

Just when you thought the Shocks had it all wrapped up, the Sparks made a comeback, twice. But the Shocks pulled out a win, and a franchise that was down and out a year before was accepting the Women's National Basketball Association championship.

Head Coach Bill Laimbeer and his staff of Laurie Byrd, Pamela McGee, and Korie Hlede provided strong leadership and solid coaching. This has resulted in a basketball team that is hard working and dominates on the basketball court.

The Women's National Basketball Association and the Detroit Shocks exemplify the highest standards of sportsmanship and success, and as such, have encouraged girls and women across the country to participate in professional sports. I congratulate them on a well-deserved win and urge the passage of this resolution.

Mr. CONYERS. Mr. Speaker, today I rise to honor the women of the Detroit Shock Women's National Basketball Association team. On September 16, 2003, the ladies of the Detroit Shock made history with their first ever Women's National Basketball Association championship, defeating the 2-time defending champion Los Angeles Sparks. Through the leadership of Rookie of the Year Cheryl Ford, Playoff MVP Ruth Riley, and Coach Bill Laimbeer, the Shocks displayed strength, resolve and the highest standard of sportsmanship.

It is fitting that H. Res. 392 will be passed today, just one day after International Women's Day and during National Women's Month. This month we are celebrating the great strides women have made in society, and must recognize and highlight the advancements women have made in professional sports. Since the passage of Title IX, which mandates gender equity in school sports, we have seen women's athletics flourish as a tool for empowering young girls. College basketball programs across the country have produced some of the most dynamic athletes of our time—including Cheryl Ford and Ruth Riley of the Shock, as well as Diana Taurasi of the University of Connecticut. These young women are clear examples to the younger generation of girls that the pursuit of athletic excellence can produce the highest rewards for women and men alike.

The Detroit Shock team has made metropolitan Detroit and greater Michigan proud by displaying the trademark Michigan values of hard work, dedication, and perseverance. We honor these women for their strength and resolve, and for being leaders of the next generation of women in sports. We look forward to another win this year!

Mr. Speaker, I yield back the balance of my time.

Mr. MICHAUD. Mr. Speaker, I have no further requests for time, I urge all Members to support the adoption of H. Res. 392, and I yield back the balance of my time.

The SPEAKER pro tempore (Mr. TERRY). The question is on the motion offered by the gentlewoman from Michigan (Mrs. MILLER) that the House suspend the rules and agree to the resolution, H. Res. 392.

The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds of those present have voted in the affirmative.

Mrs. MILLER of Michigan. Mr. Speaker, on that I demand the yeas and nays.

The yeas and nays were ordered.

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX and the Chair's prior announcement, further proceedings on this motion will be postponed.

#### CONGRATULATING THE SAN JOSE EARTHQUAKES FOR WINNING THE 2003 MAJOR LEAGUE SOCCER CUP

Mrs. MILLER of Michigan. Mr. Speaker, I move to suspend the rules and agree to the resolution (H. Res. 475) congratulating the San Jose Earthquakes for winning the 2003 Major League Soccer Cup.

The Clerk read as follows:

H. RES. 475

Whereas on November 23, 2003, the San Jose Earthquakes defeated the Chicago Fire to win the 2003 Major League Soccer Cup;

Whereas the Earthquakes achieved a 14-7-9 regular season record to finish 1st in the Major League Soccer Western Conference;

Whereas the San Jose Earthquakes finished an extraordinary season by overcoming injuries, adversity, and multiple-goal deficits to reach the Major League Soccer Cup championship match;

Whereas in the championship match, the San Jose Earthquakes and the Chicago Fire scored 6 goals combined, breaking the Major League Soccer Cup championship match scoring record;

Whereas the Earthquakes' Head Coach Frank Yallop led the team to victory;

