

Light Treatment and Biological Rhythms

Bulletin of the Society for Light Treatment and Biological Rhythms



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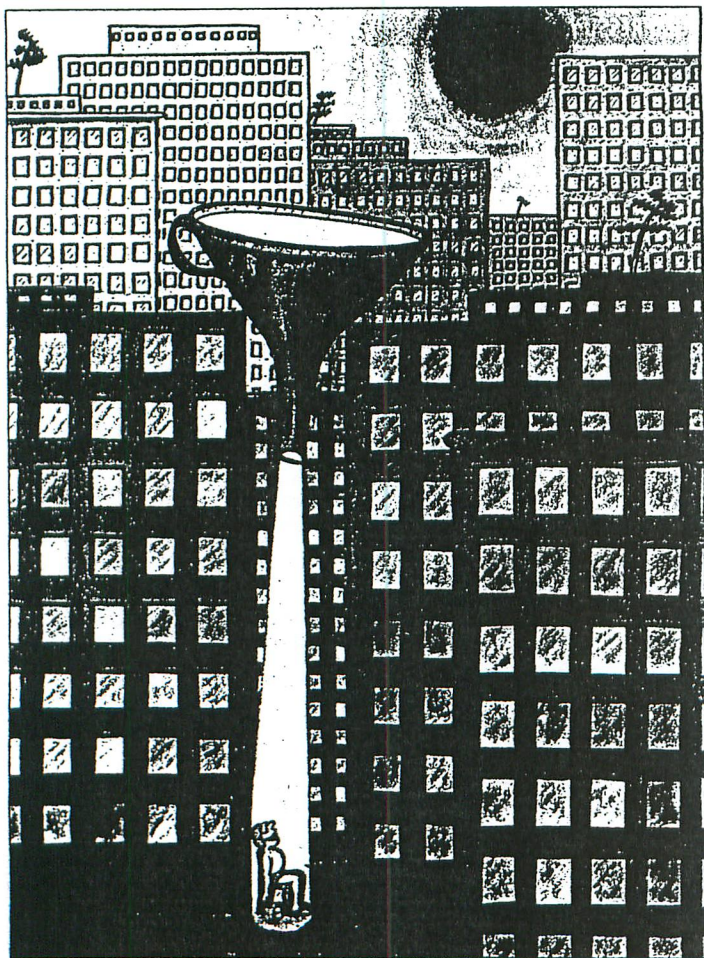
December 1992

SLTBR BOARD STATEMENT

The SLTBR Board of Directors has been extremely concerned by cases of misleading advertising that continue to come to our attention despite our previous exhortations [*LTBR* (1992) 4: 18] to colleagues who manufacture and distribute light treatment apparatus not to engage in such activities. Some advertisements — as well as product brochures and promotional letters sent to clinicians — have claimed efficacy despite a complete lack of controlled studies to support these claims, while others have recommended light intensities that are higher than those

used in any study to date, the safety of which has yet to be demonstrated. We are concerned that patients are being misled into believing that devices are safe and effective for SAD, and other potentially light-related disorders, in the absence of the necessary preparatory research and clinical vigilance. Such unfounded claims damage the credibility of our fledgling field, confuse patients and clinicians alike, and fail in distinguishing science from quackery.

To avoid these unfortunate developments, we request that all manufacturers and distributors of light treatment devices assume the required level of professional responsibility. Product descriptions should emphasize the physical parameters of the light apparatus, such as size, weight, number and types of bulbs, UV emission levels, and illuminance at recommended distances. Clinical claims or treatment advice should only be based on the findings of studies published in reputable journals. We request that if



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Unsolicited manuscripts, letters to the editor, and Bulletin Board announcements should be submitted to Dr. Anna Wirz-Justice, Editor, Psychiatric University Clinic, Wilhelm-Klein-Strasse 27, CH-4025 Basel, Switzerland. Please submit one double-spaced hard copy and a diskette file (Macintosh: Ms-Word, MacWrite; IBM: WordPerfect as Textfile); BITNET: WIRZ@URZ.UNIBAS.CH. Manuscripts and diskettes will not be returned. We reserve the right to edit and condense letters to the editor.

