Meet the Doctor Big Pharma Can't Shut Up

The pharmaceutical industry has compromised the Western medical establishment and hooked America on drugs. One psychiatrist is fighting back.

May 30, 2013 | Alternet, by Tamara Straus

For the last 33 years, David Healy, an Irish psychiatrist and professor at Cardiff University School of Medicine in Wales, has written heavily researched university press books and academic journal articles on various aspects of psycho-pharmaceuticals. His output includes 20 books, 150 peer-reviewed papers and 200 other published works. He is not only well-pedigreed, with degrees and fellowships from Dublin, Galway and Cambridge medical schools, he is a widely recognized expert in both the history and the science of neurochemistry and psychopharmacology.

Yet Healy says his output and reputation have had little to no effect—both on the pharmaceutical industry he argues buries relevant information about prescription drug harms, and on the psychiatric and medical professions he claims are being "eclipsed" by drug companies.

"It's been clear to me that writing books or articles banging on the risks and hazards of drugs is just going to increase the sale of drugs," said Healy, who speaks calmly, dresses mostly in black and looks a bit like Rod Serling.

Rather than write another university publication, Healy has taken his frustration to the street. In November, he launched a nonprofit website called Rxisk.org with a group of like-minded and highly credentialed international colleagues. The site aggregates FDA data about prescription drug side effects and urges patients to submit a detailed report on their own pharmaceutical drug reactions.

Healy is not the first psychiatrist to express boiling frustration with the pharmaceutical industry or to pen dire warnings about drug-based healthcare. He is joined by people like American psychiatrist Peter Breggin, who has written several books critical of "biological psychiatry," and Irving Kirsch, who directs the Program in Placebo Studies at Harvard Medical School/Beth Israel Deaconess Medical School and is best known for *The Emperor's New Drugs: Exploding the Antidepressant Myth*. Healy is the author of such dire sounding titles as *Pharmageddon* and *Let Them Eat Prozac: The Unhealthy Relationship Between the Pharmaceutical Industry and Depression*.

For years, it was fairly easy for people in the pharmaceutical and medical industries to label Healy, Kirsch and Breggin as alarmists. But two summers ago, one of the most prominent members of U.S. medical establishment, Marcia Angell, former editor-in-chief of *New England Journal of Medicine*, published an article damning the over-prescription of psychoactive drugs. In two essays in the June 23, 2011 and July 14, 2011 *New York Review of Books*, Angell backed arguments by the university clinician Kirsh, the mental heath journalist Robert Whitaker, and Boston psychiatrist Daniel Carlat that there is something extremely suspicious about the following trends: the number of people treated for depression has tripled since the launch of Prozac in 1987; 10 percent of Americans over age six are taking antidepressants; and 30 antipsychotics like Risperdal, Zyprexa and Seroquel are replacing cholesterol-lowering agents as the top-selling class of drugs in the U.S., largely because they are being prescribed to children.

Angell's articles should have been a bomb on the medical establishment. She wrote: "The industry-sponsored studies usually cited to support psychoactive drugs—and they are the ones that are selectively published—tend to be short-term, designed to favor the drug, and show benefits so small that they are unlikely to outweigh the long-term harms. … Both the pharmaceutical industry and the psychiatry profession have strong financial interests in convincing the public that drug treatment is safe and the most effective treatment for mental illnesses, and they also have an interest in expanding the definitions of mental illness."

But like Healy, Angell's warnings have fallen on deaf ears. Recent data indicates that U.S. prescription drug use is growing. The September 2012 Consumer Reports National Research Center report found that among the 46 percent of American adults taking prescription drugs, a fourth of those ages 18 to 39 regularly take two prescription drugs, indicating that multiple drug use is no longer confined to older Americans. Congressional testimony in 2012 by the American Society of Interventional Pain Physicians revealed that Americans consume 80 percent of opiate painkillers produced in the world. And a January 2011 report from Stanford University Medical School warned that antispychotics are now regularly being prescribed to treat conditions for which

they have not been approved, including anxiety, attention-deficit disorder, sleep difficulties, behavioral problems in toddlers and dementia.

