IMPORTANT UPDATE

The document “Legal and Regulatory Aspects of Diapulse” which begins on the next page was written in 1985. It does not reflect the important fact that the FDA relented in 1987, and granted a label to Diapulse Corporation for their device. Diapulse® has been on the market since that time.

In July, 2017, MAGNETVORTEX posted a YouTube video titled “Diapulse wave forms( PAIN ELIMINATION) FDA BANNED machine.”

When I learned that the MAGNETVORTEX posting indicated that the Diapulse is banned by the FDA, I attempted to set the record straight by posting comments to the offending webpage.

This page was added on December 20, 2017, to my website at www.loosecannon.name.

Scroll down to see the original document.
LEGAL & REGULATORY ASPECTS OF DIAPULSE

by L. Leslie Hamilton, Ph.D., P.E.

The case of the United States versus Diapulse is the longest, most expensive in the history of Food and Drug Administration litigation. The FDA spent millions of dollars in its efforts to destroy the company and its products. In my judgement, this is an incredible saga of bureaucratic error and maladministration.

To understand how a useful device like the Diapulse could be caught up in a web of red tape and bureaucratic intransigence, it is necessary to see what authority the U.S. Food and Drug Administration had over medical devices during the 1960s and '70s and to understand how the agency works.

FDA Authority Over Medical Devices

The Food and Drug Administration is authorized to enforce various laws; the primary law is the Food, Drug and Cosmetic Act. The original Pure Food and Drug Act of 1906 was amended in 1938 to grant FDA its initial authority over medical devices. The law defined medical devices as "instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals." By imaginative interpretation, the agency has determined that medical devices include such diverse products as exercise bicycles, paraquat testing kits and audio tapes that promote relaxation for insomniacs.

From 1938 to 1976, the FDA had limited authority and resources to control medical devices and their manufacturers. The FDA could take action against a product only if it were deemed to be adulterated or misbranded. The relatively small number of people the agency assigned to handle devices worked mostly with "quack" devices such as breast developers, weight reduction devices and sexual aids that failed to fulfill the claims of their promoters, in the opinion of FDA officials.

The Food, Drug, and Cosmetic Act lists "prohibited acts" which can become the basis for agency action. FDA officials believed that Diapulse machines were misbranded. The pertinent section of the 1938 law states:

"Sec. 502. A drug or device shall be deemed to be misbranded—
(a) If its labeling is false or misleading in any particular.
"... Unless its labeling bears (1) adequate directions for use; ...

During the first half of the 1960s, FDA appeared to take a non-committal approach to Diapulse. When doctors inquired to the FDA about Diapulse, the agency sent a letter citing the 1958 article in the Archives of Physical Medicine reporting on the "pearl chain effect" in which Diapulse energy rapidly produces an alignment of fat globules in milk.

The FDA's interest in Diapulse sharpened when they received a complaint from a Dr. Tepper in Atlanta. Tepper charged that his Diapulse machine did not perform as advertised and that the company had failed to give him satisfaction. FDA officials decided that Diapulse was misbranded after they reviewed the advertising, brochures and other information distributed by Diapulse. Specifically, FDA concluded that unsupported claims were made and that the labeling lacked adequate directions for use. FDA seized the machine in December, 1965.

Concerned about the effects of the seizure, Diapulse engaged a Washington attorney, Mr. Bradshaw Mintener, to advise the company. Mintener, a gifted and sensible lawyer of the old school (before coming to Washington he was general counsel at General Foods), accurately sized up the situation in a memorandum to Jesse Ross, president of Diapulse, dated January 6, 1966. Mintener wrote that Diapulse had two alternatives: "abandon the present seizure, and suffer the consequent adverse publicity and risk subsequent multiple seizures", or "contest the seizure, which will mean a long, drawn-out, expensive litigation with appeals and an uncertain result." His next paragraph was prophetic:

"FDA will not settle this case because I believe they consider it a test case on devices and it may be used as a "horrible example" to buttress and support FDA's present pending legislation to secure greater control over devices, similar to that which FDA now has over drugs."

