Light Treatment and Biological Rhythms

Bulletin of the Society for Light Treatment and Biological Rhythms

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RECENT ACTIONS OF THE BOARD

The SLTBR Board of Directors and committee chairs met in Toronto on 13 and 14 June 1991. Wilfried Köhler, of Frankfurt, substituted for Anna Wirz-Justice, who remained in Europe. The following decisions were reached:

1. A new slate of officers was elected: Norman E. Rosenthal, President; Michael Terman, President-Elect; Anna Wirz-Justice, Vice President; and Robert L. Sack, Secretary-Treasurer.

2. Committee chairs will remain the same, except that Leslie L. Powers has resigned as chair of the Insurance Liaison Committee. Any Regular Member of the Society who is interested in continuing the work of this committee — which has produced our *Insurance Reimbursement Endorsement Packet* as well as surveys of the rate of third-party reimbursement for patients' light box purchases — is invited to volunteer as chair by contacting Dr. Rosenthal. The Board also expressed its thanks to David H. Avery for his work on the DSM-IV Liaison Committee, which has completed its tasks and

...Смотреть прямо на лампу не обязательно... Достаточно просто находиться перед ней и заниматься любым делом

"A person need not look directly at the lamp. It is sufficient to be right in front of it and proceed with regular activities." [Trans. Ludmila Skaredoff.]

Reprinted, with permission, from A.A. Putilov et al. (1990) *Light Treatment of Winter Depression*, Academy of Medical Sciences, Siberian Branch, Novosibirsk. P. 24.

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Light Treatment and Biological Rhythms
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LUX

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published a series of position statements and progress reports in *LTBR*.

3. FDA Work Group reports were presented for discussion by George C. Brainard and Morris Waxler, who co-chair the Federal and Industrial Relations Committee. With the addition of some simplifying modifications *(see final Work Group reports, this issue)*, the documents were approved for transmittal to the FDA with the Society's recommendation that light box applications for treatment of SAD be reclassified as a Class 2 device.

4. Due to increased levels of SLTBR activity, especially on the public relations and publications fronts, Marty McCullough's time effort as Executive Secretary has been increased to 20 hours/week.

5. It was agreed that postdoctoral fellows with limited financial resources could become Student Members as an alternative to Regular or Associate membership.

6. The nascent proposal for formation of an independent association of lighting apparatus manufacturers — in which they would coordinate internal policy matters and potential research initiatives — was soundly endorsed.

7. The dates and site of the fourth annual meeting were selected: 30 April - 1 May 1992 on the National Institutes of Health campus in Bethesda, immediately preceding the American Psychiatric Association meeting in Washington, DC.

I am pleased to report that the Society has a substantial and growing membership and is fiscally solvent. Each year our meetings have become better organized, more cost-effective, and of higher overall scientific quality. It has been my honor to have served as President of SLTBR during its formative period, and I look forward to continuing in an active, albeit less official, role.

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LETTER FROM THE PRESIDENT

Memories of our third annual meeting in Toronto are still fresh in the minds of those who attended it. In general, most felt it was a great success, thanks in large measure to Dr. Gregory Brown and the staff of The Clarke Institute, who did a splendid organizational job. But credit is also due to the participants themselves. A total of 135 of our 370 members attended the meeting, including a significant contingent of Canadians (32) and colleagues from England, Australia, Germany, France, Finland, Iceland, The Netherlands, Japan and Israel. Five corporate members contributed their displays of lighting products: Ambulatory Monitoring, Inc., Apollo Light Systems, Bio-Brite, Inc., Health Light, Inc. and The Sun Box Company, Inc. In addition, the joint APSS/SLTBR program on 15 June attracted over 140 registrants, suggesting a remarkable acceleration in the interest of sleep researchers and clinicians in the emergent lighting technologies for treatment of sleep disorders.

There were 24 oral presentations and 20 poster presentations at our meeting. An unsystematic and scientifically invalid survey suggests that most found the presentations informative, enlightening and well done. The presentations themselves covered several areas, including new ways to administer light treatment, new applications of light treatment, explorations of the pathophysiology of seasonal and circadian disturbances, and the biological effects of light and melatonin. Not only does the new technology offer hope for better treatment, but it also challenges our understanding of how light works in SAD.

Dr. Anthony Levitt presented the results of a five-center study of the light visor, the efficacy of which seemed to bear no relation to its intensity over a wide range of strengths. Dr. James Gaddy showed the light visor to be less effective in suppressing melatonin than a box delivering light of equivalent intensity at the level of the cornea. Apparently one lux is not necessarily the same as another. Working with a dawn simulator, Dr. David Avery showed, in a controlled study, that a two-hour dawn was an effective antidepressant at a maximal intensity as low as 250 lux. All these novel findings await explanations.

Light exposure was reported to influence such diverse measures as sleep patterns in the elderly, the length of menstrual cycles, the circadian rhythms of shift workers, the drop in core body temperature at night and the levels of T-cells in HIV-infected individuals. The prevalence of SAD in Icelanders and their Canadian descendents was reported by Dr. Andrés Magnússon to be surprisingly low. Dr. Alfred Lewy reported on a complete phase response curve to melatonin administration, strengthening previous suggestions that melatonin might be clinically useful in shifting the phase of circadian rhythms. This is a brief sampler of the many intriguing reports, the details of which are outlined in *SLTBR Abstracts Volume 3* (see publications order form attached).

Three years into the life of SLTBR, we seem to be doing a reasonable job of accomplishing our original mission. Dr. Lewy, our outgoing president, deserves special thanks for his stewardship of this society through its infancy. So does Dr. Michael Terman, who has edited *LTBR* since its inception. He is stepping down from this role and his input and editorial pen will be missed. Dr. Anna Wirz-Justice will be assuming this position, bringing to it not only her editorial and writing talents, but also a welcome European perspective.

Because the World Congress of Biological Psychiatry took place just before the SLTBR meeting, many of our European colleagues were unable to join us in Toronto. At the SLTBR meeting, Dr. Wilfried Köhler commented that there is so much interest in light therapy and biological rhythms in Europe that our European colleagues are considering the possibility of having their own SLTBR meeting, in addition to the annual international meeting. Given the large European membership in the society, I would like to see our annual meeting held in Europe periodically.

