a flow-through population and when patients leave they are issued prescriptions for the medications they were treated with and that most rely on Medicaid or Medicare to pay for the drugs. This is "patient recruitment and retention" in Pharma terms, Jones says.

A report in the August 3, 2004 issue of the *Archives of Pediatric Adolescent Medicine*, based on a study conducted by Dr. William Cooper, an associate professor of pediatrics at Vanderbilt University, found that between 1996 and 2001, the rate of antipsychotic drugs prescribed to low-income children in Tennessee, had nearly doubled in the 6 year period.

After conducting an analysis of about 300,000 patient files for each year from children aged 2 to 18 who were enrolled in the state's Medicaid program, he determined that among children aged 6 to 12 there was a 93% rise, for those aged 13 to 18 there was a 116% rise, and prescriptions for preschoolers had increased 61%.

People should not believe the line about profits being spent on research and development. The truth is, that in large part, profits pay for more marketing schemes and salaries for top executives. A report by the non-profit group Families USA, showed that in 2001, former CEO of Bristol-Myers, Charles Heimbold Jr., received $74,890,918, not counting his $76,095,611 worth of unexercised stock options, and the chairman of Wyeth raked in $40,521,011, plus $40,629,459 in stock options.

Pharma spends a fortune on its combined efforts of buying influence in the media and peddling its products. Ads for prescription drugs have provided a steady revenue stream for print and broadcast media since 1997, when the FDA lifted restrictions on direct advertising.

According to contributing editor, Judy Lieberman, in the July-August 2005 *Columbia Journalism Review*, for one week in April 2005, the CJR monitored the evening newscasts of CBS, NBC, and ABC and found that network viewers saw an average of sixteen commercials for prescription drugs and an average of eighteen for over-the-counter medicines each night.

In 1999, the five networks, including CNN and Fox News, received $569 million in advertising revenue from drug companies, according to TNS Media Intelligence. By 2004, advertising revenues had nearly tripled, to $1.5 billion, according to Lieberman.

As far as money spent on print media, at the end of 2004, Lieberman reports, "drug-company ad revenue for *Time Magazine* totaled $67 million; for *Newsweek* $43 million; and for *The New York Times*, $13 million.

A 2003 Harvard Public Health study, commissioned by the Kaiser Family Foundation, shows that these investments paid off well: for every $1 spent on direct advertising, drug companies reaped an additional $4.20 in sales.

Pharma's Affair with Regulators Coming to an End

In spring 2004, after Representative Joe Barton's committee was unable to obtain documents from the NIH, his committee wrote to 20 drug companies and asked them to voluntarily reveal the consulting fees paid to NIH scientists. The names of 81 scientists with agreements with drug companies were received which were not listed in the information provided to the committee by the NIH.

Pfizer reported agreements with scientists that ranged from a minimum of $500 to one scientist receiving $517,000 over a period of 5 years. Agreements typically involved several thousand dollars for each scientist.

Once notified of the discrepancies, the NIH launched an internal review of the 81 scientists which focused on whether scientists had worked for drug companies without obtaining the required permission, whether they disclosed payments on annual forms, and whether they performed services on government time.

In a July 8, 2005 letter to the committee, the NIH reported that of the 81 scientists, 44 were found to have violated one or more of the following 3 rules: (1) reporting the income on financial disclosure forms; (2) taking personal leave to do private work; and (3) seeking prior approval for the arrangements.

NIH Director Zerhouni, wrote, "We discovered cases of employees who consulted with research entities without seeking required approval, consulted in areas that appeared to conflict with their official duties, or consulted in situations where the main benefit was the ability of the employer to invoke the name of NIH as an affiliation."

According to the letter, thirty-six of the scientists are still employed at NIH and have been referred for possible disciplinary action. Nine of those have also been referred to the HHS Office of Inspector General for investigation of possible criminal violations.

It's worth noting, that the violations identified in the review represent only a partial list of pharma's consultant agreements which actually involve hundreds of NIH scientists.

Moving on to the FDA, on July 18, 2005, Senator Charles Grassley took to the floor of the Senate in response to the nomination of Dr. Lester Crawford for Commissioner of the FDA, and gave a scathing speech on the FDA's cozy relationship with pharma as a whole, and Crawford's conduct specifically, which said in part:

During the last 18 months, this country's confidence in the FDA has been shaken. It has been shaken not because of one isolated incident or one isolated whistleblower. It has been shaken because multiple drug safety concerns have been exposed by more than one courageous whistleblower.

During Dr. Crawford's tenure, I have witnessed the suppression of the scientific process and the muzzling of scientific dissent. First, with Dr. Mosholder finding a link between antidepressants, children and suicide. And second with Dr. Graham's allegations regarding the FDA, Vioxx and post-

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marketing safety generally.

Dr. Graham's testimony before the Finance Committee suggests that the problems are systemic. Oversight of the FDA exposed the cozy relationship that exists between the FDA and the drug industry. It revealed that the FDA negotiated for almost two years with Merck about how to change the Vioxx label so people would know about the risk of heart attacks.

On March 10, 2005, Senator Grassley spoke before the Consumer Federation of America and praised the whistleblowers within the FDA who provided his committee with the truth about SSRIs and Vioxx, and said in relevant parts:

Early last year I heard that the FDA was muzzling one of its own scientists. In February 2004 the FDA held a meeting to decide whether there was a link between some antidepressant drugs and suicidal behavior in kids. Dr. Andrew Mosholder—the FDA's expert in this area—concluded there was a link. However, FDA management disagreed. So, when Dr. Mosholder stuck by his findings, his supervisors canceled his presentation to an advisory committee.

Instead of allowing Dr. Mosholder to present his findings publicly and subject them to committee scrutiny, the scientific process and his peers, the FDA effectively muzzled him.

But despite the FDA's best efforts, Dr. Mosholder wouldn't be silenced. Ultimately, months later, Dr. Mosholder was proven right.

A second case was equally explosive. As it handled Dr. Mosholder, the FDA also disregarded and stonewalled concerns raised by another one of its scientists, Dr. David Graham. Dr. Graham completed a study that found an increased risk of heart attacks and strokes in patients taking Vioxx.

Senator Grassley told the audience, "we're reminded again that whistleblowers are patriots. Think about the guts it takes to undermine your career, and to go against your supervisors at a huge federal agency, and in this case, the multi-billion-dollar drug companies. Whistleblowers are the rare birds that refuse to go along to get along. Their courage leads to the protection of public safety. The only thing they're guilty of is "committing truth."

According to the Department of Justice, Grassley said, "there are currently under seal in the neighborhood of 100 whistleblower cases involving allegations against over 200 drug companies. During the past four years, the department recovered nearly two and a half billion dollars from whistleblower cases against drug companies."

The FDA "needs to demonstrate that it is unequivocally committed to the scientific process—and those who speak up on its behalf—when it comes to drug safety and that nothing gets in the way of that, whether it's pressure from profit-oriented drug makers or institutional ego that doesn't want to admit a mistake," Grassley warned.

"The one and only client of the FDA must be John Q. Public," he told the audience.

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