

1441



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Joan Claybrook, President

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STATEMENT OF LARRY D. SASICH, PHARM. D, M.P.H. AND SIDNEY M. WOLFE,
MD OF PUBLIC CITIZEN'S HEALTH RESEARCH GROUP ON
THE WITHDRAWAL OF THE CALCIUM CHANNEL BLOCKER MIBEFRADIL
(POSICOR) FROM THE MARKET

Mibefradil (Posicor) is an example of the risks that the American public will continue to face in the future because of the flood of new drugs that the FDA has rushed to approve in the last several years. Rather than putting the safety of the American public first, the FDA now "cooperates" with the drug industry, whose only interest is selling drugs, to approve more drugs faster whether they are needed or not. In 1996 and 1997, the Agency approved 91 new drugs of which mibefradil was one.

Mibefradil is clearly a drug that the FDA knew was not needed. In its June 8 announcement of mibefradil's withdrawal the Agency said:

Since Posicor has not been shown to offer special benefits (such as treating patients who do not respond to other antihypertensive and anti-anginal drugs), the drug's problems are viewed as an unreasonable risk to consumers.

There are nine other calcium channel blocking drugs on the market in U.S. approved for high blood pressure and chest pain none of which should be used first for either of these conditions.

The FDA's advisory committee recommended approval of the drug by a vote of only 5 to 3, but the Agency is not obligated to take the committee's recommendation. The FDA knew that mibefradil was associated with serious adverse effects not seen with other calcium channel blockers before it was approved:

- The drug could cause abnormally low heart rates. Less than 45 beats per minute.
- The drug was associated with a number of potentially serious drug interactions.
- Six deaths occurred in those taking the drug in a pilot study testing mibefradil for use in patients with congestive heart failure.

-1-

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- Early analysis of the full-scale study testing the drug in congestive heart failure in 2,400 patients found 268 deaths, of which 142 were sudden deaths.

One of the advisory committee members voting against mibefradil suggested that its approval should be delayed until the completion of the congestive heart failure trial and said:

“I just wonder, aren’t we obligated to provide some assurance the ECG changes we’ve seen here today are not ultimately lethal? And wouldn’t some of that assurance be provided by waiting until the end of the heart failure trial?”

This was responsible advice the FDA ignored.

The FDA’s role has changed. Rather, than regulating the drug industry to protect the health of prescription drug consumers the Agency has become the drug industry’s partner in approving a flood of drugs that offer no advantage over older drugs and in many instances, there is clear evidence that they may be more dangerous. This places the American public at a needless risk of devastating adverse drug reactions.