

TRIBUTE TO ASHLEY TUREK OF
ADRIAN, MI—LEGRAND SMITH
SCHOLARSHIP WINNER

HON. NICK SMITH

OF MICHIGAN

IN THE HOUSE OF REPRESENTATIVES

Thursday, July 12, 2001

Mr. SMITH of Michigan. Mr. Speaker, it is with great respect for the outstanding record of excellence she has compiled in academics, leadership and community service, that I am proud to salute Ashley Turek, winner of the 2001 LeGrand Smith Congressional Scholarship. This award is made to young adults who have demonstrated that they are truly committed to playing important roles in our Nation's future.

As a winner of the LeGrand Smith Congressional Scholarship, Ashley is being honored for demonstrating that same generosity of spirit, intelligence, responsible citizenship, and capacity for human service that distinguished the late LeGrand Smith of Somerset, Michigan.

Ashley is an exceptional student at Adrian High School and possesses an impressive high school record. Ashley is President of her Senior Class and has served as Captain of her Tennis and Track teams. She has received numerous awards for her excellence in academics as well as her involvement in tennis, gymnastics, and track. Outside of school, Ashley is an active volunteer in various community organizations such as the Lenawee County Youth Council.

Therefore, I am proud to join with her many admirers in extending my highest praise and congratulations to Ashley Turek. This honor is also a testament to the parents, teachers, and others whose personal interest, strong support and active participation contributed to her success. To this remarkable young woman, I extend my most heartfelt good wishes for all her future endeavors.

HONORING PATRICIA HALSEY
LAVERDURE

HON. BARBARA LEE

OF CALIFORNIA

IN THE HOUSE OF REPRESENTATIVES

Thursday, July 12, 2001

Ms. LEE. Mr. Speaker, I rise today to honor and salute Patricia Halsey Laverdure for her faithful service to the United States Military.

Colonel Laverdure has dedicated her life to providing legal counsel to military members and their families. When she joined the U.S. Marine Corps, she was interested in criminal law, and became a very successful judge advocate. However, Colonel Laverdure was drawn to family law because she knows the burdens that military families face, such as long periods of separation, spousal abuse and low pay. She saw the need for family services so she began to practice family law. Colonel Laverdure established the first spousal abuse programs for the U.S. Marine Corps Family Service Centers.

Colonel Laverdure later became the Chief of the Legal Assistance Branch of the Maintenance and Logistics Command Pacific for the U.S. Coast Guard in Alameda, California. At a

time when the military was downsizing, Colonel Laverdure was overwhelmed with huge caseloads. Despite the large amounts of casework, she enlisted the aid of military attorneys from the Navy Reserve and, together with other Coast Guard Attorneys, completed their cases and increased the number of clientele.

Colonel Laverdure has won numerous awards such as the Meritorious Achievement Award, the ABA LAMP Distinguished Award and the Coast Guard Meritorious Award. It is only natural that Congress should recognize Colonel Laverdure for her patriotism, her service to the United States military service and her human compassion for her others.

I proudly join Colonel Laverdure's family and friends to pay tribute to Colonel Patricia Halsey Laverdure.

TRIBUTE TO ANGELA PITTS OF
LITCHFIELD, MI—LEGRAND
SMITH SCHOLARSHIP WINNER

HON. NICK SMITH

OF MICHIGAN

IN THE HOUSE OF REPRESENTATIVES

Thursday, July 12, 2001

Mr. SMITH of Michigan. Mr. Speaker, it is with great respect for the outstanding record of excellence she has compiled in academics, leadership and community service, that I am proud to salute Angela Pitts, winner of the 2001 LeGrand Smith Congressional Scholarship. This award is made to young adults who have demonstrated that they are truly committed to playing important roles in our Nation's future.

As a winner of the LeGrand Smith Congressional Scholarship, Angela is being honored for demonstrating that same generosity of spirit, intelligence, responsible citizenship, and capacity for human service that distinguished the late LeGrand Smith of Somerset, Michigan.

Angela Pitts is an exceptional student at Litchfield High School and possesses an impressive high school record. Angela has received numerous awards for her academic achievement and her success as a young athlete. She is active in student government, as well as the high school and jazz bands. Angela volunteers her time to various organizations, such as her community's youth group, and coaches young children in basketball.

Therefore, I am proud to join with her many admirers in extending my highest praise and congratulations to Angela Pitts for her selection as a winner of a LeGrand Smith Congressional Scholarship. This honor is also a testament to the parents, teachers, and others whose personal interest, strong support and active participation contributed to her success. To this remarkable young woman, I extend my most heartfelt good wishes for all her future endeavors.

AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS ACT, 2002

SPEECH OF

HON. THOMAS G. TANCREDI

OF COLORADO

IN THE HOUSE OF REPRESENTATIVES

Wednesday, July 11, 2001

The House in Committee of the Whole House on the State of the Union had under consideration the bill (H.R. 2330) making appropriations for Agriculture, Rural Development, Food and Drug Administration, and Related Agencies programs for the fiscal year ending September 30, 2002, and for other purposes:

Mr. TANCREDI. 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 prosthesis.

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 the PMA by a 9-0 vote. From this point onward, the FDA engaged in an obvious pattern of delay and deception and even went as far as to remove TMJ Implants' Fossa-Eminence Prosthesis from the market, which had been available for almost 40 years. This had done nothing more than to cause harm to patients and cost the company millions of dollars.

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 Hos-

pital 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