

TRIBUTE TO JUDGE EDMUND A.
SARGUS, JR.

HON. ROBERT W. NEY

OF OHIO

IN THE HOUSE OF REPRESENTATIVES

Wednesday, September 25, 1996

Mr. NEY. Mr. Speaker, I commend the following to my colleagues:

Whereas Judge Edmund A. Sargus, Jr. will be invested as a United States District Judge in the Southern District of Ohio; and

Whereas the Honorable Edmund Sargus has shown exemplary dedication to justice and the practice of law; and

Whereas Judge Sargus has honorably served the City of Bellaire and the State of Ohio as a Law Director, United States Attorney and Special Counsel to the Ohio Attorney General: Therefore, be it

Resolved, That the residents of Belmont County, with a real sense of pleasure and pride, join me in commending The Honorable Edmund A. Sargus, Jr. for his hard work and commitment to justice and to the law.

MEDICARE AND VANCOMYCIN:
LEGISLATION TO PRESERVE A
BENEFIT AND PROTECT THE
PUBLIC HEALTH

HON. FORTNEY PETE STARK

OF CALIFORNIA

IN THE HOUSE OF REPRESENTATIVES

Wednesday, September 25, 1996

Mr. STARK. Mr. Speaker, current Medicare pharmaceutical payment policy is creating distortions in the types of drugs prescribed in our society and contributing to a potential public health problem. This problem is the threat of increased drug resistance among bacteria that cause infections in thousands of people. The policy contributing to this public health threat is the unevenness of Medicare coverage for outpatient medications, and specifically, Medicare's coverage of a single antibacterial drug called vancomycin out of a multitude of possible antibacterials. This coverage provides an unintended incentive for physicians to preferentially choose vancomycin over other antibiotics. Inappropriate use of vancomycin will likely accelerate the emergence and spread of bacteria resistant to this drug, causing a major public health problem resulting in numerous deaths and increased morbidity. The bill I am introducing today counteracts the misdirected incentive for inappropriate use of vancomycin by insisting on certain criteria for the use of the drug in order for it to be reimbursed.

Under current law, Medicare reimburses for outpatient medications in limited circumstances. Highly specific, unrelated categories of drugs are reimbursed. These include drugs administered in a physician's office or hospital, oral anticancer drugs, immunosuppressant drugs for organ transplant patients, a drug to treat anemia in end stage renal disease patients, drugs to treat osteoporosis in certain patients, and drugs that require durable medical equipment [DME] for their administration. Approximately 20 drugs are covered under the DME benefit, of which vancomycin is one. Vancomycin is covered because it is administered intravenously through an apparatus called an infusion pump. Medicare reimburses for the infusion pump

and for the drug for which it is used. Thus, although more than 50 drugs are available to treat bacterial infections, Medicare singles out one drug for reimbursement simply because an infusion pump is used for administration. The DME benefit also includes four drugs used to treat infections caused by viruses or fungi, again because an infusion pump is used for administration, but vancomycin is the only drug used to treat infections caused by bacteria.

Intravenous vancomycin is typically used in home therapy for infections requiring prolonged courses of antibiotics, such as endocarditis, an infection of the heart valves, or osteomyelitis, an infection of bones. Generally patients are hospitalized for an initial period, and once stable, can continue treatment at home. Only a subset of patients are medically appropriate candidates to receive home intravenous therapy. Home therapy is generally cost effective because the alternative is for patients to remain in the hospital or other inpatient facility to receive the therapy.

Medicare's reimbursement system is causing overuse of vancomycin. The Health Care Financing Administration [HCFA] found a 64-percent increase in the home use of vancomycin, as measured by claims submitted for infusion pumps for vancomycin, from the fourth quarter of 1994 through the third quarter of 1995. Anecdotes from some hospitals and home care agencies indicate that vancomycin is preferentially used whenever the bacteria causing the infection are susceptible to it. This information suggests that the current Medicare policy is having the unintended effect of changing physicians prescribing practices.

