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

From: Simon Sellers, Ph.D., Chief Executive Officer, Vatex Explorations LLC,
Developer of the Divert-X System

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

Date: 6 June 2014

Subject: Payer incentives: Innovative packaging that reduces opiate abuse will reduce healthcare costs.

The Notice seeks information on **payer incentives** and the feasibility of implementation of interventions that can be applied to reducing the prescription drug crisis. Innovative packaging that reduces opioid misuse can generate significant economic benefit by reducing the excess medical costs consequential to abuse and fraud. Outcomes improving financial returns for private and public healthcare payers will drive implementation of an evidence-based drug safety system.

Divert-X – the dispensing and behavioral monitoring system under development by Vatex – tackles prescription medication abuse 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.

> "abuse and fraud can be estimated to cause an average hidden cost burden of $500 in excess medical spending added to every prescription."

The insurance community - private, Medicare, Medicaid, workers' compensation, self-insured employers, and VA - will be the customer base for Divert-X. The market for an IT service to infer patient behavior towards opiates and other Controlled Substances and to provide actionable information must be developed. Vatex expects that data from Divert-X pilots will successfully demonstrate the identification of anomalous patient behaviors and reduction in the misuse and diversion of medications. This will allow an estimate to be made quantifying the economic benefit from the introduction of Divert-X. The economic outcome will be used to petition medical insurance companies and government payers that the use of the system will generate significant healthcare savings for their organizations.

Currently there are no technology-driven methods to differentiate between legitimate opiate patients and those abusing and diverting. Without effective tools, medical practice involving Controlled Substances has devolved to speculative, ineffective patient profiling (1-5), spawning numerous lawsuits and administrative actions (6-9), documented discussion of how to lie to patients (10-12), public battles between pharmacy and physician groups (13-15), and uncertainty expressed by DEA in court regarding how to establish the legitimacy of prescriptions (16). In the 2011 Government Accounting Office publication 'Prescription Pain Reliever Abuse' (17), DEA officials report that "based on the available prescription and sales data, there is no method to calculate which prescriptions are issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice and which are not." As a result of the inability to identify and take broad action against diverters, the DEA increase their quota for opiate and Controlled Substance production based on demand- which naturally includes diverted medications. The recent Compounded Annual Growth Rates for opiate and stimulant DEA quotas are a staggering 27.0% and 33.4% respectively (18-19). Because Divert-X establishes dose-level accountability, it will reduce fraud, street medication supply, and diversion. It will provide an objective means to identify patients who are misusing opiates and other Controlled Substances and provide a novel method to combat the epidemic.

The Vatex sales channel will be direct to insurers. We expect that insurers will mandate the use of Divert-X for opiates and other Controlled Substances for their patient populations once they are convinced of the magnitude of savings that

it will generate. 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. 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. 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. Divert-X adoption will therefore create a new source of revenue for the pharmacy, which will facilitate co-operation.

Extrapolation from a 2007 insurance industry estimate (20) suggest that opiate misuse results in at least $100 billion in excess annual medical costs for insurers driven by the costs of emergency room visits, increased physician visits, diagnostic and drug-test spending, falls and other accidents, and abuse treatment programs. When this economic burden is considered against the annual volume of 200 million opiate prescriptions, abuse and fraud can be estimated to cause an average hidden cost burden of $500 in excess medical spending added to every prescription. Vatex' corporate goal is to reduce Controlled Substance misuse and diversion by thirty percent. At this level of impact, economic benefit of approximately $150 per prescription would be generated. The cost of providing a fully integrated Divert-X service is projected to be less than $30 per prescription; the net benefit to the payer will provide a strong financial incentive for implementation of the technology. Additionally, some payers will be motivated by the community, societal, and medical-system benefits that accrue by bringing Controlled Substance issues under control.

Precedent from the medical, behavioral, and economics literature show that Divert-X is likely to be a high-impact system. Vatex is combining key refinements of historical systems with its own innovation to address a pressing problem. The medical literature is replete with studies (21-24) showing that compliance to medications not regulated by DEA can be increased through a variety of actions with corresponding improvements in health and cost. Improving compliance to Controlled Substance regimens is much more challenging, however, because overconsumption is spurred by experimentation and addiction, because of the financial windfall for those patients who divert their ongoing prescriptions (25-30), and because current clinical tools cannot separate authentic patients from those exaggerating the intensity and duration of disease (31-36). Hence, the literature describing methods that improve Controlled Substance adherence is sparse. A single European trial has been completed, describing monitored-access blister cards filled with buprenorphine-naloxone, a drug that is given to opioid addicts (37). The drivers to divert buprenorphine products are strong and multifaceted, and diversion has become so widespread that the outpatient use of buprenorphine is being called into question (38). The trial (37) serves as clear precedent for Divert-X because of strong parallels in form-factor and the focus on Controlled Substances. This small study demonstrated a 39% reduction in treatment costs, principally from reduced clinic visits.

