

# Western Occupational & Environmental Medical Association

# COMPLYING WITH MEDICAL ASPECTS OF USP 800: WOEMA ADVISORY STATEMENT

[Adopted by the Western Occupational & Environmental Medical Association on 12/4/2019]

# **Executive Summary**

The recommendations of USP 800 are scheduled for implementation in late 2019. Hospitals and other credentialed health care facilities that use antineoplastic and other hazardous drugs (HDs) will be required to adopt a number of industrial hygiene practices, conduct worker training, and carry out limited medical surveillance for certain personal risk factors that may increase a health care worker's likelihood of suffering adverse health consequences if exposed to HDs.

This document is intended to provide guidance to employers, workers, and medical professionals who will be affected by the USP 800 implementation and discusses the current state of medical knowledge with regard to screening and health care surveillance related to HDs. In particular, although WOEMA recognizes that historically health care workers have experienced poorly controlled exposures to HDs and that these exposures have resulted in significant adverse reproductive and other health effects, WOEMA nonetheless cautions that no specific elements in a medical history or physical examination, and no specific lab tests have been shown to meet basic public health criteria for medical screening, related to HD exposure.

WOEMA recommends that employers faced with implementing USP 800 take the following steps:

- A. Prepare a written plan detailing the steps the employer will use to prevent environmental contamination and control HD exposures, including deployment of PPE, how the employer will involve affected staff in preparing and updating the written plan, and how the employer will address individual health concerns of potentially exposed employees.
- B. Train potentially exposed employees annually about the hazards of HD exposure and about how employees can protect themselves and report safety concerns.
- C. Assess specific health concerns of potentially exposed employees annually and provide an opportunity for an interactive process involving an occupational medicine service as a liaison between the employee and employer to address requests for reasonable accommodations regarding HD exposure.
- D. Implement screening or surveillance procedures with regard to HDs only in response to specific verified exposure events and using solid medical evidence.
- E. Respond to and keep a log of exposure episodes involving HDs.
- F. Review written plan annually with multidisciplinary committee involving pharmacy, environmental services, nursing, occupational medicine, and senior leadership.
- G. Collaborate with public health agencies who may in the future establish a registry of HD-exposed workers.



#### Introduction

The United States Pharmacopeia Convention General Chapter 800 Hazardous Drugs – Handling in Healthcare Settings (USP 800) was written to protect all employees, patients and the general public who may be accessing facilities where hazardous drugs (HDs) are prepared or dispensed. Under USP 800, healthcare workers (HCWs) whose jobs may expose them to HDs must receive training about HDs and must be assessed for their understanding of that training. All personnel who handle HDs are to be responsible for understanding fundamental practices and precautions and for periodically evaluating these procedures and the end-product quality HDs to prevent harm to patients, minimize exposure to personnel, and minimize contamination of the work and patient-care environment<sup>1</sup>.

The nationally recognized sets of standards for handling and compounding drugs are known as the United States Pharmacopeia (USP) and The National Formulary (USP–NF)<sup>2</sup>. USP standards are published as General Chapters, which cover such topics as drug toxicology, dosage forms, and compounded preparations. USP 800 provides guidance for healthcare personnel who store, prepare, transport, and administer HDs, and provides recommendations to healthcare institutions for controlling occupational HCW exposure to HDs<sup>3</sup>. Hospitals and other health facilities covered under USP 800 must have a safety and health program to control employee and environmental exposure, which should include the following elements:

- facility design and engineering controls in locations where unpacking and compounding of HDs occur;
- training requirements and safe work practices, such as use of closed systems transfer devices and the provision of appropriate PPE (personal protective equipment);
- policies for HDs waste segregation and disposal;
- a medical surveillance program.

