"Very interesting new data and concepts!"
—*Executive Director, Medical Affairs,* **PERNIX**

4th

Human Abuse Liability & Abuse-Deterrent Formulations

November 6-7, 2017 | Hyatt Regency Bethesda | Bethesda, MD

The leading industry event for overcoming the technical, clinical, and marketplace challenges of reducing the abuse potential of prescription drugs

Marta Sokolowska
Vice President, Medical and External Affairs,
DEPOMED

Karsten Lindhardt
Senior Vice President, Head of R&D,
EGALET

David Baker
CEO,
ALCOBRA PHARMACEUTICALS

Dan Cohen
Executive Vice President, Government Relations,
KEMPHARM

Angela DeVeaugh-Geiss
Director, Epidemiology,
PURDUE PHARMA

William Schmidt
CMO,
ENSYSCE

NEW THIS YEAR

- **Real-world evidence strategies**
- **Value propositions for ADFs**
- **Outreach to payers and physicians**
- **Preparation for advisory committees**

DESIGN THE IDEAL ABUSE-DETERRENT COMPOUNDS AND CLINICAL TESTING PROTOCOLS

- **ALCOBRA** Transfers Key Abuse Deterrence Lessons From Stimulants to Opioids
- **CARA THERAPEUTICS** Outlines the Latest Technical and Regulatory Milestones for Kappa Opioids
- **EGALET** Improves Standardization for ADF Testing Methods
- **ENSYSCE** Designs Oral Overdose Deterrence Technologies

MEET THE EXPECTATIONS OF REGULATORS, PAYERS, CLINICIANS, AND PATIENTS

- **KEMPHARM** Outlines Preparation for Advisory Committees
- **LEHIGH VALLEY TECHNOLOGIES** Tailors New Outreach to Clinicians and Patients
- **PURDUE PHARMA** Pinpoints Regulatory Requirements for Real-World Evidence
- **DEPOMED** Refines Tracking Methodologies and Databases

"Overall a great meeting; enhanced knowledge on ADF development and the progress being made in the field."
—*Senior Manager and R&D Team Leader,* **TEVA**

"Fantastic information related to the regulatory / legal perspective that industry does not always consider."
—*Senior Scientific and Regulatory Manager,* **CAMARGO PHARMA SERVICES**

Sponsors:

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Supporting Partners: Abuse Deterrent Coalition · CLAAD Center for Lawful Access and Abuse Deterrence

4th Human Abuse Liability & Abuse-Deterrent Formulations

Dear Colleague,

For the first time, drug overdoses have become the greatest cause of mortality for people under 50 in the United States. The opioid addiction crisis is rising out of control and leading to an increase in political and market pressure on drug companies from regulators, legislators, insurers, physicians, and patient advocacy groups. New FDA final guidelines for branded opioids were released at the beginning of 2017, and the final guidelines for generics are expected by the end of the year. How you prepare for and respond to them will shape the future of your company's regulatory compliance and market success.

ExL's **4th Human Abuse Liability & Abuse-Deterrent Formulations** conference is the largest industry event specifically focused on the full spectrum of challenges and goals required to create and market drugs with lowered abuse potential. No other event goes into as much detail about preclinical development of abuse-deterrent drugs and delivery mechanisms, clinical trial design, and building strong, reliable networks with every stakeholder throughout the regulatory and market access community.

Through research with your peers and colleagues, this year's program features all-new strategies on:

- Minimizing the **oral overdose risk**
- Envisioning the **next generation of less addictive opioids**
- Matching each ADF candidate with the **optimal clinical research methodology**
- Identifying the most useful **databases and surveillance technologies**
- Using **real-world evidence** to make a strong case for abuse-deterrent formulations among payers and clinicians

Plus – for the first time! – an in-depth, interactive workshop about preparing for **FDA advisory committee meetings!**

Venue

Hyatt Regency Bethesda
One Bethesda Metro Center
Bethesda, MD 20814

To make reservations, please call 1-888-421-1442 and request the negotiated rate for **ExL's November meetings**. You may also make reservations online at http://bit.ly/2rMm481. The group rate is available until **October 17, 2017**. Please book your room early, as rooms available at this rate are limited.

