2

Doughnuts for the doctors

Depression

The aroma of fresh baking wafts from Michael Oldani's car as the door swings open and he jumps out to open the trunk. He lifts out a carton of free drug samples and stacks on top two other boxes, all of them festooned with stickers bearing the name of a popular antidepressant. As one of an army of eighty thousand detailers working as sales representatives for drug companies in the U.S., Oldani had started his morning bearing the most beguiling of gifts—warm doughnuts.[1]

With his jet-black hair and dark Italian good looks, Oldani was at the time making daily forays to the frontline of physicians' offices, wielding the industry's weapons of mass seduction: food, flattery, friendship—and lots of free samples.[2] His primary goal was maximizing the sales of his company's antidepressant, but a key strategy to achieve it was selling a certain view of depression.

Note: The drugs discussed in this chapter have different names in some countries. For example, Paxil is Aropax in Australia and Seroxat in the UK. Zoloft is called Lustral in the UK.

For almost two decades, Oldani and thousands like him have helped instill and reinforce the notion that depression is a widespread psychiatric disease most likely due to a chemical imbalance in the brain, best fixed with a modern group of drugs called selective serotonin reuptake inhibitors, or SSRIs, that includes Prozac, Paxil, and Zoloft.[3] Their work has paid off handsomely: in some countries prescriptions for these pills more than tripled through the 1990s, making antidepressants one of the top-selling categories of drugs, and generating combined sales of more than $20 billion for their makers.[4]

Drug company spending on sales representatives and their free samples is the biggest component of the roughly $25 billion now outlaid annually in the United States for promotion, and it is the foundation of the global web of financial entanglement between the industry and the profession.[5] What starts with doughnuts for the doctors ends with lavish banquets for thought-leaders in five-star hotels. And at every opportunity, it is not just drugs being sold, but very particular views of disease.[6] As specialists in mental illness remind us, the idea that depression is caused by a deficiency of the brain chemical serotonin is in fact just one scientific view among many—and a simplistic and outdated one at that.[7] But it is a theory kept very much alive by the massive marketing machinery that starts with the morning deliveries of pharmaceutical company sales representatives.

After a major change of heart, and career, Michael Oldani is now working on his Ph.D. in anthropology at Princeton, where he is trying to make sense of the interactions between drug detailers and doctors. The detailers who succeed in such a competitive environment are, he explains, "masters at establishing trust, forging alliances, and acquiring commitments through the sharing of information and the giving of oneself."[8] Human beings have a

natural tendency to want to repay kindness, and the best way doctors can do that is by prescribing the products that the detailers are pushing.[9] For Oldani, these two-way relationships become highly personal, and "business transactions per se, are never conducted . . . never witnessed." Though these intimate dealings are largely hidden from public view, they are highly effective for those bankrolling them.

Contacts between detailers and doctors tend to lead to less rational prescribing habits, yet many physicians deny they are being influenced.[10] Research suggests doctors exposed to company reps are more likely to favor drugs over non-drug therapy, and more likely to prescribe expensive medications when equally effective but less costly ones are available.[11] Researchers have even suggested there is an association between the dose and response: that is, the more contact between doctors and detailers the more doctors latch on to the "commercial" messages as opposed to the "scientific" view of a product's value.[12]

In the case of the new antidepressants, the gap between the commercial messages and the scientific view has become frighteningly wide, with the benefits of these drugs far more modest, and risks far more serious, than a decade of promotion has suggested.[13] According to independent analysis of the clinical trials—almost all of which have been funded by their manufacturers—on average the advantages of these antidepressants over placebo or dummy pills are modest at best, yet their side effects can include sexual problems, severe withdrawal, reactions, and an apparent increase in the risk of suicidal behavior among the young.[14] Somewhat ironically, part of the marketing of these new antidepressants has played directly on fears that suicide could result if a young person's depression was left untreated.[15] While many doctors and researchers believe the

drugs do indeed prevent suicide for some people, the available evidence suggests that the children and adolescents who take these medications are likely increasing their risks of suicidal thinking and behavior.[16] Importantly, the scientific evidence doesn't point to an increase in actual suicide, rather, suicidal thinking and behavior.

As the clouds and mist of an early May morning swirl around the rooftops of Manhattan, thousands of psychiatrists stream into a giant midtown convention center to learn about the latest in scientific developments, at the annual congress of the American Psychiatric Association, the APA. On their way in they couldn't have missed the massive billboards advertising the meeting, adorned with the name of one of the congress's key sponsors, Pfizer, the maker of the world's top-selling antidepressant, Zoloft. Inside the cathedral-like convention center the first port of call for the swarming visitors is the gigantic exhibit hall, which offers a surreal trip inside the entangled world of drug company-funded psychiatry.

The first display inside the exhibit hall is Pfizer's. It's still early on a Sunday morning, the five-day conference has only just opened, yet already hundreds of doctors are lining up at the stalls like eager kids at a carnival, filling out forms and entering their names into competitions in the hope of winning tiny trinkets and treats. At one booth, the prize on offer is a simple laser pointer, but the excitement runs high nevertheless. It's circus time and working the crowds like well-dressed ringleaders are dozens of friendly and efficient salespeople. "Very nice meeting you," says one, politely.

Psychiatry's intimate relationship with the pharmaceutical

industry has become notorious. When the former *New England Journal of Medicine* editor Dr. Marcia Angell published her famous editorial "Is Academic Medicine for Sale?," it was this group of specialists that she chose to illustrate her point.[17] She wrote that when journal staff were searching for an experienced and independent psychiatrist to write a review article about antidepressants, they had great difficulty finding one, because only "very few" in the entire United States were free of financial ties to the drug makers.

The psychiatrists' industry-sponsored annual congress has similarly become legendary.[18] In 2004, drug companies paid around two thousand dollars for each tiny ten-foot by ten-foot square of real estate in the gargantuan exhibit hall.[19] But not only did companies pay for space for their stalls, they actually sponsored over fifty scientific sessions throughout the week-long congress. The APA will not confirm how much the organization charges companies for the privilege of sponsoring a symposium, but it has been reported to be tens of thousands of dollars per session.[20]

For the psychiatrists attending, the sponsorship created an orgy of culinary indulgence, because somehow the industry-funded symposia always seemed to coincide with meal times. At the New York congress, psychiatrists learned about bipolar disorder at a breakfast session in the Marriott Marquis Hotel courtesy of Lilly, the makers of Prozac.[21] At a lunchtime session in the Grand Hyatt sponsored by Paxil manufacturer GSK, delegates were educated about maternal depression.[22] And for the dinner symposia, the conscientious doctors heard about generalized anxiety disorder in the Grand Ballroom of the Roosevelt, thanks to Pfizer.[23] Welcome to the modern world of medical science.[24]

Not all psychiatrists have stayed seated on the gravy train.

