

Neutropenia Support Assoc. Inc.

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EXCITING NEWS! NEUPOGEN APPROVED IN CANADA!!

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Toronto, Ont. -- NEUPOGEN*, a new drug which significantly reduces the risk of life-threatening infections in cancer patients treated with chemotherapy, was made available today to hospital and cancer clinic pharmacies.

AMGEN Canada Inc., which markets the drug in Canada, said NEUPOGEN has been approved for use by the Health Protection Branch of Health and Welfare Canada.

The drug is a genetically-engineered human protein that stimulates the growth and recovery of specific white blood cells called neutrophils. Neutrophil or white blood cells are the body's natural defense system against infections.

Dr. Daniel Billen, general manager of AMGEN Canada Inc., estimates that one in two newly diagnosed Canadian cancer patients annually undergo chemotherapy, a form of treatment designed to kill the rapidly dividing cancerous cells.

"During such treatment, other rapidly-dividing but healthy cells are also destroyed," Dr. Billen said. "This can lead to side effects such as hair loss, nausea, as well as the more serious side effect of infection.

"NEUPOGEN* does its job by stimulating the growth and recovery of white blood cells destroyed by chemotherapy drugs. Therefore, its use as a preventative treatment can result in an overall improvement in the quality of treatment of cancer patients by protecting them against the risk of potentially life-threatening infections and by allowing them to receive planned doses of chemotherapy on time."

Dr. Billen said clinical trials and patient use have shown NEUPOGEN* to be effective in reducing by 50 percent the incidence of potentially life-threatening infections in cancer patients treated with chemotherapy.

"Prevention of infection with NEUPOGEN* therapy can produce significant cost savings to our health-care system by reducing or eliminating the associated costs of hospitalization and infection control, "Dr. Billen said.

NEUPOGEN* is a human protein known as G-CSF. G-CSF is one of a group of proteins called colony-stimulating factors responsible for regulating and controlling white blood cells. AMGEN Inc., pioneered the discovery of the gene for G-CSF, isolated it and developed the technology to reproduce it through recombinant DNA technology in commercial quantities.

In 1991, NEUPOGEN* was acclaimed, in the United Kingdom, as the most outstanding pharmaceutical product of the year. As the recipient of the prestigious and internationally renowned Prix Galien Award, NEUPOGEN* was judged by an independent jury of medical experts to have made the most significant contribution to patient care, in terms of efficacy, safety and innovation.

AMGEN Canada, Incorporated in February, 1991 is an integral part of AMGEN Inc., an International organization that develops, manufactures and markets human proteins for pharmaceuticals based on advanced cellular and molecular biology. Headquarter in Mississauga, Ont., the company is committed to bringing to market breakthrough medicines to enhance and improve the lives of Canadian cancer patients

NEUPOGEN* is a registered trademark of AMGEN Canada Inc.

Our group's executive let the cat out of the Bag ..

We scooped the National News on March 2nd, 1992. Lorna Stevens, Brian Gamley, Janice Benzelock and Dr. Jon Gerrard were on the Grant McGinnis Talk Show of CJOB Radio and announced on the air that Neupogen, the drug we had intensely lobbied for approval, was finally available to cancer patients to help them fight life-threatening infections.

Time to Forge ahead

In March, 1992, the application was submitted to the Health Protection Branch specifically for (SCN) Severe Chronic Neutropenia patients. With so few families (under 40) it may never formally be approved for this specific application. We are told physicians will prescribe as required and each Province in Canada will decide whether to add Neupogen on formulary. Major hospitals across Canada will also be addressing this issue.

We now have on file the "Economic Issues" cost of hospitalization for febrile Neutropenia extrapolated to a Canadian model. Neupogen has been shown to:

- 1. Reduce the probability of hospitalization by 50%.
- Reduce the cost of hospitalization by 50%.

We therefore, cannot understand why all SCN patients are not granted full coverage for Neupogen when it is less costly to our Medicare system to be treated with the drug versus continued hospitalization and antibiotic treatments.

Coverage of Neupogen Granted

On April 21st, 1992 Manitoba granted full coverage of Neupogen for Brian Gamley, our precedent setting SCN adult patient featured in our first Newsletter. His comments since January, 1991 are as follows:

Around January, 1991 and with the U.S. approval of Neupogen, a granulocyte stimulating factor, produced by Amgen Pharmaceuticals, I was approved for a research program to test this new revolutionary drug in Canada. Certain protocol must be met before I could be placed on the program and due to a great many surgical and administrative complications, none of which were my fault, I missed the opportunity to try out the drug, although all the protocol had been met.

Although the surgery was considered successful, I continued to have pneumonia and found the usual antibiotics that I was responding to were becoming non-effective. My condition continued to decline and in October, 1991 I had a heart attack, spending ten (10) days in the Seven Oaks Hospital I.C.U.

After the heart attack, I was advised I would no longer be considered a candidate for the drug testing program for Neupogen. Through the diligent and dedicated care of Dr. Jon Gerrard of the Manitoba Cancer Foundation and the Neutropenia Support Association, I was somehow enabled to be put on a three (3) month test program of Neupogen. I was given, at no cost, a three (3) month supply of the new drug and instructed how to give myself the daily injections. During this initial period, I attended the Cancer Clinic twice weekly.

It appears the drug is working, according to my blood count and I know the drug is working according to how I feel. I have lost

close to thirty (30) pounds, many inches, have been exposed to many viral and bacterial infections due to the public related job I hold and my children bringing home the school's many ailments and I feel stronger and more able to resist what I used to succumb to. I have passed my heart stress test amazingly well and my wife attests to my better nature and fewer devastating depressions.

With all this going for me, the three (3) months came to an end and I was faced with a return of the bad days. Due to the extreme cost of Neupogen, there was no chance of me paying for the drug on my own. Due to the continued efforts of my Doctors and my family's own anguished plea and the simple alternative of continued Prednisone use and ultimately, the province's costs in repeated doctor / specialist visits, costly specialized tests (bone marrows), treatments, surgery and hospitalization, the Manitoba Health Life Saving Drug Program has granted me continued usage of Neupogen at their expense. I can now continue to look forward to a relatively healthy life style, one that most people take for granted.

