The Canadian Addison Society
La Société Canadienne d'Addison

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In this issue:

PLEASE NOTE: The content of this newsletter is intended for basic information only and not as personal medical advice. We advise readers to consult their own doctor before making changes to their Addison management program.

President's Message:

Dear Friends and fellow Addisonians:

I would like to thank those members that replied to the survey regarding the charitable funds. To date, the one to receive the most votes was, "funding the proposed stand alone website," but "funding information packages to non-members" was a close second, and "an awareness campaign targeted at family doctors and insurance companies" was third. If you haven't sent in the survey and still wish to, please do so shortly so we can allocate these funds.

Our letter campaign to the Federal government regarding DHEA has not had a lot of direct response, although Dr. Killinger did get a letter back, which was very similar to the letter that was sent out by the government to all doctors who had applied to the government for DHEA approval in the year 2002-2003. This was sent to us by Sue from Edmonton who obtained a copy. She also sent along a website from Paladin Pharmaceuticals in Montreal that are conducting a study on DHEA. I have sent an e-mail letter on behalf of The Canadian Addison Society to Paladin asking for more information on their DHEA and the medical study but to date have not received any answer.

Please consider the available position of co- chairman of the Southern Ontario group. Jordan Latter has agreed to co-chair the group but is in need of another co-chairperson to help with meetings. Contact Jordan at jlatter@sympatico.ca for more information.

The Canadian portion of the UK survey has been completed with the results included in this newsletter. It will be interesting how the results change/are verified when compared to the UK, New Zealand and Australia results when all is completed. It has been a huge undertaking for the UK group and they are to be congratulated on their perseverance.

If you have a story to tell about Addison's disease or anything related that you think others in The Canadian Addison Society may find interesting, don't hesitate to send it along to the newsletter for possible publication. Send us those stories!

May this promised spring weather bring renewed good health and great happiness. Your thoughts and comments are always welcomed.

Sincerely,

Joan Southam (jsoutham@rogers.com)

Important Announcements:

- Membership – If you haven't yet renewed your membership, please do so. A renewal notice was sent out with the last newsletter as well as a survey regarding the priority in which funds be directed towards projects.

New News:

ADDISONIAN COMPLETES CANADIAN IRONMAN By Robert Hawes, Calgary, AB

An Ironman Triathlon consists of a 2.4 mile/3.86 km swim; 112 mile/180.2 km bike; and a 26.2 mile/42.2 km run. For anybody who is interested in learning more about the Ironman Canada Triathlon, go to www.ironman.ca.

Life before
At 32 years of age, I had always been physically active and worked long hours without breaks but this all changed in 1995 when I started experiencing fatigue. The change was so gradual we did not appreciate its significance. When playing softball, I used to be able to stretch a single to a double but now I could barely make it to first base. My diet became mostly soups, as chewing required too much effort. I remember fainting, mostly at home when I got up too quick but once I passed out in an elevator standing up. I had been to a couple of doctor clinics and had a few blood tests but nothing was diagnosed. I continued to deteriorate until it came to a crisis.

Diagnosis

After my soup dinner, I went to lie down while my wife went out for a while. As I went to sleep, I prayed, “Lord, take me now or make something happen to get me fixed.” When my wife returned, she woke me up and took me to the emergency at the hospital. The nurse could not get a blood pressure reading or any blood out of my fingertips. This captured their attention and they quickly hooked me up to a saline IV while they did more tests. The emerg doctor kept asking about my very deep, dark tan and apparently paced back and forth consulting his medical resources. About five hours later they called in a specialist to confirm that I had primary Addison’s disease. The CT scan showed that my adrenal medulla had shrunk to nothing.

Life after

A few days later with my fluids replenished, I was discharged from the hospital. My life was back to normal on a dosage of 50 mg cortisone and 0.2 mg fludrocortisone in the morning and 25 mg cortisone in the afternoon. After a year, I tried taking all of the 75 mg cortisone in the morning and later briefly tried dexamethasone instead of cortisone. What works best for me is 7.5 mg prednisone in the morning as soon as I get up. I decreased to 0.1 mg fludrocortisone in 2002 when my blood pressure increased.

Training for the Ironman

I have read many stories of Addisonians and their struggles to lead normal lives. Fortunately, my daily activities did not seem limited by new condition. When Simon Whitfield won the gold medal at the 2000 Sydney Olympics in the triathlon, I was inspired to complete a triathlon myself. I trained the following year for the Kelowna Apple Triathlon made up of a 1.5 km swim, a 40 km bike, and a 10 km run. I was capable in any of the three disciplines individually but was not sure of the cumulative toll on my body in the August heat. Fortunately, there were no incidents during training or the event, which I completed comfortably in 2 hours and 55 minutes.

Over the winter, I started thinking about the Penticton Ironman, which is 3.86 km swim, 180 km bike and 42.2 km long run, just a bit a longer than Olympic sized. My first step was to try the Victoria marathon in October 2002. I trained hard, although not smart, and had two incidents on long runs. I wasn’t really sure what happened and couldn’t find any guidance, but I learned to start taking extra prednisone after runs longer than two hours to aid in the recovery. On the big day, I was fine for the first half but didn’t feel so good over the last quarter. Maybe it was the “wall”, but I think it was more the way my body reacted to the physical stress. I ran the downhills but had to walk the rest. I finished in 4 hours and 45 minutes and then took my extra prednisone. My wife and I walked slowly back to the hotel but I threw up soon after arriving in our room. I was very nauseous for the rest of the day.

I kept a photograph of that awful recovery afternoon on my bedroom wall as a reality check. I started on a good quality multi-vitamin program to ensure nothing was lacking from my diet. I did a lot of reading that winter on training methods and the effects of training and endurance on the body. The only Addison-related event was a short article of a New Zealander who completed his marathon comfortably by doubling his prescription before the event. My specialist advised that additional prednisone would help deal with the stress on my body and that additional fludrocortisone would help keep my electrolytes in balance. I learned to take an extra 5.0 mg prednisone for a hard 2 hour run or 4 hour bike ride and ibuprofen for inflammation. I did a half Ironman in cool conditions taking

5.0 prednisone and 0.1 fludrocortisone after the 2.0 km swim and 90 km bike ride but before the 21 km run. I felt pretty good when I finished.

In Penticton, the air was somewhat clouded by the smoke from the big fire in Kelowna. Fortunately, the temperature was reasonable at 29^{o} C. On race day I took my regular dosage at 5:30 am and the following extra:

- 5.0 prednisone and 0.1 fludrocortisone after the 3.86 km swim at 8:15am,
- 5.0 prednisone and 0.1 fludrocortisone at the special needs station half way through 180 km bike ride,
- 5.0 prednisone and 0.1 fludrocortisone at the beginning of the marathon at 3:30 pm, and
- 5.0 prednisone and 0.1 fludrocortisone a couple of hours later when I felt disoriented.

In total, I needed 27.5 mg prednisone and 0.5 mg fludrocortisone and a lot of prayer for 14 hours of exercise. By controlling my pace and heart rate, I finished looking good and feeling okay. After a good nights sleep, I was only a little stiff the next day.

