November 29, 2000

Dr. Jane Henney
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Henney:

The Service Employees International Union (SEIU), with a membership of over 1.4 million members, including over 710,000 health care workers, and Public Citizen, a consumer advocacy group with 150,000 members, hereby jointly petition the Food and Drug Administration (FDA) pursuant to the Medical Device Amendments to the Federal Food, Drug and Cosmetic Act,[1] (1) to remove from the market all unsafe intravenous (IV) catheters, blood collection devices, blood collection needle sets ("butterfly syringes") glass capillary tubes and IV infusion equipment, and (2) to issue performance standards to ensure that new unsafe devices of these kinds do not enter the market, including a labeling requirement for syringes that do not adequately protect the user from bloodborne pathogens.

You must act now to limit the continuing spread of serious infectious diseases among health care workers, who each year sustain approximately 590,000 needlestick injuries in their care of patients nationwide.[2] There have been a total of 55 confirmed cases of occupational human immunodeficiency virus (HIV) transmission in the U.S. (49 of these involved sharp object injuries such as needlesticks),[3] an estimated 100-200 health care workers die annually from hepatitis B[4] and hundreds annually contract hepatitis C, although data are scant (Williams I, Centers for Disease Control and Prevention Hepatitis Branch, November 28, 2000, personal communication).

The AIDS epidemic has generated renewed interest in worker safety in this area, and the result has been the development of a number of well-designed, FDA-approved devices that have been demonstrated to reduce the incidence of needlesticks to workers by as much as 90%,[5] depending on the device. The Occupational Safety and Health Administration (OSHA), which has developed a Bloodborne Pathogens Standard focused primarily on changing work practices, admits that "as many as 60 percent of needle stick injuries [would] be unaffected by improved work practice procedures."[6] For the FDA not to ban the more dangerous alternatives is to abdicate its responsibility to protect those who care for the nation's sick and dying.

A. ACTIONS REQUESTED

The FDA has identified five design criteria for these medical devices, all of which should be met in order to maximize safety to the health care worker:[7]

a. a fixed safety feature provides a barrier between the hands and the needle after use;

b. the safety feature allows or requires the worker's hands to remain behind the needle at all times;

c. the safety feature is an integral part of the device, and not an accessory;

d. the safety feature is in effect before disassembly, if any, and remains in effect after disposal; and

e. the device should be simple and easy to use, requiring little training.

This petition requests that the FDA take three types of action. First, we request that the FDA ban the following devices:

a. unsafe IV catheters that do not meet the above criteria;

b. blood collection devices (needles and tube holders) that do not meet the above criteria;

c. blood collection needle sets ("butterfly syringes") that do not meet the above criteria;

d. glass capillary tubes; and

e. IV infusion equipment that does not use needleless technology or recessed needles.

Second, we request that the FDA issue the five criteria above as performance standards following the procedures set forth in 21 CFR Part 861 to prevent new unsafe devices from entering the market.

Third, we request a performance standard requiring that labeling for conventional syringes indicate: "TO PREVENT POSSIBLE EXPOSURE TO HIV AND HEPATITIS, DO NOT USE FOR STANDARD BLOOD DRAWS."

B. STATEMENT OF GROUNDS

1. HAZARDS IN THE USE OF MEDICAL DEVICES WITH EXPOSED NEEDLES

HIV continues to spread around the world, insinuating itself into communities previously little troubled by the epidemic. Estimates by the Joint United Nations Programme on HIV/AIDS released just yesterday indicate that 36.1 million people are currently infected with HIV and 21.8 million people have already lost their lives to the disease.[8] An estimated 297,137 people in the U.S. were living with AIDS at the end of 1998.[9]

In health care settings, HIV, hepatitis B and hepatitis C are well-documented threats to those who provide clinical care, because they can be exposed through injuries with sharp objects, including needles, or through contact between potentially infectious body fluids and the mucous membranes or skin. (The latter are not the subject of this petition.) The potential for exposure is significant: in one study 6% of 2,523 patients examined in a U.S. hospital emergency room were HIV seropositive.[10] The risk of seroconversion (developing antibodies to HIV) following a needlestick from an HIV-positive patient is estimated at 0.25% or one in 400.[11] Between January 1985 and June 1999, the Centers for Disease Control and Prevention (CDC) received reports of 55 cases of "documented" occupationally acquired HIV among health care workers in the United States and 136 "possible" cases. Forty-nine of these 55 documented cases (89%) involved sharp object injuries such as needlesticks.3 These numbers are almost certainly underestimates due to both underreporting[12] and the incorrect attribution of occupationally acquired HIV infections to other HIV risk behaviors. While the outcome for those who seroconvert is eventual death, those who do not become infected also suffer serious consequences, including adverse effects from anti-viral medications given to them prophylactically to prevent HIV infection[13] and emotional trauma while they are awaiting the results of blood tests over a six-month period.[14]

Globally, approximately two billion people have been infected with the hepatitis B virus and more than 350 million of these are chronic carriers, placing them at elevated risk for death due to cirrhosis and cancer of the liver.[15] The risk of hepatitis B seroconversion from a needlestick from an hepatitis B-positive person is estimated to be 30% if the patient is positive for HbeAg, a part of the hepatitis B virus envelope that signifies increased infectiousness.[16] In the previously mentioned emergency room study, 5% of patients were seropositive for hepatitis B.10 According to the CDC, 800 health care workers became infected with the hepatitis B virus in 1995, primarily from needlesticks.3 Between 100 and 200 health care workers die each year from chronic hepatitis B.[17] The CDC assumes that most of these infections are occupationally acquired (Williams I, Centers for Disease Control and Prevention Hepatitis Branch, November 28, 2000, personal communication). Fortunately, the number of new hepatitis B infections among health care workers is now declining. A major factor contributing to the 95% decrease in health care worker hepatitis B infection between 1983 and 19953 is the promulgation of OSHA's Bloodborne Pathogen Standard, which requires employers to provide free HBV vaccinations to their employees.[18] Vaccines are not available for many other infectious

diseases, which are spread through exposure to blood, particularly HIV and hepatitis C.

Perhaps the greatest current risk to health care workers in terms of the number of people infected is exposure to hepatitis C. Prevalences as high as 10% or more have been detected in population-based samples around the world. It is estimated that more than 170 million people worldwide were suffering from the disease in 1998.[19] In the emergency room referred to previously, 18% of patients carried antibodies to hepatitis C.10 Eighty percent of acutely infected patients progress to chronic hepatitis. Approximately 20% of those will develop cirrhosis, and 1% to 5% of those with cirrhosis will develop cancer of the liver over a 10-year period.[19] The risk of occupational hepatitis C transmission from a sharp object injury is estimated at 1.8%.[20] Hundreds of health care workers acquire HCV occupationally each year in the U.S (Williams I, Centers for Disease Control and Prevention Hepatitis Branch, November 28, 2000, personal communication).

