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

ANNUAL MEETING 1990 PREPARATIONS
The conference, to be held 13-14 May, will be coordinated by Columbia University College of Physicians & Surgeons Center for Continuing Education. It will offer the American Medical Association’s Physician’s Recognition Award Category 1 Credit Hours. In addition, under co-sponsorship of Columbia University Teachers College, it will offer American Psychological Association Category 1 Continuing Education Credit for psychologists. The program will include a tutorial symposium on light therapy for winter depression, oriented to mental health practitioners, in addition to research papers and poster sessions, a consensus-building symposium on controversial clinical issues, an open committee forum on federal and industrial relations, manufacturers’ exhibits, a bookstore for technical and popular specialty books in our field, and more. Please plan to participate, and please also invite interested colleagues outside the SLTBR membership.

Registration
...should be completed as soon as possible, using the form attached. Please note that the discounted registration fee for SLTBR members is available only to those on our 1990 roster. If you have delayed your 1990 membership renewal, you may renew it with your registration.

Call for Papers
Members active in research are urged to report on their recent findings in the slide-talk or poster sessions. Due date for receipt of abstracts is 7 March 1990. The submission form is attached. The program committee will promptly review abstracts for acceptance, and make session assignments, with feedback on about 1 April.

Exhibits
Manufacturers and suppliers of apparatus are invited to set up displays and demonstrations. To be eligible, 1990 Corporate Membership is required in addition to a $500 exhibitor’s fee. For an additional $500, Corporate Members will be listed prominently as sponsors of the meeting in the program, book of ab-

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Unsolicited manuscripts, letters to the editor, and Bulletin announcements should be submitted to Dr. Michael Terman, Editor, 722 West 168th Street, Box 50, New York NY 10032. Please submit one double-spaced hard copy and a diskette file (DOS: text or WordPerfect; Macintosh: text, Word, MacWrite, or WordPerfect). MCI Mail and BITNET files can also be received by arrangement. Manuscripts and diskettes will not be returned.

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Where to Stay Affordably in New York?

SLTBR is not managing housing arrangements, but we can offer some tips. The immediate neighborhood of Columbia’s Health Sciences Campus is not where you should plan to stay.

There are several hotels/motels in midtown and “across the Bridge” in Fort Lee NJ, which offer special rates to registrants at Columbia University functions. Both midtown and Fort Lee are just minutes away by taxi (both), subway (midtown), or bus + walk (Fort Lee).

Attendees may wish to arrange accommodations through Macpherson’s Travel Agency (tel 212/280-8728 or toll-free 800/235-1223) which offers special rates through Columbia University’s Continuing Education department. Days Inn on West 57th Street in Manhattan offers a “Corporate Connection,” with a single or double room, evening beverage, newspaper, free parking, and local phone calls, for $110. Holiday Inn in Fort Lee offers a single or double for $90 per night. If calling Macpherson’s, be sure to mention Columbia Continuing Education for the special prices. Also in Fort Lee, the Glenn Point Hotel (tel 201/836-0600) offers a “Best Buy Weekend” rate for Friday and Saturday nights only, at $79/night and corporate rate for Sunday and other days at $130/single or $150/double (be sure to request corporate rate).

Those seeking alternative lodging at lower expense may be interested in contacting Bed & Breakfast (& Books), 35 West 92nd Street, New York NY 10025; tel 212/865-8740. We suggest asking for a West Side location — West Village, Chelsea, Midtown, and Upper West Side neighborhoods are all convenient subway rides to and from Columbia.
1989 ANNUAL MEETING
WORK SESSIONS
Industrial/Federal Relations and
Criteria for Clinical Efficacy

