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Promoting diseases to promote drugs – the role of pharmaceutical industry in fostering good and bad medicalization

Abstract:

Pharmaceutical industry and drugs advertisement is sometimes accused of "creating diseases". This article assesses and describes the role of that industry in fostering medicalization. First, the notions of medicalization and pharmaceuticalization are defined. Then, the problem of distinguishing between harmful overmedicalization and well-founded medicalization is presented. Next, the phenomenon of disease mongering is explained and illustrated by the case analysis of medicalizing pain and suffering in three contexts: 1) the general idea of medicalizing physical pain, 2) the medicalization of grief, and 3) disease mongering of pseudoaddiction - a condition promoted in order to increase the demand for opioid pain relievers.

1. Introduction

Should mourning become a disease? Have some health conditions been invented or are they being promoted in order to increase the demand for antidepressants or other medicines? Pharmaceutical industry is sometimes accused of "creating diseases". This article assesses and describes the role of that industry in fostering good and bad medicalization.

First, however, it is worth stressing that in the time of COVID-19 pandemic combined with the growing popularity of the anti-vaccination movement, writing about "the dark side" of pharmaceutical industry is particularly risky. Reporting genuine abuse may be easily taken out of context and emerged into a conspiracy theory about so-called "big-pharma". [1]¹ However, this is no reason to ignore the real challenges posed by the role of drug marketing in fostering medicalization. Striving for evidence-based, not profit-based medicine; supporting impartial, reliable, scientific institutions and fixing those aspects of pharmaceutical marketing that need improvement is a way to rebuild trust in medicine. But to know what to repair, we need to know what is wrong. This article focuses on medicalization, pharmaceuticalization and "disease mongering".

2. What is medicalization and pharmaceuticalization?

Although medicalization is one of the key terms in modern sociology and the philosophy of medicine, there is no single, universally accepted definition of it. [2]² Among many

definitions of medicalization found in the literature, some are quite general (e.g. "Expansion of medicine into other areas of life"), others more specific (e.g. "Transferring self-determination and decision-making from lay people to the medical profession"), some are value-neutral (e.g. "Making a problem medical"), others value-laden (e.g. "Making an ordinary biological process or behavior medical"). [3]³

Historically, the notion of medicalization was linked to the sociological critique of medicine, seen as an institution of social control. [4-8]^{4 5 6 7 8} Although medicalization was originally not a neutral concept, (and, for some authors, still remains a critical concept) over the years it has become more a descriptive than an evaluative category. The appearance of the term "overmedicalization" proves that, for many researchers, saying that something has been medicalized does not yet imply that it was wrongly made medical. This is why the last of the above definitions rather fits the notion of overmedicalization than medicalization (it assumes that a non-medical problem has been improperly started to be treated as a medical one). For the purposes of this article, let us adopt one of Peter Conrad's definitions of medicalization, according to which something becomes medicalized when it "is defined in medical terms, described using medical language, understood through the adoption of a medical framework, or 'treated' with medical intervention". [9]⁹ This definition does not determine if there, indeed, was anything wrong with such a shift in understanding a given thing.

Among many manifestations of medicalization one may include such phenomena as replacing various authorities with medical experts, reinterpreting some behaviors (previously treated, e.g., as sins) as diseases, the expanding number of mental disorders, or growing consumption of health products. The latter example should be also assigned to another sociological term crucial for the topic of this text, namely pharmaceuticalization. [10]¹⁰ Pharmaceuticalization may be understood as one of the effects or as a subcategory of medicalization. This term describes a situation when a given phenomenon is not only started to be seen as a medical problem but also as a problem that requires treatment with drugs. It is not surprising that effective marketing and advertising on the part of pharmaceutical industry, aimed at increasing the sale of medicinal products, contributes to the increase of pharmaceuticalization. This is a simple reason why pharmaceutical industry is seen as one of the main contributors to the medicalization of modern societies.

Although the actions of drug manufacturing companies accelerate the processes of pharmaceuticalization, they are not the main or the only cause of its existence. Pharmaceutical industry functions in a culture which has been already medicalized. Therefore its actions

should be seen in the context of other broad social changes that may be observed in Western societies since the XX century, such as secularization, consumerism, the cult of youth, healthism, or population ageing. [11-12]^{11 12} All of them influence the way of understanding and handling various problems by today's societies.

Therefore, the relationship between pharmaceutical industry and medicalization resembles more feedback than a one-sided cause-effect process. [13]¹³ In other words, pharmaceutical marketing fosters the so-called "pill for everything" approach, nevertheless, the reality in which health is seen as one of the main values in our societies was not fabricated by drug companies.

