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SPF Consulting Labs, Inc.

April 30, 2002

DOCKETS MANAGEMENT BRANCH (HFA-305)
FOOD & DRUG ADMINISTRATION
5630 FISHERS LANE, - Room #1061
ROCKVILLE, MD 20852

4354 '02 MAY 1 P12:02

WRITTEN COMMENT and NEW INFORMATION REGARDING PROPOSED MAXIMUM SPF LABELLING for SUNSCREEN DRUG PRODUCTS.

Dear Sirs; **re: DOCKET 78N 0038**

PURPOSE: This comment specifically addresses the proposed maximum SPF level recommended by the AGENCY. And, this comment is a reaction to the Agency's response to our prior comment.(Comment No. C000282) regarding the limit of the SPF permitted on Sunscreen Drug Products.

NEW INFORMATION: We have again conducted a scientific study of sun exposure by human sunbathers under what we believe are "worst case" conditions. Our Study, this time, has included over 200 individuals exposed to midsummer sun on the southernmost major beach in the Continental United States. Our sampling was increased in order to address the concerns of the agency over the small , 62 subject, sample size which we used in the original survey submitted eight years ago, and the UV Exposure was determined under controlled and accepted conditions using the standardized procedure specified in the FDA Proposed Rules (Federal Register, Aug. 25, 1978 p 38260) using two freshly calibrated R-B meters as described in the Proposed monograph. Moreover, full day radiation exposure was calculated for subjects from direct reading of their UV exposure, and ranges of probability of exposure were calculated for the full cohort and most precisely for the high exposure group, from whom the conclusions about risk were drawn. In addition, our exposure data significantly verified the prior UV B irradiadiance measurements, of over 29 MED reported to FDA(Comment No.C000282). Finally, the study was published in a peer-reviewed journal this February.

We have enclosed a copy of the published study (Cosmet.& Toil., **117**, no.2, p55 – 68) for the precise purpose of assisting the agency in determining appropriate limits to apply to SPF within the United States. SPF Consulting Labs is not associated with any major brand or factor in the market, and ,as such we purport to maintain unmatched objectiveness in the evaluation of facts dealing with UV exposure.

COMMENT: We conclude that SPFs above 50 are unwarranted in any condition, for the prevention of sunburn. We also conclude that SPFs of up to and including 50 are warranted and have become accepted drug products which serve a useful purpose, and should be recognized in the regulatory monograph..

Sincerely;

CHRIS VAUGHAN
President – SPF Consulting Labs, Inc.

78N-0038

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Mr Dobbs, and Dr. Lipnicki;

I hope you find my improved study helpful in limiting the SPF race., and as a justification for a new and realistic category of sunprotection. I recognize, and support, the need for substantial UVA protection in High SPF products. And I support the need for Photostable UVA protection !

As a note of introduction, I am the original inventor (from 1985 to 1994) of the Banana Boat Sunscreen Line, and served as VP R&D at Sun Pharmaceuticals, until they were purchased by Playtex. I own a small sunscreen development lab near Ft. Lauderdale, and manufacture for a number of small sunscreen marketers. I have published approx. 25 scientific papers in peer reviewed journals, including two book chapters, and am a Fellow of the Society of Cosmetic Chemists, and a 30year member of the Am.Chem. Society. I also am proud to be the instigator of the Florida Sunscreen Symposium series for the Society of Cosmetic Chemists. This is the world's leading (and largest) sun care technology forum. We bienially invite the leading investigators in sunscreen areas of chemistry, biology, physics, medecine and regulation. Our next Symposium (the ninth) will be in Sept. 2003, at the Grand Floridian Hotel, at DisneyWorld, in Orlando, Florida.

Please feel free to contact me if you have any questions.

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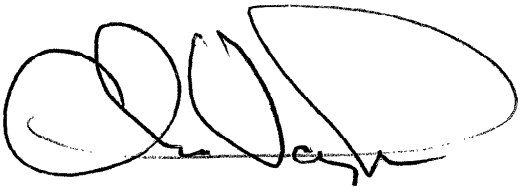

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The South Beach Sunscreen Survey 2001

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Key words
Sunscreen, UVA, UVB, SPF, skin type, sunburn resistance

Abstract
A scientific survey of sunbathers on Miami's South Beach in July 2001 helps answer the questions, "How much sunscreen SPF protection do I need?" and "What are consumers really using?".

A scientific survey of sunbathers on Miami's South Beach in July 2001 provides new information needed to answer the questions, "How much sunscreen SPF protection do I need?" and "What are consumers really using?".

