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Marketing Crazy

By Clare Blumer
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An update of the manual doctors use to diagnose mental illness has critics fearing a bonanza of over-medication.

Dr Allen Frances is a man with regrets.

The man the *New York Times* once described (http://www.nytimes.com/1994/04/19/science/scientist-at-work-allen-j-frances-revamping-psychiatrists-bible.html?pagewanted=all&src=pm) as "the most powerful psychiatrist in America" is at the career point where others would retire and board a cruise, to endlessly sail the Caribbean. But Frances can't stop now. His legacy in the field of mental health is something he's trying both to destroy and to resurrect.

Twenty years ago he chaired the task force of mental-health clinicians and academics who wrote the fourth version of what's often called the bible of mental health — that is, the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-IV). It's compiled and distributed by the American Psychiatric Association and it basically determines which symptoms equate to a mental disorder.

Now, with the fifth edition to be released on May 22 — at a mammoth four-day 'meeting' keynoted by none other than President Bill Clinton — Frances is doing everything he can to undermine the manual's contents.

Drafts have been circulated and tested for a a couple of years, but even before the formal launch of *DSM-5*, Frances had written two books criticising its content: *Essentials of Psychiatric Diagnosis: Responding to the Challenge of DSM-5*; and *Saving Normal: An Insider's Revolt Against Out-of-Control Psychiatric Diagnosis, DSM-5, Big Pharma, and the Medicalization of Ordinary Life* which was released this week). This is despite the fact that *DSM-5* still contains the legacy of his own work on *DSM-IV*. (The publishers dropped the Roman numerals.)

So why such a change of heart?

"Not a change of heart — change of the world," he says in an interview with *The Global Mail*. Frances is concerned about the rapid inflation in mental-health diagnoses over the past 35 years. He feels the ups and downs of everyday life are being turned into medical disorders, and he knows from experience that the diagnostic manual can exaggerate that effect, with the result that a disorder label will be attached to more and more people with even mild symptoms.

“We tried to be very conservative,” he says, of the work he and his colleagues did in setting the psychiatric parameters of the previous manual. “We added only two diagnoses — out of the 94 that were suggested — but the changes we made both resulted in big fads.”

The ‘fads’ generated by the additions made in *DSM-IV* are for diagnosis of bipolar II disorder and Asperger’s syndrome.

Frances and his task force thought that including Asperger’s in the *DSM* would see rates of autism diagnosis increase by three or four times. Instead, he says, “the rate of autism has increased by almost 40 times in the last 20 years”.

“And similarly, there was a small change in Attention Deficit Disorder,” Frances says, but “there's been an enormous increase in the use of medication and the diagnoses of ADD that’s really not called for.”

Mental disorders new to the *DSM-5* include hoarding disorder, binge eating, internet use gaming disorder and ‘Somatic symptoms disorder’ (defined as excessively worrying about a medical condition).

“Pretty soon everyone's going to have a mental disorder or two or three, and it's time we reconsider how we want to define this and whether the definitions should be in the hands of the drug companies, which is very much what's happened in recent years,” Frances told *Mother Jones* (http://www.motherjones.com/politics/2013/05/psychiatry-allen-frances-saving-normal-dsm-5-controversy).

Though drug companies are not involved in compiling the DSM, they pounce on any potential to sell pharmaceutical solutions to people with the illnesses defined, he says. Insurance companies and school districts rely on it. Again, he is referencing his own long experience in this field.

Dr Melissa Raven has just completed a PhD analysing (http://ro.uow.edu.au/theses/3686/) depression and use of antidepressants among Australians, and she too has been critical (http://lib.bioinfo.pl/pmid:22833879) of the formulation of the *DSM-5*.

She argues that the field-testing of the criteria for the latest edition wasn’t done in consultation with primary-care physicians, or what Australians call general practitioners (GPs). Frances agrees, noting that in the United States, primary-care doctors now prescribe 80 per cent of psychiatric medication; they are at the front line of psychiatric care, and drug companies market heavily to them.

Says Raven: “Here in Australia there are not a lot of psychiatrists to go round, and there are a very large number of people who have a mental problem, but who will never, ever see a psychiatrist.

“People see their GP, get put on an antidepressant — or increasingly these days, an antipsychotic.”

The book is designed for specialists. So the fact that these GP doctors are largely left out of creating the psychiatric user manual is, for Raven, “the overriding flaw of the *DSM-5*”.

So what impact does this book, produced and published by an American association, have in Australia?

One of the few Australians who worked on the *DSM-5* is Professor Perminder Sachdev, UNSW Professor of Neuropsychiatry. While he acknowledges the DSMs have their critics, he says for better or worse the manuals have become the standard for psychiatric diagnosis worldwide.

