

INTRODUCING THE PHARMA-
CEUTICAL RESEARCH AND MAN-
UFACTURERS ACCOUNTABILITY
(PhRMA) ACT

HON. FORTNEY PETE STARK

OF CALIFORNIA

IN THE HOUSE OF REPRESENTATIVES

Wednesday, February 16, 2005

Mr. STARK. Mr. Speaker, people are dying because the drug industry is making billions marketing drugs they know to be unsafe. Today I propose a bill that will end this dangerous practice by increasing accountability for pharmaceutical manufacturers and their executives who withhold evidence of drug risks.

The Pharmaceutical Research and Manufacturers Accountability (PhRMA) Act would impose criminal penalties and fines on those who fail to disclose evidence of serious adverse drug experiences. It is unfortunate we need this legislation, but the only way to make manufacturers accountable for drug safety is to hit them where it hurts—putting executives in jail and imposing large individual and corporate fines for wrongdoing.

In the past six months alone, Vioxx has been taken off the market for causing heart attacks and strokes, and a new “black box” warning has been added to antidepressants due to increased risk of suicide in children. What’s worse, evidence suggests the manufacturers knew about these deadly safety issues, but masked or withheld the information from consumers and the FDA because they were making so much money on these drugs.

Profit before public safety is the modern mantra of pharmaceutical manufacturers. These companies continued to market drugs that caused individuals to be severely physically disabled or die. While the companies have been civilly sued for their actions, their typical response has been to pay enormous monetary settlements that don’t even put a dent in their outrageously high drug profits. Even worse, the manufacturers never admit guilt and require injured parties to sign non-disclosure agreements as part of the settlement, effectively hiding from the public the horrific tales of death and disability.

The PhRMA Act will put an end to this irresponsible corporate citizenship by placing responsibility for the knowing concealment of serious adverse drug experiences on the pharmaceutical executives who ultimately decide to place profits over people’s lives. In the wake of Enron and other corporate accounting scandals, the Sarbanes-Oxley Act created 10-year prison terms for withholding financial information from shareholders and regulators. The PhRMA Act would impose a minimum jail term of 20 years and fines of up to \$2 million on executives who withhold information, proving once and for all that life is more valuable than the almighty dollar.

The bill would also require CEOs to annually attest that they have disclosed all evidence of serious adverse drug experiences to the FDA. Failure to meet this requirement would result in fines up to \$100,000 per month for the CEO and \$1 million per month for the Corporation.

Under today’s fast track process at FDA, drugs are often approved with the caveat that manufacturers complete specified post-marketing studies of safety and effectiveness. Unfortunately, drug companies currently ignore

these requirements because they know FDA will not revoke approval of a drug unless it is clearly unsafe. This perverse system actually provides an incentive for manufacturers to ignore required post-marketing studies so there is no new safety evidence available for FDA to justify a market withdrawal.

The PhRMA Act ameliorates this problem by requiring post-marketing studies to be completed in a time-period specified by the FDA. Failure to complete these studies can lead to fines of \$5 million for each month the study goes unfinished. As always, FDA retains the authority to pull a drug from the market, but the PhRMA Act would give them an important intermediate sanction to make drug companies accountable for meeting their obligations.

The influence of the drug industry has infiltrated every aspect of society. The Bush Administration gave drug manufacturers a huge windfall in the Medicare prescription drug bill, the FDA bows to the industry while ignoring the science, and millions are taking unnecessary prescriptions because of TV commercials or doctors bribed by manufacturers.

The PhRMA Act can begin to turn the tide on an industry that continually puts profit and shareholder earnings above patients’ lives and health. By holding pharmaceutical manufacturers and their executives responsible for the safety of their products we can ensure prescription drugs save lives, not destroy them.