Comparison to results of a similar but smaller survey conducted in July 1993 further substantiates the need for SPF 50 protection in severe conditions. More important, the new study discloses a remarkable increase in the use of high SPF products, reflecting improved consumer awareness of their need for adequate protection, and their resulting changes in preferences and choices of protection.

This study evaluates the level of risk and protection existing under a "worst case" situation in which the UV exposure approaches 30 Minimal Erythemal Dose (MED).

How Much Sun Protection Do I Need?

It is remarkable that we could find no references to published research designed to determine the maximum level of sun protection justified under worst case conditions within the territorial United States. The best references we found were photometric UV studies conducted at various US locations, and brand surveys derived from samplings of warehouse invoices from major chain stores.

Ours is the first study we know of that combines observation of exposed subjects with UVB dosimetry in a severe location. Though this may appear as a significant scientific void, it is not unusual; in many fields of science such voids exist with regularity (see sidebar).

Since the development of Robinson-Berger UV meters, many thorough studies of solar irradiance have been conducted[4] in various locations across the United States. These studies have clearly identified sites of extreme irradiance, such as Florida, Arizona and Hawaii. However, in the two studies reported here, eight years apart, we accurately measured 50% higher levels of UVB irradiance than were considered possible when the regulations controlling sunscreens were proposed.

Collecting UV irradiance data at severe locations can provide information to support rational market (and regulatory) decisions regarding the delivery of UV protection. Irradiance data becomes meaningful when it is combined with human exposure data, including the sensitivity (skin types) of exposed individuals, and the time spent in exposure by actual subjects, and the level of protection that they are using. Only

Filling in the Gaps

Research gaps exist in many scientific specialties. For example, physicists only recently claim to understand the mechanics of the most common physical force we encounter: gravity.[1] But, as yet, there have been no reliable or successful attempts at the modification of gravitational force.

Until recently, no trained biologist had ever observed a living specimen of one of Earth's largest creatures. Only sailors and fishermen had observed the giant squid in a live state until about five years ago.

We chemists will find it difficult to locate a basic textbook that explains mechanically why some things mix[2] and others don't. Recent guidance in this area, however, may be found through the tables of solubility parameters (molecular stickiness) listed in the *Cosmetic Bench Reference*.[3]

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then can we answer the burning question: "How much protection do I need?"

This is indeed the paramount question in the sun-care industry. This is the first question any consumer wants answered. It is the primary question every sun-care marketer needs to address, and for the regulators it is a question that frames the limitations to be posed upon the market.

The goal of the survey described here was to measure and record both the exposure and probable injury to sunbathers caused by solar UV, in a worst case situation. In 1993 we (Raketty and Vaughan) conceived that we could determine the exact UV exposure of the sunbathers and estimate their level of sunburn injury relatively precisely if we did the following:

1. Measure the incident UV (in MED values);
2. Simultaneously record the levels of UV protection (SPF) being used by an exposed population;
3. Rate each sunbather's skin type; and
4. Measure each sunbather's time of exposure.

Then we could calculate the sunburn (UVB) injury according to the following formula:

$$\text{MEDs Absorbed} = \frac{\text{Exposure MEDs x Adjusting Factor for skin type}}{\text{SPF protection worn by the sunbather}}$$

The Adjusting Factor compensates for the fact that MED varies with skin type. According to Pathak's study on irradiation of unexposed buttock skin,[5] it takes approximately 30% more time (or radiation) to burn Type III (medium) skin than Type II (light) skin, and it takes an additional 30% more time (or radiation) to burn Type III skin than Type I (very light) skin. Thus, a sunbather exposed to 15 MEDs with light skin (30% more sensitive) wearing SPF 22 will have received slightly less than enough UVB to produce a minimal (just visibly pink) sunburn, as follows:

$$\text{MEDs Absorbed} = \frac{15 \times 1.3}{22} = 0.89 \text{ MEDs}$$

The practical response to the question "How much sun protection do I need?" has initially been limited by the amount of sun protection available (see sidebar), as well as the consumer's perception of its effectiveness.

Surveying Sunbathers

The 1993 survey: The purpose of the first South Beach Sunscreen Survey (completed in1993) was to assist the regulators in determining the maximum level of UV protection to be permitted on a product label. The survey results were submitted to the US Food and Drug Administration (FDA)[25] during the one-year comment period following the publication of the Tentative Final Sunscreen Drug Monograph (TFM).[26]

After reviewing the initial 62-person survey, the FDA responded that the sampling was too small to extrapolate results onto the population of the United States. The FDA assessment is reasonably supported by statistical evaluation of the sample size. However, because no other scientific evidence was available, we are told, this study effectively supported the FDA's eventual decision to consider higher label SPFs because it, for the first time, defined the need for higher levels of UV protection than are permitted by the currently delayed Final Sunscreen Monograph.

