From:	Neil Gardiner (External) <NGardiner@hlxusa.com>
To:	Matthew Day
Sent:	2/27/2015 10:21:20 PM
Subject:	FW: Ad Board Summaries
Attachments:	Advocacy Summit Internal Learnings FINAL.PDF; CDM Combined Executive Summary 01.06.15.docx; Summary_Report_Appropriate_and_Safe_Use_of_Prescription_Pain_Medications....docx; TEVA_Pain Specialist Advisory Board_Executive Summary_02.13.15.docx

From: Reggio, Jaimee (CHI-GHI) [mailto:JReggio@golin.com]
Sent: Friday, February 27, 2015 3:07 PM
To: 'heather.schoenly@tevapharm.com'
Cc: Neil Gardiner; Alison Labombarda; Abbas Ebrahim, MD; Cantelmo, Jennifer (MTN-ETL); Ward, Jennifer (MTN-ETL)
Subject: Ad Board Summaries

Heather,

Attached are the summaries of recent advisory boards, including:

- Pain Specialist Ad Board
- Combined summary from both Content Development Meetings but note that those were for what we now call Pain Matters and not Vantrela
- 2013 Advocacy Summit held during the Pain Matters documentary premier
- 2014 Advocacy Advisory Board on Pain Matters

Please note that the Executive Summary for the PCP ad board held this past weekend is in development and we'll send along when complete.

Please let us know if you have any questions.

Thanks!
Jaimee and HealthLogiX team

From: Heather Schoenly [mailto:Heather.Schoenly@tevapharm.com]
Sent: Wednesday, February 25, 2015 5:55 PM
To: Reggio, Jaimee (CHI-GHI)
Cc: Ward, Jennifer (MTN-ETL); Cantelmo, Jennifer (MTN-ETL)
Subject: Ad Board Summaries

Jaimee,

We are looking for executive summaries from any pain or Vantrela ER ad boards. Do you happen to have these? Would HealthLogics have any? Can you collect these for me?

Heather

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PLAINTIFFS TRIAL EXHIBIT
P-26930_00001

Pharmaceutical Industries Ltd.

Pain Specialist Advisory Board

Saturday, December 6, 2014

TOPLINE SUMMARY

Presented by HealthLogiX

HEALTHLOGIX

Table of Contents

Topline Summary 3

Meeting Discussion and Feedback 7

Attendees 15

Topline Summary

Introduction and Program Overview

Teva Pharmaceutical Industries Ltd., in partnership with HealthLogiX, convened a Pain Specialist Advisory Board meeting at the JW Marriott in Grande Lakes, Florida, on December 6, 2014. The goal of the meeting was to better understand how recent changes in pain management have affected pain specialists and how abuse-deterrent formulations may shape and impact the use of opioids in the future. In addition, Teva sought feedback from the advisors on the abuse-deterrent platform developed by CIMA Labs, Inc., and on the clinical development program for CEP-33237 (hereafter referred to as Hydrocodone ER").

Following the welcome and introductions, Program Chair Dr Jeff Gudin led a discussion on the shifting landscape of pain management, focusing on changes at the state (eg, prescription drug monitoring programs [PDMPs]) and federal (eg, availability of Zohydro® ER, rescheduling changes) levels regarding the use of opioids, and concluding with the 2013 FDA Draft Guidance on the development of abuse-deterrent (AD) opioids. Dr Derek Moe then presented an overview of CIMA's abuse-deterrent platform (hereafter, CIMA ADT), contrasting it to other platforms commercially available/approved. This was followed by a presentation of data from the clinical development program for Hydrocodone ER, which was reported by Dr Matthew Wieman and Dr Kelli Rodvelt. Each presentation allowed sufficient time for discussion.

The program was rounded out with a small group activity, in which participants were divided into 3 groups:

- Group 1 (Drs Martin Hale, Andy Kaufman, and Joseph Valenza) was tasked with prioritizing 5 key aspects/strengths of Hydrocodone ER
- Group 2 (Drs Bart Gatz, Jeff Gudin, Xiulu Ruan, and Marcia Wolf) were asked to identify 5 limitations/challenges that may hamper uptake of Hydrocodone ER
- Group 3 (Drs Don Erb, Anthony Guarino, Melanie Rosenblatt, and Gerald Sacks) focused on patient types and how to engage in dialogue with patients who may benefit from therapy with Hydrocodone ER

Key Findings:

- With hydrocodone being reclassified as a Schedule II drug, the onus to treat patients who may benefit from opioid therapy may be shifting away from primary care providers (PCPs)
    - PCPs are becoming more averse to prescribing opioids, resulting in patients relying on pain specialists for the management of moderate to severe pain that requires opioid therapy
    - This shift may result in patients being seen before being placed on inappropriate treatment regimens (eg, high doses of short-acting opioids), which in turn may result in less polypharmacy and more rational prescribing that may include abuse-deterrent formulations of extended-release opioids
    - PCPs are not sufficiently equipped to appropriately manage pain that requires opioid therapy. As such, a strategy may be needed to empower PCPs to manage these patients effectively
- Managed care plays an increasingly influential role in prescription decision-making, and reimbursement by managed care will likely drive abuse-deterrent opioid penetration in the market
    - Many advisors were skeptical that managed care will provide coverage for abuse-deterrent opioids
    - Several advisors believed that government action requiring the use of abuse-deterrent opioids may be needed to ensure coverage and access
- There is little awareness on the part of most practitioners about abuse-deterrent technologies
    - Growing awareness and availability of abuse-deterrent opioids will result in them being considered the standard of care, but at this point, educational and promotional efforts should focus on increasing awareness of their availability and benefits. These efforts should also consider opioids without abuse-deterrent properties as the strongest competitor for the CIMA ADT platform
    - The advisors were unconvinced that physicians will differentiate between competing abuse-deterrent technologies, and as a result, favored messaging on the presence of abuse-deterrent properties rather than the specifics of the technology
    - The advisors indicated they would prescribe abuse-deterrent opioids for all their patients who require opioid therapy. Since all patients are prescribed abuse-deterrent opioids, any stigma that might be associated with their use is negated

- This would also negate the need to have a potentially detrimental conversation with a patient regarding why they are being prescribed an abuse-deterrent opioid, since all opioids written by that HCP are abuse deterrent

- Regarding the clinical data profile for Hydrocodone ER, the advisors required greater background on the Phase 3 trials. It is therefore imperative that future discussions include greater detail on study design and study endpoints
- During the afternoon workshops, the advisors were tasked with identifying 5 key strengths and limitations related to Hydrocodone ER, as well as describing key components to patient selection and dialogue. These recommendations are summarized below, with items noted by more than 1 group identified by an asterisk (*):
  - Strengths:
    - Familiarity with the molecule*
    - Lack of acetaminophen in the formulation*
    - Abuse-deterrent properties*
    - BID dosing* (seen as a limitation by some and a benefit by others)
    - Higher maximum dose*
    - Extended-release profile, with fewer peaks/valleys
    - Potential for improved access through copay programs
  - Limitations
    - Food effect,* which was seen as fairly manageable. It was suggested by Group 1 that any materials on food effect should specify that this was a high-fat meal
    - Crushed PK profile relative to intact tablet. This was considered particularly troublesome as the Silent Knight pill crusher was seen as a less stringent approach to crushing than industrial milling tools used by some competitors
    - Not being first to market
    - Lack of a 10-mg dosage strength (eg, 20 mg daily dose),* which may be alleviated by showing the doses that most people took in Phase 3 testing
    - Cost
    - Not to be used as a PRN ("as needed") medication

- Patient types/dialogue:
  - Abuse-deterrent opioids should be aimed at all patients on opioid therapy, regardless of risk; their role may therefore be positioned as an additional component of Universal Precautions
  - Regarding the specific product to use, the advisors did not have a strong feeling on this topic, and suggested the strengths and limitations of each individual product would determine their use (eg, patient preference for once-daily or twice-daily drug, access)
  - The advisors clearly favored the use of abuse-deterrent formulations for all patients who require opioid therapy, and suggested this approach would limit patient pushback on being prescribed medication with abuse-deterrent properties

- Independently licensed practitioners (ILPs; also NPs/PAs) were seen as important targets nationwide. This group was seen as being at the forefront of patient care, and as a group that is open to educational programming
- Many advisors encouraged Teva to provide additional unbranded education on opioid prescribing. This will educate HCPs regarding AD products and help position Teva as a leader in pain care

Meeting Discussion and Feedback

Welcome, Introductions and Objectives

- Teva convened a Pain Specialist Advisory Board Meeting to better understand how recent changes in pain management have affected pain specialists and how abuse-deterrent technology (ADT) may change the use of opioids in the future
- Teva also requested feedback from the advisors about the abuse-deterrent platform developed by CIMA Labs, Inc., and on the clinical development program for Hydrocodone ER
- Moderator Dr Gudin opened the meeting. welcomed the participants, and facilitated introductions
- Matt Day then reviewed Teva's current focus, which is on both central nervous system (CNS) pain and respiratory illnesses and reviewed the day's agenda
    - Several advisors commented on Teva's pipeline and suggested additional opportunities to offer ideas for novel agents to the research and development team
    - For example, they would particularly like to see an optimized NMDA receptor antagonist, which Dr Kaufman referred to as a "holy grail" for pain specialists

Pain Market Overview

- Dr Gudin presented an overview of the current pain market, focusing on opioid abuse as a public health crisis
- With respect to means of opioid abuse, most of the advisors' patients crush, chew, snort, or inject the medication, with the preferred medication being Dilaudid (hydromorphone)
    - Many of these patients use filtration techniques to remove the excipients from the formulation and inject a more pure form of the drug
    - In many cases, patients also try to alter a medication's formulation to convert it from an extended-release (ER) to an immediate-release (IR) formulation
- Dr Gudin asked the group what tools they use to help mitigate opioid abuse
    - As part of her regular patient intake process, Dr Wolf employs the Opioid Risk Tool (ORT) because completion of at least 1 tool is required for Medicare to cover clinic visits for chronic pain; however, she did not believe that the ORT or other tools like it were "worth the paper they're written on"
    - Advisors also use their states' PDMPs and lauded the regions that have given physicians access to neighboring states' databases as well
    - Most of the group also performs pill counts and issues random drug screens, but noted that PCPs and oncologists do not regularly monitor their patients' use of pain medication
    - The advisors agreed that the "Meaningful Use" program, in which physicians receive incentives for electronically communicating with patients and thus improving patient care, was not worth the time it took to install and use the system
- To segue into discussing the FDA's Draft Guidance for Industry on Abuse-Deterrent Opioids—Evaluation and Labeling, Dr Gudin stated that "the future of opioids has got to be

abuse-deterrent technology" because when abused, these drugs contribute to too many deaths and too much morbidity

