THE WHITE HOUSE
WASHINGTON

February 5, 1999

Mr. Purnell Choppin
President
Howard Hughes Medical Institute
4000 Jones Bridge Road
Chevy Chase, MD 20815

Dear Mr. Choppin:

Thank you so much for the wonderful visit in your offices at the Howard Hughes Institute. You were so gracious to take the time to show us the center and explain the key projects of HHMI. Needless to say, I was very impressed.

I would like to return the favor on some future date. Please give me a call next time you are in our part of town. I look forward to seeing you soon.

Sincerely,

Sandra L. Thurman
Director
Office of National AIDS Policy

Data Entry Form

Letter ID	Writer First Name	Writer Last Name	Received Date	Subject
11306	Katharine (Kathy)	Calhoun Wood	2/22/99	

☐ Response Required?

Response Type	Response Date	Responder ID	Responder Name	Action Promised

Action Completed	Action Date	Addressed To
		Sandy

Notes

Sender's Organization	Sender's Street1	Sender's Street2
Hurt, Norton & Associates, Inc	505 Capitol Court, Ste. 200	

Sender's City	Sender's State	Sender's Zip
Washington	DC	20002

HURT, NORTON & ASSOCIATES, INC.

February 10, 1999

Ms. Sandy Thurman
Director, National Aids Policy
736 Jackson Place
Washington, DC

Dear Sandy,

This is just a brief note to thank you for taking time from a busy schedule to meet with me and John Mitnick of MedSafe Technologies when he was in Washington at the end of last year.

We enjoyed a series of interesting and productive meetings while John was in town, and were encouraged by the positive response we received not only to MedSafe's particular product, but also to the need for true reform in this field. We appreciate your willingness to assist us in this regard, and look forward to "spreading the word" among your associates in the Executive Branch.

In this regard, we spoke of the possibility of your convening a meeting of several individuals who you believe would hold an interest in this issue and with whom we might work to further acceptance of John's product and others like it. Enclosed for your files you will find a copy of documents relating to the State of California's recent action as well as copies of the articles from the San Francisco Chronicle which served to focus attention on and efforts to mitigate needle stick injuries. John will be in town on February 22 and 23. Should such a meeting be possible then and should John be helpful in discussing the need for greater attention on this issue, we stand ready to participate.

Thank you, again, for your time and consideration.

Sincerely,

Katharine Calhoun Wood

Enclosures

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CONCURRENCE IN SENATE AMENDMENTS
AB 1208 (Migden)
As Amended August 24, 1998
Majority vote

ASSEMBLY: (May 22, 1997) SENATE: 22-12 (August 27, 1998)

(vote not relevant)

Original Committee Reference: HEALTH

SUMMARY : Requires the California Occupational Safety and Health Standards Board (Board) to revise its bloodborne pathogen standard.

The Senate amendments delete the provisions of the bill as it passed the Assembly and, instead:

1) Require the Board, no later than January 15, 1999, to adopt emergency regulations revising the bloodborne pathogen standards currently set forth in the Cal-OSHA regulations.

2) Require the Board, following the adoption of the emergency regulations, to formally adopt a bloodborne pathogen standard, to be operative no later than August 1, 1999. This standard is to be developed by the Division of Occupational Safety and Health.

3) Require the standard to include, but not be limited to, the following:

a) A revised definition of "engineering controls" that includes sharps prevention technology including, but not limited to, needleless systems and needles with engineered sharps injury protection.

b) A requirement that the sharps prevention technology be included as engineering or work practice controls, except in cases where the employer or other appropriate party can demonstrate circumstances in which the technology does not promote employee or patient safety or interferes with a medical procedure. Requires those circumstances to be specified in the standard, and to include, but not be limited to, circumstances where the technology is medically contraindicated or not more effective than alternative measures used by the employer to prevent exposure incidents.

c) A requirement that written exposure control plans include an effective procedure for identifying and selecting existing sharps prevention technology.

d) A requirement that written exposure control plans be updated when necessary to reflect progress in implementing the sharps prevention technology.

e) A requirement that information concerning exposure incidents be recorded in a sharps injury log, including, but not limited to, the type and brand of device involved in the incident.

4) Authorize the Division of Occupational Safety and Health to consider and and propose for adoption by the board additional revisions to the bloodborne pathogen standards to prevent sharps injuries or exposure incidents including, but not limited to, training requirements and measures to increase vaccinations.

5) Require the Division of Occupational Safety and Health and the State Department of Health Services (DHS) to jointly compile and make available a list of needleless systems and needles with engineered sharps injury protection.

EXISTING LAW

1) Authorizes the Occupational Safety and Health Standards Board (Board) to adopt occupational safety and health standards and orders, which are required to be at least as effective as federal standards for all issues for which federal standards have been adopted under the federal Occupational Safety and Health Act of 1970.

2) California regulations (General Industry Order 5193), adopted by the Board pertain to occupational exposure to blood or other potentially infectious materials.

AS PASSED BY THE ASSEMBLY , this bill:

1) Required DHS to collect and summarize specified information.

2) Required DHS to submit the report to the Legislature by June 1, 1998, and required DHS to absorb costs incurred pursuant to this bill's provisions.

3) Stated legislative findings regarding the needs of terminally ill patients.

FISCAL EFFECT : According to the Senate Appropriations Committee, approximately $400,000 General Fund cost.

COMMENTS :

1) Proponents state that nursing is, by definition, an activity that requires quick action and becomes dangerous where unsafe needles are able to stick employees. Therefore, the only practical way to avoid these serious, sometimes lethal, and always expensive work-related injuries, is to maximize use of engineering controls.

A recent San Francisco Chronicle investigation regarding needlestick injuries raised serious questions about the safety of our health care workers. The Chronicle reported that

needles with a simple safety feature, which often costs just pennies more to make, were available at least 10 years ago. Today, according to the Chronicle investigation, few have reached the hands of health care workers. Only 5% to 10% of syringes used for injections by the nation's medical workers have safety features. More than 1 million accidental needle injuries occur each year. Thousands of the injured will get hepatitis C and other lethal diseases, including AIDS.

In 1992, OSHA adopted a regulation that unequivocally states that hospitals and other health care employers must start 'engineering controls,' such as self sheathing needles, to protect workers from infection. Unfortunately, OSHA has not enforced this regulation and neither has Cal-OSHA, which is responsible for enforcing an almost identical California regulation.