The 2001 survey: Our follow-up 2001 South Beach Sunscreen survey was almost four times larger than the first, consisting of 208 subjects; and it introduced a new evaluation technique designed to produce predictions of UV damage with a statistically significant level of confidence.

The results of the 2001 survey support the conclusions of the original survey, with respect to the amount of solar UV radiation to which sunbathers are subjected, and the amount of protection that they must use under worst case conditions, to avoid more than one MED of sunburn.

The 2001 survey also measured UVA exposure; and for the first time we have quantitative, field-generated scientific evidence that may support the need for – and the level of – UVA protection in extended-wear (or mid-day) sun-care products designed to protect against UV exposure in an extreme environment. Although we surveyed sunbathers, we clearly expect the results to be transferable to those who must be exposed daily to solar radiation, as a result of their occupations or avocations.

Survey Methods

The First South Beach Sunscreen survey was conducted on July 3, 1993, and submitted to the FDA approximately six months later. The FDA's response was included in the Final Sunscreen Drug Monograph published in 1999. Our follow-up survey was conducted July 30, 2001. Both surveys were performed on bright sunny days.

The weather in Miami, Florida is not typically bright and sunny in June or July. In fact, National Oceanic and Atmospheric Administration 30-year weather records show that Miami has the distinction of leading the nation in precipitation, peaking in June,[27] with an average (mean) of 9.3 inches that month. The 2001 survey was delayed more than 20 days by

The Development of Sun Protection

Anyone asked for a practical response to the question "How much sun protection do I need?" must begin with a precise sun protection scale to express greater or lesser values. In 1975, the concept of SPF (Sun Protection Factor) was introduced by Sayre et al. at Coppertone.[6] Shortly thereafter, researchers in the irradiance area[7] concluded that an SPF of approximately 15 provided maximum protection, although at the time SPFs of up to 22 were feasible. The authors suspect that this assessment was based on the limited technical-level competence at that time, and also on a general belief that UVB doses above 15 MEDs per day were highly unusual. The first sunscreen monograph (proposed rule) of 1978 cites an example of 19 MEDs recorded atop Mauna Loa volcano in Hawaii. Currently the American Cancer Society recommends[8] a protection level of SPF 15 as a minimum.

Figure 1 shows the progression of increasing levels of SPF offered by the major marketers with respect to time. The maximum available formula potency in 1975 was SPF 15.

Because formula levels of sunscreening ingredients are limited by regulation, subsequent improved product benefits came as a result of the discovery of various synergisms.[9-12] Interactions between various ingredient components, which act to increase the UV blocking effect of the active ingredients, have resulted in continual product claim improvements.[13-20] The scientific progression of sunscreen synergism and efficiency will not be addressed in this article; it is covered by other articles and conferences.[21] However it is important to point out that researchers in the 1970s knew that adding common UV absorbers, such as padimate O, octyl salicylate, homosalate, or octyl methoxycinnamate, to mineral oil would provide a maximum SPF of 8 no matter how much UV absorber was added.[22] The discovery of the synergism of 3% oxybenzone and 7% padimate to provide SPF 15 protection was a remarkable advance[23,24] at the time. Recently one major brand has introduced SPF 70 protection.

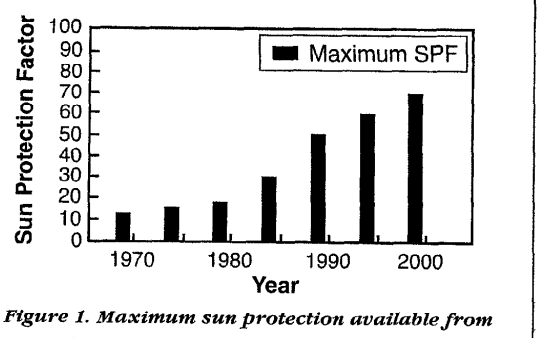

Figure 1. Maximum sun protection available from major brands

rain, and slightly lower total irradiance was recorded as a result.

Survey forms: The seven survey questions were designed for simplicity and directness. Each subject's brand preference and skin type awareness were the only expected fallout data, beyond the intended UV damage data.

The 2001 survey form (Figure 2) was changed to include room for more than one sunscreen product, and a question on UVA awareness was added.