Words from Jamie & Janis Benzelock

Hi! My name is Jamie Benzelock. I am sixteen years old and I have Neutropenia. These past sixteen years have been alright; I mean, I guess you just have to deal with the good and the bad. Like the first thirteen years had its ups and downs, mostly downs though. However, the last three have been great. I've had the opportunity to take part in sports and other activities such as going on outings with friends and family. I guess you could say that my life has taken a turn, not for the good but for the best. Sincerely,

Jamie Benzelock

I am the mother of Jamie Benzelock, a 16 year old boy with congenital neutropenia of Kostmann's Syndrome. Jamie was diagnosed with this condition in September, 1976. He was 10 months old. After having several infections of various types, doctors from the Cancer Clinic were asked to do some tests on his blood. After ruling out cancer of any type, the diagnosis was Congenital Neutropenia.

As Jamie grew, he suffered with the infections, one after another. Children's Hospital in Winnipeg must be on volume V for the number of hospital visits. His most common type of infection were in his mouth, where he would get canker-like sores that developed into very large sores that once he was on antibiotics for about one week, he would notice the sore wiggling and the white top would fall off and leave a crevice in the same spot. He has had up to nine sores at a time.

The other problem he encountered quite often were anal sores. He had a lot of discomfort with that condition. Jamie also had pneumonia a few times as well. In January of 1989, Jamie and I travelled to Ann Arbor, Michigan to take part in a clinical drug study for the drug G-CSF for patients that had chronic neutropenia. Once accepted and put on the drug, Jamie took about one and a

half weeks until his count came up to normal levels, but did go up and down like a yoyo. He has had some problems where he has taken antibiotics for about a week but since his going on the G-CSF he has not had any hospitalizations. Seeing him participate in sports with friends and basically being a "normal kid" has made everything worthwhile. Jamie is now going into grade XI and has a driver's license and recently, started working part-time at Chi Chi's. As he heads off tonight to the Winnipeg Thunder Basketball Game with three friends, I really believe he is normal! The one thing I should explain is that we know this is a treatment for his condition. It is not a cure. The side effects with the drug have been very minimal. He has never felt better or looked better plus he's eating well and is maintaining a healthy body.

Because he has had no hospitalizations since January, 1989 the Medical System has certainly benefited by this wonderful drug. We, as a family, are very grateful to our dedicated physicians at the Cancer Clinic that have helped and encouraged us through the years. Without them we would never have been involved in the drug study and Jamie would not be enjoying his life today. Submitted by:

Janis and Jim Benzelock

Traveling across CANADA

In Edmonton, Alberta on July 24th, 1992 Lorna Stevens made a presentation to a special advisory board which included the Assistant Deputy Minister for Alberta Health, with a successful outcome for the precedent setting SCN patient in Alberta. A letter from the Alberta Health Department received August 13, 1992 thanked us for our presentation and it was felt our participation will benefit similar audiences in other provinces.

NEWS FLASH: September 15, 1992.. Our Alberta SCN patient will start receiving Neupogen this week. Criteria for benefits, prescribing quidelines and a specialist list will be announced February 1, 1993. Every province has different private sector coverage and/or complicated administrative Health care policies. We know the Alberta experts now recognize Severe Chronic Neutropenia (SCN) and we respect a positive step-wise approach.

Neupogen is on formulary in Nova Scotia and Quebec has cited its use for SCN as an adjunct to chemotherapy treatment for patients over sixty-five, social assistance and in Quebec for Aids treatment as well.

... To NFLD

Excerpts from NFLD letters received

* * *

"My daughter has had Neutropenia since she was two years old. She is now twelve and a half and since she has much sickness" "I've needed for years to have someone to relate to in this matter. I have nother parent with such a problem as this"

Since this letter was received by us, the family has received an extensive package of information, documentation in support of her required dental care.

Her physician has applied for daily usage of Neupogen. The department of Health has indicated they support the concept and require Social Services to assist with funding.

The CBC (radio) interviewed the family Sept. 6, 1992 and with the assistance of the Medical Director in NFLD, Dr. Kevin Hogan, we hope financial assistance will be made available.

* * *

Dear Lorna:

Its, your Newfoundland friend. I'm writing to thank you for all your efforts. I thank God for people like you and your Group. I believe you have energy and Thank you from my heart.

I was reading there's some kind of equipment you need. You may put this money directly into your Research and where it is most needed. (N.B. Generous donations were received and were part of the \$2,000 donation given this month to the University of Manitoba Neutrophil Research under Dr. Jon Gerrard and Dr. Bonnie Cham.)

For the past ten years my husband and I have been living a real life nightmare. We wake each day, not knowing what to expect next simply because our only daughter and first child, now twelve years old, has a rare blood disorder called "Neutropenia". Almost from the first day she was born, on December 17, 1979 we have been only coping with this revelation and live our daily lives in dread and fear.

Living in Point Leamington, some forty-five minutes from a hospital, we have had to have a dependable vehicle parked by our door and full of gas at all times for fear of having to rush her to the hospital. It would either be that small splinter in her finger that has, within and hour, infected her arm to the elbow or that slight fever has somehow reached convulsion stage in a short time. Regardless of the case, she is so used to living her life in discomfort with a constant sore throat and gums, that she rarely asks questions and just puts her best side forward, never complaining, resigned to the fact that things just don't get any better.

When arriving at the hospital in one of these many emergencies, we are usually greeted with a Medical Staff that knows little or nothing of her disorder, any more than the name itself. Routinely, we refer them to Dr. Kelland or go to great lengths to fill in the gaps and educate them about this condition, practically telling them what must be done. It becomes increasingly difficult with staff and shift changes.

To tell you in detail of our situation would take forever and I do not want you to feel that we are complaining. We love our daughter dearly and we live trying to make things easier and better for her.

Until recently, we thought we were alone. However, thanks to her past pediatrician, Dr. Ali, we were put in contact with a "Neutropenia Support Group" based in Winnipeg. Needless to say, we were overjoyed at this new-found discovery. To know that others suffer as we do and understand, is in itself a miracle.

Abruptly, things became even more complicated when her new physician Dr. L. Ingram recommended a new miracle drug for her. It is called Neupogen. After an eight-day trial on this drug, flown from the United States, the change was astronomical. Her white blood cell count became normal, she no longer suffered with sore gums and throat, her teeth were firm in her gums and for the very first time in her life, she lived free of pain. We were ecstatic, to think that finally, after all of these years, things in our home would be normal and she would be well.

However, this is where the story basically ends. We have been told that to have this drug, it would cost twenty thousand dollars a year for the rest of her life. I am a hairdresser and my husband works seasonally with Atitibi Price and this is just an impossibility. Our insurance will pay only five-thousand dollars a year. We are quite willing to drain what resources we have which are few. As parents, we do not want to deprive our daughter of this opportunity but in reality, we could not even hope to give her what she needs. Dr. L. Ingram is presently working with Social Assistance for help. However, with government changes the way they are, everything could quickly come to an end. We now look to you for help. Can M.C.P. provide some assistance? Before we can say yes to Neupogen, we need to know how it will be financed.

