



# Alpha-1 Canada Community News



March 2010

## Ontario Government Withdraws Funding for Augmentation Therapy, Please Help Us Reverse this Decision

Earlier this month we sent out an e-mail about the dire situation with respect to reimbursement for augmentation therapy in Ontario.

For those of you who missed it, The Ontario Drug Benefit Formulary of the Ontario Ministry of Health and Long-term Care has ceased approving funding of alpha-1 antitrypsin augmentation therapy (Prolastin®) for newly prescribed patients. This therapy is the only treatment available for lung-involved patients with alpha-1 antitrypsin deficiency.

We explained how this decision is wrong on clinical, economic, and more importantly, ethical grounds. (The contents of that e-mail can be found by clicking here or on the last page of this newsletter.)

Your response to our request that you write the person responsible for this decision was overwhelming. Thank you so much to those of you who wrote or e-mailed



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## Travel Sponsorships Available for Canadian Alphas to Attend US Alpha-1 Conference at Disney in Orlando

Every year the American Alpha-1 Association ([www.alpha1.org](http://www.alpha1.org)) hosts a National Education Conference. This event is the largest gathering of Alphas and Alpha-1 experts held anywhere and is jam packed with educational sessions and exhibits all focused on Alpha-1. Naturally, the conference is all held in English.

This year the conference will be held at the Hilton at the



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## Health Canada approves new Prolastin®-C Alpha-1 antitrypsin deficiency augmentation therapy

Talecris Biotherapeutics recently announced that it has received approval from Health Canada for Prolastin®-C, a more purified and concentrated version of Prolastin®. Prolastin-C is produced using advances in manufacturing technology. A similar approval was granted in the U.S. by the Food and Drug Administration for Prolastin-C on October 17, 2009.

Prolastin-C will replace Prolastin, the only approved augmentation therapy in Canada for more than 20 years. According to Talecris, the price of Prolastin-C will be the same as for Prolastin. Additionally, Prolastin-C will have the same Drug Identification Number (DIN) as Prolastin so new prescriptions or applications to public and private insurance plans should be unnecessary.

Talecris' news release says, "Prolastin-C delivers twice the active protein per millilitre as Prolastin, cutting infusion time in half when given at the recommended rate. Clinical studies have shown that Prolastin-C and Prolastin are equally effective at raising AAT levels in the blood."

In clinical trials, the most common drug-related adverse reactions observed in subjects receiving Prolastin-C were chills, malaise, headache, rash, hot flush and itching. This is similar to drug-related adverse reactions observed with Prolastin.

Dr. Ken Chapman, Chair of the Alpha-1 Canada Medical Advisory Board, indicates that, "for most people the transition from Prolastin to Prolastin-C will be transparent and painless. Some patients may find that their doctors will be asked to clarify instructions about infusion times or volume of fluid to be given. Doses of Prolastin won't change."



**Steve Petteway, PhD,  
Executive Vice President,  
Research and Development  
for Talecris**

Steve Petteway, PhD, Executive Vice President, Research and Development for Talecris said, "The modified manufacturing process for Prolastin-C incorporates technological advances such as nanofiltration, a virus exclusion technology, and cation exchange chromatography, an additional purification step. We are proud of these changes as they result in an improved product."

Talecris Biotherapeutics will be providing information about the transition from Prolastin to Prolastin-C to doctors, patients and Alpha-1 Canada before the planned transition in July 2010. This process is already underway in the US since FDA approval was given sooner in the US.

Watch the Alpha-1 Canada newsletter and website ([www.alpha1canada.ca](http://www.alpha1canada.ca)) for further updates. You may also contact us with questions toll free at 1-888-669-4583 or by e-mail at [jim.mundy@alpha1canada.ca](mailto:jim.mundy@alpha1canada.ca).



**Dr. Ken Chapman,  
Chair of the Alpha-1 Canada  
Medical Advisory Board**

Talecris has a toll free information line for questions from doctors, pharmacists and patients. The number is 1-866-482-5226.

