INITIAL RESEARCH

The President's New Freedom Commission on Mental Illness - Goal 4

Targeting Children to Take Psychiatric Drugs and Benefit Pharmaceutical Company Revenues

By Lindsay Geddes

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To the Reader

INITIAL RESEARCH summarizes what I found online the summer of 2004. I write as a concerned citizen and wrote this for others like me. I am not a researcher or medical person. INITIAL RESEARCH is being reviewed by a psychiatrist. I have an MBA from an Ivy League School and wrote a business book called *Through the Customers' Eyes*, published by the American Management Association. I have worked for big companies, including a pharmaceutical company over a decade ago. I learned about mental illness working with someone whose children have mental illnesses.

Please note

- The focus is on Goal 4 with references to Goal 5. Goal 4 is about screening, assessment and referral and identifies young children first. All six Goals are listed on the last page.
- There is more detail about side effects elsewhere. They are serious and known to be. See Other Voices and Sources, eg www.antidepressantfacts.org.

* * *

The New Freedom Commission (NFC) was established in April 2002. It is an Executive Branch initiative, which I believe means it bypasses Congress. Pharmaceutical companies are among the largest contributors to the Republican Party. They contributed millions to the 2000 Bush campaign. Goal 4 in the NFC Final Report will add billions to pharmaceutical company revenues.

NFC started as a project in Texas project in 1995 as a group of people from the pharmaceutical industry, the University of Texas, and the mental health and corrections systems of Texas. The project was funded by a Robert Wood Johnson grant and by several drug companies. This is from a June article in the British Medical Journal by Jeanne Lenzer, *Bush Plans to Screen Whole U.S. Population for Mental Illness*. Other Voices and Sources says where to find it online. Robert Wood Johnson is of the Johnson & Johnson company family.

You may want to look at Other Voices and Sources before you continue reading here. Also, the British Medical Journal article gives a good overview quickly.

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Constituencies, or Target Markets

Constituencies specified in NFC reports include:

Pre-school children	Teenagers	The Aged
African Americans	Alaskan Natives	Asian Americans
Hispanic Americans	American Indians	Pacific Islanders
Juvenile Justice	Child Welfare	Adults
Prisoners	Special Ed	

July 19, 2004 the Illinois Leader, a conservative newsletter, said that pregnant women and children 0-18 will be subject to compulsory testing for mental illness. See Other Voices and Sources for where to find the article and responses. See also The States' "Progress" below.

According to the British Medical Journal article, screening will start in schools, where there are 52 million children and 6 million employees. See New Customer Recruitment … below.

Mental illness is not madness. Mental illnesses can be treated. Many people with a mental illness function just fine, at a high level of performance. Celebrities have revealed that they suffer a mental illness.

The main mental illnesses are the "serious" ones: major depression, schizophrenia and bi-polar disorder, or manic depression. All three involve suicide and are chronic, incurable. See Tens of Millions of People below. The psychiatric drugs involved are mainly anti-depressants and anti-psychotics. The drugs are mostly on patent, and expensive. See Which Drugs, Which Corporations.

See sources in Other Voices and Sources for the relative merits and side effects of the psychiatric drugs involved. For the most part, side effects are already known. For example, the wrong drug or the wrong amount is known to increase suicide attempts and completions among teenagers by five times, www.antidepressantfacts.com. Paxil is the drug in this example. Some of these drugs are banned in the UK.

Tens of Millions of People

NFC reports refer to the "prevalence" of mental illness, meaning it is widespread. The National Association of Mental Health estimates up to 50 million people have a mental illness. In addition to the three serious mental illnesses, there are traumatic stress disorder, panic attacks, anxiety and Social Affective Disorder and any number of others. The primary reference is the DSM-IV, the Diagnostic and Statistical Manual of Mental Disorders. Approximate figures for the number of people being treated (from memory, seen last year) are

Depression	19 million people People of various ages Combination of regular depression and major depression
Schizophrenia	6 million people Mainly affects teenagers or, rather, it usually surfaces in teen years
Bi-polar disorder	2.5-3 million

Media Silence

US medical journals and mainstream media have said almost nothing about NFC. The following is telling. It comes from the American Psychiatric Association's APA Advocacy News for July 2004, www.psych.org. Under News from Capitol Hill it says:

> **"11. Freedom Commission Roadmap Awaited**
> The release of the first iteration of the roadmap to operationalize the findings of the President's New Freedom Commission on Mental Health is imminent. We will disseminate the document when it is unveiled. On a related note, the British Medical Journal, in anticipation of the roll-out, alleged in a disjointed story that the Bush administration will announce a plan to screen all Americans for mental disorders and promote antidepressant and antipsychotic drug use – allegations which we are told are well beyond the scope of anything the administration has planned and which seem to stem from a psychiatric survivors group. The BMJ story has gained some traction in derivative reports on the Internet, though ***mainstream media have not touched the story, in part thanks to APA's work, for which the administration is appreciative***."
> Emphasis added. Apparently a roadmap and roll-out will happen soon.

The brother of Mark B. McClellan, who now Medicaid, Medicare and other things and who headed the FDA, is Scott McClellan, a deputy press security to George Bush. Business Week did an article about Mark McClellan. http://www.businessweek.com/magazine/content/03_22/b3835719.htm.

The BMJ article said there would be an announcement in July. I'd expected something major, fitting the size of the program and its seriousness. As it happened, the announcement was a mouse. It came from the Office of the Press Secretary on July 26, 2004. Under "Anniversary of the Americans with Disabilities Act, 2004", six paragraphs down is this.

"My Administration has also begun implementing the recommendations of the New Freedom Commission on Mental Health. The Commission was established by Executive Order and its report lays out steps that can be taken to improve mental health services and support for people of all ages with mental illness."

As a press release, this one was designed not to get attention, ie. the announcement was buried and what is says is old … old.

From the Goals and Recommendations, Goal 1 says: Americans understand that mental health is essential to overall health: Implement *a national campaign* to reduce stigma and prevent suicide; and Address mental health with the same urgency as physical health. Emphasis added. This sounds as if a major public relations effort is on the way. Goal 1. wording is from an Introduction to the Special Section on the President's NFC. Versions differ.

There are two different things: New Freedom Initiative, which is about disabilities and the New Freedom Commission on Mental Illness – though "Illness" is now being replaced by "Health".

New Customer Recruitment – and Then?

Usually, with a doctor one goes through certain steps: diagnosis, prescribing and monitoring. None of these words shows in Goals 4 or 5. I would add "administering" because children need help, teens are likely to forget. "Screening" is a Goal 4 invention.

Goal 4 of NFC Final Report Goals and Recommendations is: Early mental health screening, assessment, and referral are common practice "Are" means "will become".

- Promote the mental health of young children
- Improve and expand school mental health programs
- Screen for co-occurring mental and substance use disorders and link with integrated treatment

- Screen for mental disorders in primary care, across the life span, and link with treatment and supports

What follows is drawn from various sources, mainly NFC Goal 4, the Teenscreen® Program – yes, a commercial trademark registration -- from Columbia University Department of Child and Adolescent Psychiatry's and other reading on NFC.

Screening of children will be done in schools. I deduce adult screening will be by primary care physicians and/or in "non-medical settings." I have seen no reference to screening by psychiatrists.

Teenscreen has "bachelor's-level" people do the screening supervised by a "masters'-level counsellor". Who directs and supervises the students isn't said, nor is the organization they work for. There are also references to research assistants and "senior trainees in psychiatry" doing the screening. The figure I saw for Teenscreen was that 168 schools use it. There is an energetic program to increase that number.

Teenscreen offers food vouchers to encourage parents to sign consent forms. (Low-income parents?) About 20% of the forms are signed. First is a pencil-and-paper questionnaire administered by a bachelor's-level student (meaning undergraduate?) The next step, for the children screened *in* is "Voice Disc", which is on laptops. This is interactive. (Why voice?) If the child scores "positive" with Voice Disc, he or she proceeds to "clinical evaluation" by a "licensed counsellor". I put these phrases in quotation marks because the Teenscreen description used them, because I do not know what they mean and because I think they probably mean something else. For example, what is a licensed counsellor, who will do the clinical evaluation. A social worker? A psychologist? A new job category?