By Robert Hawes of Calgary, Alberta

UPDATE ON INTERNATIONAL SURVEY (from the UK Self Help Group)

Thank you again to everyone in the Canadian Addison's Society who completed the international Addison's questionnaire in 2003, especially to those who found a friend to fill it in as well. More than two-thirds of CAS members returned their questionnaire, and more than half of you sent back a friend's questionnaire. This is a very solid response rate and means that our findings should accurately reflect the circumstances of Canadian Addisonians. There have been similar response rates from the other countries participating in the survey, making this the largest Addison's survey conducted to date. Everyone has filled in the questions thoroughly and many people wrote detailed and informative accounts of their diagnosis experiences, giving us a large volume of information to analyze.

As you may remember, the international Addison's survey is being conducted jointly with the Australian, New Zealand and United Kingdom Addison's groups. The data entry and analysis is being carried out by a team of volunteers from the UK Addison's Disease Self-Help Group, under the supervision of Professor John Wass from Oxford.

So far our team of British volunteers (Pat Beeching, Suzannah Bartov, Dory Scott, Jan Snaith, Katherine White) have entered all the British questionnaire returns, and around half of the Australian, Canadian and New Zealand replies. Alyson Elliott, who compiled the database and is writing the analysis software, has been using the early British and Canadian returns to fine-tune the analysis.

On 9 March we are meeting with Professor John Wass to review the results we have so far and identify those areas where we believe further analysis of our findings will be most useful. We also have an international panel of endocrinologists who will comment on the findings for us: Dr Penny Hunt (New Zealand), Dr Wiebke Arlt (Germany/UK), Professor Krishna Chatterjee (UK) and Dr Ellie Gurnell (UK). They will add their contributions via e-mail.

We have already used some of the information from the early British and Canadian results to support a seminar presentation at the UK Society for Endocrinology and a letter to the British Medical Journal.

You can read both of these on the ADSHG website at www.adshg.org.uk. If you are interested, you can also have another look at the questionnaire form, which is on the website. Here are the main points from the early survey returns we have analyzed so far. These results are drawn from a sample of more than 200 Addisonians, and 190 friends, which is a bigger sample than many previous medical surveys of people with Addison's. Because of the relatively large size of these samples, we expect these early results to be accurate to within roughly five percentage points of our final totals.

Quality of life

- People with Addison's disease experience ongoing health symptoms which reduce their quality of life compared to their friends (question 19).
- Some people with Addison's achieve high levels of fitness despite these ongoing health symptoms.

Emergency treatment

- Although many Addisonians have been stable since diagnosis, a small proportion have been close to crisis and needed an emergency injection on several occasions (question 58).
- The fluid loss from vomiting or diarrhea are the main factors which lead Addisonians to need emergency treatment (question 61).

Getting diagnosed

- Over the past 10 years there seem to be more people being diagnosed with Addison's, although most people still report that it was difficult to get a diagnosis (question 38).

Most people do not have all the textbook signs of Addison's when they are diagnosed and some of the most distinctive signs are often absent (question 41). For example, less than half reported they had salt cravings when diagnosed, and over one-quarter had no extra pigmentation. Submitted by Katherine White – The UK Self Help Group

GENOME REVOLUTION by Judy Stanley

On December 6, 2003 I attended the Genome Revolution on behalf of the Canadian Addison Society. All the attendees were students, scientists or lab technicians.

Bruce Schmidt opened with an overview of Genome BC and Genomics research in BC. BC has one of five independent centers in the world. It has 50% government funding and provides non-exclusive rights for a worldwide base of licenses. They will file a patent for distribution so research doesn't become exclusive to one agent i.e. after discovering the sequence for the SARS virus it was licensed to over 70 agencies to research for a vaccine.

In the past fifty years since the discovery of the double helical structure enormous scientific advances have been made. Dr. Anne Toby, Simon Fraser University - SFU, who works with students and seniors talked about the dangers of a chasm developing between scientists and the public if

information is only available through sensational publication. How the information is released for the public to have enough information to form opinions and make informed decisions is foremost.

The adult is made up of 50 trillion cells; all contain some DNA and if stretched out would go around the sun and back. The Genome Project was completed two years ahead of time and we now have a map of the whole human genome. Genome BC's www.genomebc.ca latest funded project is the bovine genome.

How the information is used for genetic testing in health and gene therapy, the effect on future generations and the rights of the individual are all aspects that need to be considered. Such as: prenatal screening for genetic and inherited defects; test tube babies; altering a child's medical future and genetic makeup before birth; and concern for what happens if the fetus does not meet parental standards. Who should be allowed access to profile of individuals? Insurance companies and potential employers could use information against the individual. You can imagine other scenarios yourself.

We are standing on the brink of global crisis in infectious disease with increases in levels world wide being noted. Dr. Bob Hancock, Director Centre for Microbial Disease Research, www.cmdr.ubc.ca said 50% of the population in parts of Africa have AIDS and there is now a worldwide rise of antibiotic resistance. In 2001 Eli Lilly and Bristol-Meyers Squibb stopped private research. More funding is required federally to take up scientific research and to keep costs down.

There is a need to boost a host's innate immunity rather than kill pathogens with chemicals. The significance of the innate immunity response has only recently been recognized. Cationic peptides are the agents of innate immunity. How the body signals the stimulation of innate immunity is now known but there can be potentially harmful inflammatory responses as the body tries to destroy everything in sight. Peptides work best at a modest level. Presently there's not enough known about peptides for general application. In established infection introduction of peptides may not be enough without antibiotics although there could be some affect. It's not known if there would be a long-term effect by just boosting the system with peptides alone and its return to baseline after.

Information on the research can be found at www.pathogenomics.ca .The blood for test work is from students taking the courses. Results would be affected in a person with autoimmune disease and therefore I was unable to give a sample for research. I did volunteer just in case.

Pharmacogenomics is the pathway to individualized medications treating the disease by examining how your genetic makeup affects your response to drugs. Dr. Robert Sindelar, Faculty of Pharmaceutical Sciences UBC demonstrated by taking a headache tablet the delivery system of medication and explaining how your genetic makeup affects you response to drugs. The right patient-to-dose is needed. If a drug metabolizes too slowly it will have an adverse reaction but too fast and it will not be of use to the patient.

Once the patient genotype and disease phenotype is fed into a database a personalized medicine with drug target identification can be defined, resulting in reduced cost, better healthcare and new drugs. In the future as more research into pharmacogeneomics is done physicians and pharmacists might be subject to liability if they lack sufficient knowledge of genetics to adequately interpret

diagnostic tests or properly dispense pharmacogenomic based prescriptions. With greater knowledge comes greater responsibility.

