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Selling sickness: the pharmaceutical industry and disease mongering

Ray Moynihan, Iona Heath, David Henry

A lot of money can be made from healthy people who believe they are sick. Pharmaceutical companies sponsor diseases and promote them to prescribers and consumers. Ray Moynihan, Iona Heath, and David Henry give examples of "disease mongering" and suggest how to prevent the growth of this practice

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There's a lot of money to be made from telling healthy people they're sick. Some forms of medicalising ordinary life may now be better described as disease mongering: widening the boundaries of treatable illness in order to expand markets for those who sell and deliver treatments.[1 2] Pharmaceutical companies are actively involved in sponsoring the definition of diseases and promoting them to both prescribers and consumers. The social construction of illness is being replaced by the corporate construction of disease.

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. Because these "disease awareness" campaigns are commonly linked to companies' marketing strategies, they operate to expand markets for new pharmaceutical products. 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. As the late medical writer Lynn Payer observed, disease mongers "gnaw away at our self-confidence."[2]

Although some sponsored professionals or consumers may act independently and all concerned may have honourable motives, in many cases the formula is the same: groups and/or campaigns are orchestrated, funded, and facilitated by corporate interests, often via their public relations and marketing infrastructure.

A key strategy of the alliances is to target the news media with stories designed to create fears about the condition or disease and draw attention to the latest treatment. Company sponsored advisory boards supply the "independent experts" for these stories, consumer groups provide the "victims," and public relations companies provide media outlets with the positive spin about the latest "breakthrough" medications.

Summary points

- Some forms of "medicalisation" may now be better described as "disease mongering"—extending the boundaries of treatable illness to expand markets for new products
- Alliances of pharmaceutical manufacturers, doctors, and patients groups use the media to frame conditions as being widespread and severe
- Disease mongering can include turning ordinary ailments into medical problems, seeing mild symptoms as serious, treating personal problems as medical, seeing risks as diseases, and framing prevalence estimates to maximise potential markets
- Corporate funded information about disease should be replaced by independent information

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,[3] obscure or mystify sociological or political explanations for health problems,[4] and focus undue attention on pharmacological, individualised, or privatised solutions.[3] 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.[5]

Recent discussions about medicalisation[6] have emphasised the limitations of earlier critiques[1] of the

disabling impact of a powerful medical establishment. Contemporary writers argue that the lay populace has become more active, better informed about risks and benefits, less trusting of medical authority, and less passively accepting of the expansion of medical jurisdiction into their bodies and lives. Although these views may herald a more mature debate about medicalisation, the erosion of trust in medical opinion reinforces the need for wide public scrutiny of industry's role in these processes.

In this paper we do not aim for a comprehensive classification or definitive description of disease mongering, but rather we draw attention to an important but under-recognised phenomenon. We identify examples, taken from the Australian context but familiar internationally, which loosely represent five examples of disease mongering: the ordinary processes or ailments of life classified as medical problems; mild symptoms portrayed as portents of a serious disease; personal or social problems seen as medical ones; risks conceptualised as diseases; and disease prevalence estimates framed to maximise the size of a medical problem. These groups are not mutually exclusive and some examples overlap.

Ordinary processes or ailments as medical problems: baldness

The medicalisation of baldness shows clearly the transformation of the ordinary processes of life into medical phenomena. Around the time that Merck's hair growth drug finasteride (Propecia) was first approved in Australia, leading newspapers featured new information about the emotional trauma associated with hair loss. The global public relations firm Edelman orchestrated some of the coverage but largely left its fingerprints off the resulting stories. An article on page 4 in the *Australian* newspaper featured a new "study" suggesting that a third of all men experienced some degree of hair loss, along with comments by concerned experts and news that an International Hair Study Institute had been established.[7] It suggested that losing hair could lead to panic and other emotional difficulties, and even have an impact on job prospects and mental wellbeing. The article did not reveal that the study and the institute were both funded by Merck and that the experts quoted had been supplied by Edelman, despite this information being available in Edelman's publicity materials in May 1998.

Although Merck is prevented from advertising finasteride direct to consumers in Australia, it has continued to promote hair loss as a medical problem, with waves of advertisements urging balding men to "See Your Doctor." The company argues that it does not describe baldness as an illness and that men have a legitimate right to be made aware of scientifically proved options to stop hair loss (statement from Merck spokesperson, 7 March 2002).

