

# BD's Challenge: Making Everything Old New Again (A#2003800092)

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**Summary:** Recent legislation requiring hospitals to convert to safety devices to prevent needle-stick injuries has come as a kind of validation for Becton, Dickinson, the market leader in needles and syringes, whose efforts to develop safety products began well before customers or the government required them. Critics have charged that like all big companies with strong market share positions, BD has lagged in technology innovation, preferring to spend its time and energy defending its existing products. BD officials insist that just the opposite is true. But creating meaningful innovation is difficult in the kinds of high volume, low margin product lines that needles and syringes became over the 1980s and 1990s. For one thing, clinician input into new technology designs is rare; at the same time, the statistical data to back the importance of safety product conversions is scant. Perhaps most daunting, in a cost-constrained hospital market, the economic pay-off is still small, at least relative to other medical device innovation. Still, BD officials say, they persevered, leading the way in safety device innovation at a time when the company's interests, arguably, would have been better served defending its core line of conventional devices.

*You think product innovation is difficult in a rapidly evolving clinical space? Try it in a mature, price-squeezed product line like needles and syringes.*

by David Cassak

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The announcement last month that [Becton, Dickinson & Co. \(BDX\)](#) will soon stop selling many conventional needles and blood collection devices came as no real surprise. After all, legislation all but mandating that hospitals convert to needles and syringes re-designed to prevent needle-stick injuries, so-called safety products, was passed three years ago. BD, said its critics, is simply following the government's lead.

But the story behind BD's transition to safety products is more complex than that. For one thing, how often do you find a market leader with a long pre-eminent position voluntarily rendering obsolete the product line that made it so successful? For another, far from following the government's lead on safety products, BD aggressively anticipated—one could even say prompted—the safety product mandate. In the process, the company spent more than half a billion dollars on product and program development over the previous decade-and-a-half at a time when government support for safety products was far from a foregone conclusion.

Perhaps most importantly, the kind of comprehensive product redesign that safety products entailed is difficult under any circumstances; in a mature, price-squeezed product line like needles and syringes, it's enough to give a company fits. Deceptively complicated to design and manufacture, safety products are the kinds of devices for which companies typically get little credit when they work well—and lots of blame if they don't. In addition, the financial rewards are hardly enormous—even the most sophisticated safety syringe sells for well under \$1—and there are enormous countervailing pressures against adoption, including entrenched clinician habits, skeptical customers, cost pressures, and, not least, the kinds of standardization programs that lie at the heart of the success BD had achieved in conventional devices. While critics charge that large, successful companies like BD spend too much of their time and effort defending their well-

established businesses, the wonder is that BD didn't do more to defend its conventional business, that it was so much the driver of its own obsolescence.

### At First, a Focus on Sharps Disposal

Though the legislation mandating the use of safety products is less than three years old, BD's product development initiative in safety products goes back at least 20 years. "There's always been a concern here about proper usage and safety," notes Gary Cohen, president of **BD Medical Systems**, the world's leading supplier of needles and syringes and IV catheters and one of the two main business units at BD that have undergone major product re-designs to reflect safety concerns. (The other is **BD Clinical Laboratory Solutions**, which manufactures blood collection devices.) The earliest efforts, dating from around 1983, focused primarily on the safe disposal of conventional disposable needles and syringes, making sure that nurses and other hospital workers didn't infect themselves downstream of the clinical intervention, after the needle was used to inject fluids or to draw blood or some other body fluid.

In the beginning, at least, growing concerns about HIV and AIDS infection "were clearly a stimulus," says Cohen, but not really a driving force in BD's efforts—at least not in the sense that either customer worries or government initiatives pressured BD to redesign its products. Indeed, concerns about hepatitis had been around for decades, notes Cohen; few customers saw blood-borne infection as an imminent risk, and whatever work BD was doing on safety redesign was largely self-prompted. By 1987, however, the first reports of HIV transmission to hospital workers through occupational exposure were reported and became what Cohen calls "a trigger point" for a more aggressive push. That year, Janine Jagger, PhD, an infection control specialist at the **University of Virginia Medical Center**, published an article in *The New England Journal of Medicine* that provided data linking so-called sharps injuries to specific devices, procedures, and health care workers. "It was the first time that someone brought the whole issue together," notes Cohen.

As noted, BD's first generation of safety-related products, sharps containers, focused largely on removing the threat of needle-stick injuries after the clinical episode. Before the advent of specially designed containers, which prevent needle-sticks by providing a secure way to immediately encase contaminated needles, hospitals got rid of disposable syringes by placing them in a large corrugated cardboard box or, sometimes, jerry-rigging some other disposal method.

Such approaches seemed sufficient by themselves—until a needle somehow escaped the disposal system. And in the late 1980s, a number of highly publicized reports of needles and syringes and other medical waste washing up on the beaches of New York and New Jersey added fuel to the fire surrounding mounting concerns about AIDS-related needlestick injuries, leading hospitals to take more aggressive steps to ensure safe and effective disposal of contaminated needles. Within a few years, hospital waste management had become a major industry, and virtually every hospital had converted not just to specially designed sharps containers located at the nursing stations on each floor, but also to containers installed at the patient's bedside.

What hospitals did with the sharps once they were in the containers was, for BD, largely the hospitals' responsibility, though BD flirted with the idea of getting into waste disposal itself. "We looked at it quite seriously, but it was so far a field from our core business and there were other companies that were doing it well," notes Gary Cohen. In addition, in the early 1990s, BD experimented with a mail-back sharps disposal program for physicians' offices, coordinated through waste management specialist BFI. BD eventually ended that program, though last year it introduced a similar mail-back program for insulin-dependent people who administer their insulin at home.

## A Shift from Syringes to Needles

But BD's most important developments in safety-engineered products came in the redesign of needles and syringes themselves. First introduced in 1988 on a regional basis and rolled out nationally the next year, BD's *Safety-Lok* syringe was the first syringe to incorporate safety features into the product itself, rather than its disposal. At the time, one of the leading causes of needlestick injuries arose from the need to re-cap the needle after use; *Safety-Lok* addressed the problem by incorporating a shield that was pulled up over the needle, after the injection but prior to disposal.

Other designs would follow in a variety of other BD product areas—virtually a new design a year over the next 15 years. In the early 1990s, the company partnered with IV solutions leader [Baxter International Inc. \(BAX\)](#) on a system called *InterLink*, that utilizes blunt plastic cannulas and special IV ports to replace sharp needles used to connect or inject into IV lines. Notes Cohen, "The first line of defense against needlesticks is to eliminate the use of sharp needles when they aren't needed."

By 1993, BD had begun to re-engineer needles and syringes in larger sizes to incorporate safety features, developing the first 10ml safety syringe, used primarily in irrigation procedures and to flush out IV lines and sometimes for drawing blood. (The safety shield protects nurses from exposure to the needle when blood is transferred to a tube.) It was in 1993 as well that BD introduced its first safety-engineered IV catheter. And though the company was later forced to take the product off the market—competitor [Johnson & Johnson \(JNJ\)](#) blocked the sale because it owned a patent the device would have infringed—within two years, BD was back with a safety IV catheter, the *Insyte Autoguard*, that is now the worldwide market leader.

In 1996, BD introduced its second-generation safety hypodermic, the *Safety-Glide*, which incorporated safety features into the needle, rather than the syringe. After using the syringe, a nurse could, with a flick of his or her finger, trigger a hinge-activated shield that would cover the needle. The shift from safety features designed around and built into syringes to those built around needles was important. Notes Erika McGovern, Marketing Director, Medical Surgical for BD Medical Systems, "There are a lot of needles and syringes that aren't used in injecting skin at all," but rather are used in mixing medications and drawing fluids in the pharmacy, for example, or for injecting fluids without a needle into stopcocks and IV ports. "Over time," she goes on, "we came to the conclusion that the safety feature should be incorporated into the needle since the needle is the part that sticks people, and the syringe portion can be used without a needle for many other applications."

