

Citizen Petition

October 4, 2002

Dockets Management Branch
Food and Drug Administration
Room 10-61
5630 Fishers Lane
Rockville, MD 20857
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CITIZEN PETITION submitted by the undersigned Petitioner under 21CFR Part 10.30 of the Federal Food, Drug, and Cosmetic Act, for which authority has been delegated to the Commissioner of Food and Drugs under 21 CFR, Part 5.10.

ACTION REQUESTED

The petitioner requests that the FDA Commissioner better protect patients and consumers in the U.S. by amending the FDA 510(k) policy to include disclosure and labeling requirements, better evidence of the safety and efficacy of medical devices and products, and accountability for claims made by 510(k) applicants.

STATEMENT OF GROUNDS

The words "FDA Approved" should instill confidence in the American public that FDA-approved medical products or devices have been validated and proven to be safe and effective for consumers and patients. I am confident that the general public would be shocked to discover that in 1996, the FDA began approving medical devices and products based *solely* on the claims of the manufacturers, without any testing of the devices or products, or validation of the applicant's claims.

In the FDA's stated attempt to "speed up patient access to new medical devices", it appears the agency simply removed the steps of confirming that the medical products and devices actually do what the applicants claim. It appears 510(k) marketing approval is granted through a simple exchange of letters between the applicant and the FDA. Apparently, the applicant is not required to submit third-party or other unbiased test results, or even their own documented test results or studies. The only apparent criteria is the applicant's own claims or "opinions" that their device or product is similar in safety and efficacy to another device approved through the same obscure process, under the same relaxed guidelines.

Add to this the fact that a manufacturer's "SUBSTANTIALLY EQUIVALENT" (SE), claim is likely based on "research" or "studies" conducted by physicians or others who have personal financial interests in the company, the product, or the outcome of the FDA approval request. This, I believe, constitutes the *ultimate conflict of interest*, and will also shock the general public, who generally trust medical professionals to practice medicine and place patients before profits.

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It is unlikely that patients in the U.S. were lobbying the FDA to ease guidelines and “speed up access” to medical devices, as implied in the FDA’s 510(k) announcement. The lobbying was likely conducted by medical manufacturer’s and their representatives, and others whom the policy would benefit financially. It is also likely that the general public does not even know the policy exists, and mistakenly believes that “FDA Approved” still means FDA tested and validated.

Unbelievable is the only way to describe the 510(k) policy. It is an absolute betrayal of the American public, and the trust we place in the FDA.

Enclosed are copies of civil suits and reports from buyers of a \$150,000 medical device approved by the FDA under 510(k). Also included are supporting documents confirming the testing physician’s financial motives and roles in helping the manufacturer obtain FDA marketing approval of the device.

Following 510(k) approval of the **Epilight Hair Removal System** in 1997, the manufacturer, ESC Medical Systems (“ESC”), and highly-commissioned sales representatives began to aggressively market the device. Their claims were as phenomenal as was the price tag. They actively promoted the FDA approval as a virtual FDA *endorsement* of the device, with representatives claiming that “FDA protocol” had been followed in all testing procedures. The fact that the device was approved under 510(k), and that the FDA had never seen nor tested the device, or even validated the manufacturers claims was never disclosed.

Tens of thousands of patients throughout the U.S. have received treatments with the device, with many sustaining serious burns and failed results. Buyers of the device report massive losses and damages due to fraudulent claims made by the manufacturer and their representatives. Mass litigation has ensued.

As these events unfolded, Epilight buyers began to question whether the device ever produced the published and endorsed results claimed by the testing physicians. The FDA approval was also questioned. It was discovered that almost all of the physicians who helped “test” or endorse the Epilight device also had a financial interest in the company or the device itself, and in the FDA’s approval of the device. The truth about 510(k) was also discovered.

Two of the primary physicians, **Dr’s. Mitchel Goldman and Richard Fitzpatrick**, of San Diego, CA., had stock agreements with the company that had allowed them to purchase ESC stock at only \$.011 per share. ESC stock later soared to near \$40 per share. The physicians had even convinced one of their patients to invest over \$1 million to help take the company public. The physicians’ 1999 suit filed against ESC details their role in the Epilight scheme. Copies of the suit and Stock Purchase Agreements are included.

Another key physician, **Dr. Michael Gold**, of Nashville, TN., was also heavily involved in the “testing” and marketing of the Epilight device. He helped the company obtain FDA approval. He published an Epilight “study” that was reprinted by the company and used to convince other physicians throughout the U.S. to purchase the device. He turned his Nashville Dermatology office into a virtual sales office for ESC Medical Systems, and was paid to host Epilight sales seminars. He also traveled for the company, lecturing and endorsing the device. It was then discovered that he also had a separate business arrangement with the former chairman of ESC Medical Systems, Dr. Halley Faust.

