ENGLEWOOD
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March 1, 2000

Docket No. 99D-4910, Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

RE: CFR 900.12 (b)(8)(i)

To Whom It May Concern:

I would like to speak against the requirement for the fine adjustment compression controls operative from both sides of the patient.

Many mammography machines that otherwise comply with all FDA regulations would have to be removed from service if this requirement goes into effect. I believe that this is an onerous requirement for two reasons:

First, I do not believe that the fine adjustment control provides any significant improvement in the quality of the mammographic image. The amount of change in compression is miniscule. As a very experienced mammographer, I do not believe that this specific requirement will help diagnose any more breast cancers.

Second, the cost of this requirement is prohibitive. There is not some simple piece of add-on equipment that can make otherwise good machines compliant. Entire units would have to be replaced at a cost of approximately $80,000.00 each. I truly believe that this cost is not justified for such a questionable benefit. This requirement could drive some privately owned breast imaging centers out of business, decreasing access to high-quality mammograms. It seems to me that this result is contrary to the goal of the MQSA.

Please consider my comments in drafting the final regulation. I would like to be personally contacted with your decision.

Sincerely,

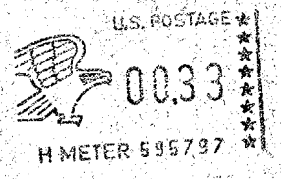
Raul R. Verde, M.D.

RRV/del

99D-4910

C12

700 Medical Boulevard, Englewood, Florida 34223



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