RADARS® SYSTEM

the Sweep

Researched Abuse, Diversion and Addiction-Related Surveillance System

Third Quarter, 2017 | RADARS.org

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In This Issue

FDA Public Workshop and RADARS System Docket Submission

The US Food & Drug Administration (FDA) held a public workshop July 10th and 11th entitled "Data and Methods for Evaluating the Impact of Opioid Formulations with Properties Designed to Deter Abuse in the Postmarket Setting: A Scientific Discussion of Present and Future Capabilities." The workshop was intended to bring together a panel of scientists, experts, and interested stakeholders to discuss how best to analyze and interpret the current data as well as brainstorm ideas for improvements. RADARS System Director of Research Administration, Jody Green, PhD, CCRP, Senior Scientist, Nabarun Dasgupta, MPH, PhD, and RADARS System SAB member, Sidney Schnoll, MD, PhD participated as panelists at the workshop.

In response to the workshop, RADARS System submitted comments to Docket No. FDA-2017-N-2903. Key points of the response are as follows.

- RADARS System recognizes the challenges faced when monitoring prescription opioid abuse and has responded to these challenges by developing a mosaic approach using multiple data sources.
- No surveillance data source is perfect and the limitations should be well understood and minimized while recognizing the value of the data.
- It is important to understand the relationships between data sources and a systematic approach to interpret the data should be developed using the mosaic design.
- The denominator used in analyzing the data should be chosen carefully. One denominator may not be appropriate for all analyses.

Click here for additional information on the workshop

Click here to read docket responses

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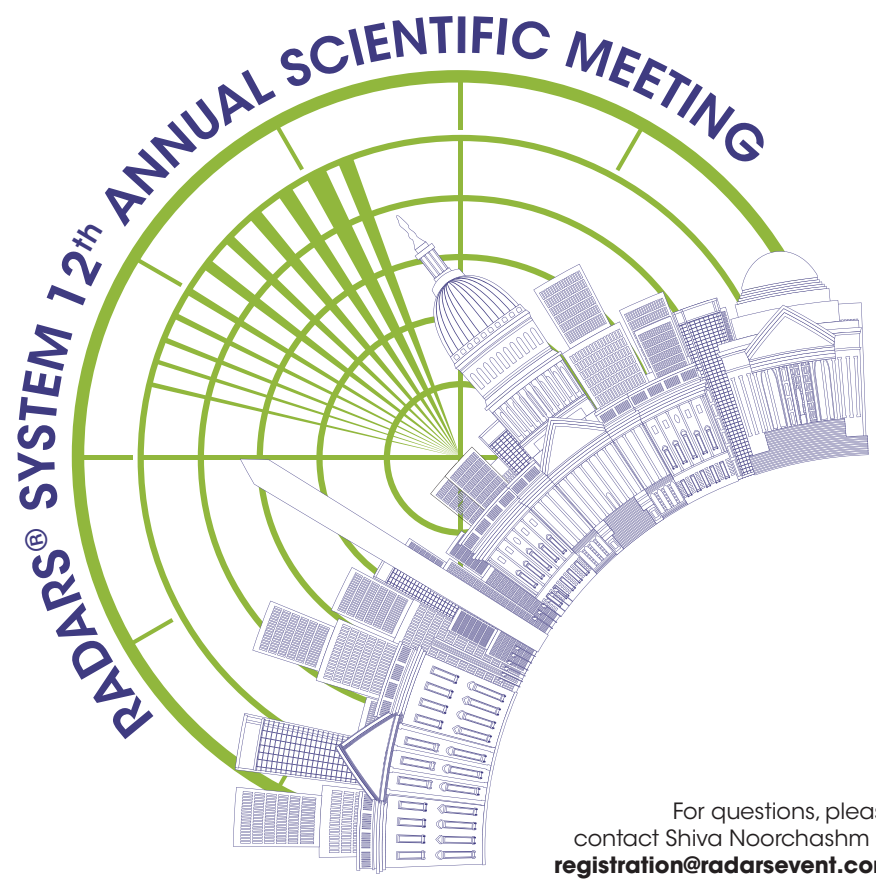
Citizen Petition to Remove High Dosage Opioids

