The “Grey Market”
CLOSE TO HOME!

Pete Grasso, R.Ph.
Chief Compliance Investigator - NH Board of Pharmacy

Cooperative Investigation
FDLE
FL AG’s Office  FL Dept. Health
Medicaid Fraud  FDA
Miami Dade PD  Texas Dept. Health
NH Bd of Rx  Nevada Bd of Rx
Georgia Drugs & Narcotics Agency

What is the “Grey” Market?

- Diverted Pharmaceuticals (high end)
  - “Stolen”
  - Bought on the street from addicts (HIV)
- Counterfeit
  - Sub-potent
  - Diluted or nothing at all
All are re-introduced into the drug delivery system

How is the drug “Re-introduced”?

- “Bogus” distributors
- “Virtual” offices
- Licenses from states with little oversight
- Phones connected to principals in another state (in most cases = So. Florida)
- Bogus distributor NEVER sees or touches the drugs
- Drop shipped or actually delivered

A “Virtual” office
One part of the story begins in Missouri in 2002 with a cancer patient on chemo.
Using Procrit® and Epogen®, which fights fatigue & anemia, bought at local pharmacy.
Injections stopped helping.
Astute nurse remembered the recent warnings about counterfeit product.
Checked the remaining vial & found to be 1/20 of labeled dose. Patient DIED. She was a victim of Lot# P002970.

2nd patient was a teenaged kidney transplant patient (2002).
Using 40,000 unit Epogen® for similar circumstances.
After 8 weeks = no increase in RBC.
Severe cramping.
Testing revealed another 1/20th strength compromised product.
Victim of Epogen® Lot# P002970.
WHERE did this product come from??
The patient’s Rx was filled at CVS
CVS bought the drug from Amerisource
Amerisource bought from a “Grey Market” distributor………..
Eventually – traced back to a NH distributor

ALL “Procrit®”

Nice mix
Procrit – Epogen -Neupogen

Serostim®

Epogen®
NH Issues
- We had a number of applications submitted
- Residential & Commercial locations
- ALL applicants were from Florida
- Monies for rental came via money orders from Las Vegas
- No one ever saw the principals
- NO LICENSES GRANTED

NH Issues
- In the “early” stages at least 3 got through
- Principals were in Florida and California and NEW HAMPSHIRE!
- In one case the license removed & fined
- In one case the license lapsed prior to formal action
- The third case referred to US Attorney & FDA’s OCI (3 years to indictment)

April 4, 2002
- FDLE agent Gary Venema poses as buyer for an export company wishing to ship medicine to the middle east.
- Delivery of Epogen® with fishy pedigree & very low price.
- Delivery made by a principal from Jemco Medical International.
- Drug traced back to L & L Distributors
Where did this come from?

BINGO!!!

Still MORE.....!

Load it up!

THANKS, guys!!!!!
- Pedigree papers were phony
- Also showed that Amgen (mfg) had sold the drug to a Houston company
- The Houston company had sold it to a Dallas firm.
- Amgen verified that this pedigree was bogus
- 100 boxes of Epogen® Lot #P002970 were seized... The original price agreed upon prior to the sting $509,000

100 Vials of Epogen®

ALL are Lot # P002970

Good day’s work—ANY DAY!

These are the guys that made it happen!

The "Horsemen of the Apocalypse"
OK, let’s connect to NH!

- August 14, 2002 Florida Dept. Health requests assistance in obtaining records from “Armin Medical Supply”
- A Nashua, NH distributor
- Alleged to have shipped 79 Vials of Epogen® Lot # P002970 to AME Rx, a Florida drug wholesaler.
- Price…….$307,000

Contact Letter from FL

September 2002

- Armin Medical licensed with NH BOP
- Served subpoena & records obtained & sent to Florida Dept. Health.
- NH BOP kept copies of all records obtained.
- Nothing further done at this level at this time. (we had no expertise or knowledge of the “counterfeit” world).
October 2002

- NADDI Conference in Charlotte, NC
- Sought out by agents Venema, Odin & Arias.
- Brought into the loop & up to speed on the grey market with much attention to Armin Medical
- Also one “Michael Carlow” of Westin, Fl.
So. FL "Distributor"

So. Florida "Rodent"

Epsom Salts from Costa Rica?

How about LIPITOR??

Counterfeit Lipitor Labels
NOW it’s ready to ship out!

