

*Message in a Bottle*

**Prozac and the Marketing of Depression**

**by Alexander Cockburn and Fred Gardner**

In January 1995 Eli Lilly, the Indianapolis-based drug company that derives more than 25% of its profits from the sale of Prozac, suffered a minor p.r. setback. Alerted by displeased parents, The Washington Post reported that two Lilly sales reps had addressed the student body at Walter Johnson High School in Bethesda Maryland on National Depression Screening Day (Oct. 6, 1994), passing out free Prozac pens and Post-it pads, and proselytizing at two assemblies on the subject of "clinical depression." A follow-up Post story Jan 27 reflected Lilly's attempt at damage control:

"The maker of Prozac, the world's most widely prescribed antidepressant, said it no longer will allow its drug salesmen to attend company-funded community programs that are intended to educate people about depression and identify individuals who may need help... Eli Lilly spokesman Ed West said that the sales representatives violated company policy, which at the time allowed salesmen to perform only clerical or administrative duties, such as putting up balloons, to support depression awareness programs... West said what occurred at Walter Johnson 'was an isolated event,' but, to avoid such mistakes in the future, the company would tighten its policy by banning on-site visits by Eli Lilly officials."

Ed West is a deft p.r. man, and his response made it seem as though the problem at Walter Johnson H.S. was one of some enthusiastic sales reps overstepping the line between educating and selling. But what if the protocols of National Depression Screening Day had been followed to the letter, and the talks

had been given by mental health professionals --what business does Eli Lilly have pushing drugs in our high schools directly *or* indirectly?

In 1994, according to its organizers, about 85,000 Americans took part in National Depression Screening Day at 2,000 sites. Public service announcements promoting the event on radio and television carried Lilly's message to millions more. We attended a presumably typical session at St. Mary's Hospital in San Francisco. It consisted of two psychiatrists giving a tag-team lecture on depression while the marketing director of the hospital's neuropsychiatric institute showed slides restating the main points. Which were:

Depression is a medical illness. It is treatable by psychotherapy, medication, or a combination of both. One in five American adults will suffer from this medical condition during their lifetime —twice as many women as men. There should be no stigma attached to seeing your doctor to get help for this widespread but treatable medical condition. And, as Dr. F. put it, "Antidepressants are not stimulants, not addictive, they make you normal."

The psychiatrists' basic material was taken from a manual written and provided by Douglas Jacobs, MD, clinical professor of psychiatry at Harvard Medical School and founder and prime organizer of National Depression Screening Day. Dr. F. mentioned Prozac by name and called it "a wonder drug in several senses." He claimed that people lose weight on it because it restores the sense of taste, thereby eliminating the patient's interest in junk food. (Lilly may have gotten more than they bargained for when Dr. F was hired to give the pitch. In response to a question he mentioned that two of his own children are on Prozac.) It turns out Prozac leads to short term weight loss followed by longterm weight gain.

"It's very unlikely that Prozac will turn out to have side-effects we don't know about," according to Dr. F. He said that when a patient tells him that Prozac has

lost its effectiveness, "the choice is to increase the dosage or switch them to Zoloft" (a similar antidepressant manufactured by Pfizer's Roerig unit. Picture the marketing specialists coming up with a name: a cross between *zaftig* and aloft... ) The loss of effectiveness isn't a matter of tolerance building up, Dr. F asserted without offering an alternative explanation. "The treatment is really simple," he breezily concluded. "You take one pill a day for two or three weeks. If it doesn't work, nothing lost."

The marketing director then showed a video called *Moving into the Light* —an infomercial produced by the National Mental Health Association with money provided by Eli Lilly-- that opens with a series of clinical-depression vignettes. A secretary grumbles about her work not being enjoyable, a man opines that life is "meaningless," a truck driver complains of a backache, etc. Eventually a narrator (sounding very much like Phil Hartman) intones, "Let us now turn to a noted medical authority, Dr. Peter E. Stokes, who has treated thousands of people successfully for clinical depression." Cut to a bald man in a white coat who takes off his glasses and leans into the camera, saying, "Many people do not understand the medical nature of this illness, clinical depression..."

National Depression Screening Day is one small element in a pervasive campaign by the pharmaceutical manufacturers --with Eli Lilly in the vanguard-- to convince the American people that there is a medical illness called "clinical depression" that results from a chemical imbalance in the brain and that is treatable by drugs. The campaign is endorsed by the psychiatric establishment and the federal government. Its goals include:

- encouraging physicians to diagnose clinical depression more frequently.
- convincing employers and the government that widespread use of antidepressants will boost productivity.

- discrediting critics by linking them to a "cult."
- keeping the American people convinced that the spreading mass misery is just so many individual cases of "chemical imbalance," correctable by drugs.

Some 6,674,000 patients were treated for depression in the U.S. in 1994, up from 5,406,000 in 1993 --an increase of 19 percent-- according to IMS America, a research organization that tracks the pharmaceutical industry. The number of new patients totaled 2,333,000, a 20 percent increase.

IMS America has analyzed "diagnosis visits for depression" and reports a 19 percent increase in visits where drugs were prescribed, administered or recommended. Prozac total US sales grew to \$1.27 billion in '94 --up 41 percent in dollar volume in '94-- making Lilly's antidepressant second only to Glaxo's ulcer drug Zantac as the top grosser. The soaring use of Prozac is often described in the media as "astounding," but in fact, it is a direct result of the campaign to market clinical depression: more visits means more diagnoses, more prescriptions, more sales.

Eli Lilly credits three researchers --Brian Molloy, Roy Fuller, David Wong-- with key roles in "discovering" Prozac. In the early '70s Molloy was looking for compounds resembling antihistamines that might function as antidepressants. Fuller suggested a concentration on compounds that would increase the available levels of a chemical messenger called serotonin (not yet a household term). Wong developed a method of measuring serotonin levels in the brain cells of rats. They and their colleagues came up with a psychoactive compound they christened fluoxetine hydrochloride, which was then given the trade name Prozac. In describing its mode of action, they called it a "selective serotonin reuptake inhibitor" or SSRI.

In the brain, serotonin is transmitted from a sending nerve cell into a gap called a synapse. Some of it is then taken up by a receiving nerve cell, and some returns to the sending nerve cell. Prozac blocks the reuptake, leaving more serotonin available in the synapse. But the first "S" in SSRI --"selective"-- implies a precision that some investigators in the field are unwilling to confer on Prozac. There are more than a hundred neurotransmitters in the brain, and an intricate network of feedback mechanisms; an impact on one neurotransmitter system usually involves secondary impacts on another. Moreover, serotonin itself does not "selectively" influence mood; it affects the sleep/wake cycle, appetite, and sexual desire.

