

SELLING SICKNESS

How the World's Biggest Pharmaceutical
Companies Are Turning Us All into Patients

by Ray Moynihan & Alan Cassels

THIRTY YEARS AGO Henry Gadsden, chief executive of one of the world's most prominent drug companies, Merck tells Fortune magazine of his distress that the company's potential market is limited to sick people. He says it is his dream to make drugs for healthy people. Because then, Merck could sell to everyone. Three decades later, the marketing strategies of the world's biggest drug companies target the healthy and the well. At a time when many people are leading longer, healthier, and more vital lives than their ancestors, advertising and awareness-raising campaigns, funded by the \$500 billion pharmaceutical industry, are changing the way people think about illness in order to expand the market for drugs.

Vince Parry, an expert in advertising, specializes in the most sophisticated form of selling medicines. He works with drug companies to help create new diseases. In an article titled, "The art of branding a condition", Parry reveals the ways in which companies are involved in "fostering the creation" of medical disorders. Sometimes an obscure condition is given renewed attention, sometimes an old disease is redefined and renamed, and sometimes a whole new dysfunction is created. A recent Reuters Business Insight report designed for drug company executives contends that the ability to "create new disease markets" is bringing in billions of dollars in drug sales.

Mild problems are being diagnosed as serious diseases.

- ▶ Shyness is a symptom of social anxiety disorder.
- ▶ The natural change of life, menopause, is considered a disease of hormone deficiency.
- ▶ Everyday sexual difficulties are defined as sexual dysfunctions.
- ▶ Distracted office workers now have adult ADD.
- ▶ Healthy middle-aged women have a silent bone disease called osteoporosis.
- ▶ Fit middle-aged men have a lifelong condition called high cholesterol.
- ▶ Premenstrual dysphoric disorder (PMDD) is so controversial some researchers claim it doesn't exist.

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Summary Information

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For most healthy people, there are much cheaper, safer and more effective ways to stay healthy such as, improving diet, increasing exercise, and not smoking. The pharmaceutical industry's influence over doctors' practices, medical education, and scientific research is widespread and controversial. Pharmaceutical companies have a significant influence on the way physicians prescribe medicines and the way conditions like irritable bowel syndrome, menopause, high cholesterol, high blood pressure, depression, osteoporosis, ADD and PMDD are defined and promoted.

Medicines sometimes cause the very harm they are designed to prevent.

- ▶ A drug claiming to help with common bowel problems may lead to deadly constipation for some people.
- ▶ Long-term hormone replacement therapy increases the risk of heart attacks for women.
- ▶ Antidepressants may increase the risk of suicidal thinking among the young.
- ▶ Antidepressants prescribed for PMDD carry many side effects, including serious sexual difficulties.
- ▶ At least one of the cholesterol-lowering drugs has been withdrawn from the market because it is implicated in causing deaths.

The U.S. Food and Drug Administration's mission is to make sure medicines are safe and effective for the almost 300 million Americans it serves. Its deliberations determine which drugs get approved for sale into the massive U.S. market, and which don't. It also influences the actions of drug regulators and health care advocacy organizations around the world. As a result, the decisions made there have a profound effect on some of the world's most profitable corporations.

Paul Stolley, a senior consultant at the FDA, a distinguished professor of medicine at several leading universities, a member of the National Academy of Science, and a long-time expert in drug safety, was asked by his superiors to look into a medication that had just come on to the market. GlaxoSmithKline's Lotronex had been recently approved for women with irritable bowel syndrome (IBS), a condition characterized by stomach pains and difficulties with constipation and diarrhea.

IBS is said to be a disease affecting up to one in every five people in the western world, nearly 45 million in the U.S. alone. During his first year at the agency, Paul Stolley was suggesting to his FDA superiors that they consider pulling the new drug from the market because of serious concerns about its safety. Prior to his arrival, severe side effects had been reported.

Two side effects in particular emerged as the most serious and potentially fatal:

- ▶ Severe constipation - after taking the drug, the patient's feces would become so impacted within their bowel that the bowel wall perforated, leading to potentially fatal infections inside the body.
- ▶ Ischaemic colitis - similar to a heart attack happening in the bowel, where the blood simply stops flowing to it.