Long before its success in court, the FDA initiated adverse publicity about Diapulse. The FDA Report on Enforcement and Compliance for March, 1966, devoted two pages to its discussion of the first seizure. The agency's position against the machine was succinctly stated:

"FDA is 'unaware of any scientifically adequate evidence from controlled studies by qualified experts to warrant offering pulsed diathermy devices for the treatment of the many conditions for which they are generally represented.'"
"FDA scientists also state that 'the timing of the pulsations emitted by the device is such that it does not permit dissipation of any heat produced...the average power output of the device is so low as to be considered worthless in therapy.'"

When the owner of a seized product wants to retrieve it, he enters the case as the "claimant." In this first Diapulse seizure, the owner didn't want it back. Officials at the Diapulse Corporation were quite concerned about the adverse publicity and they were quite confident of the medical value of their product. So they acted despite Mr. Mintener's warning; Diapulse Corporation became the claimant.

Trial was held before Judge Blumenthal in District Court in Connecticut in 1967. By that time, the FDA had assembled a long list of alleged violations of the law.

It is important to understand how the government arrived at its list of charges. Under Food and Drug law, the manufacturer is responsible for the "label" which is affixed to the article. In addition, the manufacturer or distributor is responsible for other material the company disseminates, known as the "labeling."

Medical investigators and practitioners, enthused about the results they had obtained with the Diapulse machines, were eager to publish their findings. There were symposia devoted to Diapulse. The Diapulse company distributed reprints of published and unpublished articles by these investigators, perhaps unaware that the FDA would consider each item to be labeling, and would hold the company as accountable for it as their advertising.

The FDA gathered this material and analyzed it carefully. And, because the law and its regulations are written in broad language, it was not difficult to find fault with the Diapulse "labeling." No one should underestimate the creativity of bureaucrats and federal attorneys. The government charged the company with 121 counts of misbranding.

It is interesting to see how the FDA arrived at 121 allegations of misbranding. Some 24 of the diseases and conditions listed in the FDA charges apparently came from a 1963 paper by Euclid M. Smith, M.D., and S. N. Blackberg, M.D., "Management of Rheumatic Diseases in General Practice" which appeared in the Southern Medical Journal, volume 56, number 6, June, 1963, pages 599-602. The Smith and Blackberg paper began:

"Arthritis, by definition, is any inflammation of one or more joints. With the exception of that due to local infection or trauma, arthritis is usually a local manifestation of systemic disease. It is obvious therefore, that before arthritis can be adequately treated, the
underlying systemic disturbance or disturbances must be recognized and controlled.

"The acute febrile types of arthritis include rheumatic fever, Reiter's syndrome, hypersplenism, undulant fever, tuberculosis, gonorrhea, syphilis, tularaemia, typhoid fever, serum sickness, and other systemic infections and metabolic disturbances."

Smith and Blackberg suggested the following procedure: make an accurate diagnosis; remove the cause of the ailment when possible; restore optimal nutrition. They highlighted the value of drugs like aspirin and cautioned against misuse of steroids. They warned of the hazards of diathermy, which they abandoned more than ten years before, after a few near-accidents.

They mentioned that they had given more than 1,500 Diapulse treatments in the preceding 13 months. This is followed by an extensive recitation of the history and development of pulsed ultra-high frequency energy.

They then said their own results were being prepared for publication.

The relevant conclusions by Smith and Blackberg are the following:

"7. The operation of the Diapulse generator is a simple and safe office procedure that does not require highly trained technical personnel. Applied over the region of the liver and adrenals, it stimulates the natural defense mechanisms of the body, and is therefore especially important when the etiology cannot be specifically combated. Applied over the joints, it exerts a potent but safe anti-inflammatory action, and therefore rapidly relieves pain and restores normal function.

"8. Sufficient evidence has accumulated to prove that Diapulse PUHF energy is a valuable addition to the therapeutic armamentarium for the treatment of rheumatic diseases."

The FDA chose to interpret this paper as a claim by Diapulse that their machine was effective in the treatment of all 24 of the diseases mentioned in the paper, regardless of the context. This includes the diseases named in the second paragraph of the paper (quoted above), none of which is mentioned elsewhere in the paper. I believe the FDA's use of the law was inappropriate and misleading.

A waiting room brochure published by the company served as another source for charges of false and misleading claims: for the safe treatment of the entire patient; restoring good health;
"perking-up" sick, run-down cells of the body with new life and fresh vigor; re-energizing the human mechanisms.

