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Disease Mongering in Psychiatry: Is it Fact or Fiction?

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Abstract

Disease mongering is used to refer to the attempts by pharmaceutical companies or others with similar interests, to enlarge the market for a treatment by convincing people that they are sick and need medical intervention. This paper critically analyses the "for" and "against" arguments of disease mongering in psychiatric disorders, both new and old, such as bipolar disorders, attention deficit hyperactivity disorder, restless legs syndrome, premenstrual dysphoric disorder, female sexual dysfunction, social phobia, metabolic syndrome, and road rage disorder.

Keywords: disease mongering, psychiatry, pharmaceutical companies

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If I shop too much, I suffer from compulsive shopping disorder.
If I am shy, I have social phobia.
If I shake my legs while I think, I have restless legs syndrome.
If I am driving too fast to get somewhere, I probably have Road Rage Disorder.
If I am losing hair, I am mostly stressed out and I need anxiolytics.

Introduction

Psychiatry today can be called the "discovery of the decade," with rapid advancements being made each day in understanding the human brain and, consequently, psychiatric disorders. One would only have to take a look at the increasing acceptance by both our professional brethren from other disciplines and the general public to know that this is not an exaggeration. Yet, like all good things, psychiatry comes hand-in-hand with a few negatives. It has been recently plagued with several controversies, such as the ethics of clinical trials, the "discovery" of antipsychotic-induced metabolic syndrome,[1] and of accusations of cosmetic psychopharmacology.[2] Disease mongering starts at the top of the queue here.

Concept

The term "disease mongering" was first described by Lynn Payer in the 1990s[3] and has been subsequently modified to refer to the attempts by pharmaceutical companies or others who have similar interests to enlarge the market for a treatment by convincing people that they are sick and need medical intervention.[4] What this involves is the creation of a so-called "new disease," and then rapid research into it to disseminate information. Taking the labeling theory forward,[5] critics have argued that the problem with these "new diseases" is that the diagnosis of the symptoms could span a broad spectrum of severity—from nonspecific symptoms and everyday experiences to profound suffering. Unfortunately, people associated with the label of being mentally ill consider it to be just as, or even more, stigmatizing than having the illness itself.

One may argue that knowledge about any disease is good as it helps keep the general public in good health by improving awareness and enabling them to take pre-emptive action. Unfortunately, it does another thing, too—it also helps increase the size of the market by blurring the boundaries between health and sickness so that normal experiences get labeled as pathological,

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and by expands the definition of disease to include milder and even presymptomatic forms.[6] This is easily discernible in the patterns of spending of the pharmaceutical industry, which spends more money on marketing and advertising than on research and development.[7]

However, there is another side to this story too. The critics of the concept of disease mongering in turn argue that marketing practices in the pharmaceutical industry are similar to those in other industries[8] and therefore should not be criticized for trying to expand their market, since their marketing policies dictate increasing markets for and maximizing use of their products. They also say that they are only providing the public with information about treatment options for their discomforts and that actual prescription is a matter between patient and doctor. They therefore complain that it is unfair to single them out and label them as "bad." Sometimes, critics have even accused the proponents of disease mongering of being extensions of the organizations which are part of the antipsychiatry movement[9] in an attempt to discredit psychiatric illnesses and psychopharmacology.

Disease Mongering in Psychiatry

Initially, pharmaceutical companies targeted general consumers with "lifestyle drugs" for cosmetic and sexual enhancements,[10–13] such as selling fairness creams, ginseng tablets, etc. These have recently crossed over to selling psychotropic drugs. As most of these drugs have a very wide range of active properties, the interpretation of their "effects" is also used with a great degree of "wideness" by the marketer. For example, one class of antidepressants, specific serotonin reuptake inhibitors (SSRIs), are marketed for eight distinct psychiatric conditions, ranging from social anxiety disorder to obsessive-compulsive disorder to the arguably nonexistent (at least in textbooks) premenstrual dysphoric disorder.

The broad influence of the pharmaceutical industry does not just stop there. This influence now extends to wide domains such as initiating clinical studies or influencing outcomes in research publications, lobbying with governments and regulatory agencies, getting involved in educative programs, and advertising and point-of-use promotion. Pharmaceutical companies are now engaged in direct advertisements to customers whereby they induce patients to become equal partners with industry and reap huge profits.