The FDA granted Lilly "Investigational New Drug" status for Prozac in 1976, and over the course of the next 10 years the company spent an estimated \$80 million underwriting clinical trials, first on animals, then on people. A "new drug application" was filed in September, 1983, seeking approval for marketing Prozac to the general public for treatment of "major depression." That approval was granted December 29, 1987, despite the fact that some serious red flags had been raised when the FDA examined the results of the clinical trials Lilly had conducted (i.e., paid for with grants to investigators at various universities and private research institutions).

The clinical trials of Prozac excluded suicidal patients, children, and elderly adults --although once FDA approval is granted, the drug can be prescribed for anyone of any age. According to Dr. Peter Breggin, a Bethesda-based psychiatrist who analyzed the FDA's approval of Prozac, it was based, ultimately, on three studies indicating that fluoxetine relieved some symptoms of depression more effectively than a placebo, and in the face of nine studies indicating no positive effect. Only 63 patients were on fluoxetine for a period of more than two years; therefore, *nobody knows the longterm effects.*

If fluoxetine hydrochloride posed so many problems, why did Lilly push so hard for its approval? Prozac's great selling point, from the perspective of those writing the prescriptions, would be its relative safety. According to David Dunner, MD, co-director of the University of Washington's Center for Anxiety and Depression, Prozac became popular "not because it works better than other drugs. Indeed all antidepressant drugs seem to work well in about 70% of patients. Fluoxetine has a much more benign side-effect profile than previously used drugs."

Unlike the tricyclics (Elavil, Pamelor, etc.), which have strong cardiac effects, serotonin reuptake inhibitors cannot cause death by overdose. Unlike the monoamine oxidase inhibitors (Nardil, Parnate, etc.) they do not lead to dangerous interactions with common foods. With the introduction of Prozac, physicians could prescribe an antidepressant without providing potentially suicidal people with a potentially fatal bottle of pills.

While pushing Prozac through the premarket pipeline, the company was also sponsoring research to establish that depression was much more prevalent than commonly recognized, and that doctors often failed to diagnose and treat it. Between 1985 and '86 the number of scientific journal papers on the subject jumped from 474 to 567. Increased interest on the part of researchers was then invoked by the National Institute of Mental Health (NIMH) to justify its Depression Awareness, Recognition and Treatment (D/ART) Program, launched in March 1987. "Advances in epidemiological research have documented the prevalence of clinically significant depressive disorders," asserted a major position paper in the American Journal of Psychiatry by the D/ART Program leaders (including former NIMH director Lewis Judd, and NIMH director-to-be Frederick K. Goodwin). "Today, 80% to 90% of persons with a major depressive

order can be treated successfully. Yet only about one person in three who suffers from a depressive disorder ever seeks treatment... Even when people do seek help, current evidence suggests that too often depression is poorly recognized, undertreated, or inappropriately treated by the health care system." The D/ART leaders bemoaned the fact that only 12% of respondents in a 1986 Roper poll had said they would take medication for depression; 78% said they would "live with it until it passed." It may seem odd that a government perpetually waging a "War on Drugs" would seek to weaken its own citizens' reluctance to take drugs --and yet this has been the line of the government's own top psychiatrists as they market the concept of clinical depression.

The NIMH D/ART Program was designed to ensure that "treatment of depressive disorders more closely reflects the current research-generated knowledge base." It was launched with three objectives:

"1. To increase public knowledge of the symptoms of depressive disorders and the availability of effective treatment.

"2. To change public attitudes about depression so that there is a greater acceptance of depression as a disorder rather than a weakness.

"3. To motivate changes in behavior among the public and treatment professionals."

The D/ART Program not only put the governmental stamp of approval on the corporate-funded depression research, it created a mechanism whereby corporate money and personnel could be employed to stimulate demand for corporate products. The D/ART program created a network of "campaign consultants" that included pharmaceutical company representatives --including NAME TK from Eli Lilly-- to draft promotional materials; and a "community partnership program" involving the nonprofit National Mental Health Association to "identify sources of private support to distribute print and electronic materials

and... to host talk shows, to encourage the development of professional seminars on depression, and to make referrals to treatment facilities."

Seven years after the D/ART Program was launched, its success is tangible. The National Mental Health Association's "Campaign on Clinical Depression" is being underwritten by a \$4 million-a-year "educational grant" from Eli Lilly (which gets a tax write-off and an altruistic image in the process). Its goal is to reach 90% of the population at least nine times each, according to campaign director Colleen Reilly. The people on the receiving end of this information barrage do not know its true source. For example, on December 1, 1993, millions of Americans read a "Dear Abby" letter asserting that millions of Americans suffer from clinical depression without realizing it. The letter was signed by a member of an NMHA affiliate in White Plains, New York. Abby urged her readers to call the NMHA's toll-free number --not mentioning that Eli Lilly would pay for the call-- to get the free booklet entitled "Answers to Your Questions About Clinical Depression."

Some 350,000 copies of the booklet were shipped from the NMHA in Virginia, Reilly says. It informs people that "*Clinical depression is a serious medical illness affecting millions of Americans. Each year more than 11 million people suffer from this illness, which is as common as it is misunderstood. Many people go through life suffering from clinical depression, never understanding that it is a medical illness or that effective treatments are available.... Medical research has produced a variety of effective new medications to treat the illness. The National Institute of Mental Health estimates that 80% of people with clinical depression can now be successfully treated, usually with medication, psychotherapy, or a combination of both... Clinical depression is a treatable illness and doctors know more about it today than ever before. This booklet will explain the symptoms, causes and treatments of clinical depression and where people can receive treatment*



for the *illness*." (Emphases added. Note also that "new medications" get more play than psychotherapy, and that the NIMH is invoked as an authority.)

A recent lead story in Parade magazine represented another triumph for the NMHA depression campaign. "America's Hidden Disease," by Sherry Henry gushingly described how Mildred Reynolds "today looks forward to her 65th birthday with a joy she has never known before. After a psychiatrist prescribed one of the newest antidepressant drugs a year ago, she was at last free of depression. Now she works with the National Mental Health Association's education campaign..." Eli Lilly was never mentioned in the article, which included a handy nine-symptom questionnaire enabling readers to diagnose their own clinical depression.

"The American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders lists these criteria for the diagnosis of depression. The presence of depressed mood (5) or loss of interest (6) and at least four other symptoms over a two-week period is required for the diagnosis of a major depressive episode.