- In explaining the FDA's Draft Guidance, Dr Gudin reviewed the tiering system, which seems to have created confusion among physicians but may be an educational opportunity for Teva

Group Discussion: Pain Market

- To begin the discussion about the pain market, Dr Gudin posed several questions to the advisors; first he asked whether anyone practiced in an area that was devoid of abuse, misuse, or diversion
    - Dr Rosenblatt commented that some community physicians believe that they practice in such areas, but it is unlikely that any area is completely devoid of abuse
    - Dr Wolf agreed, stating that many physicians do not believe their patients to be addicts, but recognize that they sometimes misuse their opioid medications
    - Drs Wieman and Wolf added that diversion is particularly common because most patients do not properly dispose of unused portions of opioid prescriptions
    - Dr Wolf noted that a campaign in Maryland that sought to reduce opioid diversion appeared to be successful, but actually failed because a commensurate increase in heroin use occurred during the same time period
        - Dr Rosenblatt empathized, stating that her emergency department (ED) has been overwhelmed with heroin overdoses recently
    - Several advisors also mentioned that individuals who abuse opioids have started buying pain medications illicitly because they are cheaper from drug dealers or pill mills than from the pharmacy
    - Another type of medication that has been contributing to opioid-attributed deaths is benzodiazepines; a pilot study of heroin-related fatalities found that many patients also had benzodiazepines in their systems
    - Dr Kaufman pointed to insurance companies as being partially to blame for chronic opioid abuse; he has patients who have tried to enter addiction medicine programs but have been denied coverage, and thus remain addicted to opioids
    - He also stated that as a pain management specialist, he is trained to recognize addiction, but he does not want to treat addiction; instead, he prefers to refer patients to addiction medicine specialists, who are scarce
- Dr Gudin next asked the advisors whether they use any tools not already discussed to screen patients for or educate them about opioid misuse
    - Drs Gatz and Valenza both send patients to a separate psychologist or psychiatrist for an independent opinion
        - Drs Gudin and Ruan do not have access to psychiatrists who accept insurance, making it challenging for patients to see them
    - Several physicians also check court records or simply Google their patients to better characterize their abuse potential based on their criminal and social media history
- The third question Dr Gudin posed was about how the advisors' practices will change now that hydrocodone has been rescheduled from a schedule III to a schedule II agent

- Several advisors asserted that the rescheduling will force physicians to write prescriptions for larger quantities of opioids since they will be unable to include refills on the prescriptions
- Dr Erb stated that the rescheduling has made it easier on his practice because it has reduced the number of calls from patients requesting refills; now, he only has to write prescriptions when he sees a patient
  - He also liked that earlier referrals helped him treat patients with newly diagnosed pain; these patients are easier to manage because they usually have not yet received cocktails of concomitant pain medications that he had to consolidate and taper
  - Dr Gudin thought that Dr Erb's perspective was unique and interesting; he suggested that if pain specialists do begin seeing patients with pain earlier, that it might lead to a paradigm shift in the pain field, with only minimal amounts of IR formulations being used
- The downside, according to Dr Wolf, is that PCPs are "inappropriately afraid" to write prescriptions for schedule II agents
- Dr Kaufman agreed, acknowledging that his practice has recently experienced an increase in referrals because PCPs will not prescribe opioids
  - He said, however, that his assistant tells every patient who calls that they will be evaluated, but they will not receive a prescription at their first visit
  - Several advisors recognized the utility of this approach, but noted that the reluctance of a pain management specialist to prescribe opioids at a patient's first visit underscores the complexity of managing pain and provides the rationale for why PCPs do not prescribe opioids
  - As a group, the advisors recommended that Teva develop an educational initiative designed to help make PCPs feel more comfortable prescribing opioids

- Dr Gudin then asked the group for the perceptions of abuse-deterrent (AD) OxyContin®
  - Overwhelmingly, the advisors responded that the abuse-deterrent formulation made a "huge difference," causing less people to abuse it
  - When Dr Wieman asked the advisors why the new formulation was so successful, they responded that the data were compelling, showing that patients did not desire it
    - Dr Wolf felt that patients who were abusing opioids avoided this new formulation and complained it did not work; it did, however, patients who legitimately needed the medication to treat pain had no major complaints about product efficacy
- The final questions Dr Gudin asked were about whether or not the pain market needs Hydrocodone ER in an abuse-deterrent formulation; and if so, how would physicians use it
  - There was a consensus that such a product is needed, with Dr Wolf and Valenza stating that it is "badly needed"
  - Nearly all of the advisors stated that they would begin using it immediately, "literally [on] day one"
  - Dr Valenza stated that he will substitute AD Hydrocodone ER for OxyContin®

- Dr Rosenblatt liked that it could serve as an alternative to patients with tolerance to hydrocodone IR, who take 8 to 10 pills a day
- Dr Wolf was not convinced that a dose-response relationship exists with respect to the efficacy of hydrocodone
  - Dr Hale countered that a dose-response relationship dose exist, but that not all patients are sensitive to hydrocodone
  - Dr Valenza agreed, citing clinical trial data demonstrating that only about 50% of patients experience 50% relief
- As an aside to the conversation, the advisors began discussing what is considered "high-dose" prescribing of opioids
  - In response to this discussion, Dr Gudin recommended that Teva sponsor a consensus meeting in which the advisors convene and write a paper about rational opioid prescribing for pain specialists

Review of Abuse-deterrent Technologies

- Dr Derek Moe from CIMA Labs, Inc. began the next presentation by asking the advisors to provide their general opinions about ADT
  - An opportunity exists for Teva to educate PCPs and pain specialists about the different types of ADTs available, according to the advisors
- Dr Moe told this group that the overall goal of ADT is to prevent dose-dumping—that is, to immediately release the ingredients of an ER opioid
  - Several advisors mentioned that they did not like Oxycontin® because its effects peak quickly; after the peak, patients think it is no longer working, even if its pain-relieving effects persist
  - Instead, it would be desirable to have an agent with a "flat" profile that simply manages pain without patients ever experiencing a peak high feeling
- In discussing the different types of ADTs, Dr Moe provided several examples of other drugs with these formulations, but focused on CIMA ADT
  - He explained that CIMA ADT maintains its slow-release properties even when broken down
  - CIMA ADT also contains polymers of different solubilities to make it very challenging to extract the drug, and each particle contains a protective coating that makes it difficult to crush

Group Discussion: Abuse-deterrent Technologies

- Dr Moe proposed several questions to the advisors, first asking whether it would be appealing to have an AD IR opioid that limits oral overconsumption by slowing down the release of the drug
  - Dr Wolf responded that its utility would depend on the length of the washout period; (eg, if it would still exert its AD effects when patients took 1 dose per hour for several hours, it would be "ideal" and "critically needed")
  - Drs Valenza and Kaufman said that this type of technology would be great to have—it can save lives

        - Dr Valenza interjected that this type of product would not be suitable for patients who require frequent dosing
        - Dr Kaufman cautioned that price will affect the uptake of AD IR medications, unless government begins to require ADT for opioids
        - Dr Sacks agreed, stating that it is a great idea, but that Teva will not sell much of it for at least 5 years, because it is unlikely that insurance will cover it until required to do so by the government
    - Dr Gudin opined that this is a nice niche for Teva, but he would prefer they focus on novel analgesic compounds instead of on opioids
- Dr Moe then asked the advisors whether an AD IR formulation of Dilaudid would be useful
    - The advisors cautioned that administering Dilaudid intravenously (IV) represents only a small percentage of opioid abuse and, therefore, an AD Dilaudid may not be the best investment for Teva
    - Several members of the group suggested creating an AD formulation of methadone, but not all advisors agreed
- The final question Dr Moe posed to the group was, "Is an AD IR single-agent hydrocodone a complement to that for breakthrough pain…as opposed to the combination products that are [under development]?"
    - Most advisors agreed that an AD IR single-agent hydrocodone would be useful
    - Dr Rosenblatt, however, liked that some of these products are combined with Tylenol because it gives her a reason to convince patients not to take too much of them
- When asked which patients should receive AD opioids, the majority of advisors believed that all patients should receive them
    - However, Dr Sacks asserted that although everybody should get them, only people whose insurance company will pay for it will actually receive it
    - Prescribing AD formulations in the primary care setting will be especially important, because it is unlikely that PCPs are trained to be able to recognize potential abusers

Teva Hydrocodone ER Data Review Pt. 1

- In the next presentation, Dr Matt Wieman provided an overview of Hydrocodone ER
    - The advisors strongly recommended developing 10 mg and 20 mg dose strengths, as they prefer to have more low-dose options when titrating patients' doses
        - Not having these options was perceived to be "a real problem" by Dr Rosenblatt
    - Interest was expressed in knowing more about the design of the pivotal studies, particularly the placebo-controlled design required by the FDA
        - The advisors agreed that this design is not representative of what happens in the real world, but understood that it was mandated by regulatory authorities
        - When presenting or reporting pivotal study data, Teva should take care to clarify the study design and outcomes measures, as physicians are not used to interpreting data in this format
    - The group appreciated that the AD Hydrocodone ER had sustained activity levels, but desired more information about the types and amounts of breakthrough medications patients received

        - They also requested more information about dose titration and the distribution of the dose received during the study
    - Upon reviewing the safety data from the extension study, advisors were curious as to the explanation for the emergence of sinusitus; they questioned whether it may be due to patients snorting the AD Hydrocodone ER
        - Teva should investigate the background rate of sinusitus in order to offer an explanation of its occurrence
    - Questions also arose as to why the incidence of arthralgia was so high, but most advisors did not think it was a problem

Teva Hydrocodone ER Data Review Pt. 2 and Group Discussion

- In the second half of the Hydrocodone ER presentation, Dr Rodvelt described outcomes from the phase I studies that examined the effects of alcohol and food on the safety and PKs of the medication
    - The advisors were pleased that there were minimal or no effects of alcohol on Hydrocodone ER
    - Some concern was expressed over the 7.5-hour delay in T_{max} when Hydrocodone ER was taken with food; these concerns were mostly alleviated once the group discovered that Teva is conducting a phase IV study to examine the efficacy and safety of the medication in fed or fasting states
- In response to learning the outcomes of the crushing studies, Dr Wolf said that she was "a little surprised and disappointed" about the elevated plasma concentrations observed with crushed Hydrocodone ER
    - Several advisors concurred, suggesting that these data were not as impressive as those elicited by other AD formulations, in which the curves of the crushed and intact medications were more similar
        - The advisors acknowledged, however, that they could not fully remember the outcomes of crushed Zohydro® ER or Hysingla™ ER studies; it may be worthwhile for Teva to review other drugs' data at future advisory board meetings to contextualize the Hydrocodone ER findings
- The advisors appreciated the outcomes of the likability studies for several reasons:
    - They were pleased that the likeability data mirrored the PK data
    - The control data with the IR formulation was compelling and should be shared with PCPs, in an effort to encourage them to use AD Hydrocodone ER
    - It was an advantage that the users did not "like" Hydrocodone ER
    - And finally, even though users "liked" the crushed version of Hydrocodone ER, its likability may decrease when users actually have to perform the crushing themselves, especially if it is difficult for them to do
- To put the likeability outcomes into perspective, the advisors desired more information about outcomes of competitors' studies
    - Dr Gudin thought that the data with Hydrocodone ER may not be as robust as those with other products

