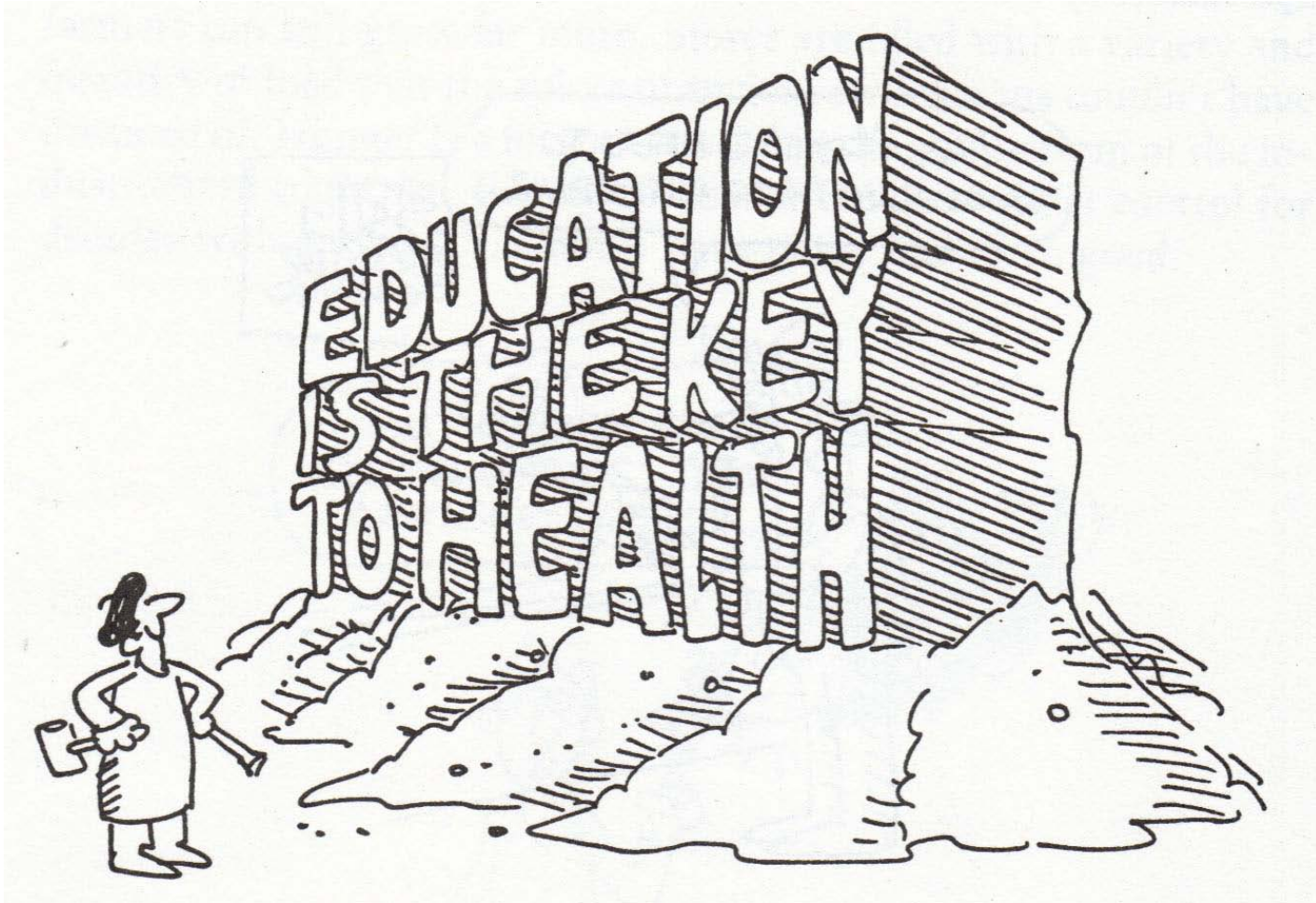


# Electrifying SCIO's



Dr John Kelsey PhD, ND IMUNE  
Vice Chancellor

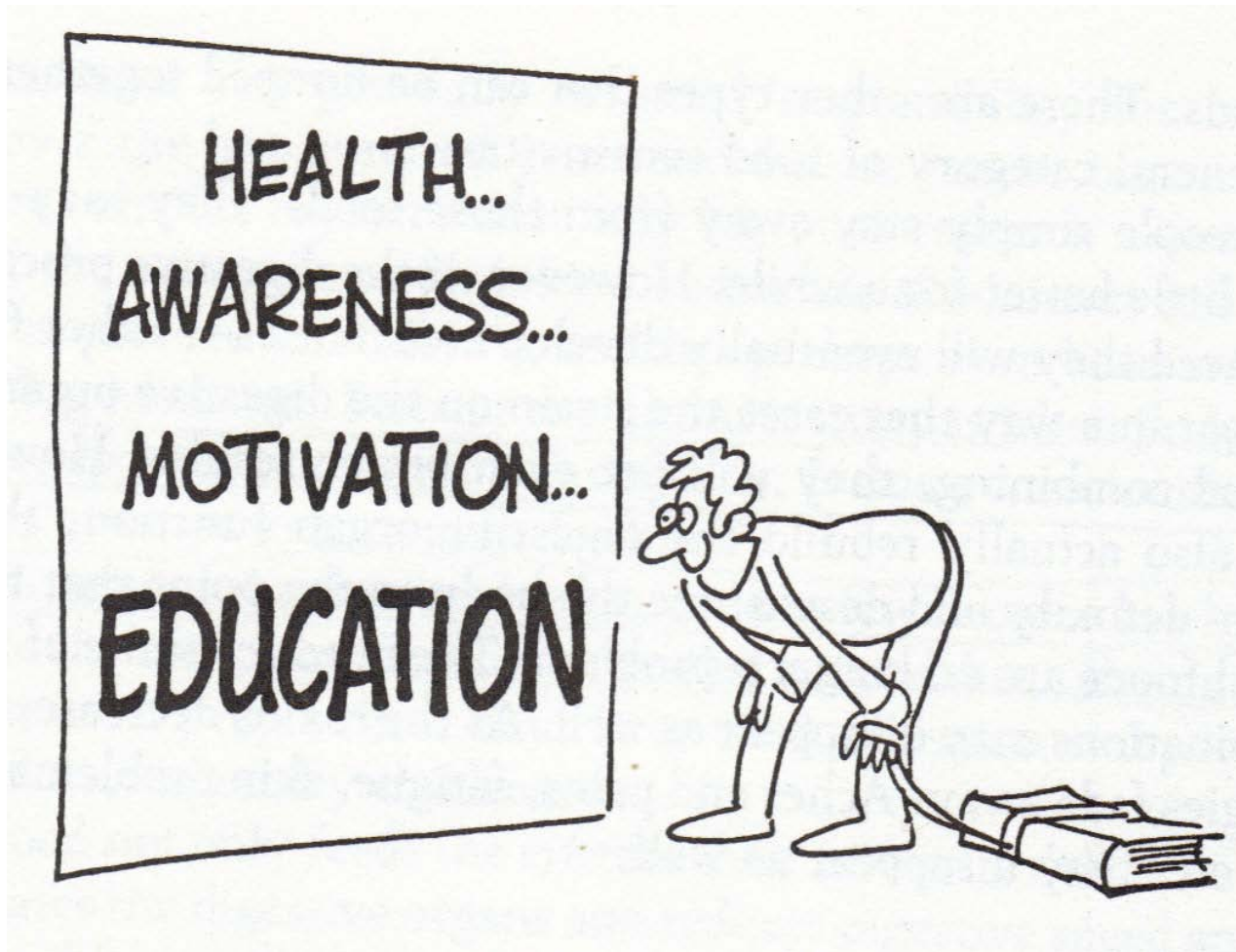
