Editorial

Criticism

Establishment critics have blasted nutritionally-oriented physicians for the past twenty-five years. A few have been self-appointed and have developed an international reputation for the ferocity of their attacks. They are the darlings of medical schools. Others have been designated by medical organizations such as the American Psychiatric Association. Generally, most of the critical reviews appear to have been written by the same person, or by a committee with frequent cross reference to each other. Journals publishing these reviews seldom accept a rebuttal.

Critics are not the favorites of those they savage, but fortunately for science and medicine, they are not as influential in the long run as are critics in the arts. They do, however, hurt patients who are denied a chance for recovery by the negative effect of the criticism. Physicians espousing newer treatments are also hurt, but they know that any physician in the vanguard of scientific discovery will be subjected to this type of pressure. They can take the heat. The cost to our patients and to society is enormous; every new schizophrenic treated only with drugs will cost the community over one million dollars over his/her lifetime. About 200 years ago, Frapolli claimed that a corn diet caused pellagra. The medical establishment ignored him. What was the cost of 200 years of pellagra? About 230 years ago Dr. James Lind proved by a clinical, controlled experiment that citrus fruit cured scurvy. Forty years later the British Navy began to issue limes to their sailors. During those forty years 100,000 sailors died from scurvy. The physicians in the Navy administration did not like Dr. Lind. But we can go back further; in the book of Daniel is the first recorded controlled nutritional experiment. Daniel and his friends were given whole foods and water, after ten days they were healthier than were others who were fed rich meats and wine common to the king's court. Who can estimate the enormous cost to humanity of the massive switch in our foods from Daniel's type to the court's type.

But let us come to more recent medical history. In 1934, ten thousand Americans died from pernicious anemia. That year Murphy and Minot shared the Nobel Prize for medicine for their discovery that patients with pernicious anemia who ate enough liver remained well. This had first been reported in 1926, but then every doctor "knew" that all diseases were caused by germs. Pernicious anemia patients died young until vitamin

B12 became available around 1950.

Perhaps the criticism has been helpful, even though any advantage is heavily overshadowed by the general harm. Massive institutionalized criticism has deterred many who might have come into this newer field. Their level of interest was low. Had they started using nutrition it could have been with little interest and even less skill. This could have harmed us even more for it would have become general knowledge that many had tried (superficially) and few had succeeded. Physicians who did enter the field had to do so against the advice of their colleagues. They were subjected to harrassment from medical organizations and hospitals. They would want to become expert in this new field, and most of them have.

Physicians in this field become hardened against their critics after one year of practice, for they have been hardened by the powerful therapeutic response to their program. So far I know of only one psychiatrist who turned against orthomolecular psychiatry. He knew it was effective, but faced with a choice of leaving town, his hospital and his colleagues or becoming a tranquilizer-only psychiatrist again, he chose the latter, with great regret.

Patients who seek nutritional therapy from their physicians will probably be faced with hostile rejection, scorn, amusement or simply indifference. One of my patients, responding well to nutritional treatment (she was manganese deficient and epileptic), was admitted to hospital for an unrelated condition. The patient's mother, an R.N., was a dedicated nutritional enthusiast and activist. Some time after the patient described the vitamins she was on, the chief surgeon arrived and subjected both to an emotional tirade for falling prey to vitamin quackery. He wound up by calling her psychiatrist (not me) a stubborn Pennsylvania Dutchman. What he did not know was that the patient's father was a Pennsylvania Dutchman. Both women were highly amused and discharged the surgeon off the case. I refer to this as one of the more bizarre critiques of orthomolecular psychiatry. I am more accustomed to a different personal attack such as the one delivered by an alcoholic psychiatrist who declared I owned all the vitamin companies, which was why I was pushing vitamins.

To counter the criticisms of orthomolecular medicine, it helps to know the language of the critic. The critic follows a certain logic which is that no new treatment can be accepted seriously unless the treatment has been tested by a double blind procedure. This is not a requirement for all treatments which may or may not help; very few psychiatrists have given up psychotherapy, yet most, if not all, controlled experiments testing psychotherapy are negative. The reason double blinds are considered essential is the placebo effect. It is believed that simply knowing or being told that a treatment will work will help many get well, no matter what the disease is. An optimistic attitude is, of course, very important. It is an essential ingredient of any therapeutic program. But it is believed that this alone will help even chronic schizophrenics. This belief is strongest with those who have the least experience with these patients. The double blind is supposed to operate equally on all treated groups and so should distinguish whether the treatment being tested is significantly better.

