



The "Grey Market"

CLOSE TO HOME!

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




An Awakening

19th Annual Mud Symposium

March 25, 2011

The Secondary Wholesale Market

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



Clearly identified !



A "Mailbox"



NO Clutter



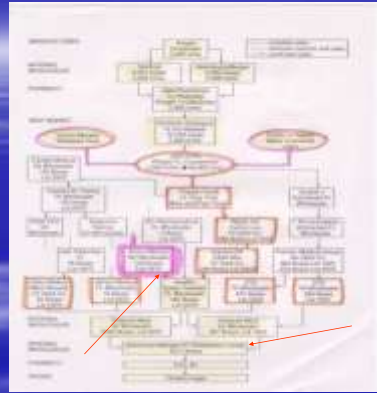
We HAVE licenses



- One part of the story begins in Missouri in 2002 with 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



Quantity	Unit Price	Total Price
79	3,887.34	307,199.86

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.

FBI - Profile Sheet		
Name	XXXXXXXXXXXXXXXXXXXX	DOB: 00/00/00
Current Address	XXXX XXXXX ST, XXXX	City: XXXX, State: XXXX, Zip: XXXXX
Sex	M	Height: 5'10" Weight: 180 lbs
Build	Medium	Hair: Brown Eyes: Blue
Education	High School Graduate	Occupation: Unknown
Skills	None listed	Interests: None listed
References	<p>XXXXXXXXXXXXXXXXXXXX</p> <p>XXXXXXXXXXXXXXXXXXXX</p> <p>XXXXXXXXXXXXXXXXXXXX</p>	
Remarks	<p>XXXXXXXXXXXXXXXXXXXX</p> <p>XXXXXXXXXXXXXXXXXXXX</p> <p>XXXXXXXXXXXXXXXXXXXX</p>	




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



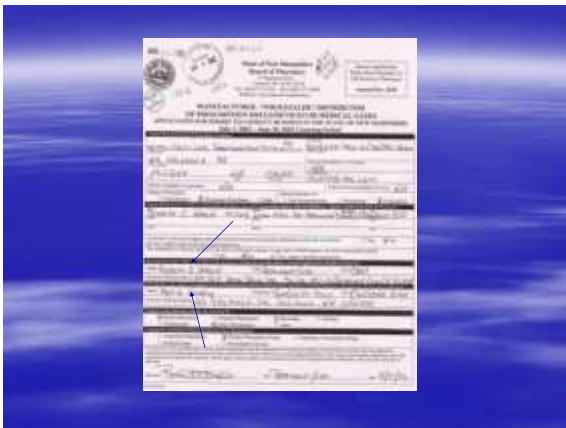
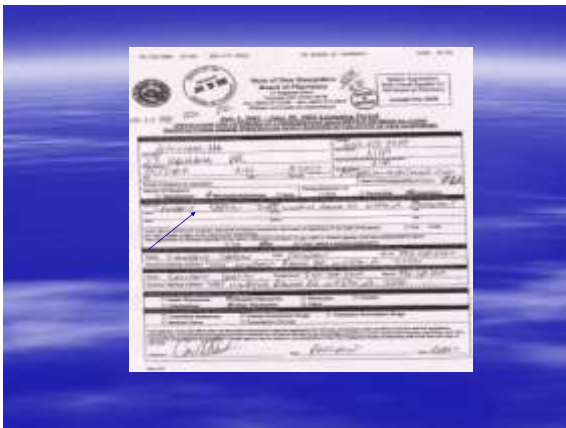
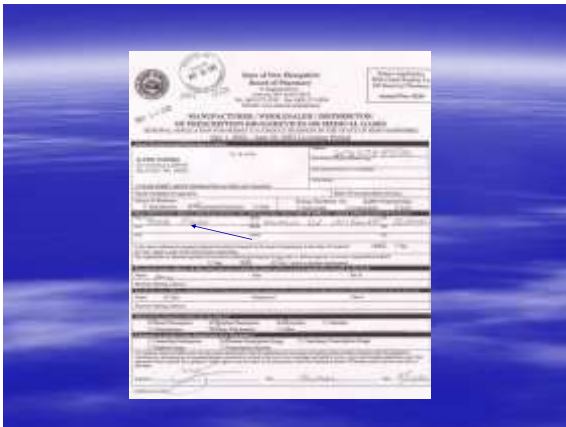
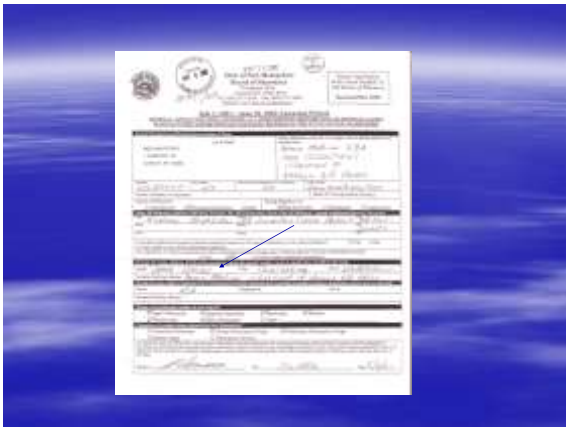
3 Distributors HERE!