Hospitals could, of course, use safety devices for most of its hypodermic needs, but they'd be paying for a more sophisticated device than they really needed in many situations. As BD worked on expanding its safety line, McGovern goes on, it became harder to make the case for a device that incorporated safety features into the syringe. "If all you're doing is drawing fluid out of a bag in Pharmacy and reconstituting medicine, you don't need a safety product," she says. Moreover, BD officials realized that the slower than expected take-up on safety products was due, at least in part, to resistance on the part of customers to a device they weren't sure they needed. "At that time, the data on the risk of needlestick injuries wasn't there," notes McGovern. "And because the safety feature was on the syringe, and many procedures, such as IV access, may not require a needle, people were paying for safety features they didn't feel they needed."

## A Retracting Device

Though conversion to safety designs was fitful during the late 1990s—rapid in some product areas, considerably less so in others—BD continued to develop new products in three directions. First, it broadened the reach of safety features in its core product lines. Thus, for example, it developed safety lancets for pediatric heel sticks, as well as surgical scalpels, under its *Bard-Parker* brand. Second, it revised and enhanced earlier safety designs—launching an *InterLink*

with a blunt-fill needle, sharp enough to penetrate a vial, but not skin, and *Safety-Glide* versions of its insulin and TB syringes. This year, it will introduce a push-button version of its wing blood collection set. Finally, it continued to create new generations and designs. Thus, in 1998, it introduced its *Eclipse* line of blood collection devices, a single-finger activated safety model used for multiple-sample needle drawing.

A syringe and needle version of the *Eclipse* blood collection needle was introduced in 2002, along with a spring-based retracting syringe, called the *Integra*, BD's most technically advanced injection safety device. If *Safety-Lok* incorporated safety features into the syringe and *Safety-Glide* and *Eclipse* built them into the needle, the retracting syringe represents a kind of hybrid approach.

Gary Cohen explains why BD took so long to introduce a spring-based retracting syringe. "Most of the designs we came across didn't meet certain clinical requirements," he says, one of the most important of which is the need to change needles, using one to draw a fluid, such as blood or medicine, and another to inject it, while using the same syringe. "It was a real technological breakthrough to make the needle removable," he goes on.

Even more importantly, most retracting needle technology today requires the needle retraction to take place while the needle is still in the patient, and BD's research indicated that at least some of the clinicians wouldn't activate the needle while in the patient out of concern for their safety. But such devices result in drug under-dosing if activated outside the patient, Cohen goes on, "so we developed a product that would be completely empty before activation." That means that *Integra* has the added benefit of reducing a hospital's pharmacy costs because it has significantly less medication waste space compared with other retractable syringes and even less than conventional syringes, say BD officials.

Today, BD offers four different approaches to safety products, just in needles and syringes: the original *Safety-Lok* sliding shield design; assisted activation devices like the *Safety-Glide*; pivoting shields, such as the *Eclipse*; and the *Integra* retracting device. The variety reflects not degrees of safety—BD officials insist all of the designs provide protection against needle sticks—but the additional features that are on the device. And that, in turn, reflects the fact that different clinicians and different hospitals prefer different devices, with personal preference, application, and price all playing a role in influencing product selection, notes Melanie O'Neill, VP, Medical Surgical at BD Medical Systems. "We don't think one size fits all," she says. While hospitals often choose one device for the majority of their needle and syringe applications, there are exceptions within every institution, particularly given the breadth of applications of the device within the hospital. "We've found that some clinicians are simply more comfortable with one technology than another," she notes.

### A Clinical Evaluation

Indeed, BD officials note that when they did research on how needles and syringes are actually used in most institutions, they were impressed most at the variety of specialty applications of the device. That alone would lead to a diverse product offering, but the breadth of line also reflects a continuing cost concern; there's little doubt that some hospitals select certain safety products because they're less expensive than more sophisticated designs. While a conventional syringe will cost a typical hospital around four or five cents, the simplest safety design, the *Safety-Lok* sliding shield, will cost around 14 cents; at the high end of the scale, a retracting needle and syringe will cost approximately 35 cents. BD estimates that conversion to safety products, overall, will cost a typical hospital about \$100,000 a year, which has to be set against the potential costs, in financial and human terms, of a needlestick injury.

Melanie O'Neill notes that, "*Safety-Lok* is a very functional product and a lot of hospitals still use it." And as a result, BD typically doesn't see many *Safety-Lok* customers move on to *Safety-Glide* devices, for example. But while the *Safety-Lok* device is still widely used, newer converts to

safety devices are more likely to use a more advanced model, such as the *Safety Glide* or *Eclipse*, given their higher degree of sophistication and wider application. "As the market converts and more and more safety products are sold, by far, the new customers are going in this direction [i.e., toward more sophisticated devices]," she says.

That's not to say that all customers want sophisticated safety technology. Erika McGovern notes that while many BD customers see a tremendous value, for example, in the drug-saving benefits of the *Integra*, "there are plenty of other customers who tell us they don't want anything fancy or over-engineered. They just want something simple." Thus, some hospitals choose to comply to mandated safety measures with the least expensive products they can find; others make needle and syringe selection an entirely clinician-driven decision, offering the highest degree of protection regardless of price. And, in fact, many hospitals will use a mix of safety products, with different departments and different clinicians selecting the device they like best.

But even if all hospitals don't migrate *en masse* toward the most sophisticated device, there are implicit benefits to BD in the introduction of safety products. For one thing, the variety in product offerings cuts against the standardization efforts that drove the price of conventional devices down. BD is, as noted, conscious of the cost pressures its hospitals are under, but notes Gary Cohen, "We always assumed hospitals would try to standardize across the board on safety devices because that's what they've always done [on conventional devices]. But we're finding that they may now use a variety of products within the same institution." Indeed, he goes on, the decision to offer a range of options was a conscious one on BD's part. "Classic economic theory would tell you that it's a mistake to segregate product development over multiple platforms because you just create uncertainty. But we knew that our customers would want to make choices and that even with our strong market position, we're in no position to tell our customers what products to use. We'd rather accommodate their desire to make choices and make every effort to have the best design in every category."

Even more importantly, as part of those utilization decisions, virtually all hospitals today submit needle and syringe selection to a clinical evaluation process—in fact, they're required to by law—and that alone represents an amazing transition in the way customers think about a mature technology like needles and syringes. "It's interesting," says Cohen. "You can go to one hospital and find very strong opinions among clinicians as to why this particular design is the best and walk across the street and find the exact opposite opinion, and both have done clinical evaluations." BD's goal: to remain as neutral in those decisions as possible. Says Cohen, "What we say to hospitals is, 'We can sell you a safety device for 14 cents, we can sell you one for 23 cents, or we can sell you one for 35 cents—you decide.'"

### **A Resistance to Adoption**

Speaking about the first generation of safety products, Gary Cohen notes "we had expectations that the market take-up would be much more rapid than it turned out to be. As we went on, we learned a lot about what it would actually take to get people to transition to these products."

Of course, in some instances, there were legitimate reasons why hospitals would and still might resist a conversion. Notes Kevin Seifert, VP and General Manager, Consumer Health for BD Medical Systems, "There are still a few specialty procedures where you might want to use a conventional device," including some procedures where there haven't been appropriate safety innovations.

Still, in the most obvious and logical applications, there were several factors behind hospital and clinician resistance to adoption. First, there's a general conservatism and resistance to change, particularly in a product line that had been mature and constant for so many years. Related to that, many nurses, even those who recognized that needle-stick injuries were, generally speaking, a problem, believed that they were skilled enough in handling conventional devices that

they didn't really need specially designed ones. "There are issues of cultural change," notes Ed Thompson, Senior Director, Advanced Protection Technologies, for BD Medical Systems. "The practice of medicine is very tactile; any time you ask people to change how they do something, it's going to take time." Indeed, he notes, once nurses start using these devices, they have as much trouble going back to conventional devices as they had converting to the newer devices.

In fact, through much of the 1980s, needle-stick injuries were thought to result from poorly trained or clumsy nurses; those who were stuck were often reprimanded for being careless. It wasn't until the early 1990s that device design became widely acknowledged as a critical factor in such injuries. Finally, and perhaps most importantly, there were cost concerns: the new devices are more expensive than conventional ones and some hospitals resisted the transition because of its potential budget impact. Still, over the course of the 1990s, resistance fell away, particularly on a product-by-product basis. Thus, by 1995, the *InterLink* needle-less IV system had penetrated the market by 70%, helped by an FDA Safety Alert issued in 1992 advising hospitals to discontinue their use of conventional needles in IV connections. Today, prompted a lot by the recent national legislation, around 90% of IV catheters and IV access devices are safety devices, while some 80% of blood collection devices and 65% of needles and syringes used within hospitals have converted. (Safety device use in alternate sites is only around 30%, say BD officials, in part because the relevant OSHA regulations are harder to enforce in alternate site settings such as doctors' offices and clinics.)