A group of scientists whom I would like to see more involved in the SLTBR are those dealing with light and rhythms in animals. Many of our current members have been — and still are — involved in animal research. Even those of us who are not, are deeply aware of our debt to animal research for many of the ideas and principles that have inspired our human studies. I would respectfully suggest that we clinical researchers may have something to offer our basic colleagues in return. In these days of animal rights activism, it is always useful to be able to point out the concrete benefits of basic research. There must surely be a few grant applications that fail to point out the clinical relevance of the basic research being proposed. I would encourage our annimal research colleagues to go even further in drawing the bridge between their work and ours — to join our society, attend our meetings and present animal work alongside the clinical. I know that there are special problems in conducting clinical research, such as the complex lives of our subjects. It is harder to control all the variables in the life of a person than in the life of a hamster. But we are eager to improve our methods and would be pleased to learn from anyone who can teach us. Such efforts will surely be repaid by the infusion of ideas that clinical problems invariably stimulate.

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EDITORIAL: CLINICAL EFFICACY OF THE LIGHT VISOR, AND ITS BROADER IMPLICATIONS

*[**Ed's. note:** A report on a multicenter clinical trial of a "light visor" system for treatment of SAD (Levitt et al., 1991) was presented at the SLTBR annual meeting. This work follows an earlier experiment (Moul et al., 1990), ensuing discussion in these pages (Rosenthal and Moul, 1990; Young, 1990), and reports on similar devices (McIntyre et al., 1990; Stewart et al., 1990). The visor encases two small krypton-halogen lamps, and by use of a battery pack allows free ambulation without reducing the amount of the light received, in contrast to standard light boxes. In the earlier trial (Moul et al., 1990), 46 subjects received light levels of 400 or 7000 lux, with either 30-min or 1-h daily exposures. Regardless of duration, more subjects showed clinical response to the*

lower light level (65% vs. 23%) — a surprising result. In the new multicenter trial, 105 subjects received illuminances of approximately 60, 600, or 3200 lux in 30-min sessions, without significant differences in response rate (all in the 40% range). Furthermore, Gaddy et al. (1991) reported significantly reduced melatonin suppression when the visor was compared with a closely-positioned light box that illuminated the full visual field while providing equal illuminance at eye level (400 or 4000 lux). The following comments are based on a discussion of the multicenter trial, presented at the annual meeting.]

The investigators are to be congratulated on their execution of an ambitious multicenter design that has provided quick results and impressive sample size in a collaborative model that would otherwise require years of effort. The study minimizes subtle experimenter bias effects and the ubiquitous flukes of small *N* that have plagued single-center studies of light therapy. This project provides a model for intensive investigation of high-priority problems, and one wishes the approach would be applied to the study of basic questions about the mechanisms underlying clinical response to light, above and beyond the evaluation of new delivery devices.

It seems doubtful that our standard granting agencies would give such a multicenter trial sufficient funding priority. Partnership with industry is likely to be a key, but the light therapy "industry" is not so well developed that we will start routinely to see multicenter trials on priority issues of mechanism. An association of our manufacturer colleagues could serve to facilitate such research, and tie the goals to generic issues; this would inevitably also serve to hone the technology. The commercially-sponsored multicenter trial shows, in principle, that such a model is achievable.

What does it mean that low, medium, and high-illuminance groups failed to show differential clinical effect in this experiment? The goal of every controlled experiment is to find a differential effect. That is a truism. The initial hypothesis predicted a standard dose-response curve. The nondifferential result could mean that placebo factors overrode the manipulation of interest — or even that the manipulation itself lay on a dimension without specific clinical efficacy. Or it could mean that the manipulation, while specifically active, was ceilinged out across experimental groups — in this case, that the visor's light exerted maximal effect throughout the range of 60-3200 lux. The latter explanation is, I hope, incorrect, given that the overall 40% remission rate is so much lower than that found in the most successful light-box studies (for review, see M. Terman et al., 1989, 1991), not to mention last year's visor result at 400 lux (Moul et al., 1990).

Characteristics of spectral emission of the halogen lamp may underlie the apparent enhanced clinical effect of "dim" light using the visor. For a given level of illuminance (lux), the visor emits substantially higher irradiance ($\mu w/cm^2$) than fluorescent sources (Z. Boulos, pers. comm.). The lux metric, which corrects for average photopic sensitivity of the human eye, obfuscates such differences.

A paradoxical response is even possible, that subjects given higher light levels in fact received *less* retinal stimulation due to avoidance behaviors such as squinting or lowering the eyelids with a downward gaze, or differential pupillary gating. Such factors could explain the finding of Gaddy et al. (1991) of reduced melatonin suppression using the visor in comparison with a light box that provided "equal corneal illuminance." The inclusion of medicated subjects in the visor study, subjects with histories of bright light treatment by other methods, and a subset which paid for participation in the research, may pose further complicating factors.

We cannot tease apart the alternatives on the basis of the current data, but it will be important to locate the source of nondifferential effect in future work. Several paradigms have successfully demonstrated differential efficacy of lighting parameters using standard light boxes in single-center trials, e.g., 2500 lux vs. $\leq$400 lux light, morning vs. evening light, and protracted vs. brief exposures (for review, see M. Terman et al., 1989). Within the bright light range, stronger response has been demonstrated for 10,000 lux vs. 3000 lux (J.S. Terman et al., 1990). Still, a definitive placebo-controlled trial of light therapy has yet to be performed, and some nail-biting seems in order. If multicenter designs continue to generate nondifferential results, our field will face its largest conceptual challenge to date.

We must refine our physical and physiological specifications of the stimulus in light therapy. Illuminance in lux, measured at the level of the hypothetical stationary eye, can only be a first crude step toward quantifying the photic energy that is being transduced by the retina. Ours is a complex stimulus that has been embarrassingly inadequately specified given the intense clinical experimentation of the last five years and the technological efforts of the manufacturers.