- 1) Changes in appetite and weight
- 2) Disturbed sleep
- 3) Motor retardation or agitation
- 4) Fatigue and loss of energy
- 5) Depressed or irritable mood
- 6) Loss of interest or pleasure in usual activities.
- 7) Feelings of worthlessness, self-reproach, excessive guilt
- 8) Suicidal thinking or attempts
- 9) Difficulty thinking or concentrating."

Frankly, we think the notion that 18 million Americans have a medical disorder evidenced by a subset of these symptoms is Emperor's New Clothes

stuff. Let us review this list in the light of common sense. (See “Who are you to talk?” in box WHERE.)

Sidebar: Who are you to talk?

Prozac is second in sales only to Glaxo’s ulcer drug Zantac which, like Prozac, is designed to treat the symptoms of a disorder without reference to the cause. Zantac’s manufacturers are also the beneficiaries of erroneous “science.” Many generations of medical students were taught that the acidic environment of the stomach could not permit any bacterial life, and that peptic ulcers were a psychosomatic disorder, treatable only by drugs that block the flow of acid --such as Zantac, and Lilly’s Tagamet. In 1984 a young Australian doctor, Barry Marshal, showed that ulcers were an infectious disease caused by a bacterium called *Helicobacter Pylori* that resides in the small intestine and can be wiped out by antibiotics. There were no loud *Mea culpas* from the medical authorities when their totally wrong line on ulcers was revealed. To the contrary, Marshall has encountered ongoing resistance as he tries to present evidence linking *H. Pylori* infection to stomach cancer.

1. “Changes in appetite and weight” is both contradictory (it includes weight gain and weight loss), vague and all-embracing.

2. “Disturbed sleep” is also contradictory --it includes sleeping too much and sleeping too little-- and vague. The Lilly-funded NMHA pamphlet “Answers to your Questions about Clinical Depression” phrases it thus, “Changes in sleeping pattern.” The federal government’s *Clinical Practice Guideline*, written for healthcare providers, words it “Insomnia/ hypersomnia.” In any event, it is a fairly common symptom of aging.

3. "Motor retardation or agitation." "Restlessness or decreased activity," is how the NMHA pamphlet puts it. Either way it's contradictory, vague and all-embracing.

4. "Fatigue and loss of energy." Contradictory. Fatigue results from overwork and/or lack of sleep. Loss of energy is usually the result of a sedentary lifestyle --which most Americans are forced into by the nature of our work, which is "increasingly remote from physical effort," as radical psychoanalyst Joel Kovel points out, "and more and more a matter of supervising technical processes, watching over the sales, distribution and wasting of commodities, and dealing with human interaction itself."

5. "Depressed or irritable mood." To say that feeling depressed is a defining symptom of clinical depression is a syllogism. And even when the external causes of a patient's "depressed or irritable mood" may be very obvious --loss of a job, a relationship on the rocks, kid trouble, etc.-- the resultant diagnosis, "Clinical Depression," will imply that his or her internal psychological condition was causal. Is there such a thing as a double syllogism?

The DSM-IV -- 'The Bible of the American Psychiatric Association,' as it is so often called, states, "The mood in a Major Depressive Episode is often described by the person as depressed, sad, hopeless, discouraged, or 'down in the dumps' (Criterion A1). In some cases, sadness may be denied at first, but may subsequently be elicited by interview (e.g., by pointing out that the individual looks as if he or she is about to cry)." Does that sound scientific?

Frederick Goodwin, formerly the government's top psychiatrist, said in an interview for this story that an episode of major depression is one of "relentless duration --week after week. You can have a grief reaction that can be every bit as intense as a clinical depression. But it doesn't last. Depressions stick around..." A key to defining depression, he reiterated, was "duration, measured in weeks and months rather than days." Two

*weeks?* Is that 'relentless duration? We don't know about you and your friends and patients in Washington D.C., doctor, but in our circles grief reactions last for years, decades, lifetimes, generations!

6. "Loss of interest or pleasure in usual activities." This can be associated with physical aging and/or deteriorating quality of life. For example, you may no longer take pleasure in swimming at a beach after you've noticed human shit bobbing in the waves. You may not find driving as pleasurable now that there's bumper-to-bumper traffic and the commute that once took 25 minutes takes at least an hour.

7. "Feelings of worthlessness, self-reproach, excessive guilt." The NMHA pamphlet puts it, "Feeling guilty, hopeless, or worthless." The Clinical Practice Guideline says "Feelings of worthlessness (guilt)" --as if the two were synonymous. However this symptom is worded, it's obviously the lot of millions in an economy characterized by "downsizing." Men who can't afford to provide for their families tend to feel worthless; women who leave their infants in day care tend to agonize over the decision and feel self-reproach; people living from pay-check to pay-check tend to feel hopeless about the future.

8. "Suicidal attempts or thinking." A suicide attempt is obviously a sign of major depression; but "suicidal thinking" is a vague term. Does it apply to everyone to whom the thought of ending it all has ever occurred? "Suicidal ideation," is how the DSM-IV puts it. The NMHA pamphlet translates this to, "Thoughts of suicide or death." Who hasn't had those now and then?

9. "Difficulty thinking or concentrating." The DSM-IV adds, "--or making decisions." Another function of the speed and stress of corporate-run society. Bob Dylan wrote a great song on the subject, *No Time to Think*, that not-so-coincidentally contains the line, "I've seen all these decoys through a set of deep turquoise eyes and I feel so *depressed*."

Convincing employers that a workforce on antidepressant medication is in their interests has been one of Lilly's major goals. In December, 1993, Tipper Gore and Fred Goodwin, then head of NIMH, held a press conference to publicize a study in the November *Journal of Clinical Psychiatry* calculating the annual "economic burden" of mental depression to be \$43.7 billion. "This study provides new evidence that employers are carrying the major burden of the costs of depression," Gore said. "Businesses have much to gain from recognizing clinical depression in the workplace and facilitating treatment for depressed workers." The study by Paul E. Greenberg and three co-authors [it has come to be known as "the MIT study" because two of the authors are at MIT's Sloan Business School] was based on data from 1990. The cost of absenteeism was calculated to be \$11.7 billion. The cost of "earnings lost to suicide" was put at \$7.5 billion (which includes how much the dead lose in potential earnings). The costliest factor, according to Greenberg *et al*, is dawdling --"the effects of poor concentration, indecisiveness, lack of self-confidence." The bottom line is, U.S. employers lose \$3,000 per depressed worker. "Given the current rate of recognition and treatment of depression," the study concludes, "a representative firm with 10,000 employees could expect to bear depression-related costs from its workforce of approximately \$1.8 million annually."