Five groups representing public health officials and doctors worked together to file a petition with the FDA to remove ultra-high dose opioid (UHDU) pills, tablets, and sprays from the market. UHDU opioids refer to those opioids whose labeled daily dose is more than 90 milligrams of morphine (MME) per day in potency, including both immediate release and extended release formulations. The petitioning groups (Physicians for Responsible Opioid Prescribing, the Association of State and Territorial Health Officials, the National Safety Council, the American College of Medical Toxicology, and Coalition to End the Opioid Epidemic) claim that high-dose opioids raise the risk of overdose and addiction, especially in children. The petition calls for the FDA to "immediately seek removal of oral and transmucosal UHDU opioid analgesics from the market." The petition is currently under review by the FDA.

Click here to read the full petition

SAVE THE DATE

MAY 9–10, 2018



WEDNESDAY, MAY 9, 2018
INTERNATIONAL PRE-SYMPOSIUM AND NETWORKING WELCOME RECEPTION

THURSDAY, MAY 10, 2018
MAIN ANNUAL CONFERENCE

Westin Georgetown
2350 M Street, NW
Washington, DC

For questions, please contact Shiva Noorchashm at **registration@radarsevent.com**.

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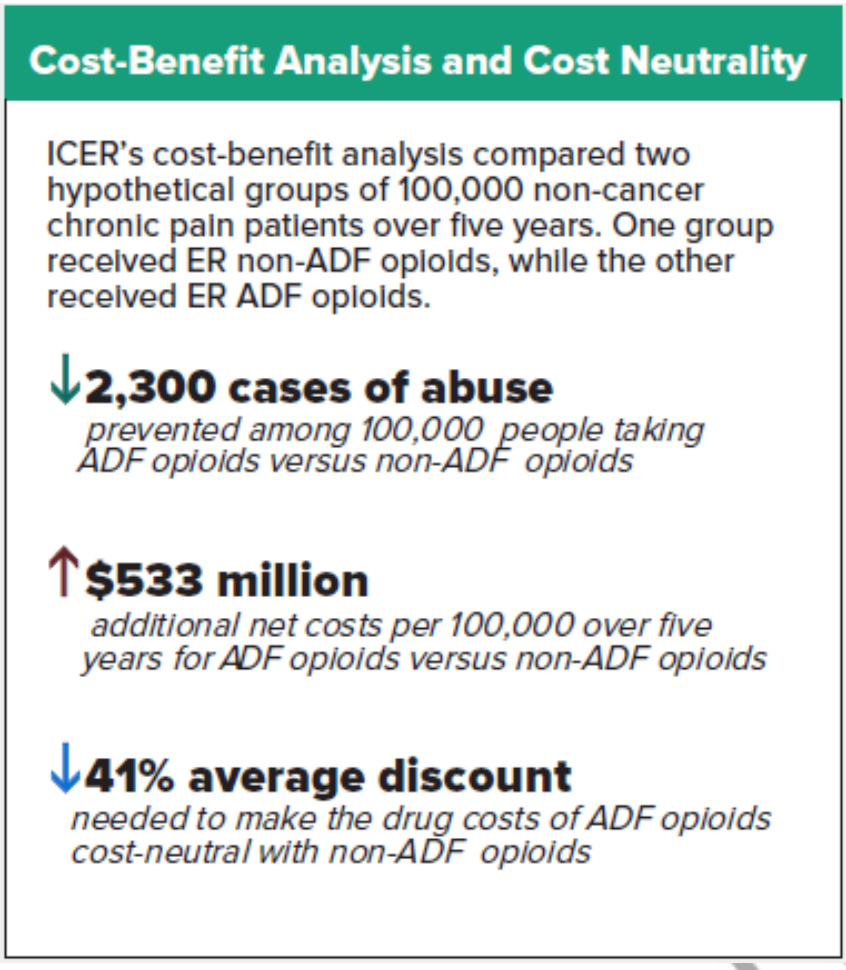
ICER Report

In August, the Institute for Clinical and Economic Review (ICER) released a report assessing the effectiveness and value of abuse-deterrent formulations (ADFs) of opioid medications. The report includes a comparative clinical effectiveness analysis, a cost neutrality analysis, and a cost-benefit analysis based on a review of ten ADFs. In addition, the report provides policy recommendations for policymakers, manufacturers, researchers, government agencies, and payers. The ICER evidence rating is as follows.