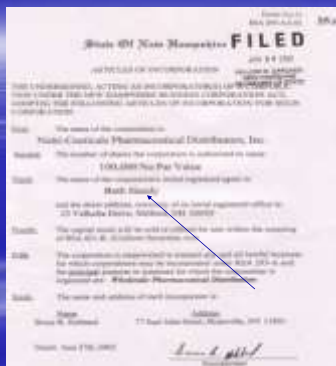
- Alpine Pharma
 - Principal: Beth Handy
- Accucare, LLC
 - Principal: Candace Carlow of Westin, FL
 - Michael Carlow's "wife"
- Neutraceutical Pharmaceuticals
 - Principal: Robert C. Hatch of Cathedral City, CA

- 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





Next stop for Mr. Hatch!



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 \$\$\$\$)

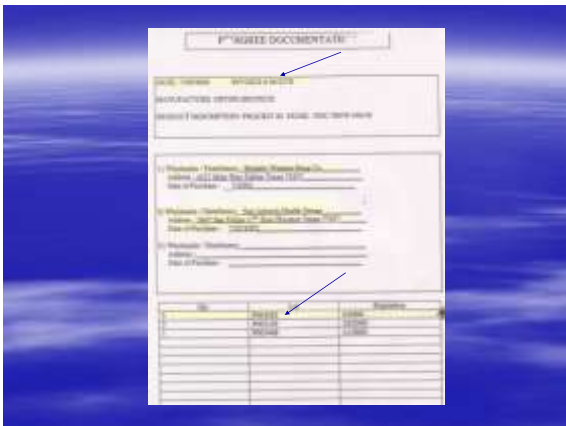
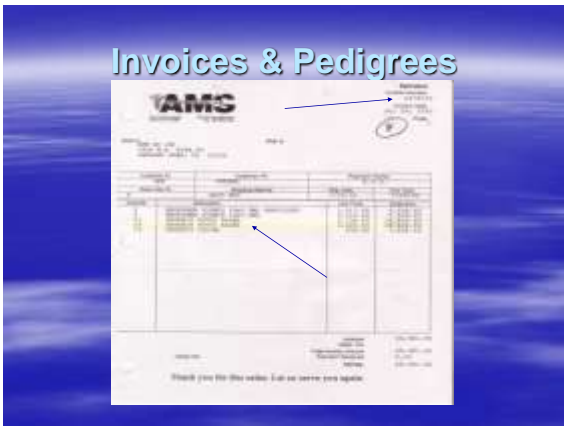
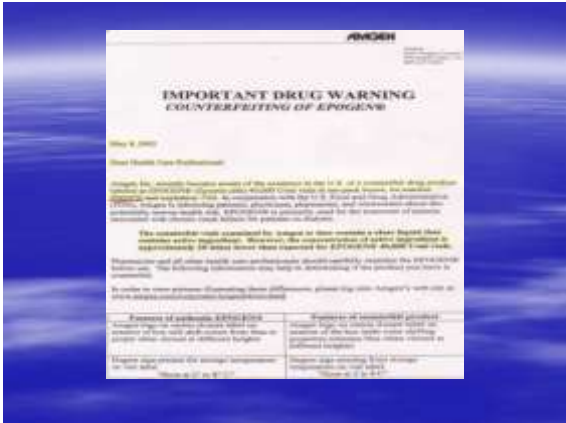
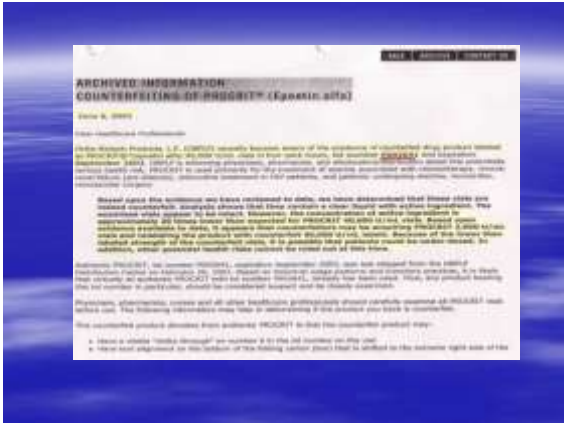
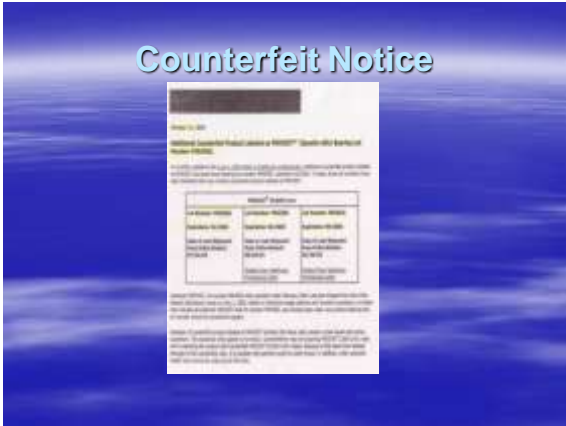
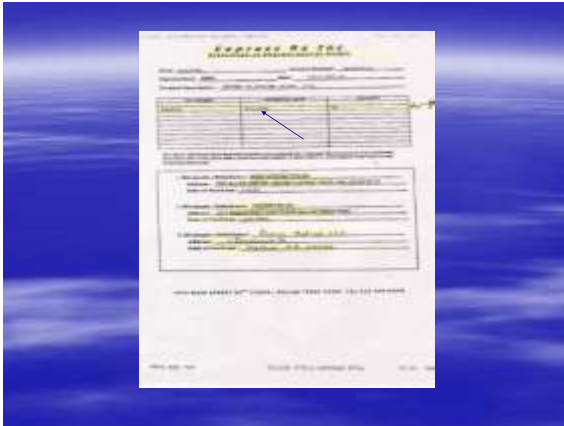
Armin Medical

