THE DISCIPLINE COMMITTEE OF THE COLLEGE OF PHYSICIANS AND SURGEONS OF ONTARIO

IN THE MATTER OF a Hearing directed by the Executive Committee of the College of Physicians and Surgeons of Ontario, pursuant to Section 36(1) of the **Health Professions Procedural Code**, being Schedule 2 to the **Regulated Health Professions Act**, 1991, S.O. 1991, c. 18, as amended

BETWEEN:

THE COLLEGE OF PHYSICIANS AND SURGEONS OF ONTARIO

- and -

DR. JOZEF KROP

PANEL MEMBERS: DR. J. THOMPSON (Chair)
DR. C. RAO
J. FINLAYSON
E. STEEP

HEARING DATES: May 11, November 7, December 4-6, December 11-15, 1995; April 28, April 30, May 2, May 6-10, May 12-15, August 11-15, November 10-11, 1997; January 19-22, January 24-25 and April 27-28, 1998

DECISION/RELEASED: December 23, 1998

DECISION AND REASONS FOR DECISION

This matter came before the Discipline Committee of the College of Physicians and Surgeons of Ontario commencing May 11, November 7, December 4-6, December 11-15, 1995, and continued April 28, April 30, May 2, May 6-10, May 12-15, August 11-15, November 10-11, 1997; January 19-22, January 24-25 and April 27-28, 1998.

The Notice of Hearing contained the following allegations of professional misconduct:

It has been alleged that Dr. Krop failed to maintain the standard of practice of the profession in the management, treatment and care of patients, in the province of Ontario, which is professional misconduct as defined in subsection 29.22 of Ontario Regulation 548, R.R.O., 1990, under the *Health Disciplines Act.*

And it is further alleged that Dr. Krop has displayed in his professional care of patients in the Province of Ontario, a lack of knowledge, skill or judgment or disregard for the welfare of those patients of a nature or to an extent that demonstrates that he is unfit to continue in practice, which is incompetence as defined in section 61 of the *Health Disciplines Act.*

The particulars of these allegations are follows:

1. With respect to his patient E.J., for the period from September 1985 through 1990:
   (a) that he failed to do appropriate tests and appropriate assessments of his patient;
   (b) that he failed to conduct a complete history;
   (c) that he failed to adequately monitor his patient with physical examinations;
   (d) that he, or someone acting on his behalf, employed unnecessary and potentially dangerous diagnostic procedures in connection with potential food, inhalant, chemical and other allergies or sensitivities;
   (e) that he, or someone acting on his behalf, employed an inappropriate test or tests in respect of his patient, including the use of a Vega computer system and

hair analysis;

(f) that he inappropriately diagnosed food, inhalant, chemical and other allergies or sensitivities;

(g) that he made an inappropriate diagnosis of systemic candidiasis;

(h) that he prescribed inappropriate treatments including use of sublingual drops, injections including vitamin, “serum” and other injections, calcium and magnesium and the use of staphylococcal lysate;

(i) that he prescribed unnecessary treatment including nystatin and ketoconazole, and that he prescribed or considered prescribing amphotericin B;

(j) that he inappropriately advised that his patient required an air purifier, could only drink pure water, which she had to purchase, and had to avoid hydro towers;

(k) that he prescribed inappropriate treatment for his patient with regard to her diet;

(l) that he placed unnecessary restrictions on his patient=s normal activities of daily living;

(m) that he directly or through the company Amican Ecology Inc., inappropriately charged his patient substantial sums for treatments which were either of no value to his patient, or harmful to her;

(n) that he failed to provide appropriate treatment for his patient; and

(o) that he failed to make appropriate referrals including a referral to a respirologist, a gastroenterologist and referral to a specialist in clinical immunology.

2. With respect to his patient, L.C., for the period from April of 1989 through 1990:

(a) that he failed to do appropriate tests and appropriate assessments of his patient;

(b) that he, or someone acting on his behalf, employed unnecessary and potentially dangerous diagnostic procedures in connection with potential food, inhalant, chemical and other allergies or sensitivities;

(c) that he, or someone acting on his behalf, employed an inappropriate test or tests in respect of his patient, including the use of a Vega computer system;

(d) that he inappropriately diagnosed food, inhalant, chemical and other allergies or sensitivities;

(e) that he prescribed inappropriate treatments including the use of sublingual

drops, injections, vitamins and nystatin;

(f) that he prescribed inappropriate treatment for his patient with regard to her diet;

(g) that he failed to provide appropriate treatment for his patient;

(h) that he placed unnecessary restrictions on his patient's normal activities of daily living;

(i) that, he, directly, or through the company Amican Ecology Inc., inappropriately charged his patient substantial sums for treatments which were either of no value to his patient, or harmful to her.

3. With respect to his patients S.O. (C.) and C.O. (C)., the children of his patient, L.C. for the period from June 1989 through 1990:

(a) that he failed to do appropriate tests and appropriate assessments of his patients;

(b) that he, or someone acting on his behalf, employed unnecessary and potentially dangerous diagnostic procedures in connection with potential food, inhalant, chemical and other allergies or sensitivities;

(c) that he, or someone acting on his behalf, employed an inappropriate test or tests in respect of his patients, including the use of a Vega computer system;

(d) that he inappropriately diagnosed numerous food, inhalant, chemical and other allergies or sensitivities;

(e) that he prescribed inappropriate treatments including the use of sublingual drops;

(f) that he placed unnecessary restrictions on his patients' normal activities of daily living; and

(g) that he failed to provide appropriate treatment for his patients.

4. With respect to his patient A.K., from July, 1984 through 1990:

(a) that he failed to do appropriate tests and assessments of his patient;

(b) that he, or someone acting on his behalf, employed unnecessary and potentially dangerous diagnostic procedures in connection with potential food, inhalant, chemical and other allergies or sensitivities;

(c) that he, or someone acting his behalf, employed an inappropriate test or tests in

respect of his patients, including the use of a Vega computer system and hair analysis;

(d) that he inappropriately diagnosed food, inhalant, chemical and other allergies or sensitivities;

(e) that he made an inappropriate diagnosis of pinworms;

(f) that he prescribed inappropriate treatments including use of sublingual drops, injections, including vitamin, “serum” and other injections, calcium and magnesium, nystatin, tid and anti-oxidant therapy;

(g) that he made inappropriate use of antibiotic therapy;

(h) that he prescribed inappropriate treatment for his patient with regard to her diet;

(i) that he placed unnecessary restrictions on his patient’s normal activities of living;

(j) that he failed to provide appropriate treatment for his patient; and

(k) that he, directly or through the company Amican Ecology Inc., inappropriately charged his patient substantial sums for treatments which were either of no value to his patient, or harmful to her.

5. With respect to his patient P.L., from May 1991, through 1992:

(a) that he filed to do appropriate tests and appropriate assessments of his patient;

(b) that he, or someone acting on his behalf, employed unnecessary and potentially dangerous diagnostic procedures in connection with potential food, inhalant, chemical and other allergies or sensitivities;

(c) that he, or someone acting on his behalf, employed an inappropriate test or test in respect his patients, including the use of a Vega computer system;

(d) that he inappropriately diagnosed numerous food, inhalant, chemical and other allergies or sensitivities;

(e) that he made inappropriate diagnoses of multiple chemical sensitivities syndrome and organo-phosphate toxicity;

(f) that he prescribed inappropriate treatments including the use of sublingual drops, injections, vitamins and nystatin;

(g) that he inappropriately advised that his patient required an air purifier;

(h) that he prescribed inappropriate treatment for his patient with regard to his diet;

(i) that he failed to provide appropriate treatment for his patient;

(j) that he failed to make appropriate referrals including a psychiatric, or psychological referral;

(k) that he placed unnecessary restrictions on his patient=s normal activities of daily living; and

(l) that he, directly, or through the company Amican Ecology Inc., inappropriately charged his patient substantial sums for treatments which were of no value to his patient, or harmful to him.

6. With respect his patient R.M., in the period from May 1990 through 1991:

(a) that he failed to do appropriate tests and appropriate assessments of his patient;

(b) that he, or someone acting on his behalf, employed unnecessary and potentially dangerous diagnostic procedures in connection with potential food, inhalant,chemical and other allergies or sensitivities;

(c) that he, or someone acting on his behalf, employed an inappropriate test or tests in respect of his patient, including the use of a Vega computer system;

(d) that he inappropriately diagnosed numerous food, inhalant, chemical and other allergies or sensitivities;

(e) that he made an inappropriate diagnosis of mucocutaneous candidiasis;

(f) that he prescribed inappropriate treatments including the use of sublingual drops, anti-fungal agents and acupuncture therapy;

(g) that he prescribed inappropriate treatment for his patient with regard to her diet;

(h) that he failed to provide appropriate treatment for his patient;

(i) that he placed unnecessary restrictions on his patient's normal activities of daily living; and

(j) that he, directly or through the company Amican Ecology Inc., inappropriately charged his patient substantial sums for treatments which were either of no value to his patient, or harmful to her.

7. With respect to his patient M.M., in the period from August, 1990 through 1991:

(a) that he failed to do appropriate tests and assessments of his patient;

(b) that he, or someone acting on his behalf, employed unnecessary and potentially dangerous diagnostic procedures in connection with potential food, inhalant, chemical and other allergies or sensitivities;

(c) that he, or someone acting on his behalf, employed an inappropriate test or tests in respect of his patient, including the use of a Vega computer system and hair analysis;

(d) that he inappropriately diagnosed food, inhalant, chemical and other allergies or sensitivities;

(e) that he prescribed inappropriate treatments including use of sublingual drops, injections, including vitamin "serum" and other injections, evening primrose oil, nystatin and sauna therapy;

(f) that he prescribed inappropriate treatment for his patient with regard to her diet;

(g) that he inappropriately advised his patient that her fat cells were storing cleaning fluids and solvents;

(h) that he failed to provide appropriate treatment for his patient;

(i) that he failed to make appropriate referrals including a psychiatric, or psychological referral;

(j) that he placed unnecessary restrictions on his patient's normal activities of daily living; and

(k) that he, directly or through the company Amican Ecology Inc., inappropriately charged his patient substantial sums for treatments which were either of no value to his patient, or harmful to her.

And it was further alleged that Dr. Krop failed to maintain the records that are required to be kept respecting patients in the Province of Ontario, which is professional misconduct as defined in subsection 29.3 of Ontario Regulation 548, R.R.O., 1990, under the *Health Disciplines Act.*

And it was further alleged that Dr. Krop sold or otherwise supplied drugs or biological preparations to the patients set out above, at a profit, which is a conflict of interest as defined in subsection 31.2 of Ontario Regulation 548, R.R.O. 1990, under the *Health*

Disciplines Act. The particulars of this allegation are that Dr. Krop, through the company Amican Ecology Inc., owned or controlled by him, his wife, or some combination thereof, sold and supplied to the above patients drugs or biological preparations including sublingual drops and injections at a profit.

1. EVIDENCE RELATING TO PATIENTS TREATED BY DR. KROP

Dr. Krop's office records pertaining to six patients were entered in evidence. The following summaries are drawn from these records as well as from notes prepared by Dr. Krop and reviewed in his testimony. They provide details of the clinical issues that form the basis of this case, as well as the diagnostic and treatment aspects of each medical record.

LC

A 31-year-old woman, wife of SO and mother of CO, LC was initially assessed in Dr. Krop's office on April 20, 1989.

LC completed a detailed pre-printed "environmental" questionnaire concerning her past health, family health, symptoms relating to the various body systems, and details of her home/work environment. She also completed a "hidden food sensitivity" questionnaire, relating to foods she habitually ate, including frequencies of ingestion, as well as details of her food likes and dislikes, reactions to foods, vitamin and food supplement use, and drug use and known drug reactions. No reactions to foods or drugs were listed in Dr. Krop’s record.

History taking elicited the main complaint of cracking of fingertip and sublingual skin as well as chronic dry and scaly skin. The patient had a history of contact dermatitis and hives. Physical examination revealed eczema on thighs and ankles.

A variety of laboratory tests were ordered. Elevated levels of IgA and IgM were noted. Sputum was negative for fungus.

The patient underwent sublingual testing, with ethyl alcohol and formaldehyde, as well as food screening on the Vega machine. Dr. Krop stated that Vega testing detected

positive reactions to baker's yeast, brewer's yeast, cane sugar, cheese, chocolate, coffee, milk, orange, peanuts, teas, wheat, honey, and table salt. Intradermal testing (serial dilution end-point titration) showed delayed reactions to TOE (triple fungus antigens), grass I, and grass terpens.

LC was given injectable serum for intradermal desensitization for TOE, mold, grass, and grass terpens. Sublingual drops for ethyl alcohol and formaldehyde were also prescribed.

