Diet Drug Maker Agrees to $3.75 Billion Settlement

American Home Products, the maker of Pondim (fenfluramine) and Redux (dexfenfluramine), recently agreed to pay as much as $3.75 billion to people who took the diet drug cocktail called fen-phen or Redux, a settlement that attorneys called the largest ever involving a US pharmaceutical firm (fen-phen was a combination of fenfluramine and phentermine). The nationwide, class-action settlement is open to all who took Redux or Pondim, regardless of whether they have filed suit or not.

The settlement has yet to be approved by a federal judge, who must certify the suit. A similar attempt to settle product liability litigation by Interneuron Pharmaceuticals, Inc, met a stumbling block last September when the US District Court for the Eastern District of Pennsylvania rejected a proposed agreement between the company and the plaintiffs’ management committee on the grounds that the proposed settlement did not meet the requirements for limited fund class actions. Interneuron, which is based in Lexington, Mass, licensed dexfenfluramine from the closely held French drugmaker Laboratoires Servier SA and manufactured it for American Home Products Corp.

The American Home Products settlement will fund the following:

- A refund program for the cost of the drugs
- Medical screening for future valvular problems
- Additional medical services or cash payments
- Compensation in the event of serious heart valve problems

Fenfluramine and dexfenfluramine were withdrawn from the market in September 1997 after physicians identified valvular abnormalities in people who had taken the diet drug combination. Concerns began when investigators at the Mayo Clinic and MeritCare Medical Center in Fargo, ND, reported that they had identified a series of 24 patients who received the combination of fenfluramine and phentermine and who had unusual valvular changes and regurgitation in heart valves on both the right and left sides of the heart. Eight of the patients also had pulmonary hypertension. All patients had symptoms of their disease and heart murmurs. By August 1997, a total of 85 cases had been reported to the US Food and Drug Administration. The agency also reported that in 5 prevalence surveys using echocardiographic testing, 86 of 271 patients who had received the fen-phen combination for 6 to 24 months had significant indications of valvular regurgitation, as did 6 of 20 patients who had taken dexfenfluramine, with or without phentermine. These findings led to the withdrawal of the drugs from the market.

Studies have since reported lower rates of valvular abnormalities in patients who took the various drug combinations. It seems that the prevalence of the problem varies with the length of time that patients took the drugs. However, the rate of disease in patients who have taken the drugs is still unclear, even when adjusted for the time of administration. In a statement released by the American Heart Association and the American College of Cardiology, it was recommended that all people exposed to fenfluramine or dexfenfluramine should see a doctor, have a medical history taken, and undergo cardiovascular examinations to determine if cardiopulmonary problems are evident. All such patients who exhibit cardiopulmonary problems should receive an echocardiogram. They also recommended that all such patients should receive echocardiograms before they undergo invasive procedures for which preventive antibiotics are recommended in 1997 American Heart Association guidelines. This includes dental procedures in which antibiotic prophylaxis is recommended. However, the groups did not recommend echocardiograms for all patients who received fenfluramine or dexfenfluramine.

The proposed settlement includes 2 funds. One, consisting of $1 billion, will cover refunds, medical screening costs, additional medical services, cash payments, education, research costs, and administration. As much as $200 million in additional funds will be available for attorneys’ fees. The second fund will begin at $650 million when the settlement receives final judicial approval. The remainder of the settlement will be paid over 15 years to a maximum value of $2.55 billion. This fund will compensate claimants with significant valvular heart disease and pay related attorneys’ fees.

Patients who took fenfluramine or dexfenfluramine for >60 days will be offered an echocardiogram and a visit to a physician. If the echocardiogram shows some level of heart valve regurgitation, patients may choose to receive $6000 in cash or $10 000 in additional medical services. They may also qualify for a refund of prescription costs of up to $500.

Those who used the drugs for ≤60 days qualify for a refund of their prescription costs, will be reimbursed for the costs of echocardiograms if they show heart valve regurgitation, and may apply for echocardiogram payments under compassionate and hardship programs. If the echocardiograms show regurgitation at a significant level, they can choose between receiving $3000 in cash or $5000 in additional medical services.

A fund of $25 million will be established for education and research about heart disease as part of the settlement.
Patients who have significant mitral regurgitation and who register for benefits will be eligible for more payments in the event that they develop heart valve disease within 14 years from final approval of the settlement. A class member may receive as much as $1.5 million in such payments, depending on the kind and degree of regurgitation at the end of the screening program, the severity of the heart valve condition, the age of the person, other medical indications, and the duration of drug use.

Patients who received the drugs can opt out of the settlement to pursue their own suits at the time the settlement agreement is signed, after participating in the screening program, or when they develop more serious conditions.

Last August, a woman from Canton, Texas, was awarded $23.5 million when she sued American Home Products and its subsidiary Wyeth-Ayerst Laboratories for the heart valve damage she sustained after taking the phen-fen combination for 3 months.

Ruth SoRelle
Circulation Newswriter
Diet Drug Maker Agrees to $3.75 Billion Settlement
Ruth SoRelle

*Circulation.* 1999;100:e133-e134
doi: 10.1161/01.CIR.100.25.e133

*Circulation* is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 1999 American Heart Association, Inc. All rights reserved.
Print ISSN: 0009-7322. Online ISSN: 1524-4539

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://circ.ahajournals.org/content/100/25/e133