Medical Xpress

New medicine insert rules effective Friday

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U.S. pharmaceutical companies this Friday will begin using clearer, more understandable package inserts for some of their newer prescription drugs.

While that might be a positive step in improving medication use, some experts worry the change will make it more difficult to sue drug manufacturers for product liability.

The U.S. Food and Drug Administration requirement calls for more concise and better organized patient information package insert sheets. The inserts will include a table of contents, a toll-free number for reporting of adverse drug events, the initial date of FDA product approval and a section that will summarize some of the most important drug information, including benefits, risks and usage.

Assistant Professor of Pharmacy Practice at Wilkes University in Wilkes-Barre, Pa., Dominick Trombetta, says the new rules will help minimize adverse drug reactions and medication errors.

But Trombetta says he is concerned the label changes will make it more difficult to sue drug manufacturers over product liability.

"FDA's response to drug manufacturer's concerns over increased liability was to include wording that would exempt them from state product liability," a decision he says is "extremely disturbing" and which is likely to be challenged in court.