How scientists and society should respond to anti-ageing

Tony Warnes¹ and Mone Spindler²

1. Sheffield Institute for Studies on Ageing, University of Sheffield, UK
2. Freie Universität Berlin, Germany
Main topics

1. The great diversity of anti-ageing
2. A case study: predictive gene testing
3. The concerns raised by anti-ageing
4. The weak scrutiny and regulation of anti-ageing claims
5. What could and should be done – by biologists, other academics and journalists – to raise the good and reduce the harm of anti-ageing
The diversity of anti-ageing
What is new about anti-ageing?

Relatively high level of societal meaning:

- New marketing strategy and new market
- New medical sub-discipline: Anti-ageing medicine
- New genre of self-help literature

→ “Anti-ageing movement” (e.g. Binstock 2003)
Current and future anti-ageing methods:

<table>
<thead>
<tr>
<th>Strategies against ageing</th>
<th>Symptoms of ageing</th>
<th>Ageing processes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hiding</td>
<td>Compensating</td>
<td>Preventing</td>
</tr>
<tr>
<td>Preventing</td>
<td>Slowing</td>
<td>Stopping</td>
</tr>
<tr>
<td>Slowing</td>
<td>Reversing</td>
<td></td>
</tr>
</tbody>
</table>

### Lifestyle techniques
- Healthy lifestyle
- Mental programmes
- Stress reduction
- Sexual activity
- **Nutrition**
- **Exercise**

### (Bio)Medical technologies
- **Food supplements**
- **Hormone therapy**
- Medication
- Medical check-ups

### Aesthetic dermatology
- **Cosmetics**
- **Plastic surgery**
- Predictive gene tests
- Stem cell banks

### Future Anti-Ageing methods:
- (Re)Producing tissues
- Manipulating age-related genes
- Nanotechnological enhancements
Case study: Predictive gene tests
What are predictive gene tests?

- **Diagnostic gene tests:**
  Testing gene variation responsible for monogenetic diseases

- **Predictive gene tests:**
  - Testing gene variations associated with polygenetic, multifactorial diseases
  - Predicting a person’s susceptibility for developing these diseases in future
  - Setting up individual prevention measures

→ **Clinical and health political focus:** breast cancer, ovarian cancer
Predictive gene tests in anti-ageing medicine

Example: Apolipoprotein E (APO E)

Function within the cell:

- Removal of LDL-cholesterol out of cell membranes
  → That keeps cell membranes flexible
- Flexible cell membranes ensure exchange of nutrients
- Reduced exchange of nutrients: reactions in cells, cell death

(see D9:52p, own translation)

“… [In the case of brain cells] this leads to the extinction of entire neurone populations, mainly in one region of the brain, the hippocampus. … This results in the loss of memory up to dementia and Alzheimer’s disease.”

(D9:53, own translation)
Major variations of APO E: APO E2, APO E3, APO E4

- **Difference:** Activity in keeping cell membranes flexible
- **Impact on susceptibility for diseases:**

‘The connection of cardiovascular diseases, cholesterol level and Apo E Type [...]’

(D6:20, own translation)
Preventive measures for carriers of APO E4:

1. “Genetic lifestyle” (D7:3)
   - Keeping cholesterol level low
   - 4-5 times per week 30 mins stamina and power training
   - Reduction of weight to BMI < 24
   - Strictly avoiding nicotine
   - Exercising concentration and reasoning
   - Changing your daily newspaper, become open for other opinions!

