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COVER STORY

Flu medicine maker eyes new markets

Local scientist conducts U.S. trials for Canadian firm seeking larger share of the anti-flu pie

By Carol Latter

An over-the-counter North American ginseng derivative that has been shown in clinical trials to dramatically reduce the incidence of colds and the flu — and has since sent its manufacturer's sales and stock prices skyrocketing — will now be more readily available to U.S. consumers.

COLD-fX, a Canadian product developed by Edmonton, Alberta-based CV Technologies Inc., is the first natural health product to successfully complete a Phase II, double-blind, placebo controlled clinical trial regulated by the Federal Drug Administration (FDA).

The trial was carried out by a local scientist, Dr. Janet McElhaney, now an associate professor at the Center for Immunotherapy of Cancer and Infectious Diseases and the Center on Aging at UConn Health Center in Farmington.

Results from that trial, conducted at U.S. assisted living and nursing homes during two separate flu seasons, showed that the product reduced the incidence of laboratory-confirmed upper respiratory infection brought on by influenza and Respiratory Synctial Virus (RSV) in elderly patients by 89 percent. These results were obtained in people who had already received a flu shot.

Dr. Jacqueline Shan, president, CEO and chief scientific officer of CV Technologies, says subsequent studies have shown that the COLD-fX also helps prevent the flu and the common cold in members of the general population who have not been immunized. Last month, results of trial number seven — involving 363 people aged 18 to 65 — showed that taking COLD-fX on a regular basis as a preventative measure reduced the incidence of recurring colds and flu by 56 percent, compared with those taking a placebo. The derivative has also been shown to shorten the duration of any illness from 11 to six days, while lessening the severity of symptoms by 31 percent.

These results, she says, shows that COLD-fX is not only useful as an adjunct to the flu vaccine, but for those people have not been vaccinated, "you can use it as an alternative."

This is promising news in light of recent vaccine shortages, she says, adding that COLD-fX has been patented worldwide.

Earlier this month, CV Technologies entered into a distribution agreement with Extended Care Pharmacy (ECP), based in Calgary, to sell the product directly to its U.S. customers and to other cross-border pharmacies in Canada. ECP is one of about 150 Canadian cross-border pharmacies specializing in providing prescription drugs, on an individual customer basis, to the U.S. retail pharmaceutical market. That market is estimated to be worth $1 billion Canadian annually.

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> *–Dr. Janet McElhaney, UConn Health Cener*

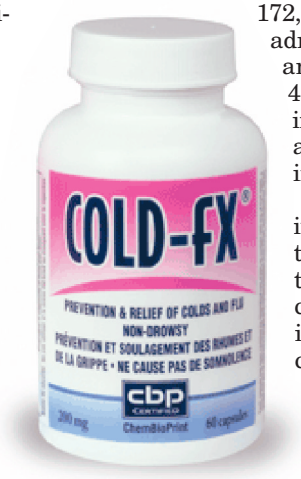
McElhaney, who spent five years as research and clinical director at the Glennan Center for Geriatrics and Gerontology at Eastern Virginia Medical School in Norfolk, Va. before coming to UConn Health Center, and previously carried out studies on the product in Alberta, says the trials not only produced statistically significant results, but "we proved that this stuff is safe in frail, older people."

She says as a scientist, she regularly conducts research on influenza and vaccination. "So this seemed to be a natural kind of fit, in terms of what we do for folks who get the flu in spite of being vaccinated. Vaccines are very effective in preventing serious illness, but they don't protect you from getting the flu."

COLD-fX, she says, appears to bridge that gap.

While COLD-fX has not yet been tested on children or pregnant women and therefore is not recommended for them, studies show it does not cause drug interactions, and has no side effects whatsoever, according to Shan. Moreover, patients who take it do not build up resistance to it over time, unlike some older anti-viral drugs and antibiotics, she says.

McElhaney's study on the product, published in January 2004 in the *Journal of the American Geriatrics Society*, notes, "despite influenza and pneumoccoccal vaccination rates exceeding 65 percent, influenza and pneumonia together represent the fourth-leading cause of death for older adults and are estimated to cause 172,000 excess hospital admissions annually, and as many as 40,000 excess influenza deaths, at a cost of $10 billion in the U.S. alone."



McElhaney says if approved for over-the-counter use in the U.S., COLD-fX could have "a huge impact" on health care costs, both in terms of preventing and treating colds and the flu. "But part of the problem is that there is not wide acceptability amongst the scientific community regarding these [natural] products, so we have really a huge hurdle to overcome. That's why we are so interested in doing some of the science on these products."

McElhaney says the trouble with most other natural health care products — it is estimated there are more than 50,000 on the market in Canada alone — is that their active ingredients frequently vary from batch to batch, making it difficult to test them for safety or effectiveness. She adds that most manufacturers of these products also make claims about them that are unsubstantiated by any scientific study. Until January of this year, such companies did not have to prove that their natural health care products actually worked in order to market them. Now, Health Canada requires all products to undergo a review process before they can be licensed for sale in Canada.

