San Diego Clinic Immunological Center Clinical Study On Cetylmyristoleate (CM) vs Arthritis
A Study on Dose Effectiveness and Patient Response Conducted by the San Diego Clinic Immunological Center

The Purpose
Having previously established the effectiveness and nontoxicity of CMO tm (cerasomal-cis-9-cetylmyristoleate) for arthritis symptoms of pain, inflammation, and impaired mobility, the purpose of the study was:
A) To determine optimum dosage levels for various types of arthritis,
B) To determine if different dosage levels would be required relative to the severity of each type of arthritis,
C) To observe response time required for initial and partial relief of symptoms,
D) To observe response time required for complete relief of symptoms, and
E) To determine factors influencing subjects who may not respond to the protocol.

The Subjects
Subjects were volunteers treated as outpatients. They presented with osteoarthritis, rheumatoid arthritis and other forms of reactive arthritis.

The Study
The study involved 48 subjects. Female subjects (28) ranged from 33 to 83 years of age. Male subjects (20) ranged from 29 to 74 years of age. All races and many ethnic backgrounds were represented. Age, gender, race, and ethnological background appeared to be irrelevant to patient response in this study.

The Protocol
CMOtm was administered orally in the form of 75mg capsules each morning and evening. The number of capsules and duration of treatment varied for each group of subjects. Subjects were advised to take capsules on an empty stomach with water only; and to avoid tea, chocolate, alcohol, coffee, cola, and other caffeinated drinks for five hours after taking the capsules. Subjects were advised to completely avoid chocolate and alcohol during the entire trial period of two to three weeks duration. With a few exceptions for subjects who could not function without them, steroids were also prohibited. Otherwise diet was not
controlled in any way. Subjects were permitted to continue taking their customary pain and non-steroidal anti-inflammatory medications until they were no longer needed. Subjects were asked to visit or call in to report progress at least twice weekly.

The Results
Only two subjects failed to show marked or complete relief of all symptoms of pain and limited mobility normally associated with arthritis. Both of these non-responding subjects had suffered prior hepatic problems: one from alcohol abuse resulting in cirrhoses of the liver; the other, a former professional athlete, presented with considerable liver damage from steroid abuse. Further studies are necessary to determine the role of liver function capacity with respect to this protocol. Liver damage resulting from steroids previously prescribed for arthritis may also prove to be a factor affecting patient response.

Group #1 Mild to moderately severe osteoarthritis & and reactive psoriatic arthritis.

In Group #1, eleven (11) subjects presented with mild to moderately severe osteoarthritis and one with reactive psoriatic arthritis were supplied with 16 capsules, two 75mg capsules to be taken each morning and evening for four days.

Nine reported about 20% to 30% improvement in articulation and inflammation and about 40% to 50% relief of arthritic pain within 36 hours. In these nine subjects, improvement continued rapidly for the next 60 hours,

reaching a 70% to 80% improvement by the end of the four days. Two of the subjects continued to improve over the following week despite the fact they were no longer taking any capsules. However about half of this group experienced the return of some mild arthritic symptoms after about three to five weeks. (Although not included as part of this study, all the subjects in this group were treated again and their symptoms have not returned.) The patient with reactive psoriatic arthritis also experienced an almost complete reversal of his associated very severe psoriatic skin condition affecting about 20% of his total skin area.

Group #2 Severe to crippling rheumatoid arthritis

In Group #2, nine (9) subjects presenting with severe to crippling rheumatoid arthritis were supplied with 50 capsules to be taken in two series, two 75mg capsules each morning and evening for seven days, with a seven day interval before repeating the same dosage for 5 1/2 more days. Four of these subjects were unable to walk and were accustomed to being transported by wheelchairs. One, her femur being fused at the hip, was unable to achieve a sitting position for wheelchair transport. She could, however, move about slowly on crutches as long as she was accompanied by someone to aid her in maintaining her balance. Otherwise she could only stand or lie down. The remaining four could move about with canes or walkers. All nine subjects presented with pain, inflammation, and marked deformation of nearly all proximal interphalangeal and large joints. Five presented with limited lumbar flexion and pain in the vertebral column. All had difficulty grasping and manipulating common objects.

On the fourteenth day, at the end of the one week interval without treatment, six(6) subjects reported minor continuing improvement; two reported maintaining their improved status and one continued to show no improvement. Treatment was resume an the fifteenth day for 5 1/2 more days.