The developing countries hold particular interest to pharmaceutical companies as they look to expand their businesses and footprints. These regions form major new markets to replace the already saturated (and increasingly skeptical) markets of the West. It is therefore imperative that the negative consequences of disease mongering are quickly realized. Many of life's normal processes like birth, aging, sexuality, unhappiness, and death have been medicalized. Since simply labeling people with disease can have negative consequences,[14] we are now confronted with a situation of every man/woman popping a pill everyday to stay away from illness. It has been called the "medicalisation of our society—the pill for every ill."[15] Yet, one fails to understand if this "panic reaction" is indeed real, or a creation of conspiracy theorists. A critical dissection of the "for" and "against" arguments is therefore essential.

Evidence for Disease Mongering in Bipolar Disorders

Bipolar disorders are one of the most investigated disorders in psychiatry, primarily because there is both an effective treatment and a prevention for them. Naturally, they have also attracted the most attention by proponents of disease mongering. An increasing number of epidemiological surveys have noted an increasing prevalence of bipolar disorders.[16] Whether this reflects an unearthing of hitherto hidden disease or an attempt to "sell" bipolar disorders[16] is not yet clear. The chief criticism in these surveys has been the absence of a clearly defined criterion for disability arising due to the illness and the manufacturing of other bipolar types such as bipolar 1, 2, 2.5, 3, 3.5, 4, 5, and 6, popularly called the "bipolar spectrum disorders."[17] Such an attempt to dilute the concept of bipolar disorders may mean that actual patients may suffer and puts a question mark on the validity of the concept of bipolar disorders. However, contrary to what has been argued by promoters of disease mongering, it is far-fetched to imagine that mania and melancholia, which are the original defining points of bipolar disorder, were also manufactured by Esquirol and Kraepelin.[18]

A similar argument has been made for treatments of bipolar disorders. Claims have been made that "studies over the past twenty years have shown beyond the shadow of doubt that people who receive the appropriate drugs are better off in the long term than those who receive no medicine."[19] However, every clinician involved in the treatment of psychiatric illnesses knows that these are difficult statements to make, especially when the risk-benefit ratio of psychotropic drugs is not that good.[20–23] There is also evidence to show that psychotropic medications have done little to change the prevalence of admissions in bipolar disorders[24] and

that there is a higher rate of suicide in bipolar patients on psychotropic medications than on placebo.[25]

A plethora of websites are being added every day to "educate" patients on bipolar disorders. A simple search on bipolar disorders on Google brings up http://www.bipolarawareness.com/, http://www.bipolarhelpcenter.com/, and http://www.bipolar.about.com/. Websites by health professionals dealing with bipolar illness are few and far between. This attempt to "educate" patients would certainly raise a few eyebrows, since the top websites are sponsored by major pharmaceutical companies. However, it is also a fact that patient education does not always amount to disease mongering. For example, http://www.psycheducation.org is a website that gives information about bipolar disorders, earning it the Moffic Award for Ethical Practice in Community Psychiatry.[26] One would have to conclude that, although not all research is "influenced," it is entirely possible that over-diagnosis is often carried out influenced by the pharmaceutical industry.[18]

Currently, there is serious criticism of the trend of diagnosing bipolar disorders in children. Since there are no established criteria to do so,[27] it is difficult to believe the increasing prevalence from 1% to 32%.[28,29] Today, even everyday behavioral difficulties are now better seen in terms of a disorder, and children as young as 2 years old are being diagnosed with bipolar disorder.[30] The fashion to diagnose bipolar disorders in children has now reached feverish proportions, with even *Time* magazine, in August 2002, featuring 9-year-old Ian Palmer and a cover title called "Young and Bipolar."[16] Although pediatric bipolar disorder is a reality, serious research into this debilitating condition has been unfortunately hampered by statements from some experts who have even gone to the extent of saying that the first signs of bipolar disorder may be patterns of over-activity in utero.[31] Such reactions have prompted modification of the diagnosis of mood disorders in children and creation of a new diagnosis, namely Temper Dysregulation Disorder with Dysphoria in childhood, in the proposed DSM-V.[32]

Evidence against Disease Mongering in Bipolar Disorders

Although most of the criticism of bipolar disorders is unwarranted, there is a need to exercise serious restraint among researchers. Juvenile bipolar disorder has been extensively researched and studied using well-designed methodologies and standard screening instruments. [33] It has also been well established that bipolar illness is a neuropsychiatric condition with its basis in genetics, neurobiology, and neuropsychology.[34–36] Currently, there is

strong evidence available for the use of lithium and valproate across all three phases of bipolar disorder. Anticonvulsants, such as lamotrigine, have strong evidence in maintenance; however, antipsychotics largely have strong evidence in acute mania, with the exception of quetiapine, which has strong evidence in bipolar depression.[37] Although there have been instances when articles have been "ghostwritten" for well-respected medical researchers in prestigious journals,[38] and even where some of them have articles authored by (prominent) people who stand to directly benefit from promoting certain treatment regimens in the articles, such articles are rare. The caveat that accompanies most research in this area is the fact that our basic emotions—love, hate, happiness, sadness, anger, etc.—cannot be medicalized. The other extreme that has been depicted in the movie *Equilibrium*,[39] where all mood fluctuations are controlled by pills, is too horrifying to be even imagined.

