November 5-6, 2018 | Hilton Washington Dulles Airport | Herndon, VA

5th

Human Abuse Liability Testing & Market Access

Lower prescription drug abuse risks and build alliances with payers and patients in order to strengthen market outlook and adapt to legal challenges

Steven Passik,
Vice President, Scientific Affairs, Education, and Policy
COLLEGIUM PHARMACEUTICALS

Richard Mannion
former Executive Director, Pharmaceutical and Analytical Development
PURDUE PHARMA

Andrew Rosenberg
Executive Director
INNOVATIVE PAIN MEDICINES ALLIANCE

Robert Radie
CEO
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Karen DiDonato
Executive Director, Medical Affairs
ACELRX PHARMACEUTICALS

Dan Cohen
Executive Vice President, Government and Public Relations
KEMPHARM

Marta Sokolowska
Vice President, Medical and External Affairs
DEPOMED

Bob Jones
CEO
ACURA PHARMACEUTICALS

WHO can build the strongest payer relationships?

WHAT can opioid manufacturers learn from stimulants and cannabis?

WHEN will FDA and CDC change their guidelines?

WHERE do payers look for opioid performance indicators?

HOW can you build broader collaborations with FDA?

WHY should chronic pain patients go without coverage?

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ALL-NEW RESPONSES TO THE GREATEST CHALLENGES IN COMMERCIALIZING PAIN THERAPEUTICS

- Identify the Best Public Health Indicators to Secure Opioid Coverage
- Conceive Study Methods for Abuse-Deterrent Opioids With Low Market Share
- Take a New Approach to the Pharmacoeconomics of Abuse Deterrence
- Improve Preparation for HAL Studies
- Maintain Empathy With Pain Patients While Avoiding Dose Escalation
- Track New Policy Implications for ADFs
- Manage the Risk Profile of HCP-Administered Opioids

"Excellent presentations and good dialogue."
—Senior Director, Clinical Research, **EGALET**

"Very interesting, interactive and relevant to generic drugs."
—Associate Director, Regulatory Affairs, **ACTAVIS**

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5th Human Abuse Liability Testing & Market Access

Dear Colleague,

The opioid crisis shows no signs of slowing, with death rates now surpassing the early years of AIDS. Abuse-deterrent formulations seemed an obvious solution for many years, but payers have proven reluctant to reimburse them. Scientific development of new pain therapeutics has largely been put on hold while the industry tries to grapple with reimbursement and market access challenges first.

Now in its fifth year, ExL's **Human Abuse Liability Testing & Market Access Summit** (Nov. 5–6, Herndon, VA) is the industry's first and largest conference devoted specifically to the latest technical and marketplace developments impacting opioids and other drugs with abuse potential. No other event gives you such intensive strategies on shrinking the abuse risk and growing the market potential for pain therapeutics.

This year's all-new agenda helps you:

- Identify the **public health indicators** most crucial to securing reimbursement
- Rethink opioid prescriptions while **maintaining patient empathy**
- Manage the development and enforcement challenges of **HCP-administered opioids**
- Conceive study methods for **new opioids with low market share**
- Analyze the **market potential for abuse-deterrent stimulants, benzos, and cannabinoids**

I look forward to seeing you in Herndon, VA, this fall!

Sincerely,

Matt Greenbaum

Matt Greenbaum
Production Team Leader
ExL Events

"Shared great, informative approaches for overcoming challenges associated with opioid abuse." —Director, Formulations, **RECKITT BENCKISER**

Venue

Hilton Washington Dulles Airport
13869 Park Center Road
Herndon, VA 20171

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WHO SHOULD ATTEND

Pharma, biotech, med device, and healthcare professionals responsible for:

- Regulatory Affairs / Intelligence
- Epidemiology / Pharmacoepidemiology
- Abuse / Deterrent / Deterrence / Abuse Deterrent / Abuse Deterrence
- Clinical Development / Operations / Affairs / Programs
- Risk Management / REMS
- Toxicology
- Drug Safety
- Pharmacology / Clinical Pharmacology / Safety Pharmacology
- CNS / Neuroscience
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- Pharmacoeconomics / Health Economics / Outcomes Research / HEOR
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- Legal Affairs / Legal Counsel
- Policy
- Cannabis / Cannabinoid
- Addiction / Addiction Treatment / Addiction Medicine
- Diversion
- Abuse / Drug Abuse
- Pain / Pain Medicine / Pain Management
- Anesthesiology
- Palliative Care
- Behavioral Psychiatry / Behavioral Health

