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DISEASE MONGERING AND PSYCHIATRY: A REVIEW

Psychiatry

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ABSTRACT

Summary: The problem of disease mongering is attracting increasing attention, though an adequate working definition remains elusive. Disease mongering is the selling of sickness that widens the boundaries of illness and grows the markets for those who sell and deliver treatments. It is exemplified most explicitly by many pharmaceutical industry funded disease-awareness campaigns, more often designed to sell drugs than to illuminate or to inform or educate about the prevention of illness or the maintenance of health. Different forms of disease mongering practices has been identified like aspects of ordinary life, such as menopause, being medicalised; mild problems portrayed as serious illnesses and risk factors, such as high blood cholesterol and low bone density being framed as diseases. Drug companies are by no means the only players in this drama. Informal alliances of pharmaceutical corporations, public relations companies, doctors' groups, and patient advocates promote these ideas to the public and policymakers, often using mass media to push a certain view of a particular health problem. While these different stakeholders may come to these alliances with different motives, there is a confluence of interests resulting in health problems routinely being framed as widespread, severe, and treatable with pills. Currently, these alliances are working with the media to popularize little-known conditions thus lending credence to inflated prevalence estimates. This is happening at a time when pharmaceutical companies perceive a need to build and maintain markets for their big-selling products and when pipelines for new and genuinely innovative medicines are perceived as being weak. Like the marketing strategies that drive it, disease mongering poses a global challenge to those interested in public health, demanding in turn a global response. A much more vigorous effort is needed from within civil society to understand and to challenge this corporate process.

KEYWORDS

INTRODUCTION

Convincing healthy people that they are sick and in need of medicines creates an enormous market for drugs and medicines. The concept of what is and what is not a disease at times can be extremely slippery. Many of life's normal processes like birth, ageing, sexuality, unhappiness and death can be medicalised. Medicalisation is the process of turning ordinary life events and its customary ups and downs into medical conditions[1].

Disease mongering is the selling of sickness that widens the boundaries of illness and grows the markets for those who sell and deliver treatments. It can also be argued that disease mongering is the opportunistic exploitation of both a widespread anxiety about frailty and a faith in scientific advance and "innovation"- a powerful economic, scientific, and social norm[2]. Disease mongering can also turn ordinary ailments into medical problems, see mild symptoms as serious, treat personal problems as medical ones, see risks as diseases, and frame prevalence estimates to increase potential markets. The problem of disease mongering is attracting increasing attention[3,4] , though an adequate working definition remains elusive. The term was first described by Lynn Payer[4] in the 1990s. It is exemplified most explicitly by many pharmaceutical industry funded disease awareness campaigns, more often designed to sell drugs than to illuminate, inform or educate about the prevention of illness or the maintenance of health. This is happening at a time when pharmaceutical companies perceive a need to build and maintain markets for their big-selling products and when pipelines for new and genuinely innovative medicines are perceived as being weak.

There is a very thin dividing line between promoting knowledge and understanding of a disease, and disease mongering, in many instances. Infact large "grey zones" exist between disease and normality and this might help to explain the increased use of "lifestyle drugs" and self prescription of psychiatric medication[5]. It may be absurd to decide on the concept of a disease and define who should be treated. There will always be "normal" people who will want treatment and "sick" people who will refuse it[5].

VARIOUS STRATEGIES OF DISEASE MONGERING

Different authors have described various forms of disease mongering activities companies can use to stimulate drug sale.

