

Light Treatment and Biological Rhythms

Bulletin of the Society for Light Treatment and Biological Rhythms



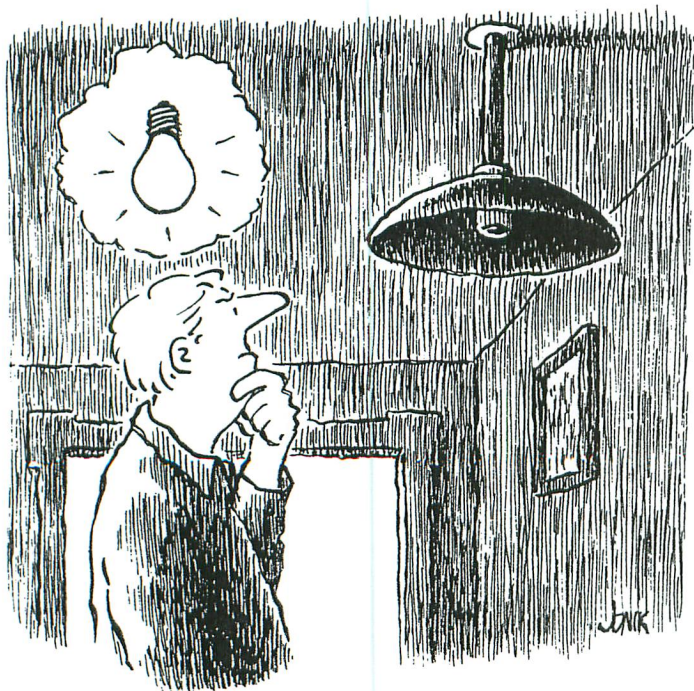
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FDA CONSIDERS LIGHT TREATMENT

Starting early in 1992, when the U.S. Food and Drug Administration (FDA) wrote many manufacturers advising them of Class III status (see definition below) of therapeutic light delivery systems, it became apparent that our field has reached a certain stage in which legal questions concerning the technology must be resolved. In several additional warning letters issued this summer, certain lighting companies were challenged on explicit or implicit claims in advertising and labelling, and ordered to halt marketing pending resolution and approval by FDA.

The May 1992 SLTBR annual meeting focused on these and related issues in an Open Forum including FDA and NIMH staff and SLTBR and industry representatives.



Man thinking of replacing light bulb.

Drawing by Jonik; © 1992

The New Yorker Magazine, Inc.

Lynn Lamberg reports on this session below. Frederick K. Goodwin, M.D., Director of NIMH, then issued an advisory report to FDA (reprinted in this issue). SLTBR has now explicitly urged FDA to postpone stop-marketing actions pending consideration of device reclassification petitions which are expected to be forthcoming from the Circadian Lighting Association — a newly-formed

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Light Treatment and Biological Rhythms
Bulletin of the Society for Light Treatment and Biological Rhythms



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manufacturers' group — and possibly from individual manufacturers as well. David H. Avery, M.D., Chair of SLTBR's Federal/Industrial Relations Committee, summarizes the current events and priorities in this issue of *LTBR*.

An additional initiative, also described below, calls for individual clinicians, researchers and users of light treatment devices to let FDA and congressional representatives know of their thinking about the matter. This special issue of *LTBR* has been designed to update the SLTBR membership so that arguments are fully informed. Your opinions need to be expressed concerning the availability of apparatus for research in SAD, in clinical practice for treatment of SAD, and on the open market for treatment of subsyndromal SAD. The availability of lighting devices for treatment of circadian disorders such as sleep phase syndromes, and the disturbances of shift work and jet lag, is an additional matter not to be disregarded. Apropos of the latter issue, the American Sleep Disorders Association, in collaboration with SLTBR, has formed a new Task Force (see p. 14) whose report and recommendations are expected within a year.

Given FDA's eventual approval of down-classification to Class II — for at least a subset of device types — there will be need to gain approval of "equivalent" devices proposed for marketing. The criteria for equivalency are judgmental. It seems clear that bright light boxes, light visors, and dawn-dusk simulators — as our main examples — are not automatically "equivalent", and may well require independent demonstrations of efficacy and safety. Even within the original category of "bright light boxes", variables include irradiance and illuminance levels, field of illumination, geometric arrangement of the lamps vis-a-vis the eyes, spectral distribution (importantly, level of short- and long-wavelength radiation, or use of restricted wavelength bands within the visual range) — not to mention instructions for use.

From this vantage point, the field should not delay in systematically organizing data and seeking new data where there are obvious lacunae, in order to define the functional boundaries with scientific rigor.

Michael Terman, Ph.D.
SLTBR President

FDA SENDS LETTERS TO SOME LIGHTING COMPANIES

"Your continued distribution, promotion, and advertising of the device is a violation of the Act."

This summer some light box manufacturers received letters from the Food and Drug Administration warning them to stop marketing bright light boxes. Last winter, the FDA sent warning letters to some manufacturers to stop advertising their light boxes as treatments for SAD. The FDA considers a bright light box a Class III medical device. Class III devices may not be used unless there is an approved Premarket Approval Application (PMA) or there is an Investigational Device Exception (IDE). The PMA process is very arduous, long and expensive. Bright light boxes can be used for investigational purposes.

Reclassification to Class II is also an option, but reclassification also takes time; usually the process takes several months to a year and a half after the petition is filed. The Circadian Lighting Association, an organization of light box manufacturers, is preparing to petition for a reclassification of light boxes to Class II. In a preliminary meeting with the FDA, Neal Owens of CLA presented

review papers of bright light therapy and other materials including SLTBR's Consensus Statements on the Safety and Effectiveness of Light Therapy of Depression and Disorders of Biological Rhythms (*LTBR* [1991] 3:45-49).

An Investigational Device Exemption (IDE) can be obtained from one's local Institutional Review Board (IRB). The subjects must be in a research protocol, and sign an IRB-approved consent which states the possible risks and benefits. The IDE is implicit in the approval of a light therapy protocol by the IRB. Obtaining an IDE would be useful for ensuring that manufacturers can make the apparatus available to researchers. Apparently, even if a company has received a letter from the FDA, they may make light boxes available for research purposes if there is an IDE.

The question before the FDA concerns primarily effectiveness of the bright light therapy in treating SAD rather than safety concerns.

Dr. Frederick K. Goodwin, the Director of the National Institute of Mental Health, as promised at our May meeting, has sent a letter to the FDA concerning this issue. On behalf of SLTBR, Michael Terman and I have sent a letter (reprinted herein) to David Kessler, M.D., Commissioner of the FDA.

