August 10, 2023

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CDRH, FDA
1903 New Hampshire Ave
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Silver Spring, MD 20093

Re: Patient Engagement Advisory Committee Comments: Advancing Health Equity in Medical Devices

Dear Advisory Committee:

We are responding to the Food and Drug Administration (FDA) Patient Engagement Advisory Committee's (Committee's) request for comments on Advancing Equity in Medica Devices. CDRH Patient Engagement Advisory Committee | FDA. Coloplast offers products and services for people with very personal and private health needs. Our business includes ostomy and continence care, wound and skin care, ENT and respiratory care, and urology care. Patients use these products in their homes to remain independent, participate in community activities, work, and go to school. Many private and public health benefit programs pay for these products. We operate globally and employ over 12,000 employees.

Coloplast works closely with individuals who use our products to be sure we create solutions that address their special, intimate healthcare needs. We strongly support the Committee's work to make medical devices more accessible to all patients. To that end, we provide comments below.

Ways to advance access to devices that allow for care outside a hospital or clinical care setting--for example, in the home setting.
We make products that let patients manage their bowel and bladder function privately and independently as they live and work their communities. Many of our patients are disabled as result of spinal cord injuries (SCI) or congenital conditions like spina bifida (SB), are often low income and have limited access to health care resources. Individuals with SCI or SB can suffer from urinary tract dysfunction or neurogenic bowel dysfunction (NBD) and must regularly perform intermittent catheterization (IC) or transanal irrigation (TAI).

Although IC devices and equipment for TAI are FDA cleared, some patients do not have access, or in the case of IC may lack access to a device that is appropriate for them, because of restrictive Medicare coverage and payment policies. CMS can determine studies submitted for FDA review do not adequately establish a device's medical necessity. It is important that FDA and CMS establish a framework for communication in all stages of review to facilitate a consistent understanding of the evidence under review according to each agency's mission.

Disabled patients who use our devices may lack transportation to and from study sites or rely on care partners to schedule visits. Transportation and scheduling pose hurdles for patients who want to participate in trials, hindering recruitment and follow-up. Many of the patients we serve have limited mobility, so a specialized equipment at the investigative sites is needed to safely position them in relation to X-ray and MRI machines for imaging. That further narrows a number the possible investigative sites and/or increases the transportation burden.

Investigative site visits for subjects who suffer from urinary and/or faecal incontinence are especially challenging. Many of these patients are unmotivated to leave their homes because they fear public embarrassment. As a result, studies of devices designed for patients with limited mobility and/or publicly embarrassing symptoms are very difficult to enroll and generally are smaller with shorter follow up.

Limitations in study size that affect FDA clearance create barriers to access if they delay a device's availability. To address these issues, we suggest FDA consider the following:

- Accepting smaller studies
- Using remote monitoring devices or telemedicine to facilitate studies in community settings that are more accessible to patients
- Giving greater weight to qualitative, self-reported and real-world evidence during review

Considerations for improving reach and comprehension of FDA's patient and caregiver communications across diverse demographic groups.

Many patients lack resources to research their injury or disease, learn about clinical trials or stay informed about their condition. We suggest FDA consider communicating directly with patient or clinician advocates at the local level. These groups have more frequent interactions with patients and care partners than their national counterparts.

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Thank you for the opportunity to submit these comments. Please feel free to contact me with any comments or questions or if I can be of assistance in any way.

Sincerely, Maria Koullick

Maria Koullick
Vice President, Payors and Evidence
Coloplast Corp