# Education- Practitioner & Client



Dr John Kelsey PhD, ND IMUNE  
Vice Chancellor

# Clients- need education!

## Practitioners need to demonstrate education



# The Typical Client



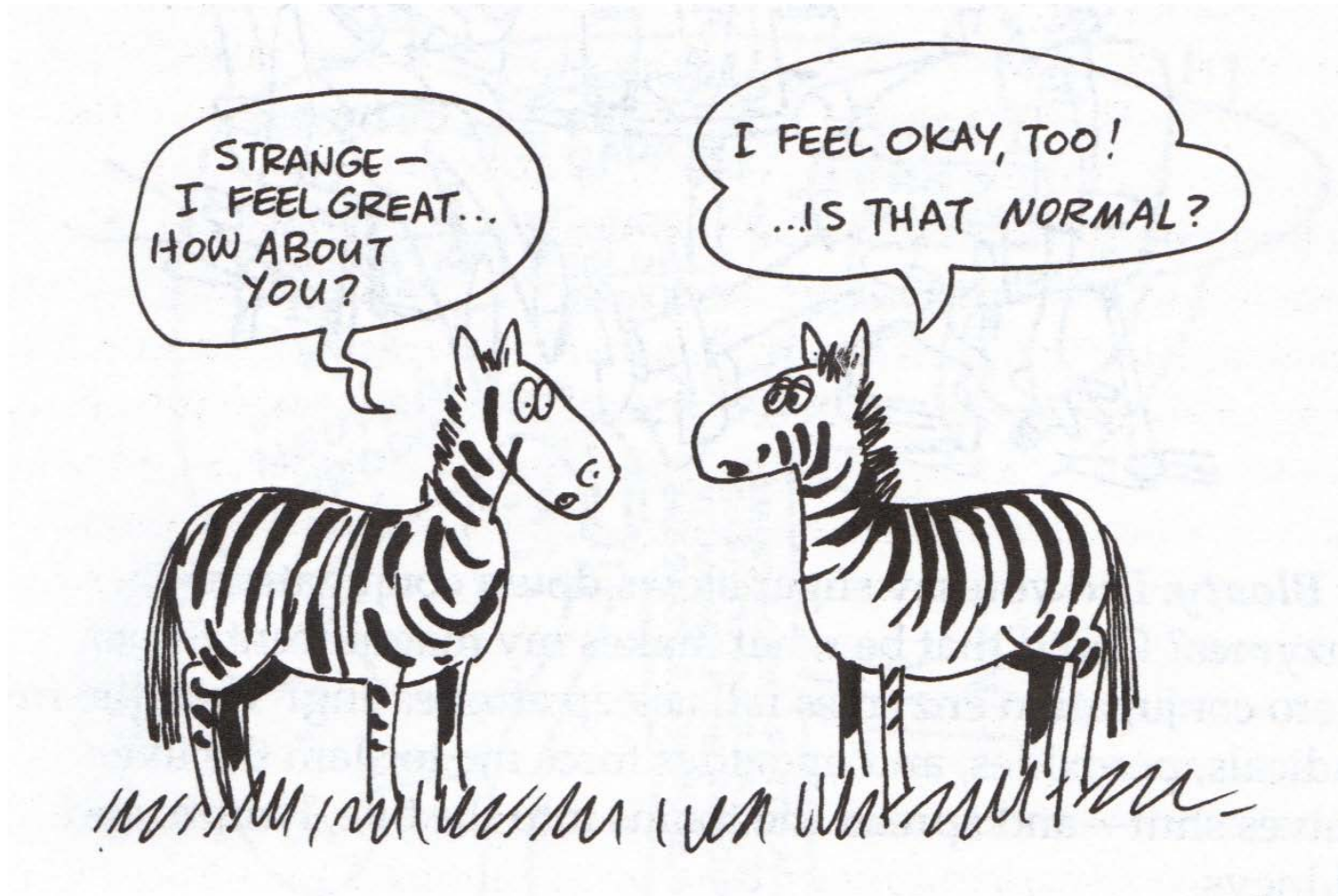
Dr John Kelsey PhD, ND IMUNE  
Vice Chancellor

