Accordingly, let us honor the sacrifices and patriotic valor demonstrated by everyone involved in this unprecedented effort. Accordingly, I urge my fellow colleagues to support this important measure.

HONORING HERMAN J. RUSSELL FOR HIS HARD WORK AND HIS SELECTION AS THE ATLANTA BUSINESS LEAGUE CEO OF THE YEAR

HON. CYNTHIA A. McKINNEY

OF GEORGIA

IN THE HOUSE OF REPRESENTATIVES

Thursday, May 23, 2002

Ms. MCKINNEY. Mr. Speaker, I rise today in honor of the achievements of Mr. Herman J. Russell of Atlanta, Georgia. Mr. Russell has been selected by the Atlanta Business League as its CEO of the Year for 2002.

Herman Russell transformed his father's small plaster business into a thriving conglomeration of property development and management businesses, which now span throughout Atlanta, Birmingham and the Southeast. Mr. Russell's 43-year old company has sculpted a number of major landmarks that are a part of Atlanta's infamous skyline.

Mr. Russell's accomplishments and influence extend well beyond the boardroom and into the community. He actively serves on several corporate boards and participates in many local, state and national charitable educational organizations. A philanthropist at heart, Mr. Russell provides scholarships for area youth, advice for budding entrepreneurs and support for economic development and empowerment.

Mr. Speaker, I rise today to honor Mr. Herman J. Russell, a pillar of the community. I am especially proud to know him and to have received lessons on the value of honesty and hard work. His unwavering integrity, consistent delivery of quality service, and generous community contributions exemplify the markings of a role model. Our community has been made better by his teachings and demonstrations of preparation, sacrifice, and dedication.

WINDSONG FILM FESTIVAL

HON. MARK E. SOUDER

OF INDIANA

IN THE HOUSE OF REPRESENTATIVES

Thursday, May 23, 2002

Mr. SOUDER. Mr. Speaker, Windsong Pictures, Inc., an independent, nonprofit motion picture company based in Fort Wayne, Indiana, is holding its Third Annual International Windsong Film Festival.

The Windsong Film Festival, which this year is featuring 25 award-winning independent motion pictures, is unique among film festivals because it specializes not only in showcasing professional independent filmmakers and films, but also in working with students of all ages who are interested in film production. This year the festival will show several motion pictures created by students at Elmhurst High School in Fort Wayne, which is also hosting the festival. College students will also be showing their work.

Holding this festival is a tremendous privilege for Elmhurst. It gives the school national attention while giving students there a rare opportunity to explore the world of filmmaking. It reminds us that even with the financial pressures that are bearing on Elmhurst—and many other schools—it is important to keep fine arts education a part of our children's education.

This film festival, and the tremendous film program at Elmhurst, is due in no small part to Michael Floyd. Floyd is executive producer of the festival and, perhaps more importantly, the leader of Elmhurst Cinema Productions, the club that allows so many students the opportunity to make their own movies.

In addition to showcasing student work, the festival this year includes special screenings of professionally-produced independent movies for students, who after watching the films will be able to talk to the directors and ask them questions about their experiences in creating the films. Also this year, 32 student groups—from elementary age through high school—will receive awards and prizes for their own student productions.

You don't have to be in Hollywood to make movies. As a matter of fact, you don't even have to wait until you graduate from high school. I am proud of our students and our community for holding this festival and displaying once again Fort Wayne's thriving arts community.

PERSONAL EXPLANATION

HON. ROBERT MENENDEZ

OF NEW JERSEY

IN THE HOUSE OF REPRESENTATIVES

Thursday, May 23, 2002

Mr. MENENDEZ. Mr. Speaker, because of a commitment to deliver a graduation commencement address in my District, I was unable to be present for all votes on May 21, 2002.

Honorable ROBERT MENENDEZ (NJ–13)

Mr. Speaker (Mr. Chairman), On rollcall no. 174, had I been present, I would have voted Yes. On rollcall no. 175, had I been present, I would have voted Yes. On rollcall no. 176, had I been present, I would have voted Yes. On rollcall no. 177, had I been present, I would have voted Yes. On rollcall no. 178, had I been present, I would have voted Yes. On rollcall no. 179, had I been present, I would have voted Yes. On rollcall no. 180, had I been present, I would have voted Yes. On rollcall no. 181, had I been present, I would have voted Yes. On rollcall no. 182, had I been present, I would have voted Yes.

CONFERENCE REPORT ON H.R. 3448 PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

SPEECH OF

HON. BART STUPAK

OF MICHIGAN

IN THE HOUSE OF REPRESENTATIVES

Wednesday, May 22, 2002

Mr. STUPAK. Mr. Speaker, I rise today to speak out against the procedure used by the majority to consider and pass the Prescription Drug User Fee Act also known as PDUFA.

Yesterday we passed the conference report on bioterrorism almost unanimously.

I voted for it.

However, I did so over my unhappiness with the procedure used to consider PDUFA.

Through PDUFA, the drug industry pays fees to the Food and Drug Administration for timely review of drugs and biological agents.

We have heard a lot about how PDUFA works, but at what cost? What have we sacrificed?

What we have sacrificed under PDUFA is honesty, accuracy, and informative labels. These are the duties and responsibilities that affect every American consumer. Therefore, we must be very careful to make sure that we do not compromise safety or effectiveness that the American public has come to expect.

The FDA reached this agreement in closed-door negotiations with the very industry they are supposed to regulate!

I have many concerns with PDUFA, but I was not able to address them because we in Congress were not allowed to bring these concerns to the floor for a full and open public debate.

We weren't even allowed to have a committee markup on it.

Well, for the record my concerns are as follows.

First of all, the FDA is financially dependent upon an industry it regulates, and because under the new agreement user fees are dramatically increased, dependence will grow dramatically.

Instead of using industry funds, Congress should appropriate enough money to ensure FDA's regulatory authority is completely independent, above reproach, and free of undue pressure from the drug industry.

Second, it is more than clear that the approval of a drug or device based on relatively short-term information does not always give us complete information about a drug.

The number of drugs pulled off the market in the last 4 years is 12.

Now, I agree that 3 were pre-PDUFA but that leaves 9 drugs that raced through an accelerated PDUFA approval process with incomplete information.

This brings me to my third point.

Phase IV studies, also known as post-marketing surveillance, are nightmarishly inadequate and neglected to a shameful extent by both the FDA and the drug manufacturers.

The 1997 reauthorization of PDUFA—called PDUFA 2—ordered a study from FDA that would summarize how well the industry complied over the past 5 years with mandates to do phase IV studies.

The results of this study show the vast majority of drug companies do not do their mandated post-marketing surveillance studies.

Now I understand PDUFA 3 comes a long way towards addressing major concerns with post-marketing surveillance, but without any enforcement, there will be no post-marketing surveillance, as we saw in PDUFA 2.

So I suggest that we put civil monetary penalties pegged to the sales of drugs as one option that we should consider.

Another area of concern is the ability of the drug manufacturers to game the system.

While awaiting requested and required information from a manufacturer, FDA should be able to ''stop the clock'' on the time constraints PDUFA imposes.

Due to extremely tight decision deadlines in PDUFA, manufacturers know they can delay their response to FDA's requests for information long enough so FDA is forced to make a