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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

Date: 16 May 2014

Subject: Patient access to Controlled Substances is severely limited by erosion of  
patient-provider trust

The Notice seeks commentary on the subject of systems that could prevent or deter misuse and abuse without diminishing **care access** for patients with legitimate prescriptions. This is indeed a critically-important issue because provider-patient trust has been lost and must be rebuilt.

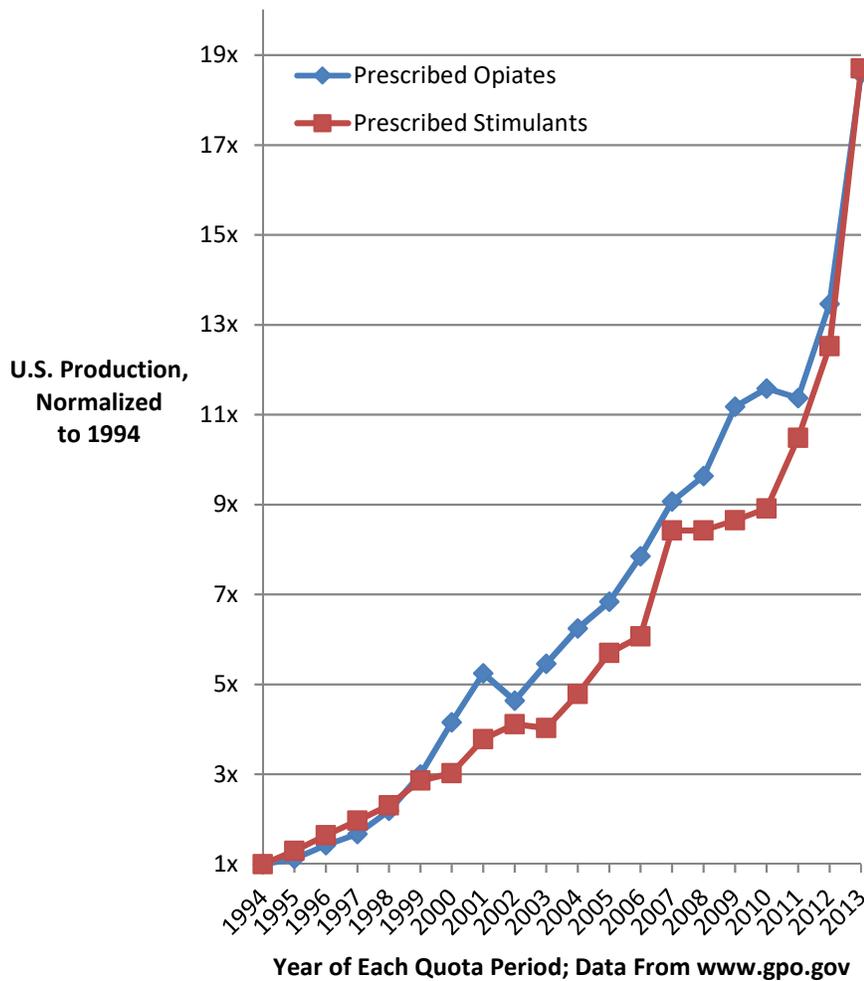
Divert-X – the dispensing and behavioral monitoring system under development by VateX – tackles this problem directly by seeking to separate authentic patients from those who are exaggerating the intensity and duration of symptoms. Those who subvert the system to feed an addiction or sell their medications 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.

Regarding patient access issues, our hypothesis is that providers, if given an objective, evidence-based method to judge the behaviors of their patients, will treat their patients with trust rather than trepidation. Secondly, those patients showing aberrancy will receive guidance and assistance that should greatly improve patient care quality.

The inability to judge motive and intent is fundamental to all Controlled Substances that are addictive or coveted by diverters. Differentiation of patient motive is the most important problem to be solved because it affects all Controlled Substances, all authentic patients, and all formulations. The truth of this statement is demonstrated by our realization that criminals (diverters) and addicts crowd out the authentic patients, driving the production and sales of Controlled Substances ever higher. According to the GAO, "DEA officials said 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." [U.S. Government Accountability Office Report Number GAO-12-115, Dec 22, 2011.] We expect that the growth trend shown below will continue until a behavioral differentiation system such as Divert-X is established as a new standard of care.

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## The Approval of Oxycontin in 1996 Coincided With the Early Industrialization of a National Black Market



If there were any doubt that patients sell their pills, then a study conducted in Florida is instructive. A university-based survey team that had engendered trust with regional criminals conducted a scientific study during 2008-10. They found that 44% of pill dealers specialized in accessing their supplies from local, insured patients who feigned intensity and duration of illness for financial gain; given that this study was conducted during a time when open-air prescription markets (“pill mills”) were tolerated in Florida, insured patients are surely a more important contributor to the supply chain in 2014. [Rigg KK, Kurtz SP, Surratt HL. Patterns of prescription medication diversion among drug dealers. *Drugs* (Abingdon Engl). 2012;19(2):144-155. PMID: 3365597.]

Because of the high profitability of the black market, honest and authentic patients are effectively pushed to the back of the line. Rather than diminishing access, Divert-X is intended to improve access for those patients who are authentic and who demonstrate safe use.

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Method used to build the chart - For each final DEA quota report printed in the Federal Register:

Prescribed Opiates: add fentanyl + hydrocodone + hydromorphone + methadone + oxycodone (sale) + oxymorphone (sale)

Prescribed Stimulants: add amphetamine (sale) + lisdexamfetamine + methamphetamine + methylphenidate