Manufacturer Trends and Updates

2015 Manufacturer Conference
National Harbor, Maryland

September 23-24, 2015

Thomas W. Prevoznik, Unit Chief
Liaison Section
Office of Diversion Control
The three most common types of prescriptions are antibiotics, antidepressants, and painkiller opioids.

70% of Americans are taking at least one prescription drug.

More than 50% are on at least two prescriptions.

Source: Mayo Clinic Press Release, 6/19/2013
Primum non nocere
Prescription Drug Abuse is driven by

Indiscriminate Prescribing Criminal Activity
United States V. Alvin Yee, M.D.

MEDICAL OFFICE

Various Locations, Orange County, California
Pharmacy tech arrested over pain pills

OCILLA, GA (WALB) - A pharmacy technician in Ocilla is charged with forging prescriptions and stealing thousands of pain pills. Tabatha Fender worked as a Pharmacy Technician at Fred's pharmacy in Ocilla. But drug agents say it was the work she was doing on the side that got her in serious trouble.

"She was basically writing forged prescriptions and using the public's information. People that go to Fred's," said Agent Eugene Paulk of the South Central Drug Task Force.

Agents with the south Central Drug Task Force in Fitzgerald looked into irregularities in the number of prescriptions being written for the pain medication hydrocodone. Their investigation indicated that prescriptions were being forged by Fender and that it may have gone for more than a year.

"Probably around 120 prescriptions or more, 180 pills at a time," said Paulk. Agents arrested Fender in August. She was arrested again this month on additional forgery counts as more customers came forward after their prescriptions were denied because they had already been filled—by Fender and for Fender.

"People that actually needed them, people with health problems were put on hold until she could fill their prescriptions," Paulk said.

Fender is being held without bond due to the seriousness of the charges.
Owner of Mobile pharmacy arrested, accused of supplying drugs to street-level dealers
Doctor Accused of Overprescribing Pills Is Guilty of Manslaughter

By MONIQUE O. MADAN JUly 18, 2014

Dr. Stan Xuhui Li outside State Supreme Court in Manhattan on Friday. He was convicted of 200 of the 211 charges against him after a four-month trial. Anthony Lanzilote for The New York Times
ANDREW WELSH-HUGGINS  02/14/12 06:45 PM ET Associated Press
COLUMBUS, Ohio — A Chicago doctor who prosecutors say dispensed more of the powerful painkiller oxycodone from 2003 to 2005 than any other physician in the country was sentenced Tuesday to four life terms in the overdose deaths of four patients.
Dr. Paul Volkman made weekly trips from Chicago to three locations in Portsmouth in southern Ohio and one in Chillicothe in central Ohio before federal investigators shut down the operations in 2006, prosecutors said. He was sentenced in federal court in Cincinnati.
"This criminal conduct had devastating consequences to the community Volkman was supposed to serve," Assistant U.S. Attorneys Adam Wright and Tim Oakley said in a court filing ahead of Tuesday's hearing.
"Volkman's actions created and prolonged debilitating addictions; distributed countless drugs to be sold on the street; and took the lives of numerous individuals who died just days after visiting him," they said.
The 64-year-old Volkman fired his attorneys earlier this month and said he acted at all times as a doctor, not a drug dealer.
"The typical drug dealer does not care how much drugs a client buys, how often he buys, or what he does with his drugs," Volkman said in a 28-page handwritten court filing Monday, maintaining that he did all those things and more for his patients.
What is the Societal Damage of Prescription Controlled Substance and Legend Drug Abuse?
In 2011, approximately 41,340 unintentional drug overdose deaths occurred in the United States, one death every 12.45 minutes. (increased for 12th consecutive year)1

Of this number, **22,810** deaths were attributed to Prescription Drugs (**16,917** attributed to opioid overdoses/74.165%).

Prescription drug abuse is the fastest growing drug problem in the United States.

1SOURCE:  CDC National Center for Health Statistics/National Vital Statistics Report; June 2014
CDC Vital Signs: Opioid Painkiller Prescribing; July 2014
Drug-Poisoning Deaths Involving Opioid Analgesics or Heroin in the US, 1999-2013

Number of Deaths in Thousands

<table>
<thead>
<tr>
<th>Year</th>
<th>Heroin</th>
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<td>'99</td>
<td>2.0</td>
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<tr>
<td>'00</td>
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<td>'13</td>
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Date Prepared/ Source: 01/28/15, CDC/NCHS, National Vital Statistics System, Mortality File
Some states have more painkiller prescriptions per person than others.

