Dragon, Karen E. (CDC/NIOSH/EID)

From: Bough, Marcie [MBough@APHANET.ORG]
Sent: Thursday, September 20, 2007 8:35 PM
To: NIOSH Docket Office (CDC)
Cc: Bough, Marcie
Subject: 105 - HazDrug Update Comments
Attachments: APhA Comments to NIOSH on Hazardous Drugs .pdf

The American Pharmacists Association (APhA) respectfully submits the attached comments on NIOSH Docket No. 105 – Process for Updating the List of Hazardous Drugs (Appendix A) for NIOSH Alert on Hazardous Drugs. Please confirm that you received this email.

Thank you,
Marcie Bough

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APhA was founded in 1852 as the American Pharmaceutical Association.

American Pharmacists Association
Improving medication use. Advancing patient care.
APhA

September 20, 2007

NIOSH Mailstop: C-34
Robert A. Taft Laboratory
4676 Columbia Parkway
Cincinnati, Ohio 45226

[Submitted electronically to nioshdocket@cdc.gov]

RE: Process for Updating the List of Hazardous Drugs (Appendix A) for NIOSH Alert on Hazardous Drugs - NIOSH Docket No. 105

Dear Sir/Madam:

Thank you for the opportunity to comment on the National Institute for Occupational Safety and Health (NIOSH) proposed addition of new drugs to the existing list of hazardous drugs in the workplace, NIOSH Docket No. 105. The American Pharmacists Association (APhA), founded in 1852 as the American Pharmaceutical Association, represents more than 60,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings such as community pharmacies, hospitals, long-term care facilities, managed care organizations, hospice settings, and the military. Within the APhA Academy of Pharmacy Practice and Management (APhA-APPM), the Section on Nuclear Pharmacy Practice is comprised of nearly 400 pharmacists involved in nuclear pharmacy.

Concerns

APhA is concerned with the number of medications that NIOSH is proposing to include in the hazardous drug list. Many of these drugs are widely-used medications in the community and institutional practice settings and have been available for years without being classified as hazardous. We question whether such a change would result in practitioners and patients recognizing the drug as "newly" hazardous. Furthermore, the proposed change may have the unintended consequence of decreasing the credibility of the hazardous designation if drugs are included prematurely, absent unsubstantiated evidence.

Additionally, the proposal includes many drugs that are supplied in solid oral dosage forms that inherently limit the risk of exposure (unless crushed). Finally, we are concerned that the

proposal could create a significant increase in administrative burden for pharmacy staff related to cost, staff time, training, storage, handling, preparation, transportation, disposal, monitoring, compliance procedures and exposure containment plans for drugs that may not have significant occupational exposure. We question whether the exposure risks of these drugs warrant these new burdens. Therefore, we ask that you reconsider the breadth of the proposed list and limit the inclusion to those medications with well defined risks for health care provider occupational exposure.

Radiopharmaceutical Regulations

The principal risk for radiopharmaceuticals is associated with ionized radiation. Existing preparation and handling controls for these products help to minimize exposure. These controls include required monitoring and recording of individual radiation exposures using personal dosimetry devices. Such devices have been available commercially for many years and their exposure readings are quantified by accredited entities using National Institute of Standards and Technology (NIST)-traceable measurement methods. In addition, radiopharmaceutical preparation, handling and use is required to conform with Federal Nuclear Regulatory Commission (NRC) or NRC-Agreement State regulations governing radiation safety.

Radiation hazards are also well-controlled in facilities preparing them. These facilities are subject to on-site audits and inspections from internal and external audit groups, such as Federal and State Agencies, as required by their radioactive materials license. Thus, independent verification that the facility is safely handling these drugs is routine and consistent in every state. In addition, oversight is provided through various other agencies, including State departments of health, State boards of pharmacy, and professional standards of practice such as the APhA Nuclear Pharmacy Compounding Guidelines.

