

Darvon that have the biological effects and abuse potential of narcotics should be called narcotics. In this sense, the law has lagged behind; for years, Lilly has successfully kept the World Health Organization and the drug enforcement establishment in the United States from controlling Darvon as a narcotic. "Lilly has been using the legal definition [of Darvon as a nonnarcotic] in a medical sense," says Jasinski.

The second problem with Lilly's early drug promotion relates to Darvon's therapeutic effectiveness. Contrary to Lilly's claims while the prescription pattern for the drug was first being established, Darvon is about half as potent as codeine, a related analgesic already listed on Schedule 2 as a controlled substance. Darvon has no particular value for migraines and menstrual pain and is in fact less effective than aspirin in treating these and other pain problems, according to data from clinical trials. Charles Moertel of the Mayo Clinic, for example, has compiled a list of 14 published clinical trials comparing aspirin and Darvon; aspirin was shown more effective in each one. Although several studies detected no statistical difference between Darvon and a placebo, the consensus now is that the drug is slightly more effective; it does, for example, have a positively sloping dose-response curve.

Lilly is well aware that Darvon, by itself, is not better than aspirin. Asked about this at the recent Senate hearings, Lilly spokesman Robert Furman said, "Aspirin is a truly remarkable drug." We are not, he said, claiming that it is better than aspirin. He emphasized, however, that several studies demonstrate that propoxyphene and aspirin together are more effective than the equivalent dosage of each drug separately, and, indeed, more than 80 percent of Lilly's Darvon tablets contain both propoxyphene and aspirin. In 1972, at the request of the FDA, Lilly mailed a notice to physicians that admitted Darvon was no more, and probably less, effective than aspirin; but once again, physician recognition and change in habit alteration have lagged behind disclosure of the facts.

One reason that recognition continues to lag could be Lilly's Darvon promotion program, which remains aggressive. Beaver, of George Washington University, notes that "The best ball point pen that I ever owned was given to me by a Lilly detail man and is emblazoned with the words, 'Darvon N-100.'" However, other drugs have not met with the same success, he says, so additional factors must be involved. The most important of

these is the fact that up to one-third of the patients in clinical trials obtain relief from a placebo alone. Thus Darvon need not be very potent to have a pain-reducing effect. According to several experts, Darvon is an effective placebo because it is brightly colored and because it is prescribed. "Many patients have a psychological need to receive an analgesic which is available only on prescription," Beaver says. FDA Commissioner Donald Kennedy agrees that "a major advantage of Darvon is that it's prescribed." The placebo effect, he adds, is nothing to sneer at. A recent study that appeared in *Lancet*,* for example, states that the pain-killing effects of a placebo were reversed in clinical trial by a narcotic antagonist, naloxone, suggesting that a placebo, given adequate patient belief in its effectiveness, may trigger the same physiological changes that a real analgesic triggers.

A problem that results from Darvon's relatively low effectiveness, however, is that patients for whom it does not work—either as placebo or analgesic—may take higher doses to gain a greater effect. Lilly's basic and probably accurate defense of Darvon is that no one has died or suffered ill effects from using it at the recommended dosage. And estimates of the number of people who abuse it, by increasing the dose or combining it with liquor, are not entirely reliable. But it is well accepted that a significant number of people do abuse it, partly for a euphoric effect, and that some proportion of the more than 500 deaths related to Darvon each year are caused by abuse and addiction. Most experts appear to agree with Lilly's claim that the majority of these deaths are suicides. Darvon users have a marked tendency for hypochondria, chronic minor illnesses and emotional problems, and misuse of alcohol or other prescription drugs.

The critical uncertainty is the number of deaths that result from accidents and addiction, and not suicides. Lilly contends that the number is small, and as a spokesman put it, "If Darvon were suddenly to become unavailable, the problem would remain the same," meaning that people would turn to pistols or other drugs to accomplish the same end. If, however, the number of accidental or addiction-related deaths is large, Lilly is manufacturing a drug that is in practical use unsafe. This issue will be the focus of the HEW review; it may also be the hardest question to pin down.

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*John Levine, Newton Gordon, and Howard Fields, "The mechanisms of placebo analgesia," *Lancet*, 23 September 1978, p. 634.

BATF Decides Against Liquor Warning Label

After laboring for more than a year on the issue, the Bureau of Alcohol, Tobacco, and Firearms (BATF) in the Treasury Department has decided not to require a label on alcoholic beverages warning women that drinking during pregnancy may cause birth defects. The label had been sought by the Food and Drug Administration (FDA) as the result of mounting evidence of a "fetal alcohol syndrome"—a set of physical and mental abnormalities, including central nervous system problems and weight and growth deficiencies in children of mothers who drink heavily while pregnant. In deciding against the warning label, BATF acted against the advice of the FDA, the National Institute on Alcoholism and Alcohol Abuse, the Institute of Medicine, its own scientific consultant on genetics, and several associations for the retarded.

BATF did, however, agree to begin an educational campaign consisting of brochures, radio and television public service announcements, and school programs to warn teenage and older mothers of the dangers that drinking poses to their unborn children. The campaign is to be funded by the liquor industry, which presumably will find it in its own best interest: if public awareness about the syndrome, as measured in polls that BATF intends to take over the next 2 years, does not increase significantly, BATF says it may change its mind and require the label. Also, promoting awareness of the syndrome is said to be a means for liquor companies to indemnify themselves against damages arising from legal suits pressed by the parents of a syndrome victim.

