

# Leading the Charge Against Prozac

Lawyer Leonard Finz  
Is Up Against Eli Lilly,  
And the Verdict Is Still Out

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NEW YORK

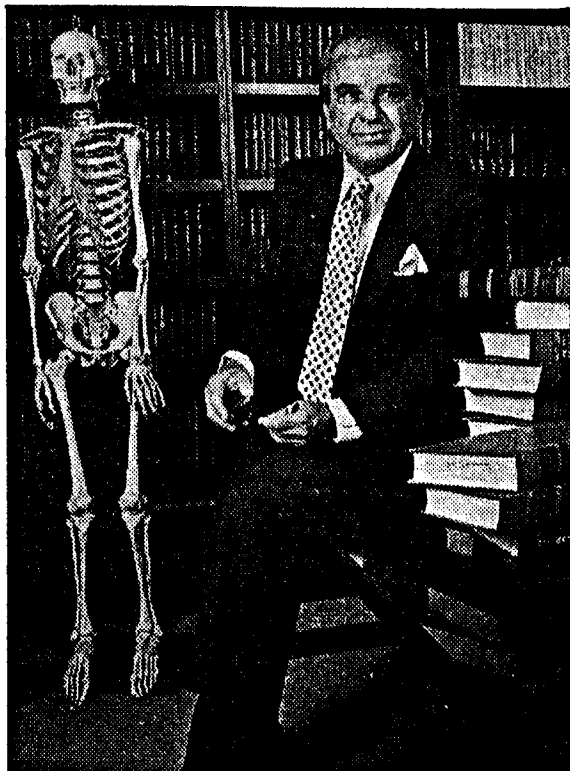
**B**y now there are so many cases—each encompassing so many details of symptoms and injuries, medical histories, hospital records or coroners' reports—that Leonard Finz's law firm has had to design a new computer database solely to keep track of its Prozac clients. Finz's associate Jerrold Parker, jabbing at the keyboard of his desktop computer, calls up a few examples.

Here's the very first lawsuit, filed a year ago, after which "we became almost a national registry, the clearinghouse for Prozac," Finz likes to say. Rhonda Hala, a secretary in a Long Island public school, sought treatment for depression after a back injury necessitated a series of hospitalizations, Parker says, reading from his computer screen. Her doctor prescribed Prozac, the world's most widely used antidepressant. Hala subsequently slashed her body with razors and scissors and made six suicide attempts. Shortly after her doctor discontinued the drug, "the suicidal thoughts and self-destructive actions went away," Parker says. Compensatory and punitive damages sought: \$150 million.

Here's Robert Ackley of Johnstown, N.Y. Forty-one, married, a family man who was prescribed Prozac in 1989 because of depression associated with "job-related stress," the computer discloses. "Within a very short period of time, he went on a circuitous route to a distant bridge in the mountains of Upstate New York, jumped off and killed himself," Parker summarizes. Compensatory and punitive damages sought by Ackley's widow: \$165 million.

There's Janet Lee, a South Carolina homemaker who ran short of an ingredient while she was preparing dinner, sent her husband to the grocery, then hanged herself in their bedroom while he was gone and their two children played in the yard. And musician Del Shannon, the '60s survivor whose new record "Rock On!" will be released posthumously: He shot himself in the head with a .22-caliber rifle in his California home last year.

And Joseph Wesbecker of Louisville. Finz doesn't need to consult the computer to outline this most notorious of the Prozac lawsuits. He and the attorneys for Eli Lilly & Co., Prozac's manufacturer, and their dueling expert witnesses will wrangle long and hard about this tortured 47-year-old man, his long history of psychiatric treatment, the weapons he stockpiled, what his doctor should or shouldn't have done. What is not in contention is that Wesbecker began taking Prozac in August 1989 and on Sept. 14 entered the printing plant where he'd worked before taking a medical



BY CORI WELLS BRAUN FOR THE WASHINGTON POST

Lawyer Leonard Finz, whose firm is handling many cases involving Prozac.

disability leave. He was carrying five guns. He turned an AK-47 assault rifle on his co-workers, shooting 20 and killing eight, and then, using a semiautomatic pistol, killed himself.

Finz and Parker claim that the side effects of Prozac, though it has been used successfully to treat millions of depressed patients, caused these individuals to become violent, self-destructive, suicidal, even homicidal. "Prozac may be safe for the greater percentage of the patient population, but for a small percentage, it is not safe," Finz says.