David Avery, M.D., Chair, SLTBR Federal and Industrial Relations Committee, Harborview Medical Center, 325 9th Ave., Seattle, WA 998104. Tel 206-223-3425; fax 206-287-8615.

FDA CLASSIFICATION OF DEVICES

The three regulatory classes (I, II, III) are assigned according to the extent of control necessary to assure the safety and effectiveness of each device:

Class I "General Controls"

Regulates device for which general controls alone (e.g., "good manufacturing practices") are sufficient to assure safety and effectiveness. Examples include: innocuous devices such as bedpans, surgical knives, etc.

Class II "Performance Standards"

Regulates devices for which general controls alone are insufficient to assure safety and effectiveness and for which existing information is sufficient to establish a performance standard that provides the assurance. Examples include: Electronic thermometers, sphygmomano-meters, UV lights, surgical lights.

Class III "Premarket Approval"

Regulates devices for which insufficient information exists to assure that general controls and performance standards provide reasonable assurance of safety and effectiveness. Generally, Class III devices are those represented to be life-sustaining or life-supporting, those implanted in the body, or those presenting potential unreasonable risk of illness or injury. New Class III devices must have been approved Premarket Approval Applications (PMA's). Examples include: cardiac pacemakers, heart valves.

In addition, new devices that cannot be found to be equivalent to devices which were on the market prior to 1976 are Class III. Because light boxes were not sold commercially before 1976, they fall in Class III.

FDA LETTER [EDITED] TO A LIGHT BOX MANUFACTURER

July, 1992

Our review of the labeling for the product referenced above reveals that it is a device within the meaning of Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) . . .

Despite the disclaimer included in your labeling, we consider the labeling to make device claims. Also in a letter dated . . . 1989, you state that "Because of . . . interest in the treatment of Seasonal Affective Disorder, I thought you would be interested in the [name of light box] described in the enclosed brochure . . ." The Agency [FDA] has not cleared for marketing any similar preamendment device that is indicated for use in the treatment of Seasonal Affective Disorders or Winter Blues. Therefore, your device is classified by statute in Class III (Premarket Approval), under Section 513(f) of the Act.

Section 515(a)(2) of the Act requires a Class III device to have an approved application of Premarket Approval (PMA) before it can be legally marketed, unless the

device is reclassified. Our records indicate that you have not submitted a PMA. Therefore, the [name of light box] device is adulterated with the meaning of Section 510(f)(1)(B).

You should not market the [name of light box] until you receive written notification from the FDA allowing you to do so. Your continued distribution, promotion, and advertising of the device is a violation of the Act.

You should take prompt action to correct this violation. Failure to promptly correct this violation may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

Sincerely yours,

Ronald M. Johnson
Director
Office of Compliance and Surveillance
Center for Devices and Radiological Health
Food and Drug Administration

NIMH ADVISORY REPORT ON LIGHT THERAPY DEVICES

August 6, 1992

To: Director, Center for Devices and Radiological Health
Food and Drug Administration

From: Director
National Institute of Mental Health

Subject: Report on Use of Light Therapy for Affective Disorders

This memorandum responds to your request for information on the research that has been performed on the efficacy of light treatment devices. Attached are two recent review papers which describe some of the important

studies on the treatment of affective disorders using light therapy. They are:

Oren, D.A. & Rosenthal N.E., "Seasonal Affective Disorders," in Paykel E.S. (ed) **Handbook of Affective Disorders**, 2nd edition, in press.

Terman M. & Terman, J.S., "Light Therapy for Winter Depression: Report to the Depression Guidelines Panel," PHS Agency for Health Care Policy and Research, New York: New York State Psychiatric Institute, 1990.

In FY 1991 alone, the National Institute of Mental Health (NIMH) spent an estimated \$4 million on light therapy research.

Background

The textbook, **Electrotherapy and the Elements of Light Therapy**, (Richard Kovacs, Lea & Febriger, 1932, pp. 347-8, 362, 391-2), describes the use of light therapy as far back as the early 1930s to treat what was then termed

"neurasthenia" (defined as a functional disorder whose symptoms included mental depression, headaches, and a lack of energy). Today light therapy is used to treat disorders that are characterized more specifically as "seasonal affective disorders", but which share some clinical features with the earlier, less precisely defined term, "neurasthenia".

Seasonal Affective Disorder (SAD): The Syndrome and Its Prevalence

SAD was first formally characterized at the National Institute of Mental Health (NIMH) in the early 1980s. It is a condition characterized by recurrent fall and winter symptoms of low energy, oversleeping, overeating, carbohydrate craving, weight gain, concentration difficulties, decreased activity, sadness, and anxiety, with remissions in the spring and summer. Since its original description, it has been recognized on all six continents and has been incorporated into DSM-III-R as "seasonal pattern", a term that can modify any form of recurrent depression. Several prevalence studies of SAD have been undertaken. One such study, performed in Montgomery County, Maryland, estimated its prevalence at 4.3 percent of the population, and the prevalence of the less severe, subsyndromal form, "the winter blues" at approximately 14 percent of the population (Kasper et al., 1989a, as cited in Oren & Rosenthal). These conditions are more common with increasing latitude, as shown in a study that found the prevalence of SAD to be only 1.5 percent in Florida but 10 percent in New Hampshire (Rosen et al., 1990, as cited in Oren & Rosenthal). Based on this study, we have estimated SAD to affect approximately 6 percent of the adult population, with a further 14 percent being affected by subsyndromal SAD. Thus, one in five adults in the United States is symptomatically affected during the winter.

Consensus of the Society for Light Treatment and Biological Rhythms

The Society for Light Treatment and Biological Rhythms (SLTBR) has a membership of approximately 400 [including about 300 clinicians and researchers in the field of light therapy]. At its 3rd annual meeting in Toronto in 1991, a work group concluded that "light therapy has been convincingly demonstrated as clinically effective only for SAD, and that further research is required before such a claim can be made for subsyndromal SAD, non-seasonal depressive disorders, PMS, sleep disorders, shift work and jet lag disturbance".

