PREMIER TRANSFORMING HEALTHCARE TOGETHER®

August 11, 2014

Ms. Leslie Kux
Assistant Commissioner for Policy
Division of Dockets Management (HFA-305)
[Docket No. FDA-2014-D-0609]
Food and Drug Administration

Submitted electronically to: http://www.regulations.gov

Re: Draft Guidance for Industry; Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification [Docket No. FDA-2014-D-0609]

Dear Ms. Kux:

On behalf of the Premier healthcare alliance, we appreciate this opportunity to submit comments regarding the above cited Food and Drug Administration (FDA) draft guidance and the related information collection provisions.

Premier Inc. is a leading healthcare improvement company, uniting an alliance of more than 3,000 U.S. hospitals and 110,000 other providers to lead the transformation to high quality, cost-effective healthcare. With integrated data and analytics, collaboratives, supply chain solutions, and advisory and other services, Premier enables better care and outcomes at a lower cost. Principally owned by hospitals and health systems, Premier is passionate about transforming American healthcare.

A key component of our alliance is the Premier *Pharmacy* Program, which combines essential clinical data with purchasing power to deliver reduced costs, improved quality and safety and increased knowledge sharing with other healthcare professionals. Sourcing committees made up of clinical experts from our member hospitals help evaluate current and emerging pharmaceuticals for contracting.

Premier offers a field team of highly qualified pharmacists to help our members enhance their use of medications. Our field experts provide clinically appropriate savings strategies that reduce overall costs and enhance the safe use of medication therapy, analyze high-volume, high-cost drugs and benchmark prescription practices that can help other hospitals improve their performance. Additionally, Premier often acts in a support role for our member facilities, providing guidance on issues of importance to them.

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Premier's pharmacy contract program includes more than 170 suppliers and more than 12,000 different products making it one of the largest of the group purchasing organizations (GPOs). The pharmacy contracting team is guided by a National Pharmacy Committee comprised of 18 members who make decisions surrounding product additions and contracted suppliers. Today we are writing to you on behalf of our members and the recommendations of a Premier pharmacy member work group (Premier Pharmacy Affairs Subcommittee) that reviewed the *Draft Guidance for Industry; Drug Supply Chain Security Act Implementation.*

Identification of suspect and illegitimate products

The draft guidance devotes considerable attention to the identification of suspect product even though a notification obligation is not triggered by suspect products, only by a determination that a product is illegitimate. In this regard, we would encourage the FDA to state clearly in the final guidance that there is no obligation to report suspect product. The current title of the guidance, "Identification of Suspect Product and Notification," might be interpreted to mean that there is an obligation to provide notifications regarding suspect products.

We would also point out that investigation of a suspect product could be exhaustive and require considerable time and effort on the part of a dispenser or other party in the drug supply chain. In this regard, we note that the burden estimates relating to completion of Form FDA 3911 and notification of trading partners obviously do not take these investigation-related efforts into account, focusing narrowly on paperwork completion tasks and notification once a determination has been made that a suspect product is illegitimate. This significantly underestimates the burden of complying with the notification requirements.

More importantly, we believe that the FDA should indicate what central resources might be available to dispensers and others in the supply chain that would assist them in monitoring the drug supply chain, watching out for suspect products, and determining whether a given suspect product might be illegitimate. For example, since the FDA will be receiving notifications of illegitimate products, does the agency intend to make this information available to the public, perhaps in some searchable database? We fear that a downstream dispenser might not have sufficient resources or expertise, by itself, to assess whether a suspect product is or is not illegitimate. Similarly, what role, if any, will the FDA play in assessing whether a product that is the subject of a notification of illegitimacy is, in fact, illegitimate, and alert stakeholders to this independent determination?

The issue of drug shortages

The Premier alliance is concerned that notifications of illegitimate product in cases where that product is in short supply could have serious consequences if not addressed promptly. We note that the termination

process in the draft guidance envisions that the FDA might need to act more promptly (within 10 business days) if the trading partner making the request for termination believes that exigent circumstances require expedited consideration (e.g., a potential drug shortage). However, draft Form FDA 3911 does not provide an easy mechanism, such as a check-box, for the request to signal that such prompt action is needed, and no dedicated section of the form for describing exigent circumstances, if any. We fear that a description of exigent circumstances in the body of the request might get lost.

More importantly, there is no similar "exigent circumstances" approach following initial notification of illegitimate product, even though such notification might trigger product hoarding or even panic among users of the product until the situation is stabilized and an "all clear" is sounded. We wonder, therefore, what plans the FDA might have with respect to its follow-up actions when it is notified about determinations of illegitimate product. Is the FDA developing a specific protocol for addressing these notifications, especially when they relate to products in short supply? If so, we think that the final guidance should provide more information about this. If not, we would urge the FDA to consider developing such a protocol, especially since products in short supply are likely to be at heightened risk for illegitimate product, and not simply be viewed as having a passive role as recipient of notifications of illegitimate product.

Termination of notification

As noted above, the draft guidance includes a process for termination of notifications of illegitimate products, which the FDA says would be binding when finalized. We believe that the draft guidance might be viewed as implying that only the party that initiated the notification of illegitimate product could request termination of such notification. We would, thus, urge the FDA to make clear in the final guidance that anyone in the supply chain could initiate such a request. This would, for example, acknowledge the fact that initial notice could come from a dispenser while the request for termination of the notification could legitimately come from an entity higher up in the distribution chain, such as a manufacturer, since multiple levels of the supply chain are likely to become involved when one of them makes a determination of illegitimate product. In addition, we see no reason why the guidance could not also provide an option for the FDA to self-initiate the termination process rather than needing to wait for a formal request to be made by some external party. In our view, this would in no way preclude the necessary involvement of relevant stakeholders in the termination process. We simply assume that the FDA could become quite involved upon initial notification of illegitimate product and might be well positioned to know, in at least some cases, when it would be appropriate to initiate the notification termination process.

Liability concerns

The draft guidance raises some potential liability issues. Would a dispenser or other party making a good-faith report of an illegitimate product, after completing an investigation commensurate with the resources and information at hand, face potential liability if more sophisticated examination later reveals that the

product was not illegitimate? Is there some legal shield inherent in a governmental requirement to report illegitimate products? Are there specific steps that dispensers and others should take to protect themselves against potential liability? If so, then the final guidance should spell these out and/or provide assurance to dispensers and other parties subject to the reporting obligations regarding these liability concerns.

We hope our comments are helpful. If you need to reach us, please contact Margaret Reagan, vice president, at 202.879.8003 or margaret_reagan@premierinc.com.

Sincerely,

Blair Childs
Senior vice president, Public Affairs
Premier, Inc.