Dr Holicks Study on UVB Light, Vitamin D and Solar D

Facts

UVB and Vitamin D

1. Solar ultraviolet (**UV**) radiation reaching the Earth's surface comprises two wavelength bands: UVB (280-320 nm) and UVA (320-400nm), the vast majority (in terms of numbers of photons) being UVA (>95%).[1] The adverse clinical effects of UV radiation are well documented and include sunburn (technically, **erythema**) in the short-term and skin cancer and photoaging in the long-term.[2] These adverse effects come about by different mechanisms.

2. UVR, specifically the UVB component, is also vital for normal health and development because it facilitates the production of vitamin D in the body. Vitamin D appears to play an important and beneficial role in numerous physiological systems, particularly bone and muscle development and immunity, and is essential for overall health. Vitamin D deficiency causes rickets in children and will precipitate and exacerbate osteopenia, osteoporosis, and fractures in adults.[3] Vitamin D deficiency has also been associated with increased risk of common cancers, autoimmune diseases, hypertension, and infectious diseases.[4]

3. Vitamin D is found in small amounts in some foods and may be obtained from consumption of those foods. However, the amount of Vitamin D obtained from food is generally only a small proportion of the average person's intake/production (less than 10%)[5], and most people get most of the Vitamin D they need from exposure to solar radiation (specifically, UVB).

4. Vitamin D is produced in the skin as a result of the photochemical interaction of UVB radiation and the steroidal compound 7-dehydrocholesterol (**7DHC**). Upon contact with the skin, photons of UVB radiation (290-315 nm) initiate the formation, from the irradiated 7DHC, of the precursor to vitamin D (**pre-D**). Pre-D is thermodynamically unstable and is subsequently converted into vitamin D, much of which is stored in body fat cells. Vitamin D which enters the circulation is converted to **calcidiol** in the liver and subsequently to its active form, **calcitriol**, in the kidneys. The serum concentration of calcidiol is the value used for determining 'vitamin D concentration' *in vivo*.[6]

Solar D Products

5. Laboratory testing commissioned by Nexdius and commissioned by the TGA & FDA demonstrates that the Solar D Products allow the transmission of higher levels of UVB radiation than 'regular' sunscreens of equivalent – or even lower – sun protection factor.[7]

6. The Solar D Products have been rigorously tested for sun protection against the relevant Australian standards, and the following matters have been established:

    6.1 they possess a Sun Protection Factor (SPF) of greater than 50, consistent with their labelling as 'SPF 50' sunscreens; and

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[1] Photoprotection and Vitamin D status.

[2] Ibid.

[3] Holick (2007) Vitamin D deficiency.

[4] Ibid.

[5] Holick Expert Report, at [].

[6] Ibid (no citation).

[7] While this is a fact as stated, it is acknowledged that the magnitude and significance of this higher transmission of UVB is in issue.

6.2 they satisfy the requirements for 'broad spectrum' sun protection.

The facts: Solar D, UVB transmittance and clinically significant vitamin D production

7. Solar D products are specifically formulated in order to permit increased transmittance of some of the UV radiation between 290-300nm (UVB), while maintaining very high levels of absorption of UV radiation outside of that range. As noted in the Internal Review Decision, both independent testing reports provided by Nexdius in the course of the submission and review of the Advertisement, and the TGA's own testing (reported in the TGA Lab Report), indicate that Solar D branded sunscreens let through more UVB radiation than other sunscreens, particularly in circumstances where the testing involved lower concentrations/thicknesses of sunscreens.

8. Dr Holick's studies demonstrates that, up to a certain threshold, there is a positive linear relationship between UVB exposure and vitamin D production, from very low levels of exposure. Accordingly, all transmittance of UVB, particularly between 295 and 297nm, causes a proportional increase in UVB production in the skin (until a threshold – discussed below – is reached), and so even low levels of transmission of UVB of the kind measured for the Solar D products will result in the production of vitamin D.

9. There is a threshold level beyond which further exposure to UVB radiation will not result in increasing levels of vitamin D. This threshold level exists because of an inherent photodegradation mechanism which ensures that continued UVB exposure will degrade pre-D (the precursor to vitamin D) in order to prevent excessive vitamin D production and therefore vitamin D intoxication.