Whereas the Earthquakes' team of world-class players, including Jeff Agoos, Arturo Alvarez, Brian Ching, Jon Conway, Ramiro Corrales, Troy Dayak, Dwayne De Rosario, Landon Donovan, Todd Dunivant, Ronnie Ekelund, Rodrigo Faria, Manny Lagos, Roger Levesque, Brain Mullan, Richard Mulrooney, Pat Onstad, Eddie Robinson, Chris Roner, Ian Russell, Josh Saunders, Craig Waibel, and Jamil Walker contributed extraordinary performances throughout the regular season, playoffs and Major League Soccer Cup;

Whereas San Jose midfielder Ronnie Ekelund scored in the 5th minute of play, tying Eduardo Hurtado for the fastest goal scored in a Major League Soccer Cup championship match;

Whereas with the victory, San Jose captain Jeff Agoos won his 2nd Major League Soccer Cup for the San Jose Earthquakes and his 5th Major League Soccer Cup overall;

Whereas San Jose forward Landon Donovan, who has been named United States National Team Player of the Year twice, scored 2 goals on 2 shots in the championship match, earning the Honda Major League Soccer Cup Most Valuable Player Award;

Whereas by winning the 2003 Major League Soccer Cup, the San Jose Earthquakes join DC United to become the 2nd team in Major League Soccer history to win the Major League Soccer Cup more than once;

Whereas the Earthquakes have brought great pride to the City of San Jose and to the State of California;

Whereas Major League Soccer has become extremely popular in only 8 seasons; and

Whereas the success of Major League Soccer has contributed to the growing popu-

larity of soccer in the United States in recent years: Now, therefore, be it

Resolved, That the House of Representatives—

(1) congratulates the San Jose Earthquakes for winning the 2003 Major League Soccer Cup;

(2) recognizes the achievement of the San Jose Earthquakes' players, coaches, staff, and supporters in bringing the 2003 Major League Soccer Cup to San Jose;

(3) commends the San Jose community for its enthusiastic support of the Earthquakes; and

(4) expresses the hope that Major League Soccer will continue to inspire fans and young players in the United States and around the world by producing teams of San Jose's high caliber.

The SPEAKER pro tempore. Pursuant to the rule, the gentlewoman from Michigan (Mrs. MILLER) and the gentlewoman from the District of Columbia (Ms. NORTON) each will control 20 minutes.

The Chair recognizes the gentlewoman from Michigan (Mrs. MILLER).

GENERAL LEAVE

Mrs. MILLER of Michigan. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days within which to revise and extend their remarks and to include extraneous material on H. Res. 475.

The SPEAKER pro tempore. Is there objection to the request of the gentlewoman from Michigan?

There was no objection.

Mrs. MILLER of Michigan. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, last November, in the championship match of the 2003 Major League Soccer season, the San Jose Earthquakes defeated the Chicago Fire 4 to 2. The win clinched the Earthquakes' second MLS title in three seasons. House Resolution 475 deservedly congratulates the San Jose Earthquakes for winning the Major League Soccer Cup. With this championship, San Jose became only the second team in MLS history to win two Cups.

Mr. Speaker, throughout the long soccer season, the steady leadership of Coach Frank Yallop guided the Earthquakes to 14 wins. And after winning the MLS Western Conference crown during the regular season, the Earthquakes rallied from behind in both the Conference Semifinals and the Conference Championship matches to reach the Championship. In the final match, the Earthquakes outlasted the Chicago Fire in the highest scoring MLS Cup final ever, winning 4 to 2.

Mr. Speaker, Coach Yallop earned his second MLS Cup with the victory, and he became the second coach in league history to lead two championship teams. Also noteworthy, the Earthquakes' star forward Landon Donovan became the first player to score two goals in an MLS Cup final match. He earned the MLS Cup's Most Valuable Player award for his performance.

Mr. Speaker, the 2003 season was certainly one to remember for the San Jose Earthquakes' players, for their coaches, for their support staff, and

their fans. I thank the gentleman from California (Mr. HONDA) for working to congratulate the champs of Major League Soccer, the San Jose Earthquakes, and I strongly support House Resolution 475.