*The Alpha-1 Canada Medical Advisory Board*

## **“How do I get the best treatment for my Alpha-1?”**

# Alpha-1 Drop-in Support Group

*It's  
for  
you*



Our next Drop-in Support Group Meeting will feature Dr. Kenneth Chapman. Dr. Chapman will speak for about 30 minutes on “How do I get the best treatment for my Alpha-1?” (lung-involved) then answer your questions for another 30 minutes.

In order to participate all you need is a telephone and the toll-free number to call.

Dr. Chapman is a Professor of Medicine at the University of Toronto and an internationally respected researcher in the field of asthma and airway diseases including Alpha-1. Dr. Chapman is also Director of the Canadian Registry for Alpha-1 Antitrypsin Deficiency and the chair of the Alpha-1 Canada Medical Advisory Board.

The meeting will be on Thursday March 25th at the following times:

5:30 pm Pacific Time	6:30 pm Mountain Time
7:30 pm Central Time	8:30 pm Eastern Time
9:30 pm Atlantic Time	10:00 pm Newfoundland Time

Please note that we've tweaked the meeting times a little to accommodate those in different time zones.

In order to participate all you need is a telephone and the toll-free number to call. The toll-free number changed recently, so if you kept the old one it may not work anymore. Please contact Jim Mundy for the phone number. He can be reached at 1-888-669-4583 or by e-mail at [jim.mundy@alpha1canada.ca](mailto:jim.mundy@alpha1canada.ca).

## **Update on Testing for Alpha-1 Antitrypsin Deficiency in Canada**

Talecris, the makers of Prolastin®, have developed and received government approval for an Alpha-1 test kit.

Once your doctor has determined that your AAT level is low (1.5 g/L or less, or below the normal mean for the testing laboratory) he or she can call the bilingual call-centre at 1-877-3 ALPHA1 (1-877-325-7421), to order a test kit. Once your doctor receives the kit, three dry blood drop samples are taken then mailed to a testing facility at the University of Florida. Within two to three weeks the doctor will receive the results through the mail.

It is important to understand that while your personal information and test results will only be divulged to your doctor, unlike test kits that were available a few years ago, these kits are not anonymous. Since the kits and results can only be sent to your doctor, he or she will place your results in your medical file (please see our web page on “Ethical Issues” to learn the implications of this fact).

Talecris provides the specimen collection kit (including a postage paid mailer pre-addressed to the testing facility) and the testing services of the University of Florida Alpha1 Lab at no charge. We congratulate and thank them for their speedy solution to this problem.

This program is being managed and operated for Talecris by third parties; Talecris will not have access to anyone's test results.

## Travel Sponsorships to US Alpha-1 Conference at Disney continued

Walt Disney Resort in Lake Buena Vista, Florida (Reservations: 1-800-782-4414) on June 11th, 12th and 13th.

The Board of Directors of Alpha-1 Canada is pleased to announce that Alpha-1 Canada will be able to make travel sponsorships available to a limited number of Canadians to attend this educational event.

The conference theme is Unlocking the Family Genes: The Key to a Healthier Life. Given both the theme and the location we would like to encourage the families of Alpha-1 affected children to consider attending.



**Hilton at the Walt Disney Resort  
in Lake Buena Vista, Florida**

Alpha-1 Canada is making available a limited number of \$1,000 travel sponsorships to the families of Alpha-1 affected children as well as a limited number of \$500 travel sponsorships to grown up Alpha's (We can only provide one sponsorship opportunity per chosen family). In addition, Alpha-1 Canada will pay the conference registration fees of the Alpha-1 affected children and their accompanying immediate family members (parents, legal guardians, brothers and sisters) who receive a subsidy. We will also pay the conference registration fees for adult Alphas who receive a subsidy. Conference registration fees include dinner and entertainment on Friday night, breakfast lunch and dinner on Saturday and breakfast and lunch on Sunday.

The American Alpha-1 Association has negotiated a room rate of US\$111 for bookings made before May 7th, 2010. This rate may also be available if you arrive a few days early or leave a few days later, check with the hotel to confirm dates (Reservations: 1-800-782-4414) and make sure you say you are attending the Alpha-1 Association conference in order to receive the US\$111 rate.

