

human erythropoietin (rHuEPO) announced by the Amgen Corporation. Such an investigation would be very important in the developing debate on the rapid rise in pharmaceutical expenses (15.4% last year) and Medicare payment policy.

Briefly put, Amgen makes about \$1 billion dollars a year *in profit* on the sale of its sole source, monopoly product EPOGEN to Medicare providers. Medicare pays \$10 for a unit that, the last we know, cost about 50 cents to make. The company recovered its entire R&D costs for this product—about \$170 million—in roughly the first year of its sales to Medicare (1990).

While the price/unit has been stable since 1991, the cost to Medicare has soared while the improvement in patients' hematocrits has been disappointingly flat. Part of the reason for the increase in dosage is that we have set a higher quality standard for the desired hematocrits. But I believe another, big part of the reason that the dosage has increased so dramatically is that while Medicare reimburses providers \$10 per 1000 units, the company provides a volume discount, which encourages providers to use more EPO, because the more they use, the more the dialysis centers make. It is reported that some providers are getting paid \$10 by Medicare for a unit that may cost them around \$8.50.<sup>1</sup> I believe this "volume discount" has caused many American dialysis centers to administer the product in an inefficient and even wasteful manner.

The national Dialysis Outcomes Quality Initiative (DOQI), and most foreign nations recommend the administration of EPO subcutaneously—in an injection rather than through the dialysis process. When administered this way, there is data that, at least for a period of time, about 60-70% of patients would need about 30% less EPO. The company's volume discount, therefore, has probably caused Medicare and the taxpayer to spend \$100 to \$200 million more per year than would be needed if we administered the drug the way the quality experts recommend and most foreign countries practice.

In addition to the waste and extra expenditure, too much EPO can be dangerous. It has side effects.<sup>2</sup>

The Amgen price increase takes advantage of the first increase in Medicare payment for dialysis in a decade. In the Balanced Budget Refinement Act of 1999, Congress increased dialysis payments by 1.2% in 2000 and another 1.2% in 2001—about \$300 million in new spending over the next five years. As one prominent Midwest nephrologist wrote me, "If my calculations are correct, this [3.9% increase in the cost of EPO to a dialysis center] almost exactly matches the fair and needed increase in the composite reimburse-

ment that [Congress] gave to the dialysis providers this year. I guess none of us anticipated that the increase would be consumed to enhance Amgen's profits. I thought it would go to computers, staff, and Continuous Quality Improvement programs in dialysis units. How naive of me." How naive of Congress.

With all this as a background, Amgen's price hike is important to understand and can help shape the Congressional debate on drug reimbursement policy and Medicare payment policy to dialysis centers.

First, I find Amgen's explanation to providers (copy attached) interesting: "This change in price, the first since EPOGEN was launched eleven years ago, is being implemented as a result of continually increasing costs associated with Amgen's business."

As I indicated there is data from a decade ago that the cost of production was about 5 percent and that all R&D costs were recovered in a year. In many industries, productivity is able to actually lower the cost of various high tech products. Can the FTC tell us what the cost of production is today, and how that compares to other increased costs of Amgen in marketing, litigation against potential competitors, overhead, and political contributions, etc.? Can the FTC give us an estimate of the current yearly profit to Amgen from sales of EPO and how much this price increase will add to those profits? The latest 10-Q for Amgen for the three months ended September 30, 1999 shows net income of \$300 million, compared to \$221 million in the same period, 1998. That same SEC filing shows product sales of \$769.2 million and cost of sales, \$98.9 million. The cost of sales as a percent of total sales actually declined between 1998 and 1999. All of this calls into question Amgen's justification for the price increase. As one security analyst is quoted as saying (attached) "They promised Wall Street a certain level of earnings this year. . . . Maybe this is the only way they can achieve that."

So did costs of production really go up that much, or did Amgen's other expenses go up, and this is just a way to tap the Medicare cash cow? The answer to this type of question is important for how we structure a Medicare prescription drug benefit.

The coincidence of Amgen's price increase absorbing most of the Congressional dialysis payment increase should inspire us to consider ways to prevent that from happening again. If we don't, it would be easy to see Amgen doing another 3.9% increase next spring to absorb the second 1.2% dialysis payment increase scheduled for 2001.

Thank you for your early review of this entire situation.

Sincerely,

PETE STARK,  
Member of Congress.

