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Specific Effects and Biofeedback versus Biofeedback-Assisted Self-Regulation Training

Robert Shellenberger[1] **and Judith Green**
Aims Biofeedback Institute

In any field, clear and logical conceptualizations are the basis of accurate models→correct research design→correct results→correct conclusions→advancement in the field. Faulty conceptualizations→faulty models→faulty research design→faulty results→faulty conclusions→confusion. In analyzing the conceptualizations of "biofeedback" as expressed by John Furedy (1987) in, "Specific versus Placebo Effects in Biofeedback Training: A Critical Lay Perspective," we focus on two issues: Does biofeedback have a treatment effect? Is biofeedback necessary for the training effect? In discussing issue (1) we describe the multiple meanings of "biofeedback" and raise the fundamental question: Is biofeedback a treatment? We argue that faulty conceptualizations of clinical biofeedback (1) assume that the treatment in clinical biofeedback is "biofeedback" with specific effects, (2) assume that the scientific basis of biofeedback is dependent upon demonstrations of these specific effects through double-blind designs that distinguish "specific" from "placebo effects," and (3) trivialize clinical research by attempting to determine the usefulness of biofeedback information—usefulness that is already understood logically by professionals and consumers and demonstrated by clinical studies in the laboratory and in the clinic. We further argue that accurate conceptualizations of clinical biofeedback (1) identify self-regulation skills as the treatment with specific effects of physiological change and symptom reduction, and (2) describe the use of information from biofeedback instruments as scientific verification of self-regulation skills. Finally, the scientific basis of clinical biofeedback is based on (1) evidence from experimental and clinical control studies that have demonstrated the effectiveness of self-regulation skills for symptom allevia-

[1]Address all correspondence to Robert Shellenberger, Aims Biofeedback Institute, P.O. Box 69, Greeley, Colorado 80632.

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tion, and (2) the use of biofeedback instruments to verify the acquisition of self-regulatory skills, thus fulfilling the scientific dictum of verifiability.

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Several years ago we became intrigued by the fact that, as reported in the biofeedback research literature, "biofeedback" often fails. Such failure was particularly interesting to us when, on the basis of research findings, it was concluded that biofeedback was not useful for a condition that we had been treating successfully in our private practice, such as Raynaud's disease. In our attempt to understand the basis for such failure, we discovered two models for biofeedback training that appeared to be both logically and empirically erroneous: the drug model and a simplistic operant conditioning model. In our book *From the Ghost in the Box to Successful Biofeedback Training.* (Shellenberger & Green, 1986) we describe 12 methodological errors that are inherent to these models. It was clear to us that these research models of biofeedback training, and the methodological errors, account for the failures that lead to faulty conclusions, creating confusion and misunderstanding in the field.

It also became clear the particular conceptualizations about biofeedback training were accepted without critical examination. The basic conceptualizations of the drug model are that (1) "biofeedback" is like the active ingredient in a drug, and (2) like a drug, it has "specific effects" that must be isolated and demonstrated. The drug model, which has been especially popular, was uncritically used in both biofeedback and psychotherapy research in an effort to be "scientific." The demonstration of "specific effects" in contrast to "placebo effects" became the hallmark of scientific legitimacy, and the sine qua non for claiming efficacy of the variable being studied, i.e., "biofeedback."

As we were preparing our book, in which we describe these findings and provide ample evidence for our views, the article by Furedy (1985), "Specific vs. Placebo Effects in Biofeedback: Science-Based vs. Snake-Oil Behavioral Medicine," came to our attention. Furedy claimed that to be "science-based" rather than "superstition-based," the specific effects of biofeedback must be separated from placebo effects. Furedy used snake oil as an example, saying that snake oil can have powerful effects, but the effects are placebo effects, based on superstition. The effects of snake oil are "placebo" rather than "specific," because snake oil does not have a specific ingredient that can create specific effects. Furedy used this example to show that unless the specific effects of biofeedback are separated from placebo effects, it cannot be claimed that "biofeedback" in itself is efficacious, just as it cannot be claimed that snake oil by virtue of its own properties is efficacious. Furthermore, "To evaluate treatments in terms of placebo rather than in terms of specific effects is to adopt, implicitly, the use of unscientific, snake-oil

logic" (Furedy, 1985, p. 156). Furedy concluded, "The snake-oil approach is one that has been implicitly adopted by many biofeedback workers" (Furedy, 1985, p. 160). In addition, he states: "The alternative approach is not espoused by the majority of biofeedback practitioners, or even of biofeedback researchers. Nevertheless, I suggest that it is the only scientific approach for behavioral medicine. In this regard, pharmacological medicine provides an appropriate model for treatment evaluation" (Furedy, 1985, p. 159).

Furedy was invited to present his 1985 article at the Biofeedback Society of American Annual Meeting in San Francisco, and we were asked to present our contrasting views. We also responded to Furedy's article formally (Green & Shellenberger, 1986b).

In the current article, Furedy describes himself as taking a minority view, but in fact he is the good company of many rearchers who have conceptualized "biofeedback" as he has, implicitly adopting the drug model. Although more researchers than clinicians have adopted the drug model of biofeedback training, some clinicians have done so, and many researchers have not, as we noted in the chapters on successful biofeedback training in our book, hereafter referred to as *The Ghost* (Shellenberger & Green, 1986). The clarification of these issues has nothing to do with a "researcher vs. clinician" focus as Furedy suggests, nor are the arguments ad hominem, nor do they involve minutiae. The issues have to do with the fundamentals of "biofeedback," what it is and what it is not, and we discuss these issues as researchers and clinicians, of which we are both, as are many others in the field. In this article we do not address the "intelligent consumer" (nor does Furedy). We are writing as researchers and providers, for researchers and providers. And we suggest that ignoring certain issues because they are of no presumed interest to the layperson is like suggesting to physicians that they need not discuss the details of bypass surgery because the patient is not interested.

CONCEPTUALIZATIONS OF "SPECIFIC AND PLACEBO EFFECTS": A CLARIFICATION OF THE ISSUES

Because conceptualizations are at the heart of the confusions in the field and the basis of research and practice, we focus primarily on conceptualizations. In any field, it is the case that faulty conceptualizations → faulty models → faulty research design → faulty results → faulty conclusions → confusion.

