REPORT TO THE SENATE COMMITTEE ON GOVERNMENT OPERATIONS BY THE COMPTROLLER GENERAL OF THE UNITED STATES

Stronger Measures Needed To Insure That Medical Diathermy Devices Are Safe And Effective

Food and Drug Administration

Department of Health, Education, and Welfare

Although the Food and Drug Administration is responsible for regulating medical diathermy devices, it has not established an effective program to insure that these devices meet Federal requirements.

The devices, which produce various levels of deep heat in human tissue, are used by medical practitioners and physical therapists to treat patients with such conditions as bursitis, tendonitis, backaches, stiff shoulders, and tennis elbow.

HRD-76-153

SEPT. 2, 1976

COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

B-114836

The Honorable Abraham Ribicoff
Chairman, Committee on Government
Operations
United States Senate

Dear Mr. Chairman:

In response to your April 15, 1975, request, we are reporting on the Food and Drug Administration's need to improve its program for regulating medical diathermy devices.

The agency is part of the Department of Health, Education, and Welfare. We obtained formal written comments on the report from the Department and Diapulse Corporation of America.

This report contains recommendations to the Secretary of Health, Education, and Welfare. As you know, section 236 of the Legislative Reorganization Act of 1970, Pub. L. No. 91-510, requires the head of a Federal agency to submit a written statement on actions taken on our recommendations to the House and Senate Committees on Government Operations not later than 60 days after the date of the report and to the House and Senate Committees on Appropriations with the agency's first request for appropriations made more than 60 days after the date of the report. We will be in touch with your office in the near future to arrange for release of the report to the Secretary and the four Committees to set in motion the requirements of section 236.

Sincerely yours,

ACTING Comptroller General
of the United States

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ABBREVIATIONS

AMA	American Medical Association
BMDDP	Bureau of Medical Devices and Diagnostic Products
BRH	Bureau of Radiological Health
FDA	Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act
GAO	General Accounting Office
HEW	Department of Health, Education, and Welfare
RCH&S Act	Radiation Control for Health and Safety Act

COMPTROLLER GENERAL'S
REPORT TO THE CHAIRMAN
SENATE COMMITTEE ON
GOVERNMENT OPERATIONS

STRONGER MEASURES NEEDED TO INSURE THAT MEDICAL DIATHERMY DEVICES ARE SAFE AND EFFECTIVE

Food and Drug Administration
Department of Health, Education, and Welfare

D I G E S T

The Food and Drug Administration is responsible for making sure that medical diathermy devices marketed in interstate commerce are safe and effective for the uses intended and are labeled properly. However, it has no effective regulatory program to carry out this responsibility.

Medical diathermy devices are used for treating many types of muscle and tendon pain. Devices which are not safe and effective could threaten consumers' health and represent an economic fraud.

Agency officials attributed the lack of an effective regulatory program to inadequate legislative authority and/or resources.

Three types of devices marketed in the United States are shortwave, microwave, and ultrasound. They are used in hospitals, medical clinics, health spas, athletic departments, nursing homes, and doctors' offices.

The Agency has developed voluntary guidelines providing basic labeling requirements for diathermy devices. However, these guidelines are not mandatory regulations under which to enforce compliance with the Federal Food, Drug, and Cosmetic Act. Regulations setting forth mandatory standards would provide a more effective basis for taking action against a device that is in violation of law.

A standard to control unnecessary radiation emissions from certain diathermy devices is being developed. However, standards are not being developed to help insure that diathermy devices are safe and therapeutically effective. (See ch. 2.)

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Although the Agency believes that these devices should meet certain heat and labeling criteria to be considered therapeutically effective, it has not enforced these criteria uniformly against the diathermy industry.

Manufacturers have been inspected infrequently and the Agency's product testing has been limited.

The Agency's inspection records indicate that some devices being manufactured did not meet the Agency's heating and labeling criteria. Inspections of manufacturers' facilities and product testing would better insure that the devices meet the Agency's diathermy heat and labeling criteria. (See ch. 3.)

The Secretary of Health, Education, and Welfare should direct the Commissioner of the Food and Drug Administration to strengthen the Agency's program for regulating medical diathermy devices by:

--Establishing standards and/or regulations to insure that medical diathermy devices are properly labeled and safe and effective for their intended use.

--Establishing an effective surveillance program, including product testing and plant inspections of diathermy manufacturing facilities.

--Taking appropriate regulatory action to insure that diathermy devices meet the Agency's temperature and other requirements.

The Medical Devices Amendments of 1976, Pub. L. No. 94-295, to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301, provided the Agency with additional authority to regulate medical devices. The Department of Health, Education and Welfare pointed out that until the Agency finishes implementing new regulations, it will continue to act against violative products

under existing authorities as resources and priorities permit. (See pp. 40 and 41.)

However, additional authority will not improve the Agency's regulation of diathermy devices measurably unless it develops an effective regulatory program for these devices.

CHAPTER 1

INTRODUCTION

By letter dated April 15, 1975, the Chairman, Senate Committee on Government Operations, told us that the Committee had received information concerning the appropriateness of the Food and Drug Administration's (FDA's) enforcement activities to insure the safety and effectiveness of medical diathermy devices throughout the Nation. The Committee was interested in determining whether FDA had operated effectively and efficiently, and with fairness and impartiality, in enforcing the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 301) with respect to diathermy and similar electromagnetic therapy devices.

The Chairman asked us to develop information on (1) FDA's standards and regulations for its medical diathermy device regulatory activities, (2) research and testing FDA has undertaken or contracted for to provide an independent technical basis for its regulation of medical diathermy devices, and (3) priorities FDA has established for expending time and resources in regulating diathermy and other medical devices that are suspected of being unsafe and those medical devices that are considered safe but ineffective.

The Chairman also asked us to give the Committee a case history of FDA's regulatory activities with respect to medical diathermy devices.

Three types of medical diathermy devices--shortwave, microwave, and ultrasound--are being marketed in the United States. (See p. 4.) They are used in physical therapy departments in hospitals, in medical clinics, health spas athletic departments, nursing homes, and private doctors' offices. All three types of diathermy devices emit radiation and use either pulsed or continuous high frequency electrical energy to produce heat in human tissue. Diathermy has been generally accepted as a safe and effective method of treating many types of muscle and tendon pain. Commonly treated conditions include bursitis, tendonitis, backaches, stiff shoulders, and tennis elbow.

FDA estimates that 13 domestic and 3 foreign manufacturers market medical diathermy devices in the United States. Because diathermy devices operate on radio frequencies which can affect interstate and foreign wire and radio communication, these devices are required to be licensed by the Federal Communications Commission before marketing. According to a Commission official, about 34 different models of diathermy devices are being marketed in the United States.

FDA, an agency within the Department of Health, Education, and Welfare (HEW), is responsible for regulating medical diathermy devices in accordance with the provisions of the FD&C Act and the Radiation Control for Health and Safety Act of 1968 (RCH&S Act) (42 U.S.C. 263b).

On May 28, 1976, the FD&C Act was amended by enactment of the Medical Devices Amendments of 1976 (Pub. L. No. 94-295), which gave FDA additional authority for regulating medical devices. Before this amendment, FDA could only require that medical devices be (1) appropriately labeled, (2) manufactured under sanitary conditions, and (3) safe for their intended uses. Medical devices were not required to be proven safe and effective for their intended use before they were marketed. To take regulatory action against a device, FDA had to prove that the device did not comply with the requirements of the FD&C Act or Federal regulations. The 1976 amendments will enable FDA to (1) require premarket clearance for medical devices used in life-threatening situations, (2) promulgate performance standards for medical devices, and (3) require general controls, such as plant and product registration, notification of defects, record and report keeping, factory inspection, and good manufacturing requirements.

Since 1965 FDA's policy for regulating medical devices under the FD&C Act has been to allocate its time and resources on the basis of established priorities. Highest priority is given to devices considered unsafe. Medical devices considered safe but ineffective may be given high priority if it is reasonable to assume that the patient will be denied adequate and proper treatment and that denial of such treatment will be harmful. The lowest priority is assigned to worthless medical devices which are economic frauds but do not pose a serious hazard to patients.

Under the RCH&S Act, FDA must establish and carry out a radiation control program for electronic products, including medical devices that emit radiation. This program includes (1) developing and administering performance standards to control the emission of electronic product radiation, (2) supporting research, training, and operational activities to minimize emissions of and the exposure of people to unnecessary electronic product radiation, and (3) testing products to determine compliance with regulatory standards.

FDA's Bureau of Medical Devices and Diagnostic Products (BMDDP)[1] administers FDA's medical device regulatory program

[1]Before February 1974 the activities of BMDDP were assigned to FDA's Associate Commissioner for Medical Affairs.

under the FD&C Act. BMDDP's responsibilities include (1) developing FDA policy on safety, effectiveness, and labeling of medical devices, (2) conducting research and developing safety and performance standards, (3) carrying out a surveillance program consisting of plant inspections and product testing to determine product compliance, and (4) taking necessary action to have violative devices brought into compliance or removed from the market.

FDA's Bureau of Radiological Health (BRH)[2] is responsible for carrying out the day-to-day operations of FDA's electronic product radiation control program.

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[2]BRH became part of FDA in May 1971. Before then it was part of HEW's Environmental Health Service.

