

7 4 0 6 '02 SEP 19 A10 :19



Indispensable to
human health

September 17, 2002

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

Re: Docket Number 01P-0120: FDA Request for Comments or Information on
Needle-Bearing Devices

Dear Sir or Madam:

Becton, Dickinson and Company ("BD") is pleased to have the opportunity to offer these comments pursuant to the above-referenced request for comments and information on needle-bearing medical devices. We understand that this request is intended to help FDA determine what additional actions, if any, the agency should take to protect healthcare workers from needlestick injuries from medical devices. It follows a petition from Public Citizen's Health Research Group and the Service Employees International Union, asking that FDA take certain actions to further reduce the risk of needlestick injuries to healthcare workers (the "Petition").

BD strongly agrees with the general goals of the Petition and believes that additional public policy actions would encourage the broader adoption and use of safety devices. BD has strongly supported such policies in the past, including the Needlestick Safety and Prevention Act, and we continue to put significant resources into raising awareness of the risks faced by healthcare workers. Moreover, BD has been and continues to be a pioneer in the development of safety products designed to protect healthcare workers.

Nonetheless, we believe that, given the legal and clinical complexity of the issues raised, implementing the requested solutions could take a considerable amount of time, and that nearer term actions could achieve similar outcomes. For these reasons, we suggest below some alternative, near-term ways to accomplish the Petition's goals.

OIP-0120

C 21

I. Comments and Suggestions

A. Implement Immediate Solutions to Attain the Petition's Goals

BD believes that pursuing a ban on conventional devices raises legal and medical practice complexities that will require substantial clinician input and possibly additional data collection and analysis prior to implementation. This will add time to the process, which we believe could be better used implementing the near-term measures outlined below. Indeed, as history reveals, it can take many years to navigate the long and arduous regulatory process involved with banning a device, time that can be better spent implementing solutions.

1. Safety Alerts

An immediate option available to FDA, which it has employed effectively in the past, is the issuance of safety alerts. According to BD's records, FDA's April 1992 Safety Alert on Needlestick and Other Risks from Hypodermic Needles on Secondary I.V. Administration Sets had an immediate and significant impact on medical practice and device development. FDA could issue similar safety alerts on the devices for which the Petition seeks a ban quite quickly. A review of the devices available and the users' practices and preferences following the issuance of safety alerts could be used to gauge their effectiveness, as well as to identify any gaps in current safety product offerings.

The Needlestick Safety and Prevention Act recognizes that there may be some exceptional clinical circumstances that require the continued use of some conventional products. It therefore allows clinicians to make critical decisions regarding the best way to perform medical procedures. Safety alerts would have the effect of further accelerating the market transition to safety products, which in some product categories is already over 80%, while preserving clinicians' final control over medical practice. Safety alerts would also offer the FDA the opportunity to advise healthcare workers regarding risks associated with a much broader array of products -- including conventional needles and syringes without safety features that are used for skin injections, conventional lancets, and conventional scalpels, among others -- without limiting clinicians' choice of technologies now or in the future.

For these reasons, we urge FDA to issue safety alerts. Doing so would be complimentary to the Needlestick Safety and Prevention Act and would add further momentum to the transition already occurring in hospitals.

2. Guidances

As FDA is aware, development of performance standards for products as diverse as conventional sharps devices is challenging and historically such standards have been unable to encompass future technologies. If FDA proceeds with performance standards, such standards would need to be imposed in a way that anticipates future technology, both conventional and safety, or the performance standards could have the unintended effect of stifling innovation. Indeed, any performance standard that "locks in" existing designs at the potential expense of future technologies can, and often does, result in the unintended suppression of innovations.

As a near-term alternative to the development of performance standards, the FDA could refine its existing guidance documents to quickly address the issues raised in the Petition. The Petition acknowledges that the five elements it seeks to have imposed as performance standards have existed as guidance "requirements" for several years. Because the guidance document process is an open and quick public process, it could be used to refine the review criteria to address the Petition's issues associated with safety devices. Furthermore, the guidance process will allow FDA to make changes easily in the future if it determines the need to alter the requirements in any way. Finally, guidance documents do not prevent the use of more sophisticated technologies, as long as the manufacturer can demonstrate that the same objectives with respect to safety and effectiveness are achieved.