Unfortunately, Furedy's conceptualizations are difficult to "pin down" partly because he fails to define terms (to our knowledge he has never defined *biofeedback* or *specific effect*) and partly because meanings seem to change. For example, Furedy (1985) originally used the term *specific effect* exactly as it is used in drug research – the specific physiological effect of the active ingredient in a drug, and *placebo effect* exactly as originally used in

medicine—"snake oil" vesus a true active ingredient. In the current article, Furedy continues to use *placebo* and *specific effects* in the medical sense. For example, his minefield parable uses *placebo* and *specific effect* in the standard way. "For example, faith healing may be quite effective under some circumstances, but the effectiveness of faith healing cannot be *scientifically* evaluated, so that, from a critical lay perspective, such treatments are not evaluatable" (Furedy, 1987b). Thus, the zigzag method of the priest cannot be evaluated. By the end of the current article, however, the "specific effect" has evolved into "specific beneficial effect" or "helpful" (Furedy, 1987b), which is a subtle shift away from the drug model and both *placebo* and *specific* are used as relational terms being defined "in relation to" the object of study (Furedy, 1987b). This metaphorical definition of *placebo* means that anything can be a placebo—even an active ingredient that creates physiological change, but is not the "object of study." For example, if the specific effects of "faith" in the physician are being studied, the drug that the physician prescribes is the "placebo."

Furedy's equivocation of "specific effect" adds additional confusion but is significant. As noted above, Furedy uses *specific effect* to mean physiological change, as in the drug model. But in the current article (Furedy, 1987b), he also uses the term to mean "training effect." "The question is not whether the mirror or the stopwatch can, by itself, produce improvement: It cannot. The question is whether the information provided by these instruments is helpful, neutral, or harmful for training" (Furedy, 1987b). Failure to precisely define terms, and shifts in meaning enable Furedy to claim that we misinterpreted him, and created a "straw man." We did not misinterpret his 1985 article; rather, he shifts his meanings back and forth from the established medical use of *placebo effects* to this metaphorical definition of *placebo* as "relational" and from the medical use of *specific effect* as the treatment result of "biofeedback" to *specific effect* as the result of something that is helpful.

Ambiguity of the term *effects* is avoided by distinguishing *treatment* and *training* effects (Fahrion, 1978; Johansen & Öst, 1982; 1987; Libo & Arnold, 1983a, 1983b; Shellenberger & Green, 1986; Steiner & Dince, 1981, 1983). We use this language to identify two issues which Furedy seems to be addressing, and which, he claims, are unanswered:

Issue 1: Does "biofeedback" have a treatment effect?

Issue 2: Is "biofeedback" necessary for the training effect?

Furedy raises these two very different issues, perhaps inadvertently. In the second part of the article, issue 2 is addressed. "The question is whether the information provided by these instruments is helpful, neutral, or harmful for training" (1987b). At the beginning of the paper and periodically, Furedy discusses issue 1 as indicated by the following: (1) "This specific-effects

form of evaluation applies, in my view, to any **treatment,** and hence to biofeedback" (1987b). (2) Furedy has the layperson ask, "Does the **treatment** *work* in the specific effects sense?" (1987b). (3) "The only question is: does the **treatment** in question 'work,' in the sense of having a specific beneficial effect that **treatments** of a different sort do not have" (1987b). (4) "It is also important to recognize that the specific-effects-oriented control is at least as important for evaluating *rival* **biofeedback-based treatments**" (1987b). (5) "This placebo treatment of nonbiofeedback factors is appropriate because what is taken to be the essense of the **treatment** or training program (i.e., that which distinguishes these sorts of **treatments** from other sorts of treatments) is *biofeedback"* (1987b). (6) "Rather, I have made only the analytic or *logical* assertion that, *if,* the active ingredient is assumed to be biofeedback, *then* to treat nonbiofeedback factors as being part of biofeedback is to commit a *logical* fallacy that is *analogous* to the logic used to evaluate snake oil. So, to evaluate **treatment** in terms of placebo rather than in terms of specific effects is to adopt, implicitly, the use of unscientific, snake-oil logic' (Furedy, 1985, p. 160)" (Furedy, 1987b). It is precisely Furedy's logic that we are examining. (The italics in these quotations are Furedy's emphasis, the bold emphasis is ours).

The question "Does "biofeedback" have a treatment effect?" is assumed in the research literature, suggesting that the scientific basis of "biofeedback" is dependent on the demonstration of the specific effects, i.e., treatment effects of "biofeedback." The purpose of the recent publication, *Biofeedback: Studies in Clinical Efficacy,* sponsored by the Biofeedback Society of America, states this assumption clearly: "The primary objective was to document the clinical efficacy of biofeedback in the context of its use in treating specific disorders. The authors were instructed to emphasize the strongest available scientific evidence pertaining to the clinical efficacy of biofeedback in the treatment of a particular disorder" (Hatch, 1987, p. x).

Issue 1 ("Does biofeedback have a treatment effect?") was also debated in the *American Psychologist* (Roberts, 1985; Green & Shellenberger, 1986a; White & Tursky, 1986), focusing on whether or not biofeedback is an effective treatment for psychophysiological disorders. The positions were as follows: (1) Research has not demonstrated that biofeedback is an effective treatment. "There is absolutely no convincing evidence that biofeedback is an essential or specific technique for the **treatment** of any condition" (Roberts, 1985 p. 940). (2) Research has demonstrated the specific effect of biofeedback as an effective **treatment** for neuromuscular disorders, epilepsy, and fecal incontinence (White & Tursky, 1986, p. 1006). (3) There is no specific effect of biofeedback. Biofeedback is not a **treatment.** Self-regulation is the treatment (Green & Shellenberger, 1986a, p. 1004; Norris, 1986, p. 1009).

Issue 1: Does "Biofeedback" Have a Treatment Effect?

