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

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

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?

Sponsors

Register by calling 201-871-0474
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

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

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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
- Pharmacy
- Education
- Medical Affairs
- Scientific Affairs
- Formulations
- Analytical Development
- Pharmaceutical Development
- Managed Care
- Market Access
- Reimbursement
- Rebate
- Clinical Development
- Preclinical Development
- R&D
- Pharmacovigilance
- Pharmacoeconomics / Health Economics / Outcomes Research / HEOR
- Commercial Affairs
- Legal Affairs / Legal Counsel / Policy
- Cannabis / Cannabinoid
- Addiction / Addiction Treatment / Addiction Medicine
- Diversions
- 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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**SPONSORSHIP AND EXHIBITION OPPORTUNITIES**

Do you want to spread the word about your organization’s solutions and services to potential clients attending this event? Take advantage of the opportunity to exhibit, underwrite an educational session, host a networking event or distribute promotional items to attendees. ExL Events will work closely with you to customize a package that will suit all of your needs.

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**Register by calling 201-871-0474**
Grasp what these policy proposals mean for the future of ADFs and Discuss Category 1 testing strategies for ANDA products Evaluate the potential for exposure to inactive excipients following Track the pioneering efforts in abuse-deterrent stimulant development Analyze links between cannabis uptake and non-overdose mortality Weigh the risks for small companies that don’t have the resources to Raise standards of transparency and confidence among all parties

Executive Director, Help policymakers differentiate between pain medications that pose Assess an ADF’s resistance to novel routes of abuse such as vaping Justify the use and consistency of methods of manipulation used Read the most likely coming changes in opioid policy Outline principles and development of new analytical methods Readily answer questions on manipulation properties

Professor, Neurology, Recognize that chronic pain patients now have minimal ways to find 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

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

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

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 naivety 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

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

Executive Vice President, Government and Public Relations, MEDICINES ALLIANCE

Introduction From Chairperson Dan Cohen, Executive Vice President, Government and Public Relations, KEMPPhARM

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

10:20

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

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

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

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 KEMPPhARM

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 have 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

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
"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
Registration Fees for Attending ExL’s 5th Human Abuse Liability Testing & Market Access Summit:

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<th>EARLY BIRD PRICING</th>
<th>Register by Friday, September 21, 2018:</th>
<th>$1,895</th>
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Conference Code: C1066

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

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