- For individual patients prescribed an opioid, evidence provided moderate certainty of a comparable or better net health benefit for OxyContin.
- Evidence for all other ADFs was promising but inconclusive, based on a lack of real-world evidence of the impact of ADFs on rates of abuse, as well as possible safety concerns.
- For the wider population of people using opioids for both therapeutic and non-therapeutic purposes, evidence was insufficient to determine a net health benefit of ADFs.

An excerpt from the cost-benefit analysis and cost neutrality is below.



Click here for more information on the ICER report

International Corner

EUROTOX

Dr. Jody Green was invited to speak at the 53rd Congress of the European Societies of Toxicology (EUROTOX) in September. Dr. Green and Prof. Bruno Mégarbane, Professor in the Department of Medical and Toxicological Critical Care at Lariboisière Hospital in Paris, France, co-chaired a session discussing the toxicity of prescription opioids and ways to improve knowledge to combat the international opioid threat. The EUROTOX conference was held in Bratislava, Slovakia and was attended by more than 1100 participants from 54 countries.

During the session, Dr. Green discussed trends in opioid abuse and mortality in Europe based on data obtained from the RADARS System. The RADARS System mosaic approach to surveillance provides valuable insight from multi-dimensional perspectives as each of the programs target different facets of prescription drug abuse, misuse, and diversion. The data show that, while magnitude and patterns vary, heroin, THC, prescription opioids, and benzodiazepines are commonly abused/misused in many countries.

Arne Kristian Skulberg, Jody Green, and Bruno Megarbane were speakers at the symposium

Click here to view Dr. Green's presentation

Bruno Megarbane and Jody Green speaking at the conference

Saudi Psychiatric Association Meeting

Dr. Richard Dart gave two presentations at a meeting sponsored by the Saudi Psychiatric Association in September. The audience included psychiatrists that treat substance abuse in Saudi Arabia and representatives of the Saudi FDA (SFDA). The proceedings were used to create recommendations on how to address prescription drug abuse in Saudi Arabia.

Click here to view Dr. Dart's presentation

Potential Solutions to Epidemic Substance Abuse in US and Europe

Click here to view Dr. Dart's presentation

Substance Abuse in US and Europe

RADARS® System Offers Wide Range of Services Both Domestically and Internationally

The RADARS System data have been utilized by manufacturers, regulatory agencies and medical and public health officials to characterize and monitor prescription drug abuse, misuse and diversion.

The data have been presented at several US Food and Drug Administration (FDA) advisory committee meetings and scientific meetings as well as in reports to the FDA, new drug applications, labeling claims, post market requirements, and Risk Evaluation and Mitigation Strategies (REMS) evaluations. Data may also be used for the development of interventions, to assess the impact of interventions and to monitor ever-changing market trends.

The RADARS System is composed of a mosaic of programs which target diverse populations. Data from these RADARS System programs are triangulated to provide a comprehensive picture of prescription drug abuse, misuse and diversion. Triangulation is an approach used in many fields of research and is especially useful in the study of hard to reach or hidden populations, such as prescription drug abusers. No single data source is expected to provide complete and representative information about a given population, but when considered together, multiple data sources strengthen the credibility of findings, reduce the risk of false

See services available through the RADARS® System

interpretations, and provide a more complete and comprehensive perspective on the behaviors of the covert population.

The RADARS System has helped clients meet pre- and post-market regulatory and business requirements since 2006. These services are customized to meet specific regulatory and business needs and may include but are not limited to the development of studies, formal epidemiological studies including protocol and statistical analysis plan development, quarterly and annual surveillance reports, and ad hoc analyses/reports as requested.

The RADARS System publishes several articles each year in noteworthy peer-reviewed journals, including the New England Journal of Medicine, JAMA Psychiatry, the Journal of Pediatrics, Drug and Alcohol Dependence and the Clinical Journal of Pain. Further, RADARS System data are regularly presented at scientific conferences throughout the world.

Take me to a list of domestic services

Take me to a list of international services