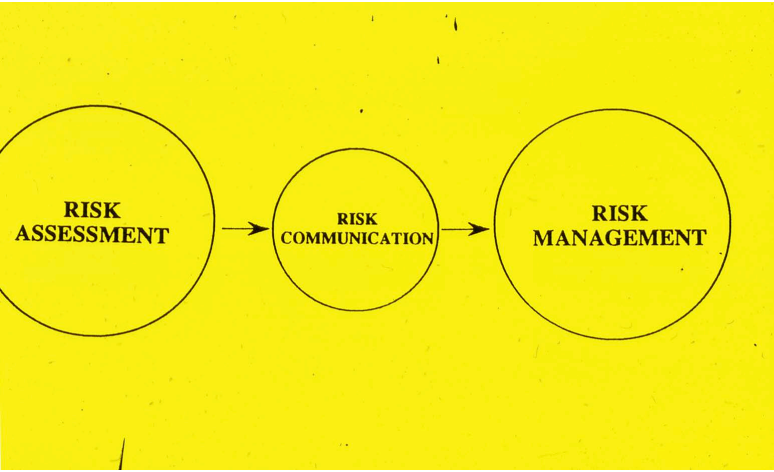
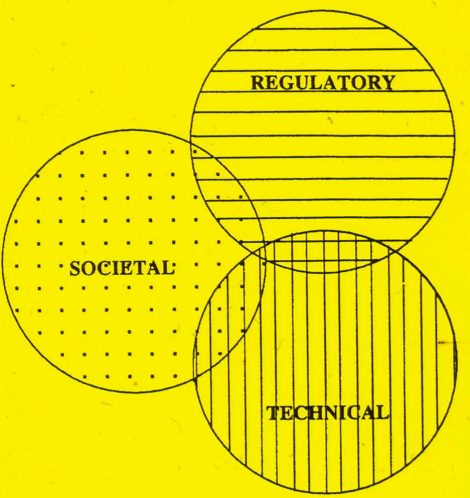
RISKS

Low-dose assessment
Lead, asbestos, fluoride, radon, etc
No bodies lying around to be counted
Cancer - the most dreaded
Assessment limited by uncertainties


RISK
ASSESSMENT
RISK
COMMUNICATION
RISK
MANAGEMENT

THREE PERCEPTIONS

Societal, regulatory, technical
Regulatory or technical conclusions not verifiable
Conclusions are not scientific ones


REGULATORY
SOCIETAL
TECHNICAL

OBJECTIVES

Identify major risks
Obtain realistic estimates
Consider benefits and risks
Recognize the 3 perceptions

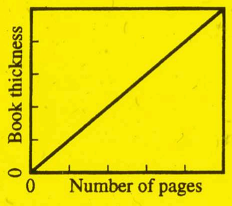
ANALYTICAL REVOLUTION

Detectability
PPM -> PPB -> PPT -> ->
Detectable amounts of most
everything in most anything
Information unsettles public
More extreme extrapolations

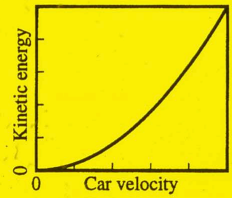
ZERO PROBLEM

Zero cannot be measured in a chemical analysis
Elimination i.e. zero impossible to demonstrate
Zero response unmeasurable
Zero not a sensible goal.

