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

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Subject: Benefits of adopting a proven drug-safety system far exceed the costs and afford large reputational improvements; only in-pharmacy assembly can deliver a broad impact on the crisis.

The Notice seeks commentary on **system incentives and workflow issues** associated with adoption of new medication management systems. It is important that pharmacy workflow disruptions are minor and thus not an impediment to adoption relative to financial and other benefits afforded to stakeholders. It is critical that packaging and medication management systems (a) are agnostic to dose, dosage form, and manufacturer; (b) do not force pharmacies to alter their supply chains and preferred vendor networks; and (c) need not be adopted by pharmaceutical manufacturers.

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.

Payers will capture the bulk of financial returns from the implementation of Divert-X and its management system, Active MTM. Active MTM is the subject of a detailed submission to this docket (search for "Management Systems"). Adoption will reduce spending by abating fraud and by reducing medical spending (clinic visits, falls and other accidents, addiction, etc.) caused by patient misuse of Controlled Substances. Payer incentives have been addressed in a separate response submitted to this docket (search for "Payer Incentives").

The reputation of the medical industry generally – of its prescribers, pharmacists, and corporations – will increase by adopting proven abatement systems. The prescription drug abuse epidemic has exposed the public to the rudimentary state of current Controlled Substance management systems and controls and has become an egg-on-face event for the industry. Adoption will also lower the enforcement burden on conscientious medical providers, because they can demonstrate a track record of diligence, enhancing community trust. Although financial incentives are not shared equally, the various types of incentives outlined below are of high value and are aligned among the participants.

Active MTM incents pharmacies and other providers to take more responsibility for Controlled Substance disposition and medication-use behaviors. In order to facilitate the cooperation of pharmacies, the Divert-X device is designed so that it can be filled in a very efficient manner with only a moderately longer pharmacy process. Filling Divert-X in the pharmacy is critical to success because it does not change pharmacy purchasing preferences and makes the intervention broadly and immediately applicable to most dosage forms, doses, and manufacturers. History shows that product-specific interventions are expensive, slow, and have failed to change the magnitude of the national crisis. Divert-X utilizes cold-seal assembly of the single-use smart blister packaging – a process already used by pharmacies nationally. Cold-seal assembly requires no capital equipment or dedicated bench space in the pharmacy, yet it provides a seal that is stronger than the paperboard used to house the individual doses.

Pharmacies charge payers a fee for the act of dispensing and a separate fee for the medication itself. A dispensing fee for Divert-X will be paid to the pharmacy that is in excess of and in addition to standard medication dispensing fees. Because the medication sourcing and the medication charge (to payers) will not change under Divert-X, pharmacies will have the same level of profitability from this sales category. The high volume of Controlled Substance prescribing will

ensure that pharmacies are responsive to the dictates of health insurance payers to dispense using Divert-X. Divert-X adoption will therefore create a new source of revenue for the pharmacy, which will facilitate co-operation.

Regarding pharmacy reimbursement and workflow, Vatex will establish a new HCPCS dispensing fee (a substitute for the bottle-fill fee) that we call a drug-safety system fee, or DSS fee. Here is an example of a pharmacy transaction: instead of the payer or payer's designee replying to a benefits query with an electronic 'OK to fill' message, the payer would instead reply with a 'fill using DSS' message for any medication of concern. These instructions can only be fulfilled by pharmacies that participate in the Divert-X System or a competing evidence-based system and, because Controlled Substances are among the most commonly prescribed medications in America, market forces would drive adoption by the pharmacy industry. A part of the DSS fee will flow to the pharmacy and a portion to Vatex to pay for IT and analytics services, consumables costs, and Divert-X unit leasing. To assist in adoption and to pay for the additional work and oversight, pharmacies will earn more money when a drug-safety system is requested instead of a bottle fill. While filling into Divert-X may take an estimated 50% more time than a regular fill, the main reason to pay pharmacies more is as follows: in the Active MTM described elsewhere in this docket, pharmacies will be contractually mandated to look at the patient data and medication-use risk score prior to dispensing additional Controlled Substances to that patient. Some payers may choose to pay the same pharmacy firm that is dispensing to also contract for the MTM services – yet another incentive for pharmacies to offer and upgrade their MTM services.

Safe use of medications is critical to the general success of our healthcare system, and pharmacists hold a high level of training compared to all providers in pharmacology and therapeutics management. Although Divert-X and Active MTM will reduce dispensing by uncovering fraud and misuse, the system is strongly positive for the profession of pharmacy because MTM – typically provided by pharmacists – utilizes and leverages a key expertise of the profession. Evidence-based assistance of patients in the safe use of Controlled Substances builds another mechanism by which pharmacies can compete for status and broaden their business. Because, under the new model, pharmacists have additional data and are being paid to apply their clinical judgment, pharmacists are no longer bystanders in the process and can better uphold their DEA-mandated vigilance duties described at 21CFR1306.04(a). Hence, and because objective data is available to multiple parties, the advice and consultation provided to patients, to prescribers, and to payers is expected to be of much higher quality.