Only the *Wall St. Journal*, among the major dailies covering the story, mentioned that the Greenberg study had been sponsored by Eli Lilly and that the press conference plugging it nationally had also been arranged and paid for by Lilly. In a Jan. 3 editorial the *Journal* challenged Gore's inference that coverage of mental illness would be cost-effective and in the interests of both the government and employers. She replied in a letter (Jan. 10 '94) that "nearly all medium and

large firms include mental illness and substance abuse coverage in their health insurance plans and see it as essential.... You belittle decades of progress in psychopharmacology in your reference to the 'Prozac craze...' The fact is, psychiatric medications, including antidepressants such as Prozac, have been developed for the treatment of diagnosable mental illnesses --not the casual pursuit of 'happiness.'"

The NIMH also lobbied for coverage of mental disorders, as did the NMHA and The Washington Business Group, a nonprofit health policy organization whose goal, according to WBGH director Veronica Goff, is to convince major employers that depression is "a disabling, but treatable illness," and that employee benefit plans should be structured to provide maximum benefits for mental disorders. Among the most "progressive" companies in this regard, according to Goff, are Federal Express, Digital, Honeywell and First National Bank of Chicago (whose chairman, Daniel Conte, took part in the Gore-Goodwin press conference praising the cost-of-depression study).

Lilly-funded research enters the national consciousness as "scientific fact" when it gets cited, without attribution or question, in the mass media. Consider this segment from Tom Brokaw's Jan. 3, 1994 nightly news show:

"Narrator (*Robert Bazell, over a shot of people walking on street*): There are 17 million others like Lissa in this country who suffer each year from clinical depression --depression that is constant and unrelenting. According to Dr. Frederick Goodwin, head of the National Institute of Mental Health, fewer than half those people will seek treatment.

Goodwin: By and large there is still that kind of stiff upper lip, you should get over it by yourself, take responsibility for your behavior...

Narrator: It is the fear of being labeled as mentally ill that prevents most people from seeking help. And the illness itself keeps people isolated and feeling worthless. Americans spend \$12.5 billion a year to treat depression. But that is far less than the \$43 billion a year depression costs this country in productivity...  
(*Shot of pills*) The advent of effective drugs such as lithium, Prozac and Zoloft, according to Dr. Goodwin, has helped reduce the stigma of depression...

Goodwin: There are now a large number of people for whom depression is simply a history of something that happened to them. People like Mike Wallace, Dick Cavett, Ted Turner, Bill Styron have gone public with their history of severe depression and the fact that a medication has reversed it means that it can't simply be your personality or a human weakness or how your mother raised you.  
(*Shots of pills*)

Narrator: Some experts worry that drugs are sometimes prescribed for people who might just need some counseling. (Shot of Lissa with plants) Still, medication has worked for Lissa. It has helped her gain stability and rebuild her life.

Lissa: On most days I can't wait to wake up in the morning because I'm excited about another day. I have a lot of hope for the future.

Narrator: Psychiatrists agree that millions of other Americans could escape the enslavement of their depression if they would only seek help. Robert Bazell, NBC News, New York."

Frederick Goodwin resigned from his position as head of the NIMH in May, 1994, and is now the director of the Center on Neuroscience, Behavior and Society at George Washington University, where his research is underwritten by Eli Lilly and the National Institutes of Health, among others. In our April 20 interview he described the focus of his current work as "the treatment-resistant patient" --precisely the market research the drug companies are most interested

in. If the marketing of clinical depression continues according to pattern, Goodwin's current work will be cited in the near future to justify government-sanctioned programs to weaken the average American's intuitive sense that it's best to work through emotional problems without ingesting foreign substances.

"The big picture is this," said Goodwin. "About half the people with major depression --the most unambiguous disorder in psychiatry-- seek treatment. In medicine in general it's about 80%. About 80% of people with arthritis will go try to have something done about. So there is still a big lag between people acknowledging that depression is something more than human weakness... What we're working on are surveys relating to the public perception of mental illness. How do people feel about treatment? How do they feel about depression --a weakness or an illness? Do people feel that because it's an illness they don't have any responsibility to do anything about it? That kind of thing."

"Is clinical depression unambiguous?" we inquired. Goodwin replied, "The interrelated reliability --clinicians being able to diagnosis depression independently-- is higher than most medical diagnoses. It's higher than the ability to read a mammogram and tell a woman whether she has breast cancer. It's higher than the ability to read an EKG and tell somebody whether they've had a heart attack." In other words, it's easier to score a questionnaire than it is to interpret a mammogram or an EKG.

The causes of the symptoms of "Clinical Depression," are, by and large, social and political forces. Undoubtedly there are changes in brain chemistry that result when homo sapiens are deprived of stable, extended families. As Goodwin aptly summarized the literature in our interview, "We know that psychological events can have enormous impact on brain function, including even some permanent changes in brain function." He also acknowledged, "There is a general socioeconomic correlation, with depression rates being higher in lower



socioeconomic status.” This, too, would imply that “brain chemistry” should be regarded as effect rather than cause.

Why, then, does the federal government’s top psychiatrist (ex) advocate adjusting the brain chemistry in millions of individuals while disregarding the cause of the maladjustment? Sound medical practice calls for prevention, if possible, or a cure if possible. Anti-depressant medication is proffered instead. Anti-depressant medication is liberalism in a bottle. It’s legal, it’s corporate-produced, and it can mask the pain that might lead to serious efforts at change --within individuals and, when administered to millions, politically. To take a political phenomenon and define it as medical is bad politics and bad medicine; it is a form of opportunism.

The supposed epidemic of a medical disorder called clinical depression is based on extensive peer-reviewed “research,” the validity of which rests entirely on the questionnaire and the symptoms discussed above. We asked Goodwin why the Clinical Practice guidelines list “female gender” as a risk factor for major depression. He explained: “There’s two sets of reasons: biological and psychosocial-environmental. The reason we know there has to be a cultural and environmental component to it is that the difference used to be 3 to 1. And as women have gained more independence, more economic security, more equity with males in the last generation, it’s settled down to 2 to 1, but it’s sort of leveled off there.” Suspiciously close to the ratio of male to female earning power, he might have added.

Goodwin’s other main research project involves a critique of “pennywise, pound-foolish” managed care practices. One of the goals --the one used as an example-- is to convince companies to include Prozac in their formularies, even though it’s significantly more expensive than the older antidepressants such as

imipramine. (A drug patent applies for 17 years, after which time other companies can manufacture generic versions and the price goes way down. Prozac, which costs pennies per pill to produce, sells for more than \$2 per pill. Imipramine generally sells for 6 cents. Both have effectiveness rates, according to the FDA, of about 70%.) Goodwin has just finished “a study in a series of HMOs where we found that the more restrictive their formularies --that is, the more they restricted doctors’ choice of different medications-- the higher their costs. So in the name of saving money, they were actually spending more and not even realizing it. Because they don’t look at their whole budget --each department tries to save money on its own.

