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Health

Bush wants pharma Trojan Horse unbridled

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March 28, 2005—The New Freedom Commission (NFC) was established by executive order on April 29, 2002.

On that date at a speech in New Mexico, George W. 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, 200,3 the NFC recommended redesigning the mental health system in all 50 states and said, "Achieving this goal will require ... 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," in a press release.

Despite a nearly 500 percent increase in psychiatric drugs being prescribed to children in the previous six years, the NFC recommended a plan of mandatory mental health screening for all public school students and follow-up treatment with drugs when needed.

The fact is, this is nothing more than another elaborate profiteering scheme hatched by Bush and the pharmaceutical industry to convert the millions of people in public systems into customers for new psychiatric drugs in order to funnel more tax dollars to pharma.

David Oaks, director of MindFreedom, a coalition of groups which advocate for the rights of people with psychiatric disabilities, says the plan amounts to "No child left undrugged."

A report by Allan Jones, claims the "pharmaceutical industry has methodically compromised our political system at all levels and has systematically infiltrated the mental health delivery system of this nation."

Jones says the NFC "doesn't have the Orwellian goal of drugging the populace for a political purpose; it's the Orwellian goal of drugging the populace for an economic purpose."

Jones was an investigator in the Pennsylvania Office of Inspector General (OIG), Bureau of Special Investigations, when the model for this profiteering scheme was implemented in Pennsylvania. He calls it a "Trojan Horse" for the pharmaceutical industry.

Jones recently answered questions from Independent Media TV regarding his investigation of the unhealthy alliance between Pennsylvania officials and pharma that facilitated the adoption of a scheme in that state that could potentially lead to thousands of people being prescribed dangerous psychiatric drugs for the sole purpose of increasing drug company profits.

"It is a story of the betrayal of our society’s most helpless citizens," Jones said.

The program being implemented in Pennsylvania was based on the Texas Medication Algorithm Project (pronounced TMap), created in 1995 while Bush was governor.

TMAP began with an alliance of persons representing pharma, the Texas university, mental health and corrections systems and was made possible through a $1.7 million grant from the Robert Wood Johnson Foundation; a Johnson & Johnson related foundation. Johnson & Johnson owns Janssen Pharmaceutica and Janssen/Ortho McNeil.

Let there be no mistake, TMAP's underlying goal was to create a marketing scheme to ensure the sale of new psychiatric drugs. Because clinical trials did not favor these drugs, an alternative market had to be created. So the alliance came up with the idea to legitimize the drugs by “Expert Consensus Guidelines,” rather than scientific studies, by soliciting favorable opinions from doctors and psychiatrists of its own choosing.

Originally, Janssen funded the “Expert Consensus” survey and analysis, but by 1996 when its results were published, Eli Lilly and Austrazeneca were also involved in the funding, and since that time, Pfizer, Novartis, Ortho-McNeil, GlaxoSmithKline, Abbott, Bristol Myers Squibb, Wyeth-Ayerst, Forrest Laboratories and US Pharmacopeia joined in.

From then on, the “Expert Consensus” process became the standard device for approving drugs for treating patients and was employed repeatedly between 1996 and 2003.

The "expert doctors" chosen to participate in the process included people who had already published articles favoring the new drugs and not surprisingly, many were later found to have secret financial ties to pharma.

For example, one doctor chosen was Jack Gorman, who, according to the March 13, 1999, New York Post, resigned from New York’s Psychiatric Institute after it was discovered that he had received over $140,000 from drug companies in the year between April 1, 1997 and March 31, 1998.

As it turns out, Gorman received speaking fees, travel accommodations, board memberships and consulting fees from Janssen, Eli Lilly and Pfizer, including $12,000 from Pfizer at the same time that he was conducting research on Pfizer drugs.

Twelve other researchers from the New York Institute were also involved in the Expert Consensus process, and each was found to have profited from drug company money.

Why Texas?

Pharma probably decided Texas was the ideal start-up location for its new marketing scheme because it had the largest prison system in the country, with approximately 150,000 inmates, and a well-populated mental health system.

