

TESTIMONY OF Chris Ellis
BEFORE A JOINT HEARING OF THE PENNSYLVANIA HOUSE JUDICIARY AND
HEALTH COMMITTEES

April 8, 2015

Good morning, Chairmen Baker and Fabrizio; and Chairmen Marsico and Petrarca and Members of the House Judiciary and Health Committees.

My name is Chris Ellis and I am Co-Founder and Principal of Beacon Information Designs, LLC. I am submitting this testimony to provide technical expertise on the oversight of highly regulated medical programs and the need for wide-ranging regulatory framework and data management protocols to ensure fair access and transparency in the Medical Marijuana Program.

My focus today will be on the critical need for a comprehensive real time compassionate drug monitoring program that will serve as a repository for each transaction from cultivation to sale within the Medical Marijuana Program. This system will provide the Commonwealth with a centralized database for registration of all industry participants ensuring a secure and streamlined application and reporting process. The compassionate drug monitoring program will limit diversion, generate sophisticated reporting tools and improve inspection and audit functions.

I also serve as President and CEO of Environmental Pharmaceuticals LLC, a full service reverse distributor supporting pharmaceutical manufacturers, wholesalers, pharmacies, hospitals and government agencies nationwide, giving me expert knowledge of the requirements for transportation, handling and destruction of all levels of pharmaceuticals and narcotics. I hold licenses from the Drug Enforcement Administration as a reverse distributor and the Arizona State Board of Pharmacy as a full service wholesaler. Beacon Information Designs was created as a result of my experiences in narcotics management and compliance to address the realization that no similar levels of accountability and compliance existed in the medical marijuana industry.

The Need for Regulation

When a physician writes a prescription for a controlled substance, the DEA and others can tell from the time a drug is manufactured until the time it is dispensed or ultimately destroyed. There is no similar federal requirement when a licensed medical provider writes a recommendation for medical marijuana. The key is to find the balance between a system that provides the safeguards needed to ensure compliance and accountability, while not hindering access to this medicine for patients or caregivers. Additionally, the system needs to have the ability to track all transactions to limit diversion and provide stakeholders with financial reporting – a critical function in an all cash industry.

Key Components of a Compassionate Drug Monitoring Program (CDMP™)

A comprehensive medical marijuana program should require the issuance of a Medical Cannabis Access Card to ensure a patient or a patient representative may purchase or possess

medical cannabis. When each cannabis purchase is entered real time into a Compassion Drug Monitoring Program this information may be accessed by stakeholders including patients, physicians, cultivators, processors, dispensary management personnel and regulators. Of course with appropriate HIPAA and privacy controls in place.

A CDMP would ease concerns that a patient or patient representative may have when purchasing or possessing medical marijuana. At any given time industry participants would be able to confirm applicable patient marijuana purchase limits and participation, without having access to sensitive patient data.

A centralized real time system provides secure and streamlined data to limit diversion and provide real time analytics to best support public safety and industry compliance. Key elements would include:

Compassionate Drug Monitoring Program or “Real Time” Registry

- Compassionate Drug Monitoring Program registration for all stakeholders from patients, physician, cultivators, processors to dispensary personnel
- Supports audit and inspection processes
- Standard and customizable reporting functions and features

A system wide real time monitoring program would allow for cultivators, processors and dispensaries to register their agents for transaction monitoring. This also provides key oversight controls to the Commonwealth crucial in limiting diversion and direct access to cash flow and inventory management related data. Additionally, the resulting information generated may be utilized by enforcement officials to support their various compliance efforts, including triggering inspections and operational certifications.

By utilizing a centralized system for not only all program participants but also all transactions, licensees have the tools necessary to comply with all rules and regulations, while also streamlining their operations. The benefits to the licensee include...

Grower, Processor and Dispensary Oversight

- **Centralized registration for all personnel including management and agents**
- **Real time verification of all program participants**
- **Capture transfers of inventory throughout the supply cycle: wholesaler to retailer to caregiver to end user**

Successful programs require both scheduled and unscheduled inspections of cultivators, processors and dispensaries. To support efficient inspections, transaction records including, cannabis inventories, for these licensees should be entered on a real time basis. By implementing a central repository for all data generated, the Department can receive real time analytics indicating anomalies prompting an unscheduled site inspection.