### **Building Awareness**

Better designs, making safety features even easier to deploy and more foolproof, helped overcome some reluctance. So, too, as noted, did a series of government initiatives, both federal regulations and legislation, beginning on the state level and culminating in national legislation, the *Needlestick Safety and Prevention Act* of 2000, which mandated the use of safety products.

But well before that, BD officials recognized that market awareness and customer education would play a major role in stimulating the transition to safety products. Indeed, says Gary Cohen, BD never looked at safety products as simply a matter of product innovation. "It was also about interacting with opinion leaders, and funding the development of data that would demonstrate both the need for the devices as well as their effectiveness," he says.

Thus, the company's first major educational effort, launched with the National League for Nursing, incorporated a number of tools, including videos explaining safety issues and posters highlighting CDC guidelines on safety issues, all packaged in a kit and presented to hospitals free of charge. In 1991, BD developed a similar educational kit for physician's offices and alternate site settings, and, the next year, worked with the American Medical Association to educate health care facilities about newly passed regulations from OSHA on blood borne pathogens.

At around the same time, BD, in collaboration with Janine Jagger at the University of Virginia, helped to launch *EPINet*, a global Internet-based registry for tracking needlestick injuries. Beginning with seed funding of \$25,000, Jagger developed a computerized surveillance system that would be implemented by hospitals to record and report all injuries. Hospitals use *EPINet* both to monitor their own safety record and to contribute to a centralized database of needle-stick injuries. (In addition to the US, hospitals in Canada, Australia, and Japan also are contributing data to *EPINet*.) The first data from the system was recently published, showing a 51% reduction in percutaneous injuries from IV catheter injections between 1993 and 2001. Ironically, because *EPINet* is an unbiased, industry-wide resource, that first study focused on a J&J catheter. "That wasn't an issue to us," says Gary Cohen. "This is all about developing awareness and market development; it's not about specific devices."

### **A Shift from Reusables to Disposables**

As safety concerns mounted, BD's sales reps were also able to step up their calls on clinicians inside the hospital, particularly infection control specialists. Cohen notes that even during the height of cost consciousness in the 1980s, BD never really lost touch with its end-user customer, though "the intensity of those interactions had sort of peaks and valleys." During the height of cost pressures, hospital material managers and hospital supply distributors were, arguably, a more important influence on the kinds of products BD makes. By the early 1980s, he goes on, "infection control became an absolute critical call point for us."

As a result, one benefit of the emphasis on safety products has been to build brand awareness among clinicians—often an elusive goal for hospital suppliers whose products are purchased largely on the basis of price-driven decisions under local and national contracts. BD officials concede that floor nurses are still likely to be unfamiliar with the BD brand. But among a growing number of senior clinicians, particularly in infection control, the technology development and market awareness efforts have begun to pay off. Says Melanie O'Neill, "Because the new legislation requires clinicians to evaluate the product and make choices, or at least have input to the choices made, a lot of clinicians who weren't aware before are becoming very aware of the different manufacturers of safety products and are starting to differentiate among the different technologies they bring to market." Still, while such efforts have helped raise awareness and promote transition, it was less in marketing and sales than in product development that BD's greatest challenge lay.

BD has been in the business of making needles and syringes since the early 1900s. The company was an early innovator, obtaining a patent on the first all-glass syringe in 1898 and introducing the first disposable needles in the 1950s. (The very first disposable medical device of any kind, a blood drawing set, was also a BD invention, as was the first disposable needle, though, ironically, the company was beat to the market with a disposable syringe by the Monoject division of Sherwood Medical Products, now the [Sherwood-Davis & Geck](#) business of [Tyco International Ltd. \(TYC\)](#)) Interestingly, the original shift from reusable to disposable products, which would have such a profound impact on hospital supplies in so many ways, was made based on what is, arguably, a safety issue: disposable syringes would, it was argued, dramatically reduce the spread of infection because only sterile syringes would be used.

Disposable hospital supplies today epitomize the low-margin, high-volume, price-sensitive product line, whose purchase is driven by hospital material managers and national hospital group purchasing contracts. But four decades ago, disposables were the quintessential clinician-driven product line. They were, as noted, adopted for their clinical benefit, and nurses and other clinicians drove product selection. Gary Cohen points out that because of disposables' high profile, "During much of the 1960s, BD was foremost in the minds of doctors and clinicians, much more so than even today," as a technology innovator.

### Do Market Leaders Really Innovate?

The widespread adoption of disposables was also something of a watershed for BD. Company executives recognized that the conversion from reusables would require tremendous capital investment, and that led to the company's 1962 IPO.

The advent of disposables drove a string of product innovation and development at BD, including the first syringe dedicated to insulin delivery. But it wasn't until the development of safety products in the late 1980s and early 1990s that BD saw what is arguably its richest and most challenging era of product development. "I would say that the transition from conventional medical devices to safety-engineered designs has been every bit as significant as the conversion from reusables to disposables," notes Cohen.

The irony is, of course, that hardly anyone thinks of BD as a technology innovator, particularly not in its core needles and syringes business. That perception stems from three inter-related factors. First, as noted, disposable products, broadly defined, have evolved from relatively high cost,

physician-preferred devices to price-squeezed, low-cost products—hardly the kind of lines that reward significant technology innovation. Second, the enhanced features and benefits of a safety-engineered product aren't as dramatically apparent as, say, advances in cardiovascular technology or orthopedics. Granted, you can document the impact of safety-engineered products in terms of reduced needle-stick injuries; but such a benefit doesn't capture the imagination the way, say, a drug-eluting stent does, or frankly deliver a commensurate clinical value. The fact that there are hundreds of medical device start-ups working on the next cardiovascular breakthrough and few, if any, focused on the next generation of safety products, only reinforces the sense that meaningful differentiation in the latter is not as clinically significant or rewarding.

Finally, BD's pre-eminence in needles and syringes, which only grew throughout the 1990s—BD won't reveal its market share, but industry estimates that it has 75-80% of the market can't be far off—fed into a common myth about large companies: that in their desire to defend a large, well-entrenched business, they focus more on protecting existing product lines, even if old and antiquated, than on innovation. The three arguments thus run together something like this: in a mature, cost-squeezed, low-margin business like needles and syringes, market leaders like BD spend all of their time pushing the products that have made them successful rather than developing new products for a customer that may not appreciate or be willing to pay for them.

That implicit criticism, which surfaced most recently, as a subtext in the Senate subcommittee investigations of hospital group purchasing practices (see *"Is Group Purchasing Broke?"* IN VIVO, November 2002 [A#2002800259] and *"Reforming Group Purchasing: How Far Is Far Enough?"* IN VIVO, January 2003, [A# 2003800016]), clearly rankles BD officials, who invested more than \$500 million in product development costs and market awareness/education programs throughout the 1990s on what was largely a self-driven, missionary project. "People accused us, particularly early on, of not being interested in safety devices, not being willing to make the capital investment necessary, just wanting to protect our market—all of which is nonsense," says Cohen.

Indeed, with only a handful of states passing legislation mandating safety products and no national mandate in sight, BD spent enormous sums with no clear indication that hospitals would adopt the new technology. Notes Cohen, "There was a time when we were essentially betting the farm, spending hundreds of millions of dollars without any certainty that the market would actually adopt these devices."

True, BD wasn't without self-interest in the promotion of safety products. The company was clearly hoping to take a mature, price-squeezed product line and transform it to a high-priced, clinically driven device. But, as Cohen notes, the strategy was not without risk. While some product lines converted quickly to safety products, others stalled. "Even though we were introducing a continuous stream of new products, there wasn't a high level of adoption, and the risk was that, as we continued to build capacity and install high-cost manufacturing equipment, we'd be sitting either on huge write-offs or an unacceptably high manufacturing cost," he recalls. "BD as a company probably wasn't fundamentally at risk, but things like that can destabilize even a large, successful company."

