Herald, entitled ''No to a World Court'' into the CONGRESSIONAL RECORD.

[From the Omaha World-Herald, Dec. 20, 2000]

NO TO A WORLD COURT

America's political leaders are being wooed with a siren song they would do well to resist. Foreign governments, political activists and academics are sounding that song with the aim of enticing the United States into ratifying a treaty to create an International Criminal Court. The song goes something like this:

Turn away from old notions. Turn away from your antiquated allegiance to national sovereignty. Embrace a higher moral order. Recognize that if nations are to promote true justice, they must swallow their pride and bow to a higher authority, a court, that will decide questions of war crimes and genocide and see that wrongdoers receive the punishment they deserve.

If a treaty establishing the court is approved by 60 nations, the world would finally have a permanent international forum with the authority to prosecute masterminds of genocide and war crimes.

It is superficially appealing. But behind the high-minded sentiments lies an agenda hostile to U.S. interests.

Foreign governments and activists organizations have sent strong indications that they envision the court largely as a tool for reining in the assertion of U.S. power. Through its ability to prosecute American officials and military people, the court would give anti-American critics a powerful new instrument for undermining U.S. military operations and intimidating U.S. leaders from launching future ones.

Creation of the court would also aid its boosters in their efforts to create a new standard for military operations, an ''enlightened'' standard that would, in effect, severely restrict U.S. military options under threat of international prosecution.

The eagerness of international activists to promote such extravagant legal claims was demonstrated this year when human rights groups tried unsuccessfully to haul NATO officials before an international tribunal investigating war crimes from the Yugoslav civil war. The activists claimed, without foundation, that NATO's 1999 bombing campaign violated international law in reckless disregard for civilians.

That air campaign, ironically, was marked not be callousness on the part of NATO officials but by the extraordinary lengths to which they sought to minimize casualties, civilian as well as military. Regrettable losses of civilian life occurred nonetheless, fanning the criticism of such interventions.

As if all this weren't enough, the proposed procedures for the International Criminal Court would place it in direct opposition to civil liberties guaranteed under the U.S. Constitution. Proceedings before the court would allow no trial by jury, no right to a trial without long delays, no right of the defendant to confront witnesses, no prohibition against extensive hearsay evidence and no appeals.

David Rivkin and Lee Casey, two American attorneys with extensive experience in international law, note that the court would serve as ''police, prosecutor, judge, jury and jailer,'' with no countervailing authority to check its power.

Rivkin and Casey also point out that trying Americans under such conditions was precisely the sort of injustice that Thomas Jefferson warned against in the Declaration of Independence more than 200 years ago.

In listing the injustices committed by the British government, the Declaration heaped particular scorn on the way Americans had been abused by British vice-admiralty courts. Such courts, the Declaration said, had subjected American defendants ''to a jurisdiction foreign to our constitution, and unacknowledged by our laws.'' The courts denied people ''the benefits of Trial by Jury'' and involved transporting them ''beyond Seas to be tried for pretended offenses.''

When the U.S. Constitution was drafted in the late 1780s, it specifically required that criminal trials be by jury and held in the state and district where the crime was committed.

The appropriate course for the United States would be to continue supporting international courts on an ad hoc basis, such as the Yugoslav tribunal, to meet the needs of particular situations. Such bodies have powers far more modest than that of the proposed court.

A chorus of foreign governments, advocacy groups and commentators has a far different agenda, however. They are urging the United States to sign and ratify the treaty creating the International Criminal Court. To hinder the court's creation, they say, would be the opposite of progressive.

But the siren song ought to be resisted. Otherwise, by bowing to foolhardy legal restrictions, the United States would be handing its clever critics the very chains with which they would bind this country. And so we would lose some of our ability to defend not only our own interests but the freedoms of others.

