

Indexed as: Ravikovich

**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 59(6)
of the **Health Disciplines Act**,
R.S.O. 1980, c. 196, as amended.

BETWEEN:

THE COLLEGE OF PHYSICIANS AND SURGEONS OF ONTARIO

- and -

DR. FELIX RAVIKOVICH

PANEL MEMBERS: DR. A. RAPOPORT (Chairman)
DR. H. GORDON
MS R. McFADDEN
J. McSKIMMINGS

HEARING DATE: FEBRUARY 7 - 11, JUNE 2, 3, 9, 10 AND JULY 5, 1994

DECISION/RELEASE DATE:

JULY 26, 1995

DECISION AND REASONS FOR DECISION

This matter was heard before the Discipline Committee on February 7-11, June 2,3,9,10 and July 5, 1994 at the College of Physicians and Surgeons of Ontario at Toronto.

The Amended Notice of Hearing contained the following allegations of professional misconduct and incompetence:

It was alleged that Dr. Ravikovich is guilty of professional misconduct as defined in Section 27(21) of Ontario Regulation 448, R.R.O. 1980 as amended, under the **Health Disciplines Act** in that he failed to maintain the standard of practice of the profession in the period January 1985 to May 31, 1991, in that he carried on the practice of medicine by employing diagnostic and therapeutic practices which had no scientific or medical validity.

It was further alleged that Dr. Ravikovich is incompetent in the same period in that he displayed in the professional care of his patients a lack of knowledge, skill or judgment or disregard for the welfare of his patients of a nature or to an extent that demonstrates that he is unfit to continue in practice.

The particulars of these allegations were set out in the Notice of Hearing as follows:

- i) He employed histamine injections or a histamine prick test for the purpose of diagnosis;

- ii) when he employed histamine injections or a histamine prick test for the purpose of diagnosis he did not employ a negative control;
- iii) when he employed histamine injections or a histamine prick test for purpose of diagnosis, no objective measurement of any change in the patient was employed in order to assess the results of the injections or histamine prick test;
- iv) he employed histamine injections for therapeutic purposes in regard to a variety of conditions when the efficacy of this treatment is unproven;
- v) prior to employing histamine injections on some patients who suffered from asthma he reduced or withdrew their regular medications;
- vi) he treated some patients who suffered from food sensitivity with histamine injections or allergens and then allowed the patients to eat suspected food in an unsupervised situation;
- vii) he treated some patients who had no skin tests by administering allergy injections.

It was further alleged that Dr. Ravikovich is guilty of professional misconduct as defined in Section 27(24) of Ontario Regulation 448, R.R.O. 1980, as amended, under the **Health Disciplines Act** in that he made misrepresentations respecting a remedy, treatment or device in the period January 1985 to May 31, 1991.

The particulars of this allegation were set out in the Notice of Hearing as follows:

- i) he misrepresented to his patients that histamine injections could be used for the purpose of diagnosis;
- ii) he misrepresented to his patients that histamine injections could be used for therapeutic purposes in regard to a variety of conditions when the efficacy of this treatment is unproven;

Dr. Ravikovich pleaded not guilty to the allegations.

Counsel on behalf of the College called as his first and only witness Dr. PLN. Dr. PLN is the Head of Clinical Immunology at Hospital PDH and an Associate Professor in the Department of Medicine at University HEJ. The Committee accepted Dr. PLN as a qualified expert witness.

In treating a patient suffering from an allergic condition such as ragweed hayfever, Dr. PLN asserted that it is essential to perform two skin tests before applying therapy. The positive control could consist of a histamine prick test. A positive reaction would be indicated by local swelling with surrounding redness. If there is a negative reaction, this may indicate that the patient was "blocked" perhaps by previous antihistamine therapy. Dr. PLN stressed that not all allergic reactions are due to histamine. He also emphasized that it is necessary to do a negative control consisting for example of a prick of the diluent or of

saline and in this case this test should be negative. If the histamine prick test is positive and the negative control is negative, then the patient is suitable for allergy injections. Counsel for the College asked Dr. PLN whether he had reviewed two papers prepared by Dr. Ravikovich concerning his use of histamine as well as the charts of 15 of Dr. Ravikovich's patients shown in the exhibits. Dr. PLN replied in the affirmative to both. When asked by counsel if the use of histamine in the manner described by Dr. Ravikovich was acceptable Dr. PLN replied "certainly not". When asked whether Dr. Ravikovich's use of histamine for treatment was acceptable in the period between 1985 and 1991, Dr. PLN again replied "certainly not". Dr. PLN stated that the list of conditions, most of which were given histamine therapy by Dr. Ravikovich, was too varied and heterogeneous.

Counsel for the College examined in detail Dr. Ravikovich's chart records of five of his patients to whom he had administered histamine therapy. The first patient, A, received a histamine injection diluted to 1:10,000,000. Dr. PLN regarded this as a homeopathic dose. Of concern to him, no negative control test was carried out in this or in any of the other patients who received histamine therapy. Dr. PLN noted that, although the patient improved initially, the symptoms recurred in a week. In 1987 the child had an acute reaction to a histamine injection consisting of headache, a rise in blood pressure followed by a fall and then asthma. At one stage the child had to be admitted to Hospital IAJ as an emergency.

Dr. PLN was questioned about a second patient, B. He observed that the patient had had anti-asthmatic medications discontinued prior to receiving histamine injections. Furthermore these injections had been administered without any skin tests. At one stage,

the patient's asthma deteriorated and Dr. Ravikovich prescribed Ventolin which helped. Dr. PLN noted that the histamine injections had not benefitted this patient and it was therefore hazardous to administer this medication without the more standard anti-asthmatic preparations.

Dr. PLN was questioned about a third patient, C. This patient apparently had a diagnosis of food allergy although Dr. PLN could not tell from the record on what basis this diagnosis had been reached. Despite the fact that this patient had had a severe reaction to an injection of histamine diluted 1:100, this was followed by a more concentrated injection of 1:10 which Dr. PLN claimed was not acceptable.

Dr. PLN was questioned about a fourth patient, D. This patient suffered from severe anxiety, depression and also possibly hypoglycemia. At one stage Dr. Ravikovich recorded a diagnosis of encephalopathy for which Dr. PLN could find no basis. This patient was taken off medication directed to her psychological problems, prior to receiving histamine injections - a step which Dr. PLN felt could be dangerous.

The final review was carried out on patient E, who presented to Dr. Ravikovich with cough and sputum, shortness of breath and runny eyes. Medications were prescribed which Dr. PLN did not feel were appropriate. This patient was given dilute histamine injections that Dr. PLN regarded as homeopathic as well as more concentrated solutions of histamine. Although the patient improved periodically, there was an invariable relapse.

In summary, Dr. PLN asserted that the use of histamine for the diagnosis and treatment of allergic conditions as demonstrated in the five charts reviewed with counsel for the College

as well as in the remaining ten charts that he examined personally, was not acceptable. He again noted that there were no negative controls used or recorded by Dr. Ravikovich during his histamine tests. When there were positive reactions to histamine skin tests, Dr. Ravikovich failed to record their intensity. Dr. PLN teaches family practice residents regarding allergy and is aware that other family practitioners, who practise allergy, performed both positive and negative control tests between 1985 and 1991. Furthermore, there are publications concerning the standards applicable to skin tests and he said Dr. Ravikovich's practice did not meet an acceptable standard.

Dr. PLN was cross-examined by counsel for the defence. When counsel suggested that Dr. PLN had never heard of or had himself interviewed the 15 patients of Dr. Ravikovich, Dr. PLN stated that he had only examined the 15 charts. When asked by counsel what percentage of drugs used by doctors have been scientifically validated as in "a double-blind study", Dr. PLN answered that he was uncertain. Dr. PLN stated that there were maybe about 150 allergens available to physicians, most of which were not useful. Dr. PLN stated that he himself does not use even 20 of these. When asked by counsel if there are ways to establish the efficacy of treatments without employing a double-blind study, Dr. PLN answered in the affirmative. Dr. PLN was asked to list some of the allergens he uses in his practice. Counsel asked which of these had been subjected to double-blind studies. Dr. PLN answered that this had been done in the case of diagnostic skin tests. Counsel suggested that if a skin test was positive, presumably Dr. PLN would then go on to treat the patient with that allergen and were any blind studies done to confirm the efficacy of these allergens. Dr. PLN answered yes and that numerous studies of this sort had been done.

Dr. PLN was questioned about the five patients concerning whom he had testified on behalf of the prosecution. Some time after a histamine injection, patient A suffered an acute allergic reaction. In this case the histamine had been diluted to 1:100,000,000 and Dr. PLN agreed that this was a very dilute solution and there was no proof that this injection caused the allergic reaction.

Concerning the second patient, B, counsel for the defence pointed out that ordinary therapy had been unsuccessful for 20 years and therefore histamine therapy was warranted. Dr. PLN answered that "ordinary" treatment had not been very good. Furthermore more people with the symptoms complained of by this patient, such as asthma and itchy nose and eyes, do not have allergy and in fact are allergic. Thirty percent of such patients might improve with placebos whereas with allergy injections, 50% of a placebo group might improve. Counsel asserted that there was no evidence that Dr. Ravikovich had removed drugs from the patient prior to his own treatment. In fact the patient had stopped all medications before consulting Dr. Ravikovich. Dr. PLN noted that, in this patient as well as in the others, that when there was a remission following histamine injections, there was always a relapse. When asked by counsel whether in the 15 patients whose charts he had examined, did Dr. PLN observe any harm from the histamine injections or that any of the patients got worse, Dr. PLN replied that all or most of the patients continued to be sick but he could not say that any of them got worse as a result of the injections.

When questioned about the third patient, C, Dr. PLN stated that he believed this patient's

symptoms were psychological in origin rather than allergic. Therefore he felt that the histamine test need not have been done. Furthermore, the concentration of histamine employed, 1:10, could be dangerous because the patient, as revealed by her symptoms, was under considerable stress. Nevertheless counsel pointed out that there was no indication that the patient had suffered as a result of this dose.

During this discussion, counsel for the defence suggested that there was nothing in the patients' charts to indicate that Dr. Ravikovich told his patients to stop their medications. Dr. PLN replied that he believed that Dr. Ravikovich's pamphlet handout to the patients indicated that this was his practice. When asked by counsel whether in his review of the charts, Dr. PLN had seen any examples of a patient requiring hospitalization after histamine treatment, Dr. PLN agreed that he could not find an example in the 15 patients. When asked whether, in any chart, did Dr. PLN note that Dr. Ravikovich had told patients to stop their medication, Dr. PLN answered he could not tell.

Counsel for the defence went on to question Dr. PLN concerning basic immunological mechanisms especially as they related to the use of histamine. After considerable discussion, counsel for the defence pointed out the distinction between immunotherapy and immunomodulation. Immunotherapy acts through the Immunoglobulin, IgE and is produced by allergen injections rather than by drugs. On the other hand immunomodulation can be produced by cytokines secreted by T and B cells and can be affected by drugs such as steroids. When Dr. PLN was asked which is the more effective, he replied that immunomodulation is his first preference. He pointed out that immunotherapy is banned in the United Kingdom even though it is prevalent in the United

States. Counsel disagreed suggesting that the use of immunotherapy is restricted to where resuscitation is available and Dr. PLN agreed. In further discussion Dr. PLN pointed out that there could be some danger in administering histamine to anyone. It depended somewhat on the route of administration. Intra-dermal injections were usually not dangerous but 1 c.c. of full strength histamine injected intradermally could produce a serious reaction. Upon questioning, Dr. PLN stated that he had never observed systemic changes with the use of histamine prick tests.

Counsel for the defence suggested in cross-examination that the objective in the treatment of the patient was ultimately to cure the patient of his condition and, secondly, to rid the patient of the need for any medicines. Ideally allergic patients would be weaned off steroids. Dr. PLN again criticized Dr. Ravikovich's use of the histamine prick test without a negative control.

In his re-examination, counsel for the prosecution asked Dr. PLN whether any of the references advanced by counsel for the defence suggested that Dr. Ravikovich's use of histamine was acceptable, Dr. PLN answered in the negative. Counsel then referred to an exhibit, an article in JAMA, September 11, 1987. He asked Dr. PLN whether he agreed with the following paragraph: "in many instances, procedures for diagnosis of and therapy for allergic and immunologic diseases have been accepted as effective by both physicians and patients before being shown to be ineffective by controlled trials. An unproved procedure should be considered to be experimental and likely to be ineffective until it has been proved effective by conducting proper trials". Dr. PLN agreed with this statement.

Dr. PLN was questioned by members of the panel. He stated that he did not believe there was any proof that histamine administration had a therapeutic value. Further, in the histamine prick test, the dose was not very important as very little histamine was absorbed. He again asserted that it could be dangerous to discontinue a patient's medications, for example, if the patient had severe asthma, before administering histamine therapy. When it was pointed out that, in Canada and the United States, there are clinics that are using histamine therapy, Dr. PLN stated that he did not know if such clinics were using it in Ontario but it was possible that there might be individuals who were administering histamine therapeutically. He again stated that the dilutions of histamine employed by Dr. Ravikovich were homeopathic and he felt there was seldom any risk to the patient either following the skin tests or even in the treatment.

