

Commentaire/Commentary

Diagnosisgate: Conflict of Interest at the Top of the Psychiatric Apparatus

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Introduction

Allen Frances, arguably the world's most powerful psychiatrist, spearheaded a massive, million-dollar project using psychiatric diagnosis to propel sales of a potent and dangerous drug by pharmaceutical giant Johnson & Johnson (J & J). Frances began the initiative in 1995, but his involvement has been little known, despite a court document written in 2010 that revealed what its author, an ethics specialist, called serious deception and corruption in that project.[1]

Frances is longtime editor of the globally influential manual of labels, *Diagnostic and Statistical Manual of Mental*

Disorders (DSM), known as the psychiatrist's "Bible". According to the court document, Frances led the J & J enterprise that involved distortion of scientific evidence, conflicts of interest, and other illegal and unethical practices.[1] The author of the court document is Dr. David J. Rothman, a Columbia University specialist in the ethics of relationships between medicine and industry. The document is an expert witness report commissioned in connection with a Medicaid fraud court case filed by the Texas Attorney General at the time, Greg Abbott.

Some mystery surrounds the matter: It remains unclear why certain crucial portions of this document have not become more widely known, given that Abbott used it as part of his case alleging wrongdoing by Johnson & Johnson subsidiary Janssen Pharmaceuticals. Major stories with references to the report appeared in 2011, 2012, and 2014 in the *Houston Press*,[2] *Businessweek*,[3] *Bloomberg.com*,[4,5] and *The Denver Post*[6] and included names of some of the other wrongdoers but not those of Frances and his two closest colleagues, whose work was the foundation of

the subsequent conflict of interest. And although in 2011, Vera Sharav of the Alliance for Human Research Protection published an online article [7] about the Rothman Report and included the names of Frances and those two colleagues, her article was apparently picked up by only two or three bloggers and not otherwise reported. The Rothman Report is in the public domain, appearing for instance on attorney James Gottstein's Psychrights.org website.[1]

The lead-up to the agreement between Frances and Johnson & Johnson

For six years, Frances had headed the task force charged with creating the fourth edition of the manual, *DSM-IV*, from 1988 until its 1994 publication by the American Psychiatric Association (APA). The APA, a lobby group, markets the book and earned more than \$100 million from that edition.[8] Under Frances's leadership, the number of categories listed as mental disorders leapt from 297 in the previous edition (published in 1987) to 374 in his edition a mere seven years later.[9] He then headed production of the minimally altered *DSM-IV-TR* that appeared in 2000 and remained in force until *DSM-5* was published in 2013. Thus, over two decades, the editions he edited were used in the labeling as mentally ill of millions more people than anyone else in history, which is why he has been called the world's most important psychiatrist.[10]

Despite evidence that the *DSM-IV* committees ignored and distorted [9] the science behind the categories of mental illness they included in the manual, Frances has continued to the present time to describe their work as "scrupulously scientific." [11] Despite evidence that the new labels failed to help therapists reduce patients' suffering and that they carried enormous risks of harm – including plummeting self-confidence; loss of employment, child custody, security clearance, and the right to make decisions about one's medical and legal affairs; skyrocketing rates of disability, etc[12]—for many years, he continued to defend psychiatric diagnosis as simply helpful and to deny the harm it could cause. Not until 2009 did Frances begin to warn about harm from psychiatric diagnosis. This new stance coincided with his campaign against the *DSM-5* that was then in preparation and on whose task force he was not included. From 2009 to the present time, in his critiques of *DSM-5*, he has often contrasted its problems with what he described as the scientific rigor of *DSM-IV* and *DSM-IV-TR*, [11] thereby positioning himself as a staunch advocate of high standards of research methodology and accurate representation of scientific findings.

Frances's campaign against *DSM-5* continued in his book, remarkably named *Saving Normal*, and included repeated warnings that Pharma would use *DSM-5* labels to promote their drugs. As a result, many people have come to regard him as an opponent of drug companies. Adding to the impression of Frances as concerned about harm from diagnostic labels, his anti-*DSM-5* writings, speeches, and media interviews have included what appeared to be his frank admission of errors by his *DSM-IV* Task Force; that is, he acknowledges that his *DSM-IV* led to three epidemics of diagnosis – Autism, Attention Deficit Disorder, and childhood Bipolar Disorder.[11,13,14,15] Despite calling this admission a mea culpa, he in fact absolves himself of blame, saying repeatedly in articles and in his book – which appeared at the same time as *DSM-5* – that he and his colleagues could not have foreseen these epidemics. He lays the blame elsewhere – largely on Pharma, but also on other psychiatrists, non-psychiatrist physicians, therapists, patients themselves, researchers, consumer groups, the Internet, and the media. [11,14,15]

