

San Francisco Chronicle

NORTHERN CALIFORNIA'S LARGEST NEWSPAPER

THURSDAY, OCTOBER 29, 1998

DEADLY NEEDLES

Last of Three Parts

World in Turmoil

Epidemic's Devastating Toll

By the early 1990s, miscalculations and missed opportunities by health officials, needle manufacturers and relief agencies had exacted a terrible price. Unsafe injections were destroying millions of lives and costing hundreds of millions of dollars every year.

*By Reynolds Holding
and William Carlsen
Chronicle Staff Writers*

Thika District Hospital Thika, Kenya

No matter how many times the memory plays in his mind, Dr. Warura Mogo cannot think what he would have done differently.

It was 1994. About 120 children waited for vaccinations outside his office. But he had only 20 disposable needles and syringes.

Mogo, a pediatrician and AIDS researcher, knew the risks. He could immunize 20 children and send the rest away, leaving them vulnerable to measles, mumps and other potentially lethal diseases.

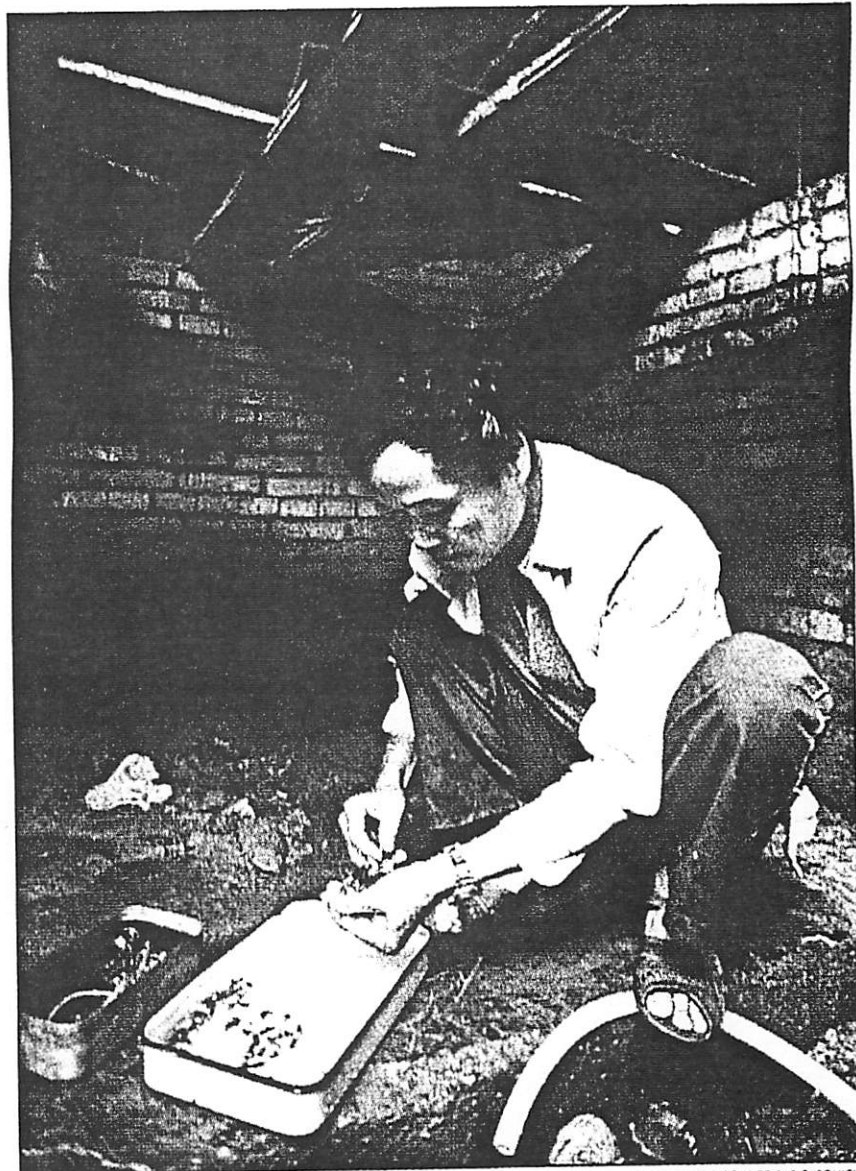
Or he could vaccinate every child, quickly boiling the syringes after each injection — knowing that if just one child carried HIV, hepatitis or some other blood-borne virus, the others might get it, too.

"The question was," he said, "would I turn people away, or do I make use of the situation I am in to give health care?"

Thousands of health care workers in every corner of the globe would face the same wrenching dilemma that year.

For decades, researchers had warned that reusing contaminated needles and syringes could transmit disease with deadly ease. Nothing seemed to prevent it. Sterilization programs failed, and inexpensive disposable syringes proved as dangerous as the glass syringes they replaced.

By 1994, health care workers like Mogo stood at the center of an international health crisis, a "ghost" epidemic claiming more than a million lives each year. But the world would be



BY DAN GROSHONG/SPECIAL TO THE CHRONICLE

IMMUNIZATIONS: Page A10 Col. 1

Wong Wing Fu washed his syringes in water after seeing a patient in Yunnan province, China.

Immunizations — Life-Saving, Life-Threatening

From Page 1

unprepared — and unwilling — to confront it.

Even after receiving reports of billions of unsterile injections every year in developing nations, world health officials would downplay the crisis.

Despite the soaring death toll, major syringe manufacturers would expand global markets for traditional disposables — and in the process be accused of sabotaging small competitors and intimidating foreign officials.

Nonreusable syringes, the best hope for a new era of safe injections, would reach few health care workers, even though the devices had been developed nearly a decade earlier.

And amid the turmoil, doctors like Mogo would be left to fend for themselves.

On that day four years ago, Mogo made the decision that troubles him to this day. He vaccinated all the children.

"I used what I had," he said.

World Health Organization Geneva

For Peter Evans and other WHO officials, the news was bad and getting worse.

In 1994, surveys showed that each year in the developing world, up to a third of the 1 billion immunizations — and half of the other 9 billion injections — were unsterile.

And using a mathematical model created two years earlier, researchers calculated the risks of reusing contaminated syringes. The initial findings, though incomplete, were "alarming," the researchers said.

The new information put Evans, a WHO immunization expert, and his colleagues in a bind.

Publicizing the dangers of unsafe injections could undermine the agency's immunization programs by deterring parents from having their children vaccinated against such deadly diseases as tuberculosis, diphtheria and tetanus.

But failing to alert the public could unnecessarily expose millions of people to HIV, hepatitis and other lethal viruses.

One high-level WHO official called it a "schizophrenic" situation akin to "walking on a minefield."

In the end, Evans said, he and his colleagues would "low key" the crisis — and protect the immunization programs to which they had devoted their lives.

Ministry of Health Yamoussoukro, Ivory Coast

They rose slowly, one by one at first, then in clusters of a dozen or more.

Before long, the entire chamber was filled with ministers of health and their entourages from 50 African nations, standing and applauding.

It was March 1994. Dr. Maurice Kaku Guikahue, the host and health minister from the Ivory Coast, had just endorsed a declaration on safe injections.

The declaration committed everyone involved with immunization programs to make injections safe, to ensure that 95 percent of vaccinations would be sterile by 1997 — and to use autodestruct syringes whenever possible.

It was already costing hundreds of millions of dollars every year to care for victims of unsafe injections, according to world health officials, and Third World nations were suffering the most. But it would cost no more than an additional \$50 million a year to supply all immunization programs with autodestruct syringes.

The troubled continent, with the highest disease rates in the world, had issued a desperate message: We must have the same health care that the developed world has.

UNIVEC Garden City, N.Y.

For Joel Schoenfeld, the timing seemed perfect.

The Ivory Coast declaration had helped boost demand for nonreusable needles. UNICEF faced back orders for 32 million, and its two main suppliers, Becton Dickinson and Bader and Partner, failed to keep up with the requests.

And Schoenfeld's prototype for a simple, inexpensive autodestruct

syringe had intrigued one of the world's largest syringe makers: Sherwood, Davis & Geck.

"They said they knew syringes were spreading disease," Schoenfeld said. "So they talked about doing a joint venture."

The idea made sense. Schoenfeld's company, UNIVEC, needed Sherwood to mass-produce components for the syringe. Sherwood could use UNIVEC and its state-of-the-art prototype to enter the rapidly expanding market for safer syringes.

"Given the potential of the product," Sherwood Vice President Michael Riddle wrote to Schoenfeld, "I am sure our relationship will develop into one of significant mutual benefit for our companies."

The prototype exceeded standards set by WHO and the Federal Drug Administration, and UNIVEC agreed to buy components for at least 50 million autodestruct syringes a year over the next five years — exclusively from Sherwood.

In mid-1995, UNIVEC began negotiating with UNICEF, offering to supply 20 million autodestruct syringes.

When the relief agency said it was interested, Schoenfeld figured he was in business.

UNIVEC Garden City, N.Y.

It didn't take long for the deal to unravel.

By April 1995, production of the syringes had run into delays. After waiting four months for syringe components, UNIVEC discovered that Sherwood had never ordered molds to make the syringe plungers.

In May, Sherwood agreed to manufacture 1,000 sample devices for UNIVEC to show UNICEF. But when the autodestruct syringes were delivered several months later, the needles fell off easily, and the agency declined to pursue UNIVEC's offer.

A year passed before Sherwood finally delivered the first shipment of autodestruct-syringe plungers to UNIVEC — but they were all defective, according to Schoenfeld.

"You name an excuse, they had it," he said.

Schoenfeld is convinced that Sherwood never intended to make an acceptable product. He has sued the company for fraud, claiming its "actions were designed ... to destroy (UNIVEC's) ability to compete."

Sherwood refused to comment, citing the pending lawsuit.

But UNIVEC wasn't the only small firm having trouble getting its autodestruct syringes into the hands of health care workers.

Atlas Medical Resources Nepean, Ontario

When Douglas Campbell was volunteering at a drug treatment center in downtown Ottawa, he thought the organization was helping addicts by giving them clean disposable syringes.

But when the regulars started to arrive with HIV, he realized they had contracted the virus by sharing the syringes.

So he designed a syringe that could not be reused. It contained two blades that cut through the barrel as the plunger was pulled back a second time, disabling the syringe after one use.

In 1994, Campbell, owner of Atlas Medical Resources, approached UNICEF and other U.N. agencies

with his simple design.

Agency officials seemed interested. They knew they were facing an epidemic, and they knew their two suppliers were not meeting the escalating demand for autodestruct syringes.

But after a series of encouraging meetings, Atlas still had no contract.

"We've had hundreds of meetings in New York with U.N. agencies," Campbell said, "and every one has been successful individually. They (U.N. officials) know precisely about the danger: That reuse is killing millions and that this (autodestruct syringe) would stop reuse."

"But then they don't order any."

UNICEF Procurement Office Copenhagen, Denmark

UNICEF contends that Atlas never entered the agency's bidding process.

But the agency hadn't put out bids for autodestruct syringes since 1990, even though its two suppliers — Becton Dickinson and Bader — fell so far behind that the agency stopped taking new orders.

In 1994, despite the supply problems, UNICEF extended its agreements with Becton Dickinson and Bader for four years.

By 1996, UNICEF had requests for 127 million autodestruct syringes, tens of millions more than the relief agency could provide.

The goal set by health ministers at the Ivory Coast summit — to ensure that 95 percent of immunizations were sterile by 1997 — seemed further away than ever.

Becton Dickinson Headquarters Franklin Lakes, N.J.

For Becton Dickinson, 1996 was another record year.

Revenues hit \$2.77 billion — a new high — and offices abroad numbered 50 in 35 countries, including a new factory in China making 300 million conventional syringes a year.

The company also acquired the rights to one of the most intriguing injection devices ever made: A tiny plastic blister attached to a needle with a one-way valve that blocks reuse.

Called Uniject, the device was created with \$2.2 million of federal money by the Program for Appropriate Technology in Health, the same nonprofit group in Seattle that gave Becton Dickinson the design for another nonreusable syringe, the Soloshot.

The company promptly touted Uniject as the centerpiece of a planned UNICEF campaign against tetanus, which health experts said would cost \$100 million to eliminate. Becton Dickinson's contribution: a total of \$1 million over five years, plus \$3 million in donated training, Unijects and other equipment.

Meanwhile, sales of the company's Soloshot syringe stalled after reaching 30 million per year.

Dr. Zeil Rosenberg, a medical director at Becton Dickinson, contends that many countries will not buy autodestruct syringes. "An American company can't waltz into a ministry of health thinking it knows the answers," he explained.

Ministry of Health Brasilia, Brazil

Early in 1996, a federal report revealed that nearly half a million Brazilians had HIV — 22 percent infected by contaminated needles.

Over the next decade, the report predicted, AIDS victims would number 7.5 million, average life expectancy would drop 12.1 years and the male population would fall by 636,000.

"We had to do something," said Brazilian Congressman Elias Murad.

On May 3, 1996, Brazil became the first country in the world to enact a law mandating only nonreusable syringes. Sponsored by Murad, the law was scheduled to take effect by the end of 1996. But it was blocked almost immediately.

Murad contends that Brazil's major syringe makers lobbied the health ministry to suspend the measure because the new devices would cut into sales of their conventional syringes.

"There are powerful people," he said, "who don't want to see the law's enforcement."

Becton Dickinson, Brazil's largest syringe supplier with close to 50 percent of the market, denies any lobbying effort.

The company's quality control officer, Afonso Medeiros, said the law was not implemented because no autodestruct syringes exist in Brazil and the government has not told manufacturers what it wants.

William Kozy, head of Becton Dickinson's injection-systems division, contends that "we have been poised to make the product ready for them. They just never implemented the law."

TECHNET Conference World Health Organization Regional Office Manila, Philippines

It was their first meeting in two years, and many of the 50 immunization field experts who flew to Manila in early 1996 were frustrated by the slow progress toward safer injections.

Countries weren't addressing the problem, said a report of the conference, and nonreusable syringes were still too expensive — more than double the price of standard disposables.

They criticized the World Health Organization for lack of leadership outside Africa and the Western Pacific.

One recommendation: Publicize the dangers of syringe reuse. When a smaller group met later that year, it warned that "the urgency of the issue had become critical."

Surveys from around the globe showed lethal diseases spreading with astounding speed — and syringe reuse compounding the problem.

More than 350 million people were chronic carriers of the hepatitis B virus, and the disease was hitting young children the hardest.

Between 60 percent and 90 percent of infected children under 1 year old — when they are most likely to be immunized — become chronic hepatitis B carriers, compared with only 10 percent of adults. And 25 percent of all carriers eventually die of liver disease.

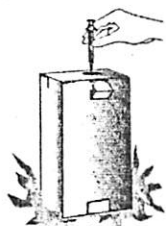
In 1996, more than 170 million people were carrying the hepatitis C virus, which attacks the liver and is even more deadly than hepatitis B.

And 30 million people carried HIV, which infected 16,000 people a day — 12,000 in Africa alone.

DISPOSAL DILEMMA

As health workers switch from sterilizable syringes to disposable ones — conventional or autodestruct — they face a new problem: safely disposing of many hundreds of millions more needles and syringes.

The World Health Organization and UNICEF have come up with two solutions:



Safety disposal boxes:

Thick cardboard cartons are shipped with some syringes for health workers to deposit the used devices. Some boxes are lined with foil and include their own combustion material, making them self-contained units that can be burned in the field.



Field incinerators:

WHO is currently testing small incinerators that can be set up in districts or provinces where health workers can bring syringes for burning. One problem with this method is the air pollution caused by the incineration.

Health officials say the disposal problem has become critical because needles and syringes show up in garbage dumps, where they can injure people or be scavenged for resale.

Health Workers Try to Make Do With Supplies on Hand

Ministry of Health Phnom Penh, Cambodia

In 1997, Cambodia adopted a national policy requiring that disposable syringes be used only once and that enough be available to prevent reuse.

But relief agencies estimate that graft consumes more than half the nation's meager health budget. Medical facilities receive only a fraction of the syringes needed for injections, forcing health care workers to reuse improperly sterilized needles.

"Monies earmarked for the health sector are not reaching the ministry of health, let alone the people," said an official with Doctors Without Borders, a French relief agency.

Thavisak Thasnabunjong, a Thai medical supplier who distributes equipment throughout Southeast Asia, said he has stopped supplying the Cambodian government with disposable syringes.

"The commission I was asked for was too high," he said. "It's the same story with officials in Laos."

In Phnom Penh, midwife Khou Kanika said Mean Chay hospital may receive only five disposable syringes per day.

Piem Row hospital in Prey province must sometimes make 200 disposable syringes last three months — almost an impossibility, said nurse Meah Sunhak.

The shortages have led to a thriving black market.

Nurse Thai Sovannara sells used syringes from his clinic near Chaba market on the outskirts of Phnom Penh. A buyer comes around occasionally to buy a box.

"I don't know where they go," he said.

Republican Center for Treatment of Infectious Diseases Outside St. Petersburg, Russia

Sixteen-year-old Sasha, ashen and exhausted, lay in the AIDS ward with an IV catheter in his arm.

He had come to the decaying two-story brick facility early this summer, traveling with his parents from his home in Kalmyk in southern Russia.

Sasha was 6 when he was infected with HIV through a contaminated syringe. It happened in 1988, during an outbreak that struck down 245 other children hospitalized in and around the town of Ellsta.

Nadzhda Burova, head of the facility, estimates that a third of the children are dead.

"Many die at home, and who knows how many died here," said Burova, whose center is so poor that it can treat no more than 20 children with new combination-drug therapies.

"It's hard working here," Burova said. "The sick never get better."

Both of Sasha's parents are unemployed. And as economic depression deepens in Russia, they don't know how much longer the government-funded treatment of their son will continue.

Sasha tries to stay upbeat. Glancing at the drugs flowing into his arm, he smiled weakly and said he is looking forward to returning to school in his village.

And he still wants to learn how to drive a car, his lifelong dream.

World Health Organization Headquarters Geneva

It was a moment world health officials had been dreading for years.

By June, the first hard estimates were in — and almost impossible to believe. The miscalculations and missed opportunities of the past decade had taken an almost incomprehensible toll.

Using the mathematical model refined since 1992, researchers now calculated that 8.3 million people were contracting hepatitis B every year through the reuse of contaminated syringes.

An additional 1.3 million were being infected with hepatitis C and 31,000 with HIV.

Up to 1.8 million a year would die from the infections, a death rate equal to that from three of the biggest childhood killers — measles, tetanus and whooping cough — combined.

At a June 10 meeting, WHO distributed the figures to 29 leading health experts, including officials from the World Bank, the U.S. Centers for Disease Control and Prevention and the Food and Drug Administration.

Some, like Dr. Ciro de Quadros, director of vaccines and immunizations for the Pan American Health Organization, were astonished.

But others knew that the calculations were, if anything, conservative.

And they had no doubts about what to do next.

"We've got to tell people what the size of this problem is," said WHO official John Lloyd. "They have to know."

EPILOGUE World Health Organization Geneva

Before they adjourned in June, WHO officials called on all nations and relief agencies that finance immunization programs to stop buying standard disposables immediately and to purchase only autodestruct syringes.

The officials also prepared to expand their safety campaign dramatically. For the first time, it would go beyond immunizations to include all 10 billion injections given every year around the world.

It was a profound shift in policy. It would require money, planning, medical training — and the aggressive marketing of autodestruct syringes for uses beyond vaccination.

The campaign would also take partners: manufacturers, health ministries, donor nations and funding agencies such as the World Bank.

"We can no longer do this by ourselves," said WHO official Michel Zaffran.

WHO officials say they plan to publish the final infections and death estimates from syringe reuse next year.

"It has been terribly frustrating," said Lloyd. "The solutions exist. It's just getting them implemented."

Becton Dickinson Plant Maryana, India

A modern, red-brick building rises three stories from the plains of the northwest. Scheduled to

open in January, it is the new Becton Dickinson syringe factory, the centerpiece of the company's 16-warehouse, 300-distributor network in India.

Like the plant the company opened two years ago in Suzhou, China, the factory will churn out hundreds of millions of standard, disposable syringes.

Executives at Becton Dickinson say they would like to sell autodestruct syringes in both countries, but the obstacles are too great.

"If we could convince a country... to use a safety device, a self-destruct syringe, we would be very happy," said Chairman, President and Chief Executive Officer Claudio Castellini. "The problem is that it is very hard to convince them to spend more money."

But Becton Dickinson relies primarily on UNICEF to buy the Soloshot and promote it around the world. And UNICEF is "a passive distribution system" that has "always been nervous about promoting technologies," said Michael Free, vice president of PATH, a nonprofit developer of health technology for developing countries.

After six years of production, Becton Dickinson still sells only about 30 million Soloshots each year. In the two years since it acquired UniJet, the company has not yet put the device on the market.

Meanwhile, Becton Dickinson is using its global sales force and production capacity to concentrate on expanding the market for disposable syringes, a plan that Castellini believes will help double the size of the \$3 billion corporation over the next five years.

"In developing countries," he said, "the strategy is really to convert them from glass to disposable syringes."

Ansari Nagar District Delhi, India

About an hour southeast, in the city's poorest neighborhood, hundreds of children crawl over a 50-foot mound of garbage, combing for syringes, gloves, scraps of bandage — any medical waste to sell on the black market.

Iqbal Malik, who studied India's ragpickers for three years, said it is "absolutely shocking."

In 1997, she uncovered a highly organized, far-flung operation of up to 10,000 people engaged in recycling syringes and other medical waste.

Her environmental group estimates that one-third of the 2.9 billion annual injections in India are administered with washed and repackaged syringes.

"There is a real danger of direct contamination by AIDS and hepatitis B," said environmentalist Ravi Agarwal.

"This is a ticking time bomb."

