

GOING NATURAL

A made-in-Alberta nutritional supplement takes on the health establishment.

By CONNIE HOWARD

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EIGHT YEARS AGO, JERRY OLER WAS AT THE END of her rope. The Lethbridge woman had been living with bipolar and obsessive compulsive disorder for 37 years. She made her first suicide attempt at the age of 14. She'd been hospitalized 18 times. She'd tried all the psychiatric drugs; all of them caused side effects that, to her, were worse than the illness itself. She was on a three-month waiting list for a new psychiatrist when a close friend told her about a nutritional supplement that had allegedly been working for others.

"I know you love me," Oler recalls saying, "but I've been getting the best medical care and the most powerful drugs all these years, and you think a nutritional supplement is going to fix me?" She rejected the idea. Three years later, at a wedding reception, Oler came across a pamphlet for the same nutritional supplement. A company representative (also a wedding guest) claimed that seriously ill people got well from using the supplement. Oler was spending over \$600 a month on prescription medications at the time. Her daughter offered to pay for the first two bottles of the nutritional supplement, and because she felt she had nothing to lose, Oler tried it.

At first she felt worse and wanted to quit, but her husband



Some studies show a “significant” improvement in psychiatric symptoms in over 80 per cent of [EMPowerplus users]. Dr. Charles Popper: “The economic implications... for the pharmaceutical industry are difficult to overlook.”

held her to her promise to stick with it for three months. Six weeks later, on August 25, 2000, Oler took her last psychiatric drug. After 37 years of misery, claims Oler, she was well.

What Oler used, and attributes her current state of mental well-being to, is EMPowerplus, a vitamin and mineral supplement developed by a Raymond, Alberta, company called Truehope. The company claims that tens of thousands of people with mental illnesses around the world have tried their product (42,000, to be specific). They claim that the majority of those people—over 80 per cent—have experienced a significant reduction of psychiatric symptoms.

It's quite a claim. The medical community has invested billions of dollars researching mental health. Pharmaceutical companies have posted profits in the billions of dollars from the sale of products aimed at alleviating the symptoms of mental illness. The brand names of some of the most common treatments—Paxil, Valium, Zoloft—have infiltrated our language and popular culture. There's a lot at stake for the pharmaceutical industry, not to mention for sufferers of mental illness and their families. And yet a rural Alberta-based company staffed by people without medical credentials now claims that their product—a mix of vitamins and minerals—addresses some forms of mental illness more effectively and safely than conventional medicine.

EMPowerplus has attracted as much skepticism, scrutiny and criticism as any legal health product in Canada over the past decade. The product is being sold to treat serious maladies such as bipolar disorder, anxiety disorder, panic attacks, attention deficit disorder, schizophrenia, autism, Tourette's syndrome, fibromyalgia and obsessive-compulsive disorder. Health Canada and many in the medical community are concerned that people suffering with disorders of the central nervous system such as these are particularly vulnerable to health products available without prescription. Critics are not convinced that symptoms of such illnesses can be sufficiently alleviated with something as simple as a nutritional formula. They're uncomfortable with Truehope's non-medical staff advising clients to begin the process of getting off their psychiatric medications as they begin their EMPowerplus “program.”

Not everyone responds as positively as Oler did. For Sheri Braun, a Sherwood Park high school English teacher, switching from her psychiatric medications to EMPowerplus was, in the end, impossible. “I wanted it and really thought I could do it, but I couldn't,” she says. Braun took Effexor, Zoloft and Xanax for many years, and wasn't satisfied with how they were working. She was particularly uncomfortable with her high dose of Xanax, and the length of time she'd used it. Xanax is a benzodiazepine, meant for short-term usage. “I

knew I had to do something about the benzo, and that I faced the gruelling hell of going off one mind-bending drug to go on another, so I was going to try a new route, one that seemed to hold a lot of potential,” she says. “I'd done what the doctors told me to do for years, taken all my medicines, and I wanted to try the Truehope program.”

In March of 2007 she started taking EMPowerplus and decreasing her doses of other medications. She reads me pieces of her own writing during that period. “I've caught a glimpse of health, of tingling that isn't anxiety, of real laughter, real tears,” she reads. “Music has returned. It's not just dead noise anymore. I'd been stolen from myself. I was colour blind and now I see.” Her energy was good and she felt she was healing.

And then, disappointment. “I'd wake in the night sobbing... I felt like a person with no skin. I'd have these brain jolts, jumps, stalls. I'd have to set the timer to remind myself to keep emptying the dishwasher.”

