Cosmetic & Laser Surgery™
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The Committee on Hydroquinone
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Re: Docket No. 1978N-0065
RIN No. 0910-AF53

Dear Committee Members,

I am a dermatologist with over 40 years of full time practice. While I see a good deal of general dermatology, I have a large cosmetic and laser surgery practice with 16 lasers in daily use. I see many patients with pigmentation disorders on a daily basis and while some of these people can be treated with intense pulse light or lasers such as the Neodynium YAG or Fraxel, the majority achieve excellent results at much less cost with the hydroquinone products. In addition, darker skinned patients (especially Asians and Blacks) treated with lasers often develop a distressing post-inflammatory hyperpigmentation which can be minimized or eliminated by pre-treament with hydroquinone.

Between the various hydroquinone products, I have prescribed more than 1000 two ounce two and four percent bottles or tubes of hydroquinone per year for more than 15 years for melasma and other forms of dyspigmentation. Most of these patients are Caucasian women, although I have a significant Asian and Hispanic patient mix as well as African-Americans. I have never seen a patient with ochronosis or anything resembling it. On the other hand, I have seen many women with low self- esteem due to pigmentary abnormalities. Many women especially comment on the need to look good in order to compete in the market place. This proposed rule is discriminatory against women of all skin colors and is poor public policy.

Elimination of all of the OTC skin bleaching creams will make it difficult to treat many of these people.

I am on the Clinical Faculty at University of California San Francisco and am current on all of the major dermatologic literature. The few reported cases of ochronosis do not warrant restricting skin bleaching agents from the US population as most of those

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cases were in women of color and the only reason they were using the products in the first place was that they had problems with dyspigmentation.

The amount of 4% hydroquinone used to treat small body areas is in no way comparable to the amounts used systemically in small animal studies. While it would be reasonable to issue a black box warning for pregnant women, many years of topical hydroquinone use have not demonstrated any carcinogenicity in people. Also, 20% monobenzylether of hydrquinone has been used to completely depigment people with severe vitiligo for more than 30 years without any long-term consequences.

There is no reason to consider hydroquinone a new drug when it has been used safely and effectively for many years. This proposed rule, if adopted, will have an adverse effect on the clinical care of many patients with dyspigmentation problems.

Sincerely yours,

Diana D. Parnell, MD
Assistant Clinical Professor UCSF
Fellow, American Academy of Dermatology

cc. Senator Dianne Feinstein
Senator Barbara Boxer
Congresswoman Lynn Woolsey