In Texas, political influence extends to state universities, hospitals and prisons, with regents and administrators appointed by the governor. So when it came time to persuade Texas officials to adopt TMAP, in addition to flooding the state with lobbyists, pharma began making campaign contributions to the governor, state lawmakers, and even judges.

For example, in 1994, the industry made no contributions to Texas politicians, according to the National Institute on Money in State Politics. However, during the 1998 campaigns, it made over 250 contributions, totaling $152,000, to candidates running for state office. In 2002, it made more than 400 contributions, totaling $384,735, and poured millions more into state universities.

The money turned out to be well spent because in the end, pharma was able to implement TMAP based on the decision of a few politically appointed officials. In addition, Texas lawmakers expanded Medicaid coverage to persons who would not ordinarily qualify and increased funding for state institutions, paving

the way for thousands of new customers.

As governor, Bush backed legislation that required private industries to increase insurance coverage for drugs, and before leaving for Washington, recommended a $67 million increase in the state budget to help pay for the drugs prescribed in public institutions.

The list of drugs chosen by the Expert Consensus included Risperdal, Zoloft, Paxil, Zyprexa, Seroqual, Geodone, Depakote, Celexa, Wellbutron, Zyban, Remeron, Serzone, Effexor, Buspar, Adderall, and Prozac and all were manufactured by the above companies.

The adoption of TMAP came with the requirement to use these drugs on all patients in the system. A doctor was free to choose which patented drug to use, but could not prescribe a generic unless treatment with at least two, often three, patented drugs failed.

Pharma claimed that these drugs were safer, more effective, and had less side-effects than generics, and saturated the medical journals with reports of favorable studies conducted by researchers who later turned out to be directly funded by the drug companies.

Many practitioners disagreed with the endorsement of the new antipsychotics. For instance, TMAP claimed Risperdal, Zyprexa and Seroqual were safer and more effective than generics in treating schizophrenia.

But according to the 2000 British Medical Journal, a study by Dr John Geddes, funded by the British Department of Health, disproved this claim. Geddes reviewed the results of independent clinical trials on over 12,000 patients to determine the actual effectiveness and dangers of the atypical and typical antipsychotics and found:

> There is no clear evidence that atypical antipsychotics are more effective or are better tolerated than conventional antipsychotics. Conventional anti-psychotics should usually be used in the initial treatment of an episode of schizophrenia unless the patient has previously not responded to these drugs or has unacceptable extrapyramidal side effects.

Its important to note that this study was conducted without drug company funding.

Robert Whitaker, the author of Mad in America, found biased reviews and deceptive reporting were used in approving and promoting these drugs. Through an FIOA request, he gained access to FDA raw data on the drug trials and found the FDA did not support claims that they were safer or more effective than generics. In fact, he discovered a letter to Janssen about Risperdal that said just the opposite and included the warning: “We would consider any advertisement or promotion labeling for RISPERDAL false, misleading or lacking fair balance ... if there is a presentation of data that conveys the impression that Risperidone is superior to haloperidol (a generic antipsychotic) or any other marketed antipsychotic drug product with regard to safety or effectiveness.”

However, the FDA warning did not keep Risperdal off the list, because according to Whitaker, "While the FDA had the authority to stop Janssen from making false claims in ads, it had no control over what physicians, paid by Janssen to conduct the trials, reported in their medical journals or told the press."

Pharma Expands Market Scheme To Pennsylvania

TMAP was lauded in NFC publications as a model program recommended for the entire country. The Pennsylvania version of the program, PennMap, was adopted in 2002, by the Department of Public Welfare (DPW), Office of Mental Health and Substance Abuse Services (OMHSAS), and fully implemented in January of 2003.

To help fund the costs that would arise under PENNMAP, the Pennsylvania Office of Mental Health & Substance Abuse Services (OMHSAS) created a special plan to pay for drugs prescribed to persons not

eligible for Medicaid and attached it to a program designed to pay for HIV drugs with public funds.

Shortly after Jones began his investigation into the possible financial influence by pharma on Pennsylvania officials in promoting PENNMAP, he discovered an off-the-books slush fund account within the OMHSAS.