Mild symptoms as portents of serious disease: irritable bowel syndrome

Irritable bowel syndrome has long been considered a common functional disorder, and a "diagnosis of exclusion" covering a range of symptom severity, yet it is currently experiencing something of a global "makeover." Without question many people with the condition are severely disabled by their symptoms, but the arrival of new drugs has seen manufacturers seek to change the way the world thinks about irritable bowel syndrome.

CHRIS GROENHOUT

Merck has widely promoted hair loss as a medical problem, including advertising on buses

What for many people is a mild functional disorder—requiring little more than reassurance about its benign natural course—is currently being reframed as a serious disease attracting a label and a drug, with all the associated harms and costs.

Confidential plan to "shape" medical opinion

A confidential draft document leaked from a medical communications company, In Vivo Communications, describes a three year "medical education programme" to create a new perception of irritable bowel syndrome as a "credible, common and concrete disease." The proposed 2001-3 education programme is part of the marketing strategy for GlaxoSmithKline's drug Lotronex (alosetron hydrochloride).

In Vivo is one of a handful of companies specialising in corporate backed "medical education," and the leaked plan provides a rare insight into the highly secretive world of drug promotion, with its new emphasis on "shaping" medical and public opinion about the latest diseases.

According to the documents, the education programme's key aim is this: "IBS [irritable bowel syndrome] must be established in the minds of doctors as a significant and discrete disease state." Patients also "need to be convinced that IBS is a common and recognised medical disorder." The other main messages are about promoting the new "clinically proven therapy"—Lotronex.

The first step is to set up an "Advisory Board, comprising one KOL [key opinion leader] from each state of Australia." Its chief role would be to provide advice to the corporate sponsors on current opinion in gastroenterology and on "opportunities for shaping it." Further work would include developing "best practice guidelines" for diagnosing and managing irritable bowel syndrome and attending overseas meetings. Another strategy was to produce a newsletter in the pre-launch period to "establish the market" and

convince the "specialist market" that the condition is a "serious and credible disease."

For general practitioners, In Vivo recommends a series of advertorials in leading medical magazines, featuring interviews with members of the company's advisory board, because "The imprimatur of [board] members is invaluable in reassuring [general practitioners] . . . that the material they receive is clinically valid."

Other groups to be targeted with promotional material include pharmacists, nurses, patients, and a medical foundation described as already having a "close relationship" with In Vivo. A "patient support programme" is also planned for 2002-3, so that GlaxoSmithKline will "reap the loyalty dividend when the competitor drug kicks in."

Medical education or marketing?

Although billed as a medical education plan, the document is clearly part of the Lotronex marketing strategy. One clause explicitly stipulates that all publications and manuscripts must be approved by the drug company's marketing, medical, and legal departments. The document also makes clear the media's role in changing public perceptions about irritable bowel syndrome, stating that "PR [public relations] and media activities are crucial to a well-rounded campaign—particularly in the area of consumer awareness."

Whatever the integrity or competence of the professionals or consumer advocates involved, and without seeking to minimise the importance of the disorder for some individuals, this plan shows that staff and organisations sponsored by a drug company are helping to shape medical and public opinion about the condition that company is targeting with its new product. Although GlaxoSmithKline has argued that its sponsorship of education can improve doctors' prescribing habits (personal communication, 7 March 2002), the conflict of interest is obvious and potentially dangerous. Self evidently, the drug company's primary interest will be shaping opinion about irritable bowel syndrome in a way that will maximise sales of its medication.

In this case the proposed campaign was stopped because of the withdrawal of Lotronex from the market, after reports to the US Food and Drug Administration of serious and sometimes fatal adverse reactions.[8] In a recent letter to patients, the administration suggested that indiscriminate use of the drug could result in more fatal adverse events and that many patients in whom the condition was non-serious could experience more harm than good.[9]

Conversations with industry insiders and other published material from the drug marketing industry confirm that the strategies proposed for promoting irritable bowel syndrome by In Vivo were in no way exceptional. A "practical guide" published by Britain's *Pharmaceutical Marketing* magazine last year explicitly emphasised that key objectives of the pre-launch period were to "establish a need" for a new drug and "create the desire" among prescribers.[10] The guide instructed drug marketers that they may need to "initiate a review of the whole way in which a particular disease is managed."

Personal or social problems as medical ones: social phobia

When Roche was promoting its antidepressant Aurorix (moclobemide) as a valuable treatment for social phobia in 1997, its public relations company issued a press release, picked up by some of the media, announcing that more than one million Australians had an underdiagnosed psychiatric disorder called social phobia.[11] The release described a "soul destroying condition" and quoted a clinical psychologist strongly endorsing the role of antidepressants in its treatment. At that time, government figures suggested the number of people with the disorder might be closer to 370 000.