- 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





INVOICE DOCUMENT # 1

DATE: 03/08/11 INVOICE # 64274

ISSUED BY: DORIS WATKINS
SECURITY DEPARTMENT (ISSUED BY: DORIS WATKINS)

1) Whittaker / Whittaker, Stability Storage Group Co.
 Address: 4821 Main, New Caney, Texas, 77355
 Date of Purchase: 03/08/11

2) Whittaker / Whittaker, San Antonio Health Group
 Address: 3802 San Felipe, San Antonio, Texas, 78227
 Date of Purchase: 03/08/11

3) Whittaker / Whittaker, San Antonio Health Group
 Address: 3802 San Felipe, San Antonio, Texas, 78227
 Date of Purchase: 03/08/11

NO	DATE	ISSUED BY	ISSUE #	ISSUED TO	ISSUED FOR
1	03/08/11	DORIS WATKINS	64274	STABILITY STORAGE GROUP CO.	STABILITY STORAGE GROUP CO.
2	03/08/11	DORIS WATKINS	64274	SAN ANTONIO HEALTH GROUP INC.	SAN ANTONIO HEALTH GROUP INC.
3	03/08/11	DORIS WATKINS	64274	SAN ANTONIO HEALTH GROUP INC.	SAN ANTONIO HEALTH GROUP INC.

INVOICE

SAN ANTONIO HEALTH GROUP INC.
 4821 MAIN, NEW CANEY, TEXAS 77355
 (281) 446-4400

ISSUED BY: DORIS WATKINS
ISSUE # 64274

ISSUED TO: STABILITY STORAGE GROUP CO.
ISSUED FOR: STABILITY STORAGE GROUP CO.

