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August 28, 2001

Kimberly Littleton Topper
Health Science Administrator
Center for Drug Evaluation and Research (HFD-21)
Food and Drug Administration
5630 Fishers Lane, Room 1091
Rockville, MD 20857

Re: Public Advisory Committee Meeting of the Anesthetic and Life Support Drugs Advisory Committee on September 13 and 14, 2001

Dear Ms. Topper:

Thank you for being so helpful with my request today to withdraw my statement submitted for the record on 8/17/01, in connection with the above scheduled committee meeting. As I mentioned, the material I used was collected and prepared, in part, in anticipation of a medical journal article that I am co-authoring on the subject. Because of pre-publication agreements and other restrictions imposed by the world of academia, I was asked to withdraw entirely the prepared statement that I delivered to your office on 8/17/01. Thank you again for being so understanding and for withdrawing and shredding the statement. As I mentioned, I am recently retired from the DEA and still getting used to the private sector and the rules of academia.

I have to be out of town on the evening of September 13 but I hope to back in time to make the public session in the morning. If so, and if I can be permitted three minutes to address the Committee, I would like to briefly state the need for creating a unified database to bring together the various drug-abuse databases that currently are used by FDA and DEA to evaluate the abuse potential of dependence-forming or dependence-sustaining drugs. Databases such as DAWN, NFLIS, STRIDE II, AERS, NHSDA, and ADAM (forgive me for not spelling these out!) are all very fine and managed very well but there presently is no system for bringing together, in one database, the results and information contained in these and other relevant systems. As a result, regulators may not have all the data they need and are understandably cautious in scheduling controlled substances. In some cases, this caution may not be justified by the actual abuse record of the substance. This, therefore, may create an unintended impediment to good patient care.

That's the gist of my two-minute drill. Thanks again for your help and I look forward to meeting you, hopefully, on the 14th.

Sincerely,

John J. Coleman