“The problem is, most of these formularies are focused around generic drugs. There’s a huge misunderstanding about what ‘generic drugs’ mean. First of all, it means old technology --17 years old or older-- in areas where there’s been a lot of progress in the last 17 years, such as depression and hypertension, where doctors have many more subtypes, many more targeted drugs, where one drug works for one kind of patient and not for another... Every antidepressant has an efficacy of about 40% on top of the placebo response. But the 40% that respond to treatment A could be totally different than the 40% that respond to treatment B. And there’s an incredible resistance to understanding what seems to me a simple, logical point. You hear [managed care decision-makers] saying, ‘Well, Prozac has not been shown to be any better than imipramine, it’s so much cheaper, it’s generic.’ But there are numerous studies in the literature showing that patients who don’t respond to imipramine respond to Prozac.

“One of the problems is, the HMOs are analyzing their data from their entire enrollee population. So they can show, because they have nine healthy patients for every sick one, they can save some money by buying generics. But the stupidity is, they’re not looking at the relevant patients. They should be saying,

'All right, maybe for colds, if we allow our doctors to give medicines at all, they ought to be using generic antibiotics... But for illnesses that are real, ongoing chronic recurrent illnesses, where you have to maintain treatment, the doctors should be able to use the latest thing that's there. The problem is for a company, the people who budget out the health costs are trying to keep them down. Somebody else is looking at productivity figures and not realizing that the buck they save in the health arena may be costing them bucks on the productivity side.'

Studying the attitude of HMO executives towards clinical depression --and generating data to convince them to buy Prozac despite its price-- is, from Eli Lilly's point of view, the most significant possible research in all of psychiatry in 1995. Managed care is supposed to lower costs by efficiencies of scale and market pressures. (Instead of an individual hospital placing an order with a drug company sales rep, the hospitals link up and seek the best possible deals on drugs, equipment, etc.) The companies representing the hospitals are said to provide cost containment services; the ones specializing in drug buys are called "prescription benefit managers." In July '94 Lilly purchased McKesson's drug distribution unit, PCS Health Systems, for \$4 billion. Newspaper coverage of the purchase focused on whether Lilly had paid too much for a company with annual earnings of "just" \$30 million. But what are the implications for the consumers who last year spent more than \$60 billion on prescription drugs?

The National Association of Chain Drug Stores --a group representing 30,000 pharmacists whose members include Thrifty, Payless, Long's, etc.-- has advised the Federal Trade Commission that its consent order in the purchase of PCS by Lilly will put consumers at risk. John Coster, NACSD'S Research Director, says, "There exist inherent conflicts of interest when a company that manufactures and

sells drugs also owns a company that is supposed to be managing individuals' therapy." The chain drugstores are affected dramatically, Coster explains, because "Pharmacy benefits management companies dictate pricing and reimbursement terms for products we dispense, and PCS controls 35 to 40 percent of the outpatient prescription-drug third-party market."

We asked Coster what happens when a patient shows up at a drug store with a prescription for a rival antidepressant --say American Home Products' Effexor. The pharmacist, he explained, "calls the physician and says 'Under this plan, Effexor isn't covered but Prozac is.' *That's the whole idea of the pharmacy benefit management company...* The physician then either authorizes it or the patient has to pay a higher co-payment or a fee for a majority of the prescription. So it's a very strong incentive to use the drug that's on the formulary. "

Lilly's acquisition of PCS, Coster adds, has enabled the drug company "to engage in direct marketing and advertising, where before it was indirect --they went to the physicians and tried to get them to prescribe it. Now they're down at the level of the prescription, where it's actually being dispensed."

Although the antidepressant manufacturers are competing for market share, they all are following Lilly's lead in marketing the concept of clinical depression. In May, 1993, readers of a prestigious scientific journal called *Postgraduate Medicine* received a special edition entitled "Depression in America --Underdiagnosed and Underreported," paid for entirely by Smithkline Beecham but bearing the name of the journal. Its message to doctors was that they should be treating more of their patients with antidepressant medication. This issue of *Postgraduate Medicine* was brought to our attention by Peter Lurie, MD, a San Francisco epidemiologist who said he hadn't noticed who funded it until he came to an article describing a very successful trial of peroxetine (Paxil).

"The drug companies manipulate the literature," says Lurie, "by means of these supplements and inserts that they pay for, put together and send out to physicians who often don't know the difference between the regular issue of the journal and the supplement, and who don't look to see that it's been paid for entirely by the drug company."

SmithKline Beecham also acquired a pharmacy benefits management company in 1994--Diversified Pharmaceuticals, for which it paid \$23 billion.

Pfizer, the manufacturers of Zoloft, are marketing clinical depression with an ad campaign bringing a do-it-yourself screening to millions. In 1994 readers of *The New Yorker* and other magazines were exposed to several full page "Pfizer Healthcare" ads providing the nine symptoms of depression in handy check-list form. Pfizer also sponsors the work of a very influential psychiatrist named Robert Spitzer --editor-in-chief of the DSM-III-- who has developed a technique whereby primary care physicians can double the rate at which they diagnose psychiatric disorders.

Spitzer's Prime-MD method, presented in arcane jargon in the Jan. 4, 1995 *Journal of the American Medical Association*, involves two questionnaires. The first, a "patient questionnaire (PQ)" consists of 26 items to which the patient answers yes/no before seeing the doctor. Alerted by a pattern of positive responses, the doc then uses the "clinician evaluation guide (CEQ)" to ask follow-up questions. This method enables the doctor to diagnose, in eight minutes, anxiety, depression, alcoholism/substance abuse, eating disorders and/or somatoform disorders ("multiple physical symptoms with no medical explanation.") Time is of the essence, the study reiterates, because the average primary care visit takes 15 minutes.

The number of patients diagnosed as suffering from anxiety or depression jumps *from 20% to 40-50%* when unexplained physical symptoms are taken into account as per the Prime-MD flowchart. In other words, *millions* of new customers for psychiatric medication will be generated if the Prime-MD approach is widely adopted. Pfizer not only funded the Prime-MD study, the company has sponsored symposiums at which some 6,000 primary-care doctors have been trained in the Prime-MD approach. (One NIH researcher describes conference sponsorship as “drug companies putting up the money to bring docs to Switzerland for a week --or some other nice place-- ostensibly for a conference, but also as a way of basically making their lives nicer through tennis and golf and free plane tickets and lots of liquor.”) As the “gatekeepers” in various healthcare reform schemes, primary care providers will play an increasingly important role, i.e., write a larger percentage of the scripts.