2. OCCUPATIONAL EXPOSURE TO BLOODBORNE PATHOGENS

The two primary sources of national occupational exposure data are EPINet, coordinated by the University of Virginia, and the CDC. Seventy-seven hospitals in the United States participate in EPINet. For 52 reporting hospitals, with a total average daily census of 9,681 patients, 3,180 sharp object injuries were recorded in the EPINet database in 1998. Sixteen percent of sharp object injuries involved physicians or medical students, 44% involved nurses and 40% other health care workers, including housekeeping staff. Patient rooms (35%) and the operating room (22%) were the most common locations for exposures. Two percent of exposures occurred before use of the device, 42% during use and 56% after use. Thirty-three percent of exposures involved syringes, 2% needles on IV lines, 8% butterfly needles, 6% vacuum tube blood collection needles, 6% IV catheter stylets and under 1% glass capillary tubes (the remainder involved other devices).[21] In some hospitals not using needleless IV systems, however, as many as 22% of exposures have been related to IV lines.[22]

Data from the CDC show similar findings. For the period June 1995 to July 1999, 29% of 4951 sharp object injuries reported to the CDC's surveillance system involved hypodermic needles, 13% butterfly needles, 6% IV catheter stylets and 4% blood-drawing needles (the remainder involved other devices). Eight percent of exposures with hollow-bore needles (the most risky exposures) were categorized as "IV line-related."3

As mentioned above, the risk of HIV seroconversion after being stuck with a contaminated needle has been estimated at about 0.25%.11 The CDC has identified the following factors as increasing the risk of HIV transmission: 1) a deep percutaneous injury; 2) a needle that was used for vascular access; 3) visible blood on the device causing the injury; 4) a source patient with end-stage AIDS or in the acute phase of retroviral disease; and 5) the failure to receive post-exposure prophylaxis with antiretroviral drugs.[23] Each of the devices specified in this petition has the potential to cause the three device-specific factors listed by the CDC.

Many different types of medical devices present a risk of occupational exposure to bloodborne pathogens. In this petition, we are asking the agency to take action with regard to devices which meet at least two of the following criteria: 1) their use creates a high risk of exposure to bloodborne pathogens, 2) their use is common in health care today, and 3) there is currently available FDA-cleared technology to minimize exposure. We have identified four types of devices that meet these criteria: IV catheters, devices used to draw venous blood samples, glass capillary tubes and IV tubing systems. (While the use of needles on IV lines is less likely to transmit disease because the tubing may only contain sterile fluid,2,[24] there are cases of HIV being transmitted by hypodermic needles used in this manner. Furthermore, the FDA acknowledged the avoidable risks represented by these devices by making them the subject of the first of only two alerts it has issued on occupational bloodborne pathogen transmission prevention.7)

We next describe cases of HIV transmission due to the devices that are the subject of this petition.

Lynda Arnold was a twenty-three-year-old nurse working in the intensive care unit (ICU) at Community Hospital in Lancaster, PA in September, 1992 at the time of her injury. She had recently graduated from nursing school and was beginning her career. Following standard ICU procedure, Ms. Arnold started an IV line on a newly admitted patient. After starting the line using an 18-gauge catheter, she withdrew the stylet from the patient. At that moment, the patient jerked his arm, forcing the stylet into the palm of Ms. Arnold's left hand. Later, she found out that the patient was an AIDS patient. Six months later, Ms. Arnold tested HIV seropositive.[25]

Ellen Dayton was stuck by a blood-drawing syringe. After drawing blood from a patient, Ms. Dayton was about to dispose of the used device when three glass blood-collection tubes started to roll off the counter

top. Instinctively, she reached over to catch the glass tubes. In the process, she sustained a needlestick from the contaminated needle that she was carrying in her other hand. Ms. Dayton subsequently tested seropositive for HIV and HCV.[26]

Peggy Ferro was a nurse's aide at a Kaiser Hospital in San Francisco at the time of her needlestick in the winter of 1990. Ms. Ferro was cleaning up a patient's bedside table when she was stuck with a blood-filled needle that was hidden from view by a piece of gauze. Several weeks later she tested HIV-positive. Ms. Ferro died on November 4, 1998 at the age of forty-nine, as a result of her needlestick.[27]

Hacib Aoun was a second-year medical resident in internal medicine when a glass capillary tube lacerated his index finger when he was attempting to seal the tube with clay. He later died of AIDS. His case was one of the first to draw attention to occupational HIV exposure when he described the injury and its devastating personal and social impact in the New England Journal of Medicine.[28]

Lisa Black was a registered nurse in her late twenties when she was stuck with a syringe while working the night shift on a medical-surgical unit in a small hospital in Nevada. On the night of her injury, Ms. Black was taking care of eight acutely ill patients, including one in the terminal stage of AIDS. When she checked this patient, she saw that his IV line tubing had become blocked and blood had backed up in the line. Although the hospital had made needleless IV access systems available, Ms. Black's patient did not have such a system and instead used a system that required a needle for gaining access to the IV line. Ms. Black tried to unclog the line by inserting a syringe into the rubber port of the IV line and aspirating. During this procedure, the patient startled and jerked his arm, causing the needle to dislodge from the rubber stopper on the IV line and puncture Ms. Black's palm. Although immediately after the injury she started a drug regimen to prevent HIV infection, nine months after the injury she was diagnosed with HIV. Shortly thereafter, she also tested seropositive for Hepatitis C.[29]

These tragic stories not only testify to the significant risks associated with needlesticks, but are also extremely distressing because all could have been prevented by safer technologies.

3. EFFICACY OF SAFETY DEVICES

In the past decade, in particular, numerous devices that either eliminate the use of needles entirely or contain safety features to prevent needlesticks have been developed. ECRI, a nonprofit health services research agency, is a kind of Consumer Reports for the device industry, and we rely heavily on its evaluations in this petition. ECRI evaluates safer medical devices based on specific criteria, including health care worker safety, patient safety, ease of use, user training and support materials, patient comfort, compatibility with other common medical devices and availability in typical sizes.[30]

A series of studies have documented the effectiveness of these needlestick-prevention devices in reducing exposure to bloodborne pathogens (see below). Unfortunately, all too often these devices are not used. Following a request for comments regarding the bloodborne pathogen transmission problem published in the Federal Register, OSHA received submissions from over 300 health care delivery institutions.[31] Among the respondents, 87% used safer medical devices for IV lines. However, only 31% of respondents did so for IV catheter insertion, 17% for intramuscular or subcutaneous injection and 41% for blood drawing. There is enormous potential for response bias in such a survey, with those implementing safer devices presumably more likely to respond, leading to overestimates of safer device use. The Veterans Administration has reported that, in 1996, 96% of its facilities used safer medical devices for IV delivery and 53% did so for IV insertion.31 On the one hand, these statistics demonstrate that it is feasible to implement these systems; on the other, the likely reporting artifact suggests that too many U.S. hospitals still lack these devices.

Intravenous Catheters

IV catheters with safety devices that protect against needlesticks have been found to be effective in reducing needlesticks without compromising patient care. These devices typically involve a plastic shield which locks and covers the introducer needle (stylet) after it has been removed from the patient (see Figure 1). ECRI has evaluated five IV catheters with safety features. Three of the five devices were described as providing "excellent protection from needlesticks without compromising patient safety and [they] are easy to use."30 Two devices were rated as providing "Adequate" protection. In the only study of the impact of safer IV catheters on injury rates of which we are aware, injury rates from IV catheters with safety features were compared to those without such features. The unsafe catheters continued to be used in the anesthesia and pediatrics departments of the three hospitals where the study was conducted. The rate of catheter stylet injury was 7.5/100,000 devices for

conventional catheters, compared to 1.2/100,000 devices for safety catheters, a reduction of 84%.[32]

Devices Used for Blood Drawing

There are two possible sources of needlestick injury in blood drawing: the needle that pierces the patient's vein (the blood-drawing needle) and the needle that pierces the rubber stopper of the test tube to fill the tube with blood (the tube-puncturing needle). Some health care workers use the blood-drawing needle to transfer the blood to the tube, but this practice is discouraged. A safer blood-collection device should provide protection from exposure from both needles. The typical methods for preventing needlesticks with the blood-drawing needle are retractable needles, self-blunting needles (in which another piece of metal slides down the inside of the needle, rendering it blunt) and protective shields (see Figure 2). Methods for preventing needlesticks with the tube-puncturing needle include retractable needles and test tube holders that cover the needle (see Figure 3).