I deduce the clinical evaluation is the "assessment" step referred to in Goal 4, since it comes after screening and before referral. I saw that 25% of those screened are referred for further evaluation. It does not say whether the referral is to a doctor, either primary care or psychiatric. If it is to a doctor, why not say so?

> Goal 4.1 includes the following. "Other important dimensions of the approach will include: … Eliminating barriers to coverage, such as a required psychiatric diagnosis when an alternative diagnosis that minimizes labeling and stigma is more appropriate; …"

I cannot decipher this. It seems to favor a non-psychiatric diagnosis. (A what?)

Who will keep and have access to screening records isn't said.

The next step is presumably to prescribe medication. Who will identify medication/s for each child or adult? Will that person be a psychiatrist? A primary care physician? Horror stories of primary care physicians prescribing anti-depressants travel the grapevine. PCPs aren't trained in psychiatry and psycho-pharmacology. What else can they do but base prescription decisions on information from product seminars put on by pharma companies?

> Goal 5 says: Excellent mental health care is delivered and research is accelerated. For "is" read "will be". Goal 5 also refers to advancing evidence-based practices and developing knowledge in certain areas, eg. long-term effects of medications and trauma.

There's no reference to *how* care will be delivered. In Goal 5 TMAP (see next paragraph) is again incorrectly listed as an evidence-based practice. No mention of treatment, no mention of physicians. Treatment seems to have fallen between the cracks of Goals 4 and 5.

The NFC has a special tool to pick medications: *the Texas Medication Algorithm Project*. TMAP descriptions I've seen are for psychiatric drugs -- formulas for conditions. A formula looks to me like a simple linear sequence: first this drug, then this, then that. Potential side effects are not an input in what I saw, though I saw them mentioned as a trigger to go to the next pre-defined medication. I do not know

how combinations of drugs are defined. Combinations are common with certain mental disorders. TMAP is known as OMAP in Ohio, PENNMAP in Pennsylvania. A New York psychiatrist Dr. Peter J. Weiden is quoted in the British Medical Journal as saying the algorithm/s are based on opinions not facts.

The MAPs require certain drugs to be used first, the expensive ones. Allen Jones explains this well. See Other Voices and Sources**.** Could it be that the algorithms are to be used by non-physicians, replacing a psychiatrist's knowledge, skill, thinking and judgment based on experience? Much is made in Goal 5 and elsewhere of the shortage of child psychiatrists and others in the healthcare "workforce", but without saying which jobs this means.

After drugs are prescribed, who

a. Will administer the medication (parent, school teacher, state employee, doctor, state contractor?), and

b. Monitor the patient while he or she is taking the drugs. The monitoring is crucial. At the beginning, dosages may increase in small steps to find the right level. Signs of side effects have to be identified early.

The monitoring applies all the time a patient is on a drug – close monitoring, done often enough and by a qualified person. That includes knowing the patient. It is by monitoring you see a need to adjust the dosage or less-than-hoped-for effectiveness or an unacceptable side effect. The regimen that works one year one isn't necessarily right the year after.

A quick look at the numbers: 20% of the children receive parental consent to be screened. Of those screened, 25% are sent for further evaluation or referral. (I assume you don't get away once referred.) Let's say this is similar to results with other screening programs. That's 5% who will receive medication. 52 million youngsters in schools and 6 million adults working in schools means 3 million people needing qualified, professional monitoring. How can monitoring be provided to such numbers? Add the figures from screening people outside the school system – all adults, in all walks of life (government, military, everything). Now allow for patients needing special attention because of side effects. It looks as if very few of those needing monitoring will receive it.

When someone is on psychiatric drug/s, what hope have they of ever coming off them? Who would direct that weaning, especially after years? The weaning process takes delicate handling. In general you have to come off these drugs slowly. The long-term – life-long -- effect of the drugs are not known. This is identified as an area of study under Goal 5, but it will take decades before results are available.