Subjects: The subjects of this survey were primarily vacationers (approximately 80%). They were of all six skin types, although we only included the five lightest skin types based on normal accepted testing protocols. The nationalities encountered on Miami Beach were diverse, with between 30% and 40% being international tourists. We were surprised that the majority of the foreigners were using American products, despite differences in European

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SOUTH BEACH SUNSCREEN SURVEY II

Date: July 30th, 2001

Subject: *MALE*____ *FEMALE*___ *AGE:*_____ *est?*

SKIN RATING by INTERVIEWER:

VERY LIGHT LIGHT MEDIUM DARK DEEP DARK

QUESTIONS:

1. **WHAT SKIN TYPE DO YOU HAVE ?**
   VERY LIGHT LIGHT MEDIUM DARK DEEP DARK
2. **ARE YOU USING SUNSCREEN?** YES NO
3. **HOW LONG DO YOU EXPECT TO BE IN THE SUN?**
   Hours: 1 2 3 4 5 6 7 8
4. **WHAT SPF IS IT ?** _____ _____
5. **WHAT BRAND IS IT ?** Fill in below
   1. BANANABOAT _____
   2. COPPERTONE _____
   3. NEUTROGENA _____
   4. STORE BRAND _____
   5. HAWAIIAN TROP. _____
   6. COPPERTONE SPORT _____
   7. NO AD _____
   8. BAIN DE SOLEIL _____
   9. OTHER _____
6. **ARE YOU SATISFIED WITH IT?** YES NO
7. **DOES IT PROVIDE UVA PROTECTION ?** YES NO Don't Know

Interviewer: C. Vaughan S. Porter Jim Gilbert Linda Dyer _____

Figure 2. The survey form and questions

and domestic SPF scales. The profile of subjects for both surveys was very similar (Table 1).

Skin types: Our interviewers were trained in use of the Harvard six-level skin typing methodology (Table 2),[28] and were instructed to use it on each subject before asking the subjects to assess their own skin type (Table 1). Thus, two assessments of skin type were made in each case. We used the ratings by the trained evaluators (experts) for the sunburn projection data.

We were surprised that 29% of the 1993 survey population could not accurately identify their personal skin type. That proportion shrank to 5.3% in the 2001 survey. Of course, in light of the changes in self-protective behavior we observed, it would be reasonable to suppose the same population has an improved awareness of many of the factors involved in sun protection, especially where failure to learn could be associated with levels of personal discomfort proportional to the size of one's error.

Table 1. Profile of subjects

		1993		2001	
		N	%	N	%
Gender	Male	31	50.0	94	45.4
	Female	31	50.0	114	54.6
	Total	62	100.0	207	100.0
Average age	Male	32.2		33.0	
	Female	28.5		28.9	
	Mean	30.3		30.8	
Skin types	(I) Very light	4	6.4	10	4.8
	(II) Light	19	30.7	48	23.1
	(III) Medium	26	41.9	111	53.4
	(IV) Dark	12	19.3	34	16.3
	(V) Very dark	1	1.6	5	2.4
	Total	62	100.0	208	100.0

Awareness of skin type and sensitivity is indeed a major tool in personal control of UV-induced skin damage from over exposure. Numerous health and welfare organizations are using charts like the one in Table 2 (used courtesy of L'Oréal) to teach skin-type awareness. Clinical test data[5] predicts that a difference of approximately 30% in UV sensitivity separates each category.

Worst case UV exposure on South Beach: Three freshly calibrated Robinson Berger Type UV dosimeters[a] were used to monitor UVA and UVB during the 2001 survey, while only one UVB dosimeter was available for the initial survey in 1993. Nevertheless, similar levels of UVB exposure were recorded during both surveys: irradiation approaching 30 MEDs. 30 MEDs comprise enough radiation to give a Type III (medium) UV sensitivity subject 30 sunburn doses. Four doses will induce a painful bright red burn, while eight will result in blistering. We recognize that these conditions present a significant health risk.

Table 3 shows hour by hour irradiation recorded at the same place on two days eight years apart. We initially recorded the UV irradiation in MED units, but Table 3 also presents MEDs adjusted for more sensitive Type I and Type II skin.

Our "worst case" scenario is based on Type I skin subjects who are exposed to the extreme UV irradiation, near the longest day (and highest sun angle) of the year and at the southern-most major beach. Based on Pathak's irradiation study,[5] the erythemal effect on Type II and Type I skin is an approximate 30% increase in sensitivity between each skin type. Therefore, 28.1 MEDs for Type III skin, recorded in 1993 converts to 47.5 MEDs for very light (Type I) skin, while the 2001 survey exposed Type I subjects to 49.5 MEDs.