Mr. Speaker, I reserve the balance of my time.

Ms. NORTON. Mr. Speaker, I yield myself such time as I may consume.

On November 23, 2003, the San Jose Earthquakes thrilled a sellout crowd of soccer fans with a 4 to 2 Major League Soccer victory over the Chicago Fire. The Earthquakes earned their second Major League Soccer Cup in 3 years and became only the second major league team to win multiple titles. My hometown team, D.C. United, has won the Cup three times in its 8-year history.

Major League Soccer could not have asked for a better and more exciting game for its network-televised event. The San Jose Earthquakes and the Chicago Fire scored six goals combined, breaking the Major League Soccer Cup championship match scoring record.

San Jose midfielder Ronnie Ekelund scored in the fifth minute of play, tying Eduardo Hurtado for the fastest goal scored in a Major League Soccer Cup championship. Jeff Agoos won his second Major League Soccer Cup as captain of the San Jose Earthquakes and his fifth Major League Soccer Cup overall. San Jose forward Landon Donovan, who has been named United States National Team Player of the Year twice, scored two goals and two shots in the championship match, earning the Honda Major League Soccer Cup Most Valuable Player Award.

Major league soccer was created in 1996 as a professional American soccer league to build on the base of popularity generated during the World Cup Finals held in the United States in 1994. Major League Soccer has aptly and skillfully filled the void that resulted when the North American League played its last game in 1984, and it has done so with teams like the San Jose Earthquakes that play with zeal and love for the game.

The sellout crowd at The Home Depot Center for the 2003 Major League Soccer Cup is a testament to the growing popularity of soccer and all those who play the game.

Mr. Speaker, I reserve the balance of my time.

Mrs. MILLER of Michigan. Mr. Speaker, I have no further requests for time, and I yield back the balance of my time.

Ms. NORTON. Mr. Speaker, I am very pleased to yield such time as he may consume to the gentleman from the gentleman from California (Mr. HONDA), who is the author of this resolution.

Mr. HONDA. Mr. Speaker, I want to thank the gentlewoman from the District of Columbia and the gentlewoman from Michigan for this opportunity to sort of crow a little here. I rise today to congratulate an extraordinary team

on a successful season through H.R. 475.

Mr. Speaker, on Saturday, November 23, 2003, the San Jose Earthquakes became the second team in Major League Soccer history to win the Major League Soccer Cup a second time. The Earthquakes' 4-to-2 victory over the Chicago Fire showcased the team's explosive talent and demonstrated why soccer is one of the fastest growing sports in America today.

The Earthquakes' rise to the MLS championship game provided soccer fans with endless drama and excitement, including a five-goal comeback against the Los Angeles Galaxy, and a 3-to-2 victory over the Kansas City Wizards.

In the championship game the Quakes showed a capacity crowd in Carson, California, four goals, one saved penalty kick, and 90 minutes of world class soccer. Throughout the game and throughout the season, this team played exciting soccer to the delight of San Jose's growing legion of fans.

Soccer is perhaps the world's most beloved sport. From Latin America to East Asia to Europe and Africa, indeed all the world's cultures play this great game. It therefore comes as no surprise that a community of San Jose's multicultural and multinational makeup should produce a soccer team of such prodigious ability.

In Latin America, soccer is called "la pasión de multitudes," and the San Jose Earthquakes have shown us why this is truly the "passion of people."

While the Earthquakes' recent performances have been impressive, their greatest success may be the team's contribution to the sport of soccer here in America. In particular, the sportsmanship and gamesmanship of the Earthquakes have helped make Major League Soccer a hit. Although it is barely 8 years old, Major League Soccer has already captured the hearts and imaginations of fans around the country and around the world. The MLS also has served as a training ground for some of the world's best players. Many of those players were instrumental in bringing the United States to the quarter finals of the 2002 World Cup.

