

a long term beneficial impact on our federal forests.

I know, Madam Speaker, that time allows me to only mention a few of the many who made this project a success, but the most exciting part of the whole story is that this is just the beginning. The City of Lakeview and Lake County are hard at work at putting other renewable sources of energy to work. They plan to expand on their already successful use of geothermal and are working toward solar generation at a former Air Force radar site in the small community of Christmas Valley.

We can all take pride in knowing that communities like Lakeview are taking their destiny into their own hands and creating models for the future that can sustain both Northwest communities and forests.

SUPPORTING THE OBSERVANCE OF
BREAST CANCER AWARENESS
MONTH

SPEECH OF

HON. HEATH SHULER

OF NORTH CAROLINA

IN THE HOUSE OF REPRESENTATIVES

Monday, October 29, 2007

Mr. SHULER. Mr. Speaker, I rise today in strong support of H. Con. Res. 230, observing Breast Cancer Awareness Month. I offer my thoughts and prayers to those who have lost family members to breast cancer, and offer hope and encouragement to those who are currently battling the disease.

Breast cancer is the leading cause of death among women aged 45 to 54, and 1 out of 8 women will be diagnosed with the disease over the course of their lifetime. It is expected that over 180,000 new cases of breast cancer will be diagnosed in 2007 alone.

Fortunately, there is hope. When breast cancer is detected at early stages the survival rate for women is over 98 percent. Annual mammograms and monthly self-examinations are essential in detecting breast cancer at early stages.

Research has significantly increased our understanding of breast cancer. While there is still no cure for breast cancer, researchers have identified key risk factors for the disease.

I applaud the national and community organizations that promote awareness of breast cancer, offer support to those that are battling the disease, and provide information about early detection. It is imperative that these organizations continue their work to educate women about the disease and encourage monthly self-exams and annual mammograms.

I ask my colleagues to join me in observing Breast Cancer Awareness Month.

CLAIBORNE E. REEDER, DISTINGUISHED PROFESSOR OF PHARMACOECONOMICS, CONCERNED ABOUT FDA POSITION ON COMPOUNDING

HON. EDOLPHUS TOWNS

OF NEW YORK

IN THE HOUSE OF REPRESENTATIVES

Thursday, November 1, 2007

Mr. TOWNS. Madam Speaker, I would like to call my colleagues' attention to an out-

standing letter written by Claiborne E. Reeder, RPh, PhD, to FDA Commissioner von Eschenbach, expressing grave concern about recent FDA actions which adversely affect the compounding of medications for individual patients which is an important part of the practice of pharmacy. With 35 years of experience as a Pharmacist and educator, Dr. Reeder is a distinguished professor of Pharmacoeconomics and a nationally recognized leader in his field. In his letter, he urges Commissioner von Eschenbach to reconsider the FDA's position on compounding and comply with the federal ruling in Medical Center Pharmacy v. Gonzales which recognizes that the practice of Pharmacy is rightfully governed by the respective State Boards of Pharmacy.

Madam Speaker, I am entering Dr. REEDER's letter into the RECORD.

COLUMBIA, SC,
October 19, 2007.

ANDREW C. VON ESCHENBACH,
*Food and Drug Administration,
Office of the Commissioner,
Rockville, MD.*

DEAR COMMISSIONER VON ESCHENBACH: I am writing to express my concerns about the Food and Drug Administration's (FDA) recent actions regarding compounded medications prepared for individual patients as part of the practice of pharmacy. The agency's position on compounding medications, coupled with its actions against several compounding pharmacies and its intervention and influence on recent Centers for Medicare and Medicaid Services (CMS) policies on compounded medications, establishes a dangerous precedent that will affect patient access to needed medications. Compounding medicines is an essential component of the practice of pharmacy that provides physicians with the opportunity to provide patients with medicines that are prepared to the specific needs of the individual. Compounding and preparing medications pursuant to a valid prescription or physician's drug order has always been and should continue to be a professional prerogative that is governed by the pharmacy regulatory boards within each state. Governance of the practice of pharmacy is a state responsibility and should not be a matter for federal intervention.