2) Opponents recognize the importance of addressing dangerous needles, but question the safety of "safety" needles and believe that measures for employee protection must be based on scientifically supportable data and are best resolved by specialists. The State Department of Industrial Relations (DIR) has convened an advisory committee to review the safety of hypodermic needles which will make recommendations by August of this year. DIR feels that legislative mandate avoids the closer scrutiny of safety professionals, and is a disservice to employees. The California Healthcare Association (CHA) supports the Occupational Safety and Health Review, noting the Federal Food and Drug Administration also regulates safety devices, and would be required to approve California's regulation. Most importantly, CHA believes that no efficacy testing is being done on sheathed needles, and it is inappropriate to require the wide use of unproved equipment. CHA believes hospitals cannot assess the efficacy of new needle technology and that demonstrating ineffective technologies is beyond the hospital's capacity.

Analysis prepared by : Stephen Holloway/ ale / (916) 445-2657

FN 043440

Assembly Bill No. 1208

CHAPTER 999

An act to add Section 144.7 to the Labor Code, relating to employment.

[Approved by Governor September 29, 1998. Filed with Secretary of State September 30, 1998.]

LEGISLATIVE COUNSEL'S DIGEST

AB 1208, Migden. Occupational safety and health: bloodborne pathogen standard.

Under existing law, the Occupational Safety and Health Standards Board may adopt occupational safety and health standards and orders, which are required to be at least as effective as federal standards for all issues for which federal standards have been adopted under the federal Occupational Safety and Health Act of 1970. Pursuant to this authority, the board has adopted a regulation containing general industry safety orders pertaining to, among other things, occupational exposure to blood or other potentially infectious materials.

This bill would require the board to adopt an emergency regulation no later than January 15, 1999, revising the bloodborne pathogen standard, as specified. The bill would require the board to complete the regulation adoption process and would require the final regulation to be operative no later than August 1, 1999. The bill would specify that the board's emergency regulation would expire when the final regulation becomes operative or August 1, 1999, whichever first occurs. Because certain violations of these new requirements would be a misdemeanor, the bill would impose a state-mandated local program. The bill would require the Division of Occupational Safety and Health to create an advisory committee with prescribed membership to review the changes in the board's regulation mandated by the bill and to report thereon to the Legislature by December 31, 2002. The bill would require the division and the State Department of Health Services to jointly compile and make available a list of needleless systems and needles with engineered needle stick protection.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The people of the State of California do enact as follows:

SECTION 1. Section 144.7 is added to the Labor Code, to read:

144.7. (a) The board shall, no later than January 15, 1999, adopt an emergency regulation revising the bloodborne pathogen standard currently set forth in Section 5193 of Title 8 of the California Code of Regulations in accordance with subdivision (b). Following adoption of the emergency regulation, the board shall complete the regulation adoption process and shall formally adopt a regulation embodying a bloodborne pathogen standard meeting the requirements of subdivision (b), which regulation shall become operative no later than August 1, 1999. Notwithstanding Section 11346.1 of the Government Code, the emergency regulation adopted pursuant to this subdivision shall remain in effect until the nonemergency regulation becomes operative or until August 1, 1999, whichever first occurs.

(b) The board shall adopt a standard, as described in subdivision (a), to be developed by the Division of Occupational Safety and Health. The standard shall include, but not be limited to, the following:

(1) A revised definition of "engineering controls" that includes sharps prevention technology including, but not limited to, needleless systems and needles with engineered sharps injury protection, which shall be defined in the standard.

(2) A requirement that sharps prevention technology specified in paragraph (1) be included as engineering or work practice controls, except in cases where the employer or other appropriate party can demonstrate circumstances in which the technology does not promote employee or patient safety or interferes with a medical procedure. Those circumstances shall be specified in the standard, and shall include, but not be limited to, circumstances where the technology is medically contraindicated or not more effective than alternative measures used by the employer to prevent exposure incidents.

(3) A requirement that written exposure control plans include an effective procedure for identifying and selecting existing sharps prevention technology of the type specified in paragraph (1).

(4) A requirement that written exposure control plans be updated when necessary to reflect progress in implementing the sharps prevention technology specified in paragraph (1).

(5) A requirement that information concerning exposure incidents be recorded in a sharps injury log, including, but not limited to, the type and brand of device involved in the incident.

(c) The Division of Occupational Safety and Health may consider and propose for adoption by the board additional revisions to the bloodborne pathogen standards to prevent sharps injuries or

exposure incidents including, but not limited to, training requirements and measures to increase vaccinations.

(d) The Division of Occupational Safety and Health and the State Department of Health Services shall jointly compile and maintain a list of existing needleless systems and needles with engineered sharps injury protection, which shall be available to assist employers in complying with the requirements of the bloodborne pathogen standard adopted pursuant to this section. The list may be developed from existing sources of information, including, but not limited to, the federal Food and Drug Administration, the federal Centers for Disease Control, the National Institute of Occupational Safety and Health, and the United States Department of Veterans Affairs.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

Notwithstanding Section 17580 of the Government Code, unless otherwise specified, the provisions of this act shall become operative on the same date that the act takes effect pursuant to the California Constitution.

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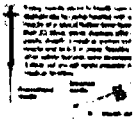
Epidemic Ravages Caregivers
Thousands die from diseases contracted through needle sticks

Reynolds Holding, William Carlsen, Chronicle Staff Writers
Sunday, April 13, 1998

URL:
http://www.sfgate.com/cgi-bin/article.cgi?file=/chronicle/archive/1998/04/13/MN64658.DTL&type=special



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 from the devastating diseases. Hundreds of 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, 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.

With cash raised from the first public offering of 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 Stathopulos, 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 months' pregnant. A letter in the March 1984 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 syringe with a simple plastic shield that could 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.

 Page A1

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

Reynolds Holding, William Carlsen, Chronicle Staff Writers THE MARRIOTT HOTEL
Tuesday, April 14, 1998

URL:
http://www.sfgate.com/cgi-bin/article.cgi?file=/chronicle/archive/1998/04/14/MN62035.DTL&type=special

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 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.

Janine Jagger, a professor in the neurosurgery 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.