Chronicle foreign correspondents Sandy Barron in Cambodia, Jack Epstein in Brazil, Steve Fennessey in Egypt, Brian Humphreys in Russia and Andrea Uscem in Kenya contributed to this report.



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Jumps to:



Epidemic Ravages Caregivers Thousands die from diseases contracted through needle sticks

Reynolds Holding, William Carlsen, Chronicle Staff Writers



UNIVERSITY OF WISCONSIN HOSPITAL

MADISON, WIS., 1978

Dr. Dennis Maki, chief of infectious diseases, was unnerved.

On a winter morning a few weeks earlier, a urology technician was inserting an intravenous needle into a patient's arm when the device slipped, piercing the 55-year-old medical worker's finger.

Not long after, the technician fell seriously ill with hepatitis B, and Maki suddenly realized his hospital -- and perhaps the rest of the country -- had a serious problem on its hands.

"This totally innocent victim had become sick," he said, "and we had to try to understand why."

So he and nurse Rita McCormick began to do some detective work. Their groundbreaking research would sound the first alarm over a deadly epidemic of needle sticks that was striking down health care workers at a startling rate.

Over the next 20 years, the epidemic would ravage the nation's medical workers. Thousands of needle stick victims would die of AIDS, hepatitis and other blood-borne infections. Tens of thousands more would suffer serious illness

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CHRONICLE SECTIONS

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DEADLY NEEDLES
SF Gate Special Report

Day Three Stories:

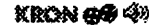
Lead: [Watchdogs Fail Health Workers](#)

[Hospitals Slow to Comply with OSHA Standard](#)

[New Technology, Old Obstructions](#) (timeline)

[A National Epidemic of Risky Needle Sticks](#) (Editorial)

KRON-TV Team Coverage



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[Female Health Workers Face Special Risk](#)

[Ellen Dayton -- Victim of the Silent Epidemic](#)

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Day Two Stories

millions of dollars would be spent every year on replacing and treating dying and infected workers.

And now, researchers fear, a new needle stick threat has been discovered: Untold numbers of female health workers may have suffered serious birth complications from transmissions of incompatible blood.

But it didn't have to happen. Needles with simple safety features -- often costing just pennies more to make -- were available at least 10 years ago. Today, however, few have reached the hands of health care workers, even at the nation's most technologically advanced institutions.

In a six-month investigation, The Chronicle has uncovered a chilling pattern of indifference and neglect within the nation's medical industry. Scores of interviews and thousands of pages of documents show that the nation's leading needle manufacturer suppressed the market for safer needles, at times using tactics that have raised serious legal and ethical questions.

Health care providers, under intense pressure to contain costs, balked at purchasing safer needles, calculating that it was cheaper to buy conventional needles than to save their workers' lives.

And, perhaps most troubling of all, government watchdog agencies failed to enact and enforce regulations that would have protected health care workers from danger.

"It's disgusting that we can allow people to die when we can easily prevent it," said Andrew Stern, president of the Service Employees International Union, the nation's largest health care workers' union.

"When a crane falls or a mine caves in, the government rushes to do something about it. But when health care workers are dying, it's invisible."

Two decades after Maki's unsettling discovery,

Lead: Becton Dickinson Sells Unsafe Needles Despite Risks

Safe Designs Proposed But Not Produced

A Scientist's Fight for Safety

Needle Stick Epidemic - Actions, Reactions (timeline)

Day One Stories:

Lead: Health workers' silent epidemic

Female health workers may face special risk

A nurse's life changed in a moment

Birth of an Epidemic (timeline)

Pipe up
"I have a sincere belief that we who administer programs to protect the health care workers and patients in our facilities must answer these concerns and must make sure that our resources are aimed in the right direction."
--from the Needlesticks topic

Crook or Genius, He's Got Their Attention
02/20/2000

the needle stick epidemic rages on. This year, the nation's 6 million nurses, doctors, laboratory technicians and hospital housekeepers will suffer 1 million needle injuries.

Thousands of them will get hepatitis and other lethal diseases. This is the story of an epidemic that could have been prevented -- how it emerged, why calls for action went unanswered and how health care workers were betrayed by the people who were supposed to protect them.

**BECTON DICKINSON
HEADQUARTERS**

FRANKLIN LAKES, N.J.

Becton Dickinson and Company, a small medical device import business, was founded in 1897, about 50 years after the first hypodermic syringe entered the market.

Even then, medical experts realized they had a problem: Blood-contaminated hollow-bore needles could transmit infectious diseases with deadly efficiency.

Researchers would soon report cases of diphtheria, malaria and syphilis from needles. The variety of diseases would grow into the dozens, with herpes, tuberculosis, even Ebola, joining the list.

By the 1960s, executives of Becton Dickinson knew that hepatitis B could be transmitted by needles -- through both the reuse of contaminated needles and through accidental needle sticks.

"It was probably the reason Becton Dickinson is a \$2 billion company today," said company executive Joseph Welch at a deposition eight years ago.

Welch explained that the soaring number of hepatitis B cases created a huge market for disposable syringes, which would make reusable needles obsolete.

Baby Lawyers Too
Costly to Waste
02/13/2000

Reynolds Holding
Archives:

January

2000

view archive

its stock in 1962, Becton Dickinson began producing tens of millions of the disposable products.

The new disposable syringes reduced infectious transmissions between patients but did nothing to decrease the accidental needle sticks that were spreading diseases to health care workers.

And the company's attention soon turned to making needles sharper, not safer.

The reason: In the late 1970s the Japanese firm Terumo had begun to flood the U.S. market with cheaper, sharper needles.

Within two years, Becton Dickinson overhauled its manufacturing facilities and was mass-producing razor-sharp needles that, in the words of a company advertisement, go through the skin 'like butter. Every time."

UNIVERSITY OF WISCONSIN HOSPITAL

MADISON, WIS., 1981

Dr. Maki and nurse McCormick were ready to publish the first systematic study of needle sticks in the United States.

They had studied 316 reported needle stick injuries over a 47-month period between 1975 and 1979. They investigated how the injuries occurred, who the victims were and how the number of accidents could be reduced.

The researchers were stunned by the high rate of needle sticks at their hospital -- an average of one out of every 12 workers reported being injured every year.

'But we believe," they wrote, 'these figures underestimate the magnitude of the problem."

It was the first indication that needle sticks were a far more serious problem than anyone had known.

And, for the first time, health care workers were warned not to recap needles -- a practice Maki and McCormick found frequently led to needle sticks.

**BECTON DICKINSON
HEADQUARTERS**

FRANKLIN PARK, LAKES, N.J.

Times were good for Becton Dickinson.

The company had overcome the threat from Terumo. Its strategy of signing needle distributors to exclusive, long-term contracts kept Terumo and other competitors at bay and helped establish Becton Dickinson as the world's largest needle manufacturer. It is a position the company maintains today with an estimated 70 percent share of the U.S. market.

But by the early 1980s the dangers of needle sticks had begun to spawn new ideas for making needles safer.

In 1981, for example, Becton Dickinson engineer Michael Bennett filed a patent for a new needle shield. At the same time, his colleagues developed designs for oversized needle covers that make syringes easier to recap as well as devices for clipping off needle points.

But Becton Dickinson did not produce any of the devices, even though "the needle stick problem was obvious at that point," said former Becton Dickinson engineer Robert Stathopoulos, an independent consultant who now works for rival manufacturers.

"The company thought that customers would not pay extra money for any of these safety measures, and they would just cut down on profitability."

In a 1990 suit filed by a needle stick victim, Becton Dickinson Medical Director Edward Duffie offered a candid assessment of the company's response to the needle stick epidemic:

I don't think we did anything, specifically.

SAN FRANCISCO GENERAL HOSPITAL

SAN FRANCISCO

Dr. June Fisher believes she would have been wasting her time if in the 1970s she had tried to persuade convince hospital administrators that needle injuries were a problem.

`If we had had a meeting on sticks at that point, no one would have come," said Fisher, a medical device expert who set up a health and safety project at San Francisco General Hospital in 1978.

`The approach would have been to modify behavior," she said, `to tell health care workers to be careful, to take their time."

That attitude persisted across the nation throughout the decade, undermining efforts to measure the epidemic's scope and leading hospitals to issue orders simply telling employees to be more cautious -- or worse, writing them up if they stuck themselves.

Some critics insist that the epidemic was ignored because of who the victims were: mostly nonunionized female or minority nurses, housekeepers and orderlies with little power.

`We are not considered important," laundry worker and multiple-stick victim Gwyen Spruill told a congressional committee in 1992. `Our work is not considered anything at all."

Even medical workers with clout rarely complained of their injuries, let alone demanded protection.

`A stick has always been viewed as a right of passage, a battle scar, a point of pride -- as in, `I've been stuck six times and never been infected,' said Patricia Wetzel, a Texas doctor who contracted the AIDS virus from a needle stick in 1991.

`The attitude is that if you think about yourself and get protective equipment, you're a sissy."

FOOD AND DRUG ADMINISTRATION

ROCKVILLE, MD.

In 1976 lawmakers gave the FDA the authority to regulate medical devices. The agency's mandate was to ensure the `efficacy and safety" of such products.

But any items marketed before 1976 were exempt from review, which, in effect, allowed manufacturers to continue producing conventional needles.

By 1983 the agency knew conventional needles could be made to be safer, because entrepreneurs had begun asking the agency to review new syringes with safety features.

But the agency took no action to compel the manufacturers of conventional needles to make their devices safer.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

WASHINGTON, D.C.

OSHA issued voluntary guidelines on hepatitis B to the nation's health care employers in 1983.

The agency's notice described the viral disease in detail and recommended work practices including hand washing and the use of a new hepatitis B vaccine.

But OSHA failed to mention the hazards of recapping needles or to convey the urgency of the needle stick problem.

CENTERS FOR DISEASE CONTROL ATLANTA

By the early 1980s, CDC officials knew they had

a serious problem with accidental needle sticks.

Thousands of health care workers were contracting hepatitis B from needle sticks every year -- and hundreds were dying.

In 1985, CDC officials came out with their recommendations to health care workers: Use gowns, gloves, masks and the hepatitis vaccine as protections against infection.

But by then, needle sticks were already spreading a new disease through hospitals and the ranks of health care workers -- a mysterious infection with no known cure that was killing its victims with brutal, tragic efficiency.

The appearance of the AIDS virus did what the hepatitis crisis could not: It put the government and the medical industry on alert.

'Had AIDS not happened onto the scene," testified Dr. Edward Duffie, Becton Dickinson's medical director, in a needle stick victim's 1990 lawsuit against the company, 'little or nothing would have been made of the ... ongoing risks ... to the health care workers.'

SINAI HOSPITAL

BALTIMORE

In February 1982, a 33-year-old housekeeper at Sinai Hospital in Baltimore was taking out the garbage when a discarded needle pricked the palm of his hand.

Fourteen months later, he checked into the hospital's outpatient center complaining of fever, chills, shortness of breath and a cough that wouldn't go away.

Tests were run; his history was checked. The final diagnosis: He had AIDS, and the only way he could have gotten it was from the needle stick a year before.

On June 12, 1983, the housekeeper died, leaving behind a 9-year-old child and a girlfriend six

issue of the medical journal Lancet noted that he was the first health care worker known to have contracted the AIDS virus from a needle stick. The news jolted the medical community. Hospitals and manufacturers began to rethink their passive responses to the dangers of conventional needles.

Still, Becton Dickinson was cautious. Standard needles had lifted the company to the top of the industry, and a sudden move toward alternative products could open the market to rival firms and erode Becton Dickinson's market share -- or worse, expose the company to lawsuits over its unshielded needles.

OFFICES OF DR. DAVID ATEFI

ROSSVILLE, GA.

On April 15, 1985, medical assistant Jenia Hamley was stuck in the left index finger while recapping a Becton Dickinson needle. Five months later, she tested positive for hepatitis B. Worse, Hamley had been five months' pregnant at the time of the stick, and she claimed the infection caused brain damage in her newborn son.

Hamley contended that she had merely followed the product's instructions, which recommended recapping before throwing the needle away. So she sued Becton Dickinson, arguing that its product was unreasonably dangerous.

The company responded that its instructions to recap the needle met industry guidelines in 1985 -- even though four years earlier the study by Maki and McCormick had specifically warned that recapping was a leading cause of needle sticks.

The company also argued that Hamley was a trained medical expert who needed no warning because she knew the dangers of needles better than the company did. It is a defense the company uses to this day.

Becton Dickinson settled the case confidentially

and denied liability.

ADMINISTRATIVE OFFICES

SAN FRANCISCO GENERAL

Managers at San Francisco General Hospital were in the forefront of treatment of AIDS patients, opening the nation's first full AIDS ward in 1985.

But they responded to employee concerns about contaminated needles by merely urging workers to use more caution around needles and to slow down.

'Here was the premier AIDS center in the world, and there was such resistance -- they just kept downplaying the risk to health care workers," said John Mehring, a health and safety officer for the Service Employee International Union.

Mehring and his union, which represented more than half a million medical workers across the country, finally realized that the battle for greater needle safety would never be won piecemeal, hospital by hospital.

So in September 1986, with several other unions that represented health care workers, SEIU petitioned OSHA to issue emergency regulations that would force hospitals to provide greater protections for their employees.

Thirteen months would pass before the agency finally responded to the petition. On Oct. 22, 1987, Assistant Labor Secretary John Pendergrass rejected it, stating that there was insufficient data to grant the emergency request.

Instead, OSHA said it would develop tough new workplace regulations to protect health care workers -- a process that would involve sending notices to 600,000 employers, gathering comments and holding public hearings.

The process would be lengthy, but health care workers were optimistic that the agency was at last paying attention to the needle stick epidemic.

WARD 86

SAN FRANCISCO GENERAL

In July 1987, a young nurse who asks to be identified only as Jane Doe was finishing the 11th hour of her 12-hour shift in the AIDS unit at San Francisco General.

She was exhausted as she withdrew an unsheathed needle from an intravenous line connected to a patient.

Safe line connectors with recessed needles were already in use at hospitals across the country. But they were unavailable at San Francisco General, where intravenous lines were still joined with a hypodermic needle held by adhesive tape.

As Jane Doe held up the intravenous fluid bag, the needle went through the bag and into her finger.

'I think I said, 'Oh, shit,' she said, recalling the horror of the moment. 'I was struck by the irony that in my three years as a nurse, I never had a needle stick.'

Six weeks later, Jane Doe tested positive for the AIDS virus and became the first documented case of a medical worker at the hospital to be infected with HIV through a needle injury.

She was the 13th confirmed case in the nation.

ST. JOSEPH'S HOSPITAL

ORANGE, CA.

Nurse Norma Sampson was concerned about the constant exposure of health care workers to hepatitis B through needle sticks.

'Then, when I read about AIDS,' she recalled, 'I thought, 'Oh, boy, this is worse than hepatitis. People will surely die.'

So Sampson came up with her own solution: A

slide over a needle. With the help of two relatives and a South Carolina engineer, Sampson refined her product.

In 1987, Becton Dickinson bought the rights to the device.

The manufacturer now had the technology in hand to produce a safer product

--one that could slash the number of needle sticks and save thousands of health care workers' lives.

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High Profits -- At What Cost? Manufacturer markets unsafe needles in light of epidemic

Reynolds Holding, William Carlsen, Chronicle Staff Writers THE MARRIOTT HOTEL



THE MARRIOTT HOTEL

NEAR FRANKLIN LAKES, N.J., 1988

Russell Kuhlman felt about an inch high.

Top sales managers for Becton Dickinson and Company, the world's largest needle maker, had gathered for their quarterly meeting, and listed on the agenda was a new device that could dramatically cut into a deadly epidemic of needle sticks among health care workers. Kuhlman, the company's 1987 sales champion, couldn't wait to talk about it.

"I piped up and said, 'This is exactly what our customers need!'"

Laughter rippled through the room.

"Nobody else in that room seemed to get it -- to see that health care workers deserved a safer product," he recalled.

Three months later, Kuhlman turned down an offer to become one of Becton Dickinson's national sales trainers and left for a competitor. He was convinced that Becton Dickinson had no intention of letting its safer devices undercut sales of conventional needles -- the lifeblood of the \$2 billion corporation.

Seven years earlier, researchers had warned that conventional needles were transmitting lethal

Tuesday, April 14, 1998

San Francisco Chronicle
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DEADLY NEEDLES

SF Gate Special Report

Day Three Stories:

[Lead: Watchdogs Fail
Health Workers](#)

[Hospitals Slow to
Comply with OSHA
Standard](#)

[New Technology, Old
Obstructions \(timeline\)](#)

[A National Epidemic of
Risky Needle Sticks
\(Editorial\)](#)

KRON-TV Team Coverage



(Requires [RealPlayer Plugin](#))

[Female Health Workers
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William Carlsen](#)

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Day Two Stories

diseases to the nation's nurses, doctors, laboratory technicians and hospital workers at an alarming rate.

Since then, infections from accidental needle sticks had grown into an epidemic -- and virtually nothing was being done about it.

But by 1988, the medical industry and the government could no longer ignore the emergency.

As many as 12,000 medical workers a year were contracting hepatitis B from needle sticks, according to the Centers for Disease Control. Two hundred to 300 were dying. And thousands more were getting hepatitis C, AIDS and other lethal diseases.

Health care workers demanded action -- in court and in Washington, D.C.

OSHA promised tough new safety regulations. Medical researchers called on needle manufacturers to replace conventional devices with new generation safety needles. And manufacturers such as Becton Dickinson introduced a small number of new designs like the one unveiled to Kuhlman and his colleagues.

At last, there was hope that the medical establishment and the government were taking meaningful steps to prevent the epidemic from needlessly destroying even more lives.

But something would go dreadfully wrong. Just as Kuhlman had feared, few of the safer needles would reach the hands of medical workers. And the epidemic would rage on.

UNIVERSITY OF VIRGINIA

CHARLOTTESVILLE, VA.

On Aug. 4, 1988, the New England Journal of Medicine published a landmark study that for the first time blamed needle sticks on syringe design rather than the carelessness of medical workers.

(Chronicle):

Lead: Becton Dickinson Sells Unsafe Needles Despite Risks

Safe Designs Proposed But Not Produced

A Scientist's Fight for Safety

Needle Stick Epidemic - Actions, Reactions (timeline)

Day One Stories:

Lead: Health workers' silent epidemic

Female health workers may face special risk

A nurse's life changed in a moment

Birth of an Epidemic (timeline)

Pipe up

"I have a sincere belief that we who administer programs to protect the health care workers and patients in our facilities must answer these concerns and must make sure that our resources are aimed in the right direction."

--from the Needlesticks topic

Crook or Genius, He's Got Their Attention

department at the University of Virginia, had analyzed 326 needle injuries. She concluded that preventing needle sticks would involve more than just warning workers not to recap needles, a procedure viewed as a major cause of injuries.

"The optimal solution is to design devices that allow the needle to remain covered during and after use," Jagger wrote.

The article offered manufacturers the first clear definition of a safer device: one that requires little or no training to use, keeps workers' hands behind the needle and has a built-in safety mechanism.

"In this way, (the safety mechanism) is certain to be available precisely when and where it is needed," Jagger wrote. "Moreover, the safety feature . . . should be in effect after disposal, thus protecting the trash handler as well as the user."

Jagger, a brain trauma expert who had earlier pushed to have air bags installed in autos, was optimistic. She said a "historic opportunity" to accelerate the transfer of new needle technology into the workplace was at hand.

"A timely response," she wrote, ". . . can bring about substantial and lasting improvements in an area in which progress is long overdue."

BECTON DICKINSON HEADQUARTERS

Franklin Lakes, N.J.

For executives at Becton Dickinson, the Jagger study posed a serious challenge: How to deal with the inevitable demand for safer needles without jeopardizing the corporation's estimated 70 percent share of the conventional needle market.

Any major shift to safer needles would require significant engineering, retooling and marketing costs, and the new needles would compete with standard designs that the company had offered for decades.

**Baby Lawyers Too
Costly to Waste**
02/13/2000

Reynolds Holding
Archives:

January

2000

view archive

The company seemed determined "to minimize the capital outlay" on any safer device, said Robert Stathopoulos, an engineer at Becton Dickinson from 1972 to 1986. "Why scrap your existing molds when you can modify them and maybe build an additional component for a safety syringe?"

Becton Dickinson had another problem: its ability to design new products. In a 1988 Harvard Business School study about the company, one Becton Dickinson manager conceded, "I'm not impressed with our R&D (research and development) capabilities."

So the company went outside for a solution: A syringe with a simple plastic shield that could slide over a needle. The device was invented by Norma Sampson, a Fullerton nurse concerned about needle sticks.

With the help of two relatives and a South Carolina engineer named Charles Mitchell, Sampson sold the rights to Becton Dickinson in 1987 for a 4 percent cut of future sales. And in 1988, the company introduced the new Safety-Lok Syringe.

But according to Mitchell, Becton Dickinson priced the syringe so high that few hospitals would buy it, leading the patent holders to doubt whether the company really wanted to sell the device.

"We certainly were disturbed," said Mitchell. "There was a tremendous HIV scare at the time, and we thought this was the right product to come to market."

Market studies conducted for the company in 1988 show that although customers expressed "tremendous anxiety and concern" about needle sticks, they had serious reservations about the new syringe's "premium selling price."

Company memorandums and court documents obtained by The Chronicle indicate that the device was initially priced as high as 78 cents --

conventional syringes.

Yet industry experts say the new product would have cost only pennies more to make in full production.

The company refused to comment on its manufacturing costs.

“If they had priced it lower, then maybe they would have sold more early on,” said Richard Coggins, an executive at Mitchell's company.

But a low price would not have allowed Becton Dickinson to maximize profits if, as expected, demand for safer needles increased.

“If you price a new product at a low point,” Coggins explained, “it's very difficult to raise the price as competition comes in.”

According to legal documents, the company felt entitled to the high price because the new device would save hospitals the cost of testing and treating health care workers for potentially lethal needle sticks.