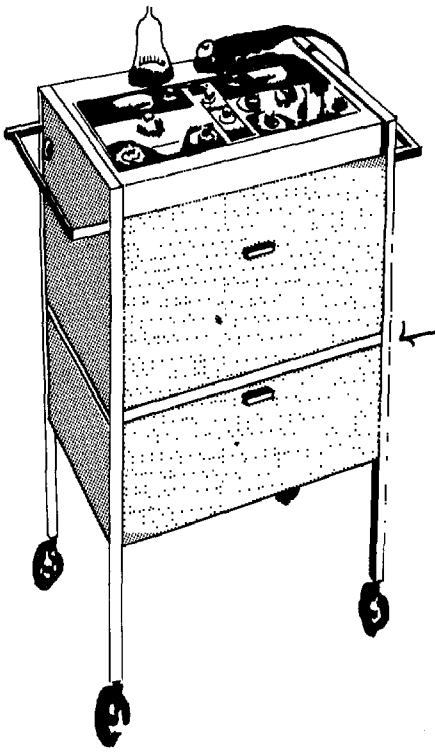

Figure 3-- Ultrasound Diathermy Device

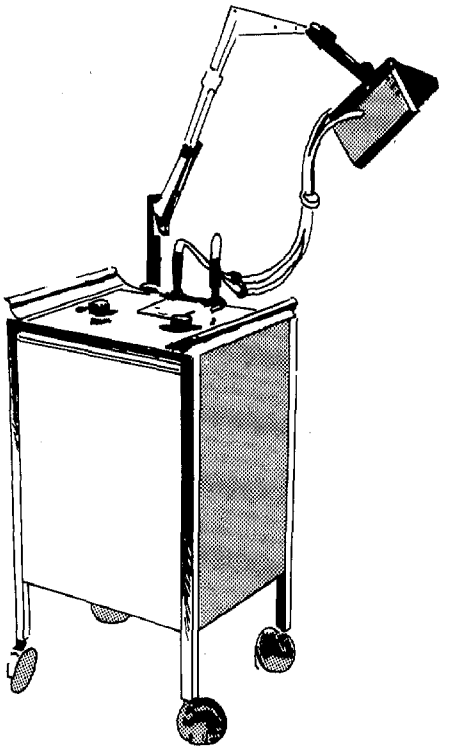

Figure 1-- Shortwave Diathermy Device

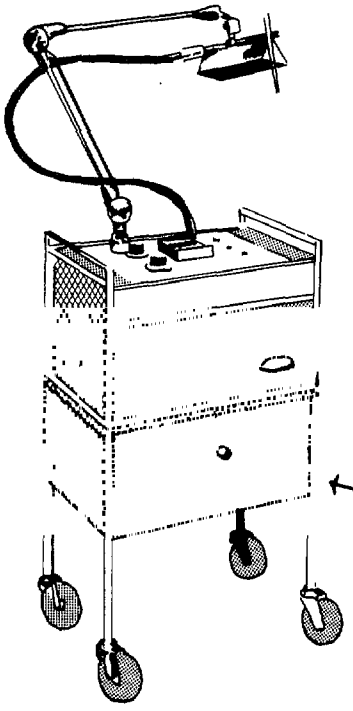

Figure 2-- Microwave Diathermy Device

CHAPTER 2

MEDICAL DIATHERMY DEVICE STANDARDS

The Food and Drug Administration has not established safety and performance standards for medical diathermy devices. Instead, FDA has generally relied on the American Medical Association's (AMA's) diathermy performance and use criteria, established about 1950, to guide its regulatory activities. Recently FDA has begun to develop radiation safety standards to control unnecessary radiation emissions from certain diathermy devices. However, safety and performance standards which would help insure that diathermy devices are safe and therapeutically effective are not being developed because of inadequate resources and higher priority work.

FDA ADOPTION OF AMA DIATHERMY CRITERIA

AMA's performance and use criteria provide that diathermy treatment may be beneficial for many physiological conditions, including chronic rheumatoid arthritis, bursitis, sprains and strains, fractures, sinus inflammation, ear infections, eye inflammation, pleurisy, and tendon injuries. According to BMDDP's Director, Medical Review Staff, AMA required that shortwave diathermy devices, to be considered therapeutically effective, should be capable of increasing body tissue temperature at a depth of 2 inches in the human thigh from a temperature of 98.6° F to at least 104° F within 20 minutes.

As AMA's criteria established a minimum heat level, BMDDP's Director, Medical Review Staff, said that since about 1968 FDA has required that diathermy devices be capable of heating deep body tissue to at least 104° F and not more than 114° F. In a letter to us dated October 30, 1975, the Director stated:

> "Since our early actions on diathermy devices, and during our ten years of litigation with the Diapulse [see ch. 4], it became apparent, based on newer scientific research, and medical texts that the original American Medical Association temperature requirement of 104° F only represented the minimum level at which a sufficient physiological response to produce medical or therapeutic effects could be obtained. The research also indicated that temperatures higher than 114° F were capable of producing tissue injury. Obvious conclusion being that s/w [shortwave] diathermy devices to be safe and effective for their intended use should be capable of producing body heat in the 104° F to 114° F

temperature range, since less than 104° was ineffective, and more than 114° F could be harmful."

In October 1972 FDA developed proposed "Guidelines for Acceptable Labeling for Diathermy Devices" to be used during informal discussions with shortwave diathermy manufacturers. Although the guidelines do not cover microwave and ultrasound diathermy devices, they provide the basic requirements for labeling all diathermy devices.

According to the guidelines, diathermy manufacturers should insure that their devices (1) meet Federal Communications Commission frequency requirements, (2) are capable of producing heat of 104° F to 114° F and (3) are labeled in sufficient detail to enable them to be used knowledgeably and intelligently. The guidelines provide that manufacturer claims for effectiveness should include only therapeutic claims for treating physiological conditions which have been found to be beneficially treated by deep heat. The guidelines state that:

"It is contemplated that for the manufacturers of a particular piece of diathermy equipment to make any claims for effectiveness in the treatment of any disease condition that he will have conducted that amount of valid scientific controlled research with that particular device to substantiate the claims he is making, both for safety and efficacy."

CONTRACT WITH THE UNIVERSITY OF WASHINGTON

Because some of AMA's diathermy criteria were considered obsolete, FDA decided that scientific information on the medical use of shortwave diathermy devices needed updating. Consequently, in January 1974 FDA awarded a contract to the University of Washington to review medical and scientific literature on shortwave diathermy and to determine the therapeutically effective temperature range for shortwave diathermy devices. Also, the university was to (1) develop information on the medical indications, techniques of application, contraindications, hazards, and clinical effectiveness for these devices and (2) determine the physiological effects that could be produced by pulsed shortwave diathermy and compare them with the physiological effects produced by continuous shortwave diathermy devices.

In its final report to FDA in March 1975, the university noted that (1) the most important factor in determining the extent of biologic reaction from diathermy is tissue temperature and (2) the temperature range which produces physiologic and therapeutic response without destructive effects is approximately 40° C to 45° C (104° F to 113° F). A second factor reportedly related to determining the biologic reaction to diathermy is "the duration of temperature elevation," and for most therapeutic purposes this extends between 5 and 30 minutes.

The report stated, however, that a method to accurately measure tissue temperature and duration of tissue temperature elevation for most clinical applications did not exist. Therefore, the intensity and duration of heat administered during a diathermy treatment is based on the patient's physical response to the heat emitted by the device.

The report stated that its recommended criteria differed greatly from the earlier AMA requirement, which provided that to be acceptable,a diathermy device must produce a temperature rise to at least 104° F at a depth of 2 inches in body tissue in 20 minutes. According to the report, the AMA criteria did not account for several variables, such as the part of the body to be treated, anatomical configurations or tissue thickness, and modifications of the temperature distribution by blood flow which could occur before 20 minutes of exposure if temperatures greater than 40° C (104° F) were achieved. On the other hand, the report noted that if temperatures great enough to trigger vasodilation (increased blood flow) are not achieved at any point in the treatment period, "vigorous therapy" may not be possible. The report stated that:

> "Since vigorous therapy is often prescribed, the output of a shortwave diathermy machine should be great enough that a vigorous response can be achieved. The energy required to produce such an effect can vary considerably, depending on the area of the body to be treated, therefore a considerable range in the amount of energy available must be retained. In using this energy, proper safeguards are taken to insure that tolerance levels of patients are not exceeded. * * *"

According to the report, pulsed shortwave diathermy was initially developed to minimize the heating effect and

produce certain nonthermal effects. Considering these nonthermal effects the report stated that:

> "There is insufficient scientific evidence that pulsed shortwave produces effects which could not have been produced by continuous shortwave of the same average power. Further, none of the non-thermal effects demonstrated have been proven to be therapeutic."

Regarding the hazards and contraindications, the report noted that shortwave diathermy devices produce radiation which could unnecessarily expose the patient and therapist. The report also stated that the devices

- --should not be applied to areas of malignancy or sensory loss, the gonads, or developing fetuses;
- --should not be used over intrauterine devices containing copper or other metals since it is not known whether their conductivity represents a serious hazard; and
- --should be used with precaution on patients with metal implants, such as metal plates, wires, cardiac pacemakers, or other electronic devices that control certain electrophysiologic conditions.

The report concluded that:

> " * * * standards are necessary for shortwave diathermy equipment to insure that equipment have sufficient power to produce vigorous therapy, that this effect be achieved in tissues in a reasonable period of time, that the highest temperature in the distribution occur in the tissues to be treated, and that stray radiation be minimized. It is essential that the manufacturer label equipment so the physician and therapist can select the proper equipment and techniques of application for specific indications."

The report stated that shortwave diathermy devices should be evaluated to determine if they produce adequate heat for vigorous therapy. Devices not capable of producing sufficient heat may not provide effective treatment for many physiological conditions.

We asked BMDDP's Director, Medical Review Staff, what effect the university's report would have on FDA's program for regulating medical diathermy devices. He said that the

report substantiated FDA's position that the temperature range of 104° F to 114° F is a valid criterion for determining the therapeutic effectiveness of any diathermy device. He said that:

> "In order that all manufacturers are made aware of the criteria for diathermy devices, the Bureau anticipates publishing in the Federal Register a notice updating labeling information on the use of shortwave diathermy based on the University of Washington study. Devices which do not meet these labeling requirements after a sufficient period of time, will be subject to regulatory action.* * * "

However, according to the Director, the notice would serve only as a voluntary guideline for industry to follow in labeling shortwave diathermy devices and would not represent a formal regulation under which to enforce compliance with the misbranding or adulteration provisions of the Federal Food, Drug, and Cosmetic Act. BMDDP's Director, Division of Medical Device Standards and Research, said that regulations setting forth mandatory standards to insure the safety and performance of shortwave, microwave, and ultrasound diathermy devices under the FD&C Act are not being developed because of inadequate resources and higher priority work.

FDA SURVEYS OF MARKETED DIATHERMY DEVICES

As part of its responsibilities under the Radiation Control for Health and Safety Act, the Bureau of Radiological Health conducted three field surveys to determine the need for radiation safety performance standards for diathermy devices. The first survey, made in 1970, covered all three types of medical diathermy devices. The other two surveys were made in 1972 and 1974, covering ultrasound and microwave diathermy devices, respectively.

1970 survey

In January and February 1970, BRH made a survey in Pinellas County, Florida, to determine the extent to which medical diathermy devices were being used to treat patients, the radiation exposure involved, and operator qualifications and training. According to the survey report, about 13,000 individuals in Pinellas County received 90,000 diathermy treatments each month. Of these treatments, 45,000 were ultrasound, 25,000 were shortwave, and 20,000 were microwave.