Furedy begins his article with a discussion of the appropriate, scientific method for evaluating a **treatment.** Furedy assumes that biofeedback is a treatment and bases his arguments and criticisms on this assumption. This primary assumption leads to the concept that like all treatments, biofeedback must have specific effects, and these specific effects must be demonstrated independently of placebo effects; if the specific effects cannot be demonstrated, then biofeedback is not an effective treatment and is not scientific, and the effects are placebo effects. "This specific-effects form of evaluation applies, in my view, to any **treatment** and hence to biofeedback" (Furedy, 1987b). In keeping with the primary assumption that biofeedback is a treatment, Furedy suggests that the best way of separating the specific effects from the placebo effects is with the same research design used in drug research, the double-blind design, referred to as "specific-effects-oriented control" in the current article (Furedy, 1987b).

We begin at a more fundamental level and ask, *"Is "biofeedback" a treatment?"* Until it is determined that biofeedback is a "treatment," it is inappropriate to discuss the correct and incorrect ways of evaluating biofeedback. **In fact, if biofeedback is not a treatment, then the issues regarding specific effects, placebo controls, science versus superstition, and zigzagging through a minefield, are irrelevant.** In our previous article we focused on the "specific effects" issues, arguing that biofeedback does not have specific effects on physiology, and research designed to isolate the specific effect fails for that reason. Here we address the more fundamental issue.

Is "Biofeedback" a Treatment?

If we were to ask the readers of this journal whether or not "biofeedback" is a treatment, the majority would probably say, "It is." After all, there are biofeedback clinics and biofeedback therapists, insurance companies pay for biofeedback, there are procedure codes for biofeedback, grant proposals are written to study biofeedback as a treatment, and when patients "do biofeedback" symptoms are reduced, so surely "biofeedback" is a treatment.

Conscientious, science-minded people, and the federal government, take a clear and correct stand on treatment evaluations—before a treatment or product of any kind can be "sold" to the consumer it must be proven both harmless and efficacious—this concept is part of our legal and cultural heritage. If "biofeedback" is a treatment, its efficacy must be evaluated.

What is a "treatment?" *Tabor's Cyclopedic Medical Dictionary* defines treatment as "1. Medical, surgical or pychiatric management of a patient; 2. Any specific procedure used for the cure or the amelioration of a disease

or pathological condition" (1970, T-44). This definition describes the common use of the word, meaning "a procedure for cure or amelioration," and in this sense a treatment has specific effects on physiology, effects that are the result of the treatment and not the result of placebos. This is the meaning of *treatment* that Furedy's hypothetical layperson uses in asking, "Does the treatment *work* in the specific-effects sense?" The use of the word *work* (highlighted by Furedy) clearly implies the common use of *treatment*—a treatment is a procedure that can work, i.e., have specific effects on symptoms.

Before deciding whether or not "biofeedback" is a treatment, it is necessary to examine the multiple meanings of *biofeedback*. Over the years, *biofeedback* has been used to describe an amazing variety of referents:

1. Miller and DiCara (1971) used the term to describe conditioning of the autonomic nervous system in curarized rats. The "biofeedback signal" was the rewarding effect of the stimulation of the lateral hypothalamus.

2. Rosenfeld uses the term synonomously with operant conditioning of evoked potentials, both auditory and somatosensory, in laboratory animals and humans. In Rosenfeld's research with humans, "feedback" is a tone indicating the "correct" change in the evoked response (Rosenfeld & Hetzler, 1978; Rosenfeld, Dowman, Silvia & Heinricher, 1984).

3. Guglielmi, Patterson, and Roberts (1982) used the term to describe a double-blind procedure with Raynaud's patients in which both EMG and temperature sensors were attached and the patient was instructed to drive the feedback meter and tone in one direction, but did not know which physiological process was generating the signal (Guglielmi et al., 1982, p. 117). In light of poor results, the authors concluded that biofeedback is not an effective treatment for Raynaud's disease.

4. In many studies, *biofeedback* refers to a procedure in which the subject is given accurate feedback of a targeted response, like feedback from a mirror. The subject is informed about the nature of the feedback and is given minimal training to learn to regulate the response being monitored, through trial-and-error learning (Davis, 1980; Volow, Erwin, & Cipolat, 1979).

5. In other studies, the effect of "biofeedback" of the trail-and-error variety is compared with the effects of a systematic relaxation training procedure, implying that whatever "biofeedback" is, it is not relaxation training. When the results show that trial-and-error learning is not as effective as systematic relaxation, the conclusion is that "biofeedback" is not effective (Nielson & Holmes, 1980).

6. The term *biofeedback* is used to describe a specific training technique for treatment of a specific disorder. For example, "biofeedback" in fecal continence training refers to a situation in which the feedback of information from the balloon catheter is essential for training very specific mus-

cles, the external and internal anal sphincters (Cerulli, Nikoomanesh, & Schuster, 1979).

7. In some situations, *biofeedback* refers to the use of biofeedback instrumentation in conjunction with a systematic procedure such as autogenic training and is referred to as "autogenic feedback training" (Fahrion, 1978; Green, Green, Walters, Sargent, & Meyers, 1975; Toscano & Cowings, 1982).

8. In the clinical setting, *biofeedback* refers to a therapy in which several efficacious self-regulation techniques are used such as autogenic training and desensitization, imagery and breathing exercises, cognitive behavior modification, and stress management. Biofeedback instrumentation is used to enhance learning of these self-regulation skills. **The instrument provides verification of the strategy used.** The Biofeedback Certification Institute of American (BCIA, 1986) has adopted meaning 8 for *biofeedback*. BCIA also states that therapists are expected to interpret the meaning of the signals to the patient as (1) accurate feedback of a targeted response system and (2) accurate physiological feedback that reflects the patients perceptions and cognitions.

Biofeedback training, biofeedback therapy, autogenic feedback training, biofeedback-assisted cognitive behavior modification, biofeedback-assisted self-regulation training are terms commonly used to describe therapy in which biofeedback instrumentation is used. Increasingly, the term is also used to mean "psychophysiological therapy," and in one institution, the Menninger Foundation, *psychophysiologic* is used instead of *biofeedback* to emphasize the role of the mind in physiological processes and to accurately represent the multi-modal self-regulation therapy that includes more than "biofeedback."