10. Furthermore, UVB-induced vitamin D production is also dependent upon the surface area of skin exposed – it is cumulative over surface area. Accordingly, a small increase in UVB exposure of only a few percent, if applied to the whole or a large proportion of the body, could result in a production of an overall amount of vitamin D that is very substantial in terms of a person's daily needs. In fact, in some circumstances, with sufficient skin area exposure, at the right location, at the right time of day, for a sufficient period, the cumulative dose of vitamin D produced as a result of exposure to even just a few percent of the UVB radiation in sunlight could be equivalent to the person's daily requirements. That combination of factors is consistent with the contextual scenarios in which the Delegate found the Advertisement would be understood, that is, periods of extended exposure to sunlight in Australia while undertaking activities like swimming, surfing and sunbathing.

11. Dr Holicks research "*clinical information to show the impact that some marginal transmittance of* [UVB] *light would have on the body's ability to produce Vitamin D with the Solar D sunscreen applied and in comparison to other sunscreens*".In particular, there is compelling evidence, presented in the Dr Holcik's's expert report, that the increased UVB transmittance permitted when Solar D sunscreen is applied to the skin will result in vitamin D production that is physiologically meaningful and, particularly when applied to large areas of exposed skin, capable of making a substantial contribution to the user's daily vitamin D requirements. Moreover, the expert evidence is also that Solar D can permit increased UVB transmittance compared to regular sunscreens of the order of tens of times, meaning that the amount of vitamin D which can be produced when Solar D is used instead of an ordinary sunscreen is of far greater magnitude.

The facts: Regular sunscreen use and vitamin D deficiency

12. There is an argument that sunscreen use does not materially impact vitamin D production, specifically that sunscreen use does not cause clinically meaningful decreases in vitamin D levels.

13. It is significant that such a conclusion is not based on the clinical data regarding the efficacy of sunscreen (which show that sunscreens are highly effective at blocking vitamin D-producing UVB radiation) but is based on assumptions about the behavioural patterns of sunscreen use which could explain why sunscreen use is not strongly correlated with vitamin D deficiency (because sunscreen is not routinely applied correctly).

> "When adults topically applied a sun screen properly…the amount of vitamin D3 produced in the skin was reduced by >95%..."

14. Sunscreen SPF and broad-spectrum ratings are not influenced by behavioural data but are the direct result of strictly controlled laboratory tests. Research shows clearly that if sunscreen is used as intended, it can be so effective at reducing vitamin D production that it can lead to potential deficiency.[8]

15. The consequence of this effect has been noted with concern by researchers in this field, including Dr Holick's expertese in numerous articles. It is of particular significance because vitamin D sourced from UVB is reported to contribute a vast majority (up to 90%) of people's vitamin D serum concentration at any one time.

16. In comparison to dietary vitamin D where, for example, one serving of swordfish (a food uncommonly high in vitamin D) is equivalent to 566 IU of vitamin D, one minimum erythemal dose (**MED**) of UVB radiation is equivalent to 10,000-20,000 IU of vitamin D.

17. As such, the evidence supporting the UVB transmittance of Solar D sunscreens, when considered alongside the evidence that vitamin D deficiency can readily occur where regular sunscreens are used extensively *in a correct manner*, is sufficient to support the promotion of the Solar D products for the benefit of wider health outcomes.

The facts: UVB radiation, sunburn and other kinds of solar UV radiation-induced damage

18. Another argument about Solar D's cliam is that, in the absence of any evidence to the contrary, UVB radiation causes, or contributes to sunburn, skin damage and skin cancer, and therefore that any additional UVB transmittance permitted by Solar D sunscreen (compared to other sunscreens) is likely to compromise the product's protective efficacy in all of those respects.

19. In particular we make reference to an article by the American Skin Cancer Foundation which states that UVB radiation is the chief cause of "*skin reddening and sunburn, tends to damage the skin's more superficial epidermal layers. It plays a key role in the development of skin cancer and a contributory role in tanning and photoageing*".

20. There is no doubt that solar UV radiation can be extremely damaging, however, importantly, different wavelengths of UV radiation are responsible for different kinds of solar UV radiation-induced damage such as sunburn, photoaging (including elastosis and wrinkling), and DNA damage which may cause skin cancer.

[8] Holick Expert Report

21. Vitamin D production and erythema both occur maximally between approximately 295 and 300 nm. However, the erythema action spectrum suggests that *both* UVA and UVB radiation are responsible for erythema and the duration of exposure and percentage of body surface area exposed to UVB wavelengths affect vitamin D production and erythema differently.[9]

22. To simplify the multifactorial process of erythema, the sun protection factor (**SPF**) index is used multinationally as the primary measure of sunscreen protection against erythema/sunburn. Simply put, a sunscreen with an SPF rating of 15, when applied correctly to an area of skin, will extend the time it takes for that skin to burn by 15 times.

