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The following letter was written November 11, 1985 in response to repeated feedback of negative and false statements stemming from the Arthritis Foundation, the Better Business Bureau and the below addressed office of the Food and Drug Administration.

Donors, arthritics, and physicians would send The Rheumatoid Disease Foundation/The Arthritis Trust of America copies of these scurrilous memos.

On receipt of this letter, Harold Davis -- or at least his office -- quit the practice of forwarding the Arthritis Foundation lies and half-truths.

A letter to the Arthritis Foundation attorney, thankfully, seemed to be effective in stopping the practice at its source.

Although many of the premises discussed herein are now moot, the summary (1) demonstrates to some extent the nature of the problem of introducing treatments contrary to large pharmaceutical company interests, and (2) well handles the problem often faced by physicians whose patients wish to try metronidazole; i.e., there is no evidence that metronidazole is or ever has been carcinogenic.

About the Philanthropic Section of the Better Business Bureau & the Arthritis Foundation!

Harold Davis
Consumer Safety Officer
Office of Consumer and Professional Affairs
Center for Drugs and Biologics, HFN-17
Department of Health & Human Services
Public Health Service
Food and Drug Administration
Rockville, MD 20857

Dear Mr. *Davis*:

Please reference your October 10, 1985 letter with Arthritis Foundation and Council of Better Business Bureau, Inc. attachments, appended hereto, and written to J.M. Blount, Jr. M.D.

You say therein that you do not take a position on the Rheumatoid Disease Foundation. If so then why -- in your second to last paragraph of your letter -- do you quote unresearched falsehoods and distortions from the Council of Better Business Bureau, Inc.? And why do you append falsehoods and distortions designed by the Arthritis Foundation and the Better Business Bureau?

Where did you get the idea that "Apparently, the foreign studies did not bear out Dr. Wyburn-Mason's contention that clotrimazole was effective against arthritis?"

According to our information, both double-blind studies by P.J. Wojtulewski (including follow-on unpublished studies) and open studies by Roger Wyburn-Mason showed an extremely high success rate when treating Rheumatoid Disease with clotrimazole.

Indeed, the rate was so high that this foundation, through the Department of Rheumatology at Bowman Gray School of Medicine, is now funding additional double-blind studies using clotrimazole.

I would greatly appreciate the source(s) of your incorrect information, that clotrimazole was shown to be ineffective.

You also state that clotrimazole is a 1% cream for dermatological use. Clotrimazole is not just a 1% cream used for dermatological purposes, but also a vaginal tablet used widely for a certain kind of yeast/fungus *Candida albicans* infection (Page 1856, 1985 PDR). *In vitro*, it has antibacterial, antiyeast/fungus, anti-amoebic qualities. To constantly quote that it is a "just a 1% topical cream" merely repeats the distortions initially laid down by the Arthritis Foundation (four years ago) to discredit us; said distortions later followed by the Council of Better Business Bureau, Inc. unethical behavior.

As to whether or not the drug is available for use in the United States -- which you say it is not -- please refer to the *Physicians' Desk Reference* where you will learn that it is available for use as indicated. [It is now available through compounding pharmacists in a form designed for arthritis treatment. Ed.] The reason we are running scientific studies with its use is to determine if it satisfies FDA requirements for safety and effectiveness in our fight against Rheumatoid Diseases. [See <http://arthritistrust.org>, newsletters: Winter 1985 & June 1993. Ed.]

As to the Council of Better Business Bureaus, Inc. attachment: All of their memos start by stating that *The information contained herein has been compiled from sources deemed to be reliable and, while not guaranteed, is believed to be factual and accurate. It is not intended to recommend or deprecate, and is furnished to assist you in exercising your own judgment.*

A worthy goal, but unfortunately the remainder of their memos go on to distort in such a fashion that, through deprecation, and half truth, they can adversely influence judgment.

Referencing their March 1985 report entitled "Quackery and Unproven Remedies": lets take up this question of the oft repeated Arthritis Foundation's title "Quackery and Unproven Remedies".

The illogical presumption by organizations that seek to maintain their power-base is that anything that is "unproven" is also "quackery." By that reasoning, every medical advance in history has first been classified as quackery. Indeed, according to the U.S. *Office of Technology Assessment* publication (1978), "Assessing the Efficacy and Safety of Medical Technology," **80-90% of all insurance-approved-medical-board-practices are unproven.**

Look at the standard treatments used by practicing rheumatologists, the very same professionals who advise both the Arthritis Foundation and the National Institute of Arthritis, Diabetes and Digestive and Kidney Diseases.

