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: Divert-X hardware is specifically engineered for its anti-diversion and anti-misuse tasks, but it will clearly be used in other therapeutic areas with drug-safety issues.

The Notice seeks commentary on **hardware design**, functionality, and adaptability of packaging systems engineered to address diversion, misuse, and abuse. Because the Divert-X hardware, data collection services in the cloud, and decision support and intervention services available to payers and providers (Active MTM) are distinct and somewhat complex, this submission to the docket focuses exclusively on the hardware. Separate submissions to this docket describe non-hardware segments of the system (search for "Patient Confidentiality" and "Management Systems").

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 Divert-X system is designed to be filled and dispensed at pharmacies. The dispensed hardware consists of a smart-blister pack and wireless module that communicates dose-access events in real time to analytics in the cloud. The pack is a single-use consumable and the module is reusable -- they are assembled at the pharmacy to yield a functioning unit. Divert-X is an open system that allows patients to access their medications as needed. To have the broadest impact and eliminate any requirements for commercial cooperation by pharmaceutical companies, the hardware is designed to be agnostic to dose, formulation and manufacturer by way of the availability of several choices of pack types (differing in blister dimensions) that are filled with medication and mated to a universal module at the pharmacy. Hence, the agnostic design can be applied to any medication with drug-safety concerns. As examples, an insurer could request Divert-X pharmacy-assembled dispensing for drugs of concern, even those that are not Controlled, or manufacturers/regulators could adopt a factory-assembled version of Divert-X to de-risk a regulatory decision.

Vatex has complete freedom to operate regarding the use of blister cards for data collection because the base technology (disruption of electrical traces during dose removal) is old, and no fundamental patents remain in force. Example predecessor devices can be viewed on the internet by conducting image searches for "Pharma DDSi" and for "Cypak." Vatex has no business relationships with either Stora Enso or Cypak, and neither company remains active in smart compliance solutions. The Vatex-designed units to be used commercially differ from predecessor approaches in the following ways: longer battery life, much smaller size, proprietary sensing, higher blister density, secure location determination, end-to-end encryption, proximity analysis, real-time 2-way messaging and alerts, child-safety certification, cold-seal assembly in a standard pharmacy, and engineering specific to drug abuse concerns rather than compliance/reminder concerns. An important non-patentable advance is the addition of cold-seal assembly that requires no capital equipment or permanent bench space in the pharmacy, yet yields a seal that is stronger than the paperboard used to house the medications. In-pharmacy assembly is critical to the Vatex goal of broadly impacting Controlled Substance diversion and misuse because in-pharmacy assembly makes the process agnostic to dose, dosage form, and manufacturer.

While Vatex does not reveal detailed schematics or specifications of its commercial hardware, a general description follows. The PCB board dimensions are 35 x 100 mm and it includes all the on-board sensing, memory, computing, power, power management, tamper and jamming detection, and cellular-communication radio and management

technology required for autonomous sensing and machine-to-machine (M2M) communication with remote servers. The devices are permanently sealed in plastic cases with no buttons, screens, screws, or switches, all engineered to minimize tampering yet make tampering abundantly obvious. Battery life is more than 1 month, compatible with the prescription cycles for most Controlled Substances. The size, power, and capabilities all leverage improved smart-phone technologies. M2M data transactions are via an embedded TCP/IP stack, secured via strong on-board encryption on a separately-encrypted GSM cellular network (T-Mobile, includes AT&T and other roaming partners). Divert-X collects and stores all data for all events that occur during a prescription cycle in the rare case that cellular service is never available. Divert-X uses approximate location of dosing events and proximity to other devices; location via GPS is insecure (easily spoofed) and location determined through the use of carrier data is prohibitively expensive. Instead, and importantly, the Divert-X device determines its own location indoors or outdoors with city block accuracy, independent of satellites and carrier assets, using a proprietary combination of onboard and server-side calculations. Another Vatex advance relates to the disposable circuitry used to detect dosing events. The photo below shows a standard circuit from an existing, dose-sensing blister pack. The circuit is made from metalized films – metal circuits applied to thin plastic films using a longstanding industrial process called sputter deposition. This is the process that is used to make foil packaging for foods (a snack wrapper made with this process is shown) and for factory-made medication bottle closures. Vatex will manufacture its blister circuitry from the same materials because metalized films are mature, inexpensive, and already registered for food and medical use. Vatex will not use the standard design approach shown in the photo, however, with individual circuits assigned to each blister, because this approach severely limits the density of doses per blister card (no commercial electronic blisters have more than 21 doses per card). Instead, Vatex has discovered and has a patent pending for a sensing method that allows the density to be dictated by the pill dimension rather than by circuit crowding.

Because Divert-X will be challenged by users who are looking to subvert it, the packaging must possess many features to resist and show tampering. A tamper assessment by the pharmacist is the final step in the Divert-X cycle prior to obtaining a final score. Vatex is advantaged by the fact that the adhesives already in use for in-pharmacy assembly of blister cards are far stronger than the materials used to make the packaging. Vatex has assessed products from all North American manufacturers of cold seal pharmacy-fill cards; in all cases, the cardstock and foils fail when attempts are made to unseal a blister card. The strength of the seal itself serves as a child-safety feature. The strength of the seal relative to the materials of construction is a key in making tampering abundantly evident. Tamper-resistance features and child-proof features augment each other, and they are tested together. For further details, please see a separate submission to this docket on the subject of assuring Divert-X is both child-safe and elderly-friendly (search for “Preventing Accidental Use”).

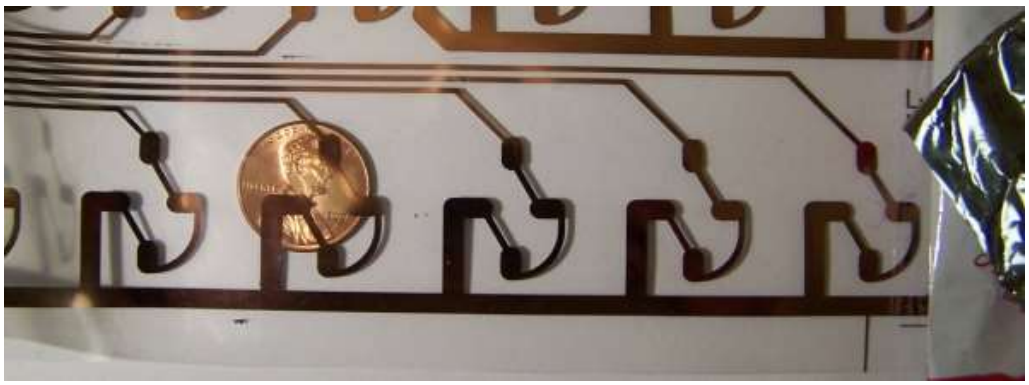

Photo: a standard circuit from an existing, dose-sensing blister pack made from metalized films – the same process used to make foil packaging for foods (a snack wrapper made with this process is shown at right) and for medication bottle closures. Vatex will not use the standard design approach shown in the photo, with individual circuits assigned to each blister, because this approach severely limits the density of doses per blister card (see text).