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WHO SHOULD ATTEND

This conference is aimed at biopharma and medical device 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
- Medical Affairs
- Scientific Affairs
- Formulations
- Analytical Development
- Pharmaceutical Development
- Clinical Development
- Preclinical Development
- R&D
- Quality
- Pharmacovigilance
- Pharmacoeconomics / Health Economics / Outcomes Research / HEOR
- Commercial Affairs
- Legal Affairs / Legal Counsel

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

Agenda day one Monday, November 6, 2017

8:00 **Registration and Continental Breakfast**

8:45 **Introduction From Chairperson**

ADAPTING TO REGULATORY CHANGE

9:00 **Work With Regulators so New Guidelines Can Handle New Abuse Deterrence Techniques**

There is a new paradigm for FDA approval of abuse deterrence. It creates a category of non-interference, following the established process of non-inferiority. The recent guidelines are appropriate for prior attempts at abuse deterrence, but are less sensible if they will still be in force in 2020.

- Anticipate the final generic guidelines and how they will differ from drafts
- Open a dialogue so that guidelines will understand approaches that differ from oxycodone reformulations
- Build a foundation that allows for clear regulatory understanding and approval of new technologies

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

9:45 **Track the Development of State Legislation on Opioids**

1,250 new bills about opioids were introduced at the state level just this year – a fivefold increase from the previous year. Many states want to introduce their own guidelines or prescription limits, and increasingly suggest taxing opioid manufacturers and/or pharmacies to pay for treatment of opioid use disorder.

- Weigh the likelihood that exceptions for ADFs could be added to state legislation
- Recognize the broader market implications and risks of taxing opioid manufacturers and pharmacies
- Find solutions that policymakers will accept – or rebuild your budgets to absorb new costs
- View the pending legal landscape for analgesics, stimulants, and treatments for opioid use disorder

Shruti Kulkarni, *Counsel,* **CENTER FOR LAWFUL ACCESS AND ABUSE DETERRENCE**

10:30 **Networking Break**

11:00 **Tampering Methods and Routes of Administration – Perspectives From Recreational Drug Users**

Tampering and altering routes of administration of prescription opioids continue to be widespread health concerns. Methods and motivations for tampering can vary widely across populations. Insights from real-world drug users can be informative in designing laboratory and clinical trials to evaluate methods of prescription opioid manipulation.

- Learn about various methods of opioid tampering from recreational drug users
- Understand the behaviors associated with altering routes of administration
- Determine what adaptations should be made to laboratory and clinical studies

Beatrice Setnik, *Vice President, Clinical Pharmacology,* **INC RESEARCH**

11:45 **Identify the Right Questions (and the Wrong Ones) for Improving Standardization in ADF Development**

It is highly challenging to compare different ADFs, even if they use the same mechanism for abuse deterrence (i.e. physical resistance). A deep dive into the specific methodologies and importance of their differences is necessary to understand the impact on data in any attempted comparison. Small differences may have a major impact on results, and an understanding of what these differences really mean is lacking.

- Avoid seeking conclusions until after a better method for standardizing methodologies has been developed
- Evaluate individual products in a way that allows for more meaningful standardization and create discussion groups for sharing best practices between academia, regulatory authorities, and the industry to speed up the learning curve
- Categorize which tests are performed and how smaller design differences may impact interpretation of this data
- Examine whether section 9.2 label language really provides meaningful information to prescribers

Karsten Lindhardt, *Senior Vice President, Head of R&D,* **EGALET**

12:30 **Luncheon**

1:30 **Spotlight New Drugs of Abuse and Their Opioid Interaction Risks**

Even as the industry is growing more aware of the interaction risk between opioids and stimulants or benzos, other prescription drugs continue to be abused at varying rates. It is important to track the changes in abuse rate among multiple types of prescription drugs, as well as each of their types of interactions with opioids.