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corporate members use the Society's name, or reprint any of its materials, the phrase "SLTBR does not endorse any particular product or company" be included.

We wish to emphasize that we value our relationship with our colleagues in industry and depend on them to provide safe and effective devices to our patients at competitive rates. We have found most companies very responsible in their advertising and responsive to our concerns. We expect that we should be able to resolve any problems with problematic advertisers in a collegial manner, as has been well demonstrated by the responsiveness of European companies in modifying their advertising based on input from the research community. Should this not occur, however, we will have to consider other courses of action such as letters of notification to FDA and removal of corporate listings from our *Public Information Brochure*. We sincerely hope that such actions are unnecessary, but recognize that our patients' access to accurate information and the credibility of our field are our highest priorities.

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FDA BEGINS REVIEW OF BRIGHT LIGHT THERAPY

A meeting was held on 5 November with the FDA, with representatives of the Circadian Lighting Association (CLA) and Norman Rosenthal, M.D., in attendance. Dr. Rosenthal reviewed the data concerning the effectiveness of bright light therapy in SAD. This meeting was viewed as preliminary to a formal petition from CLA to the FDA for reclassification of light apparatus to Class II [see review of FDA classification parameters in *LTBR* (1992) 5: 3]. The petition is not a minor undertaking; an example petition given by the FDA to the CLA is over a foot high.

As far as we know, there have been no new letters sent to light box manufacturers asking them to stop distribution.

Mark Bauer, M.D., SLTBR member from Brown University, wrote to the FDA urging them to allow bright light box therapy only by prescription from a trained professional. While noting that the data strongly support the efficacy of bright light treatment, he expressed concern that the development of mania or hypomania is a significant risk which should be closely monitored. The following is an excerpt from that letter:

... In a 4-week study of winter depressives and controls, we found that several light-treated control subjects without personal or family history of psychiatric illness developed manic-like symptoms, including racing thought, decreased sleep, irritability and feeling "sped up." The symptoms promptly remitted when light exposure was reduced or eliminated.

Others have documented similar behavioral side effects with light treatment. Kasper and coworkers [J. of Affective Disorders (1990) 18: 211-19] reported that of 40 control subjects one subsyndromal SAD subject developed hypomania and two normals developed irritability and/or dysphoric energy after one week of bright light. Oren and coworkers [Comprehensive Psychiatry (1991) 32: 147-52] also reported insomnia and hypomanic irritability as among the most frequent side effects of bright light exposure.

Earlier studies that reported lack of effect of bright light on controls [Rosenthal et al. (1987) *Psychiatry Research* 22: 1-9; Kasper et al. (1989) *Archives of General Psychiatry* 46: 837-44; Kasper et al. (1989) in *Seasonal Affective Disorders and Phototherapy*, N. Rosenthal and M. Blehar, eds., pp. 260-270, Guilford Press, New York] used only one-week treatment paradigms, and only one subject formally reported manic symptoms. If reported after only one week of treatment, our results would also have been negative. It is likely that the four-week paradigm will more closely

resemble general clinical usage than a simple one-week exposure.

Patients with pre-existing bipolar (manic-depressive) disorder who have a SAD pattern are of particular concern, even if they have the less severe "type II" course. Most of the bipolar patients we have treated with light as their only therapeutic agent have developed manic-like symptoms as described above, and we have consulted on one patient treated by a colleague who actually developed rapid cycling during light treatment which persisted long after the light was discontinued. Since the prevalence of bipolar disorder may be as high as 1% in the U.S., this is not a trivial concern — particularly since many may be undiagnosed or latent cases.

