

## **2006 NORA Partnering Award for Worker Safety and Health Winner Collaborative Partnerships and Products of the NIOSH Hazardous Drug Working Group**

### **Background**

We nominate the National Institute for Occupational Safety and Health (NIOSH) Hazardous Drug Working Group for its significant leadership and partnership efforts toward reducing worker health risks associated with hazardous drugs and for providing measures to protect their health. It seems counter-intuitive that the healthcare industry, whose mission is the care of the sick, is itself a “high-hazard” industry for the workers it employs. In fact, published studies have shown that workplace exposures to hazardous drugs can cause both acute and chronic health effects such as skin rashes, adverse reproductive outcomes (including infertility, spontaneous abortions, and congenital malformations), and possibly leukemia and other cancers. Healthcare workers who prepare or administer hazardous drugs (e.g., those used for cancer therapy, and some antiviral drugs, hormone agents, and bioengineered drugs) or who work in areas where these drugs are used may be exposed to these agents in the workplace. About 5.5 million U.S. healthcare workers are potentially exposed to hazardous drugs, including pharmacy and nursing personnel, physicians, environmental services workers, workers in research laboratories, veterinary care workers, and shipping and receiving personnel.

Under the leadership and guidance of the National Occupational Research Agenda (NORA) Control Technology and Personal Protective Equipment Team and the NORA Reproductive Health Research Team, NIOSH convened a Hazardous Drug Working Group in December 2000. This Working Group consisted of members representing government, labor, pharmacy, nursing, academia, research, pharmaceutical and safety equipment manufacturing, and trade associations. [Note: A complete list of Working Group members is shown in Appendix A.] The focus of this group was to assess the extent and impact of occupational exposure to hazardous drugs and to help NIOSH and others make recommendations for protecting workers from exposure to these drugs. As described in the following section, the Working Group helped to shape a collaborative, multi-faceted approach for developing solutions to this persistent public health problem.

### **Partnerships, Goals and Multi-faceted Approach**

The effort between the two NORA teams formed a unique and powerful partnership of labor, industry, government, and academia that resulted in the significant production and transfer of information and products into practice. At the initial meeting of the partnership, the Working Group developed a strong charge for a NIOSH policy document that made a clear statement about the presumed health effects associated with hazardous drugs. The Working Group also identified the need not only for better information on glove material selection but also for informative resources on the selection and use of engineering controls for protection against hazardous drug exposures. Because of the increased interest and support related to protecting workers from occupational exposure to hazardous drugs, others were drawn to the process. The Working Group grew from an initial twenty members to its current size of more than forty. After assessing the published literature to confirm the presence and magnitude of this public health problem, the Working Group developed the following goals: (1) to enhance awareness of the problem; (2) to provide protective recommendations based upon current knowledge and (3) to identify, research and address gaps regarding personal protective equipment, engineering controls and work practices designed to reduce occupational exposures to hazardous drugs.

## Partnership Products and Impact

- 1) The Hazardous Drug Alert: After identifying the Goals for the Hazardous Drug Working Group, the Group worked diligently with NIOSH to develop a multi-faceted strategy for their achievement. For example, over the initial three-year period of the partnership, the working group divided into several teams of subject matter experts who focused on writing specific portions of the draft Alert. These individual writings, collectively, became the foundation from which NIOSH staff developed the final Alert by way of a rigorous scientific and policy review process. The NIOSH Alert, *Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings*, summarizes the known health risks associated with handling hazardous drugs and provides guidance for their safe handling and administration. Tear-out checklists (in both English and Spanish) provide protective recommendations specific to both employers and employees and case studies that present real-world scenarios of hazardous drug exposures and their consequences.