This is the portion of the study that scientifically addresses a real consumer need for protection up to SPF 50 for persons with light skin, exposed for 6 to 8 hours on a sunny June or July day at our nation's southern-most major beach, in Miami. This, we believe, constitutes the worst case scenario for sunscreens. Under these exposure conditions, even our suggested remedy may not prevent sunburn! An SPF 50 only serves to limit the UVB injury – for those wearing a heavy (2 mg/cm^2) layer of it – to approximately one sunburning UVB dose.

According to our count, 23.6% of the sunbathers in this survey used SPF 45 or higher. Our calculations, accounting for

[a] *Solar Light Co., Philadelphia, Pennsylvania USA*

Table 2. A Harvard-based skin typing chart used in the survey[36]

Hair	Complexion	Freckles	Sun reaction	Tanning	Phototype
red	very fair	+++	always burns	never tans	I
blond	fair	++	often burns	tans lightly	II
blond or light brown	fair to medium	+ to 0	sometimes tans	tans progressively	III
brown	olive	0	rarely burns	tans easily	IV
brown to black	dark	0	rarely burns	tans deeply	V
black	very dark	0	never burns	tans deeply	VI

skin type, exposure time, and SPF, project that none of these sunbathers went home sunburned. This observation, under extreme conditions, serves to substantiate the erythemal protection value of products in the SPF 30 to 50 category.

Results

The most alarming finding of the first (1993) survey was that more than 40% of the sunbathers surveyed went home with more than 4 MED, which *usually* results in a painful and damaging sunburn. By 2001 this proportion had declined to 21.2%, and the vast majority of the 21.2% projected to be sunburned were among the unprotected group, who used no product, or who applied SPF Zero (actually SPF 1, or less) tanning products.

The recent survey (2001) disclosed that Miami beach-goers who used sunscreen had addressed the sunburn problem with remarkably higher SPF protection and significantly reduced exposure time, such that only 3.0% of the sunscreen users received a painful sunburn.

Unprotected sunbathing: The 2001 follow-up survey revealed no significant change in the 20% of beach-goers who choose unprotected sunbathing. This group is divided between the "used nothing" subjects and the subjects who used SPF Zero or tanning oil. Together, this group was responsible for 90.7% of the severe sunburns over 4 MEDs, projected for the study group.

Table 4 shows that the greater number of subjects in the 2001 survey did not alter the 4:1 ratio of sunscreen users vs. unprotected subjects. Nor did it affect the ratio of tanning oils usage by women over men (3:1). The unprotected sunbathers were predominantly among the more pigmented subjects. In data not shown in Table 4, the portion of unprotected subjects who didn't use any sun product at all slightly favored males in both surveys (58% and 62%).

Protected sunbathing: The mean SPF of all products surveyed in 2001 was 24.1, versus 9.8 in 1993. That is a 246% change. Because some subjects used two products (which were averaged), the averaged mean SPFs were 20.1 and 7.3, which is a 275% change. Such a substantial change in the SPF preference levels disclosed by the survey subjects may result in reducing the level of UV injury experienced by the sunbathers in Miami. This is a very encouraging discovery.

We further evaluated the data with respect to sunburn sensitivity as indicated by skin type. The results are shown in Table 5. The mean increase in SPFs and decrease in exposure time combine to document a 272% increase in sunburn

Table 3. UVB radiation recorded in June on South Beach, Miami

Time	Hours elapsed	Irradiation rate (MED/h)	Cumulative dose (MED)	Cumulative dose adjusted for light skin (MED)	Cumulative dose adjusted for very light skin (MED)	Irradiation (%)
7/3/93						
09:00 am	0	0.88	0.00	0.00	0.00	0.00
10:00 am	1	2.20	3.80	4.94	6.42	13.5
11:00 am	2	4.32	9.59	12.47	16.21	34.1
12.00 pm	3	4.11	14.39	18.71	24.32	51.1
01:00 pm	4	4.71	18.50	24.05	31.27	65.7
02:00 pm	5	3.77	22.32	29.02	37.72	79.3
03.00 pm	6	2.74	25.06	32.58	42.35	89.1
04:00 pm	7	1.71	26.77	34.80	45.24	95.1
05:00 pm	8	1.37	28.14	36.58	47.56	100.0
7/30/01						
09:00 am	0	0.63	0.00	0.00	0.00	0.00
10:00 am	1	1.45	0.89	1.16	1.50	3.0
11:00 am	2	4.80	3.44	4.47	5.81	11.7
12.00 pm	3	6.39	8.40	10.92	14.20	28.7
01:00 pm	4	7.12	15.60	20.28	26.36	53.2
02:00 pm	5	5.52	20.53	26.69	34.70	70.1
03.00 pm	6	4.30	24.76	32.19	41.84	84.5
04:00 pm	7	3.70	27.95	36.34	47.24	95.4
05:00 pm	8	1.74	29.30	38.09	49.52	100.0