Another part of the logic is to consider the dangers (toxicity) of the treatment. One can accept any risk associated with a drug if the disease untreated is more deadly; insulin is by no means a safe drug and has killed many by causing hypoglycemia. Yet the risk of diabetes without insulin is even greater; thus very effective drugs are used whether or not they are toxic. Pharmacology professors have been known to teach that if a drug has no side effects, it is probably inactive. This is, in fact, true of drugs. It is not true for nutrients to the same degree. When the effect is less obvious, less immediately dramatic, even weak side effects may be intolerable. Thus, critics of vitamin C as a treatment for the common cold maintain that its anti cold effect is so slight, it's almost nonexistent side effect potential is too much.

The critic uses the following key words extracted from these logical principles: double blind, placebo, anecdotal, toxicity, not proven, spontaneous recovery, controversial, and in an attempt to make his criticism scientific, refers to studies about which he has heard, or been told, but which have not

been read and studied. Original literature is almost never read even though it is cited. These citations are taken from other critics' criticisms who in turn have not read the original reports.

I will discuss the key vocabulary of the critic so patients will understand how and why it is being used.

Double Blind

A technique first developed in England for testing arthritic treatments. The English called them double dummy experiments. Two or more groups of equal samples from a larger population are given either an inactive substance (empty gelatin capsules, inert tablets, etc.), which is identical in appearance etc. to the drug being tested. Neither patients nor physicians know which is which — that is why it is called double blind.

The first double dummy (later double blind) experiments in North America were started in Saskatchewan on schizophrenic patients under Dr. Humphry Osmond's and my supervision. Since then they have become standard to the point that only double blind experiments are considered valid. Osmond and I have since 1952 realized it is not the method, but only one of many and must be used carefully lest it lead to erroneous conclusions. It has never been demonstrated to do what it is supposed to do by any empirical or experimental test; it is a test widely accepted but never validated. Many of its early proponents, including Hoffer and Osmond, have given it up as a valuable test. But all the early vitamin B3 tests on schizophrenia in Saskatchewan were double blind. Critics of vitamin therapy are ignorant of this.

When a critic damns vitamin therapists for not having used double blinds, you will know he is speaking out of ignorance of the literature. It will be helpful then to ask the critic to become logically consistent and to give up psychotherapy, insulin, surgery, and many other medical therapies.

Placebo

A placebo response is a response generated entirely by psychosocial factors. If, therefore, one is to condemn a drug treatment, it is said to have a placebo effect. But critics use the word to bolster their attack. If one gives a shot of penicillin to a patient with pneumonia and he recovers, this is a real drug effect. If one gives 100 grams of vitamin C by mouth or by vein and the patient recovers, it is said to be a placebo reaction. The response is no longer the main measure of a compound's activity.

With symptoms such as anxiety, pain, the awareness that something is being done, assurance that the condition is not life-threatening, and faith in the physician and the medication is often adequate to cause significant relief. In time the symptoms would have subsided anyway. One has then an effective placebo response. The placebo works most powerfully early in treatment. For chronic conditions it tends to become less and less helpful. Thus a mild analgesic bolstered by the placebo effect will help some mild headaches, but after several days is no longer as effective.

Nutritional therapy (except for a fast) tends to work slowly and become more effective with time. This is in sharp contrast to the placebo effect which disappears in time.

Chronic conditions such as arthritis, lupus, schizophrenia, do not respond to a placebo effect. Pain may be lessened, anxiety may be relieved, but the main process continues. But a proportion of patients do recover for reasons unknown.

These are classed as spontaneous recoveries or natural remissions. An estimate of the number who might recover spontaneously can be obtained by determining how many from a large number recover without treatment. This can be done by using historical controls, which most researchers found less desirable, and by using simultaneous controls. It is not essential to use a double blind control.

The critic invokes the placebo response for the following situations:

(1) when any compound he considers of no value is reported to be effective,

(2) especially when it is a vitamin or mineral used for conditions not thought of as nutritional deficiencies,

(3) especially when the research is reported by an orthomolecular physician,

(4) especially when it is published in this

journal.

