

Stick It To'em

When syringe inventor Thomas Shaw took on the hospital-supply industry, he won \$150 million. So why is his product still shut out?

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(FORTUNE Small Business) – For Thomas Shaw, the call to action came as he watched the news one night at his home in Little Elm, Texas. A much-beloved local doctor was dying of AIDS; he had been infected by an accidental needle prick while caring for a patient who had the disease. Shaw was horrified, not just by the talking skeleton on television but also by the primitive design of the hypodermic syringe that had sent that doctor--and apparently so many other health-care workers over the years--to an early death. As an engineer and inventor, Shaw knew he could create a safer syringe. For four years he tinkered with designs. A dartboard in his office bristled with the rejects he'd hurled across the room.

He came up with the answer: a syringe with a needle that snapped back into the barrel after the medicine had been dispensed. Hoping to license his invention for a small sum, Shaw in 1991 shipped off a prototype to hospital-supply giant Becton Dickinson. He considered himself more a tinkerer than a businessman. "I was willing to let it go for the price of a bass boat," Shaw recalls. "I thought the design was worth maybe \$50,000." A year or so later he got a note back from Becton Dickinson. Thanks, but no thanks, it said, adding that the company was developing its own safety syringes. Short and briskly polite, that note nonetheless sparked a war that drew attention to how a billion-dollar industry can foil an entrepreneur--even one with a superior product.

From the start, Shaw was convinced that his invention was a safety breakthrough--and that he had a moral obligation to make it available--so he decided to sell it himself. Reluctantly, he formed a company, but he found himself barred from the market at every turn. One after another, hospitals spurned him, saying that they were locked into contracts that required them to buy their supplies from certain giant consortiums. Many doctors and nurses who saw the syringe demonstrated at trade shows pressed hospitals to buy it, but were unsuccessful.

Finally, in 1998, Shaw took his years of frustration to court, filing a lawsuit accusing two of the largest buying consortiums and two big syringe suppliers of antitrust violations, specifically restraint of trade. In one aspect of his case, Shaw argued that Becton Dickinson, a major syringe maker based in Franklin Lakes, N.J., signed many long-term contracts with Premier, a huge medical buying consortium, that prohibited its members, mainly hospitals, from purchasing syringes from small suppliers. After six years of litigation, he won a stunning victory. Becton Dickinson paid Shaw \$100 million last year--only hours before the case was scheduled to go to trial--to settle claims that it had

illegally manipulated the market. Three other defendants had paid a total of \$50 million to settle several months earlier. The terms of the settlement are confidential, but the two consortiums, Premier and Novation, agreed to change their business practices.

Shaw is not the only entrepreneur to find himself locked out of the lucrative hospital market. For decades innovators have complained that the market is dominated unfairly by giants. In the wake of Shaw's action, the U.S. Senate antitrust subcommittee has been holding hearings on whether hospitals' buying practices are stifling competition. The U.S. Department of Justice opened a criminal investigation of hospital purchasing last year. New York State attorney general Eliot Spitzer's office is investigating Becton Dickinson's sales practices.

None of that is any comfort to the gaunt and weary Shaw, 54, who regards the settlements as an empty victory. Hospitals still won't buy his syringes--or even allow him to demonstrate them to nurses, doctors, and other clinicians. But Shaw is using the \$150 million he has wrung out of the hospital-supply giants to finance his revenge. He recently outsourced manufacturing to China, reducing his costs and, he says, enabling him to undercut his competitors on syringe pricing. After that he hopes the forces of capitalism will prevail, and the billion-dollar syringe market will crack open and let him in. "Ironic, isn't it?" he muses. "My competitors are financing their worst nightmare."

An idealistic bumpkin? no, just an engineer who thinks the stuff of physics--force and friction--might yield results in the world of capitalism. Shaw is making some headway. Retractable Technologies, his firm, recently won a federal contract to provide syringes to five African nations trying to prevent the spread of AIDS. The contract is worth less than \$1 million, but the company hopes it will give it a foothold in the federal program. Even so, Retractable has only a fraction of the \$1-billion-a-year syringe market, which is dominated by Becton Dickinson. Last year Retractable Technologies' revenue for the first nine months was \$16 million, with a net profit of \$55 million, reflecting the one-time gain from the settlements. Retractable lost money on operations for the period. Becton Dickinson posted 2004 revenues of nearly \$5 billion, with a net profit of \$467 million--down 14% from 2003, in part because of its settlement with Shaw. "I never wanted the money," Shaw says. "I just want to get into the hospitals. Doctors and nurses are dying."