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AMS
 SECURITY DEPARTMENT

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Express Rx To
 FEDERAL PRESCRIPTION FORM

Date: 03/23/2011 Invoice Number: 0000000001

Manufacturer: JANSSEN-CILAG NDC: 0000-0000-01

Product Description: 00000000000000000000

Quantity	Unit	Strength	Lot	Expiration
1	Tablet	100mg		

1. Wholesaler (Distributor): JANSSEN-CILAG
 State of Residence: NJ

2. Wholesaler (Distributor): JANSSEN-CILAG
 Address: 2300 STATE STREET, SUITE 2000, NEWARK, NJ 07102
 State of Residence: NJ

3. Wholesaler (Distributor): JANSSEN-CILAG
 Address: 2300 STATE STREET, SUITE 2000, NEWARK, NJ 07102
 State of Residence: NJ

1011 MAIN STREET 50TH FLOOR, DALLAS TEXAS 75201 TEL: 214-344-8000

TAMS

Manufacturer: JANSSEN-CILAG NDC: 0000-0000-01

Product Description: 00000000000000000000

Quantity	Unit	Strength	Lot	Expiration
1	Tablet	100mg		

1. Wholesaler (Distributor): JANSSEN-CILAG
 State of Residence: NJ

2. Wholesaler (Distributor): JANSSEN-CILAG
 Address: 2300 STATE STREET, SUITE 2000, NEWARK, NJ 07102
 State of Residence: NJ

3. Wholesaler (Distributor): JANSSEN-CILAG
 Address: 2300 STATE STREET, SUITE 2000, NEWARK, NJ 07102
 State of Residence: NJ

Thank you for this order. Let us serve you again!

Express Rx To
 FEDERAL PRESCRIPTION FORM

Date: 03/23/2011 Invoice Number: 0000000001

Manufacturer: JANSSEN-CILAG NDC: 0000-0000-01

Product Description: 00000000000000000000

Quantity	Unit	Strength	Lot	Expiration
1	Tablet	100mg		

1. Wholesaler (Distributor): JANSSEN-CILAG
 State of Residence: NJ

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 Address: 2300 STATE STREET, SUITE 2000, NEWARK, NJ 07102
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 Address: 2300 STATE STREET, SUITE 2000, NEWARK, NJ 07102
 State of Residence: NJ

1011 MAIN STREET 50TH FLOOR, DALLAS TEXAS 75201 TEL: 214-344-8000



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

COPY

1011 MAIN STREET 50TH FLOOR, DALLAS TEXAS 75201 TEL: 214-344-8000



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

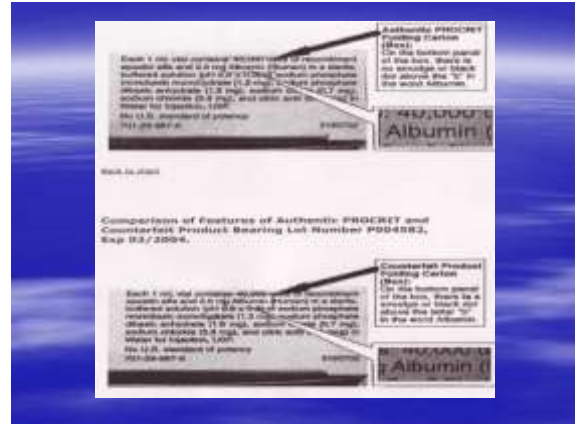
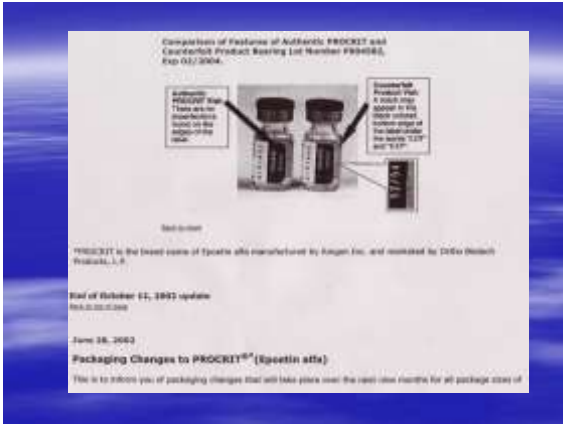


“ONE” phase of the process

- 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

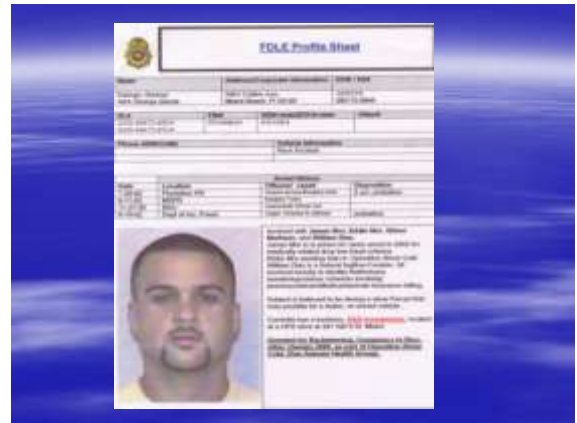
Subtle Differences





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)



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"



NH "Street Gang"

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".