ECRI has evaluated blood collection devices on two occasions.30,[33] Altogether, 10 devices have been evaluated. For three of these, the test tube holder can be detached from the rest of the device and then reused. For each of these, ECRI evaluated the device under two assumptions: that the test tube holder was not reused (safer) and that the test tube holder was reused (exposing the tube-puncturing needle). Thus, they performed a total of 13 evaluations. Two of the devices were rated "Acceptable-preferred": a system in which both needles retracted and one with a self-blunting needle, if the test tube holder was not reused. Four others were rated "Acceptable": the self-blunting needle when the test-tube holder was reused, another self-blunting needle, a system with a hinged shield to cover the exposed blood-drawing needle and a combined needle-shielding/sharps container system.

ECRI has also evaluated blood collection needle sets, colloquially known as butterflies. The safer devices allow the health care worker to retract the blood-drawing needle into a plastic sheath. ECRI rates two of these "Acceptable" and one "Acceptable-not recommended."

Blood-drawing devices that incorporate a protective mechanism in their design have been shown to be effective in reducing needlesticks. The CDC funded a study of three such devices at six university-affiliated hospitals. Statistically significant reductions of 66% and 76% were demonstrated for two blood collection devices. A 23% reduction in the needlestick rate associated with safer butterfly needles almost reached statistical significance.[34] A study evaluating the effectiveness of a 3cc shielded safety syringe demonstrated an 86% reduction in the rate (per inventory unit) of injury associated with this device during a period that the total number of needlesticks at the study medical centers actually increased somewhat.[35] In a study that also evaluated the efficacy of a needleless IV system, the rate of needlesticks (per health care worker-day) associated with 3cc syringes was reduced by 50%, although this reduction did not reach statistical significance.[36]

Glass Capillary Tubes

Glass capillary tubes are used to collect blood. The blood enters into the thin tube and then is sealed at one end with clay and placed in a centrifuge. This allows one to measure the quantity of red blood cells in the patient's blood (the "hematocrit"). To a certain extent, their use has been surmounted by the use of automated hematocrit measures. However, they are still used, and bloodborne pathogens can be transmitted if the glass breaks during blood drawing, sealing or transport.28,[37] It is estimated that there are 2800 injuries due to glass capillary tubes each year in the U.S.[38]

For several years, alternatives to glass capillary tubes have been available, although these alternatives have not been evaluated by ECRI. These include plastic capillary tubes as well as glass tubes sheathed in puncture-resistant film such as Mylar (see Figure 4). Needlestick prevention authorities have recommended that such devices replace the conventional glass versions.[39] Nonetheless, federal authorities have failed to respond in a manner that adequately protects worker health. In February 1999, OSHA, NIOSH and the FDA issued a Safety Advisory which recommended that users "consider" alternatives to glass capillary tubes.[40] These alternative devices have the potential for completely eliminating exposures from capillary tubes; for the FDA to permit glass capillary tubes to remain on the market is irresponsible in the extreme.

Needleless or Recessed Needle IV Systems

Needleless IV access lines (the port of the IV system is manufactured to accept a connector without a needle) and systems with recessed needles (the system uses a needle, but it is recessed within a plastic housing) have also been found to be very effective in reducing needlestick injuries. The attached Table describes 12 published

studies that have examined the efficacy of such devices in reducing needlestick rates, all in acute hospital settings. Among the 11 studies with specific data on IV-related exposures, the reduction in the rate or number of needlesticks ranged from 47% to 100%. Many of these did not perform tests of statistical significance, but, in four of the studies that did, statistical significance was reached.[5,41,42,43] In others, statistical significance may not have been reached due to small sample size. In five studies using before-after designs, the numbers or rates of non-IV-related needlesticks were reported and in each the reduction in IV-related needlesticks was greater.[22,41,42,44,45] Two additional studies used randomized designs to assess the impact of the needleless systems.[43,46] These two studies showed reductions in the number or rate of IV-related exposures of 89% to 100% compared to comparison wards. These studies were probably the best designed because they better accounted for trends over time in needlestick rates and needlestick reporting. They were also better able to adjust for differences between wards and for other interventions that were being carried out at the same time. This family of devices was rated by ECRI in 1994, and all 14 sets of devices were declared Acceptable for their intended uses.[47]

We acknowledge that there have been a series of reports linking needleless IV systems to patient bacterial infections.[48],[49],[50],[51] However, microbiologic studies have shown that, were health care workers to follow standard infection-control procedures, the likelihood of patient infection should be no higher than with conventional IV systems, while significantly reducing the probability of worker exposure.[52],[53],[54] Moreover, a randomized trial comparing conventional and needleless IV systems found no difference in the frequency of patient bloodstream infections.43

4. ECONOMIC CONSIDERATIONS

Analyses of the anticipated impact of implementing the new safety technology are difficult to perform because there are many unknowns. In this section, we seek simply to identify the elements of such calculations and to examine in a general way the economic impact of switching to the new technology.

Most authorities agree that the safer devices are more expensive than the conventional devices, at least at the present time. The incremental cost will vary by device, but safer devices that are twice as expensive are not uncommon,31 although the costs are likely to come down as a result of competition in the larger market that would result from this petition.

The costs of implementing the safer devices would be offset by the numbers of needlesticks prevented. Most respondents to OSHA's Request for Information estimated the cost of a needlestick injury to be between $500 and $1000.31 However, increasing use of post-exposure prophylaxis after needlesticks in which the source patient may be HIV-positive is likely to drive that figure upward. Moreover, on occasion a patient will seroconvert to HIV, leading to lifetime treatment costs conservatively estimated at $195,188.[55] In developing its own sharp object injury prevention program, California OSHA estimated that the ratio of costs (including an enhanced recordkeeping requirement, not part of this petition) to benefits would range between 0.54 and 0.81 – in all scenarios the implementation of the safer devices actually resulted in savings to society.[56]

The total additional costs of adopting safer technology would be only a small fraction of health care costs for a typical facility.56 The benefits of reduced psychological stress due to needlesticks averted by the safer technology are, of course, incalculable.

5. HISTORY OF REGULATORY EFFORTS

In 1987, the CDC issued its "Recommendations for prevention of HIV transmission in health-care settings."[57] These "universal precautions" became a mandatory requirement for health care employers in 1991 when OSHA adopted its Bloodborne Pathogens Standard.[58] The Standard requires employers to instruct health care workers on the safe handling of needles and other sharp objects, including not recapping, bending, breaking, or otherwise handling used needles and disposing of sharp objects as soon as possible after use in puncture-resistant disposal containers. It also mandates the use of engineering and work practice controls to eliminate or minimize employee exposure to blood and other bodily fluids.

Despite the improved practices mandated by the Standard, further efforts are needed to minimize the risk of serious illness and death faced by workers on a daily basis. The number of needlesticks sustained by health

care workers annually continues to be unacceptably high – approximately 590,000 annually.2

The Bloodborne Pathogens Standard did not directly mandate reductions in the use of needles or a shift to devices with safety features. Therefore, in April, 1991, SEIU first petitioned the FDA to address these issues. SEIU requested that the agency issue performance standards for Class II needle-bearing devices, amend its injury-reporting rule to include all needlesticks (many injuries to workers were not required to be reported), issue a labeling guidance for pre-filled syringes, and take certain administrative actions to increase understanding and awareness of the needlestick problem.

In response, on July 2, 1993, the agency acknowledged its "strong concern about the role of medical devices in the occupational transmission of infections" and pointed to its discussions with CDC and OSHA with regard to the problem. However, the agency refused to issue performance standards for needle-bearing devices, stating that its efforts were more appropriately directed at encouraging the voluntary development and adoption of new safer technology and developing guidances for manufacturers who chose to do so. In keeping with this approach to the problem, the agency developed and circulated the previously mentioned Safety Alert on the non-percutaneous applications of needle-bearing devices with IV administration sets.7 The Alert urged, but did not require, that hypodermic needles for gaining access to IV lines be replaced with needleless systems or recessed needle systems. The agency also developed a guidance document to assist manufacturers in preparing pre-market (510(k)) submissions for products that incorporate risk-reduction technology. The agency denied SEIU's requests that it require the reporting of all needlestick injuries and that it issue a labeling guidance for pre-filled syringes.