In his questions, counsel for the defence again asserted that there was nothing in the charts to indicate that Dr. Ravikovich withdrew medications from the patients before administering histamine therapy. Furthermore he contended that nothing in the pamphlet that Dr. Ravikovich provided for his patients, indicated that they should stop taking their medications. Dr. PLN agreed that he could not find where he read that Dr. Ravikovich recommended discontinuation of the medication but he believed that Dr. Ravikovich told his patients that his treatment would not work if the patients continued to take, for example, steroids.

Counsel for the defence called as his only expert witness for the defence Dr. MME. Dr. MME is licensed in another province and the United States and practices in both locations. His office is located in an environmental health clinic in a major U.S. city. Dr.

MME obtained his Certification in Family Medicine (CCFP) from the College of Family Physicians of Canada in 1979. Dr. MME has associate medical staff privileges at Hospital UYY, a community hospital in the U.S.A. He is also a member of two boards and an academy of environmental medicine. He does not hold a university appointment.

Counsel for the defence tendered Dr. MME as an expert in the diagnosis and treatment of allergy especially related to environmental and occupational causes as well as in the use of histamine in the treatment of allergic disorders. His qualifications as an expert witness in the use of histamine in the treatment of allergies were accepted by the Committee. However, the Committee found that he offered no assistance on the standards of practice in Ontario.

Dr. MME began using histamine as a therapy in 1987 and has used it for diagnosis and therapy in about 1,500 patients both in Canada and in the U.S. city of MKS. In MKS, he estimated that some 25,000 patients have been treated with histamine. Among the allergic problems he has seen, he listed hay fever, asthma, urticaria, eczema, irritable bowel, chemical sensitivity, chronic fatigue syndrome and industrial chemical sensitivities. He also sees patients with encephalopathy which he prefers to term as "toxic brain syndrome". He has his patients complete a questionnaire in which they list their types of problems and the details of their allergic symptoms. He then orders some blood tests on them. All these patients have intradermal testing carried out by histamine injections. He does not use the prick test employed by Dr. Ravikovich, because he does not believe that it is as reliable as intradermal injections where one knows exactly how much the patient is getting. He uses intradermal histamine injections as a positive control. A negative test

suggests the possibility that the patient has received steroid or antihistamine therapy. Following the histamine skin test, he proceeds with subcutaneous injections of histamine. He has observed that therapeutic doses of histamine often relieve milder systemic features. Nevertheless if the patient has a bad allergy, he may employ epinephrine or steroids.

Although, like Dr. Ravikovich, Dr. MME employs histamine both diagnostically and therapeutically, he tends to employ higher doses of histamine at the onset and gradually lowers the dose to a treatment level. In contrast Dr. Ravikovich tends to start with lower doses of histamine and gradually increases to higher doses. Nevertheless, Dr. MME felt that both end up at about the same strength of histamine. Dr. MME claimed that the lower doses of histamine employed by Dr. Ravikovich were not homeopathic but in fact had measurable physiological effects.

When questioned by counsel for the defence concerning the natural course of asthma, Dr. MME replied that this varied and that asthma was not a curable condition. His patients often inject themselves with histamine every four days but if necessary can give it up to four times a day and these injections may often relieve symptoms although they do not result in a cure. Dr. MME does not always use only histamine. He usually combines it with other treatments such as diet and environmental controls. However, even when he uses histamine alone the patient may react with dramatic improvement. His patients come from all over North America and they may have seen many other physicians. The patient may be taking antihistamines, bronchodilators and steroids. After his treatment they may reduce or discontinue the above medications. Steroids may predispose the patient to infection, diabetes, skin changes, stomach ulcers or even Cushing's Syndrome and is

therefore desirable to wean them off this medication.

When asked by counsel how histamine works, Dr. MME replied that it acts as its own regulator by a negative feedback mechanism. It attaches to H₂ and H₃ receptors to down regulate the internal secretion of histamine. It may also stimulate prostaglandins which are anti-inflammatory. But he stated that there was no full answer as to why histamine works. It has been used for 30 to 35 years in the United States. The American Academy of Autolaryngic Allergy which he stated is a sub-branch of the American Medical Association, has 1,000 members and these histamine techniques are taught there.

Dr. MME asserted that the low dosages of histamine employed by Dr. Ravikovich constituted no risk to the patients. When asked by counsel what is the need for a negative control which Dr. Ravikovich does not employ, Dr. MME answered that its omission probably makes no difference and it does not matter.

Dr. MME was questioned about the first patient, A. He saw no reason to think that the child should have received treatment other than employed by Dr. Ravikovich. He noted that the child received Atrovent and Choledyl and really did not require steroids or antibiotics. Furthermore he noted no evidence that Dr. Ravikovich discontinued the child's previous medication.

When questioned about patient B, Dr. MME noted that Dr. Ravikovich did not tell the patient to stop his previous medication. He also believed that a histamine trial was very reasonable in this case. He stated that 95 to 97 percent of the patients seen in his U.S.

clinic are given histamine therapy. Of these, perhaps 15 to 20 percent do not benefit from histamine therapy. He stated however that without speaking to the patient the physician cannot make a definitive judgment regarding the patient's clinical state. He asserted that nothing that Dr. Ravikovich employed put the patient at risk.

Dr. MME was questioned about the third patient, C, who was about 9 1/2 years of age in 1988 when she was first seen. He thought it possible that the patient suffered from certain food allergies and therefore histamine treatment was appropriate in her case. He again observed that Dr. Ravikovich did not stop any of the patient's previous medications nor did his own therapy put the patient at risk.

The next patient, D, was suffering from anxiety, depression and confusion. Dr. MME stated that these symptoms were commonly due to molds and that the physician should also rule out other environmental factors such as food. He believed that a trial of histamine here was reasonable. Because of deterioration this patient was sent for psychotherapy on a number of occasions. At the end, she was still taking medicines everyday and it was clear that histamine had not provided any particular relief for this patient. Nevertheless he testified that Dr. Ravikovich's employment of histamine had not done the patient any damage.

When questioned about the next patient, E, who was about eight months old when first seen, Dr. MME asserted that he would not have done standard allergy tests on a child of this age. He noted that allergic patients often improve when they are given skin tests even before receiving a therapeutic dose of the allergen. When questioned about the placebo effect of injections, Dr. MME asserted that there can be a placebo effect but these would only last for a short time. Furthermore, very young children do not exhibit placebo effects.

He stated that there were no double-blind studies concerning the use of histamine therapy. However, it has been used for a very long period of time and since it is so frequently successful, he did not feel that a study was needed at this time. He asserted that many of the treatments doctors employ, perhaps two-thirds of them, have never been proven by scientific studies to be effective. Dr. MME then referred to the Harvard Community Health Plan Annual Report 1991 where it is stated that "health researchers estimate that as few as a third of all medical interventions (drugs, surgery, tests, etc.) have been shown in scientific trials to help cure disease or preserve health." The same figure is noted in another article entitled "Flying Blind is Dangerous" by Dr. Donald M. Berwick. Dr. MME stated that histamine therapy saves a lot of money because the patient does not require other medications as the symptoms are reduced. He noted that the province in which he practices pays for histamine testing but not for histamine treatment. Finally he noted that histamine therapy was now appropriate in the light of recent advances in the treatment of allergic conditions.

Dr. MME was cross-examined by counsel for the prosecution. He stated that the environmental health clinic in MKS, where he works, has two other physicians as well as a Ph.D. biologist and two affiliated Ph.D. psychologists. Working with them at present are

an allergist and an ophthalmologist from other countries. The centre is a free standing clinic not a hospital. However he also works in the "Environmental Control Unit" which is a wing in a hospital. Although his clinic is not affiliated with a medical school, trainees from the medical school nevertheless rotate through it. None of the physicians in the clinic has a university appointment. The therapeutic approach employed in their clinic includes avoidance of allergens such as dust, molds, certain foods. However the approach is comprehensive inasmuch as not only are histamine tests used but also standard allergens are employed. The clinic also employs a binocular iris corder which is run by an ophthalmologist and which tells the tone of the autonomic nervous system. Eighty percent of their patients have been tested with this apparatus and the clinic has published an article on it. From a research standpoint, a small number of patients have undergone a SPECT scan which examines the metabolic or biochemical activity in the brain. He stated that, of 180 patients with chemical sensitivities who have undergone this examination, 95% have had an abnormal scan, whereas 25 healthy control patients have all had normal scans. The test costs about \$2,000. Under questioning he noted that the highest concentration of histamine he employed in his skin tests was 1:1800. The skin test is known as "provocation neutralization". Although he starts with a dilution of 1:1800, he then weakens his histamine solution until the injections no longer produce a wheal and a flare. He again observed that about 15 to 20 percent of his patients do not respond to histamine therapy. Nevertheless he claimed that far more allergists use histamine in the treatment of allergy than do not.

When asked about the mechanism of systemic reactions to histamine injections, Dr. MME stated that histamine is a potent mediator of inflammation and this reaction may be worse

if the patient has allergies. Histamine causes vasodilation following which the blood pressure can fall. Nevertheless it is unusual to observe major symptoms following skin testing. When asked why he limits his dilution to a maximum concentration of 1:1800, Dr. MME replied that he wanted to be safe in his injections and that there was no clinical need to go to higher strengths.

Dr. MME stated that he was only an employee and not a shareholder in the U.S. clinic. The senior physician in the clinic, Dr. FWK, also performed vascular and chest surgery. Dr. MME attends in his Canadian clinic two weeks out of every eight. The clinic is only open when he is there. Dr. MME also stated that he does use a negative saline control in his practice.

When asked how the injection of such small amounts of histamine could work, Dr. MME replied that a histamine injection acts via its own negative feedback by stimulating H₂ receptors which reduce the internal secretion of histamine.

Concerning patient D, Dr. MME was asked how he could tell if symptoms were due to diet allergy. He replied that when the physician changes the diet, some patients feel better at once or the physician may employ intradermal testing for food which could produce a wheal or symptoms. He observed that Dr. Ravikovich did not explore the dietary side in this patient but used only histamine injections. Dr. MME also replied that he never treated overwhelming depressions with only histamine but included this as part of a larger program including other skin tests.

In his testimony, Dr. MME stated that Dr. Ravikovich's technique may be taught in other units or centres but he himself did not know of this. Dr. MME stated that his own technique was taught in Ohio, in the University of Oklahoma, in Fort Worth, Texas and possibly in the College of Osteopathic Medicine. He agreed that few medical schools teach histamine treatment for allergic conditions. He also stated that in this respect there is a division between allergists and environmentalists.

Counsel for the defence, in re-direct, emphasized that one of the issues in the present hearing had to do with what the standards were in the treatment of allergic conditions between 1985 and 1991 rather than what the standards should be.

Counsel for the defence called as his second witness the defendant, Dr. Ravikovich. Dr. Ravikovich was born and raised in Russia. Before coming to Canada in 1980 he spent some six months in Italy. He graduated in medicine in 1961 from the Leningrad Medical Institute. He then worked for three compulsory years in small towns near Finland. He spent two years rotating through various disciplines in internal medicine and his training in that field included endocrinology and hematology. In 1971 he was sent to a training course in allergy in Moscow which lasted six months, following which he obtained a certificate. Initially he worked as an allergist and as an internist but, with the passage of time, he became more interested in and limited his practice almost exclusively to allergy. His publications include ten works in Russian journals. These emphasized his later interest in asthma from the standpoint of an allergist.

When he left Russia he spoke no English. He passed his ECFMG in Toronto and his LMCC

in 1981. Following this he worked for two years in Hospital SQY in a rotating internship. He obtained his licence to practice in 1985. He joined a group practice for some two to three months as a general practitioner but also worked doing geriatrics and caring for terminal cases. He then opened his solo practice in January 1986, doing general practice at first and then limiting his practice entirely to allergy including asthma. Dr. Ravikovich referred to his abstract that was published in "Allergologie" in September 1989 under the title "Histamine Therapy In Allergy". He expanded upon the material in this abstract in an article entitled "Specific Diagnosis and Hyposensitization in Allergy" published in the same year in "New American's Collected Scientific Reports". More recently he presented a paper at "The Second International Symposium on Pollinosis in the Mediterranean Area" held in Israel in March 1992. The abstract, published in "Allergie and Immunologie, is entitled, "H₂/3 Effect in Allergy". Dr. Ravikovich also stated that his attempts to publish in Canadian journals have been rejected.

Concerning his attempts at continuing medical education, he stated that, on the average, he spent an hour a day reviewing literature on allergy and asthma. Among the journals he consulted were the Journal of Allergy and Clinical Immunology, published in the United States which he regarded as the most respectable source. As well, there is a European journal entitled "The Journal of Clinical and Experimental Allergy". He also reads the New England Journal of Medicine, Lancet, Trends in Pharmacology and Science.

