

Crisis in Healthcare: the threat of untested devices

Hitherto, for family reasons, Cheryl Freeman has been reluctant to be publicly identified with her investigation of pseudo-medical devices.

We are delighted that she has now agreed to do so, thus enabling us to thank her, publicly, for her care, concern and invaluable work.

State and federal governments are now in the process of developing a national framework for establishing minimum standards for training, conduct and safety within the alternative/complementary health industry. NSW, which has an independent Health Care Complaints Commission (HCCC), but with limited legislative powers in relation to alternative therapist complaints, has a leading role. The end result will be state government accreditation and registration of qualified alternative health practitioners.

A NSW Parliamentary Committee Inquiry in 1998 recommended a 'generic' form of registration as against the 'full registration' afforded to doctors, nurses and dentists. But any form of registration will bestow a government licence and imprimatur on practitioners and all their diagnostic-treatment practices, procedures and products.

Setting standards

My investigations reveal that industry registered therapists, along with "holistic" doctors, nurses and dentists, will be involved in setting standards. Collectively they are the face of the latest concept in combina-

tion health care - "Integrative Medicine, the ultimate in orthodox and complementary medicine". They also represent the very class of people who, in the near future, will benefit from having state government licences and from the legitimacy that registration confers.

What seems to be missing from these discussions is any objective, scientific, evidence that any of these practices or devices actually do what is claimed for them. That should be the very first step, before any move towards regulation, generic or otherwise, is even considered. Further, the setting of standards should, at the very least, be at arms length from those who might benefit substantially from them.

Moreover, engaging in unsafe and potentially dangerous and financially exploitative practices is not simply a result of the actions of unqualified, unregistered 'quacks and charlatans', who are usually blamed by the qualified or registered sector. My research suggests that people at the highest levels of the alternative health industry are just as likely to make unsubstantiated claims, or offer unproven therapies, as are "renegade" practitioners.

Regulatory failures

I have discovered many cases of industry-registered therapists involved in appalling abuses, malpractices and/or financial exploitation of their clients. These represent gross interferences in the diagnostic and treatment management of serious diseases such as cancer, and also in cases of highly infectious diseases such as HIV-AIDS and hepatitis. These latter have the potential to lead, not only to bad outcomes for the individual patients, but also to serious public health consequences.

What is worse, qualified practitioners who are aware of what has been happening have tended to put the interests of victims aside, in favour of supporting the industry.

My research also reveal the seriously flawed and ineffective state and federal regulatory and complaints systems. With few exceptions, these allow complaints to go unresolved, as concerned complainants are put on a lengthy buck-passing merry-go-round from one authority to another.

We have no public alert/early warning system, which gives the authorities the power to issue immediate Public Health Warnings, nor any avenues to appeal to those with information to assist investigating authorities when serious problems with alternative health claims are uncovered.

Media blindness

The future release of an official government paper **should** result in constructive broad public discussions, but will it? The mainstream media have for many years blinded themselves to the truth, and frequently publish or broadcast favourable stories about claims about "remarkable" treatments, while failing to conduct any background research. Whether this is through ignorance of the simplest fundamental requirements of scientific medicine, or through a misplaced belief in giving a "balanced" presentation, the result is that they give the potentially dangerous practitioners, practices and products free publicity.

One example that went against this trend in the media occurred in *Reader's Digest*, (July 2000). In an article "The Truth About Natural Therapists", it reported an independent, Australia-wide, survey of 25 "alternative" therapists, which found a disorganised industry, making wild and disparate claims, in which the only consistency seemed to be "anything goes". The editor was so shocked by the results that he appealed to the public to petition their MPs for legislative protection and for victims to contact *RD* for a follow-up report. Did any other sector of the media take up this story and run with it? They did not.

Accountability

I applaud government efforts to set some basic standards which I fervently hope will lead to a total ban on some practices and products, and to encourage informed public debate about others. However, I have grave reservations about any form of state government registration especially when there has never been an open, in-depth public inquiry into **all** of the industry's diagnostic and treatment practices, machines and products and when health consumers are poorly informed and where victims live in fear of reporting abuses and malpractices. To me it is a dangerous mix.

What we need is public accountability: We need firstly to publicly focus on the victims' fears and support them, then to look at what has been happening in this industry, examine all the practices, machines and products, the practitioners involved and their training and all the regulatory and complaints systems and their flaws and errors and learn from them. Only then can governments attempt to offer health consumers a greater margin of safety than that which is currently available to them, so they can make truly informed choices.

Specific cases

Now to look at a couple of specific instances. Breast screening is a major public health issue and my reports below on breast disease detec-

tion programs reveal the extent of current industry practices. From my 16 years of experience in investigating dubious devices, these are also common standard practices in relation to many other diagnostic and treatment machines and therapies.

