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Office of the Attorney General

January 27, 2006

Robert F. McDonnell  
Attorney General

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The Honorable Michael O. Leavitt  
Secretary, U. S. Department of Health & Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Secretary Leavitt:

Please consider this letter as my expression of support for the recent ruling by the Food & Drug Administration regarding incomprehensible prescription drug labels.

The past few years have seen an unfortunate trend toward labels written more for corporate liability protection than for patient care. The main purpose of the label should be to provide concise and accurate medical information which is clearly understood by the patient. The FDA's recent ruling takes a common sense approach to this problem and will ensure that labeling of prescriptions fills its valuable and necessary role.

I also view the FDA's preamble – in which it is clearly stated that the information included on an FDA approved label pre-empts product liability lawsuits based on conflicting state laws – as a sound protection against potential abuses of our judicial system. Labeling should not become a source of mass tort lawsuits. The FDA's language addresses that concern in addition to promoting the laudable medical goals of boosting health literacy and preventing harmful drug interactions.

Please allow me to commend your department and the FDA on the five years of consideration that went into this ruling. It is an important step that properly addresses an urgent situation.

Sincerely,  
  
Robert F. McDonnell

RFM/pdw

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