PREAMBLE

1. Position Statement of PAO

The Philippine Academy of Ophthalmology (PAO) supports initiatives that promote quality, safety and effectiveness of health care for all Filipinos. The use of Iridology as a means to diagnose and treat disease is contrary to this goal and will not be sanctioned or condoned by the PAO.

It is the position of the PAO that:

(1) Iridology is not a valid diagnostic method as available scientific evidence shows that diagnosis through iridology is no better than chance.

(2) Employment of iridology may deprive patients of the well-established benefits attendant to other effective methods of diagnosing & treating diseases.
   a) Treatment based on inaccurate or false positive results can lead to emotional and economic burden of falsely labeling the healthy as having disease.
   b) On the other hand, a false negative analysis has the potential for harm when patients who rely on iridology fail to receive timely and effective therapy.

In view of this, the PAO advises the general public to exercise caution towards the practice of iridology as a means to diagnose and treat disease.

2. What is Iridology?

Iridology is an alternative medicine practice in which patterns, colors and other characteristics of stromal fibers of the iris are examined for information about a patient’s systemic health. Practitioners match their observations to iris charts which divide the iris into many zones believed to correspond to specific parts of the human body and they claim that this system of iris analysis can detect subconscious tensions, hereditary weaknesses, and states of health and disease or "imbalances" which can be treated with vitamins, minerals or herbs.
3. Increasing Popularity of Iridology

The practice of traditional and alternative medicine has gained strong foothold in the Philippine health delivery system considering the expensive and inaccessible conventional medical treatment that most Filipinos cannot afford. It has been established that a very large number of Filipinos are aware of the medicinal values of a myriad of plants that grow abundantly in the country. Since traditional and alternative health care is abundant and therefore readily available, its viability as a much cheaper alternative presents itself as an extremely attractive option. 1

The most popular alternative health care modality in the Philippines is iridology, where 78% of the household respondents said they had heard of it. 2 Advertisements and direct marketing have made iridology a highly visible & widely available industry to the general public, spawning a multibillion dollar business. Despite its popularity however, the prevalence rate of iridology users is not known.

In a study conducted by Pingoy, 3 81% of those surveyed resort to Complementary and Alternative Medicine (CAM). Three assumptions have been proposed to explain the increasing popularity of alternative medicine:

1) Dissatisfaction: a growing number of patients are dissatisfied with conventional medical care because it has been ineffective or has produced adverse side effects. It is likewise regarded as too technologically-oriented, expensive and impersonal. 2) Need for personal control: alternative treatment appears to be less authoritarian and to provide patients more personal autonomy and control over their health care decisions. 3) Philosophical congruence: Alternative therapies are attractive because they are seen to be more compatible with patients' values and spiritual beliefs regarding the nature of health and illness. The term 'natural' is always perceived as safe and harmless.

4. Supporting Evidence

For Position Statement (1)
Iridology is not a valid diagnostic method as available scientific evidence shows that diagnosis through iridology is no better than chance.

- Iridologists claim that they are able to diagnose medical conditions through iris analysis. Therefore it is relevant to ask whether this method is valid. In order to evaluate the diagnostic validity of iridology, a systematic and exhaustive search was conducted using the following databases: Medline and the Cochrane Central Register of Controlled Trials. To establish the completeness of our searches and to identify and retrieve unpublished material, authors and experts were contacted. Two independent literature searches were performed to identify all blinded tests. A total of 150 titles and/or abstracts on Iridology were identified. Most of the available data were either retrospective or uncontrolled. Only three articles were found useful and valid.

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2. 2003 National Demographic Health Survey
Of these three, the best available evidence to date is by Ernst E., Iridology: A Systematic Review, Forsch Komplementarmed 1999;6:7-9. The study’s objective was to systematically review all validity tests of iridology as a diagnostic tool. The study design included case-control, evaluator-blind or double-blind studies of diagnostic validity. The conduct of search assumed no language restriction. The results showed that iridology was neither selective nor specific, and the likelihood of correct detection was statistically no better than chance. The conclusion drawn from this review confirmed that the validity of iridology as a diagnostic tool is not supported by scientific evaluations so that patients and therapists should be discouraged from using this method.

A literature appraisal done by the committee on Evidence-based Ophthalmology showed that the Systematic review by Ernst had the following strengths: the conduct of search was proper, the study design selected was correct, inclusion of controlled evaluator-blinded studies was appropriate, validity aspects were assessed and data were extracted in pre-defined, standardized fashion. However, the over-all rating was affected by the inadequate sample size & methodology rigor of the individual studies. Just the same, the study quality of this systematic review was rated “Fair,” indicating that even as the number, quality and consistency of the studies had considerable limitations, evidence was sufficient to determine the effects on health outcomes.

