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September 13, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear FDA:

Re: Docket No. 01P-0120

We read with great interest the HRG (Public Citizen)/SEIU petition¹ and the FDA's responses that were published in the June 20, 2002, issue of the *Federal Register*. We appreciate the invitation to submit information regarding these matters to the FDA.

We strongly feel that "conventional" (non-safety) hypodermic syringes should *not* have been relegated to simply a request for a label warning in the HRG/SEIU petition. We would have included "conventional" syringes in the banning category, especially since syringes were responsible for the highest percentages of sharps injuries, by far, in both EPINet data (33 percent) and CDC data (29 percent).²

Various estimates put the number of accidental needlestick injuries that are reported annually by healthcare workers in the U.S. at between 590,000 and one million. And most studies and articles about the needlestick problem, when citing statistics, point out that *most* accidental needlestick injuries are not reported (for a variety of reasons). Whatever the numbers actually are, it is clear that many hundreds of thousands of U.S. healthcare workers, and perhaps more, are needlessly put at risk each year for life-threatening diseases. And the tragic irony is that these are the very same people who take care of the rest of us when we are ill or injured.

Over the past several months, the *New York Times* has published a series of articles entitled "Medicine's Middlemen." These articles discuss the power wielded by hospital group purchasing organizations (GPOs) and their efforts to restrict market access, especially to small, innovative medical device manufacturers. GPOs also have been the subject of recent senate subcommittee hearings because of questionable—and illegal—tactics that (despite the supposed implementation of the federal Needlestick Safety and Prevention law of 2000) prevent safer needle technologies from penetrating the market.

01P-0120

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¹ "Petition to the FDA by Health Research Group and Service Employees International Union Requesting the Removal of Unsafe Intravenous Injection Equipment from the Market," HRG Publication #1548, <http://www.citizen.org/publications/print_release.cfm?ID=6749>.

² *Federal Register*, Vol. 67, No. 119 (Thursday, June 20, 2002): 41982 (column 1).

Otherwise the annual number of needlestick injuries would not have continued to hover around 600,000; it would have diminished steeply.

Another serious problem for healthcare workers is that the major syringe manufacturers have chosen to simply pay lip service to the needlestick problem. Some so-called “safety” needle devices are, in reality, just as dangerous as their conventional, non-safety predecessors; in fact, some are *even more dangerous*. Some of these ill-conceived “safety” devices actually *increase* the number of accidental needlestick injuries rather than decrease them. They are safe in name only. The manufacturers of such products have a vested interest in maintaining the status quo and changing their products as little as possible; they have chosen to start with a conventional non-safety syringe, and then cobble on a “safety” feature as an afterthought, rather than to start from scratch and design an effective safety feature as an integral part of the syringe.

In January of this year, the California Department of Health Services issued a status report on its Sharps Injury Control Program.³ This first report did not identify the brand names or manufacturers of the needle devices that were involved in accidental needlestick incidents.

Several years ago in clinical trials at Kaiser Permanente hospitals in California, Becton Dickinson’s Safety-Lok™ syringe, during more than 18 months of use, provided no (device-related) reduction in the needlestick injury rate.⁴ When the hospitals removed the Safety-Lok™ syringe, the (device-specific) needlestick injury rate dropped. This vital information concerning the potential risks of using safety sheath syringes has been carefully garnered by Kaiser rather than being openly shared with other facilities.

The only study quoted in the above mentioned California report that cites any safety benefit in using a sheathing device is the study reported by Barbara Younger, et al. in a 1992 article in *Infection Control and Hospital Epidemiology*⁵, a study that was sponsored, in part, by Sherwood Medical (now Tyco). A review of that study shows it to be faulty both in not having included any control group and in having been extremely short. Only six weeks of product introduction was preceded by two weeks of intensive training about the dangers of accidental sticks, and the training effect could not be separated from the results. In fact, one of the three facilities involved reported an *equal reduction* in accidents during the study *where no safety product was provided*.

In light of the suppressed 18-month study at Kaiser, it is inappropriate and suspicious that the major syringe makers continue to ignore that study while continuing to cite the 10-year-old flawed study by Barbara Younger, et al. The fact that the two largest syringe

³ “Sharps Injury Control Program,” (California) Department of Health Services, January 2002:1-61.

⁴ “Safety Device and Implementation Summary, 1996 Review” Unpublished Kaiser South Internal Document, December 1996; cover sheet plus two pages.

⁵ Barbara Younger, RN, BSN, CIC, et al., “Impact of a Shielded Safety Syringe on Needlestick Injuries among Healthcare Workers,” Vol. 13, No. 6 (June 1992): 349-353.

manufacturers have made huge investments in ramping up the production of their so-called “safety” products and are ignoring the results of the extensive 18-month-long Kaiser study in favor of a six week, three hospital study with no control group and inconclusive results, should wave Enron flags around the entire safety efforts of Becton Dickinson and Tyco.