Definitions: DNA to RNA to Protein
Proteomics – identify vast array of proteins implicated as playing pivotal roles in disease processes. Some anticipate 10,000 therapeutic targets.
Difference – Allele = any of the alternative forms of a given gene.
SNP's – Single Nucleotide Polymorphisms – account for most of the genetic differences observed among humans. Identifying SNP's may hold the key for complex, polygene diseases and understanding the difference in response to drug therapy observed in individual patients. 1.4 million distinct SNP's identified of likely 3-4 million

Dr. Victor Ling, VP Research, BC Cancer Agency, www.bccrc.ca/cg/people_vling.html – cancer is the leading cause of premature death. $5.7 billion/year in direct costs and double in indirect. Earlier detection is needed with better screening tools, diagnostics and therapeutics.

Lasers are now used to capture a micro-section for taking only cells wanted from a sample. Plastic wrap is used over the slide and the laser is then used to cut out the section required for testing. The rest of the sample of non-cancerous cells for example can then be examined for comparison. Detection of chromosome changes by comparative genomic hybridization can be made – loss on slides will show green and more will show red. Genomics will help to preselect patient to treatment. To apply there is need for an integrated therapy, screening process for local and worldwide application. There is a huge potential for a cancer vaccine.

Dr. Marianne Sadar www.bccrc.ca/ce/people_msadar.html, Program Leader, Prostrate Cancer Research, gave a very technical talk on prostrate cancer of which 90% advance to bone cancer. Prostrate cancer that has already spread can become androgen independent after treatment. Bone cancer has the potential to activate androgen independence. Prostrate removal in which all cancer cells are removed is considered cured.

A new process for diagnoses ICAT – Isotope Coded Affinity Tags - is being researched. New patients are screened from proteins, which provide a proteometic profile. Proteometic patterns can also be used in screening for ovarian cancer.

The last speakers were Dr. Janet Atkinson-Grosjean, www.ethics.ubc.ca/people/atkinson/index.htm, Ph.D., UBC/Genome BC and Dr. Valia Lestou, BC Cancer Agency. Their topic was Ethics and how it applies to society.

Dr. Atkinson-Grosjean - Utilitarian approaches dominate today but there are alternate approaches: autonomy – respect; beneficence- try to do good; nonmalificence – try not to harm. Free market information and genetic discrimination i.e. mining company and potential employee's genetic predisposition to ore being mined - is not hiring discriminatory or preventative?

What do we lose by homogenizing humans? Moral status of using animals and the average response to raising human parts on animals for transplant i.e. an ear grown on a mouse! How about genetically modified food products or no genetically modified items response due to the lack of information dissemination.

Dr. Valia Leston talked of how we have to determine if autonomy of subjects is intact. A board of Ethics is needed for projects. There are about 30 – 35 new clinical trial every two weeks.

As submitted by Judy Stanley, Vice President Canadian Addison Society

Highlights From Local Meetings:

Vancouver Island Support Group (Nanaimo)

Nanaimo meetings: Christy Lapi at clapi@shaw.ca, or 250-245-7554 or Barbara Hunn at bhunn@telus.net or 250-756-4385. Nanaimo meetings are held at Nanaimo Regional General Hospital, Room G245.

Vancouver Island Support Group (Victoria)

Our first topic of discussion was the October 18, 2003 Lower Mainland group meeting report forwarded by Judy Stanley.

Once again, Victoria meeting attendees were reminded of the helplessness experienced by Addisonians in hospital emergency departments when staff are reluctant to take prompt action to treat pre-crisis symptoms. Despite having an advocate, fully knowledgeable in recognizing the signs of imminent crisis, who expressed these concerns to the emergency staff, a member of our group was detained in a waiting room, until she could no longer sit upright. Even then, she was not treated until about 45 minutes later, nearly 2 hours after her arrival at Emergency. This took place at the Victoria General Hospital. Precautions which may improve ER service are: having a letter from your physician describing your condition and necessary treatment and, if possible, contacting your physician before leaving for Emergency to ask that he alert the ER staff of your vulnerable condition and that immediate crisis treatment is imperative.

In discussions throughout the 2 hour meeting, the topic of DHEA was frequently mentioned. Firstly, those who have written the federal Health Ministry, regarding the new policy restricting access to a legal source of DHEA in Canada, have not received replies. Without availability through Kripps Pharmacy, Canadian Addisonians must rely on stockpiled replacement or products of unknown quality purchasable from internet pharmacies. Some members have noted that quality of product varies between sources. The best quality replacement provides more beneficial energy improvement and fewer undesirable side effects. Other products from US sources give mid-range quality. One member with hypopituitarism stopped taking DHEA supplements when tests showed testosterone levels were boosted beyond safe levels when taken in conjunction with regular hormone replacement. Another dropped it because of perpetual oily skin. On the positive side, many found it levelled those highs and lows experienced with cortisone replacement in some people, increased energy for others and improved mental clarity. One comment cautioned that DHEA is likely metabolized in the liver, increasing its workload.

Various items brought forward were:

- one member received a free syringe with a low cost purchase of Solu-Cortef vial at WalMart
- another member's homeopathic MD sent her for mineral toxicity testing where results showed

mercury readings well above normal, a determining factor in her decision to replace all amalgam fillings.

As submitted by Jim Sadlish

For further information: Victoria meetings: Jim Sadlish at x699@victoria.tc.ca or 250-656-6270, or Florence Weekes at fmweekes@telus.net or 250-598-0321.

BC Lower Mainland Support Group

Thanks to Marilyn for all her effort in getting Ian Brown and Samantha Sandhu from the Boucher Institute of Naturopathic Medicine in New Westminster BC. Anyone wanting to meet more frequently, for informal meetings at members homes or ???. A leader for this is needed: contact me at 604-936-6694 bugbee@shaw.ca. Marilyn is willing to have the first meeting.

- Discussion ensued on information sharing between hospitals. It was suggested that we approach our doctor to put an admitting electronic file marker on our files in the hospital we've been in. Marilyn will contact Dr. Ip to ask if he let us refer our doctors to him for help if they are not aware of the procedure.
- It was suggested that our group write to the Fraser Health Authority as it should have a meditek marker base by 2006.
- Net Lab for the province will be on line by 2009.
- Correspondence: a letter of reply Colin Hansen M.P. Health Services office from Melanie Douglas, Dir. Med. Serv. Plan Operations stating there was nothing they could do about including medical information on Care Card as an individual's medical condition can change over time and would require a re-issue to be current. Inclusion on the front or within the electronic stripe would not be a sound use of public funds. She goes on to say personnel are trained to take Medic Alert Info. from bracelets etc.

  From letter: 'With regard to your query regarding a common data source for treatment information which can be access by ER, I am not aware that this is a current Ministry project. I will ensure that your suggestion for accessible patient information is brought to Ministry executives.' We shall be sending another letter for update information on the ER situation and writing to the Fraser Health Authority, Dr. Ip as a contact for local physicians for flagging records at ER. Dr. Ip is in the process of doing this for patients who have been admitted to Surrey Memorial.
- Has anyone actually had the Triage or ER personnel look at their Medic Alert bracelet? Florence commented that she has not had any interest in her bracelet over the past 36 years.
  I will keep wearing mine but have not had anyone actually take any interest in it either. Linda had her bracelet read after an automobile accident.
- E-mail sent responding to an article on DHEA to Valerie Casselton at the Vancouver Sun mentioning that for Addisonians, DHEA is a replacement not a supplement. It's use by athletes and other non-medical conditions have made renewing prescription for those who require it almost impossible. Klara is now ordering hers from Texas 1-888-438-3432. This Texas lab supplied the UK researchers at Cambridge who completed the two studies with Addisonians.
- Judy attended the Genome Revolution at Children's Hospital and has written a report with web sites listed for the next Canadian Addison Newsletter. The BC Society of Laboratory Science will also have a shortened copy for their newsletter. It was a very informative and worthwhile day with eight guest speakers from Genome BC, SFU, UBC and the Cancer Agency.