### Do the Right Thing

Despite the risk, Cohen insists that BD officials never considered the alternative: continuing to push conventional products and abandoning safety designs. "I think the leaders of the company always perceived the issue of health care worker safety to be very important," he says. "And BD has always been a company driven by doing what's right from a public policy or societal point of view and having the business benefits follow."

Still, early on, as needle-stick injuries emerged as both a public safety and public policy issue, BD, despite its best intentions, helped to reinforce the notion that it was more interested in protecting its core business than health care workers. An early initiative to promote the use of safety products by government mandate and the banning of conventional devices through the

promulgation of a list of approved devices was opposed by BD on the grounds that hospitals would find compliance impossible. "We said, 'Wait a minute this doesn't make sense,'" Cohen recalls. BD's argued that while it was appropriate for the government to provide guidance, in the form of FDA safety alerts and the like, he goes on, "in the early 1990s, we didn't support mandating use of the products or banning conventional products. We knew that it would backfire terribly," because it would disrupt hospital procedures.

Indeed, BD officials argued that rather than accelerate innovation in safety devices, government-formulated lists of approved devices could bring further innovation to a halt. For one thing, they argued, the call for immediate adoption would push the entire market to adopt the first-generation products then available, and these early designs would become the basis for government-established standards. "As a result, any innovations that would come later, including devices we were already working on, would have faced much higher barriers because their designs would vary from the standards," Cohen says, "and that would stifle innovation."

Moreover, BD argued that FDA-mandated design standards for safety devices would make it more difficult to gain 510K clearance to sell newer devices—which, in fact, they did in guidelines for new standards the agency issued a short while later. "It would have been like getting a new drug approved," Cohen goes on. "It would have required extensive clinical trials and five years of study just to get a new safety device [approved]."

To fight the pressure, BD led an industry coalition that caused the FDA to back down and rescind the new, more restrictive 510K clearance standards for new safety devices. As a result, the company was branded by some as an industry leader fighting government regulation to protect its core business. But Cohen says BD's motivation was just the opposite: "We knew there was going to be a lot of innovation, that the first-generation products, though good, were just in their infancy in terms of product development. That wasn't the time to lock in and say, 'Everybody has to use these specific designs.'"

### Opening the Door

If anything, Cohen notes, as the only company with a complete line of safety products at the time, BD's best interests would have been served by supporting the proposed government initiative. Moreover, BD officials realized early on that their work on safety devices would open the market—one in which they had the leading market share—to competition they otherwise would never have faced. "We took what was a very standardized, very capital intensive, very low-priced market and suddenly opened the door for other companies to come in," he notes. Indeed, given the price pressures of the market, "There was no way a start-up was ever going to come into the US market and start selling a conventional syringe."

Moreover, far from delaying product development to protect an established line, BD officials argue that they were working to obsolete their core products well before they really had to. Of course, by starting early, BD officials argue they had an enormous jump on their competitors. William Kozy, President of BD's Clinical Laboratory business, notes that by 1993 and 1994, as customer interest in safety products began to heat up, "people would come to us and comment about how well our first-generation products work, but to us, they weren't first-generation products, we had been working on them for years." Adds Gary Cohen, "We started years earlier than anyone else at a time when it wasn't clear what was going to happen with safety devices, and the one thing we learned is that companies that wait until there's absolute and complete recognition on the part of customers and competitors that there's a big opportunity are often too late. The companies that lead have to be well prepared before the opportunity comes, in fact, they have to make it happen."

In short, BD officials understood there were both risks and opportunities in developing safety products. "We knew if we did it well, it was going to be a huge business for BD," Cohen recalls. But, he insists, the willingness to take the risk was driven not just by the prospect of financial

gain, but also by the fact that, particularly for a company whose name was synonymous with needle and syringe technology, "it was clearly the right thing to do."

### The Challenge of Innovation in Mature Products

Given the almost missionary quality of their safety device initiative, it isn't all that surprising to hear BD officials talk about the importance of technology development to their long-term success in terms similar to those used by their counterparts at widely acknowledged technology leaders such as [Medtronic Inc. \(MDT\)](#) or [Guidant Corp. \(GDT\)](#). But fostering meaningful innovation in a product line that is mature and low-cost presents a very different challenge than it does in a rapidly evolving technology area like cardiovascular devices or high-priced lines like orthopedics. Indeed, illustrative of the special challenges that confront device companies that play in areas like needles and syringes is the fact that while sharps containers fairly quickly gained widespread adoption in hospitals, more sophisticated safety-engineered needle technology took much longer.

There are several reasons why innovating well-established, mature product lines like needles and syringes is difficult. For one thing, because they don't enable or define a procedure *per se*, but are part of a larger episode of care, such devices often have to fit easily into a broad array of procedures performed by a variety of end-users. For that reason, the ability to conform to a well-established regimen across different procedures is vital—with a product like needles and syringes, nurses and other end-users would be defeated by syringes that had to work one way for one application and a completely different way for another. "There have been a lot of novel safety ideas that have been applied to needles and syringes and haven't been adopted," says Gary Cohen. "[Safety] devices have to work in just a certain way; they have to be just as effective and convenient and, if anything, even easier to use [than conventional devices]."

Moreover, unlike medical devices that can be tested extensively in prototypes and animal studies, with a product like safety needles, "you don't really know until they go into the clinical setting how they'll work," Cohen goes on. Phrased differently, the mechanism for providing safety may work fine; whether it will work in a device that then allows nurses and other clinicians to effectively use the syringe is another question.

BD officials realized this early on. Because needle tips are beveled to make penetration of the skin easier, any covering or protective sheath on the tip had to be designed—and manufactured—precisely, so that the sheath didn't interfere with the actual penetration of the skin. "We saw that we needed to design the safety needles with the bevel up," notes Erika McGovern, "because if the safety arm was positioned wrong, they simply wouldn't be able to use the device." Complicating the issue: BD officials not only had to design the device so the bevel would always be up, they also had to re-configure the manufacturing process so that they could continue to produce the devices with a high-speed, automated process that drives manufacturing costs low. "We're producing these at the rate of many more than one per second, and the process has to be continuous and non-stop," she goes on.

### Innovating from Within

The practical application of safety devices within the actual clinical setting is important because safety devices differ from other types of device innovation in another way: at a time when evidence-based medicine is growing more popular, there's relatively little clinical data to differentiate one device from another. For one thing, the incidence of needle-stick injuries is low relative to the number of needles used in health care: "we're dealing with tenths and hundredths of a percent [incidence]," says Gary Cohen. "It would take years of study to derive the data to demonstrate the effectiveness of device A over device B."

That's not to say there haven't been clinical studies. Research out of Janine Jagger's program at the University of Virginia has demonstrated clearly that the use of safety devices reduces the

number of needle-stick injuries, with some product categories showing a nearly complete elimination. But such studies tend to be broad-based, focusing on categories of devices, not specific designs. Thus, Cohen notes that product selection "is only in part data-driven;" much of the evaluation done by hospital product committees will look at several different products at one time and use subjective, qualitative judgments rather than hard, quantifiable analyses.

Further complicating the development process is that, again unlike other medical devices, new designs for needles and syringes rarely come from physicians or other clinicians. "We get feedback from our end-users," Cohen notes. "But these are such general purpose tools that it's unusual that a doctor will step forward and say, 'I just figured out a better way to do this.' It's much more likely that we'll determine through our internal expertise and through an outside patent search what designs we think would be most effective."

As Cohen's comments imply, BD does incorporate ideas sourced externally as well as internally into new safety designs—physicians may not be a particularly good place to get ideas, but engineers and inventors are. Thus, for example, the basic design for the *Insyte Autoguard IV* catheter was acquired from a small company, **Phase Medical Inc.**, and Erika McGovern notes that BD looked at over 630 different designs, some internal, many external in the development of the *Safety Glide*, which holds both an internal patent and an external license.

Overall, company officials estimate that more than half of BD's safety products incorporate some outside idea that the company has either acquired or in-licensed. And not surprisingly, some ideas, such as a recent hinge-based design for a shield activation, came from non-medical technology. But, perhaps for that reason, BD officials say they always have to do additional work on designs that come from the outside. Notes Melanie O'Neill, "I think there are a lot of inventors out there really focused on safety features and not on the clinical practice of how injections are given and all of the things that syringes do." Moreover, adds Gary Cohen, many would-be safety device developers fail to grasp the importance of manufacturing issues behind the device. "Even the best outside invention, in terms of both functionality as a medical device and the ability to be manufactured in a high-speed, fully automated system, has to be re-engineered," he says. "I don't think there's ever been a circumstance where we've taken a product from the outside and just brought it to market. It just doesn't work that way."