According to their peers, in *Clinics in Rheumatic Diseases*, (W.B. Saunders, 1983), the use of gold shots is at best a marginal scientific presumption, having failed double-blind standards, but being accepted nonetheless -- and in any case is proved by such studies to be ineffective after 30 months. In the case of use of penicillamine, the same peer source states that *there is absolutely no scientific evidence for use of penicillamine.*

So here we have a situation where the Council of Better Business Bureaus, Inc. quotes those who -- by their own standards -- habitually use "quackery" and "unproven" treatments; those who admittedly do not know how to treat Rheumatoid Disease, and who nonetheless continue to take money from folks for such non-treatment while at the same time persuading the sick not seek alternative treatments. *Isn't that the actual definition of a quack? One who cannot cure, but who convinces the patient to periodically pay money for a worthless treatment and to not seek help elsewhere?*

In turn, you, Harold Davis of the Department of Health & Human Services, swallowing the quacks pseudo-scientific propaganda, and claiming not to take a stand, continue to pass along

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mis-information that is, at best, most likely to keep folks from trying an alternate treatment which might get them well, while encouraging them to continue to take treatments which admittedly cannot get them well.

Rheumatoid Disease is a controversial subject. If you and the Council of Better Business Bureau, Inc. are not qualified in the philosophy of scientific method, and in the treatment and cure of arthritis, then you have absolutely no ethical right to promote one side over another -- which you are doing despite your paragraph stating that you are not.

In our case, we raise funds to do scientific studies. We are funding five different scientific studies at three prestigious university centers: Bowman Gray School of Medicine, Medical College of Virginia, and Vanderbilt University. We will shortly be funding an additional study at University of Tennessee, Knoxville. We have an additional \$2,000,000 worth of double-blind studies lined up to do that should, by rights, be done by pharmaceutical companies, the Arthritis Foundation, or the Federal Government because of drug orphan status, or other reasons. So long as you continue to send out misinformation by the likes of the Arthritis Foundation and the Council of Better Business Bureau, Inc., you are helping big pharmaceutical companies and big Foundations maintain their power status, and certainly you are not helping the sick to get well, for reasons already named.

In our case, we tell everyone exactly what medical treatment protocol to use, whether they contribute to our research or not.

Either our treatment works, or it doesn't. If it doesn't, we will most surely shrink -- instead, we are growing.

We recommend any one of eight different antiamoebics mostly available at any drugstore in America. We do not have any financial stake in any of those medicines. We recommend that every patient go first to their family doctor. We do not get a percentage from the family doctor. We have no secrets, we give information away freely, we conduct proper scientific studies at appropriate prestigious universities.

So where is the fraud implied by your letter and flyers from the Council of Better Business Bureau, Inc., and their behind-the-scenes promoter, the Arthritis Foundation?

As to the so-called "Public Information Memo" by the Arthritis Foundation 83-07, dated 8/24/83: I have read this memo dozens of times since it was first promulgated by the Arthritis Foundation. Like so many of their propaganda pieces designed essentially to keep themselves in power at the expense of the sick, this one is fraught with half-truths, innuendos, and lies.

The treatment protocol referenced in paragraph two was not developed by Dr. Wyburn-Mason, but rather by a committee set up by over 200 physicians, as attached. It has been revised twice since Roger Wyburn-Mason's death.

Roger Wyburn-Mason did not claim to find protozoons in the joints of arthritics, but rather showed that their thermotropic properties permitted their collection by certain laboratory devices when various tissues were minced and used. Roger Wyburn-Mason had an M.D. and a Ph.D. in protozoology, yet even he was unconvinced for many years that a form of limax amoeba, which he named *Amoeba chromatosa*, was responsible for RD in those that are genetically susceptible. The major work was performed in cooperation with what was then the doyen of amoebologists in England, Vice-Admiral Stamm.