And as premium prices dramatically slowed sales of the safer syringe, they also, in effect, preserved sales of conventional devices, the core of Becton Dickinson's business.

“Essentially, BD owns the market,” says Stathopoulos. “So if they could sell safety syringes to enhance the business, they would. But the strategy was not to replace conventional syringes with a safety syringe.”

Becton Dickinson, though, contends that it has made, designed and patented more safety medical products than any other manufacturer.

“The company considers safety to be of the utmost importance,” said Becton Dickinson spokesman Ronald Jasper.

But other manufacturers have reduced the price of safer needles just to get them into the market.

For example, when Gary Schwalle, vice president of marketing at International Medication Systems, realized the extent of the needle stick epidemic, he knew he had to act -- even if it meant cutting into profits.

So in July 1990, the small Southern California needle manufacturer slashed the price of its Stick-Gard Safety Needle from 45 cents to 19 cents per unit.

"Price," Schwalle said at the time, "should not be an obstacle in protecting health care professionals from life-threatening risks of the HIV and hepatitis B viruses."

MOSCONE CENTER

SAN FRANCISCO

Janine Jagger was frustrated as she prepared to address health care workers at the 6th International Conference on AIDS the summer of 1990.

As part of her presentation, she was to show slides of several new safety devices, including Becton Dickinson's self-sheathing syringes. She had data showing that the devices could eliminate up to 85 percent of needle sticks.

But Jagger felt helpless. It had been two years since the New England Journal of Medicine published her article -- and still there was little progress in controlling the needle stick epidemic.

She estimated that 64 health care workers would get the AIDS virus that year from needle injuries, and thousands more would contract hepatitis.

During her speech, she could barely contain her anger over the high cost of the new, safer needles. Her wrath was directed not only at Becton Dickinson, but at all manufacturers asking premium prices for safer products.

For example, Baxter Healthcare Corp., a major supplier of intravenous line systems, charged five times more for devices that replaced needles

plastic devices cost less to produce than the steel needles did.

“Safety is viewed as an optional market opportunity, of interest only if potential profits appear higher than those earned from conventional, hazardous technology,” Jagger told the Moscone audience.

“Health care workers cannot wait for industry to decide that it is profitable to eliminate unnecessary workplace risks. Until safety becomes mandatory by aggressive regulation, legislation and litigation, health care workers will continue to contract preventable disease while safer technology collects dust on corporate shelves.”

JOHN PETER SMITH HOSPITAL

FORT WORTH, TEXAS

When Patricia Wetzel was growing up on a Minnesota farm, a career in medicine was far from her mind. She was a musician, a flutist so talented that she earned a place at the prestigious Julliard School in New York City.

But Wetzel soon realized that she would be “less than the best in the world,” as she put it, so she quit. And to her parents' disappointment, she chose to become a doctor, one with a save-the-world attitude that would lead her to an AIDS ward in Fort Worth.

By her third year as a resident at John Peter Smith Hospital, Wetzel was known around the hospital as “the AIDS doctor,” one of the only physicians who would go near patients with the fatal disease.

“They were treated horribly,” she recalled, “and it just pissed me off. I couldn't make anyone understand that these were the neediest of the needy.”

One AIDS patient in particular -- a construction worker who had gone home to die -- concerned Wetzel because nurses refused to draw blood at

his nose.

So on a Saturday morning in September 1991, rather than have an ambulance bring him to the hospital for \$600, Wetzel went to the patient's home for blood samples. She completed the procedure and, finding no safe disposal container there, recapped the blood-drawing needle.

Upon returning to the hospital, Wetzel reached for the collection tubes

--and felt a sharp jab.

The cap had fallen off.

She jerked back her hand, shocked to see the blood-drawing needle dangling from her finger.

"You think crazy things," she recalls, "like, 'I should cut off my finger -- if I could just get rid of this finger.'"

A little more than three months later, she tested positive for HIV.

Wetzel sued Becton Dickinson, claiming the unshielded needle that had stuck her was unreasonably dangerous and that the company was negligent in continuing to sell a blood-drawing product it knew could be made to be safer.

In fact, Becton Dickinson had been selling a safer version since 1989. Like its Safety-Lok Syringe, the company priced the new blood-drawing device at a premium: more than double the cost of licensing, developing and manufacturing it, according to court documents.

As a result, many hospitals -- including John Peter Smith -- refused to buy it.

OSHA OFFICE

WASHINGTON, D.C.

When OSHA officials promised tough new safety rules to protect health care workers, there

was optimism that the government was at last paying attention to the needle stick epidemic.

The optimism wouldn't last long.

Within a year of the agency's 1987 announcement, Susan Harwood was having a tough time coping. As director of the agency's risk management office, Harwood was worried that progress on the regulations was going much too slowly.

"What keeps me up at night is knowing that people are dying unnecessarily because OSHA has delayed or failed to get out a standard," she told Congress in April 1988.

Finally, in 1989, OSHA issued its proposed regulations and called for comment. With safe needle technology still in its infancy, the proposal focused on gloves, masks, protective gowns, puncture-resistant disposal boxes and the three-shot hepatitis B vaccine.

In January 1989, Secretary of Labor Ann McLaughlin vowed that OSHA's final regulations would be released by the end of the year.

But it would take two additional years before they were published.

CALIFORNIA HOSPITAL ASSOCIATION

SACRAMENTO

Officers of the California Hospital Association thought little of OSHA's needle stick rules when the agency released them for comment.

The influential association, which represents 467 of the state's hospitals, called the proposals "too expensive, a waste of resources and overkill."

The hospital association was not alone in its reaction to OSHA's draft regulation.

Individual hospitals across the nation

groups complained that the new rules would put them out of business. And dentists mounted a nationwide letter-writing campaign demanding that their representatives and senators block any regulation.

Collectively they sent a clear message to OSHA: Back off and let us handle the problem.

SURGERY DEPARTMENT

SAN FRANCISCO GENERAL

Concern about needle sticks at San Francisco General Hospital reached the boiling point on March 29, 1991, when a medical student was stuck with a contaminated catheter needle while helping prepare a patient for surgery. The patient later tested positive for HIV.

At the time, the hospital was already using a safety catheter -- made by Critikon, a division of Johnson & Johnson -- in its emergency room. But administrators had rejected repeated requests to make it available in other departments.

At that point, at least two other workers at the hospital had contracted the AIDS virus from needle sticks.

Employees filed a union grievance petition, quoting a study stating that 36 percent of the medical staff at nearby UC San Francisco Medical Center had reported needle sticks when dealing with patients at high risk for being HIV-positive.

"The annual risk of acquiring HIV for medical interns at UCSF has been estimated to be four to ten times as high as the annual risk of occupational mortality for California police officers and firefighters respectively," wrote Dr. Peter Lurie, arguing for use of the Critikon needle in every department at San Francisco General.

Hospital managers said they did not buy more Critikons because the self-sheathing catheter cost

too much and had not been proven effective -- the same arguments hospitals throughout the country were using to reject safety needles.

But Lurie had done his homework. He cited studies praising the Critikon for its effectiveness in reducing needle sticks. He also estimated the added cost at \$86,572 per year -- or .027 percent of San Francisco General's budget.

"These costs do not account for the savings produced by the potential prevention of needle sticks," he said, noting that testing and treatment of injured workers would cost the hospital tens of thousands of dollars every year.

Three weeks later, the hospital agreed to make the Critikon available to all departments.

But it was an isolated victory.

OSHA OFFICE

WASHINGTON, D.C.

It was AIDS Awareness Day -- Dec. 2, 1991.

More than five years after health care worker unions petitioned OSHA for emergency regulations forcing hospitals to provide stronger protections for employees, the agency finally issued its "Bloodborne Pathogen Standard."

Meanwhile, tens of thousands of medical workers had contracted hepatitis, and an additional 250 had been infected with HIV through needle sticks.

Under the OSHA regulation, starting in 1992, hospitals and employers would have to give workers free hepatitis B vaccines and supply disposal boxes, protective clothing, gloves and masks.

Buried in the standard, which covered dozens of pages, was the requirement that employers use "engineering controls" to prevent needle sticks. Self-sheathing needles were cited as an example of such controls.

The American Health Care Association, the Home Health Services Association and the American Dental Association immediately filed suit in federal court to block the regulation.

Despite the long delay, the unions praised the new standard. But they worried about how OSHA would enforce it.

Testifying before Congress in February 1992, Bob Moore, a union official from Washington, D.C., called for "clear compliance guidelines" to force OSHA to follow through on the new regulation.

The same day, needle-safety expert Janine Jagger reminded congressional committee members of the stakes involved:

"Today alone, on February 7th," she said, "2,400 health care workers will have sustained preventable needle sticks, and 50 of them will plunge needlessly into crisis and uncertainty as they begin their wait for HIV test results."

Tomorrow: Broken Promises

-- Health care workers infected while OSHA rules were being developed: Approximately 60,000

--Health care workers to die while OSHA rules were being developed: Approximately 250

--Daily needle stick victims: 2,400

--Diseases transmitted by needle sticks: More than 20

THE SERIES

"Deadly Needles" is a three-part series about how the medical industry and government let deadly needle stick injuries run rampant among health care workers. Today's installment covers 1978 to 1987, when the needle stick epidemic becomes apparent to the medical establishment.

DAY 1 (1918-1919): A needle stick epidemic ravages health care workers -- but could have been prevented.

DAY 2 (1987-1992): Health care workers demanding action find a medical establishment in disarray.

DAY 3 (1992-1998): The medical industry and government do very little as thousands die.

THE DEVELOPMENT OF SAFER NEEDLE DESIGNS

By the 1980s, manufacturers knew that their medical needles could spread deadly diseases to health care workers. At the end of the decade, they began selling safer alternatives, but they continued to market the conventional needles in massive quantities.

Health care workers currently use 6 billion needles each year in the United States. The vast majority are conventional needles without safety mechanisms.

STANDARD HYPODERMIC SYRINGE

This device revolutionized the practice of medicine 150 years ago. Uses a plunger and hollow-bore steel needle to inject medications or withdraw blood and other fluids. Once the needle is contaminated with infected blood, however, it can be a dangerous, even lethal, instrument.

First Introduced

1845

Major manufacturers

Becton Dickinson, Sherwood/Davis & Geck, Smith & Nephew, and Terumo.

Approximate price

SYRINGE WITH PROTECTIVE SHIELD

The earliest safety syringe, it provides some protection from needle sticks but has been criticized because two hands are required to push the shield forward and wet hands may slip, exposing the health care worker to injury.

First Introduced

Late 1980s

Major manufacturers

Becton Dickinson and Sherwood/Davis & Geck

Approximate price

26 cents to 35 cents

SYRINGE WITH RETRACTABLE NEEDLE

The latest design for a safety syringe, it requires only one hand to operate and cannot be reused after the needle retracts into the syringe barrel. But the device is not widely available and costs almost twice as much as syringes with protective shields.

First Introduced

1997

Major manufacturers

Retractable Technologies, Inc.

Approximate price

50 cents

BLUNT-TIP BLOOD-DRAWING NEEDLE

Blood-drawing needles are more likely than other needles to transmit infections because they contain large amounts of blood after use. A Centers for Disease Control study published last year found that this device reduced needle sticks by 76 percent -- the highest figure for any blood-drawing device tested.

First Introduced

1991

Major manufacturers

Bio-Plexus

Approximate price

35 cents

WINGED NEEDLE WITH PROTECTIVE SHIELD

Also known as a butterfly, this blood-drawing device is flanked by two plastic wings that serve as handles for inserting and removing the needle. After use, the wings can be pushed forward to slide a protective shield over the needle. The device is also available without the protective shield.

First Introduced

1994

Major manufacturers

Becton Dickinson

Approximate price

87 cents

Sources: Health Devices magazine, industry advertising and Chronicle research

STEVE KEARSLEY / THE CHRONICLE

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First Introduced

1845

Major manufacturers

Becton Dickinson, Sherwood/Davis & Geck, Smith & Nephew, and Terumo.

Approximate price

5 cents to 7 cents

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Approximate price

26 cents to 35 cents

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Sources: Health Devices magazine, industry advertising and Chronicle research

STEVE KEARSLEY / THE CHRONICLE

CHART: (1):

BECTON DICKINSON AND COMPANY/At a glance

The firm manufactures and sells a broad line of medical supplies and devices and diagnostic systems for hospitals, health care professionals, medical research institutions and the general public.

Chief Executive: Clateo Castellini
Employees: 18,900
Offices: 16 states, Puerto Rico and 33 foreign countries
1997 revenues: \$2.8 billion
1997 net income: \$300 million
Total assets: \$12.2 billion
Market value of reported shares outstanding: \$8.6 billion
Safe needles sold: More than 241 million
Slogan: "Helping All People Live Healthy Lives"

Sources: Dow Jones & Company, Inc., Becton Dickinson and Company

Share of Needles and Syringes market as of 1995:

Becton Dickinson	72 percent
Sherwood Medical	23 percent
Others	5 percent

Source: Theta Corporation Data as of March 1998

CHART: (2):
WHO'S AT RISK

Injury reports show that nurses are far more likely to be accidentally stuck by needles than other types of health care workers. In addition, some work environments pose a higher needle stick risk than others.

-- Needle stick incidents broken down by occupation


Nurses	46%
Medical technicians	23%
Doctors	15%
Housekeeper/laundry workers	5%
Other	12%

-- Where needle sticks occur

Patient rooms	34%
Operating rooms	23%
Emergency departments	7%
Intensive care units	7%
Out-patient offices	5%
Clinical laboratories	5%
Others	18%

NOTE: Figures may not equal 100% due to roundingSource: EPINet data network, 1996
Steve Kearsley / The Chronicle

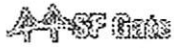
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Hospitals Slow to Comply With OSHA Standard for Safety Devices

William Carlsen, Chronicle Staff Writer



A survey of California hospitals shows hit-or-miss compliance with the 6-year-old OSHA standard that requires use of safety needles to reduce injuries.

Some hospitals have made great strides in converting to safe needle devices, and others are still trying to catch up.

Five years ago, Kaiser Permanente in Southern California moved quickly to switch to safe needles after two unions filed complaints with the California Occupational Safety and Health Administration.

The group of medical facilities, which employs 35,000 health care workers, set up a system to track needle sticks and evaluate safe needle products. By 1994, Kaiser was purchasing large supplies of safe needles, according to Enid Eck, the regional coordinator who led the effort.

At Northern California Kaiser, management claims that its sprawling system of hospitals and clinics is also using safe needles. But employees say the devices are only available in certain sections of Kaiser facilities.

Management acknowledged that its effort has not been coordinated regionwide, as it was in the south, but rather through committees in individual facilities that test and buy safe needle products.

Downsizing and the loss of key people have also affected the process, said Louise Musante,

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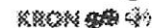
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Day Two Stories

coordinator for the system's employee health services. She said a recent merger of the Northern and Southern California Kaisers will help remedy the problem by allowing the northern facilities to use much of the evaluation data gathered by Eck.

Other Bay Area hospitals have been moving cautiously and are just now meeting the OSHA requirements. At St. Francis Hospital in San Francisco, infection control officer Fred Deneau said the hospital was in the process of fully converting to a needleless intravenous line system, something commonly used in hospitals across the nation.

"It's not necessary to buy the first edition of anything unless you collect books," Deneau said. "You just don't bring in any product. You need to look at them closely to be sure they're effective and safe."

Officials at California Pacific Medical Center, San Francisco's largest hospital, say they started in 1990 to switch to needleless IV systems and to test safety needles, which they now use.

"I'm proud of what we've done," said Barbara de Baun, the hospital's occupational safety officer.

But de Baun was surprised to learn that employees at Visiting Nurses Association, an agency owned and operated by California Pacific, were not supplied with safe syringes.

Home health nurses are particularly vulnerable to needle sticks, experts say, because they draw blood and give injections in uncontrolled environments, frequently with children or animals underfoot and other domestic distractions.

And as insurers limit hospital stays to contain costs, home health care is the fastest growing area of medicine.

"I knock on wood every day that I don't get stuck," said an employee of Visiting Nurses who goes into patients' homes every day -- often to treat HIV-infected patients -- without safety

(Chronicle):

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--from the [Needlesticks](#) topic

syringes. ``It's scary."`

John Mehring, an official with the Service Employees International Union, said that in many hospitals too much of the decision to purchase safer needles depends on particular individuals willing to fight upper management.

``If that manager leaves or moves to a different position," he said, ``the whole effort sometimes comes to a halt."`

``Kaiser (in Northern California) forced us to deal with each individual hospital. It was an incredible burden."`

Cal OSHA, the agency charged with enforcing federal and state safety regulations, has conducted only 13 inspections for violations in California's nearly 500 hospitals since 1992.

``We're a complaint-driven agency," explained Cal OSHA spokesman Rick Rice, noting that the agency targets only ``high hazard" industries for regular inspection. The health care industry does not fall into that category, he said.

Dr. Les Michaels, a senior industrial hygienist for the agency, said the federal regulation was vague on the need for safe needles. ``It's not hard-line, and any control measures can be used to address the (needle stick) problem," he said.

But Michaels was so unfamiliar with the regulation that he said safe needles did not exist when it was issued in 1991, even though they had been on the market for several years. They are specifically mentioned as an example of ``engineering controls" required to prevent needle sticks.

California hospital officials voiced frustration at the lack of national evaluation data for safe needle devices, forcing each institution to test equipment on its own.

They also complained that needle manufacturers have not produced easy-to-use safe devices that allow medical workers to switch from standard

Eck, for example, said evaluators at Kaiser in Southern California rejected by a ratio of 2 to 1 the sliding shield safety syringe produced by Becton Dickinson, the organization's major supplier. The evaluators concluded that the product was poorly designed, she said.

"They own the market," she said of Becton Dickinson, "so they don't work as hard to come up with responsive products. They simply say, 'Here's what we've got.'"

Dr. June Fisher, a San Francisco occupational



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New Technology, Old Obstructions

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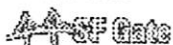
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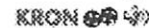
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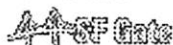
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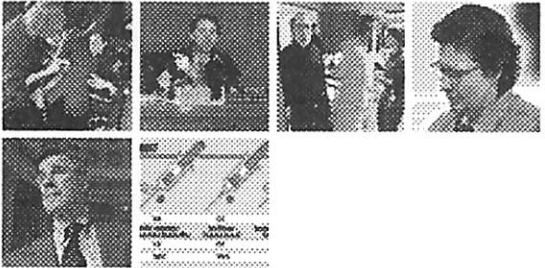
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Watchdogs Fail Health Workers
How safer needles were kept out of hospitals

Wednesday, April 15, 1998
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Reynolds Holding, William Carlsen, Chronicle Staff Writers



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Capitol Hearing Room Washington, D.C.

Congressman Ron Wyden of Oregon, chairman of a hearing on health care worker safety, was out of patience.

It was 1992, 11 years after researchers first warned that needle sticks were transmitting lethal diseases to the nation's hospital workers -- and still the medical establishment had done almost nothing.

Wyden had listened all day as experts, health care workers and needle stick victims pleaded for action by watchdog agencies and the medical industry.

Now, before him sat Charles Adkins, a top administrator at the Occupational Safety and Health Administration, beaming as he touted the agency's new regulation for preventing accidental needle sticks.

“OSHA's leadership in issuing the standard,” Adkins vowed, “. . . will have a far-reaching impact in protecting workers.”

Wyden didn't buy it. “I am very troubled about where we are at this point,” he said. “The safety rule . . . is full of holes.”

them, addressing admins and officials from the Food and Drug Administration and the Centers for Disease Control, Wyden snapped, "It seems to me about everyone has gotten the message except the government agencies. . . . I want you all to move fast."

Instead, they disappeared, ignoring their regulatory obligations and etraying the nation's 8.8 million health care workers.

Today, more than six years later, health care workers still suffer more than 1 million accidental needle injuries a year. Thousands of the injured will get hepatitis C and other lethal diseases. As many as 50 will contract the AIDS virus.

Only 5 percent to 10 percent of syringes used for injections by the nation's medical workers have safety features -- even though the safety technology has been available for more than a decade.

Powerful alliances of hospital- owned buying groups and the nation's leading needle manufacturer have effectively blocked the new technology from the market. The vast majority of the nation's hospitals have failed to buy safer needles in the absence of regulatory or legal pressure.

It was just as Wyden had suspected at his Feb. 7, 1992, hearing. Placing the health and safety of the nation's medical workers in the hands of government agencies would be a grave mistake.

OSHA OFFICES

Washington, D.C.

Within months of the Wyden hearings, OSHA began retreating from its pledge to ensure the safety of health care workers.

The agency's long-delayed regulation unequivocally stated that hospitals and other health care employers in 1992 must start using "engineering controls" such as self-sheathing needles to protect workers from infection.

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--from the [Needlesticks](#) topic

[Crook or Genius. He's Got Their](#)

But four months after the Wyden hearing, the agency's instructions to its inspectors did not require employers to automatically switch to safer needles.

Instead, OSHA told its inspectors that employers needed only to "evaluate" and "review the feasibility" of the new technology.

"It's so bloody vague," Los Angeles OSHA inspector Joyce Simonowitz said of the instructions.

Hospitals were allowed to "evaluate" safer needles indefinitely -- but they were not mandated to acquire them.

"They (the hospitals) keep doing evaluations, but they don't adopt the devices," Simonowitz said. "They don't want to incur the cost."

Even after diluting the regulation, OSHA showed little commitment to enforcing it.

In a letter to concerned health care employers, Compliance Director Roger Clark all but assured them that they had little to worry about.

"OSHA does not currently have a national emphasis program which would target employers in the health care industry," he wrote.

"OSHA is required to respond to serious, formal complaints . . . and it is within that framework that the vast majority of inspections in the health care industry take place."