In order to apply for one of these sponsorships, simply write and tell us why you would like to attend the conference. Please keep your reasons under 500 words and e-mail (jim.mundy@alpha1canada.ca) or mail (Alpha-1 Canada, 1638 Northway Ave., Windsor, ON N9B 3L9) them before April 5th, 2010.

Please note that everyone travelling to the US needs a passport now, even infants and children.

This conference is a wonderful opportunity to learn more about Alpha-1 and to meet Alpha-1 Canada representatives and hundreds of Alphas from south of the border. Please give it some thought and apply today!

## Mayo Clinic Successfully Performs Its First Lung Transplantation from Donor After Cardiac Death

Mayo Clinic ([www.mayoclinic.com](http://www.mayoclinic.com)) recently announced that it performed its first donation after cardiac death (DCD) lung transplantation a year ago. The recipient was a 59-year-old man who had alpha-1 antitrypsin deficiency was a former smoker.

The report in the February issue of Mayo Clinic Proceedings says the recipient is doing well, walking approximately 3 to 4 miles a day.

Before his transplant, his forced expiratory volume in the first second (FEV1) – a measure of lung function and the ability to breathe – was at 20% of predicted, but at his appointment in January 2010, his FEV1 was at 103% of predicted.

Lung transplantation is a common therapy for patients with end-stage lung disease. Just like patients waiting for other organs for transplantation, however, there are more recipients waiting for lung donations than there are donors.

Over the past number of decades, brain death has become the most widely used criteria for organ donation, even though the earliest organ donations were from deceased donors following cardiac death.



Donation after cardiac death organ donation expands the number of potential organs available to patients in need of transplants.

"Today, our critical shortage of organs has brought about renewed interest in DCD procurement," says Stephen Cassivi, MD, Mayo Clinic thoracic surgeon and lead study author. "As with our first patient in this report, we see this form of transplantation as a further needed opportunity to turn the inevitable tragedy for the donor and his or her loved ones into hope and life for transplant recipients."

Mayo Clin Proc. 2010 Feb;85(2):150-2, Successful lung transplant from donor after cardiac death: a potential solution to shortage of thoracic organs, McKellar SH, Durham LA 3rd, Scott JP, Cassivi SD.

## **Ontario Government Withdraws Funding for Augmentation Therapy *continued***

Ms. Stevenson. If you have not done so already, please take a few minutes to write and voice your concern.

It is important to understand that although this situation is currently Ontario-specific, cost saving moves made in one province are often followed by other provinces. Furthermore, private insurance companies frequently imitate drug reimbursement policies of provincial governments. If Ms. Stevenson decides not to reinstate funding in Ontario, the domino effect could well be felt across Canada resulting in a treatment availability disaster for the national alpha-1 community.

To express your concerns about this move by the Government of Ontario please write to:

Ms. Helen Stevenson,  
Assistant Deputy Minister and Executive Officer,  
Ontario Public Drug Programs Division,  
Ontario Ministry of Health and Long-term Care  
Hepburn Block, 9th Floor,  
80 Grosvenor Street,  
Toronto, ON M7A 1R3  
Helen.Stevenson@ontario.ca

We encourage you to personalize and individualize your letters. Form letters and letters only copied from documents like this do not have the same impact. Please write and please pass this information on to your caregivers, family and friends and ask them to support your endeavours to stop this disastrous decision.

**Our website is continuously updated with useful information for Alphas, their caregivers and healthcare providers, as well as news on promising research. Make a habit of checking our website regularly so you won't miss out on exciting updates and always read our monthly newsletter from top to bottom.**

**Help us spread awareness by sharing this newsletter with your family and friends.**

**If you would like to receive this newsletter by e-mail, please contact us at 1-888-669-4583 or [jim.mundy@alpha1canada.ca](mailto:jim.mundy@alpha1canada.ca)**

### **Alpha-1 Canada - Making a difference in the lives of Alphas**

**This newsletter is designed to support, not replace, the relationship that exists between you and your physician. It is not the intention of this newsletter to provide specific medical advice but rather to provide the Canadian Alpha-1 Community with information to better understand their health and their diagnosed disorder.**

**Specific medical advice will not be provided and Alpha-1 Canada urges you to consult with a qualified physician for diagnosis and for answers to your personal questions.**

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