

Anti-Diversion to Support Anti-Doping

A Data-Driven Proposal to Disrupt the Doping Economy

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Introduction

Anti-doping has focused on two main disciplines:

- **Lab testing** - locked in a battle with performance enhancement science, and testing manipulation
- **Education** programs to deter doping behaviors - dependent on the moral resolve of the athletes

Proposing A New Approach: Anti-Diversion



“Why don’t you try turning the problem on its head? The data you track for anti-diversion programs is already available in most healthcare systems. Choke off the supply chain.”

Peter Ambrose, Pharm.D, RPh (March 1, 1956 - July 9, 2016), UC-San Francisco School of Pharmacy; doping control officer, Atlanta 1996, Sydney 2000, Beijing 2008

Quote from my last phone conversation with Peter in late November, 2015

Anti-Diversion is a Response to Crisis

Counterfeit medication scandals and the opioid abuse epidemic



Opioid abuse accelerated from diversion of pain medication out of the legitimate supply chain

Diverted medications have been fraudulently relabeled, diluted, tampered, and resold; these counterfeits have poisoned or under-medicated patients



Anti-Diversion is Strategy and Technology

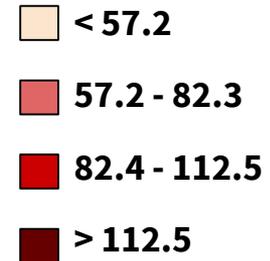
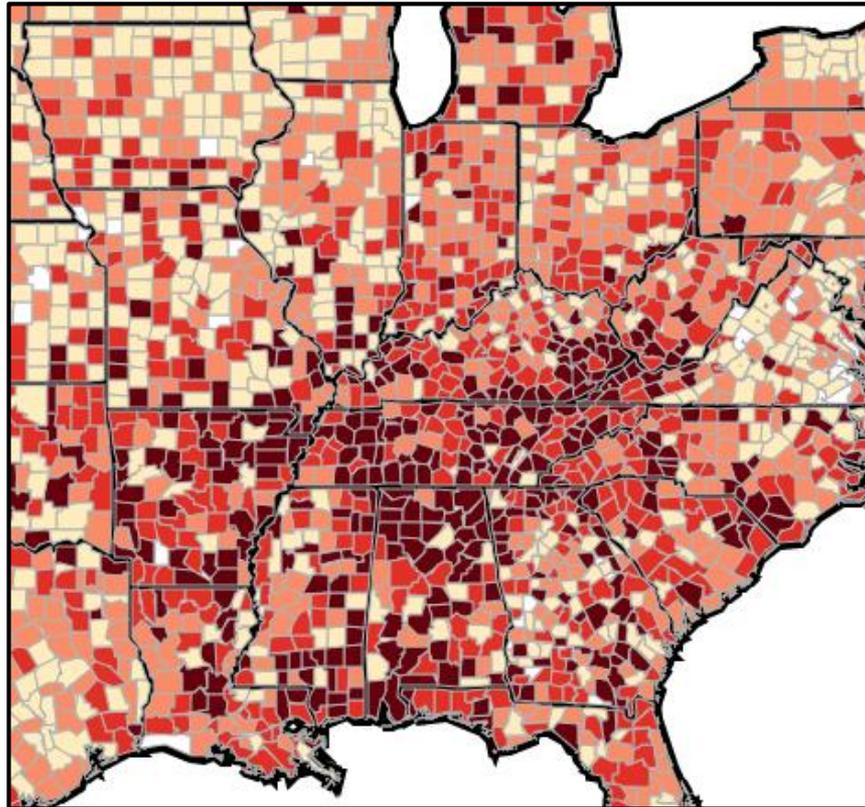
- **Strategic policies** which:
 - Protect people from counterfeit medication - **increase patient safety**
 - Prevent abuse of medication - **reduce addiction risk**
- **Data models** which:
 - Measure wide-ranging patient population demographics
 - Query healthcare and pharmacy supply chain data

The Mechanics Of Anti-Diversion

1. **Measure** the rates of diseases which are eligible for treatment with a certain class of medication, within a specific geographic region
2. **Calculate** the consumption rate for that medication, based on the number of patients in that region eligible for treatment with it
3. **Compare** data for actual prescriptions and inventory to the calculated amount that the patient population can consume
4. **Investigate** abnormal findings, and intervene