Accidental needle-stick injuries are a quiet crisis in the nation's health-care system. The U.S. Centers for Disease Control estimates that about 800,000 are reported annually in hospitals, though the agency says the actual number is probably far higher. Nurses and lab technicians who draw blood are the most common victims, and they are often reluctant to report accidents for fear of being reprimanded for being careless. Each year about 1,000 workers will contract hepatitis C, a deadly liver infection, from an accidental needle stick. Some 35 nurses will be infected each year with HIV, the virus that causes AIDS, because of accidental needle sticks.

Manufacturers have developed safety syringes over the years, but many nurses found them awkward to use, according to Dr. June Fisher, a specialist in occupational health medicine at the University of California at San Francisco. Cost was a factor, too, for

financially strapped hospitals, because so-called safety syringes made by Becton Dickinson and others are about three times more expensive than the standard versions, which typically run to about 10 cents each. But pressure is mounting on hospitals to reduce needle-stick injuries. Health-care workers' unions are fighting for safer equipment; some injured workers have sued hospitals for negligence, winning settlements. In 1998, California became the first state to pass a law requiring the use of safety needles. "Hospitals are not safe workplaces," says Dr. Fisher.

Into this fray stepped a man who has always been a maverick. Shaw studied engineering at the University of Arizona, where he scraped by with C's. His first company, launched in 1984, was a job-placement agency started in a corner of a bicycle shop in Little Elm. The profits paid for him to get his engineering certifications, and he opened an engineering firm in 1988. His first customer: an amputee with a broken artificial leg. The man's insurance company had refused to cover the cost of a new leg because it insisted he had intentionally damaged the original one; he wanted an independent engineering study to prove that the limb had a design flaw that caused it to crack. Shaw's analysis prevailed, and the amputee got a new limb.

Most of the work Shaw's firm undertook involved small-town civil projects such as roads and buildings. But Shaw was fascinated by medical devices. After a colleague complained that she was having trouble getting her elderly grandmother to take her medication regularly, Shaw won a federal grant to develop a pill machine that would dispense--and monitor--medication. Eventually he came up with an electronic device that measures and dispenses medication accurately and alerts caregivers by phone if the medication isn't taken. (The device is tucked away in a closet until he has established his safety syringe on the market.)

Shaw began work on the syringe in the early 1990s with \$650,000 in research funding from the National Institutes of Health. By the mid-1990s he was testing his device at three major hospitals in Texas. Doctors and nurses at those institutions endorsed it enthusiastically. "I was immediately impressed when I saw the prototype," recalls Dr. Lawrence Mills, former chief of thoracic surgery at Presbyterian Hospital in Dallas. "I thought the biggest problem was the company wouldn't be able to make them fast enough to keep up with the demand." (Now retired, Dr. Mills is a shareholder in Retractable.)

Shaw's first inkling that he would have problems breaking into the hospital market came at the very hospital where he had tested the syringe and gotten his strongest support: Presbyterian Hospital of Dallas. In a letter to hospital administrators, Dr. Edward L. Goodman, then Presbyterian's director of infection control, wrote that the new syringe was "essential to the safety and health of our employees, staff, and patients" and urged management to buy it. (Goodman was an early shareholder too.) But Shaw says he was told by hospital officials the institution couldn't buy the product because it was barred from doing so under a contract with Premier, a purchasing organization based in San Diego. "I grew up in the desert, and I know a scorpion when I see one," Shaw says bitterly. "At that moment, I knew the health-care system was rotten to the core."

Shaw plunged into the business of manufacturing and marketing his syringes, only to hit another barricade. He needed money to build a factory and hire workers. Many Wall Street firms were intrigued--investment bankers from Goldman Sachs made six trips to visit Shaw in Little Elm--about an hour north of Dallas--but every one of them backed out, spooked by the impenetrable hospital market. Shaw sold \$42 million of stock at \$1 a share--many buyers were local doctors--and he got the company listed on the American Stock Exchange. (Shaw owns more than 50% of Retractable.)

