SLTBR NEWSLETTER

Society for Light Treatment and Biological Rhythms

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THIS COULD BE YOUR LAST ISSUE . . .

. . . if you have not become a member of SLTBR by 15 September 1989. Starting with Vol. 2, the *Newsletter* will be sent only to members, with the exception of certain government and press agencies. We urge you to stay in touch with SLTBR by joining now *(see criteria on p. 9, and application form attached)*. Other benefits of membership include: *a)* posting notices on the *Newsletter Bulletin Board*; *b)* discounted registration for annual meetings; *c)* participating in SLTBR committees; *d)* presenting research at annual meetings; *e)* receiving and being listed in the *Membership Directory*, a source for subject recruitment and listing of professional services available; *f)* joining our active international dialogue and debate; as well as the obvious intangibles.

ANNUAL MEETING REVIEW
QUO VADIS DSM-IV/SAD?

[With this article we begin a systematic digest of papers and committee forums at our first annual meeting, which was held on 21 June 1989 at the National Institutes of Health, Bethesda MD. Future issues will report on developments in the analysis of the mechanisms of SAD and light therapy, and federal/industrial relations. Readers may also be interested in obtaining the Annual Meeting Abstracts (see order form attached).]

Previous issues of the Newsletter have reviewed the current status of attempts to refine diagnostic criteria for SAD to be incorporated into DSM-IV (the next edition of the Diagnostic and Statistical Manual of Mental Disorders published by the American Psychiatric Association). At the SLTBR annual meeting leaders of the DSM-IV debate presented their points of view. Highlights are summarized below:

Dr. David Avery, Chair of the SLTBR DSM-IV Liaison Committee, opened the session with an overview of the diagnostic issues being debated and introduced Dr. David Dunner, who is coordinating SAD matters for the DSM-IV Task Force Work Group on Mood Disorders. Task Force leader Dr. Allen Francis has requested evaluation of the data supporting the validity of individual diagnostic criteria. The report on SAD will also apply criteria of Robins and Guze *[American Journal of Psychiatry (1970) 126:107-111]* in its review of the literature. To justify SAD as a diagnostic entity by these guidelines requires data substantiating a reliable

clinical description of the syndrome, laboratory studies supporting the uniqueness of the syndrome, follow-up studies, family/genetic information, and data on therapeutic response.

Dunner emphasized that "changes in diagnostic criteria for SAD included in DSM-IV will have to be supported by data." Without such data, "SAD will continue to be a 'parenthetic' diagnosis, listed but not coded." He added that the committee may respond to a strong unity of opinion among authorities in the field, even if adequate supportive data cannot be developed in time for the writing of DSM-IV. He cautioned, however, that "DSM-IV will be around for 10 years and you don't want to be stuck with something [i.e., a set of criteria] you wouldn't want." *[Consensus report follows -- Ed.]* He noted that final recommendations of the Mood Disorders Task Force must be presented to the DSM-IV Committee by October 1989. As pointed out by a member of the audience, however, there will be time for modifications during subsequent field trials of the DSM-IV draft.

Dr. Norman Rosenthal defined a two-part agenda for investigators: the first is whether "we want to change awkward, cumbersome, inappropriate diagnostic criteria." The second is "the more profound, scientifically interesting question of whether SAD is a valid, distinct entity." Rosenthal believes that we will not be able adequately to address the latter issue before the DSM-IV deadline, and should therefore concentrate on changing those criteria in DSM-III-R with which we are least content.

The 60-day window is one such criterion, and Dr. Avery discussed new data pertinent to the question of its diagnostic validity. In a recent study of winter depressives, seven of 19 patients failed to meet DSM-III-R criteria because of the 60-day window. Onset of symptoms within the DSM-III-R window did not correlate with a superior response to either morning or evening bright light, although the symptom of hypersomnia was associated with superior response to morning light. Dr. Anna Wirz-Justice added that the diaries of 69 patients she has studied failed to support the 60-day window or the 3:1 seasonal-to-nonseasonal ratio; indeed, only approximately 2/3 of subjects fulfilled all DSM-III-R criteria.