The second work session of the annual meeting was
devoted to assessment of efficacy of light therapies,
factors involved in gaining Food and Drug Admin-
istration approval for light therapy apparatus as medical
devices and, relatedly, prevention of misleading and
fraudulent claims by practitioners or light manu-
facturers. It began with Dr. George Brainard intro-
ducing Dr. Morris Waxler who, drawing on his experi-
ence working in the FDA, explained what it consid-
ers when reviewing an application for approval of a
new “Class 3” medical device: a “medical device”
consists of both the device and the claims made for it
in each particular therapeutic application for which
approval is sought. Approval of a device requires
considering data specific to the particular claims
being made. Hence, a fraudulent claim might consist
of making claims of efficacy in one area while only
having data on other applications. Another sort of
fraud, Waxler warned, would involve a manufac-
turer making claims about the importance of specific
qualities of a product that were, in fact, common to
general-purpose equipment (e.g., making much of
the presence of green wavelength light, which is
common to most light sources). In response to a
question from the audience about the merit of releas-
ing the lighting apparatus with a disclaimer limiting
its field of valid application, Waxler responded that
disclaimers can be beneficial, but he would not guess
on how the FDA would treat it in the case of light
therapy.

Given the long process involved in manufacturers
obtaining FDA Class 3 approval for each application
of their light units, Waxler suggested that they might
apply for pre-market approval for treatment of SAD
and, later, as data become available, for other med-
cal applications. Registration of companies with the
FDA would help alert the FDA to successful applica-
tions of light therapy. Also, scientists should con-
sider applying for Investigational Device exemp-
tions, both with the aim of acquainting the FDA with
proper and successful use of “an approved therapeu-
tic, investigational unit,” and as a way of promoting
the development of light manufacturers through
limited marketing of their devices. (Waxler now
says that the latter reason for seeking pre-market
approval no longer applies.) SLTBR could assist in
the promotion and acceptance of light therapy by
fostering consensus in the field, “clearing the field”
of conflicting findings and misunderstandings, and
helping to present a coherent picture of light treat-
ments. This would probably also help to promote in-
surance reimbursements for those undergoing light
therapy. [SLTBR seeks to continue the dialogue on
insurance issues and encourages members to report
interactions with insurance companies to the SLTBR
Insurance Liaison Committee, c/o Dr. Leslie Pow-
ers, SLTBR, Box 50, 722 West 168th Street, New York
NY 10032; fax 212/960-2584.]

Proof of clinical efficacy was addressed by a panel
made up of Drs. Alfred Lewy, Michael Terman, and
Norman Rosenthal, discussing SAD research, along
with Drs. Barbara Parry, Jean Joseph-Vanderpool,
and Charles Czeisler, discussing, respectively, pre-
menstrual syndrome, sleep disorders, and shift-work
issues. Lewy began by considering the type of statis-
tical tests required now to move from the preliminary
evaluation of results in studies of SAD (which he
termed “low threshold for efficacy”) to more rigor-
ous examination of results that will lead to “valida-
tion” in testing for clinically significant differences
between presumed active treatments and placebos,
one should test that both the post-treatment compari-
sions and the change scores of the two treatments are
statistically significantly different. Further, one would
ideally perform these tests on post-treatment scores
where there are no statistically significant differ-
ences between the groups in corresponding baseline
scores. Patients should be stratified according to
baseline depression scores at the beginning of the
study. Should one find a disparity in results of the
two types of tests for difference (e.g., statistically
significant difference between change scores but not
pre- and posttreatment scores), one should accept the
results of the posttreatment comparison, unless there is a probable difference in baseline scores. (“Because,” Lewy adds, “the posttreatment scores are the most ‘blind,’ that is, patients are never — and even raters are rarely — blind to the baseline, no light, condition.”) Upon reviewing these recommendations, Lewy has added the caveat: “If baseline scores are statistically significantly different, then one should accept the result of the change score comparison should it differ from the posttreatment comparison.”

Terman spoke next about the need to move beyond tentative scientific conclusions based on pilot or incomplete data by carefully considering issues of power and effect size in experimental design. He stressed that, in testing for differences between groups, one must not only seek to avoid making Type I inference errors, in which one mistakenly concludes that a difference between groups exists which in fact does not, but also Type II errors, where one concludes there is no difference when there actually is. One may minimize likelihood of committing such errors by designing experiments in which best-estimated effect size for the given experimental procedure is used to estimate the number of subjects needed to draw valid conclusions [see J. Cohen (1988) Statistical Power Analysis for the Behavioral Sciences, Hillsdale NJ: Erlbaum; and Terman’s LTBR editorial, “Developing the Case for Efficacy,” vol. 1, no. 5]. Until they achieve adequate numbers, researchers should clearly state that the results of their studies are tentative and on-going. As Terman said in closing, “It is clear that our field is onto something hot, but now we have to prove it.”