USP 800's recommendations conform to standard industrial hygiene practices and rely on the hierarchy of controls to mitigate the risks to HCWs who may be exposed to HDs. This general chapter is a new addition to two previous documents, USP 795 Pharmaceutical Compounding – Nonsterile Preparations, and USP 797 Pharmaceutical Compounding – Sterile Preparations. Both USP 795 and USP 797 provide advisory safety standards that apply to persons who prepare compounding preparations and to all places where compounding preparations are formulated for patients; however, these recently revised chapters do not provide guidance for employees outside of the pharmacy setting, which USP 800 seeks to address<sup>4</sup>.

The revised standards of USP 795 and USP 797 and new standards of USP 800 were published June 1, 2019 and scheduled to be implemented on December 1, 2019. At the time of this statement, the implementation date for USP 795 and USP 797 has been delayed indefinitely. According to United States Pharmacopeia, USP 800 will remain official on December 1, 2019, but for informational purposes only until further notice<sup>5</sup>. Addendum 1 provides information on the USP definition of "official date" and how this has influenced hospital pharmacy certification.

#### **USP 800 Medical Surveillance and Medical Screening**

USP 800 states that medical surveillance is to be a part of a comprehensive exposure program for controlling exposures to HDs, along with engineering controls, safe work practices, and use of PPE. This general chapter is the first time that USP has included medical surveillance as part of a recommended standard. USP 800 promotes medical surveillance as a secondary prevention tool for early detection of lab abnormalities or health effects among populations of HCWs. USP 800 recommends that the entity's medical surveillance program include the following elements:

- Development of an organized approach to identify HCWs who are potentially exposed to HDs on the basis of their job duties;
- Use of Employee/Occupational Health Services to perform medical surveillance, with provisions to protect the confidentiality of personal medical surveillance data;



- Provide a baseline assessment of a worker's health status and medical history. Data elements collected include a
  medical (including reproductive) and work history to assess exposure of HDs, physical examination, and laboratory
  testing, such as a baseline CBC;
- Assess exposure history through a review of records of HDs handled with quantities and dosage forms, estimated number of HDs handled per week, and estimates of hours spend handling HDs per week and/or per month;
- Maintain medical surveillance records according to OSHA regulations;
- Provide periodic surveillance including updated health and exposure history, and if appropriate, physical assessment and laboratory testing;
- Monitor data to identify prevention failure leading to health effects; this monitoring may occur in collaboration with the employee health service;
- Develop a follow up plan for workers shown to have acute toxicity or had acute exposure that includes evaluation of current engineering and administrative controls and equipment;
- Perform a post exposure examination tailored to the type of the exposure;
- Verify and document efficiency of hazardous controls including: engineering controls efficiency, environmental samplings (if appropriate), appropriate use of PPE and compliance to administrative controls and prevention plan of action;
- Offer alternative work if medically needed;
- Provide an exit examination when a HCW's employment at the organization ends.

The language used to describe the USP 800 medical surveillance program is advisory (may, should), and does not contain any regulatory language (must, shall). The USP 800 medical surveillance program section was adapted from earlier NIOSH recommendations regarding medical surveillance of HCWs exposed to anti-neoplastic drugs and HDs. The 2010 NIOSH document, upon which USP800 is based, aims to provide information for preventing occupational exposure to antineoplastic and other HDs in health care settings, but its recommendations are general, do not establish a link between specific HDs and target organ effects, and do not meet established criteria for medical screening. Addendum 2 details how the NIOSH document informs USP 800.

Furthermore, USP 800's new provisions for a HDs medical surveillance program appear to blur the distinction between surveillance and screening. At present, WOEMA is unaware of current laws or regulations that mirror these recommendations and suggest that regulatory agencies exercise great caution in mandating specific symptom questionnaires, blood tests, or other medical screening interventions based on USP 800.