This *side company*, called Vanishing Point, was to be a national chain of hair-removal centers using the Epilight device. Dr. Faust was the chairman and Dr. Gold was the National Medical Director. Vanishing Point was incorporated more than six months before the Epilight device was even approved by the FDA. This is relevant because it indicates that Dr. Gold's financial relationships and motives may have been in place even while Epilight test studies were still underway. In other words, tens of millions of dollars in profits for Dr. Gold could have been riding on the FDA approval of the Epilight device he was testing. How's that for a conflict of interest?

It appears that many other physicians involved in the FDA application and approval process of the Epilight device also had their own financial interests in the outcome of their "studies", and the subsequent FDA approval.

Damages resulting from the Epilight failure are likely in the tens of millions of dollars. This does not include the tens of thousands of patients who were treated with the device. Ironically, Vanishing Point also failed. CFO, Glen Shipley, confirmed that the Epilight device had turned out to be a "huge disappointment". It appears that Dr. Faust convinced another entity, Light Touch, which has now failed, to absorb Vanishing Point's debts and pay off the Epilight leases, which were near default.

The word "collusion" seems fitting when describing the activities surrounding ESC Medical and all parties involved with getting the Epilight device to market. Shareholders, consumers, and patients nationwide have sustained serious damages, while inside ESC shareholders and testing physicians apparently walked away with "millions". Why? Because the FDA 510(k) policy removed all checks and balances that prevent faulty medical devices and products from reaching the market. Accountability and consequences that would discourage fraudulent test studies and FDA applications from being submitted were also removed. Because of this, I believe 510(k) not only encourages consumer and medical fraud, it appears to facilitate it.

This is just one company and one device. **Thousands** of medical devices and products are approved each year under this same relaxed policy.

SPECIFIC ACTIONS REQUESTED:

To better inform and protect the general public, the Petitioner asks the FDA to amend the 510(k) policy as follows:

1. Require labeling in all marketing/promotional materials that promote products and devices approved under 510(k), informing consumers and patients that FDA approval is based solely on the claims and opinions of the applicant, and that the FDA neither sees nor tests the device or product, nor confirms or endorses the manufacturer's claims.
2. All verbal or printed references to the FDA approval of a medical device or product by the manufacturer or its representatives must be accompanied by disclosure of the 510(k) guidelines and limitations as stated above.

3. All 510(k) applications or summaries must include copies of all test studies or other reports leading to the conclusions and/or opinions stated in the summary or application.
 - a. All studies and/or reports included in the application must be signed and certified by the authors and the 510(k) applicant(s).
 - b. All printed, verbal, or implied financial relationships or agreements or prospective financial agreements between the 510(k) applicant and any individual or entity involved in the test studies must be disclosed in the application.
4. The petitioner also asks the FDA to investigate ESC Medical Systems, now operating as Lumenis ("LUME"), the Epilight 510(k) application submitted in 1996 and all tests and studies relating to the application, as well other 510(k) applications submitted thereafter by ESC and Lumenis.

SUMMARY:

For the same reasons the SEC now requires officers of publicly-held companies to certify company financial statements, the FDA should require those who seek approval of medical products or devices to certify their claims. Otherwise, there is no accountability for misstated, misleading, or fraudulent claims that result in FDA approval of unsafe or ineffective medical devices and products. How can the agency hold someone accountable when the only criteria for approval is the applicants "opinion"?

The current 510(k) policy has no "teeth", and hurts, rather than protects American consumers and patients. Under 510(k) the opportunity for applicants to submit inaccurate or fraudulent claims with little or no recourse is too great considering the financial motives of the applicants. The petitioner asks that the FDA restore some common sense and accountability to the 510(k) process.

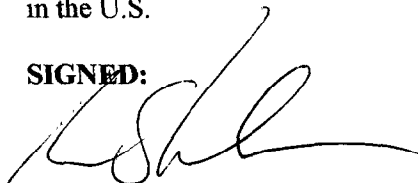
ENVIRONMENTAL IMPACT:

No environmental impact anticipated.

CERTIFICATION:

The undersigned Petitioner certifies that, to the best knowledge and belief of the Petitioner, this petition includes sufficient information and views on which the petition relies, and that no data or information is available that would prove to be unfavorable to the petition, as it relates to the interest of consumers and patients in the U.S.

SIGNED:



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FDA 510(k)

A bad policy that invites fraud and hurts U.S. consumers and patients

- Under 510(k), the FDA never sees or tests the medical devices it approves.
- Medical devices are approved based solely on the claims of the manufacturer.
- The only apparent criteria for approval is the manufacturer's own claim that, based on their own studies, the device is similar in safety and efficacy to other devices already FDA approved. They can even list one of their own 510(k)-approved devices as the predicate for the new device.