“The clamour of these critics is getting louder,” says Sachdev. But, he adds, “for the foreseeable future we will use the *DSM-5* while we continue to complain about it.”

Its influence can be seen in the legacy of past *DSM* manuals — and how diagnostic additions were applied in Australia — although the direct impact is hard to gauge.

The Global Mail’s database (http://pharma.theglobalmail.org) of education events held by pharmaceutical companies shows that mental health is the second most targeted area — after heart disease — of industry-funded education in Australia.

More than 16,000 events were held over the six years for which mental health content was included in the data, and pharma spent $37 million on these functions.

Some 1,050 events included education on bipolar disorder, and a number of these differentiated between bipolar I and bipolar II.

Eli Lilly held the most events, with 434 targeting bipolar disorder at a cost of $1.3 million. Lilly sells antipsychotic Zyprexa (olanzapine), which was the seventh most expensive drug on the Australian Pharmaceutical Benefits Scheme (PBS) in FY12.

Psychopharmacologist and Sydney University Professor Dr Iain McGregor confirms that there has been a marked increase in antidepressant use and atypical antipsychotic use showing up on the PBS — Australia’s taxpayer-funded medical bill.

McGregor and a team of researchers recently investigated (http://sydney.edu.au/news/84.html?newsstoryid=10549) the growth in use of

psychotropics (drugs used to treat mental illnesses) over the period 2000 to 2011.

He says, “It’s the first comprehensive analysis of every single prescription [of every] psychotropic drug that’s [been] available in Australia for the last 12 years.

“There were a few things that astonished us. The first was the overall rise in [use of psychotropic drugs], as the paper points out: There’s a near 60 per cent rise over the last 12 years, at a time when the population only rose by 13 per cent or thereabouts.

“Then if you look at the graph of antidepressants, it’s a straight line heading for the sky. It’s an unbelievable increase in utilisation, and more than a doubling over the period that we studied.”

McGregor says that his team had reason to think the increase should have been lower because in 2006, Australia’s Howard government introduced a program that enabled GPs to refer their patients to psychologists.

“We foolishly thought that that would be a non-medication alternative that a lot of people would use and you might see less antidepressant utilisation. But in fact what happens is most psychologists see patients who are already medicated when they arrive.

“I think maybe the threshold for getting an antidepressant has got too low. That’s certainly what we can conclude — that doctors may be a little too trigger happy or prescription-pad happy when people walk in with mild to moderate depression.”

Some of the greatest increases McGregor and his team found were in the uptake of antipsychotics, which doubled in the decade 2000-2011. These are the heavy-duty drugs that are used to treat schizophrenia and other psychosis-inducing disorders. They are now prescribed, in smaller doses, to treat ‘treatment-resistant depression’ — that is, in cases where stand-alone antidepressants aren’t working — and to treat bipolar disorder (they are usually also prescribed alongside an antidepressant).

Frances says rises in use may be directly linked to the broadened definition of bipolar disorder in the manual he authored, and the way pharmaceutical companies use this definition in their advertising to doctors and the public in the US and in New Zealand (countries in which advertising to non-doctors is permitted).

“We were trying to protect patients from the risk of [being unnecessarily prescribed] antidepressants,” he told *The Global Mail*.

While working on the fourth edition of the *DSM*, doctors found that for some patients, taking antidepressants triggered bipolar symptoms. “We [added bipolar II] to protect people from becoming bipolar because they were on antidepressants,” Frances explains.

“It made a great deal of sense at the time. However the drug companies seized on it and they began an advertising campaign that convinced patients and doctors that almost everyone who had a mood disorder was bipolar. The rates of bipolar doubled, because people were mislabeled.

“But because the drug companies advertised bipolar disorder in a very misleading way, many people thought they had bipolar disorder who didn’t.”

The addition of bipolar II to the *DSM-IV* has become a great regret for Frances, because he says it has been a major contributor to the increase in sales of antipsychotics worldwide — an effect opposite to what the task force intended.

Dr Gary Greenberg, a Connecticut-based psychotherapist, also felt compelled to speak out against the misuse of the diagnostic manual; to that end, he wrote (http://scribepublications.com.au/promotions/the-book-of-woe/)*The Book of Woe: The DSM and the Unmaking of Psychiatry*.

“I can remember when this happened in my practice: there were these people that were coming in and they seemed depressed and a little anxious, sort of your typical walking-wounded person, and they’d tell me they had a diagnosis of bipolar,” says Greenberg.