RECOGNIZING MRS. ANN HEIMAN OF GREELEY, COLORADO

HON. BOB SCHAFFER

OF COLORADO

IN THE HOUSE OF REPRESENTATIVES

Wednesday, January 3, 2001

Mr. SCHAFFER. Mr. Speaker, today I wish to recognize one of my constituents, Mrs. Ann Heiman of Greeley, Colorado. Last autumn, Mrs. Heiman received The Daily Points of Light Award for her community action and acts of generosity.

Mrs. Heiman's story is remarkable. A cancer survivor of 47 years, she has never stopped in her service to her fellow citizens. Mrs. Heiman was a founding member of the original Eastside Health Center, served on the task force for a family assistance organization, and was a founding board member of the Weld Food Bank—which distributes 37 tons of food weekly to those in need. She was also one of the first board members of A Woman's Place, a center for abused women, and she is a member of the local board of education.

I am extremely proud of Mrs. Heiman. I am proud to recognize her as an outstanding Coloradan. Her dedication to our western community and her compassion for all have made an enduring difference in the lives of her neighbors. I ask the House to join me in extending congratulations to Mrs. Heiman of Colorado.

TRIBUTE TO MARQUETTE POLICE CHIEF SAL SARVELLO ON THE OCCASION OF HIS RETIREMENT

HON. BART STUPAK

OF MAINE

IN THE HOUSE OF REPRESENTATIVES

Wednesday, January 3, 2001

Mr. STUPAK. Mr. Speaker, as you and our House colleagues are aware, I have worked since my first day in Congress to bring a broad awareness of the needs and concerns of law enforcement officials to the floor of this chamber. I experience the great joy of this personal mission when I can speak, as I do today, to celebrate the career and dedication of a law enforcement officer at the house of this retirement.

Police Chief Salvatore Sarvello joined the Marquette, Michigan, Police Department as a patrolman in 1971, about the same time that I was joining public safety department in the nearby community of Escanaba. Our careers took different paths—I became a Michigan State Trooper and eventually entered politics, while Sal worked his way up through his department, becoming chief in 1995. Despite our different paths, we had numerous opportunities to work together, perhaps most significantly on the issue of methcathinone, an illegal drug that plagued northern Michigan for several years. Production of this drug, commonly known as CAT, took root in our area. With the help of Sal and other investigators in the region, I was able to develop legislation—my very first piece of federal legislation signed into law—that took the claws out of this highly addictive substance.

Sal has always been a supporter of the COPS program, the wonderfully ambition and successful plan to help cities, counties, townships and other municipalities hire additional law enforcement officers. I have worked hard in Congress to ensure this program continued to receive funding until the goal of hiring 100,000 new officers by the 2000 was reached, and the support grass-roots support of officers like Chief Salvatore was essential in accomplishing this task. I worked with Sal for the visit of Vice President Al Gore, first in 1992 as part of a campaign swing for the Clinton-Gore ticket, and again in '94. I appreciate and applaud his professionalism in dealing with the complications, uncertainties and last-minute decisions associated with a visit on short notice of a national political to a small community.

A recent article in the Marquette *Mining Journal* notes that Chief Sarvello's law enforcement career actually goes back to the mid-60s, when he served as a U.S. Air Force Security police officer in Vietnam. This lifetime of public service, the article notes won't end with the Chief's retirement, because he plans to remain active with the Marquette West Rotary Club and with his parish, St. Michael's Catholic Church.

The chief looks forward to spending more time with Joan, his wife of 34 years, and his sons, Michael and Scott. At a special gathering Friday, the community will have a chance to wish the best to its retiring chief. Mr. Speaker, I ask you and our colleagues to join me in offering our thanks to this dedicated public servant, Chief Sal Sarvello, for a job well done.

INTRODUCTION OF BILL TO AMEND CLEAR CREEK COUNTY, COLORADO, LANDS TRANSFER ACT

HON. MARK UDALL

OF COLORADO

IN THE HOUSE OF REPRESENTATIVES

Wednesday, January 3, 2001

Mr. UDALL of Colorado. Mr. Speaker, I am today reintroducing a bill to provide additional

time for Clear Creek County to sell certain lands that it received from the United States under legislation passed in 1993.