We use the term *clinical biofeedback* in the sense of meaning 8.

9. Finally, the term *biofeedback* is used by laypersons to mean anything learned in biofeedback therapy. For example, a patient may say, "I used biofeedback when I was stressed while driving in traffic." In fact, deep breathing and positive coping statements were used, skills that were learned in "biofeedback therapy," but not "biofeedback" of the 1–7 meanings.

Now we must understand *biofeedback* as used by Furedy. In the 1985 article, *biofeedback* is not defined, but in describing his heart rate study he writes, "Subjects could not tell whether they were getting biofeedback or not, so that there was no difference in perception (and hence motivational or placebo differences) between the contingent and noncontingent conditions" (Furedy, 1985, p. 159). This meaning 3, receiving signals from a biofeedback instrument, and the signals used need not be meaningful information. We accept this as clear evidence of the drug model because biofeedback is assumed to have effects like a drug irrespective of subject awareness or learning.

In the current article, Furedy uses another definition of *biofeedback,* i.e., receiving information from a biofeedback instrument is analogous to receiv-

ing information from a mirror or stopwatch (Furedy, 1987b). This is the number 4 meaning, in which the subject receives accurate feedback of the physiological response. We conclude that although Furedy vacillates, this is the meaning of *biofeedback* that he uses most frequently.

No wonder that there is confusion in the field and difficulty in understanding Furedy's ideas. The term *biofeedback* is used in at least nine different ways, and the conceptualizations about *biofeedback* implied in each meaning are equally various. It is imperative that when biofeedback is discussed, the particular definition is clearly stated. It is equally imperative that conclusions of research based on *biofeedback* with one meaning are not generalized to *biofeedback* of a different meaning.

Having examined the many meanings of biofeedback, we can now return to the question **"Is biofeedback a treatment?"** Using *biofeedback* in Furedy's sense of feedback information from biofeedback instrumentation (4) (Furedy, 1987b), we can ask, "Does feedback of information about a physiological process have the specific effect of curing or ameliorating a symptom; i.e., is it a treatment?" The obvious answer is no, no more than a mirror can have behavioral effects even though it feeds back behavioral information. Feedback of physiological information, i.e., biofeedback, is not a treatment of any sort; it cannot "work" any more than information from a mirror "works." Drugs work but information cannot work.

To clarify this point, consider a treatment that does work, compared with feedback of information from a biofeedback instrument. Beta-blockers have the specific effect of lowering heart rate, and they are an effective treatment for hypertension. Beta-blockers work regardless of the state of the person; waking or sleeping, the beta-blocker will work, i.e., lower heart rate, even if the patient thinks that the tablet is Vitamin C. Now connect the patient to a heart rate monitor and give him information, i.e., biofeedback. What happens? Nothing. Why nothing? Because information has no power to change physiology; information is not a treatment for anything. In fact, laypersons know this.

Over the past 10 years, we have worked with at least 2,000 laypersons and not one has ever asked, "Does it work?" For example, not a single patient or student has ever received information from our automated blood pressure feedback instrument and asked, "Does this treatment work? **"How long will I need to get this information before my blood pressure goes down?"** Laypeople do not ask these questions because it is immediately obvious that the information, i.e., biofeedback, has no effect, specific or beneficial. The layperson may ask, "What should I do to lower my blood pressure?" And the truly critical layperson will ask, **"What skills do I need to learn to lower blood pressure, and what training techniques should I use?"** And finally, the truly critical layperson will ask, "If I learn these skills, and practice them, will my blood pressure go down?" These are the correct questions and are

significantly different from Furedy's question "Does it work?" (Furedy, 1987b). In a sense, then, the intelligent layperson asks, **"Will I work?"** If a less intelligent layperson asked, "Does it work?" we would explain that neither the instrument nor the information has power; only the human has the power to create physiological change, and we would add, "It depends on how much practice you do."

Of course, laypeople do ask, "Does biofeedback work?" but they are using the number 8 clinical meaning of a combination of stress management skills, relaxation techniques, breathing exercises, and cognitive training—the true treatment with physiological effects.

To summarize: *Biofeedback*, i.e., feedback of information, is not a treatment because it has no effects, either for cure or for remission of symptoms. It is erroneous to suggest that "biofeedback" as a treatment can be "the object of study" with the intent of determining its specific effects. When this is attempted, the result is failure, as has been demonstrated repeatedly (Shellenberger & Green, 1986). In short, we reject Furedy's conceptualizations about biofeedback and suggest that he and many others have been misled by the multiple meanings of *biofeedback* in which "biofeedback" may refer to a treatment, or it may not refer to a treatment. *As feedback of information, "biofeedback" does not refer to a treatment.* It is unfortunate that a therapy, i.e., treatment, was named after an instrument that is used in the therapy because it gives the impression that information from the instrument is the treatment.

Furedy is correct in insisting that the effectiveness of treatments must be demonstrated in scientific ways, i.e., appropriate research design. The problem is simply that *biofeedback* as Furedy uses the term is not a treatment, and therefore the voluminous arguments regarding science versus superstition, high priests versus scientists, specific effect versus placebo effect, qualitative versus relational, analytic versus synthetic are irrelevant.

By definition, *specific effects* of the drug model as Furedy originally used the term, are the result of an active agent or ingredient. While we reject the drug model for biofeedback, we accept the concept "specific effects" and we accept the concept of an active ingredient(s) or agent(s) that create these effects. If "biofeedback," i.e., feedback of information from a biofeedback instrument, is *not* a treatment, and has *no* specific beneficial effects, as we argue, **then what is the treatment?** What is the active ingredient with specific effects? Something is working, something is clearly alleviating symptoms, something is bringing increasing numbers of laypersons into therapy, with successful results—something is acting like an active ingredient with specific effects on physiology and symptoms. When asked to describe the active ingredient, or agent, and explain how it influences the hypothalamus, thus creating the specific effects, at the BSA Annual meeting in 1987, Furedy replied, "I don't know what the agent is, and I have heard of the hypothalamus,"

Furedy is unable to describe the active ingredient in clinical biofeedback because where he looks it is not, and where it is he cannot look. "In relation to biofeedback as the object of study (or, from the critical-lay rather than pure-science, perspective, with biofeedback training as the object of evaluation), instructional (feed*forward*) effects such as relaxation training are placebo effects" (Furedy, 1987b). In one sweeping misconceptualization Furedy makes "biofeedback" the "essence of the treatment" and relegates all else to the placebo category, relative to biofeedback (1987b).

