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Respectfully submitted,

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number NIOSH-150]

The Department of Veterans Affairs (VA) is pleased to contribute comments to the National Institute for Occupational Safety and Health (NIOSH) Request for Information on Alternative Duty: Temporary Reassignment for Health Care Workers Who Work with Hazardous Drugs.

On a national level, the Department of VA does not have a policy outlining the necessary safeguards for hazardous drug handling. Policies and procedures are developed and implemented by each individual facility. All VA facilities have a policy that addresses the safe preparation, handling/administration, storage and disposal of hazardous drugs.

With regard to policies addressing duty reassignment, some VA facilities have policies that include language stating that those employees trying to conceive (male or female), or are pregnant or breast-feeding, are exempt from working with hazardous drugs. The wording may differ between facilities. While some state that it is not recommended that the above mentioned personnel "prepare, administer or dispose of antineoplastic agents", others specifically state that those employees will be "exempt from preparing, administering or disposing antineoplastic/biotherapy waste". There are some facilities that give preference for alternative duties in these situations whenever possible.

Education is key for personnel and environmental protection. Educational tools utilized within the VA system include: USP 797 Training on Compounding Sterile Products, ASHP Cytotoxic Preparation video, Oncology Nursing Society Chemotherapy and Biotherapy Course, and the ASHP Technical Assistance Bulletin. Continuing education in the form of annual in-services and competency exams help to update employees on current practice. Formal education and the use of PPE (Personal Protective Equipment) has demonstrated a significant decrease in levels of contamination in urine samples of nurses and wipe samples of counters in the administration area; the use of PPE also educates patients, caregivers and other hospital personnel the importance of safe handling (Nixon & Schulmeister, 2009).

Recently the Oncology Nursing Society and American Society of Clinical Oncology published chemotherapy safety standards recommending that each practice to have explicit polices, procedures and/or guidelines for verification of training and continuing education for clinical staff. The comprehensive educational program should include competency assessment and annual competency reassessment (Jacobson, et al., 2009).

Exposure to antineoplastic drugs occurs through one or more common routes, such as dermal exposure through skin contact (preparation, administration, counting tablets,

contaminated gloves, touching contaminated surfaces) or inhalation and unintentional ingestion via spills or airborne contamination (Sorsa, Hameila, & Jarviluoma, 2006). Currently, there is no standard method to analyze airborne and surface contamination. Surface contamination with antineoplastic drugs has been found on a variety of surfaces: biologic safety cabinets, floors, countertops, storage areas, tables and chairs in patient treatment areas, areas adjacent to drug handling areas, and the outer surface of antineoplastic vials in their original packaging. Biologic monitoring methods, whether through urine samples for mutagenic testing or the presence of antineoplastic drug or metabolite concentrations or the more sophisticated evaluation of early DNA damage in personnel, have been inconsistent. Changes in engineering controls, administrative policies on training and education, and the use of personal protective equipment make it difficult to compare the results of clinical studies and observational studies over time and between countries. More importantly, most of the biologic monitoring data and self-reports of increased fetal loss, infertility, and congenital anomalies associated with occupational exposure are non-specific, indirect measures of exposure without validation of a defined exposure causing a disease outcome (Connor, 2006; Fransman, et al., 2007; Hedmer, Georgiadi, Bremberg, Jonsson, & Eksborg, 2005; Ursini, et al., 2006).

When considering alternative duty assignment, there are many issues that should be given consideration. First of all, there needs to be consideration of how effective the current controls (engineering controls, administrative controls, PPE) are in reducing risk of exposure. Even when controls are put into place, there is a chance of surface contamination and risk of personnel exposure, as evidenced by the literature (Connor, Anderson, Sessink, Broadfield, & Power, 1999; Touzin, Bussieres, Langlois, & Lefebvre, 2009; Touzin, Bussieres, Langlois, Lefebvre, & Gallant, 2008). Some sites of contamination exist outside of the chemotherapy mixing or administration area. So if the purpose of duty reassignment is to serve as added protection for the individual, by placing them in a safer work environment, then a safer environment needs to be defined and identified. Is duty reassignment from the chemotherapy mixing area to the inpatient procurement area really reducing risk to the individual?

Another consideration is staffing. Personnel who work with the preparation and administration of hazardous drugs are given specialty training in this area and maintain this competency on a regular basis. Because of the additional training, attention to detail and complex regimens associated with this area of expertise, it may only be the interest of a handful of people. Trying to staff this area can be difficult when very few may have the training needed to carry on the work safely. Staffing with personnel who are not adequately trained puts all individuals at greater risk of exposure.

There needs to be consideration of the message relayed when suggesting reassignment of duties. Individuals who work in this environment on a daily basis may question whether the protective controls already in place are effective.

Without evidence to guide us on the appropriate way to manage duty reassignment, perhaps our focus at this time should be on optimizing current industrial controls, intensifying educational efforts and stressing the importance of surveillance within our facilities.

Respectfully submitted,

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