Therefore, the best available evidence has shown that iridology is not valid and since the likelihood of a successful outcome is impossible to predict, patients should be aware of its associated risks.

For Position Statement (2)
Employment of iridology may deprive patients of the well-established benefits attendant to other effective methods of diagnosing & treating diseases.

a) Treatment based on inaccurate or false positive results can lead to emotional and economic burden of falsely labeling the healthy as having disease.

b) On the other hand, a false negative analysis has the potential for harm when patients who rely on iridology fail to receive timely and effective therapy.

The incidence of harm associated with iridology is not known. But serious complications have been reported and documented to the PAO. Harm caused by iridology may be summarized as follows:

1) DIRECT HARM

- Therapy based on false positive results may cause direct harm when falsely labeling the healthy as sick.

- The remedies of CAM are usually masked under the label of ‘dietary supplements.’ According to the FDA, dietary supplements in today’s market include: vitamins, minerals, herbals, botanicals, amino acids, and enzymes. Dietary supplements are regulated differently than prescription and over-the-counter drug products. While the FDA monitors adverse effects after dietary supplement products are on the market,
newly marketed dietary supplements are not subject to pre-market approval or a specific post-market surveillance period. The burden of proof rests on the FDA to show that a product is unsafe. Manufacturers are not required to submit substantiation of benefit data to the FDA.  

- Philippine BFAD (FDA counterpart) is responsible for the registration and issuance of Certificates of Registration of dietary supplements that pass set standards and requirements. The BFAD however, has warned the public that dietary supplements sold in the country are oftentimes imported and without necessarily having the papers of substantiation. Claims that they are US FDA approved or Japan FDA approved do not ensure that these products are safe, potent or effective. In fact, some dietary supplements have been reported to contain mercury, lead, arsenic or steroids in harmful amounts.  

- Reports on harm have prompted the US FDA in 2005 to implement major regulatory initiatives to assure the safety of dietary supplements.  

2) INDIRECT HARM (Harm of Omission)  
- Incorrect, delayed or missed diagnosis may deprive the sick of timely & effective therapy. A more serious cause for concern is the false negative diagnosis, when patients who are sick are given a clean bill of health.  
- Cases of glaucoma, Vogt-Koyanagi-Harada syndrome, Diabetic Retinopathy and Age Related Macular Degeneration that have led to irreversible blindness have been reported to the PAO.  

3) ECONOMIC HARM  
- It has been reported that more money is spent by patients in iridology than in conventional medical consult. The unnecessary loss of resources imposes a heavy economic burden on the vulnerable and disadvantaged sectors of society.  

4) SOCIETAL HARM  
- The impact of groups advocating mistrust of established institutions, frequently supported by the media, legislative bodies, etc., distorts progress by altering expenditure of funds, delaying public health measures and formation of laws.  

5. Current Regulatory Status  
In 1997, then Senator Juan Flavier passed into law Republic Act No. 8423 (R.A. 8423), otherwise known as the Traditional and Alternative Medicine Act (TAMA). The approval of this act gave rise to the creation of the Philippine Institute of Traditional and Alternative Health Care (PITAHC), a government corporation authorized to support the integration of traditional medicine into the national health care system. This act makes it known to the public that the Philippine
government promotes and endorses traditional and alternative medicine in general and technically speaking, legitimizes the practice of iridology in the country. The Philippines is the only country after Russia, where the practice of Iridology is fully legitimate.\textsuperscript{10}

PITAHC is mandated by law to promote and advocate the use of traditional, alternative, preventive and curative health care modalities that have been proven safe, effective, cost-effective and consistent with government standards on medical practice. The growing popularity of iridology vis-a-vis the growing number of cases of harm has prompted leading health authorities to look into the safety, effectiveness and the regulation of the practice. In 2002, the PITAHC summoned representatives from the Department of Health (DOH), the Philippine Medical Association (PMA) and lead iridologists to meet amidst continuing controversy. The stakeholders agreed then to resolve emerging issues by 1) creating a research committee who shall be tasked to gather and validate data, 2) formulating a Code of Ethics on Ads & self-regulatory function, and 3) formulating competency standard for iridologists. To better ensure the safety of consumers, the DOH suggested that a licensed medical doctor should be allowed to be within range, if not directly supervise the iridologist.\textsuperscript{11}

To this writing, PITAHC continues to recognize the legitimacy of iridology as an alternative tool for assessing health status of certain organ system/s through the iris.