The report indicated that there was little uniformity in the controls used for regulating patient exposure to radiation emitted from diathermy devices and that not all the diathermy devices had timer mechanisms to limit the duration of exposure.

The report noted that patients treated with microwave diathermy were exposed to radiation varying from 25 to more than 200 mW/cm^2 (milliwatts per square centimeter). BRH's report entitled, "Documentation Report for Microwave Diathermy Standard," stated that microwave radiation exposure of more than 10 mW/cm^2 could produce adverse effects, including altered hormone production, cataracts, inhibited cell growth, chromosomal aberration, and changes in behavior and the central nervous system. BRH's Assistant Director said, however, that these effects depend upon the level and duration of exposure to microwave radiation and that they generally occur at exposures much higher than $10mW/cm^2$.

BRH interviewed 232 diathermy device operators during the survey. Of the 232 operators, 10 to 30 percent had some type of formal training in diathermy; the others obtained their training on the job, from salesmen, or from trade literature. Of the 232 operators, about 20 percent were registered physical therapists; about 39 percent were physicians, osteopaths, chiropractors, and registered nurses; and about 41 percent were secretaries, medical assistants, practical nurses, laboratory technicians, and others.

The report concluded that, because potential hazards exist in using diathermy devices, patient exposure to such devices must be carefully controlled to minimize the possibility of injury and that a more intensive investigation of diathermy treatment was needed so that immediate constructive steps could be taken to better protect patients.

A BRH official told us that because of other priorities and limited resources, no followup action was taken regarding specific devices identified in the 1970 survey as being potentially hazardous. According to BRH's Director, the survey results were used as a guide in planning future program activities.

1972 survey

In December 1972 BRH and the Pinellas County Health Department made a joint survey of ultrasound diathermy devices being used in St. Petersburg, Florida. This survey

was a followup to the 1970 survey to obtain additional information on the performance and use of ultrasound diathermy devices.

Based on the survey report, 58 ultrasound diathermy devices were tested to measure the total ultrasound energy output for various power settings on each device. The report noted that 85 percent of the devices tested radiated 20 percent more or less ultrasound energy for at least one power setting than indicated by their meters. In one case, a device radiated about nine times as much ultrasound energy as indicated by its meter. A BRH Division of Electronic Products official said that ultrasound devices which are not properly calibrated could result in injury or ineffective treatment.

A BRH Division of Compliance official said that in each case where ultrasound diathermy devices were out of calibration, the user facility was informed of the condition. The official also said that BRH visited several ultrasound manufacturing facilities to determine whether the calibration problem was related to a manufacturing process. The visits to these facilities indicated that the calibration problem was primarily a result of inadequate user maintenance and not a manufacturing defect.

A BRH official told us that the manufacturer was required to repair a defective meter in the device which radiated too much ultrasound energy. However, FDA took no action against the other devices with calibration problems because, according to BRH officials, the RCH&S Act does not authorize FDA to regulate and control the use of inadequately maintained electronic products in the hands of an owner or user. The officials said the States are responsible for insuring that users properly maintain the equipment.

1974 survey

During February and March 1974, BRH conducted a field survey of microwave diathermy devices at five physical therapy departments in hospitals and at one educational institution in Maryland, the District of Columbia, Virginia, and California. The survey was to provide the means of determining the uniformity or consistency of operation among the various devices being used and to obtain a better understanding of the use and methods employed during treatment.

During the survey BRH observed (1) the location of the treatment facilities in the hospital and the educational institutions, (2) the operator's routine in administering diathermy treatment, and (3) how frequently microwave diathermy treatments were administered, and (4) the source of instructions for treating specific conditions.

The physical therapy departments in the five hospitals surveyed were located in remote areas away from any sensitive areas, such as operating rooms, intensive care units, and cardiac care areas. The operators' routine in administering a diathermy treatment appeared standardized. The physiological conditions being treated with microwave diathermy devices included bursitis, tendonitis, muscle strains, and arthritis.

The survey report noted that two malfunctioning devices were found which could have resulted in inadvertent patient exposure to microwave radiation. In one case the level of microwave radiation leakage was less than $5mW/cm^2$, which BRH determined did not pose a significant risk of injury, and in the other case action to correct the defect was taken.

ADVISORY PANEL REVIEW ON NEED FOR DIATHERMY DEVICE STANDARDS

In October 1973 the Secretary of Health, Education, and Welfare established FDA's Panel on Review of Physical Medicine (Physiatry) Devices to (1) review and evaluate available data concerning the safety, effectiveness, and reliability of physical medicine devices (including diathermy) in use, (2) advise the FDA Commissioner on the regulatory class most appropriate for controlling these devices, and (3) identify those devices which can best be controlled by standards.

The panel has since held a number of meetings for grouping special therapy devices into regulatory control classes in anticipation of enactment of the Medical Device Amendments of 1976, Pub. L. No. 94-295.

The amendments, enacted on May 28, 1976, require FDA to group all medical devices intended for human use into one of the three following regulatory classes based on the extent of regulation necessary to insure product safety and effectiveness.

Class I -- Devices which should be exempt from performance standards and premarket approval because they can be adequately regulated under general controls, such as

plant and product registration, good manufacturing practice requirements, notifications of defects, and maintenance of records and reports.

Class II -- Devices which cannot be adequately regulated by general controls and for which there is sufficient information to develop a performance standard to provide reasonable assurance of safety and effectiveness.

Class III -- Devices which are used to support or sustain human life, which are used to prevent impairment of human health, or which present a potential, unreasonable risk of illness or injury and cannot be adequately regulated under general controls or standards are to be subject to premarket approval.

On March 18, 1975, the panel placed shortwave (except pulsed shortwave), microwave, and ultrasound diathermy devices in class II. Pulsed shortwave diathermy devices were placed in class III because the panel believed there was insufficient information to promulgate adequate efficacy standards for these devices.

During the panel's May 6, 1976, meeting, BRH officials discussed BRH's capabilities and efforts in developing radiation safety performance standards for ultrasound and microwave diathermy devices with the panel members. Although the standards under development by BRH do not consider BMDDP's diathermy heating and labeling criteria, BRH officials indicated a willingness to work with BMDDP and the panel in developing standards under the FD&C Act and the RCH&S Act. At the conclusion of its meeting, the panel decided to split into three subcommittees -- diathermy, electromyograph, and orthotics and prosthetics -- in an effort to facilitate its work on standards development.

In August 1975, the diathermy subcommittee discussed the need for safety and effectiveness standards and the feasibility of promulgating such standards. The subcommittee concluded that developing standards for medical diathemy devices should be given a high priority. Accordingly, the subcommittee recomended to the panel in December 1975 that FDA consider having BRH and BMDDP coordinate their standard setting activities and promulgate standards which would cover both the safety and effectiveness of these devices. According to a BMDDP official, the panel accepted the subcommittee's recommendation and is finalizing a formal recommendation to be presented to BMDDP, BRH, and the FDA Commissioner for their consideration. As of May 1976 the panel's recommendation was still being developed.

STANDARDS TO CONTROL RADIATION

Radiation safety standards are being developed for microwave and ultrasound diathermy devices; however, a similar standard for shortwave diathermy devices is not being developed because, according to BRH's Assistant Director, radiation hazards associated with these devices are not known to be as great as those associated with other radiation-emitting electronic products. The Assistant Director said that BRH has had to assign its resources to those products whose potential radiation hazards are believed to be more imminent.

The Assistant Director said that the primary purposes of the microwave and ultrasound diathermy standards will be to (1) reduce unnecessary or unproductive exposure to radiation, (2) require that devices be capable of delivering a prescribed amount of microwave or ultrasound energy to the patient, and (3) insure that medical personnel have sufficient information for making informed judgments on the safe and effective use of these devices. Radiation safety standards promulgated by BRH under the RCH&S Act will not address medical effectiveness or other safety factors associated with diathermy devices during clinical application because, according to BRH officials, the RCH&S Act does not authorize developing such standards.

According to BRH's Director, publication of the microwave diathermy standard has been delayed until the Bureau completes its review of the impact the standard would have on manufacturers and the conditions under which these devices could be used. BRH officials said that BRH plans to publish the proposed standards for microwave diathermy devices for public comment in the Federal Register by about November 1976. The proposed standard for ultrasound devices was published in the Federal Register on June 14, 1976, 41 Fed. Reg. 23973.

CHAPTER 3

SURVEILLANCE AND ENFORCEMENT ACTIVITIES

The Food and Drug Administration is responsible for insuring that medical devices, including diathermy devices, marketed in interstate commerce are safe for their intended use and properly labeled. FDA has authority to inspect manufacturing facilities and test finished products. FDA does not have an effective regulatory program for medical diathermy devices.

INSPECTION OF DIATHERMY MANUFACTURING FACILITIES

According to FDA's Inspection Operations Manual, inspections of medical device manufacturing facilities are made to identify dangerous or otherwise violative devices so that they can be removed from consumer channels and further production of them can be prevented. FDA's inspections of medical diathermy manufacturers have been infrequent and ineffective.

Under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374), FDA has authority to inspect the practices, methods, facilities, and conditions under which diathermy devices are manufactured. Before enactment of the Medical Device Amendments of 1976, Pub. L. No. 94-295, the FD&C Act did not give FDA access to manufacturers' reports and records on product safety or effectiveness, however, FDA could request a manufacturer to voluntarily give such information.

FDA records indicated that, since January 1975, FDA has inspected 5 of the 13 domestic diathermy manufacturers; 1 of these had not been inspected during the previous 9 years. Of the remaining eight manufacturers, five had not been inspected within the last 2 to 6 years, and three manufacturers have never been inspected.

FDA inspection records on several of the diathermy manufacturers indicated that many devices did not comply with FDA's diathermy heat and labeling requirements. FDA did not promptly follow up on its inspection findings to insure that violative devices were brought into compliance. For example:

-- As a result of a February 1972 inspection of a medical diathermy device manufacturer, FDA determined that the manufacturer's labeling for its microwave diathermy device was deficient in that it lacked complete information on contraindications. FDA did not determine until April 1975, when FDA reinspected the manufacturer, that the labeling deficiencies were corrected. During the 1975 inspection FDA noted that a shortwave diathermy device label was deficient in that it contained "objectionable statements" regarding the recommended uses of the device and lacked adequate directions for those uses. Accordingly, in June 1975 FDA advised the manufacturer of several labeling revisions it considered necessary to bring the labeling for the shortwave diathermy device into compliance and requested the manufacturer to advise FDA within 30 days as to the corrective action taken. As of May 1976 the manufacturer had not responded to FDA and FDA had not followed up on this matter.

