



ASSOCIATION FOR MOLECULAR PATHOLOGY

Education. Innovation & Improved Patient Care. Advocacy.

9650 Rockville Pike. Bethesda, Maryland 20814

Tel: 301-634-7939 | Fax: 301-634-7995 | amp@amp.org | www.amp.org

May 13, 2014

Jeffrey E. Shuren, MD, JD
Director, Center for Devices and Radiological Health
U.S. Food and Drug Administration

Via Email: jeff.shuren@fda.hhs.gov

Dear Dr. Shuren:

The Association for Molecular Pathology (AMP) is an international medical and professional association representing approximately 2,300 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics and genomics. Membership includes professionals from academic medicine and community medical centers, commercial reference laboratories, the government, and the *in vitro* diagnostics industry.

We note the approval of the Roche cobas® HPV test and applaud FDA's continued investment to rapidly review submissions and supplements for molecular tests. While we support the use of HPV testing as a first-line primary cervical cancer screening test, we are very concerned about the inclusion of medical practice recommendations in the revised Indications for Use.

The approval letter to Dr. David Gates, dated April 24, 2014 and online at http://www.accessdata.fda.gov/cdrh_docs/pdf10/p100020s008a.pdf, includes the following in indication #5:

“...Women who test positive for HPV genotypes 16 and/or 18 by the cobas® HPV Test should be referred to colposcopy. Women who test high risk HPV positive and 16/18 negative by the cobas® HPV Test (12 other HR HPV positive) should be evaluated by cervical cytology to determine the need for referral to colposcopy.”

Although these recommendations are consistent with current clinical practice guidelines, such guidelines are and should be established and issued by relevant professional societies, and they often change over time. FDA has acknowledged that the Food Drug and Cosmetic Act was not intended to regulate the practice of medicine. In providing guidance to institutional review boards and clinical investigators regarding off-label and investigational use of marketed drugs, biologics, and medical devices the Agency has stated, “Good medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices according to their best knowledge and judgment.” (See <http://www.fda.gov/RegulatoryInformation/Guidances/ucm126486.htm>). However, including medical practice recommendations in a device product label, even when consistent with accepted clinical practice, violates these principles by making FDA an arbiter of medical decision-making.

Therefore, we respectfully request that FDA prohibit the inclusion of patient management instructions or other medical recommendations in the product labeling for in vitro diagnostic tests.

If you have questions, please contact Mary Steele Williams, AMP Executive Director, at mwilliams@amp.org. Thank you very much for your consideration of our concerns.

Sincerely,

A handwritten signature in black ink that reads "Elaine Lyon". The signature is written in a cursive, flowing style.

Elaine Lyon, PhD
President

Cc:

Alberto Gutierrez, PhD (via Email: alberto.gutierrez@fda.hhs.gov)

Margaret A. Hamburg, MD (via Email: margaret.hamburg@fda.hhs.gov)