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Memorandum May 1, 1997

From Kathryn O'Connell

To Jonathan Wilkin

Re Suggested Addition (DEPRESSION) to BOXED WARNING for ACCUTANE
CAPSULES

This data base includes a total of 51 patients on Accutane therapy who committed/attempted suicide. Of these, only 11 had documentation of previous psychiatric illness. (See Epidemiology report for details).

Conclusions

The inherent limitations in attempting to use these data sources to demonstrate cause and effect are acknowledged. However, the overall impression from these sources is that Accutane may precipitate serious psychiatric disturbance and suicide. The most serious nature of this AE and