To: U.S. Food and Drug Administration Docket No. FDA-2014-N-0233

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Subject: Divert-X goes further than any known intervention to promote safe disposal:
Unique incentive mechanisms encourage safe disposal soon after dispensing

The Notice seeks commentary on methods and systems to help ensure **safe disposal**. Because the Divert-X System is a drug-safety system that establishes a closed loop of distribution that begins and ends at the pharmacy, strong incentives can be employed to cause the return of unused medications for destruction.

Divert-X – the dispensing and behavioral monitoring system under development by Vatex – tackles the prescription drug abuse crisis directly by seeking to separate authentic patients from those who are exaggerating the intensity and duration of symptoms. Those who subvert the system to feed an addiction or sell their medications are far less likely to demonstrate the spectrum of dosing behaviors exhibited by compliant, authentic patients. A healthcare insurer has permitted Vatex to pilot Divert-X in a region it serves so that Vatex can demonstrate the efficacy of the intervention via robust science.

Figure 1 shows a DEA-generated summary of the closed loop of distribution that is federally mandated for Controlled Substances. Unfortunately, as noted by the question mark, the loop is not truly closed because contemporary management systems have no disposition information for medications that have been transferred to patients. Stated differently, no one knows where the tablets, capsules, patches, etc. go after they leave the pharmacy. When prescribed quantities exceed the needs of the patient, the spare doses often remain in homes for long periods of time. Unused doses in homes are one source of supply for non-medical use, particularly for people who have not progressed beyond occasional experimentation. While prescription take-back programs organized by DEA have destroyed 4.1 million pounds of unused medications since 2010 (1), these programs are stopgap measures offered while long-term solutions proceed through the federal rule-making process. The Secure and Responsible Drug Disposal Act of 2010 (2) establishes in-pharmacy disposal boxes and mail-back procedures for patients to return unused Controlled Substances for destruction. As of this writing (May 2014) DEA leadership claim that the rulemaking process will be completed quickly because all external-agency steps are complete (3). While Divert-X is compatible with all principals and rules associated with the Act, it goes one step further by adding incentive mechanisms to encourage return and safe disposal soon after dispensing.

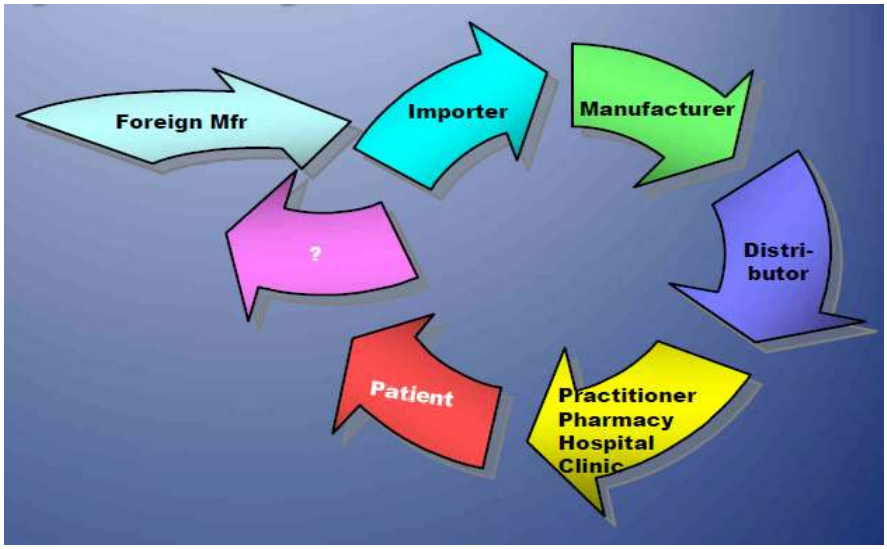

Figure 1: *The DEA Closed System of Distribution Ends at the Patient (4).*

While details of the Divert-X System are provided in other submissions to this docket (search for “Management Systems” and “Patient Confidentiality” and “Hardware Design” among others), Figure 2 shows the general features of a prescription cycle. Return of the device is the most important part of the cycle that is related to drug disposal. Completing the closed cycle for a single prescription, the packaging and electronics are returned to the pharmacy for tamper assessment by the pharmacist, for recovery of the reusable electronics, and for disposal of unused medications. Return of the intact packaging and device are fundamental to maintaining a record of high behavioral scores that would result in the patient being viewed as and treated as compliant – all necessary for trust and a basis for continued prescribing. In the case of an ongoing prescription for a chronic condition, doses may go unused and prescriptions may change because of tolerability or any number of other clinical or practical reasons.