The visor is just one case in point. It is a unique apparatus in that head movements cannot affect the signal received at the eye, a situation which contrasts with the circumstances of our evolutionary adaptation to outdoor illumination, not to mention the variability inherent in standard light box stimulation. Variability of retinal irradiance may well be a factor that maintains stimulus viability in light therapy, and the effect of head movements may be important above-and-beyond that of eye movements (which, for example, serve to prevent seeing our own retinal vasculature by continually moving the shadow of the retinal vessels across receptor groups). Although retinal cones continue to transduce light under steady bright illumination, rods can saturate and go temporarily blind even though most rhodopsin remains unbleached. We still do not know the relative contribution of cone and rod responses to the central processes that subserve antidepressant (or, for that matter, circadian phase shifting) effects. Given the visor's relatively inescapable illuminating field, a large set of ocular safety factors may require ophthalmological evaluation, at least for protracted treatment regimens, as in SAD.

The visor also contrasts with standard delivery devices in that it allows whole-body mobility. Might an increase in activity level during light therapy sessions serve to heighten clinical response to lower illuminances? Recent animal research by the investigators' Toronto colleagues has demonstrated pronounced circadian rhythm effects of behavioral activity per se (Mrosovsky et al., 1989), as well as complex interactions with the phase shifting effects of light (Mrosovsky, 1991). It is interesting to note that at least one manufacturer has recommended use of an exercycle positioned in front of a standard stationary light box.

We need to ask whether the bright-light intensity dimension is monotonic with clinical efficacy, especially now that much dimmer lights presented in the bedroom are proving effective (Terman and Schlager, 1990; Avery et al., 1991). Does the momentary state of baseline light adaptation determine therapeutic dose? Does the dark-adapted eye respond with heightened response to a dim stimulus? Is the light-onset transition curve an important variable? Does sudden switching on and off of lights differ functionally from gradually tapered signals as we see in dawn and dusk twilights? From our clinical vantage point, we don't begin to have answers, and the selection of any given set of lighting parameters can therefore continually surprise us with results of ineffective *or* effective therapeutic response.

SLTBR has yet to evolve standards for specifying the relevant parameters of light stimulation (cf. Remé et al., this issue). Safe to say the visor and standard light boxes produce different parameters of stimulation, and thus could promote physiological and therapeutic adjustments that contrast in unknown ways. The same is true in comparing one light box with another. Minimally we should know the pattern of illuminance throughout the potential field of gaze. Two light boxes of equal dimensions — not to mention differing dimensions — can produce vastly contrasting fields which, in interaction with head and eye movements, might make all the difference in therapeutic response. A nominal reading of 2500 lux or 10,000 lux at the center of the field provides only a small piece of the relevant information. There are factors of glare and subjective brightness that can vary widely at a given illuminance level. Angular vs. vertical presentation of the light field could strongly influence results. We must aim for exhaustive cataloguing of calibration variables: otherwise we are playing with a set of unknowns, which could waste effort. Lighting manufacturers should be expected to provide such information.

We need to work toward a physiological specification of the stimulus in terms of retinal irradiance, or photons absorbed, under given therapeutic conditions. How does the iris gate the input signal? Does the pupillary reflex relax under protracted light exposure, opening a floodgate for supernormal retinal stimulation? Does the retina respond by desensitizing itself through bleaching of photopigments and down-regulation of the transduction mechanism? These are high-tech questions which can be answered only in collaboration with vision scientists.

Our current collaboration of clinicians and biological rhythms experts has succeeded in laying out a challenging domain. We're at the point where a new set of subtler questions about stimulus delivery devices has come to the fore.

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STANDARDS FOR SPECIFYING PARAMETERS OF BRIGHT LIGHT STIMULATION FOR THERAPEUTIC APPLICATIONS: A PROPOSAL

Diffuse light of various intensities has been used widely to treat seasonal affective disorder (SAD). In several studies clinical response (measured as rate of remission) appears to have depended not only on the time of day the lights were administered but also on the intensity of light per unit of time — and, in a limited number of studies, on spectral composition. In contrast to detailed analyses of clinical response presented in the literature, however, there has been minimal attention to adequate specification of stimulus parameters and exposure conditions — i.e., *standards* — for the lighting systems used.

For accurate comparisons among studies, standards must be agreed upon for the most pertinent characteristics of lighting devices. In addition, exposure conditions of patients should be monitored — at least by the major research groups — in order to specify average pupillary size during light exposure sessions and, more ambitiously, retinal irradiance levels. The transmission of the ocular media (cornea, aqueous, lens, vitreous), which ultimately determines retinal irradiance, varies up to 25% among individuals (van Norren and Vos, 1974) and declines with age (e.g., Boettner and Wolter, 1962). Similarly, pupil size and motility decline in the elderly (Alexandridis, 1985; Wyszecki and Stiles, 1967). Thus, the age factor should be analyzed in group comparisons, including consideration of the spectral transmission of the eyes. For example, before puberty young ocular lenses do transmit certain ultraviolet (UV) wavelengths, perhaps with an underlying physiological "purpose" (Barker et al., 1991); with increasing age, however, the lens blocks practically all UV. To complicate matters, there are differences in definition where within the electromagnetic spectrum "UVA" begins to be emitted. One set of standards (DIN, Deutches Institute für Normung; *see References*) defines UVA as beginning at 380 nm, whereas another (CIE, Commission International d'Eclairage, 1931) specifies 400 nm. How are we to interpret results of light therapy studies that suggest a global "UV effect"?

LAMP STANDARDS

Of primary importance is to standardize the exposure geometries, i.e., the angle of tilt of the lamp and the position of the illuminated patient. For example, with a tilted light box there may be strong reflection from the surface on which the lamp rests; such reflectivity could approach 85% in case of white material. A person reading during a treatment session might therefore receive more light from a tilted light box than from one vertically positioned. Furthermore, the dimensions of the light emitting area should be specified, as well as the luminance in candela per square meter (cd/m^2). Despite the unit "lux" being more common and better known to

many researchers, the luminance given in cd/m² is more *specific* in that it quantifies the emission of a lamp independent of distance, and it provides the means to calculate retinal irradiance. By contrast, the illuminance (measured in lux) falls off with the square of the distance from the lamp, assuming that the lamp approximates a point source. Since we do not use point sources in light therapy, the dependence on distance varies complexly with the geometric dimensions of the bank of lamps. The illuminance measure comprises only a rough average estimate of light exposure over an unspecified range of light intensities.

