



August 7, 2006

Jeffrey Shuren  
Assistant Commissioner for Policy  
Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**RE: Interim Final Rule on Medical Devices; Exception from General Requirements for Informed Consent (Docket No. 2003N-0355)**

Dear Mr. Shuren:

The Health Privacy Project is dedicated to raising public awareness of the importance of ensuring health privacy in order to improve health care access and quality, both on an individual and a community level. We also recognize and appreciate the potential serious threats to public health and security and do not want to act as a deterrent to immediate action were an emergency to occur. That said, the Health Privacy Project believes that the referenced rule issued by FDA concerning the exception of informed consent in cases requiring in vitro diagnostic devices when a public health emergency is suspected does not adequately take into account the seriousness of the harms that can be experienced by persons whose privacy is violated. The Health Privacy Project therefore strongly urges FDA to amend the exception rule to more appropriately reflect the principle of privacy as a fundamental individual right and the critical role of health privacy in delivering effective, high quality health care.

We submit the comments below in response to the interim final rule establishing “an exception to the general rule that informed consent is required for the use of an investigational in vitro diagnostic device for the purpose of preparing for and responding to a chemical, biological, radiological, or nuclear terrorism event or other public health emergency.” We understand that this interim rule is already final, but we urge the Assistant Commissioner to include our recommendations in a modification to this rule or in further installments of the rule.

The Health Privacy Project’s primary concern with the rule is the vagueness of terms. While it is reassuring that substantial attention is being paid to the threat of public health emergencies and we appreciate specific examples such as “chemical, biological, radiological, or nuclear terrorism event,” the term “other public health emergency” is highly troubling. These words, in effect, give FDA a carte blanche to deem any questionable event as an instance to revoke the informed consent requirement. Were

August 7, 2006

Jeffrey Shuren

Page 2

FDA to remove those words or enumerate further, it would give us, and the public, a higher level of comfort that people's privacy rights would not be infringed without a specific reason consonant with the rule's purpose.

Another of our concerns lays in the assertion that an exception is allowed if "obtaining informed consent from the subject is not feasible because there was no way to predict the need to use the investigational device when the specimen was collected, and there is not sufficient time to obtain consent from the subject or the subject's legally authorized representative." The Health Privacy Project understands the immediacy required in testing for chemical, biological, and nuclear agents. However, we don't think that it should come at the cost of personal health privacy. Therefore, we propose that the informed consent documents include the possibility of in vitro diagnostic device testing.

If the informed consent documents had a line for in vitro diagnostic device testing, with the understanding that it was a possible rather than definite step, anyone who gave their consent in advance would not need to be contacted; thereby eradicating the problem of contacting subjects in time to perform the test. With this inclusion, only subjects who did not give their informed consent would need to be contacted. This change would cut down on the number of people whose medical records were accessed without informed consent as well as reduce the time and money lost to attempting to contact subjects.

Take the two examples that FDA provided, one in which "...the referring laboratory would not have obtained informed consent when the specimen was collected because the person directing that the specimen be collected would not have known at the time that the infecting organism could be reliably identified only by using an investigational device," and another where "the emergency nature of the event may or may not be suspected at the time the specimen is collected, and the laboratory involved may or may not be a public health laboratory." Had there been a line for in vitro diagnostic device testing on the informed consent documents that the patient originally signed, and he or she had given the affirmative, neither of these examples would pose a problem.

The Health Privacy Project's third and final concern with the interim rule is the paragraph, "[i]n addition, subjects or their legally authorized representatives will not be entitled to withdraw previously collected data from the research database, because it is critical that FDA obtain and have available for review all data on the investigational in vitro diagnostic device's use in order to determine whether it is safe and effective." While FDA product testing is critical, it cannot come before the people's right to health privacy. This exception in particular sets a dangerous precedent by allowing government research to take priority over personal privacy. As is evident by the recent disclosure of NSA activities, the American public does not take well to their privacy being violated, no matter what result the intrusion is a means towards.

The purpose of 21 CFR Part 50--Protection of Human Subjects is to do just that, protect human subjects. While protecting the public from health emergencies falls within that

August 7, 2006

Jeffrey Shuren

Page 3

heading, so does protecting individuals from having their sensitive medical information used or disclosed inappropriately and from the harm that can result from a violation of the privacy rules, which will be borne almost exclusively by the individual whose sensitive medical information is misused or unlawfully disclosed. The Health Privacy Project believes that there are a number of ways that FDA can improve the final interim rule on Exception from General Requirements for Informed Consent by strengthening privacy provisions without sacrificing public health and safety. We recommend that the rule be modified to:

1. Remove the phrase “other public health emergency” altogether or specify in exact terms what constitutes a public health emergency worthy of this extraordinary exemption from informed consent;
2. Include a line regarding in vitro diagnostic device testing on the informed consent documents that the exception from general requirements should only be relevant if the subject chose not to give informed consent, in which case the same conditions can apply; and
3. Eliminate the clause that prevents subjects or their legally authorized representatives from withdrawing previously collected data from the research database.

The Health Privacy Project recognizes the importance of proactive public health and safety measures to ensure that America is prepared in case of a national or local disaster. However, we encourage you not to let this sense of urgency overshadow the importance and value of individual privacy. We have laid out three suggestions to better incorporate health privacy into the interim rule without sacrificing public health and hope you will seriously consider them and include them in further modifications of the rule.

Thank you for the opportunity to submit these comments.

Sincerely,

Janlori Goldman  
Director

August 7, 2006  
Jeffrey Shuren  
Page 4