# The Early Client- who knows!



Dr John Kelsey PhD, ND IMUNE  
Vice Chancellor

# The “Great” Client



***Positive proof of global warming.***



**18th  
Century**

**1900**

**1950**

**1970**

**1980**

**1990**

**2006**

**And..the public likes what we have to offer**

***With thanks to Dr. James Oschman***

Dr. John Kelsey PhD, ND IMCNE  
Vice Chancellor

# Positive Proof of Global “Regulator” Cooling

## FDA USA actions

# Effective Clinical Practice-The triad

This is 50%		This is 50%
Client	Practitioner	Device
Desire to change	Knowledge	Information- hints
Power to change	Ability to corroborate	Internal corroboration
Commitment	Empowerment	Treatments
Education	Technically competent	Response tracking
Tracking	Boundaries- referrals	

# SCIO Legal use

Legal	Illegal
Biofeedback	Diagnoses
Stress assessment support	Treatment, therapy, cure - Symptoms or disease!
Stress reduction support	
Relaxation- muscle re-education	

# It's a new world

- The situation in the USA makes it  
**EXTREMELY IMPORTANT THAT WE  
WORK TOTALLY WITHIN THE LEAGL  
FRAMEWORK**
- the issues that created the USA problem  
were **misrepresentation**

# SCIO Practitioners Role

SCIO practitioners work with

Stress

using

Biofeedback

That is it- **TOTALLY** and **ABSOLUTELY**

# Words are important

**“Train” instead of “Treat”.** (Only the licensed fields “treat”, biofeedback signals “train” responses.)

**“Programs” in place of “Therapies”.** (Some States interpret “therapy” as referring only to standard medical, psychological or other licensed “therapies”, and those in the “certified” fields avoid the use of this word.)

**“Client” instead of “Patient”.** (Only the licensed fields see “patients”.)

**“Educate” instead of “Prescribe”.** Because lifestyle changes are a personal choice, clients make their own decisions based on education

# Stress- a liberation

(It is NOT a restriction)

- ✓ **A stress focused practice is liberation.**
- ✓ **It is not a limitation.**
- ✓ **Stress is a major element in the development of ill health.**

# SO STRESS IS

✓ VERY BROAD

✓ ALL YOU NEED TO REFER TO  
*PROVIDED*

YOU EXPLAIN IT WELL

✓ PROPOSED BY MANY RECOGNISED HEALTH  
BOSIES AS A PRIMARY FACTORE IN  
ILLNESSES

(see IMUNE Stress 101)

# Lets start with the probable climate for legal use

There are some key requirements, led by USA events, that would have happened sooner or later

These requirements are VERY, VERY  
IMPORTANT- following the will  
help device based medicine survive  
and

Ensure that you can continue to see and help  
clients

# Key sound operation points

- **Be qualified-**
- If you are a health professional- have as a minimum a training certificate (& check what your qualification body allows you to use)
- If you just work with Biofeedback- have a Qualification Certificate
- Be Insured

# Why be qualified?

1. It is insurance- if you can demonstrate that you have done a competent training with an assessment that will stand up to good scrutiny- you have protection if something goes wrong

AND

2. When (as it will) legislation comes in there is normally grandfathering- so if you have been in practice for 2 years and have a solid qualification it is likely that you will be accepted into a regulated qualification.

# The Probable Future Situation

The FDA (USA) is probably setting the scene in requirements- the following applies to the USA and it is known that the FDA is in touch with other agencies and there has been contact in many countries- all being successfully dealt with.