Reading the reports arriving at the FDA, and studying all the scientific data from the drug's original clinical trials, Stolley and other safety experts inside the FDA conclude that some of those taking the drug are suffering life-threatening side effects far worse than the symptoms the drug is prescribed for. Stolley discovers that more than 50 percent of the FDA's work checking the safety and effectiveness of drugs is paid for by the companies whose products are being reviewed.

The FDA rejects calls for a ban, but facing evidence of dangerous side effects and negative media coverage, the pharmaceutical company decides to voluntarily withdraw the drug from the U.S. market. Lotronex is re-approved eighteen months later. Internal FDA emails, that surface publicly some time later, suggest that in this case GSK officials and FDA staff were working closely to ensure that the advisory committee was going to give the advice that the company and the senior FDA officials sought after.

Two surveys of FDA staff:

The first survey by Public Citizen from outside the agency finds:

- ▶ Many officers feel under pressure to approve new drugs.
- ▶ They receive inappropriate phone calls from drug companies.
- ▶ FDA senior officials intervene on a company's behalf in the drug approval process.

The second survey of more than 130 officers conducted within the FDA finds:

- ▶ People reviewing drugs report feeling pressure to "favor the desires of sponsors over science and the public health."
- ▶ One-third surveyed, report they do not feel comfortable expressing their differing scientific opinion.

The portrayal of IBS as a severe, widespread disease is strongly backed by one of the leading patient advocacy groups, the International Foundation for Functional Gastrointestinal Disorders. Its president, Nancy Norton, spoke at all three FDA advisory meetings and as the transcripts show she never reveals that her foundation receives significant amounts of money from pharmaceutical companies, including GSK.

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When the Frasier sitcom star Kelsey Grammer and his wife appeared on shows like The Today Show, raising the profile of the syndrome, it was implied on behalf of Norton's

foundation, however, GSK funded the celebrity campaign. The involvement of the Frasier star was organized with the help of celebrity-broker Amy Doner Schachtel, a former drug company public relations expert in connecting high-profile celebrities with big-name drug companies.

She states, “Just one segment on a national talk show, or one print article in a major newspaper can tremendously impact patients’ decisions to seek treatment.” She helps find celebrities to raise awareness about irritable bowel syndrome, depression and social anxiety disorder. She worked with West Wing actor Rob Lowe, country singer-songwriter Naomi Judd, and television star Cybill Shepherd to raise awareness about menopause on behalf of an Australian company. “People look up to celebrities,” she says, “because they trust them.”

Celebrities are central figures in drug company campaigns.

- ▶ Celebrities are paid anything from \$20,000 to \$2 million.
- ▶ Celebrities being paid by drug companies are under no clear regulatory requirements to disclose accurate information about the nature of the conditions or the therapy they are promoting.
- ▶ There are no legal requirements for celebrities, or for the media outlets in which they appear, to disclose their connection with the drug manufacturer.

Sociologist Susan Bell has traced the medicalization of menopause back to the 1930s, when a small group of elite medical specialists started to define a woman’s change of life as a medical problem and label it as a deficiency disease. The same group of physicians was researching a new drug called DES, one of the early synthetic forms of the female hormone estrogen. Just as modern long-term hormone replacement therapy (HRT) is now known as toxic and harmful, the 1930s drug DES was ultimately found to be a dangerous carcinogen linked to birth defects in the daughters of some of those who took it.

In the mid-1960s, New York gynecologist Dr. Robert Wilson published the landmark work *Feminine Forever*, the book that helped sell to generations of women the idea that they could treat their disease of deficiency with hormone replacement. Excerpts were published in *Look* and *Vogue* and it sold one hundred thousand copies in a matter of months. His celebrity book tours and his scientific work testing estrogen were partially sponsored by the drug company that manufactured the hormones, Ayerst Laboratories, which ultimately became Wyeth.

In 2000, celebrity Lauren Hutton appears on the cover of *Parade* along with the headline, “Live Longer, Better, Wiser: This year’s indispensable guide for every one of us.” She also appears in the magazine’s main article, and is featured as the centerpiece of a Wyeth advertisement in the same issue, talking about the consequences of estrogen loss at menopause.