Although relying primarily on the voluntary efforts of manufacturers to develop safer products, the agency acknowledged the potential need for future action. Thus, it stated that it might require labeling of unprotected needle-bearing devices regarding "inappropriate uses" and that it was "considering ways to provide appropriate incentives for manufacturers to include information on risk reduction features of their product through claims in the product labeling."

In the nine years since the SEIU petition was filed, millions of needlestick injuries have occurred, and thousands of health care workers have contracted deadly diseases through exposure to blood. The data show that the FDA's most effective action was the issuance of the Safety Alert on IV tubing systems.7 Since the Alert was issued, large numbers of hospitals have shifted over to needleless systems.[31,39] On the other hand, while over 250 other safer devices have gone through the pre-market notification (510(k)) submission process,[59] hospitals and other health care facilities have been slow to adopt these safer technologies. The previously mentioned OSHA and Veterans Administration studies confirm the less-than-optimal use of these devices by hospitals. In many instances, even where a facility was using safer technology, it had not adopted the technology facility-wide and/or had not replaced all conventional devices for the appropriate applications.31 The OSHA report also found that respondents for the most part "indicated that new safer medical devices were readily accepted and correctly used by staff members when introduced into their facility."

The limited headway made in the adoption of safer technology, despite the considerable advances in the development of that technology since the submission of SEIU's first petition to this agency in 1991, shows that the FDA's reliance on voluntary adoption of this safer technology has not been successful. Too many health care workers continue to be unnecessarily exposed to the risk of infectious diseases because of unsafe medical devices that the FDA continues to allow on the market.

Nor can other agencies be expected adequately to address this problem. OSHA's 1991 Bloodborne Pathogens Standard focused on work practice controls, which are within the expertise of that agency, and only indirectly on devices. In the preamble to that Standard, OSHA explained the limitations on what could be accomplished through work practice controls. OSHA admitted that "as many as 60 percent of needle stick injuries [would] be unaffected by improved work practice procedures." Industrial hygiene principles dictate that "engineering controls [such as safer medical devices] are the best method to protect employees" from occupational exposure to bloodborne pathogens. Unlike work practice controls, which "reduce the likelihood of exposure [to bloodborne pathogens] through alteration of the manner in which a task is performed," engineering controls "act on the source of the hazard and eliminate or reduce employee exposure without [relying] on the employee to take self-protective action."6

OSHA has now made the use of safer medical devices a more explicit component of compliance with its Bloodborne Pathogens Standard. In 1999, it revised its enforcement procedures for the Standard by instructing its inspectors that preventing exposures requires a comprehensive program that includes safer medical devices. However, acknowledging that "[t]he FDA is responsible for clearing medical devices for marketing," OSHA

explicitly instructs its inspectors that it "does not advocate the use of one particular device over another." Instead, OSHA advises that employers should look to the "specific design features for recessed needle systems that the Food and Drug Administration (FDA Safety Alert, April 16, 1992 and Draft Supplementary guidance on the Content of Premarket Notification 510(k) Submissions for Medical Devices with Sharps Injury Prevention Features, March 1995) has published and agrees are important in preventing percutaneous injury."[60] On November 6, 2000, President Clinton signed a bill requiring OSHA to amend its Bloodborne Pathogens Standard to incorporate the 1999 revisions in its enforcement procedures into the Standard itself.[61]

Determinations as to which devices will prevent exposures and which should be removed from the market are the unique jurisdiction of the FDA. OSHA has required that health care employers engage in a process whereby they evaluate and implement engineering controls, including safer medical devices, but has not banned specific devices from the workplace. Because the prevention of needlesticks requires the elimination of unsafe needles from the market, action by the FDA is necessary. OSHA's process-heavy approach will not result in the immediate removal of unsafe devices from the market, even where there are well-recognized, safer alternatives. While OSHA's process approach will require employers to evaluate alternatives to unsafe devices, the unsafe devices that we have identified in the petition are among those that create the greatest risk to health care workers and should be removed immediately from the market since established, safer alternatives are available.

Seventeen states have enacted legislation in an effort to address the problem of needlesticks.[62] However, the states generally are limited in what they can do. In many states, standards established by federal OSHA preempt state efforts to regulate private health care providers and so the standards are limited to the public sector. Even in states that have their own state occupational safety and health agencies, and which may therefore establish health and safety standards for both private and public sector health care workers, state enactments have generally gone only as far as the recent federal law, although in theory they could go beyond the OSHA standard. Because the issues of needlestick prevention transcend state lines, action by the federal agency charged with regulating medical devices is necessary.

6. THE STANDARD FOR BANNING CERTAIN MEDICAL DEVICES

A device may be banned when it presents a "substantial risk of illness or injury" and labeling will not eliminate the risk.[63] In the case of each device for which we seek a ban in this petition, labeling and/or the government's actions to date have proved inadequate. For IV tubing, because the agency's effort to warn against the use of unprotected hypodermic needles in such tubing in its Safety Alert has not adequately reduced these unnecessary uses of needles, the agency should ban any IV system which does not use either recessed needles or needleless devices. For glass capillary tubes, the Safety Advisory is similarly inadequate since a ban would completely eliminate exposures from this device. IV catheters and blood-drawing devices (needles, tube holders and "butterfly syringes"), on the other hand, have not been the subject of any specific FDA action to date, but their use leads to unnecessary needlesticks that are both common and relatively likely to lead to the transmission of bloodborne pathogens. For these categories of devices, we do not believe a labeling requirement would provide sufficient protection for health care workers, who are unlikely to take the time to read the labels and whose hospitals may not provide safer alternative devices.

7. THE AUTHORITY FOR ISSUANCE OF A PERFORMANCE STANDARD

Needle-bearing medical devices are class II medical devices, subject to "special controls to provide [reasonable] assurance of the safety and effectiveness of the device[s]....including the promulgation of performance standards."[64]

In accordance with these provisions, the FDA should issue the criteria the agency itself has developed7 as performance standards. These performance standards will ensure the safety of these devices without interfering with their effectiveness.

We have also sought a label for syringes in this petition. These can also be pursued as performance standards because such standards may address "[t]he use, and the form and content, of labeling for the proper . . . operation, and use of the device."[65] The FDA may also pursue a labeling requirement under the misbranding provisions of the Food, Drug, and Cosmetic Act. A device is considered misbranded "[u]nless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions . . . where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users . . ."[66] In addition, a device is misbranded if its labeling is misleading in any particular.[67] In determining whether labeling is misleading, the FDA considers "the extent to which the labeling . . . fails to reveal . . . material with respect to consequences

which may result from the use of the article to which the labeling . . . relates . . . under such conditions of use as are customary or usual."[68]

Since syringes currently bear no warning of the hazards they represent, a label on the wrapper of every syringe should be required to indicate that the device should not in general be used for venous blood draws. Drawing blood from the external jugular vein in the neck and the femoral vein in the groin would be possible exceptions. Indeed, these uses and additional uses in the laboratory and clinical settings for which the safer devices are not known to be adequate substitutes are the reasons why we have not sought a ban for these devices.

C. ENVIRONMENTAL IMPACT

The actions requested by this petition are covered by categorical exclusions from the preparation of an environmental assessment or environmental impact statement under 21 C.F.R. §§ 25.34 (c) and 25.30(k). In addition, the actions requested would not have any substantial impact on the environme

D. CERTIFICATION

The undersigned certify that, to the best of their knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioners, which are unfavorable to the petition.