Under that legislation—the Clear Creek County, Colorado, Public Lands Transfer Act—the County took title to certain public lands with explicit authority for their sale, subject to two basic requirements: the County must pay to the United States any net proceeds realized after deduction of allowable costs, as defined through agreement with the Secretary of the Interior; and any lands not sold within 10 years after enactment of the Transfer Act must be retained by the County.

In the last Congress, I introduced a bill to extend for an additional ten years the period during which the County will be authorized to sell these lands. This has been requested by the Commissioners of Clear Creek County because it has taken longer than anticipated for the county to implement this part of the Transfer Act. Additional time would mean a greater likelihood that the County can sell these lands, and thus a greater chance that the national taxpayers will benefit from payments by the County. Last year, the House passed the time-extension bill, but the Senate did not complete action on it.

The bill I am introducing today is almost identical to the one the House passed last year. The only difference is that the new bill would extend until May 19, 2015 the time for the county to sell the lands in question—one year longer than under the previous bill. The additional year would be provided in recognition of the additional time that will now be required for the bill to be enacted into law.

TMJ IMPLANTS

HON. THOMAS G. TANCREDO

OF COLORADO

IN THE HOUSE OF REPRESENTATIVES

Wednesday, January 3, 2001

Mr. TANCREDO. Mr. Speaker, in April 1999, I received a phone call and correspondence 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 by the United States Food and Drug Administration (FDA). Over the last year and a half—and delay after delay resulting in the pulling of the implants from the market, I have watched the process drag on, leading to the loss of millions of dollars by the company and countless number of patients who have been put through unnecessary pain. While I will let my submission speak for itself, suffice it to say that I sincerely believe that most of the frustration could have been avoided had everyone sat down and laid everything out on the table in the spirit of what was called for under the FDA Modernization Act. Unfortunately, the agency has been unwilling to do so—and it seems that these problems will continue into the foreseeable future.

Over the last year and a half, my office has received numerous letters from physicians all across the country—from the Mayo Clinic to the University of Maryland—each relaying to me 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. To date, there is no scientific reasoning for the fact that the total and partial joints are not on the market. All of this calls into question the integrity of the agency—something that I find very disturbing.

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 based on solid, scientific principles and the removal of the implants from the market has been and continues to be erroneous, contrary to the Agency's earlier findings and the statutory standard that should be applied.

I would like to take this opportunity to submit into the RECORD a copy of a letter from Mr. Roland Jankelson to the FDA urging the agency to come to an agreement as soon as possible so that this disaster is remedied and thousands of patients in the general public can receive relief.

ROLAND JANKELSON,
15 PONCE DE LEON TERRACE,
Tacoma, WA, December 28, 2000.

MR. LES WEINSTEIN,
U.S. Food and Drug Administration, Ombudsman, Center for Devices and Radiological Health,
9200 Corporate Blvd., Rockville MD.

Re: TMJ Implants, Inc.

DEAR MR. WEINSTEIN,

With reference to our phone conversation today, please note the following comments (especially the last point, which I hope will shape your actions in the next couple of days):

1. There is no need for another meeting with ODE. The purposes of this meeting (as stated in the Blackwell E-mail) are bogus—just more obfuscation and more delay. As Mike Cole stated in his December 27, 2000 letter to Tim Ulatowski, a copy of which you have: ''You say we must arrive at an acceptable, consistent diagnosis criteria in order to write a label''. I say we are already there, and have been for two months . . . (Underlining is my emphasis).