While more prospectively collected data on larger numbers of subjects are needed to confirm these findings, we cannot at this time give light boxes *carte blanche* with regard to behavioral side effects. Untoward behavioral effects must be anticipated in a certain percentage of persons treated with light boxes. Some of these ill effects will be prevented or minimized if light boxes are available only while under the care of a professional, rather than if they are available to the general public via advertisements in the back of a magazine.

Others have argued that the light therapy regimen of a research protocol may have contributed to the development of the manic symptoms; in a non-research setting, administration of light causing agitation would be spontaneously reduced by the subject. Some have anecdotally noted a "treatment-onset euphoria" which is transient and does not develop into hypomania or mania even with no reduction of intensity or duration. One possible negative result of a requirement of prescription for bright light boxes by psychiatrists might be an increase in the number of persons making their own bright light boxes; some home-made light boxes might be unsafe and/or cause retinal damage.

I would be interested in hearing from SLTBR members about their views on the FDA-light therapy situation and on whether bright light boxes should be sold only with prescription. In addition, I would be interested in further views (and data) concerning the significance of hypomania or mania as a side effect of light therapy.

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LIGHT THERAPY IN (EAST) GERMANY

With our present-day neurophysiological knowledge, it is only logical to assume an important role for light, the source of life, in functional regulative processes in the individual. In addition to the function of light as *zeitgeber* for diurnal rhythms, its use as a dynamic agent has been known since antiquity.

Of anatomical interest is a detail from the well-known saurian park near Bautzen in East Germany. In one species of these vertebrates a direct pathway between the retina and the pituitary has been documented — this direct pathway has been lost in the course of evolution.

There is a long tradition in East Germany of interest in biological rhythm research and particularly in light therapy. In the former German Democratic Republic this small, rather mute group of scientists and clinicians made great efforts to keep up to date with international research. This was often extremely difficult; for example, the library inventory often took two years to catalogue new books. Selected journals were usually the only rapid source of information. In spite of this, all important research results were known in East Germany. Publication of our own results usually required 1-2 years. Unfortunately, the only specialist journal for neurology, psychiatry, and medical psychology was either unknown to most western colleagues, or was ignored. For example, a heated discussion pro and contra the placebo effect of light was already published some years ago. After the reunification of both Germanys the competence of East German psychiatrists was and still is undervalued.

The following East German Centers use light therapy to treat depressive disorders:

- The Psychiatric University Hospital Jena (Dr. K. Peter)
- The first Psychiatric Clinic of the specialist Hospital Arnstadt/Dresden (Drs. M. Heim, W. Schöne)
- The specialist Hospital Lübben/Spreewald (Drs. Wenzel, Vogel)
- The county Psychiatric Hospital Neuruppin (Dr. Gröhlert)

Even though seasonal affective disorder is considered one of the few applications of light therapy for which there is a wide consensus, the tendency in East German hospitals has been rather towards using light as an adjuvant therapy

to conventional antidepressant treatment in major depression. The hypothesis underlying this approach is that of accentuating the synchronization of circadian rhythms. In this context, systematic comparisons with sleep deprivation have been made and the results have been published.

The main focus has been on practical use of, and indications for light therapy. There is still little consensus as to preferential morning or evening treatment, which may be dependent on the rhythm characteristics of the individual patient. However, light therapy has been established in East German centers as a potent adjuvant in the battery of antidepressant therapeutic modalities, so much so that it is already a routine treatment for hospitalized patients.

We assume that in major depression a modification of rhythmic regulatory processes has taken place. Following a labile vegetative stage, increase in depth of depression results in a new partially stable balance between the rhythmic functions. In this relatively stable state of functional sensitivity, bright light (2500 - 10000 lux) hitting the retina is considered to act synergistically with other therapy methods.

In the Arnsdorf hospital we use light therapy as such a "push" in this apparently sensitive and evolutionarily vulnerable system. We consider the role of light in its widest sense as a meaningful zeitgeber to increase coupling between different rhythms. Harmony between internal and external rhythms was already a goal of medical treatment in antiquity, and can today be subsumed under the concept of well-being. This should be the broad goal of light therapy.