The SAD panel concluded with Rosenthal, who touched on a number of concerns including the importance of being conservative in making claims because of inadequate sample sizes; plausible placebo controls and factors which might act on them; the value of partial clinical responses to research concerns; the role of UV light in treatment effects; the need for studies directly comparing efficacy of drug versus light therapies for SAD; and the need for light manufacturers to police themselves in prevent-

ing charlatanry and false claims. Rosenthal echoed Terman’s call for more careful criticism of studies which lack adequate sample size, particularly those which claim no difference between treatments. On the issue of estimating placebo response in SAD studies by incorporating plausible controls, Rosenthal cited the fact that a number of researchers had demonstrated various means of raising patient expectation (e.g., Drs. Siegfried Kasper and Ray Lam’s use of dim light, Dr. Dan Oren’s use of green light and red light, and Dr. Lewy’s finding of equivalence between morning and evening treatment in arousing expectations). He noted, however, that measures of expectation do not correlate very highly with treatment outcome. Possible confounds mentioned by Rosenthal included “non-specific” influencing factors such as paying special attention to the patients, bringing them into a hospital setting, and relieving them of certain stressors, which will have effects on outcome “to some extent independent” of expectation about treatment method. Partial responses are “interesting from a clinical standpoint,” whether or not the patient completes treatment with full symptom remission. Regarding use of UV light sources, Rosenthal said, “It has been amply demonstrated that UV light isn’t critical [to treatment response]....The question is not whether [UV] is critical, but whether it makes a difference.” Rosenthal cited results by Drs. Lam and John Docherty suggesting that UV may be “helpful” to the clinical response, perhaps by potentiating the effects of visible light.

Special problems in the emerging treatment areas of pre-menstrual syndrome, sleep disorder, and shiftwork were the last issues addressed by this session. Dr. Barbara Parry, researching light therapy for PMS, listed prerequisites for evaluations of efficacy including accurate diagnosis (particularly in exclusion of traditional affective disorder patients from the population of PMS patients) and the need for standardized evaluation instruments, such as the Hamilton and Beck scales, which will allow contrast and comparison of PMS patients’ responses with those of other light-treated patients. She reiterated Terman’s call for conservatism in claims of effect, particularly
when sample size may be inadequate.

Dr. Charles Czeisler, discussing his shift-work studies, complained that many of the same problems which haunt SAD research, notably lack of proper controls, make efforts to delineate effects in shift-work studies difficult as well. He mentioned the need for systematic lab trials which consider and control for extraneous natural light exposure which may well affect the treatment outcome. This is especially crucial if one hopes to adequately support, with physiologic measures, claims of circadian phase-shift as an explanatory model. Czeisler weighed into the UV issue by noting that, in his trials, using UV-screening goggles, no diminution in response has been noted and, given the role of UV in producing ocular damage, prudence suggests that UV be excluded from the clinical preparation. This point was also stressed by Joseph-Vanderpool, who, in describing the positive response to light that he found in patients with delayed sleep disorder, remarked that as light therapies are applied to ever more types of conditions, great care must be taken in carefully assessing risk factors particular to these various phototherapeutic interventions.

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UPDATE ON THE DSM-IV DEBATE

Dr. David Dunner met with the American Psychiatric Association’s Work Group on Mood Disorders for DSM-IV. As previously noted in LTBR vol. 2, no. 1, Dunner’s recommendations included most of the changes recommended by Dr. Norman Rosenthal’s survey of SLTBR members. However, the work group recommended no changes in DSM-III-R criteria. There was a general concern that by broadening the 60-day window criteria there would be excessive diagnoses of Seasonal Pattern.

While no changes are currently planned for the criteria for seasonal pattern to appear in DSM-IV, the text accompanying these criteria will state that clinical impressions suggest that the onset and remissions windows, as stated, may not be ideal. The specific text, which has not yet been drafted, is due in June.

DSM-IV is not yet written in stone. The work group is still open to further data supporting a change. If you have such data, please send them to Dunner’s new address: University of Washington Medical Center, Outpatient Psychiatry, 4225 Roosevelt Way N.E., Suite 306, Seattle WA 98105.

