Dragon, Karen E. (CDC/NIOSH/EID)

From: Timothy Tyler, PharmD [TTyler@aptiumoncology.com]
Sent: Friday, September 23, 2011 2:16 AM
To: NIOSH Docket Office (CDC)
Subject: Docket number NIOSH-240

This comment is in response to the "Request for Information: Announcement of Carcinogen and Recommended Exposure Limit (REL) Policy Assessment"

I have been an oncology Pharmacist for 18 years, all of it while also being the director responsible for pharmacy services for a Comprehensive Cancer Center. I am commenting because I am very concerned with the limitations of current NIOSH policies on occupational exposure to carcinogens as well as reproductive hazards and neurotoxins. I have lectured on this subject nationally for the past decade after having participated in trials evaluating hazardous exposure to employees and others exposed to antineoplastics. I have become even more passionate about this after reviewing the work of the former OSHA director Dr. Melissa MacDiarmid that demonstrates changes in genetic mutations brought about exposure concentrations similar to those found in the oncology workplace (be it physician office or hospital outpatient clinic). My primary concern stems from both pharmacy and nursing staffs handling these drugs in large amounts and multiple products throughout the workday resulting in exposures extremely difficult to quantify but far in excess of what would be seen in a manufacturing setting wherein a single or perhaps second agent are manufactured. In my clinical experience I may see over 50 agents in a single week and this continues without break throughout the oncology clinician's career. As related to manufacture we have clearly demonstrated in the clinical literature that vials are in fact routinely contaminated and the only response from the manufacturing industry to date has been to offer to amend the MSDS (Material Safety Data Sheets). There are easy solutions that requiring clean vials would provide but at present the manufacturers feel that the FDA might not accept a cleaning process that might damage the drug inside and they are not willing to incur this one time set-up expense because it is not "required".

At present the only viable option to reduce exposure limits is by employing a Closed System Transfer Device (CSTD) of which there are several products purporting to provide protection but at present only one that has demonstrated a consistent reduction in exposure via numerous studies (some of which I participated and published on). This expensive burden of this protection falls solely to the health care providers with no chance of offsetting this cost as there are no regulations to require protection and no exposure limits to identify a reasonable goal of successful mitigation.

As to the specific queries that NIOSH proposes:

1. NIOSH should most definitely implement a much broader policy that will identify and classify carcinogens, reproductive hazards and neurotoxic agents.

2. IARC has already put in place the categorizations for determining carcinogenic potential in humans so the installation of that standard would be appropriate. Since data is still lacking for many of the antineoplastic drugs, some effort to categorize similar agents that produce similar negative health effects is warranted to protect workers throughout the clinical trials and early commercialization of antineoplastics.

3. I personally believe that the REL of 1 in 1,000 working lifetime risk in a manufacturing setting of that agent but in a setting where multiple agents are used simultaneously, the actual exposure is radically

higher in a workday let alone a career. Some consideration should be given to tracking actual exposure or total exposure perhaps in grades (Grade A = low such as 1-3 agents per workday to Grade F = in excess of 25 agents per workday) so as not to make the recording burden so great as to make compliance impossible.

4. The use of "extent feasible" is of concern as it can be vague and deemed to be "not feasible" for industry to appropriately respond to this problem. Working in a facility that generates hundreds of chemotherapy admixtures weekly, I have incurred tremendous expense making sure that PPE (personal Protective Equipment) is available for all workers (technicians, pharmacists and nurses) including gowns, gloves, appropriate clean rooms and equipment as well as CSTDs (Closed System Transfer Devices). The use of "safe" exposure levels to antineoplastic drugs have not been established and no practical way of measuring exists other than wipe testing which is expensive and extremely cumbersome. Seeing that, the use of containment devices such as CSTD is warranted where measuring is not practical but every study to date has demonstrated the problem exists. Their expense is significant when not able to be offset and when as a member of the APC Federal Advisory Panel or a petitioner to the RUC (relative use committee) for HCPCS there has been no interest in creating a code so that providers can pass along this legitimate cost of protecting the clinicians involved in treating cancer patients. I am concerned that again this issue will be ignored and clinicians will be at risk.

5. I believe that I have already made the case that action levels which derive from the manufacturing sector are single agent focused and clinicians are knee-deep in a myriad of agents on an ongoing basis. It would seem appropriate to extrapolate on data already in the literature that gives us some insight into the dangers of lifetime dosing and exposure for treated patients – we do need exposure levels but at present that cost would still only tell us what we already suspect/know and I would rather spend the limited resources in healthcare on a solution such as containment strategies. Therefore additional effort must be made to provide mechanisms to pay for the protective measures needed to at least reduce the exposure and allocate the costs to include the responsibility of the drug manufacturers. This can only be done when tracking and containment of exposure is a requirement. The use of CSTDs to date is the only way I have seen (since 1999) that I can demonstrably reduce contamination in the work environment. In addition, the simple provision of a plastic encasing material that is contamination free or washing the darn vial is a great alternative to the mess we currently face.

I appreciate the opportunity to comment. *(please note my comments do come in on time as I am on the west coast so it is still 9/22/11 my time).*

Sincerely,

Timothy Tyler, PharmD, FCSHP

A concerned Oncology Pharmacist