- Combine multiple drug categories to get a clearer picture of abuse risks
- Pinpoint where drugs of abuse have been significantly replaced
- Build industry and regulatory awareness of the rise of new drugs of abuse

Richard Dart, *Executive Director,* **RADARS SYSTEM**

2:15 **Effectiveness of ADFs: A Law Enforcement Perspective**

Data gleaned from law enforcement sources clearly show that ADFs are effective in reducing the diversion of the pharmaceutical product. Reformulated OxyContin® is examined as the best indicator of success or failure of the ADF since it contains by far the most abuse history prior to its reformulation.

- Examine abuse statistics both before and after reformulation
- Review statistics related to a large drug task force in SW Ohio as to the abuse and diversion issues both pre- and post-reformulation
- Discuss testimony from law enforcement officials in the Carolinas as to the extreme reduction of OxyContin® after reformulation
- Study the National Association of Drug Diversion survey about the change in diversion of OxyContin® after reformulation
- Analyze OxyContin® placebo program both pre- and post-reformulation

Aaron Graham, *Director, Brand Safety and Security,* **BOEHRINGER INGELHEIM**

John Burke, *President,* **INTERNATIONAL HEALTH FACILITY DIVERSION ASSOCIATION**

Agenda day one Monday, November 6, 2017

3:00 Networking Break
Sponsored by GRUNENTHAL

3:30 PRESENTATION BY ALCAMI

4:15 Use the Totality of Evidence to Gain Abuse Deterrence Label Claims During an ANDA Registration

When is a generic close enough to the innovator to justify a limited amount of Cat-1 testing? FDA requires that generics demonstrate bioequivalence, but it may be difficult to use a similar approach for the approval of abuse-deterrent claims: the generic product may utilize a different technology that is not applicable to the totality of evidence generated by the originator.

- Recognize when Cat-1 testing will be sufficient to support a label claim
- Aim towards meaningful comparisons for abuse testing even when significantly different ADF technologies are used
- Understand time frames for market exclusivity for originator products that allow prediction of when new label claims may be permitted

Torben Elhauge, *Director, Analytical Development,* **EGALET**

"Very interesting, interactive, and relevant to generic drugs."

—Associate Director, Regulatory Affairs, **ACTAVIS**

"Great presentations and very comprehensive review of clinical trial requirements."

—Principal Scientist, Safety Pharmacology and Drug Safety, **PFIZER**

"Shared great, informative approaches for overcoming challenges associated with opioid abuse."

—Director, Formulations, **RECKITT BENCKISER**

5:00 Cocktail Networking Reception

Sponsored by Altasciences Clinical Research Vince & Associates

6:15 ADD-ON DINNER WORKSHOP
Anticipate the Greatest Challenges When Facing FDA Advisory Committee Meetings

Under the 21st Century Cures Act, every new opioid will need to clear an FDA advisory committee meeting. Preparing for these meetings can be costly and difficult, especially given the level of background knowledge of committee members. This interactive workshop helps you set expectations for practice meetings, adapt to the likely knowledge and skill levels of committee reviewers, pick the best scientific evidence and language, fine-tune your rapid response tools, and more.

- Differentiate the proper approaches based on whether your company is completely new to the advisory committee process
- Select and work with the process manager that best meets your needs
- Practice persuading committee members who may not have specific experience in relevant medical areas

Dan Cohen, *Forum Chair,* **ABUSE DETERRENT COALITION;** *Executive Vice President, Government Relations,* **KEMPHARM**

8:15 Add-On Dinner Workshop Concludes

"About as many Americans are expected to die this year of drug overdoses as died in the Vietnam, Iraq, and Afghanistan wars combined. For more than 100 years, death rates have been dropping for Americans - but now, because of opioids, death rates are rising again.... Drug overdoses are now the leading cause of death for Americans under 50." *—The New York Times, June 22, 2017*