An important issue to resolve, according to Dr. Rosenthal, is that of nomenclature: should winter depression and summer depression be subtypes of SAD, or primary diagnoses in themselves? In addition, he felt, the question of whether responsiveness to light should be included among the diagnostic criteria could be addressed in time for DSM-IV. (The issue of light responsiveness was also raised by Dr. Dunner, prompting Dr. Daniel Kripke to remind the audience that SAD is not the only clinical syndrome which responds to bright light treatment.)

Dr. Rosenthal also addressed the larger question of satisfying the criteria of Robins and Guze for a diagnosable disorder. We have already accomplished much toward this goal, he noted, aided by "the homogeneity of the SAD population, the willingness of the patients to come forward, their cooperativeness, the prevalence of the condition and the fact that many were drug-free." In order to validate SAD as a distinct syndrome, comparisons with nonseasonal depressives will have to be made, according to Rosenthal. These studies will be difficult and prolonged, given the characteristics of nonseasonal major depressives (heterogeneous group, frequently medicated, frequently in-patient). "SAD overlaps with bipolar nonseasonal depression, atypical depression and dysthymia. To delineate the syndrome, one must do comparison studies between all these groups." As for other Robins-Guze criteria, "Biological studies of SAD patients have found abnormalities in dopamine and serotonin metabolism, circadian rhythms, hypothalamic-pituitary-adrenal axis, immune functions, sleep, and dark adaptation," Rosenthal said, adding that controlled comparisons with nonseasonal depressives looking at these biological markers will be necessary to meet the desired level of validation. The recent introduction of seasonality questions into an Australian twin registry questionnaire may provide the hoped-for genetic validation of SAD. However, Rosenthal remarked, "course (i.e., clinical history) will be more important than family studies" in the definition of this syndrome.

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THE DSM-IV DEBATE, CONT'D.
PREPARATION FOR THE DUNNER REPORT

Following up on Dr. David L. Dunner's request at the SLTBR annual meeting, Dr. Norman Rosenthal surveyed several of the SAD research and clinical groups. Opinions on the clinical criteria for the seasonal depression syndromes to be described in DSM-IV were tabulated to prepare preliminary suggestions for Dr. Dunner and the American Psychiatric Association DSM-IV Mood Work Group.

Response to the survey was prompt and detailed. Though some felt that the DSM-IV criteria for seasonal pattern would best be strictly defined, most

respondents favored "user-friendly" criteria that would be of practical use both to clinicians and for general clinical research. Reasoning that it is more important to identify and treat all seasonal patients-- even at the risk of including a few non-seasonal patients -- rather than to exclude seasonal patients who fail to meet a strict set of criteria, a somewhat looser set of criteria than presently mandated in DSM-III-R was prescribed by many respondents. Though a few colleagues were not willing to endorse all of the recommendations ultimately submitted, 30 clinicians and researchers did lend their support to the consensus report.

SUMMARY OF SURVEY RESULTS

1. *How many episodes of seasonal mood disturbance are needed for a diagnosis of seasonal pattern?* Three was chosen by a large majority of respondents.
2. *Should the ratio of seasonal to non-seasonal mood disturbance be maintained?* No -- for two reasons. In many respondents' experience, a good number of people with regular seasonal depressions are also subject to depressions at other times of the year, for example during cloudy spells or as a result of stressful life events. Although someone with too many of these non-seasonal episodes might dilute the quality of a research population, it would be unfortunate if in a clinical context their seasonality were not recognized and treated. Second, the ratio is not easily calculated.
3. *Should the entire lifetime be considered in evaluating seasonality?* Yes. This was a majority opinion and if the DSM-IV committee drops the ratio requirement, it becomes less burdensome for the clinician to review the lifetime pattern.
4. *Should 60-day windows for onset and offset of seasonal episodes be maintained?* No. Abolition was advocated by a large majority. Even those who wanted the windows to be maintained suggested expansion to 90 days.
5. *Should summer and winter type be listed separately in DSM-IV? If so, should the criteria for summer type be patterned after those for winter type?* The vast majority of responders replied "yes" to both of these questions.