By assuming that biofeedback (for pure science) or biofeedback training (for the layperson) can be a reasonable object of study, and all other factors are placebos, Furedy has defined himself into a box in which the active ingredients(s) that create specific effects cannot be found, since feedback of information has no power, and the factors that create physiological change, like relaxation, are placebos and thus cannot be the active ingredient. Furedy and others will never escape from this box, and their research will continue to fail, or be trivial, until it is clear that *self-regulation is the treatment,* not *biofeedback,* as Furedy uses the term.

Self-Regulation: The Treatment

Critical laypersons understand that the essence of clinical biofeedback training is self-regulation. By self-regulation we mean conscious control of psychophysiological processes. Because psychophysiological *self-regulation* does not come easily for people, it must be learned through a variety of training techniques, including relaxation, a powerful active ingredient that has specific physiological effects via the limbic-hypothalamus-adrenal axis and reduction of sympathetic nervous system activity. The bottom line of physiological change is psychophysiological regulation, and whether gained laboriously through trial and error or through excellent coaching, self-regulation is the treatment because self-regulation has specific effects and can be a cure or facilitate remediation of symptoms.

The essence of clinical biofeedback (8) is self-regulation. The essence of clinical biofeedback (8) is not *biofeedback*, in any meaning of the term. How did this paradoxical twist come about? Simply because the therapy, which is in fact self-regulation therapy, kept the name *biofeedback* even though the use of the biofeedback instrument is often a minor aspect of the therapy, with the possible exception of SMR training and fecal continence training. To reiterate: Feedback of information is not a treatment; it has no specific effects. Relative to self-regulation techniques, feedback of information as the object of study with specific effects is meaningless.

Self-regulation is learned through training and the training effect is psychophysiological self-regulation. Now we can address the question that

is the other focus of Furedy's current paper, "Is 'biofeedback' necessary for the training effect; i.e., is it helpful for training?"

Issue 2: Is Biofeedback Necssary for the Training Effect?

Furedy states:

> The question is not whether the mirror or the stopwatch can, by itself, produce improvement: It cannot. The question is whether the information provided by these instruments is helpful, neutral, or harmful for training. It is this question that is begged when it is asserted that "biofeedback training is the process of mastering psychophysiological self-regulation skills, with the aid of information from a biofeedback instrument" (G & S, 1986b) or that "the biofeedback machine is useful if the trainee wants to improve performance." These assertions already *assume* the question asked by the intelligent consumer: Does biofeedback (or, more precisely, the information provided by biofeedback) *really* help? (Furedy, 1987b)

A question that is already answered cannot be begged. In our article (Green & Shellenberger, 1986b) and in *The Ghost* (Shellenberger & Green, 1986) we presented both empirical evidence and logical reasons for the usefulness of the information from biofeedback instrumentation. Since Furedy fails to discuss the evidence we presented and has failed to realize that the question is not "begged," because the answer is already known and needs no further study, double-blind or otherwise, we will reexamine the importance of information for enhancing the training effect through *verification*. (This is the "help" that Furedy refers to, asking now, does it "help" instead of does it "work"—an important difference. **Things that "work" do something to us; things that "help" help us do something.** This is a move from the drug model of biofeedback to a training model, of sorts, although at times it seems that Furedy uses "feedback of information" as the active ingredient, with specific effects as in the drug model.

Empirical Reasons

In *The Ghost*, we cite 97 successful clinical biofeedback studies. Several of these studies used a crossover design in which control subjects receive a nonbiofeedback training method followed by the "crossover" to a biofeedback training method. These studies have been especially effective in demonstrating the importance of biofeedback information for training (Blanchard, Andrasik, Neff, Teders, et al., 1982; Blanchard, McCoy, Acerra, & Gerardi, 1985; Budzynski, Stoyva, Adler, & Jullaney, 1973). Freedman, Ianni, and Wenig (1983) conducted an excellent clinical trial for treatment of Raynaud's

disease using four groups. They compared (1) finger temperature feedback alone, (2) finger temperature feedback under cold stress, (3) autogenic training, and (4) forehead EMG. Thermal control and reduction of symptoms were significantly improved for the finger temperature feedback group under cold stress.

Many other controlled clinical studies are discussed or cited in *The Ghost.* Some of these are Lubar and Lubar (1984), Sterman (1973), Sterman and MacDonald (1978), Sterman, MacDonald, and Stone (1974), Burgio, Robinson, and Engel (1985), Cerulli et al. (1979), Wald (1981), Giles (1981), Neff and Blanchard (1985), Love, Montgomery, and Moeller (1974), Sedlacek, Cohen, and Boxhill (1979), Hauri, Percy, Helleckson, Hartmann, & Russ (1982), Cohen et al. (1984), Middaugh (1978), Hutchings and Reinking (1976), Patel and North (1975), and Jurish et al. (1983).

We can only conclude that Furedy is not familiar with biofeedback research or that he commits the "tomato effect" described in *The Ghost*: "The tomato effect is the rejection of an effective treatment because it does not fit an established model" (Shellenberger & Green, 1986, p. 85). Furedy cavalierly dismisses years of research, writing, "My only concern, from the critical lay perspective, is to state the proper logic of evaluation. After this is understood, the synthetic task of evaluation can begin" (1987b)—as though all the research and clinical evidence showing that feedback information is helpful counts for nothing.