Table 4. Unprotected sunbathing

	1993	2001
Subjects not using sun product - bare skin	12.9%	14.9%
Subjects using non-protecting product (SPF 0)	6.4%	5.8%
Percent unprotected subjects	19.3%	20.7%
Count of unprotected subjects	12	43
Tanning oils (SPF 0) used by women	3	9
Tanning oils (SPF 0) used by men	1	3
Unprotected sunbathers - Type I/II skin	25%	30.2%
Unprotected sunbathers - Type III/IV skin	75%	69.8%
Unprotected sunbathers - male	33%	49%
Unprotected sunbathers - female	67%	51%

Table 5. Protected sunbathing

Skin type	Population portions		Exposure		SPFs		Protection (Avg SPF/h)	
	1993	2001	1993	2001	1993	2001	1993	2001
Type I	6.5%	4.8%	5.50 h	2.60 h	15.7	27.8	2.9	10.7
Type II	30.6%	23.1%	4.74	3.36	8.5	20.8	1.8	6.2
Type III	41.9%	53.4%	4.04	3.34	8.1	21.9	2.0	6.6
Type IV	19.4%	16.4%	4.83	2.97	9.4	16.5	1.9	5.5
Type V	1.6%	2.4%	3.00	2.20	0.0	10.2	0.0	4.6
Mean			4.48 h	3.22 h	9.8	24.1	2.2	6.0

protection being used by sunbathers in the field (i.e., on the beach) under severe conditions.

Multiple product usage: During the 1993 survey we discovered that an unexpectedly large number (38.7%) of the female subjects were using two different sunscreen products: one for the face, and one for the body. Generally the multiple product users chose a higher SPF on the face and a lower SPF on the body. Our 2001 sample population has increased their SPF preference, and reduced their use of multiple products, as shown in Table 6. It appears that products once used only for the face may now be applied all over.

The widespread usage of two different sun products in 1993 was a surprise to us, and it caused us to modify our survey form before the 2001 study to allow room for multiple responses to the brand and SPF questions.

Brand data: The brand usage data showed a larger than expected component of small brands and store brands. This component varied markedly with the market shares generated

Table 6. Multiple product usage

	1993	2001
Users of multiple products	22.6%	13.6%
Percent of women who use two products	38.7%	18.4%
Percent of men who use two products	6.4%	7.5%

by the major surveying organizations, however the order of brand predominance did generally correspond with the commercial surveys.

The top brands in 1993 were Coppertone, BananaBoat, Nothing, Panama Jack, Hawaiian Tropic, Vaseline.

In 2001 the top brands were BananaBoat, Coppertone, Nothing, Hawaiian Tropic, Australian Gold, No Ad.

Exposure times and protection: The mean exposure time spent by survey subjects on the beach was 4.5 hours in 1993. In 2001 this exposure had declined to 3.2 hours, while the mean SPF of products used by the subjects on Miami's South Beach rose from 7.3 to 20.1 during the 8-year interval.

The protection and exposure times were combined with the incident UV measured during the survey. With the exception of the all day (6+ hour) sunbathers, we were unable to record the exact time position, during the day, of the exposure span of each individual subject. Therefore the exposure times may be matched with both the maximum and minimum possible UV dose to provide exposure values that may be treated statistically. For example, 1993 subjects who were exposed for 5 hours were clearly exposed to a UV dosage that could not be lower than 13.8 MEDs, because that was the smallest UVB dose recorded in any 5-hour span during the survey. Likewise they could not have been exposed to greater than 22.3 MEDs. In the 2001 survey, 5 hours exposure provided between 20.5 and 24.5 MEDs, with 100% probability.

