

Medical innovations: clash of blood, money - Patients take back seat to costs, critics say

Houston Chronicle - Sunday, April 18, 1999

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When the blood collection tube began to fall off the table, the nurse grabbed it and pricked her left index finger with a contaminated needle.

That instinctive grab three years ago, as she withdrew blood from an infected patient at a drug treatment center, has left Ellen Dayton with hepatitis C, a potentially lethal liver disease, and AIDS.

Dayton, 52, of San Francisco, takes interferon and various other drugs, but on many days she feels too sick to get out of bed.

She is among about 1,000 health-care workers who are infected with blood-borne diseases each year because of accidental needle sticks, according to federal estimates. Many become seriously ill. Some die.

Fairly simple innovations - needles that automatically retract after piercing a patient's skin, protective sheaths that cover the points - might have prevented the accidents.

But the people who make them, among others, say access to many of these products is limited because of powerful entities in the health-care industry called group purchasing organizations, or GPOs.

The GPOs say they leverage deep price discounts from manufacturers by purchasing supplies ranging from bed pans to pharmaceuticals in bulk for groups of medical facilities.

Some others in the health industry, though, are complaining that GPOs create an anti-competitive barrier with their long-term and often exclusive contracts with the nation's largest manufacturers. These critics say that innovative and lifesaving technology loses out in the quest for lower costs.

Some are skeptical that GPOs even generate savings.

"I think more and more people are looking and saying that the emperor has no clothes," said Ted Almon, former chairman of the Health Industry Distributors Association, a trade group. "The claim that you are getting better prices is not true."

Almon said he is unaware of any public or independent agency that has conducted a comprehensive economic analysis establishing that GPOs reduce medical supply costs.

The criticism of GPOs echoes a central theme in the nation's health-care debate - that business concerns are driving medical decision-making.

"GPOs take medical decisions out of the hands of patients and their physicians and place them in the hands of corporate officials focused solely on the fiscal bottom line," said Dr. Neil Kahanovitz, a Virginia orthopedic surgeon and founder of the Center for Patient Advocacy. "... Unless we educate the public about GPOs and urge public officials to examine their questionable business practices, GPOs will continue to be the gatekeepers that hold quality patient care and innovations hostage."

The retractable needle, which cannot be reused, is one such innovation, its manufacturer says.

"There's an AIDS and hepatitis C epidemic and we can't even show our retractable safety needles in most hospitals," said Thomas Shaw. His company, Retractable Technologies Inc. of Little Elm near Dallas, manufactures the VanishPoint - a patented spring-loaded syringe in which the needle retracts after injections. "Free competition as it stands in health care is dead."

He and other small manufacturers say they can't sell newly invented syringes, catheters, blood collection devices and other products to the majority of the nation's hospitals, which belong to several GPOs.

Shaw's company has filed suit in a Brazoria County state district court, charging two syringe manufacturers and a GPO-supplied hospital network with antitrust violations.

Federal regulators also have taken an interest. The Federal Trade Commission and U.S. Justice Department have advised Retractable Technologies that they are looking into restraint-of-trade and antitrust allegations.

Shaw acknowledges that his retractable syringes may be pricier than conventional needles, and that he lacks a full line of syringes. But Shaw said he can't bring down his per-unit costs until his company increases its sales volume - and it can't increase sales volume until it has sufficient access to a market now dominated by GPOs.

He also argued that such price comparison is shortsighted since it doesn't take into account the costs associated with needle sticks, such as testing and treatment.

GPO contracts with manufacturers may have terms of five years or longer - often long enough for new products to overtake the quality and value of ones under contract.

"Innovation works faster than five- or seven-year blocks," said Doug Harris, managing director of Vacuette, a division of Greiner Mediatech Inc. in Bel Air, Md., which manufactures plastic blood collection tubes. "They are essentially locking the door to newer, smaller companies and it allows the bigger companies to take over the industry."

That can stifle the price competition that tends to keep costs in check, said Bernard Weinstein, director of the Center for Economic Development and Research at the University of North Texas in Denton.

"You've got relatively few medical supply manufacturers or sellers and relatively few buyers, and they are negotiating a price not in the open market," he said.

GPO officials counter that their bulk purchases provide millions of dollars in cost savings.