Dr. Ravikovich asserted that, if he encountered a difficult clinical problem, he went to the books for help. His practice is not homeopathic but he does not reject this as a therapy. It was clinical observation that led him to histamine treatment. He felt it was up to the

treating physician to select the available medications specially if there was a favourable benefit/risk ratio. He asserted that the treating physician's first goal should be to be "serve the patient". Counsel for the defence referred Dr. Ravikovich to articles that appeared in the Canadian Medical Association Journal in 1990 by Drs. Linton and Peachey entitled "Guidelines for Medical Practice" and expressing views endorsed by the Board of Directors of the Ontario Medical Association. In general, Dr. Ravikovich agreed with the general conclusions in these articles, among them: "rigid standards must be avoided to allow for individual consideration and scientific innovation." He stated that medicine is both an art and a science and the physician must be fully informed about the medicine he is going to use including its pharmacological and physiological effects. He should weigh the good and the bad effects and at all times he must consider the patient's interests.

Counsel referred to a paper entitled "Code of Ethics" published by the Canadian Medical Association in April 1990. Dr. Ravikovich considers that he conducts himself according to the guidelines mentioned in this paper. Although his practice is sometimes not within rigid standards, he stated it is always within accepted medical guidelines. He does not accept double-blind studies as the only standard by which therapies should be judged.

Dr. Ravikovich could not find what the standard of allergy practice was from anyone with whom he consulted. He stated that he got no answer from the Ontario Medical Association. Furthermore, the College of Physicians and Surgeons of Ontario does not publish a list of such standards. When asked by counsel when he first came to use histamine in the treatment of allergy, Dr. Ravikovich replied that this occurred soon after the start of his practice in Russia. When asked about the purpose of a negative skin

control, Dr. Ravikovich replied that, if the skin reacts to the water alone, something is wrong with it that is not related to allergy. Such negative controls, he maintained are only useful in comparison with allergen extracts and have nothing to do with the use of histamine. The significance of a negative skin test, he maintained, was small and if the allergen skin test is negative one did not need a negative control.

Dr. Ravikovich was then referred to an article appearing in the "Federal Register", Volume 50, January 23, 1985. This is published by the Food and Drug Administration and, according to Dr. Ravikovich, is the most updated set of recommendations in the field of allergy. He referred to a section where it is stated "a negative reaction to an allergen which has been diluted identically to those giving positive reactions will also serve as a negative control". Dr. Ravikovich however went on to state that when he uses standard allergen skin tests he does employ negative controls. He then referred to the "Bencard", the standard Eastern Skin Test Reaction Chart, which he stated was the most widely used in Canada. When a patient first consults him, Dr. Ravikovich takes the patient's history for example: Does he or she have hay fever? Depending on the allergy history, he will then begin injections with the appropriate pollens listed in the Bencard in the form of a series of drops applied to the skin and subsequently pricked with a metal scratcher. If there is a wheal, this must be measured, the accompanying flare is not as important. Up to this stage, he claimed that his procedure was the same as any other allergists. However at this point he also does a positive control with a histamine skin test. In a subsequent visit, when he may perform standard allergen tests, he uses negative controls. He observed that histamine skin tests not only produce a reaction in the skin but also occasionally caused some systemic features. Dr. Ravikovich then asked whether the systemic features were

due to the allergens in his skin test or to the histamine. He decided to separate histamine from the allergens and now does his skin testing in two stages. He first does a skin test with histamine and he observed that histamine gave not only a skin reaction but also some systemic features which themselves could reflect either a worsening or an improvement in the asthmatic symptoms if asthma were the pre-existing complaint. He then went to the conventional method of using skin testing of allergens and found both the skin and systemic reactions (worsening or improving) and therefore observed that both approaches had similar effects. Following his skin tests, he has the patient record his symptoms in the form of a "symptom score" over a period of 24 hours. With this score he can tell how significant the systemic reaction is. He also noted that histamine is not a prescription and can be bought over the counter.

From a diagnostic standpoint, Dr. Ravikovich employs three approaches with his skin tests.

If his histamine skin test is positive after 24 hours and there is no change in the systemic features, he then proceeds to allergen skin tests, again allowing 24 hours to observe systemic changes. Secondly, if the histamine skin test is positive but there is a worsening of the systemic features, he judges that the response to histamine injection will not be favourable and he then proceeds to allergen skin tests again observing systemic reaction changes. Thirdly, if the histamine skin test leads to improvement in systemic features and if the improvement is considerable, he will not do any allergen skin tests. However, if the improvement is only marginal he will again proceed to allergen skin tests.

Dr. Ravikovich stressed that, if his histamine skin test is positive and is associated with improvement in systemic features, he will employ only histamine treatment thereafter. He

estimated that about 80% of his patients fall into this category. In other patients he is also prepared to add house dust or dust mite allergens and if, afterwards, there is deterioration, he will also use oral steroids and steroid inhalers. However he does not employ steroids and immunotherapy at the same time. He stated that some patients do not respond to histamine therapy. He stressed however that the use of steroids whether applied orally or by inhalation, has the potential for significant adverse effects. For example, growth retardation has been observed in asthmatic children treated with inhaled steroids. Accordingly Dr. Ravikovich uses steroids as a last line of defence whereas he believes Dr. PLN uses it as a first approach.

Dr. Ravikovich went on to explain that the standard ampule of histamine contains one mg. of histamine in one ml. of diluent. This is equivalent to 1 mg. of histamine in 1000 mg. of diluent and the dilution can be expressed at 10^{-3} . In his next exhibit, Dr. Ravikovich showed that the smallest amount of histamine that was still immunologically active was 10^{-9} according to Dr. Rochlin and 10^{-11} according to Dr. Melmon. In his prick test, Dr. Ravikovich used histamine dilutions of 10^{-6} to 10^{-3} whereas, in his treatment, his subcutaneous injections varied in strength from 10^{-12} to 10^{-4} . Dr. Ravikovich claimed that there were no standards in internal medicine but rather the physician must use the best available information, both scientific and clinical, available in Canada and worldwide. The physician must then use this consensus and his own clinical appraisal. He referred to an editorial in the Journal of Medical Ethics published in 1992 entitled "The Ethics of Ignorance". In it, one authority argues that only about 15 percent of medical interventions are supported by solid scientific evidence or in other words, 85 percent are not. When asked by his counsel whether, in 1985, Dr. Ravikovich had the same understanding of

standards as were discussed in articles published in 1992 and 1993, he answered in the affirmative.

When asked by his counsel to define allergy, Dr. Ravikovich stated that there were two types: immediate hypersensitivity and delayed hypersensitivity. He went on to review the role of mast cells, an effector organ which can be triggered by the immunoglobulin IgE from an antigen/antibody reaction. This is known as atopic allergy. Other triggers of mast cell release include histamine. He pointed out that the T-lymphocyte regulates allergic processes, both immediate and delayed, and that T-cells govern IgE and mast cells. He then referred to an article by Holgate published in 1989 showing that there were many target organs for histamine including blood cells, cells of the nervous system, both central and peripheral, smooth muscle and cells of the immune system including basophils and lymphocytes. He also pointed out that there were three receptor sub-types for histamine labelled, H₁, H₂ and H₃. H₂ and H₃ receptors were involved in beneficial actions while H₁ receptors had bad effects with a few exceptions. H₂ receptors were more numerous than H₁. In another article published in 1990, Dr. Ravikovich noted the statement that "histamine seems to be the natural agonist of the H₃ receptor."

Dr. Ravikovich referred to Dorland's Illustrated Medical Dictionary, published in 1988, which gives the following definition of hypersensitivity: "a state of altered reactivity in which the body reacts with an exaggerated immune response to a foreign substance. Hypersensitivity reactions are classified as immediate or delayed". In a footnote added to an article published in 1992, Dr. Ravikovich noted that histamine had been found in stored pollen as far back as 1952.

Dr. Ravikovich referred in his evidence to a review article "Skin Testing for Allergy in Children" by the Subcommittee of the Allergy Section, Canadian Paediatric Society, published in the Canadian Medical Association Journal, Volume 129, October 15, 1983. He extracted one conclusion that physicians should not rely only on skin tests in diagnosing allergies but they must also take the patients history into account. He presented two quotations from the paper: "skin tests themselves, and especially intracutaneous tests, can cause anaphylaxis and even death in highly sensitive patients." Furthermore: "in some allergies, particularly those caused by foods, tests may not be helpful and the diagnosis must be made by clinical observation alone."

Dr. Ravikovich further referred to an article in the Journal of Allergy and Clinical Immunology, published in 1993. In this study, subjects received sublingual therapy containing concentrations of histamine far higher than any Dr. Ravikovich ever uses and yet no significant adverse effects were noted after 105 daily administrations. He pointed out that sublingual administration is almost equivalent to subcutaneous injections of histamine.

In an article published in the American Academy of Otolaryngic Allergy in 1992, in a section entitled "Prime Reactions of Histamine", Dr. Ravikovich observed that, listed under this heading, was extra-cellular histamine feedback inhibition of basophil histamine release via stimulation of cyclic AMP synthesis. He also referred to another section entitled "Optimum Dosage Histamine Regimen." In the additional bibliography at the end of the article, Dr. Ravikovich observed that four important papers were published in 1971, 1973 and 1975 and that he was well aware of these publications before 1985 and had studied

them before starting his own histamine therapy. He again referred to the fact that the American Academy of Environmental Medicine was a major proponent of histamine use. Similarly, his expert witness, Dr. MME, continued to use histamine therapy in his Canadian clinic which was a branch of his U.S. clinic.

Dr. Ravikovich again referred to Dorland's Illustrated Medical Dictionary, this time for the definition of histamine where it is stated that histamine is used as a diagnostic aid in testing gastric secretion administered subcutaneously. It is also used in the diagnosis of pheochromocytoma and has been used in treating various allergic manifestations for desensitization in cases of hypersensitivity and in the treatment of peripheral vascular disease, Meniere's Disease and headache. He stressed that histamine therapy was also used in non-allergic conditions. Dr. Ravikovich reviewed two articles published in 1987 and 1991 in which a structural analogue of histamine designated as betahistine hydrochloride was successfully employed in the treatment of vertigo. Unlike histamine, this medication can be administered orally. Dr. Ravikovich referred to a section in the Compendium of Pharmaceuticals and Specialties (CPS) of 1992 dealing with histamine in which it is recorded that, in its use to test the ability of the gastric mucosa to produce hydrochloric acid, dosages of 500 to 750 micrograms are injected subcutaneously. Dr. Ravikovich pointed out that this was a massive amount of histamine compared to his usage, for example, in prick tests.

In a letter published in the New England Journal of Medicine in 1983, Dr. Ravikovich pointed out that the authors combined histamine and cimetidine (an H₂ receptor blocker) in the treatment of seven cancer patients. The doses of histamine used were very large,

amounting to one to four milligrams or up to four ampules. He pointed out that the largest dose he ever gave for treatment was equivalent to 1/8 to 1/10 of the dose used in that letter. Despite the large doses employed in that study, no significant side effects were noted.

In his testimony, Dr. Ravikovich frequently referred to articles published in the Journal of Allergy and Clinical Immunology which he stated was a highly respected journal and his favourite in the field of allergy. Dr. Ravikovich referred to an article published in that journal in 1990 in which patients with allergic rhinitis were given a placebo of histamine chloride in moderate strength and showed considerable clinical improvement. Again, in the same journal published in 1993, in an abstract submitted by a Toronto group, a higher dose of histamine than that used by Dr. Ravikovich was administered to some patients with chronic urticaria with beneficial effects. There was no mention of significant adverse effects.

In answer to a question from his counsel, Dr. Ravikovich replied that before coming to Canada he had worked in a teaching hospital in Russia and, to a certain extent, was familiar with the foreign literature dealing with allergy. Most of what he read however had been published in Europe rather than in North America. When he commenced practice in late 1985 in Canada, the first text that he read in this field was that by Kaplan published in 1985. The text confirmed his conclusion that histamine is an important immunomodulator. Among the references employed in that text, were articles by Melmon, Lichtenstein and Rochlin which emphasized the role of histamine. He studied the papers they published both before and also after 1985.

Dr. Ravikovich presented a slide and a single page exhibit entitled "Genes: Mediator Cells".

These demonstrated a balance between two types of histamine-induced factors working in opposite directions. One type, histamine-induced suppressor factors (HSF's) are anti-inflammatory cytokines (factors). The second are histamine-induced releasing factors (HRF's) comprising pro-inflammatory cytokines. The HSF's are beneficial to the patient and work through H₂ and H₃ receptors. In distinction, the HRF's are damaging to the patient and work through H₁ receptors. He listed some HRF's such as Interleukin 1 and 3 and some HSF's such as gamma interferon and Interleukin 8.

He then went on to discuss two therapeutic approaches: the first would be to suppress the bad factors, mainly the HRF's, while the second would be to stimulate the good factors, such as the HSF's. He stated that Dr. PLN, the expert witness for the College, preferred the use of corticosteroids to suppress the HRF's, while he preferred immunotherapy to stimulate the HSF's.