His firm, specializing in medical malpractice and product liability, has filed about 30 of the estimated 75 civil cases against Eli Lilly and has hundreds more under retainer. Its top-floor office in downtown Manhattan, with river-to-river views and a model skeleton hanging in the deposition room, has become Prozac Central.

Edward West, Lilly's director of corporate communications, refers to the 66-year-old Finz as "my friend Leonard," a sardonic touch. For Lilly insists that its antidepressant is a safe drug that is not responsible for any of these deaths or injuries (or for another 20 that have been blamed on Prozac in criminal cases around the country). It has mounted an unusually aggressive counterattack against "this well-funded and systematic smear campaign and the opportunism of certain product liability attorneys," as West puts it.

In doctors' offices, in the courtroom, in the media, Eli Lilly is proclaiming itself the aggrieved victim of Scientologists and of plaintiffs' lawyers. The Church of

See PROZAC, C2, Col. 1

# The Antidepressant Prozac, at the Center of a Legal Storm

PROZAC, From C1

Scientology, about which more later, denounces psychiatric drugs and psychiatry itself and has made Prozac its latest target. Lilly got a boost earlier this month when the Food and Drug Administration (FDA) announced its rejection of a Scientology-backed petition to ban the drug, a decision applauded by the American Psychiatric Association and the National Mental Health Association.

The paperwork, person-hours and expenses of this unabated high-stakes clash are mounting on both sides nevertheless. It's still in the early stages of discovery, with Finz's associates just beginning to delve through 177 boxes of Lilly's internal documents; the first of the civil suits will probably not come to trial until next year.

Much depends on the disposition of the first handful of cases. A string of early victories for Lilly would likely shut down most Prozac litigation, attorneys in the field say, much as the tobacco industry's formidable court record has discouraged smokers' lawsuits. If Finz and other product liability specialists win major early verdicts, the floodgates could open. Even a mixed record would probably provide enough encouragement to keep some plaintiffs filing and their lawyers busy for years. No wonder the Prozac cases are the object of intense interest.

Attorneys who've seen both Finz and Lilly's attorneys in action predict a bitter battle. They've been adversaries before, during the years of litigation over DES, the synthetic hormone alleged to have caused a form of cancer in women whose mothers took it to prevent miscarriage. Finz has argued a number of DES cases; Lilly, as the drug's largest manufacturer, is among the defendants he's castigated.

"I've always found [Finz] to be a very aggressive and intuitive litigator," says Washington attorney Aaron Levine, chairman of the American Trial Lawyers Association DES Litigation Group. "He's good on his feet; he asks the right questions. He's a hard fighter."

But Lilly's legal forces "are the best defenders I've seen, outside of the Japanese," Levine assesses. "They're smart, they're rich, they're vicious."

## 'The Rules Have Changed'

When Prozac (generic name: fluoxetine hydrochloride) was introduced early in 1988, after wending its way through the FDA's approval process for more than four years, it got a warm reception not only from physicians but from the media. Touted as a significant advance over earlier antidepressants—with an easier-to-establish dosage, fewer side effects and little risk of overdose—the drug was not just news, it was a cover story.

"When it made the cover of Newsweek, I knew there was going to be trouble," says psychiatrist John Zajecka, who directs the treatment research unit at Rush-Presbyterian-St. Luke's Medical Center in Chicago. "It's not a miracle drug. It's an antidepressant that works as well as or better than other antidepressants." Relief from depression, a serious illness very different from everyday "blues," can feel like a miracle to those afflicted, however. Prozac, Lilly says, is effective in 70 to 80 percent of patients suffering from "major depressive disorder." It's also widely used to treat obesity, chronic fatigue syndrome and



John McGoldrick, one of the outside counsels representing Eli Lilly & Co., the manufacturer of Prozac.

BY BILL CLARE FOR THE WASHINGTON POST

other problems for which it is not yet FDA-approved.

Like any drug, it produces side effects. The FDA had amassed 14,100 reports of adverse reactions by the end of July, "a large volume of complaints," a spokeswoman says. Though most are on the mild side (rashes, insomnia, anxiety), they range "from headaches to suicidal ideation." It's that last reaction that is causing most of the legal tumult.

In February 1990, the American Journal of Psychiatry published an article by psychiatrist Martin Teicher and two colleagues from McLean Hospital in Belmont, Mass. It wasn't a controlled study, as Prozac defenders including Lilly were quick to point out, but an account of six patients who developed "intense, violent suicidal preoccupation after 2-7 weeks of fluoxetine treatment."

