



Food and Drug Administration
Rockville MD 20857

The Honorable Lauch Faircloth
United States Senate
Washington, D.C. 20510-3305

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Dear Senator Faircloth:

This is in response to your letter of December 1, 1997, on behalf of Mr. Eugene Stewart, President of Triad Radiographic Imaging, Winston-Salem, North Carolina, regarding proposed rulemaking with regard to refurbishing of used radiographic equipment. We apologize for the delay in our response.

The Food and Drug Administration (FDA or the Agency) published the enclosed Advanced Notice of Proposed Rulemaking (ANPR) in the Federal Register of December 23, 1997 (62 FR 67011). The ANPR outlines the current limited regulatory authority over refurbished devices and requests comments from the user community regarding the need for further regulatory control. It also requests suggestions for alternative regulatory approaches for refurbishers and/or servicers.

FDA has made a special effort to inform both the user community and the industry of the ANPR because it is extremely important for those who will be potentially affected to make their views known. The Agency has suggested in the ANPR and in public speeches that it would entertain proposals from the refurbishing industry for independent third party involvement. In addition, we have accepted an offer from the Association for the Advancement of Medical Instrumentation to conduct a consensus conference in September of this year. This conference will present an additional forum for all parties to present their views.

FDA is committed to reviewing all comments and carefully considering the impact of any proposed regulatory approach. Prior to adopting a regulatory approach, FDA will publish a proposed rule in the Federal Register specifically outlining that approach and asking for comments. We have forwarded Mr. Stewart's letter to FDA's Dockets Management Branch for appropriate consideration in further development of this proposed rulemaking.

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We hope this information is helpful. If we may be of any further assistance, please let us know.

Sincerely,

Diane E. Thompson
Associate Commissioner
for Legislative Affairs

Enclosure

cc: Dockets Management Branch
(Docket #97N-0477)

United States Senate

WASHINGTON, DC 20510-3305

December 1, 1997

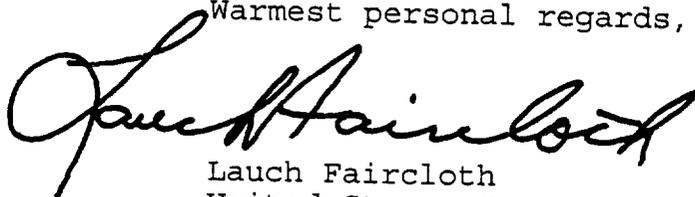
The Honorable David A. Kessler
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Commissioner Kessler:

Enclosed, you will find a letter from my constituent, Mr. Eugene Stewart, about his concern for proposed rule making with regard to radiographic equipment.

I appreciate your looking into this matter as soon as possible and will anticipate your timely and informative response. I look forward to hearing from you.

Warmest personal regards,



Lauch Faircloth
United States Senator

LF:kw
enclosure

No. 97-9678

TRIAD RADIOGRAPHIC IMAGING

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27 October 1997

The Honorable Lauch Faircloth
United States Senate
Washington, D.C. 20510-3305

Dear Senator Faircloth:

Many thanks to you and your fellow Republicans for your efforts to control both the size of government and the regulatory efforts by some federal agencies to stifle creativity and competition. The last is particularly referenced to the Food and Drug Administration.

I am writing in this instance to seek your advice and help on behalf of several concerns. With this letter, I am wearing four hats, all of which will be of interest to you. Ours is a small business in the x-ray equipment sales and service industry providing a low cost alternative for small hospitals, physician practices and clinics when they acquire capital x-ray equipment--that is hat one. A second identity is that our company is a wholly-owned, for-profit subsidiary of The North Carolina Baptist Hospitals and reports to a Board of Directors of which Len Preslar, President, is Chairman. A third hat is that we are an active member of an organization of like-minded used and reconditioned medical equipment suppliers, The International Association of Medical Equipment Remarketers, who attempts to fathom the broad-stroke regulatory efforts by the FDA regarding the industry. And, fourthly, I am your constituent.

In August of 1995, I copied you with a letter to the FDA regarding our opinions about its active efforts to bring under its regulatory authority an industry which provides cost-constraining products and services to the medical market place. You were kind enough to respond and your support is appreciated. Recent events indicated that our work is not done. While working with, and keeping abreast of, the FDA's activities, our vice president, Mr. Fred Farmer, and I have attended every meeting of which we are aware related to the difficult issues of what level of regulation is necessary for our industry. Fred's recent attendance at a meeting in Birmingham of servicers and installers of imaging equipment (who must already comply with 21CFR covering ionizing radiation products and the Medical Devices Reporting rules) and FDA enforcement personnel gave us pause about the direction such regulation will take. He and I also recently met in New Orleans with the IAMER trade group at which two administrators from the FDA presented further evidence. It is important for you to

note, as stated by Wesley Morgenstern (of the Washington office of the FDA, Center for Devices and Radiological Health) in his part of the program, that there is no record of a patient ever being hurt or killed during the use of reconditioned medical equipment.