This event is also of interest to:

- CROs
- Toxicology Specialists
- Drug Abuse Registry / Surveillance Specialists
- REMS / Pharmacovigilance Specialists
- Formulation Service Providers
- Pharmacokinetics Service Providers
- Abuse Liability Service Providers
- Regulatory Specialists
- Intellectual Property Service Providers
- Law Firms

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AGENDA DAY ONE — Monday, November 5, 2018

8:00 Registration and Continental Breakfast

8:45 Introduction From Chairperson

Dan Cohen, *Executive Vice President, Government and Public Relations,* **KEMPHARM**

WITHSTAND LEGAL CHANGES AND CHALLENGES

9:00 Washington Report: The State of Federal Opioid Policymaking

Perhaps the only healthcare issue drawing intense bipartisan interest in the nation's capital these days is the opioid crisis, and Congress has been busily passing dozens of bills while the Trump Administration unveils strategy after strategy. But what is real, and what is just noise?

- Grasp what these policy proposals mean for the future of ADFs and non-opioid pain therapies
- Help policymakers differentiate between pain medications that pose a significant risk of abuse and those that do not
- Read the most likely coming changes in opioid policy

Andrew Rosenberg, *Executive Director,* **INNOVATIVE PAIN MEDICINES ALLIANCE**

9:40 Understand the Impact of CDC Guidelines on Pain Patients and the Physicians Who Try to Treat Them

The CDC guidelines on opioid prescribing have had major consequences on the pain treatment community both intended and unintended. By accounting for their history to this point, the industry can be better prepared for the future.

- Understand the unintended consequences of the CDC guidelines and how they have negatively impacted the chronic pain population
- Recount the various methods of determining true prescription opioid-related overdose deaths
- Recognize that chronic pain patients now have minimal ways to find any legally appropriate opioid medications

Gary Jay, *Professor, Neurology,* **UNIVERSITY OF NORTH CAROLINA – CHAPEL HILL**

10:20 Better Understand Opioids with Low Market Share

It can be difficult to win label claims and payer support for ADFs due to lack of measurable data from very low market share. If an ADF is effective, then the expectation is a low number of events, which will be hard to detect with traditional surveillance. How can we draw conclusions on ADF performance?

- Understand limitations of traditional approaches when working with low market volume formulations
- Outline principles and development of new analytical methods
- Envision the potential of broader application

Elizabeth Nugent, *Director, Clinical Research and Pharmacovigilance,* **RADARS SYSTEM**

11:00 Networking Break

11:30 Rethink Opioid Prescriptions While Retaining Patient Empathy

As trends in opioid prescriptions change, it is important not to wholly disregard observations grounded in the clinical work of experts on the nature of pain management. Taking subjective pain reports at face value has led to clinical problems, including escalation of doses in non-adherent patients. However, it also is based on an honest desire to improve patient outcomes, which is a mindset we must take care not to abandon.

- Evaluate how clinical prescription trends may have resulted from poor teaching or naivete
- Consider other adjuvant treatments rather than escalating opioid doses
- Take on the role of patient advocate to improve outcomes for those in treatment for severe pain

Steven Passik, *Vice President, Scientific Affairs, Education, and Policy,* **COLLEGIUM PHARMACEUTICALS**

12:10 Category 1 Abuse-Deterrent Testing: ANDA vs NDA Requirements

Current FDA guidelines for determining the effectiveness of abuse deterrence involve four main studies. Category 1 laboratory studies evaluate and compare the product to currently marketed formulations for the ability to defeat or compromise the abuse-deterrent properties. Understanding FDA expectations for NDA and ANDA application requirements is critical for creating well-designed strategies and repeatability.

- Outline the similarities and differences in FDA guidance for NDA and ANDA products
- Discuss Category 1 testing strategies for ANDA products
- Provide insight into methodologies used in Category 1 testing

Angela Moore, *Scientist,* **ALCAMI**

12:50 Luncheon

1:50 Survey Government R&D Recommendations That Will Favor Drugs With Lower Abuse Potential

Government agencies are advancing studies for non-opioid analgesics, or those with a lower abuse risk. These are different from kappa opioids; rather, they focus on biased opioid receptors that bind at certain subtypes.