Flagyl is not a drug just for certain bacterial infections: (See: *First United States Metronidazole Conference*, Biomedical, Information Corporation, 800 Second Avenue, New York, NY 10017, Sydney M. Finegold, M.D., Editor, Feb.19-20,1982.). Like many

antiamoebics it has been shown to be antibacterial, viral-static, and antiamoebic under certain conditions. The fact is that metronidazole will not kill *Acanthamoeba* and *Naegleria* in the test tube, but must rely on its two major metabolites *in vivo*, according to research pharmacologists.

The memo states that "Protozoa have never been demonstrated by anyone else in spite of careful search including electron microscopy."

I have tried since 1983 to get someone to send me information on where and when and by whom such studies were made. With the information, we could undoubtedly save a great deal of research funds when attempting on-going efforts to reproduce Roger Wyburn-Mason's work at major university centers.

Since both the Council of Better Business Bureau, Inc. and the Arthritis Foundation are so terribly concerned about saving donor funds, why don't they answer this one question for us? Where is the reported research?

Surely the statement cannot be an outright fabrication? Or can it?

It is stated that "Attempts in England to repeat the therapeutic success with metronidazole were unsuccessful."

This is a lie.

There were no attempts made in England in recorded scientific literature to use our protocol.

There was one study made by physicians who refused to use our protocol, but rather used a dosage that our book stated in advance will not work. (Harkness, J.A.L., et. al."A Double-blind Comparative Study of Metronidazole and Placebo in Rheumatoid Arthritis," *Rheumatology and Rehabilitation*, 21, 231-234, 1982). Rather than a study of our claims, it appears almost as if someone wanted to sink the claims. You say to someone, "Look. If you use 2 grams a day, for two days in a row, skip for five days, and repeat, in all six weeks, you will get such and such an effect; and if you use anything lower, you will not," and the person goes ahead and uses 60% less than you advise, would you call that an independent test of your hypothesis? After all, if their low dosage of 800 mg/day would've worked, then use of metronidazole in treatment of vaginal infections would have brought about remission/cure in those RD patients who had both arthritis and vaginal infection. We have so advised, many times.

It is not scientifically kosher to claim that a study proved ineffectiveness when no such study has been made.

As to our tax-exempt basis, as questioned in paragraph three: we are tax-exempt by IRS on exactly the same basis as is the Arthritis Foundation and the Council of Better Business Bureau, Inc.

Rather than continue to mail out such a lie, as you have, why don't you call up IRS?

As to the Board meeting in Mississippi: I attended that meeting. Jack Blount, Jr., M.D. was not inhibited from using the treatment, although the Arthritis Foundation-backed state-attorney-general spent half his time attempting to get such a decision. I have it all on tape, if you care for the truth. Dr. Blount was restrained from giving out free prescriptions to needy patients who he had not seen, and who had been refused our treatment by their own physicians.

Since Dr. Blount is now retired from practice, why is this paragraph still printed and passed about, other than, by innuendo, to discredit our whole effort?

As to memo number 81-26, dated 12/31/81: I have also seen this set of fabrications by the Arthritis Foundation since its release.

Metronidazole is not carcinogenic. This is one of the most popular discreditations, unrelated to fact. According to a Senator Kennedy joint hearing before the subcommittee on labor and public welfare

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and the subcommittee on administrative practice and procedure of the committee on the Judiciary United States Senate Ninety-Fourth Congress, July 10-11, 1975: Searle representatives testified that some lab data had been misplaced regarding control-group rats, and that carcinogenic symptoms had been observed *in the control group*. The FDA, they said, had required them to throw the carcinogenic count into the non-control group. [See "First Session On Examination of the Process of Drug Testing and FDA's Role in the Regulation and Conditions Under Which Such Testing is Carried Out," *Preclinical and clinical testing by the Pharmaceutical Industry, 1975*, Published by the U.S. Government Printing Office, Washington, D.C. 1975]

Thus, the *Physicians Desk Reference* now contains the statement that metronidazole may cause cancers in rats. This error has never been corrected as a package insert, and probably never will be.

In an address by Wayne Martin of Fairhope, Alabama, before the Seattle Chapter of the International Association of Cancer Victims and Friends, he summarized the results of a study of Flagyl (metronidazole) in the treatment of cancer:

In the Seattle area, the Group Health Cooperative of Puget Sound has treated 12,280 patients with Flagyl mostly for the parasitic disease trichomoniasis, which causes urogenital distress. Of this group, only five patients developed cancer over a 2-1/2 year period, whereas among the 123,620 non-Flagyl users, 311 patients developed cancer over the same period of time. On a percentage basis, 0.04% of the Flagyl patients developed cancer, compared with 2.5% of the non-Flagyl users -- a score of better than 60 to 1 in favor of Flagyl users. When a correction for age was factored in, the score was still 3-1 in favor of Flagyl users (*Journal of the American Medical Association*, May 14, 1982, pp. 2498-2499.)