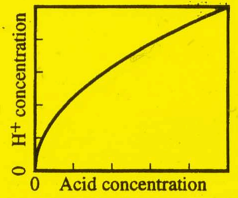
Linear

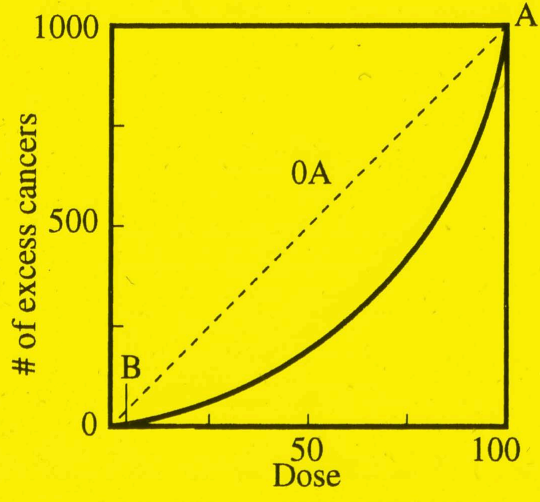


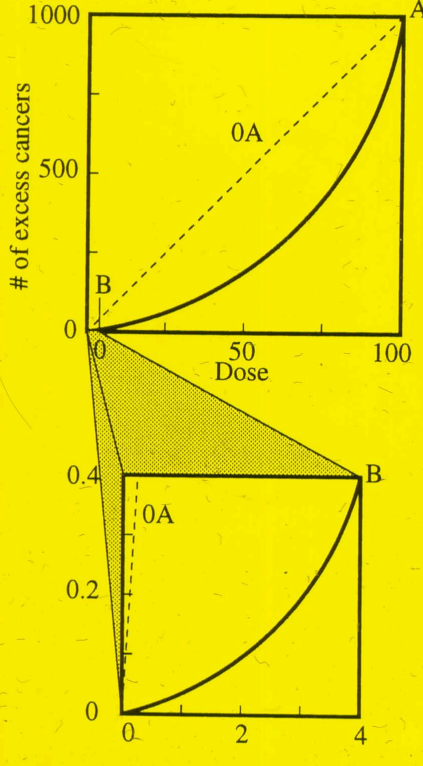
Non-linear

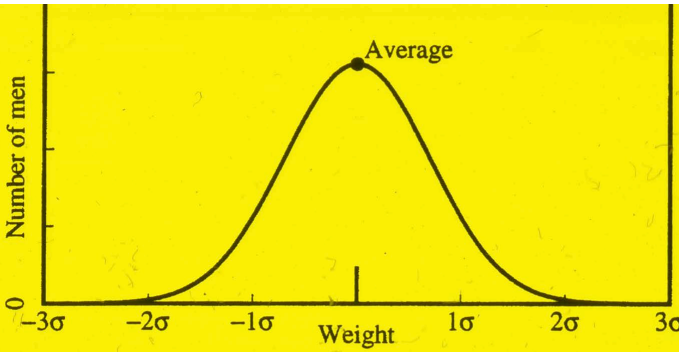


Non-Linear

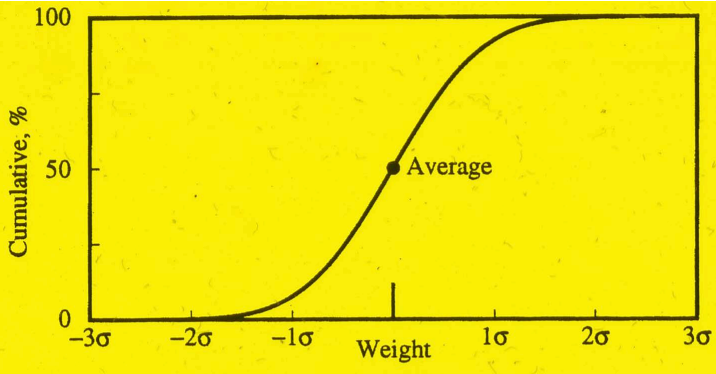



1000
500
0
# of excess cancers
A
0A
B
50
100
Dose


1000
500
0
# of excess cancers
A
0A
B
0
50
100
Dose
0.4
0.2
0
B
0A
0
2
4



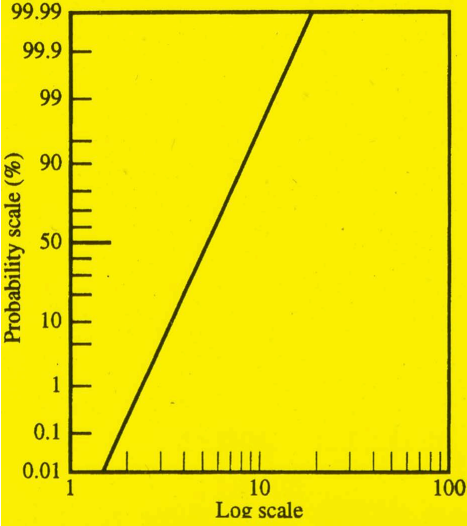
Normal probability distribution, bell curve



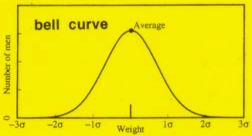
Normal probability distribution, S-curve

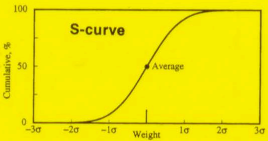
LOG SCALE

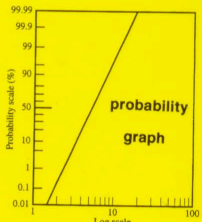
PROBABILITY SCALE



Normal probability distribution







Normal probability distribution

LINEAR MODEL

Instinctively attractive.

Regulators and many scientists favor linear model and state it as fact.

News media reinforce this intuitively attractive model.