Warning

In March 2001, the National Breast Cancer Centre launched a campaign through the national media, warning women that delays of longer than three months in the medical diagnosis of breast cancer would greatly reduce the chance of survival.

TRD/CRT tests

This study looks at the promotion and use of unscientific screening/diagnostic machines, promoted as "the latest advanced diagnostic technology" in breast screening. While the focus of this study is on breast screening, claims are made by promoters of these devices that they are also useful for diagnosis in the cardio-cerebro-vascular fields.

Thermo Regulation Diagnosis (TRD) or Computerised Regulation Thermography (CRT) tests are promoted by naturopaths and others who are publicly involved in the alternative cancer therapy industry in Australia and in numerous influential alternative cancer groups.

Unlike the field of medical thermography, the TRD-CRT machine does not use a thermal imaging camera, and is physically incapable of taking 'heat pictures'. It has a large pen-like sensor connected by cable to a control unit and VD monitor. Developed in Germany, the TRD-CRT is an updated and computerised version of an old alternative health concept. This holds that specific teeth, and skin points on the face, neck and body, are 'connected' to specific body parts and organs. Temperature change, measured at over 100 specified teeth or skin points, is alleged, by proponents, to indicate abnormal activity in the distant 'connected' organs or body parts.

It should hardly need stressing that there is no physiological, nor medical evidence to support these claims, *and in the absence of such evidence, there is no reason to believe they might be true.*

Changing stories

One prominent proponent is reported in an article in *The Australian* as claiming that the TRD machine was useful for detecting, through heat readings, abnormal activity in the breast that was worthy of examination, but she is also reported to have said that she did not claim the thermogram was a diagnostic tool for breast cancer, nor that women should avoid mammograms.

Yet I have copies of that practitioner's brochures, have read her magazine articles and visited her web site, and they tell a very different story. TRD-Thermography is described as "true preventive medicine" and "advanced technology in diagnosis" in bold red print. It is also claimed that, "this diagnostic approach is simple, non-invasive and risk free" it "provides important diagnostic information" and "TRD frequently provides indications of unrecognised disease, hidden cause and dangerous complications ... without the patient being subjected to any strain from X-rays, diagnostic operations, biopsies ..." and "assessment of the degree of illness". There are many other impressive claims including: "... Is suitable for diagnostic purposes in the cardiac field" and "assessment of circulation. Disturbances of cerebral and/or peripheral blood circulation, and (if) vascular occlusion are evident."

A front cover of *New Vegetarian and Natural Health* magazine described TRD and Live Blood Cell Analysis (LBCA) tests as "state-of-the-art cancer testing". An article by the practitioner in that issue makes such claims as: "we can also measure every tooth and various points on each breast" and "we get a crossover effect where whichever breast holds the tumour, the opposite ovary will also register a problem ... which, in patients with malignancies usually

give very low readings" and "with breast cancer we of course expect abnormal readings for the chest region and we also see abnormalities in the abdominal region", among many other claims.

A *She* magazine cover story asked: "But how do we tell helpful from hocus-pocus?" The potentially dangerous introduction began: "Going for a check-up doesn't necessarily mean a visit to your GP these days." The reporter was tested and told, "Your breasts are fine", which, the reporter noted, "gave me some relief". As a result of LBCA, another highly dubious, though widely practised "modality", the reporter wrote, "I was relieved to find out my heart, kidneys, thyroid, uterus, breasts and lungs were okay." (It is fairly obvious that *SHE* magazine did no background research, nor consulted any medical experts or health authorities)

Personal experience:

In April 2000 I contacted one such clinic (I have reports of at least 10 others operating in Australia) and told the receptionist that I had read the magazine articles on breast cancer and was very impressed. I asked if I (then aged 52), and a relative who had had breast cancer, could make appointments for the TRD test. I was not asked if I had been having mammograms, nor told the TRD test did not replace mammogram screening, that it could not detect breast cancers, nor advised that it was extremely important for my relative to know that she must also continue to have regular medical checks-ups from her cancer specialist, nor that the TRD test was not approved by orthodox breast cancer or other medical experts.

Note: None of the brochures, web sites nor magazine articles promoting TRD contain these warnings.

I also received from the clinic, a brochure for the International Cancer Association Network (ICAN), which promotes alternative cancer treatments and foreign clinics, plus a "practitioner referral brochure" which listed 19 Sydney doctors, 33 qualified therapists, and many high-

profile holistic MDs, who the mainstream media promote as 'innovative new-age doctors - the new face of Integrative Medicine.' The clinic advised me that private health fund rebates were payable on TRD tests, a fact confirmed in the *She* magazine report.