- Dr Momah explained that part of the reason for this difference may be due to the fact that other products' studies were conducted with "chewed" opioids, as opposed to "crushed" ones, which release more of the opioids
    - Although they understood this difference, the advisors thought the distinction between "chewed" and "crushed" studies was too nuanced for most physicians to grasp without proper education
    - To this end, most advisors recommended that Teva not try to position their ADT as being superior to competitors' technology, as the manufacturing process is too difficult for most physicians to understand
- With respect to the safety of Hydrocodone ER, concern was expressed over the fact that clinically significant reductions in respiration rate were reported
    - The advisors desired additional information about these events and warned Teva to be prepared to field questions about them
- The wording of the conclusions from Study 1085 was well received; these points contain key information physicians will want to hear

Workshop Group Presentations

- To synthesize the information presented throughout the day, the advisors divided into 3 groups, each of which was assigned a topic to discuss:
    - Group 1 (Drs Hale, Kaufman, and Valenza) was tasked with prioritizing 5 key aspects/strengths of Hydrocodone ER
    - Group 2 (Drs Gatz, Gudin, Ruan, and Wolf) was asked to identify 5 limitations/challenges that may hamper uptake of Hydrocodone ER
    - Group 3 (Drs Erb, Guarino, Rosenblatt, and Sacks) focused on patient types and how to engage in dialogue with patients who may benefit from Hydrocodone ER
- Dr Kaufman summarized Group 1's discussion by presenting the following strengths of Hydrocodone ER:
    - Physicians are familiar with the molecule and have a rich history of using it
    - It is a single-agent formulation, without added acetaminophen
    - The formulation deters abuse
    - It has a high maximum dose of 180 mg
    - It is administered twice daily, instead of once daily
        - The last attribute was debated, as some advisors disagreed that twice daily dosing was better than once-daily dosing; overall, they agreed that some patients prefer once-daily dosing whereas others prefer twice-daily dosing
- Group 2 agreed with all of the strengths presented, and Group 3 added that they appreciated the "flat" profile of Hydrocodone ER, as opposed to it having peaks and valleys
- In their presentation, Group 2 outlined the following limitations of hydrocodone:
    - The food effect requires patients to administer it in a fasting state, a limitation perceived to be manageable by the advisors
    - When crushed or inhaled, Hydrocodone ER was more likeable than intact drug
    - The commercial availability of the Silent Knight, which was used to crush Hydrocodone ER in its studies, was perceived to be another limitation
    - Hydrocodone ER will not be the first AD formulation to receive regulatory approval

- Cost and insurance coverage may be a barrier to its uptake
- The lack of a 10-mg or 20-mg dose strength may interfere with physicians' ability to titrate dosing and also may add to PCP discomfort with prescribing it
  - Dr Rosenblatt asserted that convincing PCPs to use Hydrocodone ER is going to be challenging
  - To do so, the panel recommended developing strong educational campaigns directed toward PCPs, orthopedic physicians, and midlevel providers to help increase their comfort with prescribing opioids and managing patients who receive them

- Group 3 then led a discussion about patient types that may be good candidates for AD opioids
  - Universally, Group 3 thought that all patients should receive AD opioids
  - With respect to which opioids to prescribe for individual patients, they would base their decisions on insurance coverage
    - If insurance was not an issue, the advisors would prefer Hydrocodone ER for patients who like twice-daily dosing
  - With respect to how they would discuss Hydrocodone ER with patients, Group 3 said that they would emphasize that it is a long-acting medication without any acetaminophen
    - They would tell patients that they would have better results and better compliance with this drug, which would translate into better pain control
    - In addition, they would recommend that patients take it when they are brushing their teeth, focusing on the fact that they do not need to carry any medicine with them throughout the day
    - Dr Erb interjected that he is more straightforward with patients, and plans to explain that the AD formulation was designed to help curb prescription drug abuse

Closing Comments

- Dr Gudin closed the meeting by thanking the advisors for the lively discussions throughout the day
- Matt Day thanked Dr Gudin for moderating the meeting and thanked the advisors for their attendance and feedback

Meeting Agenda

8:00 AM –	8:15 AM	**Welcome, Introductions, and Objectives** *Jeff Gudin, MD & Matt Day*
8:15 AM –	8:45 AM	**Pain Market Overview** *Jeff Gudin, MD*
8:45 AM –	9:15 AM	**Group Discussion: Pain Market** *Moderator: Jeff Gudin, MD*
9:15 AM –	9:45 AM	**Review of Abuse-Deterrent Technologies** *Derek Moe, PhD*
9:45 AM –	10:30 AM	**Group Discussion: Abuse-Deterrent Technologies**
10:30 AM –	10:45 AM	**Break**
10:45 AM –	11:15 AM	**Teva Hydrocodone ER Data Review – Pt. 1** *Matthew Wieman, MD & Kelli Rodvelt, PhD*
11:15 AM –	12:15 PM	**Group Discussion: Hydrocodone ER Data Review – Pt. 1**
12:15 PM –	1:00 PM	**Lunch**
1:00 PM –	1:30 PM	**Teva Hydrocodone ER Data Review – Pt. 2** *Matthew Wieman, MD & Kelli Rodvelt, PhD*
1:30 PM –	2:15 PM	**Group Discussion: Hydrocodone ER Data Review – Pt. 2**
2:15 PM	2:30 PM	**Break**
2:30 PM	3:00 PM	**Workshop**
3:00 PM	3:30 PM	**Group Presentations**
3:30 PM		**Closing Comments** *Jeff Gudin, MD & Matt Day*

Attendees

Advisors

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Kennedy-White Orthopaedic Center
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Teva Participants

Matt Day
Associate Brand Director
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Jan Faiola
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Chinedu Momah, PharmD
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Kelli Rodvelt, PhD
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Matthew Wieman, MD
Director
Medical Affairs

TEVA Pharmaceutical Industries Ltd.

Disease Awareness Content Development Meetings

Meeting 1: Friday, August 1, 2014
Meeting 2: Monday, November 17, 2014

PROGRAM SUMMARY

Presented by HealthLogiX

HEALTHLOGIX

Table of Contents

Executive Summary 3

Meeting 1: Discussion and Feedback 5

Welcome, Introductions, and Objectives 5

PAINWeek Project Overview and Draft Slide Deck 5

Breakout Presentations 7

Meeting 2: Discussion and Feedback 11

Welcome, Introductions and Objectives 11

Teva Pain Care Franchise 11

Overview of the Disease Awareness Platform 11

Evolving Roles, Same Goals Module Review 13

Modules 2 & 3 Overview 14

Breakout Presentations 15

Meeting 1: Agenda 17

Meeting 1: Attendees 18

Meeting 2: Agenda 19

Meeting 2: Attendees 20

Executive Summary

Introduction:

Teva Pharmaceutical Industries Ltd., in partnership with HealthLogiX, convened 2 Content Development meetings to support development of the unbranded disease awareness campaign. The first meeting was held at the Westin Jersey City in Jersey City, New Jersey in August 2014. The goal of the meeting was to develop slide content that would be introduced at PAINWeek 2014 as part of Teva's unbranded initiative to educate healthcare providers (HCPs) about the issues of misuse, abuse, and diversion and the potential role of abuse-deterrent formulations of opioids in pain management. To this end, Program Chair Dr. Jeff Gudin presented a draft slide deck to 5 advisors and requested their feedback to fine-tune the content. Feedback from the advisors was subsequently used to create the PAINWeek presentation titled, "Evolving Roles, Same Goals: The Changing Landscape of Pain Management."

The second Content Development meeting was convened at the Palomar Hotel in Philadelphia, Pennsylvania on November 17, 2014. The purpose of this meeting was to leverage the content included in the PAINWeek presentation to build a comprehensive, unbranded educational campaign to enhance awareness about pain management. In doing so, the advisors provided feedback about 2 key topics that emerged as being of high importance to HCPs at PAINWeek and the American Academy of Pain Management (AAPM) annual meeting: FDA guidance and abuse-deterrent technology (ADT). Recommendations from the advisors will be used to create foundational content for Teva's disease awareness platform.

Key Recommendations:

The following represents a summary of key recommendations made by the advisors:

- As a company, Teva should strive to change the conversation surrounding opioid use from a negative to a positive dialogue
  - Emphasize that opioids are useful drugs for many patients with chronic pain
  - Cite key statistics, such as the fact that the overall rate of opioid addiction and abuse is only approximately 3%
  - Encourage HCPs to be responsible prescribers of these medications
- Teva should develop a comprehensive platform to help position the company as the industry leader in pain management education
  - Such an initiative, including the PAINWeek slide deck, should feature a multipronged approach to combating opioid misuse and abuse, including efforts by HCPs, patients, the government, and industry
  - Educating the public would be a vital component of such an initiative to promote patient accountability and foster uptake of abuse-deterrent opioids
- Critical content to incorporate into the PAINWeek slide deck includes:
  - The multipronged approach to preventing opioid abuse and misuse

  - Examples of opioid abuse and ways abuse-deterrent formulations of opioids address such misuse
  - Draft guidance published by the United States Food and Drug Administration (FDA) for developing abuse-deterrent opioids
  - Types of studies required to demonstrate abuse deterrence
- The presentations should be designed to engage the audience using several key tactics:
  - Pose questions to the audience and use audience response systems (ARS) to capture their answers and guide discussion
  - If possible, build the slide content around a relatable patient case that can be used to introduce each topic
- Explore the following avenues for disseminating disease awareness content:
  - *Pain Management* or *Postgraduate Medicine* supplements
  - A consensus paper about pain management by experts in the field

Meeting 1: Discussion and Feedback

Welcome, Introductions, and Objectives

- Teva convened a Content Development meeting to develop slide content for PAINWeek 2014 that would meet the goals of their educational initiatives related to abuse-deterrent formulations of opioids
- Matt Day opened the meeting by conveying the purpose of the meeting, and introduced Dr. Gudin, who presented the draft slide deck to the group

