



David Hardy and Anthony Stephan have spent hundreds of thousands of dollars fighting a \$500 fine for operating without proper government authority. "People have to become aware of what Health Canada did," Stephan says

# Taking their vitamins

A pair of Albertan pill-makers say Health Canada abused its authority by shutting them down and denying sick people their drugs. Now they're fighting to prove it

CYRIL DOLL

**G**loria Steinlein has known torment through much of her 25 years. Although today you wouldn't know it by looking at the attractive owner of Gloria's Reflexology in Innisfail, Alta., four years of her young life were absolute hell. When she was 16, the popular student at Bowden High School was diagnosed with a major depressive disorder. The honour roll student had been working toward getting into a good university after graduation, but thanks to pre-existing stomach problems, the immense pressure she was putting on herself started wreaking havoc with her digestive system. Unable to keep any food down, Steinlein withered to just 90 pounds and fell into a terrible depression. "There's just no way of describing depression, I guess, unless you've had it," she says today. "But I guess when you get that feeling, you want to cut your skin open and rip yourself apart and mutilate yourself. And to not have that feeling is phenomenal."

For five years, Steinlein hasn't had that feeling. "Everything's great, even a bad day's great," she says, buoyantly. The credit, she insists, belongs to a nutritional supplement made by a company not more than 150 miles away, in Raymond, Alta.—Truehope Nutritional Support Ltd. The product, EMPowerplus, isn't stocked by pharmacists and would probably draw a sneer from most doctors if you told them what it was made of—and what it claims to do. But much like other eccentric therapies, such as acupuncture or chiropractics, there are legions who swear by EMPowerplus. Thousands of people affected by crippling mental illness have been liberated by a mix of 36 basic vitamins and minerals, finding relief they couldn't with conventional psychiatric drugs and treatment.

But for three weeks in March, Truehope's owners were inside a downtown Calgary courtroom, locked in what may be their final battle with Health Canada over their right to sell

EMPowerplus to the people who rely on it just to get through the day. Over the past several years, the government agency has shut down clinical trials studying the often astounding effects of the vitamin concoction, seized Truehope's inventory and blocked all shipments of the pills into Canada from its U.S.-based manufacturing plant. Health Canada even laid charges against the owners of EMPowerplus for selling the vitamin and mineral mix without proper authorization. Alberta Court of Queen's Bench Judge Gerald Meagher is expected to rule on the trial on July 28.

If Truehope is found guilty of the charges, the firm will have to pay a \$500 fine. That's peanuts when you consider how much money the firm's owners have sunk into their defence—close to \$340,000. But they're fighting on principle. The Health Canada bureaucracy, they claim, is out of control. They insist there was abuse of process by the agency. Some say the Truehope prosecution, a historic effort by the medical watchdog in terms of the amount of effort and money it spent to shut down a small western vitamin producer, may have cost people's lives. Besides, insists Anthony Stephan, one of the company's two founders, they didn't do anything wrong. "There's no way we can plead guilty to something when we aren't guilty," he says. "And it's not just a question of being defiant—this had to happen, and more importantly, people have to become aware of what Health Canada did."

**B**efore she discovered EMPowerplus, Steinlein was on the brink of desperation, maybe even death. As a teen, she was prescribed anti-depressants and anti-anxiety medications by her family doctor, but they only led to psychotic episodes. "The anti-anxiety medications cause a real bizarre anxiety—it's so severe that I just couldn't be in my own skin at all," she says. As her body developed increased tolerance to the drugs, she'd have to take larger and larger doses. Soon,

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she was hearing voices. "It sounded like somebody had the radio turned on but they were between stations; you weren't clearly getting a reception," she says.