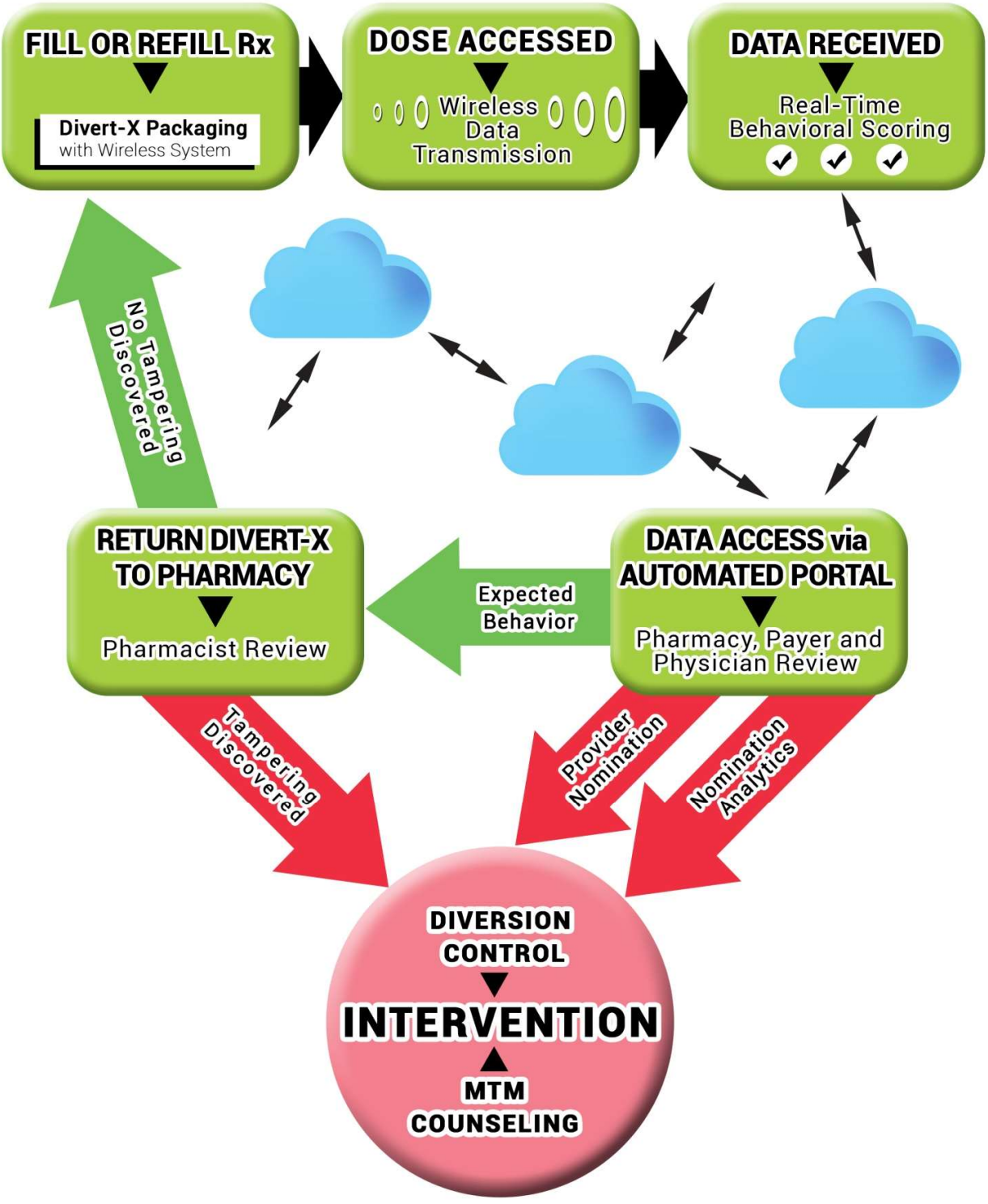

Figure 2: *The Divert-X System Extends the DEA Closed System of Distribution to the Patient by Constructing a Separate Closed Loop That Begins and Ends at the Pharmacy.*

In the case of short-term prescriptions in support of conditions that are expected to be self-limiting, we expect to see innovation from payers. For example, a number of incentive programs such as coupons or in-store rewards can be offered to prompt the return of unused doses (known to exist because of the Divert-X data) soon after dispensing. These alerts may come from the payer (whose incentive is to reduce the clinical costs of prescription drug abuse) or from the dispensing pharmacy (whose incentive is to generate another in-store visit). In either case, the public will view these steps as professional stewardship of medications that have safety concerns.

As discussed, authentic patients on chronic therapy have a natural incentive to obtain high scores. Additionally, payers are incented to help close the loop – and recover unused medications – in order to reduce their abuse-related costs. Because the insurer will be financially responsible for the economic value of lost devices, payers have a second reason to encourage, incent, and properly explain to patients the need to close the loop. Vatex believes that alignment of patient and payer self interests can be more effective in reducing the crisis than law enforcement, regulation, and education.

References

1. Drug Enforcement Administration. DEA'S National Prescription Drug Take-Back Days Meet a Growing Need for Americans. Press Release. May 8, 2014. [cited May 2014]; Available from: http://www.justice.gov/dea/divisions/hq/2014/hq050814.shtml.

2. Drug Enforcement Administration. Disposal of Controlled Substances. December 21, 2012, Docket No. DEA–316 [cited May 2014]; Available from: http://www.gpo.gov/fdsys/pkg/FR-2012-12-21/pdf/2012-30699.pdf.

3. U.S. Senate Caucus on International Narcotics Control. America's Addiction to Opioids: Heroin and Prescription Drug Abuse. Hearing, May 14, 2014. [cited May 2014]; Available from: http://www.drugcaucus.senate.gov/hearings.html.

4. Drug Enforcement Administration. Slides Presented at Meeting of the U.S. FDA Drug Safety and Risk Management Advisory Committee. January 24, 2013. [cited May 2014]; Available from: www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/DrugSafetyandRiskManagementAdvisoryCommittee/UCM337150.pdf.