RECOGNITION OF NATIONAL
BLACK HIV/AIDS AWARENESS DAY

HON. CHARLES B. RANGEL

OF NEW YORK

IN THE HOUSE OF REPRESENTATIVES

Wednesday, February 16, 2005

Mr. RANGEL. Mr. Speaker, I rise before you today to join with many of my colleagues in recognizing the fifth anniversary of National Black HIV/AIDS Awareness Day.

African Americans have been disproportionately affected by HIV/AIDS since the epidemic’s very beginning, and there’s no evidence to show that trend is changing. National Black HIV/AIDS Awareness Day not only calls attention to how HIV/AIDS disproportionately affects the Black community, but the extreme disparities in healthcare access for African Americans.

Although African Americans represent only 13 percent of the U.S. population, they account for 40 percent of the 929,985 AIDS cases diagnosed since the start of the epidemic and approximately half of the 43,171 cases diagnosed in 2003 alone. The epidemic has also had a disproportionate impact on subgroups of African Americans including women and youth.

African American women accounted for a greater proportion of new AIDS cases among African Americans overall than their white counterparts. And although African American teens (ages 13–19) represent only 15 percent of U.S. teenagers, they accounted for 65 percent of new AIDS cases reported.

Although treatment advances, along with prevention efforts, have led to the decline in new AIDS diagnoses and deaths, these declines were not as sharp for African Americans and appear to have ended.

We must continue to push for a comprehensive prevention policy that highlights the

ABCs—Abstain, Be Faithful, and use Condoms. We must strongly encourage destigmatization of the disease among African Americans, and increase funding that will allow for extensive outreach not only in our communities, but to our international neighbors as well.

We must support the goals and ideals of National Black HIV/AIDS Awareness Day and “Get Educated, Get Involved, and Get Tested.”

BLACK HISTORY TRIBUTE TO
MILDRED JUANITA SCOTT

HON. BENNIE G. THOMPSON

OF MISSISSIPPI

IN THE HOUSE OF REPRESENTATIVES

Wednesday, February 16, 2005

Mr. THOMPSON of Mississippi. Mr. Speaker, throughout the month of February, I would like to recognize outstanding African Americans of the 2nd Congressional District of Mississippi, and their contribution to Black History. The 23 counties of the 2nd District are well represented from both a local and national perspective.

Americans have recognized black history annually since 1926, first as “Negro History Week” and later as “Black History Month.” In fact, black history had barely begun to be studied—or even documented—when the tradition originated. Although blacks have been in America as far back as colonial times, it was not until the 20th century that they gained a presence in our history books.

Though scarcely documented in history books, if at all, the crucial role African Americans have played in the development of our Nation must not be overlooked.

I would like to recognize Ms. Mildred Juanita Scott of Sunflower County, Mississippi. A native of Indianola, MS, Scott attended Indianola Elementary School and later graduated from Booker T. Washington High School located in Memphis, Tennessee. She continued her education at Coahoma Community College in Clarksdale, Mississippi, where she received an AA Degree in Library Science. Ms. Scott also has worked extensively towards a degree at Delta State University, located in Cleveland, Mississippi.

Ms. Scott has worked diligently with grassroots organizations in and around Sunflower County. At an early age Ms. Scott joined the Sunflower County Branch of NAACP where she served as Secretary for this great organization. It was during this time Ms. Scott and others participated in sit-ins and boycotts throughout Sunflower County. Ms. Scott served as chairperson of the Sunflower County Democratic Executive Committee. She served as Den Mother for Boy Scouts of America and is a member of the National Council of Negro Women. For the past 11 years Ms. Scott has served as County Coordinator for the Friends of Bennie Thompson campaign committee. She recently became the treasurer for the Sunflower CO-OP for Community Improvement.

In addition to her long list of volunteer services, Ms. Mildred Juanita Scott has worked for over 38 years as an Administrative/Finance Assistant. She currently works in the Accounts Payable Department at the Bolivar County Community Action Agency.

I take great pride in recognizing and paying tribute to this outstanding African American of the 2nd Congressional District of Mississippi who deserves mention, not only in the month of February but year round.

