B. Braun Medical Inc.
824 12th Ave.
Bethlehem, PA 18018

Position Paper on Patient and Healthcare Worker Safety Issues in the US

B. Braun Medical Inc. (B. Braun) is a US corporation headquartered in Bethlehem, PA with several US affiliates including Central Admixture Pharmacy Services, Inc. (CAPS®), Aesculap, Inc. and B. Braun Interventional Systems. Together, the B. Braun Group of Companies in the US has 35 operating facilities in 19 states, with more than 6,000 employees. Globally, the B. Braun Group of Companies employs more than 64,000 employees in 64 countries.

A leader in infusion therapy, injectable drugs and pain management, B. Braun develops, manufactures and markets innovative medical products and services to the healthcare industry. Over the last two years, we announced investments of more than $1.2 billion in new and upgraded manufacturing facilities in the US to help meet increasing patient needs and ensure the reliable supply of life-saving medical products.

B. Braun is passionately committed to eliminating preventable treatment errors and enhancing patient, clinician and environmental safety with products, services and education focused on the highest quality standards and clinical practices. Our history of introducing safer products includes an innovative passive safety IV catheter introduced decades ago, market-leading innovations in infusion pump technology and hazardous drug containment equipment, and alternative pain management modalities and treatments to reduce reliance on opioids.

Despite successful interventions in recent years, patient safety remains a significant problem in the US. In its recent report, Making Healthcare Safer III, the Agency for Healthcare Research and Quality (AHRQ) identified multiple areas of potential harm in our healthcare system, including medication errors, healthcare-associated infections and opioid misuse.

We believe that with the right level of attention, resources and national resolve, far more can be done to protect the safety of people when they seek medical care. This briefing document outlines specific public policy recommendations supported by B. Braun to improve patient and healthcare worker safety in the healthcare system.

POLICY PRIORITIES

Reducing Healthcare-Associated Infections from PIVCs

According to the HHS Office of Disease Prevention and Health Promotion, Healthcare-Associated Infections (HAIs) remain a significant cause of illness and death in the US. At any given time, about 1 in 25 inpatients have an infection related to hospital care. These infections lead to tens of thousands of deaths and cost the US health care system billions of dollars each year. (ODPHP) Infections associated with the insertion of central-line venous catheters have been closely monitored for many years, and strong guidelines exist to help reduce central line-associated bloodstream infections (CLABSI). (CDC) However, research suggests that the widespread use of peripheral intravenous catheters (PIVCs) contributes to medical complications at a significant rate in US hospitals, contributing to higher spending, longer and more intensive care, and higher mortality. In addition, infections due to PIVCs may have been underreported due to the lack of mandatory reporting for these devices. (Inquiry)

⇛ B. Braun supports policy changes under the HHS Action Plan to Prevent Healthcare-Associated Infections to improve the tracking and reporting of catheter-related blood stream infections (CRBSI), with an expanded focus on monitoring and prevention strategies to reduce infection and complication risks associated with the insertion and maintenance of peripheral IV catheters.

Improve Vascular Access Standards

The most common invasive procedure in healthcare is the insertion of a peripheral intravenous catheter (PIVC); yet, only 57% of nursing students receive education on this procedure. (Journal of Continuing Ed in Nursing) Hospitals are left with the burden to train and ensure competency; however, only 46% have a process to evaluate these skills. (JAVA) Research shows that the rates of PIVC failure and unscheduled restarts are unacceptably high, with failure rates ranging from 33-69 percent. (PLOS One) This can lead to serious implications for patients and healthcare systems, including increased costs and length of treatment. (Inquiry) B. Braun is partnering with the Association for Vascular Access (AVA) to develop a common curriculum to improve training on the placement of PIVCs. We believe the creation of federal guidelines and educational materials will accelerate the wide adoption of improved vascular access standards, leading to reduced failure rates and improved outcomes.

⇛ B. Braun supports initiation of a standards review process by the CMS Center for Clinical Standards and Quality, including the establishment of clear quality measures to standardize the placement and maintenance of peripheral intravenous catheters (PIVCs) and requirements for hospital-acquired condition reporting for all medical devices dwelling in a patient's bloodstream.

