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From: Cunha, Bruce [cunha.bruce@marshfieldclinic.org]
Sent: Friday, November 13, 2009 4:59 PM
To: NIOSH Docket Office (CDC)
Subject: Docket # NIOSH-150

Attachments: Department of Health and Human Services.doc



Department of
Health and Human Services

Please see attached comments on this docket.

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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.

To Whom It May Concern:

Marshfield Clinic has a number of concerns related to the proposal that NIOSH is asking for comments on.

The topic of safety related to working with Hazardous Drugs is one that we take very seriously. It is unfortunate that NIOSH is making proposals for a topic that they do not have good current safety data on. Many of the papers that NIOSH quoted in the Federal Register publication on this docket are old and do not reflect the current state of employee safety programs or protective measures.

The publication also contains at least one statement that is not fully backed by the research paper. In the 2005 Dranitsaris et al. paper "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." Authors stated "Due to a lack of evidence, we were unable to estimate a pooled OR for the risk of cancer and acute toxic events." They further stated "Our systematic literature review and meta-analysis identified a small risk for spontaneous abortions..... However, it is important to keep in mind that only one of the five studies in the meta-analysis evaluated health care workers exposed after 1985, the year where global standards for cytotoxic drug handling were implemented. The study failed to find a statistically significant association between exposure to cancer drugs and spontaneous abortions"

While we understand and share NIOSH's concern related to these workers, we also are concerned that implementation of this program will drastically impact our ability to provide care to our cancer patients. A good number of our employees who work with hazardous drugs are of child bearing/producing age. Given that NIOSH is using time periods of when a person is trying to get pregnant, while they are pregnant and when they are breast feeding, the time that an employee would need to be reassigned could easily be years long. We are talking about highly trained personnel who are not easily replaced.

Loss of a single worker in this area either increases the workload on other employees (creating potential for safety issues due to rushing), or reduces the patients that can be treated. For specific positions such as sterile products pharmacy personnel who actually mix the medications; temporary replacement workers may not be available.

We are also concerned about the message this program sends to the employees. We do not want our employees exposed to these hazards regardless of if they are trying to get pregnant, are pregnant or have any other health condition that could be affected by an exposure. Eliminating all exposures is the basis for our safety program. We do not feel that singling out a specific group for additional safety precautions assists us in assuring all employees are provided with a safe working environment.

We have mandatory on line education and a voluntary health surveillance program (no health issues have ever been detected in our employee population). We assure new persons starting in this area are give one-on-one training and have to shadow and work directly with an experienced staff prior to being allowed to work with these agents on their own.

NIOSH listed in the document “When other types of controls, such as engineering controls and the use of personal protective equipment do not eliminate exposure to hazardous drugs...” If NIOSH can tell us how we can monitor our environment to check for potential exposures or even come up with a wipe test to assure our protocols are working; it would be helpful. At this time, we are not aware of any labs in the United States that do this testing. We are also not aware that there has been any effort to come up with an amount of exposure that may be harmful.

We would ask that NIOSH work to get scientific studies that indicate if health problems are actually occurring prior to implementing a process that could have a negative impact on patient care. We would also ask that NIOSH put efforts into assisting with safety programs that would help prevent any exposure or could assist in documenting that current safety protocol are working.

Yours Respectfully

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