

The Informed Consent (to be read by patients) included the language, “I understand that some patients, while taking Accutane or soon after stopping Accutane, have become depressed or developed other serious mental problems. Signs of these problems include feelings of sadness, irritability, unusual tiredness, trouble concentrating, and loss of appetite.” The Informed Consent also read, “Once I start taking Accutane, I agree to stop using Accutane and tell my provider right away if any of the following happen. I start to feel sad or have crying spells, lose interest in my usual activities....”

On or about February 2000, the physician first prescribed the drug to Mr. Snyder for treating acne. Treatment was continued until September 2003. But in February 2005, the patient (Mr. Snyder) committed suicide.

The goal of this narrative is solely to reveal general principles that can be learned from the courtroom case, regarding how the *Dear Healthcare Professional* letter fits into the various methods for warning physicians and patients.

#### **d. *Dear Healthcare Professional* letter regarding appetite suppressants**

*In re Briscoe et al.* (225) provides one more illustration of a *Dear Healthcare Professional* letter, this time where the goal is to inform physicians that a drug was withdrawn from the market. As in the above examples, the *Dear Healthcare Professional* letter was used in combination with other methods for warning physicians and patients. To quote from this courtroom opinion, “The publicity began on September 15, 1997. At 5:00 p.m., the Houston CBS news affiliate started the broadcast with a report that... diet drugs had been pulled from the market, announcing that the Food and Drug Administration is urging millions of dieters to stop taking them as they have been linked to serious heart problems. Similar newscasts kicked off the five o’clock news for both the ABC and NBC affiliate station in the Houston area...furthermore, [the manufacturer] sent a *Dear Health Care Provider Letter* to approximately 450,000 physicians and pharmacists in which it informed them of the withdrawal of the drugs from the market and of the potential association between use of the drugs and instances of valvular heart disease” (226).

The purpose of this narrative is solely to reveal general principles that can be learned regarding how *Dear Healthcare Professional* letters fit into the array of available methods for warning physicians and patients.

## **VIII. PATIENT-REPORTED OUTCOMES**

### **a. Introduction**

The following narrative, which concerns patient-reported outcomes (PROs), encompasses the topics of safety and efficacy. Data from patients may be classed as those that

<sup>225</sup> *In re Briscoe, et al.* 448 F.3d 201, U.S. Court of Appeals, 3rd Circuit, 2006 U.S. App. LEXIS 11990.

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