2. “Nutrigenomics” (D9:113pp)
   - Little animal fats
   - Much sea fish
   - Green and yellow garden vegetables, artichokes
   - Olive oil
   - Raw salads
   - Wholemeal products
   - Mediterranean diet
   - Food with a low glycaemic index
   - Regularly 1 glass of red wine, every second evening
   - Food supplements
   - Daily omega-3-fat acids
   - Isoflavones like soya
   - Plenty of antioxidants
   - Vitamin B6, B12, folic acid
   - Daily 1 tablet zinc

3. Medical check-ups and medication
   - “Control and regulation of homocysteine level (target <10)
   - Regular medical control of cholesterol and triglyceride level, auto-antibodies against oxidized LDL-cholesterol, liver performance and blood quality
   - Eventually medication with statines […], pregnenolone […] and co-enzyme Q10 […]”

(D9:60, own translation)
The diversity of concerns
Concerns about predictive gene tests:

1. **Scientific concerns:**
   - Validity of prediction of susceptibility, e.g.:
     - Testing too few gene variations
     - Neglecting non-genetic factors
     - Lack of statistically significant studies on impact of gene variations
   - Effectiveness of prevention measures

2. **Medical concerns:**
   - Possibly unnecessary or omitted prevention
   - Possible new health risks due to prevention measures

3. **Social concerns:**
   - “Genetic discrimination”
   - Individualisation of risk management
Broader concerns about anti-ageing:

1. **Scientific concerns:**
   - Are the claims about causes good science?
   - Are the claims about interventions evidence-based?

2. **Medical concerns:**
   - Are the interventions effective?
   - Will anti-ageing distort medical R&D priorities?

3. **Societal concerns:**
   - Does it support negative stereotypes of old age?
   - Does it create inequalities?
   - How can lay persons evaluate anti-ageing claims?
The muddle of scrutiny and regulation
Problems of anti-ageing marketing

- There are unclear lines between (a) clearly fraudulent claims, (b) hyperbolic and duplicitous marketing messages, and (c) ‘strong science’ messages
- Some products and therapies cause harm directly, and some are ineffective (or not shown to be effective), so generate false hopes
- Many are very expensive – opportunity costs and impoverishing
- The regulation of the claims is ineffective
The principal forms of monitoring and regulation

<table>
<thead>
<tr>
<th></th>
<th>Drug licensing</th>
<th>Regulation of clinical practice</th>
<th>Trade regulation (anti-trust and price fixing)</th>
<th>Truth in advertising</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ante</strong></td>
<td><strong>STRONG</strong></td>
<td>Professional self-regulation.</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Licences to practise or market</td>
<td>Evidence-based licensing before marketing: product is effective and does no harm.</td>
<td>Credentials to practise for individuals and specialties</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Penalties for mal-practice</td>
<td></td>
<td></td>
<td></td>
<td>WEAK</td>
</tr>
</tbody>
</table>
FDA regulates:

**Food**  Foodborne Illness, Nutrition, Dietary Supplements...

**Drugs**  Prescription, Over-the-Counter, Generic...

**Medical Devices**  Pacemakers, Contact Lenses, Hearing Aids...

**Biologics**  Vaccines, Blood Products...

**Animal Feed and Drugs**  Livestock, Pets...

**Cosmetics**  Safety, Labeling...

**Radiation-Emitting Products**  Cell Phones, Lasers, Microwaves...

**Combination Products**
SEP 26 2005

WARNING LETTER

President, Hydroderm, Beverly Hills, California

This letter refers to your firm's marketing of the Hydroderm brand products Body Shape Cellulite Toning Lotion, Fast-Acting Wrinkle Remover, Anti-Aging Eye Complex, and Intense Oil-Free Facial Moisturizer.

The FDA has reviewed your Internet web site ... and the literature that accompanies this product when shipped to customers. This review shows serious violations of the Federal Food, Drug, and Cosmetic Act in the product labeling.

Five pages detail the claims that are objected to, including:

Anti-Aging Eye Complex is a unique serum that diminishes the effects of aging in the delicate skin around your eyes.
MHRA is responsible for, among other things, drug licensing and regulation in the UK.

UK law defines a medicine as ... used to prevent, treat or diagnose disease ... does not include such things as contact lens fluids, food supplements and cosmetics. ...

Claims that a product “supports” health or a healthy lifestyle is not usually considered as medicinal.

No powers to review or regulate marketing of life style or dietetic therapies
Report on Miracle Health Cures

Unscrupulous sellers of medical products promise 'miracles’ … pills, lotions, creams that supposedly cure baldness, arthritis, rheumatism, heart disease, multiple sclerosis, Parkinson's disease, cancer, obesity, impotency and other ailments … it is unlikely that they have been properly tested … some might be dangerous.