While there is no doubt that many of the roles played by the FDA are directed toward assuring the public of a safe medical environment, there also appear to be other factors at work in their attempt to further regulate our industry. The growth of the used and reconditioned equipment industry apparently is threatening to large manufacturers of capital medical equipment. In short, they appear to perceive our industry as a source of vigorous competition on their turf. To that end, we have been told privately, they continue to lobby both Congress and the regulators for rules that would have the effect of eliminating that source of competition. Interestingly, some manufacturers, particularly General Electric Medical Systems, have begun actively offering reconditioned equipment themselves, recognizing that the pressures on providers to restrain cost in a rapidly evolving patient care environment is intense and growing.



Comments at the Birmingham meeting by enforcement staff of FDA seem to reflect the success of the manufacturers' efforts. The pending announcement of proposed rule making due in the Federal Register within the next few weeks, they imply, will provide them with means to enforce a set of rules (originally designed to regulate new equipment manufacturers) on used and reconditioned equipment suppliers as well. They expressed the opinion that a small dealer such as our company will need to provide and document the same certification procedures required of the original manufacturer even if a company reconditions previously certified equipment. The aim, freely admitted, is to reduce the potential liability of the manufacturers in the event of injury or death of a patient. At the same time, the reconditioning company must follow the exact test methods of the manufacturer using test equipment specified by that manufacturer even if the reconditioning company does no more than restore the equipment to its original specifications. Unfortunately, there appears to be no requirement placed on the manufacturer to provide the complete package of information necessary to comply. One inspector even ventured the opinion that in the first year following installation if a non-compliance item is noted during a facility inspection by either contracted state or federal inspectors, regardless of the practitioner's handling of the equipment, the reconditioner will be held responsible for no-charge repairs. This federally mandated "warranty," thought of little consequence to us since we provide a true warranty, is not even required of new equipment manufacturers. A second inspector stated that the equipment should be re-labeled by the reconditioner after removing the original manufacturer's label. Then the reconditioner would be required to re-certify that previously certified system by the same standards under which the system was certified in the first place. Is this last a hoop through which one should need to jump?

Senator Faircloth, the process our company employs is painstaking and thorough. We dis-assemble the systems we purchase from other hospitals and physicians, completely inspect and correct problems and re-assemble the systems to their stated specifications, install and warranty them. It can benefit no institution or patient for us then to laboriously re-document the certification of each component within the system. That will only serve to increase the cost of the equipment, defeating the true value of the reconditioning process. The institutions, mostly smaller hospitals facing severe financial pressures, would be forced to make do with older, less serviceable imaging equipment because they cannot afford the new equipment the manufacturers are, for the most part, in the business of selling. The net effect of requiring of reconditioners the same documentation and processes that an original equipment manufacturer must produce and maintain when a piece of equipment is designed and introduced into the market is to eliminate this cost constraining alternative or to drive the cost of reusing medical devices closer to the purchase price of new equipment. The beneficiary of these interpretations is the manufacturers and not the public.

From the perspective of the FDA, Congress will be asked to increase an already massive budget for the additional inspectors and enforcement personnel necessary to implement these new rules. This is an industry of more than a thousand small service and equipment providers who would become subject to the full burden of the government. Many who simply cannot afford extensive staffs whose sole purpose is documentation of each detail of their work to suit the manufacturers will cease to exist or leave the industry thus reducing competition and inflating the cost of health care.

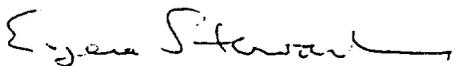
I urgently seek your help in countering the expanding encroachment of the FDA. I ask that you recommend to them a deliberate process in their rule making which takes into account the real impetus to regulate the used and reconditioned medical equipment market. Are the steps they are taking in the public interest and for the public's good? Or is this another example of the power of big business to quash competition through lobbying and the fervor of a federal agency to increase its budget in a time of Congressional attempts to restrain public debt? The idea that someday, somebody might get hurt by medical equipment reconditioned by a company other than the original manufacturer is patently a rationalization for regulation serving only the interest of the manufacturers and the regulators.

Our trade group is perfectly willing to assist the FDA to understand the true nature of the companies and industry they seek to regulate. IAMER has in the past and can in the future demonstrate both the value of the industry in holding the line on health care costs and the true "risks" it might engender. Certainly, our organization has benefited from frequent contact with administrators within FDA who appear willing to listen to and inform us, particularly, Wes Morgenstern and Phillip Frappaolo (both are Deputy Directors, FDA, CDRH). The lack of understanding evidenced by the tenor at the Birmingham meeting of that collaborative approach illustrates that the fervor of enforcement at times overwhelms reasonable efforts to attain a workable solution to a thorny, multifaceted issue.

Please intervene on behalf of our company, our owner, our industry and the public's good in the FDA's processes. Bearing in mind that the industry already exists in a highly regulated environment, please withhold your approval of money for additional inspectors, contract inspectors, administration expenses and the like which the FDA will eventually seek in order to further expand their domain.

For your time and efforts on our behalf, my sincere thanks. Accept my invitation to visit us at our facility when you are next in Winston-Salem. Our very best wishes for your continuing success.

Sincerely,



Eugene Stewart
President

xc: Len B. Preslar, Jr.
President
The North Carolina Baptist Hospitals, Inc.