

## Letters to the Editor

### Streamlining cosmetology by standardized testing?

Editor – Calling for global standardization in cosmetic testing may appear appealing, but could it be merely the revival of the quest for the Holy Grail? Dr Roberts' plea merits some reflection. First of all, in order to avoid confusion and unrealistic aspirations in cosmetology one should clearly distinguish between matters related to *safety* and matters related to *efficacy*. It is also important to define the people whose priorities should be met. Is standardization needed by the cosmetic industry, by research centre facilities, by contract research organizations, by regulatory authorities or by consumers? The variable aims, thresholds of technical know-how, and knowledge in relevant skin physiology and biology among intervening parties may indeed decipher the issue. These concerns are discussed hereafter.

I fully agree with Dr Roberts that testing should be performed in a standardized way whenever possible to predict tolerance and safety of cosmetics. The rules edicted by toxicology should be strictly applied. As indicated in her document, testing for chemical ingredients can currently be performed using laboratory animals. However, it must be stressed that this situation is no longer acceptable for proprietary cosmetic formulations that are brought to the market. Methods that avoid animal testing have been used in this field for many years.

I disagree with many of the contentions made by Dr Roberts about cosmetic efficacy testing. Indeed, I found what appear to be contradictions and misperceptions in her statements. In the field of dermatology there is little standardization in assessing drug efficacy. Similarly, cosmetology, which is constantly evolving, has also escaped rigid scrutiny of its wide varying claims. In these respects, proficiency and internal quality controls are awaited from test centres. Standards are also expected to be met by commercial instrumental devices. Beyond these controlled procedures standards can hardly be proposed to calibrate human physiology and any cosmetic effect modifying it. I suspect that their introduction would not result in improving product efficacy, but rather would curb innovations and original thought.

During the past two decades staggering advances have been made in many areas of cosmetic science. The field of objective efficacy evaluations has created a rapid flow of publications.

Although much remains to be done, the pace of scientific discoveries and technical developments has been rapid and appears to be accelerating. These advances have also been accompanied by setbacks, notably inconsistencies in technical procedures and disparate data interpretations used to support efficacy claims. In these respects, distinct guidelines in efficacy testing have been proposed independently by Colipa and the EEMCO group. They highlight the steps necessary for rigorous experiments and for clear interpretation of data. The allegation made by Dr Roberts about the EEMCO publications is particularly misleading. Indeed, in all instances, EEMCO has stressed the importance of robust scientific work supported by accurate statistical analysis. In addition, EEMCO, and many other researchers, are convinced that any specific and objective measurement only provides information about a restricted aspect of global cosmetic efficacy. A thorough assessment is most often encouraged, even though it has limits, as many variables cannot be controlled adequately. The case of sun protection factors (SPF) presented by Dr Roberts reveals a contradiction in her plea. This is a unique standardized procedure for efficacy testing; its relevance is repeatedly disputed. As a result, Dr Roberts cites it as an example of a 'standard test which needs to evolve with time'. This statement illustrates how standardization can be advocated and rejected in the same sentence. It also shows a diversity of expectations of a magic 'standardization' by different individuals. Indeed, SPF is only indicative of comparative efficacy against UV-induced erythema. It cannot cope with the interindividual physiological variability among subjects, even of the same phototype. It is clear that interlaboratory differences are important and also work against standardization applied in this field. Furthermore, erythema-driven SPF cannot be extrapolated as an indisputable predictor for UV-induced immunosuppression and UV-induced carcinogenesis. In short, both experts and laypeople must be aware that 'a controlled laboratory situation is a far cry from general slapping on of sunscreen on the beach ...'. Revisiting SPF standardization would be a huge and highly controversial topic! I am also less enthusiastic than Dr Roberts with regards to the Boots star rating system for assessing UVA protection. This approach has an attractive marketing appeal, but I do not perceive any underlying robust scientific background to it. I rather prefer the assessment of the 'persistent pigment darkening' method as used in Japan, or any other similar objective evaluation. However, for many diverse reasons there are opponents to such measurements and I am quite sure that any standardized method whatsoever would attract a round of confusing detractors. In short, in some branches of dermocosmetology,