IN HONOR OF THE MARINE CORPS
JROTC AT EMERSON HIGH SCHOOL

HON. ROBERT MENENDEZ

OF NEW JERSEY

IN THE HOUSE OF REPRESENTATIVES

Wednesday, February 16, 2005

Mr. MENENDEZ. Mr. Speaker, I rise today to honor the Marine Corps Junior Reserve Officers' Training Corps (JROTC) on its tenth anniversary of training at Emerson High School in New Jersey. The JROTC hosted a dinner celebrating the event on February 10, 2005.

The JROTC has spent a decade instructing, guiding, and inspiring students to push themselves both physically and mentally. Throughout their rigorous training, they learn valuable skills such as discipline, commitment, and perseverance. The JROTC also instills in the students a sense of honor and citizenship. By participating in the program, students grow in strength and character and are well-prepared for a wide range of pursuits after high school.

Today, I ask my colleagues to join me in honoring the JROTC for its years of outstanding work and positive leadership training in Emerson, New Jersey.

TECHNICAL CORRECTIONS TO THE
UNITED STATES CODE

HON. F. JAMES SENSENBRENNER, JR.

OF WISCONSIN

IN THE HOUSE OF REPRESENTATIVES

Wednesday, February 16, 2005

Mr. SENSENBRENNER. Mr. Speaker, today I am introducing a bill to make technical corrections to the United States Code. The bill updates cross references, corrects typographical errors, and makes stylistic changes such as conforming the capitalization of certain words.

The Office of Law Revision Counsel has prepared the bill and submitted it to the Committee on the Judiciary as a part of the responsibilities of the Office under section 285b of Title 2, United States Code that have been enacted into positive law so that those titles may be kept current.

Anyone with questions about the bill should contact Robert Sukol, Assistant Counsel, Office of the Law Revision Counsel, U.S. House of Representatives, H2-304 Ford House Office Building, Washington, DC, 20515-6711. The telephone number is (202) 226-9060.

TRIBUTE TO R.W. WILLIAM J.
EWING, 32ND WORSHIPFUL MAS-
TER

HON. DONALD M. PAYNE

OF NEW JERSEY

IN THE HOUSE OF REPRESENTATIVES

Wednesday, February 16, 2005

Mr. PAYNE. Mr. Speaker, it gives me a great deal of pleasure to recognize Worshipful

Master R.W. William J. Ewing for his leadership of Jephthah Lodge No. 56 in Montclair, New Jersey. Under Worshipful Master Ewing's leadership, overall membership increased and acknowledgments of community initiatives improved. His unwavering dedication and passion have inspired the brothers of Jephthah Lodge No. 56 to increase their own commitments to do more within their designated communities.

Worshipful Master Ewing performed his duties as caretaker of the East, not only by word, but more importantly, through his deeds. He has made in-kind donations by extending the use of his business office, including his office manager and staff, consistently throughout his tenure. He has also made substantial financial contributions to assist the lodge. These unselfish acts have contributed significantly to the success of the lodge.

In addition to his lodge activities, Worshipful Master Ewing is a good citizen, a former Assistant Prosecutor, an attorney and an excellent role model. He is a dedicated family man, a member of Trinity Presbyterian Church in Montclair and a life member of the NAACP. As a former student, he is also supportive of keeping the legacy of the Bordentown Boarding School alive. Worshipful Master Ewing is an ardent traveler and is a dedicated annual Super Bowl participant.

Mr. Speaker, as Jephthah Lodge No. 56 celebrates its annual event on Friday, February 11, 2005 at the Ridgefield Regency in Verona, New Jersey, I urge my colleagues here in the House of Representatives to join me in honoring Worshipful Master Ewing for his dedicated service. As he concludes his term in office, his ongoing commitment to Jephthah Lodge No. 56, its brothers and Prince Hall Masonry in general is truly worthy of recognition and acclaim.