CONSENSUS RECOMMENDATIONS TO DR. DUNNER

Most respondents thought that the present descriptors of seasonal pattern should be left intact with the exceptions listed below. The group requested that the DSM-IV committee:

1. consider abolishing the 3-to-1 seasonal to non-seasonal ratio;
2. consider abolishing the 60-day windows, and replacing this criterion with "gets depressed nearly every year during the same season;"
3. consider including descriptive terms for "winter type" and "summer type" seasonal patterns; and
4. consider removing the exclusion criterion involving psychosocial stressors. (This was previously agreed upon at the May 1987 NIMH workshop on SAD and light therapy.)

Co-signatories of the letter were *Janis Anderson, Ph.D., David Avery, M.D., George Brainard, Ph.D., Joanne Brown, Ph.D., Alan Buchanan, M.D., FRCPC, William Byerly, M.D., Richard Depue, Ph.D., John Docherty, M.D., Karl Doghramji, M.D., Arlene Frank, Ph.D., James Gaddy, Ph.D., Raymond Lam, M.D., FRCPC, Breck Lebegue, M.D, Alfred Lewy, M.D., Ph.D., Pamela Madden, M.S., Robert McGrath, Ph.D., Dan A. Oren, M.D., Barbara L. Parry, M.D., Ronald Remick, M.D., FRCPC, Norman E. Rosenthal, M.D., Robert Sack, M.D., Robert L. Spitzer, M.D., Jonathan Stewart, M.D., Karen Stewart, Ph.D., Jiuan Su Terman, Ph.D., Michael Terman, Ph.D., Michael Thase, M.D., Jean Joseph-Vanderpool, M.D., Thomas A. Wehr, M.D., Betty Welch, B.A., and Janet B.W. Williams, D.S.W.*

THE NEXT STEP FOR SLTBR

The recommendations made in the consensus report are only one step in an ongoing process, not the last words. In the next few months we will continue with our fax/MCI discussions and another poll in order to refine the recommendations, if necessary, and address the suggestions of all interested colleagues. Such discussions could lead to further recommendations for the APA committee. If you wish to respond to the interim recommendations, or to propose further questions for consideration, please take the initiative by writing to Dr. Norman Rosenthal, *NIMH CPB, Bldg. 10 Room 4S-239, Bethesda MD 20892; fax 301/496-5439; MCI Mail 359-4687.*

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ANNUAL MEETING REVIEW
NON-SEASONAL APPLICATIONS OF LIGHT

It is exciting that our field has expanded into new areas of inquiry, such as identifying additional seasonal syndromes, non-SAD applications of light treatment, and alternatives to light treatment for SAD. The recent SLTBR meeting featured several presentations which highlight this diversity of research interests.

Parry et al. reported on the efficacy of light treatment for premenstrual depression (Late Luteal Phase Dysphoric Disorder). In their study, patients were treated during the luteal phase with two hours of bright morning light, bright evening light, or evening dim red light, using a randomized crossover design. Significant improvements in mood were seen after treatment with bright evening light, but not dim red light. Morning light exposure resulted in non-significant changes in mood, as well as agitation in some patients. In addition, overnight melatonin samples were collected, prior to light treatment, during four menstrual cycle phases. Patients exhibited advances in the midpoint and offset of nocturnal melatonin secretion during the luteal phase, relative to controls. The post-treatment overnight melatonin profile of one patient was presented: she exhibited increased amplitude and a phase advance in response to morning light, and phase delays following bright evening light. These data suggest that there may be disturbances of circadian rhythms in premenstrual depression, and that exposure to properly timed light may correct the rhythm disturbance as well as the mood disturbance.

