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CANCER INSTITUTE

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# THE COMPREHENSIVE BREAST CENTER

at Good Samaritan Medical Center  
March 2, 2000

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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:

On behalf of Good Samaritan Medical Center in West Palm Beach, Florida, I would like to speak against the requirement for the fine adjustment compression controls operable from both sides of the patient.

Good Samaritan Medical Center owns two mammography machines that otherwise complies with all FDA regulations. If this requirement goes into effect, the facility will be forced to remove the two machines from service.

Our radiologists do not believe that the fine adjustment control provides any significant improvement in the quality of the mammographic image. We have conducted several test images with our other machines which have manual fine adjustment and the machines which do not. The experienced Radiologists did not interpret any differences in the images.

The cost of replacing the mammography units would be approximately \$80,000 per unit. In order to continue to provide mammography to all women in the community, I believe the cost is not justified for a questionable benefit.

Please consider the above comments before issuing a final regulation.

Sincerely,



Melanie Nielsen  
Manager, Norma E. and Miles M. Zisson Comprehensive Breast Center  
Good Samaritan West Diagnostic Center

99D-4910



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