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efficacy assessments do not benefit from indisputable norms. Skin physiology is so diverse in its facets, and so variable and sometimes unpredictable among individuals that it precludes any simple cookbook rule of evaluation. As a result, there is currently no definite and definitive link between standardization, scientific consensus and progress in cosmetology. This situation is unfortunate, however I do not foresee any improvement on the horizon. Nevertheless, the pace of change is nowhere quicker than in technology and biology. One day, certainly, a breakthrough will come in the controversial area of rating cosmetic efficacy. To remain realistic today, count whenever possible, measure when you can, and if there is no measurement, invent one. However, with the help of, or in spite of, ideas and technology, it all comes down to assessing one individual at a time.

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#### Author's reply

Editor – I am flattered and delighted to have a response from Professor Piérard.<sup>1</sup> Despite the length of his reply and our differing backgrounds, I suspect we share many of the same views and objectives.

We both share the view that our primary interest is the consumer. We both aspire to the best possible quality in cosmetology, as in science in general, especially when concerning safety or efficacy. It is precisely because of the variability in human physiology that I believe we should standardize other variables as much as possible.

I shall reply to specific points raised by Professor Piérard, where I suspect originally I may not have made myself clear.

Firstly, I apologise if my reference to the European Expert Group on Efficacy Measurement of Cosmetics and Other Topical Products (EEMCO) was misleading.<sup>2</sup> It was a quotation from Professor Piérard's guest editorial in the June 2000 edition of the International Journal of Cosmetic Science, Volume 22, Number 3, Pages 163–166, entitled: 'EEMCO onward and upward. Streamlining its endeavour at the European venture in cosmetic efficacy testing.' The full quotation is: 'We are well aware that standardization of procedures may erode experimental freedom and lead to 'cookbook practice'. By contrast, EEMCO guidance will continue to respect creativity and the obligation to think and to place the needs of the consumer first.' I hope this clarifies matters.

Secondly, my reference to the Boots UVA star rating system was not a personal endorsement of this method over others. I merely intended to point out that the imposition of a standard, in particular one that could convey a marketing advantage, had the effect of rapidly improving the quality of

UVA protection afforded by sunscreens marketed in the UK. Prompted by Professor Piérard's response, however, I would rather not see another UV measurement standard that involves irradiating volunteers with relatively large doses of UV at high intensity.

Finally, I agree that revisiting sun protection factor (SPF) standardization would be a huge and controversial topic. Nevertheless we should not bury our heads in the sand and wish it had never happened. I was never a fan of sun protection by numbers but, at least when products achieved relatively low SPF values, the method was able to measure SPF with reasonable accuracy. The very high UV protection possible with modern sunscreens is beyond the reliability of the method and this is why I suggested that it needed to evolve. It would be preferable to temper the labelling within the range of accuracy of the existing method. I appreciate that SPF measurement based on an erythema action spectrum may not predict UV-induced immunosuppression or carcinogenesis but it has driven the development of more effective sunscreens.

Standardization may well be an unrealistic aspiration, whether it relates to safety or efficacy. It certainly is not the easy option, given the political machinery that would have to be moved to achieve it.

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#### Author's reply

Editor – Unlike Professor Marks<sup>1</sup> we do not see our recent article<sup>2</sup> either as a retreat from our previous position,<sup>3</sup> as an apology, or as evidence of personal development, but as a clarification of our position. We are, however, delighted that Professor Marks appears to share our view about the sun exposure behaviour that should be encouraged and the need to communicate this information openly and honestly. We still believe that the basis for current advice to reduce exposure to sunlight should be reviewed in a formal and quantitative manner. The challenge will then be to regain the public's trust by correcting the misleading messages that have been promulgated in health education campaigns and materials.

