Method Used by the Office of the Inspector General to Estimate the Manufacturer's Costs of Recombinant erythropoietin

The Health Care Financing Administration (HCFA) was assisted in setting the initial rate that Medicare paid for recombinant erythropoietin by the Department of Health and Human Services' (HHS) Office of the Inspector General (OIG).[1] Based on data supplied by Amgen and other sources of information, OIG staff estimated Amgen's costs of developing and producing the amount of recombinant erythropoietin expected to be used for the dialysis population in the first year after approval by the Food and Drug Administration (FDA). HCFA used this cost estimate as one of the considerations in setting the initial payment rate for recombinant erythropoietin administered in a dialysis facility. The OIG accepted some of the cost data supplied by Amgen and modified other data.

The OIG's initial cost estimates were predicated on certain assumptions concerning use of recombinant erythropoietin in the first year after FDA approval. These estimates assumed that an average dose of 5,000 units of recombinant erythropoietin would be administered to each dialysis patient 3 times a week, for a total of approximately 156 administrations per year, and that recombinant erythropoietin would be used in 20,000-25,000 dialysis patients in the first year.[2]

The categories that the OIG used to estimate Amgen's costs were current operating expenses; research and development costs; selling, general, and administrative costs; income taxes; and payment of an appropriate rate of return to investors.

Amgen's current-year operating expenses included cost of goods sold; current research and development costs; sales, general and administrative costs; and income taxes. The cost of goods sold included the cost to produce the product, such as labor and materials; royalty payments; and product liability payments. Amgen provided the per-unit budgeted cost of goods sold for recombinant erythropoietin for the first year. Since the OIG had no historical data with which to compare these estimates, the OIG accepted Amgen's figures on cost of goods sold. The ratio of the costs of goods sold to total projected revenue for Amgen was compared with that of 19 other pharmaceutical companies and was found to be lower.

The ratio from other pharmaceutical manufacturers, however, would consist of cost of goods sold for all products made by that manufacturer including, in some cases, non-pharmaceutical products. These ratios might be equal to or lower than Amgen's if the costs of goods sold and revenues from the sales of non-pharmaceutical products were removed from the ratio calculations. For the purpose of comparing the Amgen ratio with that of other pharmaceutical manufacturers, the OIG used both the Business and Investment Almanac of 1988 and Moody's Industrial Index.

Also included in cost of goods sold category was a royalty payment of a certain percent of sales that Amgen has to make to Stanford University for its development of the recombinant gene-splicing technique used to produce erythropoietin. The estimated cost of product liability insurance, based on a certain percent of recombinant erythropoietin sales, was also calculated.

Current research and development costs were defined as the costs that would be incurred by the manufacturer in 1989 to further research and develop products under development, including recombinant erythropoietin. Past research and development

1Information in this appendix was based on personal communications with staff members from the HHS Office of the Inspector General (129).

2In December 1988, there were approximately 106,000 dialysis patients in the U.S. (1S5), and some researchers have estimated that approximately 75-80 percent are anemic (52). The OIG estimated full market penetration would take some time (129).

(R&D) costs were not included in this category. To determine the portion of total R&D on all Amgen's products to include in a cost estimate, the OIG first estimated the portion of the manufacturer's projected 1989 research and development costs that would be allocated to recombinant erythropoietin, and then estimated the portion of these expenditures that would be used for further research and refinement of recombinant erythropoietin in dialysis patients.

For sales, general and administrative costs, Amgen estimated its costs of establishing a marketing and distribution process for recombinant erythropoietin. These estimates were accepted by the OIG because there were no historical data with which the OIG could make comparisons. As was the case with current research and development costs, however, the OIG estimated the percentage of these costs that would be used for recombinant erythropoietin in dialysis patients.

Approximately 20 percent was added to the total of the above cost categories for current profit and return on historical investment. Amgen's income tax payments for the period were also estimated and included.

The OIG estimated the amount of funds invested in Amgen over the past 8 years (1981-1988), an appropriate profit or rate of return on these funds for individuals who had invested, and a period of time over which the investment would be recovered. Past incurred research and development expenses were to be included in this category.

To determine the total amount of funds that had been invested in the company prior to 1989, the OIG used, as a proxy, the value of stockholders' equity. The value of stockholders' equity was derived from analysis of the Amgen's Annual Reports and 10K reports filed with the U.S. Securities and Exchange Commission. Amgen received initial start-up funding from venture capitalists and joint ventures with other pharmaceutical manufacturers, but later obtained funds from three public stock offerings. Investments made in Amgen by other manufacturers for the purpose of licensing Amgen products or securing the rights for certain recombinant erythropoietin treatment indications were not included in the estimate of stockholders' equity.

The OIG then compounded a 20-percent rate of return on the value of the stockholder's equity for the 8-year period (1981-1988) over which these funds were invested. To determine the percentage of this amount that should be included in the cost calculations for recombinant erythropoietin, the OIG estimated the percent of company revenue over the period 1992-1995 that would be attributable to recombinant erythropoietin sales in the dialysis market. The OIG staff believed that products from Amgen's current research activities would reach maximum sales penetration in the marketplace during this period.[3] This compounded amount was then divided by 8 to determine the amount that would be included in the annual cost calculations.

After totaling the costs in all the designated categories, the OIG then calculated the annual cost per patient by dividing this total amount by the estimate of patients (20,000-25,000) expected to use recombinant erythropoietin during the first year after FDA approval. This resulted in the annual per-patient cost. This amount was then divided by the estimated number of patient dialysis sessions per year (approximately 156) to arrive at a per-treatment payment rate. HCFA used this calculated amount as only one of the considerations in setting its payment rate of $40 for any dose under 10,000 units.

In the final analysis, the OIG'S estimate of the per-unit cost of Amgen's recombinant erythropoietin consisted of approximately 27 percent for cost of goods sold; 16 percent for current research and development costs; 24 percent for sales, general and administrative costs; 11 percent for income taxes; and 22 percent for return on initial investment and profit.

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3 The OIG thought that Amgen would have two mature products in the market in that period of time, recombinant erythropoietin and granulocyte colony stimulating factor.