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LIGHT THERAPY IN (WEST) GERMANY

There are quite a few university centers in the former West Germany (Free University of Berlin, Bonn, Erlangen, Göttingen, Frankfurt, Heidelberg) that study patients with seasonal affective disorder (SAD) and explore the effects of light therapy. In addition, light therapy is used on a practical level without research protocols in approximately 15% of psychiatric inpatient facilities [data derived from sales figures provided by light manufacturers and also by a recent systematic investigation (Kasper, S., S. Ruhrmann, S. Neumann and H.-J. Möller, unpublished)]. The disorder is still too often neglected, probably due to the fact that SAD patients are seldom hospitalized (Kasper and Kamo, 1990).

Light therapy in Germany is carried out in the same way as described by the NIMH group. Mostly large light boxes are used (120 cm long and 60 cm wide), but recently smaller and lighter fixtures (75 cm long and 46 cm wide) have become available. The first systematic studies on light therapy in Germany were initiated in 1986 by the Psychiatric Department of the University of Frankfurt where patients with fall/winter difficulties were recruited (Köhler and Pflug, 1989). They have recently developed a scale to quantify depression based on a light-dark scale (Fey and Pflug, 1991). This group confirmed the beneficial effects of light therapy in SAD patients (Köhler et al., 1987; 1989). At the same time the first report from the former East Germany appeared on the

beneficial effects of light therapy in non-SAD patients (Peter et al., 1986; Heim, 1988). Most of the results reported below have been presented recently at national and international meetings and this summary brings the published information up to date.

SAD — clinical and psychopathological description

Köhler et al. (1987) described the clinical and demographical profile of SAD patients in Germany and noticed that atypical symptoms in their sample were not as markedly present as in the NIMH sample; this was confirmed by our group (Kasper et al., 1992b). Both groups found that the majority of the SAD patients are women and that the syndrome starts in the third life decade. SAD patients are mostly recruited via referrals and advertisements in newspapers, and studied in seasonality clinics at the Universities of Bonn, Frankfurt and Heidelberg. With the above mentioned sampling methodology we recruited 170 patients in Bonn (during 3 consecutive years) of whom 85 fulfilled the DSM-III-R criteria for SAD and 30 for its subsyndromal form (S-SAD).

Whereas patients in the North American studies reported that the months January and February are the worst, in two German centers (Bonn and Frankfurt) patients are already symptomatic in November/December, these latter two months also being rated as the worst months in the course of the year. In addition to the well known psychopathological description of SAD and S-SAD we recently characterized (Kasper et al., 1992a) a group of patients with fall/winter difficulties who can be classified as suffering from a seasonal type of recurrent brief depression (RBD) (Kasper et al., 1992a). The criteria for the seasonal type (fall/winter) of RBD (RBD-seasonal) have been standardized as follows: 1) diagnostic criteria for major depression (DSM-III-R) concerning mood and number of symptoms which represent a change of previous functioning, 2) duration of depression episodes less than 2 weeks, 3) at least 1 - 2 episodes per month in fall/winter, and 4) full remission in spring/summer, or depressive episodes in fall/winter should substantially outnumber the ones in spring/summer. Our preliminary data indicate that 31% of the patients who were diagnosed as suffering from either SAD or its subsyndromal form (S-SAD) can also be categorized as RBD (RBD-seasonal) in a one year observation period. The mean duration of each episode was 4 days in the RBD-seasonal group. Patients with RBD-seasonal experienced seasonal changes as more of a problem and reported a lower percentage of first degree relatives with a history of depression than the non-RBD-seasonal group.

