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 U.S. Department of Labor  
 Room N-2625  
 200 Constitution Ave. N.W.  
 Washington, D.C. 20210

[Electronic Submission. Attachments will be sent in following transmission to insure they are transmitted due to digital limitations that might exist due to size of electronic package.]

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The words spoken a decade ago, "Workers are dying because hospitals aren't using safe needles that are available for the cost of a postage stamp, " are as true today as it was when union leader Andy Stern spoke them. According to Premier, Inc., one of the largest hospital procurement organizations, "It is estimated that more than 800,000 injuries occur annually in the United States from needles....", and "more than half" of accidental needlesticks are not reported. Furthermore, a large percentage of these are due to faulty, inadequate, or otherwise problematic technology.<sup>12</sup> In 2008 and 2009, the American Nurses Association collaborated the continued high incidence of accidents among our nation's nurses.<sup>3</sup>

This Comment will focus on why the U.S. has not experienced a great reduction in accidental sticks, even a decade after passage of the Needlestick Safety and Prevention Act (2000).

According to the Premier document, "Safety devices are the law."<sup>4</sup> The language, if not the spirit of the Needlestick Safety and Prevention Act (NSSPA) is that safety devices are required to be used in the United States. However, implementation of the law is dictated by OSHA regulations, and OSHA's Bloodborne Pathogen Standard (BPS) puts the onus on employers (hospitals, laboratories, schools, etc.) to annually review and update "changes in technology" that provide greater levels of safety [29 CFR 1910.1030(c)(1)(iv)], as well as document "commercially available and effective medical devices [29 CFR 1910.1030(c)(1)(iv)(A-B)].<sup>5</sup>

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1 Premier, Inc., "Prevent Needlestick Injuries," 2007, pg. 3.

2 According to American Nurses Association, CDC, and many studies, the majority of accidental needlesticks go unreported. This is for several reasons that include social stigma issues, insurance issues, employer issues.

3 American Nurses Association, "Workplace Safety and Needlestick Injuries Are Top Concerns For Nurses," Press Release, June 24, 2008. For full research results:

<http://nursingworld.org/MainMenuCategories/OccupationalandEnvironmental/occupationalhealth/OccupationalResources/2008SafetyandNeedlestickStudy.aspx>

4 Premier, Inc., "Prevent Needlestick Injuries," 2007, pg. 2.

5 OSHA, Standard Interpretations, "Employer's responsibility to re-evaluate engineering controls; i.e. safer needle devices, at least annually," January, 20, 2004, pg. 1.

The following points discuss some of the most important barriers to the implementation of the regulations, and a few key proposed solutions.

**(I.) Requirement that the safest devices be made available by employers:** A major reason the U.S. rate of accidental sticks has not been greatly reduced is because it is difficult if not impossible for the employers to know what new technologies are available; i.e. there is no requirement that the manufactures provide, advise, educate, or inform as to: (A) the safest devices they manufacture, and (B) issues of danger relative to using the devices that are made commercially available to Americans.

Two good examples of this fact can be seen in blood collection devices: (1) the BD Vacutainer Flashback Needle, and (2) Greiner Bio-One Visio Plus. Both devices are sold around the world, but few (if any) U.S. employers or healthcare workers have any knowledge of these devices. This fact is substantiated by the past chair of the National Association of Hospital Administrators, Gene Marie O’Connell. A letter read into the Congressional Record sent to Congressman Frank Palone who held hearings on Medical Device Safety in June 2009 states:

“Since the [Needlestick Safety and Prevention] Act became effective and amended the OSHA Bloodborne Pathogens Standard, dozens of new device technologies are used daily across America, improving safety to both healthcare workers and patients, notably in reducing needlestick injuries and contamination. But we’re not out of the woods, as still hundreds of thousands of U.S. healthcare workers continue to receive accidental needlesticks annually.”

Gene O’Connell’s letter to Congress continues: “I am not endorsing these products or companies, but by way of example, since 2000 market leaders, Greiner Bio-One and Becton-Dickinson, have introduced blood collection needles that inform the phlebotomist of needle placement before insertion of the vacuum tube, the current worldwide standard device used 3 billion times annually. These are medical breakthroughs, like other new technologies including soft tubing in the IV set, (reduces the potentially dangerous memory of the collection tubing), and medicine injection technologies with safety components that provide the safety of vein entry indication passively and without major additional cost to the procedure.”<sup>6</sup>

BD and Greiner are market leaders in the U.S., and their claims about the enhanced safety of these two important inventions can be found on their European product claim catalogues (attached).