The company seemed determined ``to minimize the capital outlay" on any safer device, said Robert Stathopulos, 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 -- three to 10 times higher than Becton Dickinson's 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 Stathopulos. ``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 Schwallie, 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,'' Schwallie 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 used to enter the lines -- even though the blunt 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 house.

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 downplayed the needle stick crisis. Doctors' 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 (1978-1987): 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

5 cents to 7 cents

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

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

URL:
http://www.sfgate.com/cgi-bin/article.cgi?file=/chronicle/archive/1998/04/15/MN1902.DTL&type=special

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.''

Then, addressing Adkins 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.

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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.

When Shaw's Retractable Technologies, Inc. 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 have used legal tactics that in some cases 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.''

The agency's failure to track HIV needle stick 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 Health. ``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 gives 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

 Page A1

NORA
NATIONAL ORGANIZATIONS RESPONDING TO AIDS

NORA
A coalition convened by
AIDS Action Council
1875 Connecticut Ave., NW
Suite 700
Washington, DC 20009
202 986 1300
202 986 1345 fax

February 23, 1999

The Honorable William Jefferson Clinton
1600 Pennsylvania Ave., NW
Washington, DC 20500

Dear President Clinton:

On behalf of the National Organizations Responding to AIDS (NORA), we are writing to garner support for the condemnation of the death of Gugu Dlamini. NORA is a coalition of over 175 health, labor, religious and professional advocacy groups that represent a broad consensus on HIV and AIDS-related issues, policy and funding levels.

The New York Times recently reported the death of Gugu Dlamini in South Africa. A 36-year-old mother, Ms. Dlamini died last December 22 as a result of the beating she received by neighbors in her own home. They had accused her of having brought shame to their community in the outskirts of Durban by openly revealing on December 1 --World AIDS Day-- that she was infected with HIV.

Ms. Dlamini worked as a volunteer for the National Association of People Living With HIV/AIDS (NAPWA) of South Africa. According to the United Nations, three million people in South Africa have the infection. In KwaZulu-Natal, the province most affected by the illness, and where Ms. Dlamini lived, up to 30 percent of the adult population lives with HIV/AIDS.

On Monday December 21, Ms. Dlamini was physically attacked by a man, who ordered her to keep silent like other people living with HIV/AIDS. Although she requested help from the police, they did nothing. That same night, a group tore down her house and she was brutally stoned and hit with sticks. She died the following day.

In spite of the scourge of the epidemic in South Africa and other countries across Africa, Asia, the Caribbean and Latin America, people living with HIV/AIDS are afraid to reveal their condition due to the hostility they know they will have to face.

The murder of Ms. Dlamini not only shows the profound discrimination that people living with HIV/AIDS suffer in many countries. It is also a reflection of the flagrant violence that primarily affects women around the world, both inside and outside their homes, without assistance from authorities when this is requested. In response Mr. President, we urge you to take action in response to the murder of Ms. Dlamini and the continuing problem of discrimination, stigmatization, and violence toward people with HIV. Specificity we urge you to:

1. Issue a statement publicly condemning the killing of Ms. Dlamini and prejudice against people with HIV.

2. Direct the Assistant Secretary of State for Human Rights to review US strategy around discrimination against people with HIV and recommend means to improve its effectiveness.

3. Direct the National AIDS Policy Director to include the human rights of those infected with HIV in her upcoming "fact finding" visit to African countries and to raise these issues with the governments she meets with as your representative.

4. Direct the American Ambassador to South Africa to review US human rights policy in South Africa in light of Ms. Dlamini's murder and recommend a strategy to improve our efforts to support basic rights for people with HIV.

We would urge the Ambassador, if appropriate, to express the condolences of our nation to Ms. Dlamini's family and colleagues.

In conclusion Mr. President we hope that you and other senior U.S. officials will raise these issues with South Africa's leaders and with leaders of other countries, and that you will publicly indicate that human rights concerns of those 32 million men, women and children around the world living with HIV/AIDS are on your agenda.

The National Organizations Responding to AIDS (NORA) Coalition is steadfastly committed to the promotion and protection of the human rights of all the world's citizens regardless of their health status. We condemn the murder of Gugu Dlamini.

If additional information would be helpful, we would be happy to work with members of your staff.

Sincerely,

AIDS Action
AIDS Legal Referral Panel
American Public Health Association
American Social Health Association
Association of Nurses in AIDS Care
CAEAR Coalition

Center for Women Policy Studies
Committee for Children
Disability Rights Education and Defense Fund Inc.
HIV Law Project
Human Rights Campaign
Legal Action Center
National Association of Social Workers
National Family Planning and Reproductive Health Association
Planned Parenthood Federation of America
The National Latina/o Lesbian, Gay, Bisexual & Transgender Organization
Title II Community AIDS National Network (TIICAAN)

Cc: Hillary Rodham Clinton
Secretary of State Madeleine Albright
Assistant Secretary of State Karl Inderfurth
Assistant Secretary of State Harold Koh
Theresa Loar, Senior Coordinator for International Women's Issues
Samuel Berger, National Security Advisor
Dr. Ken Bernard, National Security Advisor
Sandra L. Thurman, Director, Office of National AIDS Policy

COMPLIMENTS OF 2/23/99

Dear Sarah!

We spoke last summer.

I ~~Hope~~ thad you find the development of this project of some interest.

Maureen McMahon

JHPIEGO CORPORATION

JHPIEGO CORPORATION

International Education and Training in Reproductive Health

An affiliate of Johns Hopkins University

February 23, 1999

Sarah Holewinski
White House
Office of AIDS Policy
736 Jackson Place
Washington, DC 20503

Dear Sarah:

You may have seen the enclosed article on the front page of the *New York Times* this week about cervical cancer. In this country, women are being screened, treated and cured of cervical cancer. In developing countries, it is the leading cause of female cancer deaths.

JHPIEGO is launching a public health intervention for the eradication of cervical cancer in developing countries. It is based on the use of proven technologies for the identification and treatment of precancerous lesions of the cervix that are appropriate for use in low-resource settings and can be provided even in the most remote areas. (See up-coming *Lancet* lead story)

Given your global presence and influence in world health and stable markets, I am delighted to enclose two press clippings on JHPIEGO's Cervical Cancer Prevention Program (CECAP), published in the latest edition of the ***World Ecology Report***. The "Promise of Prevention" article is a brief overview of the problem and possible solutions to the leading cause of cancer deaths among women in developing countries. A one column description of JHPIEGO's Cervical Cancer Prevention program is the content of the other clipping.