“The treatment was suddenly a so-called ‘low dose’ of Abilify or Zyprexa, and I’m thinking, ‘What in the world is going on out there? Those are really powerful drugs that you’re giving these people.’

“So that’s what happened. The threshold, not only clinically but also societally, for considering yourself bipolar and taking antipsychotic drugs, lowered, in the same way that it had 10 years previously lowered for taking antidepressants.”

“It’s like advertising toothpaste,” says Dr Greenberg.

“You convince people that, ‘You have tooth decay’, and then you tell people that you have the solution to their problem. And the fact that it’s happening everywhere, including countries where it isn’t advertised, is because you don’t really have to advertise to the consumers, you can advertise to the doctors.”

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Raven says that this has also happened in Australia. “There is a strong push often to augment an antidepressant with an antipsychotic,” says Raven. “It's not even that they [doctors] stop the antidepressant, it’s that they add an antipsychotic to it, which is just so scary to me.”

AN ARTICLE IN the journal *PLOS Medicine* (http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001403#abstract1), published in March 2013, concluded that antipsychotics did relieve symptoms of depression, but that “clinicians should interpret these findings cautiously” because other aspects of patients’ lives could be negatively impacted — for example, through considerable weight-gain and life-threatening diabetes.

One of the authors of the meta-analysis behind the *PLOS Medicine* article, Californian psychiatrist Dr Nicholas Rosenlicht, says he and his peers initiated the study because they’d been concerned about how little the antipsychotic drugs seemed to help depression in their patients. “They’re associated with major side-effects and health problems, so the cost-benefit-ratio is very poor for them. I think many modern practitioners aren’t aware of that.”

Although direct marketing of prescription pharmaceuticals to consumers is not permitted in Australia, Rosenlicht says pharma-company marketers frequently use other tactics to influence their target market. For example, by holding education events for doctors, and funding legal websites providing information about disorders that directly target consumers, they can seek to expand the parameters for diagnosing an illness.

He says the websites, funded by the pharmaceutical industry, “will publish articles about a disease and they’ll include a little test about whether you might have it, and they’ll have links to a pharma company’s website”.

Rosenlicht is talking generally about a world trend in propagating disease awareness, but you don’t have to look hard to find a specific Australian example.

Eli Lilly is manufacturer of antipsychotic drug Zyprexa, which, as mentioned above, is the seventh most expensive drug on the PBS and cost the federal government $160 million over the past financial year. (Zyprexa went off-patent in October 2012 and there are now generic olanzapine products available.)

Eli Lilly sponsors the website www.bipolar.com.au (http://www.bipolar.com.au), which targets an Australian audience. On this website, you can answer a questionnaire designed to assess whether you may be suffering bipolar disorder. The caveat expressed at the bottom of each page of the questionnaire says: “This instrument is designed for screening purposes only and is not to be used as a diagnostic tool.”

Sixteen of the questions begin with: “Has there ever been a period of time when you were not your usual self and …”. The end of the question could then be: “… you were more talkative or spoke much faster than usual?”; or, “… you were much more interested in sex than usual?”.

If you tick enough of the “Yes” boxes, you get this response: “You answered 'yes' to a significant number of these questions. You should discuss the possibility of Bipolar Disorder with your GP or mental-health professional. Please print this page out and take it with you to your appointment. There is also a possibility that you may have been misdiagnosed in the past. Misdiagnosis is not uncommon.”

“People get primed by these questionnaires,” says Rosenlicht.

“People get excited by thinking they’ve found a solution to their unhappiness, and they’ll come in and say ‘I’ve read about this, this sounds like me, I’ve had this.’

“That’s how we diagnose, and they’ve [consumers have] been primed to give us the answers that will drive us in that direction.”

Lilly’s bipolar.com.au website is within the advertising rules set out by the self-regulatory schemes of the peak pharma body Medicines Australia and the national Therapeutic Goods Administration. The website contains no references to any of Lilly’s drugs, just a small, hyperlinked Lilly logo tucked in the bottom right-hand corner of the predominantly purple site.

The Global Mail database shows Lilly held 199 events to inform doctors about Zyprexa’s various incarnations (injection, wafer, pill).

However, this is not the whole story as our database is missing 18 months of records for Eli Lilly Australia. The company's particularly large PDF files would not convert easily into the database and when asked to provide them to us in spreadsheet form, which would have allowed us to expedite the process, the company declined. We therefore have an incomplete picture of Eli Lilly's marketing activities in Australia.

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>
> ***– DR MELISSA RAVEN***

Lilly's American marketing operations were laid bare in a 2009 court settlement with the US government, over criminal and civil charges that the company had been engaged in illegal 'off-label' marketing of Zyprexa for dementia and Alzheimer's patients between 1999 and 2003.

