

Run, it was held from April to August on a biennial basis from 1987 to 2001 and resumed as a yearly event in 2005. The World Harmony Run seeks to promote international friendship and understanding. This year, an international team of runners will carry a flaming torch, symbolizing the human aspiration for oneness, through more than 80 countries around the globe together with a 10,500-mile, fifty State U.S.A. route. The event serves to connect thousands of grassroots efforts for world harmony taking place in communities across the globe. It does not seek to raise money or promote any political cause, but rather to create good will among peoples and nations.

The Sri Chinmoy Marathon Team has made a city block in my district world famous. It's where the longest running race in the world takes place around the shortest course—a half-mile certified loop on paved sidewalks adjacent to the Grand Central Parkway. To complete the Self-Transcendence 3,100 Mile Race, participants run 5,648,688 laps around the block, a distance equivalent to more than 118 marathons. The Tenth Annual edition began on June 11 and continues into August with the largest field yet of 15 ultra-distance runners. As in all his endeavors, Sri Chinmoy sets the highest standards of organization, logistics and support to help ultra-marathon runners achieve their greatest potential. We can expect of this race to see new world records and personal bests.

A decathlon and 100-meter sprinting champion in his youth, Sri Chinmoy believes in the necessity of a sound mind and a sound body. He began his own long-distance running career in Golden Gate Park in San Francisco on June 1, 1978. In March 1979, he ran his first marathon in Chico, California, and, later that month, his fastest marathon in 3:55:07 at the Heart-Watchers Marathon in Toledo, Ohio. He has completed 22 marathons and 5 ultra marathons and now, at age 75, still regularly exercises.

Mr. Speaker, Sri Chinmoy first began weightlifting on June 26, 1986, and embarked on a new dimension in his weightlifting career 2 years later when he inaugurated "Lifting Up the World with a Oneness-Heart." This is his way of recognizing individuals from all walks of life who inspire humanity and excel in their respective fields. At these programs, Sri Chinmoy lifts each honoree overhead on a special platform, symbolically reflecting their own uplifting contributions to the world.

Bill Pearl of Oregon, a Five-time Mr. Universe, was the first person lifted in this fashion. Sri Chinmoy has lifted Members of the U.S. Senate and House of Representatives, heads of state, ambassadors, Nobel laureates, university professors, spiritual leaders from all faiths, Olympic athletes, citizens serving their communities, and school children whose dreams are so important to our future. In Hawaii, on December 23, 1990, he lifted Senator Hiram L. Fong, who was Hawaii's first Senator at the time of statehood.

On July 10, 2001, in the Rayburn Gold Room, Sri Chinmoy simultaneously lifted my esteemed New York colleague Benjamin Gilman and me on a two-platform lifting apparatus, one of us with each arm. If I had not experienced it, I could not imagine this to be possible. In a day-long lifting program at Boeing Field Auditorium in Washington State on July 13, 2003, held to celebrate the centenary

of the Wright brothers first flight, Sri Chinmoy lifted 123 airplane pilots in appreciation of their dedicated services in carrying humanity into the skies. From 1988 to 2006, Sri Chinmoy has honored more than 8,000 individuals from many countries with this award.

Mr. Speaker, The Oneness-Heart Tears and Smiles is the voluntary humanitarian service program of the Sri Chinmoy Centre. Since 1991, centre members worldwide have collected and shipped tons of humanitarian supplies to countries in need including South Africa, Angola, Mozambique, India, and, after the tsunami, Sri Lanka. It responds to disaster relief requests, health and education needs, and regional development projects. The program obtains and distributes medical, domestic and educational supplies and toys, working closely with other aid agencies, local NGOs, community groups and corporations.

One would think that this busy schedule and numerous interests would be enough for one man, but not so for Sri Chinmoy. An accomplished composer of music for choir and instruments with 13,000 songs composed in his native Bengali and 7,000 in English, Sri Chinmoy has performed his music free of charge at over 750 concerts worldwide since 1984. Last year, to celebrate his 74th birthday, he played his original compositions on 74 different pianos at an outdoor concert in Queens.