In 2002, Lesa Henry, the public relations chief at the drug company Wyeth, and the woman helping to market HRT, picks up an advertising industry award for her work using celebrities to promote drugs. She is named one of the top twenty-five marketers of the year just as scientists discover long-term use of hormone replacement therapy is



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doing women more harm than good. She is one of the first people to recognize the value of celebrities for educating consumers about health conditions, and the drugs that go with them.

The Wyeth advertisement detailed a list of what may lie ahead for women after menopause:

- ▶ Alzheimer’s disease
- ▶ Heart attacks
- ▶ Colon cancer
- ▶ Cataracts
- ▶ Tooth loss
- ▶ Night sweats
- ▶ Vaginal dryness
- ▶ Bone fractures

In mid-July 2000, the Australasian Menopause Society developed a free information booklet for patients. Newspapers ran advertisements encouraging women to attend seminars with medical experts talking about the consequences of estrogen loss, and what to do about it at towns and cities across the country. The U.S. based Wyeth was funding the Australian campaign, and it was part of the company’s global marketing effort to boost sales of HRT. At least one of the key images in the patient information booklet was lifted directly from the Wyeth ads running at the time in the United States. The booklet states that observational studies suggest the drugs reduce the risk of heart disease. It does not reveal that one of the first top-quality randomized controlled trials, the HERS trial, suggests the drugs have no such benefit and that there is proven risk of blood clots associated with the use of these drugs. The HERS trial results had by then been known for two years.

Hormone replacement therapy proves to cause some of the health problems it is supposed to prevent such as:

- ▶ Alzheimer’s disease
- ▶ Heart attacks
- ▶ Strokes
- ▶ Blood clots
- ▶ Breast & endometrial cancer

The pharmaceutical industry and the medical profession build a foundation of a lifelong relationship.

- ▶ Physicians are strongly encouraged and sometimes formally required to attend continuing medical education, where half the funding of this billion-dollar enterprise is provided by the pharmaceutical industry.
- ▶ Under a voluntary code created by the pharmaceutical industry, it is acceptable for a drug company to fly three hundred independent doctors to a golf resort, pay them to attend, educate them about the company's latest drug, and then train them to become part of the company's stable of paid speakers.
- ▶ A global survey from Britain estimates that two-thirds of all patient advocacy groups and health charities rely on funding from drug companies or device manufacturers.
- ▶ An estimated 60 percent of biomedical research and development in the U.S. is mainly funded from drug companies.
- ▶ The Food and Drug Administration receives more than half of its funding from the drug companies whose products it is assessing.
- ▶ Research evidence is discussed and disseminated at more than three hundred thousand scientific meetings, events and conferences sponsored by the pharmaceutical industry every year.
- ▶ Dr. Bryan Brewer, a senior official at the publicly funded National Institutes of Health (NIH), one of the biggest biomedical research houses in the world, delivers a presentation at an American Heart Association seminar, sponsored by AstraZeneca describing Crestor, as safe and effective. He has received two hundred thousand dollars from outside private interests including eight other drug companies.
- ▶ In 2004, drug companies paid around two thousand dollars for each ten-foot by ten-foot square space at the annual congress of the American Psychiatric Association. They also sponsored over fifty scientific sessions throughout the week-long congress. One of the congress's key sponsors is the maker of the world's top-selling antidepressant drug, Zoloft.

- ▶ In the mid-1990s, at the international menopause congress held in Sydney, Wyeth funded almost half of the scientific sessions. To help the international delegates understand the latest science about menopause they were also offered social engagements, including trips to the Sydney Opera House and harbor cruises. Post-congress tours explored the tropical rainforest, the Great Barrier Reef, and Uluru.

Although Cholesterol is an essential element of the body's makeup and is vital to life, efforts to suppress it with medication continues.

