

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

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**From:** Werner, Katherine [Katherine.Werner@ncpanet.org]  
**Sent:** Monday, August 27, 2007 6:27 AM  
**To:** NIOSH Docket Office (CDC)  
**Subject:** 105 - HazDrug Update Comments  
**Attachments:** NHIA on NIOSH revisions-FINAL.doc

Attached is a letter from the National Home Infusion Association.

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Vice President, Professional Affairs  
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[www.nhia.org](http://www.nhia.org)

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August 20, 2007

NIOSH Mailstop: C-34  
Robert A Taft Lab.  
4676 Columbia Parkway  
Cincinnati, Ohio 45226

Dear Sir/Madam:

The National Home Infusion Association (NHIA) is pleased to submit comments pertaining to the proposed update to the list of hazardous drugs for the *NIOSH Alert on Hazardous Drugs*. NHIA is a national membership organization for clinicians, managers and pharmacy organizations providing infusion therapy services to patients in home care and outpatient settings.

NHIA appreciates that the National Institute for Occupational Safety and Health (NIOSH) will hold a public meeting and commends the agency for providing this forum to allow public and stakeholder input in the process for defining hazardous drugs and updating the list of these drug products. NHIA plans to attend the August 28, 2007 public meeting to provide oral comments—and also offers the following comments of concern, submitted by NHIA members.

NHIA members support the efforts of NIOSH in developing standards on the safe handling of hazardous drugs, as the safeguarding of healthcare workers is of utmost importance to organizations providing home and ambulatory infusion therapy. However, NHIA members have expressed significant concern about NIOSH's proposed update to Appendix A, which is a list of drugs classified as not hazardous and the list of drugs classified as "fitting hazardous":

- When a drug is classified as hazardous, strict standards of practice must be met for handling, storage, preparation, transport, administration and disposal of these drug products. Therefore, the implementation of these standards increases the cost of providing these drug therapies significantly—making it exceptionally critical to ensure that the drugs listed as hazardous truly warrant that classification.
- NHIA believes that many of the proposed drugs listed in Appendix A as "fitting hazardous" do not appear to have specific and clearly articulated scientific evidence substantiating that they do indeed propose a risk to healthcare workers.
- For instance, though it is widely believed that monoclonal antibodies are not "hazardous," there are several moABs on NIOSH's "fitting hazardous" list.
- Since some moABs are used in the treatment of cancer, they have been designated by some as "antineoplastics,"—yet, the mechanism of action of monoclonal antibodies is very different from traditional chemotherapy.
- Traditional antineoplastics act on all actively dividing cells, however moABs affect cells that carry the targeted antigen on their cell surface. It is believed by many experts that they have too large a molecular size to be absorbed into the skin and do not directly affect DNA.

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- Also of concern to NHIA members is the listing of Rituximab (Rituxan) and natalizumab (Tysabri) on the "fitting hazardous" list and the listing of trastuzumab (Herceptin) and infliximab (Remicade) on the "not fitting hazardous" list. These are very similar drugs and there is no rationale provided as to why each has been designated as such. These agents are often provided to patients by pharmacies providing therapies in the home and ambulatory setting.

NHIA clearly supports the designation as hazardous for neoplastic agents and other drug products designated or known to be probable carcinogens by the World Health Organization's International Agency for Research on Cancer (IARC) and the National Toxicology program (NTP). However, NHIA strongly believes that improper designation of drugs as hazardous places an undue burden on providers of home and ambulatory infusion.

NHIA members are encouraging NIOSH to use a sensible, consistent, defined approach based on a review of existing science when listing drugs as hazardous.

Thank you for considering the comments of NHIA and our membership. If you have any question regarding these comments, please contact me at 703-867-1090 or [Katherine.werner@nhia.org](mailto:Katherine.werner@nhia.org).

Sincerely,



Katherine Werner, MHA, BSN, CRNI  
Vice President, Professional Affairs