“It was like falling into a black hole,” she says, apologizing for the tremor in her voice. She'd wake up to terror which persisted all day, every day, for two months. She lost too much weight and wasn't functioning. She was on suicide watch. She ended up in the hospital.

“I'm on Celexa now, and just a low-dose benzo, nothing like before,” she says. “I felt like I'd failed, but I didn't. I didn't kill myself. I'm still here for my kids.” Braun is getting her life back, and has gone back to a part-time teaching position.

“[EMPowerplus] just didn't work for me. Everyone's different,” she says. “But Truehope needs a detox centre and doctors who can monitor up close and order lab tests. Long-distance just isn't enough for some of us.”

THE TRUEHOPE STORY STARTS IN 1994 when Anthony Stephan, an engineer living in Cardston, lost his wife, Debbie, to suicide. Two of his children, Joseph and Autumn, had severe treatment-resistant bipolar disorder, and Stephan worried about their future. In 1996, Stephan learned from animal nutritionist David Hardy that pigs prone to harming each other were responding well to a micronutrient supplement. He and Hardy adapted a similar formula for humans and tried it on the Stephan children. They responded “beautifully,” so Stephan stopped administering his children's psychiatric medications. The children stayed healthy. Stephan and Hardy formed Truehope and began making the product available to other bipolar sufferers. They collaborated with Alberta Children's Hospital psychologist Dr. Bonnie Kaplan at the University of Calgary. The Alberta Science & Research Authority commissioned a study, kicking in \$544,000 in funding.

The results of preliminary trials were published in the Tennessee-based *Journal of Clinical Psychiatry* in December



Critics—and some federal politicians—claim that tens of thousands of Canadian deaths each year are related to prescription drug use.

2001. Other peer-reviewed articles and small-scale trials followed. All of them reported a “significant” improvement in psychiatric symptoms in more than 80 per cent of participants, with the need for psychotropic medications reduced by more than 50 per cent. They claimed that some patients stabilized to the point of no longer needing any conventional psychiatric medications. (A larger, double-blind, placebo-controlled study is currently under way at the U of C.)

Just like the makers of pharmaceutical medicine, proponents of “alternative” medicine face legal and medical hurdles. 14 years after Stephan first tried his supplement on his children and seven years after the first study was published, Health Canada is not ready to give EMPowerplus the green light.

Health Canada is mandated to scrutinize new health products and ensure their safety for Canadians. Their major concerns about EMPowerplus include the fact that Truehope makes therapeutic claims for a product not yet widely tested, that some of the ingredients may be harmful and that non-medical staff at Truehope recommend patients decrease or eliminate their psychiatric medications as they begin the EMPowerplus program.

Health Canada’s definition of a natural health product is multi-layered; the agency determines which natural substances (originating in plants or animals) claiming therapeutic value are permissible as natural health products and which must be classified as drugs. It also determines safe dosages. Since

Truehope claims EMPowerplus is useful for treating such illnesses as depression and bipolar disorder, and since a number of nutrients in the product exceed Health Canada’s daily recommended amounts, Health Canada’s position is that the product must be tested as a drug.

In 2002, Health Canada charged Truehope with selling an unauthorized health product and advised them to apply for a Drug Identification Number (DIN). They halted the trials being conducted at the University of Calgary, sent out media advisories on the risks of EMPowerplus, ordered an RCMP raid on Truehope offices, seized patient records and began stopping shipments at the border. Some 3,000 Canadians using EMPowerplus were informed that they should go back on their psychiatric medications.

Stephan and Hardy responded by arguing they were compelled to protect the health and safety of those who had come to depend on EMPowerplus. In January 2004, the Natural Health Products Directorate (NHPD) became law in Canada; in March, minister Pierre Pettigrew granted Truehope an exemption, permitting EMPowerplus to be imported for personal use (it is manufactured in the US). With their DIN pending, and believing that EMPowerplus actually fell under the scope of the NHPD, Truehope applied for a natural product number (NPN). “[The number] was granted verbally, but then, after huge delays, we were told we’d only be granted one if we excluded boron, which is an ingredient in the product but

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available anywhere," says Truehope's director of regulatory affairs Ian Stewart. "We've kept meeting their changing list of requirements, one ingredient at a time, but they still haven't issued approval."

The case went to a hearing. On July 28, 2006, Alberta Provincial Court Judge G. M. Meagher ruled in favour of Truehope. Though EMPowerplus has yet to be issued a DIN or NPN, Truehope continues to sell their product under the ministerial exemption.