The Hazardous Drug Alert defines the properties of a hazardous drug and includes a list of drugs (Appendix B) that meet the definition. To enhance the Alert's value into the future, NIOSH established a scientific peer-review process for updating the hazardous drug definition and associated list on an annual basis. This process involves Working Group members and affected partners and will begin in January 2006. After defining and identifying hazardous drugs and educating as to their adverse health effects, the Alert provides crucial recommendations for engineering controls, work practices, administrative controls, and personal protective equipment that will help workers avoid exposures to these drugs.

One important contribution of the Hazardous Drug Alert is to introduce clear and concise engineering control recommendations focused on worker protection. The historical focus for engineering equipment used in pharmacy compounding has been upon sterile product protection. The Alert successfully expands this focus to incorporate design and operational concepts for worker protection that do not compromise sterility. Perhaps the most important engineering impact to date is the immediate response shown by engineering equipment manufacturers to introduce new engineering control products into the marketplace. Since the Alert was released in March 2004, six out of seven equipment manufacturers began marketing engineering controls specific to the guidance in the Alert.

To facilitate awareness of the Hazardous Drug Alert and its contents, Working Group members and NIOSH staff organized a Workshop, held in San Antonio, Texas, in October 2004, entitled *Alert on Reducing Occupational Exposures to Hazardous Drugs: Converting Theory to Practice*. This Workshop addressed the safe handling of hazardous drugs and, specifically, the main topics covered in the Alert. The Workshop was attended by approximately 200 representatives of government agencies, academia, the pharmaceutical industry, and trade associations in addition to pharmacy, nursing, and safety and health personnel from the United States, Canada, and Mexico. In addition to the Workshop, NIOSH staff and Working Group members are participating in numerous short communication programs, sponsored by pharmacy, nursing and occupational safety and health organizations, both national and international, on the safe handling of hazardous drugs.

Identifying and educating workers on the health effects of hazardous drugs, work practices, personal protective equipment, and engineering control recommendations were all anticipated components of the Hazardous Drug Alert. One less-anticipated aspect was adoption of the Alert's recommendations into various compliance regulations. At the previously mentioned Hazardous Drug Workshop, the principal U.S. healthcare accrediting organization, Joint

Commission on Accreditation of Healthcare Organizations (JCAHO), announced that it was incorporating aspects of the Alert's recommendations into their survey program. Additionally, the United States Pharmacopoeia (USP) announced in November 2004 a proposed change to their regulatory chapter (797) that instructed pharmacists and their employers to follow the protective recommendations in the NIOSH Alert when handling hazardous drugs. The incorporation of the Alert's recommendations into the JCAHO survey and USP standard greatly enhances the impact of the Working Group partnership.

- 2) Working with the Food and Drug Administration (FDA): Working Group members also assisted NIOSH in partnership with the FDA to update the safe handling warning on the FDA package inserts for antineoplastic drugs. The FDA is the traditional government regulator of products and processes within the pharmaceutical world. Thus, FDA's incorporation of health effect and precautionary handling information from the Hazardous Drug Alert is an important achievement toward the Workgroup's goal to enhance worker awareness.
- 3) Worker-focused Support Documents: The Working Group continues to work with NIOSH to develop and finalize several smaller, reader-friendly NIOSH Workplace Solution documents covering subjects related to the safe handling of hazardous drugs. Draft Workplace Solution documents have been prepared for the following five topics. [One document has already been finalized for NIOSH publication and the remaining four will be published by the end of 2006.]
  - Medical surveillance for health care workers exposed to hazardous drugs
  - Universal precautions for safe handling of hazardous drugs
  - Alternative duty/temporary reassignment for health care workers exposed to hazardous drugs who are at reproductive risk
  - Receipt and handling of hazardous drugs
  - Training for para-professional health care workers
- 4) Healthcare Worker Study: With assistance of the Working Group, NIOSH has identified key contacts at three institutions who have agreed to take part in the study of health care workers who handle antineoplastic drugs. NIOSH has also made site visits to each of the facilities and discussed the proposed study with pharmacy and nursing personnel. A study design and questionnaire have been developed along with sampling and analytical methods that will be used in the field studies. Upon completion of the study, some individual information will be reported back to the study participants and a summary of the study's findings will be made available to them and the three institutions. Based on the findings of the study, NIOSH will develop work practices to reduce worker exposure to these drugs and identify the exposure markers to monitor worker exposure.
- 5) Sources of Exposure Research: Collaboration between NIOSH researchers, key Working Group Members and the National Institutes of Health (NIH) resulted in a manuscript entitled, *Surface Contamination of Chemotherapy Drug Vials and Evaluation of New Vial-Cleaning Techniques: Results of Three Studies*, which was published in March 2005. These studies identified substantial levels of contamination on the outside surface of containers of several commonly used antineoplastic drugs from several different manufacturers. Additional studies on this topic produced an abstract, entitled External Contamination of Chemotherapy Vials, which was presented at the European Association of Hospital Pharmacists 10<sup>th</sup> Congress in March 2005. Results of this work were summarized in several MedWatch reports to the FDA