In the six years since the rule took effect, OSHA's compliance officers have conducted only about 200 inspections nationwide under the regulation.

Cal OSHA, which enforces California's virtually identical version of the federal regulation, has conducted only 13 inspections of the state's 467 hospitals.

"When you look at the rate of needle sticks, the

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(OSHA) standards must come first," said Bill Charney, the health and safety officer at San Francisco General Hospital.

Today, the International Health Care Worker Safety Center at the University of Virginia estimates that more than nine out of every 10 syringes currently sold in the United States have no safety features.

The safety center, which receives funding from needle manufacturers, also estimates that fewer than 25 percent of catheter needles -- considered one of the most hazardous needle devices -- include safety features.

Those figures puzzle OSHA officials.

"That's a surprise to me," said Richard Fairfax, deputy director for the agency's compliance program.

FDA'S CENTER FOR DEVICES AND RADIOLOGIC HEALTH

Rockville, Md.

In April 1992, three top executives from Becton Dickinson and Co., the nation's leading needle maker, made their way to the Food and Drug Administration's offices for a private meeting with top agency officials.

Leading the group was Marketing Director Gary Cohen, 33, a fast-rising corporate star described by one company lawyer as looking like Doogie Howser, television's medical wonder boy.

Cohen and his colleagues wanted to discuss a petition filed with the FDA a year earlier by the Service Employees International Union. The petition called on the agency to phase out conventional needles and syringes and set standards for safer replacements.

"The spread of HIV infection constitutes a national public health emergency requiring urgent steps to curb its transmission," said the union, which represented 350,000 health care workers at the time.

The petition drew wide support. The Centers for Disease Control and even the American Hospital Association, which had opposed OSHA's regulation, strongly backed the union's request.

But Becton Dickinson, a \$2.4 billion medical-devices conglomerate, sent the FDA 11 pages of objections.

Although the company sold both a syringe and a blood-drawing device with safety shields, conventional needles still accounted for almost all the company's needle business.

According to notes of the closed-door FDA meeting, Cohen argued that the regulation being considered by the FDA would stifle innovation and that demand for safer needles was skyrocketing without government help.

Cohen assured the regulators that the market and the new OSHA regulation would take care of the problem.

FDA officials asked few questions.

A year later, in July 1993, the agency rejected the union's petition -- and Becton Dickinson promoted Cohen to vice president.

BECTON DICKINSON HEADQUARTERS

Franklin Lakes, N.J.

Within months of the FDA meeting, Becton Dickinson introduced a full line of safety syringes and proclaimed itself the industry leader in preventing needle injuries.

Advertisements for the company's new blood-drawing device stressed that it ``meets OSHA guidelines."

And in a letter to customers, a Becton Dickinson division president wrote that ``where safety products are involved, we believe the interests of the health care workers should come first."

But doubts soon emerged about whether the company's safety needles were as effective as competing products .

In 1994, ECRI -- a nonprofit that tests medical devices -- said that though the Becton Dickinson Safety-Lok Syringe is safer than the company's standard design, it ``offers poor needle stick protection."

In 1994 and 1995, the U.S. Veteran's Administration ranked the company's safety products below those of several other needle makers.

And despite the company's new advertising campaign, not all of Becton Dickinson's sales agents were emphasizing the safety benefits of the new products.

In a recent suit filed by a needle stick victim, Northern California salesman Martwin Janke said he is unfamiliar with the OSHA regulation, he does not tell customers that safe needles will prevent injuries, and he never warns customers that needle sticks can transmit hepatitis B, hepatitis C or HIV.

``I think that's unfair persuasion to do that," he said. ``I think that would . . . be perceived as manipulative on my part."

RETRACTABLE TECHNOLOGIES

Little Elm, Texas

Thomas Shaw, a Texas engineer with a blunt passion for his work, won a grant from the National Institute on Drug Abuse in 1992 to develop a new syringe that would guard against needle sticks.

It was a remarkable design: An extra push on the plunger snapped the needle back into the syringe barrel quicker than the eye could see. It carries a 50-cent price, about double the cost of the comparable Becton Dickinson design.

started producing the syringe, many health care workers loved it. "Of all the new technology, it's the one I've been really impressed with," said Rita McCormick, a University of Wisconsin nurse and co-author of a seminal study on needle sticks.

And according to Shaw, users of the device have yet to report any needle sticks.

But like many new, innovative safety products, the syringe has a major drawback: Few hospitals will buy it.

Retractable Technologies has sold only 500,000 syringes -- a minuscule fraction of Becton Dickinson's sales -- and has yet to make a profit.

The reason, Shaw said, is the emergence of a powerful force in the medical supply market: Group purchasing organizations.

These buying groups require member hospitals to purchase equipment from specific suppliers. Hospitals that buy from other suppliers risk losing substantial discounts and expulsion from the group.

"Hospitals tell us," Shaw says, "they can't even look at our technology."

PREMIER INC.

San Diego

In January 1996, three large medical-purchasing groups merged to form a behemoth: Premier Inc., an organization so big that it controls buying for about 1,700 -- or nearly a third -- of the nation's hospitals. Those hospitals purchase more than \$8 billion a year in medical equipment.

By the end of 1996, Premier announced an exclusive, 7 1/2-year, \$1.8 billion "corporate partnership" with Becton Dickinson. The agreement requires member hospitals to buy at least 90 percent of their hypodermic needles and syringes, blood-collection devices and other products from the company.

Under the terms of another exclusive contract with a second group purchasing organization called Novation, an additional 650 hospitals must buy 95 percent of their blood-drawing devices and catheters from Becton Dickinson to receive significant discounts.

Both Premier and Novation deny that such contracts block hospitals from purchasing the most effective safety needles.

“Premier seeks and encourages new technology,” said Premier spokeswoman Laura Yandell, “and does not inhibit innovations that improve clinical care, employee safety and the cost of health care.” But according to Russell Kuhlman, a former Becton Dickinson salesman who heads sales for Retractable Technologies: “You can’t even take a safety device into some hospitals because they have a Premier contract and won’t even see you.”

“GPOs (group purchasing organizations) were set up to make better products available for cheaper. Now they just keep new technology out.”

BIO-PLEXUS

Tolland, Conn.

Unable to crack the market's most lucrative accounts, small manufacturers often fall prey to larger rivals.

Clateo Castellini, chairman of Becton Dickinson, has said publicly that the needle corporation plans to grow by acquiring small firms that can't get access to buying groups.

Bio-Plexus has already been forced to cut deals with its larger competitors.

Since 1991, the company has made a blood-collection safety needle that the Centers for Disease Control found reduces needle sticks by 76 percent -- the highest of any blood-drawing product the agency tested.

Bio-Plexus has sold the device to Kaiser Permanente -- at a loss -- and to several Premier clients, but the large buying groups have all but shut it out of the market, company executives say.

Bio-Plexus recently licensed its design to Johnson & Johnson and has negotiated with Becton Dickinson for a similar arrangement.

"These folks have the money and the clout and the access to people who won't let us in the door," said Bill Willoth, until recently the national accounts manager for Bio-Plexus. "We're just a little fly to them."

UC CLINIC, MISSION DISTRICT

San Francisco

On March 20, 1996, Ellen Dayton had just finished drawing blood from an HIV-positive patient at a University of California drug clinic at 18th and Folsom streets. Holding the blood-drawing needle in her right hand, she reached across with her left to catch blood-collection tubes rolling toward a counter's edge.

Suddenly, the needle pierced her left index finger.

"If there had been a needle with a safety shield on it, I would have used it, and the needle stick wouldn't have happened," she said. "It's that simple."

Less than two months later, Dayton tested positive for hepatitis C. On April 29, 1997, she learned that she had contracted the AIDS virus.

On Aug. 8, 1997, she sued Becton Dickinson, contending it makes and sells an unreasonably dangerous product.

Company spokesman Ronald Jasper disputes her claim, saying all Becton Dickinson products "are designed to minimize the potential for the occurrence of accidents during use" and "are safe when used as instructed."

But the company is also expected to defend Dayton's suit with an argument it has used in dozens of other cases: Hospitals and health care workers know more about needle safety than the company does.

``Generally, the people who are using our products . . . are really the expert in what the appropriate method is to handle these hypodermic needles and patients and that sort of thing," Michael Meehan, a division manager for the company, testified in 1990.

That argument, though, turns the legal and ethical responsibility for product safety on its head, says biomedical engineer Gary Harding, who has testified in lawsuits for some manufacturers but against others, including Becton Dickinson.

Nurses, for example, have so many responsibilities that they may deal with needles only once or twice a day, he explains, while ``Becton Dickinson sells millions a day."

``Becton Dickinson has doctors on staff . . . nurses on staff. They receive hundreds of reports from the field. That makes them the experts," Harding said.

Becton Dickinson refuses to discuss the suits further.

``We get involved in litigation from time to time involving needle sticks," said Jasper, ``and we think it would be unseemly to play this issue in the press, frankly."

ONE MARKET PLAZA

San Francisco

Jonathan Gertler, Ellen Dayton's attorney, has represented several other needle stick victims in lawsuits against Becton Dickinson -- and knows what he's up against.

In earlier cases, the company and its lawyers

challenged, if not exceeded, the bounds of the law.

In a 1993 San Diego case, for example, the company openly defied a court order to turn over documents to a needle stick victim. The conduct infuriated the judge, who called the company's actions "shocking" and directed a verdict against it.

"The defendant (Becton Dickinson) has clearly demonstrated that it believes that it, and not the court . . . nor the California Legislature is the sole arbiter of what must be produced in discovery," wrote Superior Court Judge Barbara Gamer.

Later, an appeals court ruled the case should go to trial, even if Becton Dickinson had acted improperly.

Ultimately, the San Diego suit -- like the overwhelming majority of needle stick suits filed against Becton Dickinson -- ended in a confidential settlement barring the lawyers, parties and witnesses from ever talking about the case, and preventing the public from ever knowing what had happened.

"The reason Becton Dickinson is sealing these cases," Gertler says, "is that if the medical industry knew about them, a lot would change."

RITZ CARLTON HOTEL

Washington, D.C.

Last May, Jerry Rakes, assistant vice president for risk control at Columbia/HCA, offered a chilling glimpse of the cost-benefit analysis his 350-hospital conglomerate uses to calculate the value of its employees' lives.

At a conference of safety experts and health care providers, Rakes said a typical 30-year-old nurse who contracts the AIDS virus from a needle stick might have an average expected life span of 15 years. He estimated the cost of medical treatment and lost wages over that period at

\$700,000.

“Throw in \$4,500 for burial costs and the spouse benefits of \$234,000,” he said. “Worst-case scenario -- we're talking about a million-dollar loss.”

Add that loss to the cost of testing needle stick victims for infection, Rakes continued, and the total still doesn't justify the purchase of a safe “needleless” IV system.

“I don't have the figures to go to upper management and say, ‘I can save our company X millions of dollars if we buy this product,’” he said. “The savings are still not there.”

Rakes made clear that without financial incentives, his company is not going to purchase safer needles.

“From a financial standpoint, we are right on the edge. It's going to be up to the manufacturers to make the products available at dirt-cheap prices before we can go out and spend the money to put them into the system.”

CDC OFFICES

Atlanta

For the CDC, the needle stick epidemic has been a game of catch-up.

First, the agency was late in recording thousands of cases of hepatitis B.

It still has no solid figure for the number of HIV cases transmitted through needle sticks.

And now the CDC cannot say how many health care workers are getting hepatitis C.

“I can't give you an estimate (of hepatitis C),” said Dr. Miriam Alter, chief of the CDC's hepatitis branch. “Someone will probably make me come up with an estimate one of these days, but we don't have one right now.”

cases stems from its reliance on voluntary reporting from health care providers and state officials. Many states, including California, have confidentiality laws that bar the reporting of HIV data.

To date, the agency has recorded 52 confirmed HIV cases -- and 114 cases in which the link to occupational blood exposure has not been fully documented.

Denise Cardo, acting chief of the HIV branch of the CDC's Hospital Infection Program, said: "Everyone agrees that (the 52) figure represents only documented cases and underestimates the real extent of the problem."

FDA OFFICES

Rockville, Md.

The number 52 was exactly the figure used by an administrator with the FDA who sought to minimize the scope of the needle stick problem.

"I don't mean to belittle the consequences (of needle sticks)," said the official, who asked not to be identified. "But you need to look at the dimension of the problem in the context of the billions of needles sold every year."

To this day, FDA officials still contend that taking action against conventional needles would be inappropriate because there is not enough proof that new safety devices reduce needle sticks.

It is an argument that ignores a number of well-documented studies demonstrating the effectiveness of the devices. The most recent, completed in January, found that one Becton Dickinson safety blood-drawing device reduced needle sticks by more than 53 percent at Mount Sinai Hospital in New York City.

"There are numerous designs out there, and we are working actively with the health care community on this problem," said Dr. Bruce Burlington, director of the FDA's Center for

Devices and radiologic teams. We're looking for practical solutions."

INTERNATIONAL HEALTH CARE

Worker Safety Center Charlottesville, Va.

Most needle safety experts believe that the ultimate solution to the needle stick epidemic will be found in the courts and legislatures.

Patti Tereskerz, an attorney with the safety center, says a key reason hospitals have delayed the acquisition of safer needles is that workers' compensation laws shield hospitals from legal liability for their employee's injuries.

Under the laws of most states, including California's, employees injured on the job are barred from suing employers. In exchange, the workers are eligible for wage compensation and medical benefits if they can prove their injury was work-related.

Changing the laws to allow injured medical workers to sue employers would almost certainly provide a powerful financial incentive for hospitals to acquire safer needles, Tereskerz said.

San Francisco General's Bill Charney, a national authority on hospital safety, says: "If hospitals were sued for millions of dollars every time a nurse got a needle stick and the hospital didn't supply safe needles, you can bet this problem would have gone away years ago."

Until then, health care workers will agonize every time they get stuck by a needle.

"Hospitals are the most dangerous institutions in America," Charney says, "and no one knows about it."

EPILOGUE

Two decades have passed since Dr. Dennis Maki realized that the nation's hospitals had a serious problem on their hands.

Today, experts worry that a third of health care workers still have not received hepatitis B vaccinations, which dropped needle stick infections from the disease from a high of 12,000 in the 1980s to current estimates of fewer than 1,000 a year.

Researchers are still searching for a vaccine against AIDS and the latest needle stick killer, hepatitis C, which some researchers believe is infecting as many as 9,600 medical workers every year.

And they are fearful that a new needle stick threat has been discovered: serious birth complications in pregnant health workers exposed to incompatible blood.

Last September, the CDC published a 50-page document detailing how infection control officers could prevent transmission of diseases.

It did not even mention safe needle devices.

Meanwhile, as U.S. health care workers continue to receive more than a million needle injuries every year, needle maker Becton Dickinson has embarked on an ambitious global expansion. The company now has facilities in at least 33 nations, and it recently completed construction on huge new plants in China and India.

Both make conventional needles.

Last week, the corporation's stock hit a new high.

And in August, needle stick victim Ellen Dayton is scheduled to have her day in San Francisco Superior Court.

The pressure on her to settle would seem enormous. She is fighting a corporate giant -- as well as hepatitis C and HIV. She is often so sick from medications that she cannot leave her house.

Her life, quite literally, is too short.

But she says she will press her case. And if her lawsuit does go to trial, it could finally give voice to the victims of deadly needle sticks.

"I want people to know what happened to me," she said, "because I don't want this to happen to anyone else."

THE AGONIZING WAIT

A look at the costly testing and treatment health care workers face while waiting up to a year or more to find out if they have contracted an infectious disease from a needle stick.

--RISK -- The chance of becoming infected when pricked with with a contaminated needle:
Hepatitis B -- 30 percent. Hepatitis C -- 2 to 10 percent. HIV -- One in 300.

-- TESTS

Hepatitis B -- The hepatitis B antibody test.
Hepatitis C -- The hepatitis C antibody test. HIV -- The HIV antibody test within 24 hours after being stuck and again at six weeks, 12 weeks, six months and one year. Blood count and liver function tests are conducted just before drug therapy is started and two weeks later.

-- TREATMENTS

Hepatitis B -- For a person not already vaccinated: hepatitis B vaccine and immune globulin shots. Hepatitis C -- No proven vaccine or drug therapy. HIV -- A range of potent antiretroviral drugs are to be started within one to two hours of the injury. The drugs are not 100 percent effective and may cause serious side effects.

-- COSTS

Testing, treatment, counseling, medical costs and lost wages: Without person becoming infected: \$200 -- \$2,000. With HIV infection: \$500,000 to more than \$1 million.

-- NONMONETARY CONSEQUENCES

Anxiety, emotional trauma, sickness from drug therapy, recommendations to abstain from sexual intercourse or to practice safe sex. Nursing mothers are warned not to breast-feed.

Sources: Centers for Disease Control, U.S. Veterans Administration.

ABOUT THE NUMBERS

The statistics for this series came from a number of sources:

The estimate of the current availability of safer injection syringes -- 5 percent to 10 percent -- is from the International Health Care Worker Safety Center. The figure is supported by figures from industry analysts and manufacturers.

The estimate of 1 million needle sticks per year is also from the safety center, based on data from 70 hospitals around the nation. Higher rates have been reported by the Centers for Disease Control and medical journals.

Estimates of the number of medical workers annually infected by the hepatitis B virus from needle sticks, which range from a high of 12,000 in the 1980s to the current figure of 1,000, have been reported by the Centers for Disease Control, the Occupational Safety and Health Administration and medical researchers. Death estimates of 200 to 300 a year in the 1980s are from the CDC and OSHA.

The number of workers contracting HIV from needle sticks -- 50 to 60 a year -- is an estimate by the International Health Care Worker Safety Center.

The hepatitis C needle stick cases have been poorly tracked, but most experts estimate the numbers to be in the thousands each year.

BC:
 DO SAFER NEEDLES PREVENT INJUIRES?
 A CDC study evaluated the use of three safety blood-drawing devices among three groups of hospital health workers in Minneapolis-St. Paul, New York City and San Francisco from 1993 to 1995.
 Needle stick injuries per 100,000 injections

.		
Smith Industries Venipuncture Needle-Pro		
Conventional Device (x)	3.6	
Safety device	1.2	
Percentage drop	66%	
.		
Bio-Plexus Punctur-Guard		
Conventional Device (x)	3.6	
Safety device	0.9	
Percentage drop	76%	
.		
Becton Dickinson Safety-Lok		
Conventional Device (x)	4.0	
Safety device	3.1	
Percentage drop	23%	
.		
(x) Variety of brands		

Source: Center for Disease Control
 STEVE KEARSLEY/The Chronicle

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S.F. Health Care Workers Rally for Safer Needles Chronicle series prompts calls for change

Thursday, April 16, 1998

San Francisco Chronicle
CHRONICLE SECTIONS

Reynolds Holding, William Carlsen, Chronicle Staff Writers



Hundreds of health care workers and union activists rallied at San Francisco General Hospital yesterday to demand protection against deadly needle sticks and to denounce the nation's hospitals and medical clinics for failing to provide safer needles.

Responding to Chronicle reports that thousands of nurses, laboratory technicians and hospital housekeepers have died unnecessarily from needle injuries in the past 20 years, the protesters urged the San Francisco Board of Supervisors to pass a city ordinance banning dangerous syringes and blood-drawing devices.

"We are the ones taking care of patients," said Luisa Blue, local organizing director for the Service Employees Union International, which represents hundreds of thousands of health care workers. "Now somebody has to take care of us."

The proposed ordinance would require all medical facilities owned by or doing business with the city to use safe needle products. The ordinance would affect scores of clinics, hospices and hospitals -- including San Francisco General -- as well as medical wards in city jails and schools.

"We are asking the health care industry to stand by its women and men," Supervisor Tom Ammiano, the ordinance's sponsor, said at the rally yesterday. "Needles may be disposable, but

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DEADLY NEEDLES

SF Gate Special Report

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human lives are not."

A series of Chronicle stories published earlier this week revealed that thousands of needle stick victims contract HIV, hepatitis C and other lethal infections every year -- even though needles with simple safety features that could prevent the injuries have been available for at least a decade.

Few of the needles have reached health care workers, The Chronicle found, because it is more profitable for manufacturers to sell conventional designs and less costly for medical facilities to buy them. And government watchdogs have virtually ignored the problem, failing to enact or enforce regulations that would protect health care workers.

The articles provoked a swift response from political leaders around California.

"I find this a cause for great concern," wrote Assemblywoman Carole Migden, D-San Francisco, in a letter yesterday to John Howard, the state administrator who oversees Cal OSHA.

Migden demanded "a list of specific steps you will take to assure prompt compliance with the state regulations (on safe needles) that you have been charged to enforce.

"State regulation requiring the use of safe needles has been in effect for fully six years," Migden wrote. "In that span of time, it is difficult to fathom why your agency has inspected less than 2 percent of California hospitals to assure their compliance."

State Senator Mike Thompson, D-Santa Rosa, said yesterday that solving the needle stick problem is "an easy thing to do" through the use of safe needles.

Thompson sponsored legislation in 1996 to require hospitals to use safe needles. But state hospital groups and Governor Pete Wilson's administration were overwhelmingly opposed, Thompson said, so he revised it into a statewide study of the needle stick problem.

An interview with Chronicle reporters Reynolds Holding and William Carlsen

Special Report Main Page.

Day Two Stories (Chronicle):

Lead: Becton Dickinson Sells Unsafe Needles Despite Risks

Safe Designs Proposed But Not Produced

A Scientist's Fight for Safety

Needle Stick Epidemic - Actions, Reactions (timeline)

Day One Stories:

Lead: Health workers' silent epidemic

Female health workers may face special risk

A nurse's life changed in a moment

Birth of an Epidemic (timeline)

Pipe up

"I have a sincere belief that we who administer programs to protect the health care workers and patients in our facilities must answer these concerns and must make sure that our

"I was alone on this at the time," he said.
"There was no support from the medical industry."