Rothman's revelations about Frances' work for Johnson & Johnson

The scrupulously documented Rothman Report contrasts starkly with the image of Frances as wedded to rigorous research and as an opponent of Pharma. Rothman reported that, in 1995, the very year after *DSM-IV* appeared, Johnson & Johnson had paid more than half a million dollars (USD) to Frances and two of his psychiatrist colleagues to create an official-seeming document as the basis for promotion of one of their drugs. The following year, the drug company paid them almost another half million dollars to continue and expand the marketing campaign.[1]

The practice guidelines

The initial document that Frances and his two fellow psychiatrists produced was the "Schizophrenia Practice Guidelines." Practice guidelines are presented as state-of-the-science instructions to practitioners about how to treat people who have received a particular diagnosis. Such guidelines are considered the "gold standard" of evidence-based care because they aim to convey what is deemed to be the most reliable scientific evidence at a given time. Those who follow them are often absolved of responsibility for harm that may result, because they are considered to constitute the standard of care. The APA itself produces most of the psychiatric practice guidelines, and its website includes the statement that "APA practice guidelines provide

evidence-based recommendations for the assessment and treatment of psychiatric disorders.” [16] Thus, practice guidelines are presented as being based on objective evaluations of the relative effectiveness of various treatments for a specific condition. It should be noted, however, that there is no external regulation of the guidelines, and thus those who create and promote them are rarely, if ever, held accountable if they misrepresent the state of the relevant scientific research. In fact, recent investigation has shown that professional panels creating guidelines have tended “to increase the number of individuals considered to have the disease[s], none reported rigorous assessment of potential harms of that widening, and most had a majority of members disclosing financial ties to pharmaceutical companies.”[17] In the same vein, a 2011 Institute of Medicine report included the note that “There are no universally accepted standards for developing systematic reviews and clinical practice guidelines, leading to variability in the handling of conflicts of interest, appraisals of evidence, and the rigor of the evaluations.”[18]

Nowhere in the *DSM* and its associated books and other products (such as casebooks, research reviews, and webinars)[19] has the APA disclosed the poor scientific foundation of the symptom clusters underlying the proposed disorders.[9,11,12] It is troubling, then, that diagnostic categories with poor scientific bases have led to the production of ‘authoritative’ practice guidelines.

According to the Rothman report, Frances and his colleagues wrote guidelines that were designed specifically to persuade physicians to prescribe J & J’s drug Risperdal as the first line of treatment for schizophrenia.

Frances was Chair of Psychiatry at Duke University at the time. In keeping with drug companies’ common practice of funding faculty at high-status institutions, the two other psychiatrists chosen to develop the guidelines with Frances were Professor and Vice Chairman of Psychiatry at Cornell University, John P. Docherty, and Associate Clinical Professor of Psychiatry at Columbia University, David A. Kahn. The three psychiatrists received \$515,000 of J & J funding in 1995 to produce the Schizophrenia guidelines, which before they were even written were referred to in J & J correspondence as the “RISPERDAL Treatment Guidelines.”[1 p16] J & J gave an initial, “unrestricted” grant of \$450,000 divided evenly among the three psychiatrists, promised an additional \$65,000 if they produced the guidelines fast, and paid that bonus when they speedily came up with what were called the “Tri-University Guidelines.”[1 p15-6]

According to the Rothman report, the Guidelines were constructed “in disregard of professional medical ethics and principles of conflict of interest,” and they “subverted scientific integrity, appearing to be a purely scientific venture when it was at its core, a marketing venture for Risperdal.” [1 p14] Internal emails provided to Rothman showed that Frances communicated frequently with J & J officials, failing “to keep the company at arm’s length” [1 p15], and that Frances and his team promised “wide distribution of its Risperdal product, including publication in a journal supplement”[1 p15] aimed at legitimizing the Tri-University guidelines even further.

Risperdal was one of a number of then-new drugs called atypical antipsychotics. They were so named to distinguish them from the earliest drugs that were marketed as antipsychotics, such as chlorpromazine (Thorazine©) and haloperidol (Haldol©). Frances, Docherty, and Kahn omitted from the guidelines the evidence that the atypicals were not more effective than these earlier drugs [20]. Atypicals were bumped up to the position of first-line treatment for Schizophrenia, and of the atypicals, Risperdal was recommended over the others.