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

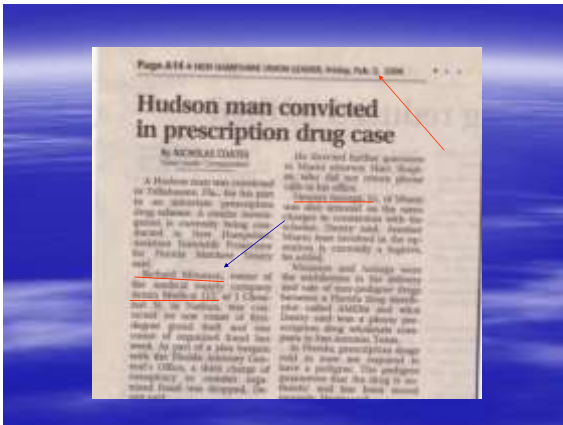
- Owner of AME Rx (Susan Cavalieri) states she had NO shipping documents, all drugs were hand delivered by Denny Astorga directly to AME Rx
- AME Rx would fax ARMIN information & Minasian would prepare a "Fake" invoice & add his name to the pedigree.....

The flower bears fruit!

The NH "Connection"



Richard "Rocky" Minasian



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)
-

DROGUERA JAVNESS
CALLE DE DIEGO 488
RIO PIEDRAS, PUERTO RICO 00967

INVOICE #008
DATE: JANUARY 1, 2008

To: **ALPINE PHARMA**
23 VALDELLA DRIVE
ROSELAND, MA 01968

Ship To: **OPTAMEDICAL**
425 N W 57 ST
MIAMI LANE, FL 33154

FX DATE	P'S NUMBER	SHIP TO	FILE POINT	TERR
120808	120804	BEST DAY	02000	00000

QTY	UNIT	DESCRIPTION	UNIT PRICE	TOTAL
80	EA	SEROSTIM (SEROSTIM) TO VIALS (SEROSTIM) 0.1	84.00	\$6,720.00
				TOTAL \$6,720.00

ALPINE PHARMA
23 VALDELLA DRIVE
ROSELAND, MA 01968
950-870-8000
950-870-8000 (FAX)

INVOICE #123002A
DATE: 10-08-05A

To: **OPTAMEDICAL**
425 N W 57 ST
MIAMI LANE, FL 33154

Ship To: SAME

FX DATE	DESCRIPTION	SHIP TO	FILE POINT	TERR
100805	TUE MARIANO	BEST DAY	02000	00000

QTY	UNIT	DESCRIPTION	UNIT PRICE	TOTAL
80	EA	SEROSTIM (SEROSTIM) TO VIALS (SEROSTIM) 0.1	84.00	\$6,720.00
				TOTAL \$6,720.00

NOTE: PLEASE NOTIFY YOUR SALES REP IMMEDIATELY WITH ANY DISCREPANCIES.

CASH WIRE INFORMATION: ALEXANDRIA ROY, 603-348-4000, 603-348-4000 (FAX), BANK OF NEW HAMPSHIRE, DIV BANKNORTH, N.A. ROUTING #011400071 ACCOUNT#2834460004

FAX COVER SHEET

ALPINE PHARMA
23 VALDELLA DRIVE
ROSELAND, MA 01968
950-870-8000
950-870-8000 (FAX)

From: WENDY BOWEN	To: WENDY BOWEN
Attention: SCOTT BRADA	From: SEROSTIM DE BAR
SCOTT BRADA	

HERE IS THE PEDIGREE FOR YOUR SHIPMENT:

AD): J M BLANCO
DIANA STREET #31
AMELLA INDUSTRIAL CENTER
GAYNADO, PUERTO RICO 00968

AW): DROGUERIA JAVNESS
CALLE DE DIEGO 488
RIO PIEDRAS, PUERTO RICO 00967

FYI, SEROSTIM IS MANUFACTURED IN PUERTO RICO.