An article in *The Australian* in November 2000 reported that the "thermogram" machine was "listed with the TGA", implying that it had been scientifically tested and approved by the TGA. No mention was made that 'listed' devices were not tested for efficacy, nor that the seriously flawed 'listing system' was abolished in 1998. The TGA has advised me that the 'listing' for the TRD-CRT machine was cancelled in mid-2000.

My concerns

Given the above detailed promotions, my personal experience with this clinic and the total lack of essential warnings on promotions and media publicity, my concerns are that women with medically undiagnosed primary or secondary cancers may avoid or delay having mammograms and essential follow-up medical tests and treatment, with tragic results. When tested with an 'advanced diagnostic machine' and reassured, "your breasts are fine" (a negative diagnosis), they might be lulled into a false sense of security. Conversely, test results that suggest their breast readings were "not quite right" or that they had "problems", "abnormalities", "abnormal activity" or "hot spots" in their breasts, ovaries and other organs could create extreme anxiety, fear and depression in women with a family history of breast cancer. It could lead to 'panic mastectomies' and other surgeries (or even suicide attempts) in those who fear secondary spread of their cancers. Sensitive women required to sit naked to the waist, to have their breasts 'probed' for what they believe is a legitimate scientific medical test, would feel betrayed and humiliated when informed of the true nature of the 'test'. Panic and extreme anxiety could strike those women who do not

have any breast problems but who have relied on this 'screening test.'

Unknown to science

In *The Australian* I was reported as a former nurse and member of Australian Skeptics petitioning for a total ban on the 'dangerous thermogram'. However it was not a thermogram, but the TRD-CRT, to which I was referring. It is an unscientific device, based on the most illogical concepts and is unknown to medical experts. It is physically incapable of performing as claimed, but it is part of the global growth industry in these types of machines being presented to medically inexperienced and easily misled health consumers as the 'latest, advanced technology in diagnosis'. It is now widely used in the alternative-holistic health industry with endorsements from holistic doctors and nurses.

Prof John Forbes, head of the Australia-New Zealand breast cancer trials, and the National Advisory Committee to the Breast Screen Australia Program both commented in *The Australian* report (unfortunately about medical thermograms). Neither had any knowledge of the TRD-CRT machine until I contacted them, nor had other medical experts I spoke to.

A solution

In this case a total ban is the only solution, given that the previously published dangerous breast cancer detection claims will remain in the public domain and on foreign web sites and will continue to influence how the machine is promoted, sold and used in Australia. At any time, anyone can become an importer and distributor of this machine, (unknown to health authorities as no licences are necessary) and promote it according to the explicit claims on the manufacturer's website and 'confidential practitioner reference material'.

The authorities

My complaint to the NSW Health Care Complaints Commission

(HCCC) and appeal for urgent public health warnings, was referred to the Australian Competition and Consumer Commission (ACCC) after being assessed as a trade practices issue. The HCCC did not refer my complaint and appeal for an urgent public health warning to the NSW Health Minister, nor to the Director-General of Public Health. My complaint to the NSW Minister for Fair Trading under the new May 2000 *Substantiation of Claims Act* was acknowledged. Both the ACCC and Fair Trading are investigating as at April 2001. The Therapeutic Goods Administration (TGA) requested that I complete a *Medical Devices Incident Report* following my complaint. ('Devices' distributors must still comply with the TGA's Advertising Code, but no penalty or public advertisement correction notice system exists.) I submitted my concerns regarding the 19 Sydney doctors listed in the practitioner referral brochure to the NSW Medical Board. My grounds were that even if some of the doctors do not actively refer their patients to a clinic for TRD breast and other TRD tests, inclusion of their names in the promotional material bestows medical credibility and endorsement by association on the TRD-CRT which could dangerously impress and reassure clients.

Senator Jocelyn Newman (herself a victim of breast cancer) referred my submission to the Federal Health Minister in Jan 2001, specifically noting that no public health warnings had been issued. The minister has not responded.

In March 2001 a concerned medical expert and I approached the NSW Health Minister to ask for investigation of all TRD-CRT clinics under the new provisions of the NSW Public Health Act, and to issue an urgent public health warning advising women who have undergone these tests not to rely on the results, but to consult their MD's immediately. We also sought an appeal to those with information on the TRD-CRT clinics to assist investigating authorities. We have had no results to date, but continue to hope.