Two presentations focused on alcoholic patients. *McGrath et al.* have identified a subtype of alcoholism which they have labelled *Seasonal Alcohol Abuse and Dependence*. The investigators have developed a screening procedure using criteria similar to the DSM-III-R criteria for seasonal depression. The cases studied so far are relatively severe, with repeated hospitalizations occurring primarily in the fall and winter months, and concurrent depression. The investigators hypothesize that alcohol intake in their patients may in part be a manifestation of seasonal increase in carbohydrate intake, and predict that prophylactic light treatment will be effective.

The effect of light therapy for detoxified alcoholics was investigated by *Yahia et al.* Their patients were men who were hospitalized in a rehabilitation unit, had been alcohol-free for two weeks, and who met criteria for non-seasonal major or minor depression. After five days of treatment with either bright or dim light for two hours in the morning, patient and physician ratings showed patients to be improved under both treatments. Light treatment appeared to be most effective in normalizing sleep and increasing motivation. It is possible that these particular symptom effects, as well as the response to dim light, may be due to nonspecific or "energizing" effects of light distinct from mood-altering or phase-shifting effects; alternatively, placebo responding or simple passage of time since detoxification could account for the results. Future studies might therefore include untreated control groups, "phase-typing" of subjects, and treatment periods extending beyond five days.

Two presentations focused on light treatment for non-seasonal depressive disorders. *J. Stewart et al.* investigated the response to two hours of morning plus evening light therapy in a group of patients with atypical depression without seasonal pattern. Their patients, and a comparison group of SAD patients, showed similar symptoms, but only the SAD patients responded to light treatment. The authors concluded that bright light was not effective for atypical depression, and suggest that atypical depression and winter depression may thus be separate disorders. *Deltito et al.* treated patients with a variety of unipolar and bipolar diagnoses, using either bright or dim light for two hours in the morning. Both unipolar and bipolar patients improved, whether they were assigned bright or dim light, although bipolar patients responded better than unipolar patients. Despite careful delineation of diagnostic sub-types and the use of standardized rating instruments in these two studies, their results are inconsistent with some previous investigations of light therapy for non-seasonal depression. Thus, this important issue remains unresolved.

Powers et al. presented data on bright light treatment of night-shift workers. Their subjects were exposed to 10,000 lux for 30 minutes each evening at home, before going to work. Subjects rated alertness, wore activity monitors, and kept sleep and work logs. During treatment, they showed increased alertness at work, and in some cases, improvements in sleep and mood. In addition, light treatment caused the usual 5 a.m. "slump" to occur later in the day. Treatment schedules had to be adjusted for some patients so as not to disrupt daytime sleep or weekend sleep. The investigators noted that evening light treatment on work days seems to permit continued reversal of sleep schedules on the weekends -- the common spontaneous pattern that may indicate lack of circadian phase reversal despite the reversed activity/rest cycle on work days.

Richter et al. investigated the efficacy of hypnotic light imagination for treatment of SAD. Their subjects received three hours of bright light imagination under hypnosis in the morning, followed by three hours of bright light in either the morning or evening as a separate treatment condition. Treatments lasted three days, and patients were withdrawn from treatment for ten days between each condition. Patient self-ratings of mood significantly improved following hypnosis and morning light, and there were no significant differences

between treatments. However, patients continued to improve following withdrawal from morning light, but relapsed immediately upon withdrawal from hypnosis or evening light. Hypnotic imagination may be a placebo; however, it is possible that refinements of the hypnosis treatment could improve efficacy. For example, hypnosis might be used to influence sleep patterns or to suggest an "energizing effect" of light. Such techniques might prove useful for treatment of those SAD patients for whom light therapy may be contraindicated.

Given the ubiquity of light, and the importance of biological rhythms in living organisms, it is not surprising that SLTBR members are exploring issues beyond SAD. Indeed, such research is important for the continued development of our field and may well increasingly define it in the future.

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EDITORIAL
DEVELOPING THE CASE FOR EFFICACY

[From a position statement given at the committee forum on federal/industrial relations at the SLTBR annual meeting.]

A convincing case for clinical efficacy of light therapy for SAD has yet to be made by most of our experiments. We are still faced with *tentative* results, many of them contradictory. I would like to urge that we deal with ambiguities more explicitly when we report our preliminary investigations in the literature.