So, the doctors added anti-psychotic drugs to the mix, which she claims caused her to develop some kind of mild form of Parkinson's disease. "I would shake, my joints would stiffen up, I had a hard time feeding myself, I couldn't take care of myself. There were points where I would just sit there and drool. I don't remember a lot of it because I was so doped up," she says. "I couldn't get a spoon to my mouth to feed myself, I didn't know who my parents were, I was just a mess." Psychiatrists would take her off one drug and try another, but nothing seemed to work. Soon, Steinlein found herself entertaining thoughts of suicide. In 2000 alone, her family had her admitted to hospital 13 separate times for suicidal tendencies.

During the regular visits to the psychiatric ward at Alberta's Red Deer Regional Hospital, Steinlein's parents met other families dealing with many of the same problems they were. And they heard about EMPowerplus—enough good things to convince them to at least make the hour drive from Innisfail to Calgary to take in a presentation by Truehope's founders, Anthony Stephan and David Hardy. At roughly \$5,000 a year for the treatment, the cost at first seemed like an unmanageable burden for someone such as Steinlein, who couldn't even hold down a job in

between psychotic episodes. But having spent years in and out of the hospital, and with the potential for suicide growing increasingly real, there seemed no other option. Within a month, she was weaned off of the drugs she was taking and started taking the vitamin concoction. Six months later, she says, her symptoms had completely subsided.

The story of how EMPowerplus came into existence may be as hard to believe as claims of the product's miraculous success. Anthony Stephan, a dog food salesman and the father of 10 children (now grown), had spent years dealing with the same issues Steinlein had. His wife was diagnosed bipolar, and committed suicide in 1994. His son and daughter were diagnosed with the same disorder. In 1995, his 15-year-old son, Joseph, weighed 215 pounds and was prone to bullying his schoolmates as a way to work out his anger. Autumn, at the age of 22, was in and out of the psychiatric ward, exhibiting suicidal tendencies. One day, she tried throwing herself out of a moving car. Desperate to help his kids—and save them from the same fate as their mom—Stephan was willing to try almost anything.

That probably explains why he was willing to listen to his old friend David Hardy's stories about pigs. For two decades, Hardy had been selling livestock feed to farms around southern Alberta. As a way to help keep pigs from hurting each other—biting each other's tails and ears, as

## Whatever works

Remember the movie *A Beautiful Mind*? Russell Crowe played John Nash—the brilliant mathematician with schizophrenia and severe hallucinations. Thanks in large part to the compassion and love of his wife, Nash ended up mentally healthy and with a Nobel Prize. The message—that compassion can cure mental illness—may make for a feel-good film, but for those with loved ones suffering from schizophrenia, the false hope created by films like that can be a cruel trick. All the love and compassion in the world won't truly make them better.

That's how some psychiatrists feel about non-traditional treatments for mental illness, such as EMPowerplus, a vitamin mixture marketed by Alberta's Truehope Nutritional Support Ltd. "There is no evidence that I know of that vitamins in high doses have ever been able to help any mental

illness," says Dr. Edward Rzakdi, chief of psychiatry at William Osler Health Centre in Toronto.

Truehope isn't the first to try it. In the 1960s, Saskatchewan psychiatrist Dr. Abraham Hoffer tried treating schizophrenics with high doses of vitamins, called orthomolecular therapy. Trouble is, his research methods made it impossible to measure the effects. When orthomolecular therapy didn't work, he began putting his patients on combinations of

vitamins and drugs. "He gave some people orthomolecular therapy, they seemed to get better and the ones that didn't, he gave orthomolecular therapy and chlorpromazine," says Rzakdi. "And those that

still didn't get better he gave orthomolecular therapy and shock therapy. And he added

them all together and said, 'You see how many people got better and they were all on orthomolecular therapy.'"

Years later, a study published in the *Canadian Journal of Psychiatry* concluded that Hoffer's orthomolecular therapy was no more effective than a placebo. But when it comes to something as enigmatic as mental illness, "You can have a pretty robust placebo affect with just about anything that you do," says Dr. Doug Mann, a psychiatrist and secretary-treasurer of the Alberta Psychiatric Association.