-- During a July 1973 inspection of another diathermy device manufacturer, FDA noted labeling violations on an ultrasound and a shortwave diathermy device. In reviewing the labeling, FDA noted that the shortwave device could barely produce 104° F, which represents only the minimum acceptable amount of heat for these devices. In November 1973 FDA sent the manufacturer a regulatory letter advising that the devices were misbranded and that corrective action should be taken. In December 1973 the manufacturer advised FDA of its plan to correct the labeling violations and noted that the temperature output of the shortwave device was adequate. FDA notified the manufacturer in March 1974 that the corrective actions planned were unacceptable and that the heating efficacy of the shortwave device was still being reviewed. In an internal FDA memorandum dated May 10, 1974, a Bureau of Medical Devices and Diagnostic Products official noted that

> "*** this device could only be offered for mild heating for conditions, wherein you would use a hot water bottle, infrared lamp, or that type of surface heating. The labeling would tend to misbrand this device. I recommend followup."

Based on FDA records, as of May 1976, FDA had taken no follow-up action.

BMDDP's Director, Division of Compliance, said that FDA has not carried out an effective inspection program for medical device manufacturers because of limited resources and lack of adequate legislative authority. The Director said that:

> "* * * Manufacturers and importers do not have to preclear their devices with FDA, nor do they have to register with the Agency. Therefore, we cannot ensure that our records include information on all manufacturers or importers of such devices.* * *"

The Bureau of Radiological Health's Assistant Director told us that diathermy manufacturing facilities have not been inspected to determine whether diathermy devices are manufactured under conditions which would insure their compliance with the requirements of the Radiation Control for Health and Safety Act. According to the Assistant Director:

> "It is not Bureau practice to make in-plant inspections of products for which there is no applicable performance standard. Knowledge that a product subject to the Act was defective, as defined by the Act, has frequently come from field tests or as a result of Bureau in-house laboratory testing."

FDA EFFORTS TO COLLECT AND EXAMINE DIATHERMY DEVICES

FDA's Inspection Operations Manual provides that collecting and examining samples of devices and inspecting manufacturing facilities, is the principal basis for determining the need for regulatory action. BMDDP's Director, Medical Review Staff, said that:

> "* * * in as much as the Agency is dependent upon information furnished by the manufacturers, the Agency with few exceptions, has not conducted actual physical tests on all devices which are on the market.* * *"

The Director also said that some manufacturers have refused to give specific information on the physical capabilities of their device to reach certain temperatures.

FDA records indicated that 5 of the 13 domestic diathermy manufacturers were marketing diathermy devices which may not be capable of meeting FDA's required temperature range of 104° to 114° F. We brought this matter to the attention of BMDDP's Director, Medical Review Staff and asked what FDA had done to insure that all marketed diathermy devices are therapeutically effective and can meet FDA's temperature requirements.

The Director said that some diathermy devices on the market may not be capable of meeting FDA's temperature requirements. He explained that:

> "* * * BMDDP does not have laboratory facilities of its won in which to conduct extensive, sophisticated tests on diathermy medical devices. BMDDP has had to rely primarily on data submitted to it by the manufacturers of the device.* * *"

The Director said that FDA has no immediate regulatory actions planned for diathermy devices which are not capable of meeting the FDA diathermy temperature requirement.

BRH's Assistant Director said that BRH has not carried out a product compliance testing program for diathermy devices because:

> "Bureau budget and manpower limitations have always made it necessary for the Bureau to establish priorities, partly in terms of the relative immediateness or remoteness of public exposure to radiation hazards. Within that context, the Bureau considered that there were other sources of manmade radiation (diagnostic X-ray equipment, lasers) which should have greater priority with respect to the public health than the development of equipment standards or carrying out a defect testing program for diathermy products."

FDA ACTIONS AGAINST VIOLATIVE DIATHERMY DEVICES

When FDA finds that marketed medical diathermy devices are adulterated or misbranded under the FD&C Act, it can request manufacturers to correct the devices on the market or to remove them from the market. FDA can also initiate one or more of the following legal actions through the Department of Justice against a violative product or its

manufacturers.

-- Prosecute a manufacturer or individual.

-- Enjoin a manufacturer or individual from shipping adulterated or misbranded products in interstate commerce.

-- Seize the device when it is introduced into, while in, or after receipt in interstate commerce.

Under the May 1976 amendments to the FD&C Act, FDA can require manufacturers to repair, replace, or refund to the purchaser the cost of medical devices which are improperly designed or manufactured and present an unreasonable risk to the public health.

Since October 1968 FDA, under the RCH&S Act, could require manufacturers to correct, replace, or refund to the purchaser the cost of any medical diathermy device which has a defect relating to radiation emissions that affect its safe use. Manufacturers who violate the act are subject to a civil penalty of not more than $1,000 for each violation and a maximum penalty of $300,000 for a series of related violations.

Seizures of violative medical devices require civil court action and are limited to the specific quantity and location of the products identified in the seizure complaint. Unlimited or multiple seizures of violative medical devices are authorized under the FD&C Act if such products are dangerous to health, are fraudulent, or the labeling is materially misleading to the consumer.

Since 1968 FDA's general policy for regulating medical devices regarded as "worthless for any medical purpose" has been to seize the devices and to take any other legal action warranted. Once a seizure action is adjudicated, the case is usually closed with little if anything being done about other violative devices that may remain on the market.

According to a November 14, 1968, memorandum, FDA does not seek to do "a trash collecting job" for worthless devices that remain on the market. FDA's Director, Compliance Coordination and Policy Staff, said that:

"The policy delineated in *** 1968 *** is still being followed by the Bureau of Medical Devices and Diagnostic Products***. We are still faced, perhaps more so than in 1968 with manpower and budget constraints which effectively preclude our pursuing a seizure to its logical conclusion - i.e., removal of all of such products from recipients.

"I wish to make it clear, however, that our policy is now, as it was in 1968, to proceed actively against products wherever they may be located when such articles constitute a definite health hazard."

In fiscal year 1974 FDA began using "regulatory letters" in an attempt to secure compliance and consumer protection as quickly and inexpensively as possible. A regulatory letter contains a formal warning to a firm that specific sections of the law have been violated and that unless corrective action is taken within a specified time, FDA will initiate legal action.

As shown in the following table, from July 1, 1971, to June 30, 1975, FDA took 732 actions against medical devices, of which 450, or about 61 percent, were against diathermy devices violating the FD&C Act. None of the actions involved radiation safety violations. Except for two seizure actions and one regulatory letter, FDA's regulatory actions involving diathermy devices were taken against one manufacturer--the Diapulse Corporation of America. (See ch. 4.)

Type of action	Total number of medical device actions	Number of diathermy medical device actions
Regulatory letter	84	1
Citation (note a)	12	3
Seizure	555	445
Prosecution	1	0
Injunction	3	1
Recall	77	0
Total	732	450

[a]Formal notice issued by FDA giving a manufacturer violating FD&C Act an opportunity to show cause why he should not be prosecuted.

According to BMDDP's Director, Division of Compliance, FDA has seized about 610 misbranded diathermy devices over the past 28 years. Of these, about 550 were manufactured by the Diapulse Corporation and 3, similar to the Diapulse device, were manufactured by the Dynapower Systems Corporation. The Director said that, except for Diapulse Corporation, diathermy manufacturers have attempted to bring violative devices into compliance or have stopped distributing them.

BMDDP's Director, Medical Review Staff, said that since 1965 FDA has spent more manpower and resources in regulating the Diapulse device than on any other medical device or class of devices, including cardiac pacemakers, heart valves, and interuterine devices. BMDDP's Director said that:

> "* * * the amount of resources FDA has spent in regulating the Diapulse Corporation has adversely impacted on FDA's program for regulating other medica devices.* * *"

BMDDP's Director, Division of Compliance, said that:

> "* * * Diapulse chose to take the matter to court before a jury. In support of the scientific and medical facts prior to the court trial and

also in support of the Government's position, the considerable and extensive scientific and medical research was more extensive than the sum total of all the research conducted on all other violative medical devices over the preceding 25 years, both in effort and money. When Diapulse lost the jury trial they appealed to the Circuit Court. When they lost in the Circuit Court, they appealed to the Supreme Court. Although certiorari was denied by the Supreme Court, the firm continued to sell its devices***." The Government then successfully enjoined the firm***"

According to the Division Director:

"***FDA instituted multiple seizures against the Diapulse device only in those cases where known users would not voluntarily destroy the devices or render them inoperable. Not to seize the devices would mean leaving a misbranded device, ineffective for its intended use, in the hands of an estimated 5,000 practitioners who could continue to use the device on perhaps thousands of patients for hundreds of conditions, many of which are of a most serious nature, and at considerable expense to the patient, and Government."

A BMDDP official said that as of May 1976, an estimated 3,500 misbranded Diapulse devices remained on the market. Regarding removal of these devices from the market, BMDDP's Director said that:

"***FDA is aware the Diapulse devices which are in violation of the present injunction are still on the market and being used to treat patients. However, the FDA has not initiated compliance action necessary to remove these devices from the market, because of its limited resources and low priority assigned to this area. Further, the FDA is not aware of the names and addresses of all those individuals still possessing and using Diapulse devices. The Diapulse Corporation of America has been uncooperative in furnishing any such identifying information to the Agency."

BMDDP's Director, Division of Compliance, said that 3 of about 400 to 500 "Standard Model" diathermy devices, manufactured and distributed by the Dynapower Systems Corporation between 1962 and 1964 were seized in 1966 and 1967 for misbranding violations. According to the Director, in 1969 the Dynapower Systems Corporation encouraged all its dealers to offer a substantial trade-in allowance on the Standard Model for a new diathermy device. The Director said that the Bureau did not know how many Standard Model devices were traded in and whether any remained on the market.

CHAPTER 4

REGULATORY CASE HISTORY--DIAPULSE

Pursuant to the Committee Chairman's request for a case history on the Food and Drug Administration's regulation of medical diathermy devices, we developed information on FDA's regulatory involvement with the Diapulse Corporation of America. FDA's regulatory activity concerning the Corporation covers more than 17 years.