This combination of factors—the wide application and variety of needles and syringes and the relatively low input from outside—makes product development unlike that of most other medical devices in yet another way. Deceptively complex, a highly engineered safety device is a technology innovation that many take for granted and few customers, on either the clinician or administrative side, pay much attention to or give much credit to—unless something goes wrong. Describing why product quality is so important, Melanie O'Neill notes, "These products can be very complex in terms of their different features but because they're used so widely in the hospital and for so many applications, if they don't perform properly every time, it becomes a big issue." And that's what makes innovation challenging. "These devices seem simple, but the development is very challenging," adds Gary Cohen. "What we have is a product that sells for 25 cents, and not only do we rarely get credit for the innovation, we'll get blamed if something goes wrong."

### Innovative But Price-Sensitive, Too

For BD, too, the adjustment was enormous. "For 100 years, we had been making devices that had maybe two or three parts," notes Bill Kozy. "And all of a sudden, we were making products with 12 or 15 parts, more complex and more fragile than anything we'd ever made." (*For more on Clinical Lab, see sidebar.*)

A related development issue: new technology iterations are more likely to be perceived by customers as simply an additional product line, rather than as a valuable and necessary enhancement over earlier-generation products. Gary Cohen notes that there is what he calls "a wow factor" associated with BD's most advanced, *Integra* device. "This is the only time I've ever

seen people respond to needles and syringes as if they were high technology." But, he goes on, after an initial positive response, whether a customer actually purchases the *Integra* is another question altogether.

But perhaps the most daunting aspect of new product development in low-cost, mature product lines is that the payoff can be extremely low. As noted, even the most sophisticated retractable safety needle sells for only around 35 cents—a significant jump from the nickel or so a conventional syringe costs, but still not a lot for a device. Similarly, in blood collection devices, all of BD's innovation moved the price of the device from 50 cents to around 70 cents.

Price pressures are nothing new to BD. The needles and syringes that are the core of BD's medical/surgical offerings have been a kind of poster child for high-volume price discounting over the past 20 years. Hospital group purchasing has played a large role in driving down prices, and some industry executives argue that the advent of [Terumo Corp.](#), the large Japanese supplier that made a strong push into the US needle and syringe market a decade ago, further accelerated price competition. Gary Cohen argues that price pressures on needles and syringes pre-dated Terumo's entry into the market, driven largely by the introduction of prospective payment at US hospitals. "Between 1983 when DRGs were introduced and 1988 when Terumo came here, prices went down 1-3% every year," he says.

Terumo's entry clearly sped up the price erosion, to something more like 3-5% a year for a couple of years, as the company offered prices to some customers 20-40% below then-current prices. When Terumo's product line ran into problems—for one thing, some of their syringes proved, early on, to be particularly brittle; for another, they didn't have a full array of devices—the problems compromised their price-cutting entry strategy. At the same time, BD launched an aggressive marketing and product development campaign within its conventional device line to forestall Terumo's efforts. Terumo came to market with what it thought was a better product and expected to catch BD and Sherwood sleeping; what they found, notes Cohen, was a BD aggressively fighting to protect its turf.

### Responding to Cost Pressures

The combination of its own product problems and BD's aggressive effort to hold on to its US market leadership meant that within a short time, Terumo's efforts to break into the US hospital market foundered—though the company was successful in reaching the alternate site market—and prices began to level off. In fact, in the early 1990s, BD even saw small price increases for a couple of years. By the mid 1990s, however, with the advent of managed care and the consolidation among hospital groups that led to the emergence of strong GPOs, such as HCA, Premier Inc., and Novation, prices begin to fall again.

Cohen insists that the transition to safety products has shielded BD from some of the pricing pressure that conventional devices have seen over the past twenty years. "The early conventional wisdom was that if conventional devices sold for a nickel and safety products for 20 cents, over time, safety products would sell for a nickel as well," he says. "But that's not going to happen. These are more differentiated products, with a clear need, and a usage mandate in place." For one thing, there's too much invested, in terms of design and materials, to have prices drift down dramatically. "These products cost significantly more to design and make and so they sell for more," says Cohen.

More importantly, hospital group purchasing is limited in what it can do to leverage suppliers in an effort to drive down prices of safety devices. Since safety products are selected by clinician-led product evaluation committees, most GPOs won't write sole-source contracts for them, preferring to offer their members a variety of products on contract. "And the degree to which GPOs can bring pricing leverage to multi-source arrangements is limited," says Cohen, at least in comparison with sole-source agreements.

Still, Cohen concedes that "there's certainly price competition among the safety devices." Moreover, BD is conscious that, notwithstanding the clinical benefits that safety products deliver, their customers are still under tremendous cost pressure. Erika McGovern notes that during the development of the *Safety-Glide*, BD took the opportunity to also focus on winnowing down the number of needle sizes the company offers. "At the time, we started hearing from materials managers that they were looking to control SKUs [stock keeping units], and we saw [the initiative in safety products] as a way of saying to them, 'OK, we don't need to offer every single needle size.'" Such an effort allows the hospital to do some standardization on needles and syringes in selected applications, while still buying more advanced safety designs for other uses.

Indeed, one major issue for hospitals is simply that the conversion of a major product line can be costly and time-consuming, particularly for a line like needles and syringes which had been so effectively standardized at most hospitals. (Ironically, opening the door to conversion works against BD's interests given its high market share in conventional devices.) "We know materials managers aren't jumping up and down for joy over this," notes McGovern. "But they understand how important safety products are and want to play a role."

"On top of everything else, these products have to be cost effective," notes Gary Cohen. "They have to be priced at price points that, if hospitals are required to use them, make them affordable." Cohen concedes that BD's margins are better on safety devices than on conventional devices. "But they're nothing like pharmaceutical margins," he goes on. "In general, we've never operated on sky-high margins; typically our margins on safety products are only slightly higher than on conventional products." (As a corporation, BD's gross margin is around 49-50%; its operating margin is in the high teens.)

In fact, in the early days of safety products, BD's margins may actually have been lower on the new devices than on conventional needles and syringes since BD was spending significant amounts of money on new equipment, plants, and new product designs, and the company had yet to achieve the kinds of scale and critical mass to support the new investments. "We operated on very low margins in anticipation that with higher volumes and scale up, we'd get to normal margins," says Cohen.

### A New Law Becomes a Turning Point

One other difference between BD's efforts in safety devices and innovation in other device areas: end-user training and education takes place not at clinical conferences or lavish off-site CME sessions, but, most often, at the hospitals themselves, grabbing time with the nursing staff between shifts. Gary Cohen recalls waking up at 4:30 in the morning to drive the two hours from his home in New Jersey to one of New York City's VA hospitals to do an in-service for the psychiatry ward. "There's no glamour in round-the-clock in-servicing for safety needles," he notes. "But it's work that has to be done."

But BD officials understand how important such in-training is to a hospital's successful conversion to safety products. At the height of such conversion efforts, BD had over 600 employees dedicated to training in-hospital staff—having added over 400 home office employees to the 200 sales reps serving both the med/surg and blood collection product lines. "You can't just throw products out there and hope the hospital uses them," adds Melanie O'Neill. "One of the things that will make a conversion fail quickly is to sell products into a hospital without having done that floor by floor, department by department in-servicing to make sure that you're supplying a full range of products to meet their needs and working through any problems they have."