In 1987, Merck launched the first of the approved cholesterol-lowering statins, Mevacor. With sales of more than \$10 billion a year, Lipitor is the world's highest selling prescription drug. Pfizer, its manufacturer, is the largest pharmaceutical company and one of the world's largest corporations. Nations everywhere have spent more on cholesterol-lowering drugs in recent years than any other category of prescription medicines, generating revenues of more than \$25 billion a year for their manufacturers.

- ▶ There is scientific evidence showing that for many people, a raised level of cholesterol in the blood is associated with an increased risk of future heart attacks and strokes, but having high cholesterol is only one of the many factors that affects your chance of future heart disease.
- ▶ Specialists in prevention, like British researcher Professor Shah Ebrahim, feel these new statin drugs are a valuable course of action for people who have already had heart disease, but believe the narrow focus on cholesterol is a potentially dangerous distraction from the real issue of prevention.

The connection between cholesterol guideline experts and the pharmaceutical industry:

- ▶ Panels of cholesterol experts in the U.S. continue to revise the definition of what constitutes high cholesterol.
 - a. In 2001, with the cholesterol definition revision, 36 million otherwise healthy Americans are classified as sick and potentially in need of drugs.
 - b. In 2004, with another revision, the number rises to 40 million.
- ▶ Five of the fourteen authors of this new expanded definition, including the chair of the panel, have financial ties to statin manufacturers.
- ▶ Eight of the nine experts who wrote the latest cholesterol guidelines also served as paid speakers, consultants, or researchers to the major drug companies—Pfizer, Merck, Bristol-Myers Squibb, Novartis, Bayer, Abbott, AstraZeneca, and GlaxoSmithKline.
- ▶ The senior physicians who write the guidelines also publish papers in medical journals with drug company advertisements and hold positions at prestigious academic institutions.

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- ▶ The Center for Science in the Public Interest has mounted a public campaign calling for an independent review of the official cholesterol guidelines.
- ▶ More than three dozen physicians, health researchers, and scientists have put their name to a strongly worded letter to the NIH director, arguing that the guidelines, with their expanded recommendations for drug therapy, are not supported by the scientific evidence.

A recent review of all of the clinical trials of the statins find that only a third of those trials fully reported on side effects, and long term side effects have been poorly studied.

- ▶ Reports of the sometimes fatal muscle-wasting is linked to Bayer's statin drug, Baycol. This led to a voluntary withdrawal from the market several years ago, and the company and its insurers have put aside more than a billion dollars to fight or settle thousands of the resulting lawsuits.
- ▶ AstraZenec receives calls from the consumer advocacy organization Public Citizen urging for Crestor's withdrawal, due to ongoing reports that some people taking the drug are experiencing muscle wasting and kidney failure.

The Therapeutics Initiative at the University of British Columbia, is a group that works to educate physicians, pharmacists and sometimes the general public, about the best ways to use prescription drugs. One of the first things they learn is that having high blood pressure is not a disease, but is one factor that can raise their risk of future heart attacks and strokes.

The trial ALLHAT was funded mainly by the U.S. federal government, with some support from the pharmaceutical industry. It had more than forty thousand participants. The study compared four different kinds of drugs, including the oldest and cheapest, the newest and most expensive. The drugs were compared in terms of how effective they were at reducing heart disease, how safe they were, and how much value they gave for the money.

The end result showed that the oldest, cheapest drugs, low-dose diuretics (or thiazides), not only did as well as the newer ones at lowering the chances of heart attacks and strokes, but came out marginally ahead because they were

slightly better at preventing heart failure. Cost of treatment with these pills is so low it is almost free.

In 2003, the year following the publication of the ALLHAT study, Pfizer, with marketing and TV ads, sold almost \$5 billion of the new drug Norvasc, making it the best-selling blood pressure medication and the fourth biggest revenue-generating drug in the world.

Research suggests:

- ▶ Doctors exposed to drug company representatives are more likely to favor drugs over non-drug therapy.
- ▶ Doctors are more likely to prescribe expensive medications when equally effective but less costly ones are available.

Excess spending:

- ▶ A study undertaken by publicly funded researchers in Norway estimates: the United Kingdom could save more than \$100 million, and the United States could save between \$500 million and \$1 billion per year, if physicians prescribed cheaper therapies.
- ▶ An Australian study estimated taxpayers could save up to \$100 million Australian dollars a year by using more of the older and equally effective medicines.
- ▶ The official U.S. guidelines state that for many people with uncomplicated high blood pressure, the cheaper diuretics should be the drugs of first choice.

