

State Attorneys General

A Communication from the Chief Legal Officers
of the Following States and Territories:

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Hawaii * Idaho * Illinois * Indiana * Iowa * Kentucky
Maine * Maryland * Massachusetts * Michigan * Minnesota
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Tennessee * Vermont * Virginia * Washington

March 12, 2014

Janice L. Weiner
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave.
Bldg. 51, Room 6304
Silver Spring, MD 20993-0002

Dear Ms. Weiner,

Thank you for the opportunity to submit comments in support of the Food and Drug Administration (FDA)'s proposed rule entitled, *Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products* (78 Fed. Reg. 67985).

The undersigned State Attorneys General support the FDA for taking this critically important step towards enabling generic drug manufacturers to unilaterally update labeling for their products in appropriate circumstances. Consumers deserve a uniform set of rules regarding the prescription medications they depend on. The FDA's proposed rule on generic drug labeling creates the same exact process for a generic drug to update its label using the Changes Being Effected (CBE) process as brand name drugs currently use. The proposed rule enables generic drug manufacturers to utilize an already known process; minimizing their learning curve and also allowing them to initiate safety labeling changes that improve public health, ensuring consumers remain appropriately informed of their products' risks and benefits. In addition, the proposed rule will ensure that state taxpayers are not forced to bear the burden of medical costs caused by defective generic drugs through funding of Medicaid or other state-based health programs. Lastly, the proposed rule will preserve the efficacy of state generic substitution laws that were created in order to make quality healthcare more affordable for state residents.

The FDA's Proposed Rule Improves Generic Drug Safety and Ensures Generic Drug Manufacturers Will Vigilantly Monitor Their Products

The proposed rule allows healthcare professionals and consumers to be made aware of health and safety concerns related to a generic drug quicker than under current regulation. Generic manufacturers will be able to update their safety labeling as soon as they are aware of a potential

hazard instead of waiting for FDA review. We also believe the rule was drafted in such a manner that will minimize the time that a brand and its generic equivalent may have different labels, diminishing labeling confusion.

Overall, the proposed rule also increases safety by encouraging generic drug manufacturers to warn consumers of potential safety hazards. The FDA has limited resources and cannot reasonably be expected to identify all emerging new risks. By reinstating the ability of consumers to bring state law-based tort lawsuits, the FDA ensures that manufacturers remain vigilant and promptly disclose the existence of a new safety risk. Generic drug manufacturers will continue to be required to monitor the safety of their products. This proposed rule neither expands nor contracts this obligation, but the reinstatement of potential tort liability encourages drug manufacturers to be extremely diligent about the safety monitoring required under the regulations. We support the FDA's proposed rule because it encourages generic drug manufactures to follow existing requirements to diligently warn consumers quickly.

The FDA's Proposed Rule Prevents Medical Costs From Shifting to State Tax Payers

Since the Supreme Court decided *Pliva, Inc., Et Al. v. Mensing*, the medical costs of consumers injured by defective generic drugs were shifted to state taxpayers. Consumers are currently unable to hold the wrongdoer financially accountable when harmed by a generic drug. The Medicaid program, which provides medical assistance for persons who cannot afford to pay their own medical costs and is funded in significant part by the states, is bearing the brunt of this shift in accountability. Previously, when consumers were harmed by generic drugs, they could seek redress from the manufacturer in order to pay for resultant healthcare expenses. Under Medicaid's third-party liability provisions, states can recoup Medicaid payments from the tort judgment or settlement. Now, since consumers can no longer hold generic manufacturers accountable in court, they increasingly turn to Medicaid to fund their necessary healthcare. However, once this rule becomes effective, tortfeasors, may once again be held responsible for medical costs caused by the use of defective drugs. This unburdens the states and their taxpayers from responsibility for medical treatment that should rightly be the responsibility of the drug manufacturer.

The FDA's Proposed Rule Protects State Generic Substitution Laws

Access to generic drugs is beneficial to individual patients as well as states and society in general. Generic drugs reduce the cost of treating health issues while increasing access to affordable healthcare. As a result, most states have laws or policies in place that encourage pharmacies to substitute generics for brand-name drugs. In many instances this takes the form of mandating a pharmacist substitute a generic drug for a brand name if one is available. Some states also have permissive generic substitution laws on the books. The purpose of these provisions is to encourage the safe use of bioequivalent drugs at a more reasonable cost. However, the inability of generic drug manufacturers to unilaterally update their safety labelling frustrates the purpose of these state substitution laws. The states' right to implement generic substitution laws and the public interest are protected by the parity that is created by the proposed rule.

Conclusion

Thank you for the opportunity to submit comments in response to the FDA’s proposed rule on *Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products*. We strongly support the FDA’s proposed rule as drafted and urge the FDA to swiftly finalize the new regulation. We believe all drug manufacturers should be actively engaged in monitoring the safety of their products and have the ability to keep the public appropriately informed of a drug’s risks and benefits. We also believe that allowing generic drug manufacturers to unilaterally update their labels will expeditiously inform consumers of drugs’ potential safety hazards, thereby better protecting the citizenry. Furthermore, we believe uniformity should be re-instated so all consumers who are adversely harmed by generic drugs have access to the courts.

Sincerely,



Greg Zoeller
Indiana Attorney General



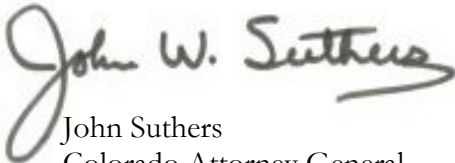
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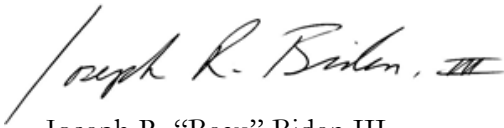
Dustin McDaniel
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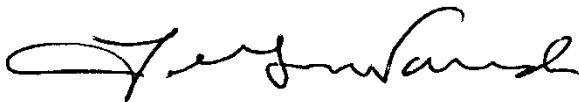
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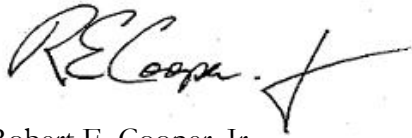
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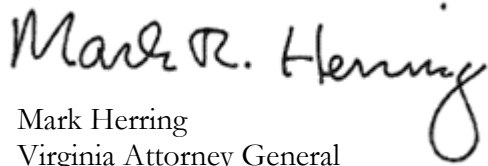
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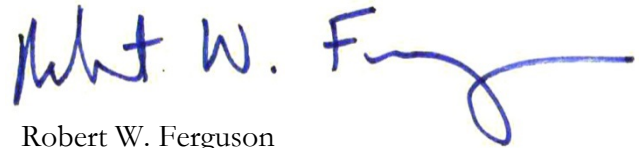
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