

November 27, 2006

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Conduct of Emergency Clinical Research

Dear Sir or Madam:

On behalf of the Medical Device Manufacturers Association (MDMA), a national trade association representing the innovative sector of the medical technology market, I am submitting these comments in response to the Food and Drug Administration's ("FDA's") recently published Federal Register Notice on the Conduct of Emergency Clinical Research.¹ MDMA is particularly interested in ensuring that FDA eliminates the confusion caused by the existing regulations. This is critical in order to advance emergency medicine clinical research in unconscious patient's presented with cardiac arrest, stroke (who are comatose), traumatic brain injury and other life threatening medical conditions.

MDMA is concerned that confusion over the current regulations has discouraged appropriate emergency research and, by making it difficult to follow up with subjects after treatment, sometimes failed to protect patients. For example, the number of published cardiac arrest trials in the United States has decreased since the guidelines were implemented, while the number of non-US studies grew.

The existing community consultation process should also be enhanced moving forward. While we support ensuring that patients and patient groups have all the necessary information, the current system often provides information that is not easily understood outside the medical profession. As a result, moving forward emphasis should be placed on making the community consultations geared more toward practical risks and benefits of the treatment. This would meet the intended goal of the consultation and benefit all parties involved.

In closing, MDMA appreciates FDA issuing a draft guidance entitled "Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors; Exception from Informed Consent Requirements for Emergency Research". Greater clarity in this area is necessary to ensure that patients are not denied access to innovative treatments and therapies that have the potential to significantly improve the outcomes for those most in need.

Sincerely,



Mark Leahey
Executive Director
Medical Device Manufacturers Association

¹ 71 Fed. Reg. 51143 (Aug. 29, 2006).