

**Headline News: Hazardous Drugs  
Did I see that on 60 MINUTES?**

Luci A. Power, BS Pharm, MS  
Senior Pharmacy Consultant  
Power Enterprises  
San Francisco, CA 94131

**Headline News**


**Dying after handling lifesaving drugs**

**Lifesaving Drugs, Deadly Consequences**

**Secondhand chemo and the workplace!**


**InvestigateWest**  
**Lifesaving Drugs may be killing health workers**


- InvestigateWest a nonprofit, investigative center based in Seattle
- Aired on Seattle PBS affiliate KCTS 9 TV



- Published in the Seattle Times
- Lead story on MSNBC.com website

<http://www.invw.org/chemo-workers>

How many of you compound or administer hazardous drugs or work in an area where HD are handled? 

**I feel safe when I handle hazardous drugs because my workplace and all my co-workers take my safety seriously** 

**A** Strongly agree

**B** Somewhat agree

**C** Somewhat disagree

**D** Strongly disagree

**InvestigateWest releases major investigation**

**Lifesaving Drugs, Deadly Consequences**

- The same powerful chemotherapy drugs that have saved hundreds of thousands of patients' lives for decades have at the same time taken a potentially deadly toll on the health of hospital and clinic workers who handled them, a major investigation reveals.

<http://www.invw.org/chemo-workers>

### Dying after handling lifesaving drugs

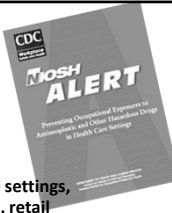
- **Pharmacist** with 23 years of mixing chemo diagnosed with pancreatic cancer
- **Veterinarian** with practice in animal oncology diagnosed with thyroid cancer at age 35
- **Oncology nurse** diagnosed with bile duct cancer in her 40s
- **Hospital pharmacist** with 15 years of mixing chemo diagnosed with Myelodysplastic Syndrome
- **Oncology pharmacist** with >25 years of clinical work and mixing; diagnosed with aggressive head and neck cancer

<http://www.invw.org/chemo-workers>

### OSHA RESPONDS


“Although this is an important safety and health issue, OSHA has not considered a standard to specifically address hazardous drugs in the healthcare setting”

### NIOSH ALERT



- 2004
- 4 years work
- > 40 people
- **The Alert addresses workers in health care settings, veterinary medicine, research laboratories, retail pharmacies, and home health care agencies**
- **Guidance = optional?**

NIOSH, 2004 <http://www.cdc.gov/niosh/docs/2004-165/>



### Work Precautions for Handling Hazardous Drugs Highlighted by NIOSH, OSHA, Joint Commission

- Hospital and health care employers were reminded today that hazardous drugs such as antineoplastic drugs can pose serious job-related health risks to workers if proper precautions are not used in handling the drugs. The National Institute for Occupational Safety and Health (NIOSH), the Occupational Safety and Health Administration (OSHA), and The Joint Commission highlighted the need for safe practices in a letter to hospitals in the U.S.


April 8, 2011 <http://www.cdc.gov/niosh/updates/upd-04-08-11.html>

### Surface Contamination in Two U.S. Studies

<u>1999 Study</u>	<u>2010 Study</u>
▪ 6 Hospitals	▪ 3 Hospitals
▪ 3 Drugs	▪ 5 drugs
▪ Pharmacy-75% wipe samples positive	▪ Pharmacy-75% wipe samples positive
▪ Nursing-65% wipe samples positive	▪ Nursing-45% wipe samples positive

Connor et al., AJHP 1999; Connor et al., JOEM 2010

### Does surface contamination mean worker contamination?



### Healthcare Worker Exposure

- As of 2010, 22 of 25 published studies measured drug in urine
- In four studies, the workers were *not* handling the drug that was in their urine
- Since 1990, two-thirds of published studies have shown a significant association between drug handling and a marker of genotoxicity

### Bio-monitoring in Healthcare Workers (1990-2009)

Assay for Genotoxicity	No. Pos.	Total
Urine Mutagenicity	2	3
Chromosomal Aberrations	16	21
Micronucleus	13	19
Sister Chromatid Exchange	8	18
Comet/DNA Damage	8/2	9/4

### HD Worker Contamination

- Abnormalities of chromosomes 5, 7, and 11, are the signature cytogenetic markers for many t-MDS/t-AMLs observed in treated patients
- 2010 study reports dose-dependent excesses of aberrations in chromosomes 5 and 7 as a function of anticancer drug-handling frequency
- Drug-handling frequency also influences the frequency of abnormalities in chromosome 7 alone

McDiarmid et al., JOEM 2010

### Authors' Concerns

- As these findings raise questions about individual or facility compliance or both with safe-handling guidelines, institutions must effectively monitor and ensure that work practices are consistent with these recommendations and provide up to date education about exposure risk.

McDiarmid et al., JOEM 2010

**Secondhand chemo and the workplace!**

**Guidance is not enough!**

I feel safe when I handle hazardous drugs because my workplace and all my co-workers take my safety seriously



- A Strongly agree
- B Somewhat agree
- C Somewhat disagree
- D Strongly disagree

### Lifesaving Drugs, Deadly Consequences Impact

Following the InvestigateWest investigation into the health hazards faced by health care workers who handle chemotherapy drugs, the State of Washington passed two new laws, creating an occupational cancer registry and mandating regulations governing how toxic drugs are handled in the workplace.

