

# Off-label Marketing: BOTOX

Special Agent Michael Badolato - FBI St. Louis

Special Agent Scott Stephan - FBI Atlanta

*(and friends...)*



**FEDERAL BUREAU OF INVESTIGATION**

## AGENDA

BACKGROUND: What is off-label marketing?

HISTORY OF BOTOX: Evolution of the drug

STRATEGIES OF THE DRUG COMPANIES:  
The Off-label push

WHAT WORKED OR DIDN'T WORK: Ideas for  
the Investigators

RESULTS: Settlement and more



AFTER THE CASE: Things to look for

# SA MICHAEL J. BADOLATO

- FBI Special Agent – Atlanta, GA & St. Louis, MO
  - Health Care Fraud Squad 8+ years
- Express Scripts – 6 years
  - Clinical Programs / Account Executive
- St. Luke’s Hospital, St. Louis, MO – 3 years
  - Medicare Coder / Utilization Review
- MHA, St. Louis University (SLU) & B.S, Health Information Mgmt, SLU
- Married with Children (2)



# SA SCOTT D. STEPHAN

- FBI Special Agent – Atlanta, GA
  - Health Care Fraud Squad 9+ years
- B.S.N., Case Western Reserve University, Cleveland, OH
- Specialized in Pediatric Cardiac Intensive Care
- Worked as an RN for 7+ years at
  - The Cleveland Clinic Foundation - OH
  - Columbia Healthcare – El Paso, TX
  - St. Joseph’s Hospital – Tampa, FL



Married with Children (2)

# Joint Investigation

- HHS-OIG
- FDA-OCI
- OPM-OIG
- USAO – Northern District of Georgia
- SA Connie Murray
- SA Pamela Chambers
- SA Bret Mastronardi
- AUSA Randy Chartash
- AUSA Doug Gilfillin
- AUSA Sally Molloy
- AUSA Chris Huber



**This is NOT a presentation on**



Or



## Off-label Marketing

IS...

When drug manufacturers and/or marketers promote their products for something other than for the FDA approved use.

IS NOT...

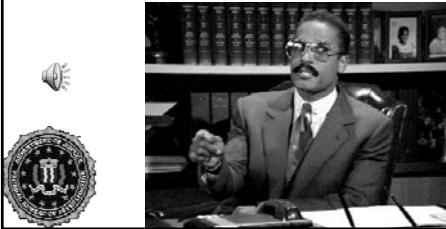
The Gov't telling a physician how to prescribe drugs. It is at the physician's discretion as to what to prescribe to for an unapproved use.



## What Has To Be Proven:

### CIVIL CASE:

- The off-label marketing led to a false claim being submitted to a Gov't Healthcare Program



### CRIMINAL CASE:

- Mis-branding
- “Introduction or delivery for introduction into interstate commerce of any food, drug, device or cosmetic that is adulterated or misbranded.”

## Qui Tam Lawsuit a.k.a. Whistleblowers Lawsuit

- When a private individual, known as a “relator,” brings a lawsuit on behalf of the United States. The relator assists the prosecution in exposing a fraud committed against the Federal Gov't.
- Sept. 2009 Pfizer Case – Pfizer paid \$2.3 Billion
- Relator (sales rep) was awarded \$51.5 million.
- Relator is awarded up to 25 % of the civil fine.
- Botox Case – Two relators were awarded \$38.7 million. (3 others filed after them)



## Where The Money Is



## Emerging Trend

- Since 1998, DOJ has made approx. 28 similar cases – which led to the Gov't collecting more than \$9 billion in penalties and fines.
- These cases are intriguing to both investigating Agencies and to the USAO because of the potential for large settlements
- Senators Chuck Grassley and Max Baucus have been probing into the drug companies use of education grants



## History of Botulium Toxin A

- Scientists in the 1950's discover it can reduce muscle spasms
- 1989 FDA approves Botox for blepharospasm (eyelid spasms)
- 2000 FDA approves Botox for cervical dystonia
- 2002 Botox Cosmetic FDA approved for glabellar (frown) lines
- 2004 FDA approves for hyper-axillary hydrosis
- 2010 FDA approves for upper limb spasticity and chronic migraine.
- Manufactured by Allergan, Inc. (AGN)
- Also makes Restasis, lap-band, breast implants, and Juvaderm.