Based on the evidence, researchers would agree that for those who are otherwise healthy, the best thing to do first is to alter one's lifestyle:

- ▶ Get more exercise
- ▶ Eat a healthier diet
- ▶ Stop smoking

For almost two decades, sales representatives for drug companies have claimed that depression is a widespread psychiatric disease most likely due to a chemical imbalance in the brain, effectively treated with selective serotonin reuptake inhibitors, or SSRIs, Prozac, Paxil, and Zoloft. In some countries prescriptions for these pills more than tripled through the 1990s, making antidepressants one of the top-selling categories of drugs, generating combined sales of more than \$20 billion for their makers. Drug company spending on sales representatives and their free samples is the biggest component of the approximate annual spending of \$25 billion in the United States for promotion.

According to independent analysis of the clinical trials, almost all of which have been funded by their manufacturers, the advantages of antidepressants over placebos are modest.

Potential complications:

- ▶ The side effects associated with Bristol-Myers Squibb's, Serzone were considered so serious it was withdrawn from the market around the world following evidence linking it to hepatitis and liver failure in some patients.
- ▶ Prozac, Paxil, and Zoloft can cause serious sexual difficulties including problems achieving orgasm.
- ▶ Perhaps as many as 25 percent of those prescribed Paxil have problems ending use because of difficult withdrawal symptoms.
- ▶ The drugs also appear to increase the risk of suicidal behavior and thinking among children and adolescents.

In the U.S., the FDA has accepted that the condition PMDD exists and has approved Lilly's drug, Prozac and several similar antidepressants for its treatment. It is not listed as a separate disorder in the World Health Organization's International Classification of Diseases. PMDD only has a partial listing in the psychiatrists' Diagnostic & Statistical Manual of Mental Disorders, the DSM, and is not seen as a fully official category of illness.

- ▶ Columbia University Professor Jean Endicott tells us PMDD is a psychiatric condition suffered by up to 7 percent of women.
- ▶ Brown University Professor Paula Caplan claims the condition has essentially been invented and there is no strong scientific evidence to distinguish it from normal premenstrual difficulties.

Scholars trace the origins of the modern concept of PMDD back to the 1930s, when the term "premenstrual tension" was first being explored. By the 1960s the medical community was describing a premenstrual syndrome (PMS) that featured common symptoms like fluid retention, irritability, and moodiness. Almost 150 symptoms are said to be associated with the condition. While women everywhere experience tension, irritability, or water retention prior to monthly periods, many do not believe this is abnormal or feel any need for professional intervention.

In the mid 1980s a small group of psychiatrists and others working with the American Psychiatric Association came together to try to define this new condition. The idea was to separate out normal premenstrual complaints from a severe form of mood disturbance that came and went every month, but was serious enough in some women to be disabling and warrant treatment.

In 1985 there were disputes about whether to include this new mental disorder, PMDD in the DSM. Part of the concern was that so little was known about its causes, or how

to treat it. Another key concern raised was that because all women experience some degree of premenstrual symptoms, there was a danger psychiatrists were going to label aspects of ordinary life as a mental disorder.

By the late 1990s Prozac, whose chemical name is fluoxetine, was about to lose its patent. Lilly stood to lose hundreds of millions of dollars because of the emergence of cheaper generic competitors. In late 1998, Lilly helped fund a small meeting, titled as a “Roundtable” of researchers, who came together to discuss PMDD. The meeting of sixteen key experts was attended by a group of FDA staff and at least four Lilly representatives. Within twelve months the minutes of that “Roundtable” would appear in a medical journal article claiming there was now a scientific consensus that PMDD was a “distinct clinical entity.” By the end of 1999, a meeting of advisers to the FDA had voted unanimously to approve Lilly’s fluoxetine for the treatment of PMDD. The pill was not launched under the name Prozac. Lilly renamed it Sarafem and designed it with lavender and pink colors.