The Corporation, located in New Hyde Park, New York, manufactures the Diapulse device--a pulsed shortwave device. According to Corporation claims, the Diapulse device, which resembles a conventional medical diathermy device, produces pulsed high peak power shortwave electromagnetic energy but does not produce heat in the diathermy 104° F to 114° F temperature range. The Corporation contends that the Diapulse device was not intended for heat therapy but was designed to achieve therapeutic effects by the penetration of the electromagnetic energy into the human body.

Because FDA concluded that electromagnetic energy without significant heat had no therapeutic value, it considered the Corporation's claims for the Diapulse device to be false and misleading and, therefore in violation of the misbranding provisions of the Federal Food, Drug, and Cosmetic Act.

In July 1972 FDA obtained a Federal court injunction prohibiting the Corporation from introducing the Diapulse device into interstate commerce until FDA approved its labeling. As of May 1976 FDA had not approved a Diapulse label. However, the Corporation is selling the Diapulse device overseas.

FDA'S INITIAL INVOLVEMENT WITH DIAPULSE

The Corporation initially contacted FDA by letter dated December 1, 1958, to inquire about FDA's requirements for examining and approving the Diapulse device for marketing. The Corporation offered to give FDA information concerning the names and addresses of doctors under whose supervision research was being conducted on the Diapulse device. On December 30, 1958, FDA requested the Corporation to provide the information it offered and stated that a complete reply would be made at a later date. Based on the records we reviewed, FDA did not give the Corporation a complete reply to its inquiry nor did the Corporation give FDA complete information on the Diapulse device research.

On January 14, 1959, the Corporation again requested information on the requirements for marketing the Diapulse device, but it did not give FDA the information it had requested concerning the Corporation's research activities. On January 27, 1959, FDA wrote the Corporation and said that:

> "In order to give adequate consideration to the status of the Diapulse device, we would like to have an opportunity to consider the experiences of doctors who have used the machine. We would therefore appreciate having the names and addresses of the doctors who have tested the device."

On the same day, FDA recommended that its New York district office schedule a factory inspection for the Corporation and noted that the inspector should request the names of all medical investigators of the Diapulse device.

On February 11, 1959, FDA's New York district office made a factory inspection of the Corporation's facilities and obtained a partial list of the medical investigators conducting research on the Diapulse device. According to FDA's inspection report, the Corporation refused to give the FDA inspector a complete list of the medical investigators. The Corporation told us that it was reluctant to supply all of the names because it was concerned about the inhibiting effect that FDA investigators might have had on the researchers.

On September 3, 1959, an FDA inspector made a followup inspection of the Corporation's facilities to obtain information on the labeling and distribution of the Diapulse device. The inspector noted in his report that the Corporation was selling "a pulsating diathermy device designed to supply extremely high electrical energy values without increasing the temperature of the treated area" and that about 200 devices had been sold since it began distribution in June 1959.

On October 12, 1959, the American Medical Association informed FDA that it had denied several Corporation requests to advertise the Diapulse device in the AMA publications and requested FDA's position on the therapeutic value of the Diapulse device. On October 22, 1959, FDA advised AMA that the Diapulse device was essentially a low-intensity diathermy device that should be sold only as a prescription item and only to the medical profession. FDA suggested that AMA review a Mayo Clinic report entitled "Certain Experimental Observations on Pulsed Diathermy Machines." According to an

internal FDA memorandum, the Mayo report indicated that the Diapulse device was "merely a poor diathermy machine, if anything." The Corporation contends that because the Mayo Clinic's study did not include clinical (human) research, the study's data cannot be extrapolated to show the effects of pulsed shortwave on humans.

In March 1960 FDA officials, at the Corporation's request, met with the Corporation's general sales manager to discuss the Diapulse device. According to FDA's March 23, 1960, memorandum of interview, the general sales manager pointed out that the Diapulse was a pulsating shortwave device and indicated that clinical studies with the device were being done at Andrews Air Force Base and at the University of Arkansas.

FDA's memorandum noted that the concept associated with using the device is that it stimulated the defense mechanism of the human body to react against disease conditions. In addition, FDA's memorandum noted that the value of the Diapulse device was still unproven and that the FDA officials questioned whether the Corporation had well-documented scientific studies to support any labeling claims.

In an internal FDA memorandum dated March 8, 1961, an official recommended that FDA establish a broad clinical testing program to evaluate the therapeutic claims made for the Diapulse device and other medical devices. According to the memorandum, in the past most of FDA's regulatory actions were against devices for which outrageous labeling claims were made, thus requiring FDA to obtain only limited medical evidence to preclude any successful legal opposition to the regulatory actions taken. The FDA official noted that, with more complex medical devices entering the market with therapeutic claims, it was increasingly more important for FDA to obtain physical and medical evidence on these devices to help decide how to regulate them.

From March 1961 to December 1965 FDA investigated pulsed diathermy devices "with special emphasis toward Diapulse since it was the first and largest in this field." In investigating the Diapulse device, FDA's medical staff members reviewed published articles on Diapulse, held discussions with experts in the field of physical medicine, and sponsored several tests on the device. On the basis of its investigation, FDA concluded that the Diapulse device was not effective for its intended purposes.

LEGAL ACTIONS TAKEN AGAINST THE DIAPULSE DEVICE

On December 17, 1965, FDA seized a Diapulse device in Atlanta, Georgia, and charged that the device was inadequate and ineffective and therefore misbranded because its labeling contained false and misleading claims for treating some 121 different diseases and related conditions. Some of the claims were that Diapulse could treat infections, low back pain, rheumatic fever, tuberculosis, osteoarthritis, gout, diabetes, ear conditions, hypertension, gangrene, and promote bone and tissue healing. To contest this seizure, the Corporation intervened in the case as claimant for the device, and, at its request, the trial on the seizure was transferred from Atlanta to the U.S. District Court in Connecticut, where a jury trial was held beginning on February 21, 1967.

On March 17, 1967, the court found the seized Diapulse device to be misbranded on the basis that 49 of the 121 labeling claims were false and misleading. No ruling was made on the other 72 labeling claims. On March 31, 1967, the court ordered that the Corporation show cause why the seized device should not be destroyed. However, on April 25, 1967, the court amended its order to give the Corporation an opportunity to relabel the device in compliance with the FD&C Act. On May 24, 1967, the court denied a Corporation request for a new trial.

The Corporation appealed the March order, as amended, to the U.S. Court of Appeals for the Second Circuit in New York which on January 30, 1968, affirmed the lower court order. The Corporation then petitioned the U.S. Supreme Court to review the case; the petition was denied on June 10, 1968.

After the March 1967 court ruling, the Corporation continued to market the Diapulse devices in interstate commerce. Therefore, the Federal Government in April 1968 filed motions for a restraining order, a preliminary injunction, and a permanent injunction in the District Court for the Eastern District of New York, alleging that the Corporation's labeling claims continued to be false and misleading. After holding a hearing on the Government's motion on April 29, 1968, the district court issued a temporary restraining order enjoining the Corporation from further marketing Diapulse devices with any of the 49 labeling claims previously found false and misleading.

The temporary restraining order and the Government's request for a preliminary injunction became moot when on May 1, 1968, the Corporation voluntarily consented to the issuance of a preliminary injunction which prohibited the marketing of

the Diapulse device with any of the 49 labeling claims. The Corporation agreed to this action "in order to effectuate an orderly procedure pending trial and determination of the action without admitting the allegations of fact or law as set forth in the [Government's] complaint." As a result, the Government's motion for a preliminary injunction was declared withdrawn.

According to court records, however, the Corporation continued marketing the Diapulse device with 25 of the 72 labeling claims which were not specifically ruled on by the courts. The Corporation believed the 25 therapeutic claims made for the device were proper and legal.

On June 10, 1969, the Corporation filed a motion before the U.S. District Court in Connecticut to further amend the March 1967 court order and requested the court to decree that the Diapulse device complied with the law when labeled as being adequate and effective for use in tissue and bone healing, sinusitis, bursitis, arthritis, and increasing blood flow to peripheral areas. These conditions were among the 72 claims not previously ruled on by the court. On June 24, 1969, the court denied the Corporation's request with "no opinion."

According to an FDA internal memorandum dated July 7, 1969, FDA's General Counsel suggested that FDA obtain evidence consisting of some well-controlled studies to show that the Diapulse device was ineffective in stimulating wound healing in humans or in treating arthritis, bursitis, and sinusitis for the injunction case that was in litigation. The memorandum indicated that some FDA officials were concerned that the outcome of the research might harm FDA's case. A BMDDP official said that such studies were not made because FDA obtained evidence of misbranding against the Diapulse device through experts' testimony.

On June 7, 1971, an evidentiary hearing on the preliminary injunction was begun before the U.S. District Court for the Eastern District of New York. The taking of evidence and testimony continued intermittently through November 8, 1971, when the district court filed an order directing that a hearing on the Government's request for a preliminary injunction be consolidated with a trial of action for a permanent injunction. On November 11, 1971, the court directed the issuance of a preliminary injunction against the Corporation and, on December 8, 1971, it granted the Federal Government a preliminary injunction prohibiting the Corporation from shipping or selling any Diapulse device in interstate commerce. The Corporation appealed the decision; however, on March 20, 1972, the U.S. Court of Appeals for the Second Circuit in New York affirmed the district court's preliminary injunction.

On June 9, 1972, the district court issued an order making permanent the preliminary injunction.

Accordingly, on July 18, 1972, the district court permanently enjoined the Corporation from causing to be shipped, sold, leased, introduced, or delivered in interstate commerce any Diapulse or similar device, in whole or part, assembled or unassembled. The permanent injunction also required the Corporation, before marketing Diapulse or similar devices in interstate commerce, to (1) assemble scientific evidence on which labeling would be based, (2) prepare labeling in full conformity with the FD&C Act and regulations promulgated thereunder, and (3) submit such evidence and labeling to FDA and obtain its approval in writing.

The district court retained jurisdiction of the Diapulse case

> "* * * for the purpose of enforcing or modifying this Permanent Injunction, and * * * granting such additional relief at the instance of any of the parties as may * * * appear necessary or appropriate."

The Corporation appealed the permanent injunction. The U.S. Court of Appeals for the Second Circuit in New York denied the Corporation's appeal. The Corporation then petitioned the U.S. Supreme Court to review the case; the petition was again denied.

