

Virtual Mentor

American Medical Association Journal of Ethics
December 2011, Volume 13, Number 12: 906-911.

OP-ED

The Pharmaceutical Industry's Role in Defining Illness

Elizabeth A. Kitsis, MD, MBE

The pharmaceutical industry develops, manufactures, and sells drugs. Defining illness is not its mission. Generally, the medications produced by drug companies target diseases that have been defined previously by the medical profession. However, there are several indirect ways in which the industry contributes to the definition of illness. Are these contributions beneficial to society and ethically sound, or are they solely aimed at maximizing corporate profit? To address these questions, I analyze some examples of how the pharmaceutical industry has played a role in defining illness.

No sharp line divides health from disease. Defining an illness is a complex process, and definitions typically evolve over time, facilitated by advances in science and validated by societal recognition. Thus, it is expected that the definition of what constitutes disease will change with time, with additions (e.g., Lyme disease), subtractions (e.g., homosexuality), and modifications (e.g., autoimmune disorders). While some of these modifications are universally accepted, others—particularly those regarding conditions that lack objective signs or laboratory abnormalities—are controversial. The term “medicalization” was introduced in the 1970s by Illich and others [1] to challenge the characterization of normal variation among humans as disease. However, defining illness can be the first step toward reducing human suffering. Thus, medicalization can alternatively be defined as “a process by which human problems come to be defined and treated as medical problems” [2].

A case in point is fibromyalgia, a chronic pain condition associated with tender points on certain parts of the body. Physicians began to see patients with this constellation of symptoms in the 1980s and cautiously and provisionally defined a new syndrome. As with many syndromes, elucidating its pathogenesis was not so easy and has lagged behind the description of the disorder. It is not uncommon, however, for clinicians and drug companies to search empirically for new treatments even without a precise understanding of pathogenesis. Several medications—including pregabalin (approved in 2007), duloxetine (approved in 2008), and milnacipran (approved in 2009)—were found to alleviate the symptoms of fibromyalgia and were the first medications to be approved by the Food and Drug Administration (FDA) for treating it.

What are the implications of these new drugs for fibromyalgia? Most importantly, they may provide relief to patients with a potentially debilitating condition. However, there may also be other, important downstream effects. First, the very fact

that drugs have been approved provides some validation that fibromyalgia is, in fact, an illness. Receiving treatment for fibromyalgia may legitimize a patient's chronic pain symptoms that might otherwise be dismissed by family, friends, or employers as hypochondriasis. Indeed, some fibromyalgia patients report improved health after diagnosis [3]. Second, if the treatment is truly effective, one would anticipate that it would reduce the use and cost of health care for sufferers, perhaps benefiting patients as well as society. Some investigators have reported these outcomes [4, 5]. Third, in a reversal of the usual direction of translational medicine, knowing the mechanisms by which effective drugs act may provide important insights into pathogenesis.

On the other hand, are there potential risks to medicalizing the symptoms of fibromyalgia? Some rheumatologists still dispute the existence of this condition. If they are correct, its medicalization could encourage inappropriate sick-role behavior. It could also expose otherwise healthy patients to medications with potential side effects and unnecessarily increase the costs of medical care. Some data indicate that pharmacy and health care costs go up among patients who have been treated with pregabalin and duloxetine [6].

In either case, it is clear that the pharmaceutical industry has played a role in the medicalization of fibromyalgia. While this process is usually driven by physician experts, the decision to develop and seek approval for new drugs can strongly influence the medicalization process—especially when those drugs are efficacious. One might question the motivations of drug companies—are they after profit, patient welfare, or both? Regardless, in the case of fibromyalgia, several new medications have been added to the treatment armamentarium.

In contrast to fibromyalgia, there are other examples in which pharmaceutical companies have played a less positive role in the definition of disease. For example, some allege that GlaxoSmithKline developed a business plan to promote paroxetine as a treatment for social phobia by depicting the disease as a severe medical problem [7]. Although the prevalence of social phobia was noted as “rare” in the 1980 *DSM-III*, it was noted to be “extremely common” by 1994. GlaxoSmithKline's extensive media campaign included posters displayed prominently across the country that showed a dejected man playing with a teacup and proclaimed “Imagine being allergic to people.” Labeling people who may simply be shy as severely ill may be stigmatizing. Encouraging them to take a medication with potential side effects raises a concern about whether patient welfare is the key objective. Expanding the boundaries of a treatable illness simply to enlarge the market for a drug has been termed “disease mongering” [8].

Occasionally, a pharmaceutical company develops a medication for a specific purpose, but later discovers that a “side effect” has the potential to solve a completely different medical problem. The well-known example is minoxidil, initially developed and effective for hypertension. Upon realizing that excessive hair growth was also observed in a significant percentage of patients [9], Upjohn developed the drug for baldness. This could be considered a form of medicalization

initiated by a drug company. Is baldness a bona fide medical disease, worthy of drug treatments and all the positive and negative consequences that entails? Or is it simply part of the normal aging process, similar to the development of facial wrinkles? Or is “medicalized” being extended here to connote any condition that is treated with a drug?

