

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 The drugs were withdrawn from the market.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 The drug was withdrawn from the market.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.