PAINWeek Project Overview and Draft Slide Deck

- In discussing the overall goals and title for the slide deck, the advisors made several suggestions:
  - Emphasize that opioids are useful drugs, but that there is a need to use them in a safer, more effective fashion
  - Focus on how opioid prescribing has changed and what its future landscape will be
  - Mention "responsible prescribing" as a key facet in pain management
  - Use the title to pose a question to the audience: "Can opioids be responsibly prescribed?"
- The advisors expressed concerns over "Part 1: Balancing Opioid Use in Chronic Pain" lacking evidence-based data; they recommended omitting or consolidating these slides
- There was general agreement that there is a need to shift the public's attitude about pain medication from a negative one, focusing on abuse and abuse, to a positive one, about how these drugs are necessary for patients suffering from chronic pain
- To transform this attitude, the advisors recommended emphasizing several key points:
  - There is a real need for safe, effective opioids for patients with chronic pain
  - The overall rate of opioid abuse or addiction is only 3.27%
  - Individuals who abuse or misuse opioids often have preexisting problems with addiction
- The advisors suggested identifying other factors that contributed to the increase in opioid prescriptions over the past 20 years; for example:
  - Managed care creates challenges when trying to admit patients for other types of treatment, such as inpatient care or physical therapy
  - The decline in nonsteroidal anti-inflammatory drug (NSAID) use, due to their association with cardiovascular events
- In discussing the consequences of drug abuse, the advisors recommended noting that most overdoses are unintentional
- To engage the audience, the advisors had several ideas for the PAINWeek presentation or for future meetings:

  - Several advisors suggested using an ARS that would allow speakers to pose questions to the audience about case patients and then segue into reviewing the data supporting opioid use and the need for abuse-deterrent formulations
  - One advisor cited a well-received program in which participants received iPods, walked through an exhibit at their own pace listening to disease state information, viewing posters, and eventually funneling into an interactive forum led by key opinion leaders (KOLs) about specific pain topics
- With respect to the terminology of opioid misuse and abuse presented, the advisors recommended using short video clips of hypothetical patients to define each term
  - A suggestion to add the term "pseudotolerance" to the list also was made
- There was an overall consensus that the "Strategies Against Opioid Abuse" was a good slide and that the PAINWeek presentation could start with this information, rather than with a pain overview
- To offer the pain overview information for interested persons, Teva can create a microsite for HCPs to visit as part of a continuum of education about pain management
  - Such a site would allow HCPs to click on topics most relevant and interesting to their practice
  - The site could serve as a platform to position Teva as a leader in education about pain management, and specifically, about opioids and ADT
- There was some disagreement about how Teva should educate HCPs about their specific opioid abuse-deterrent formulation
  - Some advisors thought it would be worthwhile to explain the different types of formulations, focusing on how their technology differs
  - Other advisors thought the technology was less important than creating a patient-centered story, highlighting the type of person who may benefit from ADT
  - One advisor tied the discussion back to "changing the conversation" from a negative to a positive one, by presenting a patient who benefitted from ADT
  - Another suggestion was to develop messaging about opioids positioning abuse-deterrent formulations as the future standard of care
- Discussing stakeholders in abuse deterrence was considered worthwhile for this presentation
- Not all advisors agreed that guidelines need to be presented, as many of the organizations that have published pain management recommendations may have biased agendas
- When discussing screening as a strategy to identify and reduce opioid abuse, there was a consensus that slides should acknowledge that most HCPs consider the likelihood of abuse among their patients, rather than positioning screening as an extraneous step that is not being done
- The slide, "Patient Responsibilities in Safe Opioid Use," was well received
- Slides about prescription drug monitoring programs (PDMPs) and the Medicaid "Lock-In" program generated a lot of enthusiasm among the advisors; they particularly liked the "1 patient, 1 PCP, 1 pharmacy" message related to the Lock-In program
  - One advisor commented that these slides served as a nice adjunct to discussion about opioid abuse-deterrent formulations; it was desirable to have a multipronged approach to combating opioid misuse and abuse

- The advisors thought Risk Evaluation and Mitigation Strategies (REMS) were important for pain management and were processes they used in routine clinical practice
  - However, the advisors did not think that including the Medication Guide and Patient Counseling information was necessary
  - Instead, one advisor suggested posting video modules of KOLs on the Teva web site, explaining the Medication Guide and counseling information to patients
  - The advisors further recommended incentivizing the videos, offering a free medication lockbox to patients completing all modules
  - There was consensus that educating the public should be an important priority for Teva
- Educating the audience about the FDA's draft guidance for abuse deterrence was perceived to be important, as many primary care physicians may not realize the steps a drug manufacturer must take to obtain abuse-deterrent labeling
  - Briefly defining each of the study types recommended by the FDA was thought to be beneficial in helping HCPs interpret results from these studies in the future
- Dose dumping may not be necessary to discuss during this presentation, as it is usually done unintentionally, and the advisors stressed the importance of keeping this presentation positive
- There was a consensus that the slides showing abuse-deterrent formulations would be interesting to the audience and should be enhanced graphically and for flow
- After Dr. Gudin finished presenting the draft slide deck, he summarized the group's discussion of Part 3 of the deck by opining that the content highlights the following key points:
  - A number of opioid-deterrent approaches have been developed, but the landscape is complex
  - Developing effective formulations that will gain FDA approval is a significant challenge
- An overarching theme for the deck was then proposed: Responsible prescribing will include ADTs
- Most advisors agreed that using a patient case to present the various content within the slide deck would be an effective way to engage the audience
  - One advisor emphasized the importance of "putting a face on pain"
  - They suggested using a patient with low back pain and comorbid hypercholesterolemia and hypertension
- The group also cautioned against over-selling ADT, as many pain HCPs do not believe that their patients intentionally abuse opioids
- On the other hand, they suggested that the slide deck focus on Part 3 of the presentation to achieve Teva's primary goal of educating HCPs about new abuse-deterrent formulations

Breakout Presentations

- After the advisors divided into 2 groups to fine tune the PAINWeek presentation, they presented their ideas to the entire group
- The first group recommended using the following outline for the slide deck:

- Use the summary slide from Part 1 as an Introduction slide, to discuss pain and the challenges associated with its management, and to present opioids as an integral part of its management
- List goals of managing pain, including improving quality of life, limiting pain, minimizing adverse events (AEs), limiting addiction and abuse, and maintaining compliance
- Introduce a patient: a 54 year-old man with at least 3 years of low back pain after failing surgical fusion
    - Patient has hypertension, hyperlipidemia, diabetes, girth, and depression
    - The patient is currently receiving statins, beta blockers, and Viagra
    - To manage his pain, he is taking 6 hydrocodone tablets a day; he previously took NSAIDs and duloxetine to manage pain
    - In terms of social history, he works as a store manager, is a smoker, drinks about 6 beers a week, has some experience with THC and street drugs but nothing in the recent past
- Ask the audience what other treatments they might consider for this patient
- Show the data demonstrating the increase in opioid prescriptions; stratify by type of HCP and immediate- vs early-release formulation
- Explain that the overall rate of opioid abuse/addiction is only 3.27%, despite the flurry of negative media attention on the subject
- Emphasize that patients without a history of abuse and addiction rarely have a problem with opioid abuse
- Acknowledge, however, that opioid misuse and abuse does exist and needs to be addressed
- Present information about mortality due to drug abuse and sources of opioid diversion
- Use another video clip of the patient, complaining that he is still in pain after taking 6 hydrocodone tablets per day; ask the audience whether they would prescribe additional opioids or a different kind
- Identify stakeholders in preventing abuse and explain strategies used to overcome abuse, such as education, regulatory initiatives (renamed guidance and tools), and opioid abuse-deterrent formulations and labeling
- Explain the REMS programs associated with opioid use
- Ask the audience this question: "What is the most common method of opioid abuse by patients with chronic pain?" as the advisors believed the answer to be overuse
- Begin the final section of the presentation by stating that advances in pain management have led to the development of abuse-deterrent formulations
- Define the various abuse-deterrent strategies currently available or under investigation
- Describe the draft guidance published by the FDA for developing opioids with abuse-deterrent formulations
- Briefly and concisely cite key features of the studies conducted to determine abuse deterrence

- Present the slide describing the real-world validity of human abuse liability (HAL, also referred to as clinical abuse potential [CAP]) studies to demonstrate the potential utility of such studies in minimizing abuse
- Revisit the case patient and describe his success while receiving an opioid with an abuse-deterrent formulation
- End the presentation by asking what percentage of patients they would prescribe an abuse-deterrent opioid for in the future

- Next, the second group presented their slide deck and suggested the following outline:
  - Introduce the prevalence of chronic pain, types of chronic pain, its economic burden, and its impact on patients' functioning
  - Present a patient case: 52-year-old woman with a 10-year history of diabetes who now suffers from painful diabetic neuropathy and has trouble sleeping
    - Social history: she's married with 2 teenage children and works as a part-time attorney
    - She experimented with drugs in college, was a former smoker, and uses alcohol occasionally
    - She is currently receiving Cymbalta at a dose of 60 mg/day, with some benefit, but is still having a lot of difficulty
    - In the past, she received short-acting opioids after a ski accident, but is not currently receiving opioids; she also previously used topical capsaicin and tricyclic antidepressants without success
  - Emphasize that the case patient has failed a lot of treatments and is a candidate for an opioid, but has concerns about safety
  - Pose a question to the audience: "How can we maximize the effectiveness of opioid therapy while minimizing its potential risks?" and list "use abuse-deterrent opioids" as an option
  - Identify stakeholders in abuse deterrence and safety, transitioning into slides about the measures HCPs and patients can take to prevent opioid abuse and misuse
  - Discuss initiatives by state governments (PDMPs) and the federal government (scheduling and labeling)
  - Describe the efforts required by industry to develop abuse-deterrent opioids
    - List the types of opioid abuse-deterrent formulations currently available and under investigation
    - Explain the 4 tiers of label claims
  - End the presentation with the case patient entering a clinical trial investigating an extended-release opioid with an abuse-deterrent formulation
- Overall, the advisors seemed to prefer the second group's approach, tailoring the presentation to the case patient more seamlessly
- Regarding how to present the slide deck, the advisors suggested having 3 speakers, each presenting a different topic, but also having an opportunity to comment on the other sections to create a dialogue
- The PAINWeek presentation should be designed to engage the audience using several key tactics:

- Pose questions to the audience and use an ARS to capture their answers and guide discussion
- If possible, build the slide content around a relatable patient case that can be used to introduce each topic

Matt Day closed the meeting by thanking the advisors for their time and valuable input.