The decision in 1992 by OSHA to issue regulations regarding blood borne pathogens represented a turning point of sorts for safety-products. "OSHA effectively canonized the CDC guidelines into regulations that health care facilities had to comply with," notes Gary Cohen. But the real impact of the regulations, for BD at least, would take years to be felt, in some degree because the regulations never actually called for the use of safety-engineered devices. (Rather, they simply

required hospital workers to use gloves, sharps disposals, and other protective items.) The passage in 2000 of federal legislation to enforce the OSHA guidelines was critical in defining and creating a market for safety products and a kind of validation for BD. "There certainly had been progress up until that point [in the transition to safety products]," says Cohen, and even without the legislation, safety-device adoption would have come, he says, "though it might have taken a little longer." But with the law's passage, "for the first time, we could breathe a little easier and say to ourselves, 'We know that all this work and investment is going to pay off.'" (*See sidebar.*)

Because of cost and price constraints, safety products will never be the kind of breakout technology development for BD that, say, drug-eluting stents will be for Johnson & Johnson or [Boston Scientific Corp. \(BSX\)](#). BD will need to rely on a tremendously efficient manufacturing process and a continued leading market share in the needle and syringe, blood collection, and IV catheter businesses to make safety devices a clear winner. But in important ways, safety products have helped to revitalize BD. "In terms of product life cycle," says Cohen, "we were in a later mature phase on our conventional devices; now we're more in a mid-growth phase."

In fact, BD's revival began well before the widespread adoption of safety products. Terumo's entry to the US market in the early 1990s was, in Cohen's words, "a kind of wake-up call" for the company. Terumo's announcement that it was going to build a facility in the US "was not going to go unnoticed here," he says. Terumo was, after all, BD's largest competitor on a global basis, and the incursion, so close to home, prodded BD into action. "In retrospect," says Cohen, "it was very good for us because it was a stimulant for us to focus on what we do best: improving our product line and developing new products, and reinforcing our relationships with customers and distributors."

#### Revitalizing a Tired Line

Cohen concedes that after years of standardization efforts and cost squeezes, product areas like needles and syringes and blood collection devices had grown tired, almost taken for granted by both BD and its customers. "The products were so routine," he says. "But we knew that with the entry of our largest global competitor in our largest product market, everything would be thrown up in the air. People would be doing evaluations and reading advertisements and getting sales calls again." In fact, BD started advertising in nursing journals for the first time in decades, ads that scored among the highest for those publications in terms of reader response. "Our first response was surprise," Cohen admits. "We thought, 'Who wants to read about needles and syringes?' But we knew we had to make sure that when customers decided which products to use, they were going to choose ours."

BD faced a similar competitive challenge in the mid 1990s, when the company's other major competitor, Sherwood Medical Products, was acquired by Tyco, though the impact was considerably less, if only because, given Tyco's strategy of emphasizing low-cost manufacturing, the company did little in the way of aggressively developing safety devices and therefore put considerably less pressure on BD to innovate and differentiate its products the way Terumo did. In the end, BD's efforts to hold off the new competition worked, perhaps better even than company officials expected. Today, Terumo is a major competitor in the alternate site market, but has yet to gain significant share in US hospitals. Ironically, Terumo faced the same issues around scale in launching its conventional device business that BD would face in safety syringes: when you have to make a huge investment in manufacturing and equipment, if the anticipated volumes don't materialize, you're stuck with a highly unprofitable business. (BD itself faced similar issues when it tried to enter Terumo's home turf, the Japanese market.)

More importantly, since, in response to Terumo, many of BD's product development and marketing initiatives began in its conventional device business, Terumo's entry, in effect, helped spike BD's then nascent efforts in safety devices. "We were so energized by the effectiveness of what we were doing," Cohen goes on, "we turned some of that energy into the resolve around safety issues." Indeed, he notes, many of the same people at BD who were behind its very

successful defense of its conventional business transitioned to working on safety products. "As we put more resources in place to defend our market position, we turned those resources into a positive effort here [i.e., safety products]."

But with the Terumo threat neutralized and safety products now mandated in US hospitals, what's next for BD? What will drive the company in the future? Safety issues will continue to be critical, particularly on an international scale. While US health regulatory policies are now squarely supportive of safety products, policies and practices elsewhere around the globe fall well short. Outside the US, reuse of injection devices is a much greater health problem than needle sticks, and in the early 1990s, BD pioneered the development of needles and syringes that can't be used more than once. It's also working with organizations like UNICEF and the World Health Organization to actively promote the use of these products in developing countries and with groups like the Gates Foundation to provide financial support for their dissemination.

There are related third-world problems around issues such as neonatal tetanus, which BD is helping to address with its products and philanthropy. BD officials acknowledge that an important driver in the US is the financial benefit of migrating customers from conventional to safety devices. But they insist that their strongest motivation comes from what Gary Cohen calls *kaizen*, a Japanese term meaning a constant push for self-improvement. "I know it sounds corny," he says. "But what drives us is simply a desire to make absolutely the best safety devices we can. There's a lot of intensity here around that. When we see a new safety device, we're all over it, because we never want to be perceived as second best." Clinical Lab's Bill Kozy agrees, "There was a tremendous momentum, a release of energy as we started to do this. Rarely in a big corporation do you get that kind of energy, but as we got into this, BD became a very exciting place to be."

Exciting, intense: unlikely descriptors for a company that, given its product line and strong market position, is more often perceived as stodgy and not particularly innovative. For BD officials, the perception comes with the territory. Particularly in today's business climate, large companies with leading market positions are always subject to skepticism about where their real motives and interest lie. But perhaps even more, the perception comes from the nature of BD's products and gets at the very heart of the challenge of innovating in mature product categories. Over the past decade, in the highly cost-constrained world of hospital supply, suppliers have been rewarded for giving customers what they want—high quality products at lower and lower prices—not with strong economic gains, but, if anything, with weaker positions, both financially and competitively (see "*Hospital, Heal Thyself*," IN VIVO, October 2001).

BD insists that it has resisted that dynamic, jumping early on the safety products initiative to revitalize its product offerings based on a clear and demonstrable benefit to customers. Of course, BD is far from the only company to have benefited from or created innovative products in safety devices; in reporting its most recent financial results, New Medical Technologies, a small manufacturer of retractable syringes, noted that sales for the first four months of 2003 beat analysts' forecasts, largely because of strong demand for its first-generation safety syringe. And the fact that large national GPOs are signing multi-source agreements on safety devices suggests that their member hospitals see companies other than BD as having strong, attractive technology in this area, a perception that could challenge BD's unquestioned pre-eminence in needles and syringes.

Still, despite a clear clinical and workplace benefit, safety devices will never have the clinical impact or capture the imagination the way other medical technology advances do. Asked about the perception that BD and companies like it spend more time defending tired technologies than truly innovating, Gary Cohen shakes his head. "Think about the position we'd be in today if we really behaved the way people say most big companies behave," he says. Let's say, he goes on, that BD *had been* asleep at the wheel, that it spent all its time and resources protecting its core business and had no interest in innovation, and that it came to the safety products market five years late, after other companies had already taken the lead on the kinds of products that hospitals now have to buy. "Where would we be then?" asks Cohen. "On the defensive from a

reputation point of view, trying to play catch up while watching our market leadership quickly drain away." Despite, or perhaps because of its strong market leadership and leading role in innovation and education in safety products, BD has drawn its share of critics over the years. But whatever else BD has done, it surely can't be accused of playing it safe.

### *We're from Washington and We're Here to Help*

Most product companies spend their days railing against the strict enforcement of federal regulations. But in the case of conversion to safety devices, a coalition of device manufacturers, working in conjunction with representatives from labor and nursing groups, actually found themselves actively promoting a more aggressive government role, culminating in the 2000 passage of the *Needlestick Safety and Prevention Act*.

Technically, notes Kevin Seifert, who played a key role in leading Becton, Dickinson & Co.'s Washington efforts, the legislation simply reinforces the 1992 OSHA regulations around blood borne pathogens, requiring hospitals to evaluate and adopt safety devices that help prevent the spread of infection by contaminated blood. Technically, too, the law doesn't require hospitals to adopt safety devices in all cases. In fact, there are even some qualifications written into the law regarding safety product use: utilization can't negatively affect patient care, the law can't discourage future technology innovation, and, safety product selection will be made by customers through a clinical evaluation process. But the process of getting a waiver to use a conventional device is onerous, and hospitals that fail to use safety devices where appropriate are subject to a \$10,000 fine, per incident.

The law was a boon for BD, not just for putting more teeth into the existing regulations, but also because the original regulations didn't call for the use of safety devices to prevent needlestick injuries. "It covered gowns, gloves, masks and products like that," says Seifert. "But hospitals quickly realized that sharps were not part of the compliance effort."

