



Charles N. Kahn III  
President and CEO

August 24, 2023

Docket Number FDA-2023-N-3032

**VIA ELECTRONIC SUBMISSION**

Food and Drug Administration  
Dockets Management Staff (HFA-305)  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852.

**RE: International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; Bromazolam; Flubromazepam; Butonitazene; 3-Chloromethcathinone (3-CMC); Dipentylone; 2-Fluorodeschloroketamine (2-FDCK); Nitrous Oxide (N2O); Carisoprodol Comments Regarding Possible Scheduling of Nitrous Oxide (N2O)**

Dear FDA Staff:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural areas across 46 states, plus Washington, D.C. and Puerto Rico. Our members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's, and cancer services.

The FAH appreciates the opportunity to provide the Food and Drug Administration (FDA) and the World Health Organization (WHO) with comments for WHO's consideration as to whether current information justifies a WHO Expert Committee critical review concerning the need for international recommendations regarding the control of Nitrous Oxide. The FAH firmly believes in having necessary controls over certain psychotropic substances to minimize the potential for abuse and diversion. The FAH believes, however, that Nitrous Oxide does not need additional controls – beyond those already in place in the United States – to deter abuse and diversion. Should Nitrous Oxide be scheduled, the FAH believes that the related controls would

place undue burdens on hospital staff who are already stretched to the limit providing quality health care to patients. Further discussion regarding the FAH's comments are set forth below.

### **Current Use of Nitrous Oxide**

Nitrous Oxide is used within hospitals for conscious sedation (OB/Labor & Delivery primarily; but could be used in dental and other procedures). Nitrous Oxide is classified as a medical gas by the FDA, not a drug. Medical gases are not procured by, stored in, or dispensed/monitored by the Pharmacy Department. Medical gas tanks are typically stored in special areas for tanks.

### **Adequate Standards Currently Exist for the Security and Control of Nitrous Oxide**

A number of organizations have promulgated standard operating procedures and recommendations regarding the storage and security of medical gases, including Nitrous Oxide.

The National Fire Protection Association's (NFPA), 2021 edition of NFPA 99: Health Care Facilities Code specifies many health care facility requirements including operational, mechanical, electrical and architectural requirements for the storage of such medical gases. These requirements not only address physical room requirements for storage of medical gases, but also include a requirement for security in that NFPA 99 requires that storage areas for medical gases must be locked when not in use to prevent unauthorized access to the gases.

FDA regulations at 21 C.F.R. § 201.161 also provide labeling requirements, including a warning statement and certain handling directions.

Moreover, hospital accreditation and certification standards from The Joint Commission provide that hospitals minimize risks associated with selecting, handling, storing, transporting, using, and disposing of hazardous gases and vapors, including Nitrous Oxide. Those standards include requiring that the hospital have policies related to certain labeling, handling, transporting and storage of cylinders, and that when the hospital has bulk oxygen systems above ground, they are in a locked enclosure. This standard gives hospitals appropriate flexibility in setting hospital-specific policies for the security and control of nitrous oxide, including a manner that works for a particular hospital's layout.

### **Additional Controls Over Nitrous Oxide Would be Overly Burdensome**

Labeling Nitrous Oxide as a controlled substance would create many operational concerns for hospitals. Requiring further stricter controls regarding storage of Nitrous Oxide may be very difficult depending on the layout of the nursing units in hospital settings. If Nitrous Oxide is scheduled, additional storage requirements will likely be required which may not be currently available on nursing units.

The storage and security of Nitrous Oxide by pharmacy departments would also present significant challenges. Pharmacy departments typically do not have the storage space and staff to keep a standing inventory of Nitrous Oxide. The Nitrous tanks would not fit in a Pyxis machine in a "controlled" locked setting.

Finally stricter controls over the distribution of Nitrous Oxide will be difficult for distributors. If Nitrous Oxide becomes a controlled substance, the distribution will need to be

taken over by one of the pharmaceutical wholesalers. This will pose some operational challenges as the wholesalers are not currently setup for the distribution of medical gases such as Nitrous Oxide. Storage, controls, and delivery systems will need to be established as Nitrous Oxide would be a new type of product for the pharmaceutical wholesalers. The establishment of stricter controls could disrupt the supply chain and result in higher costs, both of which are contrary to the interests of patient care and well-being.

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The FAH appreciates the opportunity to comment on the possible scheduling of Nitrous Oxide. We look forward to continued partnership with WHO and FDA as we strive to minimize the potential for substances to be abused or subject to diversion. If you have any questions regarding our comments, please do not hesitate to contact me or a member of my staff at (202) 624-1534.

Sincerely,

A handwritten signature in black ink, appearing to read "Andrew M. ...". The signature is fluid and cursive, with a long horizontal stroke at the end.