The *Physicians Desk Reference* also states that since 1967 there has never been a reported case of human carcinogenicity or mutagenicity through the use of metronidazole. Why didn't the Arthritis Foundation report this fact, too? The answer: they wish to propagandize through lies and half-truths, not inform and educate.

According to *The First Metronidazole Conference*, metronidazole is world-widely used, often in dosages much higher than our recommendations, and often in hospital settings where it is frequently used intravenously in very high dosages.

As to Searle's letter attached by Robert L. Alberti, M.D., Director of Communications at Searle: Isn't it obvious that Searle is bound by the legal implications of anything they state in a letter? They cannot legally make any other claim than they made, without bringing on themselves costly reprisals by governmental agencies -- no matter the value or non-value of metronidazole.

The Arthritis Foundation knows this. So why, then, do they rely on statements made by Searle company spokesmen that can not be legally constructed any other way?

What does the Arthritis Foundation think they are proving, if not simply to distort and falsify data to control people's minds?

I might also add that Searle's patent has run out on metronidazole -- so why should Searle want to promote a medicine that might compete with their very lucrative line of anti-inflammatories that treat only symptoms and keep folks sick, and paying and paying?

The Arthritis Foundation has seen studies, presented to them by several physicians. Indeed, back in 1978 the Arthritis Foundation was made aware of Roger Wyburn-Mason's massive 479 page publication detailing a lifetime of work in identifying the causation of Rheumatoid Disease.

This work - presented to the Arthritis Foundation - was not from a fly-by-night quack, but rather a very brilliant research physician.

Consider his background: He received the very highest grades

obtainable in every degree taken. He was in on the original clinical trials of sulfa drugs. He specialized in nerve diseases, and has two nerve diseases named after him. He became the very first to identify a viral cause of cancer. He wrote several very definitive books: *Trophic Nerves*, *Reticulo-Endothelial System*, *A New Protozoon*, and so on. He received an honorary degree and also earned a Ph.D. in protozoology.

Does this sound like a man set to deceive the world?

Medical doctors, at best, receive about four hours of study in protozoology. They are the last people in the world to tell you about protozoons. Protozoologists, on the other hand, understand the implications of Roger Wyburn-Mason's work quite clearly, as the attached bibliography of protozoal literature clearly shows. Indeed, Kofoed and Swezy, two University of California Protozoologists, in 1922 first reported the same phenomenon as Roger Wyburn-Mason, and published same in the *University of California Publications in Zoology*, to be ignored by physicians thereafter.

As to the Arthritis Foundation's memo 83-10 dated 12/23/83: They are finally beginning to catch up to facts, having finally corrected two out of hundreds of lies and distortions. Still they do have the unmitigated gall to suggest that after they rejected all information from Roger Wyburn-Mason and other physicians since 1978, that they should sit in judgment as to whether or not our treatment is valid and whether or not our cost ratios are appropriate.

Know that the Arthritis Foundation is supported in heavy part by the pharmaceutical industry. They do not need to go through costly direct-mail routes to raise their funds. They spend gigantic amounts on large, expensive buildings and staff salaries. All their ratios are juggled (probably in collusion with the Better Business Bureau's so-called standards) so that they can glibly make a statement that brings into question our cost-ratios.

Now as to the Philanthropic Advisory Service of the Council of Better Business Bureaus, Inc. report dated September 1984: I want to make one major comment about their report:

They state that our accountant stated that we cannot control the money prior to reaching a CPA-bonded mail-opening point, where the money is recorded by a CPA.

They point to this statement as an implication that we must be doing something not quite kosher.

In July 18, 1984, (prior to the date of the BBB memo) in a last letter to this organization, I explained that the U.S. Post Office controls all the mailed letters until it reaches the CPA.

According to their statement, above, we should then control the U.S. Post Office.