Where Painkiller Prescriptions Are The Highest

• In 2012, Southern states had the most per person.
• The top three states were Alabama, Tennessee, and West Virginia;
  Alabama: 143 per 100 people
  Tennessee: 143 per 100 people
  West Virginia: 138 per 100 people
• Lowest-Hawaii: 52 per 100 people

SOURCE: CDC Vital Signs: Opioid Painkiller Prescribing; July 2014
Prescription Drug Abuse Prevention Plan

• Coordinated effort across the Federal Government

• Four focus areas:
  1) **Education**
  2) **Prescription Drug Monitoring Programs**
  3) Proper Disposal of Medication
  4) Enforcement
Since 2011, Eleven States have Passed Legislation Mandating Prescriber Education
What People Are Abusing
Hydrocodone

- Hydrocodone / Acetaminophen (toxicity)

- Similarities:
  - Structurally related to codeine
  - Equal to morphine in producing opiate-like effects

- Brand Names: Vicodin®, Lortab®, Lorcet®

- Currently, combination products are Schedule III

- October 6, 2014 moved to SCHEDULE II

- “Cocktail” or “Trinity”
  - Hydrocodone
  - Soma® / carisoprodol
  - Alprazolam / Xanax®

- Street prices: $2 to $10+ per tablet depending on strength & region
67 countries reported an estimated need requirement for hydrocodone to the International Narcotics Control Board.

20 countries reported an estimated need of 1 kilogram or greater.

4 countries reported an estimated need between 500 grams and 999 grams.

10 countries reported an estimated need between 100 grams and 499 grams.

6 countries reported a need between 25 grams and 99 grams.

27 countries reported a need of less than 25 grams.

Worldwide Hydrocodone Use

- Of the 20 Countries that reported an estimated needs requirement for hydrocodone at one kilogram or more

- 8 countries reported an estimated need of 1 kilogram to 5 kilograms

- 4 countries reported an estimated need over 5 kilograms to 10 kilograms

- 8 countries reported an estimated need over 10 kilograms

# Top 10 List

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<thead>
<tr>
<th>Rank</th>
<th>Country</th>
<th>Quantity</th>
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<td>10 kilograms</td>
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<td>India</td>
<td>10 kilograms</td>
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<td>08</td>
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<td>07</td>
<td>China</td>
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<td>Syrian Republic</td>
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<td>03</td>
<td>Canada</td>
<td>115.5 kilograms</td>
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<td>02</td>
<td>United Kingdom</td>
<td>200 kilograms</td>
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<tr>
<td>01</td>
<td>United States</td>
<td>79,700 kilograms 99.3%</td>
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**U.S. Drug Enforcement Administration Office of Diversion Control**
The Trinity

Hydrocodone

Carisoprodol
Muscle Relaxant
C-IV as of 1/11/2012

Alprazolam
Benzodiazepine

Opiate

U.S. Drug Enforcement Administration
Office of Diversion Control
Oxycodone

• OxyContin controlled release formulation of Schedule II oxycodone
  – The controlled release method of delivery allowed for a longer duration of drug action so it contained much larger doses of oxycodone
  – Abusers easily compromised the controlled release formulation by crushing the tablets for a powerful morphine-like high
  – 10, 15, 20, 30, 40, 60, 80mg available

• Effects:
  – Similar to morphine in effects and potential for abuse/dependence
  – Sold in “Cocktails” or the “Holy Trinity” (Oxycodone, Soma® / carisoprodol, Alprazolam / Xanax®)

• Street price: Approx. $80 per 80mg tablet

• NOTE: New formulation introduced into the marketplace in 2010 that is more difficult to circumvent for insufflation (snorting) or injection. Does nothing to prevent oral abuse.
Prescription Opiates vs. Heroin
The Circle of Addiction & The Next Generation