A small survey of opioid addicted criminal offenders who were receiving or soon to receive buprenorphine-based Medication-Assisted Treatment (MAT) was conducted for Vatex. The concept of monitoring individual doses electronically was introduced to each person, along with an illustrative photo. The outcome was that 86% thought that Divert-X monitoring would reduce diversion (24 of 28) while 14% thought that Divert-X would not change diversion. The same question was posed to a group of MAT non-offenders who had become addicted from routine medical care – this group was unanimous in its view that the Divert-X approach is preventive. Regarding the non-offender population, "every patient who started using opioids after an accident or injury endorsed the idea that such a device would have saved them from a life of addiction. They believe, pretty unanimously, that such a device would have thwarted that first period of over-use, before the drugs really caught hold of them" (39).

Vatex contends that it is certain that the deployment of Divert-X will reduce misuse and diversion of opiates. Our commercialization strategy is to implement sound science to quantify this impact and to leverage the data to secure adoption among healthcare payers based on alignment with their financial self-interest. While Controlled Substances are the initial market for Vatex services, a proven drug-safety system would be utilized in other therapeutic areas.

[continues on next page]

Problem	Divert-X Impact
New addictions	Preventative - Observes developing addiction or recreational use, enables rapid intervention – improving patient outcomes
Drug trafficking, high street value	Medication-use risk algorithms identify diverters – timely interventions de-industrialize criminal activity
Unused pills	Insurer-directed incentive to return unused medications quickly - reducing exposure (insurer is financially responsible for unrecovered devices)
Addictive medications	Use of Divert-X will inhibit misuse and emphasize dangers of medication use and experimentation
High cost of misuse	Reducing misuse and diversion will lead to fewer emergency room visits, rehabilitation interventions, drug testing, falls and other accidents, and combat fraud and trafficking

Impact: Divert-X uniquely addresses prescription drug abuse through multiple modalities.

References

1. Grover CA, Elder JW, Close RJ, Curry SM. How Frequently are "Classic" Drug-Seeking Behaviors Used by Drug-Seeking Patients in the Emergency Department? Western Journal of Emergency Medicine. 2012;13(5):416-421. PMCID: 3556950.

2. Sansone RA, Sansone LA. Faking attention deficit hyperactivity disorder. Innovations in Clinical Neuroscience. 2011;8(8):10-13. PMCID: 3173757.

3. Davis JF. Professional Drug Seekers Exposed by former Addict. Medical Island. February 20, 2013. [cited May 2014]; Available from: http://www.medicalisland.net/guest-posts/professional-drug-seekers-exposed-by-former-addict.

4. Health Reference Questions. Do pharmacists lie about being out of stock if they think you have a fake RX? Yahoo Answers. [cited May 2014]; Available from: http://answers.yahoo.com/question/index?qid=20120824075113AAPLOwA.

5. Azzopardi V. Controlling Controlled Substances: The balance between proper pain management and preventing drug abuse. Pharmacy Ethics, Wayne State University. [cited May 2014]; Available from: http://rxethics.org/Azzopardi%20Edited%20PDF.pdf.

6. Drug Enforcement Administration. Walgreens Agrees to Pay a Record Settlement of $80 Million for Civil Penalties under the Controlled Substances Act - Largest fine paid by a DEA registrant. Press Release. June 11, 2013. [cited May 2014]; Available from: http://www.justice.gov/dea/divisions/mia/2013/mia061113.shtml.

7. Drug Enforcement Administration. Holiday CVS Final Order Reveals Gross Negligence By Two CVS Pharmacies in Stanford, Florida. Press Release. October 15, 2012. [cited May 2014]; Available from: http://www.justice.gov/dea/divisions/mia/2012/mia101512.shtml.

8. Leger DL. CVS pays $11M to end Oklahoma painkiller probe. USA Today, April 4, 2013. [cited May 2014]; Available from: http://www.usatoday.com/story/money/business/2013/04/03/cvs-settles-with-dea-over-drugs/2049629/.