- Addison News – Dec. 2003 had input from Missouri and New Jersey on avascular necrosis and resulting hip replacements. A recap of the 'Unfinished life of JFK'
- Dr. Killinger answered Rick Anderson's question: he was diagnosed with Addison's disease in 1992 and told that he shouldn't take anti-inflammatory medication. He is currently suffering from muscle spasms and been prescribed Baclofen vs. an anti-inflammatory.

  Answer: Anti-inflammatory medications can cause stomach irritation and ulcers. These are the major side effects of non-steroidal anti-inflammatory drugs. People who are taking steroids such as prednisone for the treatment of diseases such as arthritis, are more susceptible to these side effects. In Addison's disease the dose of glucocorticoid is physiological (within the normal range) rather than pharmacological (exceeds the normal range for treatment purposes) so the increased probability of stomach problems in quite low. In a situation where anti-inflammatory medications are indicated it is important to be aware of possible side effects but I would not hesitate to use non-steroidals. It is important to be sure that the drug is being used for the proper indications. This family of drugs is very helpful to treat inflammation, but is not likely to do much for cramping or spasms.
- Judy received a letter from UBC Ethics Dept. with a summary of the study call Democracy, Ethics and Genomics. Additional information on results is available at http://gels.ethics.ubc There is currently a series of articles on Ethics in the Vancouver Sun.
- Ginger asked if others were as tired as she feels. Most responded that they were usually tired and forgetful even after several adjustments to medication
- The next meeting will be June 5 and a social is planned. Bring appetizers or lunch and get to meet everyone.
- As per the new Privacy Legislation in BC our membership list will not be shared with any other groups or without the consent of individual members.

Ian Brown and Sam Sandhu from the Boucher Institute of Naturopathic Medicine in New Westminster BC explained the ideals of naturopathic medicine to support orthodox medical services and medication.

Ian has an undergraduate degree in Psychology from the University of Western Ontario. During his youth he traveled and competed around the world representing Canada on the Canadian Sailing Team. He has traveled to every continent on this planet, and is a six time Canadian windsurfing champion, and has attended the last two Olympics (1996 in Atlanta and 2000 in Sydney Australia). After his windsurfing and traveling career, Ian studied Naturopathic Medicine at the Canadian College of Naturopathic Medicine in Toronto for four years (1999-2003). He is currently completing his clinical training at the Boucher Institute of Naturopathic Medicine in New Westminster BC. Ian has preceptored with many notable physicians including Dr. Abram Hoffer (Victoria BC), and Dr. David Kern (Maui). Ian completed his clinical training in Mind/Body Medicine at the Mind/Body Medical Institute at Harvard Medical School in 2002. Ian is a certified TA in craniosacral levels 1 and 2 through the Upledger Foundation, Florida.

Sam has also specialized in psychology earning a Bachelor of Arts, Psychology, degree from Dalhousie University and is a 4th Year Naturopathic Medical Student at the Boucher Institute of Naturopathic Medicine. She is one of the pioneer students at Boucher, which opened in January 2000. She was a Mental Health Worker for North Shore Mental Health for five years. Sam is married with 3 children, age's 6 years, 3 years and 2 months.

Naturopaths need a pre-med. degree with studies in chemistry, biology, anatomy, physics with the first two years similar to a medical degree, 3rd year involves more practice work and the 4th year

involves seeing patients. Naturopathic Medicine is made up of 5 disciplines: Botanical Medicine, Clinical Nutrition, Homeopathic Medicine, Physical Medicine and Lifestyle Counseling. After graduation you can specialize in such fields a clinical nutrition - digestion, homeopathy – founded in Germany with the premise that like cures like and introduction of similar glandular tissue will stimulate the body for self production, physiology, Traditional Chinese Medicine – acupuncture etc.

Naturopathy is no longer covered by Pharmacare and is usually $55.00/hr. private practice or $35.00/hr. at the Institute. The first visit is 1½ hours which is a talking/listening session for overall evaluation. The second visit includes a physical and takes about 20 – 30 minutes. At the Boucher Institute you will be attended by a primary intern, a secondary intern and a licensed Naturopathic doctor. There is a naturopathic pharmacy on site for clients. It is advisable to consult your doctor, endocrinologist and naturopath for correct levels and mix of medications.

Sam – Stress is the number one affect on the adrenal glands. Stress reduction is key for all diseases including Addison's. Emotion, anxiety, depression, fear, low self-esteem, side effect of prescriptions, heat/cold, and toxins are all causes of stress. One way of reducing emotional stress is relaxation and meditation. Clearing the mind and relaxing the body done for 10 minutes morning and night is best. Mini relaxation – a) breathe deeply and mind/body will connect and relax. The way you cope with stress will be better as a result. b) taking a short walk in fresh air will relieve stress and relax the body. Massage therapy was also suggested along with chiropractors for stress relief. The West Coast School of Massage Therapy is located on Columbia St. at 6th Ave. New Westminster.

Ian – Addison's can be autoimmune or depletion of the adrenal cortex with resulting affected levels of cortisol and aldosterone. Reduce levels of caffeine, alcohol which deplete adrenal hormones further, eat lots of fresh fruit, vegetables, high protein, eat regular planned meals i.e. every three hours to stabilize sugar levels and drink lots of water.

Botanical (Herbal) Medication: for adrenals are mostly in tincture form. Be very careful where you purchase this to ensure you are receiving the proper dose.

Licorice extract – glycyrrhisa glabra – affects the blood pressure – lowers but not if you have high BP. Helps with electrolyte balance Dutch study, US study raises blood sugar levels to normal. It is a natural hormone that helps protects the liver, acts like cortone, with functioning adrenals body will extend the lifetime of cortisone in kidneys for Addison's.

