For Immediate Release: August 21, 2008

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AAJ on FDA Supplemental Labeling Rule: "Irrational and designed to assist the manufacturers"

WASHINGTON—Reacting to the Food and Drug Administration's (FDA) final rule on supplemental applications for prescription drug and device labels, American Association for Justice (AAJ) President Les Weisbrod called the FDA action, "irrational and designed to assist the manufacturers."

"Between the drug companies ghostwriting medical journal articles and misrepresenting data to the FDA in order to meet regulations, the agency's action with this rule leaves many people and their doctors in the dark without information about the hazardous side effects of prescription drugs and medical devices. The rule allows drug and device companies to claim complete immunity for failing to warn."

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Background

The rule directly contradicts congressional intent that the duty to warn people of a drug's hazards rests with the drug company, who is in the best position to warn about problems associated with the drug. A law enacted last fall (*the Food and Drug Administration Amendments Act of 2007*) required drug companies to update prescription drug labels to warn consumers of drug hazards at the earliest sign of a problem.

Under this FDA rule, drug companies would only have to update its label after they establish a "causal association" between the drug or device and the hazard, which could take years. This leaves the drug and device companies too much discretion in determining when to include safety hazards on warning labels.

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