**(II.) Insure that healthcare workers are informed about the safest technologies:** On Sept. 12, 2005, the CDC held a series of meetings to advance the Needlestick Safety and Prevention Act, which were attended by forty-one industry and government experts. The leaders developed a working document, “Proceedings Of The National Sharps Injury Prevention Meeting, September 12, 2005”, that outlines five Next Steps required to fulfill the CDC’s goal of zero accidental needlesticks due to technology issues. These

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<sup>6</sup> [www.NeedlestickSafety.org](http://www.NeedlestickSafety.org)

steps have not been implemented, and according to one of the attendees, they have been scratched due to lack of staffing and “political will.”<sup>7</sup> Another attendee at the safety conference, Cathie Gosnell of Premier, Inc., came to a similar conclusion as Ms. Beltrami,<sup>8</sup> and OSHA leaders in two departments have stated the same unfortunate conclusion.

A central focus of the CDC’s Next Steps is, “safety device development, implementation, and diffusion,” and concludes (5) steps required to reduce accidents through bringing knowledge of safety devices to what the report calls “frontline personnel”. The CDC report makes it very clear with this direction that the BPS direction that employers inform their employees is really out of sorts with business realities.

The (5) objectives our best experts from many organizations are designed to overcome the weakness in the BPS that places the responsibility to educate of new safety capabilities on employers. The CDC cited specific directives towards overcoming the lameness of the BPS in its “Proceedings Of The National Sharps Injury Prevention Meeting” (Sept. 12, 2005). CDC concluded to achieve success specific actions that include developing “toolkits that feature safety devices for frontline healthcare personnel,” sponsoring a “national device [safety] fair”, and “address impediments to the marketing and diffusion of safety devices.”<sup>9</sup>

None of the (5) actions have been achieved, and leaders stress that due to the directions given in the new healthcare legislation relative to syringe needles (“The One and Only Campaign), CDC and OSHA will not have the manpower to fulfill the mandate of the 2005 proceedings. CDC and OSHA leaders including Rosemary Sokas and Elise Handleman (Occupational Medicine, Nursing respectively) that the resources to enforce the Needlestick Safety and Prevention Act in compliance with the CDC’s 2005 initiative will not be furthered, and in fact will be placed on hold indefinitely. Ms. Handleman’s report at the CDC 2005 meeting stressed the importance of “Strengthening the BPS” with “revisions and new definitions” pointing out that part of the problem is that “Employers are responsible for choosing and implementing the appropriate engineering controls for their facilities.”<sup>10</sup>

Effectively, this means that the means to actually fulfill the objectives of the Needlestick Safety and Prevention Act will not be accomplished. Therefore, the Act will have little or no consequence going forward. Indeed, today we have over 1 million accidents annually due to technology.

The Premier Safety Institute’s “Safer Work Practices to Prevent Sharps Injuries” states “injuries can be significantly reduced”, “by using safer work practices” that “include the tools we choose to work with”. This institution concludes that 90% of the needlestick accidents would be mitigated by use of safety devices by healthcare workers. Gina Puglese head of Premier’s Safety Institute writes: “Most needlestick injuries can be pre-

7 Elise Beltrami, CDC past Director of Healthcare Quality, Interview NeedlestickSafety.org, July 2010.

8 Cathie Gosnell, Premier Safety Institute, Interview NeedlestickSafety.org, August 2010.

9 CDC, “Proceedings Of The National Sharps Injury Prevention Meeting,” Sept. 12, 2005, pg. 25.

10 CDC, “Proceedings Of The National Sharps Injury Prevention Meeting,” Sept. 12, 2005, pg. 8.

vented with the use of safety devices, which, in conjunction with worker education and training and work practice controls, can reduce injuries by over 90%.”<sup>11</sup>

If those using needles and other sharps do not know their hidden dangers, or do not know what safety functionalities are available, they can not make informed decisions that will further protect our society.

Unless we follow the CDC’s conclusions, and focus on updating and upgrading the BPS to insure better ways to notify, educate, and alert medical professionals that actually use the sharps, the accidental sharp injury epidemic will continue to take its toll on Americans.

**(III.) Update the BPS to include functionality available today, but not in 2000 :** The Act that recognizes four safety functionalities (capping, blunting, sheathing, retracting), and it also envisions new safety capabilities that had not yet been invented in 2000, so that employer safety plans “*reflect changes in technology* that eliminate or reduce exposure to bloodborne pathogens” [29 CFR 1910.1030(c)(1)(iv)].

