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Tracking the American Epidemic of Mental Illness - Part II

By Evelyn Pringle

Tax dollars are being used to fuel the American epidemic of mental illness by promoting the preemptive drugging of persons supposedly at risk of developing mental disorders, to the great benefit of the pharmaceutical industry.

In March 2010, the US Department of Health & Human Services Substance Abuse & Mental Health Service Administration Center for Mental Health Services announced $16.5 million in funding for "Mental Health Transformation Grants," one of SAMHSA's services grant programs.

An evidence-based practice, or EBP, refers to approaches to prevention or treatment that are validated by some form of documented research evidence. As an example of a practice that could be implemented, SAMHSA listed under "Prevention and Wellness: Early Intervention," the "Early Detection and Intervention for the Prevention of Psychosis Program (EDIPPP)," along with a link to its website http://www.changemymind.org/.

EDIPPP is a national program replicating the "Portland Identification and Early Referral," or "PIER," a treatment research program at the Main Medical Center, in Portland, Maine.

On a webpage for PIER on the Center's Website, under "Project Overview," it states: "The goals are to improve outcomes and prevent the onset of the psychotic phase of illnesses like Bipolar Disorder, Major Depression, and Schizophrenia."

"This is the first program in the United States to identify the entire population of at risk young persons and offer them treatment," PIER said in a September 26, 2005 press release.

EDIPPP was funded through a $14.4 million million grant for the "National Demonstration of Early Detection, Intervention and Prevention of Psychosis in Adolescents and Young Adults," from the Robert Wood Johnson Foundation, and is "designed to prevent

psychosis in teens and young adults," according to an April 10, 2007, announcement on RWJF's launch of the program.

"The national program is expanding PIER's success during the past seven years in identifying and treating young people experiencing subtle and early symptoms that herald the onset of serious mental illness," a November 2007 report in Behavioral Healthcare, by Dr James Maier, a research psychiatrist with PIER, notes.

EDIPPP works with people between the ages of 12 and 25, with an average age of persons entering the program between 15 and 16.

"Widespread dissemination of this early intervention model throughout the United States offers tremendous hope and optimism for combating some of the most devastating and costly illnesses that can afflict young people and their families," Maier claims.

The RWJF grant set up additional EDIPPP sites in Sacramento, California; Salem, Oregon; Ypsilanti, Michigan; and Glen Oaks, New York. A site in Albuquerque, New Mexico was added in 2008.

RWJF also funds a booklet for professionals, on how to prevent mental illness with early detection titled, "Recognizing and Helping Young People at Risk for Psychosis: A Professional's Guide," which can be downloaded free off the internet.

From the start, PIER has always been primarily funded by RWJF, according to its website. However, on October 13, 2003, Mental Health Weekly reported that the program had received a $3.9 million grant from the National Institute of Mental Health, and a parallel $2 million grant from the Center for Mental Health Services intended for a related program in early identification of non-psychotic disabilities.

In Portland, young people typically are referred to PIER by high school guidance counselors, pediatricians, or other clinicians who attended presentations about PIER's work, visited the PIER Website (http://www.preventmentalillness.org), and are familiar with the early warning symptoms that suggest the onset of a psychotic illness, according to the report in Behavioral Healthcare.

Mental Illness According to PIER

In a fact sheet posted to "Dispel the Myths," the PIER website claims that, "Mental disorders are as easy to diagnose as asthma, diabetes, and cancer."

"Treatments are effective 60%-80% of the time, success rates that meet or exceed success rates for cutting edge treatment for heart disease," the sheet states.

"In many cases, PIER does use medications," the Websites says. "We believe that some of the newer medications effectively improve thinking and combat early symptoms."

"Research suggests these medications may have a protective effect against changes in the brain that cause mental illness," it reports.

Under costs, it reads: "For now, services provided by PIER staff are supported by grants. However, if certain medications, medical tests, or neurological assessments are ordered, there will be a charge."

The PIER program was founded in 2000, by Dr William McFarlane, and after 10 years in operation, on May 28, 2010, the ChangeMyMind website listed only two "case studies and impact stories that illustrate the effectiveness of the Early Detection and Intervention for the Prevention of Psychosis Program."

