"Fen-phen" suits: trial lawyer gives his views on when doctors may be liable

In response, A.H. Robins and Wyeth-Ayerst Laboratories began producing and marketing a combination of fenfluramine and phentermine--Pondimin. Then Wyeth-Ayerst Laboratories and Interneuron Pharmaceuticals asked FDA to approve a stronger product version, dexfenfluramine--Redux-- labeled for indefinite use. Although there was reportedly debate within the FDA committee of experts reviewing the proposal, on April 29, 1996, dexfenfluramine was approved for sale, but with the caution that studies had spanned only one year. Soon, the drugs, sold as Redux and Pondimin, soared to popularity.

It was known at the time that fenfluramine was linked to an increased risk, although a very small one, of pulmonary hypertension, an often fatal heart condition. The real bad news started to roll in when in August, 1996 *The New England Journal of Medicine* reported than "fen-phen" increased risk of primary pulmonary hypertension by more than 30 times. In July, 1997 the Mayo Clinic reported that 24 women taking fenfluramine or dexfenfluramine had developed heart valve abnormalities. Doctors sent individual reports of 100 additional cases to FDA. The clincher came in September when five medical centers independently reported to FDA that of 291 women examined who were taking the weight reduction drugs, one-third had damaged aortic or mitral valves.

At FDA request, fenfluramine and dexfenfluramine makers withdrew their products from market.

Then the lawyers got busy rounding up "fen-phen" clients. They found them. American Home Products, whose Wyeth-Ayerst Laboratories made Pondimin and Redux, reportedly already has been hit with more than 50 lawsuits filed by individual plaintiffs and at least 21 lawsuits seeking class action status.

Right now, plaintiff lawyers are of two minds about how to pursue "fen-phen" suits. One camp wants to take each case to court separately; the other wants class-action status and establishment of a multidistrict litigation arrangement like the one set up to handle breast implant cases. Already class-action suits have been filed in federal courts in seven states, including California, Colorado, Georgia, Hawaii, Illinois, New York and Utah. The leading lawyers from around the country who want to go the multidistrict route were meeting in Chicago October 30. Those who get named to the key steering committee will no doubt get the financial plums in the ensuing litigation process.

Those favoring the multidistrict approach say it could resolve suits faster and cheaper; those opposing it say plaintiffs won't get enough in damages.

Plaintiff attorney Kenneth Moll , Chicago, filed the Illinois class-action suit against several drug companies who made "fen-phen" type products in federal court on behalf of five women on October 22. No specific damages were sought. In an interview with MLM , Moll expressed his views on physicians' potential "fen-phen" liability.

"I recommend that attorneys not file against physicians. Some lawyers want to do so. I believe that a class-action suit filed on behalf of every person who used "fen-phen" drugs is the way to go.

"The first priority should be to inform and warn people who have used "fen-phen" products. Then we must set up a medical monitoring program and pay for it. Many such individuals can't afford the echocardiograms that would show whether they had suffered heart valve damage. We need to say, 'Here is a clinic to go to for the echocardiogram. Get tested. If everything is fine, great. We'll keep you informed if other adverse reactions turn up. Right now, it's too early to tell.'"

Moll said such a system would produce hard objective data to determine what the percentage of heart valve damage is. "And, there IS evidence. There is plenty of evidence from foreign studies of fenfluramine implicating it in cases of primary vascular pulmonary hypertension and other ischemic cardiac injuries."

Fifty percent of women who used the foreign version of "fen-phen" died within 10 years, Moll said. Twenty American women already have required surgical intervention to treat cardiac problems arising from use of the diet drug, he noted.

Whether physicians can be liable will depend upon whether they knew of the drugs' dangers and if so, whether they warned patients about those risks, the attorney said.

"I will be the first one to file a lawsuit against any physician who prescribed "fen-phen" if he or she knew about the Mayo study and the study reported in the *New England Journal of Medicine*. I will be the last one to file if the physician prescribed the drugs before those studies came out," Moll emphasized.

Moll said lawsuits have already been filed against doctors and clinics for that reason alone.

If a physician did not see these studies and relied strictly upon information supplied by the pharmaceutical companies, then he or she can defend using the "learned intermediary" doctrine, Moll said.

"The physician is in the best position to rec-

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Did doctor know?.....*(Continued from 2)*

ognize adverse evidence in a patient. If he or she notices heart palpitations, shortness of breath, for example, that doctor has a duty to report it through proper channels."

What's different about "fen-phen"-related problems from those associated with breast implants is that these can be life-threatening. So physicians' level of duty to their patients is much higher when the diet drugs are involved, Moll said.

WHAT MOLL'S CLASS-ACTION SUIT ALLEGES

The class-action suit filed in federal court in Illinois follows the pattern of those filed in other states. Among allegations against drug makers are:

-- Fraudulent misrepresentation and concealment
-- Conspiracy
-- Negligence
-- Unjust enrichment
-- Breach of express warranty
-- Intentional infliction of emotional distress
-- Negligent undertaking
-- False advertising
-- Deceptive business practices
-- Wilful and wanton misconduct
-- Loss of consortium

What physicians and insurers wanted to know

What should liability insurers do to alert their physician policyholders to the potential threat of "fen-phen" suits? Are warning letters enough?

No doctor-owned companies report any actual suits as yet, but several physicians have called to report incidents. Problems insurers see:

-- Patients often have pressured doctors to prescribe "fen-phen" drugs. Were proper physical assessments done before a prescription was written?

-- Did patients truly qualify for the drugs? Drug companies specified that patients should be at least 20% to 30% overweight before the drugs should be prescribed. Had other weight reduction programs failed? Did the patient's weight pose health risks?

-- How can physicians wean patients off the drugs which have now been recalled? Drug manufacturers warn there can be serious side effects if patients stop the drugs suddenly.

-- Informed consent issues loom large. Were appropriate warnings issued?

-- Which physicians are at greatest risk--those who used the drug occasionally or those whose practices center on weight reduction? You guess.