"GPO contracts are drawn up with the advice from physicians, nurses and other medical professionals," said Robert Betz, executive director of the Health Industry Group Purchasing Association, which represents 27 GPOs and more than 110 medical supply and pharmaceutical manufacturers and distributors.

To qualify for discounts, the hospitals and other health-care facilities must purchase as much as 95 percent of their supplies from GPO-contracted manufacturers. Betz argued that these "compliance" standards still leave room for purchases of many products.

"I don't know of any contract that mandates 100 percent compliance," Betz said.

He acknowledged the difficulties new companies face breaking into the market. But he said most purchasers, including hospitals, want exclusive multiyear agreements so they can predict their costs. "If GPOs did not exist, the cost of medical care would be substantially higher than it is today," he said.

Officials of the Justice Department's antitrust division declined comment on the federal inquiries. But the agency confirmed that it launched an inquiry last year into concerns raised by several congressmen.

U.S. Sen. John McCain, R-Ariz., chair of the Senate Committee on Commerce, Science and Transportation, wrote the Justice Department that he had heard from several constituents concerned that the "current system allows GPOs to monopolize the health-care marketplace through exclusionary contracts and unfair trade restrictions."

GPOs are not new - the first was formed in 1910 - but they have gained market strength in recent years amid concern about health-care costs.

Congress provided a boost in the late 1980s when it allowed GPOs to collect "administrative fees" from manufacturers without running afoul of laws against kickbacks. Although legislative records suggest that

Congress contemplated fees of around 3 percent of sales to cover GPOs' overhead, the rules eventually adopted allow higher fees.

Officials of several GPOs declined to disclose their administrative fees, but contended that fees exceeding operating costs are passed along to member health-care facilities.

Houston attorney Michael Weiss, who has conducted extensive research into the issue, said the fees need closer oversight and regulation.

Weiss said GPOs may be creating monopolies using their market leverage to buy up manufacturers. He cited at least one instance in which a GPO may have accepted its fee in the form of options in a manufacturer's stock.

Shaw, the syringe manufacturer, characterized the administrative fees as "protection money to lock out competitors."

Shaw argues that GPOs have no incentive to cut costs because they receive administrative fees based on the total purchase of goods, and as a result represent the manufacturers, not the hospitals.

"GPOs were to have an arms-length transaction, not partnerships with manufacturers as they now acknowledge," Shaw said. "The only economic savings is for the manufacturers because they don't have to market their products."

He said GPO contracts allow major contractors to reduce their budgets for research and development. Instead, he said, big companies can simply lock up much of the market with a large GPO contract and buy up the technology of isolated, smaller companies.

"GPOs don't manufacture, buy, distribute, store or deliver products," he said. "Their only tangible service is that they are paid to restrict the market or guarantee market share to certain manufacturers."

The 10 largest GPOs now administer contracts for about 80 percent of the nation's more than 5,000 acute care, not-for-profit hospitals, industry reports show.

The most restrictive contracts require facilities to purchase 95 percent of certain products through the GPO, and to submit to GPO monitoring of all purchases.

The nation's largest GPO, Dallas-area-based Novation, has about \$1 billion of its \$11.5 billion in annual purchases under 95 percent contracts, said spokesman Lynn Gentry.

Most contracts range from 50 to 60 percent, with additional savings available to organizations in the 85 percent to 95 percent range.

The requirements provide manufacturers an incentive to offer lower prices by limiting their competition within contracting facilities, Gentry said.

He said, however, that many facilities have contracts with more than one GPO, and that many of Novation's contracts are not limited to a single manufacturer.

Novation provides its member health-care organizations with savings of 5 percent to 20 percent, Gentry said, and 1,900 facilities apparently find the arrangement attractive.

"If small manufacturers say GPOs are locking the doors to them, it is the hospital organizations who are making the decisions," Gentry said. "Obviously, they can decide if they would like to use products from a manufacturer or a GPO contract."

A few medical organizations, including Houston's Methodist Hospital System, report that they have purchased products independently and achieved savings comparable to GPO contracts. "We have the independence to select our own products through our hospital product standardization and review committee comprised of doctors, nurses and other clinical and nonclinical people systemwide," said Stefanie Asin, a Methodist spokeswoman.

The Methodist system, however, remains a member of a large GPO to take advantage of its congressional lobbying and insight on national health-care issues.