Medicated for Life

Virtually every person entering the PIER program is prescribed antipsychotics, such as Risperdal or Invega, marketed by Johnson & Johnson, the parent company of the Robert Wood Johnson Foundation. These prescriptions are off-label because antipsychotics are not FDA approved to "prevent" mental illness in any age group.

An August 2008 article, by Charles Schmidt in Discover Magazine, highlighted the PIER program with a byline that stated: "A new mix of therapy and medication may stave off psychosis among teens at risk."

Schmidt discussed the case of Camila (not her real name), who entered the program in September 2001, when she was 14. "Camila and her family stuck with PIER for the four-year treatment program, which ended formally in 2005, and still keep in touch with counselors there," he reports.

However, "Camila's health still hinges on antipsychotic medication," Schmidt says. "In the summer of 2007 she went off the drugs for a spell and her strange feelings returned."

He notes that her reliance on antipsychotics raises issues. "On the one

hand, it shows that the threat of psychosis hasn't really been removed, it's just been held in check."

"What we hope is that the benefits of treatment will be lifelong," McFarlane says in the article. "We don't have any empirical evidence to support that yet, but what we've seen is that young people who still haven't converted to psychosis after about three years of our treatment don't seem to be at much risk."

While he suggests that over time, some patients may be able to go off medications, McFarlane acknowledges that PIER hasn't developed a plan for managing that process, Schmidt reports.

"As to when or if they can go off medication, that's hard to say," he told Schmidt. "I think many of our patients don't feel a need to stop; they certainly don't feel oppressed by it. At a certain point it becomes a personal choice."

A fortune can be made from these life-long antipsychotic customers. In April 2010, the price for one box of Invega, at a middle dose, was $1,373 at DrugStore.com. Risperdal went for $788 per 90 pills. The cost was $1,395 for 100 tablets of Abilify. Seroquel cost $997 per 100. One-hundred capsules of Geodon sold for $918 and Zyprexa cost $1,523 for a hundred 10mg pills.

In 2003, McFarlane told Mental Health Weekly that with about 3% of the population at risk for a serious mental illness, Greater Portland could expect about 75 young people to develop a disorder each year.

RWJF Front Group

The founder of RWJF, Robert Wood Johnson, was chairman of Johnson & Johnson for over 30 years, from 1932 to 1963, as a member of the drug maker's founding family. Throughout the years, the majority of the Foundation's money has come from investments in J&J stock. RWJF's board of trustees has always been stacked with the drug company's executives. For instance, current and past trustees have held positions at J&J such as President, CEO, Vice President, Chairman of the Board, and Treasurer, and have served along side another family heir on the board, Robert Wood Johnson IV.

RWJF is listed in a Medicaid fraud lawsuit, filed against J&J by whistleblower, Allen Jones, a former federal fraud investigator, and joined by the Texas attorney general, as providing funding for illegal marketing schemes to increase the off-label sales of Risperdal, including funding the development of the "Texas Medication Algorithm Project (TMAP)," which required doctors to prescribe the

newest, most expensive antipsychotics, antidepressants, anticonvulsants, and ADHD drugs to patients covered by public programs, like Medicaid and Medicare, who were diagnosed with mental disorders, and a nearly identical set of child drugging guidelines known as the "Texas Children's Medication Algorithm Project (CMAP)."

In addition to Risperdal and Invega, J&J also markets the ADHD drug Concerta, and Topamax, an anticonvulsant.

A May 11, 2005, report by RWJF on the results of the funding of TMAP grants totaling $2,389,581 to the University of Texas Southwestern Medical Center at Dallas and a grant of $353,747 to the Texas Department of Mental Health and Mental Retardation, describes the supposed "Problem," that led to the creation of the TMAP drugging guidelines as:

> "In the 1980's and 1990's, as pharmaceutical companies began producing new and more efficacious medications to treat people with serious mental disorders such as depression, bipolar disorder, and schizophrenia, the question arose of how to choose the most appropriate treatment options. Concerns about wide variation in prescribing practices by physicians and complaints from consumer advocates about the negative consequences of this variation spurred the creation of evidence-based guidelines and medication treatment algorithms."