Epidemiological studies on SAD

The first study to investigate how many patients from an open inpatient ward of a German university hospital (Heidelberg) could be classified as suffering from SAD was carried out by Kasper and Kamo (1990). The results of this study indicate that 11% of these depressed inpatients experienced a seasonal pattern of feeling worse comparable to that known for SAD patients. In order to further characterize the impact of seasonality in patients of a psychiatric hospital, we administered the Seasonal Pattern Assessment Questionnaire (SPAQ) to all patients who were admitted to the Psychiatric Department of the University of Bonn ($n = 648$) during a one year period (Kasper, S., G. Höflich, S. Ruhrmann and H.-J. Möller, unpublished). The data of this study indicate that seasonality with a fall/winter pattern is more prominent in affective disorder than in other diagnostic groups.

Approximately 6 to 10% of depressed inpatients are SAD patients. They would not have been diagnosed as such by physicians had no detailed information about seasonality been obtained. Since admission to psychiatric inpatient services is influenced to an unknown extent by various factors, it is not possible to generalize this data to other facilities. However, these data indicate that, in Germany, SAD patients do exist in inpatient services. Recent observations show that centers which work with SAD patients are consulted by an increasing number of patients (especially in Frankfurt) without any new advertisements (Köhler and Pflug, personal communication). Nevertheless, there is as yet no epidemiological field study in Germany comparable to the ones which have been carried out in North America, Switzerland or Scandinavian countries (for review see: Kasper, 1991).

Effects of light therapy in SAD

The group of Köhler and Pflug were the first in former West Germany to confirm the beneficial response to light therapy with bright light in SAD patients (Köhler et al., 1987; 1989; Köhler and Pflug, 1991). This group found the dim light condition to be significantly inferior to the bright light condition. These results have been confirmed by Kasper et al. (1990) at the University of Bonn and extended to the group of subsyndromal SAD (Kasper et al., 1992a) and the seasonal form of recurrent brief depression (RBD-seasonal) (Kasper et al., 1992b). The research group of Kick et al. (personal communication) at the Psychiatric Department of the University of Heidelberg also noticed, as in the other German research groups, that approximately 80% of SAD patients respond within one week. In an attempt to find out if the type and amount of

anxiety in SAD patients is related to treatment outcome we studied 28 patients (Ruhrmann et al., 1992b). Our results indicate that a high level of anxiety is a negative predictor for treatment response with bright light. These patients are more likely to respond to the dim light condition.

Since light therapy protocols are mostly carried out in patients' homes, and since it is also hard to control the ambient light in a hospital setting, we studied the amount of light exposure during a protocol with bright and dim light by means of a portable light meter (Ruhrmann et al., 1992c). Our data demonstrate that patients receive more light during the bright than during the dim light condition or than during a natural light exposure without a light therapy protocol.

Effects of light therapy in non-seasonal depression

The group at the psychiatric department of the Free University of Berlin studied the effects of light therapy in non-seasonal depressive patients not receiving antidepressant medication. This group published its findings in a preliminary version with 30 patients (Mackert et al., 1990; Volz et al., 1990) and in a final version with 42 patients (Mackert et al., 1991). They did not find a statistically significant difference between treatment with bright light (2 hours, 2500 lux, 1 week) and dim light. On the other hand, Braunwarth et al. (1992) from the University of Erlangen reported beneficial effects of light therapy in a sample of 22 non-seasonal depressed patients concomitantly treated with antidepressants. Light therapy was applied for 3 weeks with a duration of 2.5 hours daily (1 hour in the morning, 1.5 hours in the evening). It is also the experience of our research group at the University of Bonn that in non-seasonal depression a longer duration of light therapy is necessary to achieve an antidepressant effect and that a combination with antidepressants is necessary. Kick et al. (personal communication) also noticed some beneficial effects of light therapy in combination with antidepressants in non-seasonal depression. This group works on the question of uncovering the psychopathological factors which might be associated with the response to light therapy in non-seasonal depression.

Volz et al. (1991) reported the side effect profile of light therapy in 42 non-seasonal depressed patients and found no difference between the bright and the dim light condition.