Frances was deeply involved in planning for the use of the guidelines in marketing, keeping in close communication with J & J and requesting their input on drafts of the guidelines. In Rothman’s words, Frances wrote to a J & J official “without embarrassment or equivocation” that “[w]e also need to get more specific on the size and composition of the target audience and how to integrate the publication and conferences with other marketing efforts.”[1 p15]

Using the guidelines to increase sales of Risperdal

Once the guidelines were written, Frances, Docherty, and Kahn created a new entity they called Expert Knowledge Systems (EKS) for the purpose of using additional J & J funds to create and help implement a Risperdal marketing plan.[1 p15] EKS required a further \$428,000 to fund their multi-arena plan, which included to “influence state governments and providers” [1, p. 16], including but not limited to officials connected with prison systems and mental health departments. Another goal was to identify Key Opinion Leaders (KOL)-psychiatrists J & J paid to give speeches advertised as Continuing Medical Education lectures about psychiatric treatments that specifically promoted Risperdal.

The Crucial Role of Texas. EKS’s promotional plan importantly targeted the Texas Medication Algorithm Project (TMAP). TMAP, which started in 1995, is one of a number of programs with the stated goal of identifying people with mental illness

as early as possible in order to start treatment right away; it is based on the assertion that early drug treatment improves long term outcomes. TMAP has been criticized as screening for mental illness using instruments skewed toward the positive identification of psychiatric symptoms and, therefore, the classification of subjects as mentally ill rather than as normal. The project was funded by a Robert Wood Johnson grant and several drug companies and included the University of Texas and that state's mental health and corrections systems.[21]

"Algorithm" sounds exceedingly scientific and precise. This is problematic in light of the unscientific nature of psychiatric diagnoses and of the major flaws and conflicts of interest in much drug research. Solid information about what medication actually helps with what symptoms remains minimal, to the point that many prescribers will favor a "trial and error" approach in which they try to identify the best course of drug treatment for patients. Moreover, major drug companies have recently drastically cut back on their research and development of new psychiatric drugs because, after decades of research, so little is known about how these drugs affect the brain and how a given individual will respond.[22]

EKS stated to J & J its "intent to work with the State of Texas immediately in implementing this product in a select number of CMHCs [Community Mental Health Centers] with the assistance of A. John Rush, M.D.," a key TMAP member.[1 p16] They reasoned that what TMAP implemented, other states could then replicate with minimal investment.[1 p18] Rush had previously been involved with Frances. Frances had appointed Rush one of two people to decide whether to put Premenstrual Dysphoric Disorder (PMDD) in the *DSM-IV* after Frances' committee of experts about premenstrual matters failed to reach a clear consensus. PMDD is an alleged mental illness whose very existence had not been proven; the European Union's equivalent of the Food and Drug Administration had declared that it was not a real entity [23]. Yet Rush was instrumental in ensuring that PMDD appeared in *DSM-IV* as a Depressive Disorder. This was noteworthy, because a woman did not have to suffer from depression in order to meet the PMDD criteria [23] and because Rush conducted Pharma-funded research about depression [9].

Along with Frances, Docherty, and Kahn, Rush became one of the instructors for the continuing medical education courses based on the Tri-University Guidelines. According to the Rothman report, J & J provided funding specifically to TMAP to promote its endorsement of Risperdal, relying heavily on the Tri-University Guidelines. Rush was critical to this process.[1] A major consequence of the J & J funding in

Texas was that, according to an internal J & J report, Dr. Steve Shon, director of that state's Department of Mental Health, "can and is influencing not only the \$50m [million] atypical [atypical antipsychotic drug market] in Texas, but likewise in many other states." [1 p24]

The involvement of Rush, Shon, and other Texas psychiatrists constituted such egregious conflicts of interest that the State of Texas in 2012 filed another lawsuit against Johnson & Johnson and its subsidiary, Janssen Pharmaceuticals, this time for violating the Texas Deceptive Trade Practices Consumer Protection Act.[24] The Medicaid fraud suit, for which the Rothman Report was commissioned, had gone to trial and ended in a settlement in which J & J would pay \$158 million.[20] The new Consumer Protection filing accused the defendants of engaging in "false, misleading, or deceptive acts or practices in the course of trade and commerce." Highlighted in that filing was that the drug company "masked, withheld, or failed to disclose negative information contained in scientific studies concerning the safety and efficacy of Risperdal." [24] This included evidence that Risperdal was promoted for treating many conditions for which it had not been approved by the FDA, including Schizoaffective Disorder, Pervasive Developmental Disorders including Conduct Disorder and Oppositional Defiant Disorder, Aggression Agitation, and Dementia. The state requested that the drug company be permanently enjoined from misrepresentations of Risperdal and be required to pay up to \$20,000 per violation.