The Harvard-trained psychiatrist Dr. Loren Mosher caused a stir a few years ago when he quit his professional association in disgust. An APA member for nearly three decades, Mosher said at the time that in his view, "psychiatry has been almost completely bought out by the drug companies" and that he, for one, did not want to be a "drug company patsy."[25] He counseled that the APA and other groups like it around the world were doing a serious disservice to human health care and urged them to "get real about money, politics and science. Label each for what it is . . . that is, be honest."

What irked Loren Mosher most was not the unholy alliance per se, but the corrosive effect he believed this alliance was having on the practice of psychiatry. He was horrified by what he saw as the narrowing focus on drug therapies, making physicians everywhere less able to "understand whole persons in their social contexts." Because he saw a more noble cause for psychiatry, beyond the mere technical role of realigning patients" neurotransmitters—including serotonin—he said he could no longer stand by while his profession condoned the "widespread use and misuse of toxic chemicals."

Mosher's voice is by no means the only one critical of the close links with industry and the narrowed focus on chemical causes and chemical solutions. University of Wales psychiatrist, Dr. David Healy, is a specialist in the history of psychiatric drugs, a practicing clinician who prescribes antidepressants to his patients, and an occasional consultant for several drug companies. In recent years, with many articles, books and media appearances under his belt, he has emerged as a leading critic of the way pharmaceutical marketing is shaping our perceptions of illness.[26]

Healy maintains that early theories suggesting that a serotonin imbalance causes depression have not been verified by later

research. While acknowledging a role for biological causes, Healy argues that the serotonin theory has been overplayed in order to help sell the selective serotonin reuptake inhibitor drugs, including Prozac, Paxil, and Zoloft. It's been overplayed because companies realize it makes "wonderful marketing copy" he says.[27] "It's the kind of thing that a GP [family physician] can use when they're trying to persuade a person to have pills." It's also the kind of rationale that drug reps like Michael Oldani can use to persuade physicians to use their products. "They're trying to get us to think a particular way," Healy says. "They are trying to get us doctors to see the illnesses that we will then see in you, the patients, and the sales of their product will then follow . . . I consume, by putting pills in your mouth, and you're the one who's going to have to suffer the consequences of things if they go wrong."[28]

While the industry's marketing might help to *narrow* the focus on to chemical causes and chemical solutions, it also helps to promote *wide* estimates of how many people are affected by mental disorders like depression. Over the past decade many of us have heard repeatedly that perhaps a third of the population suffers with a mental illness. A major source for that figure was a survey of Americans conducted in the early 1990s, which claimed to have found that in any given year, 30 percent of people had a mental disorder.[29] While the figure may sound so absurdly high as to be laughable, it has been widely cited around the world, in marketing and elsewhere, and it has helped build the impression of untold millions being undiagnosed and untreated.[30]

One of those who thought the figure sounded a little on the high side was psychiatrist Dr. William Narrow, at the time working for the government-funded National Institutes of Health in the U.S. He and his colleagues started taking a closer look at exactly how the survey results had been put together. What they found was

that a lot of the people classified by the survey researchers as having a "mental disorder" did not have a "clinically significant" disorder. In other words, they most likely didn't have a disorder that warranted treatment.[31] When Narrow started to separate out those who had a "clinically significant" disorder from those who didn't, a very different picture emerged.

In 2002, Narrow and his colleagues published a scientific paper called "Revised Prevalence Estimates of Mental Disorders in the United States."[32] Reading between the polite lines of academic language in the paper, the findings of the original survey were being well and truly questioned. The orthodoxy that one-third of people were mentally ill with depression and other psychiatric disorders was being directly challenged. The widely quoted estimates were dramatically revised downwards, slashing the total rate of those supposedly suffering a mental disorder in any given year from 30 percent to less than 20 percent.

In the revised estimates, the proportion of people said to be suffering major depression was virtually halved from 10 percent to under 5 percent. Most importantly, Narrow and his colleagues argued that because of problems and limitations with the methods of the original survey, it was likely the true rates of disorders were significantly lower still.[33] The bottom line was that a lot of people with mild problems had been included in those original estimates, which as a result were highly inflated.

"When you're trying to get visibility, one way to do that is to shock people with big numbers," says Narrow, speculating on why the original survey researchers chose to publish such extraordinarily large figures.[34] Asked whether he thought the original figures were fundamentally misleading, he said, "I'm going to reserve judgment on that." A practicing psychiatrist, Narrow says one of his key motivations is to make sure that people who need

help get it. But there is a real danger, he says, that by including the millions of people with mild problems in your estimates of mental illness, you risk losing public support for treating those people who have real disorders.

Dr. Ron Kessler, the lead researcher of the original survey, concedes that it's hard to believe 30 percent of people suffer a mental disorder, but he sticks by his findings, and rejects William Narrow's revision as simply wrong. Kessler, a Harvard professor of health care policy, argues that even those with mild forms of mental disorders like depression have a higher risk of killing themselves than others, and should therefore be treated—however you want to label them.[35] "If you don't want to call mild problems disorders, then don't. Let's just say mild disorders are not disorders. Let's call them risks if you want to, but whatever the case—let's treat them. We have to keep them on our radar screens because it's an area of human suffering that we should be thinking of doing something about. I like the idea of calling it a disorder because it keeps it in front of our eyes as something we need to keeping working on."[36]

Kessler's estimates of widespread mental disorders are of course music to the ears of drug marketers and while his original survey was government funded, now companies regularly court him. While he does not work as a paid adviser or speaker—financial ties many other senior researchers accept with relish—he has taken funds from several companies to help support his ongoing survey work—most recently from Lilly, GSK, and Pfizer—the makers of the world's three top-selling antidepressants.[37]

One of Kessler's latest studies involved surveys in fourteen nations, conducted between 2001 and 2003. The massive project was funded by many public and private organizations, including Lilly, GSK, and the Pfizer foundation, though the surveys were

run at arm's length from the sponsors.[38] The findings reveal some extraordinary differences between countries. Despite the criticisms from Narrow and others, this international survey declared that in any given year 26 percent of people in the United States still meet the criteria that defines them as having a mental disorder. In Mexico, the number was 12 percent, in China and Japan 9 percent, and in Italy 8 percent. Yet, of those he classified as having a mental disorder, many were in fact "mild" cases according to the definitions Kessler and colleagues were using. In the U.S., more than one-third were mild cases, meaning they may not even warrant treatment—depending, of course, whether you listen to William Narrow or Ron Kessler.