# Challenges to a Universal Screening Approach for HDs Surveillance

There are several challenges that would limit the efficacy of universal screening for exposure to HDs. First, HDs have a diverse profile of risks for injury to various target organs. Second, not all HDs pose significant risk of occupational exposure due to dosage formulations. There are currently no generalizable data that would provide specific lower and upper limit thresholds to define a significant exposure for most HDs. As such, there are no screening tests that have been proven effective for all HDs exposures, or even for many HDs. An ideal screening test would exhibit high-sensitivity and high-specificity to identify the effects of exposure prior to the development of disease. Complete blood count (CBC), liver function tests (LFTs), and urinalysis (UA) are of low-specificity and low-sensitivity for identifying disease outcomes associated with HDs exposures. Furthermore, the USPSTF offers no recommendation to screen for any malignancy with UA, LFTs, or CBC. In asymptomatic individuals, these laboratory surveillance tests are too non-specific to detect exposure, preneoplastic changes, or pre-clinical cancer. Addendum 3 provides examples of harms associated with screening asymptomatic individuals.

# Examples of Hazardous Drug Medical Surveillance at Healthcare Organizations

To date, WOEMA is aware of very few healthcare organizations that have implemented the USP 800 recommendations for medical surveillance out of concern that universal medical screening (pre-placement and periodic history, examinations and blood testing) for all exposed and unexposed employees would not be effective in detecting and preventing disease from HDs exposure.



The Journal of Occupational and Environmental Medicine (JOEM) conducted a survey of 10 academic medical centers in the United States regarding medical surveillance for HDs; 3 of 10 provided surveillance and 2 of the 3 were single hospital and not university-based. Of the three programs that offer medical surveillance, they were all voluntary, and screened employees with some combination of medical testing such as UA, CBC, liver functions<sup>18</sup>.

Healthcare organizations do rely on a wide spectrum of engineering and administrative controls to mitigate HDs exposure to HCW populations. Several institutions have informed WOEMA that they employ a rigorous environmental monitoring program, a higher level of engineering controls with closed systems for HDs, appropriate use of PPE, and routine surface swabs to detect contamination<sup>19</sup>. If contamination is detected, then a specific medical evaluation is offered to those that are potentially exposed.

Additional administrative controls include surveillance rounds, ongoing hazard identification, exposure risk assessment, medical surveillance of target populations, and post-incident examinations for uncontrolled exposures such as spills (19). Healthcare safety programs focus on educating target populations of HCWs involved with the storage, transport, compounding, and administration of HDs. These organizations follow OSHA requirements that address HDs such as the Occupational Exposure to Hazardous Chemicals in Laboratories and the Hazard Communication standard.

WOEMA believes that many hospitals and other healthcare institutions have already addressed USP 800 recommendations through implementation of upgraded engineering controls, safety policies, and standard operating procedures. However, what will likely be new for hospitals is a requirement in USP 800 calling for a medical surveillance program to monitor HD exposures and health outcomes among HCWs.

#### HCW Screening and Financial Considerations Associated with HDs Medical Surveillance

Healthcare institutions developing a medical surveillance program to monitor HDs exposures based on USP 800 recommendations for regulatory agency compliance must consider issues such as defining the exposure populations and costs associated with enrollment into a program. According to The Joint Commission, HCWs can be stratified into higher, lower, and negligible exposure populations<sup>20</sup>. Higher exposure populations are those employees with direct contact with concentrated forms of HDs such as shipping and receiving personnel, compounding personnel, and HCWs who administer these drugs to patients, especially at infusion centers. Lower exposure populations may be employees classified as environmental services workers, linen handlers, housekeeping employees, waste handlers, and any person who may cross the path of HDs. Negligible exposure populations have no contact with clinical areas such as administrative staff.

Many questions surround appropriate implementation of a USP 800 medical surveillance program such as which HCW populations should be enrolled and what program components are necessary for compliance with regulatory agencies. Decisions on these questions may affect estimates of financial costs associated with administering a USP 800 medical surveillance program. Direct costs include those associated with venipuncture, laboratory, and physician history and examination fees. Indirect costs would include approximately one hour of employee time away from work for their medical surveillance examination and costs associated with covering this employee's job duties with additional staff, unnecessary work up labs for falsely positive laboratory testings. Considering direct and indirect costs for a USP 800 medical surveillance program, estimates could vary widely depending on if a narrow population of higher-risk HCWs are enrolled compared to a broader definition that would expand surveillance to lower-risk employees.