The governor's office did not respond to The Chronicle's request for comment.

Meanwhile, U.S. Representative Pete Stark, D-Fremont, stressed that "providing basic protections for nurses and other health care professionals is the least we can do for those who take care of us when we are ill."

Stark introduced a bill last October requiring all hospitals that serve Medicare patients to use safer needles.

"Legislation is now clearly needed," he said.

But health care workers threatened every day by needle sticks told the rally yesterday that they cannot wait much longer for action.

"I've been really fortunate," said nurse Lynna Young, who works at a San Francisco medical clinic and has yet to suffer a stick. "But every time I give an injection or draw blood, you bet it's in the forefront of my mind."

Ellen Dayton, a nurse practitioner who worked with Young and contracted HIV and hepatitis C from a 1996 needle stick, was too ill to attend the gathering. But in a written statement read to the crowd by another nurse, she said, "We deserve to have our lives and health placed at the top of the list of economic priorities, not the bottom."

Although the demonstration occurred in front of San Francisco General, hospital epidemiologist Dr. Julie Gerberding contended that the workers' demands and Ammiano's proposed ordinance would probably have little effect at the hospital because it already purchases only safer needle devices.

"A great deal of progress has been made," she said. "Every needle device that can be replaced has been replaced . . . and needle sticks have

resources are aimed in the right direction."
--from the Needlesticks topic

Crook or Genius, He's Got Their Attention
02/20/2000

Baby Lawyers Too Costly to Waste
02/13/2000

Reynolds Holding Archives:

January

2000

view archive

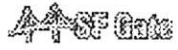
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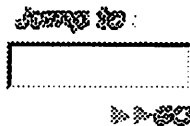
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Health care workers demand safe needles

Lisa M. Krieger
EXAMINER MEDICAL WRITER

800,000 hospital accidents each year spread infections

In response to growing concern about on-the-job needle stick injuries, health care workers gathered at San Francisco General Hospital to demand that all city-run hospitals and health clinics provide safe syringes.

"The lives of many thousands of nurses, physicians and others have been shattered by infection with HIV and hepatitis," nurse Ellen Dayton said Wednesday in a statement.

"There can be no doubt that most of those needle sticks would have been prevented if the people who supply us with billions of needles . . . were as concerned for our safety as we are concerned for those we care for," charged Dayton, who was too sick with HIV and Hepatitis C to attend the rally. Dayton became infected while drawing blood at a public substance abuse clinic.

Rally organizers, members of the Service Employees International Union, promoted legislation introduced by Supervisor Tom Ammiano three weeks ago that would require any facility getting money from The City to use safe medical devices.

On the federal level, legislation was introduced by Rep. Pete Stark, D-Hayward, last fall that would require all hospitals that get Medicare money to use safe needles.

Health care workers report more than 800,000 needle stick accidents each year. According to the federal Centers for Disease Control and Prevention, there have been 52 actual and 111

April 16, 1998

San Francisco Examiner
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possible cases of HIV transmission from needle sticks.

"Safe needle" activists say that improved devices, which have been on the market for several years, would reduce the incidence of needle stick infection by 80 to 90 percent. But the devices have been ignored by hospital administrators because of their expense, the activists say.

San Francisco health officials say all city-run hospitals and clinics already have well-established programs to reduce the risk of needle stick injury and blood exchange.

These programs have resulted in a 50 percent decrease in the number of needle stick accidents over the past eight years, according to S.F. General spokesperson Corinna Kaarlela.

"At all sites, it is a priority that safety device needles are provided and that they are available regardless of cost," said Kaarlela. "Sites are also equipped with special containers to ensure safe disposal of needles and other sharp objects after use."

Chronicle reporters Reynolds Holding and William Carlsen

Special Report Main Page.

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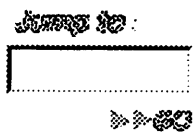
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New Year's Resolution #3:
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Boxer Wants Emergency Action On Needles

She says caregivers should be protected

Friday, April 17, 1998
San Francisco Chronicle
 CHRONICLE SECTIONS

William Carlsen, Reynolds Holding, Chronicle Staff Writers

Alarmed by reports of an epidemic of needle stick infections, Senator Barbara Boxer called on the Clinton administration yesterday to issue emergency regulations compelling the nation's hospitals and medical facilities to use safety needles.

The California Democrat said she was amazed when she learned from a series of Chronicle stories this week that thousands of health care workers are being struck down by hepatitis and HIV transmitted through accidental needle injuries.

"This is a tragedy that can be prevented," she said.

Boxer yesterday called Charles Jefferess, the head of the U.S. Occupational Safety and Health Administration, to express her concern over inaction by federal safety regulators.

"He (Jefferess) said that he's very concerned about this and is studying all the facts," she said. "Sadly, the federal regulations appear to be inadequate."

After Jefferess explained that tightening existing federal regulations could take up to eight years, Boxer said she asked him to use his emergency powers to issue a temporary regulation while the more lengthy process took place.

Boxer sent a letter to the agency later in the day that included the Chronicle series and formally asked for emergency action.

"Mr. Secretary," she wrote, "we are fortunate

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Lead: [Watchdogs Fail Health Workers](#)

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[New Technology, Old Obstructions](#) (timeline)

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[An interview with Chronicle reporters Reynolds Holding and](#)

advances at a rapid rate. One of these advances is needles which protect health care workers from accidental needle sticks.

"We simply must not stand by awaiting an interminable rule-making process while thousands of health care workers are getting sick and some are even dying as a result of our inertia."

Jefferess could not be reached for comment.

OSHA spokesman Steven Gaskill confirmed Boxer's account of her conversation with Jefferess. "We await her letter and will continue to talk with her and her office," he said. "There is not much more I can say at this point."

The Chronicle series this week reported that over the past 20 years, thousands of health care workers have died from needle injuries, and tens of thousands have contracted devastating diseases -- even though safe needle devices designed to prevent needle sticks have been available for a decade.

The Chronicle found that federal and state watchdog agencies, including OSHA, Cal OSHA and the U.S. Food and Drug Administration, have all but ignored the problem.

Cal OSHA, which enforces workplace safety regulations in the state, said yesterday that it was considering revising its standard concerning needle stick injuries.

In a letter yesterday responding to a call for action Wednesday by Assemblywoman Carole Migden, D-San Francisco, Cal OSHA chief John Howard said his agency lacks authority to require health care employers to provide their employees with safe needles.

"Only when the standard itself specifically mandates the use of the specific types of medical devices featured in the Chronicle articles can the division cite employers for their failure to comply," Howard wrote.

William Carlsen

Special Report [Main Page](#).

**The Series:
Day 2 :**

Lead: [Becton Dickinson Sells Unsafe Needles Despite Risks](#)

[Safe Designs Proposed But Not Produced](#)

[A Scientist's Fight for Safety](#)

[Needle Stick Epidemic - Actions, Reactions \(timeline\)](#)

**The Series:
Day 1:**

Lead: [Health workers' silent epidemic](#)

[Female health workers may face special risk](#)

[A nurse's life changed in a moment](#)

[Birth of an Epidemic \(timeline\)](#)

Pipe up

"I have a sincere belief that we who administer programs to protect the health care workers and patients in our facilities must answer these concerns and must make sure that our resources are aimed in the right

He said the agency would convene an advisory meeting in June to consider "recommending to the Occupational Safety and Health Standards Board several revisions in the California Bloodborne Pathogen Standard," including mandating the use of specific safe needle devices.

--from the Needlesticks topic

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Illegal Reuse Of Needles by S.F. Coroner Disposables are cleaned despite health worries

Friday, May 8, 1998

San Francisco Chronicle
CHRONICLE SECTIONS

William Carlsen, Reynolds Holding, Chronicle Staff Writers

SAN FRANCISCO -- The San Francisco medical examiner's office is illegally forcing its employees to reuse disposable needles that can transmit HIV, hepatitis C and other deadly infections through accidental needle injuries, The Chronicle has learned.

Although state safety regulators ordered the practice stopped more than eight months ago, medical examiners say office policy still requires them to clean and save needles after each autopsy.

Chief Medical Examiner Dr. Boyd Stephens has defended the policy as necessary to save money. But employees charge that he is cutting costs at the expense of their safety.

"What does it take to make this man change things -- to have somebody die?" said one of the six employees who work regularly in the office's autopsy room. "I'm afraid for my life every day I go to work."

The Chronicle detailed the dangers of accidental needle injuries in a series of reports last month. Thousands of needle stick victims contract the AIDS virus, hepatitis C and other lethal infections every year, even though safety needles that could prevent the injuries have been available for at least a decade.

Health experts say needle injuries are particularly dangerous in county autopsy rooms. Medical examiners investigate unnatural deaths, which often require examination of the bodies of indigent and homeless individuals, drug abusers and others with high rates of diseases such as

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Needle risk at S.F. Coroner's Office

Pipe up

"I have a sincere belief that we who administer programs to protect the health care workers and patients in our facilities must answer these concerns and must make sure that our resources are aimed in the right direction."

--from the Needlesticks topic

The diseases can infect examiners pricked accidentally with needles used repeatedly on cadavers -- even when the needles have been cleaned.

``Medical examiners' offices are one of the riskiest places to work in the health care industry," said Dr. Robyn Gershon, a public health expert at Johns Hopkins University. ``Bugs don't die when a patient dies, and reusing disposable needles is just a stupid, stupid cost-reduction effort."

San Francisco's medical examiners say Stephens has essentially ignored the health risks. He has not only failed to buy safer needles, but has increased the risk of infection from conventional needles by requiring their reuse.

And according to state officials, the practice is only one of several that have made his facility unnecessarily dangerous.

Last August, the California Occupational Safety and Health Administration slapped the office with 10 citations for serious safety violations. In addition to citing the office for reusing needles, the agency ordered Stephens to shield workers from airborne tuberculosis bacteria with respirators and to protect them from the blood spray caused by circular saws that cut bone.

During the past eight months, though, Stephens has delayed any action by appealing most of the citations.

According to a Cal OSHA order dated April 21, Stephens agreed to withdraw his appeal and to correct the violations. He stated in the order that the corrections were complete ``except for final approval of the written programs."

But since then, employees in the medical examiner's office say little has changed.

Some of those employees have tried for years to make Stephens take action, even at the risk of losing their jobs.

A year ago, Dr. Shayla Frisby bought a supply of disposable needles with her own money to see how much it would cost the office to stop reusing needles. Stephens suspended her for violating office policy and recommended that she be terminated. She resigned a short time later.

Now a doctor at Kaiser Permanente in San Francisco, Frisby has researched safety practices in medical-examiner offices across the country.

“Unfortunately,” she says, “the lack of safety measures, as was the case in San Francisco, is typical.”

Frisby says there is no licensing or accrediting agency that oversees safety in the offices, and she notes that the National Association of Medical Examiners gave its annual accreditation to the San Francisco office despite the 10 Cal OSHA citations.

Stephens has strongly defended his office, stressing that it operates “under strict budget constraints.”

“For us to throw away every syringe would cost the taxpayers money,” he said last week.

But last year, Board of Supervisors budget analyst Harvey Rose released an audit urging Stephens to adopt a disposable needle policy to protect autopsy personnel. Rose estimated that the additional needles would cost \$9,959, which could be absorbed in the existing budget.

In response to the audit, Stephens said needle sticks were “extremely rare events” -- despite statistics showing that more than 1 million needle sticks occur each year nationwide. And in any event, he said, “our ‘patients’ are dead, thus infection of a deceased individual is not an issue.”

But Stephens acknowledged last week that there have been two reported needle sticks since Cal OSHA's inspection last year.

“It would cost the taxpayers a whole lot more

money if either of those sticks resulted in a serious HIV or hepatitis infection," said one employee.

Under an ordinance proposed last month by Supervisor Tom Ammiano, all city departments and health care employers with city contracts would have to provide employees with safer needles designed to protect against accidental injuries.

Stephens said he is evaluating several of the safer needles but has not supplied any to his employees because there are a variety of devices to examine.

He also stressed that he is working on a plan to provide employees with respirators instead of surgical masks, which are ineffective against airborne tuberculosis bacteria. The plan has taken so long, he said, because it requires a physical examination of each worker and approval from the city's Department of Public Health.

Meanwhile, he said the office now uses a vacuum extraction saw to capture the spray of airborne bacteria released when bones surrounding a chest cavity are cut. He said he is working closely with Cal OSHA to redesign the autopsy room and to upgrade its 30-year-old ventilation system.

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DEADLY NEEDLES Fast Track to Global Disaster

Tuesday, October 27, 1998

San Francisco Chronicle
CHRONICLE SECTIONS

Reynolds Holding, William Carlsen, Chronicle Staff Writers



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DEADLY NEEDLES

A Special Series

KRON 99.5

[KRON reports on the
Deadly Needles series.](#)

Part I
[Researchers warn of
emerging epidemic.](#)

[Health workers contract
deadly diseases.](#)

[New technology not
likely to reach addicts.](#)

Part II
[Lost chance to avert a
world health crisis.](#)

[Syringes reused in U.S.
depite risks.](#)

Part III
[The epidemic's
devastating toll.](#)

[Emerging needleless
technology not ready to
replace syringes.](#)

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[Crook or Genius,
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02/20/2000

[Baby Lawyers Too
Costly to Waste](#)

For decades, researchers warned that contaminated syringes could transmit deadly viruses with cruel efficiency. But efforts to defuse the crisis were failed, and today, it has become an insidious global epidemic, destroying millions of lives every year.

[\(First Of Three Parts\)](#)

CONFERENCE ROOM A

WORLD HEALTH ORGANIZATION, GENEVA

Dr. Ciro de Quadros, chief of the campaign that eradicated polio from the Western Hemisphere, could not believe the numbers. When the esteemed Brazilian and other world health leaders arrived in Switzerland last spring, they expected to discuss the progress of the global vaccination program -- the most successful public health campaign in history.

Instead, they got a medical time bomb.

In de Quadros' hand was a chilling internal report: 10 million people a year were contracting lethal diseases such as hepatitis and AIDS through the reuse of contaminated syringes.

De Quadros rose to his feet and implored his

least until the numbers could be reviewed once more.

“These figures are so incredible,” he said, “that if they are released, they will make the front pages of newspapers around the world.”

But an earlier internal WHO study had revealed an even more alarming figure: Every year as many as 1.8 million people infected by contaminated syringes, mostly children, would die -- about one every 20 seconds.

Medical researchers had warned for decades that hypodermic needles could be deadly. But the WHO reports made it painfully clear that world health officials had an international medical crisis on their hands -- and urgent action was needed.

“We want to avoid creating a panic,” said WHO's Michel Zaffran, who helped prepare the still-unreleased infection numbers. “But maybe there is a need to create that panic to solve this problem.”

This is a story, based on hundreds of interviews and thousands of documents, about a vast, virtually invisible epidemic, a crisis that could have been defused more than a decade ago.

It is about soaring disease rates in Egypt and plunging life expectancies in Brazil; children combing garbage dumps for syringes to sell in Kenya and India; and ignorance, poverty and corruption driving medical workers in Cambodia and Russia to reuse needles dozens -- sometimes hundreds -- of times.

It is about a promising generation of nonreusable syringes that got lost in a multibillion-dollar corporate battle over the global syringe market.

It is about how the world's leading syringe manufacturers first ignored the problem, then either delayed the new technology or did little to get it into the hands of health workers.

And it is about how top world health officials -- including several with de Quadros in Conference

02/13/2000

Reynolds Holding
Archives:

January

2000

view archive

...displayed the mounting death toll for years, fearing that publicizing it would jeopardize their immunization programs.

The story began more than half a century ago with the emergence of the hypodermic syringe: an instrument of almost mystical life-saving power, yet one that can spread disease with deadly efficiency.

RURAL CLINICS

GOLD COAST, AFRICA

In 1920, the tropical disease yaws had been striking down villagers for as long as anyone could remember. The microbe invaded the body through broken skin, raising ugly lesions, inflicting excruciating pain and often totally disabling its victims.

Then, medical workers fanned across the countryside with hypodermic syringes containing a chemical called Salvarsan.

“So spectacular were the results,” a West African medical journal later reported, “that all types of patients began to clamor for injections, and most of them refused other forms of orthodox treatment.”

In 1923, Salvarsan shots cured hundreds of yaws-infected Samoans. Similar results involving other diseases and medicines were reported from Jamaica, India and Nigeria.

By the 1950s, mass injection campaigns with penicillin all but eradicated yaws. The image of syringes as magic was firmly established in the developing world, with patients often refusing to leave clinics before getting injected.

“Injections and syringes had become the symbol of modern medicine . . . a metaphor for everything fast and efficient,” two medical anthropologists later wrote.

But the talismanic attraction of the syringe began to fade among health care workers.

Patients in Madagascar, Samoa and the Congo developed paralysis from polio transmitted through injections. Cases of hepatitis spread by syringes surfaced in West Africa.

Even in the United States, studies showed that syringe reuse spread malaria, hepatitis and other serious infections.

The "Injection Age" had arrived, but it had come with a price.

D'IORIO RESTAURANT

WATERBURY, CONN.

Peter Stevens and his colleagues at Roehr Products sat around a corner table in 1954, picking at pasta and wondering how to keep the fledgling medical supply company from going under.

By then, it had become clear that a used syringe could transmit disease. Stevens and his colleagues had an idea: a plastic syringe so cheap that doctors would discard it after a single shot.

"We introduced our needle not because of moral considerations," Stevens said, "but because this is a litigious country, and everybody was afraid of lawsuits."

Within a year, Roehr was selling the world's first disposable syringe, a 5-cent plastic model called Monoject.

But there was little demand for Roehr's new product. Most doctors insisted that it was safe -- and much cheaper -- to sterilize and reuse glass syringes. "We pushed and pushed," said Stevens, but "people in the health care field just didn't want to hear about it."

BECTON DICKINSON FACTORY COLUMBUS, NEB.

Becton Dickinson and Company had heard about the Monoject and realized that plastic disposable syringes were the future.

In the summer of 1957, the nation's leading maker of glass syringes sent a small army of executives, engineers and assembly workers to Columbus, 70 miles west of Omaha.

Their mission was to create an inexpensive plastic syringe, and in the company's thermometer factory on the edge of town, they started work on a disposable version that would be called Plastipak.

At night, the team would gather at Louie's steak house to discuss their progress and belt out a theme song:

A million a week in the springtime

A million a week in the fall

A million a week in the springtime

Or we won't get home at all!

OFFICES OF DR. ALBERT L. WEINER

ERITON, N.J.

On a late winter day in 1960, Marjorie Atkins visited Dr. Albert Weiner for anxiety treatment. Weiner, an osteopath specializing in psychotherapy, injected her with a sedative.

Within six months, the 53-year-old woman was dead of hepatitis.

Fourteen more of Weiner's patients would die of the disease during the next eight months, and 29 others would fall gravely ill.

Weiner was eventually convicted of 12 manslaughter counts for injecting patients with syringes contaminated by hepatitis.

The case made national headlines and sent doctors around the country scrambling for disposable syringes. It also secured the fortunes of Becton Dickinson and Roehr Products.

Within a year of Weiner's conviction, sterile disposable syringes captured a third of the nation's needle market, and needle manufacturers were producing tens of millions of disposables annually.

The sudden demand for disposables made Roehr Products an attractive takeover target, and in 1961 the company was sold to a firm that would become Sherwood, Davis & Geck, the nation's second-largest syringe company.

But no company profited more from the soaring demand for disposables than Becton Dickinson. With cash raised by its first public stock offering, the company began making millions of the syringes, promoting them as a surefire way to stop the spread of disease.

In just three years, sales revenues quadrupled, and Becton Dickinson was on the road to becoming the most powerful needle manufacturer in the world.

AMERICAN MEDICAL ASSOCIATION CONVENTION

ATLANTIC CITY, N.J.

It didn't take long for the nation's doctors to realize that the new disposable syringes presented health hazards of their own.

As more disposables were manufactured, used and discarded, more were picked from the trash by drug addicts, children and others risking deadly infections.

At the American Medical Association's 1967 convention, Resolution No. 26 called on needle manufacturers to ``adopt designs to prevent reuse."

It was the first public warning that the new disposables could be just as dangerous as the syringes they replaced.

The resolution passed unanimously.

Needle manufacturers ignored it. Years later, Becton Dickinson officials would say they had never heard of it.

FACTORY FIRST AID STATION

STATE OF VICTORIA, AUSTRALIA

On June 27, 1969, more than 200 factory workers lined up for vaccinations against the "Hong Kong" flu.

Four days later, one worker died of septic shock. In a few more days, the plant's 51-year-old technical manager, his left upper arm swollen from a massive bacterial infection, was dead.

Medical investigators traced the deaths to streptococci bacteria spread by the vaccinations. Disposable syringes had been used, but to save money, doctors had filled each syringe with 20 doses. Although the needles had been changed between each injection, back pressure from the shots apparently forced infected blood into the syringe barrel, contaminating the vaccine.

It was among the earliest documented cases of lethal infections transmitted through disposable syringes.

WORLD HEALTH ORGANIZATION

GENEVA

In 1974, the World Health Organization launched the most powerful attack in history on deadly diseases: an ambitious campaign to vaccinate every child around the globe.

Inspired by the success of mass immunizations against smallpox, WHO's Expanded Program on Immunization focused on tuberculosis, diphtheria, tetanus, whooping cough, polio and measles.

These diseases had killed tens of millions of people in the early 1970s. But by 1974, only 5 percent of the world's children had been

Reaching more would take training, vaccines -- and millions of clean needles and syringes.

At the time, WHO believed that reusable glass syringes, properly sterilized, were safe enough for the immunization program. They were also the cheapest option, because one syringe could administer dozens of shots, whereas the new disposables were designed to be discarded after a single injection. So the agency hired armies of health experts to train immunization workers around the globe on sterilizing the reusable needles.