In a letter to Lilly, the FDA states that their advertising of Sarafem never clearly defines the difference between PMS and PMDD, and it broadens the condition unreasonably. The FDA argues that the TV ad trivialized the seriousness of this alleged new mental disorder by associating it with normal premenstrual problems. While the FDA had clearly accepted the view that PMDD exists, its criticisms of the ad reinforces the concerns of those who feel ordinary life is being made into a medical condition. The FDA has approved several other similar antidepressant medications for PMDD, including Pfizer’s Zoloft and GSK’s Paxil, also known as Seroxit and Aropax.

A panel from the European Agency for the Evaluation of Medicinal Products notes that:

- ▶ PMDD is not a well-established disease entity across Europe.
- ▶ It is not listed in the International Classification of Diseases.
- ▶ There is considerable concern that women with less severe premenstrual symptoms might erroneously receive a diagnosis of PMDD resulting in widespread inappropriate short and long-term use of fluoxetine.

The regulators question two of Lilly's key studies of Prozac/Sarafem for PMDD, finding them to have major deficiencies.

They found:

- ▶ The trials were too short.
- ▶ The patients were not representative of those who would be prescribed the drug.
- ▶ It was not clear what the trials were actually measuring so the results were of questionable value.
- ▶ The findings of this panel were in contrast to the conclusions of the Lilly-sponsored "Roundtable" of experts in the U.S.

In a little more than a year GSK generates sales of Paxil worth \$3 billion to make it the world's top-selling antidepressant. GSK claims at one point that the rare psychiatric condition now known as social anxiety disorder, affects one in eight Americans. Paxil's TV ads are the most visible part of this multi-layered campaign to influence public perceptions about shyness and uneasiness in social situations. GSK hires WPP, one of the world's big communications corporations, and that company's public relations subsidiary, Cohn & Wolfe, who specialize in unconventional ways to market pharmaceuticals. With a division dedicated entirely to health care and pharmaceuticals, Cohn & Wolfe markets drugs and it also helps drug companies with the process of seeking FDA approval.

The campaign's objectives:

- ▶ Generate extensive media coverage about social anxiety disorder, always making the link between the condition and the drug.
- ▶ Make sure Paxil outsells Zoloft.
- ▶ Educated the public about social anxiety disorder with a campaign whose primary goal is to maximize sales of a drug.

The PR firm helps organize what looks like a grassroots movement to raise public awareness about this little-known disorder. This awareness-raising campaign is based on the slogan, "Imagine being allergic to people." Posters that feature a sad-looking man and list commonly experienced symptoms are distributed across America. "You blush, sweat, shake—even find it hard to breathe. That's what social anxiety disorder feels like." The posters appear to come from several medical and advocacy groups under the umbrella of the Social Anxiety Disorder Coalition. All three members of the coalition rely heavily on sponsorship from drug companies. Calls from the media to the coalition are handled by Cohn & Wolfe.

- ▶ Direct-to-consumer advertising of drugs and diseases is now more than a \$3 billion dollar a year industry in the U.S.
- ▶ Direct-to-consumer TV advertisements introduce new diseases to tens of millions of Americans.

GSK's social anxiety disorder campaign involves the use of celebrities, including the U.S. football star, running back Ricky Williams. He only realized he had the mental illness after watching a TV commercial. In the summer of 2002, publicity revealed that Williams, who played for the Miami Dolphins, was suffering from social anxiety disorder. Stories appeared in the *New York Times* and the *Los Angeles Times*, and there was a segment on the Oprah show. The celebrity sports hero told the national network NBC, "I've always been a shy person." What some of the media stories disclosed, but others did not was that Williams was being paid by GSK. He was also taking Paxil. That same year Paxil itself became the world's top-selling antidepressant, passing both Prozac and Zoloft.

Thousands of people are taking legal action against the company, alleging they were not warned of the drug's potential to cause withdrawal and dependence. Karen Barth Menzies, the lead attorney, states, "We've had ten thousand people call us now, and all of them for the same things. 'I started taking this drug, I had no idea that I could become addicted to it, and now I'm addicted.'" While GSK concedes some people experience problems when they abruptly stop the drug, it rejects the notion that Paxil causes dependence.