Terman & Terman note that this conclusion is conservative (see pages 11 and 12). Some researchers argue for the efficacy of light therapy in those conditions where shifting circadian rhythms is desirable. For example, it has been shown that appropriately timed bright light is capable of phase advancing (shifting earlier) the abnormally delayed (late) rhythms of patients with delayed sleep phase syndrome. (See reference by Rosenthal et al., 1991, in Oren & Rosenthal.) Similarly, light therapy has been recommended by a consensus group of researchers studying advanced sleep phase syndrome in the elderly, as well as for jet lag and shift work (see Terman & Terman, 1990). Such shifting of circadian rhythms by appropriately timed exposure to bright light or darkness is fully anticipated by our understanding of human and animal circadian physiology (see reference by Czeisler et al., 1989, in Oren & Rosenthal.) Although relatively few studies have been performed in these areas on humans to date, findings obtained so far are in good accordance with what we would expect from our knowledge of the circadian system.

All evidence suggests that light therapy is effective for subsyndromal SAD (the winter blues). Although there is only one controlled study in this area (Kasper et al., 1989a, as cited in Oren & Rosenthal), the distinction between SAD and subsyndromal SAD appears to be artificial, resting on categorical criteria. There is evidence that seasonal changes in mood and behavior can be better conceptualized as falling along a spectrum of severity, with SAD and subsyndromal SAD representing different points on the spectrum. There is no reason to believe that the efficacy of light therapy would stop between these two points. A recent unpublished study (Dr. Mark Bauer, personal communication) reinforces this point of view, in that it showed that the tendency of normal controls to develop hypomanic symptoms in response to light therapy correlates with the extent of their retrospectively reported seasonal mood and behavior changes.

Research on the efficacy of light therapy for other indications such as PMS or non-seasonal depressions should continue to be encouraged.

Data on the Efficacy of Light Therapy in SAD

The consensus outlined in the above section is based on many controlled trials of light therapy undertaken at centers in the U.S. and abroad. Problems with these studies have included (1) the difficulty of controlling them, given that patients cannot be "blind" in the same sense as

in pharmacology trials; (2) small sample sizes; and (3) crossover designs, with the attendant problem of carry-over effects.

Despite these problems, researchers were able to demonstrate superiority of active versus control treatments in 14 studies (see Terman & Terman, Tables 2 and 3). No significant differences were found between treatment groups in four studies. Significant differences between treatment conditions have generally been attributed to specific psychobiological effects of light, as noted above. There is a very small minority view, expressed most strongly by Dr. Charmane Eastman in her paper, "What the placebo literature can tell us about phototherapy for SAD", *Psychopharmacology Bulletin* (1990, 26 (4): 495-504), in which she contends that most if not all the observed results could be attributed to a placebo effect.

Possible reasons for failure to show a difference between groups include (1) small sample sizes, with a resulting Type II statistical error; and (2) the control treatment may itself be active where brighter and less bright light are being compared.

In order to obviate the difficulties presented by small sample sizes, Terman and colleagues performed a cross-center analysis on all data available up until 1989 and concluded that treatment with bright artificial light was superior to treatment with a dim light control.

Side Effects and Safety of Light Therapy

To put safety concerns in perspective, it should be noted that the intensity of light delivered by light therapy devices is orders of magnitude below the intensity of light experienced by going outdoors, or even standing near a window. In 1984, NIMH, in collaboration with the National Eye Institute, performed a controlled, short-term study of the effects of light therapy on the eye using fundal photography. No retinal abnormalities were observed.

The SLTBR work group on safety "identified no hazard for a standard fluorescent lighting apparatus designed to produce 2,500 to 10,000 lux, given low levels of ultraviolet emission". This consensus reflects widespread impressions among clinicians and researchers, who have worked with light therapy over the past 10 years, that light therapy, like exposure to natural light, usually does not have side effects. Any side effects that do occur from exposure to light are generally mild; serious side effects are extremely rare. The SLTBR work group identified

several potential ocular risks (Terman & Terman, 1990). However, these concerns are theoretical since no serious ocular effects (e.g., retinal damage or cataracts) have been reported to date. Such concerns would be meaningful only in the absence of an effective UV screen.

The side effects reported most frequently are eyestrain, headaches, insomnia or hypomanic irritability (Oren et al., *Comprehensive Psychiatry*, 32 (2): 147-152, 1991), as well as dryness of the eyes and skin, and an erythematous skin reaction (see Terman & Terman, p. 18). In general, these side effects respond well to decreasing duration of light therapy or having the patient sit farther from the light fixture. Hypomanic side effects are not infrequent, however the precipitation of manic episodes, while possible, would be a very rare occurrence. To date, there are no published reports of manic episodes precipitated in patients with SAD, although one European report described the development of manic episodes in two nonseasonally depressed patients.

Clinicians agree that patients with certain retinal disorders, such as macular degeneration or retinitis pigmentosa, or patients taking certain drugs that are photoactive, should avoid normal outdoor light and, by extension, should not undergo light therapy. These indicators are generally known in the medical community.

Light Therapy Devices

Light therapy devices vary in design, with new variations constantly being developed. Three major classes of apparatus are discussed below: bright light boxes, twilight simulators and visors. Light therapy devices are described below in terms of the dimensions and intensity of the illuminated field — from the observer's point in space — and the spectral emission curve.

• Light Boxes

The fixtures used in the earliest modern studies were 2 feet by 4 feet and emitted approximately 2,500 lux at 3 feet. More recently, fixtures 2 feet by 2 feet, angled towards the subject's face so that the diffusing screen is about 18 inches from the subject's eyes, and emitting approximately 10,000 lux, have been used. The light source has been white fluorescent and research suggests that the light does not have to be "full-spectrum", nor is UV light a necessary component in order to obtain a therapeutic effect. Diffusing screens covering the fluorescent lamps have been standard features of fluorescent fixtures.

Newer Devices

Two newer devices have come onto the market more recently: the dawn-dusk simulator (SunUp, Pi Square, Inc., SunRiser, Moodlighter [*actually a visor type of apparatus, Ed.*] and others) and the light visor (Bio-Brite, Inc.). Both have been subjected to controlled studies, none of which has been published to date, as far as we know.

• Twilight Simulators

The idea behind the dawn-dusk simulator is to cause light of gradually increasing intensity to shine towards the eyes of the sleeping subject, to stimulate the eyes through the eyelids at a time of day when they are presumably exceptionally sensitive to light. The ultimate light intensities attained in studies undertaken thus far are far lower than those used in conventional light therapy (for example, 400 lux). Despite these low lighting levels, researchers in the Pacific Northwest have shown differences between "active" and "control" dawn simulations, using different durations and intensities of light. These studies have involved a relatively small number of SAD patients. Because this mode is convenient and an apparently innocuous intervention, as well as demonstrably superior to control treatment conditions, it is an encouraging option in the treatment of SAD. Further studies are needed, however, before the scope of its usefulness is fully defined and its antidepressant efficacy in comparison to conventional light box therapy can be determined.