CORPORATIONS'S EFFORTS TO COMPLY WITH LABELING REQUIREMENTS UNDER THE PERMANENT INJUNCTION

On August 18, 1972, Corporation officials met with FDA's Commissioner and Associate Commissioner for Medical Affairs to discuss the Diapulse case. An August 22, 1972, FDA memorandum of the meeting notes that the Associate Commissioner advised the Corporation officials that FDA would provide guidelines and criteria to help the Corporation develop scientific data on the Diapulse device and that FDA would review any scientific information which complied with these guidelines and criteria. Accordingly, on August 23, 1972, the Corporation was given FDA's guidelines for conducting adequate and well-controlled clinical investigations for new drugs. According to FDA's Associate Commissioner, the guidelines' basic requirements would apply to any scientific investigation, including those pertinent to medical devices. The Associate Commissioner advised the Corporation that the guidelines should be followed when performing any clinical investigation to substantiate labeling claims for medical devices.

On August 29, 1972, the Corporation submitted a proposed label for one claim--treatment of recent soft-tissue injury of the ankle. To substantiate the claim, the Corporation gave FDA a study published in the British Medical Journal dated April 29, 1972. The study, entitled "Treatment of Soft-Tissue Injuries by Pulsed Electrical Energy," was conducted in Leeds, England. The study was designed to provide a statistical assessment of Diapulse treatment in patients suffering from recent ankle sprains. Based on study results, the clinical investigator noted in his published report that:

> "As far as sprained ankles are concerned pulsed, high frequency electrical treatment [Diapulse] has a biological effect on recently-injured soft tissues. This is particularly noticeable in the reduction of pain and also disability."

To fully evaluate and determine the validity of the investigator's conclusions, in October 1972 FDA requested and later received from the Corporation additional information on the study. On January 15, 1973, FDA advised the Corporation that the supporting data used to substantiate its labeling claims was not in accordance with FDA's guidelines and, therefore, was not sufficient.

On January 22, 1973, the Corporation protested FDA's rejection of the labeling claim and advised FDA's Associate Commissioner for Medical Affairs that the Corporation believed it could not get a fair hearing on the Diapulse device from FDA and, therefore, FDA should impanel an independent committee of scientists to resolve the differences of opinion. The Director, Bureau of Medical Devices and Diagnostic Products, Division of Compliance, advised FDA's Associate Commissioner for Medical Affairs that FDA should not give the Corporation an opportunity to have their studies reviewed by outside experts because this (1) would go beyond the terms of the permanent injunction, (2) would reflect unfavorably on FDA's experts, and (3) could be used by the Corporation to delay any serious effort toward compliance.

The Corporation said that it does not agree with the Director's views. The Corporation believes that the permanent injunction neither dictates how FDA is to review Diapulse research data nor limits what FDA is to review. Moreover the Corporation believes that an independent committee review would not affect any compliance efforts and the review's impact on previous experts' views should not affect such a decision.

On January 25, 1973, the Corporation asked FDA to reconsider the British study and its proposed labeling claim. On January 31, 1973, FDA advised the Corporation that it had thoroughly reviewed the British study and that it would not do so again. However, FDA said it would be willing to review any new studies the Corporation submits that are adequate and well-controlled investigations.

On August 21, 1975, we interviewed the clinical investigator of the British study. He said that he regarded his work on sprained ankles as a preliminary investigation and that he was not aware that the Corporation had used his study to support a labeling claim for the Diapulse device. The investigator stated that, as a result of the ankle study, he later began several investigations to study the effects of the Diapulse device on nerve regeneration in laboratory animals. On March 5, 1976, he wrote us that he had used the Diapulse device on hundreds of patients for over 4 years and that he had no questions about the beneficial therapeutic value of Diapulse treatment. The investigator said that he believed "this form of treatment has a very great potential in the future which the medical profession as a whole is only just beginning to appreciate."

On March 20, 1973, the Corporation again requested that FDA arrange for an impartial ad hoc committee to review all the Corporation's studies. On April 11, 1973, FDA told the Corporation that:

> "* * * The studies have been reviewed by parties both within and without FDA and we see no benefit to be derived from the establishment of an ad hoc committee at this time to further review this material.
>
> "Until such time as you have valid scientific evidence that the device is capable of some significant therapeutic effect, as required under the Permanent Injunction, we can see no point in further discussion on this matter."

In October 1973 the Corporation submitted to FDA a proposed label for "Treatment of Recent Tissue Injuries in Animals" and the results of 10 animal studies made at medical institutions in the United States, Canada, and England, including a study on nerve regeneration in animals made by the British investigator. According to FDA records, the 10 studies were reviewed by FDA's Bureau of Veterinary Medicine and BMDDP and found to be inadequate to support the information contained in the Corporation's proposed label. In

a November 8, 1973, FDA memorandum, BMDDP's Director, Medical Review Staff, advised BMDDP's Director, Division of Compliance, that most of the studies submitted by the Corporation had been previously submitted to FDA to substantiate a variety of therapeutic claims in man. Based on BMDDP's and the Bureau of Veterinary Medicine's review of the 10 studies, the Director, Medical Review Staff, recommended that the Corporation's request for labeling be disapproved. The Director also noted that:

> "We would also further recommend that the Diapulse Corporation of America be informed that in our opinion, based on our review of all the voluminous studies and material collected over the past thirteen years on this device, that further research efforts to develop valid scientific evidence of safety and efficacy in man or animals for the use of this device offers no hope of success. The scientific evidence is so strong against the safety and efficacy of this device that the Diapulse Corporation should not be encouraged to continue to expend more time and money in what, scientifically and medically is a hopeless effort of attempting to substantiate therapeutic claims."

On January 22, 1974, FDA advised the Corporation that the proposed labeling was unacceptable because the 10 studies were unsatisfactory for scientific evaluation.

CORPORATION'S EFFORT TO MARKET A CONVENTIONAL DIATHERMY DEVICE

On March 28, 1972, Corporation and FDA officials discussed the Corporation's plan to market a new device. The device, designated "P/EmF," was a modified version of the Diapulse device that produced heat at higher temperature levels. The Corporation's general sales manager gave FDA for review, proposed labeling and laboratory test data to demonstrate the heating capability of the P/EmF device. He also indicated to FDA that the Corporation had made arrangements to secure evidence to show that the device would be effective for deep heating of muscular tissue in humans and that this evidence would be submitted to FDA. FDA's memorandum of the meeting notes that FDA officials told the general sales manager that FDA would not object to the marketing of a conventional diathermy device, provided it was properly labeled. However, the Corporation was requested to submit to FDA clinical and other test data substantiating the heating efficacy of the P/EmF device.

On April 10, 1972, the Corporation submitted to FDA clinical test data intended to show that the P/EmF device was capable of providing deep tissue heating.

On April 28, 1972, FDA advised the Corporation that the proposed labeling for the P/EmF was unacceptable. FDA told the Corporation that, until test data was developed to prove that the device could provide vigorous deep tissue heating at the approximate therapeutic range of 104° F to 114° F, it did not believe the device could be adequately labeled.

On August 2, 1972, FDA attempted to inspect the Corporation's facility but the Corporation denied FDA access. On August 8, 1972, FDA, accompanied by a U.S. Deputy Marshal, gained access and inspected the Corporation's manufacturing facilities and learned that the Corporation was manufacturing and shipping P/EmF devices.

An August 25, 1972, memorandum from BMDDP's Director, Medical Review Staff, to the BMDDP's Division of Compliance states that:

> "It is obvious * * * that the conversion unit * * * will only produce the minimum amount of heat (104°F) under the required test condition to even qualify as a diathermy unit. There is sufficient medical research to indicate that a temperature of less than 104° when used as a treatment for the conditions indicated in this labeling would be ineffective. This is not to say that heat would not be produced. It is saying that not enough heat is produced at an effective therapeutic level.* * *
>
> "* * * Were it not for the fact that the conversion unit only increases the energy output level of this device to the minimum (104°F) required for a diathermy unit, thereby preventing the creation of higher more effective deep heat temperatures, plus the continued subtle and obvious implications to the already well established indications and claims previously made for Diapulse and now made for a slightly more effective P/EmF device, the labeling would be considered generally acceptable.
>
> "* * * We cannot accept this as relabeling in that the maximum setting of this unit represents only the minimum setting for the

production of deep heat in a conventional diathermy unit * * *."

On August 3, 1973, the Federal Government filed in the U.S. District Court for the Eastern District of New York a criminal contempt proceeding against the Corporation and two of its officers charging them with (1) disobeying the preliminary injunction (see p. 28) by shipping a P/EmF device in interstate commerce and (2) violating the July 1972 permanent injunction (see p. 29) by shipping modification kits to convert Diapulse devices into P/EmF devices and Diapulse promotional literature in interstate commerce. The case was dismissed after 5 days of trial. Further hearings were held upon consent of both parties. On May 7, 1974, the district court directed that the July 1972 permanent injunction be clarified to make its terms more definite and certain.

Accordingly, on July 17, 1974, the district court amended the 1972 permanent injunction. The amended injunction required the Corporation to (1) recall the P/EmF Diapulse devices converted into P/EmF devices and bring these devices into compliance with the FD&C Act or destroy and/or salvage them, (2) inform FDA of the locations of all facilities used to manufacture and distribute any of the Corporation's devices, (3) permit FDA access to records and to inspect its manufacturing facilities, and (4) provide FDA, before shipping any device for investigational or research purposes, information on the proposed study including where, when, how, and by whom the study will be done, and periodic and final reports on the study.

The amended permanent injunction defined the term "adequate scientific evidence" as:

> "* * * evidence consisting of well-controlled investigations, including clinical investigations where appropriate, by experts qualified by scientific training and experience to evaluate the effectiveness of the device involved, on the basis of which it could fairly and responsibly be concluded by such experts that the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended or suggested in the labeling or proposed labeling thereof, unless upon the defendant's petition the Food and Drug Administration determines and advises the defendant in writing that other valid scientific evidence is sufficient to establish

the effectiveness of the device under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof."

The Corporation appealed the amended permanent injunction to the U.S. Court of Appeals for the Second Circuit in New York, which affirmed the lower court's decision on March 21, 1975. On June 18, 1975, the Corporation petitioned the U.S. Supreme Court to review this ruling; the petition was denied.