She was treated with oral Mycostatin and acidophilus, as the following factors led Dr. Krop to consider the presence of candidal infection: a history of contraceptive and antibiotic use, symptoms of periodic constipation and diarrhea, and dry cracking skin. Additional factors were positive skin tests for fungal antigens, symptoms of sinus fullness, dry mouth, stuffy right nostril, burning fingers and elevated levels of IgA and IgM.

Additionally, she was placed on a yeast-free diet, and instructed in an elimination and four-day rotation diets. She was advised on the importance of organic foods and prescribed Vitamin and mineral supplements.

LC's file includes a letter "To whom it may concern" documenting similar testing with Vega and sublingually, of both her husband and her daughter. Treatment, in the form of rotation and elimination diets and sublingual drops was prescribed for these patients, as well.

EJ

This patient was 56 years of age at the time of her first visit to Dr. Krop in 1985. She was treated and followed over a period of six years.

EJ had a number of long-standing problems for which she had seen -- and continued to see -- numerous specialists. She was also followed concurrently by her family doctor.

As a child she had numerous recurring problems with middle ear, nasal, sinus, and chest infections. As an adult she had been diagnosed with bronchiectasis and had undergone a lobectomy at age 31. Recurring respiratory infections over the years were managed with difficulty, in part because of antibiotic intolerance.

Gastrointestinal symptoms dated to her childhood as well. Nausea, bloating, and diarrhea had been attributed to "irritable bowel syndrome". Depression was being treated with amitriptyline.

For Dr. Krop, she completed a "hidden food sensitivity" questionnaire and an Aenvironmental" questionnaire, and underwent a physical examination. Her blood and immunologic lab tests were unremarkable. Vaginal and mouth swabs for candidiasis were negative (Over the ensuing six years, four of eleven oral or vaginal cultures were reported as positive for candida). Abdominal ultrasound was negative but sinus X-rays showed maxillary sinusitis.

Vega testing was recorded as showing sensitivity to 32 of the 41 foods tested. Vega testing was also carried out for organ dysfunction and electromagnetic and geopathic stress. Electromagnetic stress was deemed to be the major problem, with the dominant focus in the colon (particularly the rectal area). Additionally, Vega testing pointed to problems of sinuses, small intestine, teeth, and mercury.

Hair analysis was carried out to determine mineral levels with a view toward prescribing appropriate supplements.

The patient was weaned off amitriptyline, a drug that is commonly used to treat both depression and chronic pain, because Dr. Krop felt that it would interfere with interpretation of the tests. Subsequently, she was tested by the serial dilution end-point titration method and found to be sensitive to a wide variety of antigens, including house dust, household insects, molds, candida, mites, tree I and 11, grass terpens, and ragweed.

Her treatment included a variety of modalities: elimination and four-day rotation diets, preferential use of organic foods and bottled water and for candida-related complex, the first of many courses of antifungal treatments consisting of ketoconazole and/or nystatin powder by inhalation. Dr. Krop considered treatment with oral amphotericin B but this drug was not prescribed. It is not available in Canada.

All three drugs are used to treat various fungal infections. Nystatin is a commonly used treatment for fungal infections of mucous membranes, such as the mouth, throat and vagina. Ketoconazole is used for much more serious fungal infections as is oral amphotericin B. Both ketoconazole and amphotericin B carry risks of drug toxicity, particularly to liver and kidney, respectively.

Later treatments included sublingual drops (for food intolerance), thymus extract (as explained by Dr. Krop, to overcome her poor immune response), and staphylococcal lysate injections (again, to stimulate the immune response). Vaccines were also prepared from the patient's sputum and from the patient's blood, tested by serial dilution end-point titration, and used to treat her recurring infections. Molds grown on Petri dishes placed in the basement of the patient's home were used to prepare specific medication. Finally, as part of the regimen designed to deal with her recurring infections, over five years she received 29 courses of intravenous Vitamin C (on occasion supplemented with calcium and magnesium to deal with muscle spasms and hypocalcemia).

AJK

This young girl was four-and-a-half years of age in 1984, and continued to be treated by Dr. Krop over the ensuing nine years.

Initial health issues involved episodic skin rashes and hives, periodic noisy breathing (described by the mother as "wheezing"), recurrent upper respiratory infections (particularly in the winter), headaches, stomach aches, and a behavioral pattern characterized by poor cooperation, whining and weeping.

Questionnaires to determine "environmental history" and "hidden food sensitivities" were completed, a physical examination was carried out, and blood was obtained for testing. Blood was tested for hemoglobin, thyroid function, thyroid antibodies, folic acid and B12, serum complement, Vitamin A, electrolytes, creatinine, uric acid, and liver function.

The child was tested with sublingual solutions to determine her reaction to a variety of substances, and a number of behavioural changes (such as itchiness, yawning, tiredness, problems with writing) were noted, particularly with weed extracts. She also reacted in a similar fashion to synthetic ethyl alcohol and formaldehyde.

Vega screening for 36 phenolic food compounds is reported to have indicated negative results for only seven. Her mother was instructed in the four-day rotation diet, and Dr. Krop prescribed a program of daily desensitizing oral drops for all the positive phenolic food compounds as well as for candida, housedust, molds, grass and weed extracts, blackfly and mosquito whole body extracts. Drops for synthetic ethyl alcohol and formaldehyde were to be used on an “as needed” basis (drops for perfume and tobacco were added later). This basic program was followed for the next nine years.

One year after the initial consult, Dr. Krop noted brownish discoloration of the patient’s face, and dry and flaky skin, and prescribed a course of the oral antifungal Nystatin. Hair analysis revealed several low mineral levels (with an elevated aluminum); the child was given supplemental magnesium and selenium as well as broad spectrum Vitamin and mineral supplements. When hair analysis was repeated later that year, improvements were noted. About that time she was retreated with Nystatin as toenail fungus had been noted and Dr. Krop reasoned that treatment would reduce the candidal load in the GI tract.

In 1986 the patient reported increasing infections and pain. Dr. Krop prescribed thymus extract (TFX) injections to boost the immune response. He also repeated Vega screening and the patient was found to be sensitive to a majority of 20 food items. Sublingual drop therapy was accordingly adjusted and the rotation diet continued.

In the fall of 1987 nystatin was prescribed for an irritated umbilicus. A year later, it was represcribed because the patient had been using antibiotics. In September 1988, in view of repeated antibiotic treatments, the past toenail and umbilical changes, and irritated skin, a three-week course of ketoconazole was also prescribed. By November, Dr. K. stated, the skin was better and the child was happier and more in control. Liver function tests were done in January 1989 and found to be normal. In the following months the mother, who had her own prescription for ketoconazole, repeated the child's course of that systemic antifungal on her own initiative; Dr. Krop added nystatin to reinforce the effect.

This basic treatment regimen was followed until 1993 when AJK ceased to be a patient.

PL

This 61-year-old man was treated by Dr. Krop from 1991 to 1993. Dr. Krop diagnosed chronic fatigue syndrome related to chronic chemical exposure as part of the “sick building syndrome”.

Initial evaluation included completion of the "hidden food sensitivity" and the "environmental" questionnaires. The patient’s history revealed that his symptoms appeared to date back three years, coincident with a job change to a brand-new building. Symptoms involved virtually all systems, but particularly his eyes, ears, nose, throat, and respiratory tract. He had severe fatigue, cognitive difficulties, and at times flu-like and chronic skin symptoms. He began to lose time at work.

PL had long-standing cardiac disease and was under the care of a cardiologist.

Physical examination revealed eczema and reddened eyes and a red left tympanic membrane.

Vega screening was reported as positive for baker's and brewer's yeast, cane sugar, cheese, chocolate, coffee, milk, orange, peanuts, pork, tea, wheat, shrimp, table salt, food dyes, food preservatives, and monosodium glutamate. Sublingual testing for

chemicals, with the aid of Vega, elicited sensitivity to synthetic ethyl alcohol, formaldehyde, and phenol. Intradermal serial dilution end-point titration elicited sensitivity to a variety of tree, grass, ragweed, and weed extracts, as well as fungal, housedust, mold, household insect, and dog antigens.

Blood analysis was carried out for random cholesterol, immunoglobulins G and A, CRP (all of which were elevated), and Vitamin A, serum complement, hemoglobin, white count and differential, IgE and IgM, sedimentation rate, glucose, triglycerides, BUN, creatinine, uric acid, electrolytes, liver enzymes, thyroid indices, iron and iron binding, Vitamin B12, folic acid, serum cholinesterase, red blood cell and serum magnesium, and urinalysis (all of which were normal). A mouth swab specimen was reported as "2+ candida".

Dr. Krop prescribed allergy shots for indoor and outdoor inhalants and the patient was started on sublingual drops for chemical sensitivity. A trial elimination diet and a four-day rotation diet commenced. PL was instructed in a yeast-free diet and was treated with Mycostatin and Nystatin powder for six weeks, to be combined with acidophilus, evening primrose oil, flax seed oil and Vitamin E. Vitamin C buffered with calcium, magnesium and potassium was recommended, along with hypoallergenic multiVitamins and minerals. Tryptophan was later added to improve sleep.

Apparent sensitivity to the allergy shots was corrected by rechecking serum strengths by means of the Vega machine.

By the time of his last visit PL had decided to retire, was receiving government disability, was feeling better mentally, and was less fatigued.

RM

RM was the only patient whose charts were entered in evidence to appear before the Committee. Dr. X., who saw her as a patient after she left Dr. Krop's care, also gave testimony.

This 41-year-old office worker and mother of two was seen on six occasions over several months in 1990. Her problems included perennial rhinitis, recurrent urinary tract infections, chronic groin pain, chemical sensitivity, antibiotic overuse, mucocutaneous candidiasis and indigestion.

Before she referred the patient to Dr. Krop, her family doctor had prescribed Nystatin, but RM had a reaction to the drug characterized by generalized itching, headache, and breathing difficulty.

Dr. Krop's initial assessment was limited to having the patient complete the "hidden food sensitivity" and "environmental" questionnaires, taking on oral history, doing a physical examination, and conducting laboratory testing. Normal tests included hemoglobin, white blood count and differential, serum iron and iron binding capacity, glucose, BUN, creatinine, electrolytes, liver function tests, T3 and T4, uric acid, C3 and C4, immunoglobulins, Vitamin B12, folic acid, antithyroglobulin and antimicrosomal antibodies, antinuclear antibody, urinalysis, urine culture, and vaginal swab for fungus. Random cholesterol and triglyceride values were slightly elevated, and a mouth swab produced a heavy growth of candida albicans.

Further testing was deferred until RM had been withdrawn from amitriptyline (taken for chronic groin pain) for at least three weeks. Acupuncture was recommended as treatment for the chronic pain.

RM then underwent Vega screening which was reported to have shown that she was sensitive to baker's and brewer's yeast, banana, cane sugar, cheese, chocolate, coffee, corn, milk, peanuts, tea, tomato, wheat, cherries, goat's milk, green pea, honey, strawberries, and table salt. Serial dilution end-point titration revealed that she was sensitive to candida, housedust, insects, mites, mold mix, tree extracts, grass extracts, ragweed, weeds and weed extracts. Sublingual drop testing (with the aid of Vega) was done to assess her reactions to formaldehyde, synthetic ethyl alcohol, and phenol.

Dr. Krop's treatment program emphasized the issue of yeast sensitivity. RM was

advised to pursue a yeast-free diet which included eliminating all fermented products including alcohol and hidden vinegar, sugar, and highly refined carbohydrates. The principles behind the elimination and four-day rotation diets were explained. She was started on ketoconazole (the first of three courses that spring and early summer), and placed on nystatin vaginal tablets and acidophilus, as well as evening primrose oil and Vitamin E.

Finally, she was placed on a regimen of allergy shots, which she continued through her family doctor.

RM testified:

The patient recounted being referred to Dr. Krop by her family physician for "sinusitis and possible yeast infection." Initially, Dr. Krop deferred testing to permit withdrawal from amitriptyline. Later, over two consecutive days, she underwent extensive scratch testing, testing that involved bare feet and a metal rod, and testing that consisted of drops being placed under her tongue. She was then prescribed a number of sera which she took to her family doctor for weekly injections. She purchased a copy of "The Ecology Guide" from Dr. Krop, which she attempted to follow. Dr. Krop recommended supplemental vitamins, which the patient purchased from Amican (a company controlled by Dr. Krop's wife).

A year later RM moved to another community and was referred to Dr. X., an allergist. At this time her original symptoms -- chronic nasal stuffiness and a dry throat -- had not improved and her arm was reacting to the prescribed injections. Dr. X. tested her for several antigens and she was dismayed to learn that she was not, as she had been led to believe by her family physician and confirmed by Dr. Krop, sensitive to Candida.

Dr. William Moote testified:

RM presented with a perennial post-nasal drip. Intradermal “prick” testing was carried out to determine her reactions to house dust mite, ragweed, and candida. She responded with a positive test only to ragweed. Because the histamine control was positive, he did not believe the test results were affected by her concurrent use of

amitriptyline. He also rejected the possibility that the year of desensitizing injections could have converted a previously positive skin test for candida to negative. Even with a favourable therapeutic response, he stated, skin testing remains positive.