"When charged with examining the receipt of drug company funds by state employees," Jones said, "I 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. Trips, perks, travel, honorariums, consultant fees etc," he said.

"The most shady aspects of the program emerged quickly," he said. The recommended drugs were exclusively new, patented and expensive and were selected by persons with financial ties to pharma; and the claims of increased efficacy and safety made by the drug companies and state employees, were contradicted by the available science.

These same sentiments had already been expressed in January 1999, by Peter Weiden, MD, one of the participants in the "Expert Consensus," when he openly criticized the process in the Journal of Practice in Psychiatry and Behavioural Health:

> “The most important weakness of the EC Guidelines is that the recommendations are based on opinions, not data. History shows that experts' opinions about ”best” treatments have frequently been disproved, and there is no assurance that what the experts recommend is actually the best treatment. One danger here is that clinicians or administrators may misinterpret “current consensus” as truth.
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> "Another limitation involves the development of the survey itself. Treatment options are limited to those items appearing on the questions, and it was not possible to cover all situations.
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> "Another problem is potential bias from funding sources. The 1996 Guidelines were funded by Janssen (makers of Risperidone [Risperdal]) and most of the guidelines’ authors have received support from the pharmaceutical industry. This potential conflict of interest may create credibility problems, especially concerning any recommendations supporting the use of atypical antipsychotics."

Jones discovered this type of conflict of interest with certain Pennsylvania employees who had been paid honorariums of up to $2,000 for speaking at pharma sponsored events in their official capacities. "It is illegal for a public employee to accept honorariums and to consult with industry without permission, yet it was happening openly," Jones said.

When he tried to investigate the matter, "I was told that pharmaceutical companies are major political contributors and that I should not continue my probe," he said. "I was effectively threatened with loss of job, career and reputation, if I continued to investigate the pharmaceutical companies."

But Jones did continue to investigate and found that Janssen and Pfizer had been actively courting Steve Fiorello, Pennsylvania's state pharmacist. Each company had paid Fiorello as a consultant, treated him to travel accommodations, and provided him with educational grants to promote PENNMAP.

Then there was Gerald Radke, a former marketing director for Eli Lilly, who was appointed deputy secretary of OMHSAS, by then Governor Ridge. Radke's predecessor, Charles Currie, was also appointed Ridge, but "when Bush became president, he tapped Currie to head SAMSHA, the National Mental Health Entity," Jones explained, and then Ridge "appointed Radke from the Bush-friendly Eli Lilly."

According to Jones, Pennsylvania doctors also benefited through "trips, perks, honorariums, name in print, ego stroked, and potential advancement." For instance, the medical director of the Mental Health and Substance Abuse office, Steven Karp, left his position in state government to join the Texas group

promoting the TMAP model in Florida.

Throughout his investigation, his superiors at the OIG "maintained a deliberate ignorance of what was going on," Jones reports, "they did not want to know," he said.

His boss said the Department of Welfare (DPW) had to know what was going on, but "drug companies write checks to both sides of the aisle and that my concerns would go nowhere" Jones reports.

When he approached his boss for advice on preserving the record, Jones was told to back off and prepare a summary of his concerns so that when the investigation was over they could give it to the DPW. Although his boss acknowledged that the DPW would do nothing, he said that "if the shit hit the fan, they could say here, we told you."

In 2002, Jones finally went to The New York Times with information about drug company Janssen's attempt to influence Pennsylvania employees during the formation of PENNMAP.

Not too long afterwards, Jones was pulled off the investigation and he eventually did lose his job as well. His assistant, Katy Butler, took over as lead investigator and closed the case without ever disclosing the evidence of misconduct that Jones had filed in his report.

However, getting the boot has not deterred him. Jones has continued to investigate the matter as a private citizen and, in November 2002, filed a lawsuit to preserve his right to speak about the influence of pharma on the treatment of patients in state institutions.

This report was made possible with the permission of Allan Jones for the extensive use of information from his Whistleblower Report.

Evelyn Pringle is a columnist for Independent Media TV and an investigative journalist focused on exposing corruption in government.