Teva and Allergan Documents – Risk Mitigation

Summary and Sample Documents Explained:

Actiq was the first opioid product approved by the FDA subject to risk evaluation and mitigation strategies (REMS). The FDA required Anesta (which Cephalon acquired in 2000) to commit to a REMS program for Actiq due to its high risks of non-medical use, overdose, and misuse. This included submitting all promotional and multimedia materials to the FDA, as well as pledging to monitor and prevent off-label prescribing, both of which Cephalon failed to perform.

Sample Documents:

Document Title: 961111 20747 (Volumes 1-54)
OIDA ID: https://idl.ucsf.edu/opioids/docs/#id=srjw0312
Date: 1996-11
Description: The New Drug Application for Actiq, submitted to the U.S. Food and Drug Administration (FDA) by Anesta (which was acquired by Cephalon in 2000). The application was divided into volumes 1-54.

Document Title: Teva-Brennan-003.pdf
OIDA ID: https://idl.ucsf.edu/opioids/docs/#id=qqgp0311
Date: 2001-08
Description: Actiq's Risk Management Program (RMP), as designed by Anesta to address three "key potential risk situations"—accidental ingestion by children, improper patient selection, and diversion/non-medical use. Includes information and guidelines about labeling, education, surveillance and intervention.

Document Title: Termination of Employment
OIDA ID: https://idl.ucsf.edu/opioids/docs/#id=xfdp0311
Date: 2004-02
Description: David Brennan, senior compliance associate, was terminated from employment with Cephalon due to "inadequate" audits. His work on a 2003 audit of the Actiq RMP was cited as an example of his poor performance. According to Brennan's meeting notes about the report, he was in disagreement with his team about when and how to distribute the audit, which concluded Cephalon was not in compliance due to off-label prescribing concerns. Brennan filed and lost a wrongful termination lawsuit, but not before getting some media attention. Cephalon management also sent internal emails to explain to employees their perspective on the suit.

Document Title: Mid -Year Compliance Update
OIDA ID: https://idl.ucsf.edu/opioids/docs/#id=gxvv0336
Date: 2004-07
Description: Mid-Year Compliance Update report describes Cephalon's compliance program and its activities in 2004. Notes that Actiq was recently the subject of media attention for its diversion and off-label use, and that Cephalon was not in full compliance with the RMP. Explains how the company was updating and revising the RMP, as well as providing better training for sales professionals and in medical education programs.

Document Title: Investigations Chart 2004 through 2007.doc
OIDA ID: https://idl.ucsf.edu/opioids/docs/#id=jxjg0336
Date: 2009-01
Description: Internal compliance investigations and disciplinary action reports table from Cephalon. Alleged violations include off-label promotion, falsifying sales call data, problems with expense reports, improper relationships and more.

Document Title: speech
OIDA ID: https://idl.ucsf.edu/opioids/docs/#id=lgkp0311
Date: 2007-06
Description: Speech to sales staff in June 2007 by Robert Roche, Cephalon senior vice president for pharmaceutical operations, addressing Cephalon's legal challenges with off-label selling. "We break no laws if it is our intention to develop and be supportive of off label use of our products, as long as we don't cross the line and promote them improperly…Unfortunately however, the environment in which we are operating in has become so hostile and the penalties for slipping up have become so enormous that the kind of sophisticated, nuanced selling practice that allowed us to build Provigil, Actiq and even good old Gabitril into major brands is going to have to change some."

Document Title: ROCHE POA SPEECH DALLAS 11 09 07.doc
OIDA ID: https://idl.ucsf.edu/opioids/docs/#id=qqnx0331
Date: 2007-11
Description: Speech to sales staff in November 2007 by Robert Roche, Cephalon senior vice president for pharmaceutical operations, after a $425 million settlement was announced for their off-label selling practices. "We are all at fault for not giving you all of the necessary support, and tools, and training and oversight that you needed to be both effective and compliant…all the time. (pause) We asked you to tell a story about our products that turned out to be too complex, we gave you too much leeway to define your own message and not enough guidelines and training on what you could do and what you could not do. We should not lose sight of the fact that some of the behaviors which surfaced during the investigation were nothing more or less than stupid blatant examples of off-label promotion and those were the last straw but in most cases, there was a lot of grey around the edges and if you'll remember, around the edges was just where we wanted you to be."

Document Title: Cephalon heritage messages.doc
OIDA ID: https://idl.ucsf.edu/opioids/docs/#id=prgv0320
Date: 2008-05
Description: Talking points from Palio Communications on "the Cephalon heritage," describing the company's "continuing dedication to risk minimization" and noting "34 tools for minimizing risk" that are part of Teva's SECURE program for Fentora.

Document Title: 2009-19-2009 SC Workstream Updates.ppt
OIDA ID: https://idl.ucsf.edu/opioids/docs/#id=gpxv0334
Date: 2009-05
Description: A slide deck outlining REMS implementation. Workstreams include REMS metrics, distribution/pharmacy, and prescriber/patient education and enrollment.

Document Title: Re: DRAFT DEA comments
OIDA ID: https://idl.ucsf.edu/opioids/docs/#id=psnf0334
Date: 2016-08
Description: Email thread about Teva submitting comments to the DEA urging them to tighten distribution, not quotas, as a risk mitigation strategy. Considers the timing of comments near the anticipated FDA approval of Vantrela ER, a new Teva opioid product.

Document Title: Valli Baldassano Deposition Responses (07.29.2019)
OIDA ID: https://idl.ucsf.edu/opioids/docs/#id=nsxp0311
Date: 2019-07
Description: Written deposition of Valli Baldassano, executive vice president and chief compliance officer for Cephalon from 2007-2011. Baldassano answers questions about Cephalon's negotiation of and compliance with its Corporate Integrity Agreement (CIA) with the Office of Inspector General of the U.S. Department of Health and Human Services; she also fields questions about allegations of off-label promotion of Actiq and Fentora.

Selected Additional Documents

- zmbh0320
- mlbh0320
- fkfm0312
- ffww0334
- mfcm0333
- nhgc0312