... On to Ontario

DEATH WATCH

With the magic of Christmas everywhere, the only worry beautiful little five year old Stacey Cox had, as she laid down that snowy winter's night to go to sleep, was if Santa Claus would get her letter in time. The kiss on the cheek, the words whispered "I love you" as she lay sleeping soundly, tucked into her cozy little bed with her favorite Care Bears all around, wouldn't be enough to keep her safe and sound. The next morning would be her last because she died en-route to Sick Children's Hospital. Stacey died of the flu. She had Congenital Neutropenia, a blood disorder which limits the body's ability to fight off infection.

Eight years later, Travis Cox, a mischievous twenty-one month old, blue-eyed, blond little boy was rushed to Stevenson Memorial Hospital, the local hospital, having awoken with a high fever. Travis, like Stacey, their father Michael and four month old brother Spencer, all suffer from Congenital Neutropenia. Regardless of how well they are isolated they are still exposed to airborne viruses and sicknesses which are brought home by other members of the family. Travis too was rushed to Sick Children's Hospital and placed on a broad spectrum of antibiotics including G-CSF to attempt to fight off anything and everything that was ravaging this sweet little boy's body, whilst a multitude of tests were carried out and a firm diagnosis achieved, if he lived that long. June 20th, 1992 on his mother's birthday, Travis was released from hospital. He had survived this time.

In the early months of 1992, a new miracle drug called G-CSF (Granulocyte Colony Stimulating Factor) produced by Amgen Canada Inc. under the name of Neupogen was approved for use in Canada. Neupogen would have given Stacey a life past the age of five and could give my husband, Michael, and our two youngest children a fighting chance at normal life. A life where the children's friends wouldn't have to be "screened" before play. A life where they can go to school. A life where a little scratch won't turn into a life-threatening situation. A life where breathing won't kill them. A life where, when mommy and daddy kiss them goodnight and tuck them in, it's not in fear that it may be the last time.

G-CSF, if administered daily, gives the body a chance to fight off infections and diseases. G-CSF's costs are not covered by CHIP outside of the hospital and costs, depending on the dosage requirements, are anywhere from \$100.00 to \$300.00 or more per day, per patient. G-CSF is therefore, a drug that no normal person can afford to buy, yet, if it's needed, can they afford not to buy? Our children must have this drug so that the mornings when they wake early and crawl into our bed to cuddle their warm little bodies next to ours, we don't have to worry that those sweet helpless little boys are too warm and running a fever and that today might be their last. A kiss and a cuddle cannot keep Travis, Spencer and Michael alive, but G-CSF can.

Thousands of Canadians are institutionalized or unable to take care of themselves because of their inability to function in society or to support themselves. I am pleading that in this great land of ours, where we are all treated equally regardless of race, color or religion, that something be done quickly to save the lives of normally completely functional people across Canada, whose productivity and contribution to society is dramatically reduced, because they are frequently hospitalized and needlessly die, when there is a miracle drug available, yet financially out of reach for the vast majority.

The seriousness of this blood disorder cannot be over-emphasized as every breath could lead to inhaling an airborne disease or virus that, without G-CSF, could lead to death.

The funding of G-CSF cannot be tied up in red tape; cannot be argued over or delayed for another minute. The lives of fellow Canadians relies on the proper funding of G-CSF. Their lives are in your hands. Tomorrow could be too late.

I beg of you to do whatever you can to aid us in making G-CSF available to those who need it so much and thereby stop the senseless deaths of citizens of our great country and the heart-rending, needless tragedy of the loss of another member of my family.

Without prompt and complete funding of G-CSF, people with Congenital Neutropenia are sentenced to a life, if they live, of sickness, pain and hospitalization. When a cure is just money away, it is a completely senseless struggle. Why produce a drug if the costs result in it being unobtainable to all citizens who need it?

Ironically, if we were unemployed and on welfare, the drug costs would be probably covered. If that is the only way to get the drug, so be it!

Thanking you in anticipation for your prompt attention to this most urgent life and death matter and anxiously awaiting your reply.

Regards,

Mrs Shirley Cox Everett, Ontario

Aid sought for Waterloo tot's \$200-a-day drug

For 23 month-old Allison Riley, diagnosed at birth with an extremely rare blood disorder, the difference between the constant risk of a life-threatening infection and a chance at a normal life is a drug which costs more than \$200 a day.

Her mother, Cathy, has appealed to Waterloo North MPP Elizabeth Witmer to see if there's any help available to pay for the drug which despite a workplace insurance plan covering 80 percent, will cost her well over \$10,000 per year.

"I'm a single mother not getting support so that doesn't help matters," said the 24-year old Waterloo woman who works full-time as a customer service representative at a bank and lives with her parents. "I don't think I should be having to worry about the cost. "This is just giving her a fighting chance," she said. "It's something she will always have to have just to have a normal life....The alternative without this drug is frequent hospitalization because she'll just be getting sick."

Allison, who has Kostmann's syndrome, the most severe form of a rare disorder called chronic neutropenia, lacks a type of white blood cell called the neutrophil which fights bacterial infections, her mother explained.

Allison is subject to recurring mouth ulcers, swollen and bleeding gums and "yes, she can be hospitalized for something as small as paper cut" or a hangnail, Riley said.

Sue Craig, a communications officer with the Ontario Health Ministry in Toronto, said physicians can urge government coverage of drugs not on its list of billable medications by submitting the case to an independent body of experts that advises the ministry on the therapeutic value of drugs.

She noted there are precedents with other so-called "catastrophic" drugs-expensive new products, such as AIDS drug AZT, that a small number of patients require for serious health conditions. "There's a number which have been covered on an ad hoc basis. "I would guess we'll have an answer for (Riley) shortly."

Kitchener - Waterloo Record July 22, 1992

Stop The Presses ...

As of Oct. 7, 1992 Both Travis Cox and Allison Rily were approved for full coverage under the Handicapped Children's Benefit, Section 8 Ontario Drug Plan. Their application will be reviewed yearly. Ontario Health has established a drug reform secretariat to review their regulations Re.. billing third party insurance. They will examine case by case and the O.C.T.R.S. will help establish the guidelines for funding.