CECAP is a program that impacts on all levels—from formulating national policies regarding women's reproductive health to influencing opinion and behavior at the community level. The visibility and impact will reach all levels of the international health community—International health organizations, the United Nations, legislators, women's health and business associations, and more than 10,000 international NGO's operating throughout the world. It is our hope to enlist your interest and advocacy as we set the stage to implement this global cervical cancer prevention program (CECAP).

Please feel free to call or e-mail me at 410. 614.2460 or **mmcmanus@JHPIEGO.org** for further information.

Sincerely,

Maureen McManus
CECAP Development Advisor
cc: Noel McIntosh, President

Brown's Wharf • 1615 Thames Street, Suite 200 • Baltimore, MD 21231-3447 USA
Telephone: (410) 955-8558 • FAX: (410) 955-6199 • http://www.jhpiego.jhu.edu

Available in Arabic, English, Russian, Spanish & Ukrainian

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Vol. X, No. 3
$15. 00

World Ecology Report

Critical Issues in Health and the Environment

Knowledge brings new choices. Education brings new knowledge.

■ The Cervical Cancer Prevention Program (CECAP) is being launched in the spring of 1999 by, JHPIEGO, an affiliate of Johns Hopkins University which specializes in international education and training in reproductive health. CECAP is developing partnerships, collaborations and linkages with donors, international agencies, women groups and other institutions in a worldwide effort to reduce the incidence of cervical cancer. More than 500,000 women annually develop cervical cancer, a sexually transmitted disease and more than 200,000 annually die. Because the majority of deaths occur in developing countries, JHPIEGO is targeting 20 of the poorest and largest developing countries to benefit over 695 million women with screening to detect the early signs of cervical cancer, treatment and education programs for those women. Funding sources must be educated to the importance of the program and the dramatic results that can come per dollar spent. In the United States and Europe, JHPIEGO through CECAP is launching awareness activities that will highlight this critical public health emergency and bring support for the intervention's efforts. For additional information on the Cervical Cancer Prevention (CECAP) program, please contact JHPIEGO's Research and Evaluation Office by telephone 410-614-0518, fax 410-614-3458 or Internet E-mail (info@jhpiego.org) or write to JHPIEGO, Brown's Wharf, Suite 200, 1615 Thames Street, Baltimore, Maryland 21231-3492, USA. [See Point of View in this issue]

Available in Arabic, English, Russian, Spanish & Ukrainian

Fall 1998
Vol. X, No. 3
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World Ecology Report

Critical Issues in Health and the Environment

Knowledge brings new choices. Education brings new knowledge.

POINT OF VIEW

Sustaining Women's Health: Promise of Prevention

Rose is 35 and she has been sexually active since she was 16 years old. Recently she has been experiencing lower abdominal pain, bleeding after intercourse, and an abnormal discharge. Her three children have been immunized and she was recently treated at her local clinic for a pelvic infection. Rose doesn't know it, but next year she will die from cervical cancer because she was never offered a screening test.

Each year over 200,000 women die from a preventable disease-cervical cancer. Worldwide it is the second most common cancer among women and in developing countries, it is the leading cause of female cancer deaths. Over 90% of cervical cancer cases are caused by a sexually transmitted organism-human papilloma virus (HPV) and for most women infection occurs before age 30. Among deaths due to STDs, cervical cancer ranks the highest globally. Although women are generally infected with HPV before their 30's, for the 20-30% whose infection progresses to cancer, this progression occurs over a 10 to 20 year period. Cervical cancer is a debilitating and painful disease, but the progression could be prevented.

Why if cervical cancer is preventable are the rates so high in developing countries? Because these women do not have access to cervical cancer prevention programs. In developed countries, where national screening coverage rates exceed 70%, mortality due to cervical cancer has declined markedly over the past few decades. In developing countries, however, only 5% of the women have ever been screened. This imbalance in coverage is not because proven screening and treatment technologies do not exist. They do. It is because the infrastructure (including facilities such as clinics, hospitals, transportation, electricity, medical supplies and human resources including nurses, doctors, and cytotechnicians) in developing countries cannot continuously support a national prevention program based on the current screening standard-the Pap smear. Worldwide efforts have been launched to improve the quality of and access to the Pap smear; however, the fact remains that in most countries in which cervical cancer poses the greatest public health problem, the logistics involved in sustaining a quality cytology-based system are too cumbersome and cost-prohibitive

Do options exist? Yes. One alternative to the Pap smear is visual inspection. Visual inspection involves wiping the cervix with acetic acid (vinegar) and then looking at the cervix with or without magnification to see if there are abnormalities. Visual inspection with acetic acid (VIA) meets the requirements for a good screening test. It's safe, practical, affordable, available and effective. While recent findings have consistently shown that VIA accurately identifies the majority of cases of true disease, improvement in its specifity would render this technique even more viable as a screening option. Because VIA is noninvasive, inexpensive and can be performed by all levels of healthcare workers, in almost any setting, it could be a valuable alternative to conventional screening programs.

For cervical cancer prevention programs to be effective, widely accessed screening activities must be linked to treatment. Treatment must be as accessible as screening, and it must be safe, acceptable and affordable. Effective treatment technologies for precancerous lesions are available which could be offered on a wide-scale basis at a safe and lower cost than current treatment options in use in developing countries. How VIA based screening and treatment options are implemented at the local level will depend on the amount of attention paid to properly informing healthcare providers and the women they serve about the advantages and disadvantages involved. With this promise of prevention, countries committed to eradicating this important public health problem should now carefully consider how they could maximize access to screening and treatment given the constraints of current healthcare budgets in their countries. [See VOICES in this issue for contact information]

World Ecology Report
World Information Transfer
444 Park Avenue South, Suite 1202
New York, NY 10016

"Never doubt that a small group of thoughtful committed citizens can change the world. Indeed it's the only thing that ever has."