Assessing The Opioid Epidemic

2016 data visualization of opioid prescription density per 100 patients, per U.S. County, based on diagnosis code and drug code



Source: 2016 CDC U.S. County prescribing and dispensing data

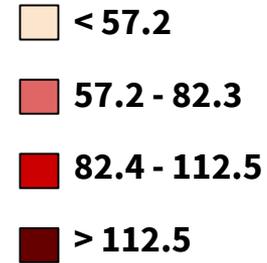
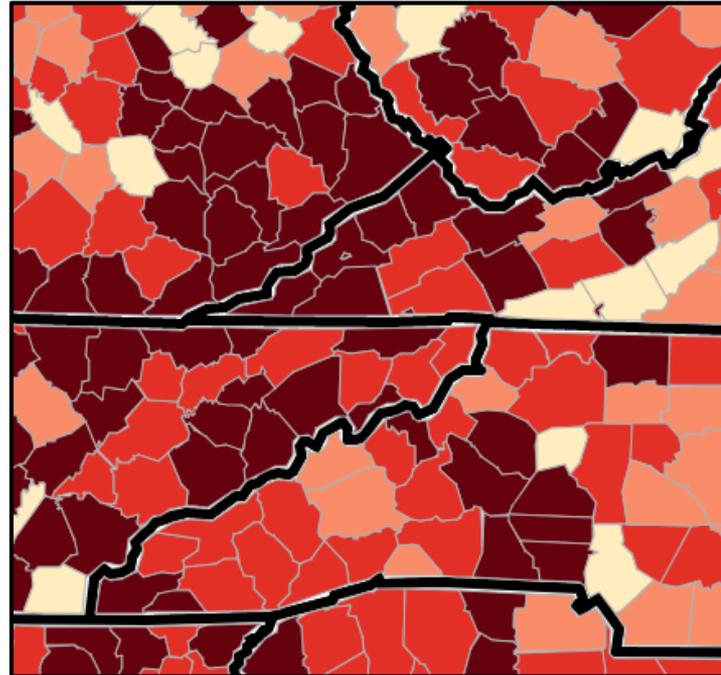
What Does The Data Show Us?

A clearer picture of addiction, prescribing, and diversion patterns

Density exceeds *any* consumption calculation, indicates high addiction risks and diversion

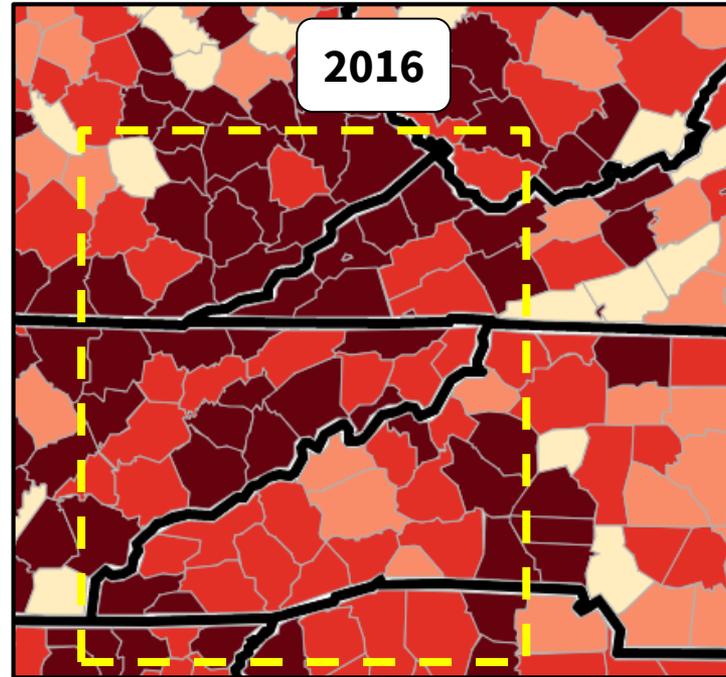
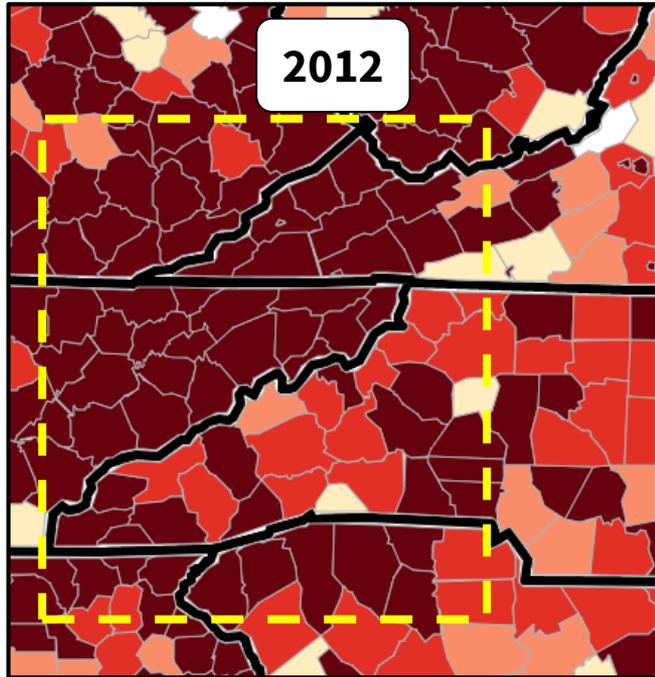
Geographic location data indicates diversion paths