Hydrocodone
Lorcet®
$5-$7/tab

Oxycodone
Combinations
Percocet®
$7-$10/tab

OxyContin®
$80/tab

Roxicodone®
Oxycodone IR
15mg, 30mg
$30-$40/tab

Heroin
$15/bag
Heroin: No Longer Confined to Urban Areas

Heroin use spikes in area suburbs

Pill addicts risk deadly drug
The CSA: Checks and Balances
The mission of the Office of Diversion Control is to **prevent**, **detect**, and **investigate** the diversion of pharmaceutical controlled substances and listed chemicals from legitimate channels of distribution

**while** ...

ensuring an adequate and uninterrupted supply of controlled substances to meet **legitimate medical**, **commercial**, and **scientific needs**
Cutting off the Source of Supply
Closed System of Distribution

1,604,158 (09/04/2015)

- Practitioners: 1,221,972
- Retail Pharmacies: 71,439
- Hospital/Clinics: 16,500
**Cyclic Investigations**

**Record Keeping Requirements**

**Security Requirements**

**ARCOS**

**Established Quotas**

**Established Schedules**

**Registration**

U.S. Drug Enforcement Administration
Office of Diversion Control
Closed System of Distribution

The DEA is responsible for:

- the **oversight** of the system
- the **integrity** of the system
- the **protection** of the public health and safety
Distributor Initiative

Educate and inform distributors/manufacturers of their due diligence responsibilities under the CSA by discussing their Suspicious Order Monitoring System, reviewing their ARCOS data for sales and purchases of Schedules II and III controlled substances, and discussing national trends involving the abuse of prescription controlled substances.

August 1, 2005 – August 19, 2015: Briefings to 85 firms with 280 registrations

U.S. Drug Enforcement Administration
Office of Diversion Control
DEA Registrant Initiatives

Pharmacy Diversion Awareness Conference

This conference is designed to educate pharmacists, pharmacy technicians, and pharmacy loss prevention personnel on ways to address and respond to potential diversion activity.
Completed PDACs

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<td>518</td>
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<tr>
<td>NY</td>
<td>9/15-16/12</td>
<td>391</td>
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<tr>
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<td>1,192</td>
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FY-2011 Total Attendance: 75

FY-2012

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FY-2012 Total Attendance: 2,429

FY-2013

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<tr>
<td>IL</td>
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<td>OR</td>
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<td>LA</td>
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<td>CA</td>
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FY-2013 Total Attendance: 2,948

FY-2014

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<td>TN</td>
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<td>MO</td>
<td>4/5-6/14</td>
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<td>PA</td>
<td>7/12-13/14</td>
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<td>CO</td>
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FY-2014 Total Attendance: 2,196

FY-2015

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<td>AL</td>
<td>3/28-29/15</td>
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<td>VA</td>
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<td>OK</td>
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<td>WI</td>
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<tr>
<td>ME</td>
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Total Attendance To Date: 9,218

Proposed FY-2016 PDACs

29-Little Rock, Arkansas November 7 & 8, 2015
30-Jackson, MS January 9 & 10, 2016
31-Charleston, WV February 27 & 28, 2016
32-Wilmington, Delaware March 19 & 20, 2016
33-Charleston, South Carolina April 2016
34-Minneapolis/St. Paul, Minnesota July 2016
35-Towson, Maryland August 2016
36-New Brunswick, New Jersey September 2016
"Stakeholders’ Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances"

- Represents the medical, pharmacist, and supply chain spectrum highlighting the challenges and “red flag” warning signs related to prescribing and dispensing controlled substance prescriptions

- The goal was to provide health care practitioners with an understanding of their shared responsibility to ensure that all controlled substances are prescribed and dispensed for a legitimate medical purpose, as well as to provide guidance on which red flag warning signs warrant further scrutiny

- NABP along with 10 national associations and 6 major pharmaceutical firms were the coalition of stakeholders of this document.
The Federation of State Medical Boards (FSMB) promotes excellence in medical practice, licensure, and regulation on behalf of 70 state medical and osteopathic Boards across the country in their protection of the public.

