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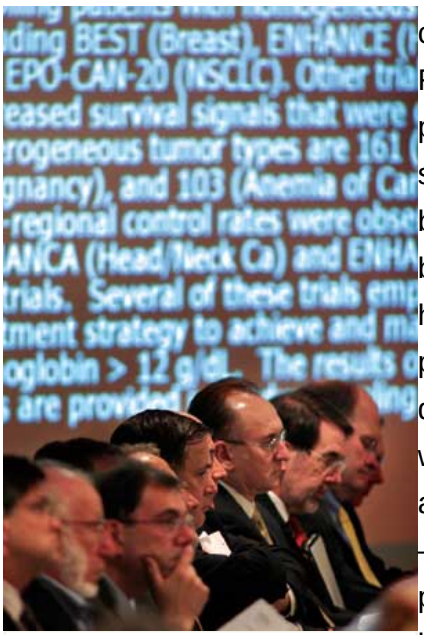
Overdose of Influence in Epogen Debate

By Kerry Young, CQ Staff

As debates over controlling health care costs rage in Congress, Medicare may finally be moving to cut one of its largest and most controversial drug costs: the roughly $2 billion it spends each year on the anemia medication Epogen. High doses of the drug, manufactured by Amgen Inc., have long been linked to increased risk of heart attack and, in some cases, death. Yet, despite years of debate over Epogen's overuse by kidney dialysis patients, Medicare continues to pay for patients to receive more of the drug than the Food and Drug Administration recommends.

What's more, the practice won't change until at least 2011, when a forthcoming Medicare rule change may finally force clinics and physicians — who have been the focus of significant Amgen largess — to prescribe the drug at recommended levels.



HIGH COST/HIGH RISK: Amgen, Inc. defends the safety of its highly profitable anemia drug, Epogen, at an FDA meeting in May, 2007. Despite medical risks,

As it stands now, Medicare's pricing policies create an incentive for overprescription. Under FDA rules, Epogen is supposed to be prescribed only in doses sufficient to prevent severe anemia by raising the percentage of red blood cells in a dialysis patient's blood to between 30 percent and 36 percent. (In a healthy adult, red blood cells account for 36 percent to 50 percent of blood cells.) But despite the FDA target of 36 percent — beyond which the agency believes the danger of heart attack exceeds the benefit of reducing anemia — Medicare's current policy allows payment for patients whose red blood cell levels reach as high as 39 percent.

Since Medicare's reimbursement level for dialysis itself is fixed, prescription drugs are one of the few discretionary treatments that generate profits for clinics. And it turns out that

heavy lobbying by Amgen has helped make Epogen a routine prescription for kidney dialysis patients and a huge expense for Medicare. (BLOOMBERG NEWS/ KEN CEDENO)

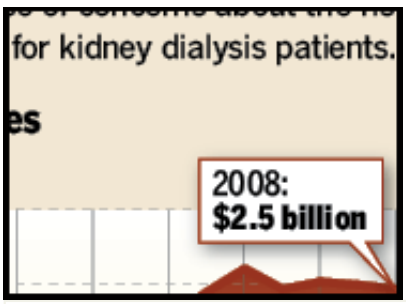
for-profit dialysis clinics have been prescribing more Epogen to patients for longer periods than nonprofit clinics.

The Epogen saga can supply material for both sides in today's fiercely pitched battle over a health care overhaul. Opponents of greater government control over the industry can point to it as a prime example of how federal bureaucracies are ill-suited to make sound judgments on issues concerning critical care. And supporters of government-backed health care can contend that cases like Epogen's illustrate the need for organizations such as the federal independent review board the White House wants to oversee Medicare expenditures, arguing that they can identify and rectify potential health hazards in the system more effectively than Congress can.

But the larger moral concerns a dynamic all but certain to endure beyond the health care debate: the power of industry lobbying to shape policy. Amgen has spent $72.1 million on lobbying since 1998, second among drugmakers only to Pfizer Inc., the world's biggest pharmaceutical company, which spent $87.2 million in the same period.

A Miracle Drug

Amgen went on its Capitol spending spree soon after the FDA cleared the drug for release in 1989. The company had been conducting research to produce genetically engineered cells from the ovaries of Chinese hamsters in order to synthesize a protein called erythropoietin, or EPO, which is normally produced by the kidneys and triggers the production of red blood cells. When kidneys are diseased, they produce less of the protein, and the body produces fewer red blood cells. Before the development of Epogen, as many as one in four dialysis patients had to undergo transfusions to increase their red blood cell counts.



A Costly Remedy: **Click**

In a 1989 op-ed for the Los Angeles Times, California Democrat Pete Stark, who chairs the Ways and Means Subcommittee on Health, hailed Epogen as a "miracle drug . . . for severely anemic dialysis patients who are in a form of limbo — permanently ill but thankful to be alive." But Stark also warned that the drug could generate "hundreds of millions — possibly billions — in potential profits for

here to view chart

Amgen Inc. — all financed by the taxpayers through Medicare, which picks up the tab for 93 percent of dialysis patients."