The "Contacts" for the grants listed in the report, were Dr A John Rush, for the University, and Dr Steven Shon for the state of Texas. Shon was fired in October 2006, after the Texas attorney general determined that J&J had improperly influenced him to make Risperdal a preferred drug on TMAP. In 2008, Rush was added to a list of psychiatric academics who failed to disclose all the payments they received from drug companies, by Senator Charles Grassley, as part of an investigation conducted on behalf of the US Senate Finance Committee, which oversees Medicaid and Medicare spending.

As a main component of the off-label marketing schemes, the lawsuits against the antipsychotic makers allege that the drug companies "seeded" the medical literature with reports and papers purporting to be written by "experts" when they were actually ghostwritten with the names of experts attached after the fact.

In its report on the TMAP grant results, RWJF boasts that: "More than 50 articles on the Texas Medication Algorithm Project have appeared in the Journal of Clinical Psychiatry, Psychiatry Research, Managed Care, Health Services Research, Journal of the American Academy of Child and Adolescent Psychiatry and other peer-reviewed journals."

"Over the next two years, Project Directors Rush and Shon and their colleagues plan to publish additional articles on other areas of interest," the report said.

On August 18, 2008, a Dallas Morning News headline read: "Conflict of interest fears halt children's mental health project," in reference to the Children's Medication Algorithm Project. "A state mental health plan naming the preferred psychiatric drugs for children has been quietly put on hold over fears drug companies may have given researchers consulting contracts, speakers fees or other perks to help get their products on the list," the News wrote.

To date, four of the five atypical makers have settled fraud charges involving the illegal off-label marketing of antipsychotics, including for use with children. Eli Lilly paid $1.4 billion for Zyprexa, Bristol-Myers Squibb's fine was $515 million for Abilify, Pfizer paid $301 for Geodon, and AstraZeneca just forked out $520 million for Seroquel.

But the fines are merely chocked up to the cost of doing business. For instance, although AstraZeneca paid a whopping $520 million fine, Seroquel had sales of $4.9 billion in 2009, with more than half coming from the US. Overall, antipsychotics were the top-earning class of drugs in the US, in both 2008 and 2009, with sales of $14.6 billion in 2009, according to IMS Health.

J&J is the only atypical maker that has not settled the off-label marketing charges against it - yet. However, two units of J&J "will pay more than $81 million to resolve criminal and civil claims over illegal promotion of the epilepsy drug Topamax," according to Bloomberg news on April 29, 2010.

Also, over the past 2 months, J&J's McNeil division has recalled over 40 varieties of child and baby medications after the FDA found massive safety and manufacturing violations at a plant in Fort Washington, Pennsylvania, including formulations of Tylenol, Motrin, Zyrtec and Benadryl. The FDA also found problems with "strength, quality and purity."

The FDA's inspection report notes that J&J received about 46 consumer complaints "regarding foreign materials, black or dark specks [in their drugs] from June 2009 to April 2010." J&J had knowledge of problems since May 2009, which means it was allowing children and infants to ingest potentially poisonous drugs for a year before the product recall took place.

Time Magazine as Promoter

On June 22, 2009, the RWJF website posted a link to download the full text of an article in Time Magazine, by John Cloud titled, "Staying Sane May Be Easier Than You Think," who reported: "The most exciting research in mental health today involves not how to treat mental illness but how to prevent it in the first place."

"In fact," Cloud said, "many mental illnesses -- even those like schizophrenia that have demonstrable genetic origins -- can be stopped or at least contained before they start."

"This isn't wishful thinking but hard science," he claimed.

The article discussed a report by the National Academics, "an organization of experts who investigate science for the Federal Government," nearly two years in the making, "on how to prevent mental, emotional and behavioral disorders." A quick check found one of the sponsors of the National Academies to be RWJF.

"The report concludes that pre-empting such disorders requires two kinds of interventions," Cloud said, "first, because genes play so important a role in mental illness, we need to ensure that close relatives (particularly children) of those with mental disorders have access to rigorous screening programs."

"Second," he noted, "we must offer treatment to people who have already shown symptoms of illness (say, a tendency to brood and see the world without optimism) but don't meet the diagnostic criteria for a full-scale mental illness (in this case, depression)."