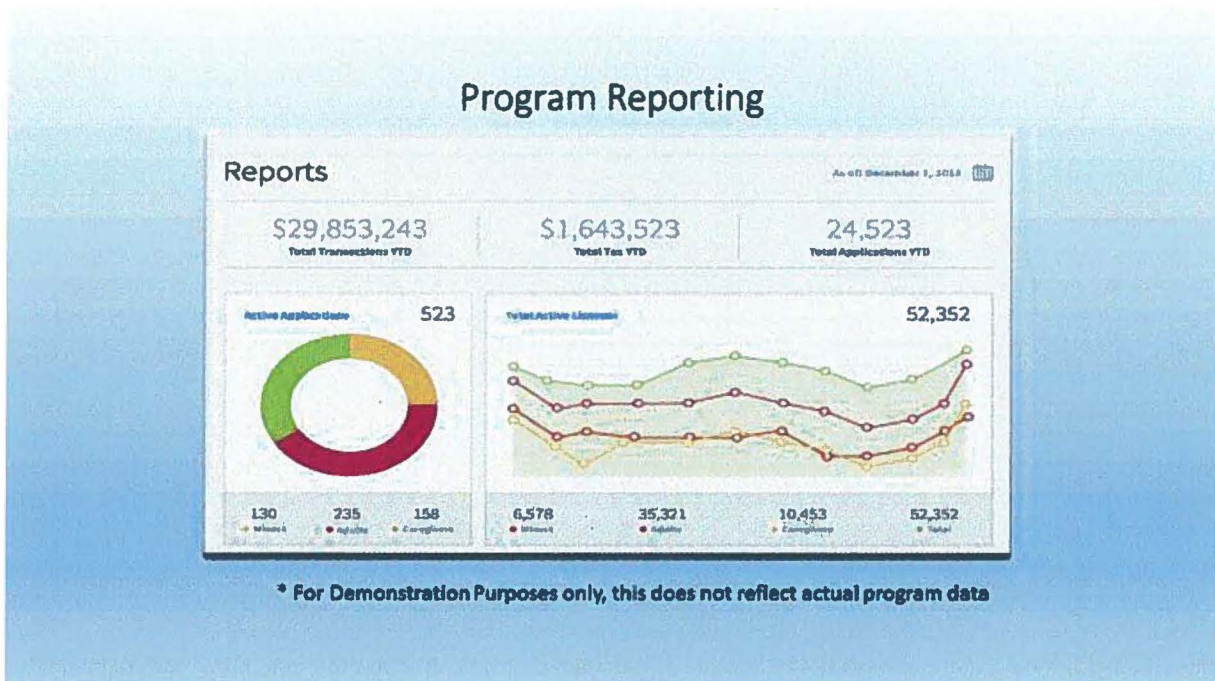
A real time registry will allow for the Department to receive timely notifications on program activities which may trigger further review. These circumstances may include the application of a grower, processor or dispensary for a license. Other events that would prompt action may be a compliance exception or complaint, or a random sampling of inspections as the Department requires.

Inspection and Audit Oversight

- Evaluate security protocols, quality controls and compliance
- Identify areas of deficiency for process improvement
- Enhance controls to assure that agency required activities are performed

A comprehensive program would detail reporting requirements that must be submitted annually to the Pennsylvania Department of Health. Through the use of a centralized registry, all requisite data can be quickly compiled and disseminated appropriately.

By housing all data in a centralized database, real time analytics will allow for a wide array of customized reports and data gathering.



If the Commonwealth elects to go forward with the introduction of a medical marijuana program, I encourage you to add all readily available and appropriate safe guards to ensure the Program's success for years to come.

Thank you for allowing me to participate in the hearing today. I welcome the opportunity to answer questions or address any concerns that you may have.