From 1974 to 1980, millions of vaccinations were administered and recorded. Children in virtually every community of every country were immunized.

But soon after the immunization campaign started, WHO officials discovered that many of the needles and syringes used had not been properly sterilized.

They realized that the children were being vaccinated and exposed to lethal diseases at the same time.

WORLD HEALTH ORGANIZATION

GENEVA

In October 1980, a WHO newsletter published a cover story on a radical new device -- a syringe containing a simple mechanism that prevented it from being used more than once.

The story called the device "the syringe of the future."

It was the first public notice that world health officials had found a simple technological solution to the problem of syringe reuse. And it suggested that the agency was acutely aware of the underlying social and economic costs of treating victims.

The story warned that "the use of contaminated

syringes, especially when they are used over and over again, can cause infections and even lead to an epidemic. . . . Such 'accidents,' which are not uncommon, can be more costly . . . than measures to prevent them."

The new syringe was "inexpensive" and would "shortly become available," the article said.

The syringe was never produced.

CENTERS FOR DISEASE CONTROL

ATLANTA

In June 1981, skittish staffers at the national Centers for Disease Control and Prevention in Atlanta slipped a disturbing report onto Page 2 of the agency's weekly newsletter. It described unusual cases of Pneumocystis pneumonia among homosexual men. The workers feared provoking panic -- and prejudice -- over a brewing epidemic unlike any they had seen before.

A year later, at a meeting of national health experts in Washington, D.C., the fatal immune-system disorder that could be transmitted by bodily fluids, blood and used needles was given a name: AIDS.

Researchers would discover that AIDS was not just a problem within gay communities in the United States and Europe. It was also rampant among heterosexuals in the Caribbean and Africa.

AIDS did what no other disease before it could: force world health experts to pursue a technological solution for syringe reuse.

"We'd been concerned about needle reuse since the 1970s," said Peter Carrasco, a technical adviser on immunization at the Pan American Health Organization. "But with AIDS in 1982, that's when we really had to start looking at it."

WHO FIELD OFFICES

CENTRAL AFRICA

Since John Lloyd joined WHO's childhood immunization campaign in the late 1970s, his most frustrating task had been to make vaccination workers properly sterilize reusable plastic and glass syringes and needles.

The workers would run out of fuel for portable field sterilizers supplied by WHO. Or they would see people waiting in line and, feeling rushed, fail to boil or steam the syringes long enough. Or experienced operators would move on, leaving the sterilizers in untrained hands.

Often, the workers wouldn't even try to sterilize the syringes and needles.

Then, in the mid-1980s, a number of African countries began using disposable syringes -- a shift that threatened to undermine the sterilization program completely.

The sterilizers could not adequately clean the plastic disposables, which also softened and bent at high temperatures. "We started getting very worried about the confusion people were experiencing with two types of syringes," he said.

Lloyd realized that sterilizers alone would not stop syringes from spreading disease.

UNITED NATIONS CHILDREN'S FUND HEADQUARTERS

NEW YORK CITY

In 1984, Lloyd went to visit his old friend Peter Evans.

Four years earlier, as a UNICEF procurement officer, Evans was fiddling with a disposable syringe when he noticed that a few simple changes would make it impossible to use more than once.

"I thought I was on to something," Evans recalled.

So he applied for a U.S. patent, but his application was rejected.

"I found there were at least four earlier patents along the same lines going back some 20 years," he said.

But Evans' modified syringe caught Lloyd's eye.

"As we were talking," Lloyd said, "I noticed that he had this intriguing gadget on his desk.

"It was like a revelation."

PROGRAM FOR APPROPRIATE TECHNOLOGY IN HEALTH

SEATTLE

Michael Free and his colleagues at PATH, a nonprofit developer of health technology for developing countries, were trying to develop a syringe that could be used only once.

In 1985, he enlisted his former student, Richard Jaffe, an anesthesiologist at Stanford University medical school, to help revamp their design.

"It was too easy to defeat (and reuse)," said Jaffe. So he and a partner made several modifications.

Free also consulted Terence Ellard, a Seattle instrument maker. Ellard said he, too, refined the PATH design, taking it "from something that was never going to work to something that worked well."

The new device worked well enough to provoke serious interest from the U.S. Agency for International Development. Over the next few years, the agency would give PATH about \$250,000 to develop the device further.

WORLD HEALTH ORGANIZATION HEADQUARTERS

GENEVA

In 1980, health experts from WHO, USAID and other agencies asked inventors and medical manufacturers around the world to submit designs for nonreusable syringes.

The syringes had to automatically destruct after one use, include needles that could not be removed, and contain other features that met the requirements of child immunization programs.

In July 1987, the health experts gathered to review the submissions.

There was one from Johns Hopkins University medical researchers, another from a small Spanish manufacturer and several from designers in England, Denmark and Switzerland.

A millionaire French inventor proposed an idea he conceived after contracting hepatitis from a hospital needle -- the same design touted in the WHO newsletter seven years before.

No designs were submitted by Becton Dickinson, Sherwood or any other major syringe manufacturer.

Still, the group of experts adjourned with 35 different prototypes.

PAN AMERICAN HEALTH ORGANIZATION

WASHINGTON

On Nov. 16, 1987, the group reconvened in the nation's capital to discuss the most promising prototypes.

Two stood out, Lloyd recalled, both developed by PATH. One included a thumbnail-size plastic bubble that could be squeezed flat to administer a shot. The other was the syringe that Jaffe and Ellard helped refine.

The need for safer syringes was becoming more urgent. Sterilization programs were failing. Disposable needles were creating new problems. And a series of reports from around the world

were out of control.

In 1984, hepatitis was found in more than 15 percent of syringes discarded in Florence, Italy. In 1986, researchers reported from Zaire that syringes transmitted monkey pox and that people who received more injections had higher rates of HIV infection.

In 1987, the CDC reported that of nine African countries surveyed, not one sterilized syringes before vaccinations.

Still, Lloyd and the other health experts were confident. They believed a powerful, though tragic, force was on their side.

“We all hoped very much,” Lloyd said, “that the AIDS crisis would provoke manufacturers to pick up the idea of the autodestruct and that the crisis would help them project it into the market.

“I can recall a great deal of optimism as I looked around the table that day. People were very intrigued and hopeful that we could achieve safety with a device.”

They thought they had reached a new era of safe injections -- and naively believed they would continue to immunize children without inflicting deadly disease.

ABOUT THE SERIES

In April, The Chronicle published “Deadly Needles,” a three-part series about accidental needle injuries. Today, we begin a new series about deadly viruses transmitted through syringe reuse -- an epidemic destroying millions of lives every year. .

-- TODAY: (1920-1987) Researchers warn of an emerging epidemic.

-- TOMORROW: (1988-1994) Prototypes of nonreusable syringes promise safer injections.

-- THURSDAY: (1995-1998) After

by needle makers, turmoil fuels the epidemic.

RELATED COVERAGE ON TV AND INTERNET

For more about "Deadly Needles" watch NewsCenter 4 at 6 p.m. tonight. Or, log onto www.sfgate.com. for this week's series, as well as The Chronicle's three-part series on accidental needle sticks published in April.

ABOUT THE NUMBERS

The statistics and other figures used in this series came from a number of sources:

The estimated number of worldwide infections and deaths caused by reuse of contaminated syringes -- 10 million infections and 1.8 million deaths per year -- came from internal reports of the World Health Organization. These reports are still under scientific review and have not been published, but WHO officials say the draft figures are conservative estimates.

The estimates of the global prevalence of the diseases that are most likely to be spread through syringe reuse -- HIV, hepatitis B and hepatitis C -- came from data compiled by WHO, the U.S. Centers for Disease Control and Prevention (CDC) and United Nations AIDS.

Figures on the number of nonreusable or "autodestruct" syringes produced and distributed were compiled from syringe manufacturers, United Nations Children's Fund (UNICEF), WHO and a group of immunization experts called Technical Network for Logistics in Health (Technet).

The funding figures for development of several nonreusable syringes were supplied by the U.S. Agency for International Development (USAID) and Program for Appropriate Technology in Health (PATH). Pricing data for the syringes came from UNICEF and individual manufacturers.

U.S. and global estimates of accidental needle sticks came from the International Health Care Worker Safety Center, CDC, WHO and from studies in Thailand, Pakistan and Tanzania.

INVISIBLE EPIDEMIC 1920-87

FIRST SYRINGE 1897: Becton Dickinson and Co. opens for business and begins selling its first syringe -- made of glass -- for \$2.50.

RISING POPULARITY

1920s-'30s: In tropical countries, injections soar in popularity after shots cure the disfiguring disease called yaws.

POLIO

1930: Researchers note an increase in polio following hypodermic injections in Madagascar.

MALARIA

1933: A medical journal reports that a rare occurrence of malaria in Omaha, Neb., is the result of a syringe shared by two drug users.

HEPATITIS TRANSMISSION

A report documents that hepatitis can be transmitted by syringe reuse. The study says the virus is almost impossible to remove from a needle through accepted disinfection methods.

CONTAMINATION DISCOVERY

A study shows that changing needles is not enough to prevent contamination because blood can back up into the syringe barrel.

HEPATITIS OUTBREAK

A hepatitis outbreak is reported among U.S. soldiers after they receive multiple-dose tetanus shots from reused syringes.

NEW TYPE OF SYRINGE

Becton Dickinson introduces the Multifit, its first glass syringe with interchangeable needles.

TUBERCULOSIS A study shows that tuberculosis can be transmitted by syringe reuse.

FIRST DISPOSABLE Roehr Products introduces the first plastic disposable hypodermic syringe, called the Monoject. The company is soon sold to a firm that will become Sherwood, Davis & Geck, the nation's second-largest syringe company.

DEATH LINK Outbreak of hepatitis is traced to a New Jersey doctor who used contaminated reusable syringes. Fifteen deaths result, propelling national sales of disposable syringes.

PLASTIPAK Becton Dickinson introduces its first plastic disposable syringe, called the Plastipak. The company goes public the following year and sells its shares on the stock market.

DOCTORS' PLEA American Medical Association unanimously adopts resolution asking manufacturers to market syringe designs that would prevent reuse. Manufacturers ignore the request.

ROYALTIES WAIVED Wyeth Laboratories, a subsidiary of American Home Products, waives patent royalties to its special smallpox needle, used to deliver 200 million vaccinations a year worldwide.

FLU SHOTS Two factory workers die in Australia from bacterial infection traced to flu shots. The shots were given with the same disposable syringe, but with new sterile needles after each injection.

GLOBAL VACCINATIONS World Health Organization launches Expanded Program on Immunization to vaccinate all children worldwide against diphtheria, tetanus, whooping cough, polio, measles and tuberculosis.

EBOLA OUTBREAK In Zaire, the Ebola virus kills 280 people, most of whom were infected by reused syringes and needles.

SINGAPORE OUTBREAK Outbreak of fatal hepatitis B cases in Singapore traced to contaminated syringes.

SMALLPOX Smallpox eradicated globally making the disease the first victim of worldwide immunization programs.

FIRST AUTODESTRUCT NEEDLE Prototype of one of the first nonreusable or autodestruct syringes, called the "syringe of the future," is described in a World Health Organization newsletter.

STERILIZERS World Health Organization orders hundreds of thousands of portable steam sterilizers for developing countries to prevent cross-infection from reused syringes.

AIDS Virus that causes AIDS is isolated in U.S. and French laboratories. U.S. Agency for International Development agrees to fund development of an autodestruct syringe with nonprofit Seattle group called PATH.

RECOMMENDATIONS WHO and UNICEF issue policy statement requiring use of a sterile needle and syringe for each vaccination and recommend steam sterilization.

Studies of children in Zaire and Haiti show those who receive more injections have higher rates of HIV.

NEW SYRINGE DESIGNS

USAID sponsors meetings in Geneva and Washington D.C., with WHO, UNICEF, PATH and a panel of experts to review 35 designs for autodestruct syringes. Among the most promising is a laminated blister model and a syringe with a metal clip that renders it nonreusable, both developed by PATH.

were immunized against the most serious childhood diseases. World Health Organization

OLD AND NEW SYRINGES COMPARED

Developed in the late 1950s for one-time use, the plastic disposable syringe is still often reused in poor countries.

-- Conventional syringe Includes a plunger and hollow needle for injecting or drawing fluids. Can be used multiple times.

Costs about 5 cents each.

-- UniJect single-use syringe.

Prefilled plastic bubble attached to a needle with a one-way valve. Can give only one injection. Not yet available, but expected to cost relief agencies about 10 cents each. Contaminated barrel can spread disease even when needle is sterile .

INFECTIONS TRANSMITTED BY SYRINGE REUSE

Hepatitis B virus

-- Hepatitis B infection can cause cirrhosis and is the leading cause of liver cancer in the world. The virus is extremely infectious and can stay alive in dried blood for up to a year. Only 10 percent of infected adults become chronic carriers, but 60 percent to 90 percent of infected children under 1 year old end up with a chronic condition. One-fourth of chronic carriers eventually die of liver cancer or cirrhosis. A three-shot vaccine has been available since 1982, but it is still too costly for widespread use in many countries.

-- Chance of getting hepatitis B from a syringe infected with the hepatitis B virus: 30%

Hepatitis C virus

-- The hepatitis C virus also attacks the liver. More than 80 percent of those infected become chronic carriers, and one-fifth of those will develop cirrhosis within 10 to 40 years. A smaller percentage develop liver cancer. The first test for the virus became available in 1989, so much is still unknown about the disease. There is no vaccine. Treatment with interferon is expensive, limited to adults and effective in less than 20 percent of cases.

-- Chance of getting hepatitis C from a syringe infected with the hepatitis C virus: 3%-5%

HIV, also known as the AIDS virus

-- The AIDS virus attacks the immune system, allowing other diseases to develop. AIDS was considered fatal until a recent combination of new drugs led to a dramatic drop in the death rate in the United States. But few people in developing regions can afford the new drugs. HIV is transmitted primarily through sexual contact. Transmission risk from a needle is low. But because the underlying prevalence of the disease is increasing at a rapid rate, particularly in Africa, where unsterile injections are common, the overall risk is rising rapidly.

More than 20 other infections can be transmitted through contaminated needles, including: -- Syphilis, malaria, tuberculosis, streptococcal and staphylococcal sepsis, Dengue fever, Rocky Mountain spotted fever, herpes, hepatitis D and G, babesiosis, brucellosis, leptospirosis, arboviral infections, relapsing fever, Creutzfeldt-Jakob disease and viral fevers caused by Ebola. -- Chance of getting HIV from a syringe infected

with the HIV virus 0.3%

STEVE KEARSLEY/THE CHRONICLE

Becton Dickinson's sales revenues took off after it started marketing its first plastic disposable needle. Becton dickinson annual sales: 1947 \$20 million 1981 \$1 billion Source: Becton dickinson

SYRINGE REUSE AND THE SPREAD OF DISEASE

Deadly viruses like hepatitis B, hepatitis C and HIV have spread rapidly over the past few decades and experts say contaminated syringes play a major role in their transmission.

Estimated total annual infections from syringe reuse:

Hepatitis B: 8.3 mil.

Hepatitis C: 1.3 mil.

HIV: 31,000

Estimated annual death rate:

1.4 mil. to 1.8 mil.

-- Sub-Saharan Africa Kenya: Rural doctors are supplied with limited numbers of syringes, forcing them to decide between not providing medical care or reusing the few syringes that they have.

Infections from syringe reuse:

Hepatitis B: 1.25 mil.

Hepatitis C: 204,000

HIV: 16,400

-- Middle Eastern crescent Egypt: Mass injections to treat a water-borne disease in the 1960s and 1970s have resulted in the world's highest incidence of hepatitis C. Investigators say syringe reuse was the cause.

Infections from syringe reuse:

Hepatitis B: 693,700

Hepatitis C: 94,400

HIV: 100

-- Latin America and the Caribbean Brazil:
Prompted by a soaring number of AIDS cases,
Brazil passed a law in 1996 mandating the use of
non-reusable syringes. But the law has never
been implemented.

Infections from syringe reuse:

Hepatitis B: 24,700

Hepatitis C: 89,600

HIV: 900

-- Former Soviet Union and Eastern bloc
countries Russia: In 1988 and 1989, 246 children
in six southern Russian towns are infected with
HIV from reused needles and syringes.

Infections from syringe reuse:

Hepatitis B: 446,500

Hepatitis C: 60,800

HIV: 7,300

-- China

A study of 294 village doctors indicates
widespread inadequacy of sterilization of
syringes and acupuncture needles.

Infections from syringe reuse:

Hepatitis B: 2.51 mil.

Hepatitis C: 339,800

HIV: 100

Other Asian/Pacific Island

Cambodia: More than half of the government's
outlay for public health care is swallowed up by
graft, resulting in limited availability of syringes
and rampant reuse.

Infections from syringe reuse:

Hepatitis B: 1.51 mil.

Hepatitis C: 246,200

HIV: 4,600

World prevalence of the hepatitis B virus More than 350 million people are now chronic carriers of the hepatitis B virus. Recent estimates of infections from syringe reuse generally track the prevalence of the disease globally.

World prevalence of the hepatitis C virus Hepatitis C infections from syringe reuse follow the global prevalence of the virus, now carried by more than 170 million people.

World prevalence of the HIV HIV infections from syringe reuse track the worldwide prevalence of the virus, which now infects more than 30 million people.

Source: World Health Organization and Chronicle research

STEVE KEARSLEY/THE CHRONICLE

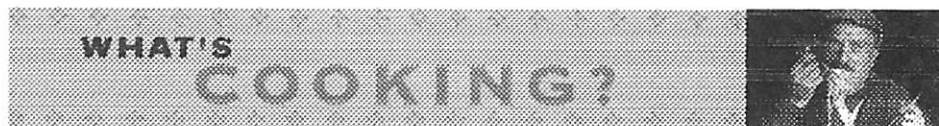
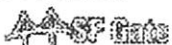
Chronicle foreign correspondents Sandy Barron in Cambodia, Jack Epstein in Brazil, Steve Fennessy in Egypt, Brian Humphreys in Russia and Andrea Useem in Kenya contributed to this report.

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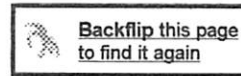
DEADLY NEEDLES Lost Chance to Avert Crisis

Wednesday, October 28, 1998
San Francisco Chronicle
CHRONICLE SECTIONS

Reynolds Holding, William Carlsen, Chronicle Staff Writers

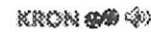


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DEADLY NEEDLES

A Special Series



[KRON reports on the Deadly Needles series.](#)

Part I
[Researchers warn of emerging epidemic.](#)

[Health workers contract deadly diseases.](#)

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Part II
[Lost chance to avert a world health crisis.](#)

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[The epidemic's devastating toll.](#)

[Emerging needleless technology not ready to replace syringes.](#)

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[Crook or Genius, He's Got Their Attention](#)
02/20/2000

Ten years ago, a new generation of syringes promised to end a global epidemic of unsterile injections. It was a golden opportunity, but health officials, needle makers and relief agencies let it slip away.

(Second Of Three Parts)

PATH OFFICES

SEATTLE

For Michael Free, the four years of humbling trial and error finally paid off.

He had in 1988 a new, ingenious creation that could save millions of lives each year. It was a syringe and needle like any other, with one revolutionary difference: a tiny metal clip that jammed the plunger and disabled the syringe after a single injection.

"You cannot pull it (the plunger) back," he said. "The syringe just locks up."

To Free and his colleagues at PATH, a nonprofit agency that creates medical technology for developing countries, a new era of safe injections was finally in sight -- one that could save millions of lives and billions of dollars in medical costs.

But the era would never arrive.

For decades, researchers had warned that syringes could spread lethal viruses with chilling efficiency. In developing nations around the world, millions of people receiving routine injections or childhood vaccinations would contract HIV, hepatitis or other dangerous viruses through contaminated syringes. Untold numbers of victims would die.

The crisis worsened as needle sterilization programs failed, and inexpensive disposable syringes proved to be just as dangerous as the traditional glass devices they replaced.

But at the end of the 1980s, a highly promising solution emerged: a new generation of nonreusable or "autodestruct" syringes.

PATH's device was one of the first.

The tiny metal clip had impeccable credentials. Its development had been funded, in part, by the U.S. government. It would be inexpensive to make in high volume and could be modified to work in different syringes. It had drawn praise from world health officials at a 1987 conference in Washington, D.C.

Free was so eager to get it on the market that he gave the design to the world's largest needle manufacturer -- for virtually nothing.

But few autodestruct syringes would find their way into hospitals, clinics or immunization sites. And the death toll from the reuse of contaminated syringes would climb higher still.

CENTRAL INSTITUTE FOR EPIDEMIOLOGICAL RESEARCH

MOSCOW

Vadim Pokrovsky, an epidemiologist investigating a sudden outbreak of HIV in 1988, was completely baffled.

The doctor had just solved one difficult case, tracing the deadly AIDS virus from a West

**Baby Lawyers Too
Costly to Waste**
02/13/2000

Reynolds Holding
Archives:

January

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African prostitute to a Soviet sailor, then to the sailor's wife and, finally, to her 1-year-old son in Odessa on the Black Sea.

But more than 650 miles east, in the southern Russian town of Elista, another baby had contracted HIV. And the probable sources -- his parents and the blood he received during emergency treatment at a local hospital -- had tested negative.

Pokrovsky was about to give up. Then word came that both infants had been at the Elista Republican Children's Hospital a few months before.

The doctor flew to Elista and quickly confirmed his hunch: Hospital workers were routinely reusing syringes, rinsing them in solutions red with blood -- and spreading disease from child to child.

"They offered the wildest explanations imaginable" for the outbreak of HIV, Pokrovsky said. "The most common being that the virus was an unknown pathogen carried by local sheep herds."