An important variable is the emission spectrum of the light source, particularly in view of studies of the relative clinical effectiveness of restricted wavelength bands within the spectrum (e.g., green vs. red, no UVA vs. some UVA). The particular model and type of lamp (fluorescent vs. incandescent) should be specified. Additional relevant information is the lamp's color rendering index and color temperature, data that are often available from the lamp manufacturer along with the emission spectrum. The lamp per se only partially determines the effective stimulus: knowledge of absorption/transmission characteristics of the light box's plastic diffusing screen is also directly relevant.

THE MOST IMPORTANT STANDARDS FOR LIGHT BOXES AND THERAPEUTIC CONDITIONS

Specified by the apparatus manufacturer:[a]

- Size of light box/luminous field, in square meters[b]
- Luminance of field, in candela per square meter (cd/m²)[b]
- Illuminance (lux) at a standard eye position[b]
- Lamp geometry (e.g., angle of tilt)
- Spectral emission of the lamps, and luminous intensity distribution
- Lamp type and model
- Lamp color temperature
- Lamp color rendering index
- Spectral filtering characteristics of the plastic diffusing screen
- Overall light transmission of the plastic diffusing screen

Specified by the light therapist or researcher:

- Exposure geometry of the patient (e.g., tilted head, distance from lamp)
- Illuminance (lux) at recommended eye position
- Exposure duration per day, and time of day
- Age of patient
- Range of pupillary diameter during treatment[c]
- Retinal irradiance and ocular transmission[c]

[a]Apparatus manufacturers should specify whether original measurements have been performed, or industry-supplied data (e.g., from light bulb manufacturer) are being used.

[b]Researchers are advised to verify these parameters independently, given the history of inaccurate specifications by some manufacturers.

[c]Desirable information that requires specialized measurement strategies, and thus will not always be available.

THERAPISTS' STANDARDS

The light therapy literature suggests that there is a reciprocity between intensity of light and duration of exposure, perhaps paralleling an effect long-established in psychophysical studies of brief light flashes. Thus it may be important for the therapist to specify the exact exposure durations at given light intensities. For scientific studies (rather more than for general clinical application), it is important to calculate retinal irradiance (in watts per cm²) (cf. Stiles, 1967; Calkins and Hochheimer, 1980; Terman et al., 1990). The latter varies with age and other individual parameters such as the focal length of the eye. One may surmise that retinal irradiance ultimately determines a given "light effect", above and beyond external measures of luminance or illuminance. Final clarification of the experimental issues may ultimately require determination of the number of photons absorbed per eye per treatment session (e.g., van Norren and Vos, 1974; Fulton et al., 1990). Although this strategy transcends the domain of clinical or private practice, it might eventually lead to some understanding of ocular mechanisms underlying the efficacy of light therapy.

SELECTED RADIOMETRIC QUANTITIES[a]

Quantity	Symbol	Unit	Symbol
Radiant energy	Q	Erg	erg
		Joule	J
		Kilowatt-hour	kWh
Radiant energy density	w	Joule per cubic meter	J/m^3
Radiant flux	Φ	Erg per second	erg/s
		Watt	w
Radiant flux density at a surface			
Radiant excitance (radiant emittance)	M	Watt per square meter	W/m^2
Irradiance	E		
Radiant intensity	I	Watt per steradian	W/sr
Radiance	L	Watt per steradian and square meter	$W/sr \cdot m^2$

SELECTED PHOTOMETRIC QUANTITIES[a]

Quantity	Symbol	Unit	Symbol
Luminous efficacy	K	Lumen per watt	lm/W
Luminous energy (quantity of light)	Q	Lumen-hour	lm·h
Luminous energy density	w	Lumen-hour per cubic centimeter	$lm \cdot h/cm^3$
Luminous flux	Φ	Lumen	lm
Luminous flux density at a surface			
Luminous excitance (luminous emittance)	M	Lumen per square foot	lm/ft^2
Illuminance	E	Footcandle	fc
		Lux (lm/m^2)	lx
Luminous intensity (candlepower)	I	Candela (lumen per steradian)	cd
Luminance	L	Candela per unit area	cd/m^2
		Footlambert ($cd/\pi ft^2$)	ftL
		Apostilb ($cd/\pi m^2$)	asb

[a]Adapted from Hughes et al., 1987.

MEASUREMENT DEVICES AND INTERNATIONAL STANDARDS

Lamp parameters should be specified on the basis of standardized methods and definitions that have been developed by agencies such as the CIE, DIN, and ANSI (American National Standard for the Safe Use of Lasers, 1986). Luminance should be measured with a photometer with large measuring head, at the patient's eye level and in the direction of gaze; the aperture size of the photometer should be specified. The color of a given emitted light is evaluated with specialized devices and is quantified according to standards within the CIE chromaticity diagram. Furthermore, the distribution of luminous intensity can be requested from the manufacturer or approximately evaluated with a photometer placed in different directions relative to the light source.

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Note: For details about the ANSI, CIE and DIN standards, readers may directly contact Dr. Remé.

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CHRONOPHYSIOLOGICAL ASPECTS OF LIGHT TREATMENT FOR SEASONAL AFFECTIVE DISORDER: SIBERIAN STUDIES

The main purpose of our biological rhythms research laboratory is to study individual differences in human rhythms. We have some research topics associated with the problems of differential chronobiology and required chronotypological approaches. One of them is the chronophysiology of seasonal affective disorder (SAD) and light treatment. This study was begun in 1987 and was further stimulated by our participation in the Alaska-Siberian Medical Research Program (Hellekson, 1989a; Ebbesson and Nikitin, 1989; Putilov, 1990a).

In a number of previous studies we constructed and validated a sleep-wake pattern (SWP) questionnaire of multivariate structure for self-assessment of individual peculiarities and adaptability of the sleep-wake cycle (Putilov, 1990b; 1991). The SWP questionnaire has been added to the questionnaire battery used in the Alaska SAD survey (Booker and Hellekson, 1991). The Russian version of the questionnaire battery has been applied for a survey of 11 residents' samples at four latitudes in the USSR. We were able to show a similarity of latitude prevalence and demographic picture of SAD in the USSR and USA. At the same time, Chukotka natives, living a largely traditional lifestyle, evidence few SAD symptoms, while non-natives in this setting showed the expected pattern of SAD. Examination of the correlations between SAD and the SWP questionnaire showed that SAD symptoms were associated with lower levels of morning wakefulness — indeed, lower capacity to be awake at any time.