Now approaching its ninth successful year, and bolstered by the inspiring play of teams like the San Jose Earthquakes, Major League Soccer is stronger than ever. The fact that 20 million fans have attended MLS matches during the league's first eight seasons is a testament to the enormous popularity of the beautiful game here in the United States.

In addition to their on-the-field performance, I would like to thank the Earthquakes for their off-the-field dedication to the San Jose community. At a time when there seem to be too few positive role models in professional athletics, the Quakes have proven themselves not only as great athletes, but good people. Players from this team have repeatedly lent their celeb-

rity and talent to numerous local organizations.

In 2003 alone, the Quakes have made appearances at the Muscular Dystrophy Association's summer camp, conducted free soccer clinics for local youth, raised money for numerous local charities, and supplied free tickets to disadvantaged youth through the Kick for Kids Program. It is deeply rewarding to witness this team's commitment to its community, and in particular, to San Jose's youth.

As a member of the San Jose community and a soccer fan, I look forward to watching the Quakes provide us with even greater inspiration in the years to come. The San Jose Earthquakes are the pride not only of the Bay Area in California, but also of America.

Mr. Speaker, I urge my colleagues to join me in recognizing the 2003 Major League Soccer champions, and I congratulate the San Jose Earthquakes on a fantastic season. And to the soccer moms and dads of this country, there is a place for youngsters to go after they play their local teams.

Ms. LOFGREN. Mr. Speaker, I rise today to congratulate the San Jose, CA Earthquakes for defeating the Chicago, IL Fire 4-2 on November 23, 2003 to win the 2003 Major League Soccer (MLS) Cup.

It was eight years ago that San Jose became the proud home of the MLS Earthquakes. In those short years, we have watched with excitement as the Earthquakes have become repeat champions and helped increase the popularity of soccer in our community and throughout the world.

The Earthquakes have many truly talented players. California native Landon Donovan for example is a two-time U.S. National Team Player of the Year and scored two goals in the championship game to earn him the MSL Cup Most Valuable Player Award. Even with individuals like Landon playing for the Earthquakes, their success has come, not as individuals but rather as a team.

It was as a team that the Earthquakes overcame injuries, critics and goal deficits throughout their 14-7-9 regular season and it was as a team that they became Major League Soccer's very best. Since coming to San Jose, the Earthquake's have represented our city with dignity.

Mr. Speaker, the San Jose Earthquakes are the standard to which all MLS teams should be compared. Their commitment to our community, the sport of soccer and to achieving excellence runs much further than any soccer field. Their success and good works are a staple in our city. For these reasons and many others, it is most appropriate that we congratulate the 2003 MLS Cup winning San Jose Earthquakes today.

Ms. NORTON. Mr. Speaker, I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentlewoman from Michigan (Mrs. MILLER) that the House suspend the rules and agree to the resolution, H. Res. 475.

The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds of those present have voted in the affirmative.

Mrs. MILLER of Michigan. Mr. Speaker, on that I demand the yeas and nays.

The yeas and nays were ordered.

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX and the Chair's prior announcement, further proceedings on this motion will be postponed.

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# MEDICAL DEVICES TECHNICAL CORRECTIONS ACT

Mr. GREENWOOD. Mr. Speaker, I move to suspend the rules and pass the Senate bill (S. 1881) to amend the Federal Food, Drug, and Cosmetic Act to make technical corrections relating to the amendments made by the Medical Device User Fee and Modernization Act of 2002, and for other purposes, as amended.

The Clerk read as follows:

S. 1881

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

## SECTION 1. SHORT TITLE.

This Act may be cited as the "Medical Devices Technical Corrections Act".