Just as important, the law helped make safety products and procedures part of the hospital's protocol. BD officials note that one obstacle to adoption of the devices was that there was no established procedure by which hospitals incorporated safety devices broadly across the institution. "There were all kinds of products and many times the nurse would come on shift and there wouldn't be the product she's accustomed to," notes Gary Cohen. "So we had to go through a re-standardization process in hospitals."

BD officials resist suggestions that earlier regulations failed to catch on because the primary victims of needle-stick injuries are nurses and non-clinical health care workers, people who aren't high on the hospital pecking order. But Ed Thompson notes that, legislation aside, one recent push toward safety devices has come from the worsening nursing shortage. "There's an historical cultural issue here, and the increasing value of nursing, given the shortage of nursing staff, is part of that," he says. More and more, he notes, hospital systems, such as Kaiser Permanente and Catholic Healthcare West, are using safety device protocols as a recruiting tool. "With salaries and benefits just about equal, the argument they're making is that they offer a safer environment because they provide safety devices across all major product categories," he says.

Interestingly, it wasn't concerns about AIDS or hepatitis B that brought infection control and blood-borne illnesses into the spotlight, but a surge in the number of cases of hepatitis C. "If you see what hep C means to health care workers and for patients, it's really serious," notes Kevin Seifert. "There's no vaccine and the drug cocktail is something people really don't like taking." As the number of hepatitis C cases reported by CDC has grown, so has the clamor for measures to safeguard health care workers.

Efforts to promote a national safety product law began in late 1998, following a statewide initiative in California, and adopted a two-track strategy, notes Seifert. Over the next two years, 26 states passed similar laws, and a coalition of nursing groups, representatives of health care workers, regulatory officials from OSHA and CDC, and product companies, some 32 in all working through

AdvaMed, the medical device trade association, lobbied the remaining 24 states to pass similar laws. At the same time, they continued to work for a national bill.

Earlier bills to mandate regulatory compliance stalled because they called for funding, albeit small (\$6-7 million) for research on needle-stick injuries; re-written without the funding provision, the bill sailed through both houses of Congress with little real opposition. Indeed, the vocal support of Representative Cass Ballinger of South Carolina, a conservative Republican with a track record of opposition to OSHA who co-sponsored the legislation, was illustrative of the bill's broad support and helped to win over other legislators.

The breadth of the coalition also helped. "Lawmakers saw industry, labor, and regulators all supporting this and saying essentially the same thing," says Seifert. But while BD and other product companies worked hard behind the scenes, they played a less public role, primarily to avoid appearances that they were promoting the legislation because of potential economic benefit. Though the overall financial impact on the hospital is relatively small—"It's not like we were coming in with a drug that costs ten times what the current therapy costs," he notes—Seifert argues that had BD been perceived as leading the charge, there would likely have been more skepticism about the goals and values of the legislation's supporters.

Gary Cohen notes that suppliers in general and BD in particular faced a damned-if-you-do, damned-if-you-don't dilemma. If they pushed too hard, they were accused of doing so to sell higher-priced products; if they didn't push aggressively, they were accused of defending their existing line of conventional devices and denying the clear benefits of the new devices for health care worker safety. "In the end, we couldn't really let those criticisms alter our course," he says. "We were focused on this because it was the right thing to do."

### *Drawing Blood Safely*

Given the importance of needle-stick injuries to the whole safety debate, it's clear how Becton, Dickinson & Co.'s core needle and syringe business is affected by the mandate to convert to safety products. But there's a second business at BD that is at least as directly affected: the BD Clinical Laboratory Solutions unit, which embraces both its *Vacutainer* blood collection devices and its microbiology diagnostic testing business.

Indeed, notes Krista Thompson, VP and General Manager, Preanalytical Solutions for Clinical Laboratory Solutions, the reason BD calls its blood collection business "preanalytical solutions" is that the way in which you draw blood and control the preanalytical variables has a huge impact on the analytical or diagnostic process. Thus, she goes on, BD officials realized quickly that in designing a new safety device, "we had to make sure that the device retains the integrity of the sample."

From the very beginning, the drawing and capturing of blood, often involving hollow, blood-filled needles, was at the heart of the safety concerns that began to be raised in the late 1980s. Bill Kozy notes that the first infection prevention measures focused on the risk to lab workers from the splatter and spillage that comes with handling blood specimens. Thus, *Vacutainer's* first safety product, the *Hemoguard*, introduced in the late 1980s, focused on making sure the blood sample was closed properly and wouldn't splatter if the cap was removed from the tube. "What we were trying to do is to allow the worker to access the specimen while dramatically reducing both aerosol and blood spatter," he says.

But, like its counterpart in injection devices, *Vacutainer's* safety initiative soon shifted from containment to protection, and a winged-set product that was a variant of the *Safety-Lok* needle was introduced in the early 1990s. Over the course of the next several years, Clinical Lab Solutions would offer other safety devices, including the *Eclipse* blood collection needle with a pivoting shield, and would begin a conversion to plastic collection tubes that, unlike the glass tubes that had been a staple, couldn't break with a lot of handling. "By the time specimens get to the lab, they go through all sorts of manipulation and handling," says Kozy.

Not surprisingly, as the *Safety-Lok* and *Eclipse* variations suggest, BD officials note that, while each business unit had its own product development group, there was extensive collaboration and coordination between the BD Medical Systems and Clinical Lab Solutions teams, particularly around key platform technologies such as safety and pivoting shields and springs and hinges.

Yet both businesses were ultimately responsible for their own developments because of important differences between the two. Krista Thompson notes that, in many respects, "the blood collection process is a totally separate process from injecting someone or putting an IV catheter into them," adding, "We do share technologies," but because each division's safety products "are used for different clinical purposes, we have to refine those technologies to make sure they work for our clinical procedure." Adds Bill Kozy, "We did a lot of sharing at the appropriate points, but as soon as product development started getting close to the customer, we had the injection people spin off and focus on nurses, while we focused on phlebotomists." (Phlebotomists are *Vacutainer's* key customers, particularly in a hospital setting, though there are many hospitals—and, of course, alternate site settings such as physicians' offices, where they share a common customer with Medical Systems in nurses.)

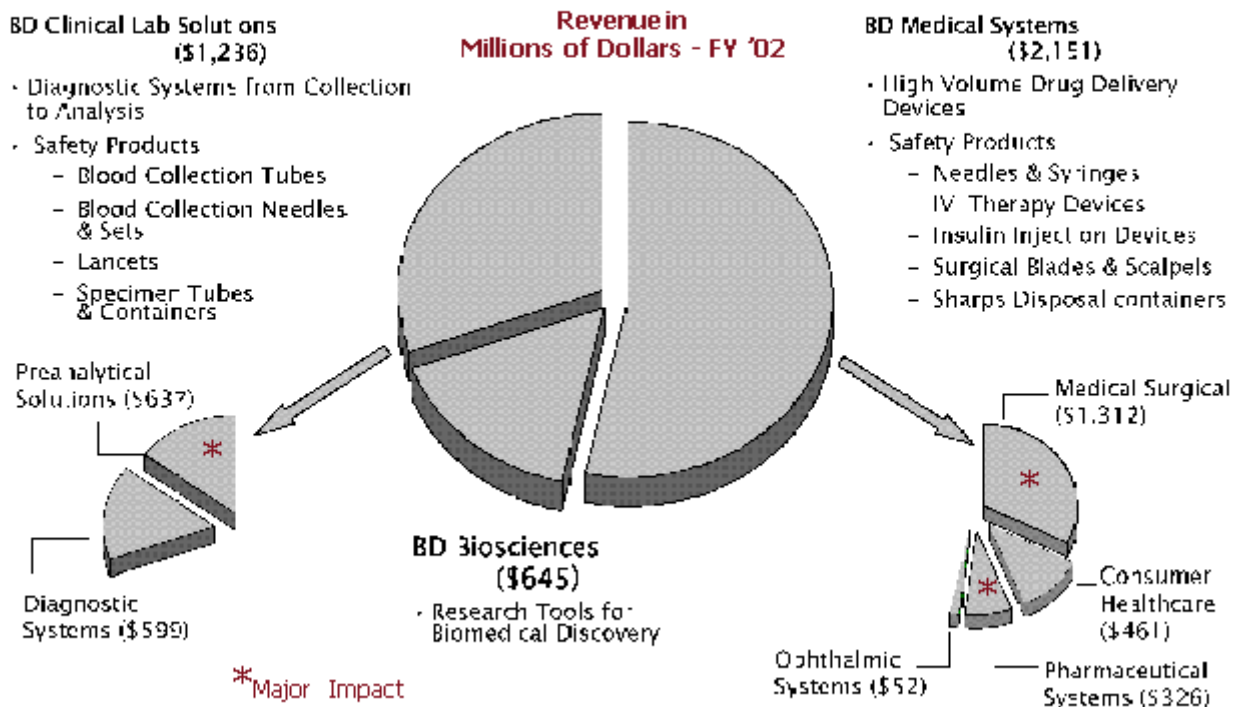
Interestingly, adoption of safety devices by phlebotomists and lab workers was much more rapid than by nurses, reaching near 90% penetration in some categories by the mid 1990s. By their very nature and training, phlebotomists are more likely to be sensitive to the risk of blood-borne infection; at the same time, early education efforts, particularly around AIDS and hepatitis B, by federal agencies helped to stimulate awareness. "In the early to mid 1990s, the CDC became very aware of the viral risks associated with handling blood specimens," notes Kozy. "And while there were no regulations issued, there was quite a bit of communication from CDC about the risks of collecting and handling specimens. The phlebotomists and lab workers were probably more sensitive to this issue than the general health care community."