## Strategies By Allergan

- Sales reps were directed to visit physicians that had no approved use for the drug
- Use of "triggers" and/or "bridges"
- Co-promotion with GSK
- CTU (Customer Team Units)
- No formal compliance program
- Acquisitions of other companies
- Internet blasts
- Research/educational organizations which "appeared" independent
- CME's and Unrestricted Educational Grants
- Promote within/Hire first-time pharma workers



## Drink The Kool-aid



## Strategies By Allergan

- Headache is a symptom of cervical dystonia
- Reimbursement assistance
- Chemodenervation  
Codes: 64613, 64614, 64630, 64640, 64653, 67345



J0585 Type A



## Strategies By Allergan

### NON-EXISTENT COMPLIANCE PROGRAM

- 30 minute compliance block as a new employee
- No formal compliance training until Allergan was aware of investigation in 2007
- Allergan created an environment where it was perceived to be appropriate to promote off-label
- Employees that expressed concern or refused were typically punished



## Strategies By Allergan

- Use of thought leaders to influence insurance companies/Medicare Contracted Carriers
- Find a physician that is well connected
- Pay them to attend conferences
- Pay them to attend company supported events
- Pay them to proctor events
- Pay them to speak at CME events
- Provide them with the materials to speak on
- Don't provide them with all of the research



## Strategies By Allergan

- The advocates are then sent to the insurance companies as experts in the field
- Advocates appear independent from the company – often not disclosing their relationships
- Get the “foot in the door”
- Once one company gives approval, then it is used as an example and others will follow
- Allergan altered study results that were provided to the physicians



## Strategies By Allergan

- Allergan could bypass FDA by seeking insurance co. approval of drug
- Medical Directors were identified and given well-rehearsed presentations as well as incomplete studies

### Medical Directors



“SPOON-FED”



## FBI's Top 10 Quotes From Medical Directors Related To Policy Changes For Botox

- 10) "Goal to keep pts. off narcotics."
- 9) "The evidence is not over-whelming."
- 8) "Opinions are like noses, everyone has one."
- 7) "I expected them (Drs.) to disclose their relationships."
- 6) "Thought it was Ok, because it was not a 1<sup>st</sup> line therapy."
- 5) "If one person has a positive outcome, then the policy change is a good one."



## FBI's Top 10 Quotes From Medical Directors Related To Policy Changes For Botox

- 4) "Where did the binder come from? "Not my job to know."
- 3) "I may or may not look at who is sponsoring the research."
- 2) "Medical Directors do not like to be pioneers; They like to have strong evidence."
- 1) "Sometimes you just have to do it."



## Control INFORMATION...



**ALLERGAN**

Our pursuit. Life's potential.®

## Strategies By Allergan

- 2004 & 2005:  
Allergan paid about \$2.5 million in grants to individual doctors.
- 2006:  
Allergan sponsored more than 1,200 programs that largely promoted the drug for off-label uses.
- For a decade:  
Allergan supported an “independent” online organization, the Neurotoxin Institute with more than \$10 million.



## Strategies By Allergan



**Neurotoxin Institute**  
TRANSLATING SCIENCE AND RESEARCH INTO CLINICAL PRACTICE

- Operated a website which disseminated information on off-label uses of Botox.
- Sales reps were trained to refer doctors to the website.



## Allergan Did It!!

- In 2007 alone, Allergan had over \$500 million in annual Botox sales for therapeutic uses.
- 70-80 percent of those sales were attributable to off-label indications, primarily for spasticity, headache and pain .



## What To Believe/What Not To Believe

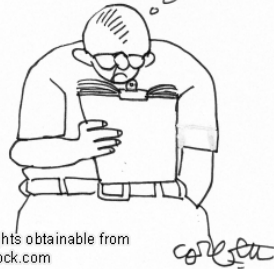
Allergan changed the endpoint...

- In one trial, patients treated with Botox had 7.8 fewer days per month of headaches

- As compared to 6.4 fewer days with a placebo

- Another showed 9 days fewer with Botox to 6.7 with an inactive injection

I hate it when the placebo does better on tests than the drug we're testing.



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## What Worked For The Investigation

- Strong insiders, often the whistleblowers need to educate you on the issues
- Covert interviews – Strategize
- Get as many interviews done as you can before the attorneys get involved
- Find the past employees
- Conflicting and negative study results
- Team approach – Divide and conquer (HHS, FDA, OPM, DCIS, AUSAs)



## What worked for this Investigation

- Consensual recordings
- 50- 60 recordings
- Sales reps to upper mgt.
- Seminar in a restaurant
- What we got...
- More importantly...What the defense thought we had
- Aggressive law enforcement & AUSAs
- Potential – Get trusted physicians involved.