Margaret Mead

The New York Times

TUESDAY, FEBRUARY 23, 1999

Experts Urge Chemotherapy For Invasive Cervical Cancer

By DENISE GRADY

Cancer experts are recommending a major change in the treatment of advanced cervical cancer, urging that chemotherapy be added to the standard treatment, radiation.

The recommendation is based on five new studies showing that the combination reduces death rates from the disease by 30 percent to 50 percent.

Officials at the National Cancer Institute announced the findings yesterday and said they were mailing the new recommendation to 20,000 cancer specialists worldwide in a "clinical announcement," only the fourth such notification issued in the past 10 years. Such announcements are used to alert doctors to important advances in treatment.

The five new studies will not be published in medical journals until later this year, but the journals' editors agreed it was imperative to release the information early so it could be used to help patients now. The New England Journal of Medicine, which will publish three of the papers in April, has already posted them on its Web site.

The new findings apply to women with cancers classified as "locally advanced" or "invasive," meaning that the tumor on the cervix is large or has spread to nearby lymph nodes or other parts of the pelvis. About 25 percent of women with cervical cancer in the United States fall into that category. An estimated 12,800 new cases of the disease are expected in 1999, along with 4,800 deaths.

In other countries, cervical cancer is a greater problem than in the United States. Worldwide, it is the second most common cancer among women, with 500,000 new cases a year. In Africa, Asia and South America, it is the most common cancer in women.

Until recently, standard treatment for locally advanced cervical cancer included only surgery and radiation, not chemotherapy. Dr. Peter Rose, an author of one of the new studies and director of gynecologic oncology at the University Hospitals of Cleveland-Case Western Reserve University School of Medicine, said research tended to emphasize radiation because the cervix, unlike many other parts of the body, could be bombarded with high doses of radiation with little damage to other organs. That approach, Dr. Rose said, made progress against the disease.

"But we still didn't cure patients all the time," he said.

The new studies, involving 1,912 patients, at various medical centers nationwide, showed it was crucial to give chemotherapy and radiation at the same time. The drugs that improved survival rates were cisplatin and 5-FU, or 5-fluorouracil.

Dr. Morris said researchers thought the combined treatment worked better than radiation alone because the drugs made cancer cells more vulnerable to the radiation.

"When radiation hits a cancer cell," he said, "it damages the DNA in that cell and can prevent it from dividing or replicating. But cancer cells have a remarkable ability to repair their DNA in order to begin dividing again. Radiation sensitizers like these drugs attach to the DNA and prevent the DNA from repairing itself. The cell can't fix the damage from the radiation, and it dies."

Pap smears could detect more than 90 percent of the cases early, when cure rates are high. About 50 million Pap tests are done in the United States every year, but a 1994 survey showed that 20 percent of women ages 18 to 64 years had not been tested in the past three years. A disproportionate number of the women who go untested and wind up with advanced cases of cervical cancer are older, uninsured, members of ethnic minorities or poor.

The recommendation for combined treatment does not apply to women with earlier stages of the disease, who do not need such aggressive therapy, or to women with cancer that has spread beyond the pelvis, who are considered unlikely to benefit. It also does not apply to women who have completed a course of radiation treatment.

"This is the first substantive change in the treatment of advanced cancer of the cervix in 40 years," said Dr. Mitchell Morris, who studied the combination treatment at the University of Texas' M. D. Anderson Cancer Center in Houston.

Dr. Edward Trimble, head of the surgery section at the cancer therapy evaluation program at the National Cancer Institute, said: "We think that based on this data the standard of care should change. These are modalities available in every hospital treating women with cervical cancer, and should be adopted into clinical practice immediately."

Dr. Trimble said he expected the combination treatment to save thousands of lives a year.

Among American women ages 35 to 54, cervical cancer is the fifth leading cause of death from cancer, after tumors of the breast, lung, colon and rectum, and ovary. The overall number of deaths, 4,800, though small compared with the 47,000 breast cancer deaths are excessive nonetheless, researchers say.

In three of the studies, women were assigned at random to a group that received either radiation alone or radiation plus chemotherapy with cisplatin alone or cisplatin and 5-FU. In all three, survival rates after about three years were higher in the women who received chemotherapy.

In the other two studies, all the women were given both radiation and chemotherapy, but some were given cisplatin, and others a different drug, hydroxyurea. Those who got cisplatin did better.

Dr. Trimble said that independent safety committees set up to monitor experiments alerted the institute when important differences in survival became apparent.

Cancer specialists have already begun using the information. At the University Hospitals of Cleveland, the treatment was offered last fall to Bethany Brogan, a 29-year-old woman with invasive cervical cancer. Mrs. Brogan, who has three young children, was not in a study, but she was being treated by Dr. Rose, who already knew of the results.

"In my mind there was absolutely no option," Mrs. Brogan said. "With three children, just starting my life, I wanted the most aggressive treatment."

She completed six weeks of therapy last December. "At that point they said everything looked very good," she said, adding that the treatment caused fatigue and nausea but not hair loss like other therapies.

OFFICE OF THE VICE PRESIDENT
WASHINGTON

February 19, 1999

John F. Joanette
Michigan AIDS Fund
Riverview Center Building
678 Front Street, N.W.
Grand Rapids, Michigan 49504

Dear Mr. Joanette:

Thank you for the invitation to Mrs. Gore to join you for the AIDS Walk Michigan event to be held on September 26, 1999 in Detroit.

Mrs. Gore is honored to be invited to participate in this important event. Regrettably, other commitments will prevent her from accepting your kind invitation. Mrs. Gore is disappointed to miss the opportunity to join you, and she has asked that I convey to you her sincerest best wishes for a successful event.

Thank you again for your letter. Please feel free to contact my office again with future requests or questions. Best wishes.

Sincerely,

Clark E. Ray

Clark E. Ray
Director of Scheduling for Mrs. Gore

cc: Sandra L. Thurman
Director of the Office of National AIDS Policy
The Honorable Dennis W. Archer
Mayor of Detroit

Riverview Center Building
678 Front Street, N.W.
Grand Rapids, MI 49504

TEL: 616-451-2394
FAX: 616-451-9180

[redacted]

MICHIGAN AIDS FUND

February 16, 1999

Mrs. Tipper Gore
Old Executive Office Bldg., Room 200
Washington, DC 20500

Dear Mrs. Gore,

First, I want to thank you for all you do to compassionately bring about positive social change. As Michigan's philanthropic response to the AIDS epidemic, the Michigan AIDS Fund also uses a compassionate approach to improve people's lives.