Rhonda Hala's doctor read the report and called her at home to tell her to discontinue the medication; Finz announced Hala's lawsuit at a press conference a few months later. Within weeks he had made the rounds: "Donahue," "Joan Rivers," "Larry King," "you name the program, I've been on it," Finz says. His costars, on several occasions, were so-called Prozac survivors telling harrowing tales of the drug's effect on them or on loved ones.

Finz estimates that a thousand people subsequently called his office with questions, fears, cases. Prozac questions even began to filter into the criminal justice system: About 20 people accused of murder or assault have adopted the "Prozac defense," asserting that the drug made them violent. These are not large numbers, given the 4 million individuals around the world who take Prozac. But a few suits and a lot of media were enough to send Eli Lilly into high gear.

The company has promptly approached prosecutors in criminal cases involving a Prozac defense, offering to supply any information that will help: scientific papers, clinical trial data, the names of expert witnesses specializing in psychopharmacology. It will even, in some cases, pay those ex-

perts' fees, which can range from \$150 to \$500 an hour. "It's our view that no jury should be deprived of the medical information that's available on this product because a prosecutor's office lacks the resources," says West.

The company has also launched an indemnification program, volunteering to pay for the legal defense (including any judgment) of a physician who prescribes Prozac and is named in a lawsuit. Most of the civil cases don't name physicians as codefendants with Lilly but several, including Finz's suit on behalf of the Wesbecker estate, do.

Finz, who's been consulted by defense attorneys but is not directly involved in the criminal cases, objects to this "intrusion by a high-powered multibillion enterprise, creeping into the criminal justice system in a very insidious way." And Lilly acknowledges that its response—for example, ordering 250,000 special reprints of Time magazine, with the "Scientology: The Cult of Greed" cover story, to distribute to physicians—has been unusual. The attack on Prozac and the attendant publicity, West says, "have created an environment where many of the rules have changed."

### 'Legal Firepower'

Everyone in his office still calls him Judge Finz, because he served as a civil court judge and sat on New York's state Supreme Court for four years. When he left the bench, in part because of the difficulty he had educating two children on a judicial salary, he turned to litigation and founded the Law Offices of Leonard L. Finz in 1984. With 17 attorneys, his is a sizable firm for the field, with the resources to risk expensive trials on contingency: If the plaintiff doesn't win, the lawyers don't get paid. (Of course, if the plaintiff does collect, the lawyers get paid a lot, a third of the judgment or more depending on which state a case is tried in.)

It's this size and specialization that will allow Finz, in his own not-entirely-humble estimation, to secure verdicts against Lilly when the attorneys using the Prozac defense in criminal cases have yet to win an acquittal. All

of the defendants in the 11 criminal cases tried to date have been convicted by juries, though two were found guilty of less serious charges than prosecutors had sought.

"Unfortunately, defense attorneys who handle garden-variety criminal matters are just not prepared to deal with a product liability situation," Finz says, excusing them expansively. To succeed, "the attorney must be extraordinarily well-versed in the entire NDA [new drug application] Lilly filed with the FDA—maybe in excess of 50,000 to 100,000 documents. You must have read the world literature on fluoxetine—hundreds of papers. You must have a cadre of experts, highly credentialed, from the finest academic institutions. . . . That's the kind of legal firepower that's necessary."

The case against Prozac, as Finz intends to press it, proceeds on dual tracks. He will argue that Prozac is dangerous and unsafe, that Lilly knew or should have known that it "caused intense agitation and medically induced preoccupation with suicide" or other violent behavior, as the complaint reads. He will also claim that Lilly negligently failed to test the drug properly and to warn the medical community of its hazards.

"Lilly's defense is very simple," responds John McGoldrick, one of the manufacturer's two outside counsels, who expects to face Finz in court. "This is a safe medicine, period. There is absolutely no scientific evidence to suggest that it induces suicide or violence."

Finz is amassing ammo with which he intends to persuade juries: charges that Lilly's tests of Prozac patients were not of sufficient duration; that it didn't test Prozac on certain kinds of depressed people; that its package-insert warnings amounted to "Orwellian doublespeak." Lilly is preparing to refute all of these allegations and more, insisting that the 155 clinical studies performed before the FDA approved the drug and ongoing studies with 32,000 patients to date make Prozac "the most thoroughly studied psychiatric drug" ever marketed, its package

insert amended 24 times to reflect new information.

Yet none of these specifics will matter in court if Finz can't show causation—that Prozac actually was responsible for the injuries and behaviors he has claimed. "If we cannot prove causation, anything they did is meaningless," he acknowledges. The difficulty of establishing that the plaintiffs behaved as they did because of the drug, not because of the very illness for which the drug was prescribed, is what leads other attorneys in the field to forecast an uphill fight. How can the jury be sure these people wouldn't have hurt themselves or others anyway?

