

Miller, Diane M. (CDC/NIOSH/EID)

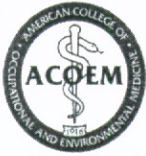
From: PSC pat oconnor
Sent: Friday, November 13, 2009 2:00 PM
To: NIOSH Docket Office (CDC)
Cc: 'Barry Eisenberg'; 'Marianne Dreger'; 'Mark Russi'; Buchta.William@mayo.edu
Subject: NIOSH Docket Number-150
Attachments: ACOEM Comments -- Docket NIOSH -- 150.PDF

Please find attached the comments from the American College of Occupational and Environmental Medicine in response to the Request for Information on Alternative Duty: Temporary Reassignment for Health Care Workers Who Work with Hazardous Drugs.

Thank you

Pat O'Connor
Director of Governemnt Affairs
ACOEM

Patrick O'Connor
Kent & O'Connor, Incorp.
1990 M St., NW
Suite 340
Washington, DC 20036
202/223-6222
f - 202/785-0687



AMERICAN COLLEGE OF
OCCUPATIONAL AND
ENVIRONMENTAL MEDICINE

November 13, 2009

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

Re: Docket Number NIOSH-150

To Whom It May Concern:

The following comments are submitted on behalf of the American College of Occupational and Environmental Medicine (ACOEM) and ACOEM's Section on Medical Center Occupational Health.

The NIOSH Request for Information on Alternative Duty: Temporary Reassignment for Healthcare Workers who work with Hazardous Drugs (Docket Number NIOSH – 150) published in the Federal Register Vo. 74, No. 178, September 16, 2009 solicits guidelines and/or recommendations for alternative duty/temporary reassignment policies in the healthcare or other industries "where exposures cannot be controlled by conventional methods (engineering controls, etc.)". NIOSH intends to publish a Current Intelligence Bulletin on alternative duty and other forms of administrative controls for healthcare workers, who work with hazardous drugs and are trying to conceive, are pregnant, and/or are breast feeding.

The hazardous effects of these drugs for the patients who receive them have been well recognized, as have been the potential acute and chronic effects for the healthcare workers who handle and administer them. This is especially the case when engineering controls, work practices and personal protective equipment (PPE) are not used optimally. Potential occupational exposure should be controlled via effective application of the most up-to-date engineering controls (Class II Type B2 Biological safety cabinets exhausted to the outdoors), safe handling/ work practices, enhanced worker protection (e.g. closed-system patient dispensing devices such as the Pha-seal) and PPE. These precautions are well known to industrial hygienists, safety personnel and occupational health specialists.

The American College of Occupational and Environmental Medicine (ACOEM), and in particular its Medical Center Occupational Health Section, supports effective programs to confirm and ensure adequate training and work practices, including training on spill and cleanup procedures. Employers and employees should be encouraged to actively seek the advice and counsel of occupational health providers regarding the adequacy of the institution's exposure prevention measures, including no-fault exposure reporting, and its medical surveillance programs.

ACOEM would like to register three concerns with a preventive approach focused on alternative duty/reassignment of workers to a position in which the worker is not required to handle hazardous drugs.

First, a clarification: the Request for Information cites the ACOEM Committee Report: 1994 ACOEM Reproductive Hazard Management Guidelines, published in the Journal of Occupational Medicine (JOEM) 1996. The 1994 ACOEM Reproductive Hazard Management Guideline is outdated and is no longer an active ACOEM position statement or reference document. It should be noted that a

policy of required or recommended work removal was not recommended for pregnant healthcare workers in the more recent ACOEM document, Guidance for Occupational Health Services in Medical Centers, September 3, 2008. This document is currently posted on the ACOEM website.

Secondly, a caveat: pregnancy is often not recognized early enough for reassignment to protect a fetus during critical periods of development. Half of all pregnancies are unplanned, i.e., are unexpected even by the healthcare worker. These realities reduce the effectiveness of a recommendation for self-reporting pregnancy.