# WOEMA Proposal for Hazardous Drugs Exposure Control Plan and Post-Exposure Evaluation

Applying USP 800 guidance pertaining to medical surveillance verbatim presents several challenges as discussed in this document. At present and in absence of very clear language, WOEMA views a medical surveillance program based on USP800 recommendations as optional.



WOEMA recommends that healthcare institutions whose employees may have occupational exposure to HDs should carry out the following steps:

- A. *A Written Plan:* The employer should prepare a written HD exposure control plan, and review and update the plan annually. Typically, responsibility for the preparation and implementation of the Exposure Control Plan will fall to the health system's safety manager, with input from various hospital committees and stakeholder groups including pharmacy, environmental services, nursing, occupational medicine and senior leadership. The following elements should be included in the written plan:
  - 1. For each work area where occupational HD exposure is reasonably expected to occur, the methods and procedures the employees are to use when handling, transporting, administering, or disposing of HDs';
  - 2. The types of PPE that employees are to use when carrying out various work tasks that include potential exposure to HDs;
  - 3. The methods that the employer will use to assure ready availability of PPE for employees potentially exposed to HDs;
  - 4. The training methods and content that will be provided to potentially exposed employees;
  - 5. The methods that the employer will use to review and modify the exposure control plan annually, and the methods the employer will use to assure effective input by representative groups of employees in that review;
  - 6. The engineering control methods (such as local ventilation and use of hoods) that the employer will use to prevent the spread of environmental contamination associated with the use of HDs;
  - 7. The methods and procedures that the employer will use to investigate exposure incidents and correct any failures in the safe handling of HDs;
  - 8. The criteria that the employer will use in assessing requests for "reasonable accommodation" made by concerned employees.
- B. *Employee Training:* Employees should receive effective training at least annually covering the following topics:
  - 1. Adverse health effects that HDs might cause as a result of occupational exposure,
  - 2. Safe work practices relevant to their specific work tasks, including the handling, transport, administration, and disposal of HDs;
  - 3. Key elements of the employer's Exposure Control Plan, including how to report health concerns or exposure episodes, including how to access occupational medicine specialists to discuss health concerns, without fear of reprisal.
- C. Annual Confidential Assessment of Employee Health Concerns: Following training, employees should be asked to document in writing whether they have personal health concerns that they would like to discuss with a physician or other health care provider; including pregnancy, reproductive health, immunity disorders, or personal medications that may produce severe immune suppression, or are used to treat cancer or organ transplant rejection. WOEMA recommends employees also be notified in writing or electronically that they may choose to discuss any questions or concerns related to exposure to HDs with an occupational medicine physician or other provider at any time, on request, and that any such discussions will be kept confidential.
  - 1. This document should conclude with a declarative statement; "Following the completion of your HDs training, if you still have questions or concerns about any of the above questions, you can discuss further with an occupational medicine physician to assess your needs for accommodation or reassignment from a high-risk area."
  - 2. Records of all such interactions between employees and medical providers should be kept confidential.
- D. **Other Preplacement or Periodic Screening:** At this time, WOEMA does not support the routine ordering of any specific diagnostic tests, without a specific individualized clinical rationale.