He recommended treatment with Beconase nasal spray and referred her for an ENT assessment. Her perennial symptoms, in the face of normal sinus X-rays, could not be explained by ragweed sensitivity alone.

The patient did not return for follow-up.

MM

This 26-year-old cleaner in a printing office, who had emigrated from her native country some four years earlier, was seen by Dr. Krop for several weeks in 1990. Her problems included chronic tiredness, depression, headaches, symptoms suggestive of irritable bowel syndrome, symptoms consistent with allergic rhinitis and conjunctivitis, and hearing difficulties.

"Hidden food sensitivity" and "environmental " questionnaires were completed and a history and physical examination completed. The latter revealed red nostrils and lower abdominal tenderness to palpation.

A panel of laboratory tests was ordered. Normal results were obtained for hematology, white blood count and differential, glucose, uric acid, sodium, potassium, liver function tests, iron and iron binding capacity, T3 and T4, antimicrosomal and thyroglobulin antibodies, CRP, sputum/urine/throat swab for fungus, folic acid, Vitamin A, C3 and C4, immunoglobulins G/A/M, and urinalysis. BUN and creatinine were low, and the serum Vitamin B12 value -although reported as "normal" -- was felt to be low. Cholesterol was mildly elevated. A vaginal swab cultured positive for candida.

Because of cost, only Vega testing was carried out to assess for chemical, food, and inhalant sensitivities. The Vega test is reported as positive for baker's and brewer's yeast, cane sugar, cheese, chocolate, coffee, corn, eggs, milk, orange, potato, tea,

wheat, and table salt. Sensitivity was similarly noted to candida, housedust, mites, household insects, mold, grass extracts, ragweed, and weed extracts. The patient was negative for tree extracts, but positive to synthetic ethyl alcohol, and phenol.

A treatment program -- including sublingual B12, nystatin, acidophilus, Vitamin C, multiVitamins and minerals including calcium and magnesium, evening primrose oil, and Vitamin E -- was recommended but not accepted.

Screening for volatile chemicals led to a determination of 1,1,1-trichloroethane of 7.9 ppb, "six times higher than the population average". This was linked to her workplace -- which clinically appeared to be tied to aggravation of her symptoms -- and it was recommended that she consider seeking other employment and undergoing sauna detoxification treatment.

2. EVIDENCE RELATING TO DIAGNOSTIC AND THERAPEUTIC MODALITIES, AND THE CONCEPTS UNDERLYING THEM, AS EMPLOYED BY DR. KROP

The following were among the witnesses called by the College:
DR. SUSAN TARLO, Staff Physician in the Respiratory Division of the Department of Medicine, The Toronto Hospital and The Gage Research Institute, and Associate Professor of Medicine, The University of Toronto.

DR. JOHN ANDERSON, Head, Division of Allergy and Clinical Immunology, The Henry Ford Hospital, Detroit, and Professor of Pediatrics, Case Western Reserve School of Medicine.

DR. GORDON SUSSMAN, Head, Section of Allergy, Department of Medicine, The Wellesley Hospital, Toronto, and Associate Professor of Medicine, The University of Toronto.

The following were among the witnesses called by the Defence:
DR. ROY FOX, Director of the Environmental Health Clinic in Halifax, Nova Scotia, and

Professor of Medicine at Dalhousie University Faculty of Medicine.

DR. JOHN BOYLES, JR., a Board-certified otolaryngologist from Dayton, Ohio, Assistant Clinical Professor, Wright State Medical School, and Past President of both the American Academy of Environmental Medicine and the American Academy of Otolaryngic Allergy.

DR. DENNIS REMINGTON, a physician engaged in Family Practice and Bariatrics in Provo, Utah, and member of the American Academy of Environmental Medicine.

PROFESSOR WILLIAM TILLER, Professor of Materials Science and Engineering, Stanford University, Stanford, California.

DR. WILLIAM RAE, Director, Environmental Health Center, Dallas, Texas, and Past President of both the Pan American Allergy Society and the American Academy of Environmental Medicine.

DR. JOHN GERRARD, Emeritus Professor of Pediatrics of the University of Saskatchewan.

DR. CHARLES HINSHAW, Board Certified in Pathology, Nuclear Medicine, and Environmental Medicine, in Private Practice of Environmental Medicine, Wichita, Kansas.

DR. FRANCIS WAIKMAN, Former President of the American Academy of Environmental Medicine, Board Certified in Pediatrics, Allergy and Immunology, Quality Assurance and Utilization Review, and Environmental Medicine, in Private Practice in Akron, Ohio.

ANN DAVIDOFF, PhD, Assistant Professor, Johns Hopkins School of Medicine, and certified by the Maryland State Board of Examiners of Psychologists.

DR. JOZEF KROP

Dr. Krop, in his testimony, described the nature and organization of his practice..

Dr. Krop trained in Poland as a pediatrician. After arriving in Canada and obtaining full licensure in the mid-1970's, he practiced family medicine. Since the early 1980's, however, he has confined his practice to what is currently known as Environmental Medicine. His patients are roughly equally divided between adults and children.

Data drawn from the practice of Dr. Rae, which Dr. Krop presented as representative of Environmental Medicine, suggests that while the greater proportion of patients are in their 30's and 40's, children and elderly are also represented. Symptoms commonly date from childhood and adolescence. At least a quarter of patients are home-makers and professionals are possibly over-represented. Virtually all patients have seen at least five physicians before the first visit, and at least a third have seen ten or more.

Over half of Dr. Rae's new patients present with headache and fatigue, and the following complaints are each found at least 25% of the time: confusion, depression, exertional shortness of breath, arthralgia and myalgia. Nausea, dizziness, memory difficulties, and gastrointestinal and respiratory symptoms are found in lesser numbers.

Dr. Krop elaborated on the theory underlying much of his practice, which he described as the concept of "total body load." This consists of the sum total of influences on the individual, and includes such factors as temperature, weather, positive ions, electromagnetic fields, and toxic chemicals, both organic and inorganic. Biologic factors such as bacteria, viruses and fungi, foods, and genetic, nutritional, psychological and emotional factors also play a part. In Dr. Krop's opinion, health status is influenced by "total body load". Therefore, diagnosis is directed toward assessing the load and treatment directed toward restructuring it.

In Dr. Krop's practice, typically, when a patient requests an appointment, he or she is given an information package. This includes an explanation of environmental medicine, Dr. Krop's office policies, consent forms, a list of charges, and a questionnaire dealing

with health, past history, known allergies and food preferences. On the first visit, the medical history is reviewed, a physical examination is performed, and blood tests are carried out. Allergy prick tests are done, if indicated. Often, but not invariably, a food screen using the Vega machine is completed.

Another of the techniques Dr. Krop uses, provocation/neutralization testing, is deferred to a subsequent visit and is carried out by a trained staff member. Counselling in environmental control and diet therapy is also provided by trained staff. If injection or sublingual therapy is recommended, patients are offered the opportunity to purchase these through a company controlled by Dr. Krop's wife. Dr. Krop described this as a form of "fee splitting", which offered a tax advantage and was set up on the advice of his accountant.

EVIDENCE RELATING TO DR. KROP'S CARE OF THE SIX PATIENTS

Central to the College's case against Dr. Krop is the allegation that certain of diagnostic and therapeutic methods used by Dr. Krop in his care and treatment of these six patients do not meet the standard of practice. As a result, the Committee heard, and carefully weighed, the evidence of each witness with a view toward determining the merit of the allegations. In these reasons, the testimony from the various witnesses is grouped under headings relating to the issues raised in the Notice of Hearing.

Defence counsel questioned the competence of the College's experts to testify as to the standard of practice by which Dr. Krop should be judged. Two main reasons were advanced -- Dr. Krop was not an allergist-immunologist and the conditions he was treating were not IgE-mediated.

The Committee observed that Dr. Krop did in fact diagnose IgE-mediated inhalant allergies, through serial end-point dilution titration. He treated these in a fashion similar to allergists such as Drs. Tarlo and Sussman, albeit with controversial low-dose immunotherapy. He also applied the language of allergy-immunology to, for example, the theoretical basis of such concepts as "candida-related complex" and used "immune

deficiency” as a rationale for employing such treatment as “thymus extract”, “staph lysate”, and vaccines derived from serum and sputum extracts. Many of the articles tendered by the defence used the terminology of allergy-immunology.

These experts were also qualified, as medical scientists familiar with the methods of critical review, to assess the relevant scientific literature. The Committee does not accept suggestions by defence counsel that these individuals were physicians who brought to their assessment a prior bias against Dr. Krop and his methods, or that their professional associations with others involved in the early stages of the investigation, with pharmaceutical companies, or with the Workman’s Compensation Board somehow impaired their ability to give their evidence objectively.

In testifying on the scientific validity of Dr. Krop's approach to caring for these six patients, these experts for the College were found by the Committee to be even-handed. They acknowledged the changing nature of medical science and, when faced with information that appeared to contradict a position they had taken, conceded that much more remained to be determined in the field of allergy and immunology.

The Committee concluded that the College’s experts, in particular because of their special knowledge in the field of allergies and immunology,were qualified to testify whether or not Dr. Krop met the standard of practice.

The Committee found the assistance provided by the experts testifying on Dr. Krop's behalf to be of variable utility. They frequently differed in their application of the diagnostic and therapeutic methods that were the focus of this hearing, and in several key areas -- notably the use of the Vega machine -- with a single exception, their practice differed significantly from Dr. Krop.

The two defence witnesses that the Committee found to be most credible were unable to comment on the specific issues under consideration. Dr. Tiller demonstrated in his testimony an exuberant, inquiring mind, but was unable to testify on the scientific basis of the electrodiagnostic apparatus used by Dr. Krop. Dr. Davidoff testified on the

epidemiologic evidence for the phenomenon of Multiple Chemical Sensitivity Syndrome, but knew of no means to either test for it or treat it.

The Committee appreciated the candour of a third witness, Dr. Fox. At his Environmental Health Unit in Halifax, he is attempting to apply contemporary medical scientific methodology to the study of many of the concerns raised in this hearing. His assessment of the strengths and weaknesses of the evidence regarding much of what Dr. Krop did with these patients seemed to the Committee reasoned and, for the most part, balanced.

In the Committee's view, Dr. Remington was an unabashed enthusiast for electrodiagnosis. The Committee did not find his anecdotal experience, or his enthusiasm, an adequate substitute for scientific evidence.

Drs. Rae, Boyles, Hinshaw, Waikman, and Gerrard demonstrated in their testimony just how much, in a number of key areas which will be discussed, their individual practices differ from Dr. Krop. However, like Dr. Krop, they are prominent figures in the field of "Environmental Medicine." In those areas they share with Dr. Krop, they were sincere, articulate advocates, although their sincerity was seldom supported by the scientific evidence that the Committee sought. It was obvious these individuals view themselves as being under attack by the "medical establishment". The Committee concluded that much of their testimony in support of Dr. Krop was coloured by this belief.

Because the scientific evidence supporting Dr. Krop's approach to these six patients is so important in determining the issues before the Committee, it carefully reviewed and assessed the more than one hundred exhibits entered. The majority of these did not appear directly applicable to the issues raised in this hearing. Many were only tangentially related to Dr. Krop's practice. Virtually all studies involving human subjects lacked the basic, essential methodology that characterizes meaningful research.

Dr. Anderson, in the Committee’s view, effectively described those features that characterize a scientifically valid study (exhibit #29).

C The hypothesis to be tested should be clearly stated and the methodology described in such a way that the work can be repeated by subsequent investigators.

C The trial should concern a homogeneous group of patients with the disorder to be studied, who are otherwise well, if necessary determining by a controlled, double-blind placebo challenge prior to study entry that the individual does indeed exhibit an adverse effect resulting from a specific disorder.

C The subjects should be described in sufficient detail that similar patients could be found by subsequent investigators. The study and control groups should be of sufficient numbers so that statistically significant results can be obtained. The study subjects should be divided into groups of equal size and assigned to either a test or a control group by random selection.

C Evaluation of results of this should be as objective as possible, with appropriate statistical methods chosen at the commencement of the study and used throughout.

C Informed patient consent is required, and the safety and scientific merit of the trial should be evaluated and approved by institutional review prior to the start of the trial.

C The results of the trial should be published in a peer reviewed (refereed) journal of established merit.

The few studies which the Committee believes meet these criteria and which are particularly relevant will be referred to in this decision. Others, equally carefully reviewed but not in the Committee's view germane, will not be mentioned.

(1) Electrodiagnostic testing utilizing the Vega machine

To quote Dr. Krop's "The Ecology Guide", on the Vega Machine: "This testing technique is based upon bioenergetic regulatory theory. The patient holds one electrode which is connected to the Vega machine. A second electrode is applied to the patient's toe (a connective tissue acupuncture point). In this fashion the machine and the patient become part of one electromagnetic circuit. When a dilution of an antigen extract is placed on the machine, any change in electric skin resistance is registered, both visually

and audibly. Using this technique any antigen can be tested and neutralizing doses discovered. Results are confirmed by placing drops of the identified dilution under the tongue. The Vega machine is time efficient and exposes the patient's body to less stress."