According to a Feb. 7, 2013 report from Drugs.com, the No. 1 best-selling U.S. drug (in dollar volume) is an atypical antipsychotic for schizophrenia treatment called Abilify. Sales for the last quarter of 2012 soared to $1.5 billion, because Abilify is widely prescribed off-label—i.e., not for schizophrenia in adults, but, for example, for irritability in children. Although Bristol-Myers Squibb, the maker of Abilify, was fined $515 million in September 2007 for recommending off-label uses of Abilify, doctors are still doling out the drug. Why?

"The reason for the increase in prescription drug use is that the entire Western medical complex is run by pharmaceutical companies," said a Stanford University professor of medicine who preferred to remain anonymous (and who was not involved in the 2011 report on antipsychotics). "The medical training you get in Western medical schools is largely about learning which drugs to treat which diseases." She added: "You would think that recent studies, such as the one that said antidepressants are no more helpful than a placebo, would have an effect. But they haven't." Other university psychiatrists and medical doctors I contacted for this article either wouldn't talk on the record or didn't want to be interviewed, confirming an atmosphere Healy describes as "McCarthyist." "There is a climate of fear," he said during our interview. "You find that they are very nervous about saying anything about drug treatments or adverse effects of drugs at all. Doctors keep patients on lots of drugs, even if they are uncomfortable with it. And if you ask them why they're doing so, the answer you'll get is: 'Well, this is the standard of care, and if I don't take care of it this way, I'm going to be in awful trouble.'"

This standard of care is why Rxisk is directed at patients, not doctors, whose financial ties to the pharmaceutical industry are well documented. Rxisk allows users to enter into its search engine the name of a prescription drug and to see the side effects that have been reported to the FDA's MedWatch website since 2004 as well as from Rxisk's international data base, for more than 35,000 drug names from 103 countries, totaling 4.5 million adverse drug event reports. The site has information "zones for sex, violence, hair, skin, and withdrawal, designed to increase awareness of seldom-publicized drug effects. Rxisk.org also allows users to add their own reports of adverse drug reactions, creating their own "Rxisk report" to share with their doctor or pharmacist. Since November 2012, the website has collected 1,500 reports.

One could argue that Rxisk is doing the same thing as MedWatch, the FDA's online gateway for "reporting serious problems with human medical products." But Kalman Applbaum, a Rxisk founder and professor of medical anthropology and global studies at the University of Wisconsin, argues that MedWatch isn't for patients—especially those "trying to sort out whether it's the drug or the illness that's causing the suffering."

“We felt there were a number of things that were lacking on most or all of the FDA sites that collect information about drug side-effects,” said Applbaum. “First, there’s a reliance on doctor reporting, and doctors report very little, very infrequently—and this is true all over the world for a variety of reasons. And what they report is extremely slim. Very common is a single word to describe a side effect, such as hypertension, ataxia, etc.” Meanwhile, said Applbaum, research shows that patients are much more motivated to report than doctors. And more importantly, “their reported data is very high quality data, because they spend a lot of time,” said Applbaum.

Since the November 2012 launch, Rxisk has received only 10,000 visitors per month. But Healy, Applbaum and the other founders, like Nancy Olivieri, a senior scientist at Toronto General Hospital and University of Toronto Professor of Pediatrics, Medicine, and Public Health Sciences, are not particularly concerned and plan to ramp up and market their efforts slowly. “We’re doing something that’s new and it’s probably going to take awhile for people to cotton on to what’s new about it,” said Healy.

David Healy does not consider himself a radical. He prescribes antidepressants and other prescription drugs to his patients. He runs a national university school of psychological medicine. “I’m fairly conservative. I’m a very mainstream doctor, really,” he said. But as *New York Times* reporter Benedict Carey pointed out in a 2005 story, the Irishman living on an island off the coast of Wales “has achieved a rare kind of scientific celebrity: he is internationally known as a scholar and pariah.”