It is worth noting that the jury in this case marked their ballots that the government had proven its case in 49 of the 116 items on the Special Verdict Form. In other words, the government did not prove its case for 67 diseases and conditions! How many devices do you know of that are of significant benefit for 67 diseases and conditions?

Was the company permitted to market for any of the other 67 diseases and conditions? Of course not. The FDA has resisted every effort by the company to market the machine for the most modest of claims, even as a veterinary device!

When Diapulse continued to market their device, the FDA decided it would be necessary to obtain an injunction against the company. In July, 1972, Judge Dooling granted a permanent injunction against the company, prohibiting the sale or distribution of Diapulse machines.

Because it was apparent that the FDA's major objection to the Diapulse was rooted in their belief that it was a diathermy device, and must produce significant heating to be effective, the company decided to produce modification kits. The kit, when applied to the original machine increased its average output power at all settings, and at the higher settings it would elevate the temperature of the treated area significantly.

The FDA people felt this was merely a ploy to get around the 1972 injunction. They brought criminal contempt charges against officers of the Diapulse Corporation. These charges were subsequently dropped, but the 1972 injunction was expanded in a 1974 injunction which is still in effect, although it was modified in 1984.

During the late 60s and early 70s, the FDA stepped up its enforcement actions against Diapulse machines all over the United States. They seized approximately 600 machines from hospitals, clinics, and the offices and homes of physicians and others.

A seizure action is an expensive multi-step process. Usually, one FDA investigator would visit the facility where they thought a Diapulse machine might be. Upon confirming the presence of a machine, the FDA would petition a court for a seizure warrant. The owner (or anyone else for that matter) could "claim" the machine. To be successful, the claimant would have to defend the machine against the government's charges.

According to the results of my 1985 survey, many Diapulse owners were distressed by the seizure of their machines, but only a relatively few sought legal counsel. In most cases, the legal
advice was that any attempt to retrieve their property would be expensive and unlikely to succeed. Very few owners actually undertook the procedure to claim their property. Those who did found that it cost thousands of dollars, stretched to years, and, sadly, every single one lost.

Remember Bradshaw Mintener's prediction? Over the next ten years, Diapulse would often be named in Congressional testimony and press releases dealing with the problems of regulating quack devices or the expanded authority sought under the Medical Device Amendments. Commissioner Alexander Schmidt testified before the Subcommittee on Oversight and Investigations of the House Committee on Interstate and Foreign Commerce on March 15, 1976. Observe how much of his statement was devoted to Diapulse:

"The Agency's efforts to remove the device known as Diapulse from the market illustrate the fact that court enforcement actions can be incredibly expensive, inefficient, and ineffective. Diapulse is a 'quack' medical device, designed to resemble a diathermy machine, which was heavily promoted as a highly effective new form of treatment for 117 different diseases and disorders, ranging from arthritis to tissue and bone healing, to infections of all sorts. FDA first seized a Diapulse machine in 1967, and obtained a court ruling that it was misbranded in 1968. The district court's opinion was affirmed by the Court of Appeals. Subsequently, FDA was also successful in obtaining an injunction prohibiting further shipment of the device by the manufacturer in interstate commerce.

"With these favorable opinions in hand, FDA then had to decide how best to take action against the many Diapulse devices already in use. The only mechanism available was seizure of each individual device, wherever found. Not only was FDA unaware of the location of all of the units which had been sold, since we had no way to obtain such information under the Act but each seizure, when accomplished, was, in fact, an entirely separate and distinct case.

"Since 1972, FDA has initiated several hundred seizure actions. Each one had the potential for developing into a full-scale jury trial, and, in fact, many were strongly contested, tying up the courts and diverting FDA's resources from other projects. Some Diapulse devices remain on the market, and occasional seizure actions are still being sent out, nearly ten years after FDA obtained the original favorable court rulings.

"Clearly, some more effective mechanism must be found to remove adulterated and misbranded products from the market. The proposed medical device legislation which has passed the Senate (S. 510) and is currently being considered by the
House, contains provisions which would permit the Agency to avoid this procedure in the future. Those provisions authorize the Agency to administratively ban devices under certain conditions. If the bill is enacted, the Diapulse situation should not recur."