Respectfully submitted,

Peter Lurie, MD, MPH
Deputy Director
Public Citizen's Health Research Group
Phone: (202)588-7781

Andrew L. Stern
International President
Service Employees International Union
1313 L Street, NW
Washington, D.C. 20005
Phone: (202)898-3200

Carol R. Golubock
Associate General Counsel
Service Employees International Union

Sidney M. Wolfe, MD
Director
Public Citizen's Health Research Group

Table: Studies evaluating the effectiveness of needleless and recessed needle IV system

Author, year	Design	Impact upon exposures
Gartner, 199241	Before-after	88% reduction in number of IV-related exposures* 34% reduction in number of non-IV-related exposures
Weinstein, 1992[69]	Before-after	47% reduction in rate (per assembly) or IV-related needlesticks
Rutowski,	Before-after	100% reduction in number of IV-related needlesticks

199344		49% reduction in number of non-IV-related needlesticks
Skolnick, 199345	Before-after	72% reduction in number of IV-related injuries 18% reduction in number of non-IV-related injuries
Wolfrum, 1994[70]	Before-after	Approximately 75% reduction in number of IV-related puncture wounds
Yassi, 199522	Before-after	79% reduction in number of IV-related needlesticks 34% reduction in number of non-IV-related needlesticks
Orenstein, 199536	Before-after**	50% reduction in rate (per HCW-day) of IV-related needlesticks 61% reduction in rate (per HCW-day) of all needlesticks*
MacPherson, 1996[71]	Before-after	23% increases in rate (per operation) of all body fluid exposures
L'Ecuyer, 199646	Randomized, controlled trial	89%*-92%* decrease in rate (per patient-day or hour worked) of IV-related injury compared to comparison wards
Lawrence, 199742	Before-after	62%-70% reduction in rate (per FTE) of IV-related needlesticks* 18%-30% reduction in rate (per FTE) of non-IV-related needlesticks*
Mendelson, 199843	Randomized, crossover trial	100% reduction in number of IV-related percutaneous injuries compared to comparison wards*
Gershon, 19995	Before-after	92% reduction in rate (per FTE) of IV-related injuries* 71% reduction in rate (per FTE) of all injuries*

*$p<0.05$, if indicated in article

**A control unit had decreases in numbers of needlesticks of 67% for IV-related needlesticks and 100% for non-IV-related needlesticks, based on small numbers

FTE = full-time equivalent

HCW = health care worker

ENDNOTES

[1] 21 U.S.C. §§ 360d, 360f, and 352, and 21 C.F.R. §§ 10.30 and 861.

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[64] 21 U.S.C. §360c(a)(1)(B)

[65] 21 C.F.R. § 861.7(h)

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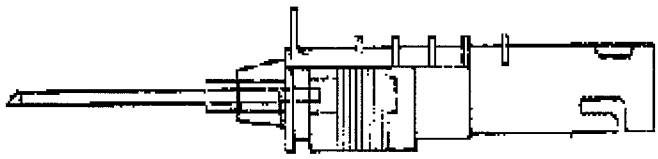
FIGURES

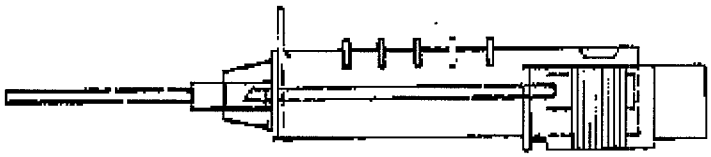
FIGURES FOR:

HRG Publication #1548 Petition to FDA to ban unsafe medical needles

Figure 1

Safety IV Catheter Devices

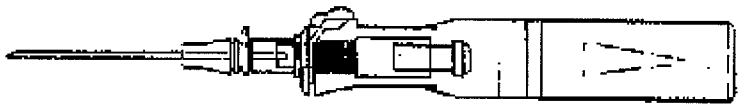




protected position

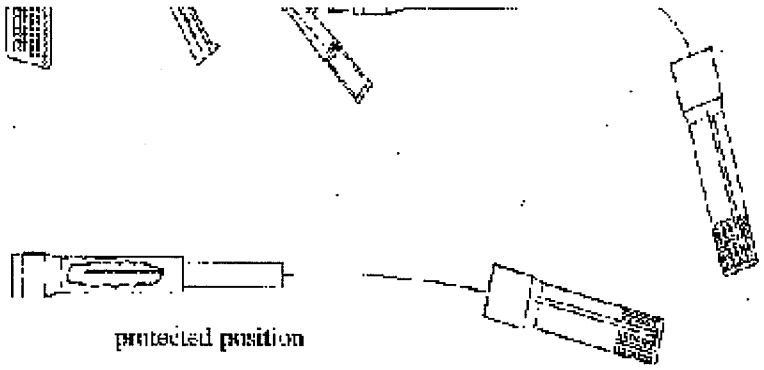
Protective™ I.V. Catheter
Safety System
Johnson & Johnson
Medical, Inc.
Arlington, TX
A protective sleeve encases the sharp stylet as it is retracted from the catheter.

Insyte® AutoGuard™
Shielded I.V. Catheter
Becton Dickinson
Vascular Access
Sandy, UT
Stylet is instantly encased inside a tamper-resistant safety barrel by pressing the activation button.



protected position

Saf-T-Intima™ I.V.
Catheter Safety
System
Becton Dickinson
Vascular Access

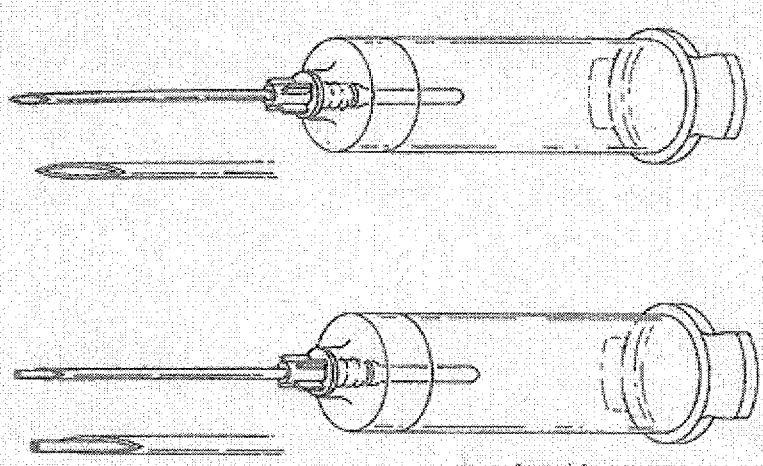


Sandy, UT
Following catheter insertion, the stylet is withdrawn and automatically covered in a telescoping safety chamber.

Source: Ippolito G, Puro V, Petrosillo N. Prevention, Management & Chemoprophylaxis of Occupational Exposure to HIV, International Health Care Worker Safety Center, University of Virginia, 1997.

Figure 2

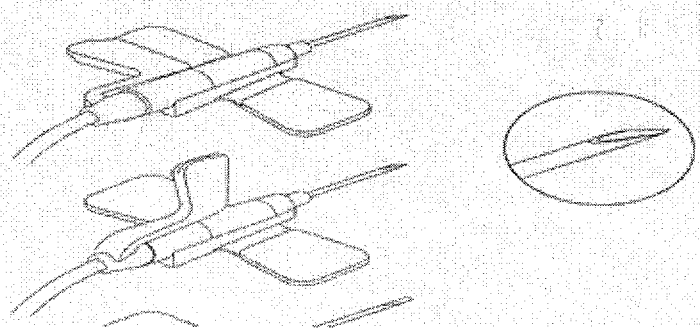
Self-Blunting Phlebotomy Needle



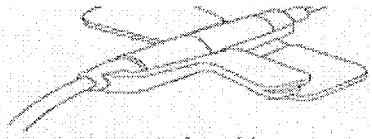
Punctur-Guard™
Bio-Plexus
Tolland, CT
After final tube of blood is drawn, blunt internal needle is activated by forward pressure of vacuum tube. Needle point is blunted before it is removed from the patient.