Comparison of sleep-wake pattern and diurnal type in 175 depressed patients of the psychiatric clinics of Novosibirsk and 175 psychiatrically healthy controls revealed that the chronobiological features of SAD are similar to those of manic-depressives, but differ from other depressive subtypes.

During the last three winters, 45 SAD sufferers and 25 healthy women were hospitalized in the Institute of Clinical and Experimental Medicine of the Siberian Branch of the USSR Academy of Medical Sciences, situated near Novosibirsk (56° N, with sunrise time at the winter solstice at about 0930, sunset time 1630. Our data showed that the clinical and demographic picture of SAD in our patients was remarkably similar to that described in Hellekson's review for the USA and Europe (1989b).

We assessed brain asymmetry, alertness, sleep architecture and dirunal profiles of physiological and hormonal variables and physical performance during two days before and after a week of morning (08-10 hr; 18 patients and 13 controls), afternoon (16-18 hr; 19 patients and 12 controls), or evening (8 patients) bright light treatment at 2500 lux. Thirty-five of these patients and 23 of the controls were studied during two days in summer. Sleep architecture of 9 patients was investigated in all four seasons. Also, 19 SAD patients, 9 of whom were not depressed, flew to southern Turkmenistan (Firusa resort, 38° N) in winter (9 patients in February 1990, 10 patients in December 1990). They were investigated before flight and after a week in Firusa.

SAD patients scored significantly higher in depression scales (21-item HAM-D and SIGH-SAD) than controls in winter before light treatment. All light treatment resulted in similar significant reduction of depression scores. All winter-depressed patients became normal after a week's stay in Turkmenistan, and in summer.

SAD patients were given a concurrent task, verbal-manual interference to infer hemispheric language lateralization. The difference between depressed patients and controls was due to greater left-hand tapping decrement among the depressives. There was a negative correlation between right-left interference differences and HAM-D score. After treatment, patients did not differ from normals in dual task interference effects. Patients also showed no difference from controls after the week in Turkmenistan, and in summer. The obtained differences in performance measures of laterality imply that winter depression is associated with shift of laterality from left to right.

Light treatment resulted in significant weight loss in patients. Increase of basal metabolic rate and decrease of body weight were found in summer as compared with winter. Nearly half the patients of reproductive age showed winter lengthening of menstrual cycle. After light treatment, 13 of 40 patients reported earlier onset of menstruation.

Depressed patients showed higher alertness levels than controls during time in bed, but lower alertness levels before and after time in bed. There was significant correlation between alertness level during time in bed and depression scale scores. The patients also showed low daytime levels of subjective vigilance. All light treatment conditions other than evening light caused normalization of the subjective indices, matching control values. Evening light treatment resulted in increase of alertness level during time in bed.

Polysomnographic abnormalities — namely prolongation of alpha-rhythm episodes till stages 2-4 and disappearance REM on the electrooculogram during paradoxical sleep (EEG REM sleep) — were found in all seasons in most patients. The percentage of REM-sleep was increased and the percentage of stages 3-4 was decreased throughout the year. The latter significantly increased after light treatment and in spring. At the same time, differences of light treatment effects between patients and controls were not significant.

Comparisons of diurnal profiles of physiological variables measured every 4 hours from 8 a.m. until 12 p.m. in patients and in controls did not reveal significant differences in phase and amplitude characteristics of axillary temperature, heart rate, respiratory rate and sodium salivary concentration, or in the ranges of their interindividual variability. Light treatment applied near times of sunrise or sunset (08-10 and 16-18 hr) did not significantly alter the phase position of physiological rhythms. Evening light (19-21 hr) significantly increased midnight temperature and heart rate. Amplitude characteristics of the diurnal rhythms did not change after light treatment. There were no significant seasonal differences in phase, amplitude or dirunal profiles of these physiological variables. Amplitudes increased after flight to the south only in depressed patients.

In patients, daily means of axillary temperature and heart rate were significantly elevated after a week of light therapy. The daytime (08-20 hr) proportion of norepinephrine excretion increased after light treatment, and this effect was correlated with SIGH-SAD score reduction. Heart rate reactivity to emotional acoustic stimulation and to standard physical load on a bicycle

ergometer also increased after light treatment. Increase in heart rate reactivity to physical load was not accompanied by a parallel increase in oxygen uptake or decrease in muscle work efficiency. Thus, these effects may be associated with an "energizing" action of bright light. We propose that it is a result of enhanced sympathetic reactivity.

The patients with SAD had abnormalities in the 24-hr profile of excreted melatonin metabolites or melatonin-like substances. The night-to-day (24-08 hr vs. 12-20hr) difference in excretion was significantly lower in patients than in controls. There was a negative correlation between the decline of psychiatric ratings and the baseline night-day differential, and a positive correlation between the decline of psychiatric ratings and the increased night-day differential. Any kind of light treatment as well as changing of season and flight to the southern part of the country resulted in heightened diurnal variation of melatonin metabolite excretion.

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CONSENSUS STATEMENTS ON THE SAFETY AND EFFECTIVENESS OF LIGHT THERAPY OF DEPRESSION AND DISORDERS OF BIOLOGICAL RHYTHMS

Society for Light Treatment and Biological Rhythms

INTRODUCTION

The following document is the result of a consensus-building process (March, 1990 - June, 1991) within the Society for Light Treatment and Biological Rhythms (SLTBR). This process involved the Committee on Federal and Industrial Relations, the general membership, and the Board of Directors.

The objective of this document is to provide a consensus statement about the safety and efficacy of light therapy for affective disorders (depression) and biological rhythm disorders. This is a "working" document which reflects the current state of scientific understanding of light therapy (June, 1991) and will be modified periodically — at least bi-annually — as new data become available.

This is a statement specifically intended as an advisory document to the FDA, not a public document.

Efficacy of Light Therapy for SAD and Subsyndromal SAD

1. Winter Seasonal Affective Disorder (SAD) can be adequately defined according to the criteria of Rosenthal et al. (1984). These criteria specify SAD as a fall or wintertime depressive episode occurring in a patient who has previously experienced two or more fall-winter depressions, of which at least two occurred successively. The subsequently proposed DSM-III-R criteria for "seasonal pattern" are controversial, since most researchers consider them difficult to implement in practice and there is no evidence that they are of particular help in determining the probability of clinical response to light.

