

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

broadening access to home and community-based services, we can help ensure that the quality of care individuals receive in their home and community is just as accessible an option as hospital and institutional attention.

Madam Speaker, this is an important resolution for three crucial reasons. First, it endorses the efforts of the elderly and individuals with disabilities to remain independent and sustain their viability during the last years of their life. Supporting studies show that individuals who receive home and community-based care have greater life expectancies than those who are moved from everything that is familiar to them and placed in hospitals and other forms of institutional care.

Second, this resolution promotes the expansion of employment opportunities in the nursing and in-home care industries. By implementing government funded in-home care as a viable alternative to that of nursing home care, more seniors will elect to be nursed at home, creating a situation that will enhance their quality of life while also increasing job opportunities.

Finally, this resolution encourages the implementation of more unified training and supervision standards for certified nurse aides and homecare aides. Through adoption of uniformly high standards, we can ensure our citizens in need have access to qualified professionals when selecting home and community-based care.

According to the National Association for Home Care and Hospice, which I am proud to report supports this resolution, patients receiving home and community-based care are more likely to enjoy better outcomes, including a greater responsibility for healthier living, increased independence and productivity, self-esteem, family cohesion and overall contribution to their larger community.

Madam Speaker, I urge my colleagues to support this legislation. As Members of Congress, we have a great opportunity to make a positive impact on this issue, an issue that is of concern to many of our grandparents, parents, and will be of concern to us. I look forward to working with my colleagues and moving this resolution forward.

HONORING THE MINNEAPOLIS  
VETERANS AFFAIRS MEDICAL  
CENTER FOR RECEIVING THE  
16TH ANNUAL ROBERT W. CAREY  
PERFORMANCE EXCELLENCE  
AWARD

**HON. BETTY McCOLLUM**

OF MINNESOTA

IN THE HOUSE OF REPRESENTATIVES

*Thursday, November 1, 2007*

Ms. McCOLLUM of Minnesota. Madam Speaker, I rise to honor the Minneapolis Veterans Affairs Medical Center, its director Stephen Kleinglass, and the entire medical center staff, for being recognized as a 2007 award recipient at the 16th Annual Secretary's Robert W. Carey Performance Excellence Ceremony on November 1st, 2007. This Department of Veterans Affairs award acknowledges the highest levels of performance and service excellence through evaluation by rigorous criteria.

As the daughter of a WWII veteran, I feel strongly about honoring our veterans and their

families. The professionalism and high quality of care provided by the staff of the Minneapolis Veterans Affairs Medical Center is evident whenever I visit.

Serving nearly 75,000 veterans each year, the Minneapolis Veterans Affairs Medical Center is among the most active in the country. Through its partnership with University of Minnesota Medical and Dental Schools, it has distinguished itself by providing the highest quality health care to veterans. Minnesota and western Wisconsin veterans and their families have long appreciated the staff commitment to serve all veterans.

The dedication of staff to provide the highest level of care is particularly visible through their work to meet the great needs of our injured veterans returning from Iraq and Afghanistan. Minneapolis is just one of four locations in the Nation with a Polytrauma Rehabilitation Center designed to provide intensive rehabilitative care to veterans and service members who experienced multiple severe injuries, including brain injuries. Construction on a new Spinal Cord Injury Center is underway, and is scheduled to open in 2008.

The success of our Nation's veterans health system depends on caring, dedicated people serving our veterans, but they cannot do the job alone. On the battlefield, the military pledges to leave no soldier behind. As a Nation, let it be our pledge that when they return home, we will leave no veteran behind.

This year, the U.S. House of Representatives passed the largest single increase in the 77-year history of the Veterans Administration—\$6.7 billion. This funding is necessary to ensure that the Minneapolis Veterans Affairs Medical Center, and VA medical centers across the country have the resources they need to fund the increasing need for mental health, posttraumatic stress disorder and traumatic brain injury care, and to provide facilities maintenance, and to continue reducing the backlog of veterans benefits claims.

The Minneapolis Veterans Affairs Medical Center has a proven record of organizational excellence. The Carey Award recognition allows the leadership shown in Minnesota to serve as a model for other organizations in assessing their own transformation efforts, effectiveness and service performance. Most importantly, this award recognizes the outstanding efforts made by the staff on behalf of our veterans at the Minneapolis Veterans Affairs Medical Center.

Madam Speaker, please join me in commending the Minneapolis Veterans Affairs Medical Center staff for earning the Robert W. Carey Performance Excellence Award. These caring people exemplify the very best in public service.

LENOX HILL HOSPITAL CELEBRATES ITS 150TH ANNIVERSARY

**HON. CAROLYN B. MALONEY**

OF NEW YORK

IN THE HOUSE OF REPRESENTATIVES

*Thursday, November 1, 2007*

Mrs. MALONEY of New York. Madam Speaker, I rise to pay tribute to Lenox Hill Hospital on the occasion of its 150th Anniversary. Lenox Hill Hospital is an accredited not-for-profit acute-care hospital and teaching affiliate of New York University Medical Center lo-

cated on the Upper East Side of Manhattan in New York City. Lenox Hill Hospital has become renowned for furthering medical research and establishing a tradition of excellence in patient care. It has earned a national reputation for outstanding medical care and treatment.

Lenox Hill Hospital was established in 1857 as the German Dispensary and today provides specialty services and ground-breaking care for millions of patients each year. Approximately 45% of Lenox Hill Hospital's patients are from Manhattan. The remaining 55% come from Brooklyn, Bronx, Queens, Long Island, the Tri-State area and around the world. Lenox Hill Hospital is particularly well known for its excellence in internal medicine, cardiovascular disease, orthopedics, sports medicine, maternal/child health and medical research.

For the past 150 years, Lenox Hill Hospital has been a leading innovator in many fields of medicine, developing standards and practices that became models for other hospitals throughout the country. In 1897, the hospital installed one of the first X-ray machines in the United States. Ten years later, the hospital established the first physical therapy department in the country.

In 1938, Lenox Hill was the first hospital to perform an angiogram in the nation and in 1955 it became one of the first hospitals in New York City to open a cardiac catheterization laboratory. The first coronary angioplasty in the United States was performed at Lenox Hill in 1978. In 1994, Lenox Hill Hospital surgeons pioneered minimally invasive direct coronary artery bypass surgery. In 2003, the first FDA approved drug coated stent in the nation was implemented at Lenox Hill. In 2006, Lenox Hill opened a new radiology center featuring the only SPECT-CT in the Northeast, a machine which allows physicians to see inside the body in great detail and a new 64-slice CT scanner, one of the most highly advanced computerized imaging technologies available today.

Lenox Hill is respected as a leading responder to health crises. When tuberculosis was becoming a growing public health threat, Lenox Hill Hospital was the first general hospital in the United States to open a tuberculosis division in 1908. In 1943, Lenox Hill Hospital sent its medical unit to England to maintain station hospitals for military personnel during World War II. In 1989, the hospital established the first Lyme Disease Center in New York City.

In keeping with its tradition of providing an immediate and necessary response during times of crisis, on September 11th, when terrorists struck the World Trade Center, Lenox Hill assembled a disaster team that came to the aid of hundreds of New Yorkers. The hospital set up a free walk-in Crisis Counseling Center as well as a blood donor center. Lenox Hill Hospital, as it has done in the past, provided aid to people when it was needed the most and became a beacon of hope for so many on that horrific day.

Madam Speaker, I rise to request that my colleagues join me in paying tribute to Lenox Hill Hospital and its legacy of medical innovation and excellence in patient care.