**6. PAO Response to Issues**

The growing public awareness on iridology through sustained advertising is generating a rapid increase in public interest and exerting a powerful influence on the medical profession. It is not a question of whether to address these issues, but of how to respond to these challenges.

1) **ON THE LEGITIMIZATION OF IRIDOLOGY**

- Licensure and registration schemes, however well intentioned, encourage questionable health practices, rather than limit them.
- Legitimizing a practice promotes public acceptance and implies that the government assures the validity of the claims made by the licensed profession.\textsuperscript{12}
- Should a practice be accredited when there is no evidence of benefit and a potential for harm? The establishment of an evidence-base for safety & effectiveness must come before, and not after, the regulation and/or integration of iridology into national healthcare.

2) **ON PROOF FOR EFFECTIVENESS/SAFETY**

- Best available evidence has proven that Iridology is not useful, and in fact, potentially harmful.

The endorsement of iridology thru ads is contrary to the goals of regulatory authorities who are duty-bound to protect the public from harm.

3) **ON RECOMMENDING FOOD SUPPLEMENTS**

- The peddling of unregulated dietary supplements and herbal preparations by iridology practitioners who may have financial incentives exposes the vulnerable public to personal and economic harm.

- Unfortunately, the BFAD has no adequate resources to conduct inspections & research on these products.\textsuperscript{13}

\textsuperscript{10} http://thenhf.com/articles_99.htm Leonard Mehlmauer, ND

“ Iridology is Legal in the Philippines!”

National Health Federation. Jan 2005

\textsuperscript{11} Consultative Meeting on Iridology. PITAHC Conference rm.

Sta. Cruz, Mla. May 6, 2002

\textsuperscript{12} Minority Report of the Special Commission on Complementary and Medical Practitioners: A report to the Legislature. Jan. 2002

\textsuperscript{13} Pingoy. CAM Use among Patients at the Cancer Institute.

UPPGH Phil J. Int Med 42: 159-171 Jul-Aug 2004
4) ON SUPERVISION OF IRIDOLOGISTS BY MEDICAL DOCTORS

- The medical profession is bound by a code of ethics that prohibits medical doctors from engaging in or assisting in a healthcare modality that has no scientific basis and has a potential for harm, may deceive the patient by giving false hope, or which may cause the patient to delay seeking proper care. The supervision of iridologists by licensed physicians is therefore lamentable.

7. Recommendations

1) TO PHYSICIANS:
- The best way to help citizens make sense of non-standard health claims, while respecting freedom of choice, is through education. Offer patients reliable information. Stay current about the benefits & risks and best available evidence.

- Encourage discussion for improving the doctor-patient relationship and for shared decision-making.

- Report incidence of harm or adverse events to regulatory health authorities such as the Department of Health or to national medical associations such as the Philippine Medical Association.

- Inhibit oneself from the business of promoting iridology even if it occurs as a result of well-intentioned efforts to provide regulation.

2) TO CONSUMERS:
- Beware of misleading advertising claims made on behalf of iridology. Because laws are political tools and not scientific ones, the political process may respond to pressures independent of scientific evidence.

- Evidence shows that iridology diagnoses and relieves symptoms with the frequency of placebo. It may be harmful.

- Nonetheless, consumers wishing to try iridology should discuss their situation with a knowledgeable physician who has no commercial interest.

3) TO LEGISLATORS:
- The legitimacy of Iridology in the Philippines poses a threat to public health and should therefore be abolished.

- Advertisements that promote the unsubstantiated claims of iridology are misleading, inaccurate and have great potential to do harm and should therefore not be allowed.

4) TO IRIDOLOGISTS:
- Make available information that allows consumers to make informed decisions regarding the safety & risks associated with services and products.

- Aim to have a clear understanding of the principles of healthcare and evidence-based medicine with the same rigor as is required of conventional medicine. Herbal preparations should be used with caution and recommended only on the advice of a practitioner familiar with conventional pharmacology.

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14 American Medical Association Code of Medical Ethics
8. CONCLUSION

Let it be known that the Philippine Academy of Ophthalmology (PAO) is not against complementary and alternative medicine practices that have been proven effective and safe. While the PAO supports the integration of modalities that are scientifically validated by stringent research into the national health care delivery system, it is apparent from the evidence that iridology is not one of them.

It is our ardent hope that this stand can inspire coalitions and not engender divisiveness among stakeholders. Where public healthcare is concerned, the common good calls for advocacy to yield to scientifically sound evidence of safety and efficacy.