EMORY HEALTHCARE

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

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Re: Proposed Disclosure of Clinical Trial Information (Docket No. 00N-0989)

Dear Sir or Madam:

I am an orthopaedic surgeon involved in human gene therapy studies at Emory University. I'm aware that FDA has proposed requiring sponsors of clinical studies related to human gene therapy or xenotransplantation to make certain information regarding those studies publicly available. I understand that the goal of the proposal is to promote communication among patients and doctors regarding these studies, and to inform potential study participants of the risks involved. As a physician and clinical investigator, I have several concerns regarding the proposal.

First, let me say that I admire FDA's goal of improved communication regarding clinical trials. Moreover, in light of the recently publicized tragedy involving a University of Pennsylvania gene therapy trial, I understand FDA's desire to protect study participants. On the other hand, I do not agree with FDA's proposal for achieving these goals. There are ample measures in place to ensure that clinical trials are conducted safely and that participants and others responsible for protecting the public health are fully informed of the risks. For example, as an investigator, I must obtain the informed consent of every study participant, communicate with the sponsor regarding the status of the study including adverse drug experiences and share information with the IRB in order to ensure the safety of participants. I understand that this information is also conveyed to FDA. In my opinion, using FDA's resources to enforce these, and other, existing good clinical practice requirements is the best way to ensure that clinical study participants -- and others charged with protecting the welfare of patients -- are well-informed.

In addition, I believe that disclosing information on the Internet regarding clinical studies will not enhance the safety of study participants, nor their understanding of clinical trials. First and foremost, I am concerned that the physician-patient relationship is undermined by FDA's proposal. Specifically, by providing potential study participants with the name and address of the sponsor of a particular clinical trial, FDA is inviting them to contact the sponsor directly to determine whether they are eligible for the study. As a result, there is a significant danger that patients will be discussing their treatment with a manufacturer (who has a commercial interest in having patients enroll in a study) rather than their own physician and the investigator. Not only does this undermine the physician-patient relationship, it also puts the sponsor into the position of practicing medicine.

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In addition, as opposed to informing study participants, I fear that FDA's proposed disclosure of clinical study information more likely will confuse patients for a number of reasons:

- First, it is my understanding that under FDA's proposal, the informed consent form that was submitted to FDA will be made publicly available. In my experience, IRBs often revise the original informed consent submitted to FDA for use at their particular site. As a result, current and future study subjects may be viewing a significantly different informed consent on the Internet than the one that they did or will sign. At the time that a participant signs an informed consent, the scope and extent of the consent is explained to him or her. Providing a different informed consent on FDA's website, particularly without the opportunity to ask questions, will only serve to mislead or confuse study participants or future participants.

- Second, I have similar concerns with regard to providing future study participants with a description of the treatment that will be administered to patients during the study. Particularly, I am concerned that people viewing the information will not understand that not all study participants will receive treatment. When a physician discusses with a patient the potential for participating in a clinical trial, he or she explains that there is a possibility that the patient will be in a control group. Even if the material posted on the Internet discusses control groups, it will be impossible to ensure that potential study participants fully understand that they may not receive the experimental therapy during the study.

- Third, I am concerned that publicly disclosing information about clinical trials involving xenotransplanation will create unwarranted concerns in the minds of potential study participants. As I noted above, the recently publicized University of Pennsylvania tragedy occurred during a gene therapy clinical trial. While I don't believe the incident justifies such a sweeping proposal by FDA with regard to gene therapy trials, it certainly does not justify applying the proposal to xenotransplantation studies. This is particularly true with regard to clinical trials that involve xenotransplants that have been considered safe for years as carriers. As opposed to educating the public, suggesting that such a clinical study poses unusual health risks will only create unwarranted fear among potential study participants.

In sum, my concerns regarding the proposed disclosure of information regarding clinical trials on the Internet stem from a belief that the most effective method of informing patients regarding healthcare issues is through direct communication with a healthcare professional. Disclosing clinical trial information on the Internet will only serve to foster unwarranted hope or concern about new treatments in the minds of patients. Combined with the danger of patients substituting the disclosed information for one-on-one communication with their healthcare provider, the effect of FDA's proposal will likely be to confuse, rather than inform, the public.

Thank you for the opportunity to provide these comments.

Sincerely,

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