<http://www.lni.wa.gov/Safety/Topics/AtoZ/HazardousDrugs/>

### Washington State Hazardous Drugs Rule

- The new standard in Washington is based on the recommendations laid out in the 2004 NIOSH Alert
- Hazardous drugs. These drugs include antineoplastic cytotoxic medications, anesthetics, anti-viral drugs, hormones, and others.
- Hazardous drugs can cause serious acute and chronic health effects such as skin rashes, fertility problems, genetic damage, birth defects, organ toxicity, and possibly leukemia and other cancers.
- Exposure occurs during manufacturing and packaging, receiving, preparation and administration, and cleaning and disposal activities.

<http://www.lni.wa.gov/Safety/Topics/AtoZ/HazardousDrugs/>

### Washington State Hazardous Drugs Rule

- Clinical and non-clinical workers with potential exposure include:
  - Pharmacists and pharmacy technicians.
  - Nurses.
  - Physician assistants.
  - Physicians.
  - Nursing home, home health care, and assistive care staff.
  - Housekeeping and environmental services staff (custodial, laundry, and waste handling workers).
  - Shipping and receiving personnel.
  - Veterinarians and veterinary technicians and assistants.

<http://www.lni.wa.gov/Safety/Topics/AtoZ/HazardousDrugs/>

### Washington State Hazardous Drugs Rule

By:	Employers must have:
<b>January 1, 2015</b>	Stage 1: Developed and implemented a written hazardous drugs control program
<b>July 1, 2015</b>	Stage 2: Provided employee training.
<b>January 1, 2016</b>	Stage 3: Installed appropriate ventilated cabinets

<http://www.lni.wa.gov/Safety/Topics/AtoZ/HazardousDrugs/>

### State OSHA Programs

- The Occupational Safety and Health Act of 1970 allows States to develop and operate their own job safety and health programs
- States that have a State OSHA Program have the option to promulgate standards covering hazards not addressed by federal standards

<https://www.osha.gov/dcsp/osp/>

### State OSHA Programs

- Washington State has its own State OSHA Program
- Maryland, California, and North Carolina, all States that have State OSHA Programs, have introduced legislation to require compliance with HD safe handling practices

<https://www.osha.gov/dcsp/osp/>

## Maryland

- The Maryland Occupational Safety and Health Advisory Board ("Board") along with the Maryland Occupational Safety and Health Program ("Program") is in the process of drafting regulations to address occupational exposure to hazardous drugs in Maryland. Prior to starting the formal regulatory adoption process, the Board and the Program are seeking input from interested stakeholders.
- You can download the draft regulation by using this link:
  - <https://mcha.memberclicks.net/assets/hazardousdrugreg06172.doc>

Current to September 23, 2013

## California

- In February, California introduced Assembly Bill (AB) 1202 that would require its state Occupational Safety and Health Standards Board (Cal/OSHA) to promulgate a standard for hazardous drugs.
- AB 1202 passed the CA Assembly May 30, 2013
- AB 1202 passed the CA Senate August 26, 2013
- Once signed by the Governor, AB 1202 will be law
- [http://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill\\_id=201320140AB1202](http://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201320140AB1202)

Current to September 23, 2013

## North Carolina

- The state of North Carolina introduced House Bill 644 on April 9, 2013: Prevent Hazardous Drug Exposure
- The complete text of the bill:  
<http://www.ncleg.net/Sessions/2013/Bills/House/HTML/H644v0.html>
- The status of the bill:  
<http://www.ncleg.net/gascripts/BillLookUp/BillLookUp.pl?Session=2013&BillID=H644>

Current to September 23, 2013

## The Big Questions

- Will the States adopt the NIOSH list of HDs or modify it?
- What will be the engineering control requirements?
- What will be the PPE requirements?
- Workplace monitoring?
- Medical Surveillance?
- **How will the States enforce the rules?**

## Take the InvestigateWest Survey

- **Healthcare worker?**
- **Take our survey:**
  - <http://www.surveymonkey.com/s/ML3YSQJ>

## Resources

- NIOSH Alert: Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings, [www.cdc.gov/niosh/docs/2004-165/](http://www.cdc.gov/niosh/docs/2004-165/)
- NIOSH List of Hazardous Drugs, [www.cdc.gov/niosh/docs/2012-150/pdfs/2012-150.pdf](http://www.cdc.gov/niosh/docs/2012-150/pdfs/2012-150.pdf)

### Washington Department of Labor Hazardous Drugs Rule

- <http://ohsonline.com/articles/2012/01/14/washington-department-of-labor-adopts-hazardous-drugs-rule.aspx>
- <http://www.lni.wa.gov/Safety/Topics/AtoZ/HazardousDrugs/>

### 2011 – 48th Annual Emmy® Nominations

#### Health/Science - Program/Special

#### *Lifesaving Drugs, Deadly Consequences;*

- KCTS; Ethan Morris, Producer/Writer
- David Ko, Photographer/Editor
- Carol Smith, Writer

### Progress or More Questions?

- Will **RULES** be more effective than **GUIDELINES**?
- How will we know?
- What will we measure?
- Is improved awareness the key?

### Conclusion

“Change requires a focus on safety,  
not occupational safety or patient  
safety, but just safety.”

Gerald Goodman, Dr.P.H.  
Texas Woman’s University

Goodman GR. Nurs Econ Jan/Feb 2004