Meanwhile, sales stalled. Kathryn Duesman, Retractable's director of clinical development, remembers a meeting with a purchasing officer at another major hospital in Texas in the late 1990s. "He told me, 'Do not show this product to our nurses because then they'll want it, and they can't have it. I just can't buy from you,'" she recalls. The man explained that by contract the hospital could buy only from a consortium.

Shaw did manage to scratch out some small victories in those years. He found customers in markets too small or too poor for the giants to even consider serving: federal prisons, Indian reservations, the Mississippi health department, South Africa. Desperate, Shaw enlisted the help of the Service Employees International Union, the largest union of health-care workers in the U.S., which was concerned about the large number of accidental needle-stick injuries, particularly in California, hit hard by the AIDS crisis. With the union's help, Retractable won a contract in 1999, supplying safety syringes to managed-care giant Kaiser Permanente in California.

From the start the relationship was troubled. When he sent staffers to show nurses how to use the new syringe, Shaw discovered that his product was missing from hospital supply rooms; he claims shipments were locked up in distribution centers so that doctors and nurses wouldn't learn about the new device. Kaiser disputes that charge. Laura Marshall, a Kaiser spokeswoman, says Retractable was unreliable, and specifically that shipments of syringes arrived irregularly. In the contract's first year, 1999, Marshall says, Kaiser ordered 2,329 boxes of syringes and received 343. Shaw calls the charges "ridiculous," adding, "We shipped millions of syringes to them, and they sat in the warehouse."

Of even more concern to Kaiser, Marshall says, were several instances of product failure, including one in which the needle detached from the syringe, remaining in the thigh of a 7-month-old baby. Shaw says the charges of product failure are "bogus." In early 2000, Kaiser ended its relationship with Retractable. In any case, Kaiser was forging an even closer relationship with its longtime syringe supplier, Becton Dickinson. In mid-1999 the two announced a partnership--a three-year, \$30 million product-development program to evaluate and develop safety devices including syringes.

Frustrated, Shaw filed a lawsuit in state court against the big hospital-supply companies and the buying consortiums. Shaw's first deposition lasted two days; Becton Dickinson was represented at the meeting by more than a dozen attorneys from firms in New York City and Dallas. Among subjects they grilled Shaw about were his religion and his health, including what prescription drugs he was taking. Pretrial proceedings dragged along for

six years, leaving Shaw's factory half-idle all the while.

Then came a stroke of luck. Mark Lanier, a fast-rising star of the plaintiffs bar, offered to take on the case on a contingency basis. That meant his Houston-based firm would invest the money to bring the case to trial, a relief for cash-strapped Retractable. Lanier also would get one-third of any winnings. Lanier's first move was to immediately refile the case in federal court in Texarkana, Texas. Under federal antitrust law, any damages would be tripled.

In 2003, as the trial date neared and the judge prodded the combatants toward settlement, Lanier met an unlikely foe: his client, Shaw. Becton Dickinson, Tyco International, and the other defendants were offering to shower Shaw with money. But he wanted access to the hospital market. Ultimately the buying consortiums agreed to change their business practices, although what they promised exactly remains confidential. Premier and Novation both bowed out, as did manufacturer Tyco, paying about \$50 million to settle the case. Becton Dickinson offered money but balked at changing the way it did business. Finally, under pressure from his lawyers and his shareholders, Shaw accepted the settlement offer: \$100 million. Lanier's firm, which had spent \$6 million, got about \$50 million, plus expenses.

But the richest citizen in Little Elm, Texas, is not a happy man. What Shaw still wants is what he has sought for more than a decade: the opportunity to sell his syringe in an open market. Despite the promises that the consortiums have made, Shaw sees little evidence that they have changed their practices. He'll continue to peck at any opportunities he can scare up. Lowering prices--outsourcing some of the manufacturing cut his costs 60%, he says--has not sparked demand so far. Through the Medical Device Manufacturers Association, a trade group based in Washington, D.C., Shaw is pressing for market-reform legislation in Congress. Staring down at the slow-moving machinery of production from a catwalk high above the factory floor, Shaw gets lost in thought for a moment; then he pulls himself back to the present. "If it's going to be business as usual in the hospital market," he says, "then we have no hope."