For “Bulk” sales

The trail gets twisted

- Began in earnest to review NH BOP’s license files on wholesaler/distributors
- Found three of such with a licensed location in Milford, NH
- Being a native of Milford, immediately recognized this was a residential area.
- Decided a “site visit” was appropriate

23 Valhalla Drive

3 Distributors HERE!

- Alpine Pharma
  - Principal: Beth Handy
- Accucare, LLC
  - Principal: Candace Carlow of Westin, FL
  - Michael Carlow’s “wife”
- Neutraceutical Pharmaceuticals
  - Principal: Robert C. Hatch of Cathedral City, CA

- Beth Handy lives at this residence
- Site visit...........................
- Candace Carlow is a “friend” from Florida who’s husband is Michael Carlow & well known to FDLE.
- Robert Hatch is “unknown” to Handy & has no idea “Why” he may have used her address…….
- ALL THREE HAD VALID LICENSES ISSUED BY THE NH BOP!
- A file search reveals Handy was previously the purchasing agent for Armin Medical.
- We’ll get back to Armin in a minute.
- There were NO records in Milford for ANY transactions by Carlow’s Accucare company.
- In the interim, her license expired & was never renewed.
- Michael used this license to engage in some “off shore” buying in FL.

Misc. Information
- Armin Medical changed name to “Med Industries”.
- Handy leaves Med Industries to open her own company “Alpine Pharma”.
- Candace Carlow licenses Accucare, LLC at Handy’s residence.
First Target

- Neutraceuticals Pharmaceuticals
- Hatch finally said he didn’t know Handy
- Filed application with false information
- Her name “given” to him & told “OK” to use her address…
- He is in CA & we are in NH…”Long arms”? 
- We revoked his license for fraud and fined him $7,500 (We DID get the $$$)

Armin Medical

- Now “Med Industries”
- Dug out copies of original paper work sent to FL via the subpoena
- Treasure trove of information once we knew “what” to look for.
- THOUSANDS of dollars worth of counterfeit product facilitated into the delivery system by this company

Pedigree Information

- Pedigree = from who to who…….
- Part of PDMA but wholesalers pressured FDA to “waive” this part of the act…for YEARS!
- Counterfeiters used this to their advantage & used “virtual” companies as brokers just to create a pedigree and move illicit drugs into the legitimate delivery system
Texas Distributor Verification

- Contacted Texas requesting information on:
  - MEDEX International
  - Express Rx
  - San Antonio Health Care
- Received NO reply
- Also tried to communicate with Express Rx.
Who is Express RX??

Eddie Mor
- Lived & worked in Florida, not Texas
- Owner of “Express Rx” (Dallas, TX)
- Conspired with a Carlos Luis to peddle millions of dollars worth of bogus meds.
- Luis owned “Medex International” located in Houston, TX
- Both locations = inactive... ALL business conducted from So. Florida.

Search Warrant - Mor’s Home
- Records & invoices for Express Rx
- Purchase orders from TNT Sales
- Express Rx checks
- TNT sales invoices for sales from Express RX
- Invoices for sales to ARMIN Medical, a Nashua, NH based distributor

Make your own “Pedigree”!
Mor & Luis
- Records identified them as the source of the 100 vials of counterfeit Epogen® purchased by FDLE agents in April 2002
- Only weeks later, Bindley Western found $1.7 MILLION of counterfeit Procrit® in a Texas warehouse...Again paperwork tracked it back to Mor & Luis
- NICE GUYS.............!

MORE from Mor
- FDLE found more phony Procrit® at TNT Sales.
- Owner disclosed he bought & resold $2.5 million of the drug (Source – Express Rx)
- Drugs not mailed but picked up at Mor’s $500,000 home in Davie, FL
- Mor’s source…. Luis’s company - MEDEX INTERNATIONAL

Back to our flow chart

“ONE” phase of the process
- A Confidential Informant revealed:
  - Bags of saline, snipped ends off & poured into a 5gal bucket.
  - Used a pipette for filling empty vials
  - Vials crimped
  - Counterfeit labels & boxes, imported from Columbia. Sent back & forth number of times until correct.
  - Labels checked with black light

Subtle Differences
Distribution Process

- Some brought to Zone Fitness Gym by Dennys Astorga & distributed from there.
- Astorga sold Serostim® and steroids at the gym.
- Astorga also identified as person delivering the drugs to AME Rx with paperwork showing shipped from San Antonio Health Group (including the drugs from ARMIN).

Looks like a reputable distributor to me!

Nice Toys!
Paul Perito, MD
- Co-owner of Playpen South
- Successful Urologist
- Drug addicted
- Associate of Carlos Luis
- Dealt counterfeit pharmaceuticals out of the back room of the strip club.

So. Florida “Wholesaler”

Back to ARMIN Medical
- October 2004: Beth Handy flown to FL & made consensual call to Armin Medical (Richard Minasian)
- He states that contrary to invoices, he never touched the drugs. They were shipped directly from Texas (SAG) to AME Rx in Florida (actually hand delivered by Astorga)
- He was just “Doing a favor”. Only made “A couple of points on the sale”.

NH “Street Gang”
What's REALLY wrong here?