FDA's own internal reports document how much effort was expended on the Diapulse case. A March, 1973, "Mid-Year Status Report on Field Medical Device Operations" includes the following table:

<table>
<thead>
<tr>
<th>Headquarters Initiated Assignments</th>
<th>Hours reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Impact-Resistant Lenses</td>
<td>165</td>
</tr>
<tr>
<td>Diapulse Removal from Market</td>
<td>3837</td>
</tr>
<tr>
<td>Oxygen Delivery Devices</td>
<td>44</td>
</tr>
<tr>
<td>Sterile IV Sets</td>
<td>24</td>
</tr>
<tr>
<td>Thermometers</td>
<td>78</td>
</tr>
<tr>
<td>Surgeon's Gloves</td>
<td>1</td>
</tr>
<tr>
<td>Sterile Disposable Devices</td>
<td>174</td>
</tr>
<tr>
<td>Pacemakers</td>
<td>67</td>
</tr>
<tr>
<td>Intra-Uterine Devices</td>
<td>0</td>
</tr>
<tr>
<td>Ozone Emitting Devices</td>
<td>0</td>
</tr>
<tr>
<td>Factory Inspections-General</td>
<td>4,390</td>
</tr>
</tbody>
</table>

We can only speculate how Dalkon Shield users might have benefited, had the FDA diverted some of the attention focused on Diapulse to IUDs.

The FDA Consumer magazine, designed to reach the general public, carried many notices about Diapulse. I counted 11 items between May, 1976, and January, 1980, including a two page spread.

Let's turn our attention to just two of the cases in which individuals fought for the right to use their Diapulse machines.

TWO CASES - OWNERS AS CLAIMANTS

Henry Niemeyer, M.D., fought valiantly to win his 1977 trial before Federal District Judge Hubert Will in the Northern District of Illinois. For about 18 months Dr. Niemeyer was permitted to use his Diapulse machines. Judge Will was so persuaded of the value of Diapulse therapy that he offered to write the labeling himself if the FDA was unable or unwilling to work out acceptable labeling with Dr. Niemeyer.
Unfortunately, the FDA appeal caused the decision to be upset on a technicality. The Court of Appeals declared Judge Will erred by hearing the case. They said he should have remanded the case to the FDA for further review. The July, 1985, opinion by the Seventh Circuit Court of Appeals has paved the way for seizure of the machines. It seems unlikely that Dr. Niemeyer will appeal to the Supreme Court. He told me earlier this year he had already spent over $70,000 on his case.

The Niemeyer case is particularly important because it is the only case where the Judge heard the evidence on the efficacy of Diapulse. Judge Will's impartial hearing of the case was a breath of fresh air; many judges seem incredulous of the notion that the FDA could be unfair or inept.

In Norfolk, Virginia, in 1977, L. Cecil Rhodes, D.D.S., was equally convinced that Diapulse had significantly benefited thousands of his patients. He sought to convince the court of its value so that he could reclaim his machine. Like Dr. Niemeyer, he was only partly successful.

Senior Judge Walter Hoffman wrote "This court would like to allow Dr. Rhodes to relabel his device ... so that he could continue to use what is a safe and perhaps effective device on his patients. In fact, the court granted a recess in the trial in an attempt to obtain an appropriate relabeling. The court, however, confronted two problems in these attempts: The relabeling must be done under the supervision of the F.D.A., and the resulting label must conform to federal laws. The F.D.A.'s attitude in this case has been uncooperative, to say the least."

In the Rhodes case, the government brought as expert witnesses Joseph B. Davis, M.D., (an FDA physician) and Dr. S. Elmer Bear, Chairman of the oral surgery department at the Medical College of Virginia, who testified that Diapulse is of no use in bone and soft-tissue healing. In Judge Hoffman's words "Dr. Rhodes protested that these men had never worked with the device and that the F.D.A. has refused to run exhaustive tests on it. However, expert witnesses for the Government do not need to be familiar with the device itself, merely with the scientific principles on which it operates."

Although Dr. Bear may be an excellent dentist, I question his expertise in pulsed electromagnetic therapy. There is not yet a widely accepted theory for Diapulse's mode of operation. And Dr. Davis, representing the FDA, was clearly biased.

