US consumer groups allege misleading drug claims

Scott Gottlieb *New York*

A coalition of US consumer groups has filed a lawsuit against Schering-Plough, the manufacturer of the allergy drug Claritin (loratadine), claiming that the company falsely advertises the benefits of the medicine.

The Boston based coalition, known as the Prescription Access Litigation project, filed a class action lawsuit accusing the drug manufacturer of misrepresenting Claritin in its advertising—causing increased demand for the drug—and of artificially inflating its price. The complaint alleges that Schering-Plough's advertising of the drug falsely depicts the benefits of the drug and how effective the drug really is.

The group filing the suit said that the advertising has made Claritin the top selling allergy medicine in the United States. Denise Foy, a spokeswoman for Schering-Plough, said that Claritin is the top selling antihistamine "because it works." She disputed the notion that the firm deceptively advertises Claritin and noted that it follows the Food and Drug Administration's regulations on drug advertising.

Last year Schering-Plough spent $111m (£79m) on "direct to consumer" advertisements promoting the allergy drug, according to the lawsuit, which said that the advertisements consistently make a false promise that Claritin works for everyone.

In fact, medical research shows that Claritin fails to provide allergy relief about half the time, and performs only slightly better than a placebo, according to the lawsuit.

Prescription Access Litigation, a coalition of more than 50 consumer, healthcare, and legal groups has filed four suits this year against large drug companies. A suit filed in May against Barr Laboratories and AstraZeneca alleged that the firms illegally kept a generic version of the breast cancer drug tamoxifen off the market, forcing patients to pay far higher costs for the brand name drug.

In a separate blow to Schering-Plough last week, another US consumer advocacy group claimed that 17 people died because of faulty asthma inhalers made by the company, millions of which were recalled (from September 1999 to March 2000) over concerns that they did not contain medicine.

Bill O'Donnell, a spokesman for Schering-Plough, said that the company had "no evidence that a patient was ever harmed by an inhaler subject to any recalls" and that "every inhaler returned to the company by a patient claiming injury and alleging the canister lacked active ingredient has been tested and found to contain active ingredient." □

Bayer faces potential fine over cholesterol lowering drug

Annette Tuffs *Heidelberg*

Bayer, the German company that was forced earlier this month to withdraw a cholesterol lowering drug from the market, might have to pay a fine of DM50 000 (£16 200; $23 400) for withholding from the German authorities information on the drug's potentially fatal interaction with another drug.

Bayer's drug, cerivastatin (Baycol in the United States, Lipobay in the United Kingdom), was withdrawn after 52 deaths occurred in patients taking the drug; 31 of the deaths were in the United States (18 August, p 359). Now the German health ministry has accused Bayer, based in Leverkusen, between Düsseldorf and Cologne, of withholding vital information from its federal drug agency.

"We did not receive any information about a new study showing the adverse risks of Lipobay until we asked for it on 10 August," said the secretary of health, Klaus Theo Schroeder.

Schroeder criticised the regulation that pharmaceutical companies have to inform only the European agency responsible for the authorisation of the particular drug, in this case the Medicines Control Agency in the United Kingdom. Nevertheless, Bayer might have to pay a fine for withholding information, the ministry said.

Bayer denies that any information was withheld. "Relevant information was given to the German drug agency before 28 April 2001," the company says. "Furthermore, the Medicines Control Agency issued an interpretation of this information at the same time and sent it to its European partner agencies."

Bayer stated that the Medicines Control Agency received a final report on 18 June and that changes to the prescription information for Lipobay were then made.

Bayer also insists that Lipobay's adverse effects were not apparent before the introduction of the drug and that a causal relation is not proved. Patients who died had been taking a combination of Lipobay and another anticholesterol drug, gemfibrozil, which lowers blood concentration of triglycerides.

"The drug was tested in 50 studies with more than 2500 patients," said a spokesman. After the authorisation further studies were done on 15 000 patients.

● The German health ministry welcomed the preparation of a law that will strengthen German patients' rights to compensation for the adverse effects of drugs, even if it is not 100% certain that the drug is the cause. However, the justice ministry points out that this law was drafted independently of the recent events concerning Lipobay. □

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US lawyer Edward Fagen is claiming compensation from Bayer for patients who believe they developed side effects from taking Baycol