

Two class actions reimburse AIDS patients for unnecessary drug

Lance Harke and Howard Bushman
Harke & Clasby

Miami attorneys Lance Harke and Howard Bushman obtained a \$24 million settlement to reimburse HIV patients and insurers who paid for an expensive AIDS treatment that they may not have needed.

The Harke & Clasby partners settled two consolidated national class actions with pharmaceutical companies Serono, Serono International and Serono Laboratories last December in Boston federal court.

The lawsuits alleged the companies schemed to get doctors to prescribe Serostim, a Food and Drug Administration-approved growth hormone for the treatment

of AIDS wasting, an often fatal disease characterized by rapid, severe weight loss.

Contending demand for Serostim was tapering off, the lawsuits said the Serono defendants promoted an unapproved device for diagnosing patients with the disease and encouraged doctors to prescribe the drug through heavy promotions including trips to Europe.

"Most of the people prescribed [Serostim] didn't need it because they never had the condition in the first place," Harke said in an interview. "The sad thing is that we're talking about a vulnerable population."

Harke, whose firm worked with attorneys David Nalven and Thomas Sobol of Hagens Berman Sobol Shapiro in Cambridge, Mass., estimated 9,000 to 10,000 patients had out-of-pocket losses and several dozen



Harke



Bushman

insurance companies paid for the medicine.

Under the settlement, \$21.6 million was allocated to insurance companies, workplace-based health plans and other third-party payers. The other \$2.4 million went to people and their heirs who paid part or all of the bill for the drug from July 1995 to December 2006.

The injectable drug cost \$21,000 for 12 weeks of treatment. Harke said the settlement reimbursed claimants in full. The claims administrator distributed settlement checks to consumers last March

and to third-party payers by September.

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a criminal conspiracy charge and agreed to pay a \$704 million penalty, including reimbursement to government programs like Medicaid and Medicare. The settlement also imposed a corporate integrity program that required both external and internal monitoring and auditing. None of the money went to drug users or their private insurers.

The defense vigorously opposed the civil litigation filed in 2005 and 2006, contested the class definitions and filed motions to dismiss before agreeing to settle, Harke

In the final order last Dec. 12, U.S. District Judge Patti B. Saris said the "highly complex case" was resolved "as a direct result of class counsel's skillful advocacy."

The defendants denied liability. Lead defense attorney Fred Kelly Jr. at Nixon Peabody in Boston did not return calls for comment.

The Swiss drug maker began marketing Serostim in 1996 when AIDS wasting was among the leading causes of death for people with HIV, but the need for the drug dropped as treatment improved and the disease became more manageable.

To keep sales up, Serono conspired with Clinton Township, Mich.-based medical device manufacturer R.J.L. Systems and its president, Rudolph J. Liedtke, to provide the unapproved device to diagnose AIDS wasting, the plaintiffs claimed. R.J.L. and Liedtke pleaded guilty to conspiracy in 2005.

Serono pleaded guilty the same year to

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said.

An outreach effort to contact potential class members was complicated by patient confidentiality issues. Class counsel advertised in dozens of HIV-related health publications and subpoenaed large pharmacies likely to dispense the drugs for their records on Serostim consumers.

The attorneys were awarded more than \$3 million in fees and \$47,000 in expenses.

— Jordana Mishory