⇛ B. Braun urges the Agency for Healthcare Research and Quality (AHRQ) to develop guidelines and educational materials for healthcare systems and learning institutions to improve and standardize the placement and maintenance of peripheral intravenous catheters (PIVCs).

Reduce Patient Exposure to Phthalates and Other EDCs

More than 40 years ago, B. Braun recognized the environmental and patient risks posed by medical products containing diethylhexyl phthalate (DEHP), a commonly used endocrine disrupting compound (EDC). B. Braun was the first medical device manufacturer to remove these harmful substances from many of our products, and remain the only supplier to offer a full line of IV drug/solution containers not made with PVC, DEHP or other phthalates. The evidence of patient exposure to EDCs during the course of clinical care is well established, and science continues to demonstrate the need to reduce patient risk from such exposure. As summarized in a recent article in the Journal of Clinical Endocrinology & Metabolism: "It is clear that medications and medical supplies contain EDCs, and some of our most vulnerable patients are those most highly exposed. It is time for a reckoning in the healthcare community to address our role in exposing patients to potentially harmful chemicals and to devise a path forward to address the ethical and clinical implications of this poorly understood iatrogenic risk." (JCEM) B. Braun is committed to working with policy leaders, scientists and other stakeholders to support the removal of EDC risk for all patients, and in all products. There are immediate opportunities where safe alternatives to EDC's already exist in the marketplace, such as IV containers, and these should be pursued vigorously. Action at the state level on this issue has been minimal, but it is worth noting that the State of California advises patients undergoing medical procedures to plan ahead by requesting medical devices that do not contain DEHP. (DEHP Fact Sheet) The adoption of broad measures to protect patients will require progress on multiple fronts – regulatory, marketplace, testing, and R&D, to encourage new, safe materials. To that end, we support the following as a starting point for federal action:

⇛ B. Braun supports the establishment of a multi-agency federal task force to examine and recommend immediate steps to reduce patient exposure to EDCs, educate healthcare providers about the science of endocrine disruption, and establish long-term plans to eliminate EDC risk.

⇛ B. Braun supports the review and updating of FDA guidelines on the use of DEHP and other phthalates and EDCs in IV bags and other medical equipment based on new evidence of exposure risks since FDA announced the availability of Draft Guidance on medical devices made with PVC and DEHP in 2002. (Draft FDA Guidance)

⇛ B. Braun applauds the adoption of the Sustainable Chemistry Research and Development Act (Senators Coons & Collins) as part of the National Defense Authorization Act for FY 2021 (H.R.6395). As part of this law, an interagency working group led by the White House Office of Science and Technology Policy will be established to coordinate federal programs and activities in support of sustainable chemistry. We believe those programs should include R&D, demonstration projects and training programs aimed at minimizing the use of EDCs and other chemicals of concern used in medical devices.

Implementation of ISO-Compliant Connectors

Healthcare institutions around the world are in the process of implementing new ISO standards for neuraxial connectors (ISO 80369-6), commonly referred to as NRFit. The new standards were developed to prevent tubing misconnections that could result in harmful, sometimes fatal, wrong administration route errors in which inappropriate medications are delivered to patients in the wrong target space. (ISMP) The FDA has compiled numerous case studies of adverse events from misconnections. (FDA) B. Braun has been at the forefront of helping health systems comply with the transition to NRFit connectors. However, with the exception of a number of leading health systems and facilities in California, where state law mandated the conversion to NRFit connectors by January 1, 2017, the conversion process in the US has been slow.

⇛ B. Braun supports increased efforts by the FDA and other health agencies to improve patient safety and minimize the risk of adverse events by building awareness and initiating programs to accelerate the transition to ISO-compliant NRFit connectors across the US healthcare system.

Prevention of Opioids Abuse

Opioids are often prescribed to treat moderate-to-severe pain, particularly following surgery or injury. The National Institute on Drug Abuse reports that the misuse of and addiction to opioids is a "serious national crisis that affects public health as well as social and economic welfare." (NIH) In 2017, prescription opioid misuse affected an estimated 11.4 million individuals in the US. (Task Force Report) To reverse this epidemic, we need to improve the way pain is treated, including the broader use of alternative or adjunctive treatments such as regional anesthesia (RA) and peripheral nerve blocks (PNBs), and when possible for immediate post-op or injury, non-opioid analgesics with better bioavailability than oral, like IV acetaminophen, which can lessen or eliminate the use of opioids. These and other recommendations are included in the 2019 report by the Pain Management Best Practices Inter-Agency Task Force convened by the Department of Health and Human Services (HHS). (Task Force Report)

⇛ B. Braun supports the development of enhanced programs by HHS and other health agencies to build awareness of alternatives to opioids, and accelerate the implementation of recommendations by the Pain Management Best Practices Inter-Agency Task Force.