The same critic does not invoke a placebo explanation for any side effect or drug, especially for vitamins or minerals. Even the possibility of a toxic reaction which does not occur, such as the production of kidney stones by ascorbic acid, is accepted as a real drug effect. Patients are warned that ascorbic acid may cause kidney stones despite the fact it has not been reported.

Anecdotal

Today the most insulting word one can use against someone not using a double blind experiment is that it is anecdotal. If physicians really did accept this bizarre view, all of medicine and surgery would collapse. We would have sick people but no epilepsy, no schizophrenia, no Huntington's disease, for the descriptions of these diseases are entirely anecdotal. Information was obtained by listening to the patient's story (an anecdote) and by the physician describing the symptoms and signs (another anecdote). The anecdotal material may be directed or guided by forms or certain questions. This applies to every patient whether that patient is in an open experiment (no blinds), in a single blind (only the patients do not know what they are getting), or double blind. I can not understand why double blind anecdotal material is any more valuable than the usual medical anecdote, i.e. the usual history. The word "anecdote" has no value except as a pejorative statement about non blind experiments. As with the placebo, the word anecdote is not used by critics when they discuss the toxicity of compounds they do not like.

Toxicity and Side Effects

These are reactions which are unpleasant, unwanted and may be dangerous. Every chemical may cause these reactions. Generally, when used in the recommended doses, nutrients are much less toxic and prone to cause side effects than are drugs. Thus, tardive dyskinesia occurs when recommended doses of tranquilizers are used. In sharp contrast, vitamins seldom cause these dangerous reactions and when they occur are always reversible when the patient stops taking the vitamin.

Critics almost ignore the toxicity inherent in drugs, reasoning it is an acceptable risk because they believe the treatment is effective and therefore tolerable. The minor degree of side effect inherent in nutrients they consider unacceptable because the vitamins are non therapeutic. Thus, critics of the use of ascorbic acid for preventing colds have claimed that even the very slight risk inherent in ascorbic acid is not worth its use since it does not prevent colds. They consider the risk of getting colds is unaltered. Anyone can compare toxicity and side effects of drugs and nutrients by reading package inserts, or physicians' drug manuals. They need only count the number of lines describing the toxic reactions.

Spontaneous Recovery (natural remission)

Most patients recover from the vast majority of diseases. Most viral infections clear due to the body's defense mechanisms. When there is no physician's intervention the disease is said to have cleared spontaneously. It is a spontaneous recovery or natural remission. The natural remission rate is reasonably well-known for most diseases. It is not a constant, varying with time, region, age, etc.

However, critics find this a very useful term. Apparently any disease, no matter how serious, is said to have gone away spontaneously if the treatment involves nutrition or supplements. I have been impressed with the remarkable property inherent in supplements, for the spontaneous remissions, according to critics, occur only after supplements are used. If a schizophrenic is ill five years, unresponsive to all treatment, but recovers after several years of orthomolecular treatment, the patient is said to have undergone a natural remission. By that they mean that there has been a placebo response, not that the supplement improved the body's defenses, allowing it to recover.

Natural remissions do occur, but when there has been no remission until after a treatment has been started, one must assume that the treatment had something to do with it. When this happens on more and more patients, certainty grows greater that there is a cause and effect relationship. If critics are to be as scientific in their logic as they claim to be in their critiques, they must explain why these "natural remissions" occur

only after the newer treatment has been started.

Not Proven

Critics wish to appear scientific by invoking science. But since they equate being scientific with double blind experiments, they are in fact again merely demanding the experiment be double blind. As I have noted previously, the double blind is not more scientific than open clinical observations. It is only one method available, and for many conditions its use is unscientific for its design flies against the principles of the doctor/patient relationship (Hoffer, 1967; Hoffer and Osmond, 1963,1961).

The double blind experiment in its usual institutional setting is as foreign to the real world of the doctor/patient relationship as is the behavior of a monkey in a small cage to its behavior in the tree tops. This is why double blinds can be manipulated so easily to confirm the wishes of any investigator. This is true of all designs, but the double blind design was supposed to remove all subjectivity from clinical experiments. Of course it does not, for by altering variables investigators can prove almost anything.

