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Dear Doctor Jacques:

I recently received your letter requesting my comments on the "role of infrared therapy and wound healing and neuropathy as well as on what conclusions, if any, are supported by the available data." This is an area of particular interest of mine, and I am happy to provide you with my thoughts.

It is important to know a person's background when you judge their comments. My initial training was in experimental physics, and I have been a board certified physician of Physical Medicine and Rehabilitation since the early 1980s. I am currently a Professor in the Mayo Clinic's Department of Physical Medicine & Rehabilitation, and the majority of my medical care and research has involved the influences of physical forces on the body. In particular, I have been involved in investigating the potential clinical benefits of light-based therapy (e.g., low energy laser, low intensity laser, infrared (IR) for more than 20 years. I have performed multiple studies in this area and have published their findings in the peer-reviewed literature. (please see my attached CV.)

As you know, mankind has been intrigued by light-based therapy for more than 2000 years. However, current interest in the non-thermal aspects of light, and specifically the IR and near-IR spectrum, began in the mid-l 960s following reports by Endre Mester that Helium-Neon (HeNe) laser irradiation appeared to speed the healing of lower extremity ulcers. Doctor Mester's reports included large subject numbers but, unfortunately, little or no blinding or controlled evaluation. Interest was initially centered in Eastern Europe and the former USSR. However by the 1970s, investigations became frequent in Western Europe and subsequently Asia and the US. I would like to cite a definitive article or two to clarify the benefits of light and non-thermal IR therapy. Unfortunately, the literature is too diverse, limited, and underpowered to permit this. I can, however, summarize the situation and perhaps direct your attention to some pertinent literature.

I believe that most people accept that light produces effects at the level of cellular function that are dependent on wavelength and are not the result of heating. Unfortunately, translation of these

results to animals and humans has been difficult with many experiments showing benefits and others showing little or no effect. Initial research typically involved low power HeNe lasers as noted above as well as other devices such as Argon and Krypton lasers. However, once superluminous and laser diodes became available, efforts focused on red and IR radiation due to cost, ease of use, improved tissue penetration and reports of benefits. Soft tissue injuries, wounds, and pain have consistently been the center of experimental and research interest.

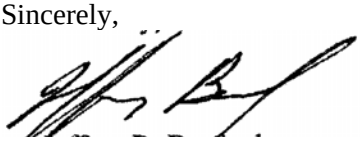
Research in the US began in the late 1970s, and in 1985, an FDA Pre-Market Approval (PMA) Review Panel reviewed the effects of HeNe laser irradiation on rheumatoid arthritis. The panel concluded that evidence of efficacy was too limited to permit a recommendation of acceptance. I performed my last published review in 1995 (see CV) and concluded the field had exciting possibilities but that clinical benefits had yet to be established. Research has improved continued subsequently with numerous investigators finding benefits: again with the most marked finding at the basic science level and with difficulty obtaining overwhelming evidence of clinical benefits.

Many in the field may consider me conservative in this assessment. However, I reviewed the Cochrane Database for this topic while writing this letter and confirmed that members of this collaboration find little or no support for the use of light therapy for osteoarthritis, lower extremity venous stasis ulcers or tuberculosis and only weak support for the treatment of rheumatoid arthritis. The overall assessment is that better designed, controlled, and powered studies are needed.

Currently about 22 devices have FDA approval. On first look, this seems to be impressive; but unfortunately, this acceptance has not been on the basis of a PMA assessment but due to the 2002 relaxation of the requirements to that of a 510K process on the basis of use as an adjunct in the treatment of pain their being "substantially equivalent" to "pre-Amendment" IR treatments.

I wish I could be more optimistic about the certainty of clinical benefits at this time. I am convinced that the numerous reports of established investigators at the cellular (e.g., T. I. Kuru), animal (J. Anders among others), and even human spinal cord (S. Rochkindet. al.) describe real findings. However, I believe that the extension of these findings to the demonstration of significant and strongly supported clinical benefit bas not yet occurred. This difficulty is not unique to light and nonthermal IR therapy-it is shared by many physical treatments and includes issues such as the semi-quantitative nature of pain, choice of appropriate outcome variables, and the natural fluctuations of pain in many of the conditions studied. In addition, dosage is important as light is attenuated as it passes through tissue. In particular: what dose is too low and is a dose > 1-4 J/cm^2 often recommended detrimental? (The World Association of Laser Therapy Website (http://www.walt.nu) presents a systematic review and recommendations for this issue.)

Sincerely,



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JRB:cab