In 1998, a newspaper article, "Too shy for words"—this time not orchestrated by Roche—suggested that two million Australians were affected by the condition.[12] All the media stories seemed to be part of a wider push to change the common perception of shyness, from a personal difficulty to a psychiatric disorder.

An important aspect of Roche's marketing for moclobemide involved working with a patient group called the Obsessive Compulsive and Anxiety Disorders Foundation of Victoria and funding a large conference on social phobia. According to the foundation's chief at the time, "Roche is putting a lot of money into promoting social phobia . . . Roche funded the conference to help get social phobia known among [general practitioners] and other health professionals … It was a vehicle to raise awareness with the media too."[11] Roche's promotion of its antidepressant drug also included working with ostensibly independent medical specialists, one of whom was later described by a public relations agent as "Moclobemide Man" (personal communication, 1998).

Pharmaceutical Marketing's practical guide singled out the promotion of social phobia as a positive example of drug marketers shaping medical and public opinion about a disease.[10] "You may even need to reinforce the actual existence of a disease and/or the value of treating it. A classic example of this was the need to create recognition in Europe of social phobia as a distinct clinical entity and the potential of antidepressant agents such as moclobemide to treat it," said the industry guide. It went on: "Social phobia was recognised in the US and so transatlantic opinion leaders were mobilised to participate in advisory activities, meetings, publications etc. to help influence the overall belief in Europe." The medicalisation of human distress seems to have no limits.[13]

A senior Roche official recently conceded that company promotion exaggerated the prevalence of social phobia in Australia. "A lot of disease estimates are blown out of all proportion . . . The marketing people always beat these things up" said local managing director Mr Fred Nadjarian (see news article).

Risks conceptualised as diseases: osteoporosis

Like high blood pressure or raised cholesterol levels, the medicalisation of reduced bone mass—which

occurs as people age—is an example of a risk factor being conceptualised as a disease.

Unlike medicalising baldness, conceiving osteoporosis as a disease is ethically complex. Slowing bone loss can reduce the risk of future fracture—just as lowering blood pressure can reduce a person's chance of a future stroke or heart attack—but for most healthy people, the risks of serious fractures are low and/or distant, and in absolute terms, long term preventive drug treatment offers small reductions in risk. For example, in a placebo controlled trial in which alendronate was taken for four years by women who were free of fracture but had bone mineral density measurements 1.6 standard deviations below the mean for normal young adult white women, the incidence of radiographic vertebral fractures was 3.8% in the placebo group and 2.1% in the treatment group.[14] This equated to a 44% relative reduction in risk but an absolute risk reduction of only 1.7%.

Furthermore, the promotional focus on chemical solutions for the complex problem of preventing fractures takes attention away from a variety of modestly effective non-pharmacological strategies, such as dietary supplementation with calcium and vitamin D, smoking cessation, and weight bearing exercise.[15]

Despite the ethical complexities, osteoporosis remains a strong example of disease mongering because the corporate role in changing the way populations think about bone loss has been so extensive. Drug companies have sponsored meetings where the disease was being defined,[16] funded studies of therapies,[17] and developed extensive financial ties with leading researchers. They have funded patient groups, disease foundations, and advertising campaigns (on both drugs and disease) targeted at doctors[11] and have sponsored osteoporosis media awards offering lucrative prizes to journalists.

A controversial definition

Contrary to much of the corporate promotion, the definition of osteoporosis is still controversial. Diagnostic criteria set by the World Health Organization, which set the bone density of young white women as "normal" and judge the bones of older women against this standard, are contentious.[16] A key meeting of the WHO study group involved in defining the diagnosis of osteoporosis was funded in part by three pharmaceutical companies.[16]

The link between bone density and fracture risk is also the subject of scientific controversy, with reviewers pointing out that while bone mineral density is associated with fracture, it is not a sufficiently accurate predictor of an individual's risk of fracture to be used as a guide to therapy.[18] A recent evaluation by the University of British Columbia concluded that "Research evidence does not support either whole population or selective . . . bone mineral density testing of well women at or near menopause as a means to predict future fractures."[16]

Good quality studies have shown that several drugs, including oestrogens, selective oestrogen receptor modulating agents, and bisphosphonates, reduce the risk of fractures.[15] However, although public promotion of those drugs often relies on presentations of relative reductions in fracture risk, the absolute reductions for healthy women are small when weighed against potential harms and costs.[19]

The marketing of fear

Osteoporosis Australia, a medical foundation, which has received funding from pharmaceutical companies, issued a press release recently urging people to take a one minute test for their risk of osteoporosis.[20] According to the foundation, "we call this disease a silent thief: if you're not vigilant, it can sneak up on you and snatch your quality of life and your long-term health." An accompanying 10 point checklist suggests that merely being a menopausal woman was enough to justify a trip to the doctor to be tested for this disease. The construction of the widely used WHO diagnostic criteria is such that large numbers of healthy women at menopause will automatically be diagnosed as having this "disease" because their bones are being compared with those of much younger women.