Meeting 2: Discussion and Feedback

Welcome, Introductions, and Objectives

- Teva convened a second Content Development meeting to expand its disease awareness educational platform by creating 2 additional pain management modules
- Matt Day welcomed the participants and described the success of the PAINWeek and AAPM presentations
- He explained that the next 2 modules under development focus on topics of high interest to HCPs who attended those meetings: FDA guidance and ADTs
  - There was a consensus that an unmet need exists with respect to educating HCPs about ADTs
  - The advisors cited several examples of gaps in PCPs', NPs', and PAs' knowledge about these technologies, including some who had never heard of abuse-deterrent opioid formulations
- In discussing other avenues for disseminating pain management information, advisors proposed several ideas:
  - Dr. Gudin recommended convening another meeting with the same advisors to craft a consensus paper about pain management, emphasizing that experts in the field will preferentially use abuse-deterrent opioids in the near future
  - Dr. Argoff suggested creating supplements in either *Pain Medicine* or *Postgraduate Medicine*, explaining that these types of publications have the potential to reach a lot of PCPs
  - Another advisor suggested posting content on Sermo, a physician social networking site that has a pain management hub

Teva Pain Care Franchise

- Matt Day provided the advisors with a foundational understanding of the Teva Pain Care franchise, including its current and new opioid assets, as well as future non-opioid alternatives that the company is exploring
- In response to Mr. Day's overview, Dr. Argoff called Teva's pain management portfolio "impressive"

Overview of the Disease Awareness Platform

- Samantha Schwarz shared information about Teva's disease awareness platform, explaining the types of evidence-based information that will be available on the web site by February or March 2015
- Keeping the campaign simple, without new lexicon, was a well-received objective of Teva's strategy

  - According to the advisors, simple, practical, and actionable information resonates with HCPs and will give credibility to the campaign
- Keeping the tone of this initiative positive will be an important goal, especially when imparting to HCPs that ADT will be the future standard of care of pain management
- The group strongly advised Teva to ensure that the platform is patient-centric, emphasizing improvements in care, and not to solely focus on drugs and ADT
- Teva should also empower patients by:
  - Working to eliminate the stigma of being a "pain patient" and legitimizing chronic pain as a debilitating medical condition
  - Encouraging patients to take responsibility for these medications and to embrace ADT as an extra safety measure, even though they may not need it
- There was a favorable reaction to naming the platform "Pain Matters" because it:
  - Captures the fact that pain is not just a symptom; it is a chronic illness
  - Is contrary to the negative attacks pain specialists sometimes endure for treating this complex condition
- "Teva is committed to building resources beyond medication" is a strong message that will likely resonate with HCPs and should be emphasized
- With respect to the credibility of the web site, the advisors recommended that Teva take the following measures to gain the trust of HCPs:
  - Include content in the campaign about other facets of pain management that are not directly related to opioids (eg, taking histories, performing physical examinations, conducting pain assessments, the role of physical therapy, when to use medications, etc.)
  - When discussing opioids, acknowledge that abuse and misuse exist and that Teva is working as quickly as possible to address these problems
  - Do not overpromise the ability of ADT to completely eliminate abuse
- Specific buckets of information to post on the web site include:
  - Patient impact—emphasizing why pain matters, the magnitude of the problem, the effects on productivity, and psychosocial aspects of the disease
  - Clinical support—containing information about opiates and non-opiate agents
  - Expectations—explaining what to expect from various pain management strategies germane to patients' outcomes
- Upon reviewing the content buckets that Teva proposed to use on the web site, the advisors felt that there was too much emphasis on opioids
  - The overall rubric should be about optimizing pain management, with opioids comprising 1 treatment option
  - Opioids and ADTs should still be covered in detail—they just need to be placed in the appropriate context of overall pain management
- Upon reviewing the creative layout of the web site, specifically on "Route 1: Focus on Pain Matters," the advisors provided the following feedback:
  - One advisor suggested using a different image, depicting a clinical setting; he noted that the current image looked like a hospital setting, which made him think of treating post-operative pain only
  - The homepage screen is too busy and hard to read

  - There are too many options; the advisors did not know whether they should click along the top menu or the bottom menu first
  - The 3 buckets outlined above should be included on the homepage
  - Replace "Abuse Deterrence Technology" with a more general title, such as "Changing Landscape"
- The advisors did not exhibit strong reactions to "Route 2: Pain Matters in Balance," but did say that the color palette was not as warm as the one used for Route 1
- Regarding "Route 3: Duality of Pain Matters," the advisors thought that the contrast between the colors made it difficult to read some of the text
- Overall, the group preferred Route 1 over Routes 2 and 3

Evolving Roles, Same Goals Module Review

- Dr. Gudin, with the help of the advisors who attended the first Content Development Meeting, reviewed the *Evolving Roles, Same Goals* module to lay the foundation for the 2 new modules that the group would be helping to create
- To make this deck more comprehensive, Teva should consider adding information about the advantages and limitations of other treatment options, like acetaminophen and NSAIDs
- When presenting the slide illustrating the rising number of opioid prescriptions over time, it may be worthwhile to mention other changes in healthcare, such as the growing number of ambulatory surgeries, that may have contributed to this increase
  - One advisor suggested writing a "Letter to the Editor" outlining the changes that have occurred over time that may have contributed to the increase in opioid prescriptions
- Specific feedback was provided about certain slides:
  - Change the title "What is the Scope of Intended Abuse/Addiction?" to "Not Every Patient Who Receives Opioids is at Risk for Addiction"
  - On the same slide, change "25X lower" to a different color, for emphasis
  - Remove the slide titled "Source of Opioid Diversion With Increasing Non-medical Use"
  - Create better REMS slides by eliminating information that is not applicable to HCPs, such as the timetable for reporting, and focus on what REMS are, why they exist for opioids, and emphasize that they exist for other drugs as well
  - On the "FDA Draft Guidance for Postmarketing Studies" slide, note that the study population should be carefully selected based on real-world abuse potential
  - Reword the "Conclusions" slide sub-bullets for clarity or delete them altogether
- For future educational modules, Teva should consider developing "How To" guides for the strategies listed on the "HCP Approaches to Mitigate Opioid Abuse"
  - Many PCPs may not understand how to perform urine screening
  - Provide accompanying instructional "How To" videos, toolkits, and opioid agreements on the web site; include the links in the presentations

Modules 2 & 3 Overview

- When presenting these modules, it will be important to put them into context by reminding HCPs that this information is for background purposes to enhance comfort when treating pain. It should also be emphasized that the HCP's goal in using these modules is to provide the highest standards of care to their patients
- To engage the audience from the start, 1 advisor suggested bringing multiple modules to each program and allowing the audience to choose which one(s) to cover, and presenting as many as possible in the allotted time
- To keep these presentations focused on the patient, several ideas were proposed:
  - Use videos showing patients abusing/misusing opioids to describe the common forms of abuse
  - Leverage patient cases that help HCPs understand which patients are at risk of opioid abuse/misuse
- Despite these suggestions, a major challenge in the pain field is getting HCPs to acknowledge that some of their patients (or their families/caregivers) have the potential to abuse or misuse opioids
  - To foster such an acknowledgement, some cases of aberrant behavior and not outright abuse should be included; for example, show a patient who takes 3 pills on bad days and only 1 pill on days he or she is not feeling as much pain
- Several advisors acknowledged that educating HCPs about the requirements for ADT clinical trials is important because it is new and HCPs will need to know how to interpret the trial data
- Dr. Gudin then covered the proposed content for Module 2, and the following preliminary feedback was provided:
  - The pharmacokinetic slides provide too much detail about the different parameters that the studies measure
  - Although the CAP studies appear to be particularly interesting to HCPs, there may be too much detail on the slides describing them
  - Using an example of a CAP study may be a better method of explaining the purpose and design of these studies
  - On the slide titled, "VAS Scales in CAP Studies," change the last 2 bullets to say "Peak effect" and "Offset"
  - Too much detail is included about post-marketing studies
  - Rather than getting lost in minutia, it will be important to emphasize that the outcomes of these studies can be used to differentiate ADTs from one another
  - To this end, the presentation should cite examples of these studies and discuss the potential implications of their findings
  - Explaining each tiers' label claims is dry and unnecessary for the audience
- Upon presenting the information for Module 3, Dr. Gudin received the following comments:
  - Use different colors on the "Pharmacokinetics and Abuse Risk" slide; otherwise, it may look like green means "go," red means "stop," and yellow means "yield"
  - More high-level information about what each slide is depicting was desired, such as providing examples of drugs that contain each type of ADT
- In preparation for the afternoon breakout sessions, the advisors made several suggestions:

- Construct these presentations to be more interactive, like a workshop
- Weave a patient case into each presentation
- Combine the 3 modules into a single hour-long presentation that covers the high- level takeaways from each topic

Breakout Presentations

- After the advisors divided into 2 groups to reconstruct Modules 2 and 3, they presented their ideas to the entire group
- The first group worked on the FDA Guidance module and recommended including the following content in the deck:
  - Acknowledge that pain is an epidemic and that prescription drug abuse exists
  - Note that all analgesics have AEs
  - Emphasize that within the field of pain management, opioids play an important role
    - Cite the fact that there are as many deaths (or more) from NSAIDs as there are from opioids
  - Explain the sources of abuse and how they change over time
  - Remind the audience that death is a consequence of opioid abuse and misuse, accounting for more deaths than heroin and cocaine
  - List mechanisms by which patients abuse opioids
  - Note that because some individuals tamper with opioids, the FDA has published guidance as to how to develop abuse-deterrent formulations of opioids
  - Briefly summarize the material contained in the FDA document, including:
    - The rationale for each category of clinical trial
    - How findings from these studies translate to a drug's package insert
  - Explain each clinical trial category at a high level and provide an example
  - Focus on Category 3 likability studies, as these are likely to pique the audience's interest
    - Explain the patient population recruited
    - Describe the outcome measures of likability studies
  - Discuss the tiers that the FDA uses to rank that abuse deterrence of a new drug and how these tiers affect the information included in a drug's package insert
    - Note the nuances of tiers, such as the fact that a drug can be granted tier 2 status without first being granted tier 1 status
  - Summarize the content by saying that opioids are an important mainstay of pain management, but that they do have risks, some of which may be mitigated by ADT
- The second group focused on ADT and presented their ideas for a module titled, "Emerging Technologies to Reduce Opioid Abuse." Recommendations included:
  - Pose a question to the audience: "Why have this discussion?"
  - Discuss intentional consequences of opioid therapy, focusing on expectations of treatment
  - Strive for a balance between the benefits of opioid therapy, pain relief, function, and restoration
  - Acknowledge that abuse and AEs exist with these medications