Senators Daniel Patrick Moynihan of New York and Claiborne Pell of Rhode Island sponsored an art exhibit of Sri Chinmoy's soul-bird drawings in the Russell Rotunda of the U.S. Senate in 1995.

All told, Sri Chinmoy has written 20,000 songs, taught 300 university lectures, authored 1,550 books, including 112,000 poems, penned 15 million bird drawings, and completed 200,000 "Jharna-Kala" paintings ("Fountain of Art" in his native Bengali).

He has dedicated his life to inspiring and serving all those trying to make the world a better place, whether ordinary citizens or those entrusted with the stewardship of a nation.

Mr. Speaker, on this, the celebration of Sri Chinmoy's upcoming Diamond Jubilee 75th birthday, I ask all my colleagues in the House of Representatives to please join me as I wish Sri Chinmoy success in the years ahead and best wishes for a long and continuingly fruitful life.

INTRODUCTION OF A RESOLUTION
CONGRATULATING THE NATIONAL LIBRARY OF MEDICINE
ON ITS 50TH ANNIVERSARY

HON. CHRIS VAN HOLLEN

OF MARYLAND

IN THE HOUSE OF REPRESENTATIVES

Thursday, July 27, 2006

Mr. VAN HOLLEN. Mr. Speaker, today I am introducing a resolution congratulating the National Library of Medicine on the occasion of its 50th anniversary.

The National Library of Medicine, which is located on the National Institutes of Health campus and is in my Congressional district, was created in 1956 by the National Library of Medicine Act. Before 1956, the National Library of Medicine was known as the Armed Forces Medical Library.

The National Library of Medicine provides invaluable tools for medical librarians such as

the Medical Librarian Association, health consumers, and health professionals to support information access and high-quality health care. With its vast collections in all areas of biomedicine and health care, the National Library of Medicine is the world's largest medical library with more than 8 million items.

Through its extramural grant programs, outreach programs, health information technology research programs, and databases such as Medline/PubMed Central and ClinicalTrials.gov, the National Library of Medicine works to provide the highest quality, most relevant, and timely health information for health professionals and health consumers.

Mr. Speaker, I salute the National Library of Medicine on its 50th anniversary and commend it for its leadership in the health sciences information field.

THE "SWIFT APPROVAL, FULL
EVALUATION (SAFE) DRUG ACT"

HON. EDWARD J. MARKEY

OF MASSACHUSETTS

IN THE HOUSE OF REPRESENTATIVES

Thursday, July 27, 2006

Mr. MARKEY. Mr. Speaker, I rise today to introduce the Swift Approval, Full Evaluation (SAFE) Drug Act. This bill is designed to ensure that the FDA can balance the need to get important life-saving drugs to the market quickly while ensuring the drugs get the full evaluation they need to ensure the safety of those products. A strong postmarketing study system allows the FDA to achieve a careful balance between speed of approval and careful scrutiny of the products. However, as both the GAO and the Inspector General of HHS recently reported, the system to ensure that postmarketing studies are conducted and completed is broken and the FDA has not made reform a priority.

Postmarketing studies are important because they prevent death, detrimental reliance and waste. They provide critical information about the risks and benefits of a drug after it has been approved and on the market. They can also provide additional information about optimal use of the product and what groups of people are most likely to benefit (or not benefit) from use. Since the long-term effects of products are not usually studied prior to approval, postmarketing studies provide critical information about the risks or benefits of long-term use. Postmarketing studies allow the FDA to approve drugs for to consumers who need them quickly while ensuring that scientists will continue to investigate the best uses of the drug. These studies are particularly important when, in the interest of speeding drugs to consumers, the drugs are approved under the FDA's accelerated approval process.