IV Insertion Equipment—Winged Steel Needles

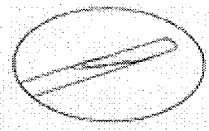
Punctur-Guard™
Winged Set
Bio-Plexus
Tolland, CT
After placement, third wing is rotated to flat position which blunts needle point

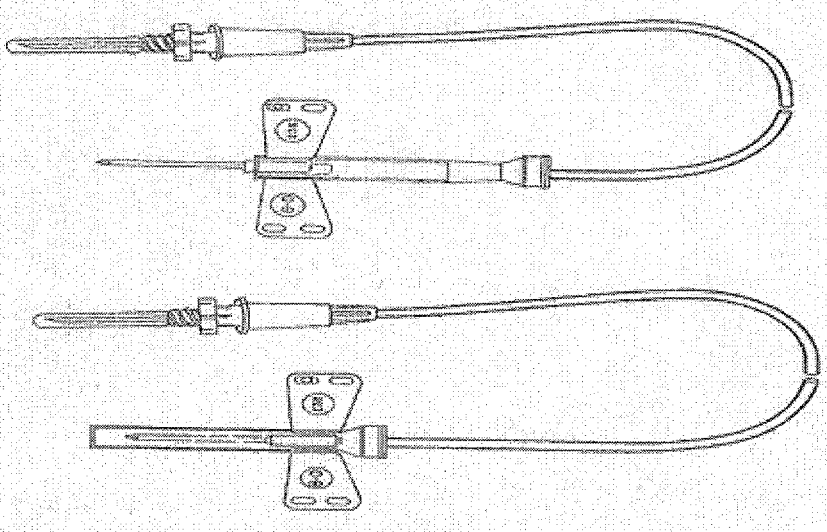


before it is removed from the patient.



protected position





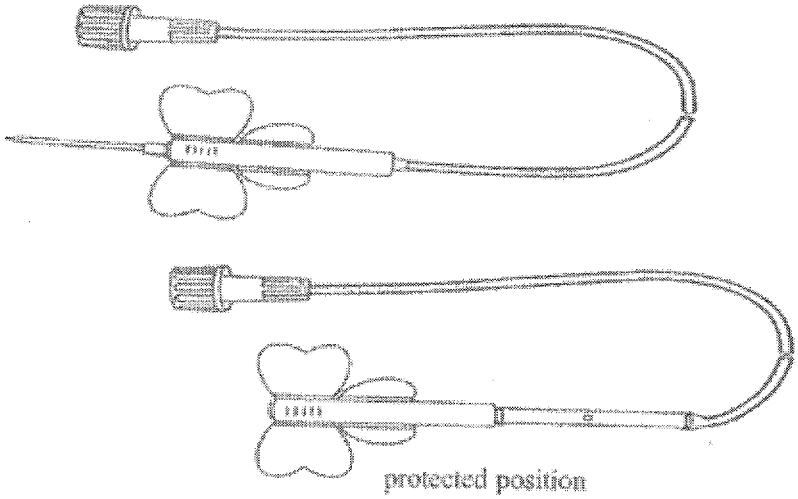
protected position

Vacutainer® Brand
Safety-Lok™
Winged Needle
Becton Dickinson
Vacutainer Systems
Franklin Lakes, NJ
After removal from patient, safety shield is advanced forward and locks in place beyond needle tip.

Source: Ippolito G, Puro V, Petrosillo N. Prevention, Management & Chemoprophylaxis of Occupational Exposure to HIV, International Health Care Worker Safety Center, University of Virginia, 1997.

Figure 2, continued

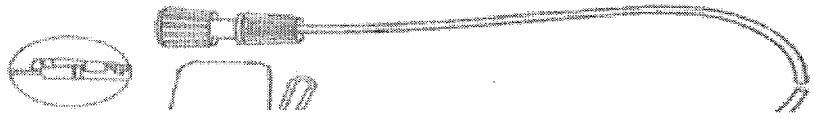
Winged Steel Needles (cont.)



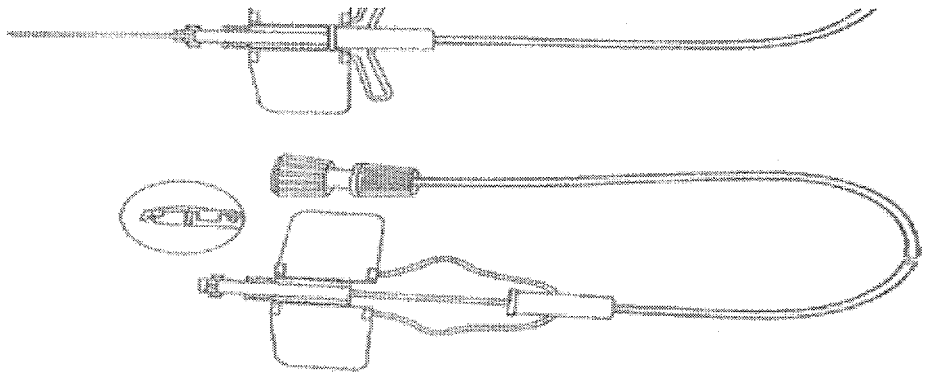
protected position

Shamrock™ Safety
Winged Needle
Winfield Medical
San Diego, CA
After removal from patient, needle is retracted backward and locks in covered position between wings.

Angel Wing™
Safety Needle

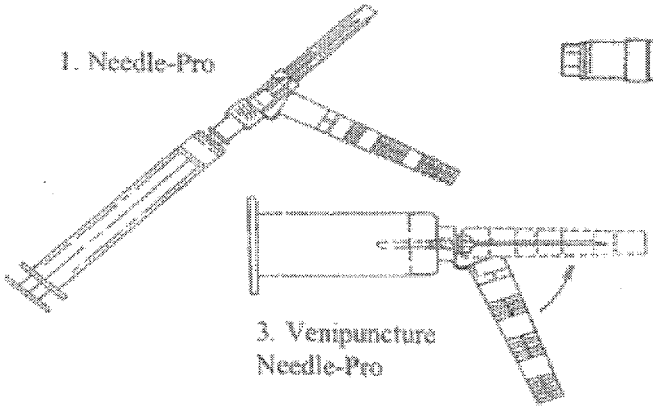


Sherwood Medical
St. Louis, MO
Stainless steel barrier tip is advanced forward to end of needle, locking over point as needle is withdrawn from patient; one-handed activation.



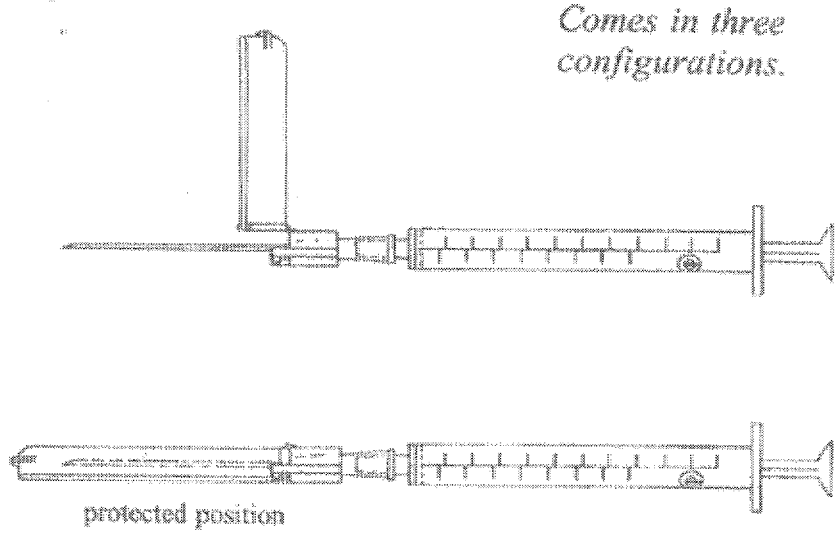
protected position

Safety Needle Shields



Needle-Pro™
Needle Protection Devices
Smith Industries Medical Systems
Keene, NH
Hinged sheath engages over needle; used needle is pressed into Needle-Pro device using one hand. Comes in three configurations.