ALPINE PHARMA
23 VALDELLA DRIVE
ROSELAND, MA 01968
950-870-8000
950-870-8000 (FAX)

INVOICE #052803A
DATE: 08/08/08

To: **TOPO**
CALLE DE DIEGO 488
RIO PIEDRAS, PUERTO RICO 00967

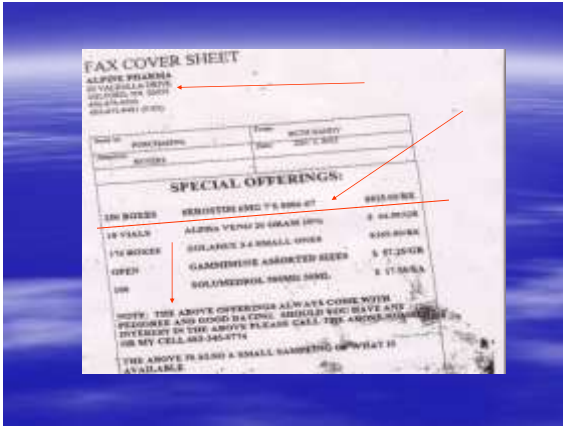
Ship To: SAME

FX DATE	DESCRIPTION	SHIP TO	FILE POINT	TERR
080808	TOPO	BEST DAY	02000	00000

QTY	UNIT	DESCRIPTION	UNIT PRICE	TOTAL
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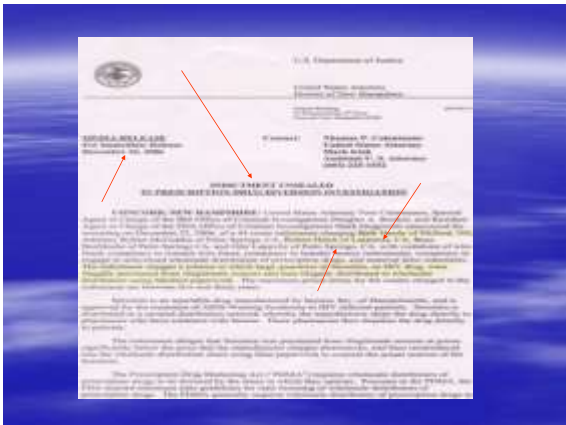
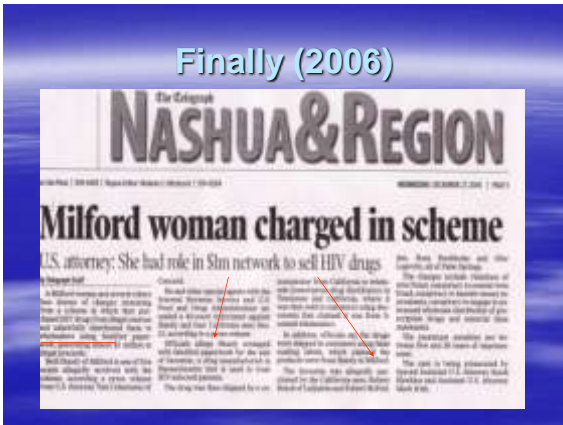
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Can't go much further

- 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.



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

Not quite over yet !



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 ?

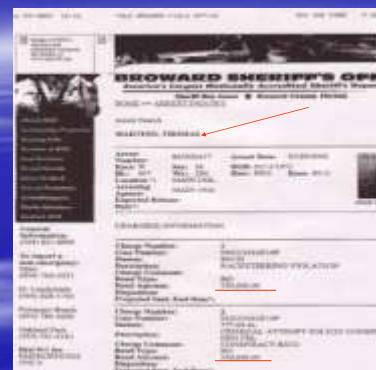
More "Players"

