



Features

Chroniques

Charlotte Gray is a contributing editor at *CMAJ*.

CMAJ 1998;158:1510-2

“Sending conventional doctors to examine [Di Bella’s] methods is like sending meat packers to review a vegetarian restaurant.”

Dr. Luigi Di Bella and the politics of elixirs

Charlotte Gray

In brief

HEALTH CANADA AND THE CANADIAN-ITALIAN PHYSICIANS ASSOCIATION recently spent \$20 000 to send 4 Canadian cancer specialists to Italy to check out the “miracle” anticancer cocktail prepared by an Italian physician. Most doctors remain decidedly sceptical about this latest “cure,” but Charlotte Gray says their suspicions count for little when an issue like this captures the imagination of the public and their politicians.

En bref

SANTÉ CANADA ET L’ASSOCIATION MÉDICALE CANADO-ITALIENNE ont dépensé récemment 20 000 \$ pour envoyer quatre oncologues canadiens en Italie se familiariser avec le «cocktail miracle» anti-cancéreux mis au point par un médecin italien. Cette dernière «cure» laisse la plupart des médecins carrément sceptiques mais, nous dit Charlotte Gray, leurs doutes ne pèsent guère une fois qu’une pareille question a enflammé l’imagination de la population et de ses politiciens.

The dying are willing to attach their hopes to any cure. This was true when the black death was ravaging Europe, it’s true at the end of the 20th century and it will likely be true when we’re touring the universe 1000 years from now. But should our politicians support such desperate hopes? That’s the question Dr. Michael Pollak asks as he observes the hype surrounding Dr. Luigi Di Bella.

Di Bella is an Italian physiologist who is purported to have found a successful treatment for cancer. Now retired and in his 86th year, he has treated 20 000 patients during the past 30 years with a cocktail consisting of vitamin A retinoids, somatostatin and melatonin. Di Bella is a modest pensioner who doesn’t appear to be growing fat off the profits from his controversial cocktail, but many of those clinging to his coattails are benefiting, particularly the Swiss pharmaceutical company that manufactures somatostatin and various practitioners who promote or administer the cocktail.

Is there a Canadian physician unaware of the recent furore over the Di Bella cocktail? There has been enormous popular interest in its potential and patients have been phoning their doctors to find out more. “I’ve had at least 50 calls,” reports Pollak, a professor of medicine and oncology at McGill University.

Most physicians, Pollak included, have responded with the facts. The Di Bella treatment is controversial because, at least this far, there has been no solid scientific evidence of its efficacy. Di Bella has never reported his clinical results in a peer-reviewed journal, and last January he refused to let a team of researchers, which included Pollak and had been selected by Italian health authorities, examine his records.

In March, 4 Canadian physicians travelled to Di Bella’s laboratory in Modena to investigate his claims. Dr. Andrew Arnold, who is with the Ontario Cancer Treatment and Research Foundation in Hamilton, says the visitors were shown the case histories of only 3 patients treated by Di Bella and none offered convincing proof that his cocktail works.



Arnold thinks the Italian physicians who administered the cocktail meant well but had “such a rudimentary knowledge of modern cancer-therapy concepts that they knew no better.” Another of the Canadian physicians, Vancouver oncologist Paul Hoskins, reported that Di Bella’s files contained little information other than notes that the patient “feels fine.” The notes did not always specify what other treatments the patients were receiving. The Canadian team told federal Health Minister Allan Rock that there is no scientific justification for starting a clinical trial of the regimen in Canada.

Yet the Di Bella story will not end there, because in the late twentieth century there is more to medicine than science — much more. When a rumour of “a miracle cancer cure” starts making the rounds today, physicians are learning, there are two results. The first is the imperative politicians feel to ride the popular-opinion horse and the second is the public distrust of conventional science.

Joe Volpe, Allan Rock’s parliamentary secretary and the Liberal member of Parliament for the Toronto riding of Eglinton-Lawrence, knows all about the intersection of public opinion and health policy. Volpe is of Italian descent and remains in close touch with Toronto’s large and powerful Italian community. He first became aware of the widespread interest in the Di Bella “cure” last Christmas, and by March was receiving 10 calls a day about it. His callers had either been told about it by relatives in Italy or they had read about it in the Italian-language Toronto daily *Corriere Canadese*. In what became a form of peer review by daily newspaper, the paper’s editor had been publishing enthusiastic articles about Di Bella’s treatment for years. (Significantly, there has been no great interest in the huge Italian community in Australia, where the local Italian newspaper is much less interested in the story.)

Most of Volpe’s callers wanted to know why the treatment was not available in Canada and he became concerned that some people were spending thousands to travel to Italy to obtain the cocktail. “They asked me, ‘If this does no harm and may do good, why is the government preventing people from getting it? Why can’t we have clinical trials here, so I can have access?’”

Volpe felt he had to provide some answers, and helped organize the trip to Italy by Arnold, Hoskins and 2 colleagues — Dr. Lou Benedet, head of gynecologic oncology at the British Columbia Cancer Agency in Vancouver, and Victor Fornasier, pathologist-in-chief at Toronto’s Wellesley Hospital. Volpe calculates that the trip cost around \$20 000. The federal government helped make arrangements and paid the air fares, and the Canadian-Italian Physicians Association, which Fornasier heads, paid the balance.