We have received reports that clinicians using some of the so-called “safety” syringes are so fearful of getting stuck by the contaminated needles that they often intentionally avoid activating the “safety” feature. This certainly shows how little faith some clinicians have in the “safety” features promoted by the industry leaders. Self-preservation is a strong instinct.

In contrast, our VanishPoint® syringes, which were originally developed under grants from the National Institutes of Health, *virtually eliminate any risk* of accidental needlestick injury. One study reported the results of a survey of 26 healthcare facilities that used a total of 86,300 VanishPoint® syringes *without a single needlestick injury*.⁶ Another study was conducted at the Mohawk Valley Psychiatric Center (Utica, New York), using VanishPoint® syringes and VanishPoint® blood collection tube holders. During the study’s two-year duration, accidental needlestick injuries were *completely eliminated*.⁷ Abbott Laboratories plans to soon publish the results of a 35-month trial of VanishPoint® blood collection tube holders at the Veterans Administration hospital in Murfreesboro, Tennessee. Here, again, there were no accidental needlestick injuries whatsoever.⁸

Professor William A. Hyman, Sc.D., P.E., chairman of the Biomedical Engineering Program at Texas A&M University, has written an article entitled “Human Factors of Needle Safety Devices.”⁹ Dr. Hyman says that a human factors analysis takes into account that the safe use of a product requires that it not only be technically able to perform the required functions, “but that the design must implement these functions in a way that assists the user in actually achieving the desired results in a safe and consistent manner.”¹⁰ Hyman says that our knowledge about the human factors aspects of error-

prone devices has been generalized, and these general principles can be applied to any specific product.

⁶ Kathryn Duesman, RN, BSN, and Jean Ross, “Survey of Accidental Needlesticks in 26 Facilities Using VanishPoint® Automated Retraction Syringe,” *Journal of Healthcare Safety, Compliance & Infection Control*, Vol. 2, No. 2 (March 1998): 111-114.

⁷ Carolyn Squillance, MS, ANP, RN, ICN, “A Team Approach to Needlestick Injuries,” *Journal of Healthcare Safety, Compliance & Infection Control*, Vol. 3, No. 8 (October 1999): 354-356.

⁸ Sandra Walters, RN, MSN, “Preventing Needlestick Injuries in Blood Collection.” The manuscript for this article is being prepared by Abbott Laboratories for publication within the next few weeks. Ms. Walters is the nurse manager of Clinical Support Services at the VA hospital in Murfreesboro, Tennessee.

⁹ Professor Hyman’s paper is scheduled for publication in the fall 2002 issue of the *Journal of Clinical Engineering*.

¹⁰ Hyman, (Abstract) 1.

Hyman continues:

This allows error-prone devices, such as many anti-needlestick devices, to be evaluated in the context of these general principles. On the basis of this evaluation, it is clear that some syringe devices intended to reduce or eliminate accidental needlesticks have been designed in conformance with human factors principles, while others have not, despite the term “safe” or “safety” in their names.¹¹

Professor Hyman evaluated several manually securing “safety” syringes: the SIMS Portex Needle-Pro™, the Becton Dickinson (B-D) SafetyGlide™, the B-D Safety-Lok™, and the Kendall Monoject™, along with self-securing (automated retraction) devices: Retractable Technologies’ VanishPoint® syringe and New Medical Technology’s (NMT) syringe. The two-page table from Hyman’s article is attached.

Dr. Hyman concludes:

It is apparent from the application of the basic principles of human factors and the ongoing discussions of use error, that the various products that have been introduced to prevent needlesticks would not be expected to be equally effective in this regard, and in some cases would increase, rather than decrease, the number of sticks observed as a result of their awkward and dangerous means of use. On the basis of first principles, and the rules for needlestick prevention products derived from these principles, only the self-securing designs meet the need for a device that can be simply and consistently activated and which achieves the goal of making the used needle unavailable for inadvertent sticks. While the visible operating principle of the two products considered here is similar, the NMT design allows for a significant additional use error. Therefore, only the Retractable Technologies VanishPoint® meets the requirements of a device that can be expected to be safely and consistently used.

