ILLINOIS ATTORNEY GENERAL LISA MADIGAN

PRESS RELEASE

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MADIGAN, 29 STATES REACH $58 MILLION SETTLEMENT WITH MERCK

Record-Breaking Agreement Requires Company to Submit Ads to FDA Prior to Airing

Chicago - Attorney General Lisa Madigan today announced a landmark financial settlement with Merck and Company, Inc., that also requires the pharmaceutical manufacturer to submit television drug advertisements to the U.S. Food and Drug Administration (FDA) for review before their broadcast.

The $58 million agreement, which is the result of a three-year, 30-state investigation led in part by Attorney General Madigan, stems from allegations that Merck employed deceptive advertising for its pain medication Vioxx and failed to properly disclose the drug's potential side effects. As a result, Illinois will receive nearly $3 million of the $58 million settlement, which is considered the largest ever multi-state pharmaceutical settlement. Along with the financial component, the settlement requires that Merck significantly change the practices it uses to market prescription drugs to patients and physicians.

The announcement comes at a time when the FDA is reviewing the effects of consumer drug advertising and considering increased regulation. While the FDA is considering imposing additional requirements on all manufacturers, it has not yet done so. As a result, the settlement makes Merck the first manufacturer that must submit TV ads to the FDA for review and wait for a response from FDA prior to running the advertising campaign.

"Merck's aggressive and premature promotion of Vioxx drove hundreds of thousands of consumers to seek prescriptions before the medical community fully understood Vioxx's risks," Attorney General Madigan said. "This settlement is designed to protect patients by deterring the use of deceptive advertising and marketing practices for new medications at a time that the risks and benefits have not yet been fully vetted and understood by the medical community."

During the course of this investigation, the state Attorneys General expressed significant concerns regarding the negative effect of consumer advertising that commences immediately at the release of a new drug—well before doctors have a chance to work with the drug and understand its potential side effects. As a result of this concern, the settlement agreement also requires Merck to comply with any recommendation by the FDA to delay consumer advertising for new Merck pain relieving drugs.

The settlement agreement also prohibits Merck from engaging in other practices that the company has used to promote its drugs.

Specifically, the agreement:

- Prohibits Merck from the deceptive use of scientific data when marketing to doctors. The settlement agreement enables the state to ensure that all Merck drug marketing and advertising is scientifically sound and not misleading.
- Prohibits the "ghost writing" of articles and studies. Recent news articles noted that Merck frequently paid academic scientists to take credit for research prepared by company-hired medical writers. This settlement should eliminate the practice. Under this settlement, all Merck-sponsored articles must be written by the listed author, and such author must have final approval rights of the version to be published. This is the first restriction on the common practice of ghost writing articles that has ever been agreed to by a major pharmaceutical company.
- Requires the disclosure of the conflict of interest of Merck promotional speakers when these speakers present supposedly "independent" continuing medical education seminars. This settlement requires doctors who receive promotional payments from Merck to disclose the promotional relationship they may have with Merck whenever they speak at continuing medical education programs.
- Prohibits clinical trial safety board members from having improper financial relationships with Merck. The settlement requires that members of clinical data safety monitoring boards, which oversee clinical trials to prove drug safety and efficacy, will not have conflicts of interest that could influence their decisions. In particular, members will not be able to hold or trade significant Merck stock or hold consulting positions whereby they would receive more than $15,000 in compensation from Merck.

Assistant Attorney General Ryan Tyrrell Lipinski is handling the case for Madigan's Consumer Protection Division.

-30-

Return to May 2008 Press Releases