<u>Aside</u> Medicare and Medicaid used to be known as the Health Care Financing Administration. This was changed to Center for Medicare and Medicaid Services (CMS) July or July 2001. March 2004, Mark McClellan was appointed commissioner for CMS. CMS is responsible for Medicare, Medicaid, *State Children's Health Insurance Program* (SCHIP), HIPAA and CLIA. CLIA stands for Clinical Laboratory Improvement Amendment. Through CLIA, CMS "*regulates all laboratory testing (except research) performed on humans in the U.S.*". CLIA covers approximately 175,000 laboratory entities. Emphasis added.

The Aside is from Medical Oncology Association of Southern California, http://www.moasc.org/legislation/mcclellan.htm and http://www.cms.hhs.gov/clia/default.asp, the CLIA home page.

<u>Who Pays For The Drugs</u>

The amounts involved are serious money. These drugs are expensive. Zyprexa is said to cost between $3,000 and $9,000 per person per year. Zyprexa sales were $4.28 billion in 2003, 70% of which was paid

by government agencies. Robert Whitaker, author of *Mad in America*, compares psychotropic drug expenditure in 1987 to that in 2002. That expenditure went from $1 billion to $23 billion in 15 years. Mental health costs in Texas grew from $10.9 billion in 1998 to $16.8 billion in an unidentified year. There was a partial breakdown of the growth. Using those numbers, an estimated 55% of the increase came from "medical and drug" costs, $3 billion. Aspirations and reasoning are evident in, "Schizophrenia has increased 500% in 6 years, which clearly indicates the need for additional screening". www. newmediaexplorer.org June 2004.

I believe the payers to be the insurance companies, Medicaid, Medicare, HMOs and individuals – and, presumably, government bodies, but I don't know enough about them to say.

Goal 5.2 in the Final Report calls for changing reimbursement policies. This is an area I know little about.

The recent law about mental health parity may be to require insurance companies to pay for drugs said to be needed under NFC screening. The cost may drive these companies out of business or force significant premium increases. Either way, the consumer has a problem.

I refer again to Goal 4.1 of the recommendations: "Other important dimensions of the approach will include: Eliminating barriers to coverage, such as a required psychiatric diagnosis when an alternative diagnosis that minimizes labeling and stigma is more appropriate; …" Are "barriers to coverage" barriers to insurance coverage, ie. an insurer's requirement for a psychiatric diagnosis before covering psychiatric drugs? Does lowering the barriers mean insurance companies have to remove that requirement and cover the much larger number of people said to have a mental illness?

There's likely to be an effect on government disability benefits. As more people are said to have a mental illness, they may qualify for disability benefits, such as SSI and SSDI.

Which Drugs, Which Corporations

The following comes from Allen Jones, the whistleblower, and my existing knowledge. These are probably incomplete listings and some companies were involved earlier than others. This listing of drugs is short considering all the companies identified. See Other Voices and Sources, www.newmediaexplorer.org.

Antidepressants include: Paxil, Zoloft, Celexa, Wellbutrin, Zyban (spelling?), Prozac, Effexor

Anti-psychotics include: Risperdal, Seroquel, Zyprexa

The drug companies Allen Jones identifies add up to "anybody who is anybody" in the business: Eli Lilly (see the BMJ article for the company's connections to the Bush family and administration, eg. Homeland Security), AstraZeneca, Pfizer, Novartis, Ortho-McNeil (J&J), Janssen Pharmaceutica (J&J) GlaxoSmithKline, Abbott, Bristol, Squibb, Wyeth-Ayerst, Forest Labs and US Pharmacopeia.

Government Agencies, Universities and Professional Associations

The National Association of State Mental Health Program Directors seems to be the main disseminator to the states. NASMHPD is part of HHS, under Tommy Thompson. Each state has a State Mental Health Agency, or Authority. The Council of State Government is involved, too.
SAMHSA – Substance Abuse and Mental Health Services Administration is part of HHS. The Center for Mental Health Services is charged with implementing NFC recommendations, but there are few references to CMHS. It is headed by Kathryn Power, M.Ed., from Rhode Island.

Universities: University of Texas in 1995, Texas University at Austin – a McClellan connection I think, check Allen Jones) and Columbia University Department of Child and Adolescent Psychiatry. Johns Hopkins may be another. (Johns Hopkins hosted a mini-symposium on Homeland Security March 13-15, 2001. This makes me suspicious, but perhaps the medical part is separate.) University of Chicago, Institute of Medicine.