- Ordinary life processes or ailments can be converted into medical problems. Baldness has been suggested as the classic example. Baldness has been publicized to lead to panic and emotional difficulties which can have impact on job prospects and personal well-being[6]. Recently, medicines are increasingly available for conditions which have so far been regarded as the natural result of ageing or as part of the normal range of human emotions.
- The second common strategy is to consider mild symptoms as portending a serious disease. This is exemplified by the case of irritable bowel syndrome (IBS). A mild functional disorder has been converted into a serious disease requiring drug treatment[6]. Mild personal and social problems are also being converted into medical ones.
- Risk factors can be conceptualized and publicized as diseases. High blood pressure, raised cholesterol levels and osteoporosis have been suggested as examples[6]. In the case of osteoporosis, drug companies have sponsored meetings to define the condition and have funded studies of treatments. Conceiving osteoporosis as a disease is ethically complex as it is a component of normal aging process. It has been publicized that slowing bone loss can decrease the risk of future fractures. However, the risk of serious fractures in absolute terms is low, and long-term preventive treatment may offer only small reductions in risk[2].
- Disease prevalence estimates can be framed to maximize the size of a problem[6]. Erectile Dysfunction (ED) is the classic example. The pharmaceutical company marketing drug to treat erectile dysfunction publicized that ED was of significant concern to many, perhaps even most, men or at least those over 40 years of age. The criterion of success for treating ED had to be redefined. And finally, the drug had to be seen as an important treatment option for men with any degree of ED, including rare or transitory failures to achieve or maintain erections.
- Promotion of anxiety about future ill health in healthy individuals and to use various life style modification drugs[2].
- Introduction of questionable new diagnoses such as social anxiety disorder that are hard to distinguish from normal life[6].
- Promotion of drugs as a first-line solution for problems previously not considered medical, such as disruptive classroom behaviour or problematic sexual relationships[4].
- Selective use of statistics to exaggerate the benefits of treatment[4].

DISEASE MONGERING IN RELATION TO PSYCHIATRY

The psychiatric community has also not been left untouched by disease mongering and has now become the major disease invention branch of big pharma ceuticals. Over the last few decades some of the new psychiatric diagnoses have come up and some of the previous diagnoses have received much attention by pharmaceutical companies. Drug companies market the "treatment" that happens to

have been recently FDA approved. It can also be noticed how new diseases or disorders only get publicized and advertised after the FDA approves a big pharma drug to treat them. These diseases apparently spontaneously afflict huge numbers of people in the days following the FDA approval of any drug that might treat such diseases. It has been claimed that big pharma hires psychiatrists to invent and then to publicize new "diseases." They actually sit around in rooms, brainstorming new disease ideas and figuring out how to convince the public that those diseases exist[2].

Bipolar Disorder: From the 1950s on, the depressions of manic-depressive illness have been treated with antidepressants and the manias with antipsychotics or lithium. Lithium was the only agent thought to be prophylactic against further episodes of manic-depressive illness[7]. But lithium was not originally referred to as a mood stabilizer. The term "mood stabilizer" had barely been heard of before 1995 when a pharmaceutical company got license for using the anticonvulsant sodium valproate for treating acute mania. After 1995, there was a dramatic growth in the frequency with which the term "mood stabilizer" appeared in the title of scientific articles. By 2001, more than a hundred article titles a year featured this term. Repeated reviews make it clear that the academic psychiatric community still has not come to a consensus on what the term "mood stabilizer" means[8,9,10]. But this lack of consensus did not get in the way of the message that patients with bipolar disorders needed to be detected and once detected needed mood stabilizers, and perhaps should only be given these drugs and not any other psychotropic drugs[10]. The first group of drugs to colonize this new mood stabilizer niche was anticonvulsants. Robert Post in the 1980s suggested that anticonvulsants might stabilize moods by a comparable quenching of the kindling effect of an episode of mood disorders on the risk of further episodes[11]. It was this idea that provided a pharmacological rationale for treatment of bipolar disorders that was so attractive to pharmaceutical companies, and, in their hands, the growth of awareness of mood stabilization and of bipolar disorders was sensational.

Bipolar disorders entered the DSM *(Diagnostic and Statistical Manual of Mental Disorders)* in 1980. At the time, the criteria for bipolar I disorder (classic manic-depressive illness) involved an episode of hospitalization for mania. Since then, the community based disorders bipolar II disorder, bipolar disorders NOS (not otherwise specified), and cyclothymia have emerged. With their emergence, estimates for the prevalence of bipolar disorders have risen from 0.1% of the population having bipolar I disorder (involving an episode of hospitalization for mania) to 5% or more when the definition of bipolar disorders includes the aforementioned community disorders[12]. There has always been a rationale to using antipsychotics in bipolar disorders, as they are effective in acute manic states. However, no companies making antipsychotics had previously sought a license for prophylaxis against bipolar disorders. Against a background of epidemiological studies indicating that the prevalence of bipolar disorders might be greater than previously though, and growing academic interest in the condition, various pharmaceutical companies (i.e. Lilly, Janssen, and Astra-Zeneca) who are the makers of the antipsychotics (olanzapine, risperidone, and quetiapine) marched in to market these drugs for prophylaxis of bipolar disorder. This, in turn, greatly expanded the number of companies with an interest in making the "bipolar market." Recently a psychiatrist stated that he is a disease monger. While the possibility of over-diagnosis of the disorder exists, the diagnosis is not invalid and the actual evidence shows that bipolar disorder has been largely undiagnosed or under-diagnosed[13]. This necessarily raises the prospect that increased efforts to detect and to treat people risks crossing the line where the benefits of treatment outweigh its risks. Along with this expansion in prevalence estimates came new journals on bipolar disorder, a slew of bipolar societies, and annual conferences, many heavily funded by pharmaceutical companies.