Dr.Krop testified that the Vega test procedure was particularly useful for very sensitive individuals, infants, and uncooperative patients. It can sometimes be used for testing sensitivity to substances other than food. It can also be used for:

- determining biologic age (as opposed to chronologic age),
- detecting specific organ damage (using, for example, a homeopathic dilution of the right or left kidney of a cow or pig to detect dysfunction of a patient's right or left kidney),
- assessing the presence of geopathic stress in an individual (induced by such factors as mineral deposits, underground rivers, and tectonic pressure), and,
- testing for cysts in various body organs, and assessing suspected psychic stress.

For the College:

Dr. Tarlo was clear in her opinion that Vega testing has no scientific basis and Dr. Krop's use of the machine does not meet an accepted standard of practice in Ontario. She stated that she based this opinion on both her review of the literature and on a computer search of the database of the National Institutes of Health in Bethesda Maryland.

Dr. Sussman indicated that the Vega was unscientific, inappropriate, unproven, and constitutes an unacceptable standard of medical practice.

Dr. Anderson referred to Dr. Krop's 1985 paper in the American Journal of Acupuncture (vol 13, no 3) in which intradermal and sublingual testing responses to a variety of food, inhalant, and chemical allergens were compared to those elicited by Vega testing. He stated that none of the individuals tested was ever convincingly shown to be sensitive to the substances tested. Lacking a "gold standard", two controversial unproven

techniques were being compared. In his opinion, Vega testing is an unproved procedure based on unscientific principles.

For the Defence:

Dr. Fox indicated that he did not use Vega testing. Further, if patients brought him results of prior testing with the Vega machine, he did not rely on these. He was not satisfied that such testing had been adequately validated although it is extensively used in Europe. In his opinion, a diagnosis of, for instance, "geopathic stress" based on Vega testing could only be a working diagnosis and a diagnosis of exclusion.

Dr. Boyles stated he did not use electrodermal testing, does not recommend it, and had no knowledge of its use as a screening instrument. He indicated that some practitioners thought Vega worked, but in his opinion there was not enough science to support its use. He noted that electrodermal (Vega) testing is not covered in courses sponsored by the American Academy of Environmental Medicine.

Dr. Remington was the only witness for the defence, other than Dr. Krop, who relied on Vega testing. He stated that he became "sold" on electrodermal testing on the basis of "one amazing demonstration." Although he uses a different apparatus from that used by Dr. Krop, he said that all such machines were based on the same basic principles. He emphasized the value of electrodermal testing as a "screen" for a wide variety of inhalant, food, and chemical sensitivities. However, he did concede, as he wrote in a 1990 submission to the Utah State Medical Association joint Committee on Unproven Health Practices, that "since there is no reliable standard by which to compare electrodermal testing, at the present time there is no reliable way to assess its accuracy." He indicated that the Utah Committee was most interested in his consent form, and approved his use of electrodermal testing, as long as patients were informed that the technique was experimental and unproven. He agreed that none of the three major organizations in the field of environmental medicine have approved electrodermal testing.

Asked to comment on the protocol outlined in the Vega test booklet, Dr. Remington

agreed that test accuracy was dependent on the operator's ability to concentrate on the test, particularly in their ability to apply the precisely appropriate level of pressure. Commenting further on the booklet's statement on Vega testing for "psychic" and "geopathic" stress, he said he did not test for these factors. As for using Vega to detect premalignant and malignant states, he said "I'd have to see the proof on that one."

Professor Tiller described his interest in the field he termed "psychoenergetics" and in particular the development of instruments to detect and study energy fields in nature. His interest has led him to investigate electrodiagnostic instruments similar to the Vega, and to conclude that there is some beginning experimental support for, and a possible theoretical model to explain, connectivity between the organs and specific acupuncture points. He was optimistic that new and more effective devices will appear during the next decade and that such devices could significantly reduce health care costs.

Dr. Rae stated that he uses electrodiagnostic testing in a small minority of his patients and does not charge for such testing. Because the Vega can produce both false positive and false negative results, in his opinion its findings require confirmation with more specific testing such as rotary diet, provocation/neutralization, or sublingual drops. Implying that the Vega was of very limited value, he stated that as a screening tool it was about as useful as a sedimentation rate or a CRP test.

Dr. Gerrard testified that although he does not use the Vega machine, it appears to be effective in Dr. Krop's hands. He cited Dr. Krop's use of the Vega to determine that sauna therapy was appropriate for a patient with intractable steroid-dependent asthma. "How he does it I don't know," he commented.

Dr. Hinshaw stated that he had been a member of the Peer Review Committee of the American Academy of Environmental Medicine (AAEM) that reviewed Dr. Krop's practice and examined the charts of the same patients introduced in evidence before this Committee. He stated that the AAEM neither supports nor condemns the use of the Vega test system. However, Vega testing is not included in the practice guidelines of the AAEM. He testified that for the Vega test system to be generally accepted "it will

take some more double blind studies and involvement of people from other disciplines who will agree with what is being done."

Dr. Waikman stated he does not do Vega testing, that testing is very operator dependent, and that he was not prepared to put in the time to become an expert in that modality.

THE COMMITTEE FINDS that there is no scientifically-valid evidence to justify the use of the Vega electrodiagnostic apparatus, or any other similar machine, as either a screening or a diagnostic tool. All the experts called by the College agreed on this; none of the experts called by the defence maintained that such evidence existed.

The Committee notes that Vega testing was central to Dr. Krop's diagnostic approach in each of the six patients under review. He relied upon it, to a significant degree, sometimes exclusively, in designing, and often subsequently modifying, the treatments he prescribed. In so doing, the Committee finds Dr. Krop to have failed to meet the standard of practice.

(2) Aprovocation/neutralization" testing for food and chemical sensitivity (including oral immunotherapy)

From the testimony of witnesses, and from documents entered in evidence, the following is viewed by the Committee as an appropriate definition of the technique:

Patients are tested with a variety of substances suspected of causing ill health. These may include inhalants, foods, chemicals, microbiological preparations, and hormones. Testing is done, usually sublingually but on occasion intradermally, in progressively dilute form. When testing is done sublingually, the drops of extract are held in the mouth for 30 seconds, then swallowed. Patients are questioned for symptoms "provoked" by each test substance and they may keep a diary of symptoms. Changes in various body functions such as pulse rate may be monitored. If intradermal testing is done, wheal size is noted. When changes are elicited weaker dilutions of the "provoking" agent are used to discover the Aneutralizing" dose (that strength which fails

to elicit signs or symptoms). The neutralizing dose is then given as long-term regular therapy, usually in the form of sublingual drops.

Dr. Krop indicated that he used provocation/neutralization testing and usually did so sublingually when testing for chemical sensitivity, such as SEA, phenol, chlorine and formaldahyde. In part he used the technique to demonstrate to the patient that the substance was causing the symptoms. If a patient is convinced that a specific food is a problem, he also tests that substance sublingually.

According to Dr. Krop, provocation/neutralization can also be used to test for inhalants. For instance, wood smoke sensitivity may be successfully determined, usually intradermally or subcutaneously. The patient is then given a bottle of drops to use whenever wood smoke exposure recurs.

Patients who are unable to stay on the rotary diet, or who have a large number of food allergies, are given sublingual or injectable treatment. Patients with a history of anaphylaxis or asthma are not allowed to self-inject, but other patients are taught the technique. Injection treatment may be based on testing by serial dilution end-point titration or provocation/neutralization. Injection therapy is attended with no serious difficulties. Dr. Krop noted that Dr. Rae's Dallas centre has supervised over ten million courses of treatment without a fatality.

For the College:

Dr. Tarlo, in her written opinion, cited a recent (1995) statement from the Royal College of Physicians and the Royal College of Pathologists of England (Clin and Exp Allergy 1995, vol. 25, pp 586-595) indicating that provocation/neutralization (also known as the "Miller technique") is of no proven value as a testing technique and therapy. She referred to a 1990 double-blind study by Jewett et al, published in the New England Journal of Medicine (exhibit #46a) which concluded the technique lacked scientific validity. On cross-examination she conceded that studies supporting the efficacy of sublingual desensitization had been done, but stated that more studies with larger numbers of patients would be required to determine the validity of the approach. She

agreed no studies existed that implied the technique was harmful.

Dr. Sussman expressed concern that intradermal provocative testing with food antigens might trigger anaphylaxis, since an individual is truly sensitive to a particular food, any amount of that substance is capable of causing a potentially fatal reaction.

Dr. Anderson indicated that provocation/neutralization is commonly employed by physicians practicing clinical ecology as a means of confirming and treating "environmentally-related illness". He stated that a positive test depends upon purely subjective phenomena. He added that when the scientific evidence supporting this modality has been evaluated objectively by a number of professional bodies (The American Medical Association, The American Academy of Allergy, Asthma, and Immunology, The American College of Physicians, The State of California Medical Association, and the Ad Hoc Committee on Environmental Hypersensitivity in Ontario), this modality has been found to be unproven and experimental.

Dr. Anderson added that until such time as such techniques have been proven as clinically efficacious, they should not be routinely promoted and used in clinical practice outside of properly conducted and controlled clinical trials which have been approved by institutional human rights committees.

Dr. Anderson opined that, while there were few reports of adverse reactions arising from provocation/neutralization, the potential for an anaphylactic reaction in a truly allergic patient is always present. Anaphylaxis, he said, is not dose-dependent.

Dr. Anderson was of the opinion that the safety of multiple exposures to biologic agents such as bacterial or viral vaccines, hormones or chemicals, as may be used in provocation/neutralization, had not been established. He stated that the obligation lies with those introducing any new test, procedure, or treatment to prove in appropriately reproducible, controlled, peer-reviewed trials that the test/treatment is efficacious.

On cross-examination, he was questioned on a number of studies which, it was stated,

were double-blind, placebo-controlled and which apparently supported the technique of provocation/neutralization. Dr. Anderson agreed that these studies existed, but he expressed concern with their methodology, their lack of reproducibility, or the journal in which they were published. He contrasted this with the 1990 study by Jewett et al (exhibit # 46a), published in the New England Journal of Medicine. This double-blind study was conducted according to the clinical ecology guidelines of the day, and failed to support the provocation technique as a means of assessing food sensitivity.

Dr. Anderson also discussed several studies which, he said, clarified the issue of "Pseudo Food Allergy". “Pseudo food allergy” refers to the belief by some patients that food allergy is the cause of their various troublesome symptoms, where subsequent careful scientific investigation is able to disprove this belief. These included (1) a National Institutes of Health consensus panel on the lack of influence of food coloring on attention-deficit disorder, (2) a study of patients with a wide variety of somatic symptoms believed due to food allergy who, in a double-blind placebo-controlled investigation were shown not to be reacting to the putative offending foods, (3) a careful review of 50 patients, allegedly disabled by food and chemical exposure, which failed to establish either common clinical features or common testing outcomes (either traditional or unproven) that would help to distinguish them from a group of normal individuals, (in this review, there was no evidence supporting the contention that interventions by the treating clinical ecologists affected the patients' presenting signs and symptoms), and (4) the Jewett study (referred to above) which was carried out in a double-blind, placebo-controlled fashion.

For the Defence:

Dr. Waikman discussed the technique and indicated that a positive response to a test substance may take a variety of forms -- drowsiness, muscle weakness, flushing of the ears, abdominal symptoms such as vomiting, diarrhea, and cramps, middle ear pain, high fever, and transient impairment of mental acuity. Once a "neutralizing" dose is established through testing, it is administered -- three drops daily, sublingually (some therapists use a subcutaneous route) -- until the patient has been symptom-free for two to three months. A slow weaning protocol is then pursued over the subsequent months.

He discussed a number of recent publications (exhibits #81-89, 91-94) which demonstrated the efficacy of oral immunotherapy. In these studies, patients with hay fever, rhinitis, conjunctivitis, and asthma who had been diagnosed on the basis of both symptoms and conventional prick testing were treated with oral preparations of the offending agent -- pollen in all instances except one where sensitivity to house dust mite was demonstrated. In most, treatment consisted of increasing concentrations of antigens, swallowed with or without protective enteric coating. In some, therapy consisted of sublingual drops taken in increasing volume with time.