On August 30, 2012, Texas Attorney General Abbott issued a press release to announce that Texas and 36 other states had together reached a settlement in which Janssen was to pay the states a total of \$181 million because of its "unlawful and deceptive marketing." [25] Here there appears another mystery: Interestingly, nowhere in either the filing or the press release did the names of Frances, Docherty, or Kahn appear, although their deceptive guidelines were the foundation for the enterprise, nor did they include the names of the other psychiatrists whom Janssen had hired to carry out the deceptive acts. Furthermore, they did not include information about harm done to the individuals who had been prescribed Risperdal.

Risks from Risperdal fail to prevent expanded use

Both U.S. and European government data have shown Risperdal to be one of a number of atypical antipsychotics which over the years have been prescribed for less and less serious emotional problems (e.g., distractibility, anxiety, insomnia, depression), including in adolescents and

even children.[26-29] Its use is marked by a vast array of negative effects on a striking number of physical systems. These include drowsiness, dizziness, nausea, vomiting, diarrhea, constipation, heartburn, dry mouth, increased saliva production, increased appetite, weight gain, stomach pain, anxiety, agitation, restlessness, difficulty falling asleep or staying asleep, decreased sexual interest or ability, vision problems, muscle or joint pain, dry or discolored skin, difficulty urinating, muscle stiffness, confusion, fast or irregular pulse, sweating, unusual and uncontrollable movements of face or body, faintness, seizures, Parkinsonian symptoms such as slow movements or shuffling walk, rash, hives, itching, difficulty breathing or swallowing, gynecomastia in male children, and painful erection of penis lasting for hours.[28] Yet Rothman showed that J & J produced papers presented as scientific, in which they claimed that long term use in children was safe (though it had not been studied over the long term) and that fully 20% of all children need long term treatment with Risperdal for "significant psychiatric illness." [1 p63]

Papers impelled by J & J were published in scholarly journals and, as Rothman reports, ghost-written by individuals selected by J & J, with high-profile names affixed as first authors after the articles had been written. These papers helped promote use of Risperdal to treat not only Schizophrenia but also Childhood Onset Schizophrenia, Schizo-affective Disorder, Bipolar Disorder in Children and Adults, Mania, Autism, Pervasive Developmental Disorder other than Autism, Conduct Disorder, Oppositional Defiant Disorder, Psychosis, Aggression Agitation, Dementia, below average IQ, and disruptive behavior. Subsequent to the production and marketing of the Tri-University Guidelines came the FDA approval of Risperdal to treat adults and then children diagnosed with Bipolar Disorder, and finally children diagnosed with Autism.[24] In light of Frances's sustained claims that he could not have foreseen the epidemics of diagnosis of Childhood Bipolar Disorder, Autism, and ADHD (see "distractibility" above), it is all the more striking that major media coverage of the trial and settlement did not mention his essential role in promoting them.

Information was omitted in other instances as well. Take for instance a 2010 article about Frances in Wired magazine.[29] The article included two statements pertinent to the contents of the Rothman Report, although the Rothman Report was not mentioned. The Wired article included (1) that one of Frances's "keenest regrets" was the epidemic of children diagnosed with Bipolar Disorder that began "shortly after" *DSM-IV* was issued, and (2) that Harvard psychiatrist Joseph

Biederman, the most prominent advocate of that diagnosis and the use of Risperdal in children given that label, had failed to disclose money J & J had paid to him. Unmentioned in the Wired piece was Frances's own connection with J & J, which was likely unknown to the author of that article. Biederman's actions were facilitated by what Frances had developed "shortly after" his *DSM-IV* was published, specifically, the very next year: The Tri-University Guidelines and related marketing plan actually legitimized Biederman's actions.

Recent developments

Frances has continued in various public arenas to cast himself in ways that are directly contradicted by his dealings with J & J. On September 2, 2014, on "The Doctors" television show, in an episode called "The secrets your doctors may not be telling you," [30] Frances said he was alarmed about the "tens of millions of people on psychiatric medication" because of Pharma's influence and "salesmanship," which is "not good practice." Without disclosing his own role in J & J's miseducation of physicians, he warned that "doctors need to be reprogrammed from the propaganda they've received from the drug companies." He specifically named Childhood Bipolar Disorder as a massive diagnostic epidemic and warned that children given that diagnosis "get dangerous medication that makes them gain lots of weight." As noted, weight gain is one effect of Risperdal. Without revealing the unscientific nature of the diagnostic manual he and EKS used as the takeoff point for their work, he cautioned that "getting a diagnosis can change your whole life," and doctors "shouldn't jump into diagnosis prematurely." He advised the audience to "Be informed. Ask lots and lots of questions. Don't be satisfied with obscure answers. Get clear answers". However, he did not divulge that their doctors would be unaware of the conflicts of interest and distortion of research that led to the EKS Practice Guidelines and their use to develop the marketing campaign (continuing medical education courses, medical journal articles) described in the Rothman Report.