Attention Deficit Hyperactivity Disorder (ADHD): Over the last twenty years, attention deficit hyperactivity disorder (ADHD) has emerged as a disorder of importance in childhood. Prescription of psychostimulants for ADHD escalated in many countries through the 1990s. Between 1990 and 1995, prescriptions of methylphenidate for young people increased 2.5-fold in the US[14] and 5-fold in Canada[15]. In some countries rates of treatment for children in 2000 were nine times those in 1990[16]. ADHD joins dyslexia and glue ear as disorders that are considered significant primarily because of their effects on educational performance. Medicalising educational performance can help children receive specialized medical and educational services, at the same time it can lead to them receiving medications or surgical therapies which may have short-term and long-term ill effects.

In the case of ADHD, there has been a complex, often heated debate in the public domain about the verity of the illness and the personal cost-benefit ratio of treatment with psychostimulant medication. ADHD is, however, a disorder of educational performance, and so teachers have a critical role in advocating for the illness, and its medical treatment.

Conrad argued that when disorders previously viewed as non-medical are redefined as sicknesses, non-medical people often perform the "everyday routine work" of disseminating understanding of the new sickness[17]. With ADHD, the teacher's work extends beyond simply ensuring the disorder is understood by parents. Instead, the teacher participates in establishing the diagnosis. The role of the teacher as the sickness and treatment broker for ADHD has been elaborated more clearly for ADHD than for any other childhood disorder. The DSM-IV diagnostic criteria accord teachers a formal role in diagnosis through specialised assessment instruments such as the Conners Teacher's Rating Scale[18]. An informal role also exists for teachers as "disease-spotters." There appears to be considerable difference internationally in the alacrity with which teachers engage in disease-spotting.

Sisi syndrome: It is an alleged form of depression that came to light for the first time in 1998 by a pharmaceutical company[19]. According to the company, people suffering with this syndrome characteristically hide their illness by pretending to be active and positive about life, while in reality they are depressed and might need treatment with antidepressants. The syndrome is named after the 19th century Austrian Empress Elisabeth, nicknamed Sisi, who was said to have suffered from it. In 2003 an analysis of the literature by independent sources revealed no proof of the existence of Sisi Syndrome and discussed the incident as an example of the new kinds of marketing strategies by drug companies, referring to it as "disease mongering"[19].

Mild Cognitive Impairment: Whether mild cognitive impairment (MCI) can be considered a clinical entity is still a matter of debate. Gauthier and Touchon have argued, based on epidemiological evidence, that many subjects labeled as having MCI do not worsen over time and may revert to normal cognitive abilities[20]. Nevertheless, specific drug treatment for MCI has been proposed. Two RCTs have been conducted to investigate whether donepezil delays the onset of dementia in people with MCI. These studies failed to demonstrate any efficacy, while showing a worse safety profile among patients receiving active drug compared with the placebo group. In the first published trial[21], significant treatment effects were not seen in the primary efficacy measures, while more patients treated with donepezil experienced adverse events compared with patients treated with placebo (88% versus 73%). Despite this negative result, a new trial was conducted by Petersen et al., comparing donepezil, vitamin E, and placebo[22]. This study did not show a significant difference among the three groups in the rate of progression from MCI to Alzheimer disease over a three-year period.

Nevertheless, the authors stress some limited effects on secondary measures: a reduced likelihood of progression to Alzheimer disease only during the first 12 months of treatment, and a benefit of donepezil among carriers of one or more apolipoprotein E ε4 throughout the three-year follow-up. This latter claim, in particular, was not supported by the data as the study was not statistically powered to evaluate the effect of the treatment in separate groups of apolipoprotein E ε4 carriers. Although Petersen et al. conceded that the results "do not provide support for a clear recommendation for the use of donepezil in persons with mild cognitive impairment," they did suggest that their findings "could prompt a discussion between the clinician and the patient about this possibility"[22].

