



## **Psychiatric Events Risk Management Issues**

- The evidence does not support a causal association of psychiatric illness with Accutane. Specific information related to possible risk of events beyond known risk factors for disease is lacking.
- Patients with severe acne, depending on age, gender, and prior history, may be at high risk for a concomitant psychiatric illness

## **Psychiatric Events Risk Management Issues**

- What information to convey, with what desired actions, to be taken by whom and in what circumstances?
- e.g.: CME
  - Psychiatric disease as a concomitant illness:
    - alert the prescriber to this phenomenon
    - use the treatment venue as an opportunity for identifying possible problems
    - applicable to all high risk patients, include Accutane information

## **Psychiatric Events Risk Management Issues**

- What information to convey, with what desired actions, to be taken by whom and in what circumstances?
- e.g.: Labeling:
  - Professional: new Accutane data, symptoms, discontinuation, alert to comorbidity in all high risk patients
  - Patients: Accutane information, alert to symptoms, inform physician of previous history, alert to possibility of psychiatric illness irrespective of acne treatment

## **Psychiatric Events Risk Management Issues**

- What information to convey, with what desired actions, to be taken by whom and in what circumstances?
- e.g.: Labeling: informed consent
  - relative strength of causal association compared to other serious adverse events
  - what to inform patients about, for consent to treatment without a strong statement of cause, or estimates of risk

## **Psychiatric Events Risk Management Issues**

- What information to convey, with what desired actions, to be taken by whom and in what circumstances?
- e.g.: assessment before and during treatment
  - simple questionnaires (waiting room) available to identify the possibility of, psychiatric illness but not to confirm or rule out
  - for all high risk patients (part of dermatological assessment)
  - potential risk of conflict with time needed for pregnancy prevention in women...compliance?

## **Psychiatric Events Risk Management Issues**

- Formal Studies:
- Prospective clinical trial:
  - control group, hypothesis/sample size, blinding
- Open cohort studies
  - matching cohorts unlikely
  - specificity of question, confidence in the answer
  - must be prospective

## **Psychiatric Events Risk Management Issues**

- Retrospective epidemiologic cohort study:
  - available databases re: size, specific coding, population definitions
- In vitro / in vivo preclinical studies:
  - specific models for specific psychiatric illness vs general CNS effects

## **Conclusions**

- The evidence does not support a causal association between Accutane and psychiatric illness
- Additional studies might somewhat clarify but not definitively resolve the issue
- Much has been learned about psychiatric disease in acne patients...there is an opportunity to enhance the overall medical impact of the management of all acne patients