## SEC. 2. TECHNICAL CORRECTIONS REGARDING PUBLIC LAW 107-250.

(a) TITLE I; FEES RELATING TO MEDICAL DEVICES.—Part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as added by section 102 of Public Law 107-250 (116 Stat. 1589), is amended—

(1) in section 737—

(A) in paragraph (4)(B), by striking "and for which clinical data are generally necessary to provide a reasonable assurance of safety and effectiveness" and inserting "and for which substantial clinical data are necessary to provide a reasonable assurance of safety and effectiveness";

(B) in paragraph (4)(D), by striking "manufacturing";

(C) in paragraph (5)(J), by striking "a premarket application" and all that follows and inserting "a premarket application or premarket report under section 515 or a premarket application under section 351 of the Public Health Service Act."; and

(D) in paragraph (8), by striking "The term 'affiliate' means a business entity that has a relationship with a second business entity" and inserting "The term 'affiliate' means a business entity that has a relationship with a second business entity (whether domestic or international)"; and

(2) in section 738—

(A) in subsection (a)(1)—

(i) in subparagraph (A)—

(I) in the matter preceding clause (i) by striking "subsection (d)," and inserting "subsections (d) and (e).";

(II) in clause (iv), by striking "clause (i)," and all that follows and inserting "clause (i)."; and

(III) in clause (vii), by striking "clause (i)," and all that follows and inserting "clause (i), subject to any adjustment under subsection (e)(2)(C)(ii)."; and

(ii) in subparagraph (D), in each of clauses (i) and (ii), by striking "application" and inserting "application, report,";

(B) in subsection (d)(2)(B), beginning in the second sentence, by striking "firms, which show" and inserting "firms, which show";

(C) in subsection (e)—

(i) in paragraph (1), by striking "Where" and inserting "For fiscal year 2004 and each subsequent fiscal year, where"; and

(ii) in paragraph (2)—

(I) in subparagraph (B), beginning in the second sentence, by striking "firms, which show" and inserting "firms, which show"; and

(II) in subparagraph (C)(i), by striking "Where" and inserting "For fiscal year 2004 and each subsequent fiscal year, where";

(D) in subsection (f), by striking "for filing"; and

(E) in subsection (h)(2)(B)—

(i) in clause (ii), by redesignating subclauses (I) and (II) as items (aa) and (bb), respectively;

(ii) by redesignating clauses (i) and (ii) as subclauses (I) and (II), respectively;

(iii) by striking "The Secretary" and inserting the following:

"(i) IN GENERAL.—The Secretary"; and

(iv) by adding at the end the following:

"(ii) MORE THAN 5 PERCENT.—To the extent such costs are more than 5 percent below the specified level in subparagraph (A)(ii), fees may not be collected under this section for that fiscal year."

(b) TITLE II; AMENDMENTS REGARDING REGULATION OF MEDICAL DEVICES.—

(1) INSPECTIONS BY ACCREDITED PERSONS.—Section 704(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(g)), as added by section 201 of Public Law 107-250 (116 Stat. 1602), is amended—

(A) in paragraph (1), in the first sentence, by striking "conducting inspections" and all that follows and inserting "conducting inspections of establishments that manufacture, prepare, propagate, compound, or process class II or class III devices, which inspections are required under section 510(h) or are inspections of such establishments required to register under section 510(i).";

(B) in paragraph (5)(B), in the first sentence, by striking "or poses" and all that follows through the period and inserting "poses a threat to public health, fails to act in a manner that is consistent with the purposes of this subsection, or where the Secretary determines that there is a financial conflict of interest in the relationship between the accredited person and the owner or operator of a device establishment that the accredited person has inspected under this subsection.";

(C) in paragraph (6)(A)—

(i) in clause (i), by striking "of the establishment pursuant to subsection (h) or (i) of section 510" and inserting "described in paragraph (1)";

(ii) in clause (ii)—

(I) in the matter preceding subclause (I)—

(aa) by striking "each inspection" and inserting "inspections"; and

(bb) by inserting "during a 2-year period" after "person"; and

(II) in subclause (I), by striking "such a person" and inserting "an accredited person";

