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**To: The Hon. Legislative members of the Health Panel**

**Medical Device registration Ordinance – for whose benefit**

**A Response to**

**The Proposed Regulation of Medical Devices**

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## **SUMMARY**

**Although the “protection of the public” always sounds so sacrosanct, this kind of pretence has often been abused by self-serving professionals.**

**There is a lack of evidence to support that this new medical device regulation will actually improve the existing measure to “protect the public”.**

**Such an Ordinance also entails a very high cost both fiscally and socially.**

**It will entrench further the monopoly of the medical establishment, which has been the root cause of the health care crisis faced by many countries including Hong Kong.**

**The interest of the public will be better served by a more open healthcare system and through real health education encouraging Hong Kong people to be more responsible for their own healthcare.**

**Instead of following the restrictive regulatory measures of other countries, Hong Kong should maintain the reputation of being the freest country in the world to do business in. This freedom has served Hong Kong well in the past and is crucial to our prosperity.**

**We should take heed of what Sir William Blackstone wrote in his “Law of England” in 1765, “*The more law, the less justice.*”**

**Instead of our government continue to mothering our citizens, we should encourage our citizens to become more independent and self-reliant.**

## REFERENCES:

**The Medical Mafia** by Ghislaine Lanctot, MD. [www.personocratia.com](http://www.personocratia.com)

How to get out of it alive and take back our health & wealth

“...but people continue to suffer and die all the same, Why?

Why is our state of health constantly deteriorating?

Why does our medical system cost so much?

Why is it maintained when everyone is so dissatisfied with it?

Whom does it profit?”

**Dirty Medicine** by Martin J. Walker

Science, big business and the assault on natural health care

Orthodox medical practitioners, pharmaceutical companies and industrial scientists, have organized against alternative and complementary medicine in Europe and America since the last century. Dirty Medicine traces the history of these campaigns, their proponents and institutions.

Dirty Medicine, is a frightening story of the free market, at war with the powerless. It exposes how, under the guise of government regulation, big business, science and medical orthodoxy defended their products and profits from competition.

**Confessions of a Medical Heretics** by Robert Mendelsohn, M.D., Contemporary Books.

Approximately 2.4 million operations performed every year are unnecessary and cost about 12,000 lives.

In six New York hospitals, 43 percent of performed hysterectomies reviewed were found to be unjustified.

Historically, when doctors have gone on strike, the mortality rate has dropped.

**Death by Diet**, by Robert R. Barefoot. [www.cureamerica.net](http://www.cureamerica.net)

**What Doctors don't tell you** - The truth about the dangers of modern medicine by Lynne McTaggart, Thorsons.

**Medical Mavericks**, Vol. 1 & 2 by Hugh Desaix Riordan, M.D. (We need to learn from medical history in order to avoid repeating the same mistakes over and over again)

WEBSITES REFERENCES:

[www.iahf.com](http://www.iahf.com)

[www.alliance-natural-health.org](http://www.alliance-natural-health.org)

[www.dr-rath-foundaton.org](http://www.dr-rath-foundaton.org)

[www.betterhongkong.com](http://www.betterhongkong.com)

## **Regulation of Medical Devices – for whose benefit**

“For the public protection,” “For the public safety” – such slogans have always sound so sacred and anyone who try to oppose them is guilty of blasphemy.

When we examine the consultation document of the Regulation of Medical Devices issued by the Department of Health in July 2003, we can see that there are basically two main reasons for introducing the ordinance:

- 1) Complaints to the Consumer Council by customers about the cosmetic laser treatments;
- 2) The practice of other developed nations need to be harmonized to Hong Kong. We have no regulation concerning the use of medical devices and this is perceived as a problem.

Whether or not we need another new ordinance, must be judged on the basis of *whether the new ordinance is going to achieve the purported goal of protecting the consuming public in Hong Kong*. In other words, it should make a noticeable difference between having such ordinance and not having one as it has been in the past. Then we need to weigh the benefit against the cost, both in terms of additional manpower cost to administrate such ordinance and the social cost to the society as a whole.

So what has been the problem with the color laser treatment used by the beauticians in the beauty parlours?

A total number of 36 complaints have been received by the Consumer Council in the year 2001-2002.

What was the nature of their complaints?

Most of them were business complains such as fees being too high or desired results not achieved. Three involved allergic reactions, six suffered from some minor burns and scarring. We do not know the number of treatments performed every year by beauticians, but judging from the number of the laser devices sold (in the hundreds) and these being very expensive equipments, they must be put to frequent use to justify the investments. So the number of complains is quite small relatively speaking.

But, the most important thing we need to consider is that, is this kind of complaints not likely to happen in the hands of the registered doctors or their staff who will be

allowed to use the same laser devices under the doctors consent? Would the fees likely to be lower if the same procedure is to be used by doctors or staff in the clinic or hospital? Doctors fee in Hong Kong is known to be among the highest in the world. *Do allergic reaction and minor burns won't happen simply because the operator is a doctor whose training in laser cosmetic is probably less than a beautician. The doctor's medical background has nothing to do with the competency of the use of lasers in cosmetic application.*

Many of us know of similar mishaps happen in the hand of the doctors and dermatologists who then have to settle the dispute privately. Consumer council finally revealed a fair number of complaints of minor burns and scarring that have happened in the medical clinics. The fact has to be dug out by direct questioning from our legislators.

Actually, people are more reluctant to complain about doctors to a special Medical Council because of the authority mystics and tend to accept the consequences. People are more willing to complain to a more neutral body such as the Consumer Council.

Point two: Why are we following the other developed countries? Is it because with their stringent regulatory laws, patients in these countries are better protected?