3. Bright and dark sides of medicalization

The fact that a growing number of human behaviors, boldly features or problems, are seen as medical issues (and not as social, political, personal, or religious ones) may have different positive and negative consequences. [14]¹⁴ Among risks connected with overmedicalization one may mention:

- “Health effects, such as harm to health caused by improper treatment (overdiagnosis, overprescription), iatrogenic diseases, health risk related to medical procedures, undesirable side effects of the medication administered;
- Economic effects, such as suboptimal expenditure and waste of public or private money, e.g. costs of treatment of iatrogenic diseases and consequences of medication errors;
- Psychological effects, such as stigmatizing certain conditions, individuals or their behavior as sick; restriction of personal freedom; pressure to adjust one's own needs and behavior to fit the prevailing standards, e.g. pharmacological treatment of low sexual desire in women;
- Social effects, such as: ignoring social, political and interpersonal background of certain phenomena and inadequate reactions stemming therefrom, such as treating victim's masochistic personality disorder as the cause behind domestic violence.”
[15]¹⁵

Whereas among advantages connected with well-founded medicalization one may mention:

- “Health effects, such as the possibility of using tools of evidence-based medicine, e.g. treating acute mental disorders at a psychiatric hospital instead of undergoing an exorcism;
- Economic effects, such as improvement in the financial situation of individuals whose condition has officially been recognized as a disease, e.g. through granting insurance coverage, reimbursement of medicines, entitlement to take a sick leave;
- Psychological effects, such as satisfaction from the increase in autonomy by controlling one's one body (e.g. birth control pills) or, in case of spreading the knowledge about a certain health condition - de-tabooisation of disease, explanatory value: patients gain the possibility to understand the causes of their condition and see that they are not the only ones to suffer from it;
- Social effects, such as: raising health awareness of the public, recognizing medical grounds for particular behaviors and starting treatment instead of punishing the patient, e.g. limited criminal liability of the mentally handicapped persons.” [15]

Potential damages and profits are substantial, therefore, the task of distinguishing between harmful over-medicalization and justified medicalization seems to be crucial. It is difficult, though. In the sociology and philosophy of medicine, there is an old and ongoing debate about proper definitions of disease and health. [16 – 18] ^{16 17 18} In another text I argued for an alternative, pragmatic approach to that problem - instead of arguing about whether a given condition is a *real* disease, I propose to carefully assess whether and why it is worth including this condition within the scope of medical interest. [15] This approach consists of four guiding questions, stimulating reflection about: harm caused by a problem that has been medicalized; adequacy, effectiveness, and safety of its medical solutions and the limits of social expectations towards the normalization of an individual's behavior. This pragmatic approach is based on comparing medicalization of a given phenomenon with alternative methods of understanding it.

Meanwhile, it is the pharmaceutical industry that actively participates in creating popular and medical discourse on health. It is in the best interest of this industry that we define our problems as medical problems which require treatment with drugs. The industry influences the perception of certain issues and promotes its tools for solving them. Pharmaceutical marketing and drugs advertisement is even sometimes accused of "creating diseases" and making healthy people think that they are ill. [19] ¹⁹ Are these types of accusations justified?

4. Pharmaceutical industry and disease mongering

In the bioethical literature, this type of accusation is usually labeled as "disease mongering" [20 – 21]^{20 21} or "disease branding" [22 -23]^{22 23}. Disease mongering may be defined as "widening of the diagnostic boundaries of illness for reasons of economic benefit". [24]²⁴ This "widening of the diagnostic boundaries" rarely consists of literal creating or making up completely new, fake diseases. Nevertheless, pharmaceutical industry may use numerous tools to increase the consumption of medicines, and some of them involve changing the way we think about diseases in order to promote drugs for them.

According to Moynihan, Heath, and Henry, we may observe the following strategies of disease mongers:

- medicalizing ordinary ailments, like in the case of baldness;
- "seeing mild symptoms as serious", like in the case of irritable bowel syndrome;
- "treating personal or social problems as medical ones", like in the case of social phobia;
- conceptualizing risk as a disease in itself, like in the case of osteoporosis;
- or "framing prevalence estimates to maximize potential markets", like in the case of erectile dysfunction. [25]²⁵

The above strategies seem to be sound, although examples given will be disputable for many. Disease mongering is a real problem, but we have to be careful not to draw hasty conclusions, like, for instance, "osteoporosis should not be treated" or "irritable bowel syndrome does not exist". Nowadays, what is considered a disease or disorder is determined by various medical bodies in a complex process (like in the case of *the International Statistical Classification of Diseases and Related Health Problems* or *Diagnostic and Statistical Manual of Mental Disorders*). The mere existence of the conflicts of interests and different market pressures exercised on this process is not enough for unequivocal rejection of it. What is more, disease mongering (e.g. through building a marketing narrative about a certain condition and its prevalence) often occurs after that condition has been included in the official classifications of diseases. That was, for example, the case of the restless legs syndrome, sometimes hastily labeled as a fictive or invented disease which began to be promoted many years after it appeared in the ICD-9, in order to increase demand for drugs for other diseases. [26]²⁶ Nevertheless, in order to assess any example of medicalization we need unbiased and reliable data about a given condition which sometimes is difficult to access.