Our attempts to demonstrate efficacy are confounded by several factors, including patients with varying symptom patterns, a wide range in severity of depression, and unverified compliance in home use of lights. We may be able to clarify results by exploiting the dosing variables of light -- intensity, duration, time of day -- in order to maximize the response of individual patients. Small sample sizes severely compromise many of our studies, and make spurious conclusions quite likely.

We need to report more than only statistical significance of the change in depression scale scores after treatment, or of the difference between experimental and control groups. Although some colleagues have argued that, from a clinical standpoint, *any* statistically significant change is to be welcomed as a sign of efficacy, we must acknowledge that in a treatment paradigm susceptible to large placebo effects we risk saying nothing specific about the efficacy of light unless we adopt an especially conservative stance.

We need to grapple openly with *both* types of statistical pitfall, that is, falsely *accepting* or falsely *rejecting* the null hypothesis. This involves calculating the magnitude of the treatment effect (e.g., d or h) and then determining the level of power achieved in testing group differences. [Useful guides include: *a)* Bartko J et al. (1988) *Psychiatry Research* 23:301-309. *b)* Cohen J (1988) *Statistical power analysis for the behavioral sciences*. Hillsdale NJ: Erlbaum. *c)* Pulver AE, et al. (1988) *Psychiatry Research* 23:295-299.] If the power is inadequate, we need to state that the conclusion is uncertain. Then we might choose to stick with the procedure and build up adequate sample size in order to sustain our initial impression. Toward this goal, we should report the target sample size at the outset. The calculations are simple, and they force us to make strategic decisions: if the sample size will be unwieldy, we may decide to change procedures in midstream -- essentially to start the experiment all over, perhaps enhancing the dosing variable or narrowing the severity range of subjects included in order to magnify the effect size and reduce the ultimate sample size required.

A reliable expected effect size is difficult to derive from pilot experiments, and in such cases the expectation can be based on those in the prior literature, as summarized in the recent cross-center analysis [Terman M, et al. (1989) *Neuropsychopharmacology* 2:1-22]. For example, a baseline/posttreatment comparison would be unimpressive with effect size less than approximately $d = 1.5$, and a well-designed and executed experiment should find values as high as 3.0. It is important to note that effect size is co-determined by the magnitude of mean score reduction and the underlying variability of scores. Working with a wide range of baseline severity (e.g., Hamilton scores from 12 to 30) necessarily compromises the magnitude of effect, and in such cases the data are properly analyzed by dividing the group into sub-ranges (e.g., mild, moderate, severe), albeit at the peril of further reducing sample size.

Until our experiments are adequate in these terms, we will not convince external critics about the efficacy of light treatment. Meanwhile, our preliminary reports should routinely state what would be required to transform them into convincing demonstrations. Pointedly, without adequate statistical power, we should be wary of claiming in the literature that two treatment conditions (e.g., morning vs.

evening light) do *not* differ.

The cross-center analysis struggled with these questions. We attempted to reveal dimensions of efficacy by pooling together large numbers of patients who underwent a common manipulation. The analysis was a heuristic exercise, not meant to draw final conclusions but rather to help narrow hypotheses for future experiments which *in themselves* would be convincing.

It is clear that our field is onto something hot, but now we have to prove it.

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WINTER DEPRESSION IN JAPAN: A NEW MULTI-CENTER STUDY

During the past five years many studies of SAD have been reported in various countries. In Japan, however, there have been only a few case studies. It is of interest to know whether or not there is any difference in susceptibility to SAD or responsiveness to light therapy between the Caucasian and Mongolian races. Members of the Japanese Research Group on Chronobiology, organized in 1986, conducted a multicenter survey of SAD last year. Sixteen facilities, from north to south, took part in the project: Hokkaido University; Shukutsu Mental Hospital, Muroran General Hospital; Akita University; Jikei University; National Center of Neurology and Psychiatry; Seiwa Hospital, Neuropsychiatric Research Institute; Saitama Medical School; Yamanashi Medical College; Hamamatsu University School of Medicine; Nagoya University; Shiga University of Medical Science; Osaka University; Kobe University; Medical College of Oita; Kurume University; University of Occupational and Environmental Health.