CV Technologies hopes COLD-fX will be

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the first natural product to be approved under that system.

McElhaney notes that CV Technologies, through a process Shan and her colleagues invented called ChemBioPrint, has been able to isolate therapeutic chemicals and eliminate undesirable chemicals that could potentially cause side effects. Through this process, it has also been able to ensure batch-to-batch consistency, a key factor in obtaining FDA approval of the conduct of the Stage II clinical trials to test COLD-fX as a new investigational drug, she says. And although CV Technologies has not been required to subject COLD-fX to the same scientific study required of prescription drugs, the company has done so — and the results from the clinical trials, says Shan, have proven that the product is effective.

After Shan took the helm as CEO last September, a decision was made to move the company from a primarily research and development footing to a fully commercialized one, by launching an aggressive marketing strategy and expanding its distribution network.

In the past, most of the sales — 60 percent — have been in the western province of Alberta where the company was founded, with 90 percent of those sales coming from COLD-fX, one of several products the company has developed.

Now, the company is making a push to expand its marketing further east, into the provinces of Ontario and Quebec, and the Maritimes.

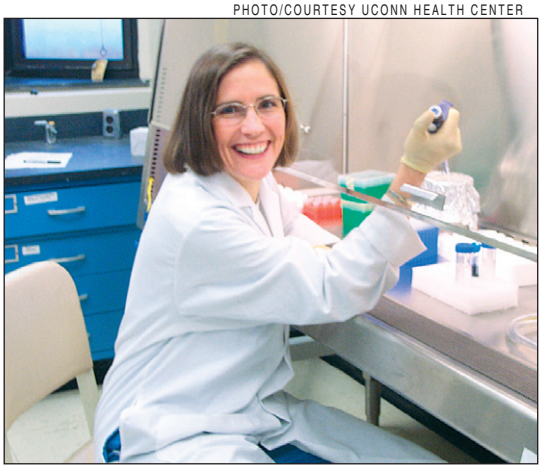
That strategy appears to be paying off. In the past year, says Shan, sales have been growing at an astonishing rate, more than 300 percent, month after month and quarter after quarter. Gross sales have risen from $1.4 million in the company's last fiscal year, which ended in September 2003, to $6.5 million in the year ended September 2004.

"And that was even before the flu season set in," she says.

So far, no marketing attempt has been made in the U.S., other than the arrangement reached with the cross-border pharmacy. Shan says the company is "close" to making moves in that direction, but says the deal with ECP will allow CV Technologies to develop brand awareness and gauge acceptance by U.S. customers before exploring the logistics of selling the product directly to retail outlets south of the border.

North of the border, COLD-fX has become something of a pharmaceutical phenomenon, attracting a flurry of national, regional and local media attention. It has been adopted with fervor by 24 National Hockey League (NHL) hockey teams, whose players say they swear by it to prevent and minimize colds and flu. Don Cherry, former Boston Bruins coach and long-time commentator on CBC's Hockey Night in Canada, has become the official spokesman for COLD-fX.

PHOTO/COURTESY UCONN HEALTH CENTER



Dr. Janet McElhaney, of UConn Health Center in Farmington, conducted clinical trials of COLD-fX.

> *'It's exciting to be able to help people.'*
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> *–Dr. Jacqueline Shan, president and CEO, CV Technologies*

PHOTO/COURTESY CV TECHNOLOGIES

Dr. Jacqueline Shan says her company's over-the-counter product could save the U.S. health care industry a lot of money.

Shan says the product's efficacy is supported by the fact that CV Technologies offers a money-back guarantee on the product, noting that of the millions of batches that have been sold, not a single container has been returned for a refund.

She adds that many satisfied customers have "put their money where their mouth is" and invested in the company's stock, which has seen a dramatic rise in the past 14 months, from 18 cents a share last September to $1.93 last week.

A case in point is Gordon Tallman, 61, the retired senior vice president of the Bank of Canada, who not only purchased stock, but later became the company's chairman in January 2003.

CV Technologies, which has been nominated as one of Alberta Venture Magazine's fastest-growing technology companies in the province, is also a finalist for the 2004 BioAlberta Awards.

While CV Technologies has become a rising star on the Canadian biotech scene, the meteoric rise of Shan herself, now 40, from a cash-strapped foreign student to the head of the company, has also attracted attention.

Now the mother of two young children, she divides her time between heading the company, attending speaking engagements across Canada and as far away as Taipei, and caring for her family.

But despite all of the attention she has received, she says, her thirst for discovery and her desire to make a difference to the world remains unquenched. Shan says it has not only been gratifying for her as a scientist and pharmacologist to discover a product that directly benefits patients, but to be able, as head of a commercial biotech company, to develop that product and bring it to market.

"It's exciting to be able to help people," she says. ■