Logical Reason 1: Clinical Biofeedback and the Principle of Verification

In addition to the empirical evidence, we argued that the most important reason for using biofeedback instrumentation is the scientific dictum of verifiability—**Self-regulation therapies using biofeedback instruments are scientific because the instruments are used to verify the acquisition of a self-regulatory skill.**

With the development of biofeedback instruments to verify the presence or absence of self-regulatory skills, a method was provided for making self-regulation therapies scientific. An aerospace engineer and psychologist, Tom Budzynski, and a physicist and psychologist, Elmer Green, developed and modified electronic instruments to assess various self-regulatory strategies, such as autogenic training (Green et al., 1975). In an excellent discussion of the history of behavior therapy and biofeedback, Tom Budzynski (1977) points out that without information from the biofeedback instruments, therapists and researchers are unable to verify the patient's mastery of self-regulation skills

such as relaxation and desensitization. The essence of the use of the information from the biofeedback instrument is verification.

Furedy (1) ignores the significance of information as verification in clinical biofeedback and (2) distorts our position on the principle of verification. Furedy writes:

> I could respond in kind by, for example, diagnosing their "inability to understand" that it is quite naive to cite Popper as accepting, along with Ayer (1936), the "principle of verification" (G & S, 1986b), or, more precisely, the principle of *verifiability*. Popper, of course (see, e.g., Popper, 1959), *rejected* the principle for his own principle of *falsifiability* and thereby rejected the idea that merely citing examples of confirmation, as they do (G & S, 1986b) is sufficient to be scientific. Psychoanalysis, to take Popper's example, has no trouble generating examples of confirmation; its scientific status is questioned by Popper because, according to him, psychoanalysis, while satisfying the principle of verifiability, could not satisfy the (Popperian) one of falsifiability. So, in this vein, I could conclude my report on Green and Shellenberger's "problem" by diagnosing them as suffering from an elementary philosophical confusion between the principles of verifiability and falsifiability. (1987b).

Furedy's diagnosis is incorrect. Furedy is evidently unaware of Ayer's writings and the fact that Popper's ideas are based on Ayer's original meaning of verification. Ayer states:

> The criterion which we use to test the genuineness of apparent statements of fact is the criterion of verifiability. We say that a sentence is factually significant to any given person, if, and only if, he knows how to verify the propositions which it purports to express—that is, if he knows what observations would lead him, under certain conditions, to accept the propositions as being true, **or reject it as being false** (Ayer, 1936, p. 35).

It does not matter whether we use *falsifiability* or *disconfirming;* the terms are synonymous. Now we can see how Furedy also distorted our position. This is what we actually said (Green & Shellenberger, 1986b, pp. 101, 102):

> But what is "scientific" in clinical research? A common principle underlies scientific methodologies, the principle of verification (Ayer, 1936; Popper, 1959; Nagel, 1961). The principle of verification defines scientific propostions as those statements that can be confirmed or **disconfirmed** by observation, and science as the process of verification. The development of instruments to confirm or **disconfirm** hypotheses has enabled science to progress by providing precise information.

Early clinical/researchers developed instrumentation for verification, and thus provided the foundation for a scientific model of clinical biofeedback (Budzyniski, 1973a, 1973b; Budzyniski & Stoyva, 1972; Budzynski, Stoyva, Adler, & Jullaney, 1973; Green, Green, & Walters, 1970).

The principle of verification includes disconfirmation (falsifiability). We highlight *disconfirm* to point out that we included both confirmation and disconfirmation in the principle of verification. Information from biofeedback instruments confirms and disconfirms, and thus clinical biofeed-

back is *not* like psychoanalysis, which relies only on confirming statements, or so Furedy claims.

We agree with Furedy that these issues are abstruse to the layperson, but they are essential for the critical researcher and clinician, regarding the scientific nature of clinical biofeedback. The essence of clinical biofeedback is self-regulation, and the essence of biofeedback information is verification of self-regulation by confirming or disconfirming the acquisition of skills. However, we can address verification issues that are meaningful to the layperson.

Logical Reason 2: The Usefulness of Information from a Layperson Perspective

The layperson knows that information for verification is always helpful—so another question that the layperson does not ask is "Is it helpful?" In our work, not a single layperson has ever received information from a biofeedback instrument and asked, "Is it helpful?" Laypeople do not ask this question because the answer is obvious. The intelligent layperson may ask, "Is autogenic training useful in lowering blood pressure?" or "Is EMG training helpful for retraining the jaw in bruxism," but no one wants to know if the information itself is helpful, not even ignorant laypeople. We can use an example of the significance of verifiability that the layperson would understand—an example from medicine.

Exercise, diet, medication, and bypass surgery are treatments for atherosclerosis. An angiogram can **help** the physician know whether or not a treatment is **working** by taking an angiogram. Information from an angiogram indicates the degree of arterial blockage. The information from the angiogram is not a treatment. The information **verifies** the success of the treatment. The angiogram provides scientific information that confirms or disconfirms the effectiveness of the treatment. The function of biofeedback information in self-regulation training is identical except that the verification process is continual. Information from biofeedback instruments verifies the effectiveness of self-regulation strategies and enables the clinician to be scientific in teaching self-regulatory skills for the treatment of psychophysiologic disorders—by verification with precise quantitative measurements. Double-blind designs are not needed to determine the usefulness of information from blood pressure units, EMGs, GSRs, angiograms, X rays, etc. Both the ignorant and the critical layperson understands the difference between a verification process and the treatment, and they understand the usefulness of information for verification.

Implications of Verifiability

The unique aspect of biofeedback instrumentation in providing information for verification has many implications for the scientific nature of clinical biofeedback.

Implication 1: Training Criteria. We can ask, "Verification of what?" In research and clinical applications of biofeedback, we mean verification of self-regulation. (We suspect that Furedy ignores the use of information for verification because, relative to "biofeedback" as the object of study, the answer to "verification of what?" is a placebo.) Training is verified by establishing training criteria and determining whether or not the subject or patient meets those criteria.

Because self-regulation skills result from training and are the treatment, it is essential to know that the skills are learned. **If self-regulatory therapies are to be scientific, it is a logical requirement that a training goal or criterion be established for determining maximum training efficacy, i.e., learning.** The requirement of training criteria is not a hypothesis in need of empirical verification but is a logical requirement for using a training treatment scientifically. The need for criteria is true in sports, medicine, and psychotherapy, or whenever the treatment effect is based on training, as in clinical biofeedback. Exercise became a more scientific treatment for coronary heart disease when it was determined that heart rate is a useful indicator of exercise level, and criteria for target heart rate were established. (Heart rate feedback is not the treatment, but it verifies whether or not the runner meets the criterion established for the treatment. And no physician has ever asked for double-blind studies on the information from the heart rate meter because the usefulness of the information is obvious.)