DEA and FSMB are currently working on developing strategies to work more effectively and jointly on indiscriminate prescriber investigations in order to facilitate the administrative process to take action against those that are a threat to the public health and welfare quickly, and at the same time not jeopardize a criminal investigation.
Scheduled Investigations

- Increase in the number of DEA registrants that are required to be investigated to ensure compliance with the Controlled Substances Act and its implementing regulations
- Increase in the frequency of the regulatory investigations
- Verification investigations of customers and suppliers
21 CFR § 1301.71(a)

“All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.”
Effective Controls

21 CFR § 1301.71(a)

In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in §§ 1301.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion.
Non-practitioners of controlled substances

“The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances...Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”
Suspicious Orders

• Reporting of a suspicious order to DEA does NOT relieve the supplier of the responsibility to maintain effective controls against diversion
  – The responsibility for making the decision to ship or not to ship rests with the supplier.

  – Once a Suspicious Order is identified by the supplier the order must not be shipped.
Suspicious Orders

Orders of Unusual Size

Orders Deviating Substantially from a Normal pattern

Orders of Unusual Frequency

These criteria are disjunctive (They can stand alone or together)
Know your Customers
Secure and Responsible Drug Disposal Act of 2010
The Problem: Easy Access
Secure and Responsible Drug Disposal Act of 2010

- CSA amended to provide ultimate users and LTCF with additional methods to dispose of unused, unwanted or expired controlled substance medication in a secure, safe and responsible manner
  
  21 USC §§ 822(f) & (g)

- Registrants authorized to collect:
  - Manufacturers
  - Distributors
  - Reverse Distributors
  - Narcotic Treatment Programs
  - Hospitals/clinics with an on-site pharmacy
  - Retail Pharmacies
  
  21 CFR § 1317.40

Authorized collectors, as registrants, are readily familiar with the security procedures and other requirements to handle controlled substances.
Secure and Responsible Drug Disposal Act of 2010

- Regulations did not limit the ways that ultimate users may dispose of pharmaceutical controlled substances ... they expanded them.
- Any method of pharmaceutical disposal that was valid for ultimate users prior to these regulations remains valid.
- Participation is voluntary.
- The DEA may not require any person to establish or operate a disposal program.

21 USC §§ 822(g)(2)
Secure and Responsible Drug Disposal Act of 2010

• Disposal rule eliminated existing 21 CFR 1307.12 & 1307.21

• New part 1317 contains the requirements on:
  – disposal procedures;
    • registrant inventory
    • collected substances
  – collection of pharmaceutical controlled substances from ultimate users;
  – return and recall; and
  – destruction of controlled substances
Practitioner & Non-Practitioner may dispose of inventory:

- Prompt on-site destruction
- Prompt delivery to reverse distributor by common or contract carrier or reverse distributor pick-up
- Return and recall: Prompt delivery by common or contract carrier or pick-up at the registered location

**Practitioner** may also request assistance from the SAC

**Non-practitioner** may also transport by its own means

21 CFR § 1317.05(a) and (b)
Requirements for Destruction of Controlled Substances
**Destruction of Controlled Substances**

All controlled substances destroyed by a registrant or caused to be destroyed by a registrant shall be destroyed in compliance with applicable Federal, State, tribal, and local laws and regulations and shall be rendered **non-retrievable**

21 CFR § 1317.90

**Non-retrievable** means the condition or state to which a controlled substance shall be rendered following a process that permanently alters the substance’s physical or chemical condition or state through irreversible means, and thereby renders the controlled substance unavailable and unusable for all practical purposes

21 CFR § 1300.05
Transfer and transport for destruction

- Transportation directly to registered location or destruction location
- 2 employees accompany the controlled substances to location
- 2 employees load & unload or observe load & unload until transfer is complete

21 CFR § 1317.95(b) and (c)
**Destruction Procedures**

- 2 employees of the registrant shall handle or observe the handling of any controlled substance until it is rendered non-retrievable, and
- 2 employees of the registrant shall personally witness the destruction of the controlled substance until it is rendered non-retrievable.

21 CFR § 1317.95(c) and (d)
Form 41 shall be used to record the destruction of all controlled substances, including controlled substances acquired from collectors.

- The Form 41 shall include the names and signatures of the two employees who witnessed the destruction.