9. Schoenberg T. Cardinal Health Set for DEA Showdown Over Pain Pill Sales. Bloomberg BusinessWeek. May 10, 2012. [cited May 2014]; Available from: http://www.businessweek.com/news/2012-05-10/cardinal-health-set-for-dea-showdown-over-pain-pill-sales.

10. Pharmacy Forum. How do you tell someone youre not going to fill their controlled Rx? [cited May 2014]; Available from: http://www.reddit.com/r/pharmacy/comments/1m15ts/how_do_you_tell_someone_youre_not_going_to_fill/.

11. Student Doctor Network Forums. What are your personal rules for fillining of C2s? [cited May 2014]; Available from: http://forums.studentdoctor.net/archive/index.php/t-1015371.html.

12. Student Doctor Network Forums. Proper verbage when refusing to fill C2 scripts. [cited May 2014]; Available from: http://forums.studentdoctor.net/archive/index.php/t-924519.html.

13. American Medical Association. Adoption of House of Delegates Resolution 218: AMA Response to Drug Store Chain Intrusion into Medical Practice. Proceedings of the American Medical Association, Organized Medical Staff Section. 2013 Annual Meeting, June 2013. [cited May 2014]; Available from: http://www.ama-assn.org/resources/doc/omss/a13-proceedings.pdf.

14. Houck LK. AMA Tells Pharmacists: “Don’t Call Us We’ll Call You.” FDA Law Blog. June 13, 2013. [cited May 2014]; Available from: http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2013/06/ama-tells-pharmacists-dont-call-us-well-call-you-.html.

15. Fudin J, Dole E. Pharmacists speak out. Drug Topics: Voice of the Pharmacist. October 15, 2013. [cited May 2014]; Available from: http://drugtopics.modernmedicine.com/drug-topics/news/pharmacists-speak-out.

16. Drug Enforcement Administration. Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195; Decision and Order. Federal Register. 2012;77(198):62316-62346. [cited May 2014]; Available from: http://www.gpo.gov/fdsys/pkg/FR-2012-10-12/pdf/2012-25047.pdf.

17. U.S. Government Accountability Office. Prescription Pain Reliever Abuse: Agencies Have Begun Coordinating Education Efforts, but Need to Assess Effectiveness. GAO-12-115, Dec 22, 2011. [cited May 2014]; Available from: http://www.gao.gov/products/GAO-12-115

18. Harris, J. Industry, Technology, and Prescription Drug Abuse. The U.S. Attorney for the Western District of Virginia, Southwest Virginia Prescription Drug Abuse Summit, November 14, 2012, Slides 7, 9, and 10 [cited May 2014]; Available from: http://www.justice.gov/usao/vaw/presc_drug_summit/JamesHarris.pdf.

19. Drug Enforcement Administration. Proposed Adjustments to the Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2013, June 20, 2013, Docket No. DEA–365 [cited May 2014]; Available from: http://www.gpo.gov/fdsys/pkg/FR-2013-06-20/pdf/2013-14723.pdf.

20. Coalition Against Insurance Fraud. Prescription for Peril: How Insurance Fraud Finances Theft and Abuse of Addictive Prescription Drugs. Insight Series, December 2012. [cited May 2014]; Available from: http://www.insurancefraud.org/downloads/drugDiversion.pdf.

21. The Center for Connected Health, Partners HealthCare. Wireless Medication Adherence Study Conducted at the Partners Center for Connected Health Shows Promising Initial Findings. June 2010. [cited May 2014]; Available from: http://www.connected-health.org/media-center/press-releases/wireless-medication-adherence-study-conducted-at-the-partners-center-for-connected-health-shows-promising-initial-findings.aspx.

22. Belluck, P. For Forgetful, Cash Helps the Medicine Go Down. The New York Times, June 13, 2010, Health section. [cited May 2014]; Available from: http://www.nytimes.com/2010/06/14/health/14meds.html?pagewanted=all&_r=0.

23. Chang A, Liberman JN, Coulen C, Berger JE, Brennan TA. Value-Based Insurance Design and Antidiabetic Medication Adherence. American Journal of Pharmacy Benefits. 2010;2(1):39-44. [cited May 2014]; Available from: http://www.ajmc.com/publications/ajpb/2010/vol2_no1/Value-Based-Insurance-Design-and-Antidiabetic-Medication-Adherence.