David Avery, M.D., Psychiatry and Behavioral Sciences, University of Washington, Harborview Medical Center, ZA-99, 325 Ninth Ave., Seattle WA 98104. Tel 206/223-3425; fax 206/223-3289.

LETTER FROM DR. RUSH ON DSM-IV

The proposal to modify criteria for the SAD criteria set was presented to the DSM-IV Work Group on Mood Disorders by David Dunner at its meeting on November 5, 1989. The presentation included recent data provided by Drs. Wirz-Justice and Avery indicating, each in small samples, that patients who met DSM-III-R criteria and those meeting the Rosenthal criteria both had appropriate responses to light therapy. The process to delete the criteria for the 60-day windows and to change the number of episodes required to diagnose the condition were discussed and reviewed in detail. The committee felt that the data presented thus far suggest that the window should be widened but that at the present time the evidence is not yet adequate to support any marked change in the criteria. The committee did recommend a change in the text description of seasonal pattern which will indicate that the criteria are viewed as too restrictive by many investigators in the field.

We appreciate your efforts in reviewing the various drafts and proposed changes for seasonal pattern. The committee is still eager to receive additional data which might lead to more useful criteria for the onset.
and offset windows as well as for the number or proportion of episodes. Several of you might want to work collaboratively in order to provide a sufficient database. There are opportunities available through the APA's grant from the John D. and Catherine T. MacArthur Foundation for funds which could help support data reanalysis of available data sets. Please do not hesitate to contact Drs. Rush or Frances for further details regarding the setting up of such a proposal. This mechanism is being used in many other diagnostic areas to help answer questions for which the published literature is insufficiently informative, and it may be especially useful for Seasonal Affective Disorders.

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QUESTIONs AND ANSWERS ABOUT LIGHT THERAPY

What is Seasonal Affective Disorder (SAD)? Everyone gets 'the winter blues' — what's different about SAD?

Many people complain of feeling down, having less energy, putting on a few pounds, and having difficulty getting up in the morning throughout the dark, short days of winter. People suffering from SAD experience these and other symptoms to such a degree that they feel unable to function normally. They often feel chronically depressed and fatigued, and want to withdraw from the world and to avoid social contacts. They may increase their sleep by as much as four hours or more per day, have greatly increased appetite — sometimes accompanied by irresistible cravings for sweet and starchy foods — and gain a substantial amount of weight. Women frequently report worsening of premenstrual symptoms. People with SAD suffer in the extreme the kinds of changes which many others experience to a much lesser degree in wintertime.

An individual SAD sufferer, however, need not show all the symptoms described above. Sleep duration, for example, may be normal, while carbohydrate craving may be extreme — or vice versa. Sometimes a symptom in the cluster is actually opposite the
norm, such as insomnia as opposed to excessive sleep. A diagnosis of SAD requires a professional evaluation by a psychiatrist, psychologist, or social worker. We caution against attempting self-diagnosis; it is easy to misinterpret symptoms or incorrectly rate their severity.

Recent studies indicate that about three times as many people suffer from “winter doldrums,” a subclinical level of SAD, as suffer at a level of clinical severity. These people notice the return of SAD-like symptoms each winter, and are bothered by them, but remain fully functional. As much as 25 per cent of the population at the middle-to-northern latitudes of the United States experiences winter doldrums.

What is light therapy for winter symptoms, and how is it delivered?
Light therapy involves exposure to intense light under specified conditions. The recommended light therapy system consists of a set of fluorescent bulbs installed in a box with a plastic diffusing screen, and set up on a table or desk top where one can sit comfortably for the treatment session. Treatment consists simply of sitting close to the light box, with lights on and eyes open. Looking at the lights is not necessary or recommended; rather, one is free to engage in such activities as reading and writing, or eating meals. What is important is to orient the head and body toward the lights, concentrating on activities on the surfaces illuminated by the lights, and not on the lights themselves. Treatment sessions can last from 15 minutes to 3 hours, once or twice a day, depending on individual needs and equipment used. Intensity and timing of treatments interact in determining the precise dosage required.

