JONES WALKER

e*bulletin

PRODUCTS LIABILITY

August 2013 Vol. 106 productsliability@joneswalker.com

FDA PROPOSES NEW RULE TO BYPASS *MENSING*

A new FDA rule may allow failure to warn claims against generic drug manufacturers.

Hinted at by the U.S. Food & Drug Administration earlier this Spring, and now forwarded to the U.S. Office of Management and Budget on July 26, 2013, is a new rule that could expose generic drug manufacturers to liability for failure to warn consumers of potential adverse side effects. Since the U.S. Supreme Court's decision in *PLIVA, INC. v. Mensing*, 131 S. Ct. 2567 (U. S. 2011), plaintiffs allegedly harmed by generic drugs have been without remedy against the manufacturers of those drugs in failure to warn claims. *Mensing* held that since generic manufacturers only had to copy the warning labels of a drug's lead brand-name drug manufacturer, state law failure to warn claims against them were preempted.

Now, the FDA has proposed a new rule that will subject generic drug manufacturers to its so-called "changes being effected" ("CBE") rules, allowing a manufacturer to alter its labeling in response to new safety information it learns about adverse reactions to the drug even before the FDA requires that the new information be included. The stated purpose of the rule would be to "create parity between NDA [New Drug Application] holders and ANDA [Abbreviated New Drug Application] holders with respect to submission of CBE labeling supplements." *See* Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, Spring 2013 Unified Agenda & Regulatory Plan, HHS/FDA, RIN No. 0910-AG94 (July 3, 2013).

Although court action would be required to interpret the new rule, if promulgated, commentators seem confident that this "could open the door to lawsuits against generic drug companies for the first time since" the Court initially curtailed such suits in *Mensing*. Katie Thomas, F.D.A. Rule Could Open Generic Drug Makers To Suit, N. Y. Times, July 4, 2012, at B2.

Even if this happens, of course, it will still be months—maybe years—in the making. The proposed rule must clear procedural obstacles before being implemented and it is highly unlikely that the rule would be anything other than prospective in application. After that, litigation with the right set of facts would ensue before we would see an appellate ruling interpreting the rule. Only then will we really know whether the rule will have its anticipated effect.

—Steven F. Casey and David A. Lester

Steven F. Casey is a partner in the firm's Business & Commercial Litigation Practice Group and enjoys a diverse practice involving product liability, mass tort, insurance, business and real estate disputes. He has extensive experience in pharmaceutical, toxic tort, electrical contact, environmental, and aviation cases, having completed over 55 jury trials. Mr. Casey recently successfully defended a generic pharmaceutical manufacturer in the first failure to warn claim to go to trial in the U.S. involving the drug metoclopramide (Reglan®). To continue reading Steve's bio, please click here.

JONES WALKER

e*bulletin

PRODUCTS LIABILITY

August 2013 Vol. 106 productsliability@joneswalker.com

Remember that these legal principles may change and vary widely in their application to specific factual circumstances. You should consult with counsel about your individual circumstances. For further information regarding these issues, contact:

Steven F. Casey
Jones Walker LLP
One Federal Place, Suite 1100
Birmingham, AL 35203
205.244.5282 *tel*
205.244.5482 *fax*
scasey@joneswalker.com

Products Liability Practice Group

Kevin O. Ainsworth
Norman E. Anseman, III
L. Etienne Balart
George (Pete) F. Bloss, III
Emily Sides Bonds
Neville H. Boschert
Melissa A. Campbell
Steven F. Casey
Thomas A. Casey, Jr.
Michele W. Crosby
John L. Duvieilh
Madeleine Fischer
Leon Gary, Jr.
Covert J. Geary
John G. Gomila
Grady S. Hurley
R. Scott Jenkins
William J. Joyce
Luis A. Leitzelar
Michael G. Lemoine
David A. Lester
Joseph J. Lowenthal, Jr.
Christopher S. Mann
J. David Moore
A. Justin Ourso, III
Lara D. Pringle
Keith R. Raulston
James Rebarchak
Lisa A. Reppeto
Joseph Henry Ros
William L. Schuette
Jefferson R. Tillery
Patrick J. Veters
Robert L. Walsh
Alan M. Warfield
Jason R. "Jay" Watkins
V. Walker Wells
Judith V. Windhorst
Amy M. Winters
William P. Wynne
Wayne G. Zeringue, Jr.

To subscribe to other E*Communications, visit http://www.joneswalker.com/ecommunications.html.