There being no objection, the material was ordered to be printed in the Congressional Record.

HHS, BAYER AGREE TO CIPRO PURCHASE
Washington, Oct. 24.—HHS Secretary Tommy G. Thompson and Mr. Helge H. Wehmeier, President and CEO of Bayer Corporation, announced the agreement for a significant new federal purchase of the antibiotic ciprofloxacin (trademarked Cipro) at a substantially lowered price. The antibiotic is expected to be available by mid-November.

Supplementing existing emergency stockpiles, it would be available for use in the event of a bioterror event. Under the terms of the agreement valued at $95 million, HHS will pay 95 cents per tablet for a total initial order of 100 million tablets. This compares with a previously discounted price of $1.77 per tablet paid by the federal government. Bayer said it will rotate the government’s inventory, as part of this agreement, to assure the American public a continued supply of Cipro. In addition, the inventory rotation adds an additional value of 30 percent for the government, which is included in the agreement.

Funds for the purchases are included in the $1.6 billion emergency proposal made by President Bush Oct. 17, which awaits Congressional approval. The agreement is also designed to make substantial new purchases of other antibiotics that are effective against anthrax, especially doxycycline. The purchases will fulfill Secretary Thompson’s proposal to quickly increase the nation’s emergency reserve of antibiotics. Resources to be on hand by January would treat up to 12 million persons immediately for anthrax exposure. Treatment would be a mixture of effective antibiotic products, with Cipro representing about 10 percent of the antibiotics on reserve. Currently, 18.6 million Cipro doses are available in the nation’s emergency reserve, which would enable immediate treatment of about 2 million persons in combination with other antibiotics.

“This agreement means that a much larger supply of this important pharmaceutical product will be available if needed,” Secretary Thompson said. “The beneficial price also means that we can have more funds available to assist state and local health responders to be ready for all eventualities. I commend the Bayer Corporation for its ongoing efforts to ensure a fully adequate supply of this valuable product.”

“Bayer is fully committed to supplying America in its war on bioterrorism. This agreement between Bayer and the Department of Health and Human Services is an important security measure that will enable the nation to have in its stockpile ample supplies of Cipro to combat the threat of anthrax,” said President Wehmeier.

“Cipro has become a standard for anthrax treatment. The men and women of Bayer are 100 percent committed to delivering this vital antibiotic to the U.S. government on schedule.”

Secretary Thompson said current supplies of Cipro and other antibiotics which are effective against anthrax “are entirely adequate for the imminent need. This purchase is aimed at expanding our emergency stand-by capacity, to make us even better prepared for the possibility of massive exposure to other biological agents.”

As a further contingency, the agreement provides for the option of a second order of 100 million tablets at 85 cents, and a third order at 75 cents, if it is determined that further orders are needed. Cipro is one of many antibiotics that have been found effective in the treatment of exposure to anthrax in the incidents in recent weeks. Current treatment practices for anthrax exposure, including those possibly exposed to anthrax, is a 60-day course, involving initial use of a broad spectrum antibiotic like Cipro, for five days, followed by determination of other antibiotics to which the pathogen is susceptible.

The Cipro to be purchased would be used to expand emergency stand-by supplies in the National Pharmaceutical Stockpile (NPS), maintained by HHS’ Centers for Disease Control and Prevention. The NPS includes both pre-manufactured 50-gallon “Push Packages” designed to be able to reach any point in the continental United States within 12 hours. The current eight “Push Packages” are to be expanded to 12, under the President’s proposal.

COMMUNITY RAIL LINE RELOCATION ASSISTANCE ACT

Mr. LOTT. Madam President, many cities and towns across our country are experiencing conflicts between railroads, motor vehicles, and people for the use of limited and increasingly congested downtown areas. High density highway-rail grade crossings, even properly marked and gated ones, increase the risk of fatal accidents. Many rail lines cut downtown areas in half while serving few, if any, rail customers in the downtown area. Road traffic can cut off one side of a town to vital emergency services, including fire, police, ambulance, and hospital services. Downtown rail corridors can hamper economic development by restricting access to bisected areas. Sadly, since September 11, we now must be concerned about freight trains carrying hazardous materials through the middle of densely populated areas being targets of terrorist actions. These problems exist in small and large cities and towns across the Nation.

While TEA–21 provides some flexibility in the use of the Highway Trust Fund to enable States to address some of these concerns, it is primarily focused on solving transportation problems by building or modifying roads, including road overpasses and underpasses, as it should be. However, in many situations, this highway-rail conflict cannot, or should not, be fixed by cutting off or modifying a roadway. The answer is often to relocate the rail line.

To address this need I introduced S. 948, the Community Rail Line Relocation Assistance Act of 2001. The bill would authorize the Secretary of Transportation to provide grants to States and communities to relocate a rail line where this solution makes the most sense. In those cases where the best solution is to build a railroad tunnel, underpass, or overpass, or even route the rail line around the downtown area, this bill will enable these cities and towns to afford to undertake such a significant infrastructure project. The bill does not tap the High-way Trust Fund. Instead, the rail line relocation grant program would compete for appropriations on an annual basis.

S. 948 is supported by the United States Conference of Mayors, the National Conference of State Legislatures, the National League of Cities, the Association of American Railroads, the Short Line and Regional Railroad Association, the Railway Progress Institute, the National Railroad Construction and Maintenance Association, and the Rail Supply and Service Coalition.