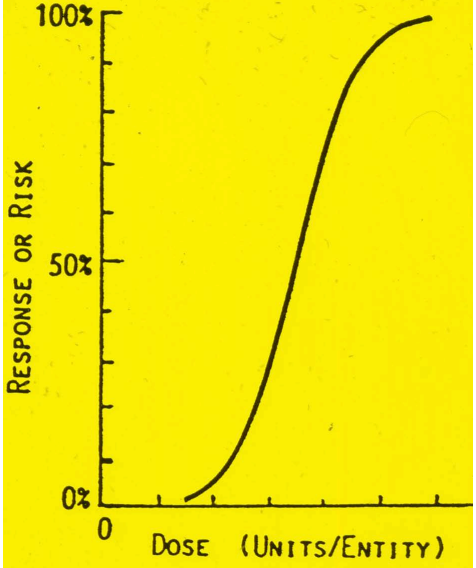
LINEAR MODEL AND RADIOACTIVITY

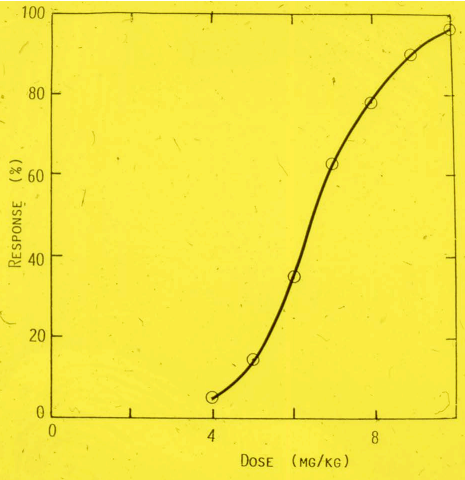
Int'l Commission on Radiological Protection (BEIR IV) specified that the risk conversion factor to be used is 0.05 excess cancer deaths per sievert of radioactivity.
("Risk conversion factor" is a euphemism for "use the linear model".)

Radioactivity dose	Resulting cancers (linear model)
0.05 sv	1
0.01sv *	0.02
0.001sv *	0.002
0.0001sv	0.0002
0.000 02sv	0.000 001

"Regulatory risk assessors, indeed risk assessors everywhere, may be faulted for failing to provide to the public a more thorough understanding of the uncertainties associated with their assessments."

Rodricks - Calculated Risks


100%
50%
0%
0
RESPONSE OR RISK
DOSE (UNITS/ENTITY)


100
80
60
40
20
0
RESPONSE (%)
0
4
8
DOSE (MG/KG)

ASSUMPTIONS

1- Same kind of adverse effect at low doses
2- No threshold
3- Target dose limit, 1 in a million
4- Low-dose effects for humans obtainable from high-dose animal tests.

THRESHOLD

A philosophical question
Not amenable to verification
If a threshold, a no-threshold assumption gives high risk estimates

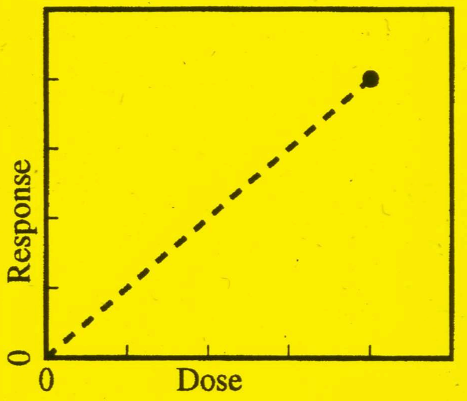
ONE IN A MILLION RISKS

Kelly - no sound basis - scientific, social, or economic

10^{-6} appears to be a number pulled out of the hat

ANIMAL DATA BASE

High doses studied - economics
Extrapolate high --> low doses
Extrapolate animal --> human



Linear model

"All substances are poisons, there is none which is not a poison. The right dose differentiates a poison and a remedy."

P. A. Paracelsus, 1493 - 1541
Swiss physician

TOXICITIES	LD_{50} (Rats)
Water	500 g/kg
Sugar	30 g/kg
Salt	4 g/kg
Ethyl alcohol	10 g/kg
Caffeine	0.1 g/kg
---	---
Arsenic (As_2S_3)	0.04 g/kg
Sodium cyanide	0.015 g/kg
Vitamin D	0.01 g/kg
Nicotine	0.0003 g/kg
Botulism toxin	Much less

ANXIETY FACTORS - examples

Imposed vs voluntary
Industrial vs natural
Exotic vs familiar
Dreaded vs not dreaded
Catastrophic vs chronic
Unknowable vs knowable
Unfair vs fair
Delayed vs immediate
Reducible vs preventable

"Scientists may tell us there is no health hazard in asbestos that has been properly applied to old buildings, or that PCBs are not really very dangerous chemicals, but the paranoiac spirit of the times shouts them down.

W. Thorsell, Editor *Toronto Globe and Mail*

ASSESSMENTS - CHALLENGES

About 70,000 commercial chemicals