"Suicidality is one of the symptoms of depression; it's part of the syndrome," says Jerrold Rosenbaum, chief of clinical psychopharmacology at Massachusetts General Hospital. Rosenbaum expects to be approached to appear as an expert witness, and he expects use to be made of a study he coauthored, published this spring in the Journal of Clinical Psychiatry. In a survey of 1,017 depressed outpatients, suicidal thoughts emerged in 1.3 percent to 6.5 percent; the differences between groups receiving Prozac, other antidepressants, or a combination were not statistically significant.

"The idea that some people can go sour on antidepressants is probably true; it happens with all antidepressants, and it's a small percentage," Rosenbaum says. "Whether it's the drug or the illness or an interaction between the drug and the illness remains to be clarified."

Zajacka, whose study of 135 depressed patients at Rush-Presbyterian-St. Luke's has not yet been published, says his preliminary data shows no correlation between Prozac and suicidality. "I don't think this phenomenon exists," he says.

The FDA, for its part, recently reiterated its position that "the data and information available at this time do not indicate that Prozac causes suicidality or violent behavior." It will, however, convene its Psychopharmacological Drugs Advisory Committee this

fall to review the possible relationship between antidepressants and suicide.

Teicher, associate professor of psychiatry at Harvard Medical School, remains the principal medical proponent of a link between Prozac and suicidal thoughts and behaviors in certain patients. "Over time, I feel confident it will be recognized," he says. He has agreed to testify as an expert witness in two cases—not brought by Finz—involving suicides; he has not yet decided whether to testify in any of Finz's cases.

It's true, Teicher acknowledges, that the six patients described in his article had long psychiatric and pharmaceutical histories; some had made previous suicide attempts. That's why the changes he observed when they took Prozac were so striking: "These were patients we had followed for many years through many bouts of depression. This was unlike anything they'd experienced before." The intense restlessness that accompanied their suicidal preoccupations, Teicher says, "is a drug-induced state." (Researchers at the Yale Child Study Center have also reported self-destructive thoughts or actions in six children and adolescents being treated with Prozac.)

Although Teicher has called for closer monitoring of patients taking the drug, he does not want it withdrawn. "It's a valuable and useful medication," he says. "I have many patients who benefit from it." Finz takes a similar position. Of the two public groups that have joined the Prozac fray by petitioning the FDA, one—the Nader-founded Public Citizen Health Research Group—has asked for a more prominent warning on Prozac's label, stating that "a small minority" of Prozac-takers have experienced agitation and intense suicidal thoughts. It's the other group that's calling for the banning of Prozac and causing much of the rumpus.

The Citizens Commission on Human Rights was created by the Church of Scientology in 1969 to "investigate and expose psychiatric abuses of human rights." By the group's peculiar definitions, psychiatry itself is

an abuse. "Psychiatry has been killing people for a number of years, and here's another example," says Legislative Affairs Director Peter Dockx. The group has a history of attacking drugs and jumped on Prozac in 1989, after a coroner's report found it in the bloodstream of murderer Joseph Wesbecker.

The commission contacted the families of Wesbecker's victims and persuaded 10 to sign a letter urging a congressional investigation of the drug. It set up a toll-free hot line for Prozac "victims" and helped launch a Prozac "survivors" network by supplying it with new recruits and printed material. It has placed commission leaders on the talk show circuit. Its photocopiers and faxes work overtime to alert the media to the latest lawsuits. Four of the full-page ads in Scientology's 10-week, \$3 million campaign in USA Today were anti-Prozac tirades. The group has been a consistent thorn in the side of Eli Lilly, which responds by blasting it at every opportunity as "a cult with a seemingly unlimited pocketbook and total disregard for the scientific process," in West's words.

While there's no question that Scientologists have helped keep the Prozac controversy boiling, distorting

See PROZAC, C3, Col 1

# Lawyers & the Drug

PROZAC, From C2

ing facts and making unsubstantiated accusations in the process, they may have provided one unintended service to Lilly: By continually linking its two adversaries and suggesting some connection with the company can portray plaintiffs' attorneys (who could, in the long run, cause more damage) as associated with a ruthless, much-prosecuted fringe group.

Dockx says that people who call the Prozac hot line with legal questions are referred to Finz and other attorneys. Finz adamantly denies any connection with the Scientologists and says that if some would-be clients came through that channel he is unaware of it. Lilly is "ignoring the victims and going after some entity totally unrelated to what we as lawyers are doing," Finz says. "It demonstrates a very weak defense."