Erectile dysfunction: Sexual life has become vulnerable to disease mongering for two main reasons. First, a long history of social and political control of sexual expression created reservoirs of shame and ignorance that make it difficult for many people to understand sexual satisfaction or cope with sexual problems in rational ways. Second, popular culture has greatly inflated public expectations about sexual function and the importance of sex to personal and relationship satisfaction. Thus the public is led to expect high rewards from sexual life without having tools to achieve these rewards. This sets the stage for disease mongering, a process that encourages the conversion of

socially created anxiety into medical diagnoses suitable for pharmacological treatment. Medications that embody these controversies are generally referred to as lifestyle drugs and perhaps the best known of these is sildenafil citrate (Viagra). The pharmaceutical company involved in marketing Viagra took steps to make sure that Viagra was not relegated to a niche role of just treating men who had ED due to organic causes, such as diabetes or prostate surgery. There is no doubt that Viagra is an effective and quite safe drug in treating ED secondary to these causes, although a systematic review of the evidence found that the drug probably only results in successful intercourse 50 to 60% of the time. Had Viagra been confined to use only in cases of ED secondary to organic causes, the drug would probably have been a modest success for Pfizer. In order to grow the market, the company had to make Viagra the treatment of choice for a much wider population of men. The perceived prevalence of ED needed to be expanded. The impression had to be created that ED was of significant concern to many, perhaps even most, men or at least those over 40 years of age. The criterion of success for treating ED had to be redefined. And finally, Viagra had to be seen as an important treatment option for men with any degree of ED, including rare or transitory failures to achieve or maintain erections.

The National Health and Social Life Survey data indicate that emotional and stress-related problems such as a deteriorating social and economic position generate elevated risk of experiencing sexual difficulties. In these cases, Viagra may be less important than counseling or help in finding a new job. These possibilities are never mentioned on the Viagra Web site.

Female sexual dysfunction: The creation and promotion of "**female sexual dysfunction**" (FSD) is a textbook case of disease mongering by the pharmaceutical industry and by other agents of medicalization, such as health and science journalists, healthcare professionals, public relations and advertising firms and contract research organizations. The sequence of events and cast of participants involved in FSD matches the classic disease-mongering tactics[4]. Each physical condition or life event that has been subject to disease mongering tactics has its own unique history.

Urologists had used the term "female sexual dysfunction" as early as 1997, referring to aspects of genital pathophysiology that might be akin to erectile dysfunction. In 1997 Cape Cod conference on sexual dysfunction, which was sponsored by pharmaceutical companies, was a watershed moment in the FSD story[23]. No agreement about the definition of sexual dysfunction, its pathophysiology or clinical manifestations, of FSD was reached. Definitional issues have plagued the FSD literature ever since, despite repeated industry-supported attempts to draw a bright line between healthy sexual function and medical disorder. For the first few years, the key players in the medicalization of women's sexual problems were a small group of urologists who capitalized on their relationships with industry and recruited many sex researchers and therapists as allies. Big pharmaceutical companies have been the main promoter of FSD from 1997 to 2004, when its quest to have Viagra approved to treat "female sexual arousal disorder" ended because of consistently poor clinical-trial results[24]. It is a classic example of starting with some preconceived, and non-evidence based diagnostic categorisation for women's sexual dysfunctions, based on the male model, and then requiring further research to be based on that structure. Increasingly it is becoming evident that women's sexual problems are not usefully conceptualised in that way. Nevertheless, Viagra (and the idea that it *must* work for women) has been so successfully branded that it continues to be prescribed off-label for women . Next in line with a potential drug for FSD has been a testosterone patch to treat "hypoactive sexual desire disorder." The unnoticed shift in 2004 in FSD identity and promotion from female sexual arousal disorder to hypoactive sexual desire disorder is another hallmark moment illustrating how the effort to match up some drug with FSD moved freely among symptoms and labels. Unfortunately for the drug company, an FDA advisory panel did not approve testosterone patch due to lack of sufficient long-term safety data. However, one-fifth of all the prescriptions of testosterone products approved for men are actually written (off-label) for women. By 2006, FSD has become a medical and media reality, despite the obvious ongoing difficulties in defining the condition and in getting a drug approved.