Table 7 shows the range of UVB exposures possible during all time spans during the day, as well as the most likely (mean) exposure for a given time span. Table 7 also shows the variance (max dose minus min dose) for each time span as well as the

Table 7. Cumulative exposure to UVB over selected exposure periods in June on South Beach, Miami

Time	Hours elapsed	Dose at 2 h (MED)	Dose at 3 h (MED)	Dose at 4 h (MED)	Dose at 5 h (MED)	Dose at 6 h (MED)	Dose at 7 h (MED)	Dose at 8 h (MED)
7/3/93								
09:00 am	0							
10:00 am	1	9.6	14.4					
11:00 am	2	10.6	14.7	18.5	22.3			
12.00 pm	3	8.9	12.7	18.5	21.3	25.1	26.8	
01:00 pm	4	7.9	10.7	15.5	17.2	23.0	24.3	28.1
02:00 pm	5	6.6	8.3	12.4	13.8	18.6		
03.00 pm	6	4.5	5.8	9.6				
04:00 pm	7	3.1						
05:00 pm	8							
Max		10.6	14.7	18.5	22.3	25.1	26.8	28.1
Mean		7.3	11.1	14.9	18.6	22.2	25.6	28.1
Min		3.1	5.8	9.6	13.8	18.6	24.3	28.1
Variance		7.5	8.9	8.9	8.5	6.5	2.5	0.0
% Variance vs mean		103%	80%	60%	46%	29%	10%	0%
Number of exposures		5	10	18	11	11	0	6
7/30/01								
09:00 am	0							
10:00 am	1	3.4	8.4					
11:00 am	2	7.5	14.7	15.6	20.5			
12.00 pm	3	12.2	17.1	19.6	23.9	24.8	28.0	
01:00 pm	4	12.1	16.4	21.3	24.5	27.1	28.4	29.3
02:00 pm	5	9.2	12.4	19.6	20.9	25.9		
03.00 pm	6	7.4	8.8	13.7				
04:00 pm	7	4.5						
05:00 pm	8							
Max		12.2	17.1	21.3	24.5	27.1	28.4	29.3
Mean		8.1	12.9	18.0	22.5	25.9	28.2	29.3
Min		3.4	8.4	13.7	20.5	24.8	28.0	29.3
Variance		8.8	8.7	7.6	4.0	2.3	0.4	0.0
% Variance vs mean		109%	67%	42%	18%	9%	1%	0%
Number of exposures		58	39	50	12	7	2	8

percentage of variance versus the mean. This percentage defines the precision of the sunburn estimate for each individual subject. As can be seen from Table 7, which shows the centralized intensity of the UV (from 11 AM to 2 PM), the range of possible MEDs declines with increased exposure.

The increased certainty of the higher exposure values provides a high level of confidence for all overexposure conclusions based on this survey. This is because data variances decrease as exposure periods get larger. Thus, the data from the high-exposure subjects, who were the focus of all questions investigating overexposure in the 2001 survey, showed mean deviations of less than 18%, which is low enough to yield projections of high precision.

Discussion

Other contributing factors: Many other arguments still remain, affecting the determination of what is an appropriate level of protection. Our study only provides a scientific benchmark from which those arguments may begin.

For example, Vorhees[29] has determined that as little as 0.25 MED will trigger the release of matrix metalloproteinases, such as collagenases and elastases, which may result in wrinkling and photoaging. Elias[30] has reported that a similar level of exposure depletes the skin's retinol (vitamin A), which is not normally replenished for four to five days.

Table 8. Mean UV exposures and erythemal damage projected (2001)

Hours Exposed	Average number of predicted burns
1	0.8
2	2.6
3	3.6
4	2.4
5	3.1
6*	25.2*
7	0.6
8	6.1
Mean	3.53

* 3/4 of this group were unprotected

Other researchers have claimed that very few sunscreen users apply the amount of sunscreen needed (2mg/cm^2) to provide the label SPF.[31] Indeed, Yankell[32] long ago reported that UV absorbers may be absorbed through the skin, resulting in a loss of protection during wear. Lorenzetti[33] in 1975 reported that formula components such as proteins can greatly effect penetration of sunscreens. Recently, Bronough and Yourick[34] identified hydrolysis by esterase enzymes found in the skin as a pathway for UV absorber loss. Conversely, Stockdale[35] has suggested that resinous materials such as PVP can trap sunscreens in a matrix on the skin surface to prevent penetration.

For this study, and in our calculations, we have decided to use the most common, but possibly not the best, benchmark of UVB damage. That benchmark is 1 MED, the UV exposure that gives the first slight redness (erythema) to exposed Type III human skin.

Sunburn resistance: It was not our goal to study UVB exposure in unprotected subjects. However, we found this cohort to be involved in most of the major intended conclusions, either as sources of anomalies, or because they introduced data deviations that had to be investigated because they were so skewed. Because each investigation seemed to end up on the backs of the great unprotected, that group may be a very fruitful field to investigate. They are vastly overexposed to UV, they are the sales holdouts, and they are possibly the future cancer cohort. They do not respond to UV the way we vacationers do. (Approximately 80% of our subjects were vacationers.) *They are sunburn resistant.*

After we generated projected burn data (Table 8), we tried to find a relationship between hours exposed and the primary expected overexposure effect, erythema. The six-hour exposure group provided a severe anomaly. On further investigation we saw that this group consisted of mostly unprotected sunbathers who should have been placed in the hospital, according to our projections. In fact, most of these sunbathers (the hard-core tanners) were still "soaking up those rays" when we passed them again in the afternoon on the way to our cars.