Evidence for Disease Mongering in Attention Deficit Hyperactivity Disorder (ADHD)

ADHD is a serious problem afflicting 5.29% of children and adolescents around the world,[40] with persistence of symptoms into adulthood noted to be in the range of 4%–66%.[41] Although there are well-defined diagnostic criteria laid down by both DSM-IV and ICD 10, the danger of over-diagnosis is constantly present and, currently, this runs a close second to bipolar disorders as the most diagnosed condition.

The DSM-IV diagnostic criterion permits teachers to play an important role in diagnosis through the use of specialized assessment instruments such as the Conners Teacher's Rating Scale.[42] In a study of 491 physicians in Washington, DC, almost half of the diagnoses of ADHD in their patients had been suggested first by teachers, an argument advanced by critics that teachers are now "disease-spotters," who engage in disease-spotting.[43] Websites funded by pharma companies are big sources of information, which "educate" teachers on the diagnosis and management of ADHD. Educational programs are also held to publicize ADHD through funding from companies.[43] And advertisements for atmoxetine, the first approved medication for adult ADHD, which suggests that consumers get checked out by their physician, so that "they stay focused and can get things done at work and at home," certainly do not help.[8]

Similar criticism has been leveled at adult ADHD. The biggest criticism has been that ADHD is just a set of normal behavioral variations, with no neurological basis for the same.[44] Unfortunately, there is also a serious dearth of epidemiological research on ADHD.

Evidence against Disease Mongering in ADHD

However, clinicians treating ADHD also know that this is a real condition that impairs and disables people, and people suffering from this condition are thankful they were "diagnosed, treated and had their attention span restored to almost normal."[8] To say that this is a complete figment of imagination[44] is pushing it too far. Since it is a condition that has only recently been recognized, it is but natural that there will be both false and true studies. Eventually, it will be as recognized and accepted as AIDS, a condition that drew similar accusations decades ago when it was first discovered. With a current understanding that there is a dysfunction in the frontostriatal circuitry in ADHD, most notably in the cerebellum and the parietal lobes,[45] involving several candidate genes such as DRD4, DRD5, DAT1, HTR1B, and SNAP25[46] and with a well-defined course and outcome,[47] stringent criticisms need to be tempered down, keeping in view the overwhelming scientific evidence. Since pharmacotherapy does not have strong evidence of improvement, care should be taken that people with this disorder are not over-treated with psychostimulants and that they are subjected to psychological interventions too.

Evidence for Disease Mongering in Premenstrual Dysphoric Dysfunction (PMDD)

The biggest support of the argument that new diseases are being created everyday comes from the diagnosis of PMDD, which does not exist in more than half the world, was earlier considered as part of the normal menstrual cycle, and is not recognized by the ICD 10. Yet the U.S. Food and Drug Administration (FDA) has already approved a treatment regimen for the same, effectively accepting the existence of the condition. One wonders what the hurry was in approving treatment for a condition that officially does not even "exist."

The story of the discovery of the "disease" is a fascinating one. Word has it that the owners of a certain brand of fluoxetine were about to lose their patent. They then funded a meeting of researchers and FDA officials, where PMDD was "officially" born and fluoxetine (in another brand name) was approved as the treatment of choice. By then the makers had redesigned and repackaged the same drug and sold it under a different brand name, "the smart drug for smart women."[48] Similarly, Australia, following the lead of the FDA, has also approved the use of SSRIs for the treatment of PMDD but does not cover the costs of treatment under medical

insurance. However, the biggest setback for PMDD promoters and a shot in the arm for activists of disease mongering came from the objections of the European Medicines Evaluation Agency, citing concerns that women "with less severe pre-menstrual symptoms might erroneously receive a diagnosis of PMDD resulting in widespread inappropriate short- and long-term use of fluoxetine," following which the company has stopped marketing the drug in Europe.[49] The debate remains wide open between supporters and those against the validity of the diagnosis of PMDD.