(iii) in clause (iii)—

(I) in the matter preceding subclause (I), by striking "and the following additional conditions are met:" and inserting "and 1 or both of the following additional conditions are met:";

(II) in subclause (I), by striking "accredited" and all that follows through the period and inserting "(accredited under paragraph (2) and identified under clause (ii)(II) as a person authorized to conduct such inspections of device establishments."; and

(III) in subclause (II), by inserting "or by a person accredited under paragraph (2)" after "by the Secretary";

(iv) in clause (iv)(I)—

(I) in the first sentence—

(aa) by striking "the two immediately preceding inspections of the establishment" and inserting "inspections of the establishment during the previous 4 years"; and

(bb) by inserting "section" after "pursuant to";

(II) in the third sentence—

(aa) by striking "the petition states a commercial reason for the waiver"; and

(bb) by inserting "not" after "the Secretary has not determined that the public health would"; and

(III) in the fourth sentence, by striking "granted until" and inserting "granted or deemed to be granted until"; and

(v) in clause (iv)(II)—

(I) by inserting "of a device establishment required to register" after "to be conducted"; and

(II) by inserting "section" after "pursuant to";

(D) in paragraph (6)(B)(iii)—

(i) in the first sentence, by striking "and data otherwise describing whether the establishment has consistently been in compliance with sections 501 and 502 and other" and inserting "and with other"; and

(ii) in the second sentence—

(I) by striking "inspections" and inserting "inspectional findings"; and

(II) by inserting "relevant" after "together with all other";

(E) in paragraph (6)(B)(iv)—

(i) by inserting "(I)" after "(iv)"; and

(ii) by adding at the end the following:

"(II) If, during the two-year period following clearance under subparagraph (A), the Secretary determines that the device establishment is substantially not in compliance with this Act, the Secretary may, after notice and a written response, notify the establishment that the eligibility of the establishment for the inspections by accredited persons has been suspended.";

(F) in paragraph (6)(C)(ii), by striking "in accordance with section 510(h), or has not during such period been inspected pursuant to section 510(i), as applicable";

(G) in paragraph (10)(B)(iii), by striking "a reporting" and inserting "a report"; and

(H) in paragraph (12)—

(i) by striking subparagraph (A) and inserting the following:

"(A) the number of inspections conducted by accredited persons pursuant to this subsection and the number of inspections conducted by Federal employees pursuant to section 510(h) and of device establishments required to register under section 510(i)."; and

(ii) in subparagraph (E), by striking "obtained by the Secretary" and all that follows and inserting "obtained by the Secretary pursuant to inspections conducted by Federal employees";

(2) OTHER CORRECTIONS.—

(A) PROHIBITED ACTS.—Section 301(gg) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(gg)), as amended by section 201(d) of Public Law 107-250 (116 Stat. 1609), is amended to read as follows:

"(gg) The knowing failure to comply with paragraph (7)(E) of section 704(g); the knowing inclusion by a person accredited under paragraph (2) of such section of false information in an inspection report under paragraph (7)(A) of such section; or the knowing failure of such a person to include material facts in such a report."

(B) ELECTRONIC LABELING.—Section 502(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(f)), as amended by section 206 of Public Law 107-250 (116 Stat. 1613), is amended, in the last sentence—

(i) by inserting "or by a health care professional and required labeling for in vitro diagnostic devices intended for use by health care professionals or in blood establishments" after "in health care facilities";

(ii) by inserting a comma after "means";

(iii) by striking "requirements of law and, that" and inserting "requirements of law, and that";

(iv) by striking "the manufacturer affords health care facilities the opportunity" and inserting "the manufacturer affords such users the opportunity"; and

(v) by striking "the health care facility".

(c) TITLE III; ADDITIONAL AMENDMENTS.—

(1) EFFECTIVE DATE.—Section 301(b) of Public Law 107-250 (116 Stat. 1616), is amended by