The American Psychiatric Association role is unknown (other than helping to keep the press quiet). I don't know the role of the American Medical Association, which I assume to be for primary care physicians. Both associations probably receive drug company money. Regular membership of these associations may not know what the Washington office is into, or know much if anything about NFC, but maybe this is wishful thinking on my part. I've asked doctors. They haven't heard of NFC.

Another organization that has taken the bait is the National Association of Mental Health Planning and Advisory Council which is touting TMAP.

The States' "Progress"

For State Implementation Activities, see http://www.nasmhpd.org/general_files/State%20table5.pdf. The text file is easier than the HML. The last update is June 17, 2004.

NASMHPD is the National Association of State Mental Health Program Directors. Each State has a SMHA, a State Mental Health Agency, sometimes Authority.

Googling Tommy Thompson (Secretary of HHS, former Governor of Wisconsin) and Perry Texas (Governor Rick Perry) produced nearly 50,000 hits.

Another indicator of the states' "progress" that's used is the "clinical treatment guidelines" in effect. "Clinical treatment guidelines" includes TMAP, an algorithm. See New Customer Recruitment below.

TMAP FL, KY, MD, NM, NV, OH, PA, TX, UT
PORT FL, GA, MD, OH, RI, UT, VT
PORT was a study on schizophrenia (Patient Outcomes Research Team) involving the National Institute of Mental Health and a university or two (Johns Hopkins? and …?)
APA FL, MD, NC, RI
The APA guidelines may be the same as TMAP and its offshoots, eg. PENNMAP. Trying to check this, there is no page of clinical or practice guidelines and, for TMAP, you get the page has been moved or deleted.
Other 12 states
The New York State Office of Mental Health lists TMAP under an Evidence-Based Practice, which it is not. The EBP were put together by New Hampshire-Dartmouth psychiatry people and have a strict definition/criterion: Proven by replicated studies over time. In other words, they are evidence-based practices. TMAP does not qualify. It is not based on studies but on a consensus of opinion and it is not a practice. The original evidence-based practices were medication, training in illness self-management, assertive community treatment, family psycho-education, supported employment, and integrated treatment for co-occurring substance use disorders.

Some Comments and Questions

How much do state governors and pharmaceutical company CEOs know about NFC, especially the side-effects of psychiatric drugs on children – who may or may not need those drugs.

Why the great emphasis on children, including pre-school. Screening alone invites a howling outcry. That's before people even think about side effects. Is the emphasis just because children are an untapped market with life-long potential? Allow me to editorialize: this is depraved indifference.

TMAP is often referred to along with TMIA, for Texas Medication Implementation Authorization. I have not looked into this.

An Orwellian possibility: prisoners are good subjects for new drug tests and clinical trials. They are in a weak position to refuse to participate. Costs are low and a prison or other corrections facility is a controlled environment.

Various government departments use outside contractors. Pharmaceutical companies customarily send out research to Contract Research Organizations (CROs). Might screening involve outsourcing? If so, it would raise the usual questions about who directs and who supervises and about accountability. And whether the contractor's personnel will have quotas. Quotas, or commissions are usual for sales people.

Future psychiatric drugs will benefit as the machinery to recruit and medicate patients for life becomes entrenched. Other categories of drugs may be screened for later: diabetes … high blood pressure …

NFC has echoes of the Iraq War: disregard for the expertise and views of the specialists (military people about troops required) and lack of thinking through (no plan for peace).

Other Voices and Sources

Allen Jones is the *first whistleblower*. He used to work in the Office of the Inspector General in Pennsylvania. He spoke within the organization and then to the British Medical Journal and New York Times and lost his job. His report is at http://psychrights.org/Drugs/AllenJonesTMAPJanuary20.pdf, the Website of the Law Project for Psychiatric Rights in Alaska. Allen Jones's report is long (60 pages) but quick to read because double-spaced and half pages. His main complaint was bribery of state officials by a pharmaceutical company, Janssen Pharmaceutica which is part of Johnson & Johnson.