23. Relevantly, independent testing and the TGA & FDA laboratory reports show that the Solar D branded sunscreens met the industry standards for SPF 30 and SPF 50 for the respective products and also for broad-spectrum UV protection. On this basis, the Solar D products must, by definition, be as effective as comparator sunscreens with equivalent SPF and broad spectrum ratings (and more effective than comparator sunscreens with a lower SPF rating) at preventing erythema. This is so even though they happen to permit increased levels of UVB to be transmitted.

24. The protective efficacy of the Solar D products is particularly significant when considering the results for UVB transmittance from the TGA Lab Report. As noted above, the Solar D products permitted greater UVB transmittance than all of the comparator products, one of which was a Nivea sunscreen with an SPF15 rating. In other words, the Solar D products permitted greater UVB transmittance than the Nivea product (which is beneficial for vitamin D production in the skin) while at the same time offering significantly <u>better</u> protection against erythema (at SPF 50).

25. From the foregoing, it is clear that the Solar D products live up to their claim of allowing the production of some beneficial vitamin D while providing the same level of protection against sunburn as comparable regular sunscreens.

26. Other solar UV radiation-induced damage depends on the ability of different wavelengths of radiation to penetrate the skin. Different wavelengths of UV radiation are therefore responsible for different kinds of damage such as photoaging, including elastosis and wrinkling, and DNA damage.

27. As established in Dr Holick's expert studies, although UVB radiation (comprising short, high energy wavelengths) can be expected to penetrate more deeply into the skin than longer, low energy wavelengths (*e.g.* UVA), the skin contains a series of macromolecules that specifically absorb UVB photons and prevent them from travelling beyond the epidermal-dermal junction in the skin.

28. In contrast, UVA photos are not absorbed and therefore travel through the epidermis and deep into the dermis. This is significant because photoaging and elastosis in particular occur in the dermis where there is an abundance of elastin fibres. The inability of UVB photons to reach the dermal layer means that UVA radiation is primarily responsible for solar UV radiation-induced photoageng/elastosis. As such, any concerns that Solar D products might increase the risk of photoaging and elastosis would be misconceived because that damage is not relevant to the radiation which Solar D permits to pass, i.e. UVB.

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[9] Effects of ambient sunlight and photoprotection on vitamin D status., Citation 17 and 18; Vitamin D in Health and Disease: Current perspectives, citation 52; Small doses from artificial UV sources elucidate the photo-production of vitamin D; On the relationship between the erythemal and vitamin D action spectrum weighted uv radiation, figure 1; the action spectrum for vitamin d3: initial skin reaction and prolonged exposure, figure 3.

29. On the other hand, DNA damage is likely to be caused by both UVA and UVB radiation. Absorption of UVA radiation and UVB radiation in the epidermis and dermis can cause the formation of free radicals and UVB-induced dimers respectively, both of which can damage the structure of DNA. The UVB-induced dimers are usually inherently repaired however unrepaired dimers are mutagenic and particular genes, such as the p53 tumor suppressor gene, if they are damaged and not repaired, may lead to nonmelanoma skin cancer.[10]

30. Accordingly, the fact is that the increased UVB transmittance of the kind and extent that is associated with the Solar D products is not associated with any increase in either sunburn or those other kinds of damage.

Summary: Compliance with the Code

31. In short:

    31.1 Solar D enables the body to generate some of the vitamin D the body needs (which is also significantly more than is able to be generated when regular sunscreens are used);

    31.2 Ordinary sunscreens, if properly used, will inhibit the body's ability to generate significant amounts of vitamin D and may prevent it altogether; if they do enable the body to generate Vitamin D, they only do so in significantly lower quantities than can be generated if Solar D is used;

    31.3 Solar D enables the body to produce some vitamin D while providing the same level of protection as regular sunscreens do against sunburn.

32. The evidence establishes that:

    32.1 The Solar D products permit transmittance of some UVB radiation, being the radiation which allows the body to produce vitamin D;

    32.2 Regular sunscreens, when applied properly, will not allow transmittance of nearly as much UVB radiation, if any;

    32.3 The UVB transmittance permitted by the Solar D products is capable of causing a physiologically meaningful (non-negligible) amount of vitamin D production to naturally occur in the skin; in fact, in contexts contemplated by the Advertisement (extended periods of exposure of large parts of the body), the amount of vitamin D which is allowed to be produced may approach a person's entire daily needs (or will at least make a significant contribution to those needs);; and

    32.4 Given their established SPF ratings, the Solar D products will protect the skin against erythema/sunburn as well as comparator products with equal SPF and broad-spectrum ratings.

Dated: 1st October 2016

[10] Ibid.