On November 26, 1975, the Government filed in the district court a criminal contempt proceeding against the Corporation and two of its officers charging that they disobeyed and violated the amended permanent injunction by refusing to permit FDA access to pertinent corporate records and by not allowing FDA to inspect the Corporation's manufacturing facility. According to a BMDDP official, action on this matter was pending before the court as of May 1976.

PRESENT STATUS OF THE DIAPULSE CASE

BMDDP's Director, Medical Review Staff, said that the Diapulse device is considered worthless for its intended purpose, and as such, cannot be adequately labeled. The Director said that it might be possible to properly label the Diapulse device if the Corporation modified it to produce heat in the full therapeutic range of 104° F to 114° F.

In response to Corporation inquiries, the FDA Commissioner in October 1975 advised the Corporation that information on the various aspects of diathermy in general and the Diapulse device in particular could be submitted to FDA's advisory committee on physical medicine for review. The Commissioner suggested that "very specific questions should be framed and jointly agreed upon by the Corporation and BMDDP" before presenting them to the advisory committee. The Commissioner suggested that the questions concern such areas as:

--"Is there scientific evidence which demonstrates conclusively that pulsed electromagnetic energy radiated into human tissue provides a therapeutic benefit solely by an athermal mechanism?"

--"Is there scientific evidence which demonstrates conclusively that therapeutic benefits can be derived from thermal heating where the temperature rise in tissue is less than six degrees Farenheit?"

--"Is there scientific evidence which demonstrates conclusively that pulsed electromagnetic radiation provides therapeutic benefits different from continuous wave electromagnetic radiation with the same average power?"

The Commissioner said that:

> "* * * [The Corporation] should provide medical and scientific data of the type we have been requesting which purport to provide answers to those questions, and the Committee should review that data. * * * [The Corporation] should have an opportunity to address the Committee directly during their review of that data. Following this, the Committee should draw its independent conclusions and provide a report to me concerning those conclusions. Finally, if appropriate and necessary, I will then agree to meet with * * * [the Corporation] to discuss any additional action."

The Commissioner also advised the Corporation that:

> "* * * [FDA] intended to follow scrupulously the terms of the permanent injunction, and therefore, would accept scientific and medical data from valid scientific studies which were not covered during the course of previous litigation."

On November 5, 1975, the Corporation told the Commissioner that it was prepared to proceed with the proposal. The Corporation, however, believed that the questions suggested by the Commissioner did not reach the crux of the problem. It believed the primary question FDA's advisory panel should address was whether there is "scientific evidence which demonstrates that the adjunctive use of Diapulse therapy has therapeutic benefit." Regarding FDA's advisory committee, the Corporation noted that:

> "* * * this committee should be completely independent of any obligation to N.I.H. [National Institutes of Health] and H.E.W. so that they cannot be unduly influenced in any way * * * [and] * * * should be qualified to evaluate any laboratory, animal and clinical evidence as regard to the adjunctive values of Diapulse therapy. Therefore, if the evaluation is to be unbiased and unpartial, it would be unnecessary and improper for FDA personnel to submit any of their comments to the Committee regarding our data."

The Corporation also told the Commissioner that the permanent injunction did not exclude from consideration scientific and medical data from valid scientific studies which were presented in the courts.

At a December 1975 meeting of FDA's Panel on Review of Physical Medicine (Physiatry) Devices, the Corporation requested and was granted time to address the panel. According to the panel's minutes of the meeting, the Corporation asked the panel whether (1) it was necessary to compare the results of the Diapulse devices with continuous shortwave, microwave, or ultrasound diathermy devices provided the Diapulse device produced a safe therapeutic effect and (2) the effect produced by the Diapulse device had to be attributed to thermal or nonthermal action. The panel advised the Corporation that with scientific, reproducible evidence, it would not be necessary to compare the Diapulse device with any other device and that the effect did not have to be attributed to thermal or nonthermal action.

On February 17, 1976, the Commissioner told the Corporation that the permanent injunction provides the only procedure for obtaining FDA approval to market the Diapulse device. The injunction requires the Corporation to submit adequate scientific data to substantiate labeling for the device to FDA. The Commissioner said that FDA will accept for review in support of labeling "any new scientific data" obtained by the Corporation. The Commissioner further advised the Corporation that:

> "* * *, if we determine that it is warranted by the data submitted in support of labeling, the Agency's review may involve one or more of our presently organized expert advisory panels, but no such committee will be asked to review evidence reviewed previously by the Agency or involved in any legal proceeding against the Diapulse device or your firm."

In addition, the Commissioner told the Corporation that:

> "I do not agree with your suggestion that the basic and primary question for advisory committee consideration is whether there is scientific evidence demonstrating the adjunctive use of Diapulse therapy has therapeutic benefit. While that question generally may be of interest to you, the labeling you propose for approval will determine the specific questions, if any,

which should be presented to an advisory panel for review."

The Commissioner advised the Corporation that, in his opinion, FDA's approach to reviewing the Corporation's scientific and medical data is consistent with the provisions of the permanent injunction and that it would offer an adequate opportunity for the Corporation's view to be submitted to the advisory panel, if FDA determines that the Corporation's data warranted review by the panel.

BMDDP's Director said that:

> "FDA would approve labeling for such a device provided the claims for the device are supported by adequately controlled scientific studies, which can be confirmed by similar independent studies. The device, however, could not be labeled and marketed as a shortwave diathermy device unless it operated in the conventional electro-physical parameters for shortwave devices and was capable of meeting the therapeutic temperature requirements, i.e., 104° F to 114° F."

The Corporation believes that adequate scientific and medical evidence is available to clearly demonstrate that the Diapulse device, as presently designed, has therapeutic value; however, according to the Corporation, "FDA, on its own volition, will never approve a label for Diapulse * * *, and the Diapulse matter should be settled by an unbiased, scientific ad hoc committee."

On April 9, 1976, the Corporation submitted studies to FDA supporting a proposed label for the use of Diapulse therapy in treating inflammation, tissue healing, and blood flow. In May 1976, a BMDDP official told us that the Corporation's proposed label was still under review.

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By letter dated July 16, 1976, the Corporation agreed that the above information accurately presents the chronology of events regarding FDA's regulation of the Diapulse device. (See app. III.)

CHAPTER 5

CONCLUSIONS, RECOMMENDATIONS, AND AGENCY COMMENTS AND OUR EVALUATION

CONCLUSIONS

Medical diathermy devices which are not safe and effective could threaten consumers' health and represent an economic fraud. FDA is responsible for insuring that all medical diathermy devices marketed in interstate commerce are safe and effective for their intended use and properly labeled; however, it has not implemented an effective regulatory program to carry out this responsibility. FDA has not established safety and performance standards for diathermy devices or carried out an adequate surveillance and enforcement program to insure that these devices comply with Federal requirements.

Standards are needed to help insure that marketed diathermy devices are safe, reliable, and effective. The Food and Drug Administration has developed voluntary guidelines providing labeling requirements for diathermy devices. However, these guidelines are not formal regulations under which to enforce compliance with the Federal Food, Drug, and Cosmetic Act. Regulations setting forth mandatory standards would provide a more effective basis for taking regulatory action against violative medical diathermy devices.

Although FDA believes medical diathermy devices should meet certain heat and labeling criteria to be considered therapeutically effective, it has not uniformly enforced these criteria against the diathermy industry. For the most part, FDA's device regulatory activities and resources over the past 10 years have been spent in regulating one diathermy manufacturer. FDA records indicate that diathermy devices produced by several other manufacturers may not be capable of meeting FDA's diathermy heat criteria; however, no action has been taken against these manufacturers.

Manufacturers have been inspected infrequently and product testing by FDA has been limited. Inspections of manufacturers' facilities and product testing would better insure that these devices meet FDA's diathermy heating and labeling criteria.

RECOMMENDATIONS TO THE SECRETARY OF HEW

We recommend that the Secretary direct the Commissioner of FDA to strengthen FDA's program for regulating medical diathermy devices by:

--Establishing standards and/or regulations which would insure that medical diathermy devices are properly labeled, and safe and effective for their intended use.

--Establishing an effective surveillance program, including product testing and plant inspections of diathermy manufacturing facilities.

--Taking appropriate regulatory action to insure that diathermy devices meet FDA's diathermy temperature and other requirements.

AGENCY COMMENTS AND OUR EVALUATION

HEW advised us that the Medical Device Amendments of 1976 provide FDA with long-needed authority to assure that the public is protected from unsafe and ineffective medical devices. According to HEW, the implementation of the amendments will provide appropriate regulations for medical diathermy devices.

HEW said the amendments mandate a very specific, sequential process for developing medical device regulatory programs. For example, FDA has already obtained preliminary recommendations on classifying many medical devices, including diathermy, into one of three regulatory classes specified in the amendments. However, an initial step in implementing this legislation requires FDA to reconvene all existing classification panels to reconsider previous decisions in light of the statutory classification criteria and other requirements of the legislation. Until this process is completed, FDA cannot establish standards for diathermy devices, since the mode of regulation previously recommended may change.

In addition, HEW said diathermy devices are only 1 of about 80 types of devices which FDA considers to be high priority. After the reassessment of classification recommendations, HEW said FDA will establish specific priorities for regulating the high-priority devices. The relative position of diathermy devices in this order of priorties weighed against the resources available to implement this program will dictate the development schedule for diathermy regulations.

HEW said that, until FDA finishes implementating these new regulations, FDA will continue to act against violative products under previously existing authorities as resources and priorities permit.

Although the Medical Device Amendments of 1976 provide FDA with additional authority for regulating medical devices, we believe that the additional authority will not measurably improve FDA's regulation of diathermy devices unless FDA develops an effective regulatory program for these devices.

CHAPTER 6

SCOPE OF REVIEW

We reviewed legislation, regulations, and practices relating to FDA's regulation of medical devices. We examined reports and records on FDA's regulation of diathermy devices manufactured by the Diapulse Corporation of America and other manufacturers. We did not review scientific evidence submitted by manufacturers to substantiate labeling claims for their products. We also examined records and reports on FDA's efforts to develop standards governing the safety, efficacy, manufacture, and use of medical diathermy devices.

In addition, we obtained information from officials at FDA headquarters in Rockville, Maryland, and its New York district office who were primarily responsible for carrying out FDA's regulation of the Diapulse Corporation and its products, and obtained the views of the Diapulse Corporation concerning its effort to obtain labeling for its products. We also interviewed a clinical researcher who studied the Diapulse device.