The FDA perspective is a sensible place to start

# **The Probable Future Situation**

## ***Biofeedback Practice Only***

### **Existing users- USA**

1. Mandatory- Register
2. Recommended- a sensible qualification

### **New Users- USA**

1. Have a sensible qualification
2. For professional use you can only buy on prescription from a licensed health care professional- who will probably have their own requirements to ensure that you are a safe user.

# Device Registered Purpose

1. It is a Biofeedback device- that is it in total!
2. It is for stress, relaxation, muscle education- that is it in total

Stress includes “assessment” and “support”

IT IS NOT FOR

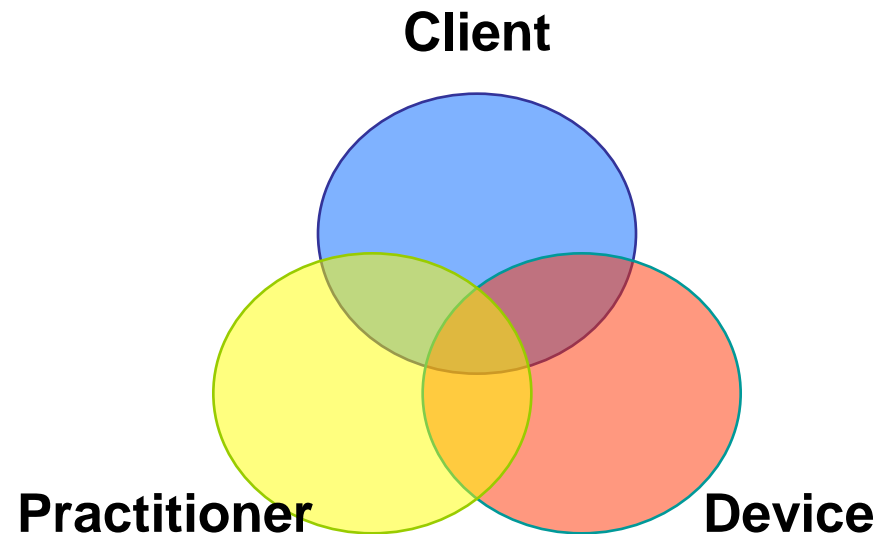
- diagnosis, cure, treatment, symptoms  
*and possibly even therapy*

# Designers Intent

- Prof. Nelson has continually stated that the device is a tool- it is not a health system.

Practitioners use tools as part of the wellness process- NOT as the totality of the process

And that at least 50% of the solution is lifestyle



## FDA Registration Information

- “The sole purpose of the EPFX system is to provide the patient with insight into the subtle changes in the temperature, skin resistance (sweat), and muscle voltage. No claims are made by the Eclosion Corporation for the ability of biofeedback to treat any medical condition. *Even claims for stress reduction are not without critics or criticism.*

# FDA Registration Information

- What we do claim is that the system measures subtle body electric and thermal changes in the patient and feeds them back to the patient via audio or video signals. These signals give the patient awareness of the electrical and thermal changes and thus allows them to better **relax.**”
- *Relaxation shows lower “stress”?*
- *When relaxed natural processes work better?*

# Claims

Inappropriate claims have exacerbated the situation with the device-

“Claims outside of the original EPFX indications for use, by a therapist are inappropriate and need to be responded to.”

**THERE IS ACTUALLY NO NEED TO GO BEYOND STRESS AS STRESS IS SO STRONGLY RECOGNISED AS SUCH A HIGH CAUSAL FACTOR TO UN-WELLNESS**

# Solutions

1. Understand Stress
2. Understand Biofeedback
3. Understand Terminology
4. Understand how to dialogue with clients  
( Client centered approach)
5. Get a qualification (IMUNE is the QX supported body)
6. Use an Informed Consent-be Insured