• Visors

The [Bio-Brite] light visor, a portable, head-mounted light delivery system, has been extensively studied. Over 200 SAD patients have been treated with this device in three multicenter studies. In these studies, a wide range of different intensities (from 30 lux to 6,000 lux) have been compared. All intensities produced results comparable with those reported previously with several of the earlier 2,500 [lux] light box studies. The median response rate, according to stringent criteria, for the 7 treatment conditions was 46 percent; range = 27 percent to 56 percent. However, it is unclear why visors of widely varying intensities showed similar efficacy. Further studies are necessary to resolve this question. Side effects of the light visor have been comparable to those of the light box.

Need for Commercially Available Light Therapy Devices

Before the advent of light box companies, patients who needed light therapy had to purchase the box in one store, the light bulbs somewhere else, and then have the fixture wired, usually by an electrician. For many depressed patients, the effort involved in coordinating these steps often proved too great and light therapy was never tried. Moreover, even if a patient succeeded in having a fixture assembled, his or her physician could never be sure whether the home-made light box emitted enough light or was electrically safe. One patient, an engineer, reportedly rigged up his own fixture, which lacked a diffusing screen. He reportedly treated himself without supervision by gazing directly at unshielded fluorescent lamps at close range, which resulted in corneal abrasions (Dr. Michael Thase, personal communication to NIMH investigator).

Conclusions

SAD and subsyndromal SAD are common conditions which appear to be caused by seasonal light deficiency and which respond well to enhanced environmental lighting. In over 10 years of using light boxes in thousands of patients, the number of serious side effects reported has been vanishingly small.

From a public health standpoint, it is important for both physicians and their patients to have stable, approved sources for light therapy devices, since they have been shown to be effective in treating a prevalent disorder. It is prudent, however, for light therapy to continue to be administered under some form of medical supervision for several reasons: (1) to be sure that light therapy is the indicated or preferred form of treatment; (2) to integrate light therapy into a comprehensive medical regimen where indicated — involving, for example, medications and psychotherapy in addition to artificial light; (3) to prevent the development of serious side effects in vulnerable individuals, for example those with retinal problems or a propensity to mania; and (4) to minimize side effects in general, by modification of dosage or timing. It is also important that light therapy devices be eligible for reimbursement to the same extent as other effective medical devices.

Please let me know if you need any further information on this or other matters. I am very pleased to be working with you to advance our shared public health objectives.

Frederick K. Goodwin, M.D.

SLTBR LETTER TO FDA

30 August 1992

David Kessler, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Kessler:

We are writing as representatives of the Society for Light Treatment and Biological Rhythms (SLTBR), a not-for-profit professional/scientific organization founded in 1988 which includes approximately 300 clinicians and clinical researchers who have been using bright light therapy for treatment of the winter depression of seasonal affective disorder (SAD).

We have been notified that FDA's Office of Compliance and Surveillance has communicated with some companies marketing relevant lighting apparatus — upon which both research protocols and clinical practice depend. Our understanding is that, given Class III status of these devices, such marketing may be considered inappropriate.

In preparation for response to FDA, several lighting companies have formed an independent Circadian Lighting Association (CLA), which has already received the advice of your Office of Small Manufacturers Assistance relevant to their pending petition for reclassification. All signals strongly indicate the industry's intention fully and promptly to address FDA's concerns.

Prior scientific literature strongly documents the clinical efficacy and safety of "bright light box" designs, as was pointed out in a recent advisory report submitted by the National Institute of Mental Health (Frederick K. Goodwin, M.D., Director) to your Center for Devices and Radiological Health, although continued research on these topics remains an active focus of NIMH and private-industry funding. In addition, SLTBR has conducted an extensive professional consensus development procedure, which resulted in a very specific (and conservative) set of recommendations published in 1991 (copy attached).

Research momentum as well as clinical application would be severely adversely affected if commercial distribution of therapeutic lighting apparatus were halted — for the first time since the technology was introduced to the market in the mid-1980's — this coming fall/winter season, when patients will become symptomatic and in need of treatment.

We urgently request that FDA postpone potential stop-marketing actions during this period, in which reclassification is under consideration. Furthermore, we hope that FDA will continue to provide lighting companies with assistance in making application and coming to closure at the earliest possible time.

We offer SLTBR's continued input to these deliberations, if you see the need.

With many thanks for your consideration,

Sincerely yours,

Michael Terman, Ph.D.
President

David H. Avery, M.D.
Chair, Federal/Industrial
Relations Committee

IF YOU ARE CONCERNED ABOUT THE FDA DECISION . . .

It is possible that patients suffering from winter depression will have no access to bright light boxes this season. Manufacturers who sell bright light boxes, despite disclaimers, risk receiving letters telling them to stop distribution, promotion, and advertising of bright light boxes. The letter by Terman and Avery to the FDA on behalf of SLTBR is no substitute for expressions of individual concern from clinicians and researchers, and from persons who suffer from winter depression.

You and your patients have a right to express your views on these FDA actions to our government. Letters expressing concern over these actions can be addressed to the following individuals:

Ronald Johnson
Office of Compliance and Surveillance
Center for Devices and Radiological Health
Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

Gordon Johnson, M.D.
Office of Health Affairs
1390 Piccard Drive
Rockville, MD 20850

cc. Ronald Parr
Division of Small Manufacturers Assistance
Center for Devices and Radiological Health
5600 Fishers Lane
Rockville, MD 20857

Your own U.S. Senators and Representatives

ANNUAL MEETING REVIEW

WHAT IS SEASONALITY?

The definition of seasonality remains a fundamental unresolved issue in light treatment, according to Mark Bauer, M.D., who serves as a consultant to the Mood Disorders Work Group for DSM-IV. "The current conceptualization of SAD is based primarily on the study of fall-winter depressions," he noted in a talk preceding the Open Forum at this year's annual meeting.

Yet patients accepted into studies of SAD, Bauer pointed out, include those with both recurrent major and minor mood disorders and various hybrids of the two. Moreover, virtually all such patients have been recruited by referral and media advertisements for light treatment. Whether the symptom pattern in such patients resembles or differs from that in patients with depressed mood and energy who happen to be diagnosed in winter is not clear. The identification of patients with subsyndromal SAD further complicates the picture, he said, since "there is evidence that most persons have some degree of mood and energy change with changing seasons." Seasonality thus may be more of a continuum than a dichotomy.