Dr. Boyles testified that provocation/neutralization is extremely safe and has been shown to be efficacious in 14 double-blind studies. It is used primarily to determine sensitivity to foods and chemicals. Foods not in the diet are not tested, nor are foods to which it is known the patient has a severe reaction. In his opinion, approximately 15 food extracts need to be tested (Dr. Boyles testified that he tests the "basic six": sugar, milk, wheat, yeast, soy and egg.) Common food sensitivities include sugar (primarily corn sugar in North America, although in France beet sugar is a common offender). Salt is rarely a problem. He noted that sublingual testing and observation of the symptoms provoked is not as reliable as intradermal testing. Once sensitivity to a specific food is identified, eliminating that food from the diet is the best treatment. Occasionally, however, Dr. Boyles uses sublingual desensitization. Dr. Boyles noted that chemical allergy testing is much less precise testing than testing for food sensitivity. He tests sublingually for petrochemical alcohol, formaldehyde, phenol, glycerin, and chlorine, as well as any chemicals suggested by history.

Dr. Boyles cited a 1988 study in which he had participated (exhibits #46b&c) as evidence for the efficacy of intracutaneous provocation/subcutaneous neutralization to "food allergies." He also provided 1981 and 1979 studies (exhibits #49&50) to support the contention that food allergy can provoke psychic and behavioural phenomena. Other papers from 1983 & 1984 (exhibits #51&53) addressed the effectiveness of neutralization therapy in food reactions and in animal antigen-induced asthma, and one from 1987 (exhibit #46g) discussed the successful treatment of a horse with heaves.

Dr. Boyles testified that food allergy, is complex. It may be "fixed" (occurring each time the food is eaten) or "cyclic" (where increased intake leads to increasing sensitivity, and avoidance leads to tolerance), and the patient's history is often misleading. "Food addiction" refers to the phenomenon where a given food stimulates a mental "high" but also provokes a physical "low", manifested by such symptoms as headache or rhinitis. Memory of the stimulatory phase encourages the patient to seek out the food more frequently, which, in turn, leads to continuous symptoms, and the "masking" of the underlying sensitivity. Withdrawal from the offending food may, in turn, lead to withdrawal symptoms. However, prolonged withdrawal leads to a gradual loss of the allergy, and usually after several months the food can be reintroduced, providing it is not eaten more frequently than once in four days. In his opinion, a rotational, diversified diet leads to tolerance.

Dr. Boyles stated that the conventional allergists' recommendation of double-blind placebo-controlled food challenge test is totally impracticable and cannot be used on a clinical basis. Moreover, in his opinion, elimination diets are complicated, difficult to use, and do not accurately diagnose the food sensitive patient. He stated that the diagnostic and treatment protocols of intradermal provocation/neutralization testing and sublingual neutralization therapy have been approved and advocated by the American Academy of Otolaryngologic Allergy, the American Academy of Environmental Medicine, and the Pan American Allergy Society.

On cross-examination, Dr. Boyles criticized the Jewett study and stated that it was published for political reasons. He agreed that the study was funded by the group of otolaryngologic allergists of which he is a leading figure, but noted that his group subsequently fired their research director and repudiated the study. He stated that the protocol from the study did not reflect the protocol used by clinical ecologists.

Dr. Rae stated that there was no onus to provide a scientific basis for a treatment and noted the difficulties in carrying out double-blind studies for dietary intolerances. Nevertheless, he stated that provocation/neutralization techniques had been proved by

more than 20 double-blind studies. He disagreed totally with the 1992 American Medical Association position paper which criticized these diagnostic techniques, because it was written by allergists.

Dr. Gerrard indicated that, while food allergy was a common cause of a wide variety of problems, his approach to diagnosis was the educated guess. At one time he did use provocation/neutralization (and serial dilution end-point titration), but he has not used these techniques for over a decade. He was a member of the Ontario Ad Hoc Committee on Environmental Hypersensitivity that produced the "Thomson Report". On cross-examination he agreed that the report concluded that both these techniques were unproven and that he had signed the document. He agreed he would not have done so if he had concerns about its conclusions.

Dr. Fox stated that provocation/neutralization is an accepted form of testing in environmental medicine and that the only paper allegedly disproving the technique, the 1990 Jewett paper, was fundamentally flawed in its design. He felt there were sufficient scientific studies to validate the technique. The evidence was stronger in the case of foods and weaker in the case of chemicals. He cited the same series of papers as Dr. Boyles. He uses provocation/neutralization in his practice, but agreed that there was a certain amount of subjectivity in interpreting test results.

THE COMMITTEE FINDS that despite the contrary assertion by defence witnesses, there is no scientifically acceptable support for provocation/neutralization as a testing/treatment technique. The Committee concurs with the conclusion reached by the Ad Hoc Committee on Environmental Hypersensitivity Disorders ("The Thomson Committee") that the primary difficulty with the sublingual test procedures is its reliance upon an exclusively subjective end-point. The 1990 study by Jewett et al, published in the New England Journal of Medicine, concluded that "...this type of testing, as well as the treatments based on "neutralizing" such reactions, appears to lack scientific validity." No evidence that the Committee accepted as worthy of equal weight, including those studies cited by Dr. Boyles, was introduced to refute this conclusion.

A number of studies were cited in defence of "neutralization" as a means of desensitizing patients to substances determined by "provocation". Most did not meet the definition of a scientifically acceptable study (as outlined in exhibit #29 and referred to previously). Those that were methodologically acceptable (for example, exhibits # 81-89 and 91-94) were not germane to the technique of sublingual “neutralization” as practised by Dr. Krop. These scientifically valid studies dealt only with certain inhalants known to stimulate IgE mediated hypersensitivity. Their results cannot be extrapolated to the treatment of alleged food, chemical, or biological product sensitivity.

Dr. Krop used the "provocation" component of the procedure in all but one of the six patients under review, although he modified the technique to include Vega testing. Instead of, or in addition to, monitoring a variety of behavioural and physiological changes, in several patients Dr. Krop considered the Vega test responses "provoked" by sublingual drops.

Dr. Fox=s undoubtedly sincere belief notwithstanding, the Committee received no evidence that it found capable of validating either the use of the sublingual provocation technique or sublingual drop "neutralization", employed by Dr. Krop. In employing provocation/neutralization, Dr. Krop failed to maintain the standard of practice.

(3) "serial dilution end-point titration"

This procedure, also known as "The Rinkel Method", is said to identify the dilution of a specific inhalant antigen that is safe and effective in initiating desensitization. Sequential intradermal injections of increasingly strong dilutions of the test serum are carried out and the diameter of the resulting skin wheal is measured. Generally the dilution that first causes a skin wheal 2 mm larger than that caused by the previous dilutions, and 2 mm smaller than the next stronger dilution, is used to treat sensitivity to that particular antigen by means of a weekly series of injections of increasingly larger volumes. However, some practitioners choose the dilution that just fails to elicit a skin response.

For the College

Dr. Tarlo indicated, while skin testing for inhalant sensitivity is a proven technique, there is no scientific support for skin testing for sensitivity to viruses, bacteria, chemicals and foods. She further stated that intradermal testing for inhalant sensitivity, while more sensitive, was less specific. It correlated with the patient's clinical status less well than prick testing. In her opinion, prick testing is also safer than intradermal testing.

Dr. Sussman testified that intradermal testing with a food runs a real risk of anaphylaxis. He was also concerned that in the case of RM, Dr. Krop encouraged the patient to self-inject the treatment antigens. Reviewing a more recent (1996) study on low-dose immunotherapy in perennial allergic rhinitis (exhibit #41) he conceded that it appeared to be a well-designed study, and that the results supported low-dose therapy. However, in his opinion the issue required further study.

Dr. Anderson stated that, for the confirmation of IgE-mediated allergy, serial dilution end point titration was not controversial. However, treatment based on the "end-point" concentration -- which he characterized as "low dose" immunotherapy -- has been shown to be no more effective clinically than placebo therapy. Only when "end-point" doses are increased upward do results of treatment begin to approach those of conventional high-dose immunotherapy.

For the Defence

Dr. Fox testified that in his practice he uses serial dilution end-point titration to determine inhalant sensitivity. Once a neutralizing dose is determined, patients are encouraged to self-inject that dose, although some patients utilize sublingual treatment. Many patients cannot tolerate conventional "build-up" immunotherapy, and some cannot tolerate even "low-dose" treatment. He stated that low-dose immunotherapy is efficacious in some people, but the difficulty with the procedure lay in determining who would benefit.

Dr. Boyles and Dr. Rae both testified that they use serial dilution end-point titration to diagnose and treat inhalant sensitivity.

Dr. Gerrard cited his 1989 article, (exhibit #73) published in Clinical Ecology during his editorship, as evidence of the effectiveness of low-dose immunotherapy in the treatment of asthma and allergic rhinitis. His treating dose was the first strength that did not elicit a positive skin reaction. On cross-examination he agreed that in his study the numbers were small. Nine of the 40 eligible patients apparently did not require immunotherapy. He also agreed that the use of symptom scores and inclusion of patients with varying sensitivities to a number of different antigens was probably a mistake.

Dr. Waikman emphasized the safety of the technique, both diagnostically and therapeutically, in inhalant sensitivity.

THE COMMITTEE FINDS that, for the purposes of determining IgE-mediated allergy to inhalants, serial end-point titration has a solid scientific basis. This is qualified by the recognition that while the method used by Dr. Krop, intradermal testing, is more sensitive than "prick" testing, it is also less specific. In other words, the procedure as practised by Dr. Krop will result in a greater number of "falsely positive" patients. Consequently, such "false positives" may receive unnecessary treatment. This may well be the explanation for the difference in skin testing results between Dr. Krop and Dr. X., in the case of RM.

Two patients, RM and EJ, were also tested intradermally for candida, and subsequently were treated for "Candida-Related Complex". The Committee heard no reliable evidence that a positive skin test for candida supports such a diagnosis and the treatment that flows from it. The Committee finds that the use of serial dilution end-point titration to diagnose non-inhalant sensitivity and, specifically the "candida-related complex", lacks valid scientific support.

The issue of the effectiveness of low-dose immunotherapy for inhalant sensitivity, based upon the results of such skin testing, is not clear. The Committee accepts that there is

at least one apparently valid study supporting low-dose immunotherapy in inhalant allergy but concludes that more study is required.

Because this single study does raise the possibility that future research will confirm the effectiveness of the technique, the Committee does not find that low-dose oral immunotherapy for inhalant allergy is totally without scientific support.

(4) Topical and/or Systemic Treatment for "Candida Related Complex" or "Candida Hypersensitivity Syndrome"

To paraphrase the "Ecology Guide", an overgrowth of candida albicans, an organism which is commonly present in the intestine and vagina of normal individuals, results in candida entering the tissues and blood stream. Toxins that weaken the immune system are produced. Further growth of the yeast is thereby facilitated.

Symptoms such as fatigue, headache, depression, irritability, memory loss, constipation, hives/itching, skin problems, diarrhea, abdominal pain, bloating/gas, decreased sex drive, muscle/joint pain, "spacey" feeling, numbness/tingling, nasal congestion, and athlete's foot may result from an overgrowth of candida. In women, vaginitis, pelvic pain, crying spells, PMS, menstrual problems, and infertility are potential symptoms of candida related complex. Men may suffer prostatitis, impotence, and jock itch.

Diagnosis is made from the patient's history, a yeast culture taken from the vagina, mouth, and sputum, and by allergy testing with Candida extract. Treatment may include a yeast-free diet, antifungal medication, garlic, lactobacillus acidophilus, linseed and primrose oils, nutritional supplements, candida immunotherapy, and lifestyle changes.

Dr. Krop indicated that he does not rely only on positive candida cultures to make a diagnosis of candida-related complex. Although he takes swabs for culture, he also bases a diagnosis on the history of typical symptoms. These include recurrent infections with repeated courses of antibiotics, typical lesions in the mouth, rectum, vagina and skin, intradermal testing for an immediate response, tests for IgM antibodies and

elevated levels of immune complexes. On occasion the proof is indirect, in the form of a favourable response to therapy -- diet, antifungal chemicals, lactobacillus, and specific immunotherapy with candida antigen. Given the opportunity to review the 1990 New England Journal of Medicine article (exhibit #131) which called into question the syndrome and its treatment, he was critical of its patient selection criteria and the use of starch as a placebo since, he stated, starch is antifungal. He also noted that the study was confined to the use of nystatin, and failed to include the additional treatment modalities he employs.

For the College:

Dr. Tarlo, in her written opinion, stated that systemic candidiasis occurs very rarely and only in markedly immunosuppressed patients. In her opinion, there was nothing in the charts she reviewed to support a diagnosis of systemic candidiasis and, therefore, no indication to employ antifungal therapy. Specifically, while vaginal candidiasis is appropriately treated with topical antifungals, such as Nystatin, the finding of candida on a throat swab from an asymptomatic patient is not uncommon and certainly does not justify such topical treatment. According to Dr. Tarlo, the use of systemic antifungals in the patients in question cannot be justified and does not meet the standard of practice in Ontario.

Dr. Tarlo cited a study which showed that patients allegedly suffering from the syndrome of "candida hypersensitivity" had been subjected to a randomized, double-blind trial of nystatin (an oral antifungal agent) and had no reduction in systemic or psychological symptoms greater than placebo. (NEJM 1990; 323, 1717-1723) (exhibit #131).