Early research used special “full-spectrum” bulbs producing light similar in color composition to outdoor daylight, but more recent efforts have used ordinary fluorescent bulbs with similar results. What appears to be critical is that the level of light produced match that of light outdoors shortly after sunrise or before sunset. Light intensity is a critical “dosing” dimension of the therapy: systems deliver varying amounts of light, and people vary in their response to light levels.

The time of day of light therapy is another important factor. Many people with winter depression respond best to treatment first thing upon awakening. Some, however, do better with evening light. It is necessary to determine the optimum time of day for each individual.

Is increased exposure to normal room light therapeutic, without the use of special apparatus?
Some very light-sensitive people, living and working in dim environments, may feel improvement with increased exposure to normal room light. Research studies show, however, that most sufferers of SAD and winter doldrums require exposure to light levels much higher than provided by ordinary indoor lamps and ceiling fixtures. Such therapeutic levels are five to twenty times higher (as measured in lux or footcandles by a light meter) than typical indoor illumination in the home or office.

If outdoor light intensities are what’s critical, can the therapeutic effect be achieved by spending more time outdoors in winter?
Again, some individuals report improvement by spending more time in the sun. For many, however, it appears that the strongest therapeutic effect requires exposure to artificial bright light in early morning — at an hour (6:30 a.m., for example) when it is still quite dark outdoors during long winter nights.

Do the lights really work?
Researchers at medical centers and clinics in both the U.S. and abroad have had much success with light therapy in many hundreds of patients with clear histories of SAD for at least several years. Marked improvement is usually observed within four or five days, if not sooner, and symptoms usually return in about the same amount of time when the lights are withdrawn. Most users therefore maintain a consistent daily schedule beginning, as needed, in fall or winter and usually continuing until spring, when
outdoor light becomes sufficient to maintain good mood and high energy. Some people can skip treatments for one to three days, occasionally longer, without ill effect, but most start to slump quickly when treatment is interrupted.

How do the lights work?
The therapeutic level of illumination has several known physiological effects, though its mechanism of effect is still unclear. Blood levels of the light-sensitive hormone melatonin, which may be abnormally high at certain times of day, are rapidly reduced by light exposure. Depending on when bright light is presented, the body’s internal clock — which controls daily rhythms of body temperature, hormone secretion, and sleep patterns — shifts ahead or is delayed when stimulated by light. These physiological time shifts may be the basis of the therapeutic response. Light may also amplify the day-night difference in these rhythms. Research into the possible mechanisms is currently underway, and the final answer is not yet in.

Are there any side effects?
Side effects have been minimal. People occasionally report eye irritation and redness which can be alleviated by sitting farther from the lights or for shorter periods. Using a humidifier to counteract the dryness of winter air indoors may also help. A few people have reported feeling mildly nauseous when beginning light treatment; this tends to pass quickly as one accommodates to the high intensity. The most dramatic side effect, and one which occurs infrequently, is a switch from the lethargic state to an over-active state in which one may have difficulty getting a normal amount of sleep, become restless — even reckless — and be unable to slow down, feel irritable, or subjectively speedy and “too high.” People who have previously experienced these states in late spring or summer are particularly vulnerable. In such cases, the guidance of a clinician skilled in the use of light therapy is important.

Do the lights cause tanning?
Not usually. Most light therapy systems shield out the ultraviolet that causes tanning, or substantially reduce it. Occasionally a person with very sensitive skin shows reddening under full-spectrum lights, in which case complete UV-blocking, with filters, alternate bulbs, or a sun screen lotion is needed. This should not influence effectiveness, however; the action of light therapy is through the eyes, not the skin, and in adults UV does not reach the retina.

Can the lights be combined with antidepressant medication?
Yes. Patients who have received partial benefit from antidepressants often begin light therapy without changing drug dose. If there is quick improvement, it is then sometimes possible to withdraw the drugs under clinical supervision, while maintaining improved mood and energy. Some patients find a combination of light and drug treatment to be most effective.

When are the lights contraindicated?
No adverse effects of light therapy have been found in ophthalmological examinations of SAD patients after treatment, but caution is warranted in cases of pre-existing eye disease. There are several conditions of retinal pathology (for example, retinopathy or detachment) under which bright light exposure would not be recommended. Given other eye conditions (for example, glaucoma, cataracts), or conditions under which the retina may be vulnerable (such as predisposing factors of diabetes) we recommend light therapy with ophthalmological monitoring. Certain medications may increase the eye’s sensitivity to light, and patients using them should also be followed by an ophthalmologist.