- E. **Follow-up and Documentation of Exposure Incidents:** WOEMA believes that exposure incidents should be viewed as sentinel events which can provide valuable feedback to the employer's safety manager about the effectiveness of the exposure control plan. Following exposure incidents, the employer should take the following steps:
  - 1. The employer should deploy knowledgeable staff, who report to the Safety Officer, to investigate the incident, searching for root causes and opportunities for improvements in the handling of HDs;
  - 2. The employee shall be offered a medical evaluation by the Employee Health Service or other occupational medicine provider. The medical provider may choose to order various diagnostic studies to characterize the exposure and to search for adverse health effects;
  - 3. Exposure incidents should be recorded on a log, with the date, location, and circumstances of the incident, together with any identified deviations from the employer's HD Exposure Control Plan. If recommended by the medical provider, the employee's name should be de-identified on the log. Any suggestions by the employee for preventing similar exposures in the future should also be recorded. This log of HD exposure incidents should be kept for a minimum of three years and should be reviewed as part of the annual update of the Exposure Control Plan.
- F. **HD Exposure Registry:** WOEMA sees great merit in the establishment of a statewide or regional Registry of HD exposure incidents but believes that the maintenance of such a registry will likely exceed the capabilities of any one employer, or group of employers. Accordingly, WOEMA encourages public health authorities to explore the establishment of such Registries, which would also be able to assist the employer's safety staff and Employee Health Service in carrying out their assessments of local data on HD exposures.



#### Addendum 1. USP Official Date Definition and Influence on Pharmacy Certification

According to the USP, the "official date" is the date by which affected users are expected to meet the requirements of a particular standard<sup>1</sup>. Ensuring compliance with the requirements of these standards is the responsibility of regulators such as the FDA, states, and other government authorities. USP has no role in enforcement. Although all USP-NF text that has reached its official date is "official text," not all official text states requirements with which compendial users must comply. Some official text is intended to assist or guide compendial users or to serve informational purposes<sup>1</sup>. The USP's quality standards for pharmacy compounding of nonsterile and sterile preparations (USP 795 and USP 797) reference the handling and administration of drugs that present physical or health hazards. Many states, including California, incorporate these USP standards into pharmacy laws and regulations<sup>2</sup>.

Furthermore, accreditation organizations such as the Joint Commission (JC) may reference USP 800 in future health system certification cycles. There is historical precedence that informs this perspective. JC develops their regulatory standards based on input from subject matter experts, government agencies such as the Centers for Medicare and Medicaid, scientific literature, and expert consensus<sup>6</sup>. According to the JC, their standards aim to be measurable, promote quality care and patient safety, have a positive impact on health outcomes, and meet or surpass law, regulation, or legislation<sup>6</sup>.

Currently, the JC oversees hospital-based compounding pharmacies through their voluntary Medication Compounding Certification which recognizes compliance with USP 795 and USP 797. Several states have enacted legislation that requires compounding pharmacies within these states to conform to USP 795 and USP 797 standards<sup>7</sup>. Given these precedents, JC's Medication Compounding Certification is expected to update its evaluation protocols to include USP 800 in order to extend health and safety protections to all HCWs who may be exposed to HDs. This is in addition to the employees working only in compounding pharmacies, as is currently the case under USP 795 and USP 797.

#### Addendum 2. Non-Specific Nature of Medical Screening for Hazardous Drugs

Medical surveillance describes activities that are designed to identify markers of exposure in workers potentially exposed to a hazard. Medical surveillance augments and evaluates protection from engineering controls, administrative controls, good work practice, PPE, and worker education. The purpose of medical surveillance is to identify the earliest reversible biologic effects so that exposure can be reduced or eliminated before irreversible damage occurs. Surveillance should be systematic and ongoing.

Medical screening is a complementary activity that is designed to detect early signs of work-related illness by administering tests to apparently healthy persons in a cross-sectional approach. Unlike medical surveillance that is systematic and ongoing, medical screening will often be time-limited. Medical screening tests should have a high-sensitivity for detecting preclinical indicators of disease and should be administered only when the prevalence of the disease outcome is high enough to justify screening. Other important factors that must be considered before embarking on widespread medical screening include test specificity, safety, and cost-effectiveness.

Even though USP 800's provisions for medical surveillance chapter were adapted from NIOSH, the NIOSH recommendations stress that the choice of specific surveillance tests should be appropriate to the exposure. At this time, no single biological marker appears suitable for all of these drugs, because the various classes of HDs differ in their modes of action and their effects on specific target organs<sup>8</sup>.