United States Senate

COMMITTEE ON
GOVERNMENT OPERATIONS
WASHINGTON, D.C. 20510

April 15, 1975

Honorable Elmer B. Staats
Comptroller General of the United States
General Accounting Office
General Accounting Office Building
441 G Street
Washington, D.C. 20548

Dear Mr. Staats:

The Government Operations Committee has received information concerning the appropriateness of enforcement activities of the Bureau of Medical Devices, Food and Drug Administration, with respect to ensuring the safety and effectiveness of the thousands of diathermy devices in use throughout the United States.

I am interested in determining whether the Bureau has operated effectively and efficiently, as well as with fairness and impartiality, in enforcing the Food, Drug and Cosmetics Act with respect to diathermy and similar electro-magnetic therapy devices.

In particular, I would appreciate your assistance in connection with the following issues:

1. What standards and regulations has the Bureau promulgated to guide its diathermy enforcement activities?

2. What research and testing has the Bureau undertaken or contracted for to provide an independent technical basis for enforcement in this area?

3. What priorities has the Bureau established for expending time and resources in enforcement activities related to diathermy and other medical devices that are suspected of being unsafe and such devices that are suspected of being safe but ineffective?

4. If possible, please cite one or more enforcement case histories to illustrate the Bureau's enforcement activities in the above cited areas.

APPENDIX I

Honorable Elmer B. Staats
Page Two
April 15, 1975

Inasmuch as this matter relates to important health and safety issues now before Congress, I would appreciate your completing this study within six months.

Thank you for your cooperation.

Sincerely,

Abe Ribicoff

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

JUL 16 1976

Mr. Gregory J. Ahart
Director, Manpower and
Welfare Division
United States General
Accounting Office
Washington, D.C. 20548

Dear Mr. Ahart:

The Secretary asked that I respond to your request for our comments on your draft report entitled, "Improvements Needed to Insure Safety and Effectiveness of Medical Diathermy Devices." The enclosed comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

We appreciate the opportunity to comment on this draft report before its publication.

Sincerely yours,

John D. Young
Assistant Secretary, Comptroller

Enclosure

APPENDIX II

DEPARTMENT COMMENTS ON GAO DRAFT REPORT TO CHAIRMAN OF COMMITTEE ON GOVERNMENT OPERATIONS, UNITED STATES SENATE, ENTITLED "IMPROVEMENTS NEEDED TO INSURE SAFETY AND EFFECTIVENESS OF MEDICAL DIATHERMY DEVICES"

GAO RECOMMENDATION

We recommend that the Secretary, HEW, direct the Commissioner, FDA, to strengthen FDA's program for regulating medical diathermy devices. Specifically, FDA should:

--Establish standards and/or regulations which would insure that medical diathermy devices are properly labeled, and safe and effective for their intended use.

--Establish an effective surveillance program, including product testing and plant inspections of diathermy manufacturing facilities.

--Take appropriate regulatory action as warranted to insure that diathermy devices meet FDA's diathermy temperature and other requirements.

DEPARTMENT COMMENT

The Medical Device Amendments of 1976, enacted into law on May 28, 1976, provide the Food and Drug Administration with long-needed statutory authority to assure that the public is protected from unsafe and ineffective medical devices. The regulatory history of medical diathermy devices is one of many examples which illustrates the need for this new authority. In fact, the report by the Committee on Interstate and Foreign Commerce on the Medical Device Amendments of 1976 made specific reference to diathermy devices as follows:

> FDA's experience in removing the Diapulse device from the market is yet another instance demonstrating the unwieldly procedures and lack of preventive provisions of the current authority. The Diapulse is a heat-generating device which has been marketed to medical practitioners for some 121 therapeutic claims. The firm lacked scientifically valid data to substantiate the efficacy of the device in any of the conditions for which it was promoted. The first seizure of a Diapulse device occurred in December of 1965. As a result of lengthy court proceedings against the device and company appeals, it was not until 1972 that injunction against the manufacturer was finally obtained, seven years after the initial seizure.

As the Committee's statement indicates, FDA's experience with the regulation of diathermy devices was considered in the development and design of the Medical Device Amendments, and clearly, this legislation was intended to strengthen FDA's regulatory authority over products such as diathermy devices.

The implementation of the Medical Device Amendments will provide appropriate regulations for medical diathermy devices. The act mandates a very specific, sequential process for the development of medical device regulatory programs. For example, FDA has already obtained preliminary recommendations concerning classification of many medical devices, including diathermy, into one of three regulatory classes specified in the amendments; however, an initial step in the implementation of this legislation requires FDA to reconvene all existing classification panels to reconsider previous decisions in light of the statutory classification criteria and other requirements of the legislation. Until this process is completed, FDA cannot establish standards for diathermy devices, since the mode of regulation previously recommended may change. Furthermore, diathermy devices currently are only one of approximately eighty types of devices which the Agency considers to be high priority. Following the reassessment of classification recommendations, the Agency will establish specific priorities for regulating the high priority devices. The relative position of diathermy devices in this order of priorities weighed against the resources available to implement this program will dictate the development schedule for diathermy regulations.

Until the Agency completes implementation of these new regulations under the provisions of the Medical Device Amendments of 1976, FDA will continue to take action against violative products under previously existing authorities as resources and priorities permit.

APPENDIX III

(516) 437-9700
(212) 343-0518

Diapulse® CORPORATION OF AMERICA
4 NEVADA DRIVE LAKE SUCCESS NEW HYDE PARK, N. Y. 11040

OFFICE OF THE PRESIDENT

July 16, 1976

Gregory J. Ahart, Director
U.S. General Accounting Office
Washington, D.C. 20548

Dear Mr. Ahart:

We appreciate the opportunity afforded us to comment on the Diapulse excerpt from your draft report to the Chairman, Committee on Government Operations, United States Senate on the Food and Drug Administration's regulation of medical diathermy devices. We feel that the excerpt accurately reflects the chronology of events. However, we believe that certain pertinent information that was not intended to be developed during the GAO review would be of interest to the Committee Chairman in his consideration of the FDA's regulation of medical devices. It concerns our personal belief that we have been victims of a vendetta spanning eighteen (18) years and that our product and Corporation have been used by the FDA as a publicity target for the purpose of convincing Congress of the need for device legislation. We request that this letter be appended to the final report submitted to the Committee Chairman. The following statements reflect our present feelings:

1. In 1958, when our Corporation began operations, there was no FDA Device Division and no FDA guidelines provided a manufacturer of new medical equipment.

   There were basically only two (2) men involved with devices at the FDA Bureau of Medicine. These two (2) men arbitrarily regulated our product as a diathermy device, despite our repeated statements that it was not. Although we constantly complained to FDA regarding the harassing tactics of these men, during these past eighteen (18) years, they remain the architects of this disgraceful travesty of justice. Data in the form of memoranda and correspondence, developed through the Freedom of Information Act shows that (a) they negatively interviewed researchers and doctors (b) one of them arranged for and in most cases personally installed and tested the one (1) Diapulse machine the FDA had purchased in October 1962 for "investigation", (c) the same man "trained" the FDA's paid investigators without ever permitting our Corporation's technicians or personnel from checking him despite an affidavit, signed by the FDA at the time they purchased the Diapulse machine, that we would be permitted to check the equipment every time it was moved (d) they drew up the standards for diathermy and literally mandated the University of Washington to confirm, in a contract

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OFFICE OF THE PRESIDENT

Gregory J. Ahart, Director July 16, 1976

issued January 1976, fully nine (9) years after the initial action against our product. Their tactics have always been for the purpose of protecting their original and now untenable position that shortwave has no therapeutic effects unless it heats tissue to at least 104°F.

2. From early 1966, we have repeatedly requested that an impartial scientific ad hoc committee be formed to review our admittedly voluminous and expanding research data, to scientifically end our controversy with the FDA.

   During the long, expensive and what we believe to have been unnecessary litigation, the Court stated that it was not a pharmaceutical testing laboratory and therefore not qualified to evaluate medical products. Incredibly, the Court returned us to the FDA (the very people who were attempting to put us out of business) to secure a label under which Diapulse could be marketed. In this predicament we increased our requests for an impartial scientific ad hoc committee review. The FDA to date has refused all our requests. They have even refused to permit their own duly constituted Physical Medicine Panel from reviewing our data. Why? WHAT ARE THEY AFRAID OF???

3. We emphatically contend, and the FDA Physical Medicine Panel (at their December 5, 1975 meeting) agreed:

   (a) It does not matter whether beneficial results of shortwave are due to thermal or nonthermal effects.

   (b) It also does not matter whether similar beneficial results can be obtained by continuous wave equipment.

   (c) What does matter is whether Diapulse Therapy, utilizing maximum nominal parameters of 27.12 MHz, 975 peak watts, pulsed 600 times per second at 65 microseconds per pulse is therapeutically safe and effective.

4. In all the past eighteen (18) years, a major Diapulse claim has been and remains, accelerated tissue healing in humans. The FDA has been fully aware of this claim for the entire length of time, yet at no time have they performed or had performed for them, a single tissue healing study on humans, to refute the claim. An FDA memo, dated July, 1969 from Division of Case Guidance to Bureau of Compliance, confirmed the need for FDA research:

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Gregory J. Ahart, Director July 16, 1976

"The General Counsel feels that some well controlled clinical evidence to show that Diapulse is not effective in stimulating wound healing, or in treating arthritis, bursitis, and sinusitis will be very important in the injunction case that is presently in litigation. We agree."

The memo concludes with a warning paragraph:

"Your should also be aware of the fact that ... (Bureau of Medicine) and ... colleagues are concerned that the outcome of the research might harm the Government's case." (Emphasis added)

NOT ONE STUDY WAS EVER UNDERTAKEN!

Our world-wide research and clinical studies performed with Diapulse Therapy (in medical teaching institutions, hospitals including Veterans Administration and clinics) confirm that Diapulse Therapy, used adjunctively, can accelerate tissue healing. That the use of Diapulse Therapy, pre and postoperatively, can effectively reduce hospitalization, thus make more surgical beds available and save billions of dollars for the patients, the insurance companies and our government.

We respectfully insist that this disgraceful inhibition of scientific progress by a bureaucratic minority, be publicly aired or at least placed before an impartial scientific ad hoc committee for review and determination. Then, and only then, will the American people again benefit from the safe, efficacious method of treatment provided by Diapulse Therapy.

Sincerely,

Jesse Ross
President

JR:gl