Since the Canadian team returned, the calls to Volpe’s

Canapress



Dr. Luigi Di Bella discusses his controversial therapy with members of visiting Canadian delegation in April

office have not abated and he feels under as much pressure as ever. His callers continue to demand to know why the Italian cocktail isn’t available here, and many are angry that the physicians who travelled to Modena returned accompanied by a healthy scepticism.

Canadian politicians don’t usually get involved in the verification of medical treatments, but Volpe’s participation here is minuscule compared with what has been going on in Italy. The “miracle cure” has been caught up in the murky undercurrents of Italian politics and become a rallying cry for the rightist opposition. Last year Di Bella’s patients banded together to demand that the cocktail, which can cost more than \$6000 a month, be covered under the national health insurance plan. The government refused, on the reasonable ground that it was unproven. However, a judge then ordered a public hospital to provide the cocktail to patients without charge. The fragmented and noisy right-wing opposition coalesced around the elderly doctor and his supporters, who are nicknamed “diBellisti,” and claimed that the left-wing government in Rome was too stingy to help the dying. Emotions ran so high that the Pope stepped in and called for peace between the 2 sides.

Italy’s health care officials do not enjoy much credibility — one former minister of health is currently in jail because of a price-fixing scheme involving drug companies. However, in an effort to defuse the situation and bring some sanity to the debate, the Ministry of Health in Rome has set up 10 clinical trials involving Di Bella’s treatment, and the results are expected in July. They will play a useful role in bringing rigour to assessments of the Di Bella cocktail, but at a price. The clinical trials will cost



close to \$20 million — the same as the entire annual budget for chemotherapy treatments for the BC Cancer Agency's 13 000 patients.

Meanwhile, the Di Bella circus has stoked up the debate between proponents of complementary medicine and more orthodox practitioners. Soon after a sceptical account by Arnold appeared in the *Globe and Mail*, the newspaper published part of a letter from Robert McMaster, editor of the alternative health magazine *Natural Affairs*. He suggested that Arnold's analysis of Di Bella's treatment was far too rigid because it stuck to conventional standards, and criticized him for dismissing "the value of a patient's subjective sense of well-being, reducing all measures to 'objective' evidence." In a paragraph that the *Globe* chose not to print, McMaster said that "sending conventional doctors to examine [Di Bella's] methods is like sending meat packers to review a vegetarian restaurant."

McMaster insists that he does not have "an antiscience bias," but he does take issue with what he calls the medical establishment's "obsession with one-size-fits-all medicine" and the disregard for a patient's own sense of well-being. "I am not talking about the placebo effect here. An individual's determination of how a treatment affects them varies according to expectations, lifestyles and perceptions. An acceptable treatment to one person might destroy the quality of life for another." If scientific methods are so good, observes Mr. McMaster, why are the results of their application so poor?

The debate between Di Bella's supporters and critics quickly became polarized, but few physicians are prepared to dismiss the cocktail altogether, although most are uncomfortable with the "diBellisti's" reliance on anecdotal evidence. The cocktail does contain an ingredient, somastatin, that researchers acknowledge may have value as a preventive cancer therapy. Somatostatin is a naturally occurring hormone commonly used to combat abnormal growths caused by excess secretion of growth hormones. McGill's Pollak has been doing re-

search on a somatostatin analogue, octreotide, for more than 8 years, and has already taken his research from the laboratory into clinical trials; other Canadian researchers are taking the same path. "There is a good possibility that if you give a woman the drug after a mastectomy, it [will] lower the risk of a recurrence of breast cancer," Pollak says. He is chairing a large clinical trial, coordinated through the National Cancer Institute of Canada, which will eventually include 800 women.

That research will take years and proceed inch by peer-reviewed inch. Di Bella's treatment, on the other hand, will either continue to grab headlines as an elixir, or self-destruct when the results of the Italian clinical trials are published.

Pollak, for one, will be very surprised if the Di Bella treatment is shown to have any value, but the affair worries him. "I am concerned that any studies on somatostatin will be side-swiped by the Di Bella results."

One way or another, the Di Bella phenomenon has not done much for doctors' image. By insisting on rigorous testing standards for the treatment, as physicians always do, the medical profession has appeared unsympathetic to patients who may be at death's door and are willing to grasp any straw. And by ignoring what was happening, the profession allowed a "miracle cure" to become politicized on both sides of the Atlantic.

"The last thing I wanted was to find my office becoming a clearinghouse for information on the Di Bella cocktail," says an exasperated Volpe. "But I am afraid that the medical profession ignores too many options. Now their patients are losing respect for their doctors because doctors won't let them have access to something that may make them feel better and live longer and have a decent quality of life."

Yet there is still only anecdotal evidence to suggest that the Di Bella cocktail can do any of those things. Unfortunately, if public confidence in the cocktail dissolves, support for some important Canadian research might evaporate along with it. ?



MP Joe Volpe: Is the medical profession ignoring some options?