One of the ways that the Fund does that is through **AIDS Walk Michigan**, the state's largest grassroots AIDS fundraiser. The Fund is working with local AIDS organizations to coordinate walks in 13 communities across the state for AIDS Walk Michigan 1999. This event supports AIDS organizations in the participating communities and provides an opportunity to share powerful prevention messages.

We're writing to ask for your help. Your partnership would greatly enhance AIDS Walk Michigan 1999, and further our efforts to stop new infections and improve the lives of those infected and affected by the epidemic.

We respectfully request your presence at AIDS Walk Michigan—City of Detroit on Sunday, September 26, 1999. We also would be delighted if Vice President Gore could participate and would appreciate your guidance in making a formal request to his office.

Detroit Mayor Dennis W. Archer and Sandra L. Thurman, Director of the Office of National AIDS Policy at the White House, both have agreed to serve as honorary chairpersons of the walk in Detroit, home to about 50% of Michigan's residents with HIV/AIDS. Ms. Thurman said she plans to participate in AIDS Walk Michigan—City of Detroit because "the level of AIDS awareness created on this scale has incalculable value and carries an impact that no amount of money can buy."

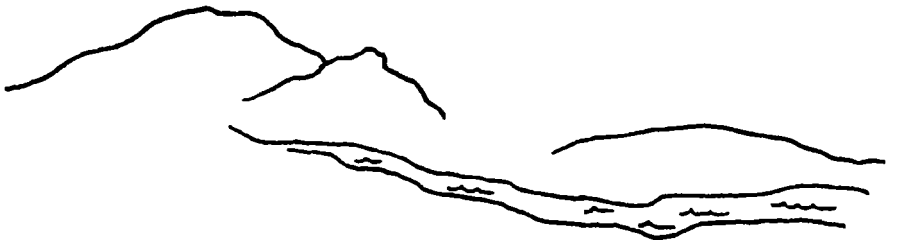
The outline of activities for the Detroit walk, to be held in the heart of the city, is as follows: 2 p.m., pre-walk main stage activities start; 2:30 p.m., the walk begins; 4:30 p.m. walk is completed and post-walk rally starts. Elected officials and other dignitaries are expected to attend the rally, and several plan to address the importance of reauthorization of the Ryan White CARE Act.

Thank you in advance for your consideration. If you need additional information or have any questions, please call me at (248) 549-7266.

Sincerely,

John F. Joanette
Michigan AIDS Fund

cc: Sandra L. Thurman
Mayor Dennis W. Archer



Harriet G. Langfeldt

February 11, 1999

Ms. Sandy Thurman
736 Jackson Place
Washington, DC 20503

Dear Sandy:

Valentine's Greetings! This is just a note to let you know that I am most grateful for your continued service on the NEAC Board. We realize that with you other commitments that attending meetings is very difficult but you are also well aware that it is probably to both of our benefit for your to serve in what ever capacity your job allows. NEAC is most grateful to those who contribute financially as well as the hours of service which comes in many different ways. Also, remember, if at any time you find that you can be present at one of our meetings we would love to have you take part. Offerings of time, money and public service helps keep our mission to support the HIV/AIDS ministries throughout our church: those persons living with HIV/AIDS, the caregivers, the educators, and to support families and loved ones who have been affected by this disease.

Take time to enjoy spring, when it decides to start coming and know that we are MOST grateful for what you do.

Shalom,

Harriet

PS: I just want to be sure you are aware of the following NEAC "dates"
Seattle: June 4/5. 1999 (Commission Hearings on 6/3 - I think)
Dubois, WY Oct. 8/9, 1999 -(Commission Hearings 10/7 - I think)
San Francisco - Forward In Faith Conference - March 23-25, 2000

744 East Twentieth Street, The Dalles, OR 97058 541.298.1864 abuna@gorge.net

FAX TRANSMISSION
HIV/AIDS PROGRAM

234 LOYOLA AVENUE, 5TH FLOOR
NEW ORLEANS, LA 70112
TEL:(504)568-7474 OR (504)568-7524
FAX:(504)568-7044 OR (504)599-1307

To: Sandra Thurman **Date:** 2/8/99

Fax #: 202-456-2438 **Pages:** [Pages (including cover sheet)], 4

From: Alyssa Lobo

Subject: Speaking Engagement in Louisiana

COMMENTS:

Thanks

Confidentiality Notice:

The document accompanying this telecopy transmission contains confidential information belonging to the sender which is legally privileged. The information is intended only for the use of the individual of entity named above. If you have received this telecopy in error, please notify us immediately by telephone to arrange for return of the documents to us.

HOPE For the Poor

Association incorporated under Section21
Program of HOPE *worldwide*

Johannesburg
Tel & Fax: 011 782-6029
PO Box 3393
Northcliff
2115
Soweto Tel: 011 984-4422

Cape Town
Tel & Fax: 021 913-5574
PO Box 2702
Cape Town
8000

Durban
Tel: 083 777-9899
Fax: 031 86-1343
PO Box 1725
Westville
3630

Port Elizabeth
Tel & Fax: 041 53-3877
PO Box 12279
Centrahil
6001

Umtata
Tel: 0471 350-551
Fax:0471 22-708
PO Box 385
Umtata
5100

Fund Raising No:
011013100003

Company Registration Number:
95/01141/08

February 9,1999

Sandra Thurman
Director of National AIDS Policy
The White House

Dear Mrs. Thurman,

The Soweto HOPE staff and their clients would like to thank you for your interest in AIDS and its effects on the people of South Africa. Many of our clients expressed sincere appreciation for the efforts of your delegation to help them and their children. Every day we face the pressure of their desperate needs. Together we can find real solutions to improve their quality of life. Please contact us if you have any questions or recommendations.

Recently, Lawton Chiles III and his family met with the President and First Lady after the memorial service for Lawton Chiles III's father in Washington. Lawton Chiles III coordinates the HOPE *worldwide* projects in New York, the Caribbean, and Africa. I have asked that he contact your office about the development of future cooperative efforts and visits. In addition, a letter of recognition from the President would mean so much to the patients of Soweto and to our program.

Thank you again for your interests and efforts.