Dr Ravikovich referred to a paper entitled "The Assessment and Treatment of Asthma: A Conference Report." This paper is based on two conferences held in Canada in May and October 1989 and was published in the Journal of Allergy and Clinical Immunology in June 1990. Among the quotes was the following: "this article is not presented as an absolute or definitive statement on assessment and treatment," then "moreover, there remains a lack of definitive information and a lack of agreement among experts on several questions.

The assessment and treatment of the individual patient remains the responsibility of the individual physician."

The accompanying text proposes a model to explain the regulatory role of histamine as part of a negative feedback mechanism on cellular immune reactions. Dr. Ravikovich presented a figure from an article published in 1979. Histamine may be liberated during an immune response via IgE mechanisms and/or by a histamine-releasing lymphokine (HRF). The liberated histamine activates a T-suppressor cell with an H₂ receptor to elaborate a lymphokine (HSF) which inhibits lymphocyte proliferation and lymphokine production thus constituting a negative feedback mechanism.

Dr. Ravikovich further made reference to a text entitled "Allergy" edited by Dr. A.P. Kaplan and published in 1985. He referred to one section entitled "Suppressor Cell Function" in which it is stated that "mononuclear cells from allergic patients have generated less histamine-induced suppressor activities than those from non-atopic control subjects. This defect appeared to be specific for histamine. It was found that the number of H₂ receptor T-cells was decreased in allergic individuals but the number of H₁ receptor T-cells was normal and this imbalance could precipitate illness. The text states "atopics had fewer H₂ receptors on their T-lymphocytes, produced less HSF in response to histamine and had a decreased monocyte response to HSF".

Dr. Ravikovich discussed a figure presented in an article entitled "Histamine-Induced Suppressor Cell Activity" published in 1984. The proposal is made that histamine activates a sub-population of T-lymphocytes to elaborate histamine-induced suppressor factors (HSF) that are capable of stimulating mononuclear phagocytes to synthesise prostaglandins that subsequently suppress lymphocyte proliferation and lymphokine production. Dr. Ravikovich referred to seven references listed in this article which had

been published between 1976 and 1983 and which he claimed to have read. He stated that his clinical observations in allergies, starting in Russia, were confirmed in Kaplan's text. He again alluded to the figure that he had presented entitled "Genes-Mediator Cells" and stated that it was unfair to deal only with anti-HRF's but that one must also consider stimulating HSF.

Dr. Ravikovich further referred to an article published in 1992 entitled "Asthma: A Follow-up Statement from an International Paediatric Asthma Consensus Group". He noted certain statements for example, "however it must be recognized that consistent delivery of effective and safe care is in the best interest of children with asthma. This is difficult to achieve because of the plethora of conflicting publications on asthma. Further, "however, the need to introduce prophylactic treatment at a very early stage remains a firm recommendation. While this might be seen as synonymous with anti-inflammatory treatment even this has yet to be established."

In an article published in 1981 by Melmon et al, Dr. Ravikovich noted that Dr. Melmon employed histamine dilutions of 10^{-11} and achieved an optimal production of HSF's in his in vitro experiments. Similarly, Dr. Ravikovich obtained good results using the same histamine concentrations in his patients. He pointed out that the expert witness for the College, Dr. PLN, suggested that employing dilutions of 10^{-11} was equivalent to employing water. Accordingly, he suggested that Dr. PLN was not in agreement with Drs. Melmon and Rochlin.

Dr. Ravikovich stated that current allergy therapy concentrates on anti-HRF drugs with a

view to suppressing HRF's. These include steroids, beta 2 agonists which are bronchodilators and H₁ antihistamines. He believes that treatment is now being directed away from these medications because of their bad side effects. In this connection, he presented a paper entitled "How to Withdraw from Steroids" published in 1994 dealing with the mechanism of action of steroids, how long they take before they work and how much care a physician should take in withdrawing steroids from a patient.

Dr. Ravikovich noted that there are two mechanisms that attempt to stimulate the HSF's. Of these the first, immunotherapy, is the most desirable. This is equivalent to hypo or desensitization and implies the delivery of allergens to the patient. He again stressed that HSF's are triggered by the good H₂ and H₃ receptors. The second stimulator would be histamine. Allergens and histamines converge in the body and have the same final effects. They boost the underdeveloped H₂ receptors in the lymphocytes.

Dr. Ravikovich further declared that physicians should not be arguing about the two approaches to dealing with allergic reactions: stimulating the HSF's and suppressing the HRF's. He feels that both approaches can benefit the patient and it is time to unite them.

Dr. Ravikovich further referred to an article published in 1989 entitled "Histamine H₂ - Receptor Antagonists in the Treatment of Urticaria." He pointed out that if large doses of histamine are used, they dilate blood vessels and therefore can drop the blood pressure. He stressed that his doses of histamine are much lower than those employed in this article and that none of his patients have ever experienced an anaphylactic reaction.

Dr. Ravikovich presented a figure from an article published in 1990 which displayed a tentative scheme of: (a) the main mechanisms involved in the initiation of airway allergic inflammation and; (b) the effector mechanisms involved in the amplification and maintenance of allergic inflammation. Among the conclusions in this article is the statement: "Thus, T-cells along with mast cells and macrophages could be considered as primary effector cells of allergic inflammation." In another figure he presented, Dr. Ravikovich stressed that IgE is the aggressive part of allergy and if the level of IgE is reduced, this results in beneficial effects in the patient's health. He again emphasized that histamine is involved in both atopic and in non-specific reactions.

Dr. Ravikovich presented data from two papers, one published in 1985 and the other in 1993 dealing with neuroendocrine-immune interactions. In the first, the conclusion is reached that "while..... the neuroendocrine system can control immune functions, it is only now becoming apparent that the control is reciprocal in that the immune system can control neuroendocrine functions". The same conclusion is arrived at, with more scientific support, in the second article published in 1993. Again Dr. Ravikovich pointed out that glucocorticoids decrease the production of histamine. Histamine in turn activates H₂ receptors to decrease the inflammatory process in both allergic and non-specific types of reactions.

At this point, by way of summary, counsel for the defence, asked Dr. Ravikovich, if at any time he instructs a patient to stop his or her previous medication. Dr. Ravikovich answered emphatically, "no!" Those patients who stopped their medication did so before they came to see him because first, the medications didn't work; secondly, there were

significant side effects from them and thirdly, they didn't want to carry on with these medications indefinitely. He estimated that 80 to 90 percent of the patients who came to him had stopped using their medications before seeing him. The balance, 10 to 20 percent, were still taking their medicines even though they were not working very well, because they were afraid to discontinue them. Dr. Ravikovich discussed other treatments with the patients and, in particular, his own histamine desensitization technique. He also gave them a pamphlet to help them understand his therapy. One of the objectives was to decide whether the patient was suitable for histamine or allergy extract therapy. In any event, the patient had to be fully informed before starting his particular histamine therapy.

Dr. Ravikovich again emphasized that the assessment of the clinical response to the various skin tests was most important in determining the course of therapy. While he tends to use negative controls (saline) with standard allergen tests, in the patients charts he records only positive tests. He stressed that patients were told that they were free to continue histamine therapy or standard allergen therapy or in fact to find another physician.

Counsel for the defence placed on record Dr. Ravikovich's disagreement with a statement made by Dr. PLN in his testimony. The latter stated that Dorland's Illustrated Medical Dictionary was directed to secretaries rather than to physicians but counsel pointed out that the "preface" in the 1981 edition of that dictionary stated otherwise.

Dr. Ravikovich testified that, in allergic reactions, the mast cell is dominant. It releases histamine which itself plays a role in allergic inflammation but at the same time, histamine releases cytokines which may perpetuate an allergic reaction. There are two phases to allergic reactions stimulated by histamine release. The early phase is atopic, related to IgE stimulation. The later phase is non-specific but there may also be an early non-specific phase entitled "physical allergy." In his view, the physician must know both the mechanisms of both the atopic and the non-specific reactions.

In a review article entitled "Atopic Dermatitis" published in December 1992, Dr. Ravikovich noted that there were two kinds of lymphocytes involved in allergic reactions: TH₂ are pro-inflammatory T-lymphocytes and the second TH₁ are anti-inflammatory T-lymphocytes which also release anti-inflammatory cytokines. Ordinarily there is a balance between these two types of T-lymphocytes but if the TH₂ cells predominate then the patient suffers disease. If TH₁ lymphocytes are deficient, similarly the patient may have a disease. The genetic predisposition that is known to be the case in allergies depends upon the T-lymphocytes.

Dr. Ravikovich referred again to Kaplan's text "Allergy". He quoted from a chapter entitled Atopic Dermatitis: "Although several factors have been indicated as causative, the etiology and pathogenesis of atopic dermatitis remain enigmatic". Dr. Ravikovich stressed that there is no clarity in our current understanding of atopic diseases. For example, IgE does not cover the whole problem of atopic illness - something else must be going on including regulation by T-lymphocytes. He estimated that IgE may be involved in only about 50 percent of allergy.

Dr. Ravikovich examined another paper published in 1991 based on a lecture presented in 1989. It points out that, in addition to mast cells and basophils being stimulated in allergic reactions by allergens, other factors most likely play a role in regulating these cells. The role of other factors or cytokines has been an active area of recent investigations. Effects of cytokines on basophils and mast cells includes cell differentiation, maturation and trafficking. Mast cells themselves may synthesize cytokines. Prior to 1985 Dr. Ravikovich was aware of the processes examined in this paper. In the present article, the statement is made, "although the mast cell is the predominant cell source of histamine and other mediators in the immediate allergic response, the pattern of mediators recovered from the late phase response or delayed response more clearly resembles the response of the basophil. In other words, the mast cell is more responsible for histamine release in the immediate allergic response while the basophil may be more responsible for histamine release in the delayed response." The paper goes on to state that a number of cytokines can induce low levels of histamine release from susceptible basophils, the most potent of which in terms of histamine releasing activity is IL-3. In another section, the statement is made that the generation of human histamine release inhibitory factors (HRIF's) is increased by physiologic concentrations of histamine suggesting a mechanism for feedback inhibition of histamine secretion. In other words, histamine can inhibit allergic reactions as well. Further, in the same paper concerning allergic reactions it is stated: "the intrinsic reactivity of basophils and mast cells may be determined by a variety of substances that increase (HRF and IL-3) or decrease (HRIF and IL-8) cellular response". Also: "Histamine, a major mediator of allergic injury, may have an additional effect by increasing synthesis of HRIF, a specific inhibitor of HRF, which may restore local homeostasis".

Dr. Ravikovich again pointed out that, in his practice, more than 50 percent of the supposed allergic reactions he deals with are non-atopic. He then went on to consider the side effects of some agents used in the therapy of allergic conditions. In a paper published in the American Review of Respiratory Diseases in 1990, Dr. Ravikovich referred to a table listing the mediators inhibited by glucocorticoids. Among these are certain hormones which are necessary for our well-being, for example, insulin. As well, certain cytokines are inhibited by glucocorticoids leading to both good and bad effects. Finally he noted that histamine listed among the inflammatory agents, is also inhibited by glucocorticoids. Therefore glucocorticoids have all kinds of bad effects as well as good effects and must be used cautiously.

In a paper published in 1992, Dr. Ravikovich pointed out that hydrocortisone induces IL-4 dependent IgE synthesis in various cells. This is another example of potential bad effects of corticoids.

Dr. Ravikovich referred to a paper published in "Diagnosis" in June 1986 in which he quoted: "Corticosteroids are recommended for severe nasal congestion or if polyps are present. Although topical steroids are effective and safe for long-term use systemic glucocorticoids have side effects and are recommended only as a last resort." Dr. Ravikovich alluded to another paper published in the "Annals of Allergy" in 1983. Here the statement is made that "it is well recognized that systemic corticosteroids are usually beneficial in this condition (perennial rhinitis). However long-term oral corticosteroid treatment cannot be justified in this chronic disease which is usually more annoying than

serious".

In another paper published in the American Review of Respiratory Diseases, 1993, it is stated that at lower doses of inhaled steroids, there was no acute measurable effect on the levels of serum osteocalcin, a marker of bone osteoblast function, and presumably of bone formation.

Dr. Ravikovich pointed out that, in an article appearing in a newspaper entitled "Dermatology Times of Canada" published in May 1994, it is stated that misuse of topical steroids in children is common and can lead to a variety of local and systemic side effects. When topical steroids have been used on a prolonged daily basis, the systemic side effects include growth failure, failure to thrive, glaucoma and flare of psoriasis.

Dr. Ravikovich went on to review the side effects of bronchodilators. He referred to a paper published in The New England Journal of Medicine in 1992 where it is stated that "morbidity and mortality from asthma appeared to be increasing and it has been suggested that medications used to treat asthma are contributing to this trend". In the conclusions it is noted that an increased risk of death or near death from asthma was associated with the regular use of inhaled beta 2 agonist bronchodilators. Dr. Ravikovich pointed out that Salbutamol (trade name Ventolin) is probably the most widely known of the bronchodilators.