On the issue of what's commonly called "unmet need" the latest Kessler study also offered fascinating, though somewhat contradictory, new insights. It found that around half of those classified as having a *serious* disorder were not getting the medical treatment they needed. In other words here was evidence of undertreatment. Yet the international study also found that at least half of the people who were receiving treatment may not in fact have needed it. The write-up of the study, published in the *Journal of the American Medical Association* by Kessler and colleagues, stated that "either the majority or a near majority of people in treatment in each country are either noncases or mild cases."[39] The global obsession with "unmet need"—a notion that is constantly pushed by doctors and drug companies as the justification for aggressive drug marketing—may well be helping to create a strange new phenomenon: "met un-need."[40]

One educational program that strongly promoted the idea of "unmet need" was run in Australia in the 1990s.[41] Groups of general practitioners attending "continuing medical education" events were told that a third of people who walked into their

surgeries were suffering a mental illness—and they were urged to be more aggressive in their detection and treatment of depression. Like a lot of medical education, the program was partly sponsored by a drug company. The response to questions about the obvious conflict of interests, where a company making antidepressants was part funding doctors" educational programs about depression, was that it was in everyone's interest to increase the numbers of people being treated, whether with psychological therapies or drugs.[42]

Those educational seminars were in fact part of a much bigger project attempting to raise awareness among Australian doctors and the public about depression, funded in part by Bristol-Myers Squibb, the makers of an antidepressant called Serzone. Funding also came from state and federal governments. In turn, this project was just one of many similar programs to "educate" doctors, funded generously by the makers of the other antidepressants throughout the 1990s. The programs reaped major benefits for their private sponsors. The volume of antidepressant prescriptions in Australia tripled between 1990 and 2000.[43] Among the young, aged fifteen to twenty-four, the rates increased tenfold.[44]

One of the key components of the Bristol-Myers Squibb funded educational program was a simple screening test—a checklist of questions—designed to be used by family doctors to diagnose whether their patients had a mental disorder. Yet this test was so broad, it classified 49 percent of people as having a "mental disorder"—roughly one-half of that 49 percent having what was described as a "Level 1" disorder and the other half having a less serious "Level 2" disorder.[45] While this is clearly good news for Bristol-Myers Squibb and other drug makers, the figures may appear to dispassionate observers as absurdly inflated

estimates that would immediately raise questions about a potentially flawed test.

In fact, researchers from the Monash Medical Centre in Melbourne later rigorously examined that screening test, and pointed to major problems. According to their calculations, the majority of people diagnosed in this test as having a mental disorder most likely did not have one at all.[46] There are obvious dangers when well-intentioned doctors use tests that may falsely classify many people as sick—not only is there a potential for inappropriate labeling, but also the potential to expose relatively healthy people to the side effects of potent medicines. It is a danger the Monash researchers themselves highlighted.

> Labeling a significant number of people who are not depressed as "probably depressed" might reasonably be considered a potential harm. We do not want to replace a situation of under-recognition with one of over-recognition, neither being of benefit to the patient.

These heavily promoted antidepressants have serious side effects. As it turned out, the side effects associated with Bristol-Myers Squibb's antidepressant Serzone were considered so serious it was withdrawn from the market around the world following evidence linking it to hepatitis and even liver failure in some patients. The company however explained the withdrawal was for commercial rather than safety reasons.[47] As for Prozac, Paxil, and Zoloft, it is well-known they can cause serious sexual difficulties including problems achieving orgasm.[48] With Paxil, perhaps as many as 25 percent of those prescribed the drug have problems ending use because of worrisome withdrawal symptoms. But most serious of all have been revelations that the drugs appear to increase the risk of suicidal behavior and thinking among children

and adolescents, discovered only after health authorities—under pressure from consumer activists and others—demanded to see the complete set of company-funded trials, some of which had been buried deep inside drug company archives.[49] These revelations came at a time when the prescriptions of these medicines to children were rising dramatically.[50] In 2002, there were more than 10 million prescriptions written for people under eighteen for the three top antidepressants in the U.S. alone.[51]

So vociferous was the public outcry about the issue of suicidal behavior that even the industry-friendly FDA was forced to convene meetings of its advisers to investigate. The first of two historic public meetings was held in February 2004, at the Holiday Inn in Bethesda on the outskirts of Washington, D.C. "Our daughter Julie had been excited about college and had scored 1300 in her SATs," Tom Woodward told the FDA advisers soon after the hearings began. A few weeks after her final school exams, following what her parents describe as a normal bout of teenage troubles, Julie was diagnosed with depression and prescribed Zoloft. After a week on the drug she went into the family garage and hung herself.[52] "Instead of picking out colleges for our daughter, my wife and I had to pick out a cemetery plot for her," Woodward said, his voice full of sadness and anger. "Instead of looking forward to visiting Julie at school, we now visit her grave."

The causes of any individual case of suicide are almost always highly complex, and disentangling the role of any underlying disease from the effects of a drug is a difficult task. In Julie's case, while her parents have strong beliefs about the cause of their daughter's suicide, at the time of writing there has been no investigation into her state of health before death, or the potential role of the drug. Yet her story was one of many presented at

the all-day hearing in Bethesda that helped focus the attention of the drug regulator on the potential harms of these widely prescribed antidepressants. Summing up a growing sense of unease among the expert advisers who had listened to Julie's parents and many others, Professor Mark Hudak from the University of Florida urged the FDA to take action to protect children with milder health problems from being treated with potent medications.

> If they are clearly very ill, anything that can be done should be done. But for a lot of the people who spoke this morning . . . the picture that was presented of their child or someone they knew, was not someone who was very, very ill, it was someone who had relatively minor type findings, put on these drugs with terrible consequences.[53]

Ultimately, the regulator's analysis of all of the company trials in children and adolescents, including the unpublished trials, would suggest that the drugs on average increased the risk of suicidal behavior and thinking from 2 percent to 4 percent. In other words, according to a summary of the trial results, 2 percent of those taking a placebo experienced suicidal thoughts or behaviors. Of those taking the antidepressants, 4 percent did.[54] The trials showed no increase in cases of actual suicide.

What's more, for almost all the drugs, except Prozac, there was no evidence from the clinical trials in children that the antidepressants worked any better at relieving depression than a placebo or dummy pill. British authorities moved in late 2003 to try to stop the drugs being prescribed to children.[55] A year later authorities in the U.S. demanded that companies add a "black box" warning to antidepressant labels—more than a decade after the drugs had first appeared on the market.[56] A strongly worded

"black box" warning is one that appears on all prescribing information, and is the toughest form of safety warning available. For Tom and Kathy Woodward, no matter how tough, the warnings were simply too late.