Wild Yam – dioscorea villosa –used for adrenal exhaustion, catarrhal for mucus – anti-phlegm

Astragalus – assists T cell in body when chemotherapy used, deep acting immune stimulant

Ginseng – helps body YIN stress

Foxglove – rehmania – supports adrenal cortex and is natural cortisol, natural prednisone

Clinical Nutrition: diet – reduce consumption of caffeine, alcohol and refined carbohydrates. Eat whole/fresh food. Sodium/potassium ratio should be 50:1. East regular, planned meals in a relaxed manner, every 3 hours or 6 small meals a day

Essential supplements:

Vitamin C – divided over 3 times a day, for stress, excess expelled in urine, help immune system work properly

B5 – used by adrenals during stress do not take with C, take as a complex vitamin for proper proportions

B6 – aids in the synthesis of steroid hormones

Zinc – (important for men) – promotes glandular health and proper functioning of the immune system

Calcium – to be taken with Vit. D, do not take with magnesium with D only. Recent studies have found that magnesium does not compliment calcium, take at bedtime to assist with sleep and check

for Elemental amount. Do not take with Vit. C as they counteract, the body excretes calcium during times of stress
Magnesium - for anxiety and stress, deficiency can result in anxiety, fear, hallucinations, it is a muscle relaxant
Homeopathic tinctures of L. Tyroseria, Barbaris - aid adrenal gland function and is effective for sleeping - Gallina etc.
Question from Sherri - Meyers Cocktail – is administered by IV and aids energy levels. They didn't find that Addisonians need more B than others but may process is differently. Complex carbohydrates are best particularly eaten in the morning. Fruit, vegetables, protein are best with complex carbohydrates.
It was suggested that you ask your local Pharmacist for a naturopath or BCNA is on the net.
For Addison's - increased amounts of water with lemon will create a desirable alkaline state to body. Pituitary – ACTH levels lead to hyperpigmentation, decreased hydrochloric acid levels cause digestion problems which can be alleviated by taking apple cider vinegar tablets or liquid. Take a hot shower for five minutes and then cold for one to stimulate, dry brushing gets the lymph system working.
A certificate for one free visit was handed out to everyone present. The Clinic is open on Saturdays as well.
Boucher Institute of Naturopathic Medicine Teaching Clinic – 604-540-2873 www.binm.org

Alberta Support Group

An informal get together was held at Krickets restaurant in St. Albert on March 23. As always, it was great to see everybody again and we had the opportunity to meet Brenda, a newly diagnosed Addisonian. The next meeting date is proposed for early to mid-September with the possibility of a Doctor of Oriental Medicine (Acupuncturist and Chinese Herbalist) as a speaker. The date, time and location of the next meeting will be included in the next newsletter.

For information on this support group or any upcoming meetings, contact Francisca Swist at francisca@shaw.ca or Ginny Snaychuk at glav@telus.net or (780) 454-3866 – both are from Edmonton.

Saskatchewan Addison Support Group

If you wish information about this support group or upcoming meetings, contact Elizabeth Hill at Meadow Lake (306) 236-5483 or Rob Zaleschuk at Caronport (306) 756-2339.

Eastern Ontario Support Group

For information about meeting dates, please call Sue Steedman at (613) 726-7414.

Southern Ontario Support Group

For information contact Jordan Latter at jlatter@sympatico.ca or call (905) 893-4374

Quebec Support Group

If you would like information about upcoming Quebec meetings or more information, please contact Sophie Lapointe at (514) 521-6538 or email sophiel@sympatico.ca

Dear Editor:

EMERGENCY SURGERY EXPERIENCE *by Ginny Snaychuk*

I had an emergency appendectomy done on Tuesday morning; I got out of the hospital yesterday (Friday). I am now 10 lbs. heavier than when I went into the hospital, but hey, that's to be expected as they have to pump you up with cortisone so your body can handle the stress. I am fine, a bit sore, but moving around okay. I always wondered what it would happen (as I'm sure other Addisonians have) if I had an emergency situation that required surgery. Well, now I know that it's okay, and with proper care I am fine. I did ask the surgeon to consult with an endocrinologist before proceeding with the surgery, which he did. He also consulted with him after the surgery. Anyway, this may be a reassuring bit of news to know we can be okay in these circumstances, for fellow Addisonians.
Ginny Snaychuk

MAYO DHEA STUDY - PARTICPANTS EXPERIENCE *by Elizabeth Hill*

This study was done to determine what dehydroepiandrosterone (DHEA) replacement had on an Addison's mood, well-being, sexual function and on muscles.

Before I was accepted into the study I had a medical examination, ECG and blood test done to determine if I had any unrecognized medical problems. (I had both my adrenals removed due to pheochromocytomas tumors in 1994.) My G.P. in Meadow Lake did this. The results were faxed to Dr. Ketan Dhatariya. Dr. Dhatariya phoned me Thursday January 15th 2003 and told me more about the study and on Monday January 19th 2003 I was flying to Rochester Minnesota. I was so excited and very nervous. I stayed in a hotel across from St. Mary's hospital, a part of "Mayo". It was a balmy 60F.

Monday January 20th 2003 at 7:00 am, I went to the General Clinic Research Center (GCRC) area, 5th floor of the Domitilla Building at St. Mary's hospital. More blood tests done and I met Debbie, an Addisonian lady from Colorado USA.

After introductions Dr. Dhatariya, Deb and I walked briskly (and I mean briskly) to another part of St. Mary's. There we were asked to walk on a treadmill. Sounds easy—Not!! They wired us up to an ECG machine, plugged our noses with a clamp and in our mouths went a snorkel- like piece of equipment then asked us to walk on the treadmill. Dr. Dhatariya was able to read our CO2 and O2 exchange, heart rate and blood pressure and the Maximum caloric expenditure measurements during the treadmill test. Those inclines were killers and the longer one walked briskly, the happier Dr. Dhatariya was. After this was done Deb and I went back to our day room and chatted. When Dr. Dhatariya got all the results back, he told us we both qualified for the DHEA study. We were free to go for today and to come back early the next morning. In walking distance of the hotel I checked out a quilting and scrap-booking store. They were fabulous!!!!

The next day Tuesday January 21st we met back at the GCRC at 7:00 am. We went for x-ray that showed the percentile muscle to bone and to body fat. Both of us were on the high normal side for

fat content. Humph. Next Deb and I stopped off to meet a dietician. She explained the special snacks / meals we had to be on during last few days of week 11 going on week 12, week 24 going on 25 of the study. It was a lot of FOOD!!! In week 11 when we came back, she would give us either the Mayo Clinic food supply or we could buy the food ourselves if it was the same as Mayo's. This depended greatly on if you could get back to your home before the frozen items thawed out or not. I chose to buy my own. Meadow Lake was toooo far.

Next, we met independently with a lady psychologist in this tiny room. I filled out a series of questionnaires regarding heath-related information, cognitive function, memory and sexual functioning. I enjoyed the memory the most. She would say 15 words and I had to repeat them back in any order. Then she would say another group of words and I would repeat these back to her. Then she would ask me to repeat the first group of words back to her without her reminding me of what they were. Interesting…. Then Dr. Dhatariya, Deb and I went to the gym again. Deb and I were put through a series of muscle strength testing—what a work out for the upper arms and legs!!! Deb was very competitive and tried hard to out do me, which she did. We were not the only ones using the gym. Lots of Mayo employees were taking full advantage of this fabulous gym!! I think it was after lunch Dr. Dhatariya gave us the medication to take back with us. We were to take one pill a day for 12 weeks. He said he did not know if there were a placebo or DHEA. We were free to go. So off to the airport I went by shuttle bus to catch my plane back to snowy Canada.