In 1992, the Food and Drug Administration, FDA, established a process that amounted to a trade-off between its mission to ensure drug safety and effectiveness and the need to speed promising new drugs to market to increase treatment options for life-threatening illnesses. Called accelerated approval, this process allows FDA to approve a drug on an expedited basis using promising but limited information about its safety and effectiveness, but only on the condition that the company agrees to conduct further studies to confirm

the safety and effectiveness of the product. Under the law, drug companies are required to do additional studies to confirm that the drug is safe, effective and works for its approved indication.

The importance of conducting postmarketing studies to ensure the safety of drugs approved through accelerated approval is illustrated by the example of encainide and flecainide. In the 1980's encainide and flecainide were approved to treat ventricular arrhythmia after myocardial infarction. Arrhythmias are a risk factor for heart attacks and encainide and flecainide are very good at suppressing arrhythmias. People assumed that because the drugs were good at suppressing arrhythmias, they would also prevent heart attacks. While this treatment was on the market between 250,000 and 500,000 people were prescribed the drug every year to prevent heart attacks. When the postmarketing clinical trial was conducted to confirm that encainide and flecainide did in fact reduce heart attacks, the study found these drugs actually tripled the rate of death. The drugs were withdrawn from the market. If the postmarketing study had never been completed, doctors would have continued to prescribe a drug that they thought was beneficial but was actually killing people.

Postmarketing studies are also important to ensure that drugs approved through accelerated approval actually work. In May 2003, Iressa, which is manufactured by AstraZeneca, was approved under the accelerated approval process for treatment of non-small cell lung cancer in individuals who have failed to respond to two or more courses of chemotherapy. Iressa showed promise in early studies. The FDA approved Iressa, on the condition that AstraZeneca continue research on the drug to confirm the early results. Complying with the FDA's mandate, AstraZeneca conducted a postmarketing study and found that, for most people, Iressa was not effective. The drug was withdrawn from the market. This trial provided critical information to both physicians and patients who are trying to determine the best course of treatment for this horrible disease. If the postmarketing study had never been completed, doctors would have continued to prescribe it and patients would have continued to spend \$1,800 a month for a drug that is ineffective for most patients when there are alternative treatments available.

Unfortunately, many companies fail to conduct the postmarketing studies they promised to complete as a condition of approval on a timely basis and the public may go years without knowing whether the drugs approved through accelerated approval are really safe and effective. According to information provided by the FDA to my staff on March 30, 2005, drug companies take a very long time before they even initiate postmarketing studies that are required as a condition of approval as of March 9, 2005; companies with outstanding trials had been selling these products to the public for an average of 1 year and 10 months and up to 6 years and 9 months without even initiating the required studies.

Despite the fact that companies often wait years before starting required postmarketing studies, the FDA has never used the only mechanism it has to enforce compliance with the requirement: withdrawal of the product. According to the HHS IG, "Currently, short of withdrawing a drug from the market—a remedy available to FDA only in limited cir-

cumstances—the only short-term, practical options available to FDA in dealing with drug applicants that do not comply with the terms of their commitments are sending letters and placing phone calls. Providing FDA reviewers with additional tools, such as the ability to impose monetary fines, may send a signal to drug applicants that there are consequences when postmarketing study commitments are not fulfilled." The SAFE Drug Act will provide additional enforcement mechanisms.

The system of tracking postmarket safety issues and monitoring and enforcing postmarketing studies is broken and failing to ensure patient safety. The SAFE Drug Act will address these problems by:

(1) Providing the FDA with authority to require postmarketing studies and enforce the prompt completion of those studies;

(2) Providing the FDA with mechanisms to help monitor the progress of postmarketing studies;

(3) Providing the Secretary with the authority to require that the label include specific wording to ensure safe and effective use of a product including special labeling to help consumers identify accelerated approved drugs or biologics until converted to full approval;

(4) Restricting direct to consumer advertising for accelerated approved drugs or biologics until converted to full approval;

(5) Providing FDA employees with enhanced whistleblower protections if they are retaliated against for reporting violations of laws or regulations or a significant threat to public health and safety to Congress, GAO, Federal Agencies, or their bosses; and

(6) Requires reports to Congress on the systems to track postmarketing safety issues and approvals that are based on Non-Inferiority Trials.