But in other ways, *Vacutainer's* development process mirrored that of its sister needle and syringe business. For one thing, the design and manufacturing process is deceptively complex. Notes Krista Thompson, "We produce three hundred of our devices each minute and have 18 different quality control steps along the production line." At the same time, manufacturing efficiency is critical because the price premium for a safety device isn't all that great—an increase from around 50 cents for conventional blood collection sets to 70 cents for safety. Indeed, one of the challenges BD has had is that the enhanced features of its blood collection safety line aren't always apparent. "A lot of people look at the device and say, 'That doesn't really look different, why do I have to pay more?'" says Thompson.

In-servicing and training are also critical. "You'd be amazed at all of the different places in the hospital where our products are found," says Thompson. But perhaps most importantly, Kozy and Thompson insist that Clinical Lab Solutions began to develop safety products, well before their customers or federal regulators mandated it, simply because it was the right thing to do. Asked about whether the potential of safety devices to transform blood collection was a factor in BD's development efforts, Krista Thompson shrugs. "We didn't start out thinking safety devices was going to be the next new thing," she says. "We were thinking that we have a customer who has a problem. People were getting stuck with winged sets, and glass tubes were breaking in the centrifuge. We knew we had to solve those problems." Bill Kozy agrees: "One of the things that you have to understand about BD is that it's heavily driven by its values. Once it became obvious that this was the right thing to do for our customer, I never heard anyone here question it."

## BECTON, DICKINSON'S BUSINESS SEGMENTS

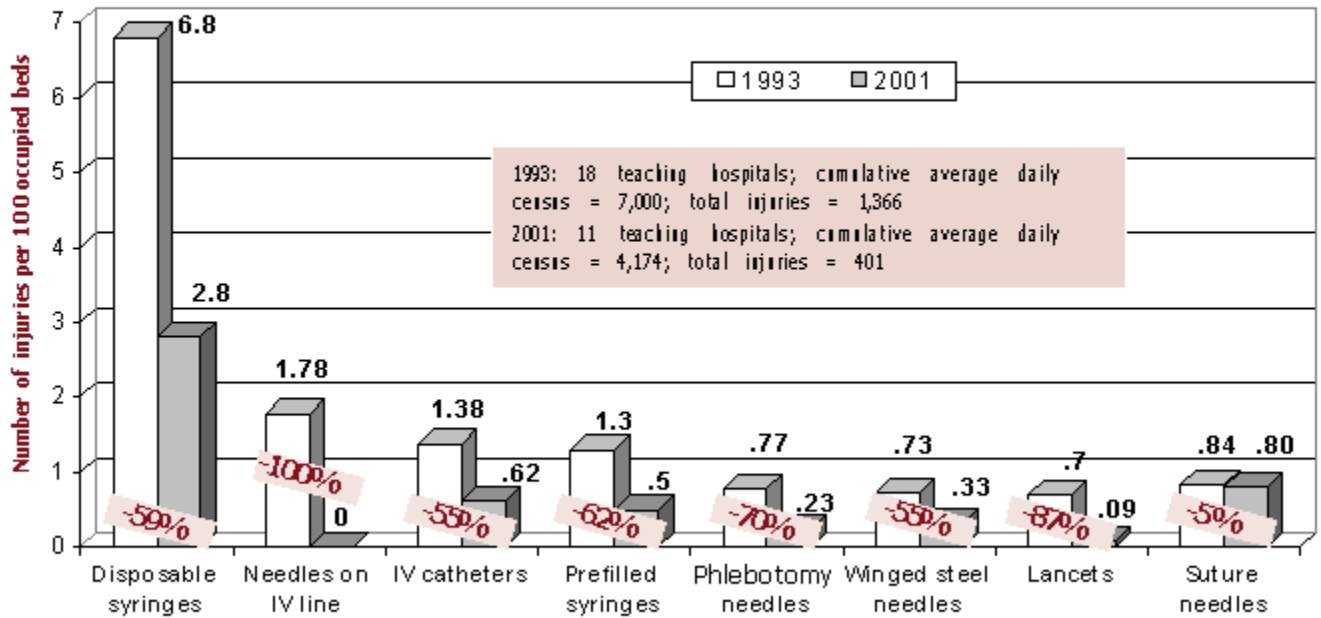
Exhibit 1



SOURCE: Becton, Dickinson & Company

## COMPARISON OF 1993 AND 2001 PERCUTANEOUS INJURY RATES FOR NURSES

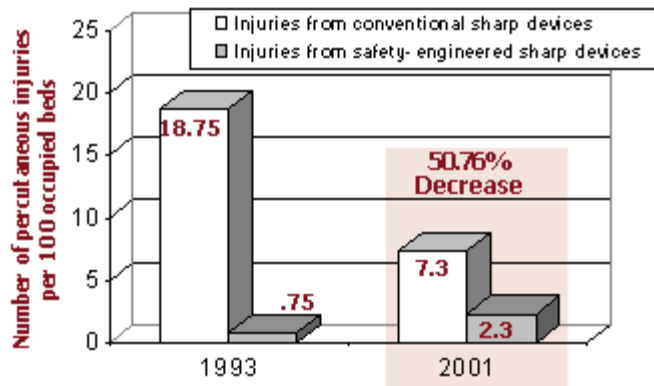
Exhibit 2



SOURCE: International Healthcare Worker Safety Center, University of Virginia

## COMPARISON OF PERCUTANEOUS INJURY RATES FOR NURSES

Exhibit 3



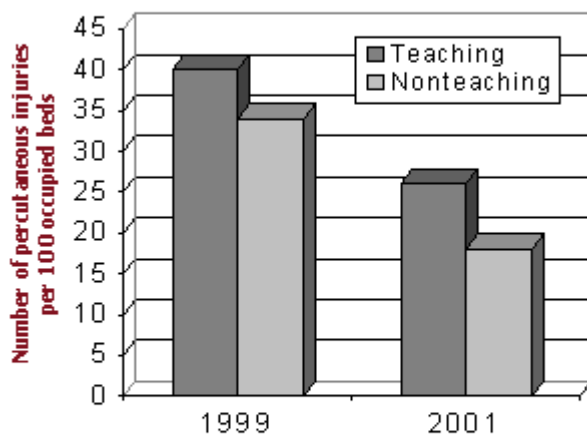
1993: 18 teaching hospitals; cumulative average daily census = 7,000; total injuries = 1,366

2001: 11 teaching hospitals; cumulative average daily census = 4,174; total injuries = 401

SOURCE: International Healthcare Worker Safety Center, University of Virginia

## USEPINET 1999 AND 2001 PERCUTANEOUS INJURY RATES

Exhibit 4



1999: 21 healthcare facilities (12 teaching, 9 nonteaching); average daily census = 5,118; total injuries = 2,025

2001: 58 healthcare facilities (13 teaching, 45 nonteaching); average daily census = 8,703; total injuries = 1,929

SOURCE: International Healthcare Worker Safety Center, University of Virginia