

(4) Workplace exposure measurement data in various types of industries and jobs.

(5) Case reports or other health information demonstrating potential health effects in workers exposed to 1-BP.

(6) Research findings from *in vitro* and *in vivo* toxicity studies.

(7) Information on controls (*e.g.*, engineering controls, work practices, PPE) including costs and effectiveness of control measures being taken to minimize worker exposure to 1-BP.

(8) Educational materials for worker safety and training on the safe handling of 1-BP.

(9) Data pertaining to the feasibility of establishing a more protective REL for 1-BP including projected costs of control strategies considered.

(10) Names of substitute chemicals or processes being used in place of 1-BP and type of work tasks.

Dated: September 9, 2009.

**John Howard,**

*Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[Docket Number NIOSH-150]

#### Request for Information on Alternative Duty: Temporary Reassignment for Health Care Workers Who Work With Hazardous Drugs

**AGENCY:** National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice of public comment period.

**SUMMARY:** NIOSH intends to publish a Current Intelligence Bulletin (CIB) on alternative duty and other forms of administrative controls for health care workers who work with hazardous drugs and are trying to conceive, are pregnant, and/or are breast feeding. Alternative duty involves transferring the worker to a similar position, but one in which they would not be required to handle hazardous drugs.

Exposure to certain hazardous drugs can affect reproduction and have adverse health effects on the developing fetus. Some hazardous drugs are known

to be present in the breast milk of patients treated with them [Briggs *et al.* 2005]. NIOSH plans to develop recommendations in this CIB on alternative duty and administrative controls that will protect the workers and their offspring from the potential adverse reproductive effects of hazardous drugs.

NIOSH is requesting (1) comments and information relevant to the potential reproductive effects of hazardous drugs, (2) reports or other data that investigate possible adverse reproductive effects in workers exposed to hazardous drugs, and (3) information pertaining to alternative duty policies and administrative controls for workers, particularly couples trying to conceive and women who are pregnant and breastfeeding, and who are exposed to hazardous drugs in health care and other industries.

**Public Comment Period:** Comments must be received within 60 calendar days of publication in the **Federal Register**.

**ADDRESSES:** You may submit comments, identified by docket number NIOSH-150, by any of the following methods:

- **Mail:** NIOSH Docket Office, Robert A. Taft Laboratories, MS-C34, 4676 Columbia Parkway, Cincinnati, OH 45226.
- **Facsimile:** (513) 533-8285.
- **E-mail:** [nioshdocket@cdc.gov](mailto:nioshdocket@cdc.gov).

All information received in response to this notice will be available for public examination and copying at the NIOSH Docket Office, Room 111, 4676 Columbia Parkway, Cincinnati, Ohio 45226. A complete electronic docket containing all comments submitted will be available on the NIOSH Web page at <http://www.cdc.gov/niosh/docket>, and comments will be available in writing by request. NIOSH includes all comments received without change in the docket, including any personal information provided.

**FOR FURTHER INFORMATION CONTACT:** Thomas Connor, PhD, NIOSH Robert A. Taft Laboratories, MS-C23, 4676 Columbia Parkway, Cincinnati, OH 45226, (513) 533-8399, e-mail [tmc6@cdc.gov](mailto:tmc6@cdc.gov).

**SUPPLEMENTARY INFORMATION:** Drugs have a successful history in treating illnesses and injuries, and are responsible for many of our medical advances over the past century. However, virtually all drugs can have side effects associated with patient use [NIOSH 2004]. In addition to risks in patients, workers who handle them are at risk of suffering these effects. In addition, it is known that exposures to even very small concentrations of

certain drugs may be hazardous for workers who handle them or work near them. Occupational exposures to hazardous drugs can lead to adverse reproductive events [NIOSH 2004, Dranitsaris *et al.* 2005].

The term "*hazardous drugs*" was first used by the American Society of Hospital Pharmacists (ASHP) in 1990 and recent updates to their guidelines [ASHP 2006] and is currently used by NIOSH [2004] and the Occupational Safety and Health Administration (OSHA) [OSHA 1999]. Drugs are classified as hazardous if studies in animals or humans indicate that exposures to them have a potential for causing cancer, genotoxicity, developmental or reproductive toxicity, or harm to organs. Many drugs with a hazardous classification are used to treat illnesses such as cancer (antineoplastic drugs) or HIV infection (antiviral drugs). See Appendix A of the NIOSH Alert [NIOSH 2004] for examples of hazardous drugs and a full discussion of criteria used to define and classify them as hazardous.

The numbers and types of work environments containing antineoplastic drugs are expanding as these agents are used increasingly for nonmalignant rheumatologic and immunologic diseases [NIOSH 2004].

When exposed to hazardous drugs, health care workers face several health risks, including reproductive risks. A reproductive hazard affects the reproductive function of women or men or the ability of couples to have healthy children [HSE 2003]. Some chemicals, including many hazardous drugs, are considered reproductive hazards because studies in humans or animals show that exposure to them may affect fertility, pregnancy outcome, or cause birth defects.

