



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: 6 June 2014

Subject: Divert-X is the only anti-diversion and anti-misuse system known that  
does not limit patient access to prescribed medications.

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The Notice states that patients should not have **access barriers** to their medications and seeks commentary on anti-diversion and anti-misuse packaging systems engineered to avoid access barriers for patients who have legitimate prescriptions. Because Divert-X seeks to analyze unfettered medication-use behaviors exhibited by individuals, it is the only anti-diversion and anti-misuse system known that does not limit patient access to prescribed medications.

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.

Many companies have developed “pill terminals” where medications are rationed to the patient and locked up the rest of the time, for example Ramm Technologies PillGuard™. The design philosophy of pill terminals is analogous to automated cat-feeding stations that are commonly available in pet stores because access to the patient is restricted to pre-programmed times. Devices to lock pill bottles (pill safes or caps that lock) to avoid non-patient access are necessary but not related to this topic. Pill terminals restrict patients’ access to their medications - which is a fundamental disadvantage and incompatible with “take-as-needed” regimens used to manage pain. Divert-X does not in any way restrict patient access to medication. Furthermore pill terminals do not have any capability to identify diversion. Although pill terminals that ration access have been available for more than a decade, there is no evidence of meaningful commercial adoption, perhaps because no study has established that these systems are effective against diversion.

Pill terminals have a higher patient-risk profile than Divert-X because a malfunction in the mechanical system or software will deprive the patient of needed medication. Because Divert-X is an open, non-mechanical system, it cannot deprive a patient of medication. If a patient can remove a dose from a blister package on the first day of a prescription cycle, then they possess the skills and knowhow to remove a dose on the last day of a prescription cycle. 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”).

While the present submission focuses on patient access to medications that have already been prescribed, a separate submission to this docket focuses on the distinct and important issue of access to care that has been disrupted due to fear and distrust among prescribers, pharmacists, and patients (search for “Care Access”).