Action -- purely advisory, for example …

Don't believe claims that a 'miracle' product will effectively treat illnesses. Don't accept testimonials or case histories from 'satisfied customers'. Don't believe claims that the medical establishment has hidden a 'scientific breakthrough'.
The ASA is the independent body set up by the advertising industry to police the rules laid down in the advertising codes.

EASA was founded in 1992 and brings together national advertising self-regulatory organisations that represent the advertising industry in Europe. It exists to help ensure that cross-border complaints are resolved as quickly and effectively as possible.
Two types of problematic claims

Type 1: An ‘apple a day keeps the doctor away’, *i.e.* a generalised health promotion message based on experience or ‘folklore’ not science.

Most consumers can recognise such messages, and evaluate ‘with a pinch of salt’

Type 2: Science shows that ‘a’ causes ‘b’ ... and that ‘c’, a product or therapy, prevents, delays or reverses ‘b’

*i.e.* draws legitimation from science: how can the lay consumer evaluate such claims?
FDA threatens to raid cherry orchards

http://www.lef.org/magazine/mag2006/mar2006_awsi_01.htm

As Americans struggle to eat a healthier diet, the FDA has taken draconian steps to suppress information about foods that reduce disease risk. (It) has issued an edict that precludes cherry companies from posting scientific data on their websites. This censorship of published peer-reviewed studies denies consumers access to information to make wider food choices.
The papers refer to the ‘natural medicines found in cherries, such as the anthocyanins that reduce inflammation for arthritis sufferers’.*

‘If Americans knew the true power of cherries to reduce inflammation, the sales of anti-inflammatory drugs might plummet, and the criminal drug pushers who run organised medicine today can’t allow that to happen. Censorship ... Is used to keep the American people ignorant and, therefore, controlled’.

* The cherry products are not intended to diagnose, treat, cure or prevent any disease
The battle of ideas

Pro-regulation

Product and therapy claims should be sound: stronger verification and regulation required

Anti-regulation

Regulation is ‘censorship of health messages’, it perpetuates ill-health and restrains trade
Salt Lake City, Utah, December 1, 2005 –

Today, 3,000 health freedom activists ... began a campaign to urge sponsorship of the *Health Freedom Protection Act, HR 4282* ... part of a national grass-roots campaign sponsored by the *Coalition to End FDA and FTC Censorship*. The Coalition ... is backed by 56 food and dietary supplement companies, advertising companies, physicians, and public interest groups. ... The bill would end FDA and FTC censorship of health information.
Conclusions on regulation

- Multiple regulatory mechanisms and agencies have grown up for historical reasons.
- None have adequate powers or, in practice, sufficient scientific capacity to regulate and verify non-drug, non-surgical, anti-ageing claims.
- Many anti-ageing claims thrive because they receive no ‘peer’ or external scrutiny.
- But ... many voices and vested interests call for less regulation than for more.
The tasks

To define what constitutes a health or longevity benefit claim that should be evidence-based and verified.

Scientists and their professional associations need to engage with and support advertising standards, drugs-licensing, trade regulation and professional (including clinicians’) agencies and organisations.

Social impact advice should be taken from consumer and older people’s organisations, ethicists, gerontologists, and media professionals.
Recommendations

- Biologists, clinicians and gerontologists in Europe should be more active in raising the public’s and the media’s understanding of the diversity and capabilities (over specified time scales) of anti-ageing medicine products and therapies.

- There should be concerted engagement between biologists of ageing and regulatory bodies, including those of anti-ageing medicine.

- Government, ‘industry’ and the believers in anti-ageing therapies must be persuaded of the need for an extension of regulation, but there will be great resistance.
How scientists and society should respond to anti-ageing

Tony Warnes¹ and Mone Spindler²

¹. Sheffield Institute for Studies on Ageing, University of Sheffield, UK
². Freie Universität Berlin, Germany