Evidence shows that these drugs have caused adverse reproductive outcomes in health care workers. For example, nurses and pharmacists exposed to hazardous drugs at their worksite reported an increase in adverse reproductive events including spontaneous abortions, stillbirths, and congenital malformations when compared with unexposed health care workers [NIOSH 2004]. In addition, some drugs may negatively affect germ cell (sperm and egg) development [McInnes and Schilsky 1996].

In the United States, an estimated 8 million health care workers [BLS 2007] are potentially exposed to hazardous drugs at their worksites and may be vulnerable to reproductive risks. These workers include pharmacists and pharmacy technicians, nursing personnel, physicians, operating room

personnel, shipping and receiving personnel, waste handlers, maintenance, housekeeping, and laundry workers, and workers in veterinary practices who may come into contact with drugs or drug waste. Health care workers may be exposed to hazardous drugs when they compound, administer, or dispose of hazardous drugs, clean up spills, or touch surfaces that are contaminated with these drugs. These activities frequently create aerosols or generate dust, thus increasing the risk of exposure [NIOSH 2004]. Skin absorption and inhalation are the most likely routes of exposure for a health care worker. However, ingestion (from hand to mouth) or injection through a needle stick or sharps injury is possible.

When other types of controls, such as engineering controls and the use of personal protective equipment do not eliminate exposure to hazardous drugs, alternative duty or re-assignment away from the potential hazard is a type of administrative control that will help protect the workers and their offspring from the potential adverse reproductive effects of hazardous drugs [Saiki *et al.* 1994; ACOEM 1996; HSE 2003].

NIOSH seeks to obtain materials, including published and unpublished reports and research findings, to evaluate mechanisms for alternative duty and administrative controls and possible reproductive health risks of occupational exposure to hazardous drugs. Examples of requested information include, but are not limited to, the following:

- (1) Trends in production and use of hazardous drugs over the past 10 years.
- (2) Descriptions of procedures with a potential for exposure to hazardous drugs.

- (3) Identification of industries or occupations in which exposures to hazardous drugs may occur.

- (4) Case reports or other health data that investigate possible adverse reproductive health effects in workers exposed to hazardous drugs or related animal data (published or peer-reviewed data are preferred).

- (5) Descriptions of work practices and engineering controls, including costs and effectiveness of control measures being taken, to reduce or prevent workplace exposure to these drugs.

- (6) Educational materials for worker safety or training on the safe handling of hazardous drugs.

- (7) Guidelines and/or recommendations for alternative duty/temporary reassignment policies in the health care or other industries where exposures cannot be controlled

by conventional methods (engineering controls *etc.*).

- (8) Data pertaining to the need for alternative duty to limit occupational exposures to hazardous drugs for couples who are trying to conceive, and women who are pregnant or breastfeeding.

- (9) Data pertaining to the feasibility of these types of recommendations, including actual or projected costs of alternative duty/temporary reassignment strategies considered.

NIOSH will use this information to determine the need for developing recommendations for alternative duty/temporary reassignment for individuals who may be at reproductive risk and/or whose fetus or offspring may be at risk from exposure to these drugs.

#### References:

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ASHP [2006]. ASHP guidelines on handling hazardous drugs. *Am J Health-Syst Pharm* 63:1172–1193.

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Briggs GG, Freeman RK, and Yaffee SJ ed. *Drugs in Pregnancy and Lactation*, 7th ed. Lippincott, Williams and Wilkins. Philadelphia, 2005.

Dranitsaris G, Johnston M, Poirier S, Schueller T, Milliken D, Green E, Zanke B [2005]. Are health care providers who work with cancer drugs at an increased risk for toxic events? A systematic review and meta-analysis of the literature. *J Oncol Pharm Practice* 11:69–78.

HSE (Health and Safety Executive) [2003]. HSE Leaflet. New and expectant mothers at work; a guide to health professionals. Available at: <http://www.hse.gov.uk/pubns/indg373hp.pdf>.

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Timpe EM, Motl SE [2004]. Environmental exposure of health care workers to category D and X medications. *Am J Health-Syst Pharm* 61:1556–1561.

Dated: September 9, 2009.

**John Howard,**

*Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[Docket Number NIOSH–186]

#### Request for Information on Glutaraldehyde

**AGENCY:** National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice of public comment period.

**SUMMARY:** The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) intends to evaluate the scientific data on glutaraldehyde, and develop appropriate communication documents, such as a Criteria Document, which will convey the potential health risks, recommended measures for safe handling, and establish an updated Recommended Exposure Limit (REL) for glutaraldehyde. The current NIOSH REL for glutaraldehyde is 0.2 ppm as a ceiling limit.

NIOSH is requesting information on the following: (1) Published and unpublished reports and findings from *in vitro* and *in vivo* toxicity studies with glutaraldehyde, (2) information on possible health effects observed in workers exposed to glutaraldehyde, (3)