Much as treatment modalities, particularly pharmacologic ones, served as diagnostic probes to define subgroups of depressives, placebo-controlled studies of light and drug therapy, Bauer suggested, may help to better organize the SAD spectrum.

Some psychiatric disorders, such as bipolar disorder, show striking seasonality. Recent studies suggest disorders other than mood disorders, including bulimia and obsessive-compulsive disorder, also may have seasonal patterns. "Determining the relationship of seasonality of mood disorders to that of other psychiatric syndromes will be important nosologically," Bauer asserted. "It also may provide important insights into the mechanisms of seasonality."

"DSM-III-R criteria are not user-friendly, especially the 60-day window," Norman E. Rosenthal, M.D. said in discussion following Bauer's presentation. "Still not settled is the issue of where summer depression fits in."

Lynne Lamberg, M.A., 3704 Gardenview Rd., Baltimore, MD 21208. Tel 410-486-0297.

FDA LIGHT BOX REGULATIONS MAY CHANGE

The NIMH will push the FDA to reclassify light therapy devices, Frederick K. Goodwin, M.D., Director of the NIMH, said at this year's annual meeting Open Forum. Along with spokespersons from the FDA, light device manufacturers, and the SLTBR, he served on a panel that explored regulatory issues and fielded audience questions.

Goodwin described his recent meeting with James Benson, head of the FDA's Center for Devices and Radiological Health. "What came out of that," he said, "was an agreement that NIMH would assume, perhaps in collaboration with this Society and perhaps involving the manufacturers' association, . . . the leadership for collating what [is] necessary for FDA in terms of a petition for reclassification."

John Stigi, director of the FDA's Division of Small Manufacturers Assistance, noted that light therapy devices currently are regulated as Class III medical devices. This class requires premarket approval of an application showing that a device is safe and effective for its intended use. Stigi said he would assist in the development of a petition to down-classify light boxes into Class II, where risk/benefit considerations are lower and premarket notification rather than premarket approval is required.

"Obviously the efficacy concerns are balanced against safety concerns," Goodwin said. "For treatments and devices which are both by evidence and common intuition a relatively low risk," he added, "issues of efficacy and the extensiveness of efficacy demonstrations are obviously less daunting."

No light box manufacturer has cleared the premarket approval process. Some have submitted applications claiming pre-1976 use of light therapy, Stigi said. "We ruled these not substantially equivalent because there was no use of these devices to treat depression before 1976, when the present medical device legislation went into effect."

"Questions of insurance reimbursability for these devices await FDA action," Goodwin pointed out. "We're now in a very gray area," he said.

Ronald Parr, chief of the operations branch of the FDA's Division of Small Manufacturers Assistance, said he would

be helping light box manufacturers to develop the required statement of clinical utility supportable by data.

Lighting device manufacturers recently banded together to form the Circadian Lighting Association. The new group's goals, Kirk Renaud of Bio-Brite, Inc., and Neal Owens of The Sunbox Co. said, are to provide information to consumers, set guidelines for advertising, and help set safety and performance standards and guidelines for supporting research.

"SLTBR does not have a commercial agenda," panel member Michael Terman, Ph.D., SLTBR President, stressed. "But we are concerned about what is made available to our patients," he added. "We will look to corporate members to develop technology spinoffs from our research."

Lynne Lamberg, M.A., 3704 Gardenview Rd., Baltimore, MD 21208. Tel 410-486-0297.

A MULTICENTER STUDY ON SAD AND SLEEP-WAKE RHYTHM DISORDERS IN JAPAN

In our country, the first workshop on circadian rhythms in psychiatry was held in 1986. About 30 physiologists and clinicians got together to communicate on mutual interests. Since then, the two-day workshop has been held annually in autumn and the number of members registered now stands at 180.

SAD study

In 1988 a multicenter study on SAD was initiated to investigate whether SAD patients exist in Japan and whether light therapy is as effective as in Caucasians. At the beginning, 19 facilities entered the multi-center study. The number of participating centers has now increased to 28. Several study doctors have written articles describing the symptoms of SAD in local and national newspapers to encourage potential SAD patients to contact the study headquarters at the National Center of Neurology and Psychiatry in Tokyo. These persons were screened by questionnaire and then referred to the nearest study doctor. Every year, the results obtained through this multi-center study are reported both at the annual meeting of the Japanese Society of Biological Psychiatry in March and the workshop of Clinical Chronobiology in September. The

first analyses have been published (Takahashi et al., 1991; Nagayama et al., 1991) and presented at two international meetings.

As of spring 1992, we had diagnosed 128 SAD patients. The following characterizes our findings:

- The gender difference was not as pronounced as in other studies: Female to male ratio was only 1.5:1 to 1.6:1.
- The atypical symptoms related to eating behavior were less frequent (female, 20-30%; male, 10-15%) than in other reports.
- Hypersomnia was common both in male and female SAD (70%).
- Bipolar II diagnosis was about 25%.
- Light therapy was highly effective, ca. 70% of SAD patients benefitted (40% remission using Terman's criteria).
- The atypical symptoms were positively correlated with the therapeutic effect of light therapy (Nagayama et al., 1991).

One of the most interesting and puzzling findings is the gender ratio. The number of male patients diagnosed is significantly higher in our study than those reported from other countries. It may be due to a race difference, since our preliminary data showed a lower rate (10%) of persons with seasonality compared with previous reports (25%). This finding needs further investigation.

In a follow-up 40 patients who have been studied for more than two years after the first interview, we found that about half of the SAD patients maintained winter-type seasonality, three changed the diagnosis to schizophrenia or schizo-affective disorder, and eight patients showed no recurrence of their winter depression. It seems to be very important to re-evaluate the patients who lost their seasonality pattern or manifested psychotic symptoms unrelated to affective disorders. The findings raise a question as to whether or not such patients were truly "SAD" in the initial assessment.