Dr. Sussman expressed concern regarding the use of systemic antifungal agents, citing in particular potential hepatotoxicity. He was particularly concerned in relation to the treatment of the child, AJK.

Dr. Anderson stated that the routine use of antifungal agents, nutritional supplements, and dietary manipulations based on the assumption of exposure to infection by candida albicans is unnecessary and wasteful.

For the Defence:

Dr. Boyles, in his written report, stated that "the theory of active mold infection or an excess of Candida albicans in the gut producing clinical symptoms is controversial and unproven. Antidotal (sic) evidence in thousands of patients, however, reveal that these problems do exist and do respond to treatment." On cross-examination he asserted that the use of the topical agent, nystatin, was harmless, and that a systemic antifungal such as ketoconazole (Nizoral) could be used even in a child, although the dose would be reduced, short-term use would be preferable, and careful monitoring for liver toxicity would be important. In response to a further question, he indicated he was not sure candidiasis is a valid syndrome. In reference to Dr. Krop's treatment of the young girl AJK, he said that he would not have treated her with a systemic antifungal agent.

Dr. Rae stated that Candida sensitivity was "well-known" in medicine, and that the treatment of AJK with systemic antifungals was justified on the basis of her fungal toe-nail infection.

Dr. Gerrard was cross-examined on the "Thomson Committee Report" which concluded that the candida syndrome was unproven and that systemic treatment based on an unproven theory of causation involved possibly serious side effects. He testified that his experience had led him to conclude that many people are sensitive to candida and to yeast in foods. They may require a yeast-free diet or long term treatment with nystatin. He indicated that double-blind studies cannot be done in this area.

Dr. Waikman, in his written report, stated that there is a great controversy over the diagnosis of what he termed the "candida related complex." He added that "...this is a difficult diagnosis but when one gets an appropriate history this kind of patient can be treated and there can be improvement of signs and/or symptoms of the candida caused signs/symptoms as well as atopic symptoms. Cultures are not that helpful. Therefore, it

has been our practice within the past 10 years not to obtain cultures… however, if one does get a culture and has a heavy overgrowth, this gives circumstantial evidence." Later, he commented that A... I do believe that this (is) a entity and I'll accept the fact that more studies need to be done. However, one must question this diagnosis by clinical suspicion only because there is no satisfactory test to make the diagnosis at this point in time."

THE COMMITTEE FINDS that the "candida related complex" or "candida hypersensitivity syndrome" (as opposed to the syndrome of systemic candidiasis seen in severely immunocompromised individuals) is an unproven hypothesis. This is clear not only from the evidence of the College experts; defence witnesses, while expressing their belief in such an entity, failed to cite scientifically valid evidence to support their position.

The Committee is concerned this diagnosis was applied to patients EJ, LC, AJK, RM, and MM, and as a result they were subjected to dietary manipulation, "immunotherapy", and treatment with topical antifungal agents. While Nystatin may cause problems that are relatively minor (such as hives and facial swelling (exhibit #38b), ketoconazole may cause fatal liver damage (exhibit #38a). The Compendium of Pharmaceuticals and Specialties (CPS), published by the Canadian Pharmaceutical Association, recommends it be used only in serious or life-threatening systemic fungal infections or where severe skin fungal infection has not responded to the usual therapy. Dr. Krop prescribed this potentially hazardous drug for EJ, RM and AJK - the latter a young child.

THE COMMITTEE FINDS that, in making the diagnosis of "Candida-related complex" and inappropriately using topical and systemic antifungal agents to "treat" it, Dr. Krop fell below the standard of practice.

(5) Rotary Diets

Dr. Krop discussed the theoretical basis of the four-day rotary diet wherein foods from four specific food families are eaten. Meals from one group are eaten on one day, and those from the other three food groups are eaten on each of the next three days. In

effect, after a four day "rest", the patient is re-challenged with a new food group on consecutive days. By observing symptoms, specific food sensitivities can be identified. Once identified and removed from the diet, specific foods can be reintroduced at a later date, though no more often than once every four days. Foods that are products of fermentation (vinegar, alcohol, root beer), yeasts and cheeses are to be avoided. Vitamin and other supplements are given to avoid deficiency states and patients who have specifically identified deficiencies receive these intravenously in order to bypass the intestinal mucosal barrier.

Dr. Krop cited a 1985 analysis (exhibit #110c) of the four-day rotation diet by a professional nutritionist. The report stated that "the principles of the Rotation Diet are sound" and Aconsidering males and females 10-15 years of age, it generally meets the Recommended Daily Nutrient Intake as set out by the Dietary Standard for Canada, Health and Welfare, Canada 1975." The nutritionist's only criticism was that the suggested meal pattern examples were impractical.

Dr. Krop also referred to a 1994 “Report on the Rotary Diversified Diet in The Treatment of Environmental Illness” which was carried out by the Department of Nutritional Sciences, University of Toronto (exhibit #110f). Patients for the study were recruited from Dr. Krop's practice. Foods were identified as offenders on the basis of Vega testing (in some cases those with a high sensitivity to distilled water could not be tested on the Vega. Instead, they were encouraged to avoid those foods they felt were offenders). "Positive" foods -- those identified as offenders -- were to be eliminated for at least three months, and the "negative" foods were eaten in four day cycles, by food family, as described above. Those identified as having a specific yeast problem (as defined by a positive Vega test, a positive culture from an orifice, or a positive scratch or provocation test) were given specific instructions for yeast/mold avoidance.

Among conclusions reached by the University of Toronto study were the following: (1) the diet is complex and non-adherence is a problem that must be overcome in future studies; (2) future studies should include a minimum six-month follow-up, since few patients were re-tested for food sensitivity over the four-months of the study; and (3)

there was some decline in the number of symptoms perceived as troublesome over 16 weeks, but the design employed did not permit attributing improvement to the diet or the overall treatment program prescribed by Dr. Krop.

For the College

Dr. Tarlo stated that elimination diets are appropriate if the patient's history gives strong indication of food allergy or intolerance. In the majority of the patients reviewed, food intolerance was not evident from the history. In cases of chronic urticaria or asthma, specific foods may play a part, and a five-to-seven-day elimination diet may be helpful in making a diagnosis. Rotation and elimination diets did not appear to be justified in these patients, particularly not on the basis of such unproven test modalities as Vega.

Dr. Anderson said that rotary diets are based on unproven theory.

Dr. Sussman, referring to the patient AJK, expressed concern that the basic nutritional needs of a five year old would not be met by an elimination diet. He was critical of the treatment received by RM because he could see no evidence of food allergy.

For the Defence:

Dr. Fox stated that the rotary diet has been used routinely in the practice of clinical ecology/environmental medicine for the last forty years. "It is fair to say," he added, "that there is a paucity of literature pertaining to the scientific validation of this approach. The clinical and anecdotal experience is that these diets are beneficial in the management of patients with multiple sensitivities."

Dr. Waikman testified that a rotary diversified diet is not an cyclic diet, and will, if followed correctly, prevent new food allergies from developing. It can also be the basis for identifying offending foods.

Dr. Rae stated that the rotation and elimination diet has been used since 1934 as part of the routine practice of environmental medicine. Its clinical usefulness was documented in a 1987 text on food allergy and intolerance. The food "allergy" in the patients in

question is not IgE-mediated and criticism of the rotation and elimination diet based on the presumption of IgE-mediated allergy is inappropriate.

Dr. Boyles repeated Dr. Rae's statement on the rotary diversified diet and added that it is not complex and can be designed to include all proper nutrients.

THE COMMITTEE FINDS that, except for the University of Toronto study cited, the "rotary diet" has never been scientifically evaluated. The University of Toronto study reached only very limited conclusions. It basically found that the diet was difficult for patients to adhere to but that this study as carried out was incapable of either proving or disproving the value of the diet. The elimination/rotary diet was prescribed by Dr. Krop in five of his six patients. Not only is the diet unproved, but Dr. Krop, unlike the experts called by the defence, relied heavily upon an unproved technique -- Vega testing -- to determine which foods he recommended for elimination for reduction in frequency.

THE COMMITTEE FINDS that, in recommending the "Rotary Diet", Dr. Krop fell below the standard of practice.

(6) Sauna Therapy for Chemical Detoxification

Dr. Krop, stated that he no longer offers sauna therapy because of its cost. He did use it in selected patients who had multi system problems and known chemical exposure. He cited Dr. Rae's writing on the subject (exhibit #111e). The patient MM, who Dr. Krop believed was suffering from 1,1,1-trichloroethane exposure, was offered the option of sauna treatment, and encouraged to leave her job, but declined both suggestions.

For the College:

Dr. Anderson said that sauna therapy was "age old", not particularly harmful. However, there is no proof that "chemicals" are leached out of the body by the sauna and he characterized its use as "anti-science."

Dr. Sussman questioned the significance of the 1,1,1-trichloroethane blood test upon which Dr. Krop based his diagnosis of solvent toxicity and recommendation for sauna

therapy on MM, and its interpretation by Dr. Krop as evidence of intoxication. On cross-examination, he said there was no doubt the patient had been exposed, but that the value was significantly smaller (7.9 ppb) than that linked to toxicity (550 ppb).

For the Defence:

Dr. Fox testified that sauna therapy is part of an overall detoxification approach. He cited articles apparently demonstrating reduction in levels of PCBs, Agent Orange, and dde. He cited Dr. Rae's 1988 study in Clinical Ecology as evidence that sauna therapy, combined with massage and exercise, was effective in the removal of xenobiotics. He commented that this was not a randomized controlled study, and that such trials were yet to be done. According to Dr. Fox, the level of 1,1,1-trichloroethane in patient RM was clearly abnormal, and constituted sufficient evidence for a xenobiotic.

Dr. Waikman stated that he did not consider himself an expert in sauna therapy, though he has used it in several patients with success.

Dr. Rae stated that most environmental medicine specialists use or support sauna therapy. In his opinion, Dr. Krop=s recommendation that RM change her employment, based on her blood test for 1,1,1-trichloroethane, was appropriate.

Dr. Boyles stated that sauna therapy is just one method of detoxification.

THE COMMITTEE FINDS that sauna therapy, though not employed, was recommended by Dr. Krop to one patient, apparently as a means of removing the toxic volatile chemical 1,1,1-trichloethane from her body. The Committee heard widely divergent estimates as to the level of this chemical that is considered toxic. However, there was no reliable testimony to support the proposition that sauna therapy has been proved effective in removing this chemical from the body.

THE COMMITTEE FINDS that, in recommending sauna therapy for chemical detoxification, Dr. Krop fell below the standard of practice.

(7) "Vaccine" Therapy

Dr. Krop, in discussing his treatment of patient EJ, referred to the use of bacterial vaccines (exhibit #116 a-g). Two were package inserts. One (dated 1993) related to an American product marketed for recurrent and chronic respiratory infections. It carried the admonition that "the Food and Drug Administration has directed that further investigations be conducted before this product is determined to be fully effective for the labeled indications." The other, from Switzerland, made no reference to studies of efficacy. Dr. Krop discussed five clinical studies -- one on the use of bacterial vaccines in recurrent otitis media (a 1965 study), two in infectious asthma (1964 and 1969 reports) and one (1994) in abstract form discussed the use of oral immunotherapy with a bacterial preparation in patients with recurrent bronchitis. He also referred to a small uncontrolled open trial using a variety of methods to deliver a variety of bacterial products to children with infectious asthma.

Regarding the use of autogenous vaccine, (that is, vaccine prepared from an individual=s own body fluids or tissue) Dr. Krop stated that he used such vaccines rarely -- five times in 10,000 patients (including one of the patients in question). In preparation for this hearing, he had read more widely and intended to use autogenous vaccine more in the future, particularly in those patients who do not respond to other treatment. He described the technique for making such vaccines: dissolving sputum in saline, placing it in a microwave and then passing it through a filter. Serial dilutions are carried out and the patient=s end-point is determined. Injections are given, initially daily and then weekly. He cited several statements endorsing the method, and as well a number of uncontrolled studies involving the treatment of venereal warts and larygeal papillomata.(exhibit #117).

Dr. Krop also described the use of flu vaccine, injected hourly, to abort the incipient symptoms of influenza and, in some, to treat individuals with chronic flu-like symptoms.(exhibit #118). He stated he uses a commercially prepared staph lysate preparation as an immunomodulator in chronically ill patients and patients with chronic recurrent plantar warts. (Staph lysate is derived from a common microbe -- the staphylococcus -- which may be found in healthy humans, but which may also cause

serious disease). The package insert carried the FDA direction that "further investigation be conducted before this product is determined fully effective for the labeled indications." (exhibit #119b). Thymus extract is similarly used for immune stimulation, almost exclusively in Europe (exhibits #120 a-f).