Since one in a Million have SCN we respect this decision for special authorization. One in three cancer patients become Neutropenic while under treatment. The Ontario Health also mentioned a communication project to properly inform the medical community as to how it is possible to provide for individual coverage of unlisted drug products under the authority of Section 8 of the Ontario Drug Benefit Act.

In the interim do not Hesitate to call Lorna Stevens for further information.

Across the border To the U.S.

I'm writing to offer my support to the Neutropenia Support Association. I'm a nurse at the Fargo Clinic Broadway Health Centre and the mother of Angela Bonnett. Angela was diagnosed with chronic severe neutropenia in 1972. I became aware of your work through Doctor Nathan Kobrinsky with the Roger Maris Cancer Center in Fargo, North Dakota. Doctor Kobrinsky is now Angela's local primary physician treating her neutropenia. We are very pleased with his excellent care and grateful for the knowledge he has regarding neutropenia.

For the past three years, Angela has been involved in Doctor Boxer's Research Program at the University of Michigan Hospital in Ann Arbor, Michigan. She is taking a daily injection of G-CSF and is doing wonderfully!

I'm sending a copy of our story regarding living with neutropenia. You may use it as you wish, circulate it, send it to government and medical personnel, whatever. We would like to do whatever we can to make G-CSF affordable and available to everyone that needs it.

Sincerely Val Bonnett, L.P.N. Fargo, North Dakota

* * *

To Whom it may concern: I am the mother of Angela Bonnett, writing this letter in behalf of my daughter who has chronic severe neutropenia. I would like the public, the Governments of the U.S. and Canada, and the medical community to know our story.

Angela was born August 31, 1972, an apparently healthy, beautiful baby girl, weighing 8 lbs., 13 ozs. My husband and I had not cared if we had a girl or a boy. We just prayed for a healthy baby, which we thought we got, and were anxious to begin our life. Angela, of course, was the joy of our lives that first year. But suddenly, our joy turned to nightmare. Our happy family was about to endure sadness and sorrow beyond explanation. A few days after my daughter's first birthday, she became critically ill. Angela had developed impetigo, a skin infection, on her chin, which is normally easily treated with an antibiotic ointment; but within one week, Angela had septicemia (blood poisoning) throughout her system. During her six-week hospital stay in a Fargo, North Dakota hospital, she had one setback after another.

Many complications occurred, some including rectal abscesses, kidney failure, high blood pressure, seizures and gangrene of the bowel, requiring removal of a portion of her small bowel. A gastrostomy tube was placed surgically into her stomach. She required intravenous medications and fluids for many weeks. they shaved all the hair off her head to use veins for IV's, they ended up needing to use veins in every part of her body, including her feet, neck areas, etc. I can't stress enough the suffering the parents and family go through, how helpless you feel, watching your child suffering this pain and unable to stop it. Most of the physicians did not expect her to live through all this, especially when her blood tests showed she had no white cells to fight this devastating infection. But miraculously, with huge doses of antibiotics and cortisone, she made it. When Angela became stable enough, she was transferred to the University of Minnesota Hospitals where she was diagnosed with chronic severe neutropenia. Our battle with this often fatal disease had begun. The next five years, Angela spent more time in the hospitals than at home. I believe she suffered more pain and illness during that period than most people suffer in a lifetime. She had numerous skin abscesses and skin infections from little scratches or cuts. She had many painful mouth sores, developing into fungus and bacterial infections. Her gums were bleeding, sore and swollen most of the time, making it difficult for her to eat many things. By the time Angela was 10 years old, she had severe damage to the roots of her teeth. Her dentist thought she would lose her teeth by the time she was a teenager. She had pneumonia numerous times, she had croup frequently. Luckily, this particular bout with the flu and croup, we had her in the hospital when she developed a mucous plug in her trachea, which required emergency surgery. Had she been home, she would have died. Through all these infections and illnesses requiring many, many hospitalizations, Angela also had to endure all the testing, probing, needle sticks, etc., which, in itself, is very traumatic. It's obvious the physical pain and suffering a child endures with neutropenia, but we must not ignore the emotional pain and suffering the child and the family go through also. As Angela got older she began to express anger about being sick so often, about not having the energy or ability to keep up with the other kids. She was angry that she had scars all over her body from all the infections. She was angry that her gums were always red, swollen, and bleeding and that people noticed that. Phys-Ed was difficult for Angela all through school, as she didn't have the energy or strength she needed for most of the activities. This is such a rare disease that, even teachers and some physicians didn't understand her complaints and her inabilities to perform normally. Emotionally, this is so draining on the child and family. Very few people seemed to truly understand the difficulties and hardships caused from this horrible blood disease.

For the next 16 years, we fought this disease. We had many sleepless nights and days of constant worry, wondering with each infection, will this be the time the antibiotics won't work and she'll die. Thank God, with prayers and excellent physicians in Fargo, she would make it through each infection. Then in 1989, Angela was now 17 years old. A pediatric hematologist Angela had had in Fargo, who now was practicing in Ann Arbor,

Michigan, called to inform us of a study program in progress using an experimental drug call G-CSF. It was like a dream come true. For 16 years, I had prayed for a treatment or cure for this disease, and finally, my prayer had been answered for Angela. In October of 1989, Angela and I traveled to Ann Arbor, Michigan to begin treatment of daily G-CSF injections under the supervision of Doctor Boxer. Within one month, we were beginning to see the remarkable effects of this miracle drug. It was unbelievable how her energy level increased. Her gums began to improve; she could brush and floss her teeth for the first time without her gums hurting and bleeding. Her loose teeth tightened up. She has now been on G-CSF for three years. There have been absolutely no side effects from the drug. Angela has been virtually free from infections and hospitalizations. She has felt better than she has ever felt in her life. We're unable to put into words the happiness and relief this has brought to Angela and her family. It is truly a miraculous drug and has, if not saved her life, given her quality of life which is as important. She can now live her life fully without frequent pain, suffering and illness, which she would surely be experiencing if it were not for the G-CSF treatment. We. as a family, are so very grateful to our superb physicians and, especially, to Doctor Boxer and all those other dedicated research people, nurses and medical staff fighting to treat and, hopefully, one day cure this dreadful disease of neutropenia. Our personal battle with the disease would seem to be won for the moment, as we, of course, are thrilled with the outcome of Angela's good health while taking G-CSF. But we cannot forget all the children and adults still suffering with neutropenia. We must also think of the future, the babies yet to be born that will have the disease. It seems inhumane to us that any country or government would not make G-CSF available to any person suffering from this disease. Only those of us that have lived with neutropenia can know and have experienced the true goodness this drug, G-CSF, must be made available and affordable to all that need it immediately! This is a miracle drug, we cannot let politics and red tape get in the way of bringing quality of life to babies, children and adults suffering and dying each day from this dreadful disease of neutropenia.

