

ONE HUNDRED TWELFTH CONGRESS  
**Congress of the United States**  
**House of Representatives**  
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April 11, 2012

The Honorable Margaret Hamburg, M.D.  
Commissioner  
The Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Commissioner Hamburg:

As you know, as a result of last year's Supreme Court decision in *Pliva v. Mensing*, patients who are injured as a result of inadequately labeled generic drugs can no longer seek redress in court.<sup>1</sup> As the Court itself virtually acknowledges, this outcome "makes little sense" since patients who take name brand drugs, rather than generic drugs, do have the ability to sue the manufacturer of that drug and be compensated for their injuries.<sup>2</sup>

Under the Hatch-Waxman amendments, which established the generic drug system in the United States, the generic drug must be the same as the brand drug in most significant respects, including the labeling.<sup>3</sup> Consequently, under FDA's implementing regulations, generic drug manufacturers are not free to change their labeling to add new safety information without first obtaining FDA permission.<sup>4</sup> This prohibition stands in contrast to the requirement in FDA's regulation that brand name manufacturers update their drug labels with important risk information at the earliest possible moment without waiting for FDA's approval.<sup>5</sup> In *Pliva v. Mensing*, the Court concluded that state law claims asserting that a generic manufacturer should have added risk information to the drug label are preempted since, under this regime, generic drug manufacturers are not free to change their labels to include safety information on their own.

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<sup>1</sup> *Pliva, Inc. v. Mensing* 131 S.Ct. 2567 (2011).

<sup>2</sup> *Id.* at 2581, contrasting *Wyeth v. Levine*, 129 S.Ct. 1187 (2009).

<sup>3</sup> *See*, 21 U.S.C. § 355(j)(2)(A).

<sup>4</sup> *Id.*

<sup>5</sup> 21 C.F.R. § 314.70(c).

As I stated in my amicus brief submitted in *Pliva v. Mensing*, it is critical that the principle of sameness in our generic drug system be preserved.<sup>6</sup> In order to have confidence in this system, consumers must know that a generic drug is every bit as safe and effective as its brand-name counterpart. Ensuring that a generic label is the same as the brand label is a critical piece of this sameness principle. An equally compelling interest, however, is that patients who are injured by inadequately labeled drugs have the ability to seek compensation for those injuries in court. These kinds of state tort claims also serve another critical function: they supplement FDA's drug regulations with an additional layer of consumer protection by holding manufacturers accountable for their failure to maintain adequate labeling. As the Administration noted in its amicus brief in this case, FDA has long viewed state tort law as complementing, not obstructing, the goals of the Federal Food Drug and Cosmetic Act.<sup>7</sup>

In my brief, I agreed with the Administration that a balance between these goals might have been attained by permitting state law claims that seek to hold a generic drug manufacturer liable for failing to "take steps" to notify FDA of important safety information that should be added to a generic drug's label—FDA could then order both the generic and the brand labels to be updated.<sup>8</sup> Unfortunately, the Court held that all state law claims against generic manufacturers for inadequate labeling are preempted so long as the manufacturer is unable to change its label on its own.

In order to protect the public health, FDA should respond to the Court's ruling by devising a system that both permits consumers injured by the use of a generic drug to seek a remedy in court and ensures that the labels of generic drugs are the same as those of their brand name counterparts. This is undoubtedly a difficult task but I am confident the Agency can formulate a way to accomplish these dual goals. I am sure that FDA has already begun this thought process.

At your earliest convenience, please provide me with a description of your conception of this revised system and your intentions with respect to implementing it. Please also provide me with a description of any new authorities you believe are necessary to implement this system.

Sincerely,



Henry A. Waxman  
Ranking Member

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<sup>6</sup> Brief for Rep. Henry A. Waxman as Amicus Curiae, p. 9, *Pliva, Inc. v. Mensing*, 131 S. Ct. 2567 (2011).

<sup>7</sup> See, e.g., Brief for the United States of America as Amicus Curiae, p. 10, 12, *Pliva, Inc. v. Mensing*, 131 S. Ct. 2567 (2011).

<sup>8</sup> *Supra* note 6, p. 14.