Against a background of controversy over disease definition, poor predictive value of bone density measurement, and heavily advertised expensive therapies offering marginal benefits to menopausal women, corporate backed promotional activities are attempting to persuade millions of healthy women worldwide that they are sick.

Disease prevalence estimates framed to maximise the size of a medical problem: erectile dysfunction

Double page advertisements told Australians recently that 39% of men who visit general practitioners have erection problems.[21] The advertisement featured an unhappy couple, who looked to be in their 30s or 40s, on opposite sides of a double bed, with the accompanying text: "Erection problems: hard to talk about, easy to treat." As with much disease mongering, the key strategy here was to make the condition seem as widespread as possible.

The 39% claim in the advertisement was referenced to an abstract of a survey finding. The full version of the published survey[22] revealed that the 39% figure was obtained by tallying all categories of difficulties, including men who reported having problems only "occasionally," and the average age of those reporting complete erectile dysfunction was 71 years. Another recent Australian study, not cited in the advertisement, estimated that erection problems affected only 3% of men in their 40s, and 64% of men in their 70s.[23]

The advertisement's fine print cited a host organisation, Impotence Australia, and two other groups but did not mention that the advertisement was funded by the manufacturer of sildenafil (Viagra), Pfizer. Impotence Australia had at that time only recently been set up with a grant of $A200 000 (£74 000; $105 200; €119 400) from Pfizer. Its executive officer told the press, "I could understand that people may have a feeling that this is a front for Pfizer."[24]

Defending the public promotion of erection problems, a Pfizer spokesperson said, "The best consumer is an educated consumer . . . Who better than the manufacturer to help this process?" (personal communication, 5 March, 2002).

Discussion

These observations of disease mongering are selective and preliminary. They are not the result of systematic study, but rather a series of anecdotal case studies designed to provoke debate. We know little of the true extent of these industry funded zones of influence, and even less of their impact. But we believe more information and analysis of the nature and functioning of these "unholy alliances"[2] is warranted. The key concern with the examples here is the invisible and unregulated attempts to change public perceptions about health and illness to widen markets for new drugs.

Although mainstream media already play an important role investigating and reporting on contemporary promotional activities, more could be done to expose and reduce misleading "wonder drug" stories, which help to facilitate so much disease mongering.

As a practical step, we suggest that health professionals, policy makers, journalists, and consumers move away from reliance on corporate sponsored material about the nature or prevalence of disease. Genuinely independent sources of information about health problems could replace those skewed towards making the maximum numbers of healthy people feel sick.

Just as researchers from the Cochrane Collaboration are generating systematic evaluations of the best evidence about therapies, a similar effort may be required in evaluating and/or producing unbiased information about illness—starting with those conditions most prone to disease mongering. Independent lay involvement is crucial to produce accurate, comprehensive, and accessible materials.

The public is entitled to know about the controversy surrounding disease definitions and about the self limiting and relatively benign natural course of many conditions. A publicly funded and independently run programme of "de-medicalisation," based on respect for human dignity, rather than shareholder value or professional hubris, is overdue.

Recommendations for "de-medicalising" normal conditions

- Move away from using corporate funded information on medical conditions/ diseases
- Generate independent accessible materials on conditions and diseases
- Widen notions of informed consent to include information about controversy surrounding the definitions of conditions and diseases

We dedicate this article to the late Lynn Payer, medical writer, who died last year. We thank David Newby for his help in conducting literature searches.

Competing interests: DH has received funding from American Home Products to conduct research into non-steroidal anti-inflammatory drugs. As a member of the Australian Pharmaceuticals Benefits Advisory Committee, he has has twice been the subject of legal action by Pfizer.