By the end of Pokrovsky's investigation, 246 children in six Russian towns had been diagnosed with HIV. More than a third of them would die over the next few years.

The Elista case offered disturbing new evidence that the "ghost" epidemic was not confined to developing nations. Even in a medically sophisticated superpower, routine injections could transmit deadly infections.

BECTON DICKINSON HEADQUARTERS

RUTHERFORD, N.J.

Becton Dickinson was just one of 12 companies that Free approached with the PATH prototype. But in many ways it was the obvious choice.

The multinational corporation was the largest

syringe market in the world, a \$2 billion behemoth selling billions of disposable syringes every year. If any company could make autodestruct syringes a success, it was Becton Dickinson.

But the company, like its major competitors, had never shown an interest in nonreusable syringes. William Kozy, head of Becton Dickinson's syringe division, said the company wasn't aware of any need for the devices until after 1988.

When the company finally agreed to make the device, it was because autodestruct syringes could "differentiate our product line," said Vice President Anthony Kosinski.

But the deal had a condition: Contrary to its usual practice of receiving royalties for its designs, PATH would have to give Becton Dickinson the design for free.

"We don't always do this," Free said, "but if it seems like the only way to get a company to invest in a market that is undefinable, then yeah, no problem."

MINISTRY OF HEALTH

KARACHI, PAKISTAN

Promising in concept, the autodestruct syringe was still unproven in practice.

Becton Dickinson had changed the PATH design slightly, adding more prongs to the clip for a firmer hold. The company then christened the new syringe the Soloshot and in 1989 shipped it to the coast of Pakistan for demanding trials in the field.

The U.S. Agency for International Development and a private consultant -- John Snow Inc. -- conducted the tests, providing thousands of Soloshots to four dozen Pakistani health care workers and asking them to compare the Soloshots with conventional syringes during their daily routines.

The results astounded even the most optimistic

advocates of autodestruct syringes. Using Soloshots, the workers drew vaccine from vials more easily, allowed less air into the syringe barrel and then left less vaccine in the barrel after each injection.

Each injection took an average of 12.6 seconds less with the Soloshot. And workers found Soloshots easier to use, no matter how much training they had.

Researchers declared that Soloshots had outperformed standard disposables and recommended them ``as a direct replacement" for most injections.

NEW YORK UNIVERSITY MEDICAL CENTER

NEW YORK

A little girl with saucer eyes grins at the camera from under the wooden bowl perched on her head. An acoustic guitar and penny whistle play in the background of the video.

The scene shifts: A towheaded child astride a stuffed tiger, then a Peruvian father and son, then a line of children with arms around each other's shoulders.

``There was a time, not so long ago," the narrator says, ``when children like these didn't have a chance to grow up. Their lives and their futures were threatened by disease."

Now things are different, we are told, because the World Health Organization has vaccinated more than 80 percent of the world's children against six horrible diseases.

But the immunization program is threatened by a critical problem: deadly infections passed from child to child by contaminated needles and syringes.

Fortunately, the narrative continues, there is a solution. It is called the autodestruct syringe, ``an effective way to help break the chain of

cross-injection."

Produced by Becton Dickinson, the video unveiled the Soloshot. It was shown at the First International Conference on Self-Destructing Syringes in 1991 and helped set an urgent tone among the hundreds of medical experts there.

C. Everett Koop, former U.S. surgeon general and the conference's first speaker, demanded action on autodestruct syringes, saying he was "dismayed that so much time has passed and nothing has happened to take this small technological step toward . . . controlling the spread of HIV infection.

"The potential number of lives saved," he continued, "and the needless suffering that can be averted through this simple development . . . may be great, particularly if this technology is widely available."

Other speakers called for federal financing of the autodestruct syringes and congressional hearings on how to promote their use.

Peter Evans, senior technical officer of the World Health Organization, assured his colleagues that success was around the corner.

"Whatever the reason," he said, "a very important part of the industry appears now to have an intention to enter into this market, and the autodestruct syringe will soon become a reality."

UNICEF PROCUREMENT HEADQUARTERS

COPENHAGEN, DENMARK

In 1991, UNICEF agreed to buy 250 million autodestruct syringes over three years from Becton Dickinson and Bader and Partner, a German automated machinery maker.

The agreement was no surprise. When Becton Dickinson received the Soloshot technology from PATH for free, the company expected that

.....

The sticking point was the price. Although the new autodestruct syringes were first projected to cost only pennies more than conventional ones, Becton Dickinson and Bader priced them far higher.

According to UNICEF, the average price for the nonreusable models was almost 14 cents in 1991 and 1992. Becton Dickinson says it charged less than 12 cents for the Soloshot.

But UNICEF officials knew few countries would pay premium prices for the autodestruct syringes when traditional disposable ones cost just 4.5 cents apiece.

So, according to Becton Dickinson, the relief agency was forced to subsidize the autodestruct syringes, selling them to developing nations for just under 9 cents.

But price would be only part of the problem.

MINISTRY OF HEALTH

CAIRO, EGYPT

In 1994, Egyptian health officials noticed the first traces of a public health disaster.

A year earlier, the government started testing for hepatitis C in the nation's blood supply. The results showed that an increasing number of blood donations -- particularly in the countryside -- contained hepatitis C antibodies, a sure sign of the virus.

At the same time, the nation's annual death rate from liver cancer was soaring.

It would take several more years to connect the discoveries and draw an alarming conclusion: Nearly one in five Egyptians carried the hepatitis C virus, the highest infection rate in the world.

Realizing that some victims do not show symptoms of the virus for up to 20 years, the researchers looked to the 1960s and 1970s for a

possible source. They found it in mass-injection campaigns against schistosomiasis, a water-borne disease that causes tissue damage and cancer.

The reuse of contaminated syringes during the campaigns, the researchers concluded, had led to widespread hepatitis C infection. Vaccination workers ``were only boiling the needles for a few minutes," said Mustafa Kamel, a doctor working with government investigators. ``They didn't kill the virus."

But researchers soon found hepatitis C in thousands of people born after 1981, when oral medication for schistosomiasis began to replace injections.

The only explanation: The reuse of syringes was continuing to spread the disease.

UNICEF PROCUREMENT HEADQUARTERS

COPENHAGEN, DENMARK

UNICEF had no trouble finding a market for the autodestruct syringes. The problem was getting Becton Dickinson and Bader to deliver them.

Orders from developing countries jumped sharply, from 9 million in 1992 to 24 million in 1993 and to 60 million in 1994, according to a newsletter published by WHO.

But by the end of 1994, UNICEF found itself 32 million autodestruct syringes short, stopping the agency from taking orders for 1995.

``Quality control problems," the newsletter said, prevented Bader from meeting demand, while Becton Dickinson ``disappointed UNICEF with lower rates of production."

``There continues to be an explosive increase in demand while production falls far behind."

BECTON DICKINSON

FRANKLIN LAKES, N.J.

An extraordinary fiscal year began in October 1994 for Becton Dickinson. It was a period of record revenues topping \$2.7 billion, a stock price soaring 30 percent and a rapid expansion in foreign countries.

The company would revitalize its disposable syringe business in Europe and create a new subsidiary to sell syringes in India. And in China, Becton Dickinson would break ground for one of its most ambitious projects ever: a huge factory that would produce hundreds of millions of conventional disposables each year.

Meanwhile, company executives blamed the meager production of autodestruct syringes on UNICEF, saying the agency failed to give the company enough time to produce the Soloshots.

"It was a timing problem," said Becton Dickinson's Kosinski. "We were willing to supply more than they were willing to buy."

UNIVEC

GARDEN CITY, N.Y.

The demand for autodestruct syringes seemed obvious to Joel Schoenfeld, a former fur trader and commercial attache to the United Nations.

He had attended the 1991 conference on autodestruct syringes. The next year, he created a company -- UNIVEC -- to make nonreusable syringes. Wanting to gauge demand for his new product, Schoenfeld canvassed African health ministers.

"In one week," he said, "we had requests for 4 billion autodestructs."

By 1994, he had a prototype: A reed-thin syringe with a sliding metal band around its plunger. After the plunger was pushed down, it could not be pulled back.

The UNIVEC syringe was similar to the

soloshot but differed in two critical ways. It was smaller, and it was cheaper.

And with UNICEF's three-year contract with Becton Dickinson and Bader about to expire, Schoenfeld was ready to do business.

UNICEF PROCUREMENT HEADQUARTERS

COPENHAGEN, DENMARK

But UNICEF wasn't interested.

Even though Becton Dickinson and Bader had failed to supply enough autodestruct syringes -- and UNICEF had been forced to subsidize their premium prices -- the agency extended its contracts with the two manufacturers through 1998.

According to Schoenfeld, UNICEF ``was never willing to write an order, even though our price was lower."

Steven Jarrett, the agency's deputy director of procurement, declined to discuss the negotiations between UNICEF and UNIVEC.

He said UNICEF wanted to maintain ``a long-term relationship" with Bader and Becton Dickinson because ``both of the companies had to invest heavily."

But he conceded that the agency may have been ``too optimistic in terms of their capacity and manufacturing abilities."

WORLD HEALTH ORGANIZATION

GENEVA Evans and other top WHO officials were worried. A series of field reports showed that the reuse of contaminated syringes was spiraling out of control.

A Dutch study of four medical centers in Java and North East Sumatra found that ``disposable needles and syringes are reused without sterilization, sometimes over 50 times."

Most doctors and nurses, the study said, believe it is ``good enough to rinse the needles with distilled water and to wipe the outside with a piece of wadding soaked in alcohol."

In Tanzania, researchers reported that one-third of the syringes sterilized in clinics and hospitals were still contaminated.

In Romania, a 1993 study found that between 1989 and 1991, 1,479 children had tested positive for HIV, an infection rate more than 20 times higher than for adults. Researchers determined that most of the infections were transmitted through contaminated syringes and needles, others by transfusions with HIV-tainted blood.

But the worst news arrived in 1994.

In four of the world's six regions -- primarily developing countries -- half of the billions of injections administered yearly were being given with unsterile needles and syringes.

The news was nearly as bad for the World Health Organization's prized immunization programs: One of every three vaccinations was potentially contaminated with lethal infections.

The figures devastated Evans and his colleagues. They had spent years teaching immunization workers safe injection practices and proper sterilization techniques. They had vaccinated millions of children in every corner of the globe.

Now they realized that they could have been exposing millions of children to some of the world's most deadly diseases.

And there was another major worry.

For several countries, demand for immunizations had collapsed over rumors that some vaccines were unsafe.

``There was a great fear," said Evans, ``that any negative news about the safety of injections themselves could also seriously impact the

immunization programs."

ABOUT THE SERIES

In April, The Chronicle published "Deadly Needles," a three-part series about accidental needle injuries. Yesterday, we began a new series about deadly viruses transmitted through syringe reuse -- an epidemic destroying millions of lives every year.

-- YESTERDAY: (1920-1987) Medical researchers warn of an emerging epidemic, but no one takes action.

-- TODAY: (1988-1994) Nonreusable syringes promise safer injections, but opportunity slips away.

-- TOMORROW: (1995-1998) After miscalculations by health officials and resistance by needle makers, turmoil fuels the epidemic.

NEW TECHNOLOGY PROMISES SAFER INJECTIONS: 1988 -- 1994

AUTODESTRUCT

1988: PATH gives exclusive license for its autodestruct syringe to Becton Dickinson, which agrees to supply UNICEF and health ministries of developing nations, and to pay a \$50,000 patent maintenance fee. PATH created the design with the help of \$250,000 in federal financing.

AIDS IN RUSSIA

246 children are infected with the AIDS virus in Southern Russia from the reuse of contaminated needles and syringes.

HIGH NUMBERS

French study finds "incredibly high" numbers of injections and multiple syringe and needle reuse in Burkina Faso, Africa.

AMA

American Medical Association reaffirms an earlier resolution asking manufacturers to make syringe designs that prevent reuse.

NEW DEVICE

1989: PATH licenses UniJect, a revolutionary single-use injection device made with a plastic bubble blister instead of a plunger, to Horizon Medical, Inc.

FIELD TRIALS

Final field trials in Pakistan of Becton Dickinson's autodestruct needle, called Soloshot, show that the syringe is effective and easy to use.

CONTRACT BIDS

1990: UNICEF invites bids from manufacturers to supply the agency with autodestruct syringes. Only Becton Dickinson and a German company called Bader and Partner qualify.

ANOTHER DEVICE

Douglas Campbell, who later formed Atlas Medical Resources, invents an autodestruct syringe.

IMMUNIZATION CAMPAIGN

Eighty percent of the 130 million children born each year are immunized against six major diseases -- diphtheria, tetanus, whooping cough, polio, measles and TB -- compared with less than 5 percent in 1974, when the immunization campaign began.

CONFERENCE

1991: New York conference on nonreusable syringes. Becton Dickinson presents videotape stressing the importance of autodestruct technology, and former U.S. Surgeon General C. Everett Koop urges the manufacture of such

devices.

IDEAS

More than 230 ideas for nonreusable syringes pour into WHO headquarters between 1986 and 1991.

CONTRACTS

UNICEF agrees to exclusive contracts with Becton Dickinson and Bader to buy 250 million autodestruct syringes over the next three years.

TAIWAN

Study shows that ethnic groups in Taiwan with very high rates of hepatitis B also have higher rates of injections with reusable glass syringes.

DIRECTIVE

1992: UNICEF issues directive stating it will phase out standard syringes in favor of autodestruct models.

HIV TRANSMISSIONS

CDC reports that three hospital patients -- in Albuquerque, San Diego and the Netherlands -- were infected in 1990 with HIV through reused needles.

MODEL

WHO researchers create a mathematical model that can estimate the number of infections for hepatitis B and HIV that will result when contaminated syringes are reused one to four times or more.

ROMANIA 1993: Study finds hundreds of Romanian children were infected with HIV and hepatitis through syringe reuse between 1989 and 1991.

CHINA

ever, with more than 100 million children immunized in a single day.

MULTIPLE INJECTIONS

UNICEF finds that nearly 50 percent of Eastern European health centers are giving unsafe injections and that children there receive an average of 115 injections in addition to immunizations during their first year of life.

UNIVEC

1994: A New York company called UNIVEC offers to license its autodestruct syringe to big manufacturers, estimating it would cost only one penny more than a standard syringe.

HEPATITIS C

Australian study shows that hepatitis C can be transmitted by syringe reuse. Egypt reports soaring rates of hepatitis C, linked to an earlier mass injection campaign against schistosomiasis.

LATE DELIVERY

More than 30 million autodestruct syringes promised by UNICEF are late for delivery to Romania, Iraq and Sudan.

NEW CONTRACTS

UNICEF extends its exclusive contracts with Becton Dickinson and Bader for four years.

ESTIMATES

WHO estimates that in most developing countries, up to one third of immunization injections are unsterile and 50 percent of all non-immunization injections are unsafe.

TYPES OF HYPODERMIC SYRINGES --

Glass reusable syringes -- Invented in 1845, glass syringes were the only type used for more than a century. They must be sterilized by steam for at least 30 minutes and can be reused hundreds of

times. -- Plastic reusable syringes - Cheaper and safer than the breakable glass syringe, the plastic reusables became popular with immunization programs in the 1980s. They were designed to withstand the heat of sterilization and to be reused dozens of times. -- Plastic disposable syringes - Made of thinner polymers than plastic reusable syringes, the disposables were designed to be used only once then discarded. They were introduced in 1955 and now make up nearly all of the world's syringe market. -- Nonreusable or autodestruct syringes - Plastic disposable syringes with a feature that makes them impossible to use twice. First designed in the 1970s, they were not manufactured until the early 1990s. They now make up a fraction of the global syringe market.

ORGANIZATIONS ENGAGED IN WORLD HEALTH CARE

-- World Health Organization (WHO). United Nations agency that sets international health policy and gives countries training and technical help for fighting disease. Headquarters in Geneva, Switzerland.

-- United Nations Children's Fund (UNICEF). UN agency that supplies health care, medical equipment, food and other basic needs to children in developing countries. Headquarters in New York, NY. -- Pan American Health Organization (PAHO). UN agency and WHO regional office that gives countries in the Americas training and technical assistance for fighting disease and supplies health care and medical equipment. Headquarters in Washington, D.C.

-- United States Agency for International Development (USAID). Part of the executive branch's International Development Cooperation Agency, it provides economic and humanitarian aid to developing countries. Headquarters in Washington, D.C. -- Program for Appropriate Technology in Health (PATH). Nonprofit organization that develops health care technology for developing countries. Headquarters in Seattle, Wash.

ABOUT THE NUMBERS

The statistics and other figures used in this series came from a number of sources:

The estimated number of worldwide infections and deaths caused by reuse of contaminated syringes -- 10 million infections and 1.8 million deaths per year -- came from internal reports of the World Health Organization. These reports are still under scientific review and have not been published, but WHO officials say the draft figures are conservative estimates.

The estimates of the global prevalence of the diseases that are most likely to be spread through syringe reuse -- HIV, hepatitis B and hepatitis C -- came from data compiled by WHO, the national Centers for Disease Control and Prevention (CDC) and United Nations AIDS.

Figures on the number of nonreusable or "autodestruct" syringes produced and distributed were compiled from syringe manufacturers, United Nations Children's Fund (UNICEF), WHO and a group of immunization experts called Technical Network for Logistics in Health (Technet).

The funding figures for development of several nonreusable syringes were supplied by the U.S. Agency for International Development (USAID) and Program for Appropriate Technology in Health (PATH). Pricing data for the syringes came from UNICEF and individual manufacturers.

U.S. and global estimates of accidental needle sticks came from the International Health Care Worker Safety Center, CDC, WHO and from studies in Thailand, Pakistan and Tanzania.

RELATED COVERAGE ON the INTERNET

For more about "Deadly Needles" -- including The Chronicle's three-part series in April on accidental needle sticks -- log onto www.sfgate.com.

THE DEVELOPMENT OF SINGLE-USE SYRINGES

The spread of serious infections provoked development of single-use -- or autodestruct -- syringes in the mid-1980s. The devices were sold primarily to developing countries through relief agencies, and only a tiny fraction of the 10 billion injections given each year are administered with autodestruct syringes.

Glass syringes could be reused but spread deadly disease when not properly sterilized. Beginning in the early 1960s, many were replaced by disposable plastic syringes designed to be used once and then discarded.

But nothing stopped misinformed health care workers -- or those short of supplies -- from using one disposable syringe on multiple patients.

- **Standard Disposable syringe**

Includes a plunger and hollow-bore needle for injecting medications or drawing blood and other fluids. Once used, it cannot be properly sterilized, making it a dangerous -- even lethal -- instrument when contaminated with infected blood.

First introduced 1955

Major manufacturers Becton Dickinson and Co., Kendall and Terumo

Approximate price 4.5 cents to 7 cents

- **Soloshot**

Developed by the nonprofit Program for Appropriate Technology in Health with federal financing. It was the first commercially available autodestruct syringe but is sold almost exclusively to UNICEF and is unavailable in the United States.

First introduced 1992

Major manufacturers Becton Dickinson and Co.

Approximate price 8.5 cents

- UNIVeC

A slim and simple autodestruct syringe made by a start-up company in New York. It was designed to meet WHO standards for immunization programs but has not been bought by UNICEF. Closely resembles a standard syringe.

First introduced 1995

Major manufacturers UNIVeC

Approximate price 8.5 cents

- UniJect

A second-generation single-use syringe, it was developed by PATH with federal financing. It was designed to give one shot of medication, inserted into the bubble before sale. Scheduled for release to immunization programs early next year.

First introduced 1999

Major manufacturers Becton Dickinson and Co.

Approximate price 10 cents

Sources: Industry advertising and Chronicle research

STEVE KEARSLEY / THE CHRONICLE

Demand soared in the early '90s for nonreusable syringes supplied by UNICEF. By 1994, UNICEF was 32 million units short of demand. The agency therefore stopped taking orders in 1995.

1992 9 mil

1993 24 mil

1994 60 mil

Source: WORLD HEALTH ORGANIZATION

Chronicle foreign correspondents Sandy Barron in Cambodia, Jack Epstein in Brazil, Steve Fennessy in Egypt, Brian Humphreys in Russia and Andrea Useem in Kenya contributed to this report.

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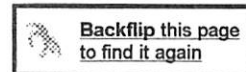


DEADLY NEEDLES Epidemic's Devastating Toll

Thursday, October 29, 1998

San Francisco Chronicle
 CHRONICLE SECTIONS

Reynolds Holding, William Carlsen, Chronicle Staff Writers


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DEADLY NEEDLES

A Special Series

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By the early 1990s, miscalculations and missed opportunities by health officials, needle manufacturers and relief agencies had exacted a terrible price. Unsafe injections were destroying millions of lives and costing hundreds of millions of dollars every year.

(Last Of Three Parts)

THIKA DISTRICT HOSPITAL

THIKA, KENYA

No matter how many times the memory plays in his mind, Dr. Warura Mogo cannot think what he would have done differently.

It was 1994. About 120 children waited for vaccinations outside his office. But he had only 20 disposable needles and syringes.

Mogo, a pediatrician and AIDS researcher, knew the risks. He could immunize 20 children and send the rest away, leaving them vulnerable to measles, mumps and other potentially lethal diseases.

Or he could vaccinate every child, quickly boiling the syringes after each injection -- knowing that if just one child carried HIV, hepatitis or some other blood-borne virus, the others might get it, too.

"The question was," he said, "would I turn people away, or do I make use of the situation I

Conference.

Thousands of health care workers in every corner of the globe would face the same wrenching dilemma that year.

For decades, researchers had warned that reusing contaminated needles and syringes could transmit disease with deadly ease. Nothing seemed to prevent it. Sterilization programs failed, and inexpensive disposable syringes proved as dangerous as the glass syringes they replaced.