  - Cite examples of what abusers seek in an opioid in an effort to introduce means of opioid abuse
  - List features of opioids that prescribers desire, such as safety and reliability
  - Pose another question: "How will FDA guidance help HCPs reach their goals for pain management?"
  - Briefly summarize the FDA guidance about ADT
  - Provide examples of abuse-deterrent opioids
  - Explain the physical and chemical properties of ADTs
  - Initiate a discussion about how this information resonates with the audience
  - Describe how the FDA's tiering system and clinical trial categories may assist pharmaceutical companies in developing opioids with lower abuse potentials
  - Relate the findings of clinical trial categories to the information that will be contained in a drug's package insert
  - Use case studies to explain how a company would take a drug with an abuse-deterrent formulation through clinical trials in order to obtain each tier level
- Dr. Argoff then presented an outline for a fourth module about protecting one's practice:
  - Start with video clips of 1 or more experts explaining how they establish a chronic pain diagnosis and the importance of reviewing a patient's medical history
  - Explain the difference between diagnosing acute and chronic pain
  - Have an expert, on video, describe the transition that occurs when an acute pain patient requires opioid therapy for a longer period of time than originally anticipated
  - Also include a video of an expert describing how to discontinue opioid therapy without the patient feeling abandoned
  - Segue into a discussion on the choice of therapy
  - Explain how to monitor patients during treatment
  - Describe the role of ADT in pain management
- Dr. Gudin presented an outline for a similar module about protecting one's practice:
  - Acknowledge that all analgesics have associated risks
  - Position opioids as a component of a multimodal pain management strategy
  - When prescribing opioids, HCPs need to do their due diligence on the risks, new therapies, and ADTs
  - Explain the patient selection process, which includes a good work-up and diagnosis
  - Discuss how to perform a functional assessment
  - List non-pharmacological treatments
  - Emphasize the importance of screening and risk stratification
  - Explain how to access one's PDMP
  - Provide an opioid rotation strategy
  - Acknowledge potential drug-drug interactions
  - Describe how to monitor patients who receive opioid therapy
  - Note that getting a second opinion may be worthwhile for some patients
  - Discuss exit strategies and emergency interventions
  - Provide published guidelines regarding opioid use
- Overall, the advisors were enthusiastic about the presentations they developed and look forward to seeing their work completed

Meeting 1: Agenda

8:15 AM – 8:30 AM	**Welcome, Introductions, and Objectives** *Matt Day*
8:30 AM – 8:45 AM	**PAINWeek Project Overview** *Jeff Gudin, MD*
8:45 AM – 9:45 AM	**Draft Slide Deck Overview** *Jeff Gudin, MD*
9:45 AM – 10:00 AM	**Break**
10:00 AM – 12:00 PM	**Breakout Session: Slide Deck Enhancement**
12:00 PM – 12:45 PM	**Lunch**
12:45 PM – 1:30 PM	**Breakout Session: Slide Deck Enhancement (cont'd)**
1:30 PM – 2:30 PM	**Breakout Presentations**
2:30 PM – 3:00 PM	**Next Steps** *Jeff Gudin, MD*
3:00 PM	**Closing Comments** *Jeff Gudin, MD* *Matt Day*

Meeting 1: Attendees

Program Participants

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CNS Marketing

Jeffrey Dierks
Director
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Chinedu Momah, PharmD
Brand Manager
Pain Marketing

Matthew Wieman, MD
Director
Medical Affairs

Meeting 2: Agenda

8:15 AM – 8:15 AM	**Welcome, Introductions, and Objectives** *Matt Day*
8:15 AM – 8:30 AM	**Teva Pain Care Franchise** *Matt Day*
8:30 AM – 9:15 AM	**Overview of the Disease Awareness Platform** *Samantha Schwarz*
9:15 AM – 9:45 AM	**Group Discussion & Feedback**
9:45 AM – 10:00 AM	**Break**
10:00 AM – 10:30 AM	**Evolving Roles, Same Goals Module Review** *Jeff Gudin, MD*
10:30 AM – 11:45 AM	**Modules 2 & 3 Overview** *Jeff Gudin, MD*
11:45 AM – 12:30 PM	**Lunch**
12:30 PM – 12:45 PM	**Workshop Goals** *Jeff Gudin, MD*
12:45 PM – 2:15 PM	**Workshops: Module Development**
2:15 PM – 3:00 PM	**Team Presentation & Feedback**
3:00 PM	**Closing Comments** *Jeff Gudin, MD* *Matt Day*

Meeting 2: Attendees

Program Participants

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Associate Brand Director
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Jeffrey Dierks
Director
Brand Marketing

Chinedu Momah, PharmD
Brand Manager
Pain Marketing

Matthew Wieman, MD
Director
Medical Affairs

Working Together for People with Chronic Pain Advocacy Summit

November 6, 2013

TEVA Pharmaceuticals

Internal Recap Report

Advocacy Summit Participants

Penney Cowan, Founder and Executive Director, American Chronic Pain Association
Wade Delk, Director of Government Affairs, American Society of Pain Management Nursing
Susie Flynn, Director of Education, American Academy of Pain Medicine
John Garrett, Executive Director, For Grace
Paul Gileno, Founder and Executive Director, U.S. Pain Foundation
Amy Goldstein, MSW, Director, State Pain Policy Advocacy Network, American Academy of Pain Management
Nicole Kelly, Board of Directors, Program Director, American Chronic Pain Association
Shawn Martin, Vice President of Advocacy and Practice Advancement, American Academy of Family Physicians

Anne Norman, DNP, APRN, FNP-BC , Associate Vice President of Education, American Academy of Nurse Practitioners
Diane Padden, PhD, CRNP, FAANP, Vice President of Research, Education and Professional Practice, American Academy of Nurse Practitioners
Lisa Pearlstein, JD, Pain Medicine and Regulatory Lobbyist, American Society of Anesthesiologists
Cynthia Porter, Associate Executive Director, American Pain Society
Cindy Steinberg, National Director of Policy and Advocacy, U.S. Pain Foundation
Sue Thompson, Director of Marketing and Communications, American Academy of Pain Medicine
Cynthia Toussaint, Executive Director, For Grace
Bob Twillman, PhD, FAPM, Director of Policy and Advocacy, American Academy of Pain Management

Teva: *Ryan Daufenbach, Matthew Day, Mara Define, Rob Falb, Nancy Leone, Richard Malamut, MD, Derek Moe, PhD, Mike Pursel,, Kathy Sapp*

Advocacy Summit Objectives

1

Determine how the chronic pain advocacy community can work together to benefit people with pain and the healthcare professionals who care for them

- Identify unmet needs in the treatment of chronic pain care
- Identify paths forward to address prescription abuse/misuse while maintaining appropriate patient access to care

2

Discuss future support and resource needs for chronic pain space

Attendees Left More Familiar with Teva, Open to Collaborative Activities

- **88%** of respondents rated the content a **4 out of 5**
- **100%** of respondents rated the moderator a **5 out of 5**
- **100%** of respondents said they understand more about Teva and the company's commitment to improving pain care as a result of the summit
- **100%** of respondents said they would be interested in participating in future program opportunities with Teva

"Thank you for including me in the meeting. I thought it was all very well done, and really enjoyed the whole experience." – Amy Golstein, American Academy of Pain Management

"It was an excellent Summit, and look forward to furthering the key priorities in addition to the further dissemination of Pain Matters." – Susie Flynn, American Academy of Pain Medicine

It was wonderful meeting and getting to know you and everyone at Teva. You all clearly have true care for those challenged with chronic pain - and John, the For Grace team and I look forward to partnering with you to better the lives of women in pain." – Cynthia Toussaint, For Grace

Note: 9 of 16 attendees participated in the feedback survey

And Found Value in the Dialogue

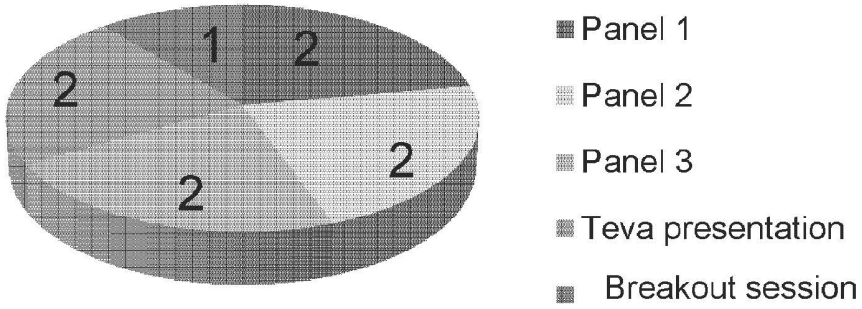
"I enjoyed the program and was very interested to learn more from the patient advocacy groups in attendance. It is always enriching to hear stories from those impacted by public policies." – Shawn Martin, American Academy of Family Physicians

AAFP

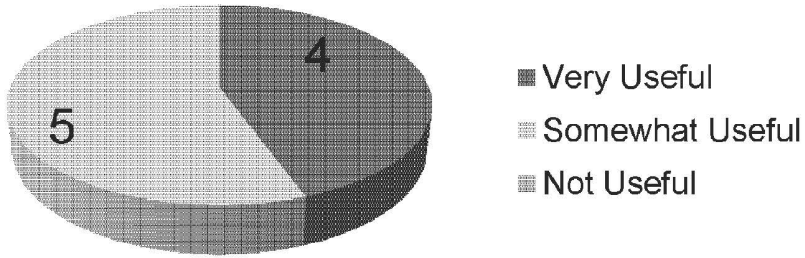
U.S. PAIN FOUNDATION

"I wanted to thank you so much for inviting and including US Pain in today's meeting and dialogue. I feel it was very empowering and well needed." – Paul Gileno, U.S. Pain Foundation

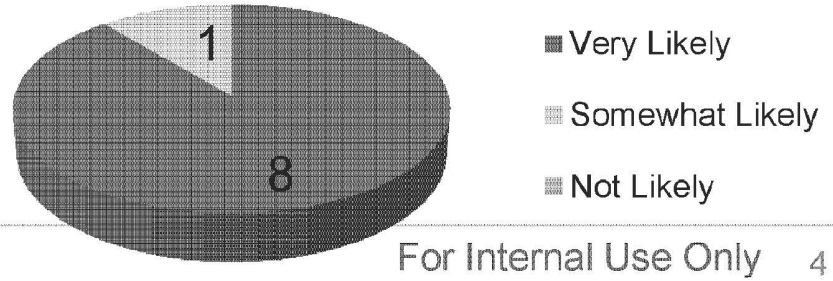
What topic did you find most interesting?