Sunday April 7th 2003 was week 11. I flew out of Saskatoon to Rochester again, but I was smarter this time. I now knew how to use an e-ticket this time around. I spent the night in the same hotel the Sunday night as last time. This time when Deb and I met at 9:00 am at the GCRC, we had another Addisonian lady join us. Shauna was from Vancouver, Washington. Along with Dr. Dhatariya we found our way back to the gym. Thank goodness he led. Swiss cheese memories!! We did all the same muscles strengths and then the treadmill test. Then back to that tiny room where a different lady psychologist had us fill out the series of questionnaires regarding heath-related information, cognitive function, memory and sexual functioning information again. Some of it was even the same!!!!! Did not help though.

This time the 3 of us were admitted to St. Mary's hospital for the night. I was in a different room than Deb and Shauna. No particular reason why. At 10:00 pm we were given a huge snack to eat. The nurses nearly had to sit on us to ensure we ate it all!!!! Sleeping in hospitals is the pits!!! We were allowed nothing to eat or drink until after the next day's tests were done. At 6:00am we were woken to swallow the tiniest mouth full of "heavy water". This special water was non-radioactive and determined our total body water. The nurses checked this tiny vial to see if we swallowed every drop. They asked us to void in a specially marked pot every hour for the next four hours. With nothing to drink in-between—amazing anything came out at all. The nurses encouraged us—"We only need a few drops…" Just after I drank this "heavy water" a respiratory tech came to me and informed me she was going to monitor my Oxygen and Carbon dioxide exchange and how many calories we burnt at rest. She put a clear dome over my head with attachments from it to her machine. I felt like a space astronaut. For one hour I had to lie there quietly and breathe my normal way. No talking or watching of TV was allowed. By now I was falling back to sleep but the tech kept asking me to breath. When this was finished then the hourly voids began.

After this test was done (10:00am) we met with the dietician again. She discussed with each of us the diet we needed to be on for 3 days prior to coming back in week 12 (the next week). They

wanted us to maintain our weight and muscle mass. I could not believe what I had to eat. Example: Breakfast consisted of 2 eggs prepared anyway with no fat, 2 slices of whole wheat bread, 2 tablespoons of Skippy creamy peanut butter, 1 med. Banana, 1 cup skim milk, 1 coffee and 2 packets of sugar. Lunch and supper were equally as LARGE!!!!!!!! This was for 3 days---I could not eat anything else. Each of us had a varied diet according to our height, weight and basal metabolic rate. Dr. Dhatariya said that as long as you ate the quantity in 1 day—you could take as long as you wished for a meal. I felt like I was grazing all day!!!!!! Oink Oink. Then we were free to go. Going back home always seems to take longer. I had figured out what to and not to bring along with each visit and how to get through airport security without lighting up at the checkpoints.

12th week April 14th 2003. I returned to Rochester and went directly to St. Mary's hospital for admission. Deb, Shauna and I shared a room this time. This was great! The nurses held my supper for me – again it was huge to my standards of eating. Of course the 3 of us compared if we felt different or not compared to before taking the medication. Wont' say what they said, sorry. I felt no different. At 10:00pm we were given a snack (more like a 2nd supper) and informed us again not to eat or drink anything except for water, until 2:00pm the next day!!!!!. After our snacks the vultures came. The nurses poked each of us and hooked us up to a Normal Saline Intravenous for the night. The word "night" does not mean 8 hours of sleeping to nurses.

At 4:00am we were gently awakened to have bloodwork done through the intravenous line. This IV line was capable of having 4 to 5 IV lines hooked into it. WOW! A glucose IV with a non-radioactive naturally occurring stable isotope was plugged into this main line. Two more intravenous bags each with different amino acids were hooked up into this main line. They both had non-radioactive naturally occurring stable isotopes as well. The nurses told us to keep sleeping!!!! Dr. Dhatariya told us these isotopes go into the bloodstream and the muscles and can be measured. Hopefully his paper will explain it better.

At 6:00am another Normal Saline IV was started but this time in our left hand—it was put in backwards to allow the flow of blood to be drawn off easier. This hand was put into a "hot box" which assisted in keeping the vein from clotting off. It was actually very comfortable for 7 of the 8 hours. Two nurses were constantly at either side of us. We remained in bed for roughly 8 hours. Dr. Dhatariya or his assistant were also in the room for the entire time. At 7:00 are or so, his assistant (which was a she) froze part of my right thigh muscle and took a small muscle specimen. Immediately following this an IV of insulin was started and another glucose solution in the main line. Every few minutes for 8 hours, blood was withdrawn from the left hand. Some of the blood was checked by special equipment with technicians in the room and the rest was kept on ice to be sent to the lab later. The results were given to Dr. Dhatariya. He needed to keep our sugars in a range known to him and the nurses. Every bodily movement made the glucose levels change and so did IV rates. Total blood withdrawn was 450 ml or 1 pint. I watched TV and had sips of water while this was all going on. I did have to use the commode once to void, which is tricky when both your hands have IV's in them. Thank goodness the three of us could babble from time to time. Near the end of the seventh hour my left hand did not like blood withdrawn, it started to spasm. The nurse made it last!! Finally 8 hours were up. The 2nd muscle biopsy was done but on the left thigh. By now all the 3 of us were starved. The nurses took all the IV's out except the glucose intravenous.

We all ate a wonderful breakfast/lunch combination meal. Once our glucose levels were good the IV came out. With yo-yoing glucose levels one does perspires a lot in bed. The three of us did not fair

very well in getting up out of bed. Our blood pressure (and we had taken our morning Addison's medications) were a little on the low side. Shauna's was naturally low but this time was much lower—but oh she needed a smoke real bad. She came back green!!
Just before we left Dr. Dhatariya gave us the next round of medication. We were instructed to start taking them after we got bloodwork done in our hometowns. A blood testing kit was sent to each of us from Mayo. My hospital Lab personal accepted Dr. Dharkyia orders and were very helpful. They sent it back to him.
So we had a two-week wash out period where we were on no study drug. After this time frame we started taking the new medication.

****I will only speak for myself. Within a few weeks on being on this new medication I started getting acne. The deep acne type under the skin, not the surface white head type. I started to notice my lip and armpit hair increasing. I had to shave my legs every two days as opposed to once a month. Lip hair was waxed more frequently. I noticed when doing my makeup in the morning I was looking different in a nice way. At first I thought it was because of the way I was doing my make up or hair not thinking it could be the DHEA. I just could not figure it out until near the end of June 2003 it was my eyes and mouth laugh lines smoothing out. (Approx. one and a half months of taking the new medication.) To me this was incredible!!!!! Could anyone else see this—No. During the last part of June I noticed I could lift a cooler of water much more easily. At first I thought this was strange because I usually need my husband to lift it. But this one day, I was in a hurry and did it myself and it was not difficult at all. I repeated lifting it from the floor to the top of the cooler again. Then I thought maybe I was on DHEA. Memory or lack of did not change.
During this time my daughter was in a serious automobile accident and I spent the end of May and all of June in Saskatoon at her bedside. Looking back I had more emotional and physical energy to sustain such long and difficult hours. I only increased my Cortef by 5 mg the first evening the next morning after her accident. ********

Anyways back to the DHEA study. It was delayed by one week because the Mayo nurses needed in assisting in this study were on summer vacation. Deb, Shauna and I met back to Rochester on week 26th,near the end July 2003 The three us chatted about the differences we felt or noticed. Deb and Shauna have no adrenal function and I cannot tell you who has hypothyroidism or who has also no hypopituitarism WE all noticed something different this time whether it was our hopeful imagination or the medication.

