

MEMORANDUM OF MEETING**April 13, 2007
Washington, DC****FDA:**

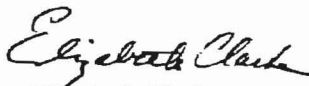
Andrew C. von Eschenbach, M.D., Randy Lutter, Sheldon Bradshaw, Jeff Shuren, Jarilyn Dupont, Jeff Senger, Jane Axelrad, Mike Landa, Linda Kahan, Dan McChesney, David Horowitz, Kristen Smith, Elizabeth Clarke,

Sidley Austin: Paul Kalb, Dan Troy, Coleen Klasmeier, Alan Bennett, Joan McPhee

Subject: Peer-review journal articles

Meeting Summary

After introductions, Mr. Troy explained that Sidley Austin represents a number of companies that are concerned about dissemination of peer-reviewed journal articles. FDAMA allowed the practice of distributing this information, but the provision has now sunset. Sidley Austin spoke about their perceptions as well as the effect and consequences of the sunset provision. Mr. Kalb provided an overview of the problems companies face. He also expressed concerns about Federal prosecutors pursuing distributors of this information for criminal misconduct. There is confusion about the rules, possibly an FDA guidance could clarify the rules.



Elizabeth Clarke
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