NATUROPATHIC FORMULARY ADVISORY COMMITTEE

Meeting Minutes

September 25, 2005

Meeting Site:	Teleconference Site:	Teleconference Site:
The Khalsa Medical Clinic 436 North Bedford Drive, Suite 308 Beverly Hills, CA 90210	Michael Traub, ND 73-1138 Oluolu Street Kailua Kona, HI 96740 (808) 329-2114	Arthur Presser, R.Ph 47 Alta Drive La Selva Beach, CA 95076 (831) 684-0214

COMMITTEE MEMBERS PRESENT:
Peter Wannigman, Naturopathic Doctor (Chairman)
Soram Khalsa, Medical Doctor (Vice-Chairman)
Trevor Holly Cates, Naturopathic Doctor
Michael Traub, Naturopathic Doctor
Arthur Presser, Pharmacist

COMMITTEE MEMBERS ABSENT:
Cynthia Watson, Medical Doctor
Mary Hardy, Medical Doctor
Paul Mittman, Naturopathic Doctor
Larry Woodhouse, Pharmacist

STAFF PRESENT:
Terri Ciau, Acting Bureau Chief
Linda Brown

I. Call to Order and Roll Call

Chairman Wannigman called the meeting to order. Roll call was taken and a quorum declared.

Chairman Wannigman welcomed Dr. Art Presser to the Committee. The Committee is now full with no more vacant seats. Chairman Wannigman invited Dr. Presser to make a few comments.

Dr. Presser stated that he does have a Doctorate Degree from the University of Southern California in Pharmacy. He doesn't practice conventional pharmacy anymore. He is currently an Assistant Adjunct Professor of Clinical Pharmacy Practice at the University of Southern California and the Curriculum Coordinator for the Complementary in Alternative Medicine Program. In addition to that, Dr. Presser is President of a distance learning institution in Tennessee called the Huntington College of Health Sciences. Dr. Presser is also a consultant to the Natural Products industry and also has a retail vitamin outlet in Salinas, CA.

Chairman Wannigman requested Dr. Presser to give a brief background about the Huntington College of Health Sciences.

Dr. Presser stated that it is a distance learning institution, which is fully and nationally accredited for college credits. It offers diploma programs in Nutrition, Sports Nutrition, and Exercise Physiology. The college offers an Associates Degree and a Masters Degree and is working on getting an accredited Bachelors Degree to have a full set. The college is also expanding offerings into Botanical Medicine, more Sports Nutrition, Exercise Physiology Department and since Dr. Presser's background and a colleague of his, who is a principal in

the college with a Pharmacy background, the college is looking at developing a department of Pharmacy Sciences and perhaps train technicians and DCE 4 Pharmacists and other allied health professionals. The college has been around for 25 years, but has specialized in nutrition up until now.

Chairman Wannigman wanted to pose that ultimately, if it is moved forwarded, with the intent of developing post graduate education and things like that with the formulary, the true value that this might truly represent with Dr. Presser and his connections to an accredited university.

II. Approval of August 28, 2005 Committee Meeting Minutes

Chairman Wannigman requested to postpone any discussion in regard to the aspect of what ended up being Michael's additions to the Graduate Certification Program where it said, "This would include requiring the ND to" and then there were four bullets, with the inclusion of the word "OR".

Chairman Wannigman then asked if there was any other discussion regarding the minutes. There was Committee discussion on the postponement of the approval of the minutes.

Chairman Wannigman postponed the actual approval of the minutes until after discussion of Item IV on the formal agenda.

It was moved and seconded (Traub/Cates) to amend the minutes as written under Item 3-A where it says, "this would requiring the ND to", remove the "OR" after the first line and insert, "which includes documentation", everything included in bullet number two becomes part of bullet number one; remove the "OR" at the end of the original second bullet; and remove the "OR" at the end of the fourth bullet. Roll was called and the move was carried by the following vote: Ayes: Khalsa; Cates; Traub; Wannigman; Abstain: Presser

III. Chairperson's Report

Chairman Wannigman discussed the Clean Up Bill AB 302. AB 302 passed unanimously out of both the Assembly and the Senate on September 9, 2005. That gave 30 days for the Governor to sign this urgency bill into law. AB 302 was also in connection with an architectural bill and both of these were going through, however in the last week and half there has been a court ruling that in effect would make a part of the architectural bill illegal. We are now potentially looking at Governor Schwarzenegger not being able to sign this bill because of what has happened legally with that ruling. Chairman Wannigman asked Terri Ciau, Acting Bureau Chief to speak about what this might mean.