In biofeedback therapy the specific training criteria needed to maximize the training are established empirically. These criteria are specified in our reply to Furedy (Green & Shellenberger, 1986b, p. 100) and developed in more detail in *The Ghost* (Shellenberger & Green, 1986, pp. 43–53, 63, 66–68, 71, 82). Furedy is incorrect in stating that we do not specify criteria. "Green and Shellenberger themselves never specify what precise 'training criteria' would meet their approval, and why" (1987b). Obviously Furedy has read our paper (Green & Shellenberger, 1986b) and has a copy of *The Ghost*; his statements are inexcusable.

In addition to our writing, the discussions by Steiner and Dince (1981, 1983), Johansson and Öst (1982, 1987), Libo and Arnold (1983a, 1983b), and Fahrion (1978) are especially valuable for understanding the importance of training to criteria for clinical biofeedback research and practice.

Patients may not need to achieve the exact training criteria that have been established in order to achieve masterful self-regulation and symptom relief; however, training criteria are needed logically for scientific precision and are needed when "biofeedback" of all meanings seems to fail. Inefficacy of treatment, i.e., no change in physiology or symptoms, can be concluded *only when* the treatment, i.e., self-regulation, is actually achieved, and criteria are necessary to determine this. To have the possibility of disconfirming clinical trials, necessary for the scientific basis of "biofeedback," it must be demonstrated that the training criteria were achieved—just as to disconfirm the effect of a medicine it must be shown that adequate doses of the medication were taken.

In addition to the logical requirement for training criteria, we stated in the article, "Without training criteria, the interpretation of physiological change is ambiguous—variations in the feedback parameter can be interpreted as (1) normal fluctuation of the psychophysiological process, (2) adaptation to the experimental situation, (3) genuine learning or (4) clinical significant learning. This ambiguity has led to serious misinterpretation of data and false conclusions regarding clinical biofeedback" (Green & Shellenberger, 1986b, p. 100). Furedy is unaware (1987b) that it is not enough to define "learning" as acquisition based on "practice" (as in acquisition of operant motor behavior) when dealing with human physiology. The problems of adaptation, variability, and reliability negate any simple measurement of learning in physiological systems. If "acquisition" means change in the expected direction over time, then in biofeedback, learning cannot be demonstrated by mere "acquisition" or change in physiology. This is one reason for developing the mastery model described in *The Ghost*. Mastery includes the demonstration of the skill under "adverse" conditions, which eliminates the problems of adaptation and variability in human physiology. The problems of the reliability and variability of physiological measures are discussed in an excellent article by Arena, Blanchard, Andrasik, Cotch, & Myers (1983) and in detail in *The Ghost*.

Implication 2: The Therapist as Scientist. Biofeedback-assisted self-regulation therapies enable the therapist to precisely assess the patient's physiological changes over time. Acquisition and use of skills when the patient is relaxed and stressed can be demonstrated, i.e., mastery. Data can be obtained with portable home units so that learning can be assessed at the "scene of the crime"—situations at home and at work. The therapist is a clinician/scientist, able to verify the learning strategies and progress of the patient. The single-subject design methodology specified by Perez and Brown (1985) provides an effective model for evaluation.

Implication 3: The Person as Scientist. Portable biofeedback units enable the patient to precisely monitor and assess self-regulation strategies at home and at work, and they facilitate extensive practice. The patient is not dependent upon the therapist or the physician; rather, the patient becomes an independent scientist and self-regulator. The patient's increased sense of self-responsibility is an added benefit of the use of home training instruments. Research on home-based versus clinic-based training demonstrates the ability of patients to become "self-therapists" through the use of biofeedback instrumentation at home (Jurish et al., 1983).

Implication 4: Trivial Questions. The question "How useful is feedback of information from biofeedback machines?" and "How useful is information from the stopwatch?" are **trivial questions.** Furedy believes that these are important questions that laypersons ask, although no evidence is provided for this assumption. As noted earlier, not a single layperson—physician, nurse, white-collar or blue-collar worker, teacher, or utilization review committee of an insurance company—has ever asked us about the usefulness of information. None of our "Iron Man" friends or their coaches ever ask, "Is the stopwatch useful?" **People do not ask the question about biofeedback information and stopwatch information because the answer is obvious.**

In spite of the obvious, Furedy says that clinicians should conduct "double-blind" studies on the effect of information from biofeedback instruments and that coaches and athletes should conduct double-blind studies on the usefulness of the stopwatch (Furedy, 1987b). Following this logic, pole vaulters should conduct double-blind studies to determine the usefulness of the crossbar in training because without the double-blind studies, pole vaulters do not really know if the crossbar is useful for training. Surely Furedy has taken us to the logical ad absurdum of the specific effects issue.

This then takes us to the final section of our paper, misrepresentations of clinical biofeedback.

MISREPRESENTATIONS OF CLINICAL BIOFEEDBACK

The Minefield Parable. Furedy suggests that biofeedback therapy is like a religious cult in which high priests believe that biofeedback is effective and convince people that biofeedback is effective, but in fact they rely on placebos, albeit effective placebos like relaxation. Furedy uses this analogy because he believes that (1) "biofeedback" is a treatment that "works" but has never been scientifically demonstrated, and (2) the helpfulness of feedback

of information has not yet been demonstrated. Following the parable, the intelligent layperson wants to know if the zigzag method works in the specific-effects sense. Furedy says that the only scientific method for getting across the field is with an instrument, the mine detector.

This is a useful parable because, contrary to Furedy's intention, it illustrates the scientific nature of clinical biofeedback. In clinical biofeedback we need not take training methods for crossing the minefield of stress and symptoms on faith—we have a mine detector—biofeedback instrumentation to verify the effectivenesss of each method.