Dr. Ravikovich then proceeded to deal with the use of antihistamines. He referred to the product Seldane listed in the CPS of 1992 in which the adverse effects of this histamine H₁ receptor antagonist are listed. He referred to another paper where histamine has been administered to reduce metastases in patients with cancer and therefore it was prudent not to use antihistamines to block the effect of histamine in such patients.

Dr. Ravikovich referred to the article "Allergy - Conventional and Alternative Concepts" - a Report of the Royal College of Physicians Committee on Clinical Immunology and Allergy published in 1992 and cited previously by Dr. PLN. Dr. Ravikovich stated that Dr. PLN used this publication to criticize his treatments. In the Summary it is stated: "Conventional doctors treat allergy by allergen avoidance - where this is possible - and drugs that relieve symptoms. In a few selected cases in which other methods have failed, immunotherapy (desensitization or hyposensitization) is recommended. Although patients who consult practitioners of alternative allergy may do so by preference, it is often also because they are dissatisfied with the conventional approach to diagnosis and treatment or because they have conditions which conventional doctors do not accept as having an allergic basis. There is a wide range of alternative approaches to allergy, including the methods used by clinical ecologists and other treatments such as acupuncture and homeopathy. Hypnosis may have a small role to play in helping the asthmatic and similar effects have been suggested for acupuncture." Dr. Ravikovich pointed out that histamine is not mentioned among these alternative therapies and he does not practice those that are mentioned. In the section entitled "Alternative Concepts of Allergy", the statement is made that "nevertheless new claims from any source about the cause of illness or the effect of treatment need to be tested and shown to be effective before they can be recommended."

Further it is stated: "Progress is sometimes made through chance or empirical findings and many of the drugs in modern use have their origins in folklore or herbal remedies. However they retain their place in modern therapy because of their efficacy and because the active ingredients have been isolated, characterized and standardized." Dr. Ravikovich referred to another section: "We believe it is important that practitioners of any form of medicine whether conventional or not, should base their claims on reasonable objective standards of evidence."

What Dr. Ravikovich drew from this paper was that if a drug is entirely new then it must undergo a double-blind placebo - controlled trial. But if the drug is already in use, then apparently he feels that it can be applied to a new disease or condition, especially if it has been found to be safe.

Dr. Ravikovich then analysed a paper published by Dr. PLN in the Journal of Otolaryngology in 1989. As well as presenting his own data, Dr. PLN referred to a paper by Dr. D.D. Stevenson among others and stated: In summary, "patients with rhino-sinusitis, nasal polyps and asthma who have reacted adversely to Aspirin ingestion in the past can now be desensitized safely to Aspirin, often with improvement in their airway symptoms." Dr. Ravikovich pointed out that these studies were clinically "open", involved small numbers of patients, were not double-blind and could be viewed as scientifically poor using a drug, aspirin that was potentially dangerous in these aspirin-sensitive patients. He pointed out that Dr. PLN did the same with aspirin desensitization as Dr. Ravikovich has done with his histamine therapy, that is Dr. PLN took an old drug namely aspirin and gave it a new use namely desensitization.

Dr. Ravikovich's views were summarized as follows: a double-blind study is not necessarily the standard for an old drug that has been in use for a long time even if it is given a new use so long as:

- 1) the patient's disorder has been fully considered by the physician;
- 2) that the patient has been fully informed of this new use by the doctor;
- 3) that the doctor has been able to find some support for his new treatment in the medical literature.

In referring again to the Royal College article entitled "Allergy". Dr. Ravikovich stated that if a drug is approved for one use it can then be used for a new use if new findings of significance have been made, for example, histamine is now known to work through new receptors.

Counsel for Dr. Ravikovich pointed out through his examination that Dr. PLN and the College had been critical of Dr. Ravikovich's failure to use objective criteria to assess improvement in his asthmatic patients, for example, the use of a peak flow meter. Dr. Ravikovich replied that the peak flow meter measures pulmonary expiratory flow and is objective. While it usually parallels the clinical state, this does not always occur. Dr. Ravikovich uses this only in some patients who buy the meter and employ it at home but only if they are in questionable health. He then referred to an article in "Contemporary Allergies" published in 1993 where it is stated that the routine use of peak expiratory flow meters has not yet been properly validated in the follow-up of asthma. He believes that, at this time, it is preferable to rely on the symptoms of the patient as for example, an increase in the daily need of bronchodilators.

In reply to his counsel, Dr. Ravikovich stated that in dealing with his patients he employs both a drug score and a symptom score in his charts.

Counsel for the defence questioned Dr. Ravikovich about the evidence of Dr. PLN that Dr. Ravikovich's dilution of histamine was really homeopathic and the equivalent of water.

In reply Dr. Ravikovich pointed out that histamine is a crystal comparable to insulin and is suspended in a diluent. The greatest dilution that Dr. Ravikovich uses is 10^{-12} and this dilution contains in fact 2×10^{-9} or 2 billion molecules of histamine. He again emphasized that this is the lowest concentration or the highest dilution that he uses and therefore this is very far from being equivalent to water.

The College had asked Dr. Ravikovich to produce charts illustrating his practice with regard

to histamine treatment. Dr. Ravikovich testified that the College had never discussed his cases with him or had ever talked to his patients concerning his treatment of them. He testified as follows about the treatment of the identified patients as disclosed in his charts.

The first patient, QHD, was about one-and-one-half years of age when Dr. Ravikovich began treating him on June 17, 1987. In connection with this case, Dr. PLN had stated that Dr. Ravikovich did not use negative controls in his skin tests. Dr. Ravikovich denied this and stated he did use saline controls when he employs an allergen. The child, QHD, presented with a stuffed nose and a generalized itchy skin rash. Dr. Ravikovich performed a histamine skin prick test at a dilution of 10^{-6} and within 15 minutes there was improvement in the nasal symptoms. Dr. PLN had testified that there had been no clinical improvement. However, 24 hours after the skin test there was dramatic improvement in both the nasal and itching symptoms. At this time, Dr. Ravikovich began employing histamine therapy with injections of dilutions of 10^{-10} of histamine subcutaneously. By October 8, 1987, about 95 percent of the lesions were gone. However there was a recurrence of running nose and itchy eyes in April 1988, and this may have been due to exposure to trees. Dr. Ravikovich then resumed histamine injections with some improvement although there may have been occasional relapses. Nevertheless, the patient had a good remission for two years between 1990 and 1992. Dr. PLN had testified that the patient had ended up in an emergency department but in fact Dr. Ravikovich's chart does not show this. The patient had had a recurrence of his skin rash and nasal congestion but this was not life-threatening. He did not experience any recurrence of asthmatic symptoms. For another recurrence in April 1988, Dr. Ravikovich actually prescribed two drugs: Alupent, a bronchodilator and Atarax, an antihistamine. When in

April 1988 the child was brought to Hospital HFG, the patient was given Ventolin and other drugs but the asthma got worse. Dr. Ravikovich subsequently gave the patient a histamine injection of 0.25 ml of a dilution of $1:10^{-9}$ and the patient's symptoms improved and as did the auscultation findings within 10 minutes.

When the child first came to see Dr. Ravikovich, he explained the new approach using histamine to his parents and they were given a pamphlet with this information. Despite any of the relapses the child may have experienced during his treatment by Dr. Ravikovich, his symptoms of eczema and asthma never reverted to the severity that he displayed on his first visit to Dr. Ravikovich.

The second patient reviewed by Dr. Ravikovich was patient UVZ. At age six or eight the patient was seen at Hospital YZM and prescribed steroids and allergens, a combination which Dr. Ravikovich feels is unacceptable. When he was first seen by Dr. Ravikovich he was taking all his medications and Dr. Ravikovich, in contrast to what Dr. PLN had testified, did not tell him to stop his medicines. He had apparently received sixteen years of allergen injections, for example, dust without success. Dr. Ravikovich then commenced histamine therapy but, when the patient needed his other medications, he was allowed to continue them. As Dr. Ravikovich gradually increased his dosage of histamine, the patient's asthma decreased and he stopped using Ventolin. Once again, Dr. Ravikovich claimed that this patient's symptoms never reverted to the severity he displayed when he was first seen. Toward the end of his treatment, he did not require other medications such as steroids. This patient also had occasional relapses during his therapy but, usually with increases in histamine dosage, he improved.

Dr. Ravikovich then went on to consider IBJ. This patient was aged nine-and-one-half when first seen in July 1988. She had a definite history of food allergy. After administering a histamine skin test, Dr. Ravikovich then began subcutaneous injections. According to Dr. PLN, at the time of the third injection of histamine, the patient underwent a severe reaction and Dr. PLN felt that the histamine had put her at significant risk. Dr. Ravikovich, however, claimed that there was no evidence of a severe reaction but rather the observed reaction was local and mild. The patient then began to improve with the histamine injections and, between 1990 and 1991, she had almost a complete remission for the whole year during which she could eat anything. Dr. PLN apparently believed that her original symptoms were psychological rather than organic but Dr. Ravikovich felt that they, in fact, were allergic in nature. The histamine dilutions that Dr. Ravikovich employed in this case were 10^{-4} and 10^{-5} and Dr. Ravikovich claimed that he had never had severe reactions with these dilutions although there had been occasional mild ones. The mother had been given a brochure and counselling and the child was not taking any medication before seeing Dr. Ravikovich.

The next patient to be reviewed was BWL. At this point Dr. Ravikovich suggested another error in Dr. PLN's testimony. Under the heading "Diagnosis" Dr. Ravikovich really listed the chief complaints of the patient whereas the real diagnosis was shown at the bottom of the page. Therefore Dr. PLN was wrong in his location of the diagnosis in Dr. Ravikovich's notes. When seen in August 1990 this patient was diagnosed as having hypothyroidism (she took Eltroxin), anxiety and hypoglycemia. Again Dr. Ravikovich never instructed this patient to stop her medications but the patient apparently did so on her own. Dr.

Ravikovich provided counselling and the pamphlet for her.

Dr. Ravikovich then referred to another paper published in the Journal of Allergy and Clinical Immunology entitled "The role of antihistamine therapy in vascular headaches" in 1990 where it states: "Further impetus may come from ongoing studies of H₃ histamine receptors, which indicate that H₃ agonists offer promise as prophylactic agents for people who suffer from vascular headaches". Histamine inhibits the re-uptake of serotonin and norepinephrine by brain tissue and use of this regulatory path may prove to benefit migraine sufferers. Dr. Ravikovich stated that H-3 receptors are important in the regulation of all neurotransmitters in the brain. Patient BWL came to see Dr. Ravikovich on August 20, 1990 at time when Dr. Ravikovich was aware that histamine inhibits the production of serotonin and therefore could be used in encephalopathy. Dr. PLN had been critical of Dr. Ravikovich for using histamine in the treatment of psychological illness which this patient clearly manifested. However, Dr. Ravikovich had also diagnosed psychological illness in this patient. He had offered her counselling and told her to see a psychiatrist. Three days before consulting him, on September 21, 1990 the patient had stopped all neuroleptics on her own. On September 21, 1990 the patient wanted to undergo histamine therapy but still needed psychotherapy. She could still use antidepressants as they were needed. She continued to use Desyrel, an antidepressant, but this was not required later as she improved on histamine therapy. Over the months she became much less depressed, but on January 7, 1991 she was under great pressure, again depressed and Dr. Ravikovich gave her both histamine and Ativan to control her anxiety. On January 14, 1991 she was now using Prozac as prescribed by her psychiatrist and was continuing psychotherapy. Although Dr. Ravikovich continued to give her histamine injections, the patient continued

with her Prozac and Ativan therapy and was not told to discontinue them. In June 1993 she switched to Imipramine, another antidepressant.

Dr. Ravikovich then went on to consider patient EOF, a girl who was 10 months old when he first saw her. She had had severe asthma and her usual medications did not help. She complained of cough, wheezing and inability to sleep. Her mother was given Dr. Ravikovich's pamphlet and was informed regarding the use of immunomodulation therapy. The mother gave her consent. The patient had been taking a variety of drugs including Alupent, Ventolin, Choledyl and Atarax but was not given steroids.

Dr. Ravikovich reviewed his procedure which consisted of first giving histamine skin prick tests, then histamine injections and, if failure, then allergens. He stated that Dr. PLN was not happy with these medications and that the child needed inhaled steroids. However Dr. Ravikovich claimed that the use of inhalers was technically impossible at such an early age. He had diagnosed bronchial asthma and allergic rhinosinusitis in his patient. His skin test consisted of a 10^{-7} dilution whereas Dr. PLN claimed it was 1 in 10 and this was incorrect. When this patient showed great improvement following the skin test, Dr. Ravikovich then began to give her subcutaneous injections. The patient continued to improve but Dr. PLN claimed that this was really a placebo effect. Dr. Ravikovich contested this making two points:

- 1) that the improvement lasted too long to be a placebo effect because the latter only lasts for a short period;
- 2) the patient was only 10 months old and it was inconceivable that she would

have had a placebo effect.