Disease Mongering in Restless Legs Syndrome

The diagnosis of restless legs syndrome requires the presence of the following four criteria according to a recent report[50]:

- An urge to move the legs because of an unpleasant feeling in the legs.
- Onset or worsening of symptoms when at rest or not moving around frequently.
- Partial or complete relief by movement (e.g., walking) for as long as the movement continues.
- Symptoms that occur primarily at night and that can interfere with sleep or rest.

After "awareness" of the so-called criteria, one major pharmaceutical company then promoted the illness, beginning with press releases about presentations at the American Academy of Neurology meeting describing the early trial results of using ropinirole (a drug previously approved for Parkinson's disease) for the treatment of restless legs.[51] Two months later, the same company issued a new press release entitled "New survey reveals common yet under recognized disorder—restless legs syndrome—is keeping Americans awake at night" about an internally funded and, at the time, unpublished, study.[51] In 2005, the U.S. FDA approved ropinirole for the treatment of restless legs syndrome, making it the first drug approved specifically for this indication. Since then, the "campaign to promote restless legs syndrome into the consciousness of doctors and consumers alike"[52] has reached disturbing levels. It has exaggerated the prevalence of the disease and the need for treatment, and failed to consider the problems of over-diagnosis.[52] Increasing numbers of articles and research papers published on this topic[52–55] have only fuelled the epidemic.

http://www.psocommons.org/wmhp/vol2/iss1/art15
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Other Psychiatric Disorders

Dementia: The use of various drugs to treat dementia, such as anticholinesterase inhibitors, has been recently criticized as lacking clinical evidence, since most trials of donepezil, rivastigmine, and galantamine have been limited by underpowered studies, poor methodological quality, and the use of invalidated scales or instruments to measure improvement.[56] Most meta-analyses and reviews of the treatment benefits of cholinesterase inhibitors in Alzheimer's, Parkinson's, and vascular dementia have found low treatment effect, minimal benefits, biased reporting, and mixed and confusing results.[56–61] This has prompted the U.K.'s National Institute for Health and Clinical Excellence (NICE) guidelines to state that the clinical outcome of the use of cholinesterase inhibitors is limited and largely inconclusive and not recommending its use.[62] However, in a later change, the updated guidelines state that they may be used for moderate types of Alzheimer's disease.[63] An integrated approach involving both psychosocial and pharmacological strategies individualized for each patient is essential as even a moderate improvement in a patient with dementia may appear ground-breaking for both patient and carer.[61]

Social phobia: Shyness has a new name—social phobia. Although this disorder exists in reality, the methods by which diagnosis is being pushed and promoted attracts criticism. In Australia, a certain pharmaceutical company claimed that one million Australians suffered from social phobia. The condition was described as "soul destroying" and antidepressants were recommended for treatment.[64] However, such a claim may be part of a wider push to change the common perception of shyness, from a personal difficulty to a psychiatric disorder. Even *Pharmaceutical Marketing*'s practical guide was led to come out and declare that the promotion of social phobia was a positive example of drug marketers attempting to shape medical and public opinion about a disease.[65] Once again, lest the real patients be missed in all this promotion, one needs to be on guard against such a blatant use of marketing.

Female sexual dysfunction: Female sexual dysfunction (FSD) was almost created overnight when pharmaceutical companies sponsored a May 1997 Cape Cod conference "Sexual Function Assessment in Clinical Trials," bringing together papers and discussion that were published in a special supplement to the *International Journal of Impotence Research*.[66] After that, there was no stopping the rapid dissemination of information on a disease that did not exist—in television programs such as *Oprah*, websites, books,

and innumerable women's magazines. Viagra and then a testosterone patch were promoted as treating FSD.[67] Efforts have begun to include this in the official directory of diseases ICD and DSM. Whether the condition exists in reality or is a figment of a marketer's imagination remains to be seen.

Metabolic syndrome: Metabolic syndrome has become the new rage in psychiatry, especially in psychopharmacology. However, this concept has not been viewed as being promoted by drug manufacturers as they only stand to lose with what is being rapidly seen as a detrimental effect of second-generation antipsychotics. Research papers on the topic are being published nearly every day, including that of this author.[68] However, the following questions have been raised: (1) Is it indeed a syndrome, particularly as the precise cause is unknown? (2) Does it serve a useful purpose? (3) Is it labeling (and medicalizing) people unnecessarily?[69] Additionally, an editorial has suggested that recognition of metabolic syndrome is being largely driven by industry to create new markets.[70] Even as serious researchers, we need to consider the likelihood of a market-driven campaign before jumping in favor of the diagnosis. Ultimately, all we are looking out for is the patient's interest.