We recruited patients through nationwide and local newspapers. One thousand two hundred ninety people returned screening questionnaires. Two hundred fifty respondents were then interviewed by project staff. We followed Rosenthal's operational criteria for diagnosis of SAD, using DSM-III-R rather than RDC criteria to evaluate a major depressive episode.

Forty-seven SAD patients (20 male, 27 female) were identified. The mean age was 33.2 yrs for males and 38.5 for females. The average age of onset was 25.6 in males and 28.4 years in females. The mean duration of the depressive episode was 4.3 months. A family history of depression and other psychiatric disorders was observed with equal frequency in the two sexes (ca 50%). Seventy percent of males and 44% of females became hypomanic during spring and summer. Although most characteristics of SAD in Japan are similar to those reported in patients of other countries, the proportion of male patients--42% -- was extremely high.

The symptoms observed were also similar to those reported elsewhere. Social withdrawal, difficulty at work, and lowered activity were most prevalent. Concomitant symptoms included disturbed sleep, eating disorders, weight change, and carbohydrate craving. Female patients often showed hyperphagia (59%), weight gain (56%), or carbohydrate craving (78%), which were less prevalent in males (e.g., 35% with carbohydrate craving). Patients of both sexes reported hypersomnia (>70%).

Eleven male and eight female patients were given light therapy. Because of the preliminary nature of the study, we observed the effect of dim light or withdrawal from light treatment in only a few cases. Cool-white fluorescent light of 2500-3000 lux was used. Patients were exposed to light for two hours during the morning, usually between 0600-0800 hr. In three cases, the therapy was effective only after the exposure period was prolonged to 4-5 hours per day.

A mean baseline Hamilton Depression Rating Scale (HAM-D) score of 16.9 was reduced to 7.9 by one week of light therapy. The mean percentage of reduction in the HAM-D was 53.6%, with no obvious sex differences. 52.6% of patients were judged to have remitted according to the dual criteria applied in the cross-center study of Terman et al. (HAM-D score reduction of at least 50% to a posttreatment score <8). This conservative estimate of rate of successful treatment equals the 53% reported for morning light in that western cross-center study. Additionally, in one male and one female patient the HAM-D reduction was >50%, while posttreatment scores remained >8. Based on the general clinical impressions of the study doctors, 9/11 male patients and 7/8 female patients benefited from light therapy. In most cases, treatment was continued until spring, at which time discontinuation did not change the mood.

The present study demonstrates that light therapy is effective for Japanese SAD patients. The higher proportion of male patients in our study is striking. Whether this reflects an actual difference in incidence of SAD, or derives from cultural factors, remains to be explored.

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BOOK REVIEW
LIGHT UP YOUR BLUES: UNDERSTANDING AND OVERCOMING YOUR SEASONAL AFFECTIVE DISORDERS

Informational advertising is becoming increasingly popular among drug companies and other health care institutions. One can easily argue in favor of such efforts. While advancing the cause of the advertiser, they can also advance the cause of scientific communication in the public interest. However, the latter cause is served only to the extent that the information presented to the public is accurate and complete.

Robert N. Moreines, M.D., and Patricia L. McGuire, M.D., have apparently undertaken such a work under the sponsorship of the Psychiatric Institutes of America *(1989; The PIA Press, a Bantam Premium Book, $7.95).* This work makes no pretense to the professional reader of being a critical evaluation of research findings. It is obviously aimed at the lay public, people who might be searching for help and explanations or who might just be curious about the human condition.

To those of us who have dealt with SAD patients in therapy and research, the authors' case presentations ring true. Their accounts of patients' difficulties in finding a correct diagnosis and appropriate treatment are familiar. One believes that they have successfully treated winter depression. These authors have made a useful contribution to the clinical literature on SAD if for no other reason than that they seem to regard light therapy as only one tool for the treatment of winter depression. They point out that individuals vary in their response to treatment and therefore may require different mixes of therapy. This basic clinical principal seems often to be forgotten in our enthusiasm for light therapy.