The Medicare reimbursement system yielded impressive profits for Amgen, which saw its sales volume for Epogen surpass $1 billion by 1996. At the same time, the company was beginning to get alarming reports about the drug's side effects. In 1996, the company halted a study when research monitors determined that high Epogen doses were putting test subjects at greater risk of heart attacks or death than members of the study's control group. Medicare sought to bring dosing back in line with the FDA's recommendations and ended its "medical justification" policy, which had allowed doctors to prescribe as much of the drug as they liked.

In short order, though, kidney specialists — and Amgen's many allies in Congress — were pressing for a reversal. At a 1998 hearing of the Senate Appropriations subcommittee that oversaw Medicare spending, chairman Arlen Specter of Pennsylvania — then a Republican, now a Democrat — scolded a Clinton administration official that lower dosing of Epogen "leaves the patient in a condition where they just cannot function." Almost immediately, Medicare went back to allowing dosage to creep up over the recommended FDA level if a doctor said it should. (The chastised official, Nancy-Ann DeParle, former head of Medicare, is now serving in the White House as a health care adviser to President Obama.)

That pro-industry policy reversal coincided with another trend that significantly improved Amgen's fortunes: the consolidation of the for-profit dialysis market around two suppliers, DaVita Inc. and The Fresenius Group Inc., that now make up about 60 percent of the market. These companies have been able to negotiate better deals with Amgen than smaller clinics, which boosted their profit margins for Epogen and led to more over-prescription. By the mid-2000s, overshooting the FDA target for Epogen was three to four times as common as it had been in 1997, and the average time people spent above the target had lengthened to more than three months, according to a study of Medicare claims by the U.S. Renal Data System (RDS), which collects and studies information on kidney disease for NIH. Moreover, despite the 2006 reports of harm linked to high doses, DaVita and Fresenius still appear to have more patients with red blood cell counts elevated beyond the FDA guidelines than nonprofit Dialysis Clinics Inc., the RDS reported last week. The nonprofit also had lower rates of hospital stays and deaths than the for-profit clinics.

Following the Money

In the years since the FDA approved Epogen, critics claim that money has become the main force driving Epogen's appeal to doctors and clinics. "There is probably no nephrologist in the United States . . . that has not received something from Amgen, a golf ball or a dinner or something," Stark remarked at a 2006 hearing of the Health Subcommittee. Former Ways and Means Chairman Bill Thomas, a California Republican — who, unlike Stark, is not known as a scourge of the health care industry — was no less blunt. "We have a payment policy that perhaps is killing people," Thomas said at the last committee hearing he gaveled before retiring in 2007.

Thomas had actually been trying to reduce spending on Epogen since at least 2003, when he helped pass legislation that ordered Medicare to determine whether a different pricing structure, such as paying for dialysis drugs in a "bundle" instead of reimbursing Epogen directly, might reduce costs. Medicare didn't report back until last year but agreed that "bundling" might work better.

Stark has noted that the Medicare officials who set the original payment rates for the drug relied principally on the counsel of physicians with ties to Amgen or large for-profit dialysis companies, such as DaVita. Epogen promoters have also lavished research and development grants — to say nothing of generous travel junkets and conference speakers' fees — throughout the nephrology field, making it even harder for Medicare to find truly independent specialists to help set policy.

Amgen has been similarly freehanded with money for lawmakers. Since 1990, Amgen employees have made donations to more than 300 campaigns, party committees and other political action committees designed to get lawmakers elected. Specter was a particular favorite, netting more than $95,000 since 1990. And Amgen's political action committee itself has spent more than $3.8 million on campaign donations — bumping up contributions when a new majority came into power, and taking care to give especially heavily to key committee and party leaders.

As a result, despite all the warnings, Medicare reimbursements for Epogen still allow doctors and clinics to routinely exceed FDA guidelines. Doctors insist they need flexibility in dosing because they say patients respond differently to Epogen and it is not always easy to gauge the dosage needed to reach the target level of red blood cells.

Dennis Cotter, president of the nonprofit Medical Technology and Practice Patterns Institute, has prodded Medicare to revisit its Epogen policy next year during a meeting of its coverage advisory committee. Cotter says the committee needs to investigate why a drug designed as a narrowly targeted treatment for patients with the most severe anemia is now automatically

prescribed to nearly all dialysis patients. It would seem, he says, that Congress has more power than the FDA to set standards for medical treatment, especially when the financial interests of doctors, clinics and drug companies are aligned.

The Epogen story, Cotter says, is “sort of what’s wrong with the health care system in a microcosm.”

FOR FURTHER READING:*Medicare physician reimbursements, 2008 CQ Weekly, p. 1774; FDA overhaul, p. 868; Medicare prescription drug law (PL 108-173), 2003 Almanac, p. 11-3.*

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