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

From: James Harris, Ph.D., Chief Scientific Officer, Vatex Explorations LLC,
Developer of the Divert-X System

http://www.divert-x.com/contact/

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Subject: Vatex-managed systems cannot identify patients because they never receive and thus cannot contain personally identifiable information.

The Notice seeks commentary on **patient confidentiality** issues related to medication management and packaging systems designed for reducing prescription drug abuse. Privacy is the paramount design feature of Divert-X in order to foster adoption and to ensure that Vatex-managed systems never identify a patient.

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.

The theory of action for our efforts is straightforward and evidence-based: checks & balances for oversight of psychoactive, addictive drugs promote thoughtful use, safer behaviors, and accountability. The Vatex hardware advancements are described in a separate submission to this Docket (search for “Hardware Design”) and are used to gather objective data on actual medication-use behaviors. The hardware and the objective data on individual prescription cycles, when stored in a proprietary cloud, are collectively termed Divert-X. Divert-X data are nameless, as described below. The application of proprietary analytics for assessing behavioral markers collected by the packaging is used in a management system designed to reduce diversion and misuse. The management system is termed “Active MTM” and is described in a separate submission to this Docket (search for “Management Systems”). Active MTM data are housed only within the healthcare system and are elements of individual patient records. Hence, Active MTM data have the same privacy risks as those data already housed within electronic medical records.

Because Vatex is completely responsible for the privacy and security of Divert-X data (the data reside within Vatex servers), Vatex has designed a nameless system that does not contain personally identifiable information. Because Active MTM data must be associated with patient identities, these data are housed only within existing medical IT infrastructure so that the data share the privacy- and security-risk profiles of existing healthcare records.

Divert-X packaging and hardware continuously monitor the disposition of each individual dosage blister and transmits data in real-time relating to the time of dose access, city-block-level location of access, and other proprietary behavioral markers associated with each dosing event. Data are transmitted using cellular networks and stored on a cloud-computing-based healthcare analytics platform. The data transmittal portion of the device remains on standby until the sensing system has been triggered by dosing, enabling battery life to exceed one month. All data transfers use internet-protocol-based (not phone channel or SMS), secure, and encrypted standard protocols – employing the same standards that are fundamental to our contemporary economy. All hardware systems are unique to Divert-X and specifically engineered for this single purpose in order to avoid the numerous attack pathways that would be available if, for example, a smartphone was used for data transfer. Divert-X does not have, does not collect, and thus cannot transmit personally identifiable information.

The pharmacy is responsible for entering into their IT system the patient demographics and an identifier for the specific Divert-X module being placed into service. No Divert-X database or system has access to the patient name or any other identity-specific information, so privacy is assured. All IT systems nonetheless comply with medical data security standards. Only the pharmacy, registered medical providers, and the payer will have access to Divert-X data for a named

patient. For example, payers using Active MTM software can automatically query the Divert-X cloud for updated patient-level data. Similarly, appropriately-provisioned providers can automatically query the Divert-X cloud for patient level data, or can run manual queries if they know the device identity and other session-specific information. The process cannot work in reverse, however, because the Divert-X cloud is anonymous storage that cannot access external records or systems. In addition to the absence of personally identifiable information within Divert-X, privacy concerns are further addressed by using only coarse location-determination tools that can pinpoint a device only to within a few city blocks.

Because the Divert-X cloud is devoid of personally identifiable information, the system does not expand the universe of entities that already have patient-specific prescription data on Controlled Substances. Said differently, so grave is the crisis that payers, providers, and state and federal governments already have prescription information by way of clinical records, pharmacy databases, prescription monitoring programs, and utilization review systems provided by pharmacy benefit managers and others. Active MTM data are simply objective dose-level data stored alongside prescription-level data that is already housed in existing patient-specific records.