1400 Crystal Drive, Suite 900
Arlington, VA 22202
Phone: 202/789-1890
Fax: 202/789-1899
apicinfo@apic.org
apic.org

July 25, 2024

Ms. Lauren K. Roth
Associate Commissioner for Policy
U.S. Food and Drug Administration
Three White Flint North, 10A-12M
11601 Landsdown St.
North Bethesda, MD 20852

RE: Docket No. FDA-2024-N-1201 Comment Request; Voluntary Total Product Life Cycle Advisory Program Pilot

Dear Ms. Roth:

The Association for Professionals in Infection Control and Epidemiology (APIC) wishes to thank The Food and Drug Administration (FDA) for providing the opportunity to comment on the Voluntary Total Product Life Cycle (TPLC) Advisory Program (TAP) Pilot and collection of information. APIC is a nonprofit, multidisciplinary organization representing 15,000 infection preventionists (IPs) whose mission is to advance the science and practice of infection prevention and control. We support FDA's efforts to improve medical device development processes at early stages to ensure patient safety when the devices are in use.

As stated in the Federal Register notice, "The long-term vision for TPLC TAP is to help spur more rapid development and more rapid and widespread patient access to safe, effective, high-quality medical devices of public health importance." APIC supports this vision and would like to recommend including IPs as important early stakeholders.

Medical devices are often implicated as the source for healthcare-associated infections (HAIs). The World Health Organization (WHO) has defined the important bacterial and fungal organisms that are often linked to medical device-associated HAIs and identified the importance of effective disinfection and sterilization protocols to prevent disease and mortality related to these pathogens.[1] All too often, a lack of compliance with protocols outlined in a medical device's instructions for use (IFU) can be linked to a device-associated HAI. APIC has recently published a white paper, *Modernizing Medical Device Instruction for (IFUs)—Infection Preventionist Speak up for Patient Safety*, which addresses this important concern with IFUs. It outlines the challenges for IPs and other device end users trying to follow medical device instructions for use but finding the IFUs difficult or impossible to follow, or the device itself designed without consideration for how to clean/disinfect/sterilize it, resulting in possible transmission of infectious pathogens.

IPs are specialists trained in preventing HAIs and understanding the transmission of pathogens. Their expertise can contribute valuable insights into the specific cleaning and disinfection protocols required for different types of medical devices to minimize infection risks. In addition, involving IPs early in the device design process may assist manufacturers to proactively address potential infection risks associated with medical devices throughout their lifecycle—from design and development to

deployment, use, and reprocessing. This ensures that devices are not only effective in their intended use but also remain safe to be used on patients.

We applaud the FDA's Center for Devices and Radiological Health for launching the TPLC TAP Pilot and we agree that early interactions with stakeholders will facilitate process improvements in medical device design that will minimize risks of infection transmission. We strongly encourage FDA to include IPs and other device end-users as stakeholders in this program, which will help with overall safety and quality of medical devices, improve patient outcomes in the long term, and enhance public health by reducing the risk of device-related infections.

Sincerely,

Tania Bubb, PhD, RN, CIC, FAPIC
2024 APIC President

[1] Garvey M. Medical Device-Associated Healthcare Infections: Sterilization and the Potential of Novel Biological Approaches to Ensure Patient Safety. Int J Mol Sci. 2023 Dec 22;25(1):201. doi: 10.3390/ijms25010201. PMID: 38203372; PMCID: PMC10778788. Accessed 7/2/24 at https://pubmed.ncbi.nlm.nih.gov/38203372/ .