How useful was the content presented during panel discussions to your group?



How likely are you to talk with others (colleagues, constituents, etc.) about topics discussed ?



Insights for Future Summits

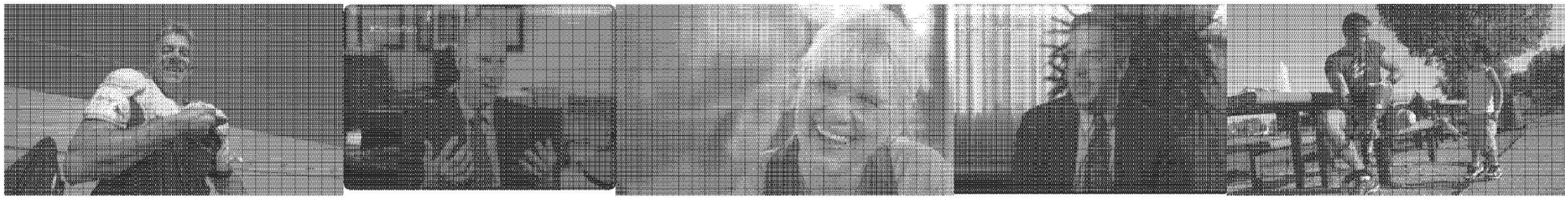
- Provide advocacy groups specific action items following the summit
- Extend beyond public affairs/education representatives to include medical affairs
- Bring in external experts/KOLs to present, share insights
- Create more opportunities for Teva attendees to contribute to conversation and engage attendees
- Organize the event flow to allow more informal conversations, such as:
  - Arrange attendees on round tables and give each a different angle to a particular topic; place a Teva representative at each table to better engage
  - Have more breakout conversations to facilitate organic conversation
- Extend invitation outside of pain community including pharmacy groups, payers and policymakers

Opportunities for Future Engagement

- Create a timeline of opportunities to consistently engage summit attendees and maintain momentum
  - Follow up on specific 2014 opportunities discussed at the summit (i.e. local Pain Matters screening events)
- Build on momentum by hosting another summit in Q2/Q3 2014 in advance of the potential FDA Advisory Committee for AD hydrocodone
- Assess and prioritize advocacy sponsorships
  - Facilitate internal communication to better take advantage of sponsorship membership benefits
- Consider Teva presence at pain patient group conventions

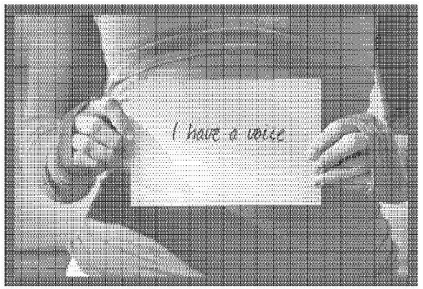
Breakout Session Feedback

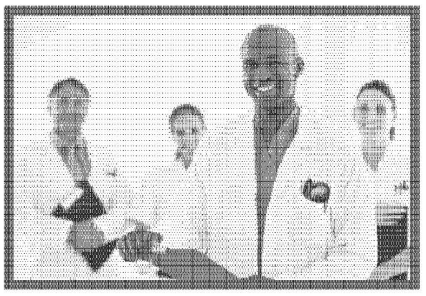
- **Extend the reach of PAIN MATTERS** in 2014 through the following:
  - Create shorter version(s) of film and host local screening events targeting:
    - **HCPs**: Via medical meetings, medical/nursing schools, hospitals/clinics
    - **General Public:** Via large groups like AARP, as well as local groups like churches, health fairs and community groups like Rotary and Lions Clubs
    - **Policymakers:** At district events
  - Create online downloadable screening toolkits that include a discussion guide for use at support groups



Breakout Session Feedback

- Attendees believe the **future of pain management** centers on three main areas:
  - Empower people with pain and their caregivers/loved ones to advocate for improved care and understanding of the condition
  - Develop and/or identify data that quantify the value and effectiveness of multi-disciplinary care to help illustrate the need to payers and policymakers
  - Need to bring payers into the conversation to deliver more accessible, multi-disciplinary pain care





Breakout Session Feedback

- Perceptions of the **role of abuse deterrent formulations** in addressing abuse and misuse include the following:
  - "Abuse deterrence" is an incremental step in the right direction and must be acknowledged as such
  - Messaging needs to separate abusers from people with chronic pain
  - Patient groups in particular want to balance conversation around abuse and misuse with stories of people with pain
  - We need to work on the "next generation" of pain medications, which include non-opioid medications

Executive Summary

Appropriate and Safe Use of Prescription Pain Medications Advisory Board
December 4, 2015

Prepared by Golin

Preface

This executive summary briefly recounts the presentations, discussions, and recommendations of the *Appropriate and Safe Use of Prescription Pain Medications Advisory Board* held on December 4, 2014, in Chicago. The summary was developed from the presentation slides and notes taken during the meeting.

Summary

- Overview
- Objectives
- Agenda
- Attendees
- Presentations and Discussions
- Survey Feedback

Overview

The Appropriate and Safe Use of Prescription Pain Medications Advisory Board was hosted at the Loews Chicago O'Hare Hotel on December 4, 2014 by Teva Pharmaceuticals. The advisory board was held to obtain expert insight into how the company can best educate on the appropriate use of opioids, abuse potential and abuse deterrence technology through its unbranded multi-faceted communications initiative called *Pain Matters*. The meeting incorporated a balance of presentation and feedback from advisors.

Below is a recap report of the meeting including a summary of the conversation topics and relevant feedback, recommendations and key action items.

Advisory Board Objectives

1. Gain feedback from a variety of stakeholders who represent different and unique members/viewpoints within the pain care market on the treatment of chronic pain
2. Identify unmet educational needs to assist with the development of Teva's unbranded multi-faceted communications program
3. Gain perspective on shifts in policy related to opioids and abuse deterrence technology
4. Assess feedback and understand stakeholder response to the changing pain landscape

Agenda

Agenda

Welcome and Introductions

- The meeting facilitator formally kicked off the meeting and introduced attendees, agenda and objectives
- Brief overview of Teva and Teva CNS
- Group discussion

Evolving Policy and the Treatment of Pain Presentation and Discussion

- Impact of evolving policy and regulations on patient access and the treatment of chronic pain
- Model policy on opioids with abuse deterrence technology
- Input on Teva legislative initiatives
- Group discussion

Role of Abuse Deterrence Technology Presentation and Discussion

- FDA draft guidance on abuse-deterrent opioids
- Patient and HCP knowledge of abuse deterrence technology
- Best practices in HCP dialogue with patients surrounding abuse and addiction
- Group discussion

Teva's Unbranded Educational Initiative Presentation and Discussion

- Summary of initiative purpose and components (e.g., microsite, state-level screening events, peer-to
- peer education)
- Feedback to programming and partnership opportunities

Future Opportunities for Appropriate and Safe Use of Pain Medication Presentation and Discussion

- AAN guidelines opinions and discussion
- Communications tools for educating HCPs and patients about safe use of opioids and abuse deterrence technology
- Group discussion

Thank You and Next Steps

Attendees

Attendees

Advisors

- Myra Christopher – Director, Pain Action Alliance
- Penney Cowan – Founder and Executive Director, American Chronic Pain Association
- Paul Gileno – Founder and Executive Director, U.S. Pain Foundation
- Amy Goldstein, MSW – Director, State Pain Policy Advocacy Network, American Academy of Pain Management

- Brian Kennedy, JD – Executive Director, Alliance for Patient Access
- Richard Payne, MD – Medical Director, Pain Action Alliance
- Kyle Simon – Director of Policy and Advocacy, Center for Lawful Access and Abuse Deterrence
- Bob Twillman, PhD, FAPM – Deputy Executive Director, American Academy of Pain Management

Teva Participants

- Karen Hill, Therapeutic Area Senior Manager, Brand Marketing, U.S. Pain Care
- Rob Falb, Director, Government and Public Affairs Department
- Heather Schoenly, Associate Director Brand Marketing

Agency Support

- Alyssa Leys, Golin
- Jaimee Lumm, Golin
- Jaclyn Slovic, McCann Echo
- Elly Wallin, Golin
- Matt West (meeting facilitator)

Presentation and Discussion

Below is a recap of the discussion points from the Teva Advisory Board. Each section summarizes the key take-aways as well as responses to the several questions that were posed to the group.

Overview of Teva (Presenter: Karen Hill)

Key Take-Aways

- External awareness of Teva as a company that makes branded products, is low
    - While there is general awareness of Teva being in the pain space, it is as a generics company, not as a company developing branded products.
    - The advisors felt that those living with pain are unfamiliar with Teva and that a patient's interest in the manufacturer of their medicine is ultimately driving by financial needs to cover the cost of their medicine
- Teva can elevate its presence by helping patients address their pain by providing offerings beyond the medicine it makes.
    - Advisors recommended initiatives different than other companies such as helping transform the discussion around chronic pain and focusing on a holistic/integrated approach to pain management
- Public-private partnerships (beyond financial support) would be of value to advocates

Areas of Discussion

Knowledge of Teva

- The advisors stressed that awareness of the medicine manufacturer is only important to people with pain when there are issues related to access and cost
- Among providers/prescribers, the advisors noted that they know Teva as a generic company and there is limited understanding that the company also makes branded products

- Some advisors noted that while the market has been dominated by others for years, Teva is moving its way to the forefront

Elevating Teva's presence in the pain market

- The advisors overwhelmingly recommended that Teva help patients by:
  - Providing offerings that go beyond medicine (e.g., wellness programs)
  - Identifying opportunities for public partnerships that help in more ways than financially
  - Supporting movement away from the current focus on the biomedical model to the bio-psychosocial model in pain treatment

Evolving Policy and the Treatment of Pain (Presenter: Rob Falb)

Key Take-Aways

- Advisors agree that patient access to medication is critical and the recent rescheduling of hydrocodone products has complicated access with physicians now even more hesitant/scared to prescribe
- There is a clear need for evidence-based data on treatment of chronic pain to help shape policy
- Behavioral health care as a component of treating chronic pain is critical and policy changes (i.e., ACA) have complicated access
- There is a need to change the narrative around chronic pain in multiple ways especially the negative tone and, as a group of committed partners, use the same language/voice when speaking with policymakers
  - The advisors noted that a common criticism from policymakers is that each party uses different language when discussing the issues
- Relationships need to be collaborative to advance policy and the advisors recommended that Teva partner with groups that can obtain data that would be impactful on policy shaping