Week 26th and 27th were identical as week 11 and 12. Same testing and the same diet to eat. Try this in the middle of a hot summer with no cool refreshing beverage to enjoy just water!!! Dr. Dharitya told us after the 2nd and last muscle biopsy was done that all three of us were on DHEA these past weeks. Then the babbling was on, "I knew it," one of them said... It was difficult to say good-bye to these Deb, Shauna and Dr. Dhatariya. Shauna is already looking for another study Deb, her and I could be in.

The weeks following not being on DHEA were interesting for me. Just a few weeks off and I had difficulty lifting the cooler and facial wrinkles reappeared. It took just over 2 months for the hair growth to slow down. I had a tough time with mood and emotional well-being. In September 2003, I required an increase in antidepressant. I do not know whether it was coming off the DHEA or dealing with my (acquired brain injured - as the professionals call it) daughter back in school. It was very tough .....

Would I go back on DHEA---No. I will take my chances and age gracefully. I can increase my muscle strength with diet and exercise. On my wrinkles I am trying wrinkle cream. If I had noticed a big difference in memory or vitality maybe.... I guess I will never know.

As submitted by Elizabeth Hill

EXPERIENCE OF ATTEMPTING TO GET DHEA IN CANADA *by Sue Fleet*

After a year's quest of trying to convince my doctors, through medical studies, to consider applying for DHEA prescription approval through Health Canada, it appeared I had won my battle on March 20, 2003. On this day I had my first appointment ever with an endocrinologist, who I had waited six long months to see. I emailed this doctor a week prior to my appointment to mention the issues I wanted to discuss and I attached a few DHEA studies too. This tactic worked very well at ensuring that all my concerns were addressed, and much to my relief the email was well received. Along with agreeing to apply for DHEA approval, this wonderful endocrinologist was even willing to give me a solucortef prescription and allow me to try Cortef instead of Prednisone, things that the Internal Specialists and doctors I had seen since diagnoses simply refused. What a shame that many of us must deal with so many obstacles simply trying to take good care of our health, all because some doctors lack knowledge about Addison's disease and the crucial need for Addison's patients to have an emergency injection kit. It is a good reminder of how important it is for us to become well informed and knowledgeable about our diseases.

I understood from talking to others with Addison's disease in Canada, who take DHEA, that the biggest challenge was finding a doctor to prescribe it. I felt confident now that I had this endocrinologist on my side that things would progress quickly and I would soon be able to try supplementing with DHEA. Unfortunately for me, my application arrived at Health Canada right when their methods and position on DHEA approvals had changed. I didn't realize it at the time, but my approval for a DHEA prescription was far from over.

My endocrinologist originally sent in my application for DHEA approval to Health Canada in March of 2003. On follow up, in July, of why the normal 24 hour special access approval period was taking so long, I was informed by Health Canada that they had changed their Special Access approval methods and had sent out new application forms to doctors who had submit recent approvals. I checked with my endocrinologist to see if he had received the new forms and was informed he had, but he hadn't sent them in yet because he felt the forms were bit intimidating and he doubted that anyone would be approved for DHEA through the new system. I decided to call Health Canada and inquire if DHEA was still in fact on the list of drugs being given approval through the Special Access program and what exactly were the procedures that the program followed in approving applications for special access of non-marketed drugs? A Health Canada staff member informed me that DHEA was in fact still available to patients through this program. I was also told that the decision for approval was based solely on the applying doctor's ability to convince the need for the medication on the form, based on the evidence they provide. There is apparently no standards, guidelines, policies or criteria that reflect the use of DHEA for specific diseases or indications, such as Addison's. Since the decision is based solely on each individuals application and their ability to convince, some Addison's patients will get it and some won't. I was so shocked by this information that I decided to send a letter to the head of the Special Access Program, Ian Mckay, to question these procedures. I felt at the time

that my letter and the list of studies I included would undoubtedly convince Health Canada to approve my application. Just to give you an idea, here is a paragraph from the letter that I sent Ian in August:

> I can't believe that if someone with Addison's, is given approval to use DHEA, due to the studies and information their doctors provided Health Canada, why wouldn't ever person with Addison's disease qualify for approval? Everyone who is not producing DHEA is in the same boat! I am aware that Health Canada approves Aides patients for DHEA because their natural DHEA levels tend to be low and some experience benefits from supplementing this hormone. I wonder how then Health Canada could not approve someone with Addison's who doesn't produce the hormone at all. It saddens me that my approval will be based on my doctor ability to convince rather then the needs of his patient. Health Canada already has the information and data they need to prescribe DHEA to Addison's patients, it is written on every form that they have already approved for people with this disease. It seems crazy that an endocrinologist can't just write me a prescription for the DHEA I don't make, much like he writes me a prescription for the synthroid, insulin, hydrocortisone or florinef, the other hormones I don't make. DHEA is available over the counter in the United States, yet here in Canada a specialist in hormones can not prescribe it to their patients who don't produce it? If there weren't penalties attached to carrying DHEA across the boarder, I would be smuggling it in from the local U.S. Wal-Mart. Unfortunately, this is exactly what many Canadian Addison's disease patients have been forced to do, due to the unjust standards of our Canadian Access Approval Board, and the difficulties in getting specialists to fill out the Special Access forms. It seems my doctor's knowledge as an expert in the endocrine/hormone system, takes second fiddle to the judgement of his convincing abilities by Health Canada's approval board! I can't help but question what kind of medical background those on the approval board have to base their decision on? Since there are no standards, guidelines or protocols to prescribing DHEA, the individual judgement of the person approving the forms that day has a huge impact on the processing of my application. This really scares me.

I contacted my endocrinologist to inform him that Health Canada was still approving DHEA and so he completed and returned the new application along with several medical studies. Health Canada returned the application form twice to my doctor. Despite my letter and efforts, on September 11, 2003, my endocrinologist was advised that my application was denied for the reason that this indication for the drug does not specify a medical emergency of a serious or life-threatening nature. Since I had just talked to someone with Addison's disease in Ontario, who had been approved through the new system, I just couldn't believe that my application was denied. Once again I sent another letter to Ian MacKay questioning my application's denial, the options available for appeal, and why I hadn't received any reply to my letters. Until this day, I have never received any response to my letters and phone calls to Ian MacKay. In frustration, months ago I followed up by writing a letter to both Dr. Brian Gillespie the acting senior Medical Advisor for Health Canada and Dr. Robert Peterson, who is one step above him, to find out why Health Canada continues to ignore my concerns. No one from Health Canada has ever attempted to respond. When I call to enquire what is going on, I am told Ian will call me back, but he never does. I have sent several letters to my MP, Ann McLellan, about these issues. At the time she was the Minister of Health, so I felt this would make a difference. Unfortunately, she too has never responded to any of my letters or calls. It has now been over six months that I have waited, I am losing faith and don't know what more I can do, other then smuggle DHEA illegally from the U.S. I strongly believe that DHEA replacement in the right dosage can make a positive impact on the current and long-term health of people with Addison's disease. My trust in the human body tells me that it doesn't produce

a hormone in great abundance for no reason and the studies seem to be coming to the same conclusion. I encourage all of you with Addison's to write a letter to Health Canada and your MP about this issue. Our numbers may be few, but perhaps together we can make a difference.