The book's difficulties manifest themselves as the authors attempt to probe the causes underlying SAD and to explore issues in basic science. As early as page 11 one is tantalized by the statement ". . . we now have a very clear picture of what SAD is. . . ." However, search as one might throughout the rest of the book, the "clear picture" does not emerge as a coherent image. Along the way we are treated to new scientific "facts." For example, the authors have determined (by unknown methodology) that ultraviolet light is "warming," and that ". . . animals such as rats who are active at night secrete melatonin during the day." The reader will also be interested to learn that the superior cervical ganglia are located in the spinal cord. Could it be that this anomaly is responsible for winter depression?

The third chapter, entitled "The Causes of SAD," is troublesome. Rather than simply say, "We don't know what causes SAD," they wander around in an overstated exposition of the role of melatonin in human functioning. They suggest that melatonin has been proven to play a major role in the control of mood and sleep induction and sleep maintenance. Few researchers in this area would be so bold in the face of a large, contradictory body of data. Neither do the authors seem to realize that the main role melatonin has played in SAD research is as a putative marker of underlying biological timing processes rather than as a causative agent. It is in this chapter that the authors have an opportunity to clearly state the alternative hypotheses of the etiology of winter depression and describe the data that support and fail to support each theory. However, they do not. One is led to the suspicion that if they had, it would have become much clearer to the lay reader that we do *not* have a very clear picture of what SAD is. Such a conclusion would not likely be seen as good advertising.

To be fair, I believe that one must judge this book as a piece of informational advertising to the general public rather than as a rigorous review of the scientific literature. Despite such allowances, the errors in scientific fact and the attempts to create a sense in the reader that the authors have a firm grasp on known biological "causes" have resulted in a book as likely to misinform as not. The paradox here is that successful treatment of SAD patients with light does not require a knowledge of where the superior cervical ganglion is located nor of the role of melatonin in the life of the rat. One should nevertheless be aware that clinical experience with light therapy alone does not make one an authority in the field. The public is entitled to the same awareness.

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FROM AMERICAN MEDICAL NEWS
ON LIGHT THERAPY: ISSUES OF EFFICACY, INSURANCE REIMBURSEMENT, FDA RESPONSE

[This item is excerpted from an article by Lynne Lamberg -- discussing the SLTBR annual meeting--

which appeared in the 28 July 1989 issue of American Medical News. Reprinted with permission of the American Medical Association.]

Light boxes are available from several manufacturers at a cost of about $300 to $500, but they have yet to receive Food and Drug Administration approval as medical devices. No manufacturer has submitted data that the FDA finds acceptable, says George Mills, a biologist with the FDA's Center for Devices and Radiological Health in Bethesda MD. Existing studies contain flaws involving intensity, duration and wavelength of the lights as well as selection of the population studied, he said, adding that no manufacturer currently has an application before the FDA for review.

In 1986, the FDA found one lamp manufacturer's claims to be fraudulent. In addition to stating that light "helps fight winter blues," the labeling implied that light treatment might also increase sexual potency and reduce dental caries. At that time, the FDA said, "Light therapy as a treatment for winter depression is still experimental and should not be attempted without professional supervision." That still stands, Mills says.

Most insurance companies fail to recognize light boxes as a medical treatment, Dr. Rosenthal said. A survey of his patients showed only five out of 25 who sought insurance reimbursement for their light boxes received it. Physician charges are covered, he says, but the device itself generally is not -- an observation confirmed by an informal survey of the approximately 100 SLTBR attendees.

"There are no hard and fast rules to say when a procedure moves from the investigational phase to become part of standard medical practice," said Joel Miller, deputy director for insurance, managed care, and provider relations at the Washington, DC-based Health Insurance Assn. of America. "Insurance companies say a treatment must be ordered by a physician and recognized as customary for the particular condition," he added. Insurers review the literature, consult medical researchers, conduct their own review, and assess policyholder and employer interest -- which "plays a critical role in determining coverage."