At the time when the middle-class couple had been considering drug therapy for their daughter's emotional difficulties, no one told them of the potential risk of suicidal behavior.[57] For Tom Woodward, his daughter's death highlights what he sees as a gross failure of regulation, made worse by the fact that the FDA relies on industry funds for much of its drug review work. "These drugs are being prescribed like candy," says Woodward. "They're being given for practically everything, it seems today, and the consequences are frightening." A long-time Republican, Woodward has become a grassroots activist exposing what he sees as the pharmaceutical industry's unhealthy influence over the U.S. Congress and the White House, and a campaigner for much tougher and more independent drug regulation.[58] "We're going to try to reach out to as many people as we can, tell our story and try to spread the word, so people can make informed decisions. If they think there is some value to these drugs, so be it. But go in with your eyes open, understanding what the downside is. 'Cause the downside could be very great."[59]

Like Tom Woodward, London general practitioner Dr. Iona Heath is concerned that too many people with ordinary life experiences are being too quickly offered a label and a drug. She is particularly worried by simple screening checklists and questionnaires that ask people if they have been feeling sad, blue, unhappy, or down in the dumps—the sort of questions to which many of us might answer yes. Heath stresses that while it is important for doctors to be diagnosing and treating genuine mental illness, these kinds of screening tests are so broad they may wrongly label healthy

people as sick in too many instances. She points out that much depression will be relatively mild and can pass within a matter of months, yet according to some estimates millions of people are prescribed these antidepressants for several years or more.[60]

Dr. Heath says that what is important is for physicians to take time to listen to patients, many of whom in her view don't want to have their complaints reduced to a simple problem with levels of serotonin in the brain. She sees many sources of emotional distress in her daily work, including people experiencing serious pain, the loss of a loved one, a job under threat, an abusive partner, or a damp, overcrowded, and dangerous home.[61] Many people struggle to make sense of their suffering and many people develop the skills to cope.

Heath, who works with the Royal College of General Practitioners as well as the *British Medical Journal*, rejects the "pill-for-every-ill" model, where the patient is characterized as "broken" and the physician is there to "fix" him or her. Instead, she sees the interaction with her patients as part of a much richer relationship. Her goal is to come to mutual agreement on the extent to which a person may want to see their difficulties as a medical problem that might require treatment. And if treatment is called for, she draws from a very large bundle of solutions, including medications and talking therapies, for which there is good evidence of effectiveness.[62] She will sometimes suggest people write things down or tell stories about their suffering and distress, and she might even recommend dancing classes or doing more exercise—strategies not as heavily promoted as the biochemical approaches pushed by company detailers.

Studies in several nations show that roughly 80 percent of doctors still regularly see drug detailers, though GPs like Dr. Iona Heath and Canadian Dr. Warren Bell do not.[63] A family

physician in Salmon Arm, a small rural town in the interior of British Columbia, Bell grimaces as he talks about the early flattery and friendship offered to him by the company detailers when he was a young intern. "I was basically offended, deeply offended by the fact that people would be nice to me not because of who I was, but because of the role I play in society. I think it was my first contact with people who were treating me as a political entity rather than a person. It really did irritate me."[64]

What Bell did as soon as he started practicing medicine in the community was cut himself off from the drug industry's marketing, completely. He has no logos in his office, and has never seen a drug salesperson, ever, in his twenty-seven years of medicine. He chuckles at the thought of his colleagues "bemused and hopelessly imprisoned within the world of pharmaceutical bafflegab . . . even quite intelligent, quite knowledgeable people can't step beyond it, because they're in this sea of drug company logos."[65]

Bell and Heath aren't the only ones who have disentangled themselves from the influences of drug company marketing. The New York–based group No Free Lunch has been running a global campaign along those lines for some time, 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.[66] The activist group has already enjoyed some considerable success. Inspired in part by No Free Lunch, a few years ago the fifty thousand–strong American Medical Student Association mounted its own "PharmFree" campaign calling for an end to all forms of free lunch.[67]

Back at the American Psychiatric Association congress in New York, it seems No Free Lunch is yet to have a big impact. Tonight the psychiatrists are scheduled to listen to a thought-

leader in the Sheraton's Imperial Ballroom tell them about anxiety disorders.[68] Cultivating a stable of thought-leaders is a key part of the industry's marketing strategies, whether for depression or any other condition. The quality of that stable depends a lot on the groundwork of drug reps like Michael Oldani, who would often assess a young doctor's potential for influencing his peers, firsthand, as part of his daily rounds.

Promising prospects might be singled out by a detailer as a potential thought-leader, and then given some small speaking assignments to test them out. Later, if they've proven their worth, they might be paid to speak regularly in small local settings about the latest new drug in the pipeline. With a bit of luck the thought-leader could eventually find themselves on a drug company's "speaker's bureau" earning thousands of dollars for making presentations to their international peers about the latest new disease, at high-profile events like the APA congress in New York.

So important are the alliances with thought-leaders that some marketing firms actually calculate the "return on investment" a drug company can reap from these sorts of presentations.[69] A thought-leader's performance can be tracked by secretly measuring the impact of their messages on the prescribing patterns of those being "educated." Oldani remembers from his time in the industry that the best spokespeople were those who appeared to deliver a balanced message—never crudely cheerleading for a drug. Attendees at such educational or scientific sessions would never know they were being marketed to. The most accomplished of his thought-leaders—or "product champions" as they are also known within the industry—could really work the crowd, and "sell without selling."[70]

By any objective analysis, one of the reasons the SSRI antidepressants were embraced by prescribing doctors so fulsomely

all over the world for so long was because the hard work of detailers like Oldani was backed with the credibility of psychiatrist thought-leaders in the pay of the drug makers. When comparing the scientific reality of these drugs' modest benefits and serious harms against the enthusiastic marketing messages espoused for more than a decade, many within psychiatry must today feel a sense of shame. And while their specialty may be more entangled than most, the same web of financial ties exists across virtually the entire medical landscape. When it comes to educating doctors with doughnuts, few medical specialties have been left behind.

For a condition like depression, trying to separate the marketing from the science has not always been easy, because many people do suffer with genuine mental disorders, many can be helped greatly with medications, and many with serious problems are not getting the treatments they need. Moreover, many of the doctors working closely with the drug companies are highly motivated to act in the best interest of patients—and their ties with industry may reflect a shared professional interest rather than an inappropriate commercial relationship. And complicating matters even further is the ongoing argument over what is "unmet need" and what is "met un-need" in relation to depression and other mental illness.

Sometimes, however, the most natural and normal processes of life are being sold as medical conditions to be treated with drugs. And sometimes that marketing is made even more powerful and effective by the intangible magic of celebrity selling.

3

Working with celebrities

Menopause

The summer of 2002 brought good and bad news for Lesa Henry, the busy public relations chief at the drug company Wyeth, and the woman helping to market one of the best-selling drug regimes of all time—hormone replacement therapy. The good news was that she'd just picked up an advertising industry award for her work using celebrities to promote drugs, and she'd been named one of the top twenty-five marketers of the year. The bad news was that scientists had just discovered long-term use of hormone replacement therapy was doing women more harm than good.[1]

In the world of drug marketing, Wyeth's Lesa Henry is seen as well ahead of the game. She was one of the first to recognize the value of celebrities for "educating consumers" about health conditions, and the drugs that go with them.[2] One of Wyeth's major coups had been hiring supermodel Lauren Hutton to help raise public awareness about a "health condition" otherwise known as the menopause—the time in a woman's life when her

periods, and her fertility, come to an end. Hutton's famous face has fronted a massive marketing campaign promoting both the "dangers" of the menopause, and the "promise" of Wyeth's hormone pills. As director of communications within the company's Women's Healthcare division, Henry was leading the way for the industry, according to the judges who gave her the award, "in appropriately using celebrity spokespersons in an innovative, results-oriented communications effort."