Agenda day two — Tuesday, November 7, 2017

8:00 **Continental Breakfast**

R&D INNOVATIONS

8:45 **Introduction From Track Chairperson**

9:00 **Overcome Challenges in the Clinical Evaluation of Abuse Deterrent Formulations: A CRO Perspective**

The use of ADFs is one strategy that can mitigate the misuse and abuse of opioid analgesics. The evolution of their misuse and abuse potential require pharmacokinetic and abuse potential studies that compare the systemic exposure and abuse liability between the manipulated and intact form of the ADF. In many cases, these studies require the use of non-dependent recreational drug users that have experience with the anticipated delivery route of abuse.

- Outline challenges in study recruitment and implementation
- Review methods for successful study design and completion
- Analyze how the type of ADF being evaluated shapes study challenges

Graham Wood, *Executive Vice President, Phase I Clinical Development,* **ALGORITHME PHARMA**

9:45 **Translate Lessons of Abuse Deterrent Development From Opioids to Stimulants and ADHD Drugs**

There has been a fourfold increase in hospitalization for prescription stimulants in the last seven years. As misuse of stimulants and ADHD drugs grows, more companies are trying to expand their abuse deterrence methodologies to this drug category. Success in this area will depend on clarifying how much of the science of ADF opioid development can carry over to stimulants.

- Review data on stimulant prescribing patterns
- Understand surveillance data regarding stimulant misuses and abuse, including routes and formulations
- Analyze the profile of patients, prescribers, and users
- Understand the differences between opioid and stimulant misuse and abuse

David Baker, *Interim CEO,* **ALCOBRA**

MARKETPLACE PROGRESS

Introduction From Track Chairperson

Assign a Market Value to Real-World Evidence for Opioids

Abuse liability tests create predictions, which need to be tested in the real world. Payers need to see the impact on their bottom line. Real-world confirmation would be of the highest utility both for validating scientific models and for advocating cost settings to payers. Major databases are already available to enable patient tracking and see if they develop addictive behavior.

- Assess the quality, size, and accessibility of claim data sets
- Refine your filtering and tracking methodologies
- Follow patient progress and outcomes to test your assumptions

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

Navigate the Data and Regulatory Requirements on Real-World Evidence for ADFs

Angela DeVeaugh-Geiss, *Director, Epidemiology,* **PURDUE PHARMA**

10:30 **Networking Break**

11:00 **Configure Studies for Opioid Interactions With Benzos**

FDA updated all labeling to highlight interactions with benzos, and politicians are increasingly concerned about the risk of respiratory depression and death. Very little data has so far been published on sedative interactions, making it a challenge to design the right studies for observing them.

- Assess the interest of regulators and policymakers in opioid/benzo interactions
- Decide on whether to conduct additional studies or modify your current approach
- Visualize the new clinical staff training and outsourcing partner selection that would be required for benzo interaction studies

Lynn Webster, *Vice President, Scientific Affairs,* **PRA HEALTH SCIENCES**

Convey the Importance of ADFs to Payers

Clinicians may hesitate to prescribe ADFs because they don't have time to deal with prior authorizations and don't want to risk extra expenses for their patients. Payers may seem more interested in reducing overall opioid prescriptions than in making abuse-deterrent opioids affordable. You need to paint a clear picture of the opioid utilization landscape for them to become more comfortable with it.

- Emphasize the importance of pain patient treatment needs and the inferiority of other approaches
- Quantify the costs of hospital visits, outpatient visits, and anti-overdose kits
- Chart a way forward when real-world evidence is lacking

Charles Argoff, *Professor of Neurology,* **ALBANY MEDICAL CENTER**

Agenda day two — Tuesday, November 7, 2017

R&D INNOVATIONS

11:45 Advance the Technical and Clinical Development of Oral Overdose Preventative Formulations

PF614 and PF329, two new candidates for Multi-Pill Abuse Resistant formulations have completed early clinical trials. Multiple protocols for later stages of development are being reviewed by FDA; implementation of one or more protocols will be announced at this year's meeting. The regulatory decision will influence the further development of oral overdose preventive technologies.

