

Ethical Reflections of an Epidemiologist: Whither Humanity?

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*School of Public Health, University of Cape Town,
South Africa - April 11, 2013*

Lecture Outline

INTRODUCTION:

Terms used, and the framework for professional ethics as normative obligations for individuals and for the profession

THREE CASE STUDIES:

- ▶ **Artificial Sweetener-Aspartame
Brigham & Women's Hospital – Harvard University**
- ▶ **Current challenges in preparation for the Rotterdam Convention relating to the listing of Chrysotile Asbestos as a hazardous substance – Canada, now Russia and IARC**
- ▶ **Alberta Tar Sands - CIHR-IPPH Ethics Case Book**

METHODS, VALUES, AND ETHICS:

- **Ethically designed research**
- **Determining causality and ethics - tying the two together**

SUMMARY POINTS AND CONCLUSIONS

Epidemiology

The study of the distribution and determinants of disease in populations and its application to the control of health problems

– *Our focus is on preventing harms to populations (morbidity; premature mortality; and well-being)*

- ▶ *Primordial prevention* ... *upstream policy interventions*
“the causes of the causes”
- ▶ *Primary prevention* ... *avoid exposure*
- ▶ *Secondary prevention* ... *early detection*
- ▶ *Tertiary prevention* ... *restore best quality possible*

Policy Relevance

Epidemiology is the science that is basic to rational (evidence-based) public health policy formulation

→ We bridge toxicologically demonstrated evidence with policy by examining the human evidence for what is found in research on animals

Epidemiology

Our job is to **inform policy with a view to reducing harms by preventing disease and premature mortality at the community level**

▶ *How can we more effectively deliver on this obligation when colleagues are tempted by forces that cause them to no longer work to protect the public interest by respecting science's need for impartiality?*

Whither Humanity?

- ▶ *To where is the human enterprise headed?*

and/or

- ▶ *Where is our humanity in terms of its integrity/decency/values/morality when professionals ‘sell their souls to the devil’, ... **and, what to do about it?***

Narrative Phrases That Frame Our Professional Lives

- ▶ Science as the pursuit of truth
- ▶ Applied science in the public interest
- ▶ **The perpetuation of myths**
- ▶ Ideologically driven policy: not to be confused by 'science' (*Don't confuse me with the facts!*)

What are some of the tensions among these different frames?

Political and/or peer pressure?

Greed? Power? Sociopathy?

Or, simply, ignorance / manipulation?

The justification often heard...

“Science advances through refutation”

But ...

- ▶ **When is it appropriate to refute?**
- ▶ **How much is one being paid to refute?**
- ▶ **And, in whose best interests ... for science or for powerful interests?**

Tobacco promotion understood

- ▶ Over 50 years of deception, since ~1952
- ▶ *For every \$1 raised for health promotion to warn the American public about the health hazards of tobacco, the tobacco industry found public relations firms to counter these messages, deceiving the public; and, also in buying scientists to prostitute themselves to the industry by designing studies to demonstrate that tobacco is not harmful ...*

Perversion through junk science

**Lawyers first cut their teeth on
tobacco litigation in tort actions**

And then on asbestos ...

**And so, the doubt industry thrives
with corporate tenacity and
unlimited financial support**

The Scientific Ethic*

A set of norms that define the scientific endeavour → an ethos that evolved gradually and organically.

PROFESSIONAL ETHICS embody some of these norms, but “The Ethic of Science” is more like the charter that makes science possible than like a law book that spells out the specific rules.

This ethic defines the **boundaries** that must be respected by those who wish recognition as part of the scientific community.

Why ethics in the professions?

- ▶ Keep ourselves on track, and keep our own house in order
- ▶ Socialise our students
- ▶ Professional accountability
 - According to norms of behaviour
 - **IN WHOSE BEST INTERESTS?**
 - **WHO IS TAKING THE RISKS?**
 - **WHO IS DERIVING THE BENEFITS?**

Deontological (i.e. duty-based/obligations)

The 'scientific ethic' expects scientists to:

1. **Use appropriate methods;**
2. **Report honestly;**
3. **Publish results - POSITIVE as well as NEGATIVE;**
4. **Prohibit distortion in, for example:**
 - Falsification of data
 - Biases inherent to study design
 - Proper analytical procedures
 - Objective interpretation
5. **Do one's own work:**
 - Plagiarism
 - Acknowledge sources
 - Graduate students, etc., not to be exploited

GOOD ETHICS ⇔ GOOD SCIENCE

THE NORMAL RANGE OF HUMAN CONDUCT



**POWER CORRUPTS. ABSOLUTE POWER
CORRUPTS ABSOLUTELY!**

(Lord Acton's premise)

NO ONE IS IMMUNE!