#### **NIOSH Recommendations for Screening Exposures to Hazardous Drugs**

In 2013, the California Legislature directed the Cal/OSHA Standards Board to adopt a new Cal/OSHA standard for control of occupational hazards due to exposure to antineoplastic drugs in healthcare facilities (Assembly Bill 1202, enacted October 9, 2013). The bill requires that the standard "to the extent feasible, shall be consistent with and not exceed recommendations in the NIOSH 2004 alert entitled 'Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings' as updated in 2010." This NIOSH document recommended the following<sup>9</sup>:



For exposed healthcare workers:

- 1. In addition to preventing exposure to hazardous drugs and carefully monitoring the environment, make medical surveillance an important part of any safe handling program for hazardous drugs.
- 2. If you handle hazardous drugs, participate in medical surveillance programs provided at your workplace.
- 3. If you handle hazardous drugs but have no medical surveillance program at work, see your private health care provider for routine medical care. Be sure to inform him or her about your occupation and possible exposures to hazardous drugs.
- 4. Refer to the OSHA Technical Manual: Controlling Occupational Exposure to Hazardous Drugs, Section VI Chapter 2 [OSHA 1999]. This document currently recommends that workers handling hazardous drugs be monitored in a medical surveillance program that includes the taking of a medical and exposure history, physical examination, and some laboratory tests.

For medical providers:

- Use a worker's past exposure history as a surrogate measure of potential exposure intensity.
- If you are an occupational health professional who is examining a drug-exposed worker, ask questions that focus on the worker's symptoms relating to the organ systems that are known targets for the hazardous drugs.
- For example, after an acute exposure such as a splash or other drug contact with skin or mucous membranes, focus the physical examination on the exposed areas and the clinical signs of rash or irritation to those areas.
- Include a complete blood count with differential and a reticulocyte count in the baseline and periodic laboratory tests. These may be helpful as an indicator of bone marrow reserve.
- Monitor the urine of workers who handle hazardous drugs with a urine dipstick or a microscopic examination of the urine for blood. Several antineoplastic agents are known to cause bladder damage and blood in the urine of treated patients.

WOEMA notes that (apart from the recommendation about a baseline complete blood count, differential, and reticulocyte count) these recommendations are quite general. NIOSH recommends that the exposed worker be questioned about "symptoms relating to the organ systems that are known targets for the hazardous drug." However, these NIOSH recommendations do not specify any particular set of questions, do not specify what symptoms are likely, and furthermore do not assert that good data exists to link questionnaire responses with likely organ toxicity.

The World Health Organization<sup>10, 11</sup> has published criteria for adopting medical screening, among which are the following:

- The objectives of screening should be defined at the outset;
- The natural history of the health condition including development from latent to frank disease, should be well understood, and the condition should be recognizable during its latent or early symptomatic stage;
- There should be a suitable test or examination for detecting the condition during this latent or early stage, with scientific evidence of screening program effectiveness;
- There should be a recognized treatment or other intervention;
- The cost of case-finding, taking account of the rates of false positive and false negative tests, should be reasonably balanced in relation to expenditures for medical care as a whole;
- Case-finding should be on a continuing basis;
- The overall benefits of screening should outweigh the harm.

WOEMA is concerned that the 2010 NIOSH recommendations for medical surveillance fulfill none of the above criteria, and therefore suggests that the Standards Board and regulatory agencies exercise great caution in mandating specific symptom questionnaires, blood tests, or other medical screening interventions.



