Parallax
Medical Inc.

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May 6, 2003

Dockets Management Branch
(HFA-305), Docket No. 02N-0475
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Comments on Draft Guidance on Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection
(Docket No. 02N-0475)

To Whom It May Concern:

Parallax Medical Inc. is pleased to submit comments in response to the FDA's Draft Guidance for "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection", Docket No. 02N-0475.

Parallax Medical is a medical device manufacturer of disposable implantable devices and materials for percutaneous injection of bone cement, opacification materials, polymethylmethacrylate for cranioplasty, bone and vertebral body biopsy needs and patient preparation.

As a small medical device company, the business relationships with physicians and researchers have been integral to the design of devices and to clinical studies. The proposed change to the current guidance to institute a third party in obtaining patient consent poses an added financial burden to the small device company undergoing clinical trials and, ultimately, may hinder the study's progress and work with investigators.

Parallax Medical appreciates the efforts by the FDA to provide additional considerations in the proposed new guidance. Parallax Medical maintains that the current regulatory requirements contain measures for financial disclosure and patient protection for research involving human subjects.

Sincerely yours,

Irma Barr

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