A second whistleblower is Harvard-trained psychiatrist Dr. Stefan P. Kruszewski, who also worked in Pennsylvania. See http://psychrights.org/opening.htm… This site has other useful material. Someone at Psychrights is close to the subject (Jim …) who knew, for example, that Dan Fisher was the last psychiatrist on the NF Commission and was able to get a response from Dr. Fisher promptly.

Dedicated Websites

- http://www.antidepressantsfacts.com/2004-06-25-Bush-Teen-Screen-Prgram.htm
- www.MindFreedom.org. MindFreedom International is an independent coalition of 100 groups working for human rights in mental health. August 17 this year they sent out "Bush Psychiatric Screening of USA Opposed, Dr. Patch Adams Volunteers to Screen President." The Executive Director is David Oaks, oaks@mindfreedom.org. He knows my name.

Health Supreme
http://www.newmediaexplorer.org/sepp/2004/06/23/bush_to_impose_psychiatric_drug_regime.htm

The *Illinois Leader*, a conservative newsletter, July 19, 2004
http://illinoisleader.com/news/newsview.asp?c=17748 Google on Illinois Leader pregnant women mental illness for responses. See also Rapture Ready Message Board – New Mental Health Program Alarms Parents in Illinois http://www.rr-bb.com/archive/index.php/t-157900

Robert Whitaker, Mad in America, Perseus Publishing, 2002

British Medical Journal, Bush Plans to Screen Whole US Population, by Jeanne Lenzer, June 19, 2004. http://bmj.bmjjournals.com/cgi/content/full/328/7454/1458? This is a good overview
Many Websites drew from the BMJ article. Lenzer was also the source of the piece from the APA Advocacy News in Media Silence above.

Government Reports. http://www.nasmhpd.org/issues.cfm?style=text has links to the Interim Report and Final Report.

- Interim Report October 29, 2002
- Progress report March 2004 New Freedom Initiative www.whitehouse.gov/infocus/newfreedom/toc-2004.html The last time I looked at this page the last two goals were missing (5 and 6).
- Final Report: Achieving the Promise, Transforming Mental Health Care in America

The *Roster of NFC Commissioners* is at
www.mentalhealthcommission.gov/reports/FinalReport/Roster.htm.
http://www.mentalhealthcommission.gov/ has links to a Commissioner Page and a Subcommittee Page. There were 15 subcommittees. Allen Jones has good comments about the Commissioners and their corporate/political connections. He says the FDA head, Mark B. McClellan was a commissioner, but his name was not on a list I've seen. This may be because of timing. McClellan was appointed late 2003. Perhaps he attended Commission meetings before being appointed.

The President's New Freedom Commission:
Goals and Recommendations for a Transformed Mental Health System

The present-tense verbs are confusing. Future tense would be more accurate and clearer.

Goal 1: Americans understand that mental health is essential to overall health

Implement a national campaign to reduce sigma and prevent suicide
Address mental health with the same urgency as physical health

Goal 2: Mental health care is consumer and family driven

Develop an individualized plan of care for every adult with a serious mental illness and child with a serious emotional disturbance
Involve consumers and families fully in orienting the system toward recovery
Align federal programs to improve access and accountability
Create a comprehensive state mental health plan
Protect and enhance the rights of people with mental illnesses

Goal 3: Disparities in mental health services are eliminated

Improve access to high-quality care that is culturally competent
Improve access to high-quality care in rural and geographically remote areas

Goal 4: Early mental health screening, assessment and referral are common practice

Promote the mental health of young children
Improve and expand school mental health programs
Screen for co-occurring mental and substance use disorders and link with integrated treatment
Screen for mental disorders in primary care, across the life span, and link with treatment and supports.

Goal 5: Excellent mental health care is delivered and research is accelerated

Accelerate research to promote recovery and resilience, and ultimately to cure and prevent mental illnesses
Advance evidence-based practices by using dissemination and demonstration projects and create a pubic-private partnership to guide their implementation
Improve and expand the workforce providing evidence-based services and supports
Develop knowledge in four areas: mental health disparities, long-term effects of medications, trauma, and acute care

Goal 6: Technology is used to access mental health care and information

Use technology to improve access to and coordination of care
Develop and implement integrated electronic health record and personal health information systems

From Introduction to the Special Section on the President's New Freedom Commission Report