to alert manufacturers about the problem and to require them to re-examine their manufacturing practices.

- 6) **Personal Protective Equipment Research:** Various glove materials from numerous manufacturers are being evaluated by NIOSH for their permeability to some commonly used antineoplastic drugs. Additionally, the American Society for Testing and Materials (ASTM) adopted a standard test procedure (ASTM D 6978-05) for chemotherapy gloves entitled *Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs*. This procedure was based partly upon test procedures and results that originated from NIOSH studies of the permeability of protective glove materials to antineoplastic drugs.
- 7) **Engineering Controls Research and Partnerships:** As a new class of engineering control equipment for compounding hazardous drugs came to market, inconsistent terminology and performance descriptions among manufacturers resulted in some consumer confusion. In April 2005, NIOSH participated with The Controlled Environment Testing Association (CETA), the American Glovebox Society (AGS) and ventilated cabinet equipment manufacturers to identify needs and opportunities for developing common terminology, voluntary testing protocols and performance specifications for new equipment coming to market. Since that meeting, the AGS has expressed interest in incorporating the terminology/descriptions into their design standards and CETA has finalized an Applications Guide which incorporates the developed terminology and some of the operational concepts resulting from the meeting. NIOSH hopes to continue utilizing this partnership as a conduit to research engineering control effectiveness and performance gaps for hazardous drug compounding.

NIOSH is also partnering with Sandia National Laboratories in developing cleaning and decontamination methods for antineoplastic drugs. Initially, three common antineoplastic drugs are being evaluated using a Sandia decontamination formulation that has been shown to be effective for neutralizing chemical and biological warfare agents, biological pathogens, and many toxic industrial chemicals. Discovery of a safe decontamination agent effective against many/most antineoplastic drugs will be a valuable contribution toward reducing such occupational exposures to both healthcare workers and associated maintenance personnel.

## **Conclusion**

The Working Group on Hazardous Drugs formed a unique and powerful partnership that has greatly improved the health and safety of healthcare workers exposed to hazardous drugs. By developing and implementing a multi-faceted approach for reducing exposures of healthcare workers to hazardous drugs, the Working Group sought to raise awareness of the problem, to better define exposures, and to make recommendations to reduce the exposures. The power of this unique partnership was the ability of Working Group members to harness their unique talents and capabilities across a broad spectrum of interests. The beauty of the partnership was that the Working Group members were able to put aside their inherently different perspectives in order to better identify and achieve the common goal of reducing healthcare worker exposure to hazardous drugs. Although much has been accomplished, work is continuing to address new problems and issues in this challenging, complex, and ever-evolving field. Through this partnership, a comprehensive culture of safety in healthcare has been crafted and promoted that allows the provision of life-saving therapies to patients, while protecting and ensuring the health, lives, and livelihood of the caregivers who treat them.