- Express Rx = NO license to ship to FL
- Medex Int. = NO license to ship to FL
- San Antonio HG = NO lic. To ship to FL
- ARMIN Medical DOES have license to ship to FL
- Minasian “Rented" his license to these bogus companies to facilitate movement of counterfeit product into the legitimate delivery channels.

MORE Evidence

- Owner of AME Rx (Susan Cavalieri) states she had NO shipping documents, all drugs were hand delivered by Denny Astorga directly to AME Rx
- AME Rx would fax ARMIN information & Minasian would prepare a “Fake” invoice & add his name to the pedigree.....
**LOVE that shirt !!!!**

**Sentenced**
- **FELONY CONVICTION**
- $50,000 Fine
- 10 Year Probation
- Divest of Armin Medical (Med-Industries)

**We’re NOT Done Yet**
- Remember “Alpine Pharma” & Beth Handy, our other target?
- Site visits turned up “Invoices” and presented another “trail” to follow…
- Handy interviewed and relinquished certain purchase & sales records
- Also “pedigree” information.
Serono Information

- By now, Serono has “ID'd” counterfeit
- Serostim ® no longer available thru
  “wholesalers” = Contractual Rx ONLY
- **BEST** price to contractual pharmacy was
  $1680.00 (NO further discount)
Can’t go much further

- Alpine Pharma / Beth Handy turned over to AUSA & FDA's OCI (Fall of 2004).
- Gave them entire file along with documented purchase/sales records, pedigrees & even set up undercover buy at a location in TN.

Finally (2006)

Milford woman charged in scheme

Is the circle complete??

- Accucare – Candace Carlow = License expired. She is indicted along with husband “Michael”
- Armin – Minasian arrested & charged along with Dennys Astorga
- NeutraCeuticals Pharmaceuticals – Robert Hatch...Whacked by NH Board of Pharmacy & again by US Attorney

4 years later! (The fed's are SLOW)
How’s your memory?
- Alpine Pharma invoices to
  - OPTIA Pharm (UT)
  - TXRX (Texas)
- WHO is TXRX (besides Novosel)?
- WHO is CSG in Tenn.?
- HOW do they connect to NH?

More “Players”
- TXRX (Texas – 2005)
  - Thomas Martino
- Genesis Pharmaceuticals
  - Amanda Cruz
  - Oscar Salinas
- Consumer Services Group (CSG) (Tenn. – 2005)
  - Joseph Parisi (also owns JUN Pharmaceuticals – Knoxville, TN)
- Genesis & TXRX = same physical address.

Off we go again!
- Martino arrested in FL (2003) along with Michael Carlow and 17 others.
- Out on $1,000,000 bond
- Goes to TX – obtains wholesaler license & opens up TXRX
- Partners with Salinas & Cruz & has ties to Genesis Pharmaceuticals

Not quite over yet!
- Solicits business & ships drugs to NH
- BOP aware & begins to check out the “Pedigree”
- None are registered with BOP
- Sent letters for registration
- TXRX applies (application held for “more information”) check deposited.
- CJ Associates = vacant lot
- Kinray = Valid, registers & when contacted, went wild!

- Contacted FDLE
- Cooperative effort with TX branch of FDA’s OCI
- August 2005 TX AG’s office serves warrant on TXRX
- Seized almost 3 Million in TX banks
- Another account with 2 Million in Costa Rica
Another bad guy down!

- Martino, again, brought to trial in FL in spring of 2006
- Sentenced to 26 years........!!
- Prior to this, November 2005, NH customers receive fax....JJN Pharmaceuticals (Parisi) to merge with TXRX.

Parisi photo

Dead End

- Contacted TN agents for info on CSG & JJN
- "NO" paper work (registrations, etc) available.
- Finally determined CSG & JJN were “Virtual” offices....
- Still don’t know where drugs stored or coming from.
- Parisi = “A cooperating witness” ?????
Redneck “Harley”

Remember this guy?

Any money to be made here?

Warrant served!

3/23/2011
Yup, it is, a VIPER!

Michael’s 1st Sentencing
- March 2007 in Missouri for his part in the counterfeit Lipitor distribution
- Convicted of racketeering, organized fraud, grand theft and illegal drug sales
- 5 years in federal prison
- Repay 3.4 Million Dollars
- Still must face charges in Broward County along with 18 other co-defendants (3/12/07)

Out of balance ????
- They distributed over 200,000 bottles of counterfeit Lipitor.
- Estimated profit of about 46 Million Dollars
- 5 years in jail & 3.4 Million dollar fine.
- **Do the math!**
- Broward County just might tip the scale.
Cooperative effort **ALWAYS** pays off!

The **COMPLETE** story, in detail

*Dangerous Doses*

*Thank you!*