On the basis of this evaluation, the use of the terms “safe,” or “safety,” (or other variations of the word) for several of the products reviewed here is unjustified and misleading. The basis for FDA 510(k) clearance of the use of these words is not obvious, if they are given any scrutiny at all. Likewise, it is apparent that some of these devices should not satisfy OSHA and other blood borne pathogen regulations requiring “engineered” safety systems, since they do not provide a safe system, and in some cases provide a more dangerous system rather than a

¹¹ Hyman, (Abstract) 1.

less dangerous one. A claim of safe, or safety, should require proof of actual safe handling in real clinical environments, even beyond small, tightly controlled pilot studies. In this regard it is unfortunate that EPINet,¹² a needlestick data collection effort based at the University of Virginia, does not request information on actual products involved in needlestick injury incidents. This information is also obscured by the FDA's curious exemption of most needlestick incidents that result from "user error" from Medical Device Reporting (MDR).¹³ Without a basis for claims of safety, and without adequate reporting, healthcare workers and others will not enjoy the benefits of truly safer needle products. Worse yet, with some products they are likely to sustain an increase in avoidable injuries.¹⁴

We suggest that both "conventional" (non-safety) syringes and ineffective so-called "safety" syringes be removed from the market and outlawed by the FDA. A sincere concern for the health, welfare—and very lives—of this nation's dedicated frontline healthcare workers demands no less. This can be (and often is) a matter of life-or-death. It is high time that we, as a society, stop playing games and tolerating dangerous products. The *Federal Register* says, "FDA may ban a device if it finds that the device presents a 'substantial deception or an unreasonable and substantial risk of illness or injury.'"¹⁵ We think the "conventional" (non-safety) syringe and some so-called "safety" syringes definitely fit this provision.

The International Health Care Worker Safety Center at the University of Virginia collects statistics and maintains a database on accidental needlestick injuries. Yet they have steadfastly refused to share information about the injury rate of each manufacturer's devices. Last year unsafe needles were the subject of a segment on the CBS television news program *60 Minutes*. Veteran investigative reporter Mike Wallace tried to get information about the efficacy of various manufacturers' devices from Dr. Janine Jagger, the Center's director, in the following encounter:

WALLACE: Dr. Janine Jagger. She's the Becton Dickinson Professor of Health Care Worker Safety at the University of Virginia. And BD (Becton Dickinson) has not only endowed her professorship with

nearly a million dollars, they also helped bankroll her efforts to create the world's biggest, most important data bank on needle stick accidents.

So we asked her, what is the most dangerous syringe on the market right now?

¹² International Healthcare Worker Safety Center, University of Virginia, <<http://www.med.virginia.edu/medcntr/centers/epinet/>>.

¹³ MDR Guidance Documents and Exemption – No. 3 – Needlesticks and Blood Exposure – E1996003, U.S. Food and Drug Administration, <<http://www.fda.gov/cdrh/manual/need2or3.html>>.

¹⁴ Hyman, (Conclusion) 9.

¹⁵ *Federal Register*, Vol. 67, No. 119 (Thursday, June 20, 2002): 41891 (column 3).

- JAGGER: OK, we can't say what is the most dangerous syringe on the market.
- WALLACE: So how about the most dangerous blood-drawing needle?
- JAGGER: Well, we—the data in our data base does not identify manufacturers, and it's not that we don't want to get that data, but it's just—it's very difficult to get.¹⁶

A recent article by Dr. Jagger and Ms. Jane Perry says, “BBF (blood or body fluids) report forms should allow workers to identify products involved in exposures. This aids in future product selection and more effective communication of problems to manufacturers.”¹⁷

We wholeheartedly agree with the above statement. The identity of the manufacturer and model of the device involved in each instance of accidental needlestick injury should be a matter of public record, accessible to all. Yet, despite what Dr. Jagger has said in print, she has not released this information to the public. Given Becton Dickinson's financial sponsorship of both Jagger's endowed professorial chair and the EPINet needlestick database, this failure to disclose crucial health-related information certainly gives at least the appearance of impropriety and conflict of interest.

The literature about the needlestick problem is filled with comments and predictions that the use of safety needle devices can reduce the number of accidental needlesticks, but often it is talking about quite modest reductions. There has not been any clinical data published to date that demonstrates a significant decrease in needlestick injuries when using so-called “safety” needle devices made by the major syringe manufacturers. In fact, Enid Eck, a senior consultant on infectious disease, in congressional subcommittee hearings, said, “Some sharps safety devices have had virtually no impact on injury reduction and others *have led to increases in injuries* due to their engineering design.”¹⁸

The three clinical studies of VanishPoint® products that were discussed earlier in this letter all reported *zero* needlesticks. The Duesman-Ross article reported zero accidental needlestick injuries out of 86,300 VanishPoint® syringes used (at 26 different healthcare facilities). The soon-to-be published Walters article reports zero accidental needlestick

¹⁶ *60 Minutes* telecast on February 25, 2001.

¹⁷ Janine Jagger, MPH, PhD, and Jane Perry, MA, “Avoiding Blood and Body Fluid Exposures,” *Nursing2002* Vol. 32, No. 8 (August 2002): 68. Perry is director of communications at the International Health Care Worker Safety Center.