B. Addressing Risks Associated with Syringe Blood Draws

The Petition requests that FDA require the unit package of conventional syringes to include the following safety instruction: "To Prevent Possible Exposure to HIV and Hepatitis, Do Not Use for Standard Blood Draws." BD believes that labeling is not the best way to address the risks associated with syringe blood draw and that warning labels would not be appropriate on conventional syringes.

The clinical techniques associated with the use of conventional syringes are so diverse that labeling is not a good way to address this issue, and may in fact, discourage the use of some safe blood drawing procedures. Drawing blood in syringes can be completed safely with certain conventional syringes and syringe-based systems, while with other syringes, including some safety syringes, there is no way to do this procedure without creating unnecessary additional risk. For instance, it is common practice to draw blood into a conventional syringe without a needle from an IV line, and then safely transfer it to an evacuated tube with a safety transfer device. In contrast, syringes with permanently attached needles, including some safety syringes, cannot be used to draw and transfer blood without creating unnecessary risk of accidental needlestick injury.

Rather than imposing new labeling requirements for conventional syringes, BD believes that the most effective means of communicating the risks associated with any syringe used for blood drawing - conventional or safety - is through safety alerts that apply to all relevant products. In preparing such an alert, FDA could engage in substantial discussions with physicians and other clinical stakeholders to understand specific devices, their uses, and associated risks, to achieve a solution that protects healthcare workers and makes sense in today's healthcare environment.

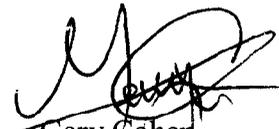
II. Conclusion

BD agrees with the goals of the Petition, but believes that implementation of its core tenets would take considerable time. For that reason, BD suggests that FDA undertake more immediate actions, such as safety alerts and guidance document development, which will meet the Petition's intent, but in a much shorter timeframe and without the potentially negative clinical consequences.

However, if FDA ultimately decides that a ban or additional labeling is an appropriate action to take, BD will certainly do its part to support the agency's efforts. While future supplies of all safety-engineered devices cannot be precisely predicted, BD can assure FDA that it already has invested hundreds of millions of dollars in production capacity to help ensure an adequate supply of its safety-engineered products.

BD appreciates the opportunity to provide the foregoing information to FDA and hopes that it will be helpful in determining the most appropriate next steps for FDA to take in this important matter. To that end, BD will commit to assisting as best it can in any activities FDA undertakes in support of safety for healthcare workers.

Sincerely,

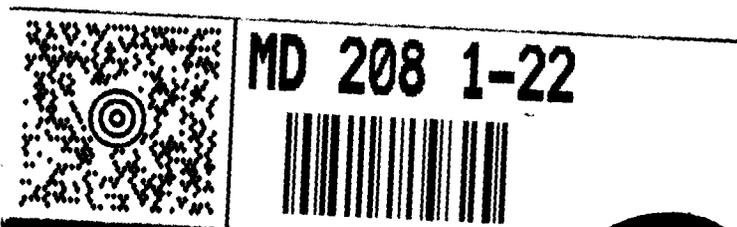

Gary Cohen
President
BD Medical Systems


Patricia Shrader
Vice President
Corporate Regulatory Affairs

SHIPPING DEPT
(201) 847-4428
BECTON DICKINSON AND COMPANY
1 BECTON DR BLDG II
FRANKLIN LAKES NJ 07417-1815

LTR 1 OF 1

SHIP TO:
DOCKETS MANAGEMENT BRANCH
FOOD & DRUG ADMINISTRATION
5630 FISHERS LANE ROOM 1061
ROCKVILLE MD 20850

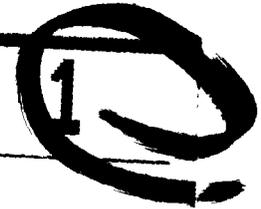


MD 208 1-22



UPS NEXT DAY AIR

TRACKING #: 1Z 058 546 01 4394 0918



BILLING: P/P

1A WESLOWSKI
REF 2: 100-5200-7001

UOM 41 16 UPS Ther 18 0A 07/2002

FDA
THIS PACKAGE
HAS BEEN
X-RAY