The allegations were that Eli Lilly "targeted its illegal marketing of Zyprexa to two types of doctors: those who treat the elderly in nursing homes and assisted living facilities, and primary care physicians.

"In September 1999, Eli Lilly began encouraging doctors to prescribe the drug for the treatment of dementia, Alzheimer's, agitation, aggression, hostility, depression, and generalized sleep disorder. Zyprexa was not approved for use for any of these disorders," according to the Department of Justice statement (http://www.justice.gov/usao/pae/News/Pr/2009/jan/lillyrelease.pdf) about the settlement, which added that Lilly's "marketing campaign raised safety issues and posed potential risk to patients".

Zyprexa had been approved by the US Food and Drug Administration for treating schizophrenia and bipolar disorder, but not for the afflictions of the elderly. Eli Lilly paid US$1.4 billion for the transgression as part of its plea agreement.

This dollar figure includes the "largest criminal fine for an individual corporation ever imposed in a United States criminal prosecution of any kind", according to the Justice statement.

Lilly chief executive John C. Lechleiter told the *New York Times* (http://www.nytimes.com/2010/10/03/business/03psych.html?pagewanted=4&_r=2&src=twt&twt=nytimeshealth) in 2010 that the company had taken steps to ensure such illegal marketing would not happen again. Lilly "put measures in place to assure that not only do we have the right intentions in integrity and compliance but we have systems in place to support that".

Eli Lilly's Australia corporate affairs manager has yet to provide responses to questions submitted in writing on May 13.

"MOST DOCTORS GO INTO DOCTORING because they really want to help people," says *Book of Woe* author Greenberg.

He taps into the common theme that every psychiatrist, psychopharmacologist, psychologist, academic and GP cited when interviewed by *The Global Mail:* Doctors want to help patients and cure their ills.

"When they hear that there's this way that they might be able to help somebody — particularly a doc who doesn't have a whole lot of time to spend with people, who doesn't believe in psychotherapy, who wants to solve the problem himself, whatever it is. The doctor 'gets educated' (in quotes) by a drug rep and he's happy to prescribe Zyprexa or whatever. They're happy to do it."

Greenberg doesn't think that more people will be diagnosed with mental illness as a result of the changes published in the *DSM-5*, but rather that diagnoses will be "reapportioned" by these changes — that is, many people will be shifted from one diagnosis to another.

Frances also hasn't rejected everything to do with the diagnoses that he helped foster in the latter part of the 20th century.

"Psychiatric diagnosis is a key point in a person's life. Done well, it can lead to wonderful things in the future. Done poorly it can be very harmful," he says.

And he says he's certainly learned from his mistakes: "I discovered, even if you're conservative and you make really small changes, you can have enormous impacts well beyond what you anticipated. That once the words are written, you don't get to control how they're used."

Having publicly expressed and published his concerns, Frances' dissenting voice won't be singing a desultory tune at the launch of the *DSM-5* in San Francisco this week. He won't attend at all.

He notes that when the *DSM-IV* was released 20 years ago, it was done very quietly, and certainly no former Presidents were there to add cachet to the event.

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16 COMMENTS ON THIS STORY

by John

@Teek: Somatic Symptom Disorder is the renamed Somatization Disorder from DSM-IV, and also incorporates the DSM-IV Pain Disorder.

May 28, 2013 @ 6:36pm

by John

DSM-5 was available on Saturday 18 May, and was not launched by Bill Clinton. Clinton was scheduled to give the keynote address to the American Psychiatric Association conference in San Francisco on Sunday 19 May; he didn't do so due to illness, giving it by videolink instead.

The American Psychiatric Association has a tradition of getting a prominent speaker to give its keynote address. In 2011, Nelson Mandela gave the keynote address in Honolulu. (In 2012, it was Carrie Fischer - I guess you can't win them all...)

The publication of DSM-5 has been a very different affair to that of DSM-IV in 1994. Technological advances have allowed publication of the proposed criteria online for much of 2011 and 2012, for public comment. The pre-publication of proposed changes generated a lot more controversy and public debate, especially in the US, where treatment eligibility is far more dependent on DSM diagnostic criteria than in other countries. (It should be noted, however, that the official diagnostic system for psychiatric disorders in the US and Australia is actually the International Classification of Diseases, which is published by the World Health Organisation, and not the DSM-5.)

May 29, 2013 @ 7:17pm

by John

Correction: The speaker at the 2011 APA conference was Archbishop Desmond Tutu, not Nelson Mandela.

May 30, 2013 @ 7:18am