Ignoring the recent Federal court decision Medical Center Pharmacy v. Gonzales, 451 F. Supp.2d 854, 865 (W.D. Tex. 2006), the FDA reasserted its legal position "that all compounded drugs are unapproved new, and therefore illegal, drugs under the Federal Food, Drug and Cosmetic Act (FDCA)". Contrary to the FDA's position, the Federal Court held that "compounded drugs, when created for an individual patient pursuant to a prescription from a licensed practitioner, were implicitly exempt from the new drug definitions contained in the Act". The Federal Court seems to understand the issue very clearly and recognizes that medications compounded for individual patients pursuant to a valid prescription are not "new drugs" and are therefore not under the purview of the FDCA or the FDA.

As a pharmacist/educator with 35 years of experience, I appreciate the FDA's concern for quality, safety and efficacy of medicines. That said, I also know that pharmacists are educated and trained in the "art and science" of pharmacy which includes compounding medicines for patients who need them. The broad interpretation "that all compounded drugs are unapproved new, and therefore illegal drugs" is a very slippery slope of regulatory intrusion on the practice of pharmacy as is FDA's practice of exercising its enforcement discretion

through reliance on the 2002 Compliance Policy Guide, Section 460.200. Many patients have medication needs that are unmet by commercially available products. Patients often require a particular strength or dosage form of a drug that is not available on the market. Also, commercially available products may contain additives or excipients to which the patient is allergic or intolerant. To declare compounded medications illegal is to deny these patients access to needed medicines.

Compounding medicines is not limited to the typical community environment. Hospitals, skilled nursing facilities, and specialty pharmacy providers prepare medications to order as part of their daily practice. Do the FDA and CMS positions mean that preparation of parenteral and enteral solutions as well as other extemporaneous products, within these settings is no longer legal? If not, then a disparity is created.

To further illustrate the consequences of the Agency's position on compounding, CMS, without explanation or medical rationale, reversed its long standing policy on inhalation medications by excluding compounded inhalation medications for Medicare beneficiaries stating that they were no longer "medically necessary". This new CMS policy, based on FDA's position, may have far-reaching and serious consequences for Medicare beneficiaries who rely on nebulizer medications. Eliminating compounding will severely restrict access to these and other critical medications for Medicare beneficiaries. Moreover, the policy will limit physicians' abilities to prescribe the medicines in the strengths, formulations, and routes of administration that are best for patient care.

I am asking that the FDA to reconsider its position and comply with the Federal court ruling. The practice of pharmacy is governed by the respective state Boards of Pharmacy through the powers granted by their legislatures. Compounding is an integral part of the practice of pharmacy and should thus fall under the governance of the profession at the state level.

Thank you for considering my comments in this matter. If you or anyone at the FDA would like to discuss this issue in more detail, I would be delighted to do so.

Sincerely,

CLAIBORNE E. REEDER,
*Distinguished Professor of
Pharmacoeconomics.*

INTRODUCING A RESOLUTION ENCOURAGING INCREASED FEDERAL AND STATE SUPPORT FOR HOME AND COMMUNITY-BASED SERVICES

HON. ALCEE L. HASTINGS

OF FLORIDA

IN THE HOUSE OF REPRESENTATIVES

Thursday, November 1, 2007

Mr. HASTINGS of Florida. Madam Speaker, I rise today to introduce a resolution calling for increased funding for Federal and State home and community-based services for individuals with disabilities of any age, and especially the elderly. It is fitting that I introduce this bill today because November is National Home Care and Hospice Month.

The resolution which I am introducing today highlights the overall cost-effectiveness and improved outcomes in quality care for the elderly and disabled who are furnished health care in their homes or other community settings. By increasing financial assistance and