Study on sleep-wake rhythm disorders

A multicenter study on sleep rhythm disorders was initiated in 1990. This study was provoked by the finding reported by Okawa et al. (1991) that a patient who free-ran for more than 10 years was successfully treated by methylcobalamin (vitamin B₁₂). Several members of the clinical chronobiology workshop had tested methylcobalamin and the majority had the impression that it is effective for both delayed sleep phase syndrome (DSPS)

and non-24 h sleep-wake cycles). In order to confirm the finding, we decided to perform a double blind study with the cooperation of the Eisai Company which produces methylcobalamin. We recruited potential patients via the mass media. During the past 1.5 years, we have received about 12,000 requests for the screening questionnaire, with a completion rate of 10%. Based on respondents' answers and their sleep logs for four weeks, we could screen suspected sleep rhythm disorders and refer them to the nearest study facility. The double blind study was completed as of March 1992 with about 80 cases. The code will be broken at the end of September. In parallel with the double blind study, we have conducted an open trial to test the therapeutic effects of both bright light and methylcobalamin. An interim report was made at the meeting of Clinical Chronobiology in September 1991. The following summarizes the main points:

- Of 491 responders to the questionnaire, 163 sleep-wake rhythm disorders were identified.
- In 36 of them, other mental disorders, including personality disorders, seemed to be a main factor underlying the sleep rhythm disorder. Accordingly, 127 cases were considered to be primary sleep-wake rhythm disorders, 35 of whom were entered into the double blind study.

The following findings were obtained in the open study on 92 patients with primary sleep-wake rhythm disorders:

- Male-to-female ratio was 1.6:1.
- Mean onset age was 15.7 yrs and 18.8 yrs in non-24 h cycles and DSPS, respectively.
- About 55% of patients showed psychosocial factors precipitating the symptoms.
- Two thirds of the sample were of the "evening active" type.
- About 20% of the sample had previously experienced various mental disorders, such as depression, anxiety, etc.
- About 30-40% of patients with sleep-wake rhythm disorders benefitted from light therapy and/or methylcobalamin.

As far as the therapeutic effect of methylcobalamin is concerned, we must wait for the conclusion of the double blind study, especially because it is well known that sleep rhythm disorders are markedly influenced by psychosocial factors.

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SRBR MEETING REVIEW

Highlights of the Third Meeting of the Society for Research on Biological Rhythms, May 6-10, 1992, Amelia Island Plantation, Jacksonville, Florida

The third biennial meeting of the SRBR opened on Amelia Island Plantation under unseasonably cool temperatures, catching many participants unprepared, dressed only in shorts, T-shirts and goose bumps. Still, trying to keep up with four concurrent slide sessions in the mornings and four concurrent workshops in the afternoons, a host of symposia, and several poster sessions was probably enough to keep everybody warm and more than enough to satisfy chronobiologists of all persuasions.

This year's Plenary Lecture was delivered by C.S. Pittendrigh, who took his audience on a sentimental journey back to a time, early in his career, when it was still possible to combine fundamental research with a fishing expedition.

The Presidential Symposium focused on Biological Clocks and Aging. F. Turek began by summarizing recent results in aged hamsters, including diminished phase shift responses to activity-inducing stimuli and their restoration by SCN transplants from young donors. D. Swaab then described some neuroanatomical and neurochemical changes associated with aging in healthy humans and in

Alzheimer patients. The latter show no daily rhythms in activity and no nocturnal elevation in pineal melatonin. They also show an earlier decrease in the number of SCN vasopressin-containing cells, which, in healthy people, starts around age 80. Interestingly, exposure to 2 h of bright light in the morning reduces the nocturnal restlessness typical of Alzheimer patients. Similar sleep disturbances in Alzheimer patients were described by P. Prinz, and these correlated with the severity of the disease. However, no differences were found in the phase or the amplitude of body temperature rhythms. Prinz also reported epidemiological data confirming earlier bedtimes in the elderly, as well as a phase advance and a decrease in the amplitude of their temperature rhythms. The temperature rhythm changes, however, were only seen in males, not in females. J. Aschoff ended the session with an overview of age-related changes in animals: changes in freerunning period (τ) are not consistent across species, but all show a shortening of their daily activity phase and a corresponding lengthening of their daily rest phase.

Symposium 5 was devoted to Human Phase-Shifting and Entrainment. C. Czeisler summarized recent data indicating that humans may be more responsive to light than generally believed. These included data from a blind person with no conscious light perception (but with some residual ERG activity), who nevertheless showed strong melatonin suppression when exposed to bright light at night. A. Lewy reported phase-shifting effects of melatonin administration in both blind and sighted human subjects, and T. Wehr described some fascinating data on sleep, body temperature and melatonin rhythms in human subjects following transfer from a standard LD 16:8 cycle to a short photoperiod LD 10:14 cycle. Surprisingly, all but one of the 16 subjects studied found living under the short photoperiod to be a very rewarding experience, despite spending up to 4 h awake in the dark each night.

M. Terman opened Workshop 5, on Circadian Disorders and Treatment, by presenting illuminance data recorded from light sensors on the foreheads of subjects during bright light treatment. Terman's conclusion: there is considerably more to nominal light intensities than meets the eye. S. Campbell then reported effects of daily 2 h bright light treatment in the evening on sleep onset time and the phase of the body temperature minimum. The former was delayed by 29 min, the latter by about 3 h. C. Eastman described her recent attempts to entrain human subjects to 26 h sleep-wake schedules, and to accelerate reentrainment to 12 h schedule shifts, using bright light treatment to nudge or squash her subjects' rhythms into compliance. R. Sack presented τ measurements from

free-running blind subjects, but did not actually entrain their rhythms with melatonin administration. A. Wirz-Justice ended the workshop with some preliminary observations of the effects of 4 h midday light exposure on melatonin and body temperature rhythms in SAD patients studied under a constant routine in both winter and summer.

Most of the presentations at the meeting dealt, of course, with animal research, much of it neuroscientific. Indeed, advances in this area are proceeding at a pace rivaling that in most other fields of neuroscience. In part, this is due to the fact that circadian pacemakers have been localized to very discrete regions of the brain, but another reason is their precise output, something we have known from the early work of Pittendrigh, Aschoff and others. Where else is an 8% difference in a behaviorally derived measure (the period of a hamster's locomotor activity rhythm) indicative of a major genetic mutation?

In addition to genetic analyses of circadian pacemakers, topics covered included:

- SCN transplants. How a mere 20,000 or so minuscule neurons can impose their will on the rest of the organism remains a mystery.
- The role of gene expression, particularly that of the proto-oncogenes in rodent SCN.
- In vitro neurophysiology/neuropharmacology of the SCN and other pacemakers.
- Neuro-anatomical studies using the latest labeling techniques for delineating, with ever-increasing precision, the neural structures involved in circadian rhythm generation and entrainment.
- Non-photic phase resetting and entrainment (by activity-inducing stimuli, food scheduling, etc.): what are the relevant pacemakers and pathways?
- Circadian photoreception: surprisingly, the identity of the photoreceptors mediating circadian effects of light in mammals is still uncertain.

