



National Association of State
Controlled Substances Authorities

NASCSA Resolution 2014-03

October 2014

Savannah, Georgia

**A Resolution to Encourage the Clinical Utilization of Opioid Analgesic Drug Products
with Formulations that Include FDA-Approved Abuse-Deterrent Characteristics**

WHEREAS, the purpose of the National Association of State Controlled Substances Authorities (NASCSA) is to provide a continuing mechanism through which states, federal agencies, and others can work to increase the effectiveness and efficiency of state and national efforts to prevent prescription drug diversion and abuse; and

WHEREAS, the Food and Drug Administration (FDA) released a draft Guidance for Industry on Assessment of Abuse Potential of Drugs in January 2010; and

WHEREAS, the FDA also released a draft Guidance for Industry on Abuse-Deterrent Opioids – Evaluation and Labeling in January 2013; and

WHEREAS, there are only three opioid analgesic formulations with FDA-approved labeling referring to abuse-deterrent properties; and

WHEREAS, there are over 20 opioid analgesic drugs intended to embody abuse-deterrent characteristics in development by at least a dozen innovator or generic pharmaceutical manufacturers; and

WHEREAS, on a prescription-share basis, the vast majority of opioid analgesics prescribed are generic drug products;

NOW, THEREFORE BE IT RESOLVED that NASCSA encourages FDA to finalize both draft guidance to provide clear direction to pharmaceutical manufacturers developing opioid analgesics in formulations designed to deter abuse; and

BE IT FURTHER RESOLVED that NASCSA encourages FDA to release a draft Guidance for Industry on developing of generic opioid drug products with abuse-deterrent characteristics and that such Guidance make clear that generic products must demonstrate abuse-deterrent characteristics that are at least equivalent to the innovator opioid drug product they reference; and

BE IT FURTHER RESOLVED that NASCSA encourages innovator and generic drug manufacturers to develop opioid analgesics in a manner than comports with Guidances from FDA; and

BE IT FURTHER RESOLVED that NASCSA encourages public and private payors to avoid disadvantaging opioid drug products with FDA-approved abuse-deterrent characteristics by use of differential copayments, formulary tier placement, prior authorization, or other means so as to preferentially increase clinical utilization of opioids with approved abuse-deterrent characteristics in an effort to reduce diversion and abuse of opioid analgesics and eventually ensure that only opioid analgesics with abuse-deterrent characteristics are in clinical use.

A handwritten signature in black ink, appearing to be 'Rafael O.', written over a horizontal line.

ATTEST: _____
President

DATE: October 24, 2014