Healy’s status as an outcast arises from his grave concern that blockbuster drugs like Prozac and other antidepressants can lead to suicide, murder and unforeseen mental health problems. In the 1990s, he began to publish academic journal papers providing evidence that antidepressants could increase the risk of suicide. Although many colleagues denied the link, by 2004 American and British drug regulators issued strong warnings supporting Healy’s and other’s claims. This was vindication for Healy. But it did not prevent him from losing in 2001 a job offer to direct the Center for Addiction and Mental Health in the University of Toronto’s Department of Psychiatry. There is an entire website devoted to Healy’s travail, what’s known as the “Toronto Affair.” The assembled documents—a lecture by Healy, email exchanges, and Healy’s legal claim against the university (which he won out of court)—form a parable on the limits of academic freedom. They also show how radical Healy’s beliefs are when set against the standards of privately supported research universities.

In a brief, sweeping and somewhat rambling history of psychopharmacology, Healy hit a lot of fly balls. He said that drugs "have played or threaten to play a part in a changing of the social order." He intimated that psychiatric drugs, unlike illegal drugs, are a form of institutional control. In the Nov. 30, 2000 lecture, titled "Psychopharmacology and the Government of the Self," he also made the following statements:

1. "…The era of Depression that we have lived through in the 1990s in the West has arguably been a politically and economically constructed era that bears little relationship to any clinical facts. An era that has changed popular culture by replacing a psychobabble of Freudian terms with a new biobabble about low serotonin levels and the like."
2. "…Both psychiatry and anti-psychiatry were swept away and replaced by a new corporate psychiatry. [John Kenneth] Galbraith has argued we no longer have free markets; corporations work out what they have to sell and then prepare the market so that we will want those products. It works for cars, oil, and everything else, why would it not work for psychiatry? Prescription-only status makes the psychiatric market easier than almost any other market—a comparatively few hearts and minds need to be won."
3. "…The best-selling drugs in modern medicine do something similar—they don't treat disease. They manage risks. This is clearly true of the anti-hypertensives, the lipid-lowering agents and other drugs. It is true also of antidepressants, which have been sold on the back of efforts to reduce risks of suicide. We are in an era, which is popularly portrayed as an "Evidence Based Medicine" era. What can go wrong if we have clinical trial evidence to demonstrate what works and what doesn't work, if we but adhere to this evidence. What more can we do than that?"

What's amazing about Healy's lecture is that he thought he could deliver it and still work at a university psychiatry department. According to the UK *Guardian*, the Center for Addiction and Mental Health has received more than $1.5 million in recent years from Eli Lilly, the manufacturers of Prozac. On the other hand, nothing that Healy said in Toronto, he hadn't said before.

In the most comprehensive news article on the Toronto Affair, the *Guardian*'s Sarah Boseley reported that Lilly and Healy had previously "crossed swords" in the U.S. courts: "Dr. Healy has been an expert witness against [Lilly], backing the claims of families who say the drugs have caused people to kill and commit suicide. In June 2001, just six months after his Toronto job was rescinded, a US jury agreed with him that Paxil (Seroxat in the UK), an SSRI manufactured by the British giant GlaxoSmithKline, caused Donald Schell to kill his wife, daughter, granddaughter and himself and awarded the remaining family members £4.2m compensation."

More recently, Healy has tried to draw attention to the connection between the increasing use of antidepressants and antipsychotics and the increasing number of school shootings. On a Jan. 30, 2013 blog and video on Rxisk.org, he claimed that 90 percent of school shooters in North America and Europe were on or withdrawing from meds at the time of the incident. In our interview he pointed to a list on SSRIStories.com, a patient anecdote website that is being integrated into Rxisk, that documents which perpetrators were on which drugs for violent acts in schools between 1988 and 2011.

The only semi-mainstream figure to have paid attention to this claim is filmmaker Michael Moore, who created a video on the subject in 2012, calling for an investigation. Unsurprisingly, there has been no move to look at the correlation, since one could argue that the school shooters are psychologically disturbed and should be on more meds. Indeed, across the country, there is a drive to keep a lookout for students with possible mental health problems and to report those who seem odd.

“The problem is,” says Healy, “that it’s really going to lead to a greater use of pills. The key thing is to make sure that people who get put on them are really going to be helped by them. Once you identify the problem, the pill will be the answer, because it’s the answer for the person who has identified the problem. It may not be the answer for the person who is having to take the pill.”