After a close examination of the GSK-funded trials of Paxil in children and adolescents with depression, the regulators in the UK and the U.S. found there was no clear evidence that the antidepressants were any better than a placebo. In the U.S. alone, 5 million prescriptions a year were being written for Paxil and Zoloft for people under eighteen. In court documents the company argued that because Paxil was not officially approved for use in children (it was being prescribed by doctors off-label), GSK had therefore been legally restricted from distributing all the information from its clinical trials. According to press reports, an internal GSK memo sent to its drug detailers in 2003 specifically advises the company's sales representatives not to discuss the potential link with suicidal behavior with prescribing doctors.

Factors which may influence mental health are:

- ▶ Education
- ▶ Economy
- ▶ Environment
- ▶ Inequality

CHADD, the Children and Adults with Attention-Deficit/Hyperactivity Disorder patient advocacy group with fifteen thousand members and two hundred affiliates across the United States holds a charity golf classic each year. The lead sponsor of the CHADD charity golf classic is a drug company called Shire, who sells more than half a billion dollars of the amphetamine, Adderall every year. Shire is also a sponsor of the group's annual conference, and it supports the group's magazine, *Attention*, which is distributed to thousands of patients, families, and physicians. CHADD receives almost \$700,000 annually from drug companies, which is just under one-fifth of its total income of around \$3 million.

Conflicting information about ADD:

- ▶ Estimates of the numbers of children suffering ADD range widely, from less than 1 percent to 1 in 10 kids.

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- ▶ There is much scientific uncertainty about whether these difficulties are primarily due to biological and chemical problems in the brain, or are the result of a complex interplay of physical, social, cultural, and economic factors.
- ▶ The NIH concludes that the causes of the condition remain speculative, and there is not enough evidence showing that ADD is a brain disorder.
- ▶ CHADD and its drug company partners promote the condition as a common neurobiological disorder affecting between three and seven percent of school age children and is to be treated primarily with drugs.

The industry magazine Pharmaceutical Executive, published a special report by PR practitioner Teri Cox called “Forging Alliances, Advocacy Partners.” According to Cox, advocacy groups:

- ▶ Help companies provide the media with patients for their stories.
- ▶ Help defuse the arguments of industry critics by offering positive messages about drug companies.
- ▶ Help influence the decisions of policy-makers and regulators.

A sociology professor writing in the mid-1970s describes:

- ▶ Officials in some states were alarmed that between 5 and 10 percent of elementary school children were using medically prescribed amphetamines including Ritalin to control their fidgety restlessness or lack of attention in the classroom.
- ▶ The increasing tendency to define unpleasant human feelings and troublesome behavior as a ‘disease’ to be corrected with drugs may serve to:
 - a. Diminish pressures to seek more fundamental approaches to the real sources of the drug user’s distress.
 - b. Individualize and depoliticize complex social problems.

Psychiatrists have been broadening the definition of ADD that appears in their diagnostic manual. Lists of ADD symptoms in the DSM include behaviors such as:

- ▶ Often talks excessively
- ▶ Often does not seem to listen
- ▶ Often forgetful

Some researchers have done studies comparing the definitions of ADD:

- ▶ One American study found that when the definition in the psychiatrists' manual in 1980 was compared with the definition published in 1987, 50 percent more children received a diagnosis of ADD under the newer definition.
- ▶ A study in Germany compared the 1980 definition to the 1994 definition, and found the numbers of children receiving the diagnosis of ADD rose to more than 60 percent.

Amphetamines like Ritalin seem to improve anyone's attention, even horses, according to Dr. Judith Rapoport, a senior ADD researcher at the NIH. She is involved in an ongoing long-term study looking at the brain development of those diagnosed with the condition. More than twenty years ago Dr. Rapoport did ground breaking research showing amphetamines had effects in normal kids as well as those who were hyperactive, a finding that is still cited today in the scientific literature.

Researchers question whether or not osteoporosis should be considered a disease.