Rogue pharmacies are unlikely to participate in a drug-safety system, but pharmacy chains will adopt the system if positive payer economics and safety considerations demand it. Upstanding pharmacies cannot be seen as avoiding proven safety tools, and they must serve the Controlled Substances market because of the size of the attendant revenues and number of store visits. Adoption is straightforward because capital equipment is not required to assemble Divert-X units, and the system accommodates all oral, solid medications stocked by the pharmacy. Appropriate measures can be taken by each payer to ensure that Controlled Substances and other medications of concern are filled in a drug-safety system at their request. For example, because each Divert-X unit is unique and reports in real-time, an insurer that informs Vatex of all drug-safety fill requests can receive back reports that highlight mismatches between requests and completed work. This real-time capability will assist in enforcing payer choice and finding cases of overutilization or false billing quickly.

Currently prescribers are entirely responsible for the disposition and use of Controlled Substances by their patients. Given the grave climate surrounding prescription drug abuse, pressure from DEA and state medical boards is intense. For honest prescribers, this concentration of risk (without corresponding objective information and reimbursement) has become onerous, leading to diminished access for patients in need (see the Vatex filing "Care Access" submitted to this docket). Under Active MTM risks and accountability are shared by six entities. Checks & balances among these providers will identify problems early and actively, and new liabilities will develop for ignoring data flow. Active MTM promotes active discovery of safety issues and information sharing. As a single example, patients who have been nominated for MTM intervention will have access to the shared wisdom and mutual oversight of their MTM Provider and their prescriber. In addition to enhanced care quality, a web of shared accountability and scrutiny should increase trust for patients who are truly in need, increasing care access.

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All medical-system stakeholders will benefit from the market introduction of Divert-X and its management system Active MTM, which should accelerate the adoption of the product. Selected impacts are summarized below:

Pharmacies	• Source of new revenue via increased dispensing fee and MTM service opportunities • Shielding from DEA and other regulatory actions, reduction in liability via evidence of diligence • Enhanced system trust and professional reputation • Increased care quality • End to subjective patient profiling
Physicians	• Capability to differentiate between compliant and non-compliant patients • Re-establishment of doctor-patient trust • Early indicators of drug misuse and developing addiction • Reduction of iatrogenic addictions and improved outcomes • Shielding from DEA and other regulatory actions, reduction in liability via evidence of diligence • End to subjective patient profiling • Enhanced system trust and professional reputation
Patients	• Improved standard-of-care • Re-establishment of doctor-patient trust • Enhanced access to medications • End to subjective patient profiling • Reduction of iatrogenic addiction and improved outcomes
Payers	• Reduction in costs associated with addiction treatment, emergency room visits, drug testing, more efficient prescribing, exaggerated intensity and duration of symptoms, fraud and diversion • Reduction in liability via evidence of diligence • Enhanced system trust
Regulatory & Enforcement Agencies	• Identification of criminal activity • Reduced public pressure • Unused Controlled Substance doses returned to pharmacy
Societal	• Reduction in overdose deaths and family disruption • Increased economic productivity

We expect that payers will mandate the use of Divert-X for Controlled Substances such as opioids once they are convinced of the magnitude of savings that it will generate. Unlike most mobile-Health initiatives and unlike previous attempts to commercialize regimen-compliance products for medications that are not Controlled Substances, the Vatex business approach focuses completely on reimbursement (from insurers, in pursuit of their own self interest) and is not a self-pay model. Reimbursement established from insurance companies and federal healthcare agencies will be contractually split between pharmacy partners and Vatex. Access to the EMR- and web-based data and analysis will be provided to accredited healthcare providers free-of-charge. The market for Divert-X has to be created, but is potentially very large with more than 500 million prescriptions for Controlled Substances written per year in the US. Pricing for the Divert-X service in the range of $20-30 per prescription is anticipated. The “hidden” excess costs derivative of opiate misuse and diversion can be computed to be about $500 per prescription (200 million opiate prescriptions, $100 Billion excess healthcare costs) so even modest reductions in the problem will result in a fully viable product. Vatex expects a strong adoption ramp for Divert-X because it addresses pressing societal, clinical, safety, healthcare economic and law enforcement issues simultaneously. Divert-X appears to be the first integrated product to address the full breadth of the prescription drug abuse and diversion epidemic.