To end this letter, a most recent update on Angela. She is now 20 years old; a beautiful, caring, sensitive young lady with chronic severe neutropenia taking a daily dose of G-CSF. The difference today from three years ago is that, she is healthy, energetic, free from infections, and grateful to be alive! Thanks again to all those involved in neutropenia research and support programs and a very special thanks to the Study Program with Doctor Boxer in Ann Arbor, Michigan.

Sincerely,

Val Bonnett

Hematologists and Health Care Policy in America

When I was first asked to write a perspective on American health care policy for Blood, my response was that this might not be a good idea. After all, hematologists and our flagship journal Blood should worry about curing leukemia or, finding new hematopoietic growth factors, or gene therapy-but not politics. However, on reflection, it becomes apparent that we hematologists are affected as much or more by our country's health care decisions as anyone. For example, hematologists in practice spend a big part of their time doing things such as arguing with clerks about whether or not a patient can be hospitalized or can receive erythropoietin, G-CSF, or GM-CSF, or worrying about losing their practice to new HMOs or PPOs. Hematologists performing clinical science in universities will not be able to do their research if their university hospital cannot stay competitive in a changing environment. Funding, or lack of it, to support hematologists performing laboratory science is dependent upon national health care policy. America's position of leadership in medical science is not likely to survive a dramatic decrease in support for research.

American health care policy really is in a crisis. However, the problem is so big that we sometimes have trouble defining it and are discouraged from trying to deal with it. There are two underlying issues that can be identified. The first issue is cost. America is currently spending approximately 14% of our gross national product on health care (i.e. more than 5800 billion in 1992). in contrast to 8% in Germany, 7% in Japan and 6% in England spent in 1989 (i.e. the last period for which I was able to obtain data). Because there is no evidence that spending more money makes us healthier and more productive, this differential impairs the competitiveness of American industry. In a world in which business competition is increasingly international, this factor alone might eventually force a change. Because health care costs are currently increasing much faster than the gross national product, if present trends were to continue our economy would consist only of the health care industry sometime early in the next century. Obviously, this is not going to happen.

The second basic problem is that a significant number of Americans (some suggest as many as 40 million) lack adequate health care coverage. This presents a problem of basic fairness. Anyone involved in bone marrow transplantation has seen patients who did not have the opportunity for curative therapy because they lacked insurance or had purchased insurance from the wrong company. Our patients with malignancies, even if cured, cannot change their jobs for fear of losing coverage. It is difficult to quantitate how much lack of access to adequate health care contributed to the frustration seen in the recent civil disturbances in our cities. This situation might not be appropriate for a country as rich as America is a source of great concern for many.

America's problems with health care are obvious to most and, as public opinion polls indicate, the level of concern is increasing. Numerous proposals have been developed to address these issues. However, most focus on either the cost or the fairness aspects of the problem, and not both. Addressing only one of the two

naturally tends to accentuate the other (i.e. expanding coverage naturally increases cost, while reducing cost tends to reduce coverage to the less privileged). Also, approaches to resolving the problem might come at the expense of funding for clinical and laboratory research. For us as hematologists it is easy to be discouraged about our ability to affect events. We are busy caring for patients and/or working in out laboratories. Unfortunately, what this means is that we are being left out. Because many politicians and business people see physicians as the problem—the public too often sees us as greedy—we are losing our ability to affect the outcome.

This need not necessarily be the case. We physicians still know more about health care delivery than any other group in our country. People generally go into medicine because they want to help others and there is a great amount of good will and altruism in our profession waiting to be tapped. I believe that many hands-on medical providers (i.e. internists, hematologists, etc.) would be willing to trade the present system for one that provided a fair income but less oppressive regulation, in which patients could get the therapy they need and for malpractice reform!

To have a voice in any change, we as physicians must regain public support. As a friend of mine says, everyone used to love doctors. Then they began to not trust doctors in general but love their own doctor. Now they are not too certain about her/him. There are many things we as a group could do to change this trend. For example, we could publicly declare our willingness to participate in change (we are perceived to have the opposite goal at the present time) and make it clear that we are necessary participants for change to succeed in improving the situation. We need to make it clear that we will help those patients who cannot pay for care, whether or not anyone else is interested. Most physicians do this anyway. We should take the lead in inserting cost-effectiveness into health care delivery and not allow this task to fall to nonphysicians. Through our organizations we could volunteer our time to improve the health in our communities doing things such as working with the schools to teach our children about healthy life styles. We must make it clear that we are more about America and our fellow citizens than we do about the level of our income. Paradoxically, this is likely to protect our income in the long run, while continuing to focus our efforts on our own economic issues will probably have the opposite effect. Something is going to happen. We cannot stay on the present pathway and succeed. America will be better off if we are not only part of the change but leaders in change. However, this will require that we regain the public's faith. The fact that hematologists are only a small proportion of the physicians in America and cannot succeed without participation of the rest, is no excuse not to become involved.

Artical from .. Blood The Journal of the American Society of Hematology By James O. Armitage August 15, 1992

Amgen Study Families

Hello Everybody! I hope everything is going well. We welcome your response to this Newsletter. We would like to include your comments and stories in future articles. We look forward to hearing from you. We hope in the future to be communicating with and supporting each other around the World. We can all help each other and build a strong network with our common goals and needs. Any helpful suggestions as well would be appreciated. Would you like a Question and Answer column?, or Helpful Hints?

Sincerely, The Benzelock Family on study, Ann Arbor. Michigan living in Winnipeg, Manitoba.

Please submit your letters to the Newsletter address with our thanks.

Encouraging words from Dr. Nathan Kobrinsky

Over the years, I have been extremely impressed with the excellent work that you have accomplished in broadening the general understanding of both the lay and medical community to the issues related to patients afflicted with congenital neutropenia. This, of course, has become an extremely important issue now that growth factor therapy with G-CSF, GM-CSF and, perhaps in the future, IL-3 has become available.