Another major study designed to increase the rate at which depression is diagnosed and antidepressants prescribed was published in JAMA January Jan. 4, 1995 —“How Can Care for Depression Become More Cost-effective?” by Roland Sturm, PhD, and Kenneth B. Wells, MD, MPH. The authors conducted a three-city study and calculated the cost of a typical primary-care-doctor’s treatment of a depressed patient (\$1,060); the cost of a psychiatrist’s treatment (\$3,760); and their relative success rates (as measured in the ability of the patient to work). They concluded that if primary care doctors would prescribe antidepressants and/or recommend psychotherapy at a higher rate, they would enable their patients to overcome more “functional limitations” --a cost-effective trade-off, resulting in increased income for the patients, mental health professionals, and antidepressant manufacturers. Sturm and Wells’s bottom line recommendation was that an effort should be made to encourage doctors to heed

the federal government's Clinical Practice Guideline for the treatment of depression.

### **Discrediting the Critics**

Soon after the approval of Prozac by the FDA, a small percentage of users started to report serious side effects, including bizarre, violent thoughts and outbursts. Violent acts attributed to Prozac were often said to be out of character—they occurred "out of the blue," impulsively, without notes or foreshadowing—and a shocking number involved people killing their own children or parents. As could be expected, the negative publicity had an impact on the number of Prozac prescriptions being written. Whereas U.S. sales had more than doubled between 1989 and '90 --\$320 million to \$650 million-- they flattened in 1991 to \$690 million. Had it not been for a price increase that year, they actually would have fallen off. Eli Lilly, which was getting 14% of its \$5.19 billion in total revenue from Prozac sales, saw its stock drop by 20 percent between June and August 1990 --a \$5.8 billion decrease in overall value. Clearly the corporate strategists had to defend their product.

According to a Wall St. Journal story, members of Lilly's 1,700 person sales force were instructed to advise the doctors they called on that criticism of Prozac stemmed from the Scientologists. The drug company also mailed a "Dear Doctor" letter to every physician in the country, denouncing the Scientologists "campaign" and offering to underwrite any legal costs they might incur as a result of prescribing Prozac properly (i.e., for severe depression). The whole situation was neatly summarized in the *Journal* headline and subheads: "Anti-Depression Drug of Eli Lilly Loses Sales After Attack by Sect. Scientologists Claim Prozac Induces Murder or Suicide, Though Evidence is Scant. Campaign Dismays Doctors." The

story quotes Eli Lilly's medical director, Leigh Thompson, stating, "It's a demoralizing revelation to watch 20 years of solid research by doctors and scientists shouted down in 20-second sound bites by Scientologists and lawyers." [Note the similarity of this to Tipper Gore's "You belittle decades of progress in psychopharmacology in your reference to the 'Prozac craze'... Almost as if they came from the same word processor.]

The FDA scheduled a special hearing in September 1990 at which its Psychotropic Drugs Advisory Committee --nine specialists appointed by the FDA to three-year terms-- voted not to require a more prominent warning on the Prozac label. Five of the committee members had apparent conflicts of interest. David Dunner acknowledged that his current research was supported by grants totaling \$500,000 from four antidepressant makers, and that he had \$200,000 worth of grants from Eli Lilly pending. (At the time Dunner was also a member of the six-person "Mood Disorders Work Group" drafting the definition of clinical depression for the forthcoming edition of the *Diagnostic and Statistic Manual of Mental Disorders*.)

The net effect of the Psychotropic Drug Advisory Committee hearing was to restore Prozac's reputation for safety. Sales that had leveled off soared again after the FDA's 1991 endorsement of Prozac. By 1992 Prozac sales had risen to \$785 million in the US and \$910 million worldwide. They continue to soar. Given such success --and competition from Zoloft and Paxil-- it is evident why Lilly is reluctant to put a strong warning about suicidal ideation on the Prozac label.

One of the first "Prozac cases" to capture national attention involved Joseph Wesbecker, a Louisville, Kentucky press operator who, on Sept. 14, 1989, took an AK-47 into Standard Gravure, the printing plant where he'd been employed, and



killed eight co-workers and injured a dozen others before committing suicide. Wesbecker had been prescribed Prozac five weeks before, and a coroner's jury found that it "may have been a contributory factor" in his rampage. Some 24 parties --victims who survived the shooting, relatives of those who died, and members of Wesbecker's own family-- subsequently sued Eli Lilly, charging that the drug company "knew or should have known that Prozac was unsafe for use by the general public for the treatment of depression" and that the company "knew or should have known that users of the drug can experience intense agitation and preoccupation with suicide, and can harm themselves or others."

When the case came to trial in September, 1994, Lilly's head of corporate communications, Ed West, held a press conference which the Associated Press recounted thus: "West and Dr. Frederick Goodwin, who recently stepped down as director of the National Institute of Mental Health, say the anti-Prozac litigation was spawned by the Church of Scientology, which for decades has campaigned against psychiatrists and the drugs they prescribe.

"West said Scientology kicked off its national effort to discredit Prozac at the 1989 coroner's inquest into the deaths of Westbecker and his victims. The head of a California-based group affiliated with Scientology testified at the inquest."

The Wesbecker trial ended in early December '94 with the jury voting 9-3 not to hold Eli Lilly & Co. in any way responsible the murderous rampage. (It emerged at the trial that Wesbecker had been hospitalized for emotional problems on several occasions before he had ever taken Prozac, and harbored a fierce resentment towards his employers.) Lilly made the most of the verdict p.r.-wise. "We have proven in a court of law," stated CEO Randal Tobias, "just as we have to more than 70 scientific and regulatory bodies all over the world, that Prozac is safe and effective."

But there has been an unusual, unpublicized coda in the Wesbecker case. On April 19 --the day that the federal building was bombed in Oklahoma City and not much else made the news-- the judge who had presided, John Potter, filed a motion to change his own order from "the dismissal was based solely upon a jury verdict" to "*settled.*"

Potter's motion explained his revised decision. "Much of the evidence in the trial centered around whether Lilly had adequately tested the drug and fairly reported the test results and other information to the FDA which ultimately approved the drug. A significant portion of Lilly's evidence emphasized that the FDA had approved the drug after reviewing the extensive and complete data supplied by Lilly. A major thrust of the plaintiffs counter attack was that the data was not complete. Of particular significance in this regard was evidence designed to prove that Lilly had not accurately reported adverse comments and evaluation upon the drug's performance made by the BGA (the German counterpart to the FDA).

"At the commencement of the trial and over the plaintiffs' objection, the Court ruled that evidence of Lilly's alleged misdeeds with other drugs would not be introduced.