Celebrities have become central figures in drug company campaigns to change the way we think about the common ailments of life. Baseball stars help transform fears about sexual performance into pills for sexual dysfunction, and football heroes now help sell shyness as a symptom of a mental illness. For their trouble the stars are paid anything from $20,000 to $2 million, yet the exact size of these paychecks are well-kept secrets.[3] What's more, many of the talk shows and the tabloids will portray these celebrities as being engaged in worthwhile "awareness-raising" activities, while making no mention of the fat fees flowing to the stars behind the scenes. One of the most cynical campaigns of all has been Wyeth's attempt to inflame fears about the menopause at the same time as scientists have been documenting the dangers of the company's menopause drugs. The supreme irony is that hormone replacement therapy, after finally being properly studied, would ultimately be shown to cause some of the very health problems it was supposed to prevent.

A milestone in the campaign to "educate" consumers about menopause was a cover story in 2000 in *Parade*, the weekly magazine inserted into newspapers across the United States.[4] Seen by an estimated 70 million Americans every Sunday, it is arguably one of the most widely read magazines on the planet,

and a cover story here is a marketer's dream.[5] Photographed with two other beaming celebrities, the sexy Hutton adorned the *Parade* cover along with the headline, "Live Longer, Better, Wiser: This year's indispensable guide for every one of us." Blurring the lines between news and advertising, Hutton not only appeared on the magazine cover and in its main article, she also featured as the centerpiece of a Wyeth advertisement in the same issue—talking about the consequences of "estrogen loss" at menopause.

The Wyeth advertisement detailed a horrifying list of what apparently lies ahead for women after the menopause: Alzheimer's disease, heart attacks, colon cancer, cataracts, teeth loss, night sweats, vaginal dryness, bone fractures, and more. "Talk to your doctor," urged Hutton's reassuring image, "because the more you know about menopause and its associated estrogen loss, the more you'll want to take an active interest in your health."

Just a few pages away from the advertisement was an article called "Celebrities Reveal Their Secrets," where the fifty-five-year-old supermodel and health advocate shared her tips for feeling good and looking fabulous. First she praised the virtues of apples, fish, pasta, and yoga. Then came the most important part of Hutton's message. "My No. 1 secret is estrogen," she said. "It's good for your moods, it's good for your skin. If I had to choose between all my creams and makeup for feeling and looking good, I'd take the estrogen." U.S. FDA regulations forbid Wyeth executives from making such one-sided claims about the company's hormone drugs in their advertising, with no mention of side effects, yet their paid celebrity is apparently not under the same FDA constraints.

Selling menopause as a fearful time of hormone *loss* lays the groundwork for selling the promise of hormone *replacement*. As

the industry magazine *DTC Perspectives* rightly recognized when it anointed Lesa Henry one of the top marketers of the year: using celebrities brings results. And Lauren Hutton is not the only star in the Wyeth stable. Soul diva Patti LaBelle and actress Cheryl Ladd have also been on the payroll.[6] Not surprisingly, Lesa Henry won that same industry award a second time round, the following year.[7]

Wyeth strongly defends the use of celebrities, arguing that the women are prompted to participate in educational programs because of their own experiences, and their desire to share those experiences with other women. In relation to the awards, a Wyeth spokesperson said the company was pleased when employees are recognized for their professional achievements.[8]

"These campaigns are extremely effective in reaching consumers," says celebrity-broker Amy Doner Schachtel. Working from her office in New Jersey, the attractive former drug company public relations expert has moved to the leading edge of medical marketing.[9] Sometimes juggling two phones at once, she connects high-profile celebrities with big-name drug companies keen to educate the public about common conditions. "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 says. The goal of these company-funded celebrity campaigns, as she stresses repeatedly, is to drive patients into doctors' offices to seek treatment. Schachtel has helped find celebrities to raise awareness about irritable bowel syndrome, depression and social anxiety disorder. She's worked with *West Wing* heartthrob Rob Lowe, country singer-songwriter Naomi Judd, and television mega-star Cybill Shepherd. "People look up to celebrities," she says, "because they trust them."

Hutton's role, like that of other celebrities, was not to create

a condition, but rather to help sell a certain perception of one. In this case the Wyeth advertisement featuring her was helping to persuade women that the menopause was not simply a natural part of life, but rather a condition of "estrogen loss" which brought an increased risk of deadly and frightening diseases, and required a visit to a medical doctor. This picture of the menopause is by no means a new one, but in recent years Wyeth's reasons for promoting it have intensified, as the world has learned more and more about the dangers of the company's hormone pills. By the time of the famous *Parade* front cover in the year 2000 the preliminary findings were starting to flow from a massive government-funded study of long-term use of the drugs. As we would all later learn, the combined form of long-term hormone replacement therapy—one of the most prescribed drug therapies ever—was doing more harm than good to the millions of women around the world who were taking it: slightly *increasing* their risks of heart attacks, strokes, blood clots, and breast cancer.[10]

Promoting a woman's natural change of life as a medical condition of "estrogen loss" has a history dating back several decades at least. And just like today, drug company-backed celebrities were at the center of the action. In the mid-1960s, New York gynecologist Dr. Robert Wilson published the landmark work *Feminine Forever*.[11] The book's cover declared a revolutionary breakthrough: "the discovery that menopause is a hormone deficiency disease, curable and totally preventable" means that "every woman no matter what her age, can safely live a fully-sexed life for her entire life." Excerpts were published in *Look* and *Vogue* and it sold one hundred thousand copies in a matter of months.[12] The book became a bestseller, and Wilson a celebrity physician. "Instead of being condemned to witness the

death of their own womanhood during what should be their best years," said the book's preamble, "they will remain fully feminine—physically and emotionally—for as long as they live."

> . . . menopause is a hormone deficiency disease, curable and totally preventable . . .
>
> —*Feminine Forever,* 1966

The central claim of *Feminine Forever*—and one that echoes through Hutton's celebrity scripts almost forty years later—was that menopause is a condition that requires medical help. It is a *deficiency disease* to be fixed with hormone pills. "With estrogen therapy," proclaimed Wilson, "her rapid physical decline in post-menopausal years is halted. Her body retains its relative youthfulness just as a man's does." A host of scientific articles were used to support Wilson's claims about the miracle properties of estrogen. While it was clear the pills could offer short-term benefits in terms of symptom relief, their long-term risks and benefits were simply unknown.[13]

Against the backdrop of the emerging women's movement of the 1960s and its language of emancipation, Wilson's book argued that his revolutionary view of menopause, and its treatment, was a way of helping to liberate women—particularly sexually. He attacked a predominantly male medical profession that had failed to appreciate menopause "as a serious physical and mental syndrome." By acknowledging the sometimes severe suffering of his menopausal patients, Wilson firmly aligned himself with women, standing courageously against the "indifference" of male physicians who dismissed women's suffering as simply a state of mind.

