

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.