"Some prevention programs even prescribe psychiatric medications, including antipsychotics and antidepressants, to people who aren't technically psychotic or depressed," Time reported.

"This is a big concern," Joseph Rogers, founder of the Philadelphia-based National Mental Health Consumers' Self-Help Clearinghouse told Cloud. "Because, gee, if you miss, you can really do more harm with some of these drugs than good."

"But those who contributed to the National Academies report say preventing the suffering of people with mental illness is worth the risk of some false positives, partly because of the enormous cost of treating mental illness after it's struck," Cloud reported.

The article profiled PIER and McFarlane, who was described as "one

of the world's top authorities on preventing mental illness."

According to Time, the "National Institute of Mental Health is funding a trial of McFarlane's work, and while he is still writing up his data for publication, his anecdotal results are promising: most of the kids are so far avoiding a first psychotic episode."

Preemptive Drugging Unsupported

In a 2008 paper titled, Atypical Antipsychotic Agents For the Schizophrenia Prodrome: Not a Clear First Choice," published in the "International Journal of Risk & Safety in Medicine," Dr Stefan Kruszewski, a psychiatrist, and Dr Richard Paczynski, a neurologist, both from Harrisburg, Pennsylvania, explain that, "Pharmacologic intervention at the earliest stages of suspected psychotic illness is an intuitively appealing concept and a logical extension of the current approach to many other diseases of the central nervous system."

"However," they report, "a critical analysis of the results of structured clinical investigations which have explored the use of ATAPs for new-onset psychotic symptoms raises safety concerns and does not support pre-medication in this setting as a preventive strategy."

"Over the past several years," the paper states, "a voice has emerged in the international psychiatric community recommending early prescription of the atypical antipsychotic agents (ATAPs) for adolescents and young adults who appear to show signs consistent with a schizophrenia prodrome. Early use is predicated on the possibility that ATAPs may prevent progression to full-blown psychotic illness in this high-risk population. "

"This trend has been encouraged despite a paucity of data which clearly support the effectiveness of these agents for this indication, and despite evidence of adverse side effects including," the authors note.

These circumstances prompted their literature review, "focusing on the five published studies that have explicitly addressed the preventative efficacy of the most widely prescribed ATAPs in structured (i.e., non-anecdotal) clinical settings."

In the summary and conclusion section of the paper, the authors report that the results from the available controlled trials reviewed are in line with several of the conclusions of the naturalistic study by Cornblatt et al. "That is, early prescription of ATAPs to adolescents and young adults seeking medical attention for prodromal psychotic symptoms is associated with high rates of medication non-adherence."

"Additionally," they say, "the introduction of ATAPs was not associated with reduction in the rate of conversion to formal psychosis beyond that explainable by chance and/or the introduction of bias secondary to baseline imbalances, inadequate blinding or even differential psychosocial supports."

"We suggest caution in making any assumptions that justify changes in prescription-writing behavior when it involves patients who are at high risk for developing long-term psychotic illnesses but have never demonstrated sustained psychosis (psychotic illness by DSM-IV criteria)," Kruszewski and Paczynski advise.

"This would include but is not limited to persons with suspected schizophrenia prodrome," they add.

"Even in the hands of experienced investigators using detailed screening protocols in controlled settings, only one-quarter to one-third of high-risk patients converted to full-blown psychosis," they report.

"Consequently," they warn, "if early use of ATAPs continues as a quasi-standard of care for new-onset psychotic symptoms, a large majority of these often young individuals will be exposed unnecessarily to poorly defined but likely substantial risks, including but not limited to obesity, hyperlipidemia, metabolic syndrome, increased rates of type II diabetes mellitus and extrapyramidal syndromes, both acute and chronic."

"Considerations of safety must come first when the preventative efficacy of these agents remains so poorly defined," they conclude.

(Part III of this series will highlight the Psychiatric Industrial Complex as the driving force behind the American Epidemic of Mental Illness)

Evelyn Pringle

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Author's Bio: Evelyn Pringle is an investigative journalist and researcher focused on exposing corruption in government and corporate America.

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