The meeting also saw the passing of the SRBR Presidency from F. Turek to R. Moore, and the election of A. Wirz-Justice to the SRBR Executive Committee, making her the first person to serve on the Boards of both SRBR and SLTBR. And yes, the weather did eventually improve and Amelia the Beautiful did live up to its billing.

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SAD ASSESSMENT TOOLS PACKET REVISED

New SIGH-SAD, HIGH-SAD and SIGH-SAD-SR

After many months of preparation, significant editorial revisions of SLTBR's *SAD Assessment Tools Packet* have been completed, and are ready for use in the field for this year's winter depression studies and clinical practice. The instruments, written by Janet B.W. Williams, D.S.W., and colleagues at New York State Psychiatric Institute and the National Institute of Mental Health, include the *Structured Interview Guide for the Hamilton Depression Rating Scale — Seasonal Affective Disorder Version (SIGH-SAD)*, the *self-rating version (Self-Report Inventory, SIGH-SAD-SR)*, and the *Hypomania Interview Guide (Including Hyperthymia) for Seasonal Affective Disorder (HIGH-SAD)*.

The instruments provide standardized interview guides in order to increase intra- and inter-rater reliability, and to strengthen comparisons of clinical results across centers. The SIGH set includes the 21-items of the original Hamilton (HAM-D) scale as well as eight supplementary items that assess the reverse atypical symptoms often seen in SAD. The self-rating instrument allows patients to generate a SIGH-SAD score independently, which can be useful for outpatient monitoring, verification of interview rater reliability, and use when interview sessions are infeasible. The validity of the first edition of the SIGH-SAD-SR, tested against the interview, was high (HAM-D subscale, $r=0.84$, $p<0.001$; atypical subscale, $r=0.92$, $p<.001$) (Terman et al., 1991). The validity of the new revision should be even higher, since the wording of the interview and self-rating versions has been brought closer together.

The HIGH-SAD includes specific interview questions for current and retrospective ratings of hypomania and hyperthymia. The retrospective version is useful for administration to SAD patients when first seen in fall or winter while depressed — it yields an estimate of the degree of spontaneous bipolar swing in late spring and summer, which may guide the clinician to probe for and monitor possible hypomanic responses to light treatment.

The new editions of the interview guides greatly improve the conversational flow and ease of questioning. The instruments also define many of the symptoms with greater behavioral specificity than previously.

The basic item sets, question sequences, and point allocations have not changed. However, scoring instructions have been made more specific to avoid common rater errors and confusions. For example, for the SIGH-SAD atypical symptom of weight gain, the instructions advise that the item "should be rated positively whenever the patient has gained weight relative to the baseline weight. Once the patient has begun reducing weight, the item should not be scored positively even if the weight is still above baseline, because the patient is not currently gaining weight. Additionally, the item should not be scored positively when there is weight gain toward the baseline level following depression-related weight loss." As for the weight loss item, raters are advised to avoid coding a score of "3" ("not assessed") if possible, because this violates the general scoring principle that, "except for [the Insight item], all of the symptoms should be rated on a scale that considers both frequency and severity." The corresponding SIGH-SAD-SR item now omits the possibility of a score of "3".

Further from the SIGH-SAD Instructions: "The [instruments] elicit [new] ancillary information that supplements the clinical picture but does not contribute to the score. In item A5 (Carbohydrate Craving and Eating), for example, one notes whether carbohydrates are only craved, or are actually eaten excessively, and the time of day is noted. (In a large sample of SAD patients in Switzerland, those reporting excessive eating of sweets in the afternoon or evening showed relatively strong response to light therapy.)" Similarly, for the atypical symptom of afternoon or evening slump (Diurnal Variation Type B), the nature of the slump (mood, energy, or both) is specified, and "slumps" are distinguished from Diurnal Variation Type A (worse before going to sleep) in that they are "defined as transitory event[s] from which the respondent recovers at least an hour before bedtime." Although from this description the increased specificity may seem complicated, the instruments are designed to make the proper scoring decisions rapidly and efficiently.

Since the new revisions have not changed any fundamental aspects of the scales, the scores obtained with them should be sufficiently equivalent to previous versions so that research continuity is maintained.

Although both the SIGH-SAD and HIGH-SAD instruments originally were developed for use with SAD patients, they may be useful for a comprehensive assessment of depressive and hypomanic symptoms in any patient

population: none of the questioning assumes or refers to seasonal variation per se.

Master sets of the *SAD Assessment Tools Packet* are available from the *SLTBR Executive Office*, P.O. Box 478, Wilsonville, OR 97070; fax 503-694-2404. Please include prepayment of \$15 for members, \$20 for non-members. Fax orders must include VISA/Mastercard number and expiration date. Permission is granted for reproduction for use by researchers and clinicians. Colleagues who have been using earlier versions are urged to adopt the new versions for protocols beginning this fall. Colleagues who have been planning translations into other languages likewise should use the new versions, and should consult with Dr. Williams on translation strategy.

Michael Terman, Ph.D., and Janet B.W. Williams, D.S.W. Department of Psychiatry, Columbia University, 722 West 168th Street, New York, NY 10032. Dr. Terman: tel 212-960-5712; fax 212-960-2584. Dr. Williams: tel 212-960-552; fax 212-960-5525.

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Terman, M., J.B.W. Williams and J.S. Terman (1991) Light therapy for winter depression: A clinician's guide. In *Innovations in Clinical Practice*, P.A. Keller and S.R. Heyman, eds., 10: 179-221, Sarasota, FL: Professional Resource Exchange.

TASK FORCE FORMED FOR LIGHT TREATMENT OF SLEEP DISORDERS

Input Solicited

SLTBR has joined with the American Sleep Disorders Association to form a task force to evaluate the efficacy of light therapy in the treatment of sleep disorders. The group will work over the next nine months to generate a report covering applications for advanced and delayed sleep phase syndromes, hypersomnia of SAD, sleep disturbances of the elderly, sleep disturbances of jet lag and shift work, and the alerting/activating effects of light. The final report will be submitted for publication in *Sleep*, following an open forum at the June 1993 meeting of the Association of Professional Sleep Societies in Los Angeles (directly after SLTBR's annual meeting in San Diego). Where the data are convincing, clinical guidelines or

options may be recommended to the ASDA Standards of Practice Committee.