Lilly spokesman West fires back, noting that Scientology's assault on psychiatry is that of a competitor, since it markets its own costly programs. When it comes to Scientologists' and plaintiffs' attorneys' attacks on Prozac, West says, "I think the motivation is exactly the same for both camps—to make money."

Of course, Eli Lilly is hardly without a financial interest in this dispute. Prozac is its second-largest-selling drug, and despite an apparent decrease in new prescriptions, the company projects record sales this year. Industry analysts have predicted that 1991 sales will top \$1 billion.

## 'Whoever the Jury Believes'

"I consider myself almost like an ombudsman," Leonard Finz says. "The pharmaceutical companies look at me not as a nemesis, but as someone looking over their shoulders all the time."

Pharmaceutical manufacturers, who might choose less flattering language to characterize the plaintiffs' bar, already have an entity looking over their shoulders; it's called the Food and Drug Administration. But years of a relatively quiescent FDA, only now growing more active, combined with the growing number of liability lawsuits, have given plaintiffs' attorneys considerable influence.

"They're surrogate regulators, with a much more powerful arsenal of weapons at their disposal than any regulator has," says Robert Litan, senior fellow at the Brookings Institution and co-editor of the Brookings-published book "The Liability Maze." When it comes to their relative effectiveness, "the plaintiffs' lawyers have nuclear weapons; the regulators have machine guns."

It was lawsuits brought by women claiming injuries from the Dalkon Shield that bankrupted its manufacturer, A.H. Robins, and that have virtually eliminated intrauterine devices from the U.S. marketplace. Bendectin, once widely prescribed for nausea in early pregnancy, was voluntarily withdrawn by manufacturer Merrell Dow after a tide of lawsuits claimed it caused birth defects. Though Merrell Dow won most of the cases that came to trial, litigation costs rendered the drug unprofitable; there is no anti-nausea drug now available for pregnant women. Litigation is also cited as a reason most American pharmaceutical companies no longer make or market vaccines.

"The prospect of being found liable has put some chilling effect on the drug industry," Litan says. "How much is a question of debate."

The lawyers bringing the suits retort that they protect the public by forcing drug companies into safety consciousness. "Dangerous products have been removed from the marketplace," says Parker, Finz's associate. "Without this litigation, they'd still be injuring adults and children."

Still, even attorneys who regularly wade into drug liability cases wonder how Finz et al. are going to fare in the Prozac fight. So far, six cases are no longer active, five of them discontinued by plaintiffs (not dismissed by courts, as Lilly spokesmen often claim). A sixth was dismissed by a California court but "not on a substantive issue," according to McGoldrick. One of those ex-cases, in Pennsylvania, was Finz's, withdrawn because of "certain things we learned that we had not been aware of at the time," Parker says. The firm is being highly selective in the cases it accepts; it needs many to amortize the high costs, but it can't afford to hand Lilly easy marks.

Liability cases involving mental illness as opposed to physical injuries are hard to win, attorneys in the field say, particularly given the lack of any controlled scientific study that shows a causal connection between Prozac and suicide. "You're dealing in an area of medicine that is difficult," says William Trine of Boulder, Colo., chairman of the national litigation group bringing suits against a maker of L-tryptophan. "The defense can always point the finger at some other underlying cause for the condition."

Aaron Levine's Washington firm will not take Prozac cases. "I don't know that they're winnable," he says.

On the other side of the aisle, Jay Mayesh of Stroock & Stroock & Lavan in New York, who's defended drug companies and argued several DES cases against Finz, thinks Lilly deserves to win but may not. "We've seen such a huge amount of junk science admitted into courtrooms in the past 10 years," is his complaint.

"There's a big lottery component to this," Brookings's Litan says. Unless the plaintiffs locate a "smoking gun" document, as in the Dalkon Shield litigation, "it'll be a battle of the experts. It's whoever the jury believes."

"And juries are heavily influenced by the bleeding-heart factor. As a matter of law, it's irrelevant how much the plaintiff suffered or what the circumstances are. In reality, it has everything to do with it, which is why plaintiffs' lawyers pick high-damage cases with gut-wrenching circumstances."

Indeed, Finz and his associates have selected some heartbreakers. But can they pin the blame on Lilly? "Lilly is going to put up a very formidable defense; we never underestimate them," says Parker. "But we feel we're on the correct side of this issue."

Plaintiffs do win such cases sometimes, even when the scientific evidence is ambiguous, it is suggested to Edward West, the man from Lilly. His reply is brief and grim. "Not in this instance," he says.