Gentry said Novation has a cost analysis to show that it offers cheaper products, but said the analysis was available only to members or prospective members.

Its parent company, VHA Inc., is a defendant in Shaw's antitrust suit, along with syringe manufacturers Becton Dickinson & Company and Tyco International, Inc.

San Diego-based Premier, the nation's second largest GPO, provides more than \$8 billion annually in medical supplies for about 1,700 health-care sites, often under tight rules.

A Premier group purchasing policy obtained by the Houston Chronicle warns health-care facilities that "members will not contract independently for products in areas covered by these contracts, nor review or extend existing agreements for such products."

Premier officials contend that such agreements reduce medical costs and foster safety and technology. A recent survey of its members showed savings of 7 percent to nearly 30 percent, the company said.

"They (hospitals) still would have long-term, exclusive contracts with the big manufacturers regardless if GPOs existed, so there must be something else going on here," said Pat Poston, a Premier senior vice president for communication and planning. "... GPOs aren't totally the problem and not totally the answer."

Besides cost and safety issues, the rising prominence of GPOs has raised concerns about the quality of care. Several orthopedic specialists said that GPO contracts may keep patients from getting top-quality hip and knee implants. "The GPO may lock the hospital into buying the cheapest, low-end implant, forcing the physician into an ethical dilemma of whether to continue to work there," said Dr. William Head, a Plano orthopedist.

A Wisconsin orthopedist told of exactly such an experience. Dr. Jeffrey McLaughlin, who performs 750 hip and knee replacements each year, said his hospital's supply administrator threatened last year to stop sending him patients if he did not switch to implants contracted for by the hospital.

Only after McLaughlin threatened to move his practice to a nearby hospital did the administration back down and grant the surgeon a four-year contract allowing him to use the implants he preferred.

Head said some hospital officials fail to take into account a hidden cost of cheaper implants - that they may require replacement years sooner than top-quality devices.

Similarly, protecting health-care workers from on-the-job injuries is likely to cost less than treating the injuries after the fact.

"It's also cost effective to have safety devices because it costs from \$2,000 to \$4,000 to test and medicate those who have accidents," said Dr. Patti Wetzel, 38, a Fort Worth family physician who became HIV infected after an accidental needle stick in the early 1990s. "And that doesn't take into account the potential days missed from work or the potential cost of hundreds of thousands of dollars if the worker develops AIDS."

The federal Centers for Disease Control in Atlanta estimates that as many as 1 million health-care workers, mostly nurses, suffer accidental needle sticks each year, and at least 1,000 contract serious infections as a result. Fifty-four AIDS cases have been documented, and an additional 132 cases are suspected.

"We are talking about life and death products where the decisions on the life and death products are done by administrators, not health-care professionals," said Bill Borwegen, director of Health and Safety for the Service Employees International Union. "If health-care workers could choose their products, I know overnight they would choose retractable syringes and self-blunting collection devices."

Two states, California and Tennessee, have enacted legislation requiring many hospitals and clinics to take specific steps to prevent accidental needle sticks.

At least 17 states, including Texas, have drafted such legislation. A hearing on the Texas proposal is scheduled for Wednesday in Austin.

Shaw, an engineer, designed the retractable, disposable syringe after a childhood friend and an employee became HIV infected. Two research grants totaling \$650,000 from the National Institute on Drug Abuse helped fund development.

The U.S. Food and Drug Administration approved the syringe for sale in 1995. Shaw said the product gained excellent medical reviews during a 1997 trial in which no accidental needle sticks were reported among health-care workers in 26 Dallas-area health-care facilities that purchased 86,300 retractable syringes.

The year before the trial, the facilities had reported an average of one accidental needle stick per 3,288 conventional syringes purchased.

Although several major manufacturers offer safety features, including a plastic sheath or safety lock, Shaw argues that his retractable needle is unique in that it is nearly foolproof.

But Shaw said he quickly came to understand that it would be difficult for his fledgling company to sell the product in most of the nation's hospitals due to GPO contract restrictions.

Only late last year did the the nation's two largest GPOs begin showing much interest in his company's product, Shaw said.

In late March, a committee from Premier met for the first time with Shaw's representatives to evaluate his safety needle. Premier has an exclusive, 7 1/2-year, \$1.8 billion corporate partnership with Becton Dickinson & Co. The agreement, according to a Premier contract information sheet, requires member hospitals of the commitment program to buy at least 90 percent of their syringes and blood collection devices from the company.