The Senate may soon consider other legislation to authorize funding to increase security for Amtrak, other modes of transportation, and our nation’s ports. I ask my Senate colleagues to consider the needs of their own States, to cosponsor S. 948, and to support inclusion of this provision in the next transportation authorization bill to be considered by the Senate. So far, working with representatives of our Nation’s cities, I have identified 40 cities in 23 States that are concerned about rail crossing problems and for which rail line relocation may be the solution. I am sure there will be several more such cities that will be identified in the weeks to come. I ask unanimous consent that the list of these cities be printed in the RECORD. There being no objection, the list was ordered to be printed in the RECORD, as follows:

CITIES CONCERNED WITH RAIL CROSSINGS AND RAIL LINE RELOCATION

ARIZONA: Marana and Tucson.
California: Fremont, Hemet, Mountain View, Paramount and Richmond.
Colorado: Arvada.
Georgia: Augusta.
Iowa: Cedar Rapids.
Illinois: Carbondale, Elgin and Roselle.
Indiana: Portage.
Massachusetts: Boston.
Minnesota: Rochester.
Mississippi: Biloxi/Pascagoula, Greenwood, Jackson, Meridian, Tupelo and Vicksburg.
Missouri: St. Joseph.
North Carolina: Winston-Salem.
North Dakota: Fargo.
Nebraska: Grand Island and Lincoln.
Nevada: Reno.
New York: Hempstead.
Ohio: Brooklyn, Lima and Mansfield.
Oklahoma: Edmond.
Pennsylvania: Pittsburgh.
South Carolina: Columbia.
Tennessee: Germantown.
Texas: Beaumont, College Station and Laredo.
Wisconsin: Madison.

AGRICULTURE APPROPRIATIONS

MEDICAL DEVICE TECHNOLOGY

Mr. JOHNSON. Madam President, first I thank Chairman Kottt and Senator Cochran for their outstanding work in putting together an excellent bill. An important part of this legislation provides funding for the Food and Drug Administration to perform its
vital mission to protect and promote the public health. That mission includes the help of patients in an expedient manner. However, we must be sure that this amendment for Devices Radiological Health (CDRH) are provided with the adequate resources to carry out their work. The number of patents issued in the medical device sector has increased by 30 percent in recent years. The private sector is committing substantial increases in funding to healthcare research and development. We are fortunate that the FDA will be faced with the task of evaluating many new technologies that will benefit all of us next year. It is my hope that we could review this issue in conference to ensure that the premarket review function at CDRH receives an appropriate level of funding to carry out their mission.

Mr. DORGAN. I thank my colleague for raising this matter. It is my concern that the premarket review function at the Center for Devices and Radiological Health does not have sufficient resources to keep up with the tremendous pace of innovation that is now taking place in the health sector. Despite the FDA’s ongoing efforts to improve in this area, review times for breakthrough devices are lengthy and likely to get longer. While this bill makes important progress toward giving the FDA the funds it needs to carry out its mission, I hope the chairman would work with us in conference to find a way to provide the resources needed to redress medical device application review times.

Mr. KOHL. I appreciate the remarks and understand the concerns expressed by my colleagues. I agree that patients should not have to wait for promising new therapies due to insufficient resources at FDA. Language in the report accompanying the Senate bill states that the increase received by FDA’s Devices and Radiological Health Program for fiscal year 2002 is consistent with agency estimates for bringing medical device application review times within statutory limits. While this statement is accurate according to the budget submitted to congress by the FDA, I have been informed that in testimony to the House Appropriations Committee, FDA officials stated the agency would need more funds than requested in their budget to decrease application review times. I believe it is important for us to work together to resolve this issue, and look forward to working with my colleagues and our House counterparts in the Conference Committee.

Mr. VOINOVICH. Madam President, I was proud to offer an amendment to the fiscal year 2002 agriculture appropriations bill.

The amendment I offered last week set aside $500,000 from the Office of Generic Drugs at the Food and Drug Administration for use in the education and dissemination of information to America’s senior citizens regarding the efficacy, safety and availability of generic drugs.

Currently, the FDA informs the public and providers about generic drugs through print advertising, reaching a limited number of individuals. It is my hope that this amendment will allow the FDA to enlarge its outreach, utilizing not only print media, but also radio and television public service announcements.

In the absence of a Medicare prescription drug benefit, it is imperative that Congress provide alternative avenues for seniors needing to lower their out-of-pocket prescription costs.

Although millions of seniors already know about and use generic drugs, there are still many others who are not aware of their availability. Indeed, many highly used brand-name drugs have close chemical equivalents that are just as effective as their name-brand counterpart. These generic drugs are chemically identical in their active ingredient to their brand-name counterparts and are sold at substantial discounts from the branded price.

For example, the prescription drug Kelflex, an antibiotic, costs approximately $88 per month. Its generic equivalent costs about $13 per month, a potential annual savings of $900 for an individual who uses this product. In fact, according to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion per year at retail pharmacies.

As each of my colleagues knows, the nature of health care has changed dramatically in America since the creation of Medicare in 1965. In many instances, diseases or conditions that once required hospitalization are now treated by pharmaceuticals. However, as advances in pharmaceuticals continue and the population ages, the Centers for Medicare and Medicaid Services reports that the increase received by the Department of Health and Human Services to provide seniors with thorough information regarding high cost specialty drugs is expected to more than double from an estimated $117 billion in 1996 to $366 billion over the next ten years.

Mr. CONRAD. Madam President, section 214 of the Congressional Budget Act of 2002 requires that the Chairman of the Senate Budget Committee adjust the budgetary aggregates and the allocation for the Appropriations Committee by the amount of appropriations provided to the Social Security Administration for continuing disability reviews, up to $520 million in 2002, and the amount of appropriations provided to the Department of Health and Human Services for adoption incentive payments, up to $250 million in 2002, the Department of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act for 2002, provides a total of $453 million for the two activities.