On October 24, 2014, in a panel discussion at the Mad In America International Film Festival near Boston, Massachusetts, again without divulging his work for J & J, Frances presented himself as alarmed about overdiagnosis and overmedication, specifically naming antipsychotic drugs, among others, and citing Pharma's profit motive as a major contributor to harm done to patients. His remarks included the following dramatic statements:

We're terribly overtreating kids and old people

who don't need medication.... The figures for overtreatment are startling.... The drugs that kill are much more the drugs that come from drug companies than the drugs that come from drug cartels... Until recently, the antipsychotics were amongst the biggest revenue producers for the drug companies -- \$18 billion a year. ...Horrible problem with overtreatment for many people who don't need it, largely pushed by a diagnostic system that's too loose, drug company misinformation.... So we have this terrible problem where we're doping up the population, we don't know the effect of these drugs on kids long term, we do know that the drugs -- the anti-psychotics particularly -- make kids fat, make almost everyone fat, with all the risks that come with obesity. We do know that they shorten life expectancy in nursing homes. So there's a scandalous overtreatment... of the people who don't need it, we need to control the drug companies, we need to reduce the amount of primary care medicine that's giving out pills haphazardly, we need to control the diagnostic system... diagnosis has been terrifically oversold, and I've done my best to point that out.... We all have a responsibility, we all need to meet that responsibility.[31]

When panel moderator Robert Whitaker said that diagnosis is not reliable or valid, Frances responded: "I know the flaws of the diagnostic system better than anyone, having worked on this for many years, and I've criticized in oodles of writings... they're not useless... They still serve heuristic value when they're used well. They still help to predict prognosis, they still help to guide treatment when they're used well." And in a later statement, he stated: "The drug companies... inundated [physicians] with marketing... How do you stop this? Big Pharma has to be tamed. And that's impossible, because they spend tens of billions of dollars with misinformation to everyone and control the government." Referring to "overdiagnosis, overtesting, overtreatment" he asserted that psychiatry needs to "be reformed." [31]

Frances was invited to deliver a lecture on November 14, 2014, to the International Society for Ethical Psychology and Psychiatry. The conference announcement shows the title of his talk as "Where Ethics Meets Practice in Psychiatric Diagnosis and Treatment" and includes the following:

Psychiatric diagnosis can be extremely helpful when done cautiously and correctly, but extremely harmful when done exuberantly and carelessly. "Mental disorders" are no more and no less than constructs—necessary and useful, but also fallible and subjective. Experience teaches that anything that can be misused in the *DSM* will be misused—particularly under the pressure of well-financed drug company propaganda that mental disorders are under-diagnosed, are easy to diagnose even by untrained primary care doctors, are caused by a chemical imbalance, and require a pill solution. The combination of an overly inclusive *DSM* and misleading Pharma marketing has resulted

in a massive mislabeling as mental disorders what are instead the expectable everyday aches and pains of everyday life and of childhood development. ... The sad result is that we are massively over treating people who don't need it.[32]

In his half-hour, November 14, 2014 lecture at the ISEPP conference [14], he alluded to irresponsible diagnoses of mental disorders and their lack of scientific basis numerous times:

- He called it "absolutely absurd" and "an elaborate overestimate" to state that one quarter of our population is mentally ill and said it is "bad for society to think that one-fourth of individuals are sick. The line between mental disorder and normality is fuzzy....there's no clear, bright line that separates distress, traumas, aches and pains of everyday life from mild mental disorders";
- He referred to "the foolishness of the medical model";
- He called psychiatric diagnosis "disease-mongering, spreading misinformation" that mental disorders are underdiagnosed;
- He gave as an example of medicalizing normality through diagnosis that "Childhood is now a disease," referring to classification as mental illnesses ordinary childhood behavior.[14]

Also within that half-hour, he attributed harm to the drug companies five different times, saying:

- "[We are] terrifically and terribly overtreating with medication people who don't need it...driven by [Pharma]";
- [Psychiatrically diagnosing 1/4 of the population is] an elaborate overestimate. The drug companies love it;
- [Psychiatrists have conveyed the impression that emotional problems are] easily treated with a pill;
- [Specifically naming antipsychotic medication, which as seen above was the subject of the Tri-University Guidelines and EKS marketing campaign, naming as a serious problem that] 50% of antipsychotics are prescribed by primary care doctors [whom he described as unduly influenced by drug company advertising]; and
- We have more deaths from prescription pharmaceuticals than we do from street drugs, more from drug companies than from drug cartels.... We give people in nursing homes medication if they get agitated...it reduces their life expectancy...more deaths when people go on anti-psychotics... [anti-psychotics and mood stabilizers are] given out like candy to kids, childhood obesity problem is made worse, metabolic syndrome, cardiovascular risk, we should be much more careful whom we give medication to....[14]

In this last series of statements, one notes that the prescribing

of Risperdal for people in nursing homes and for children were some of the outcomes targeted by the J & J campaign [1]. There is no indication that the campaign included warnings that the serious symptoms Frances listed in this lecture ought to lead to a conservative approach to prescribing that medication.