2. There never has been any credible evidence before the FDA of a safety problem (in over thirty plus years of use) that would prevent the Christensen devices (total and partial joint) from meeting the required standard of reasonable assurance of safety. Approval was given to TMJ Concepts device with limited data and little history. The information, data and history given to FDA for the TMJ Implants device exceeds many-fold, by every possible measure, the composite of information used to approve its competitor. The Christensen Company, its consultants and its attorneys have responded to every issue, every hypothetical concern posed by FDA, no matter how far-fetched these issues and concerns were. See Mike Cole's notes attached for just a quick summary of the Company's responses since the October Panel meeting. As Mr. Cole states in his letter, the questions posed in the Blackwell E-mail were addressed two months ago. Yet, for two months, there has been no response from the Ulatowski side. You and Mr. Ulatowski have been informed that this was a company on the verge of financial ruin. This does not make any difference to Mr. Ulatowski—It is not his concern, not his focus. A man's reputation, ruined. A company financially gutted. Patients suffering. ''Myotronics'' all over again. How could this happen again? it has.

With respect to the meeting called for in the Blackwell E-mail: There is no more explanation needed from the Company. There is no more ''perspective (Blackwell's word) to share. Just more delay.

3. Forget that Dr. Christensen faces financial ruin. Forget that his company's resources are nearly exhausted. Every day that goes by without FDA approval of the TMJ Implants, Inc. total joint, and partial joint in particular, is a day that patients suffer. The PMA record is indisputable. Physicians and patients have uniformly made it clear that the FDA is harming them. The FDA is on notice that physicians are withholding needed surgery, waiting for the Christensen devices, both total and partial joint. The physicians have uniformly made it clear to the FDA that the TMJ Concepts, Inc. joint is unacceptable for their patients. Others have made it clear that without the availability of a partial joint, patients will be subjected to surgery that unnecessarily destroys healthy anatomy. Witholding approval of these devices is a willful disregard by FDA of the public health. Ulatowski does not care.

4. About five years ago, Rick Blumberg, Deputy Counsel for Litigation, for whom I have great respect, persuaded me to forego what would have extended FDA's involvement in the Myotronics matter, i.e. litigation by Myotronics that would have further publicized the already well-publicized findings of more than two years of Congressional hearings, OIA and IGHHS investigations. Rick assured me, and I believe he believed, that the FDA was, indeed, changed in reaction to the revelations of the multiple and extra-legal activities of FDA employees intentionally directed at and intended to harm Myotronics. BUT HE WAS WRONG! The abuse, misuse of agency authority for the pursuit of a private agenda to harm a targeted company, retaliation and punishment, is all repeated against TMJ Implants, Inc., whose devices for thirty plus years served a specialized ''salvage need'' and relieved human suffering. Standing in the middle of these abuses: the same Mr. Tim Ulatowski.

5. The record cries out for intervention by you and other responsible FDA officials. Neither Susan Runner nor Tim Ulatowski have credibility in this matter. In reviewing this matter, you and senior FDA and OIA officials should look at a number of issues:

(a) A phone call from Dr. Susan Runner to Dr. Christensen days before the May 1999 Panel meeting informing Dr. Christensen that his PMA would be disapproved, and advising him to withdraw it.

(b) Information leaked by the FDA prior to the 1999 Panel that TMJ Implants, Inc. devices ''were either withdrawn by FDA or would soon be''. Remember the FDA leaking in the Myotronics case.

(c) Treatment of TMJ Implants, Inc. PMA's with standards different than used for its competitor, TMJ Concepts, Inc.'s PMA: TMJ Concepts, Inc. was approved without delay in spite of a device history covering only a few years and limited data, compared to a device history of more that thirty years for the Christensen devices, and much more data.

(d) Removal of the partial and total joint form the market in spite of a 9–0 Panel approval and a need acknowledged the FDA Panel.

(e) Allegations that Dr. Susan Runner had a conflict of interest stemming from her past relationship with Dr. Mecuri, TMJ Concepts, Inc. chief technical consultant—allegations rejected by OIA without any apparent serious injury.

(f) Data and evidence covering over thirty years of use that demonstrates a remarkable safety record. Why has this device been held hostage?

(g) Staff's dismissal of TMJ Implants, Inc. request for the addition of qualified experts for the October 2000 Panel.