Safety Tip™
Needle Shield
SMS/Safety Medical Supply Intl.
Burlington, MA
Hinged sheath covers and uncovers needle; to cover, needle is pressed into the sheath using a one-handed technique.

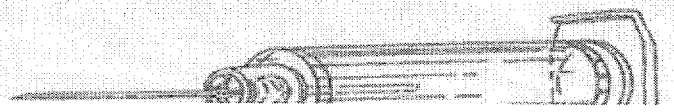


protected position

Figure 3

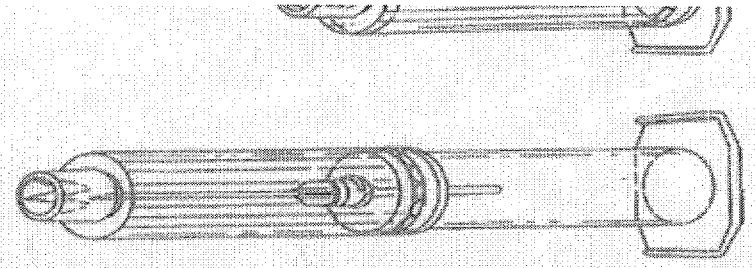
Safety Blood Tube Holders

Vacutainer® Brand
Safety-Lok™

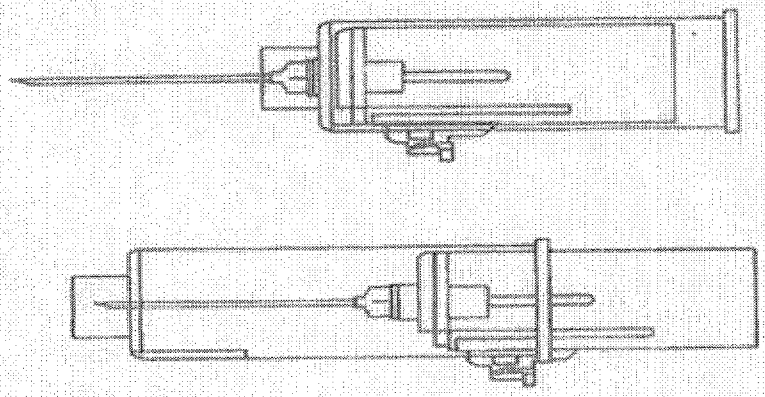


Becton Dickinson
Vacutainer Systems
Franklin Lakes, NJ

Single use vacuum tube/ needle holder with protective sliding sleeve that pushes forward after use and locks in place.



protected position



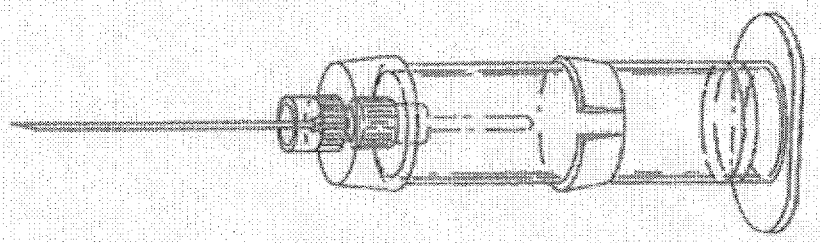
protected position

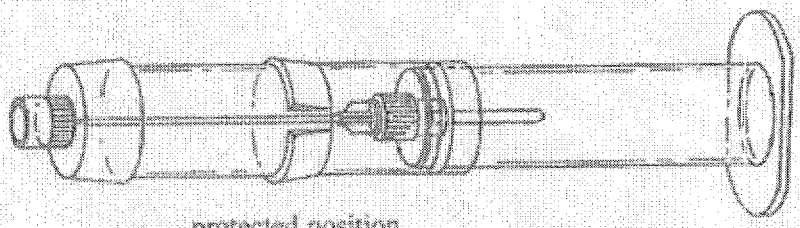
Safety-Gard™
Becton Dickinson
Vacutainer Systems
Franklin Lakes, NJ

Multiple use vacuum tube/ needle holder with protective sliding sleeve that pushes forward; after use, needle disengages directly into disposal container. Holder is then returned to original position for reuse.

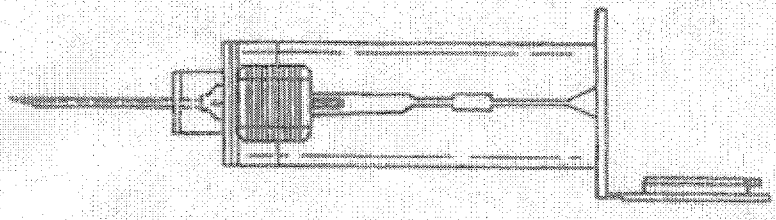
Saf-T Clik™
Winfield Medical
San Diego, CA

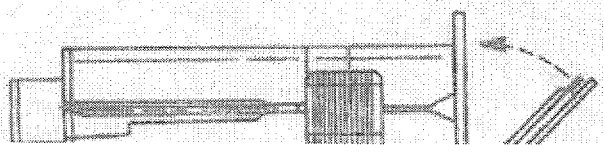
Single use vacuum tube/needle holder with protective sliding sleeve that pushes forward after use and locks in place.





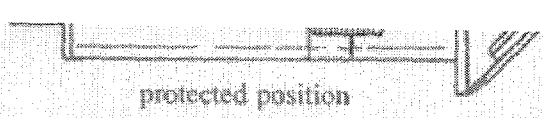
protected position





Proguard II™
Care Medical Products
Ontario, CA

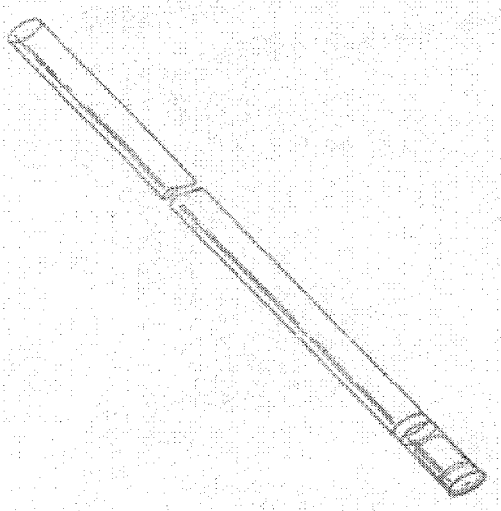
Single use vacuum tube/needle holder; after use needle is manually retracted into holder. End cap seals opening.



Source: Ippolito G, Puro V, Petrosillo N. Prevention, Management & Chemoprophylaxis of Occupational Exposure to HIV, International Health Care Worker Safety Center, University of Virginia, 1997.