# Training for the “new game”

- Training- should be hands on
- IMUNE Support Information CD
  - Stress 101 (Text and lecture)
  - Biofeedback 101 (Text and lecture)
  - Clinical Practice 101 (Terms)
  - Lifestyle 101- client education handouts
  - Client Interaction Skills 102
  - Home Review Question Sets
  - Home Review Case Learning Worksheets

# Biofeedback Qualification

## *For Biofeedback Practice Only*

### For Biofeedback Practice Only

- USA/Canada regulation requires qualification-  
IMUNE or NTCB
- Other countries require at least a training  
certificate
- >> many will probably require more formal  
certification and will introduce regulation
- >>there is no established Biofeedback  
organisation in many countries or relevant to  
advanced biofeedback
- >>>>IMUNE is for this.

# Biofeedback Qualification

## - *for health professionals*

- You may have more scope of practice
- You may have Professional Body Restrictions
- You still CANNOT say the device is other than biofeedback/stress OR make diagnostic interpretations from it alone (it just is not designed for that!) or talk about disease cure or treatment using the device- the device is just for stress!

# Biofeedback Qualification

## - *for health professionals*

If you are practicing as a licensed health care professional you can use all your skills

- You can take the device information as part of the information that you do use with other information to make a diagnosis (if you are legally entitled to diagnose)
- You can also use other legal skills in treatments

IF you are functioning as a biofeedback professional **ONLY** then the Biofeedback rules apply.

# IMUNE Biofeedback Qualifications

**Student-** this is specifically designed for USA Insurance

**Practitioner-** this is designed for *general* stress practice

**Therapist-** this is designed for deeper and more specific stresses

# IMUNE Advanced Qualifications

- For Practitioners and therapists we have approved for Insurance in the USA the following additional categories
  - **Nutritional Coaching**
  - **Lifestyle coaching**

***BECAUSE-***

-that is what you also do (or should be doing!)

# IMUNE requirements-

## *for existing users*

- In general (depending on length of use and training)
- Usually purchase before 1 Jan 2007
  - One general stress case study, 1 client x 3 visits
  - One specific stress focus study, 1 client x 3 visits
  - % home-online exams (stress, biofeedback, intelligent device use questions)
- Cost      £120/\$200/€140
- This provides an IMUNE Cert and for USA/Canada an NEHCB Cert.

# IMUNE Requirements

## *for New users- Practitioner*

FOUNDATIONAL*	Anatomy, Physiology, Pathophysiology 101*
TECHNICAL STUDY	Biofeedback Principles 101 Clinical Practice 101* Device Operation Skills101 Device Application Skills 101 Stress 101 Lifestyle 101 Treatment Responses 101
CLINICAL HOURS	150 hours (3 months min. in practice) with device
CLASS TUITION ASSESSMENT	14 hours minimum
CASE STUDIES	Case Studies 3 clients, 1 session each
ON LINE EXAMS	

# IMUNE Requirements

## *for New users- Therapist*

FOUNDATIONAL*	Anatomy, Physiology, Pathophysiology 102*
TECHNICAL STUDY	Client Interactions Skills 102 * Device Operation Skills 102 Device Application Skills 102
CLINICAL HOURS	+250 (6 months min. in practice.) (total 400 clinical hours) with device
CLASS TUITION ASSESSMENT	28 hours minimum
CASE STUDIES	Case study analysis Client Interaction skills video Case Studies 3 clients, 3 sessions each
ON LINE EXAMS	

# IMUNE Insurance

## USA

- Student \$125
- Professional \$290

See [www.nehcboard.com](http://www.nehcboard.com)  
(Downloads>Insurance)

# Requirements

- Use correct terminology> stress, biofeedback
- Do NOT make claims for the device outside its registration
- Existing users in the USA are to register with the FDA- see R Lloyd in Eclosion for details

# Recommendations

Be a professional Biofeedback Practitioner

- Do stress reduction & Biofeedback- if this is all you do then do not include other “terminology”
- Have a qualification in Biofeedback-
- Use an informed consent