Pharmaceutical industry has numerous tools that, inappropriately used, may bias our perception of diseases and their treatment, such as pharmaceutical sales representatives and marketing drugs to physicians, direct-to-consumer advertising, content marketing on the Internet, disease awareness campaigns, sponsored medical associations, lobbying, astroturfing, sponsored patient organizations, sponsored medical education, sponsored research, sponsored medical conferences and broader influence of medical experts hired by a company - called key-opinion leaders. [27 - 31] ^{27 28 29 30 31} In the name of profit all those tools may be used to exaggerate efficacy and safety claims about drugs, encourage unapproved uses (off-label prescriptions), reduce thresholds for diagnosing diseases, or disseminate unvalidated data about the prevalence of a disease. [32] ³² As Brody and Light rightly stated: "the scientific arm of the industry works hard to discover new drugs that are both effective and safe. The marketing arm then turns those good drugs into bad drugs, in effect, by extending their use beyond the proper evidence base." [32]

5. Case study: medicalization of pain and grief

In his influential book *Medical Nemesis* Ivan Illich, one of the first social critics of modern medicine, clearly disapproved the general idea of medicalizing pain. [6] According to him, by treating pain only as a medical problem we try to escape, in vain, from the fact that suffering is an inevitable part of human existence. In the past, our societies had different cultural, religious, or philosophical ways of explaining the role of pain in human life. Nowadays, due to the medicalization of pain, every suffering became senseless and meaningless, and our only weapon against pain are pain-killers.

Although I find some of Illich's arguments appealing, according to my pragmatic approach toward assessing medicalization mentioned before [15], the medicalization of physical pain is well-founded. This is not a case of overmedicalization because: 1) pain causes harm, 2) recognizing physical pain as a problem is not an example of the undue limitation of the diversity of individuals for the sake of normalization, 3) medicine provides the most adequate methods of understanding physical pain and its causes, 4) and, medicalizing pain ensures the most effective and safest methods of relief. Therefore, in general, medicalization of physical pain may be seen as an example of good medicalization. It does not imply, however, that each medical or pharmaceutical reaction to any kind of pain or mental suffering will be equally justified.

For instance, medicalization of grief, especially if only short periods of mourning were seen as healthy, may be an example of overmedicalization. According to DSM IV, bereaved people could be diagnosed with major depression only if the symptoms were “unduly severe or prolonged”, where prolonged was defined as “more than two months after the death.”³³ [33] In DSM IV, what is now called the prolonged grief disorder or the persistent complex bereavement-related disorder, has not yet been recognized as a separate mental condition. However, defining prolonged depression after the death of a close-one as more than only two months is disputable. Nowadays, the prolonged grief disorder is recognized as a separate mental health condition with distinct diagnostic criteria. In the eleventh revision of the International Classification of Diseases (ICD-11) still under review, the threshold of six months has been introduced for the diagnosis of the prolonged grief disorder. [34]³⁴ In the DSM-V there is one year threshold [35]³⁵.

My goal of writing about the medicalization of grief is not to imply that people who cannot come out of mourning should never help themselves with antidepressants. Nevertheless, pharmaceuticalization of bereavement is disputable in the light of my pragmatic approach because the causes of suffering related to grief are not medical, and setting time limits for "normal" grief may be seen as excessive standardization and pathologization of individual personal experiences.

Determining which human emotional and behavioral responses are considered normal or healthy is a difficult and value-laden task. This is why in the debate about medicalization and the influence of pharmaceutical industry, the field of psychiatry is sometimes described as particularly prone to creating new disorders in order to increase the demand for some drugs. [36]³⁶ The process of elaborating new psychiatric diagnostic criteria was also criticized because of conflict of interests and close ties of experts with pharmaceutical industry. [37]³⁷ Yet it is the domain of physical pain treatment that has become the field for some of the worst abuses by drug manufacturers in recent decades.

5.1 A painful example of what pharmaceutical marketing may lead to: the opioid overdose crisis and promoting "pseudoaddiction"

My previously stated claim that, in general, medicalization of physical pain is an example of good medicalization, means that pain can be justly “understood through the adoption of a medical framework, or treated with medical intervention.” [9] Of course, it does not imply that each pharmaceutical reaction to any physical pain will be equally well-founded: to be

justified it should be, among others, safe and effective compared to available alternatives. Treating pain caused by, e.g. a sprained ankle with the strongest painkillers available would not meet that criteria. Unfortunately, some forms of advertising opioids in the 90., led to systemic overprescription of this type of drugs, which stimulated the opioid overdose crisis in the United States. [38]³⁸ According to Centers for Disease Control and Prevention "from 1999 to 2018, more than 232,000 people died in the United States from overdoses involving prescription opioids." [39]³⁹