## INDIA'S RELIGIOUS TYRANNY GOES ON

HON. EDOLPHUS TOWNS

OF NEW YORK

IN THE HOUSE OF REPRESENTATIVES

Thursday, March 9, 2000

Mr. TOWNS. Mr. Speaker, I was distressed to read an article in the Washington Times of February 25 datelined Calcutta reporting that

the government of India's state of Orissa is now requiring anyone converting to Christianity to get a government permit. This policy has been met with protests in front of government offices in Calcutta, because it is just the latest chapter in the ongoing religious tyranny in India.

As you know, thousands of Sikhs languish in Indian jails without charge and without trial. These Sikhs are political prisoners in "the world's largest democracy." Many of them have been in prison illegally since the Indian government attacked the Sikhs' holiest shrine, the Golden Temple in Amritsar, in June 1984. That is coming up on 16 years now!

The BJP, which runs the central government, destroyed the most revered mosque in India, the mosque at Ayodhya, intending to put a Hindu temple on the site. Hindus affiliated with the BJP's parent organization, the RSS, burned a Christian missionary and his two sons, ages 8 and 10, to death in their jeep while they slept. The mob surrounded the family's jeep and chanted "Victory to Hannuman," a Hindu god. RSS-affiliated Hindu extremists have burned down Christian churches, schools, and prayer halls. They have murdered priests and raped nuns. In 1997, the police broke up a Christian religious festival with gunfire.

The Indian government has sent over 700,000 troops to Kashmir and half a million to Punjab, Khalistan, to suppress the freedom of the Muslim and Sikh populations there. It has killed tens of thousands of Christians, Sikhs, Muslims, Assamese, Manipuris, Dalits, and others.

President Clinton will soon be going to India. While he is there, one important thing that he should do is to press the Indian government on the subject of human rights. If we do not support the human rights of all the people of South Asia, who will?

I call on the President to raise these issues in the strongest terms. Also, we should cut off aid to India until it observes the basic standards of human rights for all and we should support freedom for the people of South Asia by going on record in support for self-determination for the people of Punjab, Khalistan, Kashmir, Nagaland, and the other nations of South Asia that now live under occupation.

Mr. Speaker, I would like to submit the Times article into the RECORD.

[From the Washington Times, Feb. 25, 2000]

CHRISTIANS IN INDIA PROTEST 'BIAS' ORDER

CALCUTTA—Hundreds of Christians converged on a government office yesterday to protest what they said was a discriminatory order by the Orissa state government on religious conversions.

The protesters said the order, which requires people who are converting to Christianity to apply to a local official and get police clearance, violates the Indian Constitution.

The protesters belong to the Bangiya Christiya Parishad, or United Forum of Catholics and Protestants. They delivered a statement to the Orissa government through its local office in Calcutta.

<sup>1</sup>One physician has indicated to me that Amgen discounts EPO linked to the potential growth in use per year. "Rumor has it that the target growth is greater than the incident growth in the ESRD program. In other words, if the ESRD program grows by 7%, the Amgen target for discount is some larger number, like 10%." Another expert tells me that the volume incentive is based on 5% growth per quarter. (If the FTC could determine the exact nature of the discount, it would be very helpful to understanding prescribing patterns.)

<sup>2</sup>One analyst notes that between 1989 and 1995, fifteen month survival has decreased by 20% for hemodialysis patients. This analyst asks if it is possible that inappropriate dispensing of EPO may play a contributing role? See attached. This is a question I believe needs to be investigated by public health authorities.

PERSONAL EXPLANATION

**HON. DANNY K. DAVIS**

OF ILLINOIS

IN THE HOUSE OF REPRESENTATIVES

*Thursday, March 9, 2000*

Mr. DAVIS of Illinois. Mr. Speaker, on March 8, 2000 I had to delay my return to the Capitol

in order to attend to personal business in my district. During my absence, I missed rollcall vote 29, 30, 31 and 32.

Had I been present, I would have voted yes on the motion to suspend the rules and pass H.R. 2952, the Keith D. Oglesby Post Office, H.R. 3018, the South Carolina Post Office Designation and S. Con. Res. 91 recognizing the forcible incorporation of the Baltic states of

Estonia, Latvia, and Lithuania into the former Soviet Union.

I would have also voted "yes" on final passage of H.R. 1827 the Government Waste Corrections Act on March 8, 2000.