

troglitazone use. With continued follow-up after the advisory meeting, our expectation was confirmed that heightened ALF risk continued for as long as troglitazone was used. In other words, the risk of ALF did not disappear after the first few months or even first 18 months of use. The pattern suggested that cumulative risk of ALF would continue to rise for as long as troglitazone was used, having important implications for a drug intended to be used for 20, 30 or 40 years or longer.

Against this backdrop of case reports, epidemiologic data suggested that the expected incidence rate of ALF in the general population was about 1 case per million per year. The data from case reports were markedly higher than this. At the March 1999 advisory meeting, we presented data showing that if we assumed there was no underreporting, the cumulative risk of ALF was about 1 case per 15,000 patients who used troglitazone for at least 8 months. If we factored into the analysis that only 10% of cases had been reported, the cumulative risk became 1 case per 1,500 at 8 months (about 1 case per 1,000 per year). With an additional year's worth of case reports (through December 1999), the cumulative risk was 1 case per 7,000 patients after 18 months of troglitazone use, assuming no underreporting. With 10% reporting, this would be 1 case per 700 patients at 18 months (about 1 case per 1000 per year). The first analysis through 8 months of use led us to conclude prior to the March 1999 advisory meeting that the risk of ALF with troglitazone was probably increased at least 1000-fold over the expected background rate.

Independent population-based data prior to the March 1999 advisory meeting supported this. In two separate postmarketing clinical studies, one conducted by the National Institutes of Health and one conducted by the company, a case of fatal ALF occurred among small numbers of patients treated with troglitazone. This was highly statistically significant, and suggested that the incidence rate of ALF with troglitazone could range from 1,200 to 1,700 per million per year, with upper bounds approaching 10,000 cases per million per year. These data, in combination with case reports data, formed the basis for this medical officer's recommendation prior to the March 1999 advisory meeting that troglitazone be removed from the market. Subsequent to the advisory meeting, FDA learned of a third post-marketing study, this one randomized and double blinded, in which a patient treated with troglitazone died of ALF just three days after the advisory meeting. The incidence rate of ALF in this study was over 17,000 per million per year.

An important component in the troglitazone analysis was an assessment of the effect of FDA interventions in the form of labeling changes recommending periodic liver enzyme monitoring as a means of managing the ALF risk of troglitazone. The FDA study from UnitedHealth Group found that monitoring was not regularly or reliably performed and that repeated labeling revisions had not meaningfully improved the performance of monthly liver enzyme testing. Based on the data at hand prior to the March 1999 advisory meeting, we concluded that FDA labeling had not had a clinically important effect on medical practice and that monthly enzyme testing was largely not being performed. From our case analysis, we concluded that monitoring, were it performed, would fail to prevent most or all cases of troglitazone ALF.

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## CHARITABLE LANDMARK: ON VERGE OF EXTINCTION

### HON. CLIFF STEARNS

OF FLORIDA

IN THE HOUSE OF REPRESENTATIVES

*Wednesday, December 5, 2001*

Mr. STEARNS. Mr. Speaker, today I rise in recognition of a Washington institution. In this city of lawmakers and policy, Sholl's Cafeteria has adopted a policy of its own: for over 70 years, the downtown landmark has never turned away a hungry soul. This cafeteria, this "triumph of charity," has fed thousands with warm, free meals. In recent months, however, Sholl's has faced dire straits with the recent economic downturn. Declining tourism and rising rent have forced Sholl's Cafeteria to consider closing its doors to the thousands of devoted patrons who have frequented the famed eatery. With all that Scholl's Cafeteria has done for our community, it is time for us to give back and maintain what has become a 70-year tradition. With that said, Mr. Speaker, I submit to the CONGRESSIONAL RECORD a letter written by Sholl's Chairman Jim McGrath to the Washington Post on October 14, 2001.

[From the Washington Post, Oct. 14, 2001]

#### ON THE EDGE OF EXTINCTION

As the nation mobilizes to combat the insidious foe of terrorism, another drama of a far different kind and scope is playing itself out in downtown Washington—the struggle for survival of Sholl's Cafeteria. Despite heroic sacrifice and Herculean labors by many—most notably its beloved proprietors, George and Van Fleishell—absent a substantial financial remedy, Sholls will be forced to close its doors as soon as Oct. 31.