BATF based its decision not to require a label on the paucity of data demonstrating the effects of the syndrome on babies of mothers who drink only moderately (less than 3 ounces of alcohol per day). Several experts in the field, however, including Judith Hall of Children's Orthopedic Hospital in Seattle, a consultant to BATF, have suggested that the effects of the syndrome in less than full-blown form may be present in the children of mothers who are light to moderate

drinkers or indulge in one-time binge drinking. The March of Dimes, for example, recommends that the only safe course for a pregnant woman is not to drink at all. One of the other BATF scientific consultants, Sergio Fabio of George Washington University, declined to recommend for or against a label, and a third consultant, Amitai Etzioni, currently of the Brookings Institution, recommended greater study of the efficiency of warning labels first, as did the National Research Council.

Richard Davis, Assistant Secretary of the Treasury for enforcement and operations, says that "we decided that labeling is not the best approach because it would take a paragraph to convey the warning accurately. Also, overwarning could result in guilt and other problems in a family where the mother had too many drinks and the child is not as smart as they think he should be." Davis' decision was strongly supported by the National Council on Alcoholism and the American Council on Alcoholism, both of which concluded that warning labels would add to the negative stigma of being an alcoholic. The alcoholic beverage industry also opposed the labeling requirement, and mounted a major letter-writing campaign against it from the wine-producing states of New York and California.

FDA Commissioner Donald Kennedy agreed to support the BATF plan in exchange for a BATF agreement to require ingredient labeling on alcoholic beverages, a long-sought FDA interest because of complaints that many of the additives in liquor provoke allergic responses.

What Evil Lurks at DOE? The Shadow Knows

Washington, D.C., has a new secretary of energy. The current pipe-smoking feather-ruffling energy czar, James Schlesinger, has not yet been banished from the realm, but now he has a competitor. Chagrined at Schlesinger's failure to adopt its suggestions, the public interest energy movement has appointed an energy secretary of its own, a sort of shadow secretary of energy with whom it may expect good relations. Nine assistant

shadow secretaries have also been appointed, as well as several shadow directors, a shadow general counsel, and a shadow inspector general. Together, the activists are calling themselves the Shadow Department of Energy.

The shadow secretary's office is located in the downtown Washington suite occupied by the law firm of Lobel, Novins and Lamont. John Lamont, who has worked on energy matters for the Justice Department, state governments, and private clients for 30 years, is the shadow secretary. Lamont, 61, is a bright engaging man who offers to pull out his shirttail for photographers (in a parody of Schlesinger's frequent dishevelment). The similarities between his department and the real thing seem astonishing. A visitor finds the office in vast disarray, with great stacks of paper and waist-high piles of energy tomes lining the passageways and office floors. The group as a whole has few identifiable goals. And in an endearingly bureaucratic touch, Lamont confesses his inability to quickly locate relevant documents "because the office is being repainted just now."

But there are also significant differences between the shadow and the real thing. One clue is Lamont's background and area of expertise: at Justice, he worked in the antitrust department, specializing in oil pipelines and imports until he roiled John Mitchell enough in 1972 for the two of them to agree on Lamont's retirement. "The blame for the shadow department may be laid at the door of Jim Flug," Lamont says. "In the long tradition of secretaries of energy, I'll be the head of it but let someone else do the work." Flug is a former staffer of Senator Edward Kennedy (D-Mass.), currently the director of Energy Action, a consumer activist group, and most recently, shadow inspector general. Despite an occasional humorous tone, Flug and Lamont, along with several other attorneys and representatives of the Environmental Policy Center and the Consumer Energy Council, formed the shadow department for largely serious purposes.

"For nearly a year and a half, the Department of Energy has been establishing new records for chaos, mismanagement, and bungling in energy policy," reads an open letter the shadow group wrote to employees of the

real thing. "We therefore invite you to be in touch with one of us. . . . Whenever you think we can be of assistance to you in getting a problem seen and solved, in doing something from the outside which ought to be done from the inside but isn't, let us know."

The lists of intentions and criticisms are both longer, but in essence the shadow department hopes to em-

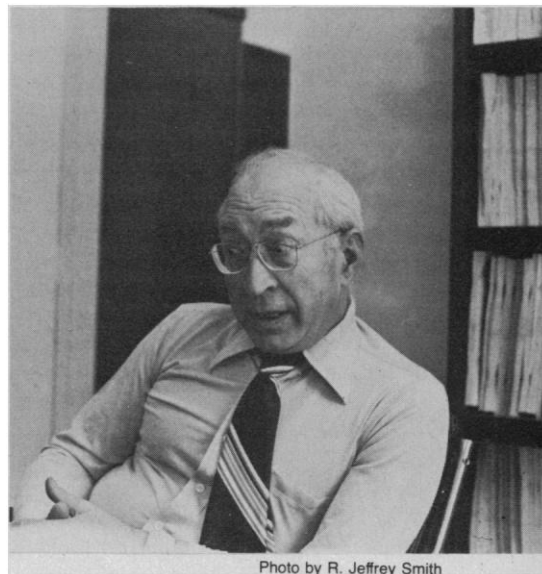


Photo by R. Jeffrey Smith

John Lamont

barrass the real thing through its very existence and the information fed it by whistleblowers, to facilitate more coordination among the various activist groups, and to issue periodic critiques of agency performance and nonperformance. The bent of the group is clearly toward the soft path and small company. "We are true free enterprise freaks," says Lamont. "The large companies already get the best audience with DOE that money can buy."

Though the specific criticism may not be universally shared in Washington, Schlesinger has come under similar fire from a wide spectrum of individuals lately, mostly over his poor administrative abilities. "It's convenient to make me the fall guy," he was reported as saying recently in his own defense. "I'm trying to sell an unpleasant future by offering pain today."

Lamont accepts no excuse. "If the energy crisis demands the moral equivalent of war," he says, "is the failure of DOE to resolve it the moral equivalent of treason?"

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