2. Controlled trials performed at research centers around the world have demonstrated the clinical efficacy of light in the treatment of SAD. Typical dosage regimens for light therapy involve white fluorescent light at 2500 lux for two to four hours per day for at least one week. There is also one published study documenting the

efficacy of light administered at 10,000 lux for one-half hour per day for 10-14 days. Documentation of such efficacy may be found in the published articles based on controlled trials listed at the end of this statement.

3. A number of studies have documented a milder form of seasonal affective disorder called sub-syndromal SAD. Although two studies have shown that light therapy may be beneficial for treating sub-syndromal SAD, there are fewer controlled trials in the published literature for recommending the clinical use of light therapy for sub-syndromal SAD.

4. Occassional side effects of light therapy include nausea, headaches, eye strain, irritability, insomnia, and other symptoms of activation.

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Efficacy of Light Therapy for Non-SAD Conditions

Efficacy of light therapy for non-SAD depression.

Light therapy may have positive effects in both primary and adjuvant use. Reports of both positive and negative findings indicate that further research is necessary.

Parameters: There are insufficient data to make recommendations for general practice.

Contraindications: Bipolar I without adequate lithium dosage.

Side effects: Insufficient data

Efficacy of light therapy for premenstrual syndrome.

Light therapy may be effective against late luteal phase dysphoric disorder.

Parameters: There are insufficient data to make recommendations for general practice.

Contraindications: Insufficient data

Side effects: Insufficient data

Efficacy of light therapy for circadian disorders. There is ample evidence that light can advance, delay, and entrain human circadian rhythms. The amount of phase shift and its direction depend on when the bright light is used.

Parameters: The dominant strategy among researchers at this time is to time light in accordance with a human phase response curve (PRC), which approximates those of other mammals. Thus, to advance circadian rhythms, bright light should be aimed at the advance portion of the PRC (i.e., morning) and bright light should be avoided during the delay portion of the PRC (i.e., evening). To delay circadian rhythms bright light should be aimed at the delay portion of the PRC and avoided during the advance portion of the PRC. Assessing exactly when these portions of the PRC occur in any given individual may be difficult, especially for shift workers and jet travelers.

Contraindications: Insufficient data

Side effects: Insufficient data

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The Safety of Light Therapy Devices

Light therapy devices used to treat seasonal affective disorder (SAD) and other disorders of biological rhythms must be as safe as current knowledge allows. The literature on the photobiological safety of lamps shows that there is adequate information to permit the safe use of light therapy devices for the treatment of SAD and other disorders of biological rhythms. Most safety guidelines, however, have been derived primarily from animal experiments. Although caution should be exercised in extrapolating biological effects from one species to another, animal data from well controlled experiments are fundamental to setting safe threshold limit values in humans (ACGIH 1989; UNEP/WHO/IRPA, 1979). Based on these currently accepted international guidelines, we believe that light therapy devices are safe when manufacturers, therapists, and patients take into account the following facts, factors, and principles.

These considerations are set out below first for low pressure mercury vapor lamps ("fluorescent" lamps) and then for filament and arc type lamps. Items 1c and 1d apply to all light therapy devices. Items 2a and 2b apply only to devices using filament and/or arc type lamps.

1. Fluorescent Lamp Light Therapy Devices

a. The optical radiation emitted by these devices is not a thermal hazard to the skin or eyes [ACGIH (1989); UNEP/WHO/IRPA (1979); Sliney and Wolbarsht (1980)].

b. The "blue" light (380-480 nm) emitted by these devices does not exceed threshold limit values established to protect the retinal pigment epithelium from damage [Sliney and Wolbarsht (1980)].

c. The ultraviolet-B (280-315 nm) radiation (UV-B) emitted by these devices can exceed threshold limit values [Oren et al. (1990)], and there are reports of skin erythema and photokeratitis in humans exposed to UV-B emitted by these lamps [Soc. Light Treatment Biol. Rhythms (1990)]. Much higher intensities of UV-B (e.g., that contained in sunlight) are associated with skin cancer [Van der Leun, 1984], cataracts [Taylor et al. (1988);Pitts et al. (1986)] and corneal disorders in humans. Therefore, the UV-B emitted by these lamps should be attenuated by filters with properties similar to UF3 and UF4 Plexiglas. If UV-A (315-380 nm) is to be used in an experimental clinical study, the protocol should be submitted for approval to an Institutional Review Board or to the Food and Drug Administration through application for an Investigational Device Exemption.

d. Quantitative data on the dose of light (380-760 nm) which could damage the photoreceptors (rods and cones) are predominantly from nocturnal animals. Neither the rodent nor the primate data (Sykes et al, 1981) have been extrapolated to the human eye or formulated into an accepted safety standard. Therefore, threshold limit values have not been established in this wavelength region for this kind of damage. However, photoreceptor damage has been demonstrated in animals using light emitted by fluorescent lamps under a number of experimental conditions. These experiments provide some guidance about limiting the theoretical possibility that such damage might occur in the course of light therapy for SAD.

Some of the factors which might increase the risk of photoreceptor damage are listed below. It should be emphasized that none of these factors are specifically known to increase photoreceptor damage to the human eye from light emitted by fluorescent lamps. Nevertheless, these factors should be carefully

considered in a regime of light therapy for SAD to determine that the benefit of its inclusion outweighs the potential risk to the patient. Where there is doubt about the relative health of a patient's eyes, the appropriate eye care professional should be consulted.

- pupil dilation [Sliney (1984)]
- drug photosensitization [Dayhaw-Barker et al. (1986);Terman et al. (1990)]
- prolonged (days) dark adaptation prior to phototherapy [Organiciak et al. (1989)]
- allowance of an insufficiently-short recovery time (<8 h) between exposure sessions, e.g., intermittent therapy sessions with 1-2 hour intervals [Organiciak et al. (1989)]
- treatment of patients with
  - genetic vulnerabilities [Naash et al. (1989)]
  - retinal degenerative problems or a family history of such problems [Young (1988); Tso (1990)]
  - aphakic or pseudophakic eye without a corrective filter [Werner and Spillman (1989)]
  - work/recreational history of more than 10 years of prolonged daily exposure to sunlight [Munoz et al. (1990); Taylor et al. (1990)]

2. Filament and Arc Type Light Therapy Devices

a. If light therapy devices are used which incorporate filament or arc type lamps, a hazard analysis must be performed on the final device configuration to minimize thermal, UV and blue light (380-480 nm) injury to the human eye. Safe times for each of these hazards should be calculated [Sliney and Wolbarsht (1990)] using the most recent threshold limit values (TLVs) published [American Conference of Governmental Industrial Hygienists (1989)]. Each safe time must be longer than the light therapy session.

