



**SafeBiologics**

ALLIANCE *for* SAFE BIOLOGIC MEDICINES

16 April 2018

Submitted via e-mail to: [hazardousdrugs@cdc.gov](mailto:hazardousdrugs@cdc.gov)

NIOSH Docket Office  
Robert A. Taft Laboratories  
MS-C34  
1090 Tusculum Avenue  
Cincinnati, OH 45226-1998

***RE: Alliance for Safe Biologic Medicines comments on NIOSH Hazardous Drugs List Additions for 2018; Reference CDC-2018-0004 and Docket Number NIOSH 233-B***

The Alliance for Safe Biologic Medicines (ASBM) appreciates the opportunity to comment on the proposed additions to the NIOSH Hazardous Drug List for 2018 as posted to the Federal Register in February of this year.

ASBM is an organization composed of diverse healthcare groups — from patients to physicians, medical innovators, and others who are working together to ensure patient safety is at the forefront of biologic and biosimilar policies.

We respectfully suggest that **therapeutic proteins of large molecular weight are categorically excluded from the NIOSH Proposed List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings**. Therefore, we recommend that **blinatumomab, bevacizumab, and trastuzumab, and darbepoetin alfa are removed from the current NIOSH Proposed List**.

As we understand it, the routes of exposure for healthcare workers are mainly inhalation, ingestion, and skin contact. Large molecular weight proteins pose very little risk from exposure via any of these routes. These proteins are too large to be absorbed through skin contact, and if ingested, they would be destroyed by digestion; if inhaled, the pulmonary system would prevent absorption. Consequently, these drugs are all administered by injection. The only potential risk to healthcare workers is of an accidental needle stick, which would not inject a pharmacologically active dose.

It is for these reasons that ASBM recommends that darbepoetin alfa, blinatumomab, bevacizumab or trastuzumab are removed from the NIOSH Proposed List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2018, as these medications do not pose a realistic hazard to the health care workers handling them.

Thank you for the opportunity to comment.

Sincerely,

A handwritten signature in black ink that reads "Michael S. Reilly". The signature is written in a cursive style with a prominent loop at the end of the last name.

Michael Reilly  
Executive Director  
The Alliance for Safe Biologic Medicines