Road Rage Disorder: Road rage disorder is the latest disease drummed up by the pharmaceutical industry. It has been reported that millions of American have undiagnosed Road Rage Disorder, also sometimes called **Intermittent Explosive Disorder** (IED). By definition, intermittent explosive disorder involves multiple outbursts that are way out of proportion to the situation. These angry outbursts often include threats or aggressive actions and property damage. The diagnosis of **Intermittent Explosive Disorder** is based on the definitions that one can be qualified as "ill" by simply having three major anger outbursts in the entire life. The disorder typically first appears in adolescence; in the study, the average age of onset was 14 years[25]. About 5 percent to 7 percent of the nationally representative sample had the disorder in U.S., which would equal up to 16 million Americans. That is higher than better-known mental illnesses such as schizophrenia and bipolar disorder[25].

Experts claim IED is caused by inadequate production of serotonin in the brain, which regulates our moods. It is felt that treatment with antidepressants can help the condition and treatment may be required for life[25].

Video game addiction: A proposal was recently brought before the annual meeting of the American Medical Association to designate **video game addiction** as a psychological disorder (Hassan, 2006). Advocates of the disorder label estimate that approximately 10 percent of players of video and computer games (particularly online games) devote excessive time to them, to the detriment of other aspects of their lives. However, the committee of doctors that introduced the motion backed away from it during the debate, recommending instead that the American Psychiatric Association study the issue carefully and considers making the change for the next edition of its diagnostic manual. Because of the influence of the DSM on pharmaceutical and insurance companies as well as physicians, including video game addiction would clear the way for insurance coverage of treatment.

Compulsive shopping (Shopaholic): It is defined as buying items that are really not needed, or buying huge quantities of items based on large discounts or other factors. It is also known as **"shopaholic"**. These people shop compulsively, buy things they do not need and often cannot afford; the unnecessary purchases can result in the jeopardizing of their jobs, finances, families and mental health[1]. Recently some psychiatrists are pushing to label excessive shopping a mental imbalance that needs to be treated with prescription drugs. There may be more than 10 million people in the United States that psychologists classify as "shopaholics" according to a study published in the American Journal of Psychiatry. On the contrary, many researchers argue that categorizing binge buying as a strictly mental problem takes the focus away from social factors, such as the impact of advertising, easy credit and commercialization.

CONSEQUENCES OF DISEASE MONGERING

Whereas some aspects of medicalisation are the subject of ongoing debate, the mechanics of corporate backed disease mongering, and its impact on public consciousness, medical practice, human health, and national budgets have attracted limited critical scrutiny. Within many disease categories informal alliances have emerged, comprising drug company staff, doctors, and consumer groups. Ostensibly engaged in raising public awareness about underdiagnosed and undertreated problems, these alliances tend to promote a view of their particular condition as widespread, serious, and treatable. Alternative approaches emphasising the self limiting or relatively benign natural history of a problem, or the importance of personal coping strategies are played down or ignored[4].

Inappropriate medicalisation carries the dangers of unnecessary labelling, poor treatment decisions, iatrogenic illness, and economic waste, as well as the opportunity costs that result when resources are diverted away from treating or preventing more serious disease. At a deeper level it may help to feed unhealthy obsessions with health, obscure or mystify sociological or political explanations for health problems, and focus undue attention on pharmacological, individualised, or privatised solutions. More tangibly and immediately, the costs of new drugs targeted at essentially healthy people are threatening the viability of publicly funded universal health insurance systems[26].

The social and economic consequences of disease mongering may be high. Enhancement of personal attributes and function through the use of lifestyle drugs has been identified as a "growth market" by the industry. These aim to create dissatisfaction with the present personal attributes and attempts to improve them through medicines. The

disillusionment and disappointment if the results are not up to the hyped-up expectations have to be carefully considered.

In India, the healthcare system is partly funded by the government but the private sector also plays a huge role. With regard to the other Asian countries, in some, the government is an important player; in others, the private sector is dominant; while some others have a mixed system. The role of medical insurance companies also varies across the continent. The majority of the population lack medical insurance and the capacity to pay for expensive medicines.