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Commentary: Medicalisation of risk factors

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A middle aged man with pneumonia may wonder why the attending doctor is inserting a finger into his rectum. This is a screening test—it has nothing to do with the patient's disease. The physician may find a localised prostate cancer, and the patient may subsequently undergo radical prostatectomy, although no evidence from randomised trials shows that this operation is effective. The patient with pneumonia cannot be sure that the prostatectomy will increase his chance of living longer, but his life will probably feel longer, because the operation renders most men impotent.[1] This disastrous consequence has received too little attention, but when properly informed, many men will decide not to have a screening test.[2]

The man's risk factor for prostate cancer was his age. Increased age leads to other unanticipated interventions. In some countries, women are invited for mammography in a letter in which the date and time of the appointment have already been fixed. This puts pressure on these women, who must actively decline the invitation if they don't want to be screened. Sometimes, women are asked to give reasons for not attend-

ing appointments, as if it were a civic duty. In leaflets, women get simple messages—that cancer detected early can be cured, and early cancers can often be treated with breast conserving surgery. The data tell another story: no reliable evidence shows that breast screening saves lives; breast screening leads to more surgery, including more mastectomies; and estimates show that more than a tenth of healthy women who attend a breast screening programme experience considerable psychological distress for many months.[3 4]

Senior scientists argue that this debate should not be taking place in public.[5] This misguided paternalism makes us wonder why health professionals are so eager to intervene in healthy people's lives and about those people's own perspectives on risks. In Denmark, the most common cause of death from cancer among women is no longer breast cancer but is now lung cancer, which is mainly self inflicted.

It seems that every person aims to balance the rewards of taking risks against perceived hazards.[6] This can probably explain why laws on wearing safety belts have not reduced deaths from road crashes. Such deaths now happen to those outside rather than inside the vehicle—probably because drivers who wear safety belts feel safer and drive faster or more carelessly than those who do not.[6]

Another important consideration is the reliability of studies of risk. Increased risks are often reported in case-control studies, which do not reliably identify moderate increases in risk. A much quoted and carefully done meta-analysis of case-control studies claimed to show a 30% increase in the risk of breast cancer after induced abortion,[7] but this was later refuted by a large cohort study.[8] Most epidemiologists interviewed by *Science* said they would not take seriously a single study reporting a new potential cause of cancer unless it increased the risk by at least a factor of three; some even noted that the lower limit of the confidence interval should exceed 3.[9] Nevertheless, lay people are influenced by increases in risk of 50-100%, and this leads to much public anxiety and many negative changes in lifestyle. Some people, for example, will follow unappealing diets or quit sports when told that their bone mineral density is low, even though these diets may not affect bone mineral density and inactivity increases the risk of fractures.

Mass intervention on a fragile basis may lead to mass harm. The main outcome of cancer screening trials—disease specific mortality—is unreliable and biased in favour of screening.[3 4 10] It therefore seems prudent to show an effect of a screening programme on total mortality in good randomised trials and to inform the public fully about the adverse effects before the programme is implemented. The biggest risk for the population right now may be the uncritical adoption of screening tests for cancer—for example, for cervical, breast, prostate, colon, and lung cancer,[1 3 10 11] despite lack of evidence of an effect on total mortality. Precursors to cancer can be seen in most healthy people above middle age, and the potential for screening to cause harm and lead to a diagnosis of "pseudo-disease" is frightening. Whether risk factors should be turned into diseases also needs careful reflection for other screening tests—for example, detection of mild hypertension or mild hypercholesterolaemia.

Perhaps it is time to rethink what life is all about and remind ourselves that most people are willing to run substantial risks in their ordinary life to preserve their joy and autonomy. In *Out of Africa*, Karen Blixen wrote that the European wants to get insured against fate, whereas the African takes it as it comes. She also wrote: "Frei lebt wer sterben kann" [Those who can die live freely].

Competing interest: None declared.

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Endpiece

On music

Music authorises, invites the conclusion that the theoretical and practical sciences, that rational investigation will never map experience exhaustively. That there are phenomena "at the centre"… which will endure, boundlessly alive and indispensable, but "outside." This is, quite straightforwardly, the proof of the meta-physical. Music is significant to the utmost degree; it is also, strictly considered, meaningless. There abides its "transgression" beyond intellect.

George Steiner. *Errata: an examined life.* London: Phoenix, 1998:75-6

The dangers of our times

Both cancer and heart disease intensify our awareness of the dangers of our times and of the man-made sources of much misery. But the governmental response is meant to obfuscate this vision of sickness as meaning something is wrong with the social order and to replace (medicalize) it with narrowly technical questions. Is there a better mirror of what we are about?

Arthur Kleinmann. *The illness narratives. Suffering, healing, and the human condition.* New York: Basic Books, 1988

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