



## Association for Molecular Pathology

Promoting Clinical Practice, Basic Research, and Education in Molecular Pathology

9650 Rockville Pike  
Tel (301) 634-7939

Bethesda, Maryland 20814-3993  
Fax (301) 634-7990

amp@asip.org  
www.amp.org

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

December 8, 2005

**Re: Department of Health and Human Services**

FDA Docket No. 2005N-0394  
Food and Drug Administration's Communication of Drug Safety Information  
Notice of Public Hearing; Request for Comments

To Whom It May Concern:

The Association for Molecular Pathology (AMP) would like to provide comments to the Food and Drug Administration regarding Communication of Drug Safety Information as requested in Federal Register Docket No. 2005N-0394.

As background, AMP is a national not-for-profit educational society representing over thirteen hundred physicians, doctoral scientists, and medical technologists who perform molecular diagnostic testing based on nucleic acid technology. AMP members practice their specialty in academic medical centers, independent medical laboratories, community hospitals, federal and state health laboratories, and the *in vitro* diagnostic industry. In this capacity AMP members are involved in every aspect of molecular diagnostic testing, administration and interpretation of molecular diagnostic tests, research and development, and education. For the last several years AMP has provided national leadership for the advancement of safe and effective practice and education for molecular diagnostic testing in the health care industry.

This response focuses on Issue #3, for which public comment was solicited. This issue was stated as follows: "Do these tools provide the right kind and information that health care professionals need to make informed decisions about whether to prescribe drug products, and that the public needs to make informed decisions about whether to use those products?"

An important consideration regarding whether to prescribe or use drug products is the individual's inherited variability in drug metabolizing enzymes, receptors or transporters. Such variability can affect the pharmacokinetics of a drug and/or the response to a drug. The FDA has begun to approve drug labeling that includes pharmacogenetic information (e.g. irinotecan and UGT1A1\*28). Corresponding pharmacogenetic tests to predict drug response are now available through clinical laboratories for several well characterized variants known to affect specific drug metabolism, with the potential for a poor clinical outcome. We recommend that the FDA's communication tools include relevant pharmacogenetic information for a drug's metabolic or signaling pathway, particularly when (or as) genes with detrimental allelic variants are known, and when (or as) dosing recommendations or adjustments to standard doses based on the presence or absence of such variants are proposed.

We thank the FDA for the opportunity to comment on this important issue of communication of drug safety information. Please contact the AMP Professional Relations Committee Chair, Deborah Leonard, MD, PhD at [dgl2001@med.cornell.edu](mailto:dgl2001@med.cornell.edu) if we can provide further information.

Sincerely,

Mark A. Lovell, MD  
President