Similar charges are regularly leveled against the medical profession from within the women's movement. Just like Wilson,

advocacy organizations like the National Women's Health Network criticize clinicians who dismiss the problems experienced by women at midlife as "just" menopause. Echoing his arguments, the feminist group urges clinicians to be more sensitive to reports of the uncomfortable changes that many women experience at menopause, and to try to offer remedies for them.[14]

Yet that same women's group is scathing about the celebrity book *Feminine Forever,* and Wilson's claims that menopause is a disease. "Menopause has become medicalized," the group claims. "This approach is not useful to women,"[15] The Washington, D.C. based network is one of the few high-profile consumer outfits in the U.S. that remains totally independent of pharmaceutical industry funding and support. Acknowledging the need for effective remedies for menopausal symptoms, and for good, accurate information about staying healthy, the group strongly objects to the view that the normal change of life is a deficiency disease. "Menopause is a natural bodily function, not a disease, and does not automatically require treatment."[16]

Sociologist Susan Bell has traced the medicalization of menopause back well before the book *Feminine Forever*—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.[17] Coincidentally, the same group of physicians was researching a new drug called DES—one of the early synthetic forms of the female hormone estrogen.

According to Bell, there were benefits for women from the process of thinking about menopause as a medical condition: complaints of hot flashes (hot flushes), sweats, and other symptoms were now legitimized and explained by modern medical science, and in some cases relieved with medical therapies, instead of being dismissed as figments of women's imagination.

But for Bell, the downsides of medicalizing menopause far outweighed the benefits. Once menopause was defined as a deficiency disease, its treatment with estrogen was not only legitimate, it became an obligation—a line of thinking that echoes today with supermodel Hutton urging women to take an *active interest* in their health. And many readers will already have made another connection here. Just as modern long-term hormone replacement therapy is now being exposed 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.[18]

Both doctors and drug companies have much to gain from the construction of menopause as a condition that requires treatment and, as occurs with other conditions, elements within the two groups worked closely together on this one.[19] The perfect illustration is perhaps *Feminine Forever*—the book that helped sell to generations of women the idea that they could treat their disease of *deficiency* with hormone *replacement*. What wasn't clear to many of those who read the late Dr. Wilson's bestseller was that his celebrity book tours and his scientific work testing estrogen were in part sponsored by the drug company that manufactured the hormones, Ayerst Laboratories, which ultimately became Wyeth—the same company that sponsored Hutton's celebrity selling nearly four decades later.[20]

While this alliance between parts of the medical profession and drug companies is sometimes referred to as the "menopause industry," some writers are keen to point out that the process of transforming a woman's change of life into a medical condition is not part of a dark commercial conspiracy. Rather, there is a complex interplay of images and ideas back and forth between society and the world of medicine, fed by deep-seated and wide-

spread anxieties about aging, femininity, and sexuality.[21] While there may be no conspiracy here, this does not stop critics from calling for a halt to what they see as medicine encroaching way too far into ordinary life—and taking too much power away from ordinary people as a result. Two researchers, Susan Ferguson and Carla Parry, recently argued there was an urgent need to "demedicalize the language and experience of menopause," and describe and understand it as a natural and healthy process.[22]

Groups like the National Women's Health Network see themselves as doing exactly that—advocating a view of menopause as a natural process, at the same time as exposing the marketing campaigns that reinforce the idea of a disease of deficiency or loss.[23] The group's director of programs and policy is Harvard graduate Amy Allina—a strong critic of the marketing of menopause.[24] She says Wyeth's campaign featuring Hutton "plays off the celebrity worship in this country." Allina boasts an extraordinary collection of drug ads including Hutton's *Parade* appearance that come in very handy whenever she speaks publicly about the way menopause has been sold, and is still being sold to women. "We use the ads to show how drug companies expand the market for HRT," she says. "They all promote the idea that there is something wrong with women's bodies, there's something wrong with getting older, and these drugs are going to fix you."

"This wasn't a change, it was a catastrophe," says a middle-aged woman in one ad from a medical magazine of the 1970s. Another features a large close-up photo of the joyless face of a very depressed woman, with three words printed starkly beside her in bold type: Estrogen Deficient Woman. That ad urges the physician to Treat Her With Premarin, and Keep Her On Premarin, the Wyeth drug that would become one of the biggest-

selling pills of all time. Looking over the ads with Allina in her downtown office, one doesn't know whether to laugh or cry.

While company advertisements were urging physicians to Keep Her On Premarin, early studies were already suggesting women taking the drugs were at an increased risk of endometrial cancer. Public controversy over the use of hormones was growing, and in fact it helped create the very network where Amy Allina works today, a quarter-century later. Following those initial cancer findings, a second drug called progestogen (or progestin) was added to estrogen, to make a combined form of hormone replacement therapy, sold by Wyeth as the popular Prempro with the promise of being safer than estrogen alone.

By the late 1980s and into the 1990s millions of women worldwide would start taking this combination hormone replacement therapy—or HRT—promoted on the basis of evidence suggesting that not only could it help relieve symptoms, but that in the long term it might reduce a woman's risk of bone fracture, heart disease, and cognitive decline.[25] Essentially HRT would be seen as the elixir of life.

Much of that evidence was from the beginning weak scientifically, and many of the promises would later prove utterly false. Yet the fiction that HRT was a panacea was reinforced at company-sponsored medical meetings and scientific conferences all over the world, including the international menopause congress held in Sydney's famous harbor one springtime in the mid-1990s.[26] Not only did industry heavily sponsor the congress, individual companies, including Wyeth, were able to fund almost half of the scientific sessions, just as the maker of antidepressants helped fund the psychiatrist meeting in New York. On each afternoon of the four-day conference, the

symposia were all drug company funded, including a Wyeth session on brain function and hormone replacement therapy. To help the international delegates understand the latest science about menopause they were also offered a sumptuous smorgasbord of Sydney social engagements, including trips to the celebrity landmark the Sydney Opera House and romantic harbor cruises. Post-congress tours explored the tropical rainforest, the Great Barrier Reef, and Uluru.

While some of the thought-leaders at Sydney Harbour that year were still singing the praises of hormone replacement therapy for the menopause, and organizing or attending conferences sponsored by drug makers, others were offering much more sober assessments of the state of the existing evidence. That same year as the Sydney conference, two doctors in the United Kingdom published a letter in a medical journal strongly questioning the ability of long-term HRT to reduce a woman's risk of heart disease, and suggesting much safer options might include more exercise, a healthier diet and stopping smoking. "The menopause is a normal physiological state," they wrote, "not a disease."[27]

At the time of that Sydney meeting, combined hormone replacement therapy had been widely used since the 1980s, yet it was not until 1998 that a rigorous top-quality study, called the HERS trial, actually assessed its long-term risks and benefits.[28] Until then, these drugs were being taken by women who were essentially unwitting participants in a giant uncontrolled global experiment.