"As the trial progressed, Lilly introduced evidence of its reputation for maintaining a good system for collecting and reporting adverse data on its products.

"Representative testimony put on by Lilly was to the effect that 'Lilly had the most sensitive and elegant system of collecting adverse events...' 'The FDA has repeatedly said... Lilly [has] the best system for collecting and analyzing and reporting adverse events...'

"On several occasions throughout the trial the plaintiffs moved the court to reconsider its prior ruling and admit evidence of Lilly's conduct in regard to

other drugs. As the case progressed and as more self-serving laudatory evidence came in, the Court became more inclined to reconsider whether Lilly had 'opened the door' to such evidence.

"On December 1, 1994, the plaintiffs filed [motion] to introduce evidence that in August, 1982, the House Committee on Government Operations conducted an investigation into the FDA's and Lilly's handling of the drug Orflex. A house report was issued in November 1983, which concluded, among other things, that 'Lilly did not report serious adverse reactions associated with use of Orflex prior to the approval of the drug.' the referenced adverse reactions included over 20 deaths occurring in foreign countries. The report was equally critical of the FDA.

"In addition, the plaintiffs sought to introduce evidence that in June, 1985, Lilly, as a corporation, pled guilty to a criminal indictment of 25 counts of failing to report adverse reactions to Orflex to the FDA, and shortly thereafter Dr. Ian Shedden, the head of Lilly's research, also pled to 15 counts.

"On December 5, 1994, Lilly filed a reply memorandum. These motions were argued in chambers on December 6, 1994, and on December 7, 1994, the Court ruled in the plaintiffs favor. On December 8, 1994, after a day's delay at the parties' mutual request and without explanation, the plaintiffs elected not to introduce the evidence they had fought so hard to get admitted, and closed their case."

Even if it not been settled, Wesbecker --although it was first to come to trial, and though Lilly's publicists had tried to position it as such-- "was not a true landmark case," according to Los Angeles attorney Skip Murgatroyd. "Most of the other Prozac cases currently in the pipeline involve people who went to the doctor for depression stemming from marital problems, financial problems,

girlfriend problems, who were not suicidal. It is only a matter of time until there are successful plaintiffs."

Murgatroyd thinks his clients Susan and Bill Forsyth will be successful. Susan is a 30-year-old woman who runs a property management business in Malibu and has set up a "Prozac Survivors Support Group" phone line. Her brother Bill, who skips a whale-watching boat on Maui, has set up a Prozac Survivors phone line there. William Forsyth Sr. --Susan and Bill's father-- was a successful businessman with no history of depression. When he retired in the late '80s, he and his wife of 37 years, June, moved to Maui to be nearer their grandchildren. Forsyth was put on Xanax, a sedative, after telling a doctor he was having trouble adjusting to retirement. "On the Xanax he became depressed and went to see a psychiatrist for the first time," recounts Bill. After poor results on a tricyclic called Pamelor, the doctor switched him to Prozac. "It seemed to be good for him at first. But on the second day he seemed to be really up, in a really fast, speed-like state. My wife and I both said it was a little odd, we knew it was chemically induced and it kind of scared us." After three days on Prozac William Forsyth, Sr. begged to be taken to a hospital, saying he didn't feel like himself and didn't want "to do something strange." His doctor recommended against hospitalization but the elder Forsyth insisted. The hospital released him seven days later, after convincing his wife that he belonged at home. The next morning, March 4, 1993, William Forsyth stabbed his wife, and then himself, to death.

Susan and Bill Forsyth filed suit March 3 in Federal Court in Hawaii against Eli Lilly and the FDA. According to the suit, both Lilly and the FDA negligently ignored sound principles of scientific research in the development and oversight of Prozac, resulting in a dangerous drug being falsely presented to consumers as "safe and effective."

The Forsyths' case against Lilly will join more than 200 other civil cases now working their way towards trial in various courts. Some 74 of these have been transferred to federal court at Lilly's request and consolidated so that the pretrial proceedings are being conducted by the US District Court for the Southern District of Indiana in Indianapolis.

The organization in which the Forsyth are active --the Prozac Survivors Support Group-- consists of 26 regional directors who field phone calls from people with questions about Prozac (or Zoloft and Paxil). National Director Guy McConnell gets about 20 calls a week at his home in Fresno. He logs his conversation summaries into spiral notebooks. The adverse reactions he hears about most commonly are agitation and insomnia. "Also very common is sexual dysfunction," he reports. "Another would be what people describe as 'my character changed.' 'I've got a new personality now. I don't like it.' 'My children are saying I'm acting bizarre.' 'I have these uncontrollable obsessions.'"

McConnell, a 47-year-old Vietnam vet, has never taken Prozac. Like the about half the people in the Survivors group, including the Forsyths, he got involved in response to a loved one's ordeal. In 1990 his fiance, a nurse named Gail Ransom, soon after being prescribed Prozac, strangled her mother. She spent HOW MANY years in WHAT INSTITUTION. Their relationship did not survive --but McConnell has continued to devote himself full time to building what he describes as a "seat of the pants support group."

McConnell says he sometimes worries that all the media attention and court cases stemming from various tragic episodes add up to "a misdirection play that serves Lilly's interests --since most Prozac users can read about the bizarre flip-outs and say, 'Well thank goodness, Prozac didn't cause me any problems besides a little insomnia... But the truth,'" he adds, "is that nobody knows the longterm effects of Prozac. If, in 20 years, there's a pattern linking Prozac use to

early onset of Alzheimer's, or leukemia, Ed West's successor can shake his head and say truthfully, 'We had no idea...' They have no idea. And it's not in anyone's short-term interest to find out, either. They want to stall until their patent runs out. Then, let the insurance companies deal with it, if and when."

If and when may come before the Prozac patent expires in 2003. There is very disturbing research linking Prozac use to tumor growth. LJ Brandes and his group at the Manitoba Cancer Treatment and Research Foundation in Winnipeg conducted a study in which rats with cancer were given Prozac or Elavil in doses equivalent to what people take (not the megadoses customarily employed in drug research involving animals). A few weeks later the rats were sacrificed and their tumors were found to be two to three times heavier than tumors in a drug-free control group. The investigators repeated the procedure with five antihistamines and observed that three of them sharply accelerated tumor growth. They concluded that antihistamines and antidepressants may bind to the same enzyme, displacing histamine and disrupting normal cell growth. [Antihistamines and antidepressants --tricyclics as well as SSRIs-- are similar in terms of molecular structure. It will be recalled that the Lilly chemists who "invented" Prozac were modifying antihistamines.]

