Lawyers file most isotretinoin adverse drug reports

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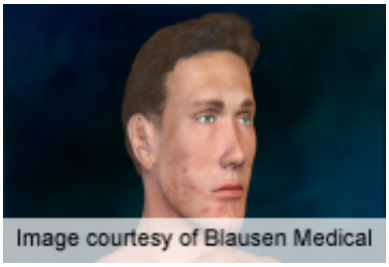
Image courtesy of Blausen Medical

(HealthDay)—Attorneys have submitted a disproportionate number of isotretinoin-associated inflammatory bowel disease (IBD) cases to the U.S. Food and Drug Administration, according to a study published in the September issue of the *Journal of the American Academy of Dermatology*.

Derrick J. Stobaugh, from the Center for the Study of Complex Diseases in Evanston, Ill., and colleagues analyzed data from the FDA Adverse Event Reporting System (FAERS) to identify IBD cases reported with isotretinoin for a usage indication of acne. Reporter category was recorded. The distortion of pharmacovigilance signals for IBD with isotretinoin were determined with the signal inflation factor calculation.

The researchers found that there were 2,214 cases of IBD resulting from isotretinoin, with attorneys reporting 87.8 percent of cases (1,944),

physicians reporting 6 percent (132 cases), and consumers reporting 5.1 percent (112 cases). For the same time period, only 3.6 percent of all reported drug reactions to the FAERS were reported by attorneys (87,905 of 2,451,314). The signal inflation factor for isotretinoin-associated IBD for attorney-initiated reports was 5.82, signifying a clear distortion.

"Attorney-initiated reports inflate the pharmacovigilance signal of isotretinoin-associated IBD in the FAERS," the authors write.

More information: Abstract
Full Text (subscription or payment may be required)