I encourage you to continue the work that you have started with a broad educational campaign aimed at both physicians and the lay public. I also would encourage you to pursue your efforts on a political level so that support for growth factor therapy can be made available to all potentially affected subjects with neutropenia. Very clearly, growth factor therapy improves the life-style for such individuals. The fight for this therapy is reminiscent of the fight for factor replacement for hemophiliacs which was a political battle some twenty years ago. Very clearly, by replacing the missing factor (in the case of hemophilia, factors VIII and IX), affected individuals can lead normal productive lives, and invariably, cost analysis studies have shown that such therapy is appropriate, not only from the emotional and medical points of view, but also from a financial point of view as well. Sincerely,

Nathan Kobrinsky, M.D, FRCPC

Bring on the Neutrophils

Cancer and chemotherapy. Two of the most feared words to a large number of Canadians. Why? Cancer the second leading cause of death and touches the lives of practically all Canadians directly or indirectly through friends and relatives. After the shock of the initial diagnosis, comes the fear of therapy. Will the chemotherapy cure me or increase my survival? What are the treatment options and are there any breakthroughs? Cancer treatment is also a concern for the Canadian government from an economic perspective. What is the most efficient long term use of our health care dollars? Cost-effective treatment options have

become a focus because of the shrinking health care dollar at a time when demands for quality of health care are increasing.

New and improved chemotherapeutic agents have increased the possibility of a cure or prolonged remission for many cancers. Some tumours are more sensitive than other tumours especially if they are treated early before they develop resistance to the chemotherapeutic agents. (Table 1)

Chemotherapeutic agents preferentially affect rapidly growing

cells. However, they cannot differentiate between a malignant, rapidly growing tumour and a rapidly dividing normal cell. The side-effects associated with chemotherapy reflects this mechanism of action. The most sensitive normal target tissue to chemotherapy is the bone marrow. The degree of myelosuppression varies with the type of chemotherapeutic agents and the patient. Chemotherapeutic agents can potentially affect all of the myeloid cell lines. Based on the kinetics of the various cell lines, chemotherapy-induced myelosuppression granulocytopenia, thrombocytopenia and anemia in the order. Neutrophils are the most common granulocytes and are the primary defence mechanism of the body against bacterial and fungal infection. Hence, severe neutropenia contributes to the morbidity and mortality associated with myelosuppressive chemotherapy as a result of infection and its complications. This also impacts on the quality of life of the patient since febrile neutropenia requires immediate hospitalization and initiation of empiric antibiotics. These antibiotics are costly, require I.V. administration and have their own side -effects.

In addition to the resultant potential life-threatening infection, the other serious consequence of neutropenia is the requirements for dose reduction and/or delays in subsequent cycles of chemotherapy. Two of the basic principles of chemotherapy are

"Drugs should be used in their optimal dose and schedule"
- and -

"Drug combinations should be given at consistent intervals. The treatment-free interval between cycles should be the shortest possible time period necessary for recovery of the most sensitive normal target tissue, which is usually the bone marrow "

To further quite Devita "ad hoc adjustment of dosing is probably the main reason for treatment failure in patients with drug sensitive human tumors undergoing their first treatment".

The haematopoietic growth factors play a major role in the growth and differentiation of mature cells found in peripheral blood. The development of recombinant human granulocyte colony-stimulating factor (G-CSF) is a major break-through in the treatment of neutropenia of various origins. The brand name for G-CSF is Neupogen*.

G-CSF, by reducing the indicidence, duration and severity of chemotherapy-induced myelosuppression has been shown to reduce the incidence of infection and hospitalization. Furthermore, G-CSF allows the physician to administer the optimal dose of chemotherapy on time to more patients. Hence, for chemosensitive tumors, the patient's potential for a cure or a prolonged remission may be increased.

G-CSF can be self-administered, subcutaneously. This allows patients to live a more normal life-style and permits more time with family and friends and less disruption with their normal working schedule and routines. In addition, their chemotherapy cycles take less time to complete. Hence, the anxiety associated with delays of potentially life prolonging chemotherapy treatment is alleviated. G-CSF has also been used successfully in neutropenias of other origins. There are many potential causes of neutropenia (Table 2). Various haematological disorders of a non-malignant nature have been treated with G-CSF. Prior to the availability of G-CSF, these patients were treated only to control symptoms because there were no drugs to ameliorate the underlying neutropenia.

Disorders of granlulocyte production may be due to defects in the hematopoietic pluripotent stem cell, the committed progenitor cell or the myeloid precursor cell.

Neutropenia resulting from abnormal, committed progenitor cell proliferation include reticular dysgenesis and cyclic neutropenia. Reticular dysgenesis is a rare disorder occurring in infants and usually these babies fall victim to infections. Cyclic neutropenia is a benign disorder characterized by regular episodes of severe neutropenia lasting 3 to 6 days. Clinical symptoms during neutropenic episodes consist of fever, anorexia, infections, malaise and mucosal ulcers. The major hope for these patients is correction of the underlying problem with the use of G-CSF alone or in combination with other growth factors.

The non-cyclic chronic neutropenic disorders are comprised of a variety of abnormalities with several clinical presentations. The treatment of these patients in the past has been predominantly supportive care. The clinical spectrum ranges from chronic benign neutropenia to the more severe forms of chronic idiopathic neutropenia. The latter category of patients have recurrent infections and may not survive beyond the first decade of life. These patients include those with Kostmanns Syndrome, otherwise known as severe congenital neutropenia. Patients have such low neutrophil counts that they are at major risk for life-threatening infections involving multiple organs (skin, mucosal surfaces, lungs, liver, ears, blood). Treatment with G-CSF attempts to correct the underlying clinical problem. Consequently, these patients can be treated at home and hospitalization and antibiotic use is decreased.

Another interesting area for the use of growth factors is in the area of autologous bone marrow transplantation (ABMT). G-CSF has been used to reduce the morbidity of high dose myelosuppressive chemotherapy with ABMT. Patients receiving G-CSF had accelerated neutrophil recovery after ABMT and consequently reduced hospitalization. There was also a reduction in mucositis and hence, a reduction in the requirement of total parenteral nutrition.

Haematopoietic growth factors have recently been used to mobilize peripheral blood progenitor cells (PBPC). These can be collected by a process called leukopheresis and then used as an alternative or adjunct to ABMT. The advantage of PBPC collection following the administration of G-CSF as opposed to collecting bone marrow (i.e. ABMT) is that PBPC collection is less painful for the patient, easier, less expensive and theoretically there should be less risk of tumor contamination than in ABMT

Preliminary data also indicates that the addition of PBPC to patients treated with high-dose chemotherapy followed by ABMT and daily administration of G-CSF had a significant acceleration in platelet recovery as compared to those patients with ABMT and G-CSF alone.