- Secure approval for individual drug components before forming a combination product for overdose protection
- Construct and manage Multiple Ascending Dose studies to show that the PK and safety profiles are maintained with and without overdose protection
- Situate oral overdose deterrent technology in the ADF ecosystem

William Schmidt, *CMO,* **ENSYSCE**

MARKETPLACE PROGRESS

Craft the Correct Messaging for Clinicians About Abuse-Deterrent Formulations

It can be difficult for clinicians even to breach the topic of painkiller abuse with their patients, let alone get them to convert to using an ADF. Both patients and clinicians are often highly suspicious of this new category of products – how can you best address this in your outreach?

- Select your language properly – recognize what claims you cannot make
- Draw clinician messaging considerations into your drug development process
- Outline the greatest challenges clinicians have when talking to opioid patients

Gene Levinstein, *CMO,* **LEHIGH VALLEY TECHNOLOGIES**

12:30 Luncheon

1:30 Survey the Latest Technical and Regulatory Developments for a Novel Kappa Opioid Receptor Agonist (KORA) for Acute and Chronic Pain

Positive clinical trial results and human abuse liability data have been gathered for CR845, a first-in-class peripherally selective kappa opioid agonist. To date, results support the view that CR845 is unlikely to be recreationally abused or lead to physical dependence.

- Trace the history of kappa opioid receptors as targets for analgesic drug development
- Review the abuse liability and respiratory safety data for CR845
- Envision a new approach to managing acute and chronic pain

Joseph Stauffer, *CMO,* **CARA THERAPEUTICS**

Work With KOLs to Educate Clinicians and Forecast Developments in Pain Management

Most clinicians don't know ADFs exist, nor do they understand the four data categories or the risk levels of opioid diversion. KOL advisory boards can help highlight the trends most relevant to clinicians and prescribers and most influential for the future of pain management.

- Properly frame technical development and risk issues for clinicians
- Identify pain experts who develop guidelines and perform key studies
- Mingle the expertise of your clinical and medical affairs teams

Colville Brown, *Medical Director,* **EGALET**

2:15 Find the Ideal Match Between ADF Candidates and Study Designs

The ADF product landscape can provide a clear view of the types of candidates that are working, those that have found less success, and the levels to which each of the four data categories has been put to practical use. It is vital to be able to see from FDA's perspective when envisioning what the studies for these products should look like in order to fairly test their properties.

- Track the approval history and prospects for ADFs
- Pinpoint how each category of data has been used (or not) by ADF candidates and in advisory committee meetings
- Recognize the features that regulators expect in preclinical and clinical studies

Revise Physician Outreach to Emphasize Reduced Diversion Potential for ADFs

75% of opioid abusers get their drugs without a prescription, and prescribers know this. They typically don't believe their patients are at high risk for abuse, especially with the monitoring and screening techniques already deployed. ADF uptake can be eased by changing outreach to physicians to focus more on avoiding diversion among the general public.

- Outline how ADF technologies can interfere with prescription opioid diversion
- Find the best databases and surveillance evidence in the case for reducing diversion
- Frame the conversation as making sure the best medications stay available for patients that need them

Jeremy Adler, *COO,* **PACIFIC PAIN MEDICINE**

3:00 Conference Concludes

"Some attorneys general and advocates are now asking in court whether the pharmaceutical companies who marketed the drugs and downplayed their addictive nature can be held legally responsible for - and made to pay the consequences of - the crisis."

—The Atlantic, June 2, 2017

Registration Fees for Attending ExL's 4th Human Abuse Liability & Abuse-Deterrent Formulations Conference:

Early Bird - *Register Before Friday, September 22, 2017*	
Conference	**$1,995**
Conference + Dinner Workshop	**$2,395**
Standard Pricing	
Conference	**$2,195**
Conference + Dinner Workshop	**$2,595**
Onsite Pricing	
Conference	**$2,295**
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