Biofeedback Therapists Are "Hawkers." "So the hapless layman is left among clinicians who compete for his attention by hawking their wares rather than providing him with information concerning exactly how those products compare with each other" (Furedy, 1987b). Furedy needs to back up derogatory comments about clinicians with empirical evidence. (We note that this is the kind of statement that widens the researcher/clinician rift). The use of *wares* and *products* indicates that once again Furedy slips into the "active ingredient," drug model concept in which treatment is the result of a product rather than the result of a learned skill.

From the context of his statement it is clear that Furedy totally misunderstands the role of clinical biofeedback in a general practice for treatment of stress-related psychophysiological disorders, and the error is compounded: "It is also important to recognize that the specific-effects-oriented control is at least as important for evaluating *rival* biofeedback-based treatments" (Furedy, 1987b). The concept "rival biofeedback-based treatments" bespeaks ignorance of clinical biofeedback.

Therapists do not have competitive biofeedback modes for the simple reason that in the treatment of stress-related disorders the therapy includes EMG and/or thermal and/or EDR feedback, not EMG versus thermal versus EDR, with different clinicians specializing in different modalities. Apparently Furedy does not work with patients, but regardless, it is not useful to make up concepts, such as rival treatments, the "hapless consumer," and "hawkers" to support an idea.

Clinical Testimonials. Furedy distorts the empirical evidence for successful clinical biofeedback by calling it "clinical testimonials" (Furedy, 1987b) and the basis for using biofeedback instrumentation as "superstitious" (Furedy, 1987b). It is fallacious to refer to the excellent controlled clinical studies cited on pages 196-197 of this paper as "testimonials."

Methodological and Logical Errors. Our objection to Furedy's position is the logic of his conceptualizations of biofeedback from which evolves erroneous methodology and criticism of others. In footnote 4, Furedy states

that by "elimination" he means "holding constant in critical comparisons" and not "in isolation." These distinctions are irrelevant and do not resolve the logical problems inherent to his conceptualizations of biofeedback that lead to erroneous methodology. It does not matter whether biofeedback is an active ingredient by itself or in combination with other ingredients, or whether it is "isolated" or "held constant." The conceptualization is still false. The fundamental problem is the belief that there is an independent variable biofeedback, that can be isolated or held constant as the object of study.

Second, the suggestion of "degraded accuracy of information" (Furedy, 1987b) is conceptually confused. Active ingredients in drugs can be degraded but the accuracy of information is not degradable. Information is either true or false. The response is either confirmed or disconfirmed. The biofeedback signal can be changed in intensity or frequency or duration, but the accuracy of the information cannot be changed or degraded.

Although we suspect that few clinicians or researchers will be persuaded by Furedy's arguments and conduct double-blind studies, we are curious to know how Furedy would advise a clincian to conduct a double-blind study using accuracy of information that is "degraded."

CONCLUSION

Sometimes we feel like the kid who shouted, "The emperor has no clothes!"—claiming that biofeedback has no specific effects; biofeedback is not a treatment that can "work"; double-blind design is inappropriate because biofeedback is not an active ingredient like a drug; biofeedback cannot be an independent variable; biofeedback as the object of study, in relation to nonfeedback factors, is trivial.

Our position is that the conceptualizations and methodology of the "specific-effects" approach to biofeedback as described by Furedy (1) are false because they assume an active ingredient, or (2) focus on a trivial question, "Is feedback of information from biofeedback instruments useful?" When the "specific-effects" approach assumes an active ingredient that acts upon human physiology, then a conceptual error is made by attributing a nonexistent property to information—information does not have the power to affect physiology. On the other hand, when the question "Is information useful?" is the focus of the specific-effects research, then the research is trivial. It is obvious that information from biofeedback instruments is useful for

verification, whether the instrument is a simple 45-cent thermometer or a sophisticated computer feedback system.

Contrary to Furedy's belief that clinical biofeedback has no scientific basis, we argue that the scientific basis of clinical biofeedback is clear and rests upon (1) experimental and clinical studies that demonstrate the efficacy of self-regulation skills for symptom alleviation, referenced in this article; (2) the use of biofeedback instruments to verify the acquisition of self-regulatory skills. Although, for some patients, feedback of information may be a less important element in self-regulation training than for others, in all cases, the information is essential when the therapist or the patient wishes to verify the success of training manifested in physiological change. The process of verification brings science into clinical biofeedback, making it unique among nonpharmacological/medical therapies. Treatment evaluation need not be based on "outcomes"—treatment efficacy can be based on verification of self-regulation skills.

Part of the confusion of the specific-effects approach arises from reversed causality, i.e., "biofeedback affects my physiology" versus "I affect my physiology so I affect the feedback," "biofeedback works" versus "I work," "the essence of the treatment is 'biofeedback' " versus "the essence of the treatment is self-regulation." The issue of causality is crucial. When research attempts to study a nonexistent cause, it is doomed to failure or triviality or, on rare occasions, serendipity.

We are speaking of nothing less than a paradigm shift—a shift from a paradigm that made scientific legitimacy based solely on the study of operationally definable external causes of behavior, to a paradigm in which the study of internal self-regulation processes is a legitimate and important scientific endeavor.

Self-regulation is a continual theme in clinical biofeedback because in this unique nonpharmacological/medical treatment, **lasting** physiological change and symptom alleviation is the result of psychophysiological regulation, and nothing else. Therapists know that the effects of positive expectations and faith (no longer referred to as placebo effects) are powerful and may facilitate short-term change, but ultimately, lasting change results from mastery of self-regulation skills gained through practice of a variety of techniques ranging from the more physiological, such as breathing exercises, to the more mental, such as imagery, and gained through life-style change. From this clinical perspective, the academic discussions of the relational nature of "specific" and "placebo" effects, of science versus superstition, and most important, of the lack of evidence for the efficacy of "biofeedback" seem both atavistic and irrelevant.

Clinicians and researchers who accept the model of self-regulation as treatment have made major contributions to the relief and prevention of illness, and will continue to do so through the development of conceptualizations, research methodologies, and therapeutic techniques that are true to the phenomena of psychophysiological self-regulation.

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