The CPA refers to the fact that it is impractical to audit the 1-1/2% to 2% return that comes to our bonded CPA from our half million per-month mailings. Why is it impractical? Because to sample-audit tens of thousands of monthly returns through the U.S. Post Office would require expenditure of funds far greater than we receive, and additionally would require some rather sophisticated cooperation with the U.S. Post Office.

We cannot control funds mailed because the U.S. Post Office has charge of the mail until it is delivered.

See what I mean?

Catch 22 used in the worst way!

Deliberate distortion of truth in order to place us in the worst light.

The Philanthropic Advisory Service of the Council of Better Business Bureaus, Inc. is neither an objective advisory service, nor Better, nor even a business. They are an IRS tax-exempt, charitable foundation that operates on exactly the same basis as do we; and they have no more legal and/or ethical right to judge us, then we have to

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judge them -- or said another way: we have as much right to judge them, as they do us -- and you should enclose this letter to those who query, along with theirs, if you continue to insist on sending out theirs.

The Council of Better Business Bureaus, Inc. holds itself out to be a watch dog to prevent abuses by charitable organizations and as an authority to which the general public may turn to know whether it is wise or foolish to give to this or that worthy cause.

It is not a governmental agency, and has no legal authority to require anyone to report to it. Yet, through a combination of pressure and publicity it persuades a great many charitable organizations to provide it with data and to seek its blessing.

We do not supply the Better Business Bureau, Inc. with data because at the very first it became clear that it fails to act with objectivity or fairness or to meet its own published standards for charitable and philanthropic organizations.

We are also concerned about the nature of the reports that the BBB publishes about charitable organizations. They are usually filled with factual errors, distortion by omission, innuendo by choice of words and positioning of sentences, and general bias in tone.

BBB sprinkles its reports with opinionated value judgments -- sometimes blatantly and sometimes subtly.

BBB is not an authority on Rheumatoid Disease, and therefore is not in a scientific position to evaluate whether or not this organization is correct. Indeed, the history of most medical advances in the field of medicine are fought against this very authoritarian, non-informed resistance: Semmelweis, Koch, Sister Kenney, Pasteur, Ehrlich, Roentgen, Lister, Jenner, Harvey, and Ross, to name a few. So far as we are concerned, and from what we have seen in our office, the BBB sits in bed with the large foundations, and uses every unethical tactic to stifle small organizations.

The standards that are promulgated by the BBB are designed to assist those whose major income is non-direct mail.

The BBB preaches that responsible organizations should supply it with information. Until it learns something more about responsible behavior itself, they do not deserve the honor.

Their assertion on one point only -- that of our presumed lack of control during U.S. Post Office distribution -- so violates the ethical standards required by the American Institute of Certified Public Accountants and universally adhered to by responsible professionals in the fields of accounting and financial analysis, that we do not intend to comply with their unsolicited requests until such time as we are assured that their standards and their behavior is cleaned up.

The ethical standards of the American Institute of Certified Public Accountants prohibit the publication of selected portions of financial statements, and for very good reason -- it is easy to create any desired impression simply by including or excluding particular data. No reputable accounting firm engages in such practices, which appear to be routine for the BBB.

The question legitimately arises as to whether the BBB performs any service of value to the public at all.

Organizations, such as ours, must file detailed reports with the Federal Government and also with charity regulating agencies in most states. The reports are available in their entirety from either source. How, then, does the BBB serve a public interest by demanding that we spend additional time and money answering their questions based on data already supplied to appropriate governmental agencies?

All governmental agencies operate within a framework of administrative hearings, court and law. Against the BBB we have no such recourse, indeed, at best (which is worse) they set up a slander and/or libel campaign that is not subjected to the safe-guards of

Federally guaranteed due-process rights. Their constituents are not, for the most part, those with Rheumatoid Disease seeking alternate ways to wellness, but rather that of big-business and big-foundations seeking subtle ways and means for controlling the almighty buck for their own power and profit.

BBB remains free to distort and misuse any information that we might supply -- as already demonstrated -- and at best our response would be to engage in a very costly court battle, where our contributors would not be the winners.

We send out a great deal of information, mostly free. If you have any further questions about our literature, or goals, and/or our research projects, please call or write. I will be most happy to supply you with whatever you require, so that you do not need to rely on destructive hearsay and gossip from either the Arthritis Foundation or the so-called Better Business Bureau.

Cordially,
Perry A. Chapdelaine, Sr