By 1994, health care workers like Mogo stood at the center of an international health crisis, a "ghost" epidemic claiming more than a million lives each year. But the world would be unprepared -- and unwilling -- to confront it.

Even after receiving reports of billions of unsterile injections every year in developing nations, world health officials would downplay the crisis.

Despite the soaring death toll, major syringe manufacturers would expand global markets for traditional disposables -- and in the process be accused of sabotaging small competitors and intimidating foreign officials.

Nonreusable syringes, the best hope for a new era of safe injections, would reach few health care workers, even though the devices had been developed nearly a decade earlier.

And amid the turmoil, doctors like Mogo would be left to fend for themselves.

On that day four years ago, Mogo made the decision that troubles him to this day. He vaccinated all the children.

"I used what I had," he said.

WORLD HEALTH ORGANIZATION

GENEVA

For Peter Evans and other WHO officials, the

Crook or Genius,
He's Got Their
Attention
02/20/2000

Baby Lawyers Too
Costly to Waste
02/13/2000

Reynolds Holding
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2000

view archive

news was bad and getting worse.

In 1994, surveys showed that each year in the developing world, up to a third of the 1 billion immunizations -- and half of the other 9 billion injections -- were unsterile.

And using a mathematical model created two years earlier, researchers calculated the risks of reusing contaminated syringes. The initial findings, though incomplete, were "alarming," the researchers said.

The new information put Evans, a WHO immunization expert, and his colleagues in a bind.

Publicizing the dangers of unsafe injections could undermine the agency's immunization programs by deterring parents from having their children vaccinated against such deadly diseases as tuberculosis, diphtheria and tetanus.

But failing to alert the public could unnecessarily expose millions of people to HIV, hepatitis and other lethal viruses.

One high-level WHO official called it a "schizophrenic" situation akin to "walking on a minefield."

In the end, Evans said, he and his colleagues would "low key" the crisis

--and protect the immunization programs to which they had devoted their lives.

MINISTRY OF HEALTH

YAMOUSSOUKRO, IVORY COAST

They rose slowly, one by one at first, then in clusters of a dozen or more.

Before long, the entire chamber was filled with ministers of health and their entourages from 50 African nations, standing and applauding.

It was March 1994. Dr. Maurice Kaku

Goukane, the post and health minister from the Ivory Coast, had just endorsed a declaration on safe injections.

The declaration committed everyone involved with immunization programs to make injections safe, to ensure that 95 percent of vaccinations would be sterile by 1997 -- and to use autodestruct syringes whenever possible.

It was already costing hundreds of millions of dollars every year to care for victims of unsafe injections, according to world health officials, and Third World nations were suffering the most. But it would cost no more than an additional \$50 million a year to supply all immunization programs with autodestruct syringes.

The troubled continent, with the highest disease rates in the world, had issued a desperate message: We must have the same health care that the developed world has.

UNIVEC

GARDEN CITY, N.Y.

For Joel Schoenfeld, the timing seemed perfect.

The Ivory Coast declaration had helped boost demand for nonreusable needles. UNICEF faced back orders for 32 million, and its two main suppliers, Becton Dickinson and Bader and Partner, failed to keep up with the requests.

And Schoenfeld's prototype for a simple, inexpensive autodestruct syringe had intrigued one of the world's largest syringe makers: Sherwood, Davis & Geck.

"They said they knew syringes were spreading disease," Schoenfeld said. "So they talked about doing a joint venture."

The idea made sense. Schoenfeld's company, UNIVEC, needed Sherwood to mass-produce components for the syringe. Sherwood could use UNIVEC and its state-of-the-art prototype to

syringes.

``Given the potential of the product," Sherwood Vice President Michael Riddle wrote to Schoenfeld, ``I am sure our relationship will develop into one of significant mutual benefit for our companies."

The prototype exceeded standards set by WHO and the Federal Drug Administration, and UNIVAC agreed to buy components for at least 50 million autodestruct syringes a year over the next five years -- exclusively from Sherwood.

In mid-1995, UNIVAC began negotiating with UNICEF, offering to supply 20 million autodestruct syringes.

When the relief agency said it was interested, Schoenfeld figured he was in business.

UNIVAC

GARDEN CITY, N.Y.

It didn't take long for the deal to unravel.

By April 1995, production of the syringes had run into delays. After waiting four months for syringe components, UNIVAC discovered that Sherwood had never ordered molds to make the syringe plungers.

In May, Sherwood agreed to manufacture 1,000 sample devices for UNIVAC to show UNICEF. But when the autodestruct syringes were delivered several months later, the needles fell off easily, and the agency declined to pursue UNIVAC's offer.

A year passed before Sherwood finally delivered the first shipment of autodestruct-syringe plungers to UNIVAC -- but they were all defective, according to Schoenfeld.

``You name an excuse, they had it," he said.

Schoenfeld is convinced that Sherwood never intended to make an acceptable product. He has

sued the company for fraud, claiming its ``actions were designed . . . to destroy (UNIVEC's) ability to compete."

Sherwood refused to comment, citing the pending lawsuit.

But UNIVEC wasn't the only small firm having trouble getting its autodestruct syringes into the hands of health care workers.

ATLAS MEDICAL RESOURCES

NEPEAN, ONTARIO

When Douglas Campbell was volunteering at a drug treatment center in downtown Ottawa, he thought the organization was helping addicts by giving them clean disposable syringes.

But when the regulars started to arrive with HIV, he realized they had contracted the virus by sharing the syringes.

So he designed a syringe that could not be reused. It contained two blades that cut through the barrel as the plunger was pulled back a second time, disabling the syringe after one use.

In 1994, Campbell, owner of Atlas Medical Resources, approached

UNICEF and other U.N. agencies with his simple design.

Agency officials seemed interested. They knew they were facing an epidemic, and they knew their two suppliers were not meeting the escalating demand for autodestruct syringes.

But after a series of encouraging meetings, Atlas still had no contract.

``We've had hundreds of meetings in New York with U.N. agencies," Campbell said, ``and every one has been successful individually. They (U.N. officials) know precisely about the danger: That reuse is killing millions and that this (autodestruct syringe) would stop reuse.

``But then they don't order any."

UNICEF PROCUREMENT OFFICE

COPENHAGEN, DENMARK

UNICEF contends that Atlas never entered the agency's bidding process.

But the agency hadn't put out bids for autodestruct syringes since 1990, even though its two suppliers -- Becton Dickinson and Bader -- fell so far behind that the agency stopped taking new orders.

In 1994, despite the supply problems, UNICEF extended its agreements with Becton Dickinson and Bader for four years.

By 1996, UNICEF had requests for 127 million autodestruct syringes, tens of millions more than the relief agency could provide.

The goal set by health ministers at the Ivory Coast summit -- to ensure that 95 percent of immunizations were sterile by 1997 -- seemed further away than ever.

BECTON DICKINSON HEADQUARTERS

FRANKLIN LAKES, N.J.

For Becton Dickinson, 1996 was another record year.

Revenues hit \$2.77 billion -- a new high -- and offices abroad numbered 50 in 35 countries, including a new factory in China making 300 million conventional syringes a year.

The company also acquired the rights to one of the most intriguing injection devices ever made: A tiny plastic blister attached to a needle with a one-way valve that blocks reuse.

Called UniJect, the device was created with \$2.2 million of federal money by the Program for

Appropriate technology in health, the same nonprofit group in Seattle that gave Becton Dickinson the design for another nonreusable syringe, the Soloshot.

The company promptly touted UniJect as the centerpiece of a planned UNICEF campaign against tetanus, which health experts said would cost \$100 million to eliminate. Becton Dickinson's contribution: a total of \$1 million over five years, plus \$3 million in donated training, UniJects and other equipment.

Meanwhile, sales of the company's Soloshot syringe stalled after reaching 30 million per year.

Dr. Zeil Rosenberg, a medical director at Becton Dickinson, contends that many countries will not buy autodestruct syringes. "An American company can't waltz into a ministry of health thinking it knows the answers," he explained.

MINISTRY OF HEALTH

BRASILIA, BRAZIL

Early in 1996, a federal report revealed that nearly half a million Brazilians had HIV

--22 percent infected by contaminated needles. Over the next decade, the report predicted, AIDS victims would number 7.5 million, average life expectancy would drop 12.1 years and the male population would fall by 636,000.

"We had to do something," said Brazilian Congressman Elias Murad.

On May 3, 1996, Brazil became the first country in the world to enact a law mandating only nonreusable syringes. Sponsored by Murad, the law was scheduled to take effect by the end of 1996. But it was blocked almost immediately.

Murad contends that Brazil's major syringe makers lobbied the health ministry to suspend the measure because the new devices would cut into sales of their conventional syringes.

don't want to see the law's enforcement."

Becton Dickinson, Brazil's largest syringe supplier with close to 50 percent of the market, denies any lobbying effort.

The company's quality control officer, Afonso Medeiros, said the law was not implemented because no autodestruct syringes exist in Brazil and the government has not told manufacturers what it wants.

William Kozy, head of Becton Dickinson's injection-systems division, contends that "we have been poised to make the product ready for them. They just never implemented the law."

TECHNET CONFERENCE

WORLD HEALTH ORGANIZATION

REGIONAL OFFICE

MANILA, PHILIPPINES

It was their first meeting in two years, and many of the 50 immunization field experts who flew to Manila in early 1996 were frustrated by the slow progress toward safer injections.

Countries weren't addressing the problem, said a report of the conference, and nonreusable syringes were still too expensive -- more than double the price of standard disposables.

They criticized the World Health Organization for lack of leadership outside Africa and the Western Pacific.

One recommendation: Publicize the dangers of syringe reuse. When a smaller group met later that year, it warned that "the urgency of the issue had become critical."

Surveys from around the globe showed lethal diseases spreading with astounding speed -- and syringe reuse compounding the problem.

More than 350 million people were chronic

carriers of the hepatitis B virus, and the disease was hitting young children the hardest.

Between 60 percent and 90 percent of infected children under 1 year old -- when they are most likely to be immunized -- become chronic hepatitis B carriers, compared with only 10 percent of adults. And 25 percent of all carriers eventually die of liver disease.

In 1996, more than 170 million people were carrying the hepatitis C virus, which attacks the liver and is even more deadly than hepatitis B.

And 30 million people carried HIV, which infected 16,000 people a day -- 12,000 in Africa alone.

MINISTRY OF HEALTH

PHNOM PENH, CAMBODIA

In 1997, Cambodia adopted a national policy requiring that disposable syringes be used only once and that enough be available to prevent reuse.

But relief agencies estimate that graft consumes more than half the nation's meager health budget. Medical facilities receive only a fraction of the syringes needed for injections, forcing health care workers to reuse improperly sterilized needles.

``Monies earmarked for the health sector are not reaching the ministry of health, let alone the people," said an official with Doctors Without Borders, a French relief agency.

Thavisak Thasnabunjong, a Thai medical supplier who distributes equipment throughout Southeast Asia, said he has stopped supplying the Cambodian government with disposable syringes.

``The commission I was asked for was too high," he said. ``It's the same story with officials in Laos."

in Phnom Penh, midwife Knou Kanika said Mean Chay hospital may receive only five disposable syringes per day.

Piem Row hospital in Prey province must sometimes make 200 disposable syringes last three months -- almost an impossibility, said nurse Meah Sunhak.

The shortages have led to a thriving black market.

Nurse Thai Sovannara sells used syringes from his clinic near Chaba market on the outskirts of Phnom Penh. A buyer comes around occasionally to buy a box.

"I don't know where they go," he said.

REPUBLICAN CENTER FOR TREATMENT OF INFECTIOUS DISEASES

OUTSIDE ST. PETERSBURG, RUSSIA

Sixteen-year-old Sasha, ashen and exhausted, lay in the AIDS ward with an IV catheter in his arm.

He had come to the decaying two-story brick facility early this summer, traveling with his parents from his home in Kalmyk in southern Russia.

Sasha was 6 when he was infected with HIV through a contaminated syringe. It happened in 1988, during an outbreak that struck down 245 other children hospitalized in and around the town of Elista.

Nadezhda Burova, head of the facility, estimates that a third of the children are dead.

"Many die at home, and who knows how many died here," said Burova, whose center is so poor that it can treat no more than 20 children with new combination-drug therapies.

"It's hard working here," Burova said. "The sick never get better."

Both of Sasha's parents are unemployed. And as economic depression deepens in Russia, they don't know how much longer the government-funded treatment of their son will continue.

Sasha tries to stay upbeat. Glancing at the drugs flowing into his arm, he smiled weakly and said he is looking forward to returning to school in his village.

And he still wants to learn how to drive a car, his lifelong dream.

WORLD HEALTH ORGANIZATION

HEADQUARTERS

GENEVA

It was a moment world health officials had been dreading for years.

By June, the first hard estimates were in -- and almost impossible to believe. The miscalculations and missed opportunities of the past decade had taken an almost incomprehensible toll.

Using the mathematical model refined since 1992, researchers now calculated that 8.3 million people were contracting hepatitis B every year through the reuse of contaminated syringes.

An additional 1.3 million were being infected with hepatitis C and 31,000 with HIV.

Up to 1.8 million a year would die from the infections, a death rate equal to that from three of the biggest childhood killers -- measles, tetanus and whooping cough -- combined.

At a June 10 meeting, WHO distributed the figures to 29 leading health experts, including officials from the World Bank, the U.S. Centers for Disease Control and Prevention and the Food and Drug Administration.

Some, like Dr. Ciro de Quadros, director of vaccines and immunizations for the Pan

But others knew that the calculations were, if anything, conservative.

And they had no doubts about what to do next.

``We've got to tell people what the size of this problem is," said WHO official John Lloyd.
``They have to know."

EPILOGUE

WORLD HEALTH ORGANIZATION

GENEVA

Before they adjourned in June, WHO officials called on all nations and relief agencies that finance immunization programs to stop buying standard disposables immediately and to purchase only autodestruct syringes.

The officials also prepared to expand their safety campaign dramatically. For the first time, it would go beyond immunizations to include all 10 billion injections given every year around the world.

It was a profound shift in policy. It would require money, planning, medical training -- and the aggressive marketing of autodestruct syringes for uses beyond vaccination.

The campaign would also take partners: manufacturers, health ministries, donor nations and funding agencies such as the World Bank.

``We can no longer do this by ourselves," said WHO official Michel Zaffran.

WHO officials say they plan to publish the final infections and death estimates from syringe reuse next year.

``It has been terribly frustrating," said Lloyd.
``The solutions exist. It's just getting them implemented."

HARYANA, INDIA

A modern, red-brick building rises three stories from the plains of the northwest. Scheduled to open in January, it is the new Becton Dickinson syringe factory, the centerpiece of the company's 16-warehouse, 300-distributor network in India.

Like the plant the company opened two years ago in Suzhou, China, the factory will churn out hundreds of millions of standard, disposable syringes.

Executives at Becton Dickinson say they would like to sell autodestruct syringes in both countries, but the obstacles are too great.

``If we could convince a country . . . to use a safety device, a self-destruct syringe, we would be very happy," said Chairman, President and Chief Executive Officer Clateo Castellini. ``The problem is that it is very hard to convince them to spend more money."

But Becton Dickinson relies primarily on UNICEF to buy the Soloshot and promote it around the world. And UNICEF is ``a passive distribution system" that has ``always been nervous about promoting technologies," said Michael Free, vice president of PATH, a nonprofit developer of health technology for developing countries.

After six years of production, Becton Dickinson still sells only about 30 million Soloshots each year. In the two years since it acquired UniJect, the company has not yet put the device on the market.

Meanwhile, Becton Dickinson is using its global sales force and production capacity to concentrate on expanding the market for disposable syringes, a plan that Castellini believes will help double the size of the \$3 billion corporation over the next five years.

``In developing countries," he said, ``the strategy is really to convert them from glass to disposable

syringes."

ANSARI NAGAR DISTRICT

DELHI, INDIA

About an hour southeast, in the city's poorest neighborhood, hundreds of children crawl over a 50-foot mound of garbage, combing for syringes, gloves, scraps of bandage -- any medical waste to sell on the black market.

Iqbal Malik, who studied India's ragpickers for three years, said it is "absolutely shocking."

In 1997, she uncovered a highly organized, far-flung operation of up to 10,000 people engaged in recycling syringes and other medical waste.

Her environmental group estimates that one-third of the 2.9 billion annual injections in India are administered with washed and repackaged syringes.

"There is a real danger of direct contamination by AIDS and hepatitis B," said environmentalist Ravi Agarwal.

"This is a ticking time bomb."

ABOUT THE SERIES

In April, The Chronicle published

"Deadly Needles," a three-part series about accidental needle

injuries. On Tuesday, we began a new series about deadly infections

transmitted through syringe reuse -- an epidemic destroying

millions of lives every year.

-- TUESDAY: (1920-1987)

Medical researchers warn of an emerging epidemic.

-- YESTERDAY:

(1988-1994) Nonreusable syringes promise safer injections, but

the opportunity slips away.

-- TODAY: (1995-1998) After

miscalculations by health officials and resistance by needle

makers, turmoil fuels the epidemic.

WORLD IN TURMOIL: 1995 - 1998**PRODUCTION PLAN STALLED**

1995: Sherwood reveals to

UNIVAC that no molds for making a new autodestruct syringe have been ordered, launching a series of excuses that would scuttle sales to UNICEF and seriously delay the device's introduction.

UNICEF SCANDAL

UNICEF discloses that its Kenya operation lost as much as

\$10 million to fraud and mismanagement by employees.

MALARIA VACCINE

Dr. Manuel Patarroyo grants WHO an exclusive, worldwide, royalty-free license to the patent for his vaccine against malaria.

SAFE-SYRINGE LAW

1996: Brazil becomes the first nation to pass a law mandating autodestruct syringes. Almost immediately, the law is blocked from taking effect.

DEFECTIVE SYRINGE PARTS

Sherwood ships its first order of syringe parts to UNIVAC, but all are defective.

OPTIMISTIC FORECAST

Becton Dickinson acquires rights to Uniject single-use syringe. Gary Cohen, head of Becton Dickinson's worldwide injection systems business, predicts that the syringe will help the division earn \$950 million in revenues by 1999.

AIDS CASES

The Centers for Disease Control and Prevention discloses in its weekly newsletter that one-third of new AIDS cases reported in 1995 were associated with the reuse of syringes.

AMA RESOLUTION

The American Medical Association reaffirms its resolution calling on all manufacturers of disposable needles and syringes to "adopt designs to prevent reuse."

TECHNET MEETING

Field experts from international relief agencies meet in Manila and vent frustrations over the lack of progress toward ending unsafe injections.

UNICEF DELIVERIES

UNICEF receives requests for 127 million autodestruct syringes but can deliver only 56 million to 23 countries.

CHINA PLANT

In Suzhou, China, Becton Dickinson opens a new factory with the capacity to make 300 million standard disposable syringes each year.

ATLAS AUTODESTRUCT DESIGN

1997: Atlas Medical Resources of Nepean, Canada, patents a new design for an autodestruct

syringe.

FLU-SHOT REUSE

A doctor in Monroe, Conn., reuses syringes while administering flu vaccines to almost 500 town residents. "I didn't know the procedure had changed," he protests.

AUTODESTRUCT SYRINGES ADVISED

WHO and UNICEF ask all financial backers of immunization campaigns to buy only autodestruct syringes and to package them with vaccines and safety disposal boxes.

CAMBODIA POLICY

Cambodia adopts a policy requiring that disposable syringes be used only once and promising adequate supplies. But graft prevents clinics from receiving more than a fraction of the syringes needed.

JET INJECTORS

WHO withdraws approval of needleless jet injectors for mass immunizations after studies show contamination of the reusable nozzles can spread infections.

SHERWOOD GIVES UP

Sherwood returns to UNIVAC the mold for making syringe plungers and abandons the UNIVAC project.

BD OFFER

According to UNIVAC, Becton Dickinson offers to buy the company for \$100,000. UNIVAC turns down the offer.

BD PARTNERSHIP

1998: Becton Dickinson announces partnership with UNICEF to support elimination of neonatal

...stands. The company commits to contribute \$1 million worth of products and \$3 million worth of technical assistance over five years.

REVENUE PLAN

At the annual Becton Dickinson shareholders' meeting, Clateo Castellini

--president, chief executive officer and chairman of the company

--announces plan to double revenues over the next five years.

SHERWOOD SOLD

American Home Products sells Sherwood to Tyco International Ltd.

UNICEF BIDS

UNICEF announces results of bids for contracts to supply autodestruct syringes. Although four companies offered syringes for between 8 and 9 cents each, only Bader and Becton Dickinson receive commitments.

BD CHARGED

Managers at the Becton Dickinson plant in Brazil are charged with selling blood-collection tubes below cost and other ``economic crimes." Charges are later settled.

SAGE RECOMMENDATION

WHO's Scientific Advisory Group of Experts recommends that donors supporting immunization programs buy only autodestruct syringes and encourages local production of the devices.

DISPOSAL DILEMMA

As health workers switch from sterilizable syringes to disposable ones -- conventional or autodestruct -- they face a new problem: safely disposing of many hundreds of millions more

needles and syringes.

The World Health Organization and UNICEF have come up with two solutions:

Safety disposal boxes:

Thick cardboard cartons are shipped with some syringes for health workers to deposit the used devices. Some boxes are lined with foil and include their own combustion material, making them self-contained units that can be burned in the field.

Field incinerators:

WHO is currently testing small incinerators that can be set up in districts or provinces where health workers can bring syringes for burning. One problem with this method is the air pollution caused by the incineration.

Health officials say the disposal problem has become critical because needles and syringes show up in garbage dumps, where they can injure people or be scavenged for resale.

Source: World Health Organization

STEVE KEARSLEY/THE CHRONICLE

RELATED COVERAGE ON TV AND INTERNET

For more about "Deadly Needles" -- including The Chronicle's three-part series on accidental needle sticks in April -- log on to sfgate.com

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