Adam Lotspike

Who is commenting? *(choose the best fit)*
Representative of a product manufacturer(s)

If you are commenting as a representative, what is the name of the entity you are commenting on behalf of?
Becton, Dickinson and Company (BD)

If you represent a product manufacturer or industry group, what industry(ies) do you represent?
Medical technology manufacturer

If you represent a product manufacturer, what types of components, products, or product categories do you manufacture that you will be requesting a CUU determination for?
Medication dispensing and pharmacy automation systems, as well as research and laboratory instruments, including Research Use Only (RUO) and
Laboratory Use Only (LUO) products, that support scientific research, diagnostics, and medical innovation.

Do you have any recommended changes or other considerations that you think the MPCA should take into account when defining the term "essential for health, safety, or the functioning of society"? *(Please review the proposed definitions in the rule concept document prior to answering)*
When defining what is “essential for health, safety, or the functioning of society,” it is important to consider the full ecosystem that supports healthcare delivery, innovation, and ability to manufacture critical healthcare products. Essentiality should extend beyond products that directly interact with patients to include technologies that, while not regulated as FDA medical devices, are integral to patient safety, healthcare efficiency, and the ability to design, produce, and deliver essential medical technologies. A definition that reflects these realities more accurately captures how modern healthcare systems and their supporting supply chains function in practice.

Do you have any recommended changes or other considerations that you think the MPCA should take into account when defining the term "alternative"? *(Please review the proposed definitions in the rule concept document prior to answering)*
MPCA should define “alternative” to mean a material, technology, or design that is commercially available, functionally equivalent in the intended application, and capable of meeting all applicable safety, performance, and regulatory requirements. The existence of a PFAS-free option alone should not be sufficient if it cannot be implemented without compromising product performance, patient safety, regulatory compliance, or continuity of

essential healthcare and research products. MPCA should also consider system-level and supply-chain impacts when determining whether a true alternative is available.

Do you have any recommended changes or other considerations that you think the MPCA should take into account when defining the term "reasonably available"? (*Please review the proposed definitions in the rule concept document prior to answering*)
MPCA should define “reasonably available” to mean available at sufficient scale, quality, and reliability for the intended application, and capable of being implemented without undue delay or disruption. Materials or technologies should not be considered reasonably available if they require extensive redesign, re-validation, or regulatory re-approval, or if supply constraints would jeopardize continuity of essential products. MPCA should also consider real-world manufacturability and supply-chain feasibility, not just theoretical or limited availability.

When considering the proposed definition of “product category”, how broadly should the agency group product categories? *(Examples: “vehicles” versus “sedans, SUV’s, vans, trucks, RV’s” or "printers" versus "receipt printers, thermal printers, label printers, residential printers, commercial printers, etc.")*
Product categories should be defined at a functional level, rather than through narrow or highly granular distinctions. Grouping products based on their core function provides clarity, consistency, and regulatory efficiency. Overly narrow categories risk creating artificial distinctions among products that serve the same essential purpose and could complicate implementation without improving outcomes. A function-based approach supports sound policy while maintaining administrative simplicity.

Should each request for a CUU determination be limited to a single product category, or should applicants be allowed to submit a request for a CUU determination for multiple product categories?
MPCA should allow applicants to submit a single CUU request covering multiple product categories where those categories share similar functions, performance requirements, and reliance on PFAS for the same essential purpose. Allowing consolidated requests would improve administrative efficiency, reduce duplicative submissions, and better reflect how products are designed, manufactured, and used in practice.

What safety or other standards require the use of PFAS in a product? *(Please include the specific citation)*
Certain safety, quality, and performance expectations necessitate the use of PFAS in specific healthcare-related products and components. PFAS-based materials are used because they provide unique properties, such as thermal stability, chemical resistance, durability, and reliability, that are critical for products to function safely and as intended in healthcare and laboratory environments. The U.S. Food and Drug Administration has recognized that certain medical-grade PFAS, particularly fluoropolymers, have a long

history of safe use in medical technologies and that suitable alternatives are not always currently available without compromising performance or reliability.

The agency is seeking feedback on the potential that the initial positive CUU determination duration for existing products will expire eight years from the date of issuance regardless of product category. This is intended to stagger renewal deadlines and ease the administrative burden of processing renewals.