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FAST FORWARD TO THE SPRING OF 2008 and the emergence of Bill C-51, a proposed amendment to the Food & Drugs Act. The Bill was not passed before the October 14 federal election, but opponents believe a similar bill will be reintroduced in the new parliament. C-51 would have required life-cycle monitoring of pharmaceuticals, mandatory reporting of adverse events, and a separate category for natural health products (NHPs) with an approval process that takes into account traditional knowledge, history of use and such products' low risk profiles.

The new categorization of NHPs—under the umbrella of therapeutic products—has Truehope worried. The company actively opposed C-51, and was one of the parties chiefly responsible for the "Stop C-51" website. The tenor of the site, particularly its accusations of corruption at Health Canada, raised questions about the credibility of its arguments—and prompted people to ask why Truehope would behave antagonistically toward the agency, given its mandate of protecting public health.

Truehope defends the website. "[C-51 would've] given our health minister power to decide which products should be categorized as natural health products and which [ones] should be categorized as prescription-only medicines," says Stewart. "Anything that has serious benefit for serious illness... could be moved to prescription status."

The problem, from the perspective of the makers and potential users of EMPowerplus, is that psychiatrists are trained in pharmaceutical medicine and, having little knowledge of biological and nutritional medicines, are, with few exceptions, reluctant to work with natural products.

Alberta psychiatrist Dr. John Boodhoo is one of those exceptions. "I'm an allopathic doctor: I prescribe treatments I've been trained to prescribe," he says. "But I do support alternatives

and choices. I have patients who use pharmaceuticals and EMPowerplus because sometimes one isn't enough, and, as we know, [psychiatric] medications don't work for everyone. So when clients want to use it, I see my role as one of support. I work with them."

Is EMPowerplus safe? Truehope claims the risk of harm is "remote." Health Canada will not discuss details about risk assessment and licence application status, for reasons of confidentiality. Health Canada has, however, begun to track adverse reactions to EMPowerplus, and has nine physician-reported reactions thus far. "We've looked into the reactions we've had access to, and each case involved other medications known to cause the adverse effects that were recorded," argues Stewart. "We've asked for the rest of the files, but so far haven't been given access." Truehope has thousands of people in their participant database and claims to have received no reports of serious reactions that don't match complications of the drugs participants are phasing out. Adverse reactions reported in Bonnie Kaplan's preliminary clinical trials at the U of C were limited to "infrequent, minor and transitory" nausea.

The bigger concerns seem to lie elsewhere. Marc Banik, a professor of bioindustry at l'Université du Québec à Montréal (UQAM), is currently examining EMPowerplus. There is "some scientific evidence supporting the claim that many of the conditions targeted by EMPowerplus may be treatable by vitamin and mineral supplements," he says. "To my knowledge, Health Canada has not contested this, and its own health hazard evaluation doesn't raise significant concerns as to the toxicity of the product. The main point of contention is whether the use of the product is safe in light of the fact that potential users end up abandoning their conventional therapy prescribed by their licensed physician or psychiatrist. It's known that ceasing conventional antidepressants can cause serious side effects or cause symptoms of mental illness to return."

Of course, symptoms can return on psychiatric medications too—psychiatric medications often lose their effect over time, and some are known to be unsafe if taken for more than a short time. While many sufferers owe their lives to them, others are what is known as "treatment resistant" and experience little or no symptom improvement. And most people using EMPowerplus are those for whom conventional medications haven't worked. "Many of our clients have been so successful that they're symptom-free and need no more than a seasonal check-up visit," claims Stewart.

Most of the staff at Truehope—from the founders on down—have no conventional medical training. UQAM's Banik says that people without medical training giving medical advice "shouldn't be permissible... and in fact isn't, according to NHP regulations."

Harvard psychopharmacologist Dr. Charles Popper testified in court that Truehope's founders taught him how to help patients manage the transition from pharmaceuticals to EMPowerplus, calling Stephan and Hardy "experts" on the product for use with mental health conditions. He also testified that clinicians and researchers may need to rethink the traditional bias against nutritional supplementation as a potential treatment for major psychiatric disorders, and that EMPowerplus can restore normal behaviour to seriously ill patients—a testimony that, given Popper's initial resistance and preference for the drug protocols he knows well, carries some weight.