Also during the lecture, he drew the direct line from use of *DSM* diagnoses to use of psychiatric drugs: "A straight medical model that doesn't think about the person...treating people with checklist *DSM* things is ridiculous, not understanding the psychosocial context is absurd, interviews that [lead to] a prescription [is not good]".[14]

Following Frances' lecture and one by Robert Whitaker immediately afterward, both speakers participated in a question-and-answer session, during which Frances three more times warned of the harm caused by Pharma and three more times described serious problems with psychiatric diagnoses.[14] One questioner noted that Frances had overseen the largest increase in psychiatric diagnoses in history and that this had led to increased use of psychotropic drugs, especially in children. Frances responded by claiming that his work on *DSM-IV* and *DSM-IV-TR* had been responsible and scientific. He stated that they had received suggestions for 94 new diagnoses but included only two.[14] It should be noted that *DSM-IV* actually included 374 categories, 77 more than the 297 in *DSM-III-R*, which was published seven years earlier. Moreover, the increase between Frances's editions and *DSM-5* actually took place at a slower rate.[9, 12] Frances claimed that for his editions:

We set up a very conservative standard...before [a diagnosis was] added,[we did] extensive literature reviews, field trials. Our standard was that we wouldn't add anything new unless it could be proven but we wouldn't subtract unless it could be proven.

In another statement, he presented himself as an open, critical thinker: "You need to be as critical of your own views and the ways they may be biased." [14] One example he gave to illustrate how he avoided pathologizing normal experience was that in *DSM-5*, "grief became Major Depressive Disorder." Curiously, in his *DSM-IV*, under Major Depressive Episode (MDE, my emphasis), the common manifestations of grief were described as criteria for diagnosing MDE even on the first day of bereavement.[12] In the same response in which he stressed the scientific foundation for his editions of the *DSM*, he also said that, in *DSM-IV*, psychiatric categories were considered to be "constructs".[14] He urged that there be blackbox warnings about the problems with psychiatric diagnosis[14] (something that had been suggested by this

author in a previously published article[12]). Also in that response, he acknowledged that "The APA has done a lot of wrong things" [14], something he had long denied about his manuals[9,12] but said that to blame the guild interests of psychiatry for harm to patients "tremendously underestimates the power of the pharmaceutical industry."

Whitaker referred to Frances' denial that psychiatrists had created a disease model through the *DSM*, noting that a disease model was indeed used in *DSM-IV*. "We were told these were diseases". Frances replied that "the real problem in the world is that Pharma companies control Washington, the airwaves... the APA is a Wizard of Oz thing,^a remarkably stupid. Big Pharma has power and dollars, and they control the narrative." He said further that he had "fought this conception as hard as I can, the overdiagnosis..."[14]

In a subsequent article in *Madinamerica*,[15] Frances described himself as "no defender of the APA" and said he has "harshly condemned its incompetence and financial conflict of interest". He declared that the APA "became far too dependent on drug company money" but did not mention his own employment by Johnson & Johnson. His attacks on Pharma's misleading marketing were extensive, including the following from the online article:

The real gorilla in the room is Big Pharma. The drug companies are rich, are powerful, are clever, and are highly motivated to spend billions of dollars selling ills to push pills. Big Pharma's massive marketing campaign has convinced the public and doctors that life's everyday distresses and problems are really undiagnosed mental disorders caused by a chemical imbalance requiring a pill solution... The effective marketing muscle is all with Big Pharma... The only meaningful way to contain the quick-draw craze for medication is to end all direct-to-consumer Big Pharma advertising (allowed only in the US and New Zealand) and all marketing to doctors. This strategy of ending marketing propaganda worked to contain previously impregnable Big Tobacco — it could also work also to stop Big Pharma and to protect people from pills they don't need.[15]

Such statements give the impression that Frances is a white knight aiming to warn and protect the public from Pharma. How could fellow professionals and the public, reading such statements, ever suspect that he had created the Johnson & Johnson marketing campaign for Risperdal?