The thermal, UV, "blue hazard" threshold limit values will minimize denaturation of the retina, photochemical damage to the skin, cornea, lens and retina of the eye, and photochemical damage to the retinal pigment epithelium.

b. Flashed or strobed sources should be used with extreme caution [Sliney and Wolbarsht (1980)]. Calculation of the threshold for thermal injury to the retina requires special equipment and expertise. In addition, selective damage to short-wave cones may occur from pulses of blue light of approximately 3.0 J/cm^2 [Sperling et al. (1980); Szel et al. (1988)]. Although insufficient quantitative information is available to establish a TLV at this time, Berninger et al. (1989) have some data which suggest that the short-wave length cones in the retinas of ophthalmic surgeons can be damaged by flashback of the 488 nm line of the argon laser photocoagulator.

Additional putative safety measures have been proposed [Terman et al. (1990)]. However, consensus has been reached only on items 1a through 2b. Application of the knowledge outlined in this document by manufacturers, therapists and patients will provide safe light therapy for SAD and other disorders of biological rhythms.

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BOOK REVIEW:

THE PHYSIOLOGY OF CHANGE

Review of ***Rheostasis****, by Nicholas Mrosovsky, published by Oxford University Press, New York, 1990, 183 pp.*

The main aim of this monograph, as stated explicitly in the Preface, is "a reexamination and elaboration of the concept of homeostasis to include changes in regulated levels, rheostasis."

In numerous examples throughout the book it is shown that rather than constancy of the *"milieu interieur"*, regulated change is the prevailing mode of operations in many physiological systems. The examples cover processes as diverse as the regulation of body temperature during hibernation and osmoregulation during pregnancy. The species mentioned are as common as the laboratory rat or as exotic as the pintailed sand grouse, *Pterocles alchata.*

In the first chapter, the concept of homeostasis is considered. After introducing well known terms such as "feedback", "feedforward" and "set point", it is shown that early formulations of homeostasis failed to take into account that the defended level (i.e., the set point of a certain physiological variable) could change over time. Perhaps more importantly, the issue of competition between different regulatory systems is introduced and elaborated upon, in Chapter 2. After first pointing out that many animals can resolve conflicts by a sometimes astonishing flexibility in their behavioral response, the theoretical models that were developed (especially by Houston and Macfarland) to deal with interaction between different regulated variables are briefly described.

Chapter 3 is devoted to terminology and definitions, and disturbingly interrupts the main line of the monograph. Chapter 4 introduces the term "programmed rheostasis". It is convincingly shown that conflicts between different needs are sometimes resolved by lowering the defended level of one variable. For example, in incubation anorexia the conflict between keeping the eggs warm and protected, and searching for food, is resolved by a regulated lowering of the set point for body weight. It is in this chapter that the shortcomings of homeostasis, and the need for a concept like rheostasis, become most apparent.

Although a few sections are devoted to circadian and circannual rhythms, it is surprising and disappointing that the physiological basis of "circadian rheostasis", especially, is not discussed in more detail. For example, the suprachiasmatic nuclei are mentioned only in the last chapter, and there only in the context of an absence of an effect of ablation on cyclic changes in the body weight of hibernators. That photoperiodic responses in some mammals are mediated through changes in melatonin secretion by the pineal is nowhere to be found. Although circadian rheostasis is not discussed at length, I do not mean to imply that this monograph should not be recommended to circadian rhythm researchers. On the contrary, the concepts developed by Mrosovsky may turn out to be very useful, especially in those areas of circadian rhythm research where the interaction of the circadian pacemaker with other regulatory processes (e.g., sleep) is being investigated.

After having described programmed rheostasis, Mrosovsky turns to "reaction rheostasis," exemplified, for example, by baroreceptor resetting after brief and long periods of altered blood pressure. In Chapter 6 the concept of "second-order rheostasis" is introduced. Basically, this refers to changes in, for example, the rate of change of set points of body weight during development. In the last two chapters, some problems and cautions are discussed and an attempt is made to relate the concept of rheostasis to molecular and integrative biology.

This monograph certainly is an excellent example of how thinking in terms of concepts and processes can be

helpful in organizing physiological data, even in an era that seems so very much dominated by reductionistic approaches.

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ON FINDING EFFECT

[Ed's. note: We reprint, with permission, the Appendix to a recent article by Robert Rosenthal. Ph.D. (1991). SLTBR researchers would do well to attune themselves to the highly concise and systematic arguments presented in this article concerning measures of size of effect vs. estimates of significant difference when reporting research results of both novel and replication experiments. For reprints of the full article: Dr. Robert Rosenthal, Dept. of Psychology, Harvard University, 33 Kirkland Street, Cambridge, MA 02138.]

I. The Problem

Oh, F is large and *p* is small
That's why we are walking tall.

What it means we need not mull
Just so we reject the null.

Or Chi-square large and *p* near nil
Results like that, they fill the bill.

What if meaning requires a poll?
Never mind, we're on a roll!

The message we have learned too well?
Significance! That rings the bell!

II. The Implications

The moral of our little tale?
That we mortals may be frail
When we feel a *p* near zero
Makes us out to be a hero.

But tell us then is it too late?
Can we perhaps avoid our fate?
Replace that wish to null-reject
Report the *size* of the effect.

That may not insure our glory
But at least it tells a story
That is just the kind of yield
Needed to advance our field.

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BULLETIN BOARD

WELCOME TO NEW MEMBERS

We welcome the following new members who have joined SLTBR since publication of the May 1991 issue:

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Paul R. Marques
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1991 ANNA-MONIKA PRIZE

We are delighted to report that SLTBR colleagues Norman E. Rosenthal and Thomas A. Wehr are the recipients of this year's second prize from the Anna-Monika Foundation for their "investigations about the nosologic elaboration of seasonal affective disorder and about the development of light therapy." In the words of the award committee, "You have thereby introduced a new principle of antidepressant/effective biological treatment into psychiatry and at the same time very much encouraged the investigation of the biological substrate of depressions."

