This was done at the same time that the application for TMJ Concepts, a competitor of TMJ Implants, sailed through the process. Several allegations have come to light over the last two years detailing the fact that several Agency employees have worked under the direction of TMJ Concepts' associates.

The agency went so far as to reconvene a new Medical Devices Advisory Committee late last year, with a clear majority of its members lacking the required expertise, which denied the company's application.

It was not until Mr. Bernard Statland, the new Director of the Office of Device Evaluation (ODE) was brought in that the logjam was broken the PMA was quickly approved.

As the above demonstrates, several concerns remain about the process that has taken place over the last two years. It is no secret that everyone involved in this case believes that there have been significant questions raised about the process—the sluggish pace of the review of the engineering data for both the total and partial joint and, more importantly, the constant ''moving of the goal posts'' during the review of both PMAs.

Over the last two years, my office has received numerous letters from physicians all across the country—from the Mayo Clinic to the University of Maryland—each describing the benefit of the partial joint and the fact that the partial and total joint results in immediate and dramatic decrease in pain, an increase in range of motion and increased function.

While I am, of course, pleased that the application has been approved by the FDA after much delay, the circumstances of the last two years calls into question the integrity of the agency and, it is for this reason that I bring it to the House's attention.

Dr. Christensen is a true professional and a pioneer in his field and holder of the first patents. His implants are widely accepted as effective and safe throughout the dental and surgery community—indeed, several of my constituents have literally had their lives changed by the procedure. I am convinced that the work of TMJ is and always has been based on solid, scientific principles and the removal of the implants from the market had been erroneous, contrary to the Agency's earlier findings and the statutory standard that should be applied. This was devastating to thousands in the general public and devastating to the financial status of the company.

Later this year, the House of Representatives will consider legislation reauthorizing the Food and Drug Administration and I would like to urge the House Commerce Committee to hold hearings on the TMJ Implant case and to conduct a thorough investigation into the FDA's review of the Premarket Approval Application of the TMJ Fossa-Eminence Prosthesis.

I would like to take this opportunity to submit into the record two articles from FDAWebview which shed light on the TMJ Implant case.

HOSPITAL INVESTMENT ACT OF 2001

HON. GERALD D. KLECZKA

OF WISCONSIN

IN THE HOUSE OF REPRESENTATIVES

Thursday, July 12, 2001

Mr. KLECZKA. Mr. Speaker, today Mr. Stark from California and I are introducing the Hospital Investment Act of 2001, which aims to address concerns regarding potential conflicts of interest raised by the advent of free-standing specialty or ''boutique'' hospitals with joint investor-physician ownership arrangements.

Over the past several years, we have seen a growing expansion of these ''boutique'' hospitals. Each of these hospitals specializes in one particular area of inpatient procedures—such as heart, orthopedic, or maternity—which is high-volume, high-cost, and high-profit to these new for-profit institutions.

Among the many problems associated with these boutique hospitals is the issue of self-referrals, where physicians refer their patients to a hospital in which they have a preferential ownership stake.

Under current federal law, a doctor may not refer his patients to a health care facility in which he has a financial interest. This includes clinical laboratory services, physical therapy, speech pathology, radiology services (such as MRIs, CAT scans, and ultrasound) and other auxiliary health services. Before these laws, commonly referred to as Stark I and Stark II, were passed in 1989 and 1993 respectively, the HHS Inspector General had discovered that Medicare patients received 45 percent more laboratory services when the doctor owned the lab than when the doctor did not.

One exception to the Stark laws allows a physician to refer patients to a hospital in which he or she has a financial interest, as long as that interest is in the whole hospital and not just a particular department or clinic within. With the proliferation of specialty hospitals, this exception has become a loophole by which physicians can legally refer patients to a boutique hospital in which they have a direct personal financial interest.

This preferential ownership provides physicians with increased financial incentives to engage in the very type of overutilization of medical services that the HHS Office of the Inspector General disclosed in its 1989 report, which invariably leads to increased federal Medicare and Medicaid spending without increased quality of patient care. This, as we all know, is the scenario that the Stark laws were designed to prevent in the first place.

The bill we are introducing today, the Hospital Investment Act of 2001, would address this problem by tightening the current law to prohibit preferential hospital ownership terms for physicians who wish to be able to refer patients to the facility. Under this legislation, physicians would be allowed to refer patients to a hospital in which they had an ownership interest, but only if the interest was purchased on terms also available to the general public.

Physicians and facilities that violate this new law would be subject to a civil monetary penalty of up to $15,000 per referral plus twice the amount billed for the referred service. In cases where there was an arrangement or scheme to refer patients to facilities owned by the physician, penalties could be as high as $100,000 and twice the amount billed for referred services. Also, the physician and specialty hospital would be denied participation in the Medicare program.

Mr. Speaker, it is imperative that Congress closes the hospital ownership loophole in the Medicare physician self-referral laws to ensure our nation's health care system is not compromised and to protect the viability of our nation's Medicare and Medicaid programs. I urge my colleagues to cosponsor and support this important legislation.

HISPANIC RECOGNITION AWARDS

HON. BARNEY FRANK

OF MASSACHUSETTS

IN THE HOUSE OF REPRESENTATIVES

Thursday, July 12, 2001

Mr. FRANK. Mr. Speaker, I was delighted to be given a chance to send my congratulations to the winners of the Hispanic Recognition Awards which are going to be held on August 3 in North Dartmouth, Massachusetts. The Hispanic Recognition Awards Committee has assembled a very diverse and valuable group of individuals and institutions to receive well merited recognition for their work in helping preserve Latino culture and values in the framework of our national unity. I am delighted to have a chance to share with my colleagues the work of this important organization and I ask that the names of the award winners be printed here so that they may get the recognition to which they are entitled.

MEDICARE PHYSICIAN SELF-REFERRAL—A BILL TO KEEP SPECIALTY HOSPITALS FROM SKIRTING THE INTENT OF THE LAW

HON. FORTNEY PETE STARK

OF CALIFORNIA

IN THE HOUSE OF REPRESENTATIVES

Thursday, July 12, 2001

Mr. STARK. Mr. Speaker, Rep. KLECZKA—who represents Milwaukee and serves with me on the Ways and Means Health Subcommittee—brought to my attention a report by the Milwaukee Journal Sentinel on Monday, June 25, 2001, that two Milwaukee hospital groups are planning to open free-standing heart hospitals. Both of these specialty hospitals will jointly owned by the hospitals and the groups of physicians who will be referring patients to the facilities. The newspaper article pointed out the potential conflict-of-interest, and the resulting ethical concern, for physicians who refer patients to facilities in which they have an ownership interest. These joint ventures may induce investor physicians to base their treatment decisions on profits generated by the facility rather than on the clinical needs of their patients.

Mr. Speaker, the situation in Milwaukee is similar to other reports that hospitals and physicians are engaging in such clinical joint ventures, including both freestanding specialty hospitals (e.g., heart, orthopedic, or maternity hospitals), and arrangements in which a high revenue generating unit or service (e.g., cardiology or cardiac surgery) of an existing hospital is restructured and legally incorporated as a separate hospital.

Typically, these point ventures are marketed only to physicians in a position to refer patients to the facility, and they are structured to take advantage of a loophole in the Medicare physician self referral law permitting physician investments in ''whole hospitals''.

Mr. Speaker, the development of specialty hospitals is of great concern because they deprive full-scale hospitals of their most profitable business, leaving those existing hospitals much worse off financially. The investors in these joint ventures and specialty hospitals skim the profits of full-scale hospitals, leaving