

# Largo Medical Center

A New Commitment to Healthcare... Together

2796 '00 MAR -6 P1:34

March 2, 2000

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.

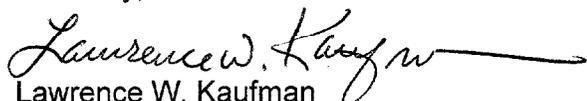
Many mammography machines that otherwise comply with FDA regulations would have to be removed from service if this requirement goes into effect. I believe that this is an onerous requirement for two reasons:

1). I question that the fine adjustment control provides any significant improvement in the quality of the mammographic image. After reading about this proposed requirement, I discussed this with my Imaging Medical & Technical Director, who have researched this with several technologists (who are experienced with the GE DMR machine). All are in agreement that the amount of change in compression is minute as well as the minimal difference in images obtained. This leads me to believe that this specific requirement will not help to diagnose any more breast cancers.

2) In reference to the GE DMR machine, our technologists personal experience with the usual foot pedal compression compared to adding the manual fine tune adjustment, is that there is no change in image quality. Again, I do not believe that this specific requirement will help diagnose more breast cancers.

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

Sincerely,

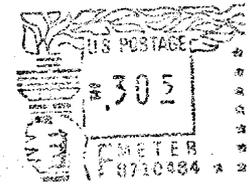
  
Lawrence W. Kaufman  
Administrator/COO

99D-4910

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Administration

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