- Do you have any concerns about unintended consequences with this proposal?
- Do you have any alternative recommendations to stagger renewal deadlines?

BD supports MPCA's objective of staggering renewal deadlines to manage administrative burden and agrees that a defined duration for initial CUU determinations can provide regulatory certainty. However, BD recommends that MPCA retain flexibility to adjust the renewal timeframe where appropriate, particularly for product categories with long development cycles, extended regulatory timelines, or limited prospects for viable alternatives.

What are the potential ongoing costs to society if the commissioner issues a positive currently unavoidable use determination for the continued use of PFAS within a product or product category? *(For example: environmental, human health, or remediation costs)*
Allowing continued use of PFAS in limited, essential healthcare applications helps avoid significant societal costs. Restricting access to foundational healthcare technologies could disrupt access to care, impact patient safety, and undermine healthcare system reliability. These downstream impacts pose far greater risks to public health and societal functioning than the continued, limited use of PFAS in essential products. Preserving access to these technologies supports patient safety, healthcare continuity, and innovation.

For manufacturers: Administrative cost of requesting a CUU determination (Part 1 of 2). *Please provide your best estimates or rough orders of magnitude (for example "approx. 200 hours"). Precise accounting data is not necessary to answer this question.*

If your company currently possesses information regarding intentionally added PFAS (to the CAS number level) for all components in your product lines, please estimate the number of technical staff hours that were required to establish this baseline.
More than 500 hours

For manufacturers: Administrative cost of requesting a CUU determination (Part 2 of 2). *Please provide your best estimates or rough orders of magnitude (for example "approx. 200 hours"). Precise accounting data is not necessary to answer this question.*

If your company does not possess information regarding intentionally added PFAS (to the CAS number level) for all components in your product lines, please estimate the number of technical staff hours needed to obtain this data from your Tier 2 or 3 suppliers for a single product line.
More than 500 hours

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March 27, 2026

Katrina Kessler
Commissioner
Minnesota Pollution Control Agency
520 Lafayette Road North
St. Paul, MN 55155-4194

RE: Response to Request for Comments on Proposed Rulemaking Regarding Criteria for Currently Unavoidable Uses of PFAS in Products

Dear Commissioner Kessler,

BD appreciates the opportunity to submit comments on the Minnesota Pollution Control Agency's proposed rulemaking to establish criteria for determining currently unavoidable uses of intentionally added per- and polyfluoroalkyl substances (PFAS) in products sold, offered for sale, or distributed for sale in Minnesota, pursuant to Minn. Stat. § 116.943.

BD is a global medical technology company that develops and manufactures a broad range of medical devices and systems used across healthcare settings. BD devices and systems are relied upon by healthcare professionals in hospitals, pharmacies, laboratories, and long-term care facilities to support patient care and clinical operations.

BD appreciates the Agency's recognition that PFAS uses in certain medical devices and medical device and system components, including specialized electronics, are critical. In medical technology applications, PFAS-based materials are used to support performance characteristics such as thermal stability, chemical resistance, durability, and reliability under demanding clinical and operational conditions. BD is actively engaging with suppliers to understand the materials used in its products and to support compliance with applicable regulatory requirements.

BD understands that its products are exempt under Minnesota law with respect to the PFAS prohibitions and appreciates the Agency's approach to implementing the statutory framework. While certain BD products may not be regulated by the U.S. Food and Drug Administration and therefore may not fall within the FDA-specific exemption as described, some components of those products are internal components that are not intended to be touched during normal use.

By way of example, medication dispensing and pharmacy automation systems used across care settings, including hospitals, retail pharmacies, and long-term care facilities, support the storage, dispensing, and management of medications through automated technologies that rely on electronic internal components. Other examples relying on internal electronic components are Research Use Only (RUO) and Laboratory Use Only (LUO) products, that support scientific research and medical innovation. In limited instances, PFAS-containing materials are used within fully enclosed, non-user-accessible internal components to meet performance and reliability requirements.

BD remains committed to responsibly managing the materials used in its products while ensuring continued access to essential medical technologies relied upon by patients and healthcare providers. BD appreciates the Agency's consideration of these comments.

If you have any questions, please contact Adam Lotspike at adam.lotspike@bd.com.

Sincerely,

Adam Lotspike
Senior Director, U.S. Government Relations
Public Affairs