Healthcare and inventory data indicate the actors



INSET: State-line borders of West Virginia, Virginia, Kentucky, Tennessee, and South Carolina - AKA "Appalachia"

Focusing On The Problem



**Regulatory and law enforcement intervention over a four year campaign:
reduced diversion channels, reduced addiction risks, reduced addiction rates**

Anti-Diversion Outcomes

- Addiction factors can be interrupted, intervened
- **Algorithms identify deceptive inventory and dispensing techniques; data can reveal the individual pharmacy, pharmacist, and prescriber**
- Pharmacists, physicians, diversion intermediaries and enablers are being jailed, and fined into the tens of millions of dollars

Applying Anti-Diversion To Anti-Doping

Medications with very limited therapeutic applications like recombinant Erythropoietin (EPO), abused as PEDs by endurance athletes, can provide unique and accurate indicators of a doping supply chain

- Like many other controlled medications, EPO prescription and inventory data can be audited by Boards of Pharmacy and traced by the DEA and FDA



EPO Is A Highly Desired PED, *but...*

- Incredibly difficult to bioengineer it from genetically modified cells
- Very unstable: must be stored between 2 - 8 °C; spoiled or contaminated EPO can sicken or kill
- Supply chain is tracked unit-for-unit due to patient safety concerns
- Enablers and athletes increasingly demand authentic medications, by brand name and label, to prevent “accidental positives” (Rodchenkov, *Icarus*)
- **EPO-to-athletics channel has narrowed significantly: Physician-prescriber / Pharmacist-dispenser / Athlete-consumer**



Comparing The Math

<u>Opioids</u>	vs	<u>EPO</u>
<p>Prescribed for thousands of pain management and other conditions; each diagnosis has a unique International Classification of Disease (ICD10) code</p>		<p>Can only be prescribed for a handful of ICD10-classed conditions: kidney disease, certain anemias, post-chemotherapy support</p>
<p>Hundreds of opioid medications can be dispensed, each with a unique National Drug Code (NDC number) for manufacturer and dose strength</p>		<p>Approximately 50 types of EPO medication classed in the NDC for dispensing</p>
<p>Terabytes of data must be analyzed to spot addiction and diversion risks</p>		<p>The data analysis is discrete enough to catch diversion of single doses</p>

Potential For Anti-Doping Improvements

**NADOs could partner with and benefit from healthcare regulator
disruption of the PED black market economy**

- The scientific anti-diversion investigative toolkit opens opportunities to reinforce anti-doping by:
 - Enhancing targeted tests
 - Revealing enablers



What's Next

- Proposals for new anti-doping policies must be considered
- Problem: what happens if anti-diversion overtakes anti-doping in cost-efficiency and results?
 - WADA and NADOs have absolutely no say in criminal matters of anti-diversion; ***when*** large numbers of athletes are caught in anti-diversion sweeps, what happens?
 - Non-analytical findings could become the norm, not the exception
- **Benefit: anti-diversion can be a powerful deterrent by preventing doping substances from reaching the athletes, and significantly enhancing the mission by targeting hotspots for intervention**