The HERS trial was a particularly significant landmark because it was among the first of what's called a *randomized controlled trial* of these drugs—the form of study that is now considered a gold standard in science for evaluating how well a treatment works. It might sound like an awkward scientific term,

but a randomized controlled trial is a relatively simple yet very powerful way to test drugs or other treatments.

A group of people are randomly divided into two groups. One group is given the drug, and the other group, called the control group, is given a placebo or dummy pill. Then at the end of the trial the health of both groups is compared.[29] In the HERS trial, a group of almost three thousand older women who already had some form of heart disease were randomly divided into two groups—one group received combined estrogen plus progestin—HRT—while the control group received a placebo. The trial was run by researchers at the University of California, San Francisco, and funded by Wyeth. Its results were startling.

Researchers found that after four years, the group of women taking the drug had done no better than the group who were taking the placebo. The drug had failed to prevent any heart attacks—contrary to a lot of what women had been led to understand for a decade or more. More worrying still, in the first year of the study, a slightly higher number of women had had heart attacks in the group taking hormone replacement therapy.[30] Before this, the studies purporting to show that the drugs reduced the chance of heart attacks were mainly *observational studies*—rather than the more reliable randomized controlled trials.[31] But despite this frightening new evidence about a popular medicine, coming from a top-quality trial, the HERS study received remarkably little public attention—and certainly no celebrity endorsements.[32]

In fact, rather than focus people's attention on the important new scientific findings about HRT's lack of long-term effectiveness, in that same year, just a few months before the publication of the HERS trial results, Wyeth unleashed a worldwide campaign to remind women and their doctors of the dangers of

"estrogen loss" at the menopause. Inflaming fears about the disease would serve to counter what Wyeth marketers knew would be growing fears about its drugs.

Wyeth wrote to physicians across the U.S., not to warn of the mounting concerns about HRT, but to advise them of a new patient education campaign designed primarily to "educate women about all the consequences of estrogen loss at menopause, and the different, sometimes serious, effects it can have on their bodies."[33] The second aim of the campaign, according to the Wyeth letter, was to encourage women to see their health care provider "to learn more about menopause and . . . estrogen loss." The excerpt from the patient education material that was attached to the letter to doctors featured the sketched image of a naked woman surrounded by the frightening array of threats to her health associated with "estrogen loss": Alzheimer's, heart attacks, etc. . . . virtually the same list that appeared surrounding the image of supermodel Hutton in the *Parade* advertisement.

The letter to doctors is important not only because it reveals Wyeth's growing commercial need to reinforce public fears about the menopause, but also because it sheds light on the shared interests of doctors and drug companies. A well-funded "awareness-raising" campaign that urges women to see their health care providers about a natural event they will all experience is clearly going to be good for the business of doctors, as well as drug companies.

Like many modern marketing campaigns, Wyeth's new wave of promotion was global, and eventually reached the shores of distant Australia around the same time Lauren Hutton was adorning the front cover of *Parade* magazine. In Australia the marketing of menopause at the dawn of the new millennium would become a textbook case of selling sickness.

At two minutes past two one afternoon in mid-July 2000, a facsimile arrived at the Sydney newsroom of an influential national newspaper.[34] Like dozens of faxes that arrive in newsrooms around the world every day, this one was from a global public relations firm, advising journalists of the latest important piece of health news. This fax was from the Manhattan-based Hill & Knowlton, announcing the launch of a new national awareness campaign about menopause "devised by a group of experts" from the Australasian Menopause Society. As part of the campaign, the fax explained, the Australian experts had developed a free information booklet for patients, and a series of consumer seminars would soon be held around the nation.

This Aussie campaign was no small affair. A week after the fax, 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.[35] Like the press release, the newspaper ads featured the name and logo of the Australasian Menopause Society.

What both the faxed release and the newspaper ads failed to mention was that 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—the drug regime soon to be hit by a hurricane of bad news. Contrary to the suggestions in the Hill & Knowlton press release, the Australian experts from the menopause society did not devise the so-called "educational materials" being distributed to the public. Drafts of the materials, including the patient information booklet, had come from Wyeth and its PR team, Hill & Knowlton, before being revised and signed off by the Australian experts—a fact admitted months later by the menopause society president.[36]

At least one of the key images in the supposedly independent

patient information booklet—notably the sketch of the naked female—was lifted directly from the Wyeth ads running at the time in the United States. Similarly, it listed the now familiar health threats to women at the menopause: Alzheimer's disease, heart attacks, and so on. The front page of the booklet featured the name and logo of the Australasian Menopause Society, and while Wyeth's funding was revealed in tiny print on the back page, its role in developing and distributing the booklet and orchestrating the wider "awareness-raising" campaign was not disclosed.

The company-funded patient booklet distributed to Australian women in 2000 stressed the many purported "dangers" of menopause, yet it failed to mention the latest evidence about the dangers of Wyeth's HRT. Under the section about the benefits of HRT, the booklet stated that observational studies suggested the drugs reduced the risk of heart disease. It did not reveal that one of the first top-quality randomized controlled trials, the HERS trial, had suggested the drugs had no such benefit. Yet the HERS trial results had by then been known for two years. Similarly, the booklet totally failed to inform women of the well-proven risk of blood clots associated with the use of these drugs.[37]

Here was another model example of astroturfing, the use of corporate money to try to create the appearance of a grassroots campaign. In this case, biased and unbalanced marketing materials were signed off by so-called Australian experts and dressed up as independent patient information. Yet again marketing masquerading as education. And what's worse, the web of company sponsorship was hidden in some of the campaign's dealings with the media and the public. Perhaps most importantly, despite clearly misleading materials being promoted to the public about one of the biggest-selling drugs of all time,

virtually no one within the medical establishment would bat an eyelid, and no one within the health authorities would take any action to hold those responsible accountable.

What made that campaign even more misleading was that early findings from the much bigger and far more important study were by then also ringing alarm bells about HRT. The timing here is critical. In mid-2000, as Wyeth's latest wave of marketing was washing around the world, capturing the front cover of *Parade* magazine with its paid celebrity Lauren Hutton and flooding Australia with supposedly independent materials, the first frightening findings were already starting to surface from the enormous randomized controlled trial set up almost a decade earlier by the U.S. federal government. It was called the Women's Health Initiative, and its findings would turn established medical wisdom on its head.

The HERS trial, published in 1998, had been conducted among women who already experienced some form of heart disease. But the Women's Health Initiative was the first large, long-term trial of the hormone drugs among *healthy* women. And it was much bigger, involving more than sixteen thousand women, making its findings far more relevant to a broad range of women. The U.S. National Institutes of Health had launched it in the early 1990s, following pressure for such a rigorous trial from women's groups like the National Women's Health Network. The U.S. taxpayer was funding it and Wyeth was providing the pills.