The task force aims for a comprehensive review of clinical and experimental data, and to this end solicits input from the professional and scientific community. Workers in the field are requested to compile their reprints, preprints, and descriptions of important unpublished results for submission to task force members — by 1 November 1992 — according to topic:

Sleep disturbances of jet-lag

Ziad Boulos, Ph.D., Institute for Circadian Physiology, 677 Beacon Street, Boston, MA 02215-3203. Tel 617-247-4900; fax 617-247-9047.

Sleep disturbances of the elderly; Alerting/activating effects of light

Scott S. Campbell, Ph.D., Institute of Chronobiology New York Hospital, 21 Bloomingdale Road, White Plains, NY 10605. Tel 914-997-5924; fax 914-682-1536.

Sleep disturbances of shift work

Charles A. Czeisler, Ph.D., M.D., Laboratory for Circadian Medicine, Brigham and Women's Hospital, 221 Longwood Avenue, Boston, MA 02115. Tel 617-732-4011; fax 617-732-4015.

Basic processes: Effects of light on circadian rhythms and sleep

Derk-Jan Dijk, Ph.D., Institute of Pharmacology, University of Zürich, Gloriastrasse 32, CH-8006 Zürich, Switzerland. Tel 411-257-2676; fax 411-261-5684.

Sleep phase disorders; Hypersomnia of winter depression

Alfred J. Lewy, Ph.D., M.D., Sleep and Mood Disorders, Laboratory, L-469, Oregon Health Sciences University, 3181 S.W. Sam Jackson Park Road, Portland, OR 97201-3098. Tel 503-494-7746; fax 503-494-5738.

Suggestions or information for the task force as a whole should be addressed to the chairperson, *Michael Terman, Ph.D., Department of Psychiatry, Columbia University, 722 West 168th Street, Unit 50, New York, NY 10032. Tel 212-960-5712; fax 212-960-2584.*

BULLETIN BOARD

WELCOME TO NEW MEMBERS

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

Regular Members

Hans-Joachim Haug
Dan A. Waniek

Steven S. Krauss

Associate Members

Alan Bachers
Ron Cornick
Robert A. Goldbeck
David S. Mora
Aylin Radomisli
Marc Weissbluth
Karen K. Yackley

Robert Carnahan
Susan E. Cremin
William H. Huebner
Michael R. Privitera
Patricia E. Thompson
Sheila J. Woodruff

SLTBR membership now stands at 408, including 114 Regular, 252 Associate, 9 Corresponding, 18 Student and 14 Corporate members.

SLTBR 1993 ANNUAL MEETING SCHEDULED

The Annual Meeting Program Committee has begun working on plans for the Society's Fifth Annual Meeting to be held at the University of California, San Diego, Medical Center, 19-20 June 1993. Complete meeting information, registration and abstract submission forms will be mailed to all SLTBR members in early 1993. Our meeting date precedes that of the APSS Annual Meeting scheduled for 22-27 June in Los Angeles. We will work with the APSS Program Committee to develop a jointly sponsored CME course similar to that presented at the Toronto meeting in 1991.

APSS PLANS JUNE 1993 MEETING IN LOS ANGELES

The Association of Professional Sleep Societies will hold its annual meeting 22-27 June 1993 in Los Angeles, California. Deadline for abstracts is 5 December 1992. Information and abstract forms can be obtained from the *Scientific Program Committee, APSS, 1610 14th Street, N.W., Suite 300, Rochester, MN 55901, USA. Tel 507-287-6006; fax 507-287-6008.*

CELLULAR CONSEQUENCES OF SLEEP CONFERENCE

The World Federation of Sleep Research Societies is holding an international conference on The Cellular Consequences of Sleep in Maui, Hawaii from March 13-17, 1993. The accent on basic mechanisms underlying sleep regulation is reflected in a program of symposia whose themes include immunology, humoral, neurotransmitter and nucleoside involvement, molecular mechanisms of circadian timekeeping and gene expression in sleep, neuropharmacological probes of regional brain function, cellular events and EEG rhythms in waking and sleep, factors in hibernation, endocrine consequences of sleep deprivation. Deadline for abstracts is 30 September 1992. Information and abstract forms can be obtained from *Judy Franzblau, Conference Coordinator, Global Events, 710 N. Trenton Drive, Beverly Hills, CA 90210 USA. Tel 310-247-8004; fax 310-247-8457.*

NEW SLTBR PUBLICATIONS LIST

Included with this *LTBR* issue is the revised SLTBR publications list which reflects the recent change in publication format. Please note the availability of individually bound compendiums of *LTBR* and annual meeting abstracts, as well as the addition of the SAD information packet which has been widely distributed by our executive office for the last two years. SLTBR members may order at the discounted member prices indicated on the form.

SAD BIBLIOGRAPHY AVAILABLE

The National Library of Medicine has published a bibliography on seasonal affective disorder as part of its *Current Bibliographies in Medicine* series. The publication contains 402 citations dated from January 1986 through December 1991 categorized into six subject areas: overview, diagnosis, epidemiology, etiology, therapy and miscellaneous. Individual copies of the publication may be ordered by sending payment of US \$3.00 (\$3.75 foreign orders) to *Superintendent of Documents, Government Printing Office, Washington, DC 20402-9371 USA.* Include the following citation information with your order: *CBM: Seasonal Affective Disorder, CBM 91-18, GPO List ID: CBM91.*

REIMBURSEMENT UPDATE

Recent correspondence from Aetna Insurance Company to a major clinical facility requests names and types of antidepressant medications prescribed and used by a patient prior to commencement of home bright light treatment. Clinician initiative in providing insurance companies with this and other pertinent treatment history may help speed consideration of claims for SAD patients seeking reimbursement for purchase of light apparatus.

SCIENCE NEWS COVERS SLTBR ANNUAL MEETING

In the July 1992 issue of *Science News*, Bruce Bower's article entitled "Here Comes the Sun" gives credit to the recent SLTBR and APA annual meetings for presenting

much of the latest research on seasonal affective disorder. Following an overview of SAD symptoms and treatment, Bower reviewed the simulated dawn studies conducted by David Avery of the University of Washington School of Medicine and Michael Terman of the New York State Psychiatric Institute. Also mentioned were the retinal response and corneal electrical-wave pattern studies of Raymond Lam's group at the University of British Columbia, the light visor studies presented at SLTBR's 1991 (Levitt et al.) and 1992 (Teicher et al.) annual meetings, the night-length findings of Thomas Wehr at the National Institute of Mental Health, and the Swiss epidemiological survey and "morning walk" study conducted by Anna Wirz-Justice and colleagues at the Psychiatric University Clinic, Basel.