Still, whether it's vitamins, Tic Tacs or Tylenol, many psychiatrists will cautiously welcome a patient's progress, no matter what treatment gets the credit. "If one individual, or two individuals, comes into your office and says this is a great drug, you can be very happy that their problem is gone at least for now, but at least a little bit skeptical as to whether you'll have problems down the road," says Mann. Whether the Albertan vitamin-makers are offering Truehope or false hope, however, is something that most psychiatrists just aren't willing to test out on their own patients. **W**

—ANDREA MROZEK



pigs do when they get stressed out or irritable—Hardy had begun adding a mix of vitamins and minerals. “We’d seen some very, very interesting things with pigs, who are quite similar to humans,” Hardy says. “I just thought that there were some things similar to what [Stephan] was describing with his son and what was happening with the animals. Hyper-irritability is the most common symptom and indication of bipolar disorder.”

Hardy had begun to wonder if bipolar disorder might have something to do with nutritional deficiencies. He put together a combination of vitamin and mineral products and gave them to Joseph. “Not taking it very seriously, we tried it with some things that were quick to get a hold of and we saw a little bit of an effect,” he says. “Not a lot, but it was enough to lead me to believe that we were on the right track.” Together, the two pals started frequenting the health food store and experimenting with different vitamins and minerals. “We put together four different commercially available products and the response to that was absolutely incredible,” says Hardy. “That led us to believe that this wasn’t only going to be a benefit to these kids but it could be a great benefit to humanity.” Neither Joseph nor Autumn have experienced any symptoms of mental illness since.

The ingredients in EMPowerplus are little more than off-the-shelf vitamins and minerals: calcium, iron, magnesium, potassium, vitamins A, C, D, E, B1, B2, B3, et cetera. Nothing new there. What is new is that Hardy and Stephan believe their vitamin mix—which is available only by mail order—helps people overcome mental illness, and they’re not shy about saying so. On their corporate website, their claims are asserted as fact: “Truehope has helped thousands effectively manage mental illness, particularly bipolar disorder, using our carefully formulated nutritional supplement called EMPowerplus.” And for Health Canada, that kind of certainty is a problem.

Up until Jan. 1, 2004, Ottawa had strict requirements for anything being marketed as a health product. Whether they were selling a synthetic pharmaceutical, say, like Viagra, or a nutritional supplement, manufacturers had to obtain a drug identification number. That meant submitting your product to Health Canada’s therapeutic products directorate, which looks at the claims made about the product by the manufacturers, and considers, based on scientific evidence, whether they’re accurate.

Until recently, anyone selling a drug or a nutrient without a drug identification number (DIN) could be shut down. And that’s what nearly happened to Truehope. Health Canada officials were reluctant to discuss details of the case while it’s before the courts, but spokeswoman Jirina Vlk notes, “The manufacturer has not provided us with scientific evidence that the drug is safe and effective.”

In 2000, University of Calgary pediatrics and pharmacological researcher Bonnie Kaplan was attempting to provide the evidence—or the lack of it—when she began a 100-person clinical trial into the effects of EMPowerplus. Kaplan not only had the blessing of the university’s science and ethical committees, she had received \$540,000 from the Alberta Science and Research Authority to fund the study. Midway through the trial, Health Canada informed Kaplan that it deemed the vitamin and mineral supplement to be a drug, and therefore required the school to apply for special permission to do experimental trials. University lawyer, Lynn



Before she started taking EMPowerplus vitamins, Gloria Steinlein was depressed and suicidal. Today, she credits the vitamins for her recovery

McCrae, wrote to Health Canada reminding them that: “The product in general is not a drug within the definition of the Food and Drugs Act.” The government wasn’t persuaded. In 2002, it ordered the research stopped. Truehope couldn’t get a DIN from Health Canada because it had no research to back up its claims, but the same agency had prohibited the firm from getting the research.