The use of PBPC may allow the feasibility of haematopoietic reconstitution along with PBPC. This, thereby, may extend the use of potentially curative high-dose chemotherapy to those patients in whom bone marrow aspiration is not possible either because of prior trauma, radiation treatment of tumor contaminated marrow.

G-CSF has also been used in aplastic anemia where the underlying problem is a hypocellular marrow and a deficiency o haematopoietic progenitor cells. Preliminary results have indicated an elevation of neutrophil levels in patients with moderate aplastic anemia but results in very severe cases of hypoplasia results have been disappointing. More clinical trials are needed in this area. AIDS is another area of research with respect to the use o haematopoietic growth factors. Some drugs used in the treatment of AIDS cause myelosuppression and thereby can compromise further treatment. G-CSF elevates depressed neutrophil counts as a result of AZT treatment and does not change titers of the human immunodeficiency virus nor does it elevate p24 antigen levels. Other recent developments in the use of G-CSF have been in the treatment of drug induced agranulocytosis. Drugs can induce neutropenia through a number of mechanisms. The most common mechanism is direct bone marrow suppression. Other mechanisms may include antibody and compliment-mediated damage to precursor cells or peripheral destruction and clearance o neutrophils. Summary

The benefits of G-CSF are multi-factoral. For the physician treating a patient, there is a better chance of desired therapeutic outcome as a result of lower morbidity and fewer adjustments o potentially curative chemotherapeutic regiments. G-CSF facilitates patient management, in that less time is required to treat chemotherapy related myelosuppression and fewer changes in office schedules are needed as a result of chemotherapy delays and rescheduling. In haematological disorders of various origins resulting in neutropenia, the administration of G-CSF attacks the underlying pathological problem rather than merely treating it symptomatically. The overall outcome is better patient-doctor relationships.

What are the benefits to the patient? The potential clinical benefits from chemotherapy are maximized. The anxiety associated with chemotherapy delays and hospitalizations due to infection is reduced. The completion of the chemotherapy regimens is shortened and allows the patient to return to a normal life-style quicker. The economic benefits as a result of the decrease in hospitalization and antibiotics allows more efficient use of our limited health care resources. The future direction of the haematopoietic growth factors will continue to make major breakthroughs in medicine since the focus is curing underlying problems rather than merely treating symptoms.

TABLE 1: Cancers Responsive to Chemotherapy

Cancers in Which a Fraction of Patients are Cured with Chemotherapy

Choriocarcinoma Acute lymphocyte leukemia (in children and adults) Hodgkin's disease Diffuse large cell lymphoma Lymphoblastic lymphoma (in children and adults) Follicular mixed lymphoma Testicular cancer Acute myelogenous leukemia Wilm's tumor Burkitt's lymphoma Embryonal rhabdomyosarcoma Ewings's sarcoma Peripheral neuroepithelioma Neuroblastoma Small cell cancer of the lung

Ovarian cancer

Cancers Curable in the Adjuvant Setting by Chemotherapy

Breast cancer Osteogenic sarcoma

Soft tissue sarcoma Colorectal cancer

Cancers Responsive in Advanced States But Not Yet Curable by Chemotherapy

Bladder cancer Chronic myelogenous leukemia

Chronic lymphocytic leukemia Medulloblastoma Hairy cell leukemia Multiple myeloma Follicular small -cleaved cell

lymphoma Gastric carcinoma Cervical carcinoma Soft tissue sarcoma Head and neck cancer Endometrial cancer Adrenocortical carcinoma

Polycythemia rubra vera Prostate cancer

Glioblastoma multiforme

Insulinoma Breast cancer Carcinoid tumors

Colorectal cancer

Cancers Poorly Responsive in Advanced Stages to Chemotherapy

Osteogenic sarcoma Pancreatic cancer Renal cancer

Non-small cell lung cancer Melanoma

Thyroid cancer Hepatocellular carcinoma

Carcinoma of the vulva or penis

TABLE 2: Causes of Neutropenia

Acquired neutropenia

Postinfectious Drug-induced neutropenia Benign familial neutropenia Chronic benign neutropenia of childhood Chronic idiopathic neutropenia Autoimmune neutropenia Isoimmune neutropenia

Neutropenia associated with immunologic abnormalities

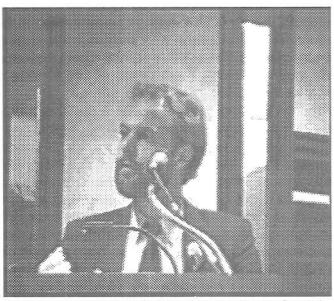
Neutropenia associated with metabolic diseases Neutropenia due to increased margination Nutritional deficiency

Instrinsic defects

Kostmann syndrome (severe infantile agranulocytosis) Myelokathexis/neutropenia with tetraploid leukocytes Cyclic neutropenia Shwachman-Diamond-Oski syndrome Chediak-Higashie syndrome Reticular dysgenesis Dyskeratosis congenita

Re-Viewed By Jon M. Gerrard, M.D., Ph. D., FRCP(C) Section Head, Pediatric Hematology/Oncology Manitoba Cancer Treatment and Research Foundation

Fashion Show Booming Success !!



Our guest speaker at the fashion show Dr. Jon M. Gerrard

The show was an overwhelming success and all told approximately \$5,000.00 was raised for Neutrophil research here in Winnipeg. Because of the enormous popularity, plans are already in the works for another fashion show on Sunday, April 18, 1993, same place, same time. For information or tickets please call Lorna Stevens ..home 489-2487 ..work 989-5000, or Janis Benzelock 667-0324. We hope we can count on your support again. An event of this kind involves a great many people and at the risk of offending those we may have forgotten to thank personally, we extend our sincere appreciation to all those involved.

We are capable of accepting donations " In memory of ", Tax deductible receipts and appropriate acknowledgements will be

Our next fund-raising project is to raise \$5,000 for a Fluorescent Detector for the Neutrophil Lab, so Don't forget to renew your annual membership, use the handy form at the end of this newsletter to send in your Donations. We thank you for your continued support.

Alexander Lions Club put on their CowBoy boots



The Gamley family, Brian, Karen, Ryan, Sean

On June 13, 1992 the Gamley family were invited to attend a fund-raising event held by the Lions Club - specifically the Alexander-area Chapter. Alexander is a small town, twenty miles west of Brandon with a population of approximately three hundred but this was no small town effort and certainly no small turn-out. The event, a country-western theme, was sold out and the dinner starting the evening off at 6 p.m. was buffet-style made up of pit-baked beef, homemade salads, good ol'baked beans, cake, ice-cream, coffee and more. An Auction followed supper, raising a great deal of money which was made in the form of a donation to the Neutropenia Support Assoc. Inc.

