SafeBiologics
ALLIANCE *for* SAFE BIOLOGIC MEDICINES

30 July 2020

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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 List of Hazardous Drugs in Healthcare Settings, 2020* ; Reference CDC-2020-0046 and NIOSH-233-C

The Alliance for Safe Biologic Medicines (ASBM) appreciates the opportunity to comment on the proposed additions to the NIOSH Hazardous Drug List for 2020 as posted to the Federal Register in February of this year.

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

ASBM was among several organizations which had previously issued comments arguing against the inclusion of several monoclonal antibodies on the NIOSH List of Hazardous Drugs in Healthcare Settings. These comments read, in part:

> Monoclonal antibodies (*i.e.,* therapeutic proteins) are of such a large molecular weight that they do not pose a realistic risk to healthcare workers. For example, monoclonal antibodies "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."

This comment was referenced, and responded to thusly by NIOSH in the May 1, 2020 Federal Register:

> Accordingly, the monoclonal antibodies bevacizumab, blintumomab, and trastuzumab should not be placed on the *List,* and pertuzumab should be removed from Table 1.

While as NIOSH's response indicated, "other monoclonal antibodies that have properties meeting the NIOSH definition of a hazardous drug remain on the List", ASBM appreciates NIOSH acknowledging and responding to our comments, and revising the list accordingly with respect to several of the drugs identified.

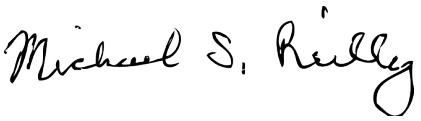
The placement of these medicines on the NIOSH List would have compelled healthcare workers to take extraordinary precautions when handling and dispensing these drugs- including stringent facility, personal protective equipment, training, and waste disposal requirements specified in standards such as USP chapter <800>. This would have imposed a significant burden on health

care providers, imposing requirements for safe receipt, storage, preparation, and administration. These burdens would have increased health care costs unnecessarily and negatively affected access to these new, breakthrough therapies; such as by limiting which sites these critical medications are available and can be administered, such as infusion clinics and a physician's office setting.

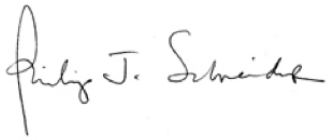
ASBM recognizes that balancing health care worker safety against health care cost impact and patient access is a complicated consideration in policy development, and we trust that NIOSH will continue to make good decisions as it attempts to strike the proper balance during its deliberations.

Thank you for the opportunity to comment.

Sincerely,



Michael Reilly
Executive Director
Alliance for Safe Biologic Medicines



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