To foster public safety, OSHA must add new language to the BPS that reflects the latest technological inventions available. One of these is the function of *vein entry indication*. Another example of this can be found in B.Braun’s Introcan Safety Catheter sold in the U.S.. The catheter has two functions that provide the tell-tale sign that the needle is correctly seated inside the vein before retracting the needle to leave in the catheter.<sup>12</sup>

Clearly, vein entry indication (VEI) early in the procedure is safety for catheter placement and blood collection. In blood collection as much as 40% of needlestick accidents occur during the probing phase (before the specimen collection).<sup>13</sup> But, because the BPS does not list this function, many manufacturers and employers do not recognize its importance.<sup>14</sup>

Another safety function in standard syringe needles now produced by multinational corporations selling their needle products in the U.S. are designs that are engineered to prevent reuse of syringe needles. Mary Foley, the past president of the American Nurses Association, is championing this functionality and heads the group “Safe In Common” to achieve this purpose.

Regarding the winged set (a.k.a. “butterfly”) for blood collection, according to many sources, “Butterfly needles are high risk devices for needlesticks.” And, Premier Inc.’s guidance is, “Limit the use of this device.”<sup>15</sup> They are so dangerous that BD’s CEO, Chairman, and President Edward Ludwig announced on the third anniversary of the

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11 Premier, *Ibid.*, pg. 9.

12 B.Braun, “Promote First Stick Success”, <http://introcansafety.bbraunusa.com/default.aspx?pageid=675>

13 Premier, *Ibid.*, pg. 5.

14 Dr. Ana Stankovic, BD Medical Director, interview with Dr. Paul Zeltzer, February 2010 -- Dr. Stankovic stated BD does not recognize vein entry indication (VEI) as safety feature because the BPS does not list VEI functionality in its safety designations.

15 Premier, Inc., *Ibid.*, pg. 2.

Needlestick Safety Act a paper entitled, “BD Announces Plans for Discontinuation of Conventional Needle Sales in the U.S: Reflects Progress in U.S. Transition to Safety-Engineered Devices”.<sup>16</sup> The butterfly is used for two primary reasons: 1) to provide vein entry indication (VEI), and 2) because of its flexibility a slight angle of insertion can be achieved (versus straight needle design). However, the long tubing is cumbersome and makes the device dangerous. Shortening the tubing will allow to hold the sharp in place and also hold the entire device comfortably in one hand, thereby freeing the other hand to attach and detach the specimen vial.

Many healthcare professionals enjoy the VEI and flexibility of angle insertion, and unfortunately, BD has not shortened the length of the tubing of their butterfly vacutainer devices; and, nor has any of the other companies that supply U.S. workers over 200 million of these a year. OHSA must demand that winged set tubing be shortened.

**(IV.) Lower healthcare costs:** The hidden costs to our society stemming from accidental needlesticks run over \$1 billion annually. Gene Marie O’Connell’s letter to Deputy Assistant Secretary of Labor Jordan Barab cites the incremental costs that are well known and documented, and are in part the *raison d’etre* of the Needlestick Safety and Prevention Act 2000 to which GAO testimony was given in 1998-1999.<sup>17</sup> According to the research cited herein, 90% of the accidents can be prevented based on safety technologies being utilized. Implementation of blood collection and injection safety devices will provide a savings of billions of dollars in direct and hidden costs.

**(V.) Extend the comment period:** Ms. Foley, an eminent leader and nurse practitioner American hospital practice, only learned about this OSHA review *two weeks ago*. We have heard from many leaders, including Gene Marie O’Connell on the West Coast, Jeff Shufro (New York Committee for Occupational Health and Safety), as well several union leaders that very few healthcare workers and the public have been made aware of this look-back review. It is possible that understaffing at OSHA contributed to the problem. In any case, due to the severity of the importance to improve implementation of our important U.S. legislation, OSHA has a duty to extend the comment period for the BPS in order to give more people an opportunity to submit comments.

[Attachments will be submitted in following E-mail and U.S. Post due to size considerations in the transmission process.]

Attachments:

1. Gene Marie O’Connell letter to Deputy Assistant Secretary of Labor Jordan Barab, July 14, 2010; 3 pages.
2. BD Vacutainer Flashback Passive Safety Needle Claims Sheet; 1 page.
3. Greinr Bio-One Visio Plus Passive Safety Needle Claims Sheet; 2 page.
4. B.Braun Introcan Double Flashback Safety Catheter; 1 page.
5. PowerPoint Presentation; “OSHA- 2007-0080” sent via U.S. Post.

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<sup>16</sup> See BD press release.

<sup>17</sup> Gene Marie O’Connell letter July 14, 2010 to Deputy Assistant Secretary of Labor Jordan Borab.

6. BD Press Release "BD Announces Plans for Discontinuation of Conventional Needle Sales," April 16, 2003.