A study published by the Journal of American Medical Association in 2000 showed the statistics that medical mishaps and side effects from drugs have become the No. 3 killers in the industrialized nations. In the United States 225,000 die as a direct result of conventional medicine go wrong. In China, about 200,000, in U.K. about 50,000, and one in five Australians die in the hands of their doctors.

*So you see, medical regulation designed to protect the public by the Food and Drug Administration in the United States, the Medical Control Agency in United Kingdom, the Therapeutic Goods Act in Australia have not protected the public at all. On the contrary, they make the situation worse.*

Why?

Because, most of us tend to put down our guard if we thought there are already some safety regulations in place and people tend to blindly accept whatever were being offered by the medical establishment. A good example is our recent experience with SARS. Hong Kong SARS patients have the highest mortality (17%) and worse morbidity among the survivors in the world. With the help of traditional Chinese

medicine, Beijing has 5% mortality and Guangzhou 3% mortality, considerably lower than Hong Kong. People were being killed by their doctors willingly, even though it should be obvious that their treatment is not effective.

You may argue that at least we will know the true incidence if we have a reporting system in place.

As an example, the Medical Control Agency which monitors the safety of drugs in UK after they reach the market, reported that, in the year 2000, 33,109 adverse reactions to drugs were reported, of which 14,500 were serious and 600 were fatal. Perhaps those figures represent more of the image of a world we believe we live in, one where we can trust those in positions of authority to ensure our safety and wellbeing. Unfortunately the figures cannot be relied on. The U K in particular, and Europe in general, suffer from a massive underreporting of drug side effects and adverse reactions. It's impossible to measure what is not known, but it's been reckoned that just 1 per cent of adverse reactions are reported to the American drug regulator, the FDA, and a similar estimate could be applied in UK. One French study found that just 1 out of every 20,000 reactions to prescriptions drugs is ever reported

Let's say, we don't care. It seems to make sense that we need to offer some kind of protection for the public, and maybe the situation will be worse without such regulations. Maybe, unregulated medical treatment may become the No. 1 killer.

*We will only know the truth by performing a scientific experiment.*

*Let us try to open up the health care market. We will encourage people to be more responsible for their own health through proper health education not the existing scare tactics and medical dogma. We will restore more competitions into the healthcare market and totally open up the healing activities to everyone except with the use of dangerous drugs. Then we will know the truth and whether we have been on the wrong track all along in the past by trying to play protective mother and discourage the ignorant public from growing up.*

We should also look at the cost of implementing such ordinance.

If we are going to register hundreds and thousands of devices which can affect human physiology and therefore fallen into the definition of medical devices given by the Department of Health in the document.. Do we have enough manpower to handle all such work? How long is it going to take to properly register a medical device?

If it is going to take one and half year to register a medical device using the time for registering a vitamin as a reference, many medical devices will become obsolete before registration.

Besides, health and beauty are inseparable. Promoting optimal health and treating diseases are the two ends of the same continuum. We have allowed the medical establishment, carte blanc power to exclusivity in the treatment of diseases and we can see that they are not doing a good job in spite of the abundant resources provided by our society and now they want to also control the business of beauty industry and take the right to healthcare tools from the people and make it theirs again.

Hong Kong is faced with a serious deficit budget. One contributing factor is our ever-increasing health care budget, which is over 30 billions a year. We can easily reduce them by half if we break up the medical monopoly and do not allow only one system of medicine to be the **judge** and **juror** and **prosecutor** on all matter concerning health. We need a truly scientific way to evaluate what works and what don't work and open up the market to more competition.

Many of us have been fooled into thinking that our conventional medicine is based on science and others are not. If it is really scientifically proven, why we still cannot cure 80% of the diseases affecting us?

The truth is, besides trauma, accidents, and necessary surgery, which make up 10% of the health problem affecting modern civilized society like Hong Kong. The conventional medicine has very little else to offer to the patients.

*The Office of Technological Assessment study in 1978 and Academy of Science study in 1985 both show that only 10 - 20% of the conventional medicine has scientific basis. By allowing a largely unscientific medicine to control our health care is the root cause of our healthcare problem and why we are facing financial ruin in this area.*

Hong Kong people have been very lucky in the past because we have always enjoyed a reputation of being the *freest country to do business in* and, largely because of this, HK prosper in spite of the lack of natural resources and technology.

Sir William Blackstone, a 1765 writer of law wrote in his <Laws of England>, “*The more laws, the less justice.*”

**Is it just to introduce any more regulations that will further strengthen the monopolistic power of the medical establishment ?**

It is not difficult to see that the real motive of the Department of Health is not trying

to protect the public but to further gain control of the health care business through more legislation.

If only a small percentage of the medical devices such as Class IV, about 7%, are classified as high risk. When we should have ordinance to regulate only the high risk medical devices. Called it "*The **high risk** medical device regulation ordinance*". We should also set up a training program to certify the color laser operators regardless of their background to ensure a good standard of operation. This is in line with the "re-training program" our government is actively promoting in Hong Kong recently. It would be immoral to simply take the jobs away from the beauticians and give them to the well off doctors.

To solve the healthcare crisis, we must totally revamp our old thinking, our false assumption that "more medical protection is better for our health", and reintroduce the *Freedom of medicine as our birthright*. That is -

*"Each and every Hong Kong citizen has the right to choose and practice the form of medicine that the citizen deems most beneficial to personal health, without economic, physical, political, or verbal interference or abuse, and any institution or governmental agency assigned to protect the state of the individual's health should be empowered only to make recommendations that do not infringe or prevent the individual's right to choose and practice any form of medicine."*

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