One of Healy’s main problems these days is that few people listen to him. “I published a list of 98 drugs that can cause you to commit suicide or homicide. I was waiting for the world to come to an end, but nothing happened.” He continued, “If I make a claim and I don’t have scientific proof to back it up, pharmaceuticals are going to sue me.” There have been no lawsuits, which makes Healy think that silence is part of pharmaceutical companies’ tactics. “They’ve learned that the worst thing they can do is argue. If they jump up and down and say, ‘Listen to the foolish things Healy is saying,’ that would be a good way to hear about Healy. So they’re very good at not responding, maintaining their cool.”

All of this sounds rather paranoid, but then again none of the dozen university psychiatrists or drug company scientists I reached out to wanted to talk about Healy or his claims. Neither Eli Lilly nor GlaxoSmithKline could "find time” to respond to my inquiries about Healy and Rxisk. I was permitted, however, to send questions by email to MedWatch, the website that culls adverse reactions to pharmaceuticals run by the FDA. Dr. Lisa Kubaska of the FDA’s press arm, CDER Trade Press, wrote, “Rxisk.org’s efforts to increase awareness of drug/medication associated risk, harm and best practices, along with their message about the value of voluntary reporting may also serve to advance this patient safety goal in parallel with FDA’s work.” But when I

emailed her back, to ask how the FDA works with a pharmaceutical company if it gets multiple reports from patients or doctors about an adverse effect to a drug, I received no answer.

Among David Healy's many concerns about the state of modern medicine is the marginalization of doctors. Doctors, he's said, are like cogs in a machine, spending a minimum of time with patients, doling out drugs pushed by pharmaceutical companies, and wrangling with insurance companies over costs. He argues that one rectification to the sad state of his profession is to abandon "evidence-based medicine" for "data-based medicine." The difference between the two goes to the root of why Healy founded Rxisk.org.

Evidence-based medicine categorizes different types of clinical evidence—such as randomized, triple-blind, and placebo-based control trials—and rates or grades them. Because evidence-based medicine relies on scientific methods that can have wide acceptance among medical practitioners, it has become the standard approach to health services and public health—and is one of the ways nations can arrive at universal healthcare systems.

But Healy and his colleagues at Rxisk argue that evidence-based medicine is flawed because important information ends up being systematically buried or corrupted. In his 2012 book *Pharmageddon*, Healy argues (and provides evidence) that close to 30 percent of the clinical drug trials that have been undertaken remain unreported; and of the 50 percent that have been reported, almost all are ghostwritten by scientists for pharmaceutical companies. Perhaps more frighteningly, Healy reports that roughly 25 percent of published clinical drug trials are statistically altered, to provide evidence that a drug works well and is safe. And in 100 percent of the cases, the data from the trials remain inaccessible to scrutiny. Yet, he writes, 80 percent of the reports on adverse consequences of drug treatment, dismissed as anecdotes, have turned out to be correct. "Given these facts," Healy writes, "it is not reasonable to suggest that the observations of doctors and patients are less reliable than clinical trial evidence."

Healy's push to abandon evidence-based medicine is not at attempt to get rid of randomized, triple-blind and placebo-based control trials, but to show the degree to which these trials are controlled by the pharmaceutical industry. So Rxisk's preference for "data-based medicine" is simply a euphemism. It's a push to expand evidence-based medicine to include full clinical trial transparency and to put anecdotes, specifically from patients, into the wider scientific analysis of drug efficacy.

It seems reasonable. But can it be done?

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Tanya Jensen is a fairly typical middle-aged woman. She is 37 years old, has two little kids, and occasional bouts of mild depression. (To protect her identity, her name has been changed.) When her husband lost his job in 2008 and had trouble finding work, Tanya took on a full-time job with a long commute and a part-time job. Within a few months, she felt frazzled. She began to notice that some of her mom friends, who had their own reasons for feeling frazzled, were taking antidepressants, especially Celexa. So at a checkup with her general practitioner, she inquired whether she could try the drug. Her physician agreed and wrote her a prescription for the generic version of Celexa, citalopram, at 10 mg a day, the lowest dosage, asking Jensen to check in if anything went wrong.