According to a recent Wall Street Journal Online/Harris Interactive health-care poll, a majority of the American public is concerned about the FDA's ability to ensure the safety and efficacy of drugs. We need to stop the erosion of public confidence in the FDA, reform the system of postmarketing studies, and ensure that FDA balances the desire to speed drugs to market with its critical role as the watchdog of public health. I urge my colleagues to support the SAFE Drug Act.

TRIBUTE TO RUKERT TERMINALS CORPORATION'S 85TH ANNIVERSARY

HON. BENJAMIN L. CARDIN

OF MARYLAND

IN THE HOUSE OF REPRESENTATIVES

Thursday, July 27, 2006

Mr. CARDIN. Mr. Speaker, it is with great honor that I rise today to commemorate the Rukert Terminals Corporation's 85th Anniversary. Located in Baltimore, Maryland, Rukert Terminals Corporation, which specializes in salts, metals, ores, and fertilizers, is one of the city's premier privately owned marine terminal operators.

Since its foundation in 1921 by William G. Norman or "Cap" Rukert, Rukert Terminals has been a hard-working, family owned business that has thrived due to its strong commitment to quality service. Due to the leadership of Norman Rukert and his son, Rukert Terminals has developed over the years from a sin-

gle truck and stable business to occupying more than one million square feet of storage space. Through the use of the most modern techniques, Rukert Terminals handles the nation's dry and break-bulk cargoes to ensure transfer and storage of the highest caliber. For several decades, the company has continuously provided quality jobs to the citizens of Baltimore.

The city of Baltimore is an excellent place to live, filled with hard-working, dedicated citizens. The Port of Baltimore's economic contributions have been tremendous, generating \$2 billion in revenue annually, and employing 19,000 Marylanders in direct jobs, and another 87,000 in indirect and maritime-related occupations. Rukert Terminals is part of the success of this port city, supplying superior warehousing, stevedoring, and vessel transfer services for the region.

I urge my colleagues in the U.S. House of Representatives to join me today in honoring this third generation family business, which for eighty-five years has provided quality marine services to one of America's premier cities while maintaining a standard for excellence that is a model for the rest.

RECOGNITION OF LIEUTENANT COLONEL KEVIN STODDARD OF THE UNITED STATES ARMY

HON. MELISSA L. BEAN

OF ILLINOIS

IN THE HOUSE OF REPRESENTATIVES

Thursday, July 27, 2006

Ms. BEAN. Mr. Speaker, I rise today to pay tribute to Lieutenant Colonel Kevin Stoddard of the U.S. Army who is the Program Manager for Crew Served Weapons.

Col. Stoddard has set a standard of excellence for himself and his office, constantly striving to ensure that our troops are issued the best equipment possible during the Global War on Terrorism. Though he has had many great achievements, Col. Stoddard should be recognized for his contributions to the Common Remotely Operated Weapon Station, or CROWS project.

Col. Stoddard has had the individual responsibility for ushering this innovative piece of technology out of development and into the hands of our Soldiers. His steadfast commitment to protecting the force has ensured that today's standard for Humvee convoys in Iraq and Afghanistan is a soldier operating CROWS from behind life saving armor, protected from lethal IEDs and gun fire.

Col. Stoddard used firsthand feedback from Soldiers to lead his program office and partner contractors in ensuring that the CROWS developed today is the technology soldiers want and need. His high standards of leadership and commitment to program excellence brought him to Iraq where he personally observed CROWS in combat to prove his concept and vision. Indeed, Col. Stoddard is personally responsible for saving the lives of many Soldiers currently deployed overseas.

Mr. Speaker, Col. Stoddard and CROWS have truly been a force protection success story for the Army and our soldiers. He embodies the highest tenants of leadership, acquisition reform, and the Army's innovative rapid fielding initiative and is worthy of our commendation today.