It is important to note, however, that in the same article,[15] Frances wrote:

...medication is used way too often for people who don't need it, but my clinical experience, research experience, and reading of the literature convince me that it has an essential role in stabilizing people

during what are often risky acute psychotic episodes and also in reducing the risk of relapse.... it is risky and clinically unsound to argue against medication for people *in the midst of an acute episode of psychosis*. ... there are people who desperately do need medication and do terribly without it.... So I heartily support Bob's [Whitaker's] crusade against over-medication when it is inappropriate, but worry that it can be harmful when extended to those who really do need medication to stabilize symptoms that will otherwise get them into prison or on the street. [15, my emphasis]

It is noteworthy that the one kind of drug whose use remains important for Frances is antipsychotic medication, the kind for which he created the Johnson & Johnson campaign.

The December 2014 issue of *Lancet Psychiatry* carries a piece by Frances[33] that includes many strong assertions supporting use of psychiatric drugs. He makes no mention still of his previous dealings with Johnson & Johnson. He states that the *DSM* has "lent itself to pharmaceutical company disease-mongering"; that "Big Pharma has also had a large role in the promotion and profiting from biological reductionism, with the misleading marketing ploy that symptoms result from a chemical imbalance that requires a chemical solution"; and that, along with housing and social support, for example, drugs are "essential ingredients for a flexible and responsive treatment system". He then warns that one must not deny the need for drugs, "even for those who most obviously need it [sic]".[33] He asserts in addition that "Mental health disorders are clearly associated with very complex and perhaps undecipherable genetics," a claim often used to promote the notion that individuals who suffer emotionally must have physiological/chemical imbalances that justify the use of psychotropic drugs. He also claims that *DSM-III* improved reliability and consistency of diagnosis. Though incorrect [34], this claim about reliability and consistency is relevant because of the use of the medical model embodied by *DSM* to justify the prescription of psychiatric medications. Remarkably, despite the *Lancet's* policy regarding the mandatory disclosure of conflicts of interests, Frances writes after his one-line biography, "I declare no competing interests." [33] Conflicts of interest of the kind documented in the Rothman Report therefore remain obscured.

As recently as January 12, 2015 in a blog post called "The crisis of confidence in medical research," Frances warns of the dangers of drug companies' misrepresentation of scientific findings and of their high-powered marketing and concealment of harm:

It's been many years since I have trusted anything I read in a medical or psychiatric journal. ...findings never seem to replicate; benefits are hyped; harms are hidden. Drug companies bear most of the blame -- the research they sponsor is shoddy and market driven. Scientists are also to blame when they torture data so much it will confess to anything. Medical journals are to blame when they publish positive findings from lousy studies and reject negative results from well done studies.... The only responsible courses of action are to improve designs and measures, standardize implementation, change sponsors, achieve complete transparency, report harms as thoroughly as benefits, and eliminate hype.... But it is clearly allowing the fox to guard the henhouse to give drug companies the franchise in conducting the studies that lead to the regulatory approval of their products. The huge financial rewards will inevitably lead to badly biased implementation that cannot be adequately corrected even if there is complete after the fact transparency. [35]

A start on prevention of harm

Psychiatric diagnosis is completely unregulated.[9,36-38] No one other than the APA controls what goes into the *DSM*, and no one has held them accountable for their claims that it is scientific, helpful, and not harmful. This allows for the opacity of enterprises involving the use of diagnoses in ways that are both unscientific and unethical and that often lead to harming the very people who have turned to the mental health system for help. Essential solutions include:

- Legislative bodies' hearings about psychiatric diagnosis, to provide a respected forum where those harmed by diagnosis can testify about it, and legislators can begin to explore ways to establish regulation of creation and use of these labels.
- Creation of entities to oversee and regulate the creation and application of psychiatric labels, including blackbox warnings on all publications and other products involving psychiatric diagnoses; [36-38]
- Establishment of entities charged with systematically soliciting, collecting, and publishing information about harm from diagnosis; and
- Establishment of entities given the mandate of ensuring that restitution is made for financial and other kinds of losses impelled by psychiatric labels. [12,37,38]

Attempts were made, via the filing of complaints by those harmed by psychiatric diagnosis, to persuade the American Psychiatric Association's Ethics Committee and the United States Department of Health and Human Services' Civil Rights section to do any of the above. The complaints were summarily dismissed with no attention to their merits. [36-38]

Current biographical information

Rothman is a specialist in medical ethics and the Bernard Schoenberg Professor of Social Medicine at Columbia College of Physicians and Surgeons, the medical school of Columbia University. He is also director of the Center for the Study of Science and Medicine at Columbia and at the time of writing his expert witness report was president of the Institute on Medicine as a Profession.[39]

Currently, Frances is Professor Emeritus at Duke University [40]. Docherty is Adjunct Professor of Psychiatry on staff at Cornell Weill Medical College.[41] Kahn is the Diane Goldman Kemper Family Clinical Professor of Psychiatry Emeritus, Columbia University Medical Center; and attending psychiatrist, New York Presbyterian Hospital.[42]

Timeline

1988: Allen Frances is appointed head of American Psychiatric Association's Task Force to prepare *DSM-IV*.