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## A sunny rapprochement

Editor – It would appear that Ness and colleagues have moderated their claims<sup>1</sup> from those stated some two years ago.<sup>2</sup> They now agree that moderation in sun exposure is indeed the appropriate approach. This is the same approach as mine and, I believe, that of the majority of dermatologists, at least as far as fair-skinned subjects are concerned. Dark-skinned people are essentially not at risk from sunlight-induced cancers, although they are still clearly subject to sunlight-induced skin ageing, as demonstrated by dark-skinned elderly folk who live in tropical climes.

Nevertheless, Ness and his co-authors still do not seem to recognize that there are differences between exposure to sunlight's ultraviolet (UV) radiation on the one hand and to its warmth and visible light on the other. UV is present in the middle of the day (broadly speaking between about 10.30 am and 3.30 pm) in summer, and throughout the year in tropical latitudes. It is not UV that makes us feel good. The only components which do that are the warmth and visible light of the sun.<sup>3</sup> Nor do Ness *et al.* yet state that only small amounts of sun exposure to small areas of the body (say for about 5–10 min to face and hands, twice or three times a week) are enough to maintain vitamin D levels in fair skinned subjects (who are of course the subjects at risk of skin cancer) and that this is easy to achieve without sunbathing. Photoageing is not even mentioned by Ness *et al.*

The advice to fair-skinned sun expositors should be to take care in the middle of the day in summer and on sunny vacations but to enjoy the feel good factors of (1) the usually pleasant appearance of the sun's rays falling on our surroundings; (2) the mood-elevating effect of sun's visible light operating through our eyes, and (3) the sun's warmth. We will then not suffer sunburn, skin cancers or the eventual ubiquitous photoageing (all of which makes us look and feel bad, the latter often by being associated with dry, itchy skin).

So take care in the middle of the day in summer and on sunny vacations, even on cloudy or cool days, by seeking the shade, covering up or wearing copious sunscreen. Enjoy the sun at other times. Otherwise, many non-fatal skin cancers, itchy, unpleasant old-looking skin and relatively uncommon but fatal skin cancers will all continue to occur. From what I can assess of Ness and colleagues' latest work<sup>1</sup> however, they would now appear largely to agree with this as well!

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## Use of phenol to induce pigmentation in vitiligo

Editor – Vitiligo causes significant cosmetic disability in dark skinned populations. This is reflected in Omar Quayyam's poignant remark – 'A black spot on a white skin may be a blessing, but a white spot on a dark skin is a curse'.<sup>1</sup> While a search for an effective treatment for vitiligo continues, different surgical methods such as split thickness Thierch graft, punch graft, suction blister graft, etc. have been tried in recent years, to treat stable lesions of vitiligo.<sup>2</sup> Other reported surgical methods include dermabrasion,<sup>3</sup> dermabrasion with application of 5-fluorouracil,<sup>4</sup> and spot chemabrasion by the use of chemical caustics such as trichloroacetic acid.<sup>5</sup> These latter methods depend on the stimulation of follicular melanocytes with in the lesions, to produce spotty perifollicular pigmentation.<sup>5</sup> Phenol, an agent used to achieve medium depth to deep chemical peeling of face, is known to cause post inflammatory pigmentation as a complication in dark-skinned patients. Use of phenol in vitiligo has not been previously reported and we describe successful use of phenol to achieve pigmentation in vitiligo.

We use absolute phenol for this purpose. The preparation of the patient is essentially the same as in any phenol peel or chemical cautery. Informed consent should be obtained. The procedure should not be used in patients with a tendency towards keloids.