In addition, a requirement for employee notification of pregnancy, intended pregnancy or infertility status to the employer is intrusive and discloses intimate personal details. Such disclosure includes health information that would otherwise be protected under federal law. Employees may, for whatever reason, choose not to identify themselves as being at risk, making passive and universal preventive measures, as well as no-fault exposure reporting programs, all the more important. Furthermore, we are not aware of any evidence that self-identification to the employer of reproductive status is an intervention of more than limited impact, particularly after pregnancy or infertility has been diagnosed. In the case of infertility, we are not aware of any evidence of the expected attributable fraction of infertility due to the hazardous drugs, and for how long would job reassignment be indicated.

This approach is also fraught with potential legal pit falls. For example, HIPAA regulations cover medical information after it is introduced into personnel/human resources records; those records then become subject to its provisions. The Americans with Disabilities Act 2009 Amendments Act would clearly apply to the employee who self-reports fertility issues. Whether handling of hazardous drugs is an essential job function or not may be a critical factor in the employer's response to this disclosure since the ADA, even as amended by the ADAAA, does not require an employer to remove the essential functions of a job in order to accommodate the employee's disability. Additional legal implications for the healthcare facility include the management, confidentiality and use of the health information disclosed, once the employee becomes one "with a record of physical impairment" or "has been regarded as having an impairment".

Finally, a request for clarification: if alternative duty is to be considered "where exposures cannot be controlled by conventional methods," its use is being qualified. This clause implies that there are means to verify whether exposures can or cannot be controlled. We are also unaware of any guidelines for minimal acceptable levels of exposure and find "any measurable level" on swipe tests to be lacking in scientific rigor. In the healthcare setting, inpatient or outpatient, how would exposure be determined in a practical and cost-effective manner? Would routine industrial hygiene environmental monitoring form the basis of this determination? What are the recommended metrics? Could other approaches be adopted, such as development and use of a checklist to become an option for smaller institutions?

While we recognize that adherence to current recommended precautions may not be universal in all facilities and may not be 100% effective, overall, current practices have been effective in decreasing the magnitude and frequency of exposures. Much of the literature on adverse health effects and employee exposure cites data from exposures occurring decades ago. Even more current publications are often based on older data and reflect older work practices; for example, Valanis' 1999 report on miscarriages and stillbirths among nurses and pharmacists is based on exposure data collected in 1988 and 1989. The recent literature on residual surface contamination is robust, but demonstration of resultant employee exposures via biomarkers is less compelling. Contemporary hazard assessment and risk communication efforts must consider current work practices, not historical risks. Lawson *et al*, 2006, suggest that "existing gaps in the science on this topic include the full toxicologic characterization of these drugs in healthcare exposure settings, the

industrial hygiene methods to describe exposure, adequate risk communication to affected workers, and vigilance in assuring safe handling and work practices." ACOEM heartily supports efforts to close those gaps.

In the meantime we understand that in the face of continuing uncertainty, there may be impetus to take **some** action, such as recommending job reassignment. In actual practice, this could become disruptive and intrusive in a workplace that is increasingly specialized and plagued by shortages of highly-trained personnel. This approach may provide the appearance of doing something while delivering very little, for the reasons noted above. We strongly advocate education of healthcare workers as to the potential risks of their work exposures as well as ongoing training and annual competency assessment in mitigation of those risks, which empowers the employee to protect him-/herself and weigh the relative benefits of the job against the possible risks.

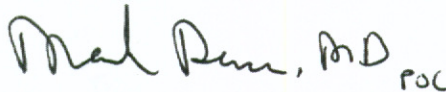
Each employee should have access to qualified occupational health professionals who can help them in that process and advocate for work restrictions should they be warranted in a particular case.

Thank you for your consideration of these comments.

Sincerely,



Pamela Hymel, MD
President
ACOEM



Mark Russi, MD
Chair
Section on Medical Center Occupational Health

Enclosure

References

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