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June 1, 2016

Ms. Leslie Kux  
Assistant Commissioner for Policy  
U.S. Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

***Re: Docket No. FDA-2015-N-5017; Banned Devices; Proposal to ban powdered patient examination gloves, and absorbable powder for lubricating a surgeon's glove, proposed rule.***

Dear Ms. Kux:

The Association for Professionals in Infection Control and Epidemiology (APIC) wishes to thank the Food and Drug Administration (FDA) for the opportunity to provide input to this proposed ban on powdered patient exam gloves and absorbable powder for lubricating a surgeon's glove. APIC is a nonprofit, multidisciplinary organization representing over 15,000 infection preventionists whose mission is to create a safer world through prevention of infection. We are pleased that the FDA continues to demonstrate its commitment to improving patient and provider safety through this proposed ban.

A review of the literature does not seem to suggest any increased infection risk associated with the use of powdered exam gloves or use of powder to lubricate surgeon gloves. In addition, APIC did not find any documented information that powdered gloves offer a unique benefit over powder-free gloves. Evidence does exist that powdered gloves may increase the risk of intraabdominal adhesions.<sup>1</sup> Powdered gloves are also implicated in occupationally acquired latex allergy via contact with healthcare workers skin and respiratory tracts.<sup>2</sup> Therefore, it is prudent to ban the use of powdered gloves to provide a safer environment for both patients and healthcare workers. APIC supports the proposed ban.

APIC appreciates the opportunity to provide input on the proposed ban on powdered gloves and lubricating powders on behalf of our members. We look forward to continuing to work with FDA to safeguard patient and provider safety with appropriate controls on the manufacture and use of medical devices.

Sincerely,

A handwritten signature in cursive script that reads "Susan Dolan".

Susan Dolan, RN, MS, CIC  
2016 APIC President

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<sup>1</sup> Mavros MN, et al. Morbidity related to concomitant adhesions in abdominal surgery. J Surg Res 2014;192.2:286-292.

<sup>2</sup> Allmers H, et al. Reduction of latex aeroallergens and latex-specific IgE antibodies in sensitized workers after removal of powdered natural rubber latex gloves in a hospital. J Allergy Clin Immunol 1998;102.5: 841-846.