The Anna-Monika Prize is the most prestigious international award in the field. The foundation has acknowledged most of the important developments in depression and its treatment, often before general acceptance — e.g., Burkhard Pflug received the prize for his work on sleep deprivation in the early '70's, and Wehr and Anna Wirz-Justice received it in the early '80's for their introduction of circadian rhythm concepts in the analysis of depression. Most of the prizes, however, have been given to researchers in recognition of career-long accomplishments — e.g., Robert Post for his work with carbemazepine and the role of "kindling" in affective course. The recognition of Wehr, in translating hypotheses into novel treatments, and Rosenthal, for developing and expanding the description of SAD and configuring light therapy for wide application, is a sign that our field has come of age. We regret, however, that the committee did not concurrently recognize the pioneer role of Alfred Lewy in the critical discovery of light suppression of melatonin in humans, which led directly to the first collaborative light treatment studies of SAD at NIMH.

The awards ceremony will take place in Berlin on 11 October 1991 on the occasion of the foundation's 25th anniversary. — *A. W.-J. and M.T.*

CLINICIAN'S GUIDE TO LIGHT THERAPY

Innovations in Clinical Practice, vol. 10, includes a comprehensive 43-page clinician's guide to SAD and light therapy written by the Columbia group (M. Terman, J.B.W. Williams, and J.S. Terman), covering topics on description of the syndrome, clinical credentials and third-party reimbursement, clinical assessment strategy, therapeutic strategy, treatment of non-SAD conditions, evaluation and choice of apparatus, safety measures, and a step-by-step treatment guide. Resources include the latest editions of paper-and-pencil SAD assessment tools in copy-ready format. Thirty six other chapters in this extensive handbook cover topics such as Diagnosis and Treatment of Mood Disorders, Assessment and Treatment of Childhood Depression, Treating Chronic Pain Patients, A Brief Screen for Depression, and Interventions for Health Maintenance and Recovery. Psychologists may receive 20 continuing education credits based on study of selected handbook chapters. The publisher offers a special discount price for orders placed before 15 September ($39.95 loose-leaf or hardbound); regular prices are considerably higher ($54.95 loose-leaf, $49.95 hardbound). Additional costs: $4.25, US shipping; $6.00, foreign shipping; 7% sales tax, Florida residents. *For credit card orders, tel 800-443-3364, fax 813-366-7971. For mail orders: Professional Resource Exchange, P.O. Box 15560, Sarasota, FL 34277-1560.*

SYMPOSIUM: BIOLOGICAL EFFECTS OF LIGHT

Sponsored by the Light Symposium Foundation, this meeting is scheduled for 13-15 October in Atlanta, GA. Widely-ranging topics include Circadian Rhythms, SAD, Biological Effects on Skin, Photomedicine, Photoimmunology, Vitamin D, Photocarcinogenesis, Light Protection and Retinoids, Artificial Lighting, Ozone Layer Depletion, and Safety Measures. Several SLTBR members will be presenting overview lectures and research reports. *For registration information: Dr. Michael Holick, Boston University School of Medicine, 80 East Concord Street, M-1013, Boston, MA 02118; tel 617-638-4545, fax 617-638-8882.*

INTERNATIONAL SYMPOSIUM ON GLARE

Sponsored by the Lighting Research Institute, this meeting is scheduled for 24-25 October in Orlando, FL. It grows out of a 1989 study of lighting and human performance conducted and presented by the National Electrical Manufacturers Association (NEMA) and LRI. A prominent panel of speakers will discuss topics including discomfort glare and its evaluation for interior lighting, the concept of visual comfort probability, calculation of disability glare and how to apply it, and recommendations to predict discomfort glare for lighting systems. The domain of inquiry, though new to most SLTBR members, is directly relevant to light therapy apparatus design and evaluation. *For registration information: Lighting Research Institute, 345 East 47th Street, New York, NY 10017; tel 212-705-7511, fax 212-705-7641.*

PROBLEMS OF CHRONOBIOLOGY

This journal, published by the Armenian Ministry of Health, includes clinical and experimental research reports, technology reviews, and monographs and conference proceedings, with a primary USSR audience. The Editor-in-Chief is R.A. Baghdassarian, with an editorial board located primarily at research institutes in Yerevan, Leningrad and Moscow. Papers appear in Armenian, English and Russian. An article (in Russian) on SLTBR appeared in the July 1990 issue. Other recent articles have covered topics such as melatonin function, "hemodynamic" rhythmicity in newborns, and elucidation of biological rhythm parameters. Western colleagues interested in building bridges are invited to submit manuscripts. For a copy of the style sheet and submission and subscription information contact Marty McCullough at the SLTBR Executive Office.

PSYCHOPHARMACOLOGY BULLETIN: SAD ISSUE

We reported in the November 1990 issue of *LTBR* (*3*: 13) the pending publication of *Psychopharmacology Bulletin*, Volume 4, which features SAD and light therapy, including a long, critical review of research, discussion papers and a comprehensive bibliography in the field.

The National Institute of Mental Health has generously provided SLTBR with approximately 100 extra copies of this volume which we now make available to our members at cost (our postage and administrative expense) on a first-come, first-served basis. If you wish to receive a copy, please send your **written** request with payment in $US as follows:

1-3 copies . . . . . $4.00 ea.

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PUBLICATIONS LIST INCLUDES 1991 MEETING ABSTRACTS, *COMPLETE WORKS* REVISION

The publications order form included in this issue of *LTBR* includes description of and cost for *SLTBR Abstracts, Volume 3*, a compilation of all abstracts presented at our annual meeting held in Toronto on 13-14 June 1991. In addition, the revised edition of *The Complete Works* now incorporates all *LTBR* issues through August 1991 (Vols. 1-3) as well as the latest edition of the SIGH-SAD-SR instrument (revised February 1991).

MARK YOUR CALENDAR

SLTBR's 1992 annual meeting is scheduled for 30 April - 1 May 1992 at the NIH Campus in Bethesda, Maryland. The meeting dates are earlier than in previous years. Therefore, abstract submission will have to be expedited. The fall 1991 issue of *LTBR* (November) will contain abstract submission and preregistration materials. The program committee will need to receive abstracts for review in early March, exact date to be announced.

Society for Light Treatment
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