Patient advocacy, Dr. Rosenthal suggested, may boost improved coverage. A support group for patients and families, the Washington, D.C.-based National Organization for Seasonal Affective Disorder, was organized last year.

Blue Cross/Blue Shield has a formal process to evaluate new technologies for its 74 member plans, said Sue Gleeson, executive director of technology management for the Blues in Chicago. To gain a recommendation for reimbursement, new technologies must be approved by a regulatory body, such as the FDA, she said. Additionally, a staff committee, along with outside consultants, evaluates peer-reviewed literature on benefits and risks and evaluates evidence that the new technology has a positive impact on health outcome, is at least as beneficial as an existing technology used in the same situation, and is feasible outside a research setting. "Many of the plans follow our recommendations, but decisions are made on a local level," Gleeson said.

"We all have evidence that shows with light treatment, patients have fewer sick days," noted Dr. Rosenthal. "This is an important point to get across to insurers."

INSURANCE ENDORSEMENT PACKET NOW AVAILABLE

Discussion at the annual meeting surfaced the need to provide insurance companies official documentation of the validity of the SAD diagnosis and administration of light therapy as the established treatment of choice when endorsing patients' reimbursement requests. The SLTBR Insurance Liaison Committee (Leslie L. Powers, M.D., Chair) has therefore prepared an explanatory letter accompanied by a set of published clinical appraisals of light therapy, for use by clinicians, researchers, and patients *(see order form attached).*

WELCOME TO NEW MEMBERS

SLTBR membership continues to grow rapidly (now >200), and those joining since publication of our last issue are mentioned below. We are issuing a comprehensive membership directory in the fall, *for which all members should send information requested on the form attached by 15 September.*

Regular Members

Dominicus Beersma, Mary Blehar, Philip Boyce, Gregory Brown, Robert Buchanan, William Dement, John Docherty, Richard Ferber, Paul Forlot, Peter Graw, Cornelis van Houwelingen, Jean Joseph-Vanderpool, Jamie Lilie, Peter Marriott, George Meyer, Harvey Moldofsky, Giovanni Muscettola, Michael Norden, Charles Pollak,

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MEMBERSHIP INFORMATION

If you are considering applying for individual membership *(form attached)*, please note criteria:

Regular -- for researchers with Ph.D., M.D., or equivalent degree who are actively working in the field of bright light treatment or biological rhythms. Only regular members have voting privileges. The Board of Directors will vote on applications for regular membership.

Associate -- for any interested persons such as scientists in other fields, clinicians, patients.

Student -- for students pursuing an advanced degree (post-bachelors) and engaged in research related to bright light treatment or biological rhythms. Anyone holding an M.D., Ph.D. or comparable degree is not eligible for student membership (e.g., postdoctoral fellows, residents).

Corresponding -- for research colleagues working in countries from which dues cannot be transferred in US$ or SFr to our membership offices. Criteria are the same as for regular membership.

As a special inducement for prospective members, SLTBR will extend the term of active membership through 1990 for anyone applying after 15 August 1989. For current members, 1990 membership dues will be due as of 1 January. Remember also that you will receive future Newsletters only if you have joined (exceptions: certain government and press agencies).

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Chronobiology International is an international transdisciplinary journal encompassing biological rhythm investigations in all life forms. It has been published since 1984 (now listed in *Current Contents, ADIS, CABS, BIOSIS Database, Cambridge Sci. Abstr., Index Medicus, MEDLINE, and MEDLARS*). The journal is dedicated to both basic and applied research, as well as the methodology, instrumentation and statistics of chronobiology.

The editorial board actively invites all researchers in the field of light treatment to submit papers in the form of *original research articles* (peer reviewed research investigations which represent new and significant contributions to science), *short communications* of two pages or less focussing upon preliminary findings of ongoing research, *editorials* written by leaders in chronobiology or supporting fields, and *letters to the editor* presenting comments on papers published in the journal.

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