

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20857



August 4, 2006

The Honorable Andrew C. von Eschenbach, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

The nation's public health laboratory directors welcome the opportunity to comment on the interim final rule on *Medical Devices: Exception from General Requirements for Informed Consent*. The directors are the principal members of the Association of Public Health Laboratories (APHL), an association that advocates a strong public health system that integrates public health laboratories as a vital resource for protection against diseases and other health threats. APHL connects the public health laboratories in all 50 states and six territories.

APHL is very pleased that the FDA has issued this interim final rule and believes that it will greatly improve the ability of public health laboratories to respond to a public health emergency by providing an exception from the requirement to obtain informed consent prior to conducting analyses of patient specimens when using investigational devices. We would request some additional clarification that could substantially benefit the implementation of the rule.

We would be very interested in learning whether the term "investigator" can be used to identify the single entity that is associated with the initial deployment of the investigational device. Doing so would also enable the use of a centralized institutional review board; both developments would considerably relieve the burden of the reporting requirements by the end user of the investigational device. We would also encourage the production of templates, developed collaboratively with the public health laboratory community, which could be used to easily provide the detailed information required to be included in the reports.

Additionally, we would encourage further consideration of extending the requirement that the written certification for the exception be submitted within 5 working days of the use of the investigational device again with the goal of easing the reporting burden, and we would be happy to participate in any further discussions on this matter.

Once again, we are very pleased that the FDA has taken this step and we stand ready to assist in its implementation of the rule. Please contact Peter Kyriacopoulos at APHL at 240.485.2766 or peter.kyriacopoulos@aphl.org should you have any questions. Thank you.

Best regards,

Handwritten signature of Jane P. Getchell in black ink.

Jane Getchell
President, APHL

Handwritten signature of Scott J. Becker in black ink.

Scott J. Becker
Executive Director

8815 Georgia Avenue
Suite 700
Silver Spring, MD
20910-3403

240.485.2745 phone
202.485.2700 fax

www.aphl.org