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materials; and (2) the scope of dissemination of the February 23, 1998 "Dear Doctor" letter communicating revised labeling regarding psychiatric disorders.

[BTS note this information on advertising, etc]

### **Memorandum of Teleconference**

Date January 13, 1998  
Re Accutane and Depression

This teleconference was requested by Hoffman La Roche to discuss procedural options for redressing the Accutane labeling issue.

HLR asked for an extension and it was granted, but should be resolved by Feb 6, 1998.

### **Liam Grant's Fax of April 4, 98**

Need clean copy of Liam's March 5, 1998 correspondence to Kevin White bottom cut off, but Liam makes point about the inconsistency in numbers.

### **Memorandum of Teleconference**

Date November 24, 1997  
Subject NDA 18-662 Accutane  
Re Depression and Suicide ADRs

3rd paragraph The Sponsor indicated that they have completed a comprehensive review of the reported case depression and suicide associated with Accutane therapy. The Sponsor concurred that there does appear to be a problem.

### **Medical Officer's Review Pediatric Labeling Supplement NDA 18-662 S-035**

Submission date 10 Dec 96  
Received date 13 Dec 96  
Review Date 05 Dec 96

Summary This submission seeks approval of Accutane labeling for pediatric patients with severe recalcitrant nodular acne.

Original NDA 18-662 (1981)