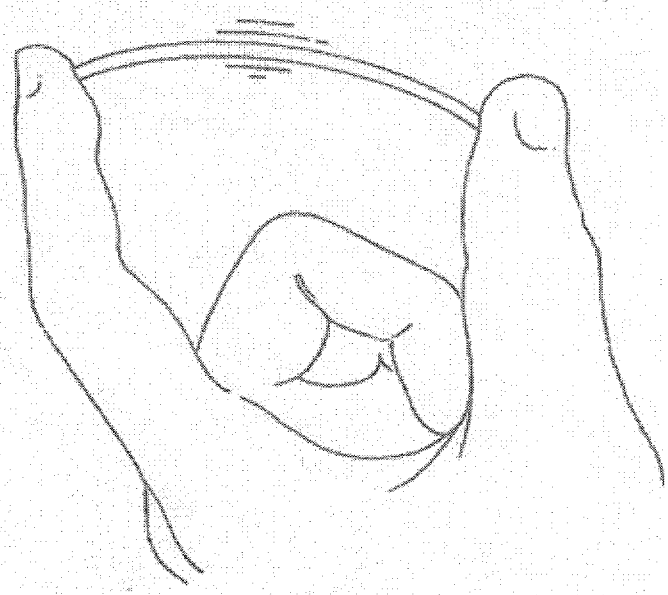
Figure 4

Safety Capillary Tubes



Clay Adams Brand
SurePrep™ Capillary Tube
Becton Dickinson/B-D Primary
Care Diagnostics
Franklin Lakes, NJ
Seals automatically when blood sample touches self-sealing plug. Protective mylar wrap helps contain blood and minimize exposure to glass fragments.

SafeCrit™ Plastic
Microhematocrit Tube
Statspin/IRIS
Norwood, MA
Capillary tube made of plastic avoids hazard of glass breakage.



Source: Ippolito G, Puro V, Petrosillo N. Prevention, Management & Chemoprophylaxis of Occupational Exposure to HIV. International Health Care Worker Safety Center, University of Virginia, 1997.

Nov. 29, 2000

Public Citizen, SEIU Petition FDA to Immediately Ban Unsafe Medical Needles

Health Care Workers Infected by Unsafe Devices Call for Safer Alternatives

WASHINGTON, D.C. -- The Food and Drug Administration (FDA) should immediately ban a variety of unsafe devices used by health care workers so they can be protected from contracting deadly diseases from accidental needle sticks, Public Citizen and the Service Employees International Union (SEIU) said in a petition filed today with the FDA.

U.S. health care workers sustain 590,000 needle sticks annually. Thousands have contracted HIV or hepatitis C after being accidentally stuck by infected needles while on the job, and many have died. Their deaths and suffering are unnecessary because safer alternatives exist.

"The FDA is the only entity that can completely remove these unsafe devices from all health care facilities," said Dr. Peter Lurie, deputy director of Public Citizen's Health Research Group. "For the sake of medical workers throughout the country, the FDA's immediate action on this petition is imperative. Cutting off an epidemic of needle-borne infections at the source is the only effective public health strategy."

Said SEIU President Andrew L. Stern, "Without FDA action, thousands of nurses, doctors and other health care workers will lose their lives. Not one more health care worker should needlessly suffer from unsafe needles when proven, safer alternatives exist."

The petition calls for the FDA to remove from the market all unsafe intravenous catheters, blood collection devices, blood collection needle sets (also known as butterfly syringes), glass capillary tubes and intravenous infusion equipment. The petition also asks the FDA to issue performance standards to ensure that similar unsafe devices do not enter the market.

There have been 49 documented cases of U.S. health care workers contracting HIV from patients after being stuck by infected needles or similar sharp medical devices, although the actual number is likely much higher because there have been no needle stick reporting requirements. One hundred to 200 other workers die annually from hepatitis B, and the Centers for Disease Control and Prevention (CDC) believes most of these cases are occupationally acquired. Hundreds of health care workers also contract hepatitis C every year.

Noreen Prill, a nurse who became infected with hepatitis C in 1978 and who appeared at today's press conference, said the ban is long overdue. Her hand was pierced by a contaminated needle when a

dialysis patient grabbed her arm while she was taking blood from him.

"It is sad and ironic that the same kind of needle that infected me more than 20 years ago is still on the market today," Prill said.

Ellen Dayton, a California nurse, became infected on the job in 1996. She was reaching to grab several blood-collection tubes that were rolling off a counter top when her finger was pricked by a contaminated butterfly syringe. She subsequently tested positive for HIV and hepatitis C. Although she was too sick to travel to today's press conference, she provided a videotaped statement.

"It is time for the FDA to act to take needles like the one that I was stuck with off the market, so that no other nurses will have to suffer like I have," Dayton said.

Safer devices exist, including retractable needles, self-blunting needles and protective shields. Plastic capillary tubes used for measuring red blood cell counts can replace glass tubes. Intravenous catheters can be equipped with plastic shields that lock and cover the needle after it has been removed from a patient. Intravenous tubing that uses no needles has been developed and has been shown to reduce needle sticks.

Such devices can be more expensive, but their cost can be offset by the number of needle sticks prevented, the petition states. Such injuries typically cost between $500 and $1,000 for each worker who sustains a needle stick, including blood tests, counseling and appropriate medications. Treatment costs increase dramatically if workers become sick.

In 1991, the SEIU petitioned the FDA to issue performance standards for a variety of unsafe needles devices, but the FDA refused to do so. Since the petition was filed, millions of workers have been stuck by needles and thousands have contracted deadly diseases. Many hospitals and health care facilities have begun to use safer devices, but their use is not widespread.

Congress recently approved a law that strengthened the Occupational Safety and Health Administration's (OSHA) Bloodborne Pathogens Standard to require most – but not all – health facilities to evaluate the needles they are using and use safer needles. During the evaluation process, unsafe needles will continue to be used. The evaluation process will be inconsistent and unnecessarily time-consuming unless the FDA leads the way by banning devices that have been proven unsafe and for which there are proven, safer alternatives.

"It is time for the FDA to live up to its responsibility to regulate unsafe medical devices and take them off the market," said Dr. Sidney M. Wolfe, director of Public Citizen's Health Research Group. "The FDA needs to act now. Otherwise, hundreds of workers will continue to become infected each year."

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D. CERTIFICATION

The undersigned certify that, to the best of their knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioners, which are unfavorable to the petition.

Respectfully submitted,

Peter Lurie, MD, MPH
Deputy Director
Public Citizen's Health Research Group
Phone: (202)588-7781

Andrew L. Stern
Andrew L. Stern
International President
Service Employees International Union
1313 L Street, NW
Washington, D.C. 20005
Phone: (202)898-3200

Carol R. Golubock
Carol R. Golubock
Associate General Counsel
Service Employees International Union

Sidney M. Wolfe, MD
Director
Public Citizen's Health Research Group

ROUTING SLIP
GENERATED BY: HF-40
DATE: FEB 26, 2001

FDA CONTROL NUMBER: 01 977 **TRACER #:** **OS #:**

DATE OF CORRESPONDENCE: 11/29/00 **DATE INTO FDA:** 02/26/01

TO: JANE E HENNEY HF-1

FROM: PETER LURIE, PUBLIC CITIZEN'S HEALTH RESEARCH GROUP

SYNOPSIS: REQUESTS THAT FDA BAN UNSAFE IV CATHETERS, BLOOD COLLECTION DEVICES AND NEEDLE SETS, GLASS CAPILLARY TUBES AND IV INFUSIONN EQUIPMENT THAT DOES NOT REACH THEIR STANDARDS TO PROTECT HEALTH CARE WORKERS FROM INFECTIOUS BLOODBORNE DISEASES

LEAD OFFICE: HF-40 **HOME OFFICE:** HF-40

CONTACT/PHONE#: MIKELE A BRYANT 301-827-4450

COPIES: HF-1 BERNARD A SCHWETZ
HF-40 LAJUANA D CALDWELL
HFA-305 JENNIE C BUTLER
HF-40 LINDA H GANGLOFF
HFZ-1

COORDINATION:

SIGNATURE REQUIRED: COMMISSIONER

REFERRALS FROM HF-40

ASSIGNED TO		ACTION	DUE DATE
HF-40	RUSSW	PREPARE DIRECT REPLY	03/08/01

REMARKS: NOTE: OES HAS NO RECORD OF THIS DOCUMENT