In April 2003, the government ordered all sales of EMPowerplus halted, and ordered customs to block any of the vitamin being shipped north across the U.S. border (while Truehope sells the product, the manufacturing is outsourced to a firm

in Utah). Some users resorted to smuggling the product into Canada, hidden in the trunks of their cars. In July 2003, Health Canada officers raided the Raymond, Alta., offices of Truehope, seizing all the product on site. In July 2004, Hardy and Stephan—who had been selling a concoction of the same vitamins and minerals you'll find at your local health food store—were charged with operating without a DIN number.

Two years after being forced off the market, thanks to regulatory changes, a new version of EMPowerplus ended up getting a green light from Health Canada. Historically, most nutritional supplements had either been classified as "food" or "drug," but in January 2004, the rules for selling most vitamin, mineral and herbal products had gone through major changes, and they would now be classified as "natural health" products. Any item classified as such wouldn't require a DIN. And in May 2005, Hardy and Stephan were granted permission to sell EMPowerplus in Canada without the designation. Stephan points out the fact that the company was more than happy to obtain permission under the new, less stringent rules. "We are trying to maintain law and follow regulations," Stephan says. "It's just that it was impossible to get the DIN."

Truehope wasn't the only firm having trouble with the DIN process. At least 90 per cent of natural health products sold before the 2004 rule change didn't have a DIN either, estimates Bruce Dales, president of Dales Product Development and Regulatory Specialists, a Vancouver-based firm that helps pharmaceutical companies navigate regulatory compliance issues. "In 2003, on these types of vitamin-mineral products, in my opinion a DIN really served nothing more than to give Health Canada some money as part of their cost-recovery program," says Dales, "which, in my opinion, was really just a hidden tax." In 2003, he says, Health Canada was "turning a blind eye" to all kinds of supplements coming into Canada. "I'm confused why Health Canada has targeted this company so extensively," he says.

Getting a drug identification number was no mean feat, Dales notes, estimating that the process would have taken a minimum of five years and probably cost Truehope roughly \$5 million. For a multinational pharmaceutical firm, that's a reasonable price. "For the most part, only medicines with good patent protection go through such a process because of the expenses involved," says Dales. But for a couple of former animal feed salesmen starting a small business in Southern Alberta, the expense was formidable—not to mention the human consequences of keeping the product off the market for so long. Following the 2003 raid on the company offices, Ron LaJeunesse, executive director of the Canadian Mental Health

Association's Alberta division reported that two mentally ill people committed suicide after they were forced to stop taking EMPowerplus.

So, does that mean the stuff really works? That depends on who you ask. Dr. Terry Polevoy, an Ontario pediatrician who operates several websites devoted to exposing quackery, has called Truehope's claims of being able to effectively treat depression "crap." Since 2000, he's dedicated himself to publicly debunking the product—including writing a self-published book in 2003 called *Pig Pills Inc.* "The biggest . . . 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 in many cases, stop their psychiatric medications altogether," Polevoy wrote, at the time.

But the 3,000 customers that Hardy and Stephan claim are currently using the product clearly think there's something to it. Still, psychiatrists are disinclined to even look at a product that hasn't undergone clinical trials, says psychiatrist Dr. Charles Popper, a professor at Harvard University's McLean Hospital, one of the U.S.'s most renowned psychiatric hospitals, and a founding editor of the *Journal of Child and Adolescent Psychopharmacology*. When Popper took the stand for the defence at the Calgary trial in March, he testified that, at first, he was extremely skeptical of claims being made by Hardy, Stephan and Kaplan at a presentation at McLean Hospital in 2000. He wasn't interested in attending the seminar in the first place, since the idea that nutritional deficiencies can cause mental illness is not generally accepted in psychiatry. He went as a favour to a friend, a former professor of Kaplan's. But when Stephan began making seemingly unbelievable claims—that 80 per cent of bipolar patients reported EMPowerplus had alleviated their symptoms, and that patients who had not tried any drugs before taking EMPowerplus had reported relief in as little as five days—Popper dismissed the stuff as modern-day snake oil. "As a journal editor I had seen a lot of treatments look good on paper, but [Truehope] made claims that were ridiculous," the doctor testified.