In early 2000, before Wyeth even kicked off its Australian campaign, the researchers running that giant Women's Health Initiative trial had written an extraordinary letter to the thousands of women taking part. The letter informed them that the study participants taking the combined version of HRT were in

fact experiencing slightly more "heart attacks, strokes and blood clots" than those women taking the placebo—or dummy pill.[38] This was a historic finding—backing up what the HERS trial had found two years earlier—and seeming to contradict much of what was widely believed within the medical world. The increase was only slight, and it was hoped that over time, as the trial continued, it might disappear. But it was still cause for major concern, given that the drugs were supposed to be reducing women's risks, not increasing them. For women taking part in the trial this must have been alarming news, particularly because as part of the trial design they were not even aware whether they were taking the real drugs or the placebo.

Ultimately, those increased risks associated with the drugs did not disappear. Two years later the trial was stopped early because hormone replacement therapy was found to be doing more harm than good. In mid-2002, the first results of the Women's Health Initiative were published in the *Journal of the American Medical Association*, sparking front-page headlines around the world.[39] A small benefit in terms of reduced risk of fractures and colon cancer was outweighed by increased risks of heart attack, stroke, blood clots, and breast cancer.[40]

For every hundred women taking combined hormone replacement therapy long term, the drugs were *causing* one extra serious adverse event—including heart attacks and strokes.[41] Rather than preventing heart disease, the drugs were causing it. Among the older women in the trial, over five years the drugs doubled the risk of developing "probable dementia," from roughly 1 percent to 2 percent.[42] Rather than prevent Alzheimer's, the drugs appeared to be causing more of it. Apart from the slight reductions in fractures and colon cancer, the long-term health benefits of these drugs simply did not exist. The promise

to fix *hormone loss* with *hormone replacement*, the very basis of Wyeth's award-winning celebrity campaigns, had proved utterly false.

What's more, the claims that the drugs alleviated many of the symptoms associated with the menopause—the reason many women start therapy—were also thrown into some degree of doubt when further findings from that same trial were released. As one part of the huge Women's Health Initiative, the researchers had tested how well HRT improved quality of life. They looked at effects on general health, vitality, mental health, and sexual satisfaction. After three years of treatment they found there were "no significant benefits in terms of any quality-of-life outcomes." However, among a subset of those in the study, the younger women, aged fifty to fifty-four, who experienced moderate to severe symptoms, the drugs offered some benefit with hot flashes (hot flushes) and sleeping problems.[43] Importantly, there is a strong body of good evidence that these drugs are very effective in reducing the frequency and severity of hot flashes (hot flushes) for many women.[44]

These extraordinary findings have brought a mix of shock and disbelief, and forced many physicians to face the fact that their beliefs about the long-term health benefits of hormone replacement therapy were based on flawed science, and were sustained in part with the help of celebrity awareness-raising campaigns funded by the drug makers. However, some company-funded medical groups have been particularly slow to acknowledge the new scientific reality. A full two years after the release of the groundbreaking HERS trial in 1998 that found no heart benefits for women taking HRT, the influential American College of Obstetricians and Gynecologists was still recommending that women take HRT to "reduce the risk of cardiovascular disease."[45] Similarly, the results of the Women's

Health Initiative have been criticized by many researchers as being flawed, despite its rigorous quality and enormous size.

Some observers like Amy Allina believe there has been a concerted campaign to try to minimize the impact of these two important studies on both public understanding and doctors' prescribing habits. She points out that company-funded medical groups are trying to suggest the Women's Health Initiative results are of limited relevance, particularly to younger women. She worries that good science is again being undermined by marketing. Certainly it is the case that our knowledge about the risks and benefits of HRT, like all scientific knowledge, is evolving, and it is important to place the findings of these latest studies in the context of all the relevant data. But that said, few unbiased observers would question the assertion that the publicly funded Women's Health Initiative is one of the biggest and the best trials so far conducted in this field. Despite the criticisms of that study, and the ongoing defense of the drugs from those who have long championed them, the rates of prescriptions for HRT have fallen dramatically since 2002.[46]

Ironically, as the dangers of hormone replacement therapy have become better known, and rates of prescriptions of HRT have fallen—in spite of the concerted campaign to defend the drug—other companies selling different medicines or alternative therapies have attempted to muscle in on the "menopause market." often also enlisting stars to help out. In one case celebrity broker Amy Doner Schachtel helped hire Cybill Shepherd to raise awareness about menopause on behalf of an Australian company that makes a popular soy-derived supplement.[47]

"A partnership between a celebrity and a brand has an intangible sort of magic," said a senior marketing executive recently, offering tips to her peers in the pharmaceutical industry.[48] One

tip was to have celebrities appear on talk shows or do media interviews, rather than straight advertising. Why? Because the "great advantage over advertising is that the airtime is practically free, and there is no fair balance to worry about."[49] The now infamous endorsement of estrogen in the *Parade* magazine article made no mention of the side effects of the drug, presumably because there was no fair balance to worry about.[50] Neither did the article mention the celebrity's paid work for the company which markets estrogen.

"This is an outrageous circumventing of public health protections," says Allina, arguing that in her view, if paid celebrities appear in public hawking a disease or a drug, without disclosing their links to the manufacturer, it's equivalent to "outright deception." Yet celebrities being paid by drug companies have been under no clear regulatory requirements to disclose accurate information about the nature of the condition or the therapy they might be promoting. Similarly, there are no legal requirements for them, or for the media outlets in which they appear, to disclose the link with the drug manufacturer, even though the public may sometimes be misled into thinking the star is independent.[51] Until the health regulators awake from their dreamy slumbers, these star-studded marketing campaigns will continue to dazzle consumers around the world, and the complexity of the science will continue to get lost under the bright lights.

For many observers, the appropriation of a woman's change of life is the perfect illustration of the dramatic transformation of a normal human experience into a treatable medical condition. The stars in this drama now include "A-list" celebrities with strong ties to the drug companies. As we'll see, they also include some of the world's best-known patient groups.

4

Partnering with patients

Attention deficit disorder

The rolling green fairways of the Norbeck Country Club shimmer in the welcome sunshine of a long overdue spring. A good hour's drive from the sirens and stress of downtown Washington, D.C., the manicured private golf course sits amidst the wealthy suburbs of the state of Maryland. The silence here, like the surrounding affluence, is striking. Being May, the quiet is interrupted by the occasional bursts of birdsong, and on this particular Monday afternoon, by the gentle sounds of middle-aged male golfers teeing off at the start of the annual CHADD charity golf classic. CHADD stands for Children and Adults with Attention-Deficit/Hyperactivity Disorder—the energetic patient advocacy group that now boasts fifteen thousand members and two hundred affiliates across the United States.

A scene of such tranquillity might seem an unlikely setting for an ADD charity event, but really the location is perfect. White suburbs like those around the country club are among the healthiest and wealthiest places on earth, yet they are also