Dr. PLN referred to a recurrence of this patient's symptoms suggesting that in fact the treatment was of no benefit at all. Dr. Ravikovich stated that in treating asthma there were always ups and downs and this patient was definitely better than when she was first seen. Her drug score was better and she had fewer visits with him because the symptom score was favorable. He also listed the number of molecules in his diluted histamine and again stated that this could not be a placebo or the equivalent of water as Dr. PLN had claimed. Furthermore, in a young child 10 months of age, it was impossible to use a flow meter to measure the progress of her asthma.

Because Dr. Ravikovich wanted the patient in a better state he discontinued the histamine injections and began testing with allergen skin tests and in these he did use a negative control. Because of improvement with the injections of allergy extracts, Dr. Ravikovich no longer used histamine in this patient and by March 17, 1990 she was in complete remission.

Dr. Ravikovich discussed in his testimony two papers which represent his beliefs concerning the standards of allergy practice between the years of 1985 and 1991. The first is by Dr. R. Smith and was published in the Journal of Medical Ethics in 1992. In it the author quotes others concerning the quality of medical "knowledge." They estimate that "only about 15 percent of medical interventions are supported by solid scientific evidence; in other words, 85 percent are not". The second paper is by Dr. D.M. Eddy, entitled "Three Battles to Watch in the 1990's" that appeared in JAMA in 1993. Dr. Ravikovich referred to the section "Who Has the Burden of Proof?" It states "the Food and Drug Act is based on the premise that a new drug is assumed to be investigational for an indication until it is shown in "multiple, well-controlled studies" to be effective. On the other hand, once a drug is approved to be marketed for any one indication, physicians are legally free to use it for any other indication without any additional evidence. Hundreds of diagnostic tests, devices, procedures and services are currently used and paid for without any evidence of effectiveness for any indication."

Counsel for the defence asked Dr. Ravikovich if he was aware of any studies, published before 1985, concerning the use of histamine therapy. Dr. Ravikovich referred to an article, published in 1967 by W. H. Wilson, entitled "Histamine Therapy". The article reviews the reported use of this therapy beginning in 1924 when two authors described a method by which asthmatics were treated by hypodermic injections of histamine. In 1939 two authors reported on the use of intravenous histamine in the treatment of Meniere's Disease, published in 1967. In the article it is evident that both intradermal and subcutaneous injections of histamine were also reported. In the summary of his paper, Wilson states that the particular histamine dilution technique that he describes can be used

in selected cases of headaches and episodic vertigo. Dr. Ravikovich stated that he was aware of the 1924 publication concerning the use of histamine injections in asthmatics. Dr. Ravikovich stated that he was also aware of the definition of histamine in Dorland's Medical Dictionary concerning its use in the desensitization of allergic manifestations in peripheral vascular disease, Meniere's Syndrome and headaches.

Dr. Ravikovich further referred to an article published in French in the Annals of Dermatology and Venereology in 1980 where chronic urticaria was treated by subcutaneous and intradermal injections of histamine. Dr. Ravikovich stated that he was aware of pre-1985 publications in journals other than American ones. He reviewed an article by Girard and colleagues published in 1983 in a Swiss journal, PRAXIS, which he claimed was a very reputable journal. Here the authors used a combination of histamine and human gamma globulin (Histaglobin) for hayfever and claimed 60 percent improvement.

Dr. Ravikovich referred in his testimony to another paper, again by Girard, published in PRAXIS in 1989. This is a double-blind study using histaglobin in the treatment of pollinosis (hayfever). Histaglobin was apparently introduced in 1959 for the treatment of certain allergy illnesses. In their conclusion, the authors state that the results showed unequivocal superiority of histaglobin over the placebo, human gammaglobulin in the control of nasal and ocular symptoms of pollinosis. It should be stated that this article in PRAXIS is a follow-up to the article published by the same author in 1983. In the latter article, Dr. Ravikovich was aware of references published in 1977 and 1981.

By way of summary, Dr. Ravikovich made three points:

- (1) he knew that histamine prick or intradermal tests are used through out the world by allergists and that histamine is absorbed into the blood in these tests unlike what Dr. PLN claimed;
- (2) large doses of histamine used in the prick test are unacceptable because they may cause shock. Dr. Ravikovich uses low doses at the start and these are invariably safe;
- (3) histamine is a component of the allergen skin extracts used by all allergists.

In this connection Dr. Ravikovich reviewed an article entitled "The Histamine Content of Allergen Extracts" published in the Journal of Allergy and Clinical Immunology in 1992. In a table in this article, the histamine content of a number of commercially available allergen extracts is presented. Dr. Ravikovich pointed out that he never uses such large doses of histamine to start with and rarely reaches them toward the end of his treatments. He again emphasized that the amount of histamine present in the placebo dosages employed by allergists is greater than what he uses.

Dr. Ravikovich went on to consider the use of histamine in non-allergic conditions. He pointed out that some of these have immunological mechanisms. He reviewed the published use of histamine in vertigo and Meniere's Syndrome, and quoted from an article that appeared in Seminars in Neurology in 1988. In it, histamine desensitization was used

in histaminic cephalalgia (Horton's Syndrome). Finally he closed with reference to a number of articles appearing between 1976 and 1990 in which histamine desensitization was used in the treatment of Meniere's Syndrome, vertigo, vestibular nystagmus and combined with cimetidine in the management of cancer.

In reply to a question from counsel for the College during cross-examination, Dr. Ravikovich stated that although he has high respect for the reference papers of Dr. Holgate he feels that Dr. Holgate does not follow the newest trends and therefore he pays more attention to Drs. Rocklin and Melmon. When counsel pointed out that Dr. Melmon is not a clinician and he does not employ histamine desensitization, Dr. Ravikovich replied that Dr. Melmon is Professor of Medicine and the Associate Chairman of the Department of Medicine in Stanford Medical School. Furthermore, he did not agree that Dr. Melmon's work was confined only to animal tissues.

In reply to a question from counsel for the College concerning Dr. Ravikovich's use of the Standard Eastern Skin Test Reaction Chart (Bencard), Dr. Ravikovich replied that he only uses this chart for allergen extracts, that he records the skin reactions but he does not use the "treatment" column.

Dr. Ravikovich estimated that 70 to 80 percent of his patients receive histamine desensitization. The ranges range from babies to any adult age perhaps up to 70 years. He feels that the younger patients do better because their immune systems are more resilient. He stated that in 1990 he treated some 2,500 patients with immunomodulation and believes it is about the same each year thereafter. The number of histamine injections

that patients would receive is very individual and unpredictable.

In reply to a series of questions by the College's counsel, Dr. Ravikovich made the following replies: his pamphlet was indeed distributed to new patients between 1985 and 1991. Immunotherapy is equivalent to desensitization. However steroids should not be administered at the same time as allergens. Although he tells patients that they cannot have both steroids and histamine therapy (the combination is not effective) he does not have a universal answer with regard to the patient stopping steroids. Since he is not a gastroenterology specialist, he does not use histamine for testing gastric acidity.

Under cross-examination, Dr. Ravikovich stated that he first used histamine in the diagnosis and treatment of allergic conditions in 1971 while in Russia. Twenty to thirty percent of his patients do not get histamine treatment. In 1990 ninety percent of his practice consisted of allergy patients while less than ten percent involved family medicine. He does refer patients to consultants according to the patient's needs. He may refer patients to psychiatrists if he cannot manage them but this type of referral constitutes five percent or less of his practice at this time.

Again in reply to a series of questions, Dr. Ravikovich stated that he does not give each patient the same dose of histamine. In severe cases of asthma, the physician must be more cautious and on average these patients require lower doses than do mild cases of asthma. The dose of histamine he starts with depends on his histamine prick test but, very importantly, the dose also depends on the patient's symptomatic response to the skin test. As an example, Dr. Ravikovich referred to patient EOF in whom he employed a

histamine prick test of a 1:10,000 dilution. This did not give a skin reaction but it did improve the patient's symptoms. Accordingly, about ten days later he commenced histamine injections using a dilution of 1:10,000,000 or 1,000 times less strength than the original prick test. Again he stated that, in his histamine prick test, he does not always use the same dilution and that he must be more cautious for example, in dealing with babies.

When asked by counsel for the College whether he was the only physician who treated patients with his histamine desensitization procedure, he replied "yes" and that he was unique in that no one else starts with a low dose of histamine and goes high. Others, for example Dr. MME, start with higher doses of histamine and go lower. Perhaps they both meet at the same final dose. In 1992, Dr. Ravikovich did not know of Dr. MME or of the Otolaryngic Academy.

When counsel for the College suggested that there was no medical study that showed that histaglobin and histamine diluted in distilled water were equivalent. Dr. Ravikovich replied that Dr. Girard, a Swiss physician, uses histaglobin and says that the effects of such injections are the same as those of histamine diluted in distilled water. According to Dr. Ravikovich's previous testimony, he really developed his full procedure for presentation at the West Berlin World Congress in 1989. However he understood histamine mechanisms including the negative feedbacks as far back as 1985 when they were mentioned in Kaplan's textbook. Obviously there has been a growth in knowledge since that time.

When counsel for the College pointed out that Dr. Ravikovich had tried to interest

Canadian doctors (30 or 40 of them) to do double-blind studies with histamine, Dr. Ravikovich stated that no one in Canada accepted his ideas or procedures and he therefore failed to interest them in doing such a study. Again in reply Dr. Ravikovich stated that there was a trend in medicine to get away from treating asthmatics with steroids because the physicians were not happy with achievements of this therapy and were concerned about its side effects.

Counsel for the College then presented a document entitled "International Consensus Report on Diagnosis and Treatment of Asthma" published in June 1992. When counsel referred to some of the participants and consultants who reviewed this report, Dr. Ravikovich stated that he agreed with some and disagreed with others in terms of their views. Counsel referred to the "Executive Summary" of this report, where it is stated "anti-inflammatory medications such as inhaled corticosteroids, sodium cromoglycate and nedocromil sodium are the primary therapy for the chronic care of all but mild, intermittent asthma. Further, early introduction or an increase in the dose of corticosteroids is an important component of treating severe exacerbations in order to speed resolution of the exacerbation and prevent recurrence". Dr. Ravikovich replied that he disagreed with some aspects of this summary. For example, it is accepted that there is a worsening in the morbidity and mortality of asthma and it is therefore clear to him that steroids have not interrupted these serious trends. Dr. Ravikovich does agree with the use of steroids in severe exacerbations but not as a general rule in patients requiring chronic treatment.

Counsel proceeded to quote from the paper entitled "Asthma: A Follow-up Statement" from an international paediatric asthma consensus group that appeared in Archives of

Diseases in Childhood in 1992. "As with the previous consensus meeting, more questions than answers were raised in relation to all the areas of management of asthma. There is still a need for basic well-controlled clinical trials." Dr. Ravikovich replied that he only partly agreed with this statement. When counsel for the College claimed that there never have been well-controlled clinical trials establishing the use of histamine therapy, Dr. Ravikovich disagreed "absolutely".

Counsel referred to the paper "International Consensus Report on Diagnosis and Treatment of Asthma" that appeared in 1992. Dr. Ravikovich had previously quoted a section of this paper but had omitted a sentence which followed his quote and which counsel now referred to "For NSAID sensitive asthma patients who require NSAID for other medical conditions, a desensitization may be conducted in the hospital under the care of a specialist."

The College's counsel quoted from the report of the Royal College of Physicians Committee on Clinical Immunology and Allergy entitled, "Allergy - Conventional and Alternative Concepts" published in 1992: "Apart from these situations we have yet to be convinced by substantial evidence that any of the other alternative methods of diagnosing or treating allergic disease are a proven value. There have however been many false and misleading claims and serious harm may be caused by misdiagnosis or delays in appropriate treatment. The public should be warned against costly methods of diagnosis and treatment which have not been validated." Dr. Ravikovich replied that the physician can put an old drug to a new use. The risk/benefit ratio is the only answer because medicine is uncertain. When counsel stated that nothing in the Royal College report validated

histamine therapy, Dr. Ravikovich referred to another chapter in that report entitled "Alternative Concepts of Allergy." In it he referred to the section: "We believe it is important that practitioners of any form of medicine, whether conventional or not should base their claims on reasonable objective standards of evidence. the evaluation of their work can and should still include clinical trials comparable to those required by conventional medical practice. ----- If double-blind trials cannot be carried out, biochemical tests or other methods of assessment should be developed and validated." Counsel then pointed out that histamine desensitization was not mentioned in that section read by Dr. Ravikovich or, in fact, in the entire article. However, Dr. Ravikovich again pointed to double-blind studies carried out by Dr. Girard in Switzerland and published in 1989. When asked "what are the biochemical tests establishing the efficacy of histamine treatment?", Dr. Ravikovich replied that there were two pieces of evidence: the first in Dr. MME's clinic in the U.S. City of MKS, where they measure the reaction of the iris to histamine injections and he stated that 30,000 patients have been treated over 15 years in that clinic. Secondly, he referred to Dr. Girard's scientific study. When counsel for the College stated that Dr. Girard used histaglobin and not histamine, Dr. Ravikovich replied that the globin or globulin component was equivalent to water, that it was the histamine in histaglobin that was the effective agent and that histamine is used in allergy placebos. When asked by the College's counsel whether he treated Meniere's Disease with histamine, Dr. Ravikovich replied, that although he has seen some such cases and treated a few, this condition is not really a significant part of his practice.