**Be aware of forces that influence
both science and policy.**

**... Great vigilance and personal
integrity are required to serve
the public interest**

Manufacturing Doubt

- ▶ Epstein.
The Politics of Cancer, 1978
- ▶ Davis.
When Smoke Ran Like Water: Tales of Environ Deception ..., 2002
The Secret History of the War on Cancer, 2007
Disconnect: The Truth About Cell Phone Radiation ..., 2010
- ▶ Michaels.
Doubt is their Product: How Industry's Assault on Science..., 2008
- ▶ McCulloch & Tweedale.
Defending the Indefensible: The Global Asbestos Industry ..., 2008

By fomenting uncertainty, the health policy-maker's role is undermined ...

→ the subversion and ambushing of science

Influences and pressures from:

- ▶ **Funding sources to peer review**
- ▶ **Questions we ask through access to data**
- ▶ **Study design to data analysis and interpretation**
- ▶ **Dissemination to job security**

“Industry’s offensive against the regulation of health and safety hazards uses academics to downplay or deny the seriousness of the hazards ...”

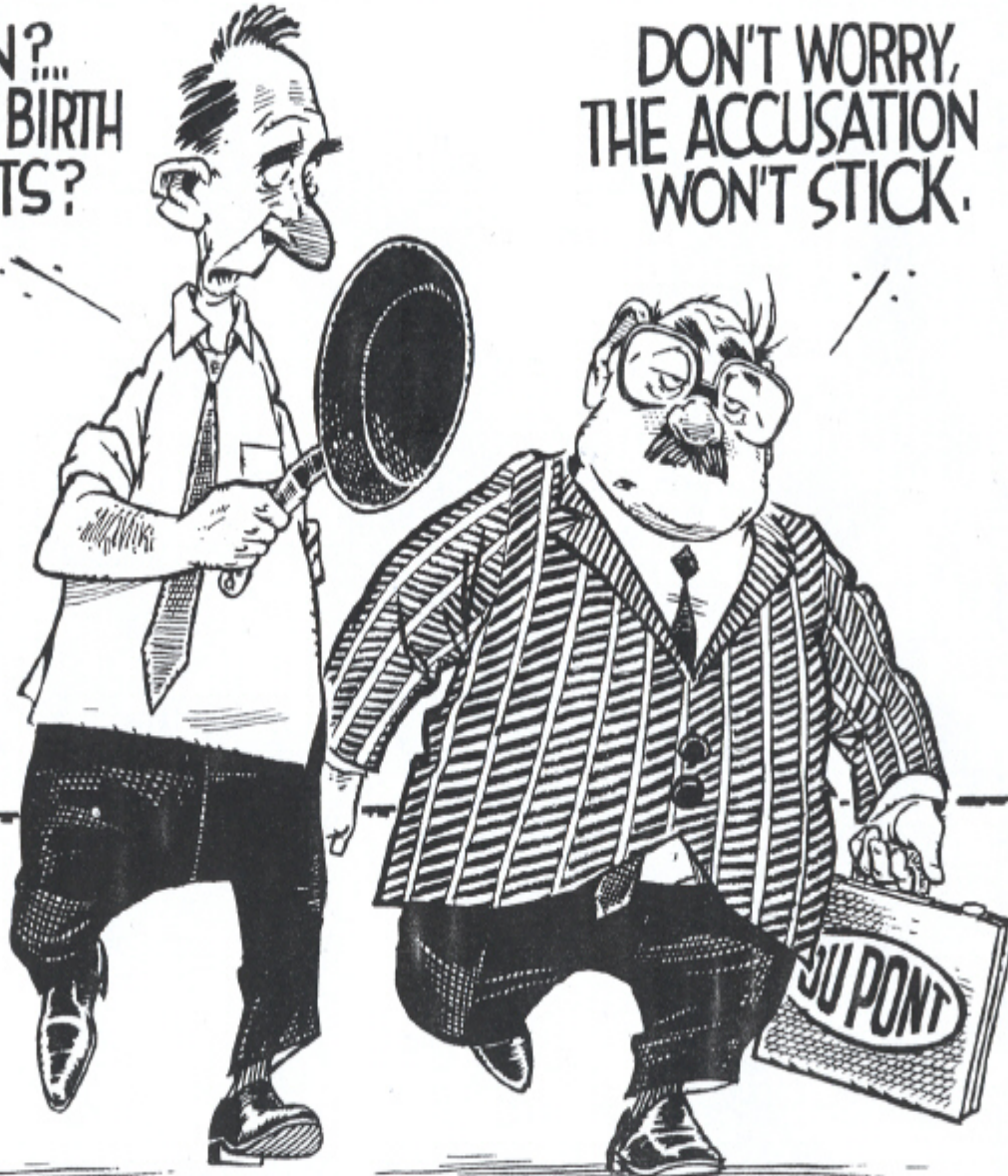
Clayson and Halpern

J. of Public Health Policy

September, 1983

TEFLON?...
LINKED TO BIRTH
DEFECTS?

DON'T WORRY,
THE ACCUSATION
WON'T STICK.



Myles
Edmonton
Journal

THE GOLDEN RULE - adapted

- ▶ **What is hateful unto you, do not do unto your neighbour**

Hillel, Babylonian Talmud, Tractate Shabbat, 31B

- ▶ **Treat others as we would want them to treat us or our loved ones**

Luke 6:31 and Matthew 7:12

- ▶ **Treat others justly so that no one would be unjust to you**

From the Prophet Mohamed's Last Sermon

-
- ▶ **Do our level best**

- ▶ **Assert ourselves if we find someone else who has done ill**

**But, “applied ethics” is
context-related**

The Hill “criteria”/“aspects”. Is an observed association **causal** in nature?

- ▶ **Strength of association**
- ▶ **Consistency across studies**
- ▶ **Specificity of effects**
- ▶ **Temporality of effects**
- ▶ **Biological gradient (dose-response)**
- ▶ **Plausibility of (biological) effects**
- ▶ **Coherence with other knowledge**
- ▶ **Experimental evidence**
- ▶ **Analogy based on experience**

Hill concludes (1965)...

“All scientific work is incomplete – whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. That does not confer upon us a freedom to ignore the knowledge we already have, or to postpone the action that it appears to demand at a given time.”

An application issue