#### Addendum 3. Harms Associated with Screening Asymptomatic Individuals

Evidence suggests that screening tests for asymptomatic conditions can do more harm than good. Several examples include:

- **Complete Blood Count (CBC)** The usefulness of CBC in asymptomatic patients as a case-finding tool was assessed in 595 patients at their initial clinical visit to a university-based outpatient primary care and general internal medicine clinic. 1540/2378 tests were classified as "routine", defined as tests conducted, but not indicated for diagnostic or management purposes in asymptomatic patients. Percentages of abnormal test results were: leukocyte count 7.6%, hemoglobin 5.8%, mean corpuscular volume 7.9%, platelet count 4.5%. Of all CBC tests, only 3 patients received new diagnosis. An average of two additional visits were necessary because of abnormal results on routine tests<sup>12</sup>.
- Urine dipstick Urinary abnormalities are a common finding in primary care. Prevalence of hematuria in asymptomatic adult patients range from 1% 13%. Hematuria is confirmed if 3 or more erythrocytes per high-power field are identified in at least 2/3 samples<sup>13</sup>.
- Urinalysis (UA) 610 patients underwent urine testing at their initial clinic visit to a university-based outpatient primary care and general internal medicine clinic. 427/610 of these tests were considered "routine" and performed in asymptomatic patients. UA abnormalities were identified in 17% and consisted of vaginal contamination (3.0%), pyuria (4.7%), hematuria (3.3%), proteinuria (1.4%), bilirubinuria (1.4%), glucosuria (1.2%), ketonuria (0.9%), and casts (0.7%). Abnormal findings lead to a change in management in only three patients<sup>14</sup>.
- Liver Function Tests (LFTs) Biochemical screening of healthy, asymptomatic people reveals that up to 6% have abnormal liver enzyme levels. Prevalence of liver disease in general population 1%. One-third of individuals with chronic hepatitis C have normal LFTs, as do many cirrhotic patients<sup>15</sup>.
- LFTs LFTs are often ordered as part of a screening examination or general workup. In 1864 adult U.S. men and women assessed from National Health and Nutrition Examination Survey (NHANES) data, the following LFT abnormalities were identified: AST 6.2%, ALT 5.9%, GGT 17.9%, Alkaline Phosphatase 11.7%, bilirubin 9.3%. Of those that underwent a second test in response to these abnormalities (intraindividual reliability), more than 30% of AST, ALT, and bilirubin abnormalities were normal on the second test<sup>16</sup>.
- LFTs The American Gastroenterological Association in its Technical Review of the Evaluation of Liver Chemistry Tests reported that elevation of LFTs occurs in 1 4% of the asymptomatic population and that most elevations do not represent liver disease<sup>17</sup>.

These laboratory tests reveal lab abnormalities that occur commonly in the population for reasons other than chemotherapy exposures. Test-retest reliability is variable. Taking these studies into account, an expected result of screening of among one-thousand HCWs would yield abnormal results in 62 AST, 59 ALT, 179 GGT, 117 alkaline phosphatase, and 93 bilirubin tests, leading to a total of 510 LFT abnormalities. In one thousand screened HCWs, up to 130 will have hematuria. These abnormal results would require further workup leading to harms of additional expense, potential morbidity, and anxiety. Even if abnormalities were not common, no correlation has been shown between occupational HDs exposures and laboratory abnormalities. Conversely, a normal test provides no basis for reassurance.

As discussed above, the problem with universal medical screening is the non-specific nature of testing, and the resulting subsequent follow up for abnormal test results that often have no connection to occupational HDs exposure.

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**ABOUT WOEMA:** The Western Occupational and Environmental Medical Association (WOEMA) is a regional component of the American College of Occupational and Environmental Medicine (ACOEM), and is dedicated to high quality medical care and ethical principles governing the practice of occupational medicine. WOEMA represents over 500 physicians and healthcare professionals in five western states (AZ, CA, HI, NV, UT). It is the mission of WOEMA to promote and protect the health of people at work and in their environment through preventive service, clinical care, research, and evaluation. WOEMA is committed to assuring a safe work place, minimizing worker injury and illness, and serving as leaders, educators, collaborators and facilitators in preventing and resolving marketplace health problems. We value and focus on preventive medicine as well as the expeditious and effective management of illness and injury.