This persisting public health crisis has numerous structural causes, and pharmaceutical industry is not the only one to blame for current overdose death rates (nowadays the majority of deaths is caused by opioids bought on the black market). However, after numerous lawsuits, several convictions, guilty pleas, and billion-dollars fines, it is already well documented that in the marketing strategies used to sell some opioids medicines (e.g. OxyContin marketed by Purdue Pharma [40]⁴⁰ or Subsys marketed by Insys Therapeutics [41]⁴¹) many of the previously mentioned abuses were committed, like exaggerating efficacy and safety claims about new drugs (in this case: that opioids drugs are less addictive than they in fact are) or encouraging off-label prescriptions (in this case: to prescribe medicines approved for the treatment of severe cancer pain for alleviating other, far less severe kinds of pain). [42]⁴² To achieve those goals numerous tools and strategies were used: pharmaceutical sales representatives, sponsored patient organizations, key opinion leaders, or the promotion videos targeted toward physicians and patients. [43-45]^{43 44 45}

The history of marketing of opioids is an example of disease mongering not only because drug producers successfully tried to encourage unapproved uses of their products; they also tried to shape the way the public and medical community think about managing pain and painkiller addiction. In order to do so, some drug producers engaged in the promotion of a new medical condition called pseudoaddiction.

The notion of pseudoaddiction was introduced by J. David Haddox and David E Weissman in their case-study clinical note published in *Pain* in 1989. [46]⁴⁶ The general idea of pseudoaddiction is that a patient treated with opioids who has symptoms of addiction or a withdrawal syndrome, is not in fact addicted, but in need of the stronger dose of opioids. In the original article about pseudoaddiction there is no declaration of any conflict of interest, but one of the authors, David Haddox, was, in the following years, professionally related to the Purdue Pharma (he was the company's "primary spokesperson from at least 2001 until 2018." [47]⁴⁷)

According to Greene and Chambers who did a review of 224 articles covering pseudoaddiction up to 2013, “nearly half of the subsequent papers on pseudoaddiction that did disclose pharmaceutical support (9 of 22) list Purdue Pharma. From the 12 papers that support and elaborate on pseudoaddiction as a true clinical entity, 4 list pharmaceutical industry support. None of the six papers that dissented or questioned the construct validity of pseudoaddiction listed pharmaceutical support. (...) Pseudoaddiction is a quarter-century-old concept that has not been empirically verified. Although no evidence supports its existence as a diagnosable clinical entity with objective signs and specific treatments, the term is widely accepted and proliferated in the medical literature.” [48]⁴⁸

Obviously, the fear of addiction is not a sound reason for denying opioids medications to many patients (for example to those who are dying, those who suffer from unbearable pain resistant to other drugs or as part of anesthetizing the patient for surgery). However, the risk of addiction is more relevant in patients with chronic moderate pain, meanwhile, some opioids were promoted as the perfect solution for those patients. Some opioids producers’ strong assurances about the low risk of addiction (“less than 1%”) were based on a weak scientific foundation [49]⁴⁹, just like the discourse about pseudo-addiction.

Another typical strategy of disease mongering that could be found in the history of promoting opioids may be labeled as astroturfing and information laundering. Astroturfing consists in funding actions or organizations that look like bottom-up, grassroots movements to promote their funder's ideas. [50-51]^{50 51} Information laundering is a process of creating such a flow of information that separates a given message from its original source in order to make it look more credible (in the literature this process has been mainly analyzed in the context of slipping radical political views or fake news into mainstream media [52]⁵², but it seems to be relevant in the public relations strategies and commercial interests too [53]⁵³). In the case of drug companies, those practices often rely on funding patient organizations, different kind of associations, health campaigns or websites which promote the company's narrative about a given condition and its treatment but do not inform about their sponsors or funders. [54]⁵⁴ The credibility of those sources of information is based on their seeming independence when, in fact, they are cells in the chain of a complex marketing strategy. Boundaries between impartial information and advertising are being intentionally blurred.

6. Conclusions

Anti-vaccination movement, alternative medicine or conspiracy theories related to big pharma are current and often life-threatening dangers. Yet overmedicalization, excessive pharmaceuticalization, and disease mongering are real issues too. The reasonable reaction to the problems described in this article is:

- to monitor how pharmaceutical industry influences public and scientific discourse about diseases, and
- to ensure that institutions which decide about official classifications of diseases and clinical practice guidelines are as objective, independent, impartial, and scientifically reliable as possible.

The awareness of the problems described in this article seems to grow and a lot has already been done (for example, in the field of disclosing and managing conflict of interests). However, in the realities of modern medicine, economics, and information flow, both above mentioned tasks are still a challenge.

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