## Where To Next?



# What Worked For The Investigation

**cafepharma.com**  
The website for pharmaceutical and medical sales professionals

- Allows posting by “healthcare professionals”
- Use it to develop leads
- Use it to generate leads



**cafepharma.com**  
The website for pharmaceutical and medical sales professionals

06-14-2008, 12:26 AM #20  
Anonymous Posts: n/a

**Re: FEDS GOT NOTHING**

Lynn, Donnie, Mike, Julian, Doug and even David knew that the BMCs were doing off label promotion. All you have to do is go back and look at Nina's email when she was a rep. She held headache training when it was not the right thing to do. Look at Marina she was actually promoted for doing off-label spasticity. The management at Allergan knows that they were having sales push off label and no matter what anyone tried to do to stop it they kept moving forward. It is about time that someone step in and stop it.



Print Thread



<http://www.cafepharma.com/boards/showthread.php?p=250690>

6/18/2008



06-03-2008, 03:22 PM

# 16

Anonymous

Posts: n/a

Re: This should be fun...

Quote:

Originally Posted by **Anonymous**

We all know that Allergan lawyers will not represent us individually. How many of you out there are seeking representation on your own?

There are plenty of attorneys out there to represent you if you think you need it - BUT more importantly, if you have a story to tell BEFORE Allergan tells their side, you may want to speak with the 2 FBI agents that I spoke with: Michael Badolato 404-679-6511 and Scott Stephan 404-679-6105. They told me they eventually wanted to speak to everyone. I chose to call them first...If Allergan's not going to represent us, then who do you think they are going to point the finger at??? This is Huge...and is NOT going away!!!

Quote

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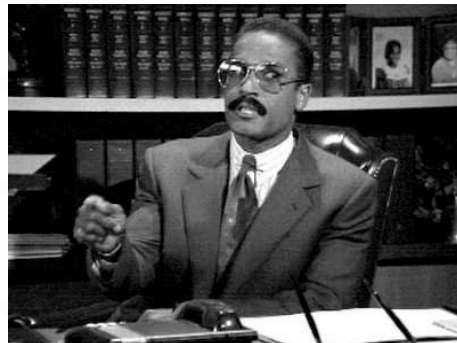


<http://www.cafepharma.com/boards/showthread.php?t=260339>

6/18/2008

## What Didn't Work

- Be prepared for the dump...
- Received approx. 6 million documents – mostly by subpoena
- Must be in a searchable format



## What Didn't Work

- Employee interviews with the attorneys
- Loss of control – Communication with other Agents, Investigators, and AUSAs



## Investigative Results

- Investigative delays lead to:
  - \$225 million – Civil
- Civil and Criminal
  - \$350 million – Criminal fine
  - Misdemeanor for the company
- Misdemeanor
  - \$25 million forfeiture clause
  - \$600 million total
- CIA (Corporate Integrity Agreement)





# Department of Justice

United States Attorney Sally Quillian Yates  
Northern District of Georgia

FOR IMMEDIATE RELEASE  
09/01/10  
<http://www.justice.gov/usao/gan/>

CONTACT: John Horn  
(404)581-6335  
FAX (404)581-6160

**PHARMACEUTICAL COMPANY ALLERGAN AGREES TO PLEAD GUILTY  
AND PAY \$600 MILLION TO RESOLVE ALLEGATIONS OF  
OFF-LABEL PROMOTION OF BOTOX®**

*Settlement is the Fifth Largest Amount Paid by a Single Defendant in a  
Pharmaceutical Off-Label Marketing Case and  
Largest Settlement in History for the Northern District of Georgia*



## Big Pharma's View.....



## Results

- FDA approves Botox for Migraine weeks later



## Looking Forward

- Potential for fraud
- Only FDA approved for chronic migraines - Average greater than 15 days per month and longer than 4 hours.
- Allergan estimates there are 3.2 million Americans affected by chronic migraines.
- Lobbying of medical directors?
- Make sure your company's policy requires the other methods have to be tried first – Not a first line treatment.



## Looking Forward

- The average neurologists injects a total of 155 units of Botox into 7 sites of the head and neck for headaches.
- In many cosmetic sessions, the doctor injects a total of 100 units of Botox into the forehead and around the eyes (20 units is approved)
- Botox sales total around \$1.3 Billion a year and analysts believe the FDA approval could add \$1 Billion to that total.



## Notes:

- No clinical studies have shown that Botox works as a treatment for other types of headaches or that occur 14 days or fewer



## Dollars for Docs

- <http://projects.propublica.org/docdollars/>
- ProPublica
- \$761.3 million in disclosed payments
- 12 companies have begun publicizing the dollars paid to physicians
- Can be searched by State, company, or physician



## Parting Thoughts...

The most common side effects for migraine patients treated with Botox...  
**NECK PAIN and HEADACHE !**



## QUESTIONS & COMMENTS

