Warning: Side Effects

A MESSAGE IN A BOTTLE COULD SAVE YOUR LIFE

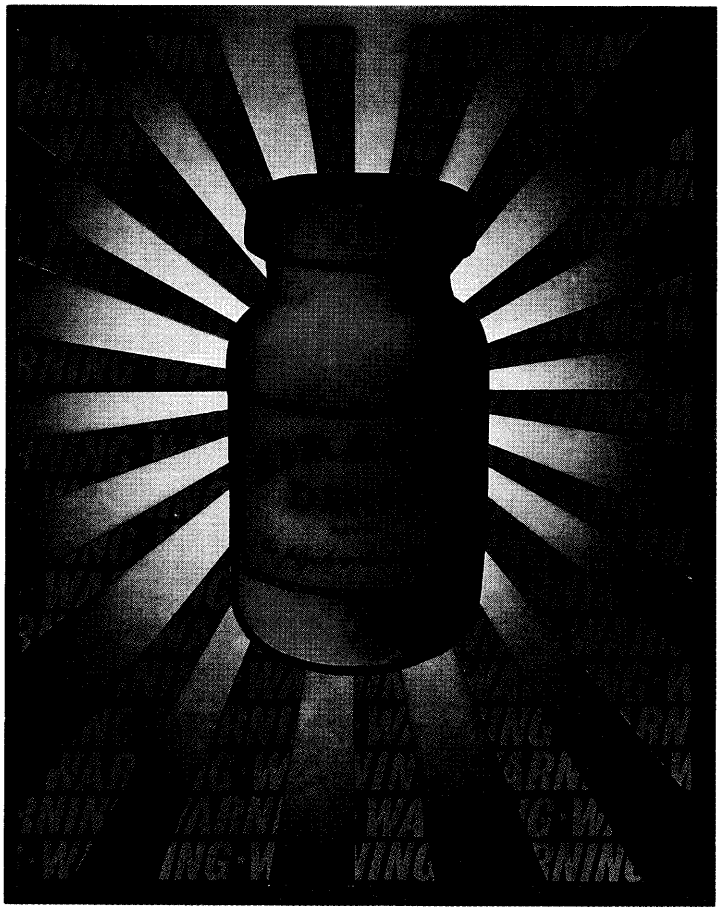
MY DAD, aged 83, had been taking the antidepressant drug Prozac for a couple of weeks when he phoned me. "I've swallowed the rubbing alcohol," he told me, "and I just wanted to say good-bye." My response was swift: I hung up and dialed 911. The medics arrived to whisk him away to a locked psychiatric ward in a grim city hospital, where one man rocked back and forth incessantly and another mumbled on about distant galaxies and UFO's. Feeling my dad's Prozac dose had been ineffective, the doctors decided to double it. But he continued to deteriorate until he couldn't even talk, except to say, "I want to die."

We transferred him to a private psychiatric hospital as soon as we could. His new doctor took him off Prozac, put him on a healthy diet and monitored his blood pressure and heart rate throughout the day. Within a week my dad had almost completely recovered. "It's a miracle," was all my mother and I could say.

My father's troubles with Prozac have convinced me that consumers need to be better informed about the side effects of antidepressants and other mood-altering drugs. In 1989 pharmacies dispensed 158 million prescriptions for these psychoactive drugs, according to the Food and Drug Administration (FDA). And certain side effects are well documented: Tricyclic antidepressants such as Norpramin can lead to nausea, low blood pressure and sexual dysfunction; Prozac can result in insomnia and agitation; and Halcion, a sleeping pill, can cause dizziness.

Knowing about and monitoring side effects is largely your doctor's job. That's if you're lucky enough to have a doctor who sees you frequently and keeps track of subtle changes in behavior. But even if your doctor is doing a good job, drug therapy is an inexact science. "A doctor may decide to increase the dose of an antidepressant if the patient's condition worsens, even though it may be hard to tell whether the downturn is related to the depression or the drug," says Dr. Jerrold Rosenbaum, chief of the clinical psychopharmacology unit at Massachusetts General Hospital in Boston.

And doctors don't always know *all* the side effects. Since clinical trials generally involve only 1,000 to 3,000 people and last only six or eight weeks, not all drug reactions surface immediately. Moreover, it takes at least a year before pregnant women, the elderly, patients on other medication, children and others who are traditionally excluded from studies report side effects to the drug company, their doctors or the FDA.



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To make matters worse, the FDA relies on drug companies to provide information about the safety of the drugs they are testing because the agency doesn't conduct such studies itself. Recently scientists accused the drug manufacturer Upjohn of fraud. Its product Halcion, banned last October in Great Britain, is still the most popular sleeping pill in the U.S. (Both President Bush and Secretary of State James A. Baker have used it when traveling.) Although Upjohn has long promoted it as the safest sleep aid around, critics contend that the company concealed data showing the

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drug can cause hallucinations, depression, amnesia and paranoia.

Upjohn denies all wrongdoing and maintains Halcion is safe, but the firm has agreed to provide stronger written warnings stressing that doctors should prescribe small doses for short periods. And a "patient package insert," or PPI, will describe in laymen's terms the drug's side effects.

Currently the FDA is asking four other sleeping-pill manufacturers to include easy-to-read warnings. "We urge that PPI's be included with all prescription drugs," says Sidney Wolfe, director of the Public Citizen Health Research Group, a Washington, D.C.–based consumer group Ralph Nader helped start. "That way consumers can decide for themselves if they want to take a drug that's addictive or causes serious side effects. And if they do, they'll know how to use it more safely and effectively."

Drug companies say such written warnings are not needed for antidepressants because these products are safe. Eli Lilly, the maker of Prozac, notes that contemplating suicide is a symptom of depression, the condition for which most patients take Prozac in the first place.

Despite thousands of patient reports connecting Prozac with suicide and violence, the FDA has so far sided with Eli Lilly's contentions that stronger warnings are unnecessary. "The drug and the reports could be related," admits Dr. Robert Temple, director of the FDA's Office of Drug Evaluation I, "but there's no way to know for sure."

But don't consumers need to know for sure? Dr. Ida Hellander, formerly a researcher for Public Citizen, says yes, absolutely. "We include extensive warnings with birth control pills," Hellander notes, "even though the evidence connecting estrogen and breast cancer is still unclear."

Of course, my father might have tried Prozac despite any warnings. But when he suddenly started to become obsessed with suicide, a PPI might have at least given my family some idea of what was going on.

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