He left the talk early, but Hardy caught up with Popper on his way out and pushed a bottle of EMPowerplus into his hands (Popper testified that he even tucked it under his arm, so his colleagues wouldn't see him with it). Later that day, the psychiatrist met with a new patient, a 10-year-old boy who had been throwing severe temper tantrums for several hours a day, every day, for months. So violent were the fits, that Popper described them as resembling a cocaine overdose.

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He diagnosed the child as bipolar, warning the parents that it would take several months to gradually introduce the level of medication that would be required. Unable to wait, the parents pleaded with Popper for a more immediate fix. On a whim, he passed the EMPowerplus bottle to the parents, hoping for a placebo effect, at best. Three days later, the boy's father called Popper, amazed. The symptoms had disappeared. After a few more days, Popper met with the boy again. All the violent behaviour he had observed personally, he confirmed, was gone: "Not better, not a lot better; gone."

Today, the Harvard professor says he can't legitimately prescribe or recommend EMPowerplus until it undergoes clinical trials, but he regularly lets his patients know that it's out there. And of those bipolar patients who try it, he says, about 80 per cent show a marked improvement—just as the



owners had claimed. Shawn Buckley, the Kamloops, B.C., lawyer representing Truehope, asked Popper to imagine if he himself had been diagnosed with bipolar disorder: would he try EMPowerplus? Popper weighed the question for a couple of minutes, and replied, "I would choose EMPower. I know the trials aren't there, but I've actually seen it. Given the choice between a life of mental instability, I would first want to try EMPower."

The government's takedown of Truehope was one of the largest in Canadian history, according to the testimony of Sandra Jarvis, the Health Canada enforcement officer in charge of the operation. The purpose of the prosecution was to stop anyone from getting their hands on a product the government had not yet approved. The feds even established a toll-free number to help EMPowerplus users adjust to life back on synthetic drugs. As shown in Health Canada documents, operators fielded 199 calls from May 29, 2003, until



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June 5, 2003—including one suicidal caller.

On the stand, Health Canada officials were unrepentant about the consequences. They were, testified Inspector Miles Brousseau, merely following orders. Questioned by Buckley about whether he thought he might be putting the lives of mentally ill people at risk by ordering EMPowerplus imports turned away at the border, Brousseau explained that his opinion was irrelevant, since he was only adhering to policy. "So if you were sent a document, basically showing that people were dying because of what Health Canada was doing . . . you would just ignore that because it's not a policy or directive?" Buckley asked. To audible gasps in the courtroom, Brousseau said he would.

Even today, the product still isn't easily available. Before Ottawa reclassified EMPowerplus as a nutritional health product last year, it insisted that Hardy and Stephan remove the ingredient boron, which it considers an experimental drug. Canadians are allowed to have the product shipped from the Utah factory, but only in quantities sufficient for 90 days or less. Officially, Health Canada has listed EMPowerplus as a Class 2 health hazard—meaning any exposure to the product may cause temporary adverse health consequences or that the probability of serious adverse health consequences is remote. In other words, even the government doesn't deem the so-called pig pills to be all that dangerous. Whether it works or not remains a controversy. Kaplan's started a new study at the university, and Truehope has set up two more clinical trials in the U.S. that will begin this summer. But for people such as Steinlein who rely on EMPowerplus to enjoy normal lives that others take for granted, they have more than enough evidence. "Life is fabulous," says Steinlein. "I'm free." **W**

David Hardy, an animal feed salesman, says he first linked vitamins to mental angst when he began using them to calm hogs that were prone to biting one another. Skeptics have suggested the "pig pills" are really just modern-day snake oil