A published work of relevance

► **Weed, Douglas L.**

Underdetermination and
incommensurability in contemporary
epidemiology. Kennedy Institute of
Ethics Journal, Vol. 7(2); 1997:107-
127

Two examples (from Weed 1997)

► **Meta-analyses:**

- **Alcohol & breast cancer**
- **Induced abortion & breast cancer**

Three Case Studies

Case 1: Aspartame at Brigham & Women's Hospital – Harvard University

Case 2: Rotterdam Convention – listing Chrysotile Asbestos as a hazardous substance – Canada, now Russia and the International Agency for Research on Cancer (IARC)

Case 3: Alberta Tar Sands - Canadian “Ethics Casebook”

Case 1 – Aspartame (1 of 5)

- ▶ **Italy** - Toxicological Study (rats) published in 2005 (Eur J Oncol) and 2006 (EHP). Demonstrated a definitive dose-response relationship **in both male and female rats (aspartame-induced lymphomas and leukemias)**.
- ▶ Researchers at the Channing Laboratory (affiliated with Brigham and Woman's Hospital (BWH) and Harvard Medical School, Boston, USA) recognized that they had access to a **human data repository containing the prospective collection of aspartame-related information on a large, long-term nutrition study cohort of both men and women**. With this data source, they explored the relationship between aspartame and cancer incidence in humans.

Case 1 (slide 2 of 5)

- ▶ Their human study demonstrated a significant increase of certain haematopoietic cancers **in men** (correlated with aspartame consumption), **but not in women**, thus, at least partially, replicating in humans the findings from the Italian animal models.
- ▶ On October 24 2012, the Board of Regents cast doubt, **some 35 minutes prior to the embargoed on-line release time for the accepted article**, on the soon to be published article in the American J of Clinical Nutrition.

Case 1 (slide 3 of 5)

Questions of ethical relevance

What was the reason for attention being brought to this particular article?

What interests were at play to bring such pressure to bear?

To what extent, if any, is the artificial sweetener industry behind the tactic of the Harvard Medical School and BWH's Board of Regents?

Does the artificial sweetener industry, or its affiliates, donate money to Harvard University et al?

Was there pressure from the industry? Was it a veiled threat that donations could cease if this line of research incriminating their products continues at Harvard and BWH? How does this operate at other universities?

