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Docket No. 99D-4910, Dockets Management Branch
Division of Management Systems & Policy
Office of Human Resources & 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 operable from both sides of the patient.

A significant number of 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:

1. I do not believe that the fine adjustment control provides any significant improvement in the quality of the mammographic image. When I first saw this proposed requirement, I had my technologist (who is quite experienced with the GE DMR machine) perform one of the CC views with the usual compression she would obtain using the foot pedal. Then, without moving the patient, she would add the manual fine adjustment and repeat the view. The amount of change in compression was minuscule, and I see no difference in the images. As a very experienced mammographer, I do not believe that this specific requirement will help diagnose any more breast cancers.
2. 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 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,



Rafael Aponte-Lopez, M.D.

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