

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

years of exceptional service to the Northern Virginia community. Its dedication throughout our region has been, and will continue to be, an asset to the residents of the West Springfield area.

The West Springfield Civic Association was formed in 1961 by residents of West Springfield, Westview, and Keene Mill Manor neighborhoods. The motto of the association is *Utile Dulci*, Latin for "the useful with the pleasant." This civic association, together with many other area civic associations, formed the Greater Springfield Community Council.

With the growth of the community, a need for a new high school became evident. The civic association was influential in naming West Springfield High School after its community, rather than being named for a famous Virginian like most other Northern Virginia high schools are.

Within the community, the West Springfield Civic Association worked hard to keep the area filled with trees. It was also instrumental in the creation of bike paths and sidewalks along main roadways, and replaced a plank bridge covering the railroad tracks.

Since its inception in 1961, the members of the West Springfield Civic Association has always been a positive force for the development, progress and recognition of the Greater Springfield area. Not only has this organization held many meritorious events, but has also served in informing the residents of current issues affecting the community. In addition, the members of the Association have created a website which provides news, information, and events in the area, in addition to previous newsletters and minutes from past.

Mr. Speaker, in closing, I want to thank the West Springfield Civic Association for their hard work and dedication throughout the past forty years. I ask my colleagues to join me in congratulating an extraordinary group of devoted men and women.

150TH ANNIVERSARY OF THE IMMACULATE CONCEPTION CHURCH IN MORRIS, ILLINOIS

HON. JERRY WELLER

OF ILLINOIS

IN THE HOUSE OF REPRESENTATIVES

Wednesday, December 5, 2001

Mr. WELLER. Mr. Speaker, I rise today in recognition of the 150th anniversary of the establishment of the Immaculate Conception Church in Morris, Illinois.

In the fall of 1852, John McNellis, a local grain dealer, deeded two and a half acres of land to people who were interested in forming a Roman Catholic Church. Mr. McNellis also provided land for a parsonage and two schools, and he built a three story brick school because he felt that education was very important and believed that every child deserved to have an education. The church became the Immaculate Conception Church in Morris, Illinois.

On December 8, the church will start a year long celebration in commemoration of the establishment of the parish. The past 150 years have been full of progress and history. A fire almost destroyed the church in 1903, and in

1988, lightning struck the bell tower, causing an estimated \$90,000 worth of damage, but the church prevailed. Throughout adversity the church keeps growing due to the hard work of the parishioners and the community of Morris. Many additions have kept the grounds looking fresh. A new parish center was dedicated in 1988. A group of parishioners transformed the lawn between the church and the parish hall into a beautiful prayer garden in 1991. Another major project was the restoration of the rectory in the Father Poff Center, which houses the meeting rooms and offices.

Mr. Speaker, I would like to commend the parishioners for all of their hard work and dedication to the church and to the city of Morris.

TRIBUTE TO LODGE FIGLI DELLA SICILIA NO. 227, COLUMBIAN FEDERATION AND VITO MANZELLA, 2001 MAN OF THE YEAR

HON. DAVID E. BONIOR

OF MICHIGAN

IN THE HOUSE OF REPRESENTATIVES

Wednesday, December 5, 2001

Mr. BONIOR. Mr. Speaker, the Lodge Figli Della Sicilia No. 227 "Sons of Sicily" is a lodge of the Columbian Federation of Italian-American societies, and is one of the largest Italian-American organizations in the State of Michigan. Serving the tri-county area of metropolitan Detroit, Lodge 227 includes over 250 families whose purpose is to promote and preserve the Italian-American heritage through language, culture, music, and social events. Each year the Lodge 227 holds its annual banquet, honoring distinguished Italian-Americans in the community who have shown outstanding support and activism in their local community. On Saturday, September 29, as the Lodge Figli Della Sicilia celebrated its 65th Annual Banquet, they recognized Vito Manzella as their "2001 Man of the Year".

Faithfully committed to the preservation of Italian heritage, the Lodge Figli Della Sicilia No. 227 has been a cornerstone of the Italian American community since its founding in Detroit on February 10, 1936. As a dedicated member of over 30 years, President Salvatore Previti's outstanding leadership has motivated families to reach out to surrounding communities in friendship and charity. From preparations for the Columbus Day Parade and festivities to annual can and clothing drives for the Capuchin Food Kitchen during the holidays, the Lodge has truly become a part of the Metro Detroit family. The tireless efforts of Lodge 227 are outstanding, and will continue to be appreciated for years to come.

The Lodge Figli Della Sicilia's "2001 Man of the Year", Vito Manzella has demonstrated dedication and commitment to his family, his work, and his community for so many years. Born to Salvatore and Rosa Manzella in Detroit in 1967, who had just emigrated from Sicily 5 years before, Vito grew up in St. Clair Shores as a hard worker for the family business, Manzella's Fruit Market, and an athlete and leader in his community. Upon the untimely death of his father in 1995, Vito took over the store and has since continued the

traditions of warmth and generosity Manzella's Fruit Market has always brought to the community. As a sponsor of churches and charities across Macomb County, Manzella's is a drop off site for "Toys for Tots", and after the September 11 tragedies, Vito donated 10 percent of profits from sales on September 19th, 2001. Vito's hard work and innovative ideas have been the driving force in the success of Manzella's, and his generous contributions and active involvement as a distinguished business owner and friend to all truly makes him this year's "2001 Man of the Year."

I applaud the Lodge Figli Della Sicilia No. 227 Columbian Federation and Vito Manzella for their leadership, commitment, and service, and I urge my colleagues to join me in saluting them for their exemplary years of leadership and service.

EDUCATION

HON. JOHNNY ISAKSON

OF GEORGIA

IN THE HOUSE OF REPRESENTATIVES

Wednesday, December 5, 2001

Mr. ISAKSON. Mr. Speaker, within days, the Conference Committee on House Bill 1 will complete its work and President Bush's campaign commitment to "leave no child behind" will be before Congress for final approval.

As a member of the Conference Committee, I am very proud of the months of work, and the tireless efforts of Chairman JOHN BOEHNER. As a result of JOHN's leadership, America's public schools will have the resources, the tools, the flexibility, and the accountability to close the achievement gap between our best and our poorest performing children.

Since its inception thirty-five years ago, Title One of the Elementary and Secondary Education Act was designed to improve the performance of America's poorest and most at risk students. One Hundred and Twenty Five Billion Dollars later the performance of these children has not improved and the gap between our poorest and our best has actually increased. America's children and America's taxpayers deserve better, and this Conference Report demands better.

In my home district in Atlanta, Georgia, there is a talented and nationally syndicated talk show host named Neal Boortz. Neal is a conservative libertarian whose favorite target for criticism is often public schools or as he calls them, government schools. While Neal sometimes carries his criticism to the extreme, he is often on target. Neal will be happy that this Education Reform requires exactly what he has sought: accountability, competition, and results.

There is another reason Neal Boortz should be very happy. His able and talented assistant, Belinda Skelton, is expecting her first child in May, and when that child reaches six years of age America's schools will have improved dramatically because of five major provisions of this reform.

1. President Bush's Early Reading First initiative will ensure that every child reaching third grade will be able to read and comprehend at that level.