The practical consequences are that many of the so-called disease awareness campaigns that inform our contemporary understanding of illness—whether as citizens, journalists, health professionals, industry leaders, academics, or policymakers—are now underwritten by the marketing departments of large drug companies rather than by organizations with a primary interest in public health. And it is no secret that those same marketing departments contract advertising agencies with expertise in "condition branding," whose skills include "fostering the creation" of new medical disorders and dysfunctions. New drugs aggressively promoted for created diseases may divert funds and attention from the treatment of infectious diseases and other important problems. The corporate sponsored creation of disease is likely to increase further in the coming years[3].

COMBATING DISEASE MONGERING

Role of doctors: The first step to combating disease mongering has to be a genuine disentanglement of healthcare professionals from the pharmaceutical industry. Politicians interested in the welfare of patients and health of citizens should promote such independence[27]. Doctors should be careful and avoid drug treatments for physiological states and life processes. They should be careful while attending CME programmes which are sponsored by the industry. They should also develop the capacity for critical analysis of journal articles and research reports, and should avoid being misled by biased presentation and interpretation of data. The Teacher's Guide to Good Prescribing describes a facilitator's checklist for evaluating published clinical trials. For medical doctors, the availability of independent sources of drug information is essential. The World Health Organisation publication "Guide to Good Prescribing" makes an inventory of available sources of information and describes choosing between the sources.

In an Indian study it was demonstrated that the awareness of the problem was greater among pharmaceutical students as compared to medical students[28]. So doctors and healthcare personnel should generate knowledge about disease mongering. Medical associations and medical college administrators should alert their members to cross-check the information provided in drug company literature.

Prospective studies of the launch of a new or recently expanded disease or condition are required. Family care physicians and general practitioners should be aware of and be involved in combating disease mongering. Gillman has suggested that the medical profession should consider being more proactive with regard to the various problematic areas in their interaction with the pharmaceutical industry[13]. Systems should be in place in countries for provision of unbiased information.

Role of patients: With increasing levels of education and economic prosperity, patients should increasingly take greater responsibility for their treatment. They should be provided with and have access to information about their disease. The ultimate decision about whether or not to go in for drug treatment should be the patient's. However, as illiteracy is still a big problem in many parts of Asia, what to do when the patient is illiterate has to be discussed.

Role of politicians and government: Politicians play a vital role in overseeing the organization of society. Socioeconomic deprivation has been described as a "fundamental cause" of disease. Population approaches to tackling the fundamental causes of deprivation remains the most effective way of tackling inequalities of health[29]. Regulating drug advertising and the relationship between doctors and the pharmaceutical industry can be considered. The government may fund organisations providing independent, unbiased information on medicines. Government regulatory agencies are working towards regulating advertising[30]. The regulatory agencies should have sufficient political will to enforce the existing regulations governing drug promotion.

Role of alternative medicine practitioners and beauticians: Studies on disease mongering and the traditional focus on the topic have mainly targeted the pharmaceutical industry. However, in Asia and even in other regions, a number of other players are involved. Alternative medicine practitioners and unqualified healthcare providers often promise to treat disorders of sexual function and improve virility and vitality. They also make tall claims about treating sexually transmitted diseases. However, scientific proof for the efficacy of these products is lacking. Beauticians and associated advertising agencies may promote an ideal body image, and then emphasise drugs and other treatments to attain and maintain the particular image. A youthful image is emphasised and treatments like botulinum toxin (botox) and others are promoted to maintain youth and beauty. These treatments are not free from adverse effects. A number of treatments for baldness are also promoted by alternative medicine practitioners. However, scientific studies on these products are lacking. The alternative medicine practitioners and beauticians should also be made aware and incorporated in efforts to combat disease mongering.

CONCLUSION

Disease mongering turns healthy people into patients, wastes precious resources, and causes iatrogenic harm. Different forms of disease mongering practices has been identified like aspects of ordinary life, such as menopause, being medicalised; mild problems portrayed as serious illnesses and risk factors, such as high blood cholesterol and low bone density being framed as diseases. Like the marketing strategies that drive it, disease mongering poses a global challenge to those interested in public health, demanding in turn a global response. We hope that the coming years will also bear witness to a much more vigorous effort from within civil society to understand and to challenge this corporate process.

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