

**Gastroparesis and Dysmotilities  
Association  
GPDA**

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**Press Release**

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**Calgary, AB**

**Miserable with symptoms, vomiting 50 times a week, feeding tube hanging from her abdomen to bypass her poorly functioning stomach — 44-year-old Jacqueline MacPhee would sure like a second shot at a more normal life. But lack of leadership from our Minister of Health, Iris Evans, has left Jacqueline's future in limbo.**

Forty-four-year-old Jacqueline MacPhee is suffering from a poorly understood digestive problem known as gastroparesis. Over the past ten years, for unknown reasons, her stomach has slowly quit working, leaving her days filled with despair.

But in mid-July, hope was to return with a call from the out-of-province insurance program to her surgeon's office giving the green light for Jacqueline to book her flight to Quebec where she would be able to seek a new treatment. Just three days after the call, with all arrangements made, Jacqueline's life was turned upside down when this verbal commitment was withdrawn in a written letter to her.

Jacqueline's Calgary surgeon had referred her to the only centre in all of Canada that offers a new implantable device which has demonstrated itself to be a potent anti-nauseant, anti-vomiting device. Specifically developed and brought to the market for the treatment of more severe cases of gastroparesis, the implantable device has been in use for over 13 years.

Manufactured by Medtronic Inc. and approved by the Federal government's Therapeutic Products Directorate office for marketing in Canada, the device, called Enterra Therapy™, looks much like a heart pacemaker. Two wire leads are sutured to the outside surface of the stomach and attached to a small battery pack that cycles very weak electrical shocks to the stomach wall. While not a cure, this stomach-pacer system effectively puts a lid on symptoms, providing a reduction in relentless nausea and vomiting. The response is so dramatic as to render some patients nearly symptom-free. Able to eat again, they can have feeding tubes removed and get back to living.

With over 1,000 patients in the United States implanted, researchers no longer ask if the device works; instead, they are now asking how it works.

Press Releases: Patient fights AB for GES - 1 -

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But for those suffering, it doesn't matter how this treatment works. For them, nothing is worse than the daily bouts of nausea and vomiting that they have endured for years, and which, despite having tried every available medication, have disabled them in the prime of their lives.

Life for Jacqueline has been hell for the last couple of years. No longer able to work and forced to rely on disability insurance, Jacqueline experienced financial difficulties. "About two years ago, things took a really bad turn with my disease," says Jacqueline. "My last gastroenterologist told me nothing more could be done and sort of wrote me off."

Earlier this year, Jacqueline learned about a North American-wide non-profit association, the Gastroparesis and Dysmotilities Association (GPDA) which was seeking action from the Alberta Minister of Health. GPDA had submitted a 46-page report to the Alberta Minister of Health outlining the reasons why Enterra Therapy should be included as an insurable device in Alberta, as it is in Quebec.

The Federal government, by granting marketing rights to the manufacturer had established the device's safety and effectiveness. By late July, GPDA was surprised to receive a rejection letter from Iris Evans' office declaring this treatment to be experimental and unproven.

"All our patients want is what is wanted by any other group facing a chronic, life-threatening illness; we want access to the one treatment developed specifically for our digestive disease," says Ms. Keith-Ferris.

"Iris Evans and many others don't understand the seriousness of this digestive illness," says Ms. Keith-Ferris. She continues, "For some, the risk of not trying Enterra Therapy places their lives in jeopardy."

The constant vomiting borne by people like Jacqueline puts them in harm's way. "These are people that would eat if they could but their stomachs won't allow food to stay down," reports Ms. Keith-Ferris.

The placement of feeding tubes is not an easy procedure and brings on a medical management nightmare for many. Severe dehydration and loss of body electrolytes can also lead to frequent visits to the emergency room. "These patients cost our system a lot of money and many gastroenterologists don't want to deal with them because, in this province, we have limited tools and expertise," says Ms. Keith-Ferris.

"It's crazy. First the out-of-province department gave me approval to go to Quebec to see the surgeon who implants Enterra Therapy; then they withdraw my approval saying that the device is not yet approved by the Albert Minister of Health's office. It is a Catch-22 and I'm caught in the middle," says Jacqueline. In Canada, a representative of Medtronic

Inc. reports that Enterra Therapy costs \$10,000.

For many gastroparetic patients who are already spending thousands of dollars every month on medication, the cost of the device is an additional burden. Furthermore, withholding approval of the device denies these patients the right to access a safe and effective treatment. (In the US, each state-funded Medicare insurance plan provider covers the device.)

With a 70 to 80% response rate, not everyone will respond to the effects of Enterra Therapy, but many patients express the desire to try it out, especially, since it is reversible.

“While the Minister’s letter to our non-profit association did not close the door tight on including this device as an insurable procedure, it very much looks like a stalling tactic and leaves lives, like Jacqueline’s, in chaos. It is morally wrong that this patient population is left to suffer so horribly, to be denied access under our tax-payer funded system. “Remember, this is the only treatment developed for our digestive disease,” say Ms. Keith-Ferris.

**Facts:**

- Enterra Therapy is the **only** treatment that has been specifically **developed and brought to the market for the treatment of gastroparesis**. Currently, **all** other treatments are borrowed from other uses.
- Gastric electrical stimulation has been used in gastroparetic patients for close to 14 years.
- Medications used to treat gastroparesis are off-label uses. Currently, no medication has been brought to the market specifically for the treatment of gastroparesis.
- The insertion of feeding tubes (undertaken to nutritionally rescue chronically vomiting gastroparetic patients) carries a mortality rate of 1%. Feeding tubes frequently plug up, or come out, so that patients require constant medical management, which taxes our medical system.
- Feeding tubes have a 10% rate of infection.
- The cost of feeding one patient via a tube is approximately \$4,000/month.
- Surgically implanting Enterra Therapy does not have any rates of mortality and infection rates are similar to heart pacemakers (approximately 4%).
- Patients who respond to Enterra Therapy may be spared a feeding tube or have their tube removed because they can eat more normally.
- In Canada the cost of the Enterra Therapy device is \$10,000.
- In the United States, all state-funded Medicare programs cover the cost of Enterra Therapy.