

Tufts Mammography Center

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FEBRUARY 29, 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 OBJECT STRONGLY AGAINST THE PROPOSED POSSIBLE REGULATION CFR 900.12 (B)(8)(I).

MANY VERY GOOD MAMMOGRAPHY MACHINES THAT OTHERWISE COMPLY WITH ALL FDA REGULATIONS WOULD BE REQUIRED TO GO OUT OF USE IF THIS REQUIREMENT BECOMES RULE.

THIS IS SCIENTIFICALLY NOT JUSTIFIED AS THE NECESSITY OF FINE TUNING COMPRESSION ADJUSTMENTS ON BOTH SIDES IS NOT NECESSARY FOR VERY GOOD MAMMOGRAPHY.

I HAVE SURVEYED MY SIX FULL-TIME MAMMOGRAPHY TECHNOLOGISTS, WHO HAVE 75 YEARS COMBINED EXPERIENCE DOING NOTHING BUT EXCELLENT MAMMOGRAPHY, AND THEY AGREE THIS REQUIREMENT OF FINE ADJUSTMENT COMPRESSION CONTROLS OPERABLE FROM BOTH SIDES OF THE PATIENT IS NOT NECESSARY TO PRODUCE CONSISTENTLY GOOD MAMMOGRAMS.

FURTHERMORE, THE COST OF THIS REQUIREMENT IS PROHIBITIVE. TO REPLACE GOOD MACHINES IN THE NEIGHBORHOOD OF \$60,000-\$90,000 FOR SUCH A REQUIREMENT THAT IS SCIENTIFICALLY NOT NECESSARY, IS MUCH TOO ONEROUS FOR BREAST IMAGING CENTERS TO SURVIVE IN THIS DAY AND AGE OF REDUCED, IF ANY, COST OF LIVING INCREASE IN REIMBURSEMENT.

PLEASE CONSIDER THESE THOUGHTS IN DRAFTING THE FINAL REGULATIONS.

SINCERELY,



T.W. TUFTS, M.D., F.A.C.R.
FORMER CHAIRMAN MAMMOGRAPHY COMMITTEE
FLORIDA RADIOLOGICAL SOCIETY 1991-1995

TWT/SGH

99D-4910

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ISS#1606 FT LAUDERDALE FL 33301 FEB 20 2000

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