EXTENSIONS OF REMARKS

Mr. TANCREDO. Mr. Chairman, I rise in opposition to H.R. 2330, the Agriculture Appropriations Act, a bill considered on the floor today which makes appropriations for the Department of Agriculture and related agencies. But more specifically, I rise in strong opposition to the increase provided in the bill for the Food and Drug Administration (FDA) and would like to call the House’s attention to a problem that one of my constituents has been having with the agency and one that I believe deserves careful consideration by the oversight committees in this chamber.

Recently, the FDA gave final approval of my constituent’s Pre-Market Application for both total and partial joint implants after an exhaustive and blatantly biased two year review, but not before costing his company over $8 million in legal fees, lost wages and profits.

In April 1999, I received a phone call and letter from TMJ Implants, a company located in Golden, Colorado, in my district, which had been having problems with the review of its Premarket Approval Application of the TMJ Total and Fossa-Eminence Prosthesis. Up until last year, the company was the premier market supplier of temporomandibular joint prostheses.

Over the last two years, I have taken an active interest and an active role in monitoring the progress of TMJ Implants’ application, which was finally approved in February. On numerous occasions, I met with Dr. Bob Christensen, President of TMJ Implants, to find out information about the approval of the Partial and Total Joint, and personally talked to FDA Commissioner Jane Henney and to members of the Agency about the status of the company’s applications. I was also, and continue to be, in contact with the House Commerce Subcommittee on Oversight, which has sole jurisdiction over the FDA and issues relating to abuse and the internal operations of the agency.

Specifically, I closely followed this case since my office’s first contact with Dr. Christensen and TMJ Implants in early May 1999, after a meeting of the FDA’s Dental Products Panel of the Medical Devices Advisory Committee was held to review the company’s PMA and recommended approval of
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 structures.

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 personal 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 reason 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. Allowing such facilities to operate in the Medicare program would be disastrous for the Medicare program and the health care system as a whole.

Mr. Speaker, I am delighted to be given a chance to share with my colleagues the work of this important organization and to ask that the names of the award winners be printed here so that they may get the recognition to which they are entitled.

Mr. FRANK. Mr. Speaker, I was delighted to receive numerous letters from physicians all across the country—from the Mayo Clinic to the University of Maryland—each describing the benefits 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 cast a shadow over the agency and its integrity. It is for this reason that I bring it to the House's attention.

Dr. Christiansen is a true professional and a pioneer in his field and holder of the first patients. 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 results remain impressive and valuable.

The FDA's review of the Premarket Approval Application (PMA) for TMJ's Fossa-Eminence Prosthesis was lengthy, with the agency indicating that it would need months to conduct a thorough investigation into the FDA's review of the Premarket Approval Application of TMJ's Fossa-Eminence Prosthesis. The agency went so far as to recommend 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.

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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 be 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 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. Allowing such facilities to operate in the Medicare program would be disastrous for the Medicare program and the health care system as a whole.

Mr. Speaker, I am 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 12 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 to ask that the names of the award winners be printed here so that they may get the recognition to which they are entitled.