MEMBER ALERT:

SVU recently learned that a complaint was filed by the United States Department of Justice (DOJ) against Pharmaceutical Innovations, Inc. (PI). This complaint is of potential interest to SVU Members because it asks the Court to order PI "to cease directly or indirectly manufacturing, packing, labeling, and distributing" any device, unless and until PI remedies all alleged past and ongoing violations relating to the manufacturing, sale, and distribution of its devices, such as ultrasound gels and pads. A complaint reflects allegations made by a litigant; it is not a finding by the court.

Specifically, the DOJ's complaint alleges that PI has violated, and continues to violate, several provisions of the Federal Food, Drug, and Cosmetic Act (FDCA). First, the complaint alleges PI failed to comply with current good manufacturing practice requirements. Second, the complaint claims PI did not apply for appropriate premarket approval or submit the requisite notifications to the Food and Drug Administration (FDA) prior to manufacturing and selling some of its gel and pad products. Third, the complaint contends that PI failed to comply with FDA's medical device reporting requirements. Finally, the DOJ's complaint alleges that PI continues to violate the FDCA and will continue to do so "unless restrained by order of this Court."

The link to the FDA's press announcement regarding the DOJ complaint against PI: *http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm417280.htm*