Position Statement
On Isotretinoin
(Approved by the Board of Directors December 9, 2000;
Amended by the Board of Directors March 25, 2003, March 11, 2004 and November 13, 2010)

1. The Association is committed to the safe and responsible use of isotretinoin. Isotretinoin is
FDA approved for and generally considered by dermatologists to be the most effective
treatment for severe recalcitrant nodular acne. The effectiveness of systemic isotretinoin
therapy in the treatment of acne has been demonstrated in randomized, double blinded
clinical studies. It is known to effectively reduce acne and lead to a reduction in scarring.  1-4

2. The Association recognizes there is sufficient evidence for the use of isotretinoin in severe
forms of acne, particularly (but not limited to) severe recalcitrant nodular acne or acne which
has proven refractory to other forms of therapy. Assessment of severity includes the impact
of the disease on the patient, both physical and psychological. 1

3. The Association recognizes that isotretinoin has been used off-label in the treatment of
conditions such as disorders of cornification and in chemoprevention of skin cancer in high
risk individuals. The Association believes such off-label uses are permitted under the FDA’s
“practice of medicine” exception to its drug approval process. Physicians considering the
use of isotretinoin in such off-label indications should make the patient aware that off-label
usage has not been specifically approved by FDA.

4. The Association promotes compliance with the manufacturer-sponsored and FDA-approved
risk management program for prescribing isotretinoin (iPLEDGE). It opposes on-line
Internet dispensing, sharing, or use without physician supervision, because these activities
do not provide for sufficient patient education about isotretinoin risks and do not require
participation in the iPLEDGE program

5. The Association supports continuing education for physicians, their office staff, allied
medical personnel, and patients on the potential risks connected with the use of isotretinoin.
In particular, prescribers, patients, pharmacies, and manufacturers must comply with the
iPLEDGE risk management program as outlined on the iPLEDGE web site
(www.ipledgeprogram.com) to prevent fetal exposure during treatment with isotretinoin. 1

6. A correlation between isotretinoin use and depression/anxiety symptoms has been
suggested but an evidence-based causal relationship has not been established. Other
studies give evidence that treatment of acne with isotretinoin was accompanied by
improvement of both depressive and anxiety symptoms, as well as improved quality of life of
patients with acne. 1 5 6

7. Current evidence is insufficient to prove either an association or a causal relationship
between isotretinoin use and inflammatory bowel disease (IBD) in the general population. 7,
8 While some recent studies have suggested such a relationship 9,10, further studies are
required to conclusively determine if the association or causal relationship exists and/or
whether IBD risk may be linked to the presence of severe acne itself.

8. The Association concludes that the prescription of isotretinoin for severe nodular acne
continues to be appropriate as long as prescribing physicians are aware of the issues
related to isotretinoin use, including IBD or psychiatric disturbance, and educate their
patients about these and other potential risks. Physicians also should monitor their patients for any indication of IBD and depressive symptoms.

References:
10. Crockett SD, Porter CQ, Martin CF, Sandler RS, Kappelman MD. "Isotretinoin Use and the Risk of Inflammatory Bowel Disease: A Case-Control Study," Am J Gastroenterol. 2010 Mar 30 online