Sincerely,

Mark Ottenweller

Dr. Mark Ottenweller
Director for Africa
HOPE *worldwide*
e-mail <hope@global.co.za>
Fax: 011-2711-476-9389

February 2, 1999

General Barry R. McCaffrey (Ret.)
Director
Office of National Drug Control Policy
Executive Office of the President
750 17th Street, NW
Washington, DC 20503

Dear General McCaffrey:

At the time of your visit to Food & Friends, I briefly mentioned our need for upgraded food delivery vans. You very kindly offered to try and be of assistance in obtaining the necessary funds. Please find enclosed material which describes the particular vehicles required by Food & Friends.

Currently, our food is delivered daily to persons living with AIDS and their dependents in the District of Columbia and thirteen surrounding counties in Maryland and Virginia. More than 950 clients living in these jurisdictions depend upon us for either freshly prepared meals or frozen entrees supplemented by groceries. Food & Friends is fortunate to have about 165 volunteers each week who deliver some of these meals in their personal vehicles. Their efforts account for approximately 40% of our weekly deliveries. About 60% of the deliveries are made by Food & Friends staff drivers. We own seven Ford Windstar and Econoline vans. While they are generally dependable, none of these are outfitted with the customized storage units and refrigeration units which would increase our efficiency, food quality and food safety. Given our very large delivery area, refrigerated vehicles have become essential so as to properly carry out our mission. The technology within our kitchen is excellent but we do not meet the same standard with respect to delivery service.

The enclosed material describes the units which we would like to purchase. A photograph is also included. The list price of each unit is $35,321. [I anticipate that we could purchase these for approximately 15% less]. Consequently, our need is for seven vehicles which each cost about $32,000. Total cost $224,000.

We appreciate your willingness to help us obtain necessary funding. With these vehicles, we can more safely deliver our food and more effectively reach the very large region which depends upon

58 L STREET, S.E. • WASHINGTON, D.C. 20003-3353 • (202) 488-8278 • FAX (202) 863-1284 • TDD (202) 554-2944
E-MAIL: info@foodandfriends.org

us in the battle against AIDS. You know from your visit to Food & Friends that we are a spare organization which makes good use of personnel, funds and equipment.

We are very grateful to count you among our friends and advocates.

Sincere regards,

Craig Shniderman
Executive Director

cc: Sandy Thurman,
Mickie Ballotta, Director of Development & Public Relations
Fay Slattery, Director of Client & Volunteer Services
William Z. Goldstein, President, Food & Friends

DELIVERY CONCEPTS EAST
Food Delivery Equipment

Delivery Concepts East

351 Dogwood Lane
Hampstead, NC 28443
(910) 270-2090 (800) 255-5183
(910) 270-2091 Fax

DATE: **October 7, 1998**

QUOTE

To:

Food & Friends
58 "L" Street SE
Washington, DC 20003

Attention:

Tom Koucky

Tel: (202) 863-1821
Fax: (202) 863-1284

SALESPERSON	P. O. NUMBER	DATE SHIPPED	SHIPPED VIA	F.O.B. POINT	TERMS
			Contract Driver	Washington, DC	COD

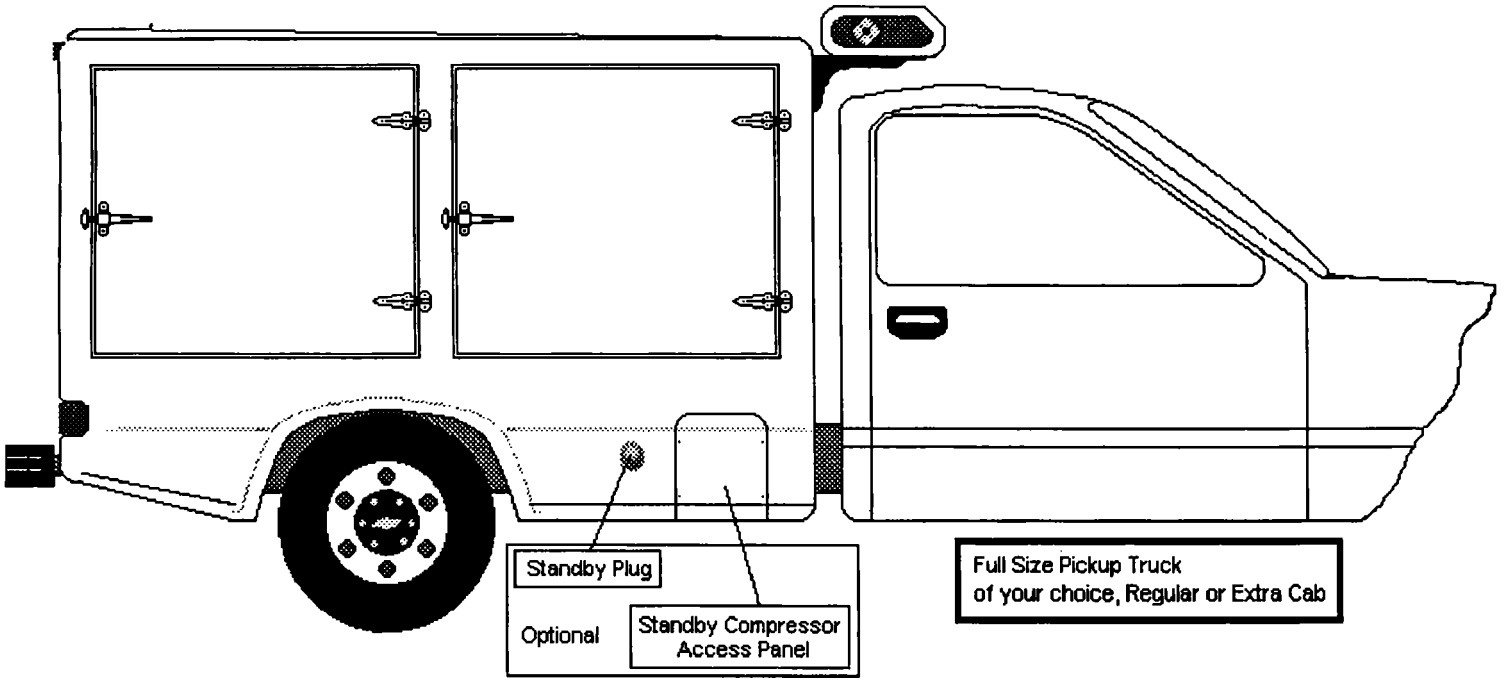
MAKE	MODEL	YEAR	SERIAL NUMBER	ORIGIN
Ford	F-150 XL	1999		
Delivery Concepts	HotShot IIXL	1999		