**APPENDIX A**  
**MEMBERS OF THE**  
**NIOSH HAZARDOUS DRUG WORKING GROUP**

**Government Agencies:**

Burroughs, Edward, NIOSH  
Connor, Thomas, NIOSH  
Coyle, Barbara, Wisconsin State Lab of Hygiene  
DeBord, Gayle, NIOSH  
DeChristoforo, Robert, NIH  
Edens, Mandy, OSHA  
Freeman, Caroline, OSHA  
Hammond, Duane, NIOSH  
Harrison, Bruce, Veterans Affairs Medical Center  
Hatch, Mark, OSHA  
Hathon, Lee, OSHA  
Hogan, Amber, Becton-Dickinson (formerly with OSHA)  
Kim, Hye-Joo, FDA  
Lin, Chiu S., FDA  
MacKenzie, Barbara, NIOSH  
Mead, Ken, NIOSH  
Meson, Kristina, USEPA  
O'Lone, Martha, FDA  
Phillips, Jerry, FDA  
Presson, Angela, ret (formerly with OSHA)  
Reed, Larry, NIOSH  
Sands, Melody, OSHA  
Schill, Anita, NIOSH  
Schnorr, Teresa, NIOSH  
Williams, Dionne, OSHA

**Pharmaceutical Manufacturers:**

Abromovitz, Marc, Johnson & Johnson (formerly with GlaxoSmithKline)  
Frobel, Janice, Baxter Healthcare  
Hecker, Larry, Hospira, Inc. (formerly with Abbott Laboratories)  
Heidel, Donna S., Johnson & Johnson  
Lauper, R. David, SuperGen  
McConnell-Meachen, Mary, Boehringer Ingelheim Pharmaceuticals, Inc.  
McGrath, William, Bristol Myers Squibb Company  
Naumann, Bruce, Merck & Co.  
Proulx, Denise, Sanofi-Aventis Research  
Reinke, Lucy, Johnson & Johnson  
Sargent, Edward, Merck & Co.  
Sawyer, Charles, Eli Lilly and Co.  
Van der Sluis, Debora, Genentech, Inc.

### **Pharmacy:**

Anderson, Roger, Medco Health Solutions, Inc. (formerly with MD Anderson Cancer Center)  
Deffenbaugh, Joseph, ret (formerly with American Society of Health-System Pharmacists (ASHP))  
King, L D, Intl Academy of Compounding Pharmacy  
Power, Luci, University of California Medical Center

### **Nursing:**

deCastro, Butch, University of Chicago (formerly with American Nurses Association (ANA))  
Polovich, Marty, Oncology Nursing Society  
Pamela Hagen, ANA

### **Health Care Worker Labor Unions:**

Borwegen, Bill, Service Employees International Union (SEIU)  
Lane, Jim, SEIU  
Matthew-Brown, Diane, American Federation of State, County and Municipal Employees (AFSCME)

### **Academia:**

McDiarmid, Melissa, University of Maryland

### **Protective Equipment Manufacturers:**

Aldape, Tito, Microflex  
Ekblad, Agneta, Carmel Pharma, Inc.  
Griffin, Larry Palestine Regional Medical Center, (formerly with Carmel Pharma, Inc.)  
Peters, William, NuAire, Inc.  
Rahe, Hank, Containment Technologies Group, Inc.  
Stuart, Dave, Baker Company, Inc.

### **Consultants:**

Ader, Allan, SafeBridge Consultants, Inc.  
Smith, Charlotte, PharmEcology Associates, LLC  
Yurichuk, Sandi, Consultant, Oncology Business Development

### **Home Health Care:**

Kramer, Nancy, Coram Healthcare  
Leone, Melissa, Apria Healthcare

### **Oncology Centers:**

Dugger, Philip, US Oncology  
Greene, Dori, US Oncology

### **Accrediting Bodies:**

Berek Britton, Joint Commission on Accreditation of Healthcare Organizations (JCAHO)