(Strengthened by his knowledge of Diapulse's value and undaunted by his loss in court, Dr. Rhodes is assembling a book which will present, in organized form, highlights of the considerable literature on Diapulse. He already has many of the necessary permissions from authors and publishers.)
DIAFPULSE WINS A BIG ONE

The Freedom of Information Act has been a boon to individuals and organizations on whom the United States government has information. It was the Freedom of Information Act that enabled the Diapulse Corporation to obtain copies of numerous FDA documents that clearly revealed persistent bias and prejudice against the company. Moreover, documents showed that not all FDA scientists subscribed to the oft-spoken opinion that pulsed electromagnetic energy is of no value in medical therapy.

In fact, one memo, which could be called a "smoking gun" showed that FDA officials feared to conduct a study of Diapulse efficacy. The memo stated, in pertinent part:

"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."

...  

"You should also be aware of the fact that Dr. Evans and his colleagues are concerned that the outcome of the research might harm the Government's case."

Federal Judge Jacob Mishler, in his opinion of November, 1983, commented "If the outcome of the research demonstrated the effectiveness of the Diapulse, then the government's duty was to change its position and not to discourage such results." Mishler found that the FDA had been arbitrary and capricious in denying Diapulse approval to market its pulsed diathermy machine, known as the P/EmF.

The FDA appealed Judge Mishler's decision. Oral arguments were held before the Second Circuit Court of Appeals on August 9, 1984. Assistant United States Attorney Cyril Hyman represented the FDA. Mr. Hyman's statements were so outrageous that the author independently sought the Court's permission to get a transcript of the hearing. The official transcript was released by the Clerk of the Court in June, 1985. Among Mr. Hyman's statements are the following:

"It has been proven scientifically that two wet towels have more therapeutic value than an $8000 machine.

(Pointing to ceiling light fixture): "You get more therapeutic value from sitting under this bulb, which is not a pulsed electromagnet ..."
"There's not one scientific study, Your Honors, produced by the Diapulse Corporation or anyone else that would show that there's any therapeutic effect whatsoever in pulsed electromagnetic energy, period."

On October 31, 1984, the Court of Appeals upheld Judge Mishler's decision. They ordered the FDA to either allow Diapulse to market the P/EmF device or else remove the Magnatherm from the market. FDA did not appeal to the Supreme Court. Thus, the court order resulted in a modification of the 1974 injunction. In March, 1985, the FDA finally wrote to Diapulse. They called the P/EmF a "post-enactment device" (i.e., one not on the market before the Medical Device Amendments of 1976 were enacted). Incredible! The P/EmF was named explicitly in the 1974 injunction! Finally, FDA accepted documentation from the company showing the P/EmF was a pre-enactment device and it is now on the market. Thirteen years of litigation -- and the FDA didn't admit its error or apologize.

On June 10, 1985, I filed a complaint about Assistant U. S. Attorney Cyril Hyman with the Office of Professional Responsibility of the Department of Justice about the false statements he made before the Appeals Court on August 9, 1984. Mr. J. Thomas Ezell was assigned to the complaint. Ezell cannot estimate when the investigation may be completed; it is now in its seventh month.

On September 21, 1985, I submitted a Freedom of Information request to the FDA, asking for citations to the studies that prove "scientifically that two wet towels have more therapeutic value ..." and for other information related to Mr. Hyman's presentation. The FDA acknowledged the request on November 6, but has not supplied the requested information.

In addition, I requested that the General Counsel of the Department of Health and Human Services investigate the role of FDA attorneys in the development of Mr. Hyman's arguments. I believe it is unconscionable that they could take a position that clearly contradicts the current thinking of FDA scientists, many of whom now accept the fact of pulsed electromagnetic therapy in general, and some of whom accept Diapulse therapy in particular. The General Counsel replied that he saw no basis in my letter for an investigation.

The story is not over, but perhaps the final chapters can soon be written.

Because the FDA will not clean up its own act, and because justice in the courts is so long in coming (if one can afford it), I continue to believe that a Congressional investigation is
needed. Please, if you agree, write to your congressman asking him to request an investigation by the Energy and Commerce Committee in the House or the Labor and Human Resources Committee in the Senate. Send copies to Senator Orrin G. Hatch, U.S. Senate, Washington, D.C. 20515 and Congressman John D. Dingell, Washington, D.C. 20510.

The American people deserve the benefits of Diapulse therapy, which is available to people all over the world but banned within the United States.

L. Leslie Hamilton, Ph.D., P.E.
13002 Autumn Drive
Silver Spring, MD 20904

December 27, 1985

**** "The Price of Liberty is Eternal Publicity" ****