Road rage and compulsive shopping have been added to the ever-growing list of doubtful diagnoses.[71,72] Promoted by both media and psychiatrists, these have invited serious concerns on whether psychiatry is turning every aspect of human behavior into a disease. Such has been the ridiculousness of disease mongering that when *BMJ* printed a "news" item that appeared in its April Fool's Day edition 2006, titled "Scientists find new disease: motivational deficiency disorder," people actually thought it was true and started writing in to say they suffered from it.[73]

Disease Mongering—The Other Side of the Coin….

Disease mongering, as has been discussed above, does not just influence the general population, susceptible to the ever-increasing idea that there is some illness within them. It has now extended to pharmaceutical companies offering various gifts to lure and change the prescribing habits of physicians. Gifts distributed to practicing clinicians, however nominal, do have an impact on physician prescribing practices.[74,75] Further, the receipt of gifts, payments, and perks—large and small—engenders a loyalty (or feeling of obligation) in the receiver to reciprocate.[74,75] Even medical practitioners stand to gain handsomely when they serve as *Consultants* on the boards of different pharmaceutical companies. On the other hand, professional bodies are not

without blame. Many of them collude with pharmaceutical companies to sponsor conferences and CMEs.[76] Medical representatives are allowed free, unrestricted access to doctors, and medical conferences are now strongly dominated by the industry.[77] Even influential societies such as the American Psychiatric Association would perhaps not be able to organize its congresses were it not for the contributions of pharmaceutical companies. In such a scenario, it is often at the cost of true medical knowledge and impartial research that such symposia are held.

Conclusions

As doctors, we are often so pressed for time that we take research at face value as we do claims by pharmaceutical representatives. One is reminded of Aristotle, who so rightly observed that "truth could influence only half a score of men in a century, while falsehood and mystery would drag millions by the nose." Psychiatry, although not the top priority for most pharma companies, has started to be "recognized" as a potential field of play. Even though we may argue that there may be no way out of this, we as doctors can do our bit. Psychiatric professional organizations have the most important responsibility of regulating the information being shared in CMEs/conferences, especially those that are industry sponsored. Regulatory bodies such as the FDA need to play a far bigger role in limiting industry funding for research projects and subsequent (biased) research findings. Finally, the World Health Organization can play a pioneering role in disseminating authentic critical analyses of all health-related information.

Recommendations

Some of the key recommendations to combat disease mongering are detailed below. However, the list is not exhaustive and fresh recommendations will need to be added as the time comes.

1. A voluntary code of conduct by pharmaceutical companies that guides ethical behavior by its members should be developed.
2. Doctors should develop the capacity for critical analysis of research reports and should avoid being misled by biased presentation and interpretation of data.

3. Journal articles, although highly valuable sources of information, should not be depended on as the only source of information. Critical appraisal skills, along with prescribing skills, should be made part of the undergraduate medical course in order to enable doctors to understand journal articles.
4. The economics of each drug should be acquired and remembered while prescribing.
5. Doctors should be more careful while attending CME programs and conferences that are sponsored by the industry.[77]
6. Payments or other subsidies (including tuition, fees, travel, lodging, or other incidental expenses) to support attendance as a participant at an accredited continuing medical education program should be prohibited.
7. Physicians interested in learning about new products may be allowed to accept literature about new treatments and therapies and listen to company presentations in a clinical setting, but they should be required to pay the fair market value for any refreshments provided.
8. Physicians should disclose whether they accepted more than Rs. 10,000 during the last two years from manufacturers in the form of compensation, food, travel, consulting fees, or honoraria, funding for research, funding for education, stock or stock options, ownership or investment interest, or any other economic benefit. This should be renewed periodically with each state medical council.
9. All information provided at CMEs/conferences should be accredited by an independent body such as the Accreditation Council for Continuing Medical Education in the United States.
10. Programs that allow community hospitals to ensure that the acceptance of industry funding for CME does not skew the message of educational sessions should be created.

Finally, disease mongering is neither purely black nor purely white. Unfortunately, the concept of disease is also a "gray zone," with an inadequate definition of boundaries. There will always be "normal" people who will want treatment and "sick" people who will refuse it.[78] A holistic approach to the patient and patient care is therefore required when deciding on treatment strategies.

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