



October 3, 2011

NIOSH Docket Office
Robert A. Taft Laboratories
MS-C34
4676 Columbia Parkway
Cincinnati, Ohio 45226

Re: NIOSH Docket No. 190 – NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2012: Proposed Additions and Deletions to the NIOSH Hazardous Drug List

Dear Sir/Madam:

The American Society of Health-System Pharmacists (ASHP) is pleased to submit comments pertaining to updating the list of hazardous drugs for the National Institute for Occupational Safety and Health (NIOSH) alert. For more than 60 years, ASHP has helped pharmacists who practice in hospitals and health systems improve medication use and enhance patient safety. The Society's 35,000 members include pharmacists and pharmacy technicians who practice in inpatient, outpatient, home-care, and long-term-care settings, as well as pharmacy students. Pharmacists in hospitals and health systems are experts in medication use who serve on interdisciplinary patient-care teams. They work with physicians, nurses, and other health-care professionals to ensure that medicines are used safely and effectively.

ASHP has long supported the safe handling of hazardous drugs that may present an acute or chronic occupational hazard to health care practitioners. ASHP considers the protection of these individuals to be of paramount importance. In fact, ASHP has had long-standing, comprehensive guidelines outlining the handling of hazardous drugs in the workplace. When a drug is defined as "hazardous" health care practitioners must follow strict standards of practice for the receipt, storage, preparation, transport, administration, and disposal of that drug product.¹ However, the Society would advise caution in the evaluation and classification of drug products. These standards, which are designed to ensure the safety of health care workers, will place undue burden on health systems in terms of time, resources, and costs if the designation of hazardous is applied to drug products for which toxicity from occupational exposure has not been demonstrated and is unlikely.

As a member of the reviewer panel established by NIOSH to assist in the hazardous drug list update, ASHP commends NIOSH for removing a number of drugs from the 2012 proposed list. However, based on the following, previously communicated considerations, we urge NIOSH to re-evaluate the decision to include the agents listed below on the hazardous drug list.

Classification based on risk for selected or pre-disposed populations

ASHP questions the need for hazard precautions for health care workers who are not at risk for reproductive hazards or others who do not have predisposing conditions that may increase their susceptibility to harm from the drug. These drugs include: paroxetine, bismuth biscaltrate/metronidazole/tetracycline hydrochloride, and valproic acid. In light of the resource-intensive activities associated with hazard management, only those individuals who may be at risk should be protected from these drugs, rather than all health care workers. This approach is consistent with how other drugs with reproductive risks, such as finasteride, are currently managed.

Classification based on inherent toxicity, without consideration of drug formulation, likelihood of occupational exposure, or association of occupational exposure with toxicity

There are variable data supporting the hazardous effects of ambrisentan, carbamazepine, paroxetine, pitavastatin, phenoxybenzamine, plerixafor, nilotinib, simvastatin, and valproic acid in vitro or in animals with therapeutic or supra-therapeutic dosing. However, additional discussion is warranted for these drugs since no harm is anticipated from the lesser extent of occupational exposure. For example, paroxetine tablets are film-coated, which greatly reduces powdering. At present, there is no evidence to support the assertion that limited exposure to these agents in the workplace presents a health risk to the health care practitioner. A formal risk assessment including the extent of workplace and worker contamination (e.g., air and surface contamination, dermal contact and skin absorption, and urine testing) may be warranted. It is premature to designate these drugs as hazardous before such evidence is available. This is especially pertinent with intact dosage formulations.

Some monoclonal antibody products appear have been designated as hazardous strictly based on their AHFS classification as an antineoplastic agent. However, some researchers have noted that these drug molecules are too large for absorption through intact skin.² In the absence of accidental injection or a skin condition that would allow absorption, the occupational exposure with normal preparation and administration of these drugs is expected to be minimal. However, ASHP recognizes that this rationale is controversial and recommends additional research on these molecules.

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National Institute for Occupational Safety and Health
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The Society appreciates this opportunity to comment on the NIOSH List of Hazardous Drugs. Please contact me if you have any questions on ASHP's comments. I can be reached by telephone at 301-664-8806, or by e-mail at ctopoleski@ashp.org.

Sincerely,



Christopher J. Topoleski
Director, Federal Regulatory Affairs

¹ American Society of Health-System Pharmacy. ASHP guidelines on handling hazardous drugs. Am J Health-Syst Pharm. 2006; 63:1172-93. Also available at <http://www.ashp.org/DocLibrary/BestPractices/PrepGdlHazDrugs.aspx>

² Bos JD and Meinardi MMHM. The 500 Dalton rule for the skin penetration of chemical compounds and drugs. Exp. Dermatol. 2000;9;165-9.