¹⁸ Testimony of Enid K. Eck, RN, MPH, before congressional Subcommittee on Workforce Protections, “OSHA Compliance Directive on Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens,” <<http://edworkforce.house.gov/hearings/106th/wp/needlestick62200/eck.htm>>.

injuries out of more than 219,000 VanishPoint® blood collection tube holders used.¹⁹ The Squillance article also reported zero accidental needlestick injuries but did not state the number of VanishPoint® blood collection tube holders used.

Based upon the above studies, it is obvious that we at Retractable Technologies are not exaggerating when we say that the VanishPoint® devices *virtually eliminate* the risk of accidental needlestick injury. This is no idle claim; it is a well-documented, scientific fact. It is clear that the VanishPoint® products are in a different league from many so-called “safety” needle devices. The VanishPoint® products are obviously *several orders of magnitude* better than most others.

How can a modest, token needlestick reduction be acceptable in a life-or-death matter when there are products available that, in clinical studies, have been shown to be extremely effective? Why not use products that virtually eliminate accidental needlesticks?

We propose that “conventional” (non-safety) hypodermic syringes and blood collection tube holders should be banned *along with* any so-called “safety” syringes and “safety” blood collection tube holders that have not been clinically proven to substantially reduce the incidence of accidental needlestick injury.

We will be happy to provide further information or documentation. Thank you for this opportunity to address the FDA about this important matter.

Sincerely,



Thomas J. Shaw
President and CEO

Attachment and enclosures

¹⁹ Walters reports that the hospital performed approximately 219,000 venipunctures in just the first 24 months of the 35-month study. (So probably more than 300,000 blood draws were performed over 35 months, and with zero accidental needlestick injuries.)

Table 1 - Application of design rules to product categories

Note: Products within categories do not have equal design and performance characteristics. See text.

ABBREVIATED RULE	TRADITIONAL	MANUALLY SECURING ¹	SELF SECURING ²
<p>The required procedure should be immediately available so that the hazard is eliminated quickly.</p> <p>sub-issues:</p> <ul style="list-style-type: none"> manipulation additional steps obviousness consistent easy to learn easy to remember 	<p>Not available. The needle must be carried to a disposal box, and inserted without injury. The hazard continues even post disposal from the potential for further access to the device during subsequent disposals or other contact.</p> <ul style="list-style-type: none"> yes yes reasonably obvious, but introduces other risks no yes in principal, but not in practice yes in principal, but not in practice 	<p>Marginally available. The device grip must typically be changed and/or the other hand brought into use, or a hard surface be used. Post implementation, the safety feature is easily defeated in some products.</p> <ul style="list-style-type: none"> yes yes marginally obvious no no not demonstrated 	<p>Immediately available. Continued pressure with the same grip, with the same hand. The protection continues post disposal.</p> <ul style="list-style-type: none"> no no obvious yes yes yes
<p>The required procedure must not add any new opportunities for the hazard to produce an injury event</p> <p>(continued)</p>	<p>Introduces many opportunities for self sticks, and sticks to others, during delay, transport, disposal, and post disposal.</p>	<p>Further manipulation introduces stick opportunities. The need to use the other hand is particularly dangerous.</p>	<p>Required action presents no new problems.</p>

Table 1 - Continued

ABBREVIATED RULE	TRADITIONAL	MANUALLY SECURING ¹	SELF SECURING ²
No or minimal temptation to postpone implementation	Implementation is inherently delayed, adding temptation to put the used needle down. Disposal box may not be immediately available.	Since the process requires extra steps, there is a temptation to delay implementation, including putting the syringe down somewhere.	The process is immediate, and simple. Therefore there is no motivation to delay implementation.
Obviousness of deployment of safety apparatus	Appears obvious once in box, but needle may still be accessible.	Some designs allow for partial deployment which can be confused with full deployment.	By intent, the needle is gone when deployed, with no intermediate positions (However see discussion of NMT.)
Discouragement of alternate means	Intended use is inconvenient and alternatives are therefore likely.	Need to use two hands or complicated manipulation encourages delayed implementation.	Immediate activation eliminates the need for alternatives.
Potential for false reliance	Low in transit, but high after placement in disposal box.	High, because high potential for additional risk and/or non-implementation.	Low, because system is easy to use so that reliance is appropriate. (However see discussion of NMT.)

1. Manually securing devices include the SIMS Portex Needle-Pro, The B-D SafetyGlide, the B-D Safety-Lok, and the Kendall Monojet Safety syringes.
2. Self securing devices include the Retractable Technologies VanishPoint and the NMT Safety Syringe.