Chronic worker exposure to ionizing radiation is regulated and must be monitored as previously described. Individual radiation worker radiation doses must be within federally-assigned permissible limits which have been shown not to cause any radiation-induced injuries. Workers must continually monitor their personal protective equipment (PPE) and skin for radioactivity contamination. Whereas non-radioactive hazardous drugs are difficult or impossible to immediately monitor for skin or surface contamination, radiopharmaceutical contamination is immediately recognized through existing radiation detection equipment available in all facilities where such drugs are prepared and dispensed. Such detection equipment is mandated by NRC and NRC-Agreement State regulations.

The method of radiopharmaceutical dispensing is also carefully controlled and involves a closed aseptic transfer from the manufacturer's vial to a syringe for direct patient injection. Radiopharmaceuticals are often available from the manufacturers already prepared in single-dose vials. As done with all radiopharmaceuticals, one dose is drawn from the vial under specific conditions using equipment designed to limit worker exposure to the drug. The dose dispensing process is routinely monitored for drug aerosol or surface radiation contaminations as required by existing NRC or NRC-Agreement State regulations.

Given the myriad of current regulations, we question whether additional NIOSH-related procedural controls and requirements for radiopharmaceuticals will result in increased worker safety. Additionally, we are concerned that they may result in fewer facilities preparing these drugs, having the unintended consequence of limiting patient access to these valuable therapeutic medications.

Radiopharmaceutical Recommendations

The proposed Alert indicates that the risk associated with Quadramet and Metastron are characteristic of NIOSH's definition of a hazardous drug. This statement is inconsistent with the information in the Material Safety Data Sheets (MSDS), which for both drugs indicate that the primary risk for worker exposure to these drugs is from ionizing radiation – a characteristic not represented in NIOSH's definition.

- The Quadramet MSDS states, *"The primary occupational hazard associated with QUADRAMET is related to the presence of Sm 153, a moderate beta and low gamma and x-ray radiation emitter... Hazards of the non-radioactive chemical component of QUADRAMET...have not been fully evaluated in humans, although animal data are available...None of the components present in this material at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA or ACGIH as a carcinogen... Ingestion is not considered a potential route of exposure. Consult with radiation safety officer."*
- The Metastron MSDS Sheet states that under chronic exposure, *"Data on biological effects of Ionizing Radiation are based on exposures much higher than those permitted occupationally. No effects are expected from exposures received as a result of normal use."*

The MSDS information clearly indicates that the nature of the hazard associated with radiopharmaceuticals is directly related to their emission of ionizing radiation, unlike the existing drugs listed in the Alert for which chemical toxicity is the primary hazard. Therefore, it is inappropriate to suggest that all radiopharmaceutical drugs have similar exposure routes to chemotherapeutic drugs. APhA recommend that the radiopharmaceutical drugs Metastron (strontium-89 chloride) and Quadramet (samarium-153) be removed from the proposed list.

Conclusion

APhA appreciates and supports NIOSH's efforts to update the hazardous drug list. Ongoing updates are needed to reflect new risk information and ensure the safety of health care workers. APhA also agrees that there are risks associated with worker exposure to ionizing radiation with Metastron and Quadramet, just as there is with all radiopharmaceuticals. However, requiring additional protection, as proposed by NIOSH , would not add material benefit to worker safety in the nuclear pharmacy practice setting. Thus, we repeat our request that NIOSH remove both Metastron and Quadramet from the proposed Alert.

Thank you for the opportunity to provide comments on this important issue. If you have any questions or require any additional information, please contact Marcie Bough, Director of Federal Regulatory Affairs at (202)429-7538 or at MBough@APhAnet.org.

Sincerely,

John A. Gans, PharmD
Executive Vice President

cc: Richard A. Nickel, MS, RPh, 2007-2008 Chair, APhA-APPM Nuclear Pharmacy Practice Section, USP Ad-Hoc Advisory Panel on Chapter <797> (Radiopharmaceuticals)
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