Hip fractures due to falls, which can be devastating to people and costly to a health system, are a huge public health issue affecting millions of elderly people around the world every year. The loss of bone density is something that occurs naturally in many people as they age. Although, the value of the bone density tests is highly controversial, in recent years there has been a focus on such measurements, coinciding with the release of new drugs that slow its loss.

Marketing specialist, Kym White, a PR professional with Ogilvy Public Relations, has spent nearly twenty years advising the world's major health care, pharmaceutical, and biotechnology companies on how to mount successful disease awareness campaigns. White explains: "We needed to convince women who were much closer to the age of fifty that osteoporosis was something that they needed to be thinking about then, because there were steps they could be taking in their fifties and in their sixties, to make sure that they didn't end up being that little old woman that they saw on the street."

In 1995, even before the osteoporosis drug Fosamax was available in the U.S., Merck was subsidizing the distribution of the bone density testing machines needed to ensure the diagnosis for which its drug would be prescribed. Not long before Fosamax's

launch, a new definition of osteoporosis had been written by a study group of the World Health Organization. That group decided that normal bone density was the bone density of a 30 year old woman, a definition that automatically made the bones of many older women abnormal.

A 1997 report from the British Columbia Office of Health Technology Assessment based in Vancouver examined the entire body of evidence for bone density testing to try to find out what the scientific data was showing. The authors concluded: “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.” The conclusion strongly contradicts the marketing messages urging widespread testing. On the basis of the evidence, the authors of the latest guidelines recommends that routine screening should not start until age sixty-five.

One of the key studies of Fosamax was a Merck-funded study called the Fracture Intervention Trial. It compared the drug to a placebo over four years. According to advertisements, widely read newspaper reports, and TV broadcasts, that study found that the drug reduced the risk of hip fracture by 50 percent. The published study was only for women at “high risk” of a future fracture, older women who had already experienced at least one fracture. The results of a much larger government-run trial show that for most healthy women the long-term benefits of drug therapy are minor in terms of reducing the risks of hip fractures.

In 1996, the first year Fosamax was on the market, there were more than six thousand formal adverse drug reactions reported to the U.S. government, the most reports made about any single drug that year.

Potential side effects of Fosamax include:

- ▶ Severe corrosive damage to the esophagus and stomach
- ▶ Rashes
- ▶ Headaches
- ▶ Diarrhea
- ▶ Muscular pain
- ▶ Flatulence

There are several safer ways of preventing fractures in the elderly:

- ▶ Fall prevention programs
- ▶ Weaning them off large multiple-medication regimes
- ▶ Changing household arrangements
- ▶ Repairing footpaths
- ▶ Improving eye wear
- ▶ Improving diet and exercise

If you like this summary, you'll definitely want to order the complete book *Selling Sickness: How the World's Biggest Pharmaceutical Companies Are Turning Us All Into Patients*.

In the fall of 2004, at Union Station in Washington, D.C., the world's first new major medical journal in seventy years, Public Library of Science Medicine is launched. It plans to challenge the status quo, disentangle from drug company influence, promote

more independent medical information and provide free web access to all of its scientific articles. Unlike nearly every other leading medical journal in the world today, this journal will not accept any drug company advertisements, nor will it publish company-funded studies that are considered to be marketing appearing as science. The aim is to break “the cycle of dependency” that has formed between medical journals and the pharmaceutical industry.

The New York based group, No Free Lunch has been running a global campaign featuring its slogan “Just say no to drug reps” and its high-profile “pen amnesty” that encourages doctors to send back their drug company pens and other paraphernalia. A few years ago the fifty thousand member, American Medical Student Association mounted its own “PharmFree” campaign urging medical students to simply say no to the free lunches, the gifts, the paid speaking engagements, and the lucrative consultancies. As part of its charter the association takes no sponsorship from the pharmaceutical industry.

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Sometimes diseases are real, painful, and deadly, and treatment with the latest and most expensive drug or other medical technology or procedure is highly desirable. Yet there are many cases where a person's health problems are so mild or temporary that doing nothing may be the best option. There can be great value in talking with family and friends about the appropriateness of a particular medical label, and debating whether the problem at hand is really a sign of disease or simply one of the ups and downs of ordinary life. ■