- Compare and contrast recent initiatives from CDC, VA, DoD, and NIH
- Review the likelihood of recommendations of non-opioid or even non-pharma treatment options
- Account for pain treatment innovations that are already available but have not been used much

Peter Pitts, *President,* **CENTER FOR MEDICINE IN THE PUBLIC INTEREST**

2:30 Focus on the Abuse Liability Challenges of Cannabis, Benzos, Stimulants, and Other New Drugs of Abuse

Cannabis is still a schedule-1 product on a federal level, but is accessible thanks to stage regulations, making it much more accessible to students and young people. What impact have communities seen from greater uptake of cannabis, and what impact will this have on drug abuse research?

- Analyze links between cannabis uptake and non-overdose mortality (i.e., car accidents)
- Examine the dramatic rise and potential health impact of vaping
- Anticipate new areas for addiction drug development as we make addictive drugs more available

Marta Sokolowska, *Vice President, Medical and External Affairs,* **DEPOMED**

3:10 Transfer Lessons Learned on Abuse Deterrence From Opioids to Stimulants

Stimulant abuse is usually not fatal, but interest in technical developments that limit abuse is still growing. The development path for opioid ADFs may forecast the market potential for stimulants.

- Look into the status of FDA guidance and likelihood of change
- Track the pioneering efforts in abuse-deterrent stimulant development
- Weigh the risks for small companies that don't have the resources to build something that must be shut down

Presentation by **KEMPHARM**

3:50 Networking Break

4:20 Prepare for Ever-Increasing Scrutiny from FDA and Advisory Committees

The FDA and the Anesthetic and Analgesic Drug Products Advisory Committee have become increasingly interested in non-standard routes of abuse, and following the removal of Opana ER from the market they ahve requested more information about excipient safety during non-oral administration. The committee has also become interested in consistency of manipulation methods used during Category 1, 2, and 3 studies in an attempt to tie in the in vitro and in vivo results together, the better to determine if an investigational product will meaningfully deter abuse while insuring the product will not introduce unforeseen safety-related problems. Sponsors should consider and understand these unknowns prior to any submission.

- Assess an ADF's resistance to novel routes of abuse such as vaping and rectal administration
- Justify the use and consistency of methods of manipulation used throughout all stages of the abuse-deterrent testing program
- Evaluate the potential for exposure to inactive excipients following manipulation, extraction, and administration through non-oral routes

Christopher Altomare, *Director of Pharmaceutical Services,* **DRUGSCAN**

5:00 Improve Preparation Methods and Confidence for HAP Studies

Discussions with FDA tend to be focused on documentation, and the creation of programs and briefing books. Opioid manufacturers could get a clearer path to proceed if they had more regular and open interaction with FDA while the program testing is under way. By giving FDA a better view of how you are manipulating your materials, they will have a fuller data picture when they receive your submission.

- Readily answer questions on manipulation properties
- Outline your rationale for expecting what abusers will attempt with your products
- Raise standards of transparency and confidence among all parties trying to develop products in this space

Richard Mannion, *former Executive Director, Pharmaceutical and Analytical Development,* **PURDUE PHARMA**

John Hsu, *CEO,* **QUIVIVE PHARMA**

5:40 **Assess and Incentivize Innovation in Abuse Deterrence**

Many drug companies believed they had a novel approach to abuse deterrence. How many are still working on R&D, and which are the most likely candidates for release and reimbursement?

- Assess the number of INDs that FDA may be reviewing
- Candidly discuss the healthiness of the marketplace for abuse-deterrent opioids
- Welcome new thinking and approaches from companies breaking into this space

Dan Cohen, *Executive Vice President, Government and Public Relations,* **KEMPHARM**

6:20 **Day One Concludes**

AGENDA DAY TWO Tuesday, November 6, 2018

8:00 **Registration and Continental Breakfast**

8:45 **Chairperson's Recap of Day One**

Dan Cohen, *Executive Vice President, Government and Public Relations,* **KEMPHARM**

OVERCOME OBSTACLES TO MARKET ACCESS

9:00 **Strategize Your Response to the Reimbursement Challenges Facing ADFs**

Payers and PBMs have put up many cost-related roadblocks to the reimbursement of ADFs. This has caused the number of ADFs at market to drop, some fully developed candidates to have their launch indefinitely postponed, and a shrinking of investments in future R&D. At what point can we expect these trends to reverse?