1994: *DSM-IV* is published.

1995: TMAP is created.

1995: Allen Frances on behalf of himself and his colleagues John P. Docherty and David A. Kahn informs Janssen Pharmaceuticals that in return for \$450,000, they will create Practice Guidelines to treat Schizophrenia, specifying that atypical antipsychotic drugs are superior to earlier antipsychotics and that of the atypicals, Risperdal is the drug of choice. Janssen pays them this sum and an extra \$65,000 for producing those Guidelines quickly. Risperdal has not been approved by the FDA to treat Schizophrenia.

1996: Allen Frances informs Janssen that he, Docherty, and Kahn have constituted themselves as Expert Knowledge Systems and for an additional \$428,000 from Janssen creates "multi-arena plan" to market the Guidelines.

1996-present: Multi-arena plan includes articles ghostwritten by Janssen that expand use of Risperdal, including for distractibility or Attention Deficit Hyperactivity Disorder (ADHD), Autism, and Bipolar Disorder in children, as well as a host of other indications, such as agitation, disruptive behavior, insomnia, and below average IQ. Many people suffer from negative effects of Risperdal.

2000: *DSM-IV-TR* is published with minor changes from *DSM-IV*.

2009: Frances begins to critique editors of in-preparation *DSM-5*, warning that it is unscientific and will cause harm, especially by facilitating heavy marketing of psychiatric

drugs by Pharma. His critique frequently includes explicit contrasting of the *DSM-5* work with his work on *DSM-IV*, which he repeatedly describes as scrupulously scientific.

2009-present: Frances continues his critique of *DSM-5* and representation of *DSM-IV* as scientific. He frequently acknowledges three "epidemics of diagnosis" caused by *DSM-IV* – Attention Deficit Hyperactivity Disorder (ADHD), Autism, and Bipolar Disorder in Children, but he denies responsibility for these and attributes much of the blame to Pharma.

2010: Ethics expert David Rothman writes expert witness report, concluding on the basis of internal documents from Janssen that there have been serious conflicts of interest.

2011-2014: The names of Frances, Docherty, and Kahn are not mentioned in five articles in major media about the Rothman Report – Houston Press, December 14 2011; Businessweek, January 18 2012; Bloomberg.com, April 12 and June 11 2012; and Denver Post, April 14 2014 – although one major blogger, Vera Sharav, named the three on June 15 2011 in her essay about the report.

September 2, 2014: On "The Doctors" television show, Frances makes statements warning the public about the harm that he and EKS specifically impelled, but he does not mention his involvement with J & J that led, and continues to lead, to that harm.

October 24, 2014: At the Mad In America Film Festival in Massachusetts, Frances again neglects to reveal the work he did with J & J, while he expresses alarm about misuse of psychiatric diagnosis and about the "startling" overmedicating of children and the elderly. He specifically names antipsychotic drugs and blames both drug companies for providing misinformation and misuse of psychiatric diagnosis.

November 14, 2014: Frances gives an invited address titled "Where Ethics Meets Practice in Psychiatric Diagnosis and Treatment" in Culver City, CA, at International Society for Ethical Psychology and Psychiatry conference. The abstract in the conference announcement includes that "Psychiatric diagnosis can be...extremely harmful when done exuberantly and carelessly," that "'Mental disorders' are no more and no less than constructs...fallible and subjective," and that diagnosis can be misused under "pressure of well-financed drug company propaganda that mental disorders...require a pill solution". His presentation is filled with warnings about the fallibility and harm caused by psychiatric diagnosis, the way the diagnoses lead to prescription of psychiatric drugs,

and Pharma's hard-selling of their drugs through misleading the public.

December 2014: In a *Madinamerica.com* article, Frances cites Pharma for its intense and misleading marketing but strongly asserts the usefulness of antipsychotic drugs in particular. The same month, in a *Lancet Psychiatry* article, Frances makes strong statements supporting the use of psychiatric drugs even while attacking Pharma for using psychiatric diagnosis for purposes of "disease mongering". He declares that he has no competing interests.

Notes

^aIn Caplan P J. Response to the *DSM* wizard. *Canadian Psychology*, 32(2), 1991, 174-175, I had compared Allen Frances and his colleagues to the Wizard of Oz, because when the lack of scientific foundation of the *DSM* and the harm often caused by psychiatric diagnoses were pointed out, their defense was to claim that critics did not know what they were seeing.

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