Recently, Haslam and Dalby completed a double blind crossover design study on a small sample of six children out of forty-one who had responded to vitamin therapy. After a brief washout period, these children were restarted on vitamins or placebo, but the treatment period before switching from vitamin to placebo (or the reverse) was too short, so that there was a vitamin effect carryover.

I have extracted some data from the tables presented by Haslam et al. They did not present the numerical data from which they prepared their tables. Using mothers' evaluation only I have compared initial and final scores in each treatment phase. Mothers have most to do with these children. The teachers' scores showed almost no relationship to mothers' scores. They were probably evaluating different, less relevant aspects of behavior. The trends are. shown in Table 1. I have divided scores into 16 to 30 as sick scores, (the authors did not include children unless initial scores were over 15), and to 0 to 15 scores.

Those children on vitamin with high scores all improved, (i.e. scores went down). Three on placebo all got worse. When their initial scores were in the low range, on vitamins four showed an increase or no change while five got better. On placebo six got worse.

Altogether on vitamins 14 out of 18 improved, while on placebo 9 out of 10 got worse. In other words, the differential response was very evident when the children were ill and much less evident as they became well. In the same way, if one were to

Table 1

Analysis of Trends from Tables in Haslam and Dalby. Mothers' scores only, using first and last scores.

	On Vitamin	**On Placebo**
Initial scores 16-30		
Increase or no change (1)	0	3
Decrease (2)	9	0
Initial scores 0 -15		
Increase or no change	4	6
Decrease	5	1
Initial scores 0 - 30		
Increase or no change	4	9
Decrease	14	1

(1) no improvement
(2) improvement

measure the effect of penicillin on fever in patients with pneumonia against placebo, there would be a marked effect. However, a similar study one week later when body temperatures were normal would show no difference, i.e. random fluctuations.

Another way of looking at this scanty data is to examine scores derived from the diagrams. Four children had a 12 week washout period, their scores increased from 13 to 16.5.

If Haslam et al. had allowed each child to remain on placebo until original scores were regained (relapse scores), they would have persuaded themselves of the efficacy of the vitamins. But ignoring the variable washout period and lumping all items together on such a small sample, any statistical significance is washed out, as it would be with a pneumonia fever study. Haslam and Dalby (1983) concluded, "This study has conclusively demonstrated that large doses of vitamin have no beneficial effect."

Here is an excellent example which shows how statistics can be used to confirm a preconceived conclusion, even in a double blind experiment. An inspection of their diagrams proves vitamins worked while their misuse of data proved for them it did not.

Scientific proof as used by a critic means: (1) the experiment must be double blind, (2) conducted by a physician critical of orthomolecular medicine, (3) published in an establishment journal. Double blind experiments published by orthomolecular proponents are not scientific, even though the double blind is supposed to prevent bias and subjectivity.

But even their own criteria are not followed consistently; the more skeptical a critic is, the greater is the level of proof required. Many years ago, one of the establishment leaders in schizophrenia research declared that he would not believe vitamins could help schizophrenia if every psychiatrist in the United States were using them. Another leading psychologist told me, while he was almost drunk at a party, that no amount of proof would ever convince him. These are two men with very strong convictions, but certainly, by their own admissions, would never change their minds. Thus when arguing with a critic they should be asked to define what they mean by scientific and what level of proof would they be willing to accept. Other critics use scientific in a different sense. For them, nothing is scientific unless there is an acceptable mechanism which will account for the therapeutic response. They will accept small doses of vitamins for deficiency diseases, but not large doses for non deficiency conditions. They will accept tranquilizers because they quieten, calm, sedate, even though no more is really known about how they work than how vitamins work. Scientific here means a therapeutic test using double blind using a drug which is a member of a class of drugs already in common use, for which there is a shared consensus within the establishment. These critics confuse observation (the patients given a treatment recover), with explanation (why did it work). They appear to be indifferent to the fact that observations are eternal, (epilepsy described 2000 years ago will describe epilepsy today), while explanations are ephemeral, (the explanation for epilepsy 2000 years ago is not acceptable today).

Controversial

Critics are very fearful of anything controversial. They apparently think the public shares the same view, for at every opportunity they refer to alternative treatments as controversial. On the contrary, for many years I was routinely introduced at meetings as a controversial psychiatrist by chairmen of meetings friendly to me. Non professional people do not find controversial treatments to be frightening. On the contrary, a new treatment has little chance of making any headway until it does become controversial. Every respectable treatment today was at one time controversial, from clean water, to vaccination, to the use of anaesthesia, antibiotics, tranquilizers, antidepressants, coronary bypass surgery, heart transplants — all were, and some still are, controversial.