DITI tests

This report focuses on the current trend of establishing breast screening programmes in suburban clinics using Meditherm DITI machines - without any approval or support from state health authorities or medical experts. We know of 15 Meditherm clinics, but we do not know how many other brands of DITI screening machines are in use in Australian clinics

Digital Infra-red Thermal Imaging (DITI), more commonly called 'medical thermogram or thermography', uses a portable thermal imaging camera connected to a standard PC to take 'heat pictures' of body surface areas. In simple terms, in relation to breast screening, the rationale is that the area surrounding a tumour will present with increased blood supply and therefore heat which can be detected and recorded by the camera.

Personal experience

I found a practitioner in the Hunter Telephone directory under the heading 'Thermology'. She promoted herself to me as a 'thermologist', with no formal health or medical qualifications. She explained that she was qualified to take thermal pictures "just as radiology technicians are trained to take X-rays". To obtain her qualifications she did a two-week training course followed by six months 'on-the-job' supervision from an Australian man who trains operators for the USA-based company. She skirted around my question to avoid having to identify this man, but added that the practice was relatively new in Australia, with 15 clinics being set up in the past four years, including several in various Sydney suburbs.

After introducing myself as a 52 year old (female age being a very important factor) who had had mammograms, I was told that DITI was better than X-rays and MRI scans and could pick up tumours earlier than mammograms - before the cancer became clinical and was in a precancerous state she called *neovascularity*. This was especially so in

younger women who had denser breast tissue, making mammogram detection of tumours impossible. She added that she now has women patients who refuse to have mammograms which, she said, can be very painful for some women, especially those who have had surgery or who are small breasted. She talked of 'temperature differentials,' referrals from doctors (but self-referrals were acceptable) and referred me to the USA website.

'What is the test procedure?' I asked. She explained, that Test 1 is performed, then three months later Test 2 and the results then compared. This forms a baseline. Then Test 3 is performed yearly and compared with your baseline. She takes a 'full case history', conducts the tests, interprets the results and informs the patients of her assessment, providing them with a print-out of their test and results. There is no medical consultation, assessment of tests, nor supervision.

As a follow-up, I contacted a Sydney centre which also conducts a DITI 'Early detection of breast disease program' as well as offering such other dubious services as "Listen screening!" and "Rife-Bare treatments".

Note: Neither of these clinics advised me that it was most important to realise that DITI did not replace regular mammograms.

The Meditherm Website lists 75 conditions including 'breast disease' as indications for DITI which is "state of the art PC based IR technology" able "to detect early lesions before they are clinically evident. It is used as an aid for diagnosis and prognosis ... within clinical fields that include oncology and many others."

Breast cancer experts and national breast screening bodies are on public record as condemning claims that 'medical thermography' can detect small breast tumours. They say that tumours must be at least 2cm in diameter before they can be detected with medical thermography.

My concerns

As I have detailed in the TRD-CRT report above, the giving of both negative ('your breasts are fine, no problems') and positive ('there are some hot areas, abnormal activity') diagnoses to women can carry very serious risks. Misdiagnoses and delays in obtaining medical diagnoses and treatment can have very grave physical and emotional ramifications for some women. The test procedure of having one test then another three months later to determine a 'baseline' for future yearly tests is, in my view, a potentially deadly practice. How a person, who has no formal health or medical qualifications, can achieve medical expertise after a two-week training course then six months under supervision (which, incidentally, may be by distance consultation) sufficient to be able to assess a 'full patient case history', conduct a 'medical' test, assess and deliver the results to patients who may be suffering from any of 75 minor, serious or life-threatening conditions, astounds me.

It appears that the time has come for state health authorities to prohibit the operation of 'breast screening' clinics, or any other type of 'organ screening' clinic using any type of machine that has no government approval nor medical supervision and accountability.

The authorities:

In November 2000, aware of the NSW Health Care Complaints Commission's legislative limitations, I bypassed the HCCC and forwarded by complaint directly to the ACCC which advised me in December 2000 that my "concerns were acknowledged but the matter is not an issue for the ACCC at this point in time".

In March 2001 I submitted my concerns to the NSW Health Minister under the new provisions of the NSW Public Health Act, appealing for an urgent public health warning and an appeal to those with information on DITI clinics to assist investigating authorities.

In both these reports, I have not visited clinics operated by "fakes and charlatans", but those run by high-profile leaders in the field of alternative medicine and well-publicised proponents of "Integrative Medicine, the ultimate in orthodox and complementary medicine". These are precisely the sort of people who might well be setting the standards of training and practice in these fields, if "generic registration" comes into effect and if the regulatory authorities do not take a lot more notice of what is going on than they have to date.

Refs

1. ACCC website for landmark ACCC-LISTEN prosecution case, April 2000

Note

I have fully documented details of all the claims I have made in this article and have made them available to the various regulatory authorities as part of my complaints.

