Skepticism About an Unconventional ALS Therapy

Dr. Bedlack and Duke Neurology supported by the ALS Association list "Ten Red Flags" for alternative therapies at <u>ALSuntangled.com</u>; the list is hereafter annotated for *Natural Science Therapy for ALS* by Steve Spiegel (principal investigator for trials).

- 1) Large out of pocket cost: This treatment is absolutely free and will remain free.
- 2) Advertised as effective for multiple incurable conditions with different causes: Natural Science Therapy for ALS focuses on ALS.
- **3) Lack of safety and scientific oversight:** Since the treatment is a naturopathic "brain exercise", it is safe and FDA approved by definition.
- 4) Absent or limited informed consent process: N/A as per the previous "red flag."
- **5) Lack of an evidenced mechanism by which the intervention might help:** ALS mechanisms are explained in the program and based on a linked naturopathic breakthrough unifying eastern and western neuroscience theory.
- **6) Absence of regularly measured validated outcomes:** Outcomes are based on reports about clinically documented ALS measures from mainstream quarterly physician visits (especially from the Revised ALS Functional Rating Scale and qualitative measures of breathing and limb strength).
- **7) Vague or no plan to present outcomes for peer review:** Trials participants are encouraged to participate in documenting trials' outcomes as recommended by ALSuntangled.com, PatientsLikeMe.com and the NIH's ALS Registry.
- **8) The only evidence of benefit is anecdotes:** The program seeks to duplicate the common element of therapies attributed to ALS Reversals documented by Dr. Bedlack and Duke Neurology.
- **9) Proponents have no relevant training, presentations or publications:** The principal investigator is advocating the accepted science protocol of focusing on anomalies like ALS Reversals for science breakthroughs. Moreover, the principal investigator provides a short science thesis linked through the homepage that explains basic "hard" science support for the naturopathic treatment.
- **10) Proponents portray themselves as victims, advise "divorce" from mainstream doctors:** The principal investigator seeks inclusion of mainstream doctors since the science is real and the therapy program is free, complementary, and deserves testing.