Shaw said that in a recent meeting with him and his staff, a Novation representative suggested "private labeling" Retractable Technologies' blood collection tube holder and selling it for \$1, rather than Shaw's bid price of 27 cents. "Novation and our company would split the profits," Shaw said. "How does that save money?"

Novation spokesman Gentry denied that claim. He said Novation has since awarded the contract to Becton Dickinson because the company's blood collection devices were cheaper. Gentry said Novation asked Shaw's company to submit a bid on a syringe contract to be awarded later this year.

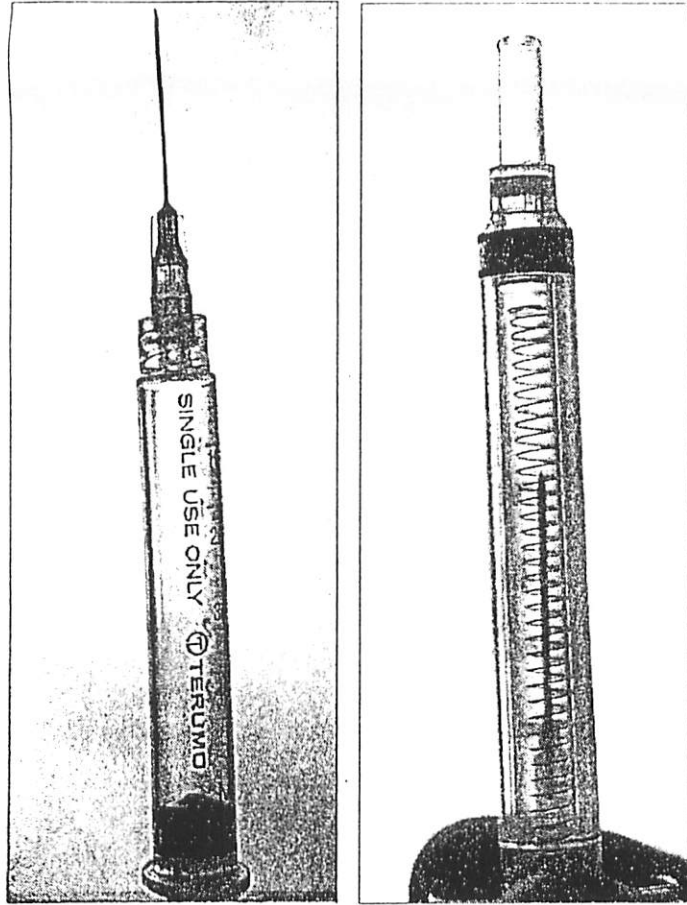
Shaw acknowledged that his company recently signed contracts with two other GPOs, but argued that the agreements lack sole-source or minimum compliance requirements and, as a result, do not alleviate his concerns about anti-competitive practices.

He says his company has made inroads in hospitals that use competitive bidding, without administration fees, to buy supplies - including 30 percent of the Veterans Affairs hospitals.

Other manufacturers maintain that they are nearly shut out of the U.S. market, but have reported dramatic increases in sales in less restrictive foreign markets.

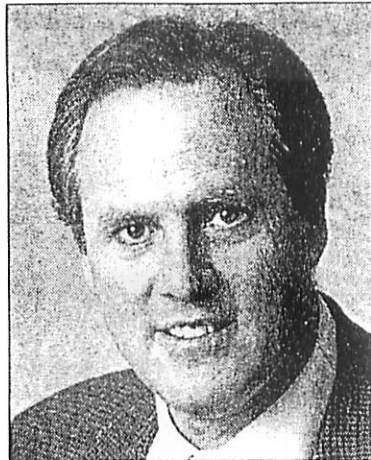
One medical industry analyst, who asked not to be identified, said that if the issue is not addressed soon, serious damage could be done to the competitive bid process.

"In terms of antitrust issues, if anything is going to come to all of this, it might be some federal legislation that might not break up the groups but set some ground rules," the analyst said. "We need a few rules so the little guy doesn't get trampled."



Photos by Karen Warren / Chronicle

The needle in a conventional syringe, left, can cause injury and infection through accident or intentional misuse because it stays locked in position. The VanishPoint syringe uses a needle attached to a coiled spring.



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