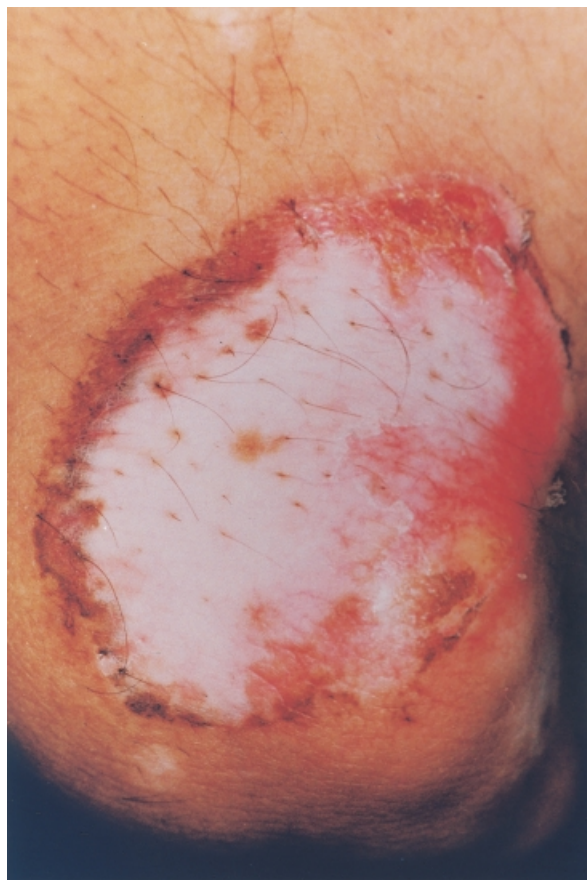
Phenol is applied lightly with a cotton stick applicator over the lesion, until a uniform frost is achieved. The patient may experience a mild burning sensation and discomfort, which is usually well-tolerated. Care should be exercised to prevent phenol streaming on to the surrounding skin.

The lesion undergoes erythema (Fig. 1) over the next 2–3 days, subsiding in 7–10 days. Mild scaling may result. Emollients may be prescribed at this stage. Hydrocortisone ointment may be used if erythema is severe.

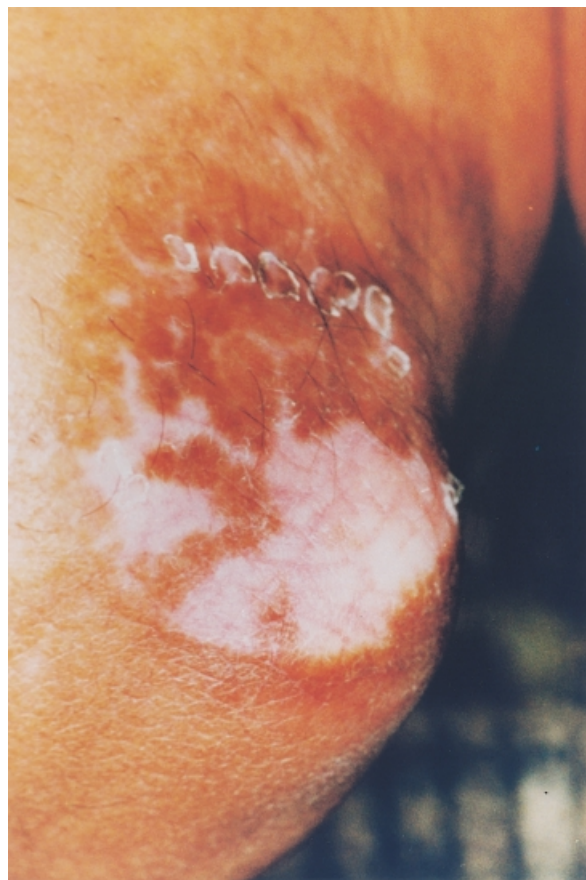
The erythema is followed by rapid perifollicular pigmentation within the lesion and a uniform pigmentation at the borders of the lesion, over 2–3 weeks (Fig. 2) The pigmentation is usually darker than the surrounding skin, however this is acceptable to our patients. The pigmentation can be further enhanced with the use of PUVA therapy after this period. The procedure can also be repeated after an interval of 6–8 weeks.

We do not recommend using this procedure on the face, as it may be difficult to achieve uniform, cosmetically acceptable

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**Figure 1** Vitiligo lesion over elbow, one week after phenolization, showing erythema.



**Figure 2** Lesion three weeks after phenolization, showing spotty pigmentation.

pigmentation. So far we have used the procedure in 10 patients and have found it to be very useful as it is easy, safe, and produces a rapid response in patients with darker skins.

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