

But certain truths stand unchanged—and they are embodied in the principles for which we together stand, in Washington and here at home.

Please accept my very best for a joyous celebration.

Sincerely,

WILLIAM D. DELAHUNT.

IMPORTING DRUGS SAFELY

HON. JOHN D. DINGELL

OF MICHIGAN

IN THE HOUSE OF REPRESENTATIVES

Tuesday, July 11, 2000

Mr. DINGELL. Mr. Speaker, last evening I voted against the prescription drug import amendments offered by my good friends and colleagues Representatives CROWLEY and COBURN. I want my colleagues to know that I wish to work with them to craft legislation that achieves the goals they seek, while ensuring that the prescription drugs that Americans consume are as safe as possible. I see no reason why the Commerce Committee cannot roll up its sleeves and mark up good legislation for presentation on the House floor shortly after the August recess.

Mr. Speaker, the Crowley and Coburn Amendments block a key provision of the Prescription Drug Marketing Act (PDMA). This law came into being after an investigation revealed serious irregularities with respect to imported drugs. As stated in the April 1987 report of the Commerce Committee, “[t]he purpose of the legislation is to protect American consumers from mislabeled, subpotent, adulterated, expired, or counterfeit pharmaceuticals. . .”

Recent investigations of Internet web sites indicate there is still cause for concern. In fact, the U.S. Customs Service recently reported a more than 400 percent increase in the amount of pharmaceuticals being shipped into this country via the U.S. mail, and that in many cases, the origin, purity, or history of the drugs being shipped is indeterminable. These are drugs with major health implications. A May 22 letter from Commissioner Kelly addressed to me and Representative KLINK noted the following: “[a]mong the most common types of pharmaceuticals seized by Customs are Diazepam; Tylenol with Codeine; Mathandienone; Alprozolam; Xanax; Valium; Codigescic; Lorazepam; Fenfluramine; Thyroid tabs; Panzatazocine; Cetabon; Andriol; Premarin; and Rohypnol, a powerful sedative sometimes described as a ‘date rape’ drug.” Commissioner Kelly said that “[i]n most of the mail seizures that Customs encounters, the brand name and manufacturer of the products are not identifiable because the original packaging has been removed and repacked into containers that bear no marks or identification.” These are the same sorts of mislabeling and repackaging shenanigans that the Subcommittee first identified when it investigated this issue more than a decade ago, and led to the PDMA.

Equally alarming are the findings of a hearing held just last month by the Subcommittee on Oversight and Investigations on the potential dangers of counterfeit bulk drugs, and the global problems they pose. Chairman UPTON, in his opening statement, said: “[t]he inter-

national community is also increasingly concerned. Just last month, the World Health Organization and international pharmacists and international drug manufacturers publicized their concerns about counterfeit drugs. Some have estimated that 50 to 70 percent of the drugs in some developing countries are counterfeit.” Why is it that we don’t believe these drugs can find their way into countries where U.S. consumers may wish to purchase their medications? This is particularly troubling given the FDA’s confirmation later in the hearing to Representative BURR that it has information that there were injuries to American citizens associated with counterfeit products.

Chairman BLILEY has also documented potential serious dangers with drugs from foreign sources. In a lengthy May 8, 2000, letter to FDA Commissioner Henney he suggests that not only have Americans possibly been injured or even killed from foreign-made pharmaceuticals, but that “[d]evelopments from this investigation require the Committee to intensify its examination and request that the FDA consider taking certain actions to protect the American public.”

First and foremost, the PDMA is a public health and safety law. We should therefore tread carefully before changing it. I am greatly concerned that the amendments adopted by the House lack the care and craftsmanship needed to ensure both access to less expensive prescription drugs and assurance of safety for the consumer.

The investigation that led to the PDMA discovered a “diversion market” that prevented effective control over the true sources of merchandise in a significant number of cases. The integrity of the distribution system was insufficient to prevent the introduction and eventual retail sale of substandard, ineffective, or even counterfeit pharmaceuticals. As the Committee report stated, “pharmaceuticals which have been mislabeled, misbranded, improperly stored or shipped, have exceeded their expiration dates, or are bald counterfeits are injected into the national distribution system for ultimate sale to consumers.”

The PDMA was “designed to restore the integrity and control over the pharmaceutical market necessary to eliminate actual and potential health and safety problems before serious consumer injury results.” The Committee report specifically outlined the concerns PDMA was intended to address: “Reimported pharmaceuticals threaten the American public health in two ways. First, foreign counterfeits, falsely described as reimported U.S. produced drugs, have entered the distribution system. Second, proper storage and handling of legitimate pharmaceuticals cannot be guaranteed by U.S. law once the drugs have left the boundaries of the United States.” The PDMA is not perfect. But I dare say that the PDMA has saved a lot of lives.

Now let us note why legislation to modify the PDMA in a responsible fashion is an idea whose time has come. Foreign drugs are often less expensive than domestically available products. Notwithstanding the range of safety risks they pose, many Americans seek them out because of outrageously high domestic prices that make drugs unaffordable for many Americans, particularly the elderly. I am open to a careful review and revision of PDMA for

the purpose of creating a paradigm for drug importation that is safe for our consumers while facilitating access to the international market prices at which many commonly prescribed prescription drugs are available.

Mr. Speaker, I do want to acknowledge beneficial aspects of the amendments to which these comments are addressed. An overwhelming majority of my colleagues from both sides of the aisle are now on record for the proposition that the price Americans pay for prescription drugs is too high. Lack of access to medically necessary prescription drugs is a real problem faced by millions of Americans. Let us do better and give consumers access to lower priced prescription pharmaceuticals that are safe.

CAPTAIN ADAN GUERRERO

HON. SOLOMON P. ORTIZ

OF TEXAS

IN THE HOUSE OF REPRESENTATIVES

Tuesday, July 11, 2000

Mr. ORTIZ. Mr. Speaker, I rise to pay tribute to a special service officer, Captain Adan Guerrero, commander of the United States Coast Guard Marine Safety Office in Corpus Christi.

Captain Guerrero is the model service officer for the Coast Guard. In addition to being a great guy who deals squarely with whatever comes up and a tireless advocate for the United States Coast Guard and the men and women who serve in his command, he is also a hometown boy.

This Coastie from Corpus Christi began his service with the U.S. Coast Guard after graduating from the Coast Guard Academy in 1974. He served first as a deck officer on the USCGC *Morgenthau* from 1974 to 1976 when it was homeported in New York City. He served as engineer officer aboard the USCGC *Durable* homeported in Brownsville, Texas from 1983–1986.

Captain Guerrero started a career in marine safety at the Marine Inspection Office in New Orleans, where he served as a marine inspector, investigating officer and licensing examiner. He also served as the Coast Guard liaison officer at the United States Embassy in Mexico City before returning again to the Marine Safety Office Training Office. From 1990–98, he served as the executive officer responsible for marine safety and environmental protection on over 500 miles of the Ohio River.

Before returning to Corpus Christi, he was chief of the Vessel and Facility Operating Standards Division, Office of Operating and Environmental Standards, Coast Guard Headquarters in Washington, DC. He represented the United States when he headed the delegation on Ship/Port Interface Working Group of the International Maritime Organization in London.

He also served as director of the National Offshore Safety Advisory Committee and the Commercial Fishing Industry Vessel Advisory Committee. He has been awarded two Coast Guard Commendation Medals and three Coast Guard Achievement Medals with Operational Distinguishing Device.

I ask my colleagues to join me today in wishing Captain Guerrero well upon his retirement with his wife, Silvia DeLaRosa of Corpus