Areas of Discussion

Reaction to the FDA rescheduling

- Overall, the group felt the recent rescheduling was a short-sighted action and has contributed to patient access issues
- Advisors noted that the rescheduling further perpetuates physician fear in prescribing

Need for additional data on chronic pain

- The advisors recommended that Teva partner with groups that can get data that would be impactful on policy shaping, for example partnerships with organizations like Pew Research Center or Medscape to extract data (Medscape is already gathering lifestyle, etc. data and would be an interesting partner on the professional side)
- The advisors shared that Mallinckrodt organized an alliance which drafted a policy agenda, with one of the action items around abuse deterrence. They noted that we all should be working together on these issues so that there aren't multiple entities pushing for the same thing without a unified voice

The current narrative around chronic pain

- The advisors stressed the need for messaging around supporting comprehensive treatment and to treat the abuse issue as a public health issue vs. a law enforcement issue

- Overall, the group would like to see Teva's efforts be reframed around comprehensive pain management in the 21st century and movement towards a bio-psychosocial approach
- There was agreement among the group that the media drives predominately negative messages around chronic pain, and that the positive/hopeful stories are not being told
- People with pain should be invited to tell their story as part of any initiatives to reshape the dialogue

State Model Bill

- The advisors reacted positively to the bill and expressed interest in knowing when the bill would be ready
- They also encouraged collaboration with others to move the bill forward and suggested Millennium, the Consumer Pain Advocacy Task force, as well as people with pain

Teva's NTEs

- The advisors recommended coupling it with compressive pain center/management program in the 21st century

Role of Abuse Deterrence Technology (Presenter: Heather Schoenly)

Key Take-Aways

- While there is a role for ADT, the advisors feel it should be a minimal part of the discussion, framed as part of the solution
- The advisors cautioned that emphasis on ADT without appropriate balance may inadvertently make medicines (opioids) seem more safe than they are with potential for unintended consequence
- One message around storing/sharing/etc. from pharmaceutical companies would be helpful for consistency across the board with all stakeholders
- For public health, there needs to be a very clear understanding of the technology with a clearly defined audience for use of this technology
- The advisors felt that prescribers understand ADT at a basic level, but may not be able to explain it in detail to their patients

Areas of Discussion

Knowledge level and understanding of ADT and draft guidance

- The advisors stressed that knowledge and understanding of ADT is varied by specialty with PCPs needing the most education. One advisor noted that even the most savvy, have little understanding of this technology
- The advisors felt that education overall is critical to understanding the technology and that consistency in messaging and language is key
- In terms of people with pain, the advisors noted that they learn through their doctors. They also stressed that if they don't understand the value/need for the technology patients will react negatively if it impacts cost/access to their medication
- The advisors recommended several ideas to help educate about ADT:
    - Handouts/checklists on medication and technology could be helpful in communicating with patients
    - Include family members in the discussion so they are also aware of the benefits of ADT

- Include information about the technology and how it works in the medicine's package inserts
- Consider initiatives that educate state medical advisors
- Use graphical tools and videos in education efforts
- Explain not just how the technology works, but why it is needed to individuals who don't abuse see the value

Role of the pharmacist in educating/communicating about ADT

- The advisors expressed that pharmacists understand meds on a level than none of us ever will and therefore don't necessarily need to be educated, but do need to be part of the solution
- Because cost may arise in conversations with customers, pharmacists need to justify the increased cost with the answer that the technology is necessary because others are impacted/abuse

Role of Teva in educating about ADT

- The advisors believe that there is an opportunity for industry to educate PCPs specifically on abuse deterrence, what the technology can/cannot solve and the different types/tiers
- They encouraged collaboration with a third-party resource to further education. Medscape and UpToDate were noted as frequently visited resources to consider leveraging

Teva's Unbranded Educational Initiative (Presenter: Jaimee Lumm)

Key Takeaways

- Overwhelmingly, the advisors preference is for educational programs to focus on whole person care/integrated care, and they were not as receptive to programming that is too drug or abuse focused
- They emphasized a need to translate current science and evidence to help improve and promote a comprehensive approach to care
- Website:
  - The advisors expressed concern that the website is similar to others available and that there needs to be a differentiated approach to break through
  - Site needs to provide more than just information on medication
  - Content should include board of directors/who is sponsoring, links to the documentary, references, accessing medicines, story-sharing and latest studies
- Survey:
  - Issuing a survey should be done in partnership with third parties and published to help create awareness. Survey topics of interest include:
  - Understanding general public attitudes, perspectives, perceptions regarding chronic pain; understanding barriers to treatment
  - Survey within the pain community to outline priorities and get experts on same page
  - Use results to drive policy discussion and educate media to drive the narrative
- Pain Matters film:
  - Should be shared in as many ways as possible. Advisors recommended sharing via advocacy toolkits, distribution to large companies, health fairs, gyms, community health programs, and via film trailer viewings at Film trailer in theaters where the movie Cake is playing
- Policy Maker Outreach:
  - Elevate current evidence to advocate/promote comprehensive care and policy

- Create policy briefs, create trained, credible advocates (preferably constituents) who are able to talk in an effective way to policymakers, and who have developed the right resources
- Patients play a different role, but need to also be trained as ambassadors on how to share their stories and on what the discussion points are
- Provide data that's citable and anecdotes from HCPs

Areas of Discussion

Overall Reaction to Educational Initiative Objectives and Target Audiences

- The advisors like the name Pain Matters and the logo design
- They suggested considering targeted programming to the business community, faith community, acupuncturists, massage therapists, etc. in addition to the outlined target audiences
- Suggestions on objectives:
  - The advisors suggested that the initiative also help to translate current science and evidence to improve and promote comprehensive care and policy to advocate for individuals living with pain
  - The advisors cautioned that educating on ADT technology as a key objective may be too narrowly focused

Survey on Attitudes and Perceptions of Abuse and ADT

- The advisors raised concern that there are several surveys on chronic pain and that it would be important to have a different focus to break through. They also raised that a similar company is planning a survey in contract with a third party, on a similar topic
- The advisors suggested considering the following topics for the survey to support the initiative:
  - PDMP and recent rescheduling impact on prescribing behavior
  - Reaction to ADT: How are they categorizing the different technologies
  - Current barriers in the system to optimal care
  - Several advisors supported the idea of a national survey of consumers assessing their attitude towards people with pain
- Overwhelmingly the advisors recommended that Teva partner with other groups to add credibility to the survey and cautioned that if the company goes alone on the execution, it will be scrutinized
- PCPs were noted as a crucial audience to include in the survey given that they see a majority of the patients
- The advisors discussed at length how best to raise awareness of and discussion about the survey results to ensure the strongest impact. They recommended considering publication of the results and extending reach through social media

Policymaker Outreach

- The advisors supported the idea of Teva helping to support speaker training for patients and HCPS to hold conversations with legislators
- They also noted that the company could help:
  - Support planning a Hill Day for chronic pain discussions
  - Develop an infrastructure to connect all groups on legislative efforts to ensure one voice/one message

Website Feedback

- The advisors shared several recommendations for the website:
    - Clearly explain on the homepage what the site is, what it will offer and who is supporting the site
    - Consider information on how to locate a local doctor, as it was noted as one of the biggest resource needs
    - Ensure that the sites content/feel is different from other pharma-sponsored sites on this topic so it breaks through
    - Consider bringing together a coalition of groups to contribute to the site's content/development for additional credibility and include links to their organization websites.
    - Include a bibliography of relevant peer-reviewed studies for reference
    - For patient resources, include information on accessing medications and financial resources for helping pay for medications
    - If possible, include an area for people with pain and the doctors that treat them to share their stories with others on the site
    - They also liked the that documentary was featured on the site

Movie Called CAKE

- While the advisors agreed that it doesn't seem the film will depict a typical journey living with chronic pain, they did feel there could be an opportunity to leverage the visibility/discussion around the film to show the realities of living with pain using real stories
- The advisors mentioned working with highly-credible journalists, like Bill Moyer, to chronicle more stories of living with pain in documentary format and leveraging social media to show the other side of the story

Pain Month

- Overall, the advisors feel that National Pain Month in September is important, but limited resources make it difficult for the organizations to focus on the month in a way to make a major impact
- That said, the advisors do feel there is an opportunity to leverage this month to bring together all the groups and talk about pain issues to drive awareness among the community, but also understanding and compassion among the general public
- When discussing the focus for the initiative, the advisors gravitated towards ideas that emphasize how common pain is (It can happen to you, You are not alone, Pain is Real, You are not invisible) and encouraging movement and abilities (vs. disabilities)
- The advisors pointed to a few campaigns that they felt were effective in driving change, including Movember for prostate cancer awareness and a recent effort in Australia that focused on initially on low back pain and emphasized movement

Reaction to AAN Guidelines

- Overall, the advisors dismissed the AAN guidelines as foolishness and additional noise given discrepancies in the data presented and that they were authored by one person
- The advisors felt American Pain Society should issue updated guidelines, as it has been nearly 8 years since the last set of guidelines were issued
- The advisors noted that it is critical that the next set of guidelines be evidence based to better patient care and they mentioned the oncology community as a great example as one that has done a great job of building evidence to support care

Close/ Advisor Feedback Regarding Meeting

Advisors unanimously agreed that approaching chronic pain could not be done alone or by one single group. Advisors agreed that we all need to be committed to addressing chronic pain and to work together to achieve the needs of individuals with chronic pain

Survey Feedback

A survey was distributed to advisory participants following the meeting to assess value of the discussion. Key findings included:

- **90%** of attendees rated the quality of content as **4 out of 5** and believe they understand more about Teva's commitment to improving pain care
- Participants felt that "The Evolving Policy and Treatment of Pain" portion was the most relevant discussion of the day (5) followed by:
  - Role of Abuse Deterrence Technology (3)
  - Teva's Unbranded Educational Initiative (2)
  - Future Opportunities for Appropriate and Safe Use of Pain Medicine (1)
- **100%** of attendees said their organization would be interested in partnering with Teva in various educational initiatives
- Attendees felt the best components of the meeting were:
  - Teva's efforts/committeemen to advance issues in a positive way
  - Diversity of the topics and the unique perspectives
  - Helping educate on ADT
  - Pain Matters as a focus could be a very effective tagline/name
    - Pain Matters to me because…
    - Pain Matters and here's how I care for people who have it
    - Pain Matters and here's how I get relief
- Attendees felt topics that could be addressed in future meetings include:
  - Addressing evidence data
  - Doing more about the self-management of PWP and role in modifying from patient to person
  - Analyzing strategies of proponents and adversaries for opioid use to influence opinion
  - Merging need for comprehensive pain management with use of AD opioids
- Areas for improvement include:
  - Sharing agenda and attendee list

###