Light therapy in indications other than depression

Rüther et al. (1991) reported that light therapy with an intensity of 5000 lux was used to entrain the circadian

sleep-wake cycle in a patient with otherwise free running rhythms. Unsystematic studies indicated that light therapy is also beneficial in patients with premenstrual syndrome (Kasper et al., 1990). Höflich et al. (1991) described the beneficial effects of light therapy in a seasonal form of obsessive compulsive disorder (OCD). Zinner et al. (1991) explored the effects of light therapy in schizophrenia and pointed out that schizophrenic patients with seasonally occurring depressive and/or so-called negative symptoms might benefit from light therapy as an adjunct to neuroleptic medication.

Pharmacological treatment of SAD patients

There are valid reasons to explore other treatment modalities than light therapy in SAD patients: 1) light therapy does not work in all SAD patients, 2) it is not accepted by all patients with fall/winter difficulties, 3) there is some evidence that specific neurotransmitter systems, like the serotonergic system, are specifically involved in SAD symptomatology, and 4) light therapy is a time consuming therapy and SAD is a life-long illness. We therefore initiated a treatment protocol in which the specific serotonin re-uptake inhibitor fluoxetine is compared with bright light in a controlled setting during a 6 week observation period (Ruhrmann et al., 1992a). The study is not yet finished nor the blind broken, but a low drop-out rate and the overall good outcome indicate that both treatment modalities seem to be equally effective. Based on our clinical experience we think that the choice of treatment, light therapy or pharmacological approach, is more dependent on personality and coping factors than on specific efficacy criteria, except for the occurrence of side effects which also might depend on a specific disposition.

The effects of light therapy on biological parameters

There are a few reports about the effects of light therapy on biological parameters. The research group at the University of Frankfurt focuses on the impact of light therapy on circadian rhythms (Köhler et al., 1987; 1989). From the studies of this group there is some evidence that a lengthening of the photoperiod with light therapy intense enough to suppress melatonin function is associated with antidepressant efficacy. At present this group focuses on the question whether non-photic Zeitgebers are an antidepressant and, if they, like light therapy, can phase shift the circadian system.

Rao et al. (1990) reported circadian profiles of melatonin (serum) and serotonin (blood) which were obtained in 30 patients with non-seasonal depression before and after light therapy (design and clinical variables see Mackert et al.,

1990 and Volz et al., 1990). Light therapy marginally modified circadian melatonin profiles in depressed patients and healthy controls but it augmented blood serotonin throughout the day. It was somewhat conflicting that this serotonin increase was seen in all patients and also in healthy controls, after the bright as well as after the dim light condition. From the same sample, Hegerl et al. (1991) reported the auditory evoked potentials in connection with blood serotonin levels. They found that N1 and N1-P2 amplitudes are negatively correlated with blood serotonin levels after therapy with bright light or fluvoxamine.

Braunwarth et al. (1992) studied the TRH test and the DST (1 mg dexamethasone) before and after three weeks of light therapy in non-seasonal depressed patients. Although patients improved with bright light (as an adjunct to antidepressants) there was no significant change in these tests after three weeks of light therapy.

Ruhrmann et al. (1991) could not confirm the findings of Szádóczy et al. (1989) that increased platelet imipramine binding is associated with the beneficial effects of light therapy in SAD patients. Furthermore, there was no association with changes of blood serotonin levels before and after light therapy. Since changes in body temperature have been reported after light therapy, we are currently exploring the relationship between thyroid hormones and response to light therapy, a study which is at present not yet finished (Ruhrmann S., S. Kasper, I. Pertuch and H.-J. Möller).

Conclusions

The existence of SAD and its subsyndromal form, and the possibility for their treatment with light therapy is slowly becoming recognized in Germany. On a practical level, it is important to know that most insurance companies reimburse SAD patients for their light therapy equipment if there is certification by a specialist about its therapeutic indication. Although there are a number of psychiatrists in private practice who have heard about light therapy, they are still hesitant to use it for their patients since there is as yet no adequate way to get reimbursed by insurance companies for their specific work with this type of treatment. Nevertheless, the few psychiatrists who use it have results which are as good as the ones mentioned above from research facilities (Schuchardt & Kasper, 1992). From our point of view it seems worthwhile to specifically focus on the course of SAD in prospective longitudinal studies which might result in more specific diagnostic subgroups, like the recurrent brief depression form of SAD. With this longitudinal approach we could also learn more about coping styles and shifts of diagnoses.