Considering whether aspects of normal aging should be treated with medical interventions raises many ethical questions. For example, respect for autonomy, a strongly held principle in Western societies, may justify allowing individuals to opt for such treatments as long as they are aware of potential risks. On the other hand, critics might argue that such “nonessential” therapies waste resources that could be better used for more serious medical conditions. Concerns about justice come into play here, since only those with adequate resources can afford elective or cosmetic treatments not routinely covered by health insurance.

Sildenafil is a somewhat different case. Initially developed for a cardiovascular indication, the efficacy of the drug proved insufficient, leading to discontinuation of the clinical development program. However, a product safety specialist at Pfizer observed that a substantial number of male patients enrolled in clinical trials of the drug reported erections as a side effect [10]. Erectile dysfunction was already recognized as a medical condition, often caused by diabetes or subsequent to prostate surgery. Previously available treatments were not well-tolerated by patients. This led Pfizer to develop sildenafil for erectile dysfunction. In this case, the company did not medicalize the condition. Rather, using Bob Dole as its spokesperson, it raised awareness of a little-discussed medical problem and lent credibility to its diagnosis and treatment. Thus, the drug appeared to address an unmet medical need.

But Pfizer did not stop there. Realizing the potential for further profits, it began advertising sildenafil to a broader audience [11]. Other companies developed similar drugs. Marketing strategies leveraged the fact that many men experience occasional erectile dysfunction unrelated to organic causes. Eventually, these drugs were perceived by the public as “lifestyle modifiers” that could enhance sexual function rather than solely treat disease. This broadening of the use of sildenafil raises questions similar to those involved with treating the normal aging process.

Some of the drive for public demand for medications comes from direct-to-consumer (DTC) advertising. Corporate expenditures on DTC advertising were \$4.2 billion in 2005 [12]. While this approach does not necessarily result in the definition of new disease, it can facilitate the expansion of a market, as in the cases of social phobia and erectile dysfunction.

Critics of the pharmaceutical industry rail that the main motive for industry involvement in DTC advertising is to increase market size and profitability [12]. DTC advertising, they say, is a ploy to make people think that normal variations in their level of social comfort, satisfaction with life, sleep habits, or numerous other complaints are medical disorders, and to request, by name, the specific drugs being

promoted. The FDA Revitalization Act of 2007 reauthorized the Prescription Drug User Fee Act, which—among other things—allowed the FDA to levy fines of \$250,000-\$500,000 for false and misleading advertisements. This act could have helped to keep DTC advertising in check. However, in 2008, the part of the act that created a user fee program to review television commercials was terminated due to insufficient funding by Congress [13].

Not all DTC advertisements should be vilified. Some, in fact, can empower patients. DTC advertisements provide information, possibly enabling people to make more informed, individualized decisions about their health care. That said, it is in the public's best interest that all DTC advertisements be reviewed stringently by independent referees—FDA or otherwise—to insure that pharmaceutical companies do not equate symptoms with diseases and suggest that diseases are more common or serious than they really are.

As we complete the first decade of the twenty-first century, some would argue that the pendulum has swung too far toward medicalization, and that the pharmaceutical industry has contributed significantly to this situation. Aspects of normal human life, including childbirth, weight control, and menopause, that used to be managed without medical intervention have been placed into the medical care paradigm. Behaviors deemed unacceptable by society, such as alcoholism, drug addiction, and attention deficit hyperactivity disorder, have also been medicalized. They are now ascribed in large part to chemical imbalances or genetic predispositions, potentially absolving affected individuals of personal responsibility for their behavior [14].

However, defining a problem in medical terms is not necessarily bad [14]. For example, data about maternal and fetal death in groups with poor access to health care suggest that considering pregnancy within a medical framework may lead to positive outcomes. Recognizing the severe medical consequences of obesity and providing treatment options can reduce comorbidities associated with this condition. Helping people overcome problems that cause them distress—whether through changes in behavior or pharmacologic intervention—can help physicians fulfill their obligation to optimize patient welfare.

As the major developer of new drugs, the pharmaceutical industry unquestionably influences the process of defining illness. This influence can be positive, as when drug companies increase public awareness of disease and develop effective therapies for distressing conditions. On the other hand, the influence of the industry becomes harmful if it pushes the boundaries of illness too far in pursuit of profit. The pharmaceutical industry could augment its positive contributions by consistently providing the public with unbiased information and by supporting biological and population research that would more precisely define specific diseases. This information could help to identify those individuals who would most likely be helped by specific drugs. Discoveries such as these would benefit both the industry and society.

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Elizabeth A. Kitsis, MD, MBE, is director of bioethics education at the Albert Einstein College of Medicine in the Bronx, New York, and a practicing rheumatologist. She was previously vice president of a global pharmaceutical company.

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