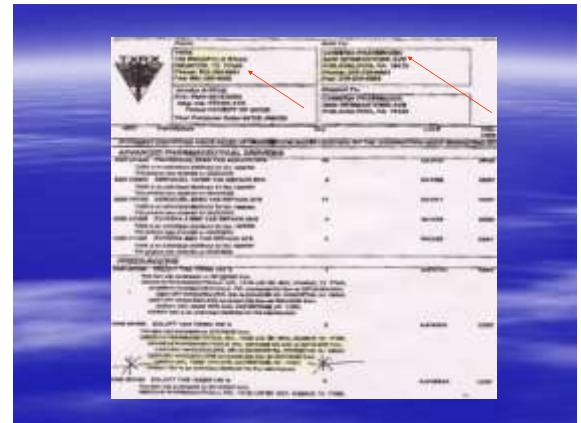
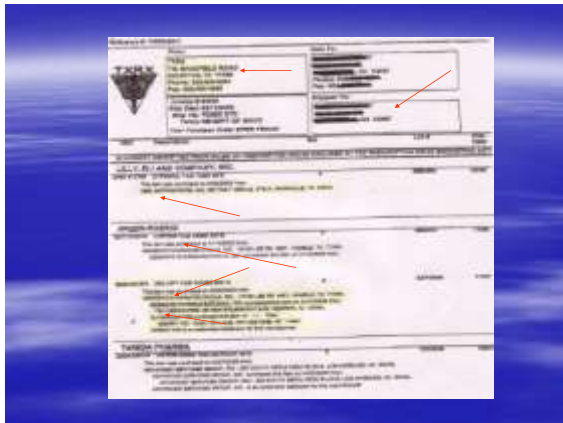
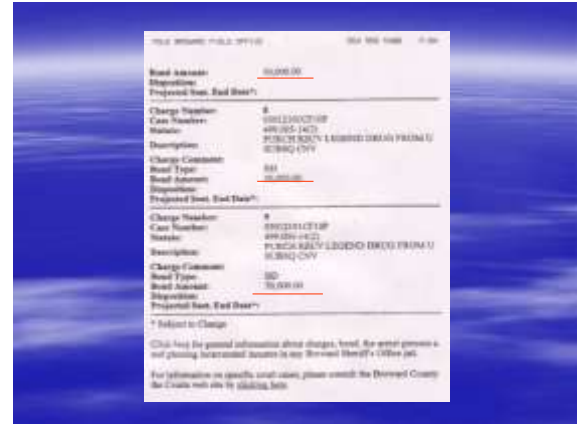
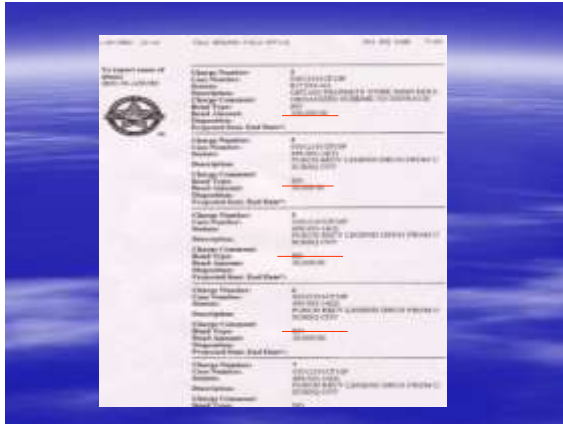
- TXRX (Texas – 2005)
 - Thomas Martino
- Genesis Pharmaceuticals
 - Amanda Cruz
 - Oscar Salinas
- Consumer Services Group (CSG) (Tenn. – 2005)
 - Joseph Parisi (also owns JJN Pharmaceuticals – Knoxville, TN)
- *Genesis & TXRX = same physical address.*



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



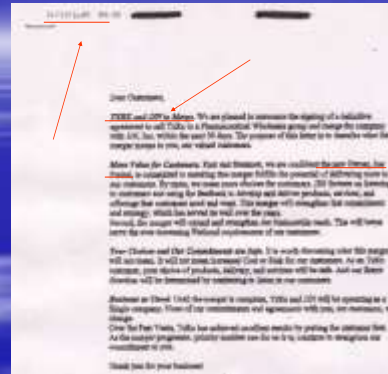


- Solicits business & ships drugs to NH
- BOP aware & begins to check out the "Pedigree"
- None are registered with BOP
- Sent letters for registration
- TXRX applies (application held for "more information") check deposited.
- CJ Associates = vacant lot
- Kinray = Valid, registers & when contacted, went wild!

- Contacted FDLE
- Cooperative effort with TX branch of FDA's OCI
- August 2005 TX AG's office serves warrant on TXRX
- Martino arrested & jailed in FL (Aug. 2005)
- 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....JNN Pharmaceuticals (Parisi) to merge with TXRX.



Parisi photo



Dead End

- Contacted TN agents for info on CSG & JNN
- “NO” paper work (registrations, etc) available.
- Finally determined CSG & JNN 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 !



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