Furthermore, the fascinating area of the underlying biological profile of SAD still needs further exploration, especially in the longitudinal course of the illness, which probably should be addressed in a multicenter collaborative study in order to avoid the disadvantage of small sample sizes. Finally, since light therapy does not work in all SAD patients and since it is not accepted by all patients with fall/winter difficulties, for instance due to its time consuming properties, it is necessary to initiate therapy protocols with different kinds of treatments which have been effective in major depression.

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BULLETIN BOARD

WELCOME TO NEW MEMBERS

We welcome new members who have joined SLTBR since publication of the September 1992 issue:

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MEMBERSHIP RENEWALS DUE

Included with this issue of *LTBR* is an invitation to renew your SLTBR membership for 1993. The membership renewal form includes space for you to update address and communication information for our files as well as the opportunity for clinician and research members to provide data on practice interests. Please note the renewal deadline of 20 January 1993. Renewals received after 1 February 1993 will be assessed a \$10.00 late penalty. Clinician referral information and corporate membership listings will be revised after the renewal deadline to reflect current members. SLTBR does not endorse either clinical services provided or products manufactured by its members.

SLTBR ANNUAL MEETING UPDATE

Plans are being finalized for the SLTBR 1993 annual meeting to be held at the University of California, San Diego, School of Medicine from 19-20 June. Registration information and abstract submission forms will be mailed to all SLTBR members in January 1993.

ASDA/SLTBR TASK FORCE ON THE USE OF LIGHT TREATMENT FOR SLEEP DISORDERS

This new Task Force, described in our September issue [*LTBR* (1992) 5: 14], will have assembled its first draft — for internal review by task force members — by the end of the year. Their aim is for *comprehensive* consideration of published and unpublished data on the efficacy of light treatment for sleep disturbances of jet lag and shift work, of the elderly, of SAD, and the chronic sleep phase syndromes. It is the responsibility of the research community at large to assure that the task force receives thorough input. Deadline for receipt of additional materials: 1 January 1993. Draft completion is scheduled for early in the new year. Please promptly mail materials to the task force member responsible for each section: jet-lag (Z. Boulos); the elderly, and alerting/activating effects of light (S.S. Campbell); shift work (C.A. Czeisler); basic processes (D.-J. Dijk); sleep phase disorders, and hypersomnia of winter depression (A.J. Lewy). Addresses are listed in the September issue of *LTBR*.

SIGH-SAD NOTES

The July 1992 revisions of the SIGH-SAD and HIGH-SAD instruments introduced significant clarifications of — and additions to — the questioning. Now that the interviews have been patient-tested, several additional changes in phrasing have been suggested to improve the conversational flow. These have been incorporated into a November 1992 edition, which will be mailed automatically to everyone who purchased SLTBR's *SAD Assessment Tools Packet* since July. The *Packet* itself will henceforth include the new edition. Researchers who have already begun using the July 1992 revision for this season's clinical trials may wish to substitute the November update when it arrives or continue with the earlier version until next year. Scoring is unaffected. The SIGH-SAD-SR (self-report version), also dated July 1992, has not been altered.

BIOLOGICAL EFFECTS OF LIGHT SYMPOSIUM

The third Symposium on the Biological Effects of Light, to be held in Basel, Switzerland from 3-5 June 1993, is currently accepting abstracts. Submission deadline for all abstracts is **15 February 1993**. A half-day presentation on "Light and Circadian Rhythms" is being organized by Anna Wirz-Justice and George C. Brainard. Abstracts and inquiries should be addressed to *Light Symposium Foundation, Bahnhofstrasse 47a, CH-4132 Muttenz, Switzerland; fax (41) 61-610051*.



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