SUPPORT OF BURMA'S
DEMOCRACY MOVEMENT

HON. JOSEPH R. PITTS

OF PENNSYLVANIA

IN THE HOUSE OF REPRESENTATIVES

Wednesday, February 16, 2005

Mr. PITTS. Mr. Speaker, on February 17, 2005, Burma's ruling military junta, a regime that Secretary of State Rice has rightly called an "outpost of tyranny," will reconvene a national convention to draft a new constitution. Sadly, this convention, which excludes anyone interested in democracy and freedom of expression, appears to be yet another attempt to place a veneer of legitimacy on the dictatorship's rule. General Than Shwe, the recognized leader of Burma's military and the dictatorship, must understand that the international community and the people of Burma are not fooled by this latest attempt to establish legitimacy.

On February 14th, Burma's Committee for the Restoration of the People's Parliament (CRPP), an umbrella organization including over 200 Members of Parliament elected in 1990, called for all of Burma's ethnic groups to boycott the military's convention. The CRPP includes Nobel Peace Prize Laureate Aung San Suu Kyi's National League for Democracy (NLD). The statement by CRPP demonstrates once again the incredible bravery of the Burmese people in their battle against the ruling generals.

Mr. Speaker, it is time for the international community to face the facts: Than Shwe and other leading participants of this rogue regime have shown that they have no desire to seek political accommodation or peaceful dialogue with the Burmese people. Their actions show that they have chosen the path of tyranny and terror—the impact of this decision will increasingly be felt throughout the region.

The Association of Southeast Asian Nations (ASEAN) must realize that Burma's military junta is an iron anchor wrapped around the neck of this important organization. The actions of the military junta are draining economic growth from regional states, promoting the spread of HIV/AIDS throughout Asia, protecting indicted drug smugglers and flooding Thailand with methamphetamines and heroin, that eventually makes its way to the shores of the U.S. The regime fundamentally promotes regional instability and obstructs regional growth.

Recently, the U.S. Federal Court in New York City indicted eight drug traffickers from Burma in absentia. According to court documents, they are leaders of the United Wa State Army, one of the largest drug producers and traffickers in the world. This group is responsible for importing \$1 billion worth of heroin into the U.S. between 1985 and 2004. These criminals could not operate without the active collusion of the ruling generals. Moreover, the legendary drug kingpin known as Khun Sa, also under indictment in the U.S. on heroin trafficking charges, is living under the protection of the dictatorship of Rangoon. On November 18, 2003, the Department of the Treasury announced the designation of Burma and two Burmese banks to be of "primary money laundering concern" under Section 311 of the USA PATRIOT Act. In addition, The Department of Treasury, acting through the Financial Crimes Enforcement Network (FinCEN), has instituted sanctions against two Burmese financial institutions, Myanmar Mayflower Bank and Asia Wealth Bank, due to money laundering concerns.

ASEAN is serving in a critical role in the recovery and rebuilding efforts after the horrible tsunami that devastated parts of Asia. As a leader in the international community, ASEAN must come to understand that the organization must actively challenge Burma's military regime to work with Aung San Suu Kyi and the NLD. It must not be forgotten that the NLD won over 80 percent of the seats in the 1990 parliamentary election. A stable and democratic Burma is good for the entire region and the world. I would like to strongly commend and welcome the work of the Burma Caucus members in the Indonesian and Malaysian parliaments who are pressing for greater involvement by their countries in pressing the Burmese junta to bring positive change.

ASEAN cannot afford to have its leadership role sidetracked as it is forced to account for the acts of terror and oppression a member nations, Burma's junta, inflicts on the Burmese people. Last year's Asia-Europe meeting (ASEM) was delayed for months due to negotiations surrounding the participation of Burma. ASEAN is heading for another diplomatic fiasco as Burma is set to assume the chairmanship of ASEAN in 2006. ASEAN must understand that when the group spends more time addressing the latest crisis created by the junta, instead of focusing on plans to promote economic growth, fight the war on terror, and