For the 6-hour sun-exposed group we predicted an average of 25 sunburn doses per subject, with some receiving up to 39 MEDs. The unprotected group averaged 13.2 MEDs adjusted for skin type, split between the oil-users (Avg 21.2 MEDs) and the bare-skinners (Avg 10.1 MEDs). We estimate that this group most likely exhibits a natural protective response equivalent to an SPF of 4 to 8, because we did not observe the expected symptoms of overexposure on these sunbathers.

UVA exposure: The 2001 survey included a question designed to evaluate each subject's awareness of the UVA protection provided by the products the subject used. The sample population responses to this question were rather confused and highly inaccurate. 12% admitted they didn't know about the UVA protection offered by their products, and an additional 26% claimed they were getting UVA protection,

when it was not in the product! Only 47.7% of the products surveyed contained the recognized strong UVA absorbers titanium dioxide, zinc oxide or avobenzone, while 73.6% of the subjects thought that they were getting UVA protection. Curiously, amidst this confusion, 10 of the 12 SPF zero users accurately knew that they were getting no UVA protection.

We believe this situation emphasizes the need for better consumer education, and supports the current FDA work designed to provide a uniform and accepted scale of UVA protection. Because we have found that the buying public has adopted higher SPFs, it is reasonable to conclude that UVA protection will be likewise adopted once the consumer understands the value.

We hope that this survey data may serve as a benchmark with which to measure the understanding and adoption of uniform protection measures when they become enacted. Since the discovery of UVA's role in triggering melanoma, the FDA has determined that claims for high levels of SPF should be accompanied by required minimal UVA protection. The development of these requirements is the current impediment to implementation of the Final Sunscreen Monograph. However, the FDA's work is progressing rapidly.

In the future, data from this study may help evaluate consumer acceptance of UVA benefits, as it has for UVB sunburn protection. We have seen in this study that consumer acceptance of SPF benefits initially lagged behind the permitted regulatory product classifications. In 1993 SPF 30 became the maximum SPF permitted by the FDA. In the survey that year, less than 2% of the products used by our subjects were above SPF 30. Today that technically illegal portion has risen to 23%, but the SPF Maximum has remained at 30. A regulatory revision now will be retrospective rather than proactive. So, we will be curious to know if the rate of regulated UVA change will initially preceed the adoption rate of new products by the market as occurred with UVB (SPF) regulation.

Conclusion

We have twice measured and recorded an upper limit near 30 MEDs of UVB exposure risk within the United States to qualify our data for a "worst case" analysis. Recording incident UV data is not new, but we have, for the first time, tied that data to exposure risk of sunbathers, and recorded their response to this risk.

We have also analyzed the consumers' adaptation to the risk they are facing. Our surveys show that most consumers have adopted improved sunburn protection, but are, at best, confused about UVA protection.

We found that there still exists a hard-core 20% of the beach population who shun commercial UV protection, and develop a natural UV resistance of their own.

Moreover we have presented data sufficient to evaluate the delay between the availability of new sunscreen technology and its eventual adoption by consumers almost 10 years later.

Finally, we discovered it was nice to get out of the lab and go to the beach once in a while!

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Post Script on Sunscreens

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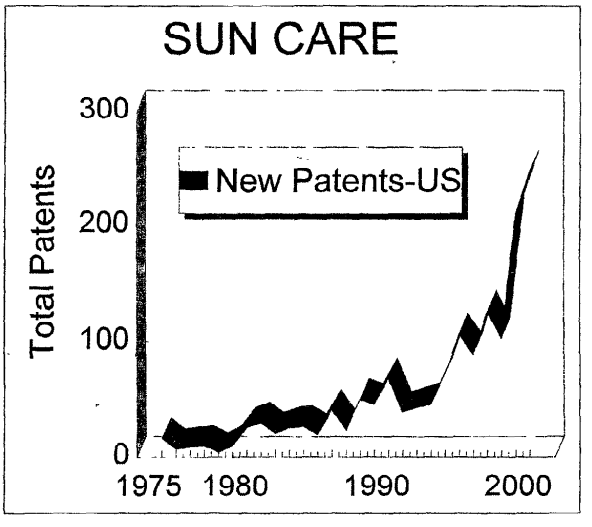

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