

**MINI-SUMMIT IX:  
COMPLIANCE IN MEDICAL AFFAIRS:  
MEDICAL LIAISONS, PUBLICATIONS, AND  
CLINICAL TRIALS**

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Pharmaceutical Regulatory and Compliance  
Congress and Best Practices Forum

# Please Note:

- ⦿ **This program presents a hypothetical that incorporates various fictitious entities, individuals, products and scenarios. Any resemblance to actual entities, individuals, products or scenarios is unintentional.**
- ⦿ **The views expressed by the members of the panel today are their personal opinions, and should not be deemed to reflect the position of their employers, or a waiver or admission in any respect.**

# Case Study:

## TinEar Pharma and Pharmona

- **TinEar Pharma** is a pharmaceutical company based in Cambridge, MA.
- TinEar's only product is **Pharmona**, which was approved in 2013 for the treatment of **Pediatric Tinnitus**.
  - Pharmona has been a commercial disappointment to date.
    - The product is perceived as providing only marginal benefit, and costs \$20,000 per year
  - Pharmona bears a **black box warning** stating that patients should be monitored for hypotension -- dangerous drops in blood pressure
  - The company is under enormous pressure from investors to produce returns on the investment in Pharmona.

# TinEar Pharma and Pharmona (cont'd.)

- Although the Pediatric Tinnitus patient population is about 50,000 patients in the U.S., a recent Phase 2 study led by the eminent Dr. Kettering showed encouraging results in the use of the product in improving hearing in the elderly.
  - TinEar Pharma is in discussions with FDA regarding the pivotal trials for this indication, but any approval for use in improving hearing in the elderly is years away.

# TinEar Pharma and Pharmona (cont'd.)

- A study last year involving 50 elderly patients with deteriorating hearing – conducted under a TinEar Pharma grant by Dr. Sloan (a friendly KOL/promotional speaker) – was “inconclusive.”
  - The clinical study report remains in draft and there are no plans to publish.

# TinEar's New Strategic Plan

- TinEar's Vice Presidents of Commercial Operations and Medical Affairs are charged by the CEO with coming up with an integrated strategic plan to "jump start" prescribing of Pharmona.
- You are providing compliance and regulatory support for TinEar Pharma, and are now asked to provide your views on the Strategic Plan.

# Pharmona Strategic Plan (1)

- ◎ The VP of Medical Affairs proposes to fund the development of a series of publications:
  - The first is an exploration of Pharmona's mechanism of action in Pediatric Tinnitus, and the relevance of those findings to the mechanisms involved in the loss of hearing in the elderly.
  - Dr. Cornell, a consultant, will be paid to develop and publish this review article.

# Pharmona Strategic Plan (2)

- ◎ The second publication will be developed under a grant from TinEar.
  - The chosen grant recipient, Dr. Sloan, will publish a clinical case series representing the results of his use of Pharmona in the treatment of elderly patients with severe hearing loss.
    - 40 out of 50 patients showed a striking improvement in hearing.



# Pharmona Strategic Plan (3)

- Medical Affairs has also developed a press release on the presentation of the Kettering study at the annual meeting of the Geriatric Audiology Society (GAS) meeting, entitled “Encouraging Results in the Safe Pharmacological Treatment of Hearing Loss in the Elderly.”
  - The press release and Kettering study abstract will be distributed at the TinEar Medical Booth at the GAS meeting

# Pharmona Strategic Plan (4)

- ⦿ Although TinEar's Medical Science Liaisons have previously been limited to reactive discussions with physicians, under the Strategic Plan every physician on the Marketing call plan will receive at least one visit from a TinEar Pharma MSL, who will provide a disease education presentation on Pediatric Tinnitus.
- ⦿ As part of the package of background materials, each physician will also receive a reprint of a journal article on the Kettering study, the Cornell article, and the Sloan clinical case series.

# Pharmona Strategic Plan (5)

- The Plan also contemplates the preparation of a Medical Affairs video disease education program on Pediatric Tinnitus and mechanisms of hearing loss.
  - Sales representatives will introduce the Medical Affairs video education program at dinners for ENT physicians and their staff.
    - An MSL will also attend each program, and Dr. Kettering will call in to answer questions from attendees.

# Pharmona Strategic Plan (6)

- Another element in the Strategic Plan is a \$1 Million Medical Affairs founding grant to the “Hear Clearly” Foundation.
  - The Foundation has provided TinEar with a proposal under which it would launch a “Hear Clearly 2015” campaign to make available to patients the most up-to-date information on Pediatric Tinnitus, as well as mechanisms for hearing loss.
    - These activities would be managed by a joint Foundation/TinEar Pharma committee
  - As part of the campaign, the Foundation will recruit and deploy “patient ambassadors”
    - The patient ambassadors will “engage with the patient community in long term care facilities.”

# Pharmona Strategic Plan (7)

- TinEar Pharma's grant to the Hear Clearly Foundation will also permit the development of a new website focus on tips for elderly patients suffering hearing loss.

# Pharmona Strategic Plan (8)

- The Strategic Plan also envisions a radio talk show tour in which the TinEar Pharma VP of Medical Affairs and the President of the Hear Clearly Foundation will focus on Pediatric Tinnitus and “the growing patient need for drug treatments in hearing conditions as the population ages.”

# Pharmona Strategic Plan (9)

- Medical Affairs has also produced a proactive joint Medical/Commercial presentation for payors focusing on treatment of Tinnitus.
  - The presentation focuses on Tinnitus treatment and associated cost savings and enhancement of quality of life.

# Pharmona Strategic Plan (10)

- Medical Affairs will conduct 20 advisory board meetings with ENT physician KOLs across the country, soliciting feedback on a presentation regarding Pharmona, the Kettering study, and the Sloan clinical case series.



# Pharmona Strategic Plan (11)

- Medical Affairs will also conduct a survey of physicians seeking feedback on their use of Pharmona in hearing loss in the elderly.
  - Physicians will be paid \$100 for participation in the survey

# Pharmona Strategic Plan (12)

- Given the costs associated with the Strategic Plan, the VPs of Medical Affairs and Marketing are asked to report to the Board monthly on the return on investment.