As submitted by Susan Fleet

LETTER SENT TO DOCTOR'S RE: DHEA ISSUE

Finance Bldg, 2nd Floor
Tunney's Pasture, PL0202C1
Ottawa, ON
K1A 1B9

February 16, 2004

Dear Doctor,

Subject: Release of DHEA through the Special Access Programme

This letter is in response to your request(s) to the Special Access Programme (SAP) for access to DHEA and to advise you of changes regarding its availability for widespread or long-term use.

Health Canada's Health Products and Food Branch takes an integrated approach to the management of the risks and benefits to health related to health products by minimizing health risk factors to Canadians. Within this framework, the SAP has a mandate to provide access to non-marketed drugs to practitioners treating patients with serious or life-threatening conditions when conventional alternatives have either failed or are inappropriate. However, as an emergency provision within the *Food and Drug Regulations*, the SAP is not a mechanism to circumvent the clinical trials process or the new drug review process nor is it intended to promote or encourage the commercialization or early use of drugs before safety and efficacy is clearly established.

In 2001, the SAP introduced two programme initiatives. The first, a drug audit process, was implemented to monitor all drugs on the programme and identify those for which there are identified concerns of safety, efficacy or quality and/or there is limited data to support widespread access. The second, a quality initiative, was implemented to review the administration of the programme to preserve its use as an emergency mechanism in accordance with the SAP provisions of the *Food and Drugs Regulations*.

DHEA was identified early in the drug audit process as a product for which there was limited data to support widespread access or long-term use and for which product development was limited.

Shortly after DHEA was identified in the audit process, the SAP introduced a new request form as part of the programme's quality initiative. The new request form more clearly directed practitioners to provide both clinical justification for the use of the drug and the sources of scientific information supporting that justification as required by section C.08.010(a) of the *Food and Drugs Regulations*.

Unfortunately, many of the DHEA requests received under the amended form lacked acceptable clinical justification and scientific support for the use, safety and efficacy of the drug. In addition, the

drug was often requested for conditions that are generally not considered to be serious or life threatening. The SAP responded to these deficiencies through a fax-back procedure for incomplete requests that identified specific request deficiencies and outlined our minimal request standards.

Despite these efforts, the SAP continued to receive a large volume of DHEA requests that did not meet the minimal regulatory requirements of the SAP provisions of the *Food and Drug Regulations*. Consequently, beginning in December 2002, the SAP sent a communication to all physicians requesting access to DHEA to outline common deficiencies with DHEA requests and to provide further guidance on the basic requirements of the programme. That letter also explained that clinical trials might be pursued to better understand its safety and whether it is effective for specific indications.

In the months after this letter was distributed the SAP noticed minimal change in the volume of DHEA requests received that did not meet the regulatory requirements of the SAP provisions. This led Health Canada to conduct a review of the scientific evidence to support the use, safety and efficacy of DHEA, as they related to the emergency uses for which this drug has been requested.

Based on this review, it has been determined that significant new evidence would have to be included with any SAP request, before any further sales of DHEA could be authorized pursuant to requests made under section C.08.010 of the *Food and Drug regulations*. Given this determination, it is unlikely that the SAP will authorize the sale of DHEA for new patients. During an interim period of 1 year, the SAP will take account of the special considerations relating to patients currently receiving the drug, who in the opinion of the practitioner have not experienced adverse effects from their ongoing treatment, and may continue to authorize requests made for such patients. The SAP then will revisit the merits of any such continued authorizations on the basis of reports filed on the previous use of the product, including any adverse events, in accordance with subparagraph C.01.010 (b)(i) of the Food and Drug Regulations.

If you wish to pursue the use of DHEA, I recommend that you work with a manufacturer to develop and sponsor a clinical trial. A clinical trial would provide an opportunity to better understand the safety and efficacy of DHEA for specific indications and conditions. In addition, the regulatory review of the clinical trial would ensure that formal scientific and medical scrutiny is applied to the method of manufacture of DHEA and the protocol and data supporting the use of DHEA in the proposed treatment. Most importantly, a clinical trial would ensure that the best interests of patients are protected through the required involvement of research ethics boards.

For more information about the regulatory requirements for conducting a clinical trial, please consult our website:

www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/index.html

or contact Dr. Christine Nestruck in the Clinical Trials Division of the Senior Medical Advisor Bureau at (613) 941-0570.

Regards,

Original signed by/

Brian Gillespie, MD
Director, Senior Medical Advisor Bureau
Therapeutic Products Directorate

Reminders:

- Medical Questions and Answers - Dr. Donald Killinger, MD, Phd, FRCPC, from London, Ontario, who is the Medical Advisor for The Canadian Addison Society, will answer your questions about Addison's disease. Questions and answers that may be of interest to everyone will be published in the newsletter. Dr. Killinger has asked that we not write him directly, but to address your questions by letter/e-mail or fax through The Canadian Addison Society and they will be forwarded on to Dr. Killinger.

  Q. I was diagnosed with Addison's disease in 1992. I have always been told that I shouldn't take anti-inflammatory medication, can you tell me why. I am currently suffering from muscle spasms. I have been prescribed Baclofen vs. an anti-inflammatory.

  A. Rick has stated that he has been told not to take anti inflammatory medications because he has Addison's disease. Anti inflammatory medications can cause stomach irritation and ulcers. These are the major side effects of non steroidal anti inflammatory drugs. people who are taking steroids such as prednisone for the treatment diseases such as arthritis, are more susceptible to these side effects. In Addison's disease the dose of glucocorticoid is physiological (within the normal range) rather than pharmacological (exceeds the normal range for treatment purposes) so the increased probability of stomach problems in quite low. In a situation where anti inflammatory medications are indicated it is important to be aware of possible side effects but I would not hesitate to use nonsteroidals. It is important to be sure that the drug is being used for the proper indications. This family of drugs is very helpful to treat inflammation, but is not likely to do much for cramping or spasms.

- Please – If you are pleased with your endocrinologist – LET US KNOW! We have many requests not only from recently diagnosed Addisonians but other Addisonians from all parts of the country, who may be moving from one area to another and require the services of an endocrinologist knowledgeable about Addison's disease and its treatment.

This is your newsletter! We need your contributions. Please send your stories, tips, ideas directly to our editor Sharon Erickson via email: ericksons@shaw.ca or c/o the Addison Society.