Fraud Alert Pertaining to the Distribution of Ozempic, Semaglutide, and Tirzepatide

The following is a recent <u>Pharmaceutical Cargo Security Coalition</u> (PCSC) alert regarding fraudulent activity surrounding the distribution of the pharmaceutical products Ozempic, semaglutide, and tirzepatide that has been occurring within the industry.

The Food and Drug Administration (FDA) Office of Criminal Investigations (OCI) has identified cases where wholesalers (licensed and unlicensed) are offering to sell Ozempic with large discounts [anywhere from Wholesale Acquisition Cost (WAC) -10 to WAC -40]. In some instances, the investigation has revealed it to be a "No Delivery Scheme," where the purchaser would make payment and not receive the product. In other instances, the product offered for sale is diverted from foreign countries or counterfeit. In some of the transactions currently under investigation, it is suspected that the sellers are involved in account takeover, in which they obtain the licensing, management, and location information from licensed wholesalers and pretend to be employees of such companies. This information is easily accessible online.

The sellers offer sufficient information and documentation to give the appearance the transaction is legitimate. The transaction requires full or partial payment upfront via wire transfer, non-disclosure agreements, establishment of purchase accounts, and on occasions, have involved fraudulent transaction statements (old pedigree). In some of the cases, the offer comes from a company that does not distribute temperature-controlled drug products. It is important to verify the legitimacy of the offer and that the company offering the product for sale and distribution actually distributes Ozempic or other semaglutide drug products.

For your awareness, the FDA is also working on investigations involving the sale of semaglutide and tirzepatide online. It appears that most of the products offered for sale are counterfeit. These products, however, are not made to look like legitimate Ozempic pens; they are sold in the form of injectable vials and labeled as semaglutide.

Lastly, the FDA has also found several companies importing a salt form of semaglutide (semaglutide sodium and acetate) for distribution and sale to compounding pharmacies. The FDA issued a guidance indicating the salt form of semaglutide is prohibited from its use in compounding human drugs. This bulk API is purchased and distributed to compounding pharmacies, who then compound semaglutide pursuant to individual prescriptions and in bulk, which has resulted in patients suffering adverse events.

<u>This illicit activity has been detected at both the distributor and pharmacy levels.</u> If you have been approached about the purchase/distribution of Ozempic, semaglutide, tirzepatide, or the salt form of semaglutide (and you haven't spoken to the PCSC already), please contact Chuck Forsaith at <u>cforsaith@hda.org</u> or 401-623-1344, and he will put you in touch with the OCI agent leading the investigation.