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:

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This Position Statement is provided for educational and informational purposes only. It is intended to offer physicians guiding principles and policies regarding the practice of dermatology. This Position Statement is not intended to establish a legal or medical standard of care. Physicians should use their personal and professional judgment in interpreting these guidelines and applying them to the particular circumstances of their individual practice arrangements.