Drug, Device and Biotechnology Section

The March 2017, Charleston Meeting will host the DD&B Section program entitled *"Promotional Claims: Off-Label Promotion - Debunking the Theory and Defending the Claim."* The panel will address one of the more controversial issues facing FDA regulated industry today.

DD&B Section member Andy Johnson of Bradley offers the following insight into relying on sound science:

On December 16, 2016, FDA issued a Safety Announcement that gave notice of the removal of the boxed warning from the drug label for Pfizer's smoking cessation medication Chantix® (varenicline) (here). This was an important development for the medication because boxed warnings are rarely – if ever – removed from FDA labeling. Chanitx® was approved in 2006 and has proven to be an effective treatment for smoking cessation, and its initial labeling had no boxed warning. The publicity following the unfortunate death of a notable musician after being prescribed the medication (here) led to more anecdotal adverse event reports, and ultimately a label change in July 2009 that added the boxed warning. Along with the publicity, lawsuits alleging exacerbated depression, suicide and other psychiatric issues were filed and ultimately consolidated in an MDL proceeding in the USDC for the ND of Alabama. *In Re: Chantix (Varenicline) Products Liability Litigation*, 2:09-cv-02039, MDL No. 2092. As with other pharmaceutical products liability litigations, the claims and allegations in *In Re: Chantix* litigation involved the adequacy of the warnings in the label and the timing of label changes. In fact, the MDL court granted summary judgment for Pfizer on all claims arising after the July 2009, label change that added the boxed warning, finding that the warning was adequate as a matter of law. *See In re Chantix (Varenicline) Products Liability Litigation*, 881 F.Supp.2d 1333 (N.D.Ala. 2012). Claims arising under the pre-boxed warning label continued and were ultimately settled by the company in 2013.

The real story here, however, is that the publicity and litigation raced far ahead of the science. The boxed warning was ultimately removed based on a large observational study – the EAGLES study – designed to answer the question of whether Chantix® was associated with the sorts of injuries alleged in the litigation. (here)

The results of this study were published in June of 2016, and effectively show that Chantix® is not associated with a significant increase in neuropsychiatric events as compared to the nicotine patch or placebo (the alleged risks discussed within the boxed warning). The study also reinforced that Chantix® is a more effective method of helping smokers quit. Cases that were settled in 2013 would be subject to intense scrutiny today based on the scientific evidence that general causation cannot be established, and plaintiffs' experts in the MDL would have had to overcome an observational study of more than 8,000 participants that contradicts their theories. While no litigant wants to wait for years to have scientific questions answered, this is an example of where patience would have been helpful and informative, and might serve as an example to cite to future courts.

Andy Johnson of Bradley served as Co-Defendant's Liaison Counsel for Pfizer in *In Re: Chantix (Varenicline) Products Liability Litigation*, 2:09-cv-02039, MDL No. 2092. http://www.bradley.com/people/j/johnson-andrew