Counsel asked Dr. Ravikovich whether it was true that Canadian schools had turned down his proposal to do a double-blind study on the use of histamine. Dr. Ravikovich replied,

yes, this is true but "they are ignorant". When counsel pointed out that Dr. Ravikovich could not get his study done abroad for example, in Israel, Dr. Ravikovich agreed. When counsel emphasized that in fact no country was prepared to do such a study, Dr. Ravikovich replied that he had been too busy with his College problems to pursue this matter any further.

Counsel for the College then went on to question the scientific basis for Dr. Ravikovich's histamine treatment. He pointed out that among the favorite authors that Dr. Ravikovich quotes are Drs. Kaplan and Lichtenstein. In a letter to Dr. PLN written on January 20 this year, Dr. Kaplan took the position that nothing in his textbook supported Dr. Ravikovich's histamine therapy. Further, Dr. Lichtenstein in a letter to Dr. PLN also written in January of this year, stated that he had never written about or defended histamine desensitization.

Further he stated "I believe it has no role in any medical therapy." Dr. Ravikovich replied that he could not explain or understand why these authors were reluctant to apply to patients histamine desensitization when the mechanisms favouring such desensitization had been developed in their laboratories and in particular, he noted the "negative feedback" effect of histamine. He referred to a paper published in 1974 by Drs. Lichtenstein, Melmon and others which demonstrated in particular this negative feedback. He felt that there was a contradiction between Dr. Lichtenstein's views of 1974 and those expressed in his letter to Dr. PLN of 1994.

The College's counsel then referred to Dr. S.T. Holgate who Dr. Ravikovich accepts as an outstanding authority in the field of immunology. In a reply letter written to Dr. Ravikovich by Dr. Holgate on November 2, 1989, the latter states "looking through your papers I do

not see any evidence of a placebo controlled trial and certainly for me to be convinced that this form of therapy is efficacious, this is something that really should be undertaken". In this connection, Dr. Holgate sent another letter to Dr. Ravikovich dated April 15, 1991. This was apparently a reply to Dr. Ravikovich's description of his histamine therapy of allergic disease. Dr. Holgate wrote "As I believe I mentioned in a previous letter what is needed now is a placebo controlled trial which I am sure should be possible to organize to prove unequivocally whether or not your treatment is of benefit to patients." Again, Dr. Ravikovich replied that no one in Canada wanted to do this type of study with his method of treatment. Furthermore, at the time of his first letter from Dr. Holgate in November 1989, he was not aware of Dr. Girard's paper published in 1989 which was a double-blind study employing histaglobin in the treatment of pollenosis. When asked by counsel for the College whether he had, in the period between 1985 and 1991 been familiar with either of Dr. Girard's publications in Praxis, Dr. Ravikovich replied that he did not know of these papers at that time.

Finally, counsel referred to Dr. Ravikovich's article published in New Americans' Collected Scientific Reports, Volume 1, 1989. In reply to a question, Dr. Ravikovich conceded that this journal was probably not peer-reviewed in the usual sense. Counsel pointed out that following the references at the end of Dr. Ravikovich's paper and under a new heading "From the review:", there is a quotation from Dr. Holgate's letter to Dr. Ravikovich of November 2, 1989 as follows: If the results are positive then this would be quite an outstanding contribution to the field of allergy." It was suggested that, when this quotation was brought to Dr. Holgate's attention sometime in September 1992, Dr. Holgate was apparently very upset at the use of his name in this way because he had not

in fact reviewed Dr. Ravikovich's article and it was therefore a misrepresentation to use his name at the foot of the article.

When asked in re-examination by defence counsel to define an "acute allergic reaction" Dr. Ravikovich replied that this phrase referred only to the speed of the reaction following his injections, and not to their severity.

In answer to another question, Dr. Ravikovich referred to a paper entitled "Prevention of Allergies and Asthma" published by Redfearn and Dolovich in 1993 in the journal "Contemporary Allergies." In this paper, in a section titled: "Disease suppression and disease modification", Dr. Ravikovich quoted as follows, "avoidance of allergen by allergic people is an unquestioned anti-allergic, anti-inflammatory treatment. Unfortunately, even with optimal efforts, avoidance procedures are often inadequate by themselves. Disease suppression can often be accomplished by medication such as adrenocortical steroid, but at the price of inconvenience and side effects and often with less than satisfactory results.

Allergen immunotherapy can produce a suppression of responsiveness to environmental allergen resulting in decreased symptoms and a reduced need for medication which can be long-lasting. Limitations include the unpredictability of results, the risks of serious acute reactions and the aggravation of disease including asthma and infantile eczema. There are a great number of modern initiatives to develop new modalities of treatment to produce disease modification. Some of these are antigen-specific and some focus upon the inflammatory responses. The authors predict that antigen-specific strategies and successors to the present methods of allergen immunotherapy will prevail."

Dr. Ravikovich went on to claim that Dr. Dolovich had changed his mind regarding asthma therapy between the years 1992 and 1993. In 1993, in the paper quoted above, he expressed concern about the use of adrenocortical steroids in allergic diseases both because of their side effects and because of their often less than satisfactory results. In contrast, Dr. Ravikovich stated that Dr. Dolovich had been a participant in the International Consensus Report on Diagnosis and Treatment of Asthma published in 1992 which tended to be more supportive of the use of steroids in allergic conditions.

In reply to one of the Committee members, Dr. Ravikovich stated that about 75 to 80 percent of his patients receive histamine treatment. He has had failures with this therapy and at that point he may add a dust or a mite vaccine as in Patient UVZ. Other physicians combine histamine with allergens and he does this too. When asked how he selected patients for histamine therapy, Dr. Ravikovich replied that he did this largely on the basis of his histamine prick test of the skin. He claimed that the skin is an immunological organ and in the prick test some histamine is absorbed so that there is also a systemic not only a skin response. If there is a favourable systemic reaction, say in ten minutes after the skin prick test, then he views the patient as a candidate for histamine therapy. However, because there are always fluctuations in immunological reactions, he avoids these by using the smallest concentrations of histamine when he starts his tests.

In reply to questions put by another Committee member, Dr. Ravikovich replied that he does not have diagrams of either the patient's symptom or drug scores. He agreed that there were no consultation letters in the files of the five patients presented at the hearing.

When asked about his safety precautions in cases of bad allergic reactions, Dr. Ravikovich replied that he does have an oxygen supply, adrenaline is available for injections and that he may himself inject corticoid steroids under these circumstances. When asked about the term "counselling" written in his charts, Dr. Ravikovich replied that histamine and counselling go "hand in hand". He again stated, in reply to another question, that his paper had been rejected by Canadian journals. He estimated that about 20 percent of the patients that he treats with histamine injections failed to have a favourable response.

When asked by counsel for the College why no consultation notes were included in the charts of the five patients, Dr. Ravikovich replied that they may not have seen any consultants after they became his patients. The Committee noted in a subsequent review of Exhibit #1, the College's Brief of Documents, that, in the charts of three of the five patients, there are in fact reports from consultants.

The Committee received in evidence a video examination of Mrs. PFB, whose daughter, IBJ, had been a patient of Dr. Ravikovich. Mrs. PFB could not appear in person. A verbatim transcript of this examination was also provided. The evidence disclosed that IBJ began suffering from allergies at age seven and first saw Dr. Ravikovich in July 1988 when she was about nine and a half years. Her complaints included headaches, chest pain and stomach pains. The symptoms tended to be produced by certain foods that she ate. At that time her son who has asthma and allergy problems had more serious symptoms

than his sister, IBJ and she was finally persuaded to take these children to Dr. Ravikovich by a friend who had been a patient of Dr. Ravikovich. The doctor gave her his pamphlet outlining his proposed histamine treatment. Dr. Ravikovich did not guarantee a cure of Patient IBJ because food allergy was more difficult to treat. He thought that he would be more successful in the management of her brother's asthma. However after commencing his treatment of Patient IBJ, her symptoms improved and at no time did they ever revert to the severity of the original symptoms that brought her to the doctor. From time to time there were relapses but these would improve with more histamine injections. At no time, according to the mother, did her daughter ever suffer a severe reaction to these injections.

She had no recollection of Dr. Ravikovich either giving her daughter chocolate or cheese or instructing her to give her daughter these foods or any other foods to which the child might have been allergic. Although her son responded well to the prednisone prescribed by her family doctor, his symptoms recurred shortly after discontinuing the medication. Mrs. PFB did not want her child on long-term prednisone therapy or taking nasal sprays containing corticoids. In reply to a question, she emphasized that, at no time, did Dr. Ravikovich insist that her son discontinue medication such as Ventolin, which he was taking for his asthma. Following the Court Order that prevents Dr. Ravikovich from administering histamine, she informed defence counsel that her son had required prednisone therapy throughout the summer of 1993 until the first freeze in the late Fall and she was not pleased with this situation. She would have preferred histamine injections and accordingly she plans to take her son to Florida where medical friends will provide the histamine treatment. Concerning her daughter, IBJ, Mrs. PFB is concerned that she has developed allergies to more foods.

In reply to questions from counsel for the College, Mrs. PFB made the following statements:

She herself had been a patient of Dr. Ravikovich having seen him for allergies and asthma.

She last saw him about a year or a year-and-a-half before this examination. She had been taking Ventolin before she consulted Dr. Ravikovich but had been receiving histamine injections from him over a period of about five years. Since she can no longer receive the histamine injections, she has been taking Ventolin and agreed that her asthma is under control with this medication. Concerning her son, his asthma was under control with both Ventolin and prednisone medications. She also stated that, prior to his seeing Dr. Ravikovich, it had been her decision to discontinue all the medications that her son had been taking except for the Betnavate ointment. It was in fact her son who was the first of the family to see Dr. Ravikovich as a patient. Apparently her son is not presently taking any medication even though he has bad times between the Spring and the first freeze of the Fall.

In reply to another question she stated that Dr. Ravikovich maintained that it was her decision if she wished to continue the histamine treatments of her children. He would even ask her children if they were feeling better and if they wished to continue with the treatments or to stop them. Again, in reply to counsel for the College, she maintained that at no time did Dr. Ravikovich advise her to try her daughter with chocolate and cheese to see how she responded. She may have told Dr. Ravikovich that her daughter had eaten these foods and had not reacted to them. The mother herself stated that her last attack of asthma occurred about a year-and-a-half ago and she had not had a bad attack since then

because she was using Ventolin. She last saw Dr. Ravikovich as a patient in 1993, having come to see him for histamine injections but was told that she could not have any.

In re-examination by defence counsel, she stated that she took Ventolin for her asthma only when she was in distress and had required it for the previous two weeks. However, she had not taken it for a long time before then.

Counsel for Dr. Ravikovich presented two additional witnesses who appeared on behalf of the defence.

The first witness, UVZ, is now aged 44 and has been suffering from asthma since the age of three. He also has other allergies. He had been seen by some five physicians before consulting Dr. Ravikovich on July 12, 1989. Over the course of many years, he had received allergy injections, bronchodilators, anti-histamines and Beclovent. He had discontinued the use of any steroids in the late 1980's before consulting Dr. Ravikovich. His treatment consisted of Ventolin nebulizers four times a day, seven days a week. Despite all his medications his asthma had been relatively uncontrollable. His son also has asthma which was not helped by Ventolin and, because his wife had heard of Dr. Ravikovich, they took their son to him for treatment. He received some ten injections of histamine and immediately improved to the point where he did not require any other medications. The son never required hospitalization again, never uses a nebulizer and only rarely takes Ventolin at this time. Dr. Ravikovich never told his son to discontinue medications and actually prescribed the Ventolin.

Because the treatment was helping his son, Patient UVZ then consulted Dr. Ravikovich himself for treatment of his asthma which was out of control and for his allergies which were especially bad toward the end of the Summer. Dr. Ravikovich gave him a pamphlet outlining his treatment. He and his wife had also received one when his son consulted Dr. Ravikovich. He felt fully informed before the therapy was begun either for himself or for his son. Dr. Ravikovich always explained everything even the choices. He did not guarantee success and explained that the treatment did not work for everyone.

During Dr. Ravikovich's histamine treatments, he got better week by week and gradually stopped his other medications. His asthma improved more than the other allergies. For the latter, he might have required antihistamines from time to time. He also pointed out that his drug treatments, prior to his seeing Dr. Ravikovich, were very expensive whereas the histamine treatments for both his son and himself were low in cost.

On October 16, 1989 he did suffer a relapse of his asthma probably related to cigarette smoke. However he emphasized that he did not feel that his health or life was threatened by this reaction.