Overuse of antibiotics is a principal risk factor for the development of drug resistant bacteria. Antibiotics kill or inhibit bacteria that are susceptible to them, but the resistant bacteria survive. The Centers for Disease Control and Prevention [CDC] has documented a major increase in infections among hospitalized patients due to vancomycin resistant bacteria called vancomycin-resistant-enterococci [VRE], from 0.3 percent in 1989 to 7.9 percent in 1993. In addition to this increase, a major concern is the possibility that these bacteria will transfer their vancomycin resistance to other families of bacteria. This transfer has occurred in a laboratory setting but has not yet been documented in humans; when it does occur, a major public health problem will arise since some of the bacteria to which vancomycin resistance may be transferred, such as *Staphylococcus aureus*, are common causes of infection and may already be resistant to many other drugs. In a 1995 report about the impacts of antibiotic resistant bacteria, the Office of Technology Assessment concluded that steps should be taken to preserve the effectiveness of currently available antibiotics. It noted that Medicare's vancomycin policy runs counter to recommendations published by the CDC for judicious use of this drug. It also advised that a change in the Medicare policy may secondarily create positive influences on other insurers to consider whether their policies might also be creating unanticipated effects on antibiotic prescription patterns.

Clearly, some patients need to be treated with vancomycin; it can be a lifesaving treatment in patients with serious infections caused by bacteria resistant to other drugs, or in patients who are allergic to certain other drugs. Unfortunately, HCFA's response to the prob-

lem of vancomycin overuse is to curtail coverage for vancomycin altogether. HCFA has announced that it is planning to curtail coverage of vancomycin under the DME benefit starting September 1, 1996. It has determined that vancomycin does not require an infusion pump for administration and thus will not be reimbursed. Surely, there must be a better way to address this problem than penalizing patients who truly need vancomycin.

Instead of curtailing coverage, my bill addresses the public health threat by insisting that vancomycin use complies with certain criteria. The CDC's published recommendations for preventing the spread of vancomycin resistance include guidelines for prudent vancomycin use. The bill incorporates the two CDC recommendations that seem most applicable in the outpatient setting. Implementation would involve having physicians indicate on the request for vancomycin and DME reimbursement that the treatment meets at least one of the criteria delineated in the bill.

Vancomycin is used to treat bacteria which are characterized as gram-positive; this property means that when the bacteria are applied to a microscope slide and subjected to a technique called the Gram stain, the bacteria pick up the color of the stain, which is a positive result. The ability of these bacteria to pick up the stain is related to their outer structure; the ability of certain antibiotics to harm these bacteria is related to the antibiotic's ability to penetrate or disrupt this structure.

Another large family of antibiotics effective against gram-positive organisms is termed the beta-lactam antibiotics because they have in common a chemical structure called the beta-lactam ring. The prototype and most well-known of the beta-lactam antibiotics is penicillin. Penicillin is the first choice treatment for certain infections. However, penicillin has been widely used since the 1940's and many bacteria currently are resistant to penicillin; in this case, certain other beta-lactam drugs are usually effective. Since the 1980's, however, an increase in infections due to *Staphylococcus aureus* strains which are resistant to the whole family of beta-lactam drugs has been documented in hospitals; in these infections, vancomycin is often effective. Vancomycin is generally the last drug available to effectively treat these infections. Thus, today's bill reserves vancomycin use for when the bacteria are resistant to beta-lactam antibiotics. Although vancomycin could also be used against bacteria that are not resistant to the other drugs, it is more prudent to use the other drugs whenever possible and to save vancomycin as the last resort. Current law does not prevent physicians from prescribing vancomycin for infections that could be effectively treated with a beta-lactam antibiotic. In contrast, my bill provides for reimbursement of vancomycin and the equipment used for its administration if the physician indicates that treatment is for a serious infection caused by beta-lactam-resistant bacteria.

Vancomycin is also used for patients who have serious allergies to penicillin and other beta-lactam antibiotics. Thus, the bill also provides for reimbursement of vancomycin and the equipment used for its administration if the patient has a serious allergy to beta-lactam antibiotics.

The bill I am introducing is one attempt to address the public health threat of drug resistant bacteria while protecting the needs of