

June 25, 2020

John Howard, MD, MPH, JD, LLM, MBA
NIOSH Docket Office
Robert A. Taft Laboratories
1090 Tusculum Avenue
Cincinnati, OH 45226

Re: Hazardous Drugs: Draft NIOSH List of Hazardous Drugs in Healthcare Settings, 2020;
Procedures; and Risk Management Information; CDC–2020–0046 and NIOSH–233–C

Dear Dr. Howard,

On behalf of the Endocrine Society, I am writing to request that liraglutide be removed from the Hazardous Drugs in Healthcare Settings List.

Founded in 1916, the Endocrine Society is the world's oldest, largest, and most active organization dedicated to the understanding of hormone systems and the clinical care of patients with endocrine diseases and disorders. The Society's membership of over 18,000 includes physicians who prescribe liraglutide to their patients to treat diabetes or obesity and researchers searching for new treatments to treat these diseases.

In 2014, liraglutide, a GLP-1 receptor agonist, was placed on National Institute for Occupational Safety and Health's (NIOSH's) Hazardous Drug List because it deemed the drug to meet its criteria for reproductive, carcinogenic and teratogenic hazard. This designation was based on findings from the pre-clinical study of the drug in rodents. More than 10 years of human data in clinical trials and real-world evidence has shown no evidence that liraglutide poses a safety risk to healthcare workers. Furthermore, accidental exposures to liraglutide in an occupational setting are highly unlikely, as it is administered via a pre-dosed injectable pen. As a polypeptide, it has a relatively large molecular size, limiting absorption through the skin or aerosolization.

Placement of liraglutide on the Hazardous Drug List may influence prescribing habits and, consequently, influence patient care. The Food and Drug Administration does not require special handling instructions in the prescribing information, but Lexicomp and UpToDate, citing NIOSH's Hazardous Drug List, suggest that "double gloves and a protective gown are required during administration." This guidance has raised concern among prescribing physicians and pharmacists about the safety of routine handling of the drug.

We support the intent behind NIOSH's Hazardous Drug List of keeping workers safe from unnecessary harm, but do not believe that available evidence points to a need for the inclusion of liraglutide. Therefore, we respectfully ask that you remove the drug from the



list. If we can provide any additional information, please contact Mila Becker, JD, Chief Policy Officer, at mbecker@endocrine.org.

Sincerely,

A handwritten signature in black ink that reads "Gary D. Hammer".

Gary D. Hammer, MD, PhD
President
Endocrine Society