Ms. Ciau stated that there are four options right now on the table: 1) the Governor could sign the bill; 2) the Governor could veto the bill; 3) the Governor could red line that particular language out on the architect's board, but that's not usual or very routine; 4) the Governor could not sign at all and it becomes law without the urgency status. The worst scenario is that the whole bill is vetoed, which means that we don't have the extension on the Committee reports. Then we would need some type of draft report to go forward by November 1, for review so it could be submitted to the legislature by January 1. The reason for the November 1 day is to give everybody an opportunity to review it before it gets released to the legislature.

Committee Members had discussion regarding the options for AB302.

Chairman Wannigman explained the process by which the Committee is trying to accomplish things and how they are going to go. In the aspect of what has happened the last four meetings, the Committee came under general consensus on the first meeting that what we were going to try to do was to address the regulatory aspects of things that we thought

needed to be done and then we were going to address legislative things. The aspect that we've been working on for the last three meetings have been the IV Parenteral Use and situations such as that which, under our observation, was going to be something that would be regulatory administered and they wouldn't need legislation. In that capacity, what we would basically be doing with our regulation recommendations is we would submit them to the Advisory Council. The Advisory Council would then hopefully continue the recommendations and approve them to send to the Department of Consumer Affairs Executive Staff.

The other avenue is that if we're going for legislative things to happen. What that would be is that everything would still happen the same way, going through the advisory council to the executive at the DCA ultimately getting out of the DCA to go to agency. I don't know if anybody is familiar with agency, but from what I've taken it is, its kind of if you would, the Cabinet to the Governor. And in agency they would then say, should we move this on the Governor and ultimately it would go to the Governor, the Governor would then hopefully approve it and then from there it would go into the Senate and the Assembly to reappear back more than likely in the Business and Professions Committees, which is where were heard originally. Since there are no appropriations involved in this, I don't know if there would be any other committees that would really hear on it, but perhaps one. I think we were heard by three committees when we originally did it. And then ultimately to go back to the floor of those two. So that's really the path of the things that we are trying to accomplish and what we're looking at. Most critical I would say is when we're doing the legislative is to bring in and really get cooperative development with the CMA as well as maybe the Medical Board on what we are making suggestions for the legislative aspects so that we don't go through this whole thing, get to the end and have it just dry out.

If the clean up bill is what that was in essence it took care of addressing all of the pharmacy health and service codes as well and B&P codes to really make room for naturopathic medicine in the particular areas that would say whether or not we can furnish, whether or not we can prescribe. It also would very importantly identify a seat in the Supervisory Body of our organization. Currently it is the CAMP, which is no longer an organization that even exists. If somehow anybody did grab that title right now they would currently in effect be in control of naturopathic medicine. That's the biggest reason why this is an urgency. And then as we've discussed for really naturopathic practice purposes, it was the inclusion of the language was on 3640(c)(1) the additions of the words at the end of that to include, consistent with the routes of administration described in 3640(d)". Which ultimately was the gray area that was preventing pharmacies from being able to sell Parenteral items that would fall into 3640(c)(1) being vitamins, amino acids. They would be able to sell those now to naturopathic doctors because it is the routes of administration that changed those items to being a prescription drug and the law now states that naturopathic doctors that prescribe consistent with the routes of administration, so they don't lose that product simply because the routes of administration changed and thus the classification changed. That was the intent of the original legislation and it was just part of the clean up bill that needed to be cleaned up, so the intention of the naturopathic doctors act could actually take place. Ultimately, what that really means is that then as an urgency process in the State of California, naturopathic doctors would have the ability to order and utilize Parenteral items described in 3640(c)(1) as of the date it is signed. There is a little bit of a hole in what we are trying to accomplish as a subcommittee and the enactment of that in that there are no regulations that prohibit a naturopathic doctor for a short period of time from doing anything. And so the things that we are really coming up with, it behooves us to get these regulations into place, because if this is going to take one year we really need to get this done.

Committee Members had lengthy discussion regarding Naturopathic Doctors.

IV. Recommendation for IV Course Requirements

Chairman Wannigman confirmed what was agreed to and what the Committee saw fit at the last meeting. The specifics were on numbers is that we came up with a didactic course, a didactic and practicum course which would cover 32 hours over four days. It was a class that would include the need for 20 observations and five practicum participations in which a live patient was used and case follow-up was required.

The Committee Members had lengthy discussion regarding the requirements for IV therapy.

After discussion it was recommended to alter the recommendations of last time of five and 20 to be ten successful insertions and set ups; 20 observations total, adverse reactions and events, pre-discussion with patients, possible adverse reactions and symptoms and to expect.

