



BY ELECTRONIC MAIL

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Dear Doctors Throckmorton, Verbois, and Jung:

As the leading advocate for protecting patients from counterfeit medicines, the Partnership for Safe Medicines (PSM) could not be more excited about the implementation of this set of DSCSA goals. PSM is a cheerleader for the DSCSA's rollout and for over a year we have been delivering free continuing education courses at state pharmacy association annual meetings to train pharmacists about their responsibilities under the system. We are writing today to urge the FDA to require that pharmacists have access to complete transaction histories until the fully electronic information exchange system is ready.

Even before the DSCSA was fully implemented, pharmacists have used DSCSA data to identify and quarantine unsafe HIV medication. In July 2021, DSCSA data showed that counterfeit HIV medication was sent to a Texas pharmacist investigating a price discrepancy. A very brief inquiry by the pharmacist uncovered counterfeit HIV medication using the DSCSA's serialization and record keeping requirements.<sup>1</sup> It is a testament to the DSCSA that this dangerous medication was revealed and quarantined from the public even when the pharmacist in this situation wasn't pursuing a safety inquiry. The key to his discovery was the requirement that the vendor deliver

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<sup>1</sup> "Drugmaker Gilead Alleges Counterfeiting Ring Sold Its HIV Drugs," Joseph Walker and Corinne Ramey, *The Wall Street Journal*, January 18, 2021, [www.wsj.com/articles/drugmaker-gilead-alleges-counterfeiting-ring-sold-its-hiv-drugs-11642526471](http://www.wsj.com/articles/drugmaker-gilead-alleges-counterfeiting-ring-sold-its-hiv-drugs-11642526471).



him the complete transaction history. Upon discovery of the fraud, the pharmacist quarantined the medicine and it was not dispensed to vulnerable patients. The wholesaler who sold it to him is now under federal indictment.<sup>2</sup>

Access to the complete transaction history makes it easier for pharmacists to detect fraudulent transactions. For example, many pharmaceutical manufacturers of patented medication only sell their products to a small set of first-sale distributors in the United States. Falsified transaction logs that show a sale to an unauthorized first-sale distributor allow a pharmacist to quickly reveal fraud. In the Texas case mentioned above, the pharmacist used the full transaction log to quickly identify the supply chain participant most likely to provide a quick answer (a prime wholesaler with a strong commitment to DSCSA implementation) and the fraud was revealed.

When the DSCSA's final deadline, currently scheduled for November 2023, is enacted, full transaction histories will no longer be required to be given to pharmacists. When this happens the wholesalers who sell to pharmacists will only be required to provide the entity they purchased the medicine from. This is how the DSCSA has always been expected to operate, and it is a fair tradeoff. In a system that has gone fully electronic, it will be easier to conduct tracing investigations and a complete transaction log will not be as critical.

With advocates from all parts of the supply chain urging the FDA to postpone the November deadline, it seems likely that FDA is already contemplating a phased delay. Many of the participants have urged that the requirement to provide a complete transaction history upon sale to stay in place until the system goes fully electronic. PSM strongly urges the FDA to keep the complete transaction history requirement in place throughout any phased delay until the entire supply chain is ready to switch to the "one up one down" method of electronic transaction information transmission.

Keeping this requirement in place will ensure that pharmacists have the easiest access to the provenance of any medication they purchase, and make it as easy as possible to validate the medicine's authenticity.

We would welcome the opportunity to assist FDA staff in any way on this topic. Feel free to contact PSM through our Executive Director, Shabbir Imber Safdar at [shabbir@safemedicines.org](mailto:shabbir@safemedicines.org).

Shabbir Imber Safdar  
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<sup>2</sup> "United States v. Steven Diamantstein, Court docket: 3:23-CR-511-MAS, [/www.justice.gov/criminal-vns/case/united-states-v-steven-diamantstein](https://www.justice.gov/criminal-vns/case/united-states-v-steven-diamantstein).