

MAY 6 1998  
MAY -7 10:29

The Honorable Fred Thompson  
United States Senate  
Washington, D.C. 20510-4204

Dear Senator Thompson:

This is in response to your letter of January 29, 1998, on behalf of Mr. Charles Rose of Rockford, Tennessee, regarding his concerns about the Food and Drug Administration's (FDA or the Agency) proposed rulemaking to regulate the independent equipment service providers industry and others involved with the refurbishing of medical devices.

The "Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Quality System Regulation" was published in the Federal Register of October 7, 1996 (61 FR 52601). This regulation sets forth revised Good Manufacturing Practice (GMP) requirements for medical devices that are harmonized with International Standards Organization 9001, the quality system used by the European Economic Union. Medical device manufacturers and remanufacturers are subject to compliance with the GMP/Quality System Regulation; refurbishers, independent service organizations, and hospitals are exempt.

FDA's Medical Device GMP Advisory Committee assisted in the development of the GMP/Quality System Regulation. There were sharply divided views among the members of this committee regarding the need to make medical device refurbishers and servicers subject to compliance with the regulation. The Medical Device Advisory Committee was told that the Agency would explore alternative regulatory approaches and address the application of the GMP requirements specifically to medical device servicing and refurbishing functions outside the control of the original manufacturer in separate rulemaking.

FDA published its intention to review and, as needed, to revise or to amend its regulatory approach with respect to those persons who refurbish, recondition, rebuild, service, or remarket medical devices in 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.

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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 on these issues in September of this year. This conference will present an additional forum for all parties to present their views.

The comment period of the ANPR has been extended until June 1998, as published in the enclosed Federal Register of March 25, 1998 (63 FR 14390). Your letter, including Mr. Rose's comments, have been submitted to the docket. 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 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

2 Enclosures

cc: Dockets Management Branch  
(Docket No. 97N-0477)

# United States Senate

WASHINGTON, DC 20510-4204

January 29, 1998

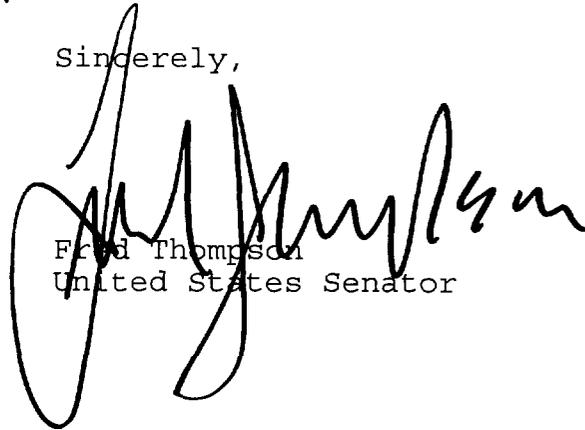
Dr. Michael A. Friedman  
Acting Commissioner  
Food and Drug Administration  
5600 Fishers Lane  
Room 1471, HF-1  
Rockville, Maryland 20857

Dear Dr. Friedman:

I have enclosed a copy of correspondence from one of my constituents, Charles Rose, who is concerned about Food and Drug Administration (FDA) regulation of independent medical equipment service providers. I would appreciate a written response addressing Mr. Rose's concerns that I could share with him. In the meantime, please keep his thoughts in mind if the FDA considers any changes in this policy.

Thank you for your assistance in this matter. I look forward to hearing from you.

Sincerely,



Fred Thompson  
United States Senator

FT:fcc

Enclosure

No. 98-1220

**FRED**  
**THOMPSON**  
U.S. SENATOR • TENNESSEE

**FAX**

TO: Julia Pounds

OFFICE: FDA

FAX NO: 301-443-2567

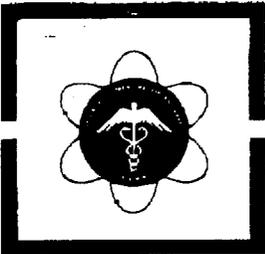
DATE: 2-17-98

PAGE 1 OF: 3

FROM: Christian Clymer (202) 224-4944

SUBJECT: \_\_\_\_\_

Senator Fred Thompson  
523 Dirksen Senate Office Building  
Washington, D.C. 20510  
Tel (202) 224-4944  
FAX (202) 228-3679

Q6376-C  
Q6378-A**CHARLES ROSE & ASSOC., INC.**

HOSPITAL &amp; MEDICAL ELECTRONIC SERVICE AND REPAIR

JAN 23 1998

January 19, 1998

Senator Fred Thompson  
U. S. Senate  
523 Dirksen Off. Bldg.  
Washington DC 20510

Dear Senator Thompson,

We would like to bring a matter to your attention that greatly concerns our company while also significantly increasing healthcare costs. It involves the announced intention of the Food and Drug Administration (FDA) to regulate independent medical equipment service providers despite clear evidence that this action is neither necessary nor desirable.

Here are some of the facts we'd like you to consider:

- The medical equipment service industry has an annual volume variously estimated at \$5 to \$7 billion.
- Hospitals and other healthcare providers have been able to cut their medical equipment maintenance costs by 20 to 30% using independent service companies as an alternative form of service. For a typical hospital, this amounts to \$200,000 to \$400,000 annually.
- Medical equipment manufacturers typically charge \$150 to \$200 per hour for service. Independents charge \$60 to \$80 per hour. Their technical skills are equivalent; many independent service technicians have international certification, and many have been trained while serving in the Army, Navy or Air Force.
- Independent service companies neither design nor modify medical equipment. They merely repair it or perform preventive maintenance. If they do not perform competently, users immediately cease to use them.

Senator Fred Thompson

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- The Emergency Care Research Institute, a not-for-profit medical organization similar to UL, has provided data to the FDA demonstrating that regulation of independent service companies is not needed. ECRI does not provide such maintenance services itself, but it does monitor the provision of service by others.

Senator Thompson, when health care costs are such an issue and when they make up such a large share of the Federal budget, why would any Federal agency seek to increase them? Why is the FDA seeking to solve problems that don't exist, rather than attending to those that do? We ask that you take action with your colleagues to prevent this increase in health care costs, either by remonstrating with the FDA, or by passing a bill to stop such regulation.

We'd be more than happy to present any additional information at any time, and would appreciate a response to this letter indicating what action you intend to take. Thank-you.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Charles R. ...". The signature is written in a cursive style with a long, sweeping tail that extends to the right.