The Partnership for SAFEMEDICINES.org®

WORKING TOGETHER TO PROTECT THE SAFETY OF YOUR PRESCRIPTION DRUGS

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Docket # FDA-2024-N-5468

The Partnership for Safe Medicines, America's leading nonprofit organization studying the danger of counterfeit medicines to American patients, writes today to endorse the proposed changes to the reporting system for medical adverse events that is a central part of the MedWatch Program.

In particular we are excited to endorse the questions that would add the collection of Where and When a product involved in an adverse event was purchased. These are shown in the following areas:

> Changes proposed for Form FDA 3500
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> "Add field for Where (e.g., website, pharmacy/store/state of purchase) was the suspect product obtained and When (date) was the suspect product obtained"
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> Changes proposed for Form FDA 3500B
>
> "Add a field for Where (e.g., website, pharmacy/store/state of purchase) was the suspect product obtained and When (date) was the suspect product obtained. Propose addition of fields to capture 'Place of Purchase Name,' 'Web Page/URL (if purchased online),' and 'Place of Purchase City and State/Province'"

Pharmacovigilance is a vital safety activity accomplished by FDA staff as well as state regulators, independent researchers, and even media and watchdog groups such as PSM. The data in FAERS is a valuable resource to all these parties and its public visibility contributes to a trustable, transparent healthcare system.

One recent example of the value of FAERS to public safety is the paper, "Safety analysis of compounded GLP-1 receptor agonists: a pharmacovigilance study using the FDA adverse event reporting system" published by Dr. Kenneth L. McCall[1]. This paper used FAERS data to compare adverse events for compounded GLP-1's vs traditionally manufactured GLP-1's. It found that compounded GLP-1 RAs may be associated with a higher odds of AEs, safety concerns, and product quality issues compared to non-compounded products.

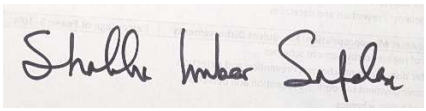
As valuable as this research is, it would be even more valuable if the researchers were able to differentiate where the products that caused the adverse events came from. Some of these compounded GLP-1's with higher adverse events may be associated with illegal online peptide vendors instead of 503B outsourcing facilities, a fact

[1] McCall KL, Mastro Dwyer KA, Casey RT, Samana TN, Sulicz EK, Tso SY, Yalanzhi ER, Piper BJ. Safety analysis of compounded GLP-1 receptor agonists: a pharmacovigilance study using the FDA adverse event reporting system. Expert Opin Drug Saf. 2025 Apr 29:1-8. doi: 10.1080/14740338.2025.2499670. Epub ahead of print. PMID: 40285721.

not discernible with the existing FAERS data. With the addition of product sourcing information, more insightful research is possible, resulting in better future health policy recommendations.

We heartily endorse these additions to the adverse event reporting system, and thank you for your consideration.

Sincerely,



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