Popper also noted that "the economic implications... for the pharmaceutical industry are difficult to overlook." Indeed, Truehope and its proponents believe that the pharmaceutical lobby was the main force behind Bill C-51. Duff Conacher of the Ottawa-based citizen advocacy group Democracy Watch provides specifics about the industry's influence: "Canadian figures on what the lobby spends are estimations at best, as neither our provincial nor the federal government require disclosure on how much comes in from Big Pharma," he says. But US figures may give an indication of the magnitude of influence—the pharmaceutical industry spent \$168-million on lobbying Washington last year, and was, in 2006, the largest lobby group in the US.

Health Canada's concerns are shared by many in the medical community and by "skeptical groups" such as Quackwatch, a US non-profit that combats health-related frauds and which lists EMPowerplus as a "questionable treatment." Quackwatch itself has critics; natural health advocate Helke Ferrie has written that its funding sources were readily available on the Internet until recently, and that donors listed in past annual reports included "all the big petroleum and pharmaceutical companies."

The co-authors of *Pig Pills Inc.*, Dr. Terry Polevoy, Marvin Ross and Ron Reinhold, argue that EMPowerplus is unproven. "The biggest scandal of all," they write on their website, "is the number of innocent people who have been or could have been harmed because they followed the advice of untrained lay people who advised them to either take their special 'pig pills,' or... stop their psychiatric medications altogether. The issue here is not the fact that people just wasted their money; some have had their hopes for good health shattered once again." Critics of the book note that Ross has acknowledged that a pharmaceutical company helped cover his travel costs for an event at which he spoke against EMPowerplus. They also cite writing he has done on behalf of various pharmaceutical companies.

ROUGHLY 23,000 CANADIAN DEATHS EACH YEAR are related to prescription drug use, claims Helke Ferrie. Conservative MP for Yellowhead and former chair of the House of Commons health committee Rob Merrifield says that the figure is "maybe 10, 20, 30,000 deaths a year." What is clear, however, is that North Americans are the most medicated people in the world. And while prescription drug sales in the US tripled between 1980 and 2000, life expectancy dropped

from 11th place to 42nd. There are, of course, many factors at work, but some medical professionals are starting to express concern that a reliance on pharmaceuticals is as much a cause of declining health as a reflection of it.

Alberta Health & Wellness reform initiatives include expanding and improving mental health services to include a greater focus on preventive health. This could include alternative treatments. Some doctors trained in traditional psychiatric medicine have already waded in beyond the shoreline of convention. "I just love getting up to go to work," says psychiatrist Estelle Goldstein. "It's very satisfying to see [mental illness] symptoms recede, and to see them recede without side effects is even better. But the life changes that go over and above the change expected to come with the alleviation of symptoms... it's just very, very exciting." She's talking about the people she sees in her psychiatry practice, people she now treats primarily with an array of natural health products—of which she says EMPowerplus is now the cornerstone.

Goldstein, who has served residencies in general surgery, neurosurgery and psychiatry, and fellowships in neurology and psychopharmacology, was a big fan of psychopharmacology... at least until she found herself in "some serious metabolic misery." She learned about natural approaches to health, and found, much to her surprise, that the topic of nutritional therapies was backed by sound science and discussed even in mainstream medical journals. Wanting to apply her newly discovered knowledge to psychiatry, she stumbled upon Truehope through the research conducted by Dr. Kaplan at the U of C.

"I opened Pandora's box," laughs Goldstein. "I called Bonnie [Kaplan] and asked if this stuff really works, and she told me 'You bet it does!' Which it does, though I have to insert a disclaimer here. Not everyone responds equally, and I don't use only EMPowerplus. I use it in conjunction with essential fatty acids and specific amino acids, and, when patients still don't respond fully, a holistic approach that addresses related underlying health and metabolic disorders. But still, I see so much I never dreamed I'd see. I've been in practice for 17 years and I'm amazed with the results I see. These nutrients get past the blood/brain barrier and they work."

OVER THE PHONE FROM HER HOME IN LETHBRIDGE, Jerry Oler tells me it's been eight years since she left psychiatric medications behind in favour of a nutritional supplement.

"I was taking over 70 pills a day, couldn't work, depended on social workers, welfare, home care support, you name it," she says. "Now I can work, pay taxes, enjoy my grandkids. I haven't been back to the psych ward. I haven't needed to be on suicide watch. I used to have rages, I used to beg for death. I needed someone to stay with me when my husband went to work. Now I'm fine. And I wouldn't go back on psychiatric meds, not for anything, not ever." ■

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