In August 1990, because his allergies but not his asthma, were continuing to trouble him, Dr. Ravikovich gave him some injections of Pollinex R. This treatment actually made him feel worse and he required more Ventolin. However, once again after his histamine injections he improved fairly quickly.

In reply to questions from defence counsel, the patient emphasized that once he had

started treatment with histamine, his asthma never reverted to its original severity. Throughout his therapy, he was never in a life-threatening situation. He was always permitted to take any of his previous medications. Dr. Ravikovich never treated him casually but was always available for help and in fact spent more time with him than any other allergist had. For four to five months toward the end of 1990 he did not require any medications at all and this was the first time this had happened since about three years of age. His son had experienced similar benefit. On August 29, 1991, because his other allergies were still troubling him, Dr. Ravikovich combined a vaccine with his histamine therapy and the patient believed that this helped. Since Dr. Ravikovich could no longer employ histamine therapy, the patient has had to continue with the vaccine alone. He also has to take Ventolin treatments several times a week for his asthma. Since his sinus congestion also troubles him now, he has to take antihistamines which make his mouth dry and give him a tired feeling. In addition he believes that they elevate his blood pressure which had fallen to normal when he was taking histamine therapy and had risen when off this therapy. Furthermore, his son now complains of blocked nose much more frequently and this did not happen when he received histamine therapy.

During cross-examination by counsel for the College, the patient stated that his high blood pressure had in fact been treated by Dr. Ravikovich. Furthermore, when he and his son received histamine injections they required other medications very infrequently but if necessary they could take the Ventolin even with the histamine injections.

Counsel for the defence then called as his next witness, Mrs. CXM. Her son, QHD, now eight years of age had become Dr. Ravikovich's patient at about 18 months of age. He

suffered from severe eczema, hay fever and other types of allergy. This had become apparent at about four months of age when the child was greatly troubled by an itchy rash. She estimated that her son had been seen by some forty to sixty physicians before he consulted Dr. Ravikovich and that nothing they had prescribed had helped. His rash got progressively worse despite steroid creams and Atarax. She had refused to give him oral steroids because she had heard or read that these would stunt his growth. When she consulted Dr. Ravikovich she was extremely desperate. The child appeared to be allergic to every protein including nursing milk and between April and the end of September he literally could not go outside the house. Dr. Ravikovich never told her to stop her previous medications although they were ineffective. He also showed her his pamphlet and gave her a lot of verbal information. She felt fully informed before her son undertook his histamine treatment. Dr. Ravikovich never guaranteed success and pointed out that eczema was more difficult to treat than asthma. From about four months of age the child could not sleep through the night because of the itchy rash. After about four histamine injections he began to sleep through the night and his skin was much improved. By the tenth injection his skin had cleared almost 100 percent. At no time since he had begun therapy did his symptoms ever revert to their original severity.

She first took her child to see Dr. Ravikovich on June 17, 1987 after he had been hospitalized for the first time as a result of asthma. None of the prescribed drugs appeared to help the child so that the mother removed him from the hospital after five days and phoned Dr. Ravikovich. About one or two days after the child received his first injection of histamine, the improvement was so great that she literally discarded all his previous medications. She never felt that the child was at risk with histamine therapy. She

emphasized that the aggravation of symptoms recorded by Dr. Ravikovich on June 20 following an injection of histamine was not acute and had not alarmed her. She stated that after the first few months of histamine injections, her son never again suffered from severe eczema.

The Committee had the benefit in this case of seeing and hearing the witnesses who testified. They also had the benefit of extensive written arguments provided by counsel for the parties. After serious deliberation, the Committee came to the conclusion set out in the following paragraphs.

DECISION

PROFESSIONAL MISCONDUCT

In arriving at its decision, the Committee first determined what had been established in evidence as the standard of practice of the profession in Ontario with regard to the diagnosis and treatment of allergic conditions and asthma. The Committee then made factual findings as to what had been proved in evidence that Dr. Ravikovich did and did not do to determine if he fell below the standard proved. The Committee then determined if professional misconduct had been established.

A) DIAGNOSIS STANDARD

The Committee considered Dr. PLN to be a reliable and trustworthy witness. It accepted his evidence that the standard of practice of the profession in Ontario between the years 1985 and 1991, to properly diagnose allergies, required the physician to conduct tests on

the patients' skin with a positive and negative control before testing with allergens. Dr. PLN testified that testing with both positive and negative controls enables the physician to determine what the patient's skin reactivity is like before testing with allergens. Normally the skin will react to a positive control by producing a local swelling a couple of millimetres in diameter with surrounding redness. The skin will not normally react to a negative control. By employing both control tests, the physician can determine that the skin and the system of the patient are behaving within normal parameters. The physician can then interpret the response of the skin to specific allergens in relation to its reaction to the positive and negative control tests.

Dr. PLN testified that in instances where the patient's skin does not react to either the positive or negative control tests, the physician should ask himself what is inhibiting the skin's reaction. If the skin reacts to both the positive and the negative tests, the physician will have difficulty in interpreting the reaction of the skin to allergen tests.

Dr. PLN testified that the histamine prick test acts only as a positive control; a physician cannot make a diagnosis or interpret disease by looking at a reaction to the histamine prick test.

Dr. PLN further testified that a negative control test which involves pricking the skin with a solution of inert materials such as saline, must be employed alone with the positive control test. It was his opinion, accepted by the Committee, that the standard of practice in Ontario at the material time required a general practitioner to conduct a negative control test in the diagnosis of allergy.

B) THE TREATMENT STANDARD

The Committee accepted the evidence of Dr. PLN regarding the standard of practice of the profession in the treatment of allergies in the period 1985 to 1991. He testified that drug therapy is ultimately the most effective way to treat patients with allergies. An appropriate method of treatment might begin with a blocking H1 histamine, nasal spray or topical nasal steroid. Another common treatment is to administer allergy shots containing an extract of the same substance to which the patient is allergic.

In the treatment of asthma and of psychological disorders, Dr. PLN testified that he expects that if the patient's condition is sufficiently severe, the patient should be put on medication. He also testified that it is not acceptable management of patients to use histamine injections to treat patients with allergies and that there is no beneficial pharmacological effect in the use of histamine.

C) FINDINGS OF FACT

The Committee made the following factual findings:

- a) Concerning diagnosis:
 - 1) Dr. Ravikovich did employ histamine injections or a histamine prick test for the purpose of diagnosing allergies and asthma.
 - 2) When he employed histamine injections or a histamine prick test for the purpose of diagnosis, he did not employ a negative control. Dr. Ravikovich claimed that he did employ negative controls when he treated the patient with allergens. However, there is no record of such controls being employed in the

patients whose records were examined.

- 3) When Dr. Ravikovich employed histamine injections or a histamine prick test for purposes of diagnosis, no objective measurement of any change in the patient was employed in order to assess the results of the injections or histamine prick test. Dr. Ravikovich's procedure was to record symptom scores and drug scores along with certain aspects of physical examination of the patient including measurements such as blood pressure, heart rate and clinical assessments of changes in the patient's condition. However, Dr. Ravikovich failed to measure any of objective changes as might have occurred in the patient's pulmonary function tests.

b) Concerning Treatment:

Dr. Ravikovich employed histamine injections for therapeutic purposes in regard to a variety of conditions when the efficacy of this treatment is unproven. Dr. Ravikovich presented a double blind study published by Dr. Girard and his colleagues in 1989. However, Dr. Ravikovich was not aware of this study before 1991. Furthermore, Dr. Girard did not employ histamine but rather "Histaglobin", a combination of histamine and gammaglobulin. As well, Dr. Girard studied patients who had only very minor asthma.

Dr. Ravikovich treated some patients who had no skin tests by administering allergy injections. Although the Committee accepted the truth of this particular, it does acknowledge that Dr. Ravikovich sometimes selected his allergens on the basis of the substances to which the patients claimed they were allergic.

c) Conclusion

The Committee found that Dr. Ravikovich is guilty of professional misconduct as defined in Section 27(21) of the Ontario Regulation 448, R.R.O 1980, as amended under the **Health Disciplines Act**, in that he failed to maintain the standard of practice of the profession in the period January 1985 to May 31, 1991, in that he carried on the practice of medicine by employing diagnostic and therapeutic practices which had no scientific or medical validity.

MISREPRESENTATION CHARGES

- 1) With regard to the allegation that Dr. Ravikovich misrepresented to his patients that histamine injections could be used for the purposes of diagnosis, the Committee found:
 - a) That he did tell his patients this, and
 - b) That since histamine injections could not be used for the purpose of diagnosis, this statement was indeed a misrepresentation.
- 2) Concerning the allegation that histamine injections could be used for therapeutic purposes in regard to a variety of conditions, the Committee found:
 - a) That Dr. Ravikovich did represent to this patients that histamine injections could be used for therapeutic purposes for a variety of conditions, and
 - b) Since the efficacy of this treatment is unproven, such statements amounted to a misrepresentation.

INCOMPETENCE

It was alleged that Dr. Ravikovich was incompetent in the period 1985 to 1991, in that he displayed in the professional care of his patients a lack of knowledge, skill or judgment or disregard for the welfare of his patients of a nature or to an extent that demonstrates that he is unfit to continue in practice.

The Committee believes that Dr. Ravikovich showed a lack of judgment in his use of histamine for therapeutic purposes. The Committee wishes to affirm that there are certain obligations which a physician must accept if he or she employs a drug for a new or non-traditional treatment. The drug must be proven safe. The physician must record in considerable detail the clinical state of the patient and the changes in this state, both good and bad, that are produced by the medication. The physician should be aware of all of the pertinent publications that bear on the clinical problem as well as on the proposed treatment.

It is the opinion of the Committee that Dr. Ravikovich's employment of histamine therapy did not fulfil all these criteria. However, in the circumstances present, the Committee believes that Dr. Ravikovich was acting in good faith and that he had the welfare of his patients in mind. Although his judgment in the circumstances was inadequate, it was not established that the lack of judgment was of such a nature or extent that as to demonstrate that Dr. Ravikovich is unfit to continue in practice.

The Committee directs the Discipline Office to contact the appropriate parties to set a date to hear evidence and submissions related to penalty.

Indexed as: Ravikovich (Re)

**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 59(6)
of the **Health Disciplines Act**,
R.S.O. 1980, c. 196 as amended.

BETWEEN:

THE COLLEGE OF PHYSICIANS AND SURGEONS OF ONTARIO

- and -

DR. FELIX RAVIKOVICH

PANEL MEMBERS: DR. A. RAPOPORT (Chair)
DR. H. GORDON
R. McFADDEN
J. McSKIMMINGS

HEARING DATE: FEBRUARY 7 - 11, JUNE 2, 3, 9, 10 AND JULY 5, 1994

PENALTY HEARING DATE:

MAY 24, 1995

DECISION/RELEASE DATE:

JULY 26, 1995

PENALTY AND REASONS FOR PENALTY

This matter came before the Discipline Committee at the College of Physicians and Surgeons of Ontario on May 24, 1995 at Toronto.

No evidence related to penalty was presented by either the prosecution or by the defence but the Committee heard full submissions from both parties and a statement from Dr. Ravikovich.

The Committee wishes to reiterate in imposing penalty, that it accepts the principle, now encoded in Ontario Regulation 52/95 made under the Medicine Act, 1991, which states "the fact that a member uses or recommends a non-traditional treatment is not, by itself, determinative of deficient clinical ability". The penalty imposed follows from the findings of the Committee as set out in our Reasons for Decision.

After careful consideration, the Committee makes the following Order as to Penalty:

- 1) Dr. Ravikovich is to be reprimanded and the fact of the reprimand is to be recorded on the Register;
- 2) A restriction on Dr. Ravikovich's Certificate of Registration is to be imposed for an indefinite period, prohibiting Dr. Ravikovich from employing histamine for purposes of diagnosis or therapy in the practice of medicine except for the employment of histamine as a positive control in standard allergy skin testing. Furthermore, such prohibition is not to apply to the employment by Dr. Ravikovich of standard allergen extracts in accordance with the accepted standard of practice of the College of Physicians and Surgeons of Ontario. Apart from the two exceptions listed above, Dr. Ravikovich is not to employ for diagnostic or therapeutic purposes, any biological material which contains histamine;
- 3) Dr. Ravikovich's Certificate of Registration is to be suspended for three months, the suspension to be suspended on condition that Dr. Ravikovich submits his practice to inspection by an inspector appointed by the Registrar, including the production of the records of his practice, within six months of

this Order becoming final.

The Committee is of the opinion that a more serious penalty is not warranted in the circumstances of this case. However, Dr. Ravikovich has shown himself to be lacking in awareness of the potential for harm to patients in employing histamine as he did when he said, in his statement to the Committee, at the penalty hearing, "... my errors remain unknown to me." The Committee believes that the public is protected by the Order it made, in that it prohibits Dr. Ravikovich, as a condition of his Certificate of Registration, from using histamine as a diagnostic or therapeutic tool when there is no scientific or medical validity to its use.