

January 29, 2007

Division of Dockets Management
HFA-305 Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20850

RE: 2006D-0336 (For ASR Guidance)
2006D-0347 (For IVDMIA Guidance)

To Whom It May Concern:

The Association of American Physicians and Surgeons is a national organization of physicians in all specialties, founded in 1943 to preserve and promote the practice of private medicine, the sanctity of the patient-physician relationship, and ethical medical practices. According to the Oath of Hippocrates, physicians are obligated to prescribe for the good of their patients according to the best of their ability and judgment.

We are very concerned about the potential destructive impact of the proposed guidance, for several reasons:

1. Professional discretion is essential if the medical profession is to serve individual clinical needs. The guidance constitutes regulation of the practice of medicine.

Physicians undergo a very lengthy period of rigorous education, including scientific reasoning and standards. They have long been recognized as independent professionals. Professional discretion is necessary, as the FDA has long recognized, in order to competently serve the needs of patients. There is tremendous individual variation in clinical problems as they present and in the individual responses of patients to various

diseases and other insults. Increasingly, we are recognizing tremendous biochemical individuality, and differences in the response of patients to therapeutic regimens, particularly drugs, based on genetic variability.

This guidance would not only deprive physicians of the clinical tools that they need to meet their patients' needs, but new regulations encroach upon the practice of medicine itself. The FDA is supposed to be regulating products, not services. But with this guidance, it appears to be trying to declare which methods of mathematical analysis may or may not be used by professionals!

2. Innovation is needed to meet new threats

Human health is endangered by an increasing array of new threats, as microorganisms adapt to antibiotics, and as mutant organisms, including influenza viruses or vector-born diseases such as West Nile Virus, gain the ability to proliferate rapidly throughout the world as a consequence of modern transportation. Genetic engineering also raises the sinister threat of bioengineered organisms being used as terrorist weapons. Of course, there is the AIDS epidemic, the manifestations of which appear to be rapidly changing.

As diseases change, physicians must have the ability to respond rapidly. Physicians' ability to serve their patients well would be crippled without innovation in laboratory testing and data analysis. This innovation can only be achieved if laboratories are able to use their personnel, facilities, and other resources in creative, efficient ways determined by the needs of the clinical situation, rather than rigid and ambiguous bureaucratic diktat.

3. The FDA lacks the statutory authority to expand its power as contemplated in the guidance.

We are strenuously opposed to the FDA overreaching its statutory authority and attempting to regulate laboratory-developed tests that have previously been explicitly exempt.

4. The proposed guidance will stifle innovation.

Neither scientists nor investors will have any interest in using their talents and resources in ways that could be instantly stifled at bureaucratic whim.

It appears that the FDA's new proposed regulations will not only make it more difficult and expensive for laboratories to comply, but may make it altogether impossible to comply with conflicting demands from the FDA and the Centers for Medicare and Medicaid Services under the Clinical Laboratory Improvement Act.

It is highly improbable that the intent of Congress was to freeze medical progress, or that statutes having that effect would have any public support.

Our member physicians and the millions of patients that they serve need access to innovation, including laboratory-developed tests, and also the freedom to practice their profession without constant fear of violating ambiguous bureaucratic guidelines concerning allowable methods for diagnosing or analyzing a problem.

6. The proposed guidance will increase the cost of innovation, already extremely burdensome, possibly to insupportable levels.

We know that lifesaving drugs have been delayed by years or decades because of FDA requirements and that the cost of bringing a new drug to market has rapidly escalated to

the point that it is not profitable to develop any but potential blockbuster drugs.

Everyone is concerned about the high and rising cost of medical care. Regulation makes a tremendous and a usually unacknowledged contribution to these costs. A large portion of the regulatory burden is counterproductive. We believe that the FDA should not be allowed to impose new regulations without employing the equivalent of evidence-based medicine to show that the regulations do not do more harm than good, with the waste of resources being included in the calculation of harm. No such methodology has been applied to the proposed guidance.

7. The net effect of the guidance is likely to imperil patient safety rather than improving it.

The FDA attempts to justify the delays and regulatory barriers as necessary to protect patient safety. Its record of protecting safety is not impressive, as recent drug recalls have shown, but it never even attempts to calculate the lives that are lost because better products are prevented from entering the marketplace—some of them permanently because the cost barrier cannot be overcome. The cost of a regulatory delay needs to be measured in lost lives as well as dollars.

Conclusions

In summary, we agree with the concerns expressed by the Coalition for 21st Century Medicine that the new FDA guidance documents are impermissibly vague, and also are in violation of existing statutes such as the Administrative Procedure Act. Their effect will be to increase costs enormously, while decreasing physicians' ability to serve clinical needs. The proposed changes would impose an unlawful straightjacket upon clinical

practice. They would force laboratories, if they continue to function at all, to develop wholly new, expensive, and nonproductive infrastructures in an effort to do what is impossible to begin with, namely to comply with conflicting obligations.

The FDA has not stated a problem that this guidance is supposed to solve. In fact, it apparently cannot even define terms such as "service," "product," and "device" in a clear and rational manner.

This guidance should simply be rejected in its entirety. If the FDA is able to define a problem, then new guidance to address the need in the least costly and intrusive manner, in compliance with existing law, should be proposed.

Presented by Michael Ostrolenk
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