- Communicate to all stakeholders that innovation needs to be paid for
- Review refusals to pay and "fail-first" requirements that slowed R&D
- Find voices in regulatory policy who can help keep R&D advances available and relevant to pain patients

Robert Radie, *CEO,* **EGALET**

9:45 **Brainstorm the Pharmacoeconomics of Abuse Deterrence**

FDA wants to incentivize abuse deterrence, but how well can you prove your product's performance? If you can demonstrate that your product is technically superior to standard oxycodone, you may find a pathway to market access.

- Prove to payers that your candidate is superior
- Learn from past successes in the industry
- Recognize when new features make old versions inherently unsafe

Bob Jones, *CEO,* **ACURA PHARMACEUTICALS**

10:30 **Networking Break**

11:00 **Meet Regulatory Requirements for Evaluating Potential Abuse-Related Events in Clinical Trials**

FDA guidance states that all safety and efficacy trials of CNS-active drugs should be monitored for events that may indicate abuse potential. However, traditional methods of assessing abuse potential during clinical trials are inadequate and can cause misclassification of events, leading to overestimation or underestimation of a drug's true abuse potential. MADDERS is a prospective and systematic method implemented in 17 clinical trials to date that captures potentially abuse-related event data in near real time to distinguish signals of abuse from other plausible explanations.

- Comprehensively and systematically assess all CNS-active compounds for abuse potential during clinical trials
- Benefit from a tool developed with input from the ACTTION-FDA initiative that standardizes the identification, evaluation, classification, and reporting of potentially abuse-related events
- Satisfy regulatory requirements for assessing abuse potential during clinical trials

Ryan Lanier, *Senior Consultant, Drug Development,* **ANALGESIC SOLUTIONS**

"The opioid epidemic cost the American economy $504 billion in 2015 — the equivalent of 2.8% of GDP that year."
—Bloomberg News, February 27, 2018

11:45 **Cross Technical Obstacles on Clinical Development of ADFs**

A proper series of PK and abuse potential studies will compare the systemic exposure and abuse liability in both the manipulated and intact forms of an ADF candidate; this is an essential step in advancing ADFs to mitigate the abuse of opioid analgesics. Tests of this nature require identifying and recruiting non-dependent recreational drug users, and seeing eye to eye with them about opioid abuse routes.

- Match study methodologies to the specific needs of each ADF
- Grasp the greatest obstacles for recruiting and implementing clinical studies
- Map study design and endpoint methodologies crucial to success

Graham Wood, *Chief R&D Officer,* **ALTASCIENCES CLINICAL RESEARCH**

12:30 **Luncheon**

1:30 **Identify the Best Public Health Indicators to Secure Opioid Coverage**

The bar for determining public health benefits of ADFs can be unclear due to lack of data. Identifying comparator drugs remains a serious challenge, especially if the study drug has low utilization and many generics are available.

- Dialogue with insurers about the evidence they require
- Determine when baseline historical data can be used
- Secure preferred coverage in formulary

John Hsu, *CEO,* **QUIVIVE PHARMA**

2:15 **Manage the Risk Profile of HCP-Administered Opioids**

Sublingual opioid delivery can be very effective on patients with acute pain, but require navigating a learning curve for products that can only be administered by healthcare practitioners. By keeping the settings of drug availability completely under control, opportunities for abuse can be restricted. However, it can be very hard to find credible data on abuse or diversion from an HCP-administered setting.

- Define medically supervised settings of use and prepare for suggestions and modifications from FDA
- Prioritize tamper-evident features
- Move forward with REMS development for a new category of opioids

Karen DiDonato, *Executive Director, Medical Affairs,* **ACELRX PHARMACEUTICALS**

3:00 **Correct for Gender-Based Disparities in Drug R&D and Law Enforcement**

Painkillers and hypnotics are among the many types of prescription drugs that have different effects on women than they do on men – yet clinical research protocols are slow to recognize and account for these differences. Drug researchers and healthcare providers should more strongly emphasize gender-based disparities in both research and access to drug treatment programs.

- Internalize FDA recommendations about including gender difference recognition in clinical studies
- Highlight where mandatory reporting laws impact child custody
- Explore the disincentives to substance abuse treatment that can disproportionately impact women

Shruti Kulkarni, *Director,* **FORCE FOUNDATION**

3:45 **Conference Concludes**

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EARLY BIRD PRICING	*Register by Friday, September 21, 2018:*	**$1,895**
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