The Sholl's story could easily get lost amid the tumult of our national preoccupation and suffering in the wake of Sept. 11, but that would be a profound shame, because the cafeteria's story has been one of special triumphs: of old-fashioned, all-American food, wonderfully prepared and wonderfully served; of humane pricing, so that nearly anyone can afford to eat there, of multiculturalism, with terrific employees, many there for generations, reflecting every spectrum of the human family; of kindness, with an atmosphere that welcomes everyone. It is a story of the triumph of charity—Sholl's has given away enough free food to feed an army 100 times over.

During the past several years, however, Sholl's has suffered from the decline in downtown dining. Its tour-bus trade has eroded because of the weak economy. It has endured bus-unfriendly parking restrictions. It has had to deal with prolonged building renovation and reconstruction while paying a huge rent. It has been put through the economic wringer.

Now another mobilization is needed to save this beloved institution. I am not alone in expressing those sentiments. They have been voiced by many, from the high and the mighty to the mighty humble. They have come from legions of senior citizens, bus loads of squealing kids and homeless people.

On Aug. 10, 1999, for example, the World Bank wrote to the cafeteria's owner: "You are correct characterize Sholl's as a charitable landmark. It would be a significant loss to our neighborhood if you were to close your doors, particularly for the large number of senior citizens, young kids, disabled and homeless people whom you serve."

On July 8, 1998, U.S. Sen. Max Cleland of Georgia read into the Congressional Record, "Patrons of Sholl's have described members of the Sholl family, who have owned and operated Sholl's over the last 70 years, as having the biggest hearts in Washington."

On March 7, 1999, Mike Kirwan, the late, great apostle to the homeless, said, "The stories I've heard from people on the streets, their quiet moments of dignity, respect, warmth and a full and nourishing meal at the hands of this wonderful cafeteria could fill a book of essays."

Possibly, the one who said it best, though, was a child who, on arrival from Pennsylvania on a school bus, told a WTOP reporter. "If it weren't for Sholl's Cafeteria, we couldn't afford to come to Washington."

The hour is late, and the odds are long. Although some say the time for Sholl's has passed, I profoundly disagree, and I hope others do too. Long live Sholl's Cafeteria.

JIM McGRATH,

*Chairman of the Save Our*

*Sholl's Cafeteria Committee.*

## THE 150TH BIRTHDAY OF SEATTLE, WASHINGTON

### HON. JAY INSLEE

OF WASHINGTON

IN THE HOUSE OF REPRESENTATIVES

*Wednesday, December 5, 2001*

Mr. INSLEE. As our country recently prepared for its annual commemoration of the first Thanksgiving, my state was also honoring those who founded the city of Seattle 150 years ago. On November 13, 1851, the Denny Party, composed of 22 men, women, and children arrived at Alki Point in the pouring rain. They arrived only to find the cabin which the leader's brother, David Denny was supposed to prepare, unfinished and without a roof. David Denny himself lay sick and feverish.

Like those who survived the first tough winter in Plymouth, the Denny Party persevered. Their dreams of a city would not have survived, however, without the help of Native Americans. As the sopping wet and nearly helpless Denny Party struggled to survive, the Duwamish tribe, led by Chief Sealth, chose to camp around the party in order to protect them.

While Seattle celebrates the landing of the Denny Party, we must also remember those who lived here before- and continue to live here today. Without the assistance of Chief Sealth, the Duwamish tribe, and other tribes, the Denny Party could not have achieved their dreams of a city; a city named for the Chief who protected and helped those early settlers in their quest for a new home.

## HONORING THE 40TH ANNIVERSARY OF WEST SPRINGFIELD CIVIC ASSOCIATION

### HON. TOM DAVIS

OF VIRGINIA

IN THE HOUSE OF REPRESENTATIVES

*Wednesday, December 5, 2001*

Mr. TOM DAVIS of Virginia. Mr. Speaker, I would like to take this opportunity to honor the West Springfield Civic Association for forty