For the College:

Dr. Sussman expressed concern that patient EJ was treated with vaccines prepared from her own blood and sputum. This, he stated, was unethical and not an acceptable standard of treatment. He characterized the use of antigens such as virus, bacteria, mold such as fusarium, phoma, and epicoccum, household insects and staphylococcus lysate as "potentially dangerous". He described the use of viral extract injections as highly controversial and staphylococcal lysate injections as experimental.

Dr. Tarlo, in her written report, stated there was no demonstrated benefit from serum injections. She was unaware of any documentation to substantiate the use of staph lysate.

For the Defence:

Dr. Fox supported the use of Staph lysate and postulated that staphylococcal antigen played a part in patient EJ's illness. As such, in his view, the prescription was appropriate.

Dr. Waikman stated that staph lysate has a long history of use as an immunomodulator in both the treatment of cancer and specific infections. He did not find its use inappropriate.

Dr. Rae stated that he employs autologous vaccines based on sputum and blood serum and in some people it seems to work. On cross-examination he stated that controlled studies on "designer" autologous vaccines would be impossible to do.

Dr. Boyles, on cross-examination stated that he did not inject patients with extracts of sputum or blood serum.

Dr. Hinshaw, on cross-examination, stated that he does not do blood serum injections. He initially denied using extracts of a patient's own sputum for treatment, although he stated that he was familiar with the underlying reasoning and technique. However, he then recalled using the method in one or two patients.

THE COMMITTEE FINDS that there is no scientific evidence to support Dr. Krop's use of staph lysate, autogenous vaccine with serum or sputum extracts in patient EJ, or thymus extract in patients EJ and AJK. There is no scientific evidence that any of these agents stimulate weakened human immune defences, nor is there any evidence that any of the patients Dr. Krop treated in this fashion suffered from immune deficiency.

THE COMMITTEE FINDS that, in employing these agents, Dr. Krop fell below the standard of practice.

(8) Intravenous Vitamin C, Ca++, Mg++ Therapy

Dr. Krop indicated that patient EJ was given intravenous Vitamin C to successfully treat her exacerbations of infections. Intravenous calcium and magnesium were given because at one time a low blood calcium level was detected. As well, the patient had problems with muscle spasms.

For the College:

Dr. Sussman was critical of intravenous Vitamin C and indicated that the high doses Dr. Krop used could be very toxic. He saw no reason why oral therapy using the vitamin would not be acceptable. Similarly, he stated that intravenous Ca++ and Mg++ therapy was not without risk. He saw some minimal evidence in the charts which indicated that the levels of these therapies had been monitored.

For the Defence:

Dr. Waikman indicated that studies exist which demonstrate Mg++ deficiency in patients with status asthmaticus, and subsequent improvement when they are given Mg++ intravenously. In his opinon, intravenous therapy with Vitamin C can clear signs and

symptoms of chemical sensitivities within four hours.

Dr. Rae stated that intravenous Vitamin C will abort early infections, thus avoiding antibiotics to which patients may be sensitive.

THE COMMITTEE FINDS no acceptable rationale for Dr. Krop's intravenous treatment of patient EJ with either Vitamin C or calcium or magnesium solutions. Testimony that parenteral magnesium may be effective in the treatment of severe asthma does not justify its use in EJ, whose respiratory problem was long-standing bronchiectasis and recurrent infections. The Committee notes that Dr. Sussman's concerns are amplified in the "Thomson Report", as follows: "...the possible impact of massive Vitamin C injections on acid-base balance, and... the danger of generating the hydroxyl radical, a particularly reactive and dangerous molecule, through the interaction of ascorbic acid with oxygenated hemoglobin and other blood components." (exhibit #76, p 202).

THE COMMITTEE FINDS that, Dr. Krop's use of these agents in this patient constitutes a failure to meet the standard of practice.

(9) Hair Analysis

Dr. Krop indicated he uses hair analysis in specific cases. He estimated the frequency at 26 a year, out of 660 patients seen. Regarding AJK, he stated that he carried out the test for two reasons -- she lived in an urban centre with substantial environmental pollution, and her scoliosis led him to suspect a nutritional deficiency. In his opinion, the fact that hair analysis results had changed significantly between the two tests reflected successful nutritional correction, with mineral suppliments, including magnesium and selenium.

For the College:

Dr. Tarlo included hair analysis in the list of unproven diagnostic tests condemned by the American Council on Health and the Royal College of Physicians. She concluded that its use in patients AJK and EJ does not meet the standard of practice in Ontario.

Dr. Sussman referred to the 1982 College of Physicians and Surgeons of Ontario statement on hair analysis (exhibit #17) which concluded that "The use of commercial hair analysis by physicians in clinical practice is, in the present state of knowledge, a procedure that is imprecise, unnecessary, and probably wasteful." (That paper points out the many methodological pitfalls involved in the preparation and collection of samples and underlines the lack of controlled studies to confirm the association between clinical syndromes and deficiencies of trace elements.) He pointed to the completely different results of testing of samples taken six months apart in the young patient AJK. This, he said, demonstrated the imprecision of such testing. On cross-examination he agreed that even though other, more conventional, tests may give inconsistent results they are not necessarily considered unreliable.

Dr. Anderson, stated that while hair analysis can detect the presence of trace elements, with the possible exception of zinc deficiency, such analysis has not proved helpful in any clinical syndrome or disease. The routine use of hair analysis in clinical practice is unnecessary and costly, in his opinion.

For the Defence

Dr. Boyles, in cross-examination, commented that he orders hair analysis possibly three times a year, when he is looking for toxic metals. Having examined the records, he was unable to determine why Dr. Krop ordered hair analysis in AJK's case.

Dr. Rae stated that he did not use hair analysis a lot, and that in many situations it is a waste of time and money. In his opinion, it is useful for those with suspected heavy metal poisoning. He noted that in the case of AJK, testing was for a suspected deficiency.

Dr. Gerrard has not used hair analysis in his practice and believes it is reserved for highly selected patients. In his opinion, it is not a routine test.

Dr. Waikman testified that he uses hair analysis once or twice a month, particularly if he suspects the presence of toxic elements, as in the case of lead poisoning in hyperactive children.

Dr. Fox, in his written report, indicated the procedure is well-accepted for discovering such toxic elements as arsenic. In cross-examination, he referred to hair analysis as a means to assess the nutritional status in a patient with multi-system problems. Referring to the case notes on AJK, he stated he did not see anything that immediately struck him as an indication for such testing.

THE COMMITTEE FINDS that, while hair analysis may be useful in the diagnosis of heavy metal toxicity or in essential element deficiency, such situations are rare. These exceptional situations bear little resemblance to Dr. Krop's use of hair analysis in patients EJ and AJK, Dr. Krop's rationale of possible atmospheric pollution and scoliosis notwithstanding. The Committee heard no evidence on the potential harm of prescribing mineral supplements, including selenium and magnesium, for the child AJK. However, it also heard no reliable evidence that this treatment was justified.

THE COMMITTEE FINDS that, Dr. Krop's use of hair analysis in these patients constitutes a failure to meet the standard.

3. EVIDENCE HEARD ON RELATED ISSUES

(1) "Multiple Chemical Sensitivity Syndrome (MCSS)"

The Committee believes that this issue is important in that it not only plays a central role in Dr. Krop's construct of "total load" as a cause of illness, but it also informed his approach to the care and treatment of his patients, in particular, MM, AJK, LC, and PL.

For the College:

Dr. Tarlo stated that, "Multiple chemical sensitivity is a term which has been used to describe patients who do not have a clear allergic cause for their symptoms and who ascribe usually multiple symptoms to exposure to numerous chemicals in the environment. There has been no accepted uniform criteria for diagnosis of this condition, and no objective tests to confirm the diagnosis. There remains controversy as to whether this is a distinct entity. Many reports have suggested that the cause of this syndrome may be multifactorial. In many patients there are psychiatric diagnoses

and the symptoms may be from misdiagnosed physical or psychological illness."

Dr. Anderson refers to MCSS as being based in the theory that low concentrations of a variety of chemicals damage the immune system over time and are responsible for a variety of somatic signs and symptoms. Advocates of this theory feel that the total body load of environmental insults are critical for the induction of illness. They report that unrecognized immune system dysfunction develops over time. Overt manifestations of illness may be triggered in susceptible individuals by almost any stress including chemical, hormonal, allergic, viral, or fungal (especially candida albicans) exposure.

For the Defence:

Dr. Boyles stated that MCSS has nothing to do with hormones, viruses, or fungal problems, but is "due to chronic exposure to toxic chemicals or large exposures." Referring to his 1985 article in the Otolaryngologic Clinics of North America (exhibit #58), he indicated that history taking may be misleading in diagnosing the chemically sensitive patient. Sublingual testing is practiced by most clinicians, though it is not as accurate as a new form of brain imaging, SPECT scanning. He characterized an article on MCSS (exhibit #59) as an even-handed report. (That article includes the statement, "This enigmatic syndrome has no generally accepted definition or proved physiologic mechanism, yet it is increasingly being recognized in government regulations and the courts.") In cross-examination he stated that sufferers from MCSS respond to levels of chemicals ordinary people don't react to.

Dr. Waikman testified that Dr. Anderson misstated the putative non-chemical etiology of MCSS. He cited one study (exhibit #95) that demonstrated changes in pulmonary function in asthmatics exposed in a blinded fashion to paper strips impregnated with perfume. He testified that he has patients who are similarly sensitive, and who respond not only with asthmatic symptoms but also stuffy nose, sleepiness, headache, and personality changes. He tests a limited repertoire of chemical antigens (formaldehyde, phenol, glycerin, ethanol, diesel fuel, and gasoline).

Dr. Rae suggested Dr. Anderson had not informed himself on the pertinent scientific

literature, including his (Dr. Rae's) multi-volume text on the subject.

Dr. Davidoff described her knowledge of, and research into, MCSS and Sick Building Syndrome (SBS). She stated that the working definition of MCSS is evolving. While there is no universally recognized consensus, working groups in a number of academic centres have definitions that for the most part coincide. Patients are not just sensitive to one agent, but to several. MCSS encompasses a constellation of symptoms, generally capable of categorization into five general groups -- systemic (profound fatigue is almost universal), central nervous system, respiratory, gastrointestinal, and musculoskeletal. Onset is insidious, symptoms are multiple and experienced on a daily basis. No objective biochemical or physiologic markers to assist diagnosis have been identified, and treatment consists primarily in removing the sufferer from the environment.
Her research has pointed to similarities in symptom patterns and health characteristics in four groups exposed to quite different environments, and significant differences from carefully matched controls (exhibit #99). She has published articles criticizing studies which suggest a psychogenic origin for MCSS and has (exhibit #101), concluded that they were so badly flawed methodologically as to be invalid.

Dr. Davidoff concluded that she was neither familiar with the case notes introduced in evidence nor with the practice of Dr. Krop.

Dr. Fox stated that a consensus definition of MCSS has been proposed by the National Academy of Science, a definition that has been urged upon Health Canada by a workshop on the subject. Dr. Fox's Halifax Environmental Health Clinic, funded by the Nova Scotia Department of Health, has as its mandate the investigation and treatment of MCSS. He found the terminology used -- multiple chemical sensitivity, environmental illness, environmentally-induced dysfunction -- to be problematic because these patients are a heterogeneous group. He said that there was no scientifically valid research to support the contention that these patients were either malingering or suffering from psychological illness.

THE COMMITTEE CONCLUDES that the concept of Multiple Chemical Sensitivity Syndrome is worthy of further study. However, the Committee finds that there are no objective biochemical or physiological markers that conclusively identify this condition, and no scientifically validated treatments for it. The use of the Vega and/or sublingual drops to diagnose this syndrome, and sublingual drops to treat it falls below the standard of acceptable medical practice in Ontario.

(2) Informed Consent

Because Dr. Krop includes, as part of the package provided to each patient, at or prior to, the initial visit, a document headed "Informed Consent Agreement" (included in exhibit #20), the Committee believes it important to comment on this document and the role it plays in Dr. Krop's practice.

Dr. Krop was asked, in cross-examination, why, if his procedures were so safe, his consent form included the sentence, "I agree to undertake the testing described above and discharge and release you from all claims and damages arising from or related to such testing and treatment as prescribed by you." He replied that it was drafted by his lawyer in view of the controversy surrounding environmental medicine. On re-examination he stated that, despite the disclaimer “I understand that none of these tests have been scientifically proven to be reliable and that you, as my physician, must still rely upon my observations as to the efficacy of the test and the treatment", he was convinced that what he was doing was supported by double-blind studies.

For the College:

Dr. Tarlo, referring to Dr. Krop's consent form, noted that it involved agreement to undergo a range of testing (Vega, sublingual, intradermal, intranasal) that the consent characterized as "investigational" and not generally employed by the majority of physicians for this purpose. In her opinion that statement, as well as the phrase, "I understand that the results of this study may be published in a medical or scientific journal, and a number or letter designating my case, but not my name, may be used in reports of this study," implied that this testing was part of a scientific research study approved by an appropriate ethics committee. She contrasted this with a consent form (exhibit #22) for a study in which she was involved, and which had been approved by

the Ethics Committee of the University of Toronto.

