The Fifth Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum

Pharmaceutical Compliance Case Study

James G. Sheehan
Associate U.S. Attorney
215-861-8301
Jim.Sheehan@usdoj.gov

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FDA approves SwarthmorePharma's new antidepressant, Viaxal for an indication of depression.

Clinical studies show Viaxal matched the success of the most effective SSRIs but avoided the well-known sexual side effects of the SSRI class in both men and women.

Aggressive direct-to-consumer marketing program promoted Viaxal as a treatment for depression, and mentioned the research showing reduced effects on libido.

FDA warning letter.

Advertisements back pages of USA Today's sports section offering internet sales of Viaxal

Passengers on cruise ships met by hawkers in pharmacists' jackets offering Viaxal without a prescription.

Dr. Timothy Cleary's bestseller, Viaxal Boomers

SwarthmorePharma had no formal company relationship with Dr. Cleary

Vboom! Website, t-shirts, mugs, greeting cards, bumper stickers.

Sales of over $4 billion annually.

Anecdotal reports of hyperactivity, agitation, aggressive behavior, and suicide related to use of the drug by some patients. (many of the leading SSRIs had similar anecdotal reports).

Two researchers with the Australian medicines regulatory authority became concerned, and began reviewing previous studies and doing retrospective studies to determine the existence and extent of these problems.Their negative article has been submitted to the New England Journal of Medicine.

Six months ago a scientist who had worked with the CRO, CroData contacts the Wall Street Journal, alleging that the CRO engaged by SwarthmorePharma had suppressed and manipulated Viaxal data.

Two weeks ago, the Journal printed a story, on the second page of the business section. CroData and SwarthmorePharma could not be reached for comment.

Last week, the US Attorneys' Office in Miami served an Authorized Investigative Demand(AID) on the offices of SwarthmorePharma

AID served on CroData same day .

CAROLYN MCELROY, ESQUIRE

Mintz Levin Cohn Ferris Glovsky & Popeo
701 Pennsylvania Avenue
Washington, DC 20004
202-434-7408

DAVIA B. TEMIN, PRESIDENT
Temin and Company
136 E. 57th Street
Suite 1700
New York, NY 10022
212-588-8788

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ONE YEAR LATER . . .