The donation wasn't the only highlight of the event though; it was the rare gift of the people in attendance showing their great sympathy, interest and caring for the disease suffered by our neutropenic members. Having had occasion to attend many fund-raising events in the past, we felt this one special. Although, my husband Brian and his parents, Madge and Lloyd Gamley, are well known in the Alexander Community, it was the welcoming I personally felt and will remember. I entered knowing few but left richer for meeting many. The music, provided by the "Booger Band" was of particular notice by our young sons, Ryan and Sean. Not only was the music our kind of footstompin' stuff, but the band themselves made the unusual effort to stop, introduce themselves and shake the hands of two small boys who were mesmerized by their music and will never forget the handshakes.

We understand this was the first event attempted by the Alexander Lions Club - they'll have to go a long way to top this effort. The use of the Alexander Arena was a brainstorm; generous donations of many using plywood, haycarts, trees, etc. turned a skating rink into a park-like setting. The warm summer night (one of our few), great food, music and outstanding hospitality all contributed to a most memorable evening, enjoyed by all but especially the Gamley family.

Submitted by Karen Gamley for Brian, Karen, Ryan and Sean

Research in Manitoba

We welcome to Winnipeg, Dr and Mrs. Murthy and their family. Dr. M. Murthy as part of his research being continued here is focusing on factors that affect Neutrophil functions; Alpha TNF and Beta TNF and continuing to look at dietary Neutrophil factors such as fish oil and flax oil.

Research in Canada

There are many fine physicians we are aware of involved with projects we would like to support. As we establish a solid base in Manitoba, we would like support and groups to form in other provinces to fund-raise for their local medical community. We would establish Accounts, maintain the Charitable tax deductible receipts issued from our "Winnipeg, Manitoba base" and route the designated funds to the Specific Provincial Projects. We welcome your response to this idea.

CANO '93 WORKSHOP

On September 20th, 1992 Janis Benzelock and Lorna Stevens attended the CANO Symposium. at the Westin Hotel, Winnipeg. The focus was on Biotherapy and treatment management of patients receiving Biologics. Judy Doe from Amgen Canada Inc., presented on Neupogen, (G-CSF) and how this growth factor is helping revolutionize the treatment of certain diseases.

Other topics from this seminar included:

Hematopoiesis	Overview all cell lines
Immune System	
Overview of Clinical Trials	
Biotherapy	History, goals, side effects and clinical applications
IL-2	
TNF	Research with IL-14
IFN	was also Mentioned
MoAB	
CSFs	

Nursing Care of the Patient Receiving Biotherapy Specifically NEUPOGEN

Words from Dr. Jon M. Gerrard

During the last three years, I have been involved with the treatment of three patients with congenital neutropenia using G-CSF (Neupogen). G-CSF has made an incredible impact on the lives of these three patients, two children and one adult. From having a miserable time with frequent infections, school or work absences resulting, all three are free of infections and doing well.

October 29, 1992 Workshop to be Held in Winnipeg With World Renowned Doctor

David C. Dale, MD
Professor of Medicine
Deptartment of Medicine
University of Washington School of Medicine
Seattle, Washington

Possible Lecture Titles:

Colony-Stimulating Factors: From Laboratory to Clinical Applications

Treatment of Cyclic and Chronic Neutropenia with Granulocyte Colony-Stimulating Factor

Neutropenia: Causes, Consequences and Treatments

Infections in the Compromised Host

Septic Shock & Treatment

Aging and Susceptibility to Infections

Training:

Medical Degree - Harvard University

Intern and Assistant Resident - Massachusetts General Hospital, Boston

Chief Resident - University of Washington, Seattle

Senior Staff Fellow, Laboratory of Clinical Investigation - National Institute of Allergy and Infectious Diseases, National Institutes of Health

Areas of Current Research:

Pathophysiology and Treatment of Neutropenia

Physiologic Effects of G-CSF Administration in the Normal Young and Elderly Subjects Aging and Hematopoiesis

Most Representative/Recent Publications:

Hammond Wp, Csiba E, Canin A, Hockman H, Souza L, Layton J, Dale DC.

Chronic Neutropenia: a new model induced by human granulocyte colony-stimulating factor, J Clin Invest. 1990;87:704-710.

Dale DC: Myelopoietic factors in the prevention and treatment of infections in neutropenic patients.

In: Sande MA, Root RK, eds. <u>Treatment of Serious Infections in the 1990's.</u> New York:

Churchill Livingston. (in press).

Dale, DC: The Febrile Patient. In: <u>Cecil Textbook of Medicine</u>. Wyngaarden, JB et al. eds. Philadelphia: WB Saunders. (in press).

October 29, 1992

For information Call

Dr. Jon Gerrard (204-787-2115 or 204-787-4135)

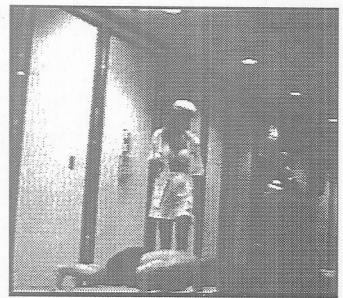
or

Lorna Stevens (204-989-5000 or 204-489-2487)

Co-Sponsored by:

Neutropenia Support Assoc. Inc. and Manitoba Cancer Treatment & Research Foundation

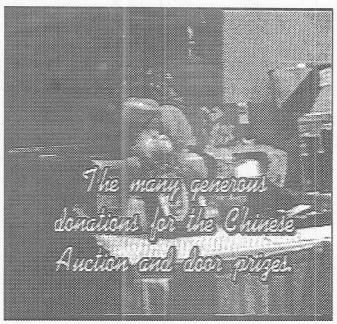
Potpourri and tid bits



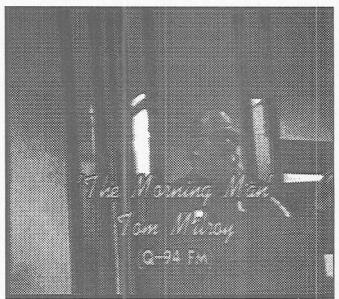
Heat seekers 1992 Calender Firefighters &

Peepers "Fun in the Sun fashion model





Many Thanks to All who Donated



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Send to Neutropenia Support Assoc. Inc. P.O. Box 243, 905 Corydon Ave. Winnipeg, Manitoba R3M 3S7