24. Cutrona SL, Choudhry NK, Fischer MA, Servi A, Liberman JN, Brennan TA, Shrank WH. Modes of delivery for interventions to improve cardiovascular medication adherence. American Journal of Managed Care. 2010;16(12):929-942. PMCID: 3115758.

25. Rigg KK, Kurtz SP, Surratt HL. Patterns of prescription medication diversion among drug dealers. Drugs (Abingdon Engl). 2012;19(2):144-155. PMCID: 3365597.

26. United States Court of Appeals, Tenth Circuit. United States of America vs. Martha Earlene Phillips, 2012, Appellate Case 11-6000. [cited May 2014]; Available from: http://www.gpo.gov/fdsys/pkg/USCOURTS-ca10-11-06000/pdf/USCOURTS-ca10-11-06000-0.pdf.

27. Hamacher B. Miami Lakes Man, His Wife and Mother Arrested in $25 Million Prescription Drug Trafficking Scheme: FDLE. NBC 6 South Florida. June 18, 2013. [cited May 2014]; Available from: http://www.nbcmiami.com/news/Miami-Lakes-Man-His-Wife-and-Mother-Arrested-in-25-Million-Prescription-Drug-Trafficking-Scheme-FDLE-212000121.html.

28. Office of Inspector General (OIG), U.S. Department of Health & Human Services. Beneficiary Fraud. The National Consumer Protection Technical Resource Center. [cited May 2014]; Available from: http://www.smpresource.org/Content/NavigationMenu/HealthCareFraud/OIGMedicareFraud/Beneficiary_Fraud.htm.

29. U.S. Government Accountability Office. Medicaid: Fraud and Abuse Related to Controlled Substances Identified in Selected States. GAO-09-957, September, 2009. [cited May 2014]; Available from: http://gao.gov/new.items/d09957.pdf.

30. U.S. Senate Committee on Homeland Security & Governmental Affairs. A Prescription for Waste: Controlled Substance Abuse in Medicaid. Hearing, September 30, 2009. [cited May 2014]; Available from: http://www.hsgac.senate.gov/subcommittees/federal-financial-management/hearings/a-prescription-for-waste-controlled-substance-abuse-in-medicaid.

31. Grover CA, Elder JW, Close RJ, Curry SM. How Frequently are "Classic" Drug-Seeking Behaviors Used by Drug-Seeking Patients in the Emergency Department? Western Journal of Emergency Medicine. 2012;13(5):416-421. PMCID: 3556950.

32. Sansone RA, Sansone LA. Faking attention deficit hyperactivity disorder. Innovations in Clinical Neuroscience. 2011;8(8):10-13. PMCID: 3173757.

33. Davis JF. Professional Drug Seekers Exposed by former Addict. Medical Island. February 20, 2013. [cited May 2014]; Available from: http://www.medicalisland.net/guest-posts/professional-drug-seekers-exposed-by-former-addict.

34. Beck M. Doctors' Challenge: How Real Is That Pain? Even When Patients Describe Pain in Vivid Detail, Doctors Have Few Tools to Determine What's Real. The Wall Street Journal. July 15, 2011. [cited May 2014]; Available from: http://online.wsj.com/news/articles/SB10001424052702304450604576419810283786774.

35. Newton P. How easy is it to fake ADHD? Fake ADHD in just 5 minutes with Google. Psychology Today Online. July 3, 2010. [cited May 2014]; Available from: http://www.psychologytoday.com/blog/mouse-man/201007/how-easy-is-it-fake-adhd.

36. Anonymous. Drug Seekers Suck. Emergency Physicians Monthly. February 4, 2008. [cited May 2014]; Available from: http://www.epmonthly.com/whitecoat/2008/02/drug-seekers-suck/.

37. Tacke U, Uosukainen H, Kananen M, Kontra K, Pentikänen H. A pilot study about the feasibility and cost-effectiveness of electronic compliance monitoring in substitution treatment with buprenorphine-naloxone combination. Journal of Opioid Management. 2009;5(6):321-329.

38. Anson P. Suboxone: The New Drug Epidemic? National Pain Report, American News Report. September 23, 2013. [cited May 2014]; Available from: http://americannewsreport.com/nationalpainreport/suboxone-new-drug-epidemic-8821747.html.

39. Personal communication with Jeffrey Junig MD,PhD, Medical College of Wisconsin and Fond du Lac Psychiatry. October 16, 2013.