What does requiring clearance by “the scientific leaders” at any academic institution mean for academic freedom? **Is this censorship leading to the suppression/oppression of science?**

Case 1 (slide 4 of 5)

Questions of ethical relevance

Should the public and, indeed, other scientists be concerned about the kind of public relations exercise used by the Harvard Medical School and BWH? What are the implications for other researchers on other topics? **Academic freedom.**

First six journal editorial boards rejected it. Are these boards infiltrated with editors/board members aligned with or even beholden to the sweetener industry? **Impartiality in pursuit of truth.**

It is possible that the researchers could lose their jobs if they were to persist in working in this area of inquiry, unless, of course, they were in the future to show “no harm” or raise doubt as to the relationship between aspartame and hematopoietic cancers? **Tenure/promotion.**

Does this give us pause to examine the relationship between academia and industry? **Undue influence in the pursuit of truth.**

Once ethics clearance is obtained, is it not right that the research move to completion (including dissemination), as long as it complies with the rigours of scientific ethics and integrity? **Respect for autonomy.**

Case 1 (slide 5 of 5)

Questions of ethical relevance

Are there similarities between this experience and others relating to, e.g., tobacco, asbestos, cell phones, etc., behind which powerful moneyed interests wield dominating influences?

SUPPRESSION BIAS /OPPRESSION BIAS/ REPRESSION BIAS? Could these be operating at some level in this situation?

These questions might be discussed among all scientists, especially applied scientists, internationally, if the integrity of the scientific enterprise, academic freedom, and the public interest are to be protected.

Case 2-Chrysotile Asbestos (CA) (1 of 2)

- ▶ **Rotterdam Convention**
 - Prior informed consent
- ▶ **Ukraine, Kazakhstan, Kyrgyzstan, India, Vietnam and Canada**
- ▶ **When facts (evidence) and the ethical principle of solidarity are overruled by ideology ... “business above all other considerations”**

Case 2 (2 of 2)

Since Canada has withdrawn from its obstructionist role, **Russia appears to have taken over.**

Russian scientists are conducting what appear to many of us who consider the evidence strong enough to warrant the banning of CA, questionable studies and deceiving the world.

It appears that Russia has infiltrated IARC, publishing work we believe will be used to block CA listing in April-May, 2013. We have responded to their work and hope that it will counter-balance their perceived biased approach to science.

Case 3 - Alberta Tar Sands

CIHR-IPPH Ethics Case Book (1 of 3)

**Canadian Institutes of Health Research –
Institute of Population and Public Health:
Ethics Casebook, released Feb 22, 2013**

*“Population and Public Health Ethics: Cases
from Research, Policy, and Practice.”*

Accessible on U of Toronto Joint Centre for
Bioethics website at www.utoronto.ca/jcb.

Case 3 (2 of 3)

 **Case #15: Alberta Oil sands: A Toxic Mixture of Bitumen and Economic Prosperity, pp. 164-167.**

The Case Discussion in response to this case by Colin Soskolne appears on pages 168-175.

Case 3 (3 of 3)

Rigorous solicitation of cases and commentary was adopted ... a model now being emulated at the U.S. CDC for its own publication in 2014.

The Case: Dr John O'Connor's story.

The commentary is one not to seek retribution, but to move the issue forward. *Watch Downstream at <http://www.downstreamdoc.com/>*

Summary attention to:

- ▶ **Ethics: core values, normative practices**
- ▶ **Conduct of individual professionals**
- ▶ **Manipulation of science and its methods**
- ▶ **Role for vigilance in protecting the public interest and in maintaining public trust**
- ▶ **Self-interest vs. public interest**
- ▶ **Influence, transparency and democracy**
- ▶ **The independence of academia**

What junk science does

- ▶ **Inappropriate comparison groups (exposed vs. unexposed)**
- ▶ **Under-powered studies**
- ▶ **Inadequate latency/time to follow-up**

TAKE HOME MESSAGES

- ▶ **Uncertainty IS inherent to science**
- ▶ **Science strives to be value-neutral/value-free, but the human instrument is not**
- ▶ **Look first to ourselves, because causal inference is a function of who it is that is making the inference which, in turn, is a function of:**
 - **study design**
 - **so-called causal “criteria”/Hill “aspects”**
 - **weights assigned to each “aspect”**

Conclusions: what to do?

- ▶ **Be aware and vigilant of the forces that would serve to derail science**
- ▶ **Apply the Golden Rule (adapted) by being assertive in the face of the abuse of science**
- ▶ **Always serve the public interest over special interests**

Whither Humanity?

Discussion

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