How did this treatment develop? How long has it been in use?
The first demonstration of clinical effect was at the National Institute of Mental Health in the early 1980’s. Soon after, several research centers initiated clinical trials, and more than 600 SAD patients have been studied to date. The method has also been used in private practices, mostly by psychiatrists, but also by family doctors and psychologists. The number of
clinicians offering light therapy is increasing dramatically year by year, though compared to drug treatments or psychotherapy, the method is not yet in widespread use.

Are the lights medically approved? Is a prescription needed? Does insurance cover their cost? Both the American Psychiatric Association and the Society for Light Treatment and Biological Rhythms have recommended use of light treatment for winter depression. The apparatus is not a prescription item, and the Food and Drug Administration has not ruled on its use. Light boxes are available “over-the-counter,” but anyone suffering serious depression should seek a doctor’s recommendation before obtaining a unit, and use it under the doctor’s supervision. Some people have been successful in obtaining insurance reimbursement for purchase of light therapy apparatus, based on their physician’s statement that the lights are medically indicated and effective for the individual. Medicaid does not yet cover this expense.

Our Society makes available to clinicians a packet of information, including a statement of our position on light therapy for SAD, for use in supporting insurance claims. *This endorsement packet can be ordered from the Society by sending a check of $15 (U.S. funds only) payable to “SLTBR Publications,” which will cover printing and mailing costs, and handling.* If the insurance policy covers psychiatric care or psychotherapy, it is very likely that it will reimburse for clinical sessions involved in diagnosis of SAD, evaluation for light treatment, and follow-up.

How much do the lights cost? Can individuals build them for personal use?
Light therapy apparatus is available from several manufacturers, at prices ranging from approximately $300 to $550, depending on configuration or the components and special features.

We do not recommend home construction of the apparatus. Output must be specifically calibrated for the proper therapeutic effect. A danger of creating electrical or heat hazard exists. Apparatus on the market should have been carefully evaluated for output intensity, compatibility of components, visual comfort, maximum transmittance with minimal heat build-up — and, importantly, clinical efficacy in controlled research studies. These factors should be checked before purchasing any light system.

We urge careful comparison shopping, and seeking the advice of an experienced clinician. Lighting manufacturers and suppliers who have joined our Society as Corporate Members include: . . .

Is free treatment available?
Free treatment is available for research volunteers at SAD clinical research centers in the United States, Canada, and abroad. Recruitment for the winter season often begins in late summer or early fall. If you are seeking to participate in such a study in your area, you may write the Society for information. Please enclosed a self-addressed, stamped envelope with your request.

What other treatments are available for SAD?
Apart from moving to or taking long vacations in a climate with more available natural light, some sufferers find that standard antidepressant medications provide relief, even if they do not reach their normal level of well-being until spring or summer. Many patients have been in psychotherapy and found it to be helpful to them in many ways, including coping with SAD — but unfortunately not in relieving the SAD symptoms.
Welcome to New Members

The Board of Directors is pleased to welcome the following people who have become members of SLTBR since the last Bulletin.

Regular Members
Philippe Bovier, Oliver Cameron, Philip Carney, Margot Dietzel, Gail Eskes, Jean Foret, Alessandro Meluzzi, Masako Okawa, Atul Pande, Paul Pevet, David Sack, Chris Thompson, Janet Williams.

Associate Members

Student Member
Bonnie Eberhardt.

Corresponding Members
Michael Heim, Konrad Peter, Zoltan Rihmer.

Corporate Member
Ener-Glo Systems.

If you are not yet a member of SLTBR, but are interested in joining, please write for application information: SLTBR Membership, 722 West 168th Street, Box 50, New York NY 10032; fax 212/960-2584.

Membership Directory
The long-awaited publication of our Membership Directory unfortunately continues to be delayed due to a temporary administrative overload in conjunction with annual meeting preparations. We hope it will appear in about a month, with copies sent to all members. Thank you for your forbearance.