By the end of the treatment period, all but two subjects reported to be 90% free of pain with a return of 70% to 100% mobility. The fused hip joint remained fused, of course, but with a return of over 70% mobility in other joints, the subject felt hip surgery now to be worth consideration. The nonresponsive subject proved to have cirrhoses of the liver, which may have been the reason for her inability to respond to treatment. Further investigation is necessary to determine the role of liver function in this protocol.

Group #3 Mild to moderately severe rheumatoid arthritis

In Group #3, fourteen (14) subjects presenting with mild to moderately severe rheumatoid arthritis were supplied with 24 capsules, two 75mg capsules to be taken each morning and evening for 6 days. After three days of treatment, eleven reported about 20% to 30% improvement in articulation and inflammation, and about 40% to 50% relief of arthritic pain. In these eleven subjects, improvement continued rapidly over the next four days, approaching the 80% to 100% level. The remaining three subjects reported similar improvement by the end of the fourth day, with an overall improvement of 70% to 80% after seven days.

Most of the subjects continued to report minor additional improvement for one week or more, even though they were no longer under treatment. However, six in this group began to experience the return of some mild arthritic symptoms after about three to four weeks. (Although not included as part of this study, all subjects in this group were treated again and their level of improvement has subsequently stabilized.)

Group #4 Severe to crippling osteoarthritis

In Group #4, fourteen (14) subjects presenting with severe to crippling osteoarthritis were supplied with 50 capsules to be taken in two series, two 75mg capsules each morning and evening for seven days, with a seven day interval before repeating the same dosage for 5 1/2 more days. Three of these subject were unable to walk and were accustomed to being transported by wheelchairs. The other eleven could move with crutches, walkers and canes. All presented with pain, inflammation and marked deformation of nearly all interphalangeal and

large joints. Four presented with limited lumbar flexion and pain in the vertebral column. Ten had difficulty grasping and manipulating common objects.

After four days of treatment, ten in this group reported 30% to 50% improvement in articulation and inflammation and about 40% to 60% relief of arthritic pain. In these ten subjects, improvement continued rapidly over the next three days, reaching 80% to 100% by the end of seven days. One reported no perceptible change.

On the fourteenth day, at the end of the one week interval with out treatment, nine subject reported continuing minor improvement, four reported maintaining their improved status and one continued to show no improvement. Treatment was resumed on the fifteenth day for 5 1/2 more days.

By the end of the treatment period, eleven subjects reported 80% to 100% relief of pain with a return of 80% to 100% mobility. Two subjects reported a 70% to 80% of articular mobility with a 70% to 90% reduction of arthritic pain. The one non-responsive subject proven to have previous liver damage as a result of sports related steroid abuse. Further studies are necessary to determine the role of liver function in this protocol.

Summary

The results of this study lead to several conclusions regarding its five principal objectives:

1) Optimum dosage levels appears to be equal for all three types of arthritis investigated: osteoarthritis, rheumatoid arthritis and reactive psoriatic arthritis. This is evidenced by the gradual return of minor arthritis symptoms in several of those treated with only 16 to 24 capsules, and no regression in those treated with 50 capsules in two series separated by one week without treatment.
2) Dosage level requirements appear to be equal irrespective of the severity of the subjects condition.
3) Initial response time for minor improvement appears to vary from two to seven days, irrespective of the severity of the subject's condition.
4) The time for maximum attainable response appears to vary from seven to twenty one days, resulting in 70% to 100% overall improvement. (Apart from this study, three of the most severely afflicted subjects were treated again after a five week interval, resulting in an additional 10% to 20% overall improvement.)
5) The two non-responding subjects both proved to have suffered previous damage to the liver from steroid or alcohol abuse, indicating that impaired liver function may preclude success with this protocol.

In addition, it was evident that for many subjects, the relief of inflammation resulted in marked improvement in joint deformation.

Other CM/CMO Research and References

1.Diehl, Harry, and E.L. May, "Cetyl Myristoleate Isolated from Swiss Albino Mice: An Apparent Protective Agent against Adjuvant Arthritis in Rats". Journal of Pharmaceutical Sciences, Vol. 83, No. 3, March, 1994.
2.Siemandi, H., MD., et al. "The Effect of cis-9-Cetyl Myristoleate (CMO) and Ajunctive Therapy on the Course of Arthritic Episodes in Patients with Various Auto-Immune Diseases Characterized by the Common Terminology, 'Arthritis' and 'Psoriasis': A Randomized Clinical Trial."