This adjective has no significance with respect to the value of any new treatment. The controversy vanishes when most physicians use the once controversial treatment but rekindles when a better alternative treatment develops.
Physicians are afraid of controversial

treatment because they fear (1) their colleagues' negative opinion, (2) their professional or licensing body, (3) legal action because they would not find enough colleagueal support if it did come to a court of law. When they use the word controversy to avoid using newer treatment, you will understand the basis of their fear.

Physicians using orthomolecular treatment have been described as charlatans, quacks, senile and even Pennsylvania Dutch, and have been charged with being incompetent and lacking judgement. But then medical research and controversy has always been a rough game from the time of Sir T. Sydenham, now revered as the father of clinical or bedside medicine. He nearly lost his license because he had developed a new treatment for smallpox which markedly reduced the death rate, but he went against the views of centuries of physicians. He was challenged to a duel but this was avoided. At least today we attack each other with words, not swords and pistols.

Constructive Criticism

Criticism can be very constructive. Its aim is to show errors in research design and/or in the conclusions which derive from the study. It must be fair, objective, balanced and free of ad hominum attack. The critic should not espouse any cause because this creates a conflict of interest.

I am not convinced we need critics, but since they will not go away, how can they be best used to help us shorten the gap between discovery and application? There is a forty year gap. It could be shortened significantly without increasing the danger of introducing non effective treatments. I believe this can be done.

Each country should create one or more research institutes funded by government. These must be independent of any university or other institution. Research scientists working there would not be allowed to have any university or other affiliation. These institutions would be ordered by law to examine therapeutic claims made by scientists using the following procedure.

1. When any physician reports that a treatment has been more effective than the standard treatment for any disease, the library or abstracting section would alert the director of that institute.

2. The director must (by law) initiate a complete review of the literature and of the work reported by visiting the physician to examine his studies and his patients.

3. The director must then invite that physician to come to the institute to discuss his work with the institute's clinical team, to advise them on treatment design and to express approval of any design. The design must satisfy the institution and the original proponent of the treatment. A preplanning trial may be run in which the physician will demonstrate the treatment in action. If, out of a substantial series of such pilot studies treated at the institute by the physician, not one or very few responded, the study would terminate.

Once the study is underway the physician could return home, but would be kept informed of the progress of the study.

4. Upon completion of the study the director would publish a paper detailing the study and the results of the treatment. The director would pass no judgement but would merely describe how many out of the series had responded in the treatment and control groups.

Thereafter the public and clinicians would draw their own conclusions. The new treatment, if effective, would rapidly penetrate establishment medicine.

Let's see what would have happened in England if such an institute had been operating in Dr. James Lind's time.

The major problem in the Navy was scurvy. European navies were afraid of being away from home too long because their sailors would die of scurvy. British explorers lost up to 70 percent of their sailors on long voyages, except for captains such as James Cook who carried fruit and green vegetables.

Dr. Lind reported that out of eight sailors dying of scurvy, two given citrus fruit recovered in a few days and were put to work nursing the other six who remained ill on the standard treatment of that day. That report was squelched and buried and was acted on forty years later after losing 100,000 sailors.

Had an institute such as I have described been available, Lind's findings would have been repeated, confirmed and published within a year.

Suppose the disease was schizophrenia. In 1957 my colleagues and I reported that the addition of vitamin B3 to acute and subacute patients doubled the natural recovery rate one year after discharge.

Had such an institute been in existence, our work would have been examined, repeated and confirmed within a couple of years, and would have saved twenty years of delay. At a cost of one million dollars per patient, how many billions would have been saved, how many families preserved, how many patients would have been healthy, productive people? So far not a single research group has tried to repeat our basic double blind controlled experiment we completed on thirty patients using a placebo, niacinamide and niacin plus the standard 1952 -1955 treatment.

Conclusion

Medical critics have been harmful to the development of effective treatment because they have acted for the medical establishment. We must devise a way of shortening the gap between discovery and application. Perhaps special therapeutic research institutes would make newer treatments available much more quickly.

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