Chairman Wannigman restated that the recommendation for Dr. Osborne's course having 10 and 20 must include complications and emergencies of management, as well as instructions of adverse reactions and events. This is the curriculum for Dr. Osborne teaching it in this particular state, but we will hopefully see the schools adopt this as minimal requirements, so that once again, just because you've taken a course, the schools need to have the element of what we've included here to be present in order for the DCA to accept that.

Ms. Ciau asked a point of clarification regarding utilizing Dr. Osborne basic syllabus to establish a model that will go into regulation and hopefully pass so that Dr. Osborne or any other person who wants to provide this course will have the guidelines to use.

Chairman Wannigman asked Dr. Osborne to submit an outline that would include the hours devoted to each particular part and include the language, "including but not limited to".

Chairman Wannigman summarized: 32 hours/4 days, 10 do's with 20 observations total, but not limited to that; Adverse reactions and events; follow-up's; complications; emergencies and Dr. Osborne will submit a syllabus to the DCA for distribution to us and on this point alone, I will expect nothing less than we zip this thing completely tight by our next meeting.

Chairman Wannigman moved to the next point, which would be grandfathering. We need to define what is going to be our grandfather. We need to develop some criterion for people who do want to do this. After discussion, the Committee determined that grandfathers would have to take the course.

Chairman Wannigman moved to the next item, which is the recertification process. After discussion, the Committee agreed to make recommendations to the Bureau for recertification on a five-year basis for the Bureau to develop a recertification of didactic 8 hours of continuing education.

Chairman Wannigman moved to the next topic of discussion on chelation and the definition of chelation, where the Committee has discussed it a couple of times, one being investigational and the other being metal toxicity. We are going to need to define that for regulatory purposes where one is okay for a naturopathic doctor to do and one is not.

After discussion the Committee came to the following recommendation that the Bureau limit the use of chelation for naturopathic doctors for any metal detoxification and require 16 additional hours of didactic and practical training for chelation. Chairman Wannigman requested that Dr. Osborne present a syllabus for the 16 additional hours.

The Committee Members discussed the use of existing PIC lines and ports. Dr. Khalsa requested that further discussion on this topic be tabled until other medical doctors are

available for the discussion.

Chairman Wannigman tabled this discussion to the next meeting and asked members involved in this discussion to come up with specific recommendations of what they would like to see next time.

V. Discussion on Parenteral Botanicals/Supplements
a. Quality Assurance
b. Inclusionary vs. Exclusionary List

Chairman Wannigman stated that unfortunately this was the part that Dr. Hardy and Larry Woodhouse were going to do in discussion with Virginia. Virginia is present. There was concern at the last meeting brought up by Dr. Hardy as well as Dr. Khalsa that the inclusion of botanicals without limitation by use of naturopathic doctors and Parenterals was something that they were not willing to endorse. We were going to talk a little more about it. Dr. Hardy brought up things about certificates of analysis and description of the true formulation of the botanicals by the compound pharmacies and what would be an okay one and what wouldn't be okay. Chairman Wannigman asked Dr. Osborne to comment on the certificate analysis and levels of quality assurance that she had.

Dr. Osborne reported that when she spoke with Dr. Mary Hardy last Sunday, her biggest concern is about the botanicals and the certification because she herself has a great deal of background and experience in that realm and has seen the problems that arisen from that. Dr. Osborne stated that she was sure that she would be much more detailed in her explanation of it, but overall it is the concern about listing with the Inclusionary list.

Chairman Wannigman stated that he feels that less is more and in the aspect of regulation, the same thing goes. The more we complicate it the more we set ourselves up for a conundrum in the future. To make it acute and understandable at the beginning is what we need to do. This is presented in the class. He suggested that we put this concept of concern into the collection of a blueprint of what will be taught in the class but dismissing it from regulatory process and allowing the naturopathic doctor to make their own judicious decisions for their patients best interests in that capacity.

Dr. Khalsa stated that speaking as an MD, the list needs to be Inclusionary and would totally agree with Dr. Hardy that measurements of quality assurance must be somehow ensured to allow the IV administration of these different pharmaceuticals. No matter how difficult it is to maintain an Inclusionary list, it has to be done and that it's our job to support the safety of the public who will be coming to physicians for these IV's.

Dr. Cates asked that this discussion be postponed until Dr. Hardy and Mr. Woodhouse can be present.

The Committee Members continued with lengthy discussion regarding Parenteral Botanicals/Supplements. Chairman Wannigman stated that the Inclusionary list is going to need to be beyond just botanicals, but it's going to need to include every foreseeable phytopharmaceutical and supplement that could possibly be used for administration. The task of actually identifying the individual ones is ultimately insurmountable and we have to put the onus back on the physician. Chairman Wannigman deferred the discussion until next time stating he is not in favor of an Inclusionary list, but in favor of education and bringing the standard up of the education and then putting it into the physician's hands.

