

DOWLING & DENNIS

PUBLIC RELATIONS

August 28, 2002

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

RE: Docket No. 01P-0120; Medical Devices; Needle-Bearing Devices; Request for
Comments and Information

To Whom It May Concern:

My firm represents the National Alliance for the Primary Prevention of Sharps Injuries (NAPPSI), a 501(c)(3) organization that promotes primary prevention and secondary prevention of medical sharps injuries. We have previously submitted comments on the above referenced matter to Timothy Ulatowski. In those comments, we requested that FDA issue a Notification to Clinicians on Sharps Injury Prevention. The text of that proposed notification and our previous correspondence are enclosed.

I'm writing now regarding several items:

1. Request that FDA post and disseminate NAPPSI's Safety Device List.
2. FDA's interest in discussions with any organization that wishes to develop a voluntary consensus standard for the devices listed in the HRG/SEIU petition.
3. Request to receive written notification of FDA actions on the above-referenced matter and on any public hearings or other public meetings regarding this matter.

We offer the following comments regarding the above three items:

1. Request that FDA post and disseminate NAPPSI's Safety Device List.

NAPPSI requests that as part of FDA's stated interest in distributing information regarding sharps-injury prevention, the agency provide clinicians with NAPPSI's Safety Device List. Information about this list can be disseminated through an electronic link from FDA and other government Web sites, as well as through printed FDA and other agency information. The NAPPSI Safety Device List of sharps-injury-prevention devices

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is based on the respected EPINet list of such devices, compiled by the International Health Care Worker Safety Center, at the University of Virginia. To date, the states of Tennessee and Alaska have posted and disseminated information about the list, and Georgia health officials have indicated they will do the same.

Enhancing the helpful purposes served by the EPINet list, the NAPPSI Safety Device List incorporates what we believe to be two helpful revisions to the EPINet list:

First, devices listed in the EPINet compilation have been divided between those that provide primary prevention of sharps injuries, and those that provide secondary prevention of sharps injuries. We define "primary prevention" as practices and technologies that eliminate the need to introduce sharps into the workplace, thereby reducing the total number of sharps and healthcare workers' exposure to bloodborne pathogens carried by such sharps. In this regard, NAPPSI takes its cue from NIOSH, which in DHHS (NIOSH) Publication No. 2000-108, advises employers of healthcare workers to "eliminate the use of needles where safe and effective alternatives are available." Secondary prevention practices and technologies -- which NAPPSI also supports and recognizes as extremely valuable -- render safer those sharps that must be introduced into the healthcare workplace.

Second, the NAPPSI Safety Device List has been updated since creation of the EPINet list, to include additional FDA-cleared and FDA-approved devices now available to clinicians to promote sharps-injury prevention. It is the most current and extensive compilation of FDA-approved devices for preventing accidental needlesticks. NAPPSI will continue to update this list as new devices become available.

2. FDA's interest in discussions with any organization that wishes to develop a voluntary consensus standard for the devices listed in the HRG/SEIU petition.

The Advance Notice of Proposed Rulemaking states FDA is "prepared to enter into discussions with any organization that wishes to develop a voluntary consensus standard for one or more of" devices referenced in the HRG/SEIU petition. As an organization that draws upon the professional expertise of its members -- which encompasses several hundred healthcare clinicians, professional clinician organizations, and companies that manufacture medical devices -- NAPPSI would be happy to contribute to discussions with FDA and any other interested organization, aimed at developing a voluntary consensus standard for one or more of these devices. Please feel free to contact me directly regarding any contribution NAPPSI may be able to make to these discussions.

3. We would like to receive of any additional actions FDA is contemplating on the above-referenced matter, including any upcoming public hearings, discussions among interested parties, or deadlines for submission of additional comments to FDA. Please send such written notification to: Brad Poulos, Executive Director, NAPPSI, 1778

Callissia Court, Carlsbad, Ca. 92009; and Gregory Dennis, Dowling & Dennis, 1053
Hermes Avenue, Encinitas, CA 92024.

Thank you for your consideration of these requests, and for the previous assistance we
have received from Timothy Ulatowski regarding these matters.

Sincerely,

A handwritten signature in black ink, appearing to read "Gregory Dennis", written in a cursive style.

GREGORY DENNIS

Enc.: Previous correspondence to FDA; proposed Notification to Clinicians on Sharps
Injury Prevention; NAPPSI Safety Device List

cc: Timothy Ulatowski