Lilly has published its own study in the Dec. 15, 1992 issue of *Cancer Research* (based on the traditional high-dose, lifetime-span technique) showing that Prozac neither caused nor promoted cancer. Lilly concluded that Brandes's tests "have not been established as having utility in human cancer risk assessment for regulatory purposes." Other evidence is coming in, however. Susan Wright of the Palo Alto Institute of Molecular Medicine has studied the action of suspected tumor promoters, including Prozac and Elavil, on human cancer tissue in vitro and discerned that the drugs interfere with the normal process of cell death.

Anybody taking SSRI antidepressants --or contemplating taking them, or with a loved one taking them-- should bear in mind that the long-term adverse effects are simply not known. As for short-term adverse reactions, corporate science is so corrupt that anecdotal evidence is now more reliable than many clinical trials. For example, our anecdotal evidence is that sexual dysfunction is experienced by 90% of all Prozac users, and the other 10 percent may be lying. (SmithKline markets Paxil as a sexual aide for men prone to premature ejaculation, whatever that is.)

It is not our intention to advise anyone to get off Prozac. Our thesis is that the epidemic of "clinical depression" is part and parcel of a marketing strategy designed to sell legal, corporate-produced anti-depressant medication. We think the very concept of this "illness" affecting 17.6 million individuals is inherently bogus. People exist --thrive or suffer-- in families and other groups. Individual depression is almost always rooted in some form of loneliness and/or insecurity. To oversimplify (but not by much): happiness is a function of having friends, family and meaningful work. By taking a pill that leaves more serotonin in their synapses, some individuals may achieve a substitute "happiness" without changing the conditions or even the circumstances that made them miserable. Loneliness and economic insecurity can be eliminated only by political means. If we had a system that didn't encourage so much moving around, millions of people wouldn't feel isolated. If the economic goal was to produce life's necessities in a sustainable way, millions of people wouldn't be impoverished and hopeless.

*"You got unrighteous doctors  
dealing drugs that'll never cure your ills"*

--Bob Dylan, When You Gonna Wake Up?

By misdiagnosing our mass misery as 17.6 million discrete cases of an "illness," the unrighteous doctors prevent us from seeing its cause and maybe doing something about it. The absolute best they offer is a quick fix for some.

Is there hope? We are greatly encouraged by the students at George Washington H.S. in Bethesda who saw right through the corporate propaganda on National Depression Screening Day. "They were telling people to believe that if you ever thought, 'Oh I could just die,' then you had a problem," said Evi Georgiou, a ninth-grader... "The message was, "If you feel sad, drop a Prozac," said Maria Virker, an 11th grader... "The whole thing was about selling a drug," said Saul Pineda, a ninth-grader. "It was kind of hypocritical when you think about all the other 'Just Say No' to drug talks that we hear."

The kids are very hip.

#### Biographical note:

Alexander Cockburn has written about Eli Lilly's marketing efforts for *The Nation*. Fred Gardner is the managing editor of *Synapse*, the weekly newspaper at the University of California San Francisco Medical Center. He is a former editor of *Scientific American*.



There is an almost seamless pattern to the literature generated by the drug companies, the nonprofit foundations carrying their message, and the government itself. Even the graphics seem to have been inspired by Eli Lilly.

GRAPHIC:

PROZAC LOGO, NMHA LOGO, NIMH DEPRESSION LOGO

#### Oprah sidebar

George Mair's recent biography of Oprah Winfrey, *The Real Story*, describes how Burson Marteller, the p.r. firm representing Eli Lilly, transformed one Oprah show into "a free infomercial for their product by packing the audience with guests flown into Chicago by the firm to appear on the show so they could describe their dreadful experiences and how their lives were saved by the medicine made by the manufacturer who was secretly underwriting their appearance." The stated subject of the show was not "Prozac" but "Depression."

"What makes this incident even more significant," according to Mair, is that "(a) it happens all the time, (2) it was done with the full cooperation of the show's producer, and (3) Oprah didn't tell her audience the truth about Sandra and the other shells who appeared on her program under the guise of random audience members."

### OCD Sidebar

In July, 1994, after winning FDA approval for Prozac as a treatment for obsessive-compulsive disorder, Eli Lilly sent out an oddly worded “Dear Healthcare Professional” letter:

“Eli Lilly and Company is pleased to announce the addition of obsessive-compulsive disorder (OCD) as an indication for Prozac (fluoxetine hydrochloride). Prozac has over six years of US experience, worldwide experience in over 10 million patients, and availability in more than 60 countries. Prozac is the first US drug indicated for both depression and obsessive-compulsive disorder...”

The letter calls OCD “the fourth most common psychiatric disorder.” A market of 5 million prospective customers is envisioned.

Although Lilly anticipated \$30 million in additional sales thanks to the additional “indication” for which it can be prescribed, the IMS America data show no growth in the use of Prozac for treatment of OCD, i.e., the entire 1994 sales rise stems from its use as an antidepressant. (Once a drug has been approved by the FDA, doctors can prescribe it at their discretion for any disorder.) Nor was there any increase in the use of Prozac for bulimia, an indication for which Lilly is seeking FDA approval.

Brave New World sidebar TK

Turf war between the psychologists and the psychiatrists sidebar TK

DIDN'T MAKE THE CUT: Another reason the strategy of marketing clinical depression (and by the way, we have the cure) is brilliant: federal law prohibits the direct advertisement of prescription drugs without acknowledgement of their adverse effects. The adverse effects of Prozac include insomnia, agitation, sexual dysfunction (loss of desire and ability to get a hard-on in men, inability to come in women. Our anecdotal evidence suggests its prevalence rate is 90%. Studies in peer review journals are now acknowledging 40%. The Prozac package insert refers to GET EXACT NUMBERS

The various pop versions of the test for depression that millions of Americans have been exposed to in the media conform to the criteria set forth in the *Diagnostic and Statistic Manual*, the so-called "bible" of the American Psychiatric Association. "The essential feature of a Major Depressive Episode," according to the DSM-IV, "is a period of at least 2 weeks during which there is either depressed mood or the loss of interest or pleasure in nearly all activities. In children and adolescents, the mood may be irritable rather than sad. The individual must also experience at least four additional symptoms drawn from a list that includes changes in appetite or weight, sleep, and psychomotor activity; decreased energy; feelings of worthlessness or guilt; difficulty thinking, concentrating, or making decisions; or recurrent thoughts of death or suicidal ideation, plans or attempts... The mood in a Major Depressive Episode is often described by the person as depressed, sad, hopeless, discouraged, or 'down in the dumps' (Criterion A1). In some cases, sadness may be denied at first, but may subsequently be elicited by interview (e.g., by pointing out that the individual looks as if he or she is about to cry)."