VI. Discussion on Medical Malpractice Under Physician Supervision

Chairman Wannigman stated that in the aspect of developing a formulary for allowing naturopathic doctors to have a more liberal right of prescribing, one of our case points, is that in the state of California the current aspect of furnishing must be under MD supervision and we are finding pretty predominately that this is something that is turned out to be an impossible task and it will never come to fruition, but maybe for a handful of doctors to find and MD supervisor simply based upon the aspect of the degree of malpractice liability that the physician undergoes by taking on a naturopathic doctor. What are the rates and what is the potential coverage? The Bureau has taken that on and hopefully Terri has something for us today.

Ms. Ciau apologized to the Committee for not having any new information. Joanne Davis has contacted the insurance companies but they have not responded to her.

Dr. Khalsa offered to contact The Doctors Company to see if he could get information from them.

The Committee deferred further discussion to the next meeting.

Dr. Khalsa asked which companies had been contacted and what their replies were.

Ms. Ciau stated they would work on a written status report regarding the insurance companies for the next meeting.

VII. Discussion on Formulary

Chairman Wannigman stated that he would cover two points and see where everyone is at on it and will probably defer this topic again. The two points are a. Homeopathy and b. Local Anesthetics.

a. Homeopathy (HPUS)

It has been brought up very clearly to us that 3640(c)(1) currently states that a naturopathic doctor may administer, prescribe, etc. homeopathy and we did not make clear reference to the Homeopathic Pharmacopoeia in the United States. Because of some of the homeopathic preparations, some of the no-sos (phonetic) as well as some of the things such as opium, things like that require a prescription. So now in some unfortunate aspects of it, the homeopathic pharmacies are a little bit hand tied to realize that they can't even dispense these things to naturopathic doctors because we didn't clearly state as stated in HPUS. It does behoove us to request the Bureau to support legislation to make a change to 3640(c)(1) to include homeopathy (HPUS).

The Committee Members discussed the fact that this seemed to be a technical amendment. The law does not mention HPUS now. Dr. Traub suggested that language could be included that would define homeopathic medicines as those that are included in the HPUS and other recognized international pharmacopoeias.

Chairman Wannigman summarized that basically the Committee would be making a recommendation whether through regulation or through law to include homeopathy (including but not limited to HPUS) and other recognized international pharmacopoeias.

b. Local Anesthetics (Procaine) under Section 3640.7 of the Code

Chairman Wannigman stated that the Committee has had this item for discussion three times. Chairman Wannigman asked if anybody was unclear as to why we want to get 3640.7 expanded before we come up with any other recommendations to allow for the use of local

anesthetics? Truly this whole thing could come down to simply Procaine. Dr. Khalsa stated that if it comes down to Procaine not being available OTC, that's not true, it is available OTC. It's known as the GH3 formula and it's a combination of Procaine and some other mineral and it's available OTC.

Chairman Wannigman asked members to research any information regarding Procaine being available OTC. Dr. Presser stated that he had it and would e-mail it to everyone.

c. Post-graduate Pharmacology Certification Program

(Tabled for next Committee Meeting)

d. Review of Naturopathic Medical School Pharmacology Curriculum

(Tabled for next Committee Meeting)

e. Review of North American Board of Naturopathic Examiners (NABNE) Blueprint

(Tabled for next Committee Meeting)

f. Drug Exclusion List

(Tabled for next Committee Meeting)

VIII. Public Comment

Chairman Wannigman opened the floor to public comment.

A member of the public stated that unless somebody spells it out specifically, the pharmacists are not going to want to give us Procaine whether it's OTC available. Pharmacists are going to want to know that they are behaving properly and there's topical and injectable. There's a lot of companies that do a lot of different types of injectables and I just wanted to point out as diplomatically as I can that the FDA has not been real friendly to the natural products and am curious is there is some other body that could approve laboratories. The malpractice rates are ridiculously high for MD's. I don't think there's anyway we could possibly not address that and eliminate that from the bill. I'm a cancer survivor and I had two PIC lines, I put them in when I was an intern in Arizona. I think with proper training and I understand your concerns and respect them, I think with proper training it doesn't have to be something that most of us are not going to get, you know, supervision under an oncologist. Putting an IV in my arm right now would be difficult.

IX. Adjournment

The next meeting is set October 23, 2005 at 2:00 p.m. The November meeting is scheduled for November 20, 2005 at 10:00 a.m.

The meeting was adjourned.