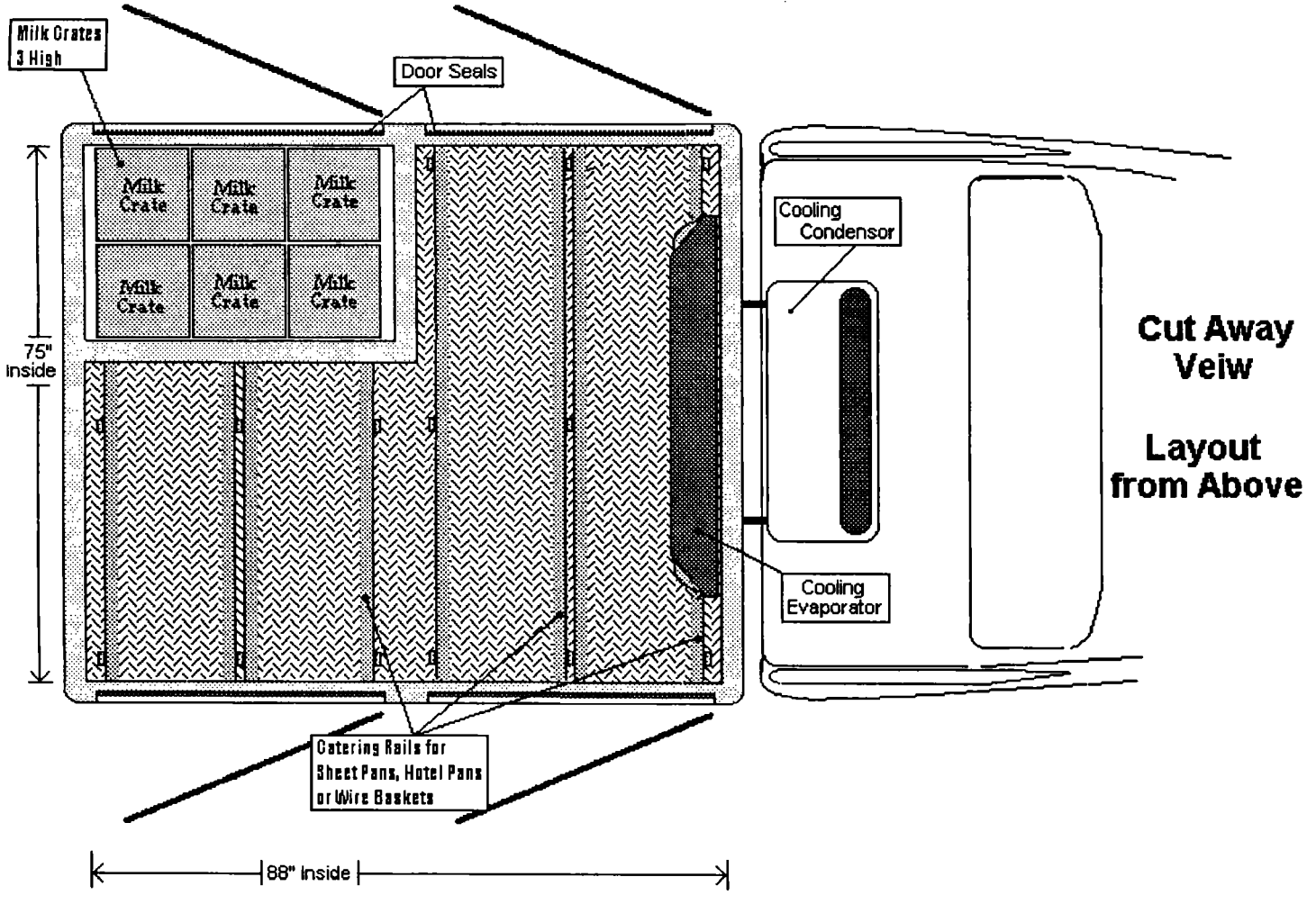
1 - Ford F-150 XL Regular Cab, Cab/Chassis Color: White
4.2 Liter EFI V-6 — 4 Speed Auto. Trans. W/OD — 3.55 Ratio Rear Axle
Power Steering — Power Brakes — GVW Rating 6,000 lbs.
Cab Air Conditioning — Front Bench Seat — ETR AM/FM Radio

1 - Delivery Concepts HotShot II XL Freezer/Refrigerated Food Transport Unit:
Freezer Racking - consisting of rails to hold sheet pans, hotel pans or wire baskets
Refrigeration Section open with rubber floor mat
Locking Handle Package
Back Up Alarm
Cab Air Equipment
Suspension Upgrade Kit (Springs)
40 Coated Wire Baskets (20 Meal Capacity Ea.) @ $49.00 ea.

Cab/Chassis	$16,800.00
HotShot IIXL	$13,269.00
Freezer Racking	$1,400.00
Rubber Floor Mat	$ 145.00
Locking Handles	$ 108.00
Back Up Alarm	$ 103.00
Cab Air Equipment	$ 721.00
Suspension Kit	$ 350.00
Coated Baskets	$1,960.00
UNIT SUB TOTAL	$34,856.00
Transportation Charge	$ 450.00
Temporary License	$ 15.00
TOTAL	$35,321.00

adh





Inside Dimensions
Height is 38 1/2" High , Length is 88", Depth is 75"
Total Volume is 147 Cubic Feet

Doors on Both Sides
Door Openings are 33 1/2"High X 38" Wide

NOT TO EXACT SCALE

Delivery Concepts East, Inc.

Title: **HotShot IIXL** Type: **Refrigerated/Freezer**

Drawing By A. D. Hanson Date: 6/5/97

PO Box 487, Hampstead, NC 28443 Tel: 910 270-2090


PENDER ADULT SERVICES INC.
MEALS ON WHEELS
259-9119
Please Call for donations or to volunteer
Please Call for donations or to volunteer
259-9119