- Exceptions for DEA Form 41:
  - Destruction of a controlled substance dispensed by a practitioner for immediate administration at the practitioner’s registered location, when the substance is not fully exhausted (i.e. wastage) shall be properly recorded in accordance with § 1304.22(c), and such record need not be maintained on a Form 41
  - Transfers by registrant to a reverse distributor must be recorded in accordance with § 1304.22(c), and such record need not be maintained on a Form 41
# Registrant Record of Controlled Substances Destroyed

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<th>DEA Registration Number</th>
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## B. Item Destroyed

### 1. Inventory

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<tr>
<th>National Drug Code or DEA Controlled Substances Code Number</th>
<th>Batch Number</th>
<th>Name of Substance</th>
<th>Strength</th>
<th>Form</th>
<th>Pkg. Qty.</th>
<th>Number of Full Pkgs.</th>
<th>Partial Pkg. Count</th>
<th>Total Destroyed</th>
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<td>60mg</td>
<td>Capsules</td>
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<td>2</td>
<td>0</td>
<td>120 Capsules</td>
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<tr>
<td>0555-0767-02</td>
<td>N/A</td>
<td>Adderall</td>
<td>5mg</td>
<td>Tablet</td>
<td>100</td>
<td>0</td>
<td>83</td>
<td>83 Tablets</td>
</tr>
<tr>
<td>9050</td>
<td>B02120312</td>
<td>Codeine</td>
<td>N/A</td>
<td>Bulk</td>
<td>1.25 kg</td>
<td>N/A</td>
<td>N/A</td>
<td>1.25 kg</td>
</tr>
</tbody>
</table>
## 2. Collected Substances

<table>
<thead>
<tr>
<th>Returned Mail-Back Package</th>
<th>Sealed Inner Liner</th>
<th>Unique Identification Number</th>
<th>Size of Sealed Inner Liner</th>
<th>Quantity of Packages(s)/Liner(s) Destroyed</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>MBP1106, MBP1108, MBP1110, MBP112</td>
<td>N/A</td>
<td>15 gallon</td>
<td>21</td>
</tr>
<tr>
<td>X</td>
<td>CRL1007 - CRL1027</td>
<td>5 gallon</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>X</td>
<td>CRL1201</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Notes:**
- See instructions on reverse (page 2) of form.
C. METHOD OF DESTRUCTION

<table>
<thead>
<tr>
<th>Date of Destruction:</th>
<th>Method of Destruction:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Location or Business Name:</td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td></td>
</tr>
<tr>
<td>City:</td>
<td>State:</td>
</tr>
</tbody>
</table>

D. WITNESSES

I declare under penalty of perjury, pursuant to 18 U.S.C. 1001, that I personally witnessed the destruction of the above-described controlled substances to a non-retrievable state and that all of the above is true and correct.

<table>
<thead>
<tr>
<th>Printed name of first authorized employee witness:</th>
<th>Signature of first witness:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Printed name of second authorized employee witness:</td>
<td>Signature of second witness:</td>
<td>Date:</td>
</tr>
</tbody>
</table>

E. INSTRUCTIONS

1. **Section A. REGISTRANT INFORMATION**: The registrant destroying the controlled substance(s) shall provide their DEA registration number and the name and address indicated on their valid DEA registration, in addition to a current telephone number and a contact name, if different from the name on the valid DEA registration.

2. **Section B. (1) Inventory**: This part shall be used by registrants destroying lawfully possessed controlled substances, other than those described in Section B(2). In each row, indicate the National Drug Code (NDC) for the controlled substance destroyed, or if the substance has no NDC, indicate the DEA Controlled Substances Code Number for the substance; if the substance destroyed is in bulk form, indicate the batch number, if available. In each row, indicate the name, strength, and form of the controlled substance destroyed, and the number of capsules, tablets, etc., that are in a full package (pkg. qty.). If destroying the full quantity of the controlled substance, indicate the number of packages destroyed (number of full pkgs.). If destroying a partial package, indicate the partial count of the capsules, tablets, etc. destroyed (partial pkg. count). If destroying a controlled substance in bulk form, indicate that the substance is in bulk form (form) and the weight of the substance destroyed (pkg. qty.). In each row, indicate the total number of each controlled substance destroyed (total destroyed).
National Take Back Initiative
September 26, 2015

Got Drugs?
Turn in your unused or expired medication for safe disposal Saturday, September 26, 2015
Click here for a collection site near you.

10:00 AM – 2:00 PM