

My article accurately states that the Kimera Society registered on ClinicalTrials.gov a pay-to-participate study in which adipose derived stem cells are administered to individuals with Chronic Obstructive Pulmonary Disease. The ClinicalTrials.gov listing does not disclose that study subjects are charged but this information is in the public domain and Duncan Ross, founder of Kimera, acknowledges that study subjects with COPD pay to participate in this study. My article also argues that studies involving administration of autologous adipose-derived stem cells to individuals with COPD appear to require an Investigational New Drug application that has been submitted to the FDA for review and cleared by CBER. In response, Duncan Ross has called for a retraction of my article and threatened that he will sue for libel or defamation if the article is not corrected or retracted.

Mr. Ross' threat is all-too-representative of the responses that emerge from individuals associated with businesses that charge patients for unproven stem cell interventions. When critiqued, they have a habit of attempting to threaten critics and intimidate them into silence. Such threats have a chilling effect on scholarship. In particular, they make academic journals and researchers wary of identifying businesses by name and critiquing specific commercial practices. The threat of litigation has impeded the ability of researchers to conduct research on such business and publish articles that address important ethical, legal, and scientific issues associated with their marketing claims, business practices, and clinical activities.

I have asked Mr. Ross to identify particular problems with my article and to date he has not identified any specific errors in my analysis. However, he has provided me with an IRB Certificate of Approval that expired more than two years ago and confirmation that study subjects were charged \$6,500 per person to participate in this study. He has also acknowledged that the physicians administering stem cells to individuals with COPD are cosmetic surgeons. Asked to provide evidence that he had permission from the FDA to conduct his study without an IND, Mr. Ross has provided no documentation of such assurances. Asked to provide an up-to-date IRB Certificate of Approval or Letter of Approval, Mr. Ross has provided no such documentation. Asked why cosmetic surgeons were operating outside their usual scope of medical practice, Mr. Ross was unable to explain why such doctors were administering stem cells to individuals with Chronic Obstructive Pulmonary Disease. Despite my requests, Mr. Ross is also apparently unable to provide any data from his "study." Given his apparent inability to answer the most elementary questions about his "pay-to-participate" study, I can see why Mr. Ross is attempting to intimidate me.