I would suggest that the chairman of ABCMT, ICCIM and ACAM write individual letters refuting the presumptions in this alert. I would suggest that Tony Lamas be contacted to verify what I will write from memory.

First, it is an accepted drug approved by the FDA. Once a drug is approved by the FDA for any purpose, it may be used by any physician as he deems appropriate (see forward to the 62nd edition to the PDR (2008) first column, para 2 under About the Book), "The FDA has also recognized that the FD&C Act does not, however, limit the manner in which a physician may use an approved drug....."

Deaths may have occurred when the patient has been receiving the referenced medication but there is no acceptable autopsy or medical scientific proof that the medication in question was the cause of that death. It is hypothesized that the theoretical possibility of a slight hypocalcemia occurring was associated with the death. It could well have been the normal course of the disease such as sudden cardiac deaths (over 250,000/year) when patients were on statin medications, anti-hypertensive medications, etc. Are these drugs held up to similar scrutiny?

If memory serves me correctly, the TACT trial has given over 35,000 IV treatments, one half of which contained the drug in question. To my knowledge there has been no significant adverse effect with this number of treatments, a safety record almost unheard of in medicine. There have been episodes of mild hypocalcemia, none of which were thought to be clinically significant. Please contact Tony Lama for confirmation of the above.

I was taught by John Henry recognized as a leading pathologist and textbook writer in US medicine. He taught that it was impossible to have zero calcium in any blood sample unless the calcium was absorbed by a chemical in the collecting tube such as EDTA.

I have little knowledge in treating children and will defer to others more knowledgeable in that venue. However, the total numbers of death are minuscule with any treatment using EDTA if the correct protocols as taught by the above organizations were followed. I would have every other medication in the PDR be compared with the number of deaths occurring while on those medications. I believe the total number in each case would exceed those of the approved FDA drug, EDTA, based on the safety record of the TACT trial.

I use disodium calcium EDTA preferentially, but am on the TACT Data and Safety Management Board and have seen no danger to any adult patient as noted above.

I believe that the Federal Court case of Dr. Evers, in 1978, was unanimous in its finding. The Solicitor General of the U.S. chose not to appeal it to the U.S. Supreme Court, making it the law of the land. It had to do with the use of the drug in question. I would suggest that other forces than scientific medical proof might be considered as causing this alert.

Please act expeditiously and vigorously with the information above and additional information as obtainable to confront another erosion of scientific medical truth. I'm certain that with reflection the CDC and FDA do not wish to go against the law of the land established by the judicial system, against the current ongoing scientific evidence of the NIH sponsored TACT trial and the past 5 year record of partiality to certain pharmaceutical houses by the FDA. Transparency is called for and once it is, a revision of the alert should be issued.

Good Luck,

Robert Nash, MD, Past Chairman of ABCMT