Improving Infusion Pump Safety Standards

Intravenous (IV) infusion pumps are a mainstay throughout healthcare, including in hospitals, infusion centers, emergency medical service vehicles, and other settings. As a primary source of fluid and medication delivery, the role of these pumps in patient care is critical. At the same time, infusion pumps have been associated with persistent safety problems that can result in over- or under-infusion, and missed or delayed therapy. To address these issues, in 2010 the FDA undertook the Infusion Pump Improvement Initiative, which established new requirements for infusion pump manufacturers, facilitated device improvements, and increased user awareness. This effort and other industry safety programs have led to a decline in the number of Class I recalls over the past several years, but recalls continue to occur. (Answering the Call for Quality) As the use of automated IV infusion pumps, or "smart" pumps, continues to increase, it will be important for the FDA to continue its active engagement in public/private partnerships and other actions to help ensure that patients are protected from harm.

⇛ B. Braun encourages close involvement by the FDA in the development of improved industry standards for IV infusion pumps, including efforts with the Association for the Advancement of Medical Instrumentation (AAMI) to finalize new Technical Information Reports related to pump safety.

Protecting Healthcare Workers from Exposure to Hazardous Drugs

Closed-system transfer devices (CSTDs) are medical devices designed to protect the healthcare workforce from occupational exposure to potentially hazardous drugs, such as antineoplastic drugs. There are two major types of CSTDs in the commercial marketplace that are both subject to clearance by the FDA – physical barrier and air cleaning CSTDs. For the last several years, the National Institute for Occupational Safety and Health (NIOSH) has struggled to develop and finalize a testing protocol that could be used to evaluate all types of CSTDs. As a result, NIOSH has alternated its approach to developing a testing protocol by, at times, focusing on developing a testing protocol for only one type of CSTD, and at other times announcing its intention to establish a universal testing protocol. NIOSH's lack of a clear and consistent approach to developing a protocol to test the relative performance of CSTDs has resulted in marketplace confusion over the years and, at times, has distorted the competitive landscape by driving purchasers to use the type of CSTD with a NIOSH draft testing protocol.

⇛ B. Braun urges NIOSH to refrain from releasing a testing protocol that can only evaluate one type of CSTD, and commit to either developing a comprehensive solution that applies to both types of CSTDs or defer to private entities to develop a testing protocol that applies to both types of CSTDs. A prudent approach to achieve this goal would be to request additional comments and assistance from all public stakeholders and active engagement with industry experts to develop a protocol that allows for direct comparisons of all existing products. Alternatively, NIOSH should commit to issuing dual testing protocols simultaneously for the two major types of CSTDs.

Quality and Safety of Compounded Drugs

Central Admixture Pharmacy Services, Inc. (CAPS), an affiliate of B. Braun in the US, is the nation's largest network of outsourcing admixture pharmacies. CAPS supports the FDA's policy for 503B outsourcing facilities, a category defined by the 2013 Drug Quality and Security Act (DQSA), to only compound from FDA-approved, commercially available products, rather than bulk drug substances. This policy allows outsourcers to compound from bulk drug substances only if a drug is listed on FDA's shortage list or if there is an FDA-recognized clinical need. This policy is essential to protect the integrity of the FDA's drug approval process and ensure the safe supply of compounded drugs. (Modern Healthcare)

⇛ B. Braun and CAPS support the FDA's policy on bulk drugs compounding as a critical step forward to protect patients. We believe the FDA must accelerate its process for reviewing bulk drug substances nominated to be included on the agency's clinical need list. This would more quickly close the loophole some outsourcers use to compound from bulk drugs. Further, the FDA should clearly communicate its policy on bulk drugs compounding to strongly emphasize that hospitals and pharmacists should not purchase and dispense products compounded from bulk drugs when a drug compounded from an FDA-approved alternative exists.

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