Jensen liked the drug. It made her feel less anxious. But a year later, the Jensens' situation improved and Tanya decided it was time to wean herself from the pills. Jensen said she worried "about being on the drug for the rest of her life, when it was unclear how it could affect her brain or behavior long-term." As recommended by her physician, Jensen cut the dosage to 5 mg a day for 10 days and then to 5 mg a day every other day for the next 10 days. But at the end of the 20-day period, she had withdrawal symptoms: night sweats, emotional volatility, anger, aggression, suicidal impulses. Her husband begged her to go back on citalopram and she did.

A year passed, and Jensen decided she was ready to go off citalopram again. She proceeded with the same reduced dosage regimen and by the end of the 20-day period was, she said, "as close to manic as I hope I'll ever come: full of rage, prone to tantrums, sweating buckets at night, and feeling suicidal, especially while driving." Again her husband begged her to go back on citalopram and she did so.

That's when Jensen started doing Internet research on citalopram and found Rxisk.org. There, she said, she found the best available information on citalopram and other people's withdrawal symptoms, including a long list of adverse side-effects and the percentage of people who had reported them. When Jensen filled out a Rxisk Report, she received a 9+ score, indicating that she had become drug dependent. "This was alarming, but not really surprising," she said.

Per RxISK's recommendation, Jensen made an appointment with her doctor to discuss her problem. Jensen had switched health insurance providers, so she had a new general practitioner, a female MD with a degree from the University of Bombay, whom she chose, "hoping that she would be a less typical American doctor." But Jensen was disappointed. The doctor said, "But you feel less anxious, and your dose is so low. When I fill out a prescription for 10 mg of citalopram, the computer prompts me to up the dose. It actually recommends I prescribe 20 mg, not 10 mg." Jensen asked if she had other recourse, but her doctor waved off her concern. Before leaving the examination room, she handed Jensen a six-month prescription of citalopram. Jensen did get her

doctor's permission to review her Rxisk Report. But Jensen said that since emailing the report on May 10, 2013, she has heard nothing from her doctor.

"What upsets me most," Jensen said, "is that my original doctor never told me about citalopram's very well-documented withdrawal problems. This was just never part of the discussion, either because she didn't have the time or didn't know that stopping citalopram can be very tricky for some people. And what's scary is that when I tried to communicate my problem with the second doctor, I was patted on the head like a child and handed 900 more pills."

Healy is aware that changing doctor's views on pharmaceuticals is a David and Goliath battle. That's why he and his colleagues have another potential audience for Rxisk data: investors and insurance companies. "The shrewd investor in pharma companies wants to know what the adverse effects of a drug are," said Healy. Rxisk is therefore positioning itself to provide data from the trials the companies are most keen to hide. In addition, Rxisk hopes to find clients in HMOs and insurance companies, which are looking for ways to cut drug costs.

"Many of drugs advertised are rigged to look better than previous generations of drugs and are costed sometimes 10, 20, 30, or 40 times higher than the generic drug," Rxisk co-founder Applbaum said. "A bit of research through the data will show that the claims of improvement are false."

Applbaum and Healy also point out that the cost of adverse side-effects to prescription drugs in the U.S. is huge—estimated to be $100 million in hospital costs alone. The same 1998 University of Toronto study they cite found that pharmaceuticals are the country's fourth leading cause of death. Healy and Applbaum point to other galling statistics: the U.S. spends twice as much on healthcare as anyone else in the world, consuming a total of 45 percent of the world's pharmaceuticals. Meanwhile, the World Health Organization ranks the country 37th in the quality of our care.

"So it's killing the economy overall, and the recognition is seeping in that we're doing something wrong," said Applbaum. "We believe that our little piece of it—the over-prescription of drugs, the polypharmacy, the prescribing of drugs when none are needed—can help healthcare costs come down."

Both Applbaum and Healy believe the FDA won't or can't be a force for change. Since the Drug Efficacy Amendments were passed in 1962, requiring drug manufacturers to prove to FDA the effectiveness of their products before marketing them, Healy says drug makers must show, first, that a drug works, and second, that it is safe. "The result has been that the effectiveness

profile has taken over and safety has been lost sight of," said Healy. "At Rxisk, we're trying to restore safety to its due place."

Tamara Straus has served as senior editor of the Stanford Social Innovation Review and a news features editor at the San Francisco Chronicle.