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Hospital Products Get Seal of Approval at a Price

By BARRY MEIER

A group that says its mission is to find the best medical supplies for some of the nation's biggest children's hospitals is endorsing certain products in return for a percentage of sales and, in some cases, shares or warrants from their manufacturers.

Companies that do not pay the group do not get its endorsement. "If they don't pay, they don't get the seal," said Edward Kuklenski, senior vice president of the group, the Child Health Corporation of America.

As a result, some experts question not only the seal's value, but also whether a medical group should be making money from endorsing medical products.

Founded in 1985, Child Health's 38 pediatric hospital members purchased nearly $1 billion of supplies last year. The group awards its seal to certain products and then helps market them to hospitals. But the arrangement differs significantly from those of other groups that evaluate products. Unlike the Child Health Corporation, Consumers Union, the publisher of Consumer Reports, and its equivalent in the medical world, ECRI, do not accept money from manufacturers.

Also, these groups compare a number of products in head-to-head tests and then publish the results of which fared better and why. But Child Health does not test products against similar devices and does not disclose the names of products that fail to win its seal.

The chief executive of ECRI, considered the country's most-respected laboratory for testing medical products, said that even if the devices Child Health approved were good, it could not know without comparative testing whether they were the best.

"If your objective is to have the best product available then you are definitely cutting off options," said the executive, Jeffrey C. Lerner.

The Child Health program is similar in some respects to an endorsement plan begun five years ago by the American Medical Association that was later abandoned after widespread criticism.

Officials of Child Health, based in the suburbs of Kansas City, Kan., said hospital personnel carefully tested every product the group endorsed. They added that the program had helped set high product standards and improved pediatric care.

"We established a Good Housekeeping seal for products we determined to be efficacious for pediatric care," Mr. Kuklenski said of Child Health.

The Good Housekeeping seal, which is not connected to Child Health's plan, is essentially a guarantee by Good Housekeeping magazine to replace or refund the cost of any advertised product that proves to be defective. But Good Housekeeping, unlike Child Health, does not also serve as a supposedly unbiased purchasing agent whose job is to find the best products at the best price.

Child Health said products "would be turned down for failure to excell" in areas like safety and efficacy. The group did not specify how many products had been denied its endorsement.

Mr. Kuklenski's comments came in an interview last year, and Child Health subsequently responded to questions in writing.

The selling of product endorsements is an example of the potential conflicts of interest among some groups that help hospitals nationwide buy medical supplies. Groups like Child Health are supposed to act as objective middlemen, using the collective buying power of their member hospitals to negotiate with manufacturers for the best prices on the best products. But unlike other purchasing agents, hospital buying groups like Child Health are financed not by the hospitals that buy supplies but by the companies that sell them.

Two major buying groups — Novation and Premier Inc. — dominate the industry, though neither endorses medical products. Novation and Premier negotiated contracts covering $34 billion in supplies last year. Child Health is a much smaller group.

Child Health, like Premier and Novation, has aggressively expanded beyond purchasing. Along with its endorsement program, Child Health has also invested more than $25 million in 37 medical products companies. Until three years ago, it also ran a unit that manufactured and marketed pediatric products.

Some medical experts like Mr. Lerner of ECRI worry that in running such overlapping businesses buying groups may be pursuing their own interests ahead of those of their hospital members.

"The middleman has grown into the business," Mr. Lerner said.

Child Health's pediatric hospital members include Children's Hospital of Boston and Children's Hospital of Philadelphia. Several of those institutions said in statements that they were happy with the group.

The group's endorsement program, which earned about $350,000 last year, is run through an arm called the Alliance of Children's Hospitals. To win its Seal of Acceptance, a manufacturer's product is reviewed by a panel that includes clinicians to make sure that it performs as promised, Mr. Kuklenski said.

Since 1990, the group has issued endorsements of 44 products, and 21 currently hold its seal. Typically, a company that receives an endorsement will pay a fee of 0.5 percent to 1.5 percent of product sales to the alliance.

Mr. Kuklenski said the manufacturers' payments, which are distributed to member hospitals after expenses, were used to help market the product and so represent reduced selling costs for manufacturers. He added that the program also helps smaller companies that do not have contracts with buying groups.

Some companies eager to break into the hospital business have issued warrants or sold stock to Child Health or its wholly owned subsidiaries, or agreed to pay fees of as high as 3 percent of their sales.

For example, Iomed, which makes devices that deliver drugs subcutaneously without needles, agreed in 1996 to give the Alliance of Children's Hospitals a warrant for 44,791 shares of company stock in connection with the endorsement of its product. At the same time, Iomed, based in Salt Lake City, sold 37,202 shares of its stock for $250,000 to Child Heath's venture capital fund, records show.

Another company, Luther Medical Products, of Tustin, Calif., agreed in 1996 to pay up to 3 percent of sales to the alliance if certain revenue goals for its products were met, records show. Ronald Luther, the chief executive, said he viewed Child Health's program as a way for his small company to enter the market.

Mr. Kuklenski said that Child Health had taken stock in Iomed instead of cash because it was a small company and that it had never exercised its warrant because the stock price had fallen. He added that the fees collected from Luther Medical were very small because its sales goals were not reached.

Another manufacturer said he was approached by a Child Health official about getting the group's endorsement only to be told he would have to give up 6 percent of his product's sales in return.

Joe E. Kiani, chief executive of that company, Masimo, said he refused to pay because he thought hospital groups were supposed to pay him for his products, not the other way around. Masimo makes a device, called a pulse oximeter, that measures blood oxygen.

"We thought they were taking advantage of us because we were a little company," he said.

Mr. Kuklenski said that while his group had discussed investing in Masimo he did not recall any conversations about an endorsement. He added that because the group's seal had marketing value it simply was not given away.

Manufacturers that receive the seal hold it up as a major independent endorsement. And Novation, the buying group that represents about 25 percent of the nation's nonprofit hospitals, cited the award of Child Health's "prestigious seal of acceptance" in 2000 to a pulse oximeter made by Nellcor when it recently awarded that company a contract for such devices.

But Eldon Petersen, a senior vice president at Novation, said he had not known that Child Health's endorsement carried a price.

Securities and Exchange Commission records show that Mr. Kuklenski, the group's senior vice president, owned about 90,000 shares in the publicly traded parent of Promedix, a company that ran an Internet-based ordering system. In mid-

2000, when Child Health awarded a contract to Promedix, he announced and praised the deal, saying a Child Health panel had found Promedix "the only e-commerce solution to enable access to a marketplace of premium specialty products."

At that time, Mr. Kuklenski's stake in Promedix's parent, Ventro, was worth about $2.5 million and Child Health's venture capital fund also held Ventro stock, records show. About seven months after Mr. Kuklenski praised the deal, Promedix failed.

In a written response, Mr. Kuklenski said his investment in Promedix had been made in compliance with his group's "conflict of interest policy and was fully disclosed at the time." Mr. Kuklenski also stated that he had "invested in additional companies" in which Child Health had invested, but he declined to elaborate.

While Child Health's guidelines allow its executives to invest in companies in which the group also invests, officials of several hospitals that belong to Child Health said they were unaware of Mr. Kuklenski's investment at the time of the group's deal with Promedix.