Dr. Sussman stated that "Dr. Krop was misleading patients with a consent appearing as if he was doing scientific research and asking for payment." This was reiterated on cross-examination. Consent to participate in research should be linked to a trial protocol and here, there was no trial protocol apparent. He added that there are ethical implications to asking for payment when participating in a research study. He further expressed concern that "patients were not given an adequate explanation of the testing techniques and potential serious consequences of the prescribed treatment."

THE COMMITTEE has serious doubts that these six patients' consent to diagnosis and treatment by Dr. Krop was truly informed.

The issue of informed consent may arise in several contexts.

In some instances, informed consent will be given for participation in a clinical trial. As in the case of the University of Toronto study of the "rotary diet", the protocol will be approved by an institutional review board. The patient will be fully apprised of the purpose of the trial, including its potential risks and benefits. The patient formally agrees to take part, and the financial costs of the necessary testing and treatment are fully borne by the investigator or sponsoring agency -- not the patient.

As previously noted, Dr. Krop's "Informed Consent Agreement", signed by each patient, contains the statement AI understand that the results of this study may be published in a medical or scientific journal, and a number or letter designating my case, but not my name, may be used in reports of this study." Similarly, the earlier statement, "I understand that the testing procedures to be used are *investigational* (our italics) and not generally employed by the majority of physicians for this purpose," is ambiguous. Both statements tend to mitigate the disclaimer, "I understand that none of these tests have been scientifically proven to be reliable..." contained in the same document.

It is clear to the Committee that none of these patients was participating in a clinical trial, but had they been, the minimal requirements for such a trial, as outlined in Dr. Anderson's testimony (exhibit #23), were not met.

In other instances, informed consent to a test procedure or a treatment may be given, outside of a clinical trial, and in circumstances where scientific support for the manoeuvre is lacking. Consent, however, must be truly informed. It must be made clear to the patient where scientific evidence exists, and where it does not, as well as the risks and potential benefits of consent.

Dr. Krop's confident assertion to the Committee of the proved scientific basis of his approach is reflected in "The Ecology Guide", the handbook which he authored and sold to his patients. While outlining in careful detail the rationale and specifics of his diagnostic methods and treatment approaches, the Guide contains no suggestion that, contrary to the findings of this Committee, these methods and treatments -- singly or as a group -- are scientifically unproven.

The six patients in question could not have given truly informed consent to Dr. Krop's testing and treatment.

(3) The Issue of "Harm"

The Committee considered whether or not Dr. Krop, in his treatment of these six patients, caused them harm.

The patient RM who complained of local pain and swelling at the site of her desensitization injections may or may not have been reacting to antigen therapy inappropriately prescribed. The Committee was unable to determine that issue on the evidence before it.

Of greater concern is the use of the systemic antifungal agent, ketoconazole, in several patients, and in particular the child AJK. The Committee"s concern goes beyond whether or not appropriate monitoring for toxicity was carried out and whether or not

significant deviations in liver enzymes were detected. The central issue has to do with the use of a scientifically unproved hypothesis -- that of the “andida related complex” -- to justify exposure, in some cases repeatedly, to a drug capable of causing liver failure.

While the extensive testing many of these patients were subjected to for detection of hematologic and biochemical -- and in some cases immunologic and hormonal -- abnormalities was undoubtedly paid for by OHIP, the costs of unconventional testing were borne by the patients. The Committee is aware of substantial sums expended by the patient RM for recommended sera and supplements and is concerned about the potential hardships of such expenditures.

Recommendations for life-style changes -- such as the elimination of a wide variety of foods from the diet, rigid adherance to a variety of “desensitising” regimens, and the recommendation to quit a job and undergo sauna treatment -- pose additional costs. In the Committee=s view, if unjustified, these constitute a form of harm.

The Committee concluded that Dr. Krop's management of these six patients, while it did not harm them in any physical sense, was not without cost to the individuals involved. Moreover, it exposed several patients unnecessarily to the hazards of systemic antifungal drugs.

(4) Other Allegations

Dr. Krop is alleged to have fallen below the standard of practice in a number of other respects. This includes the failure to do appropriate tests and assessments and the failure to make appropriate referrals. Without direct information on the clinical status of each of these patients (RM is an exception in that the Committee had both her testimony and the testimony of another treating physician), such allegations can only be conjectural and based on the information in Dr. Krop’s files. Similarly, the allegation that Dr. Krop failed to take a complete history is difficult to judge. Although the handwriting and notations in the patient record were difficult to interpret, it appeared to the Committee in the course of the hearing that the basic essentials of an acceptable

patient record were included.

A further allegation dealt with Dr. Krop's failure to communicate with other physicians involved in the care of each patient. The Committee notes that in only one instance of the six did Dr. Krop do so. It was evident from his testimony that Dr. Krop depended on each patient's "usual" physician to manage issues which Dr. Krop felt fell outside his area of interest. While it may not be the standard of practice for all physicians involved in the care of a given individual to communicate freely with each other regarding past or current investigations and treatment, it is in the Committee's view highly desirable. Nevertheless, Dr. Krop's failure to do so does not constitute a breach of the standard.

It was further alleged that Dr. Krop fell below the standard in that he inappropriately, through the company controlled by his wife, charged substantial sums for treatments which were either of no value, or harmful. There is no question that at least one patient, RM, made at least one purchase of $196.75 from Amican, the company in question. The Committee notes that Section 31(2) of Regulation 548/90 makes two exceptions to its conflict of interest prohibition against the sale, by a member or a member of his or her family, at a profit, of drugs or appliances. Those exceptions are "drugs required in an emergency" and "allergy preparations". While RM testified that she purchased Vitamin supplements, other evidence suggests that Amican was supplying her with injectable sera to a variety of inhalants and candida.

Given the evidence before it, the Committee is not prepared to reach a finding that Dr. Krop fell below the standard in this matter.

(4) DECISION OF THE COMMITTEE

First, the Committee wishes to emphasize that the focus of this hearing was the practice of Dr. Krop as it related to his management of the six patients whose charts were entered in evidence. "Environmental Medicine" was not the issue being deliberated. Indeed, in the course of the hearing it became apparent that Dr. Krop's methods differ significantly from the majority of the practitioners tendered by the defence as knowledgeable in environmental medicine. The central role of Vega testing in Dr. Krop's practice appears to be unusual. He used the Vega apparatus to screen for a broad range of sensitivities (as the only method of evaluation in at least one patient), as an integral part of the provocation/neutralization procedure in a number of patients, and as a means of adjusting previously prescribed treatment sera. Only Dr. Remington, an outspoken advocate of the approach, who relies on Vega to the exclusion of serial end-point dilution titration and provocation/neutralization, placed a similar emphasis on this method of testing.

The six patients whose records were the focus of this hearing presented with a wide variety of complaints: chronic dry and cracking skin (LC), recurring respiratory infections and infections and bloating and diarrhea (EJ), skin rashes, "wheezing", recurring respiratory infections, headaches, stomach aches, and whining and crying (AJK), chronic fatigue, cognitive difficulties, and "flu-like" symptoms (PL), recurrent rhinitis and urinary tract infections, chronic groin pain, and indigestion (RM), and chronic tiredness, headache, depression, gastrointestinal upset, and symptoms or rhinitis and conjunctivitis (MM).

Despite the wide range of symptoms, the patients' assessments were remarkably similar. All completed exhaustive "environmental" and "food sensitivity" questionnaires, all charts contained the same physical examination check-list, and virtually all received the same battery of tests. All were "screened" with Vega testing. Intracutaneous testing with serial dilution end-point titration was foregone only in the case of the child AJK and the adult MM, in the latter instance because of cost. All but MM underwent "provocation/neutralization" sublingual testing. All underwent extensive conventional hematologic and biochemical testing, the results of which were uniformly unremarkable. In a number of patients, subsequent treatment was modified by repeat Vega testing.

Treatments prescribed or recommended were similarly formulaic. Injectable sera for a variety of inhalants, including fungi, were prescribed in LC, PL, and RM. Three (EJ, AJK, PL) were given sublingual drops. All were given or recommended oral antifungals and three received the systemic antifungal ketoconazole. The rotary/elimination diet was recommended in all but MM. In addition, a yeast-free diet and acidophilus supplements were recommended to several, as were Vitamin and mineral supplements, organically-grown food, evening primrose oil, Vitamin E, and bottled water.

In the Committee's view, the testing techniques and treatment approaches employed by Dr. Krop have in common a lack of scientific validation. This judgment includes, in particular, the Vega machine which Dr. Krop additionally used to assess a wide variety of putative stressors, to "screen" for occult disease, and to adjust treatments which in themselves are questionable. Our conclusion also includes the diagnostic/therapeutic technique known as "provocation/neurtralization", hair analysis, the rotary diet, the use of staph lysate, autogenous vaccines made from serum and sputum, "thymus extract" injections, repeated high dose parenteral Vitamin C infusions, and sauna therapy. It includes the diagnosis of "candida related complex" and thus the treatment that flows from that diagnosis.

The experts called by the College reviewed each of these diagnostic and therapeutic modalities in the light of their experience and in the light of their review of the scientific literature. All condemned their use. Drs. Tarlo and Sussman stated that Dr. Krop's use of these techniques in the six patients in question constituted a failure to meet the standard of practice in the Province of Ontario.

For the reasons already stated, the Committee accepted the evidence of Drs. Tarlo, Sussman, and Anderson in preference to that of the experts called by the defence. The Committee did not view the latter's evidence as worthy of equal weight in that it lacked the authority of acceptable scientific evidence.

The Committee, therefore, finds Dr. Krop guilty of professional misconduct in that he

failed to maintain the standard of practice of the profession in the care of the patients in question in that he:

- employed inappropriate tests, including the use of the Vega machine, (patients LC, EJ, AJK, PL, RM, MM), provocation/neutralization (patients, LC, AJK, PL, RM), and hair analysis (patients EJ, AJK)
- inappropriately diagnosed food, chemical and other allergies and sensitivities (patients LC, EJ, AJK, PL, RM, MM)
- inappropriately recommended sauna therapy for chemical detoxification (patient MM)
- made inappropriate diagnoses of systemic candidiasis (patients LC, EJ, AJK, RM, and MM)
- prescribed inappropriate antifungal agents, both topical and systemic (patients LC, EJ, PL, AJK, RM, and MM)
- prescribed inappropriate treatments including sublingual drops (patients LC, EJ, AJK, PL), injections of various types including Vitamin C (patient EJ), "vaccines" derived from serum and sputum (patient EJ), staph lysate (patient EJ), thymus extract (patient EJ and AJK), calcium and magnesium (patient EJ)
- recommended life-style changes, including such unproved measures as a "rotary diet" (patients LC, EJ, AJK, PL, RM), based on the above diagnostic methods.

THE ISSUE OF ABUSE OF PROCESS

The issue of abuse of process was raised by the defence both at the commencement of the hearing and in final argument.

At the outset, a *voir dire* was held regarding the admissibility of the patient records to be tendered as evidence in the proceeding. This in turn led to a review of the manner in which Dr. Krop's practice came to be investigated and in which the resulting referral to the Discipline Committee was made. The Committee held at the conclusion of the *voir*

dire that the investigation into the practice of Dr. Krop was carried out with the authority of, and in compliance with, Section 64 of the *Health Disciplines Act*. It further found that Dr. Krop and his position was dealt with by the College with the degree of fairness that was appropriate at each stage of the investigation and referral process. The process by which patient records were selected did not breach the privacy rights of the patients involved nor did it constitute unreasonable search and seizure.

At the end of the hearing, counsel for Dr. Krop again raised the issue of abuse of process, this time pointing to the factor of delay. This Committee has already reviewed the issues leading up to the referral of Dr. Krop to the Discipline Committee, and the issuance of the Notice of Hearing in July of 1994. The Committee will not re-open those issues which were earlier addressed in detail. It cannot help but note, however, that if delay occurred, it was in part due to the College's efforts to be scrupulously fair to Dr. Krop in naming an inspector acceptable to him.

Several years have passed since the Notice of Hearing was issued in July 1994. Does the four-year "delay" meet the test required to be seen as "abuse of process", or impaired Dr. Krop's ability to make full answer and defence?

As pointed out by College counsel, to satisfy the onus of proof that lies on the party alleging abuse, that party must establish that "there has been conduct that shocks the conscience of the community, and is so detrimental to the proper administration of justice that it warrants intervention." The Committee finds that, regarding the issue of delay, these criteria have not been met. Furthermore, the Committee notes the extensive and detailed testimony of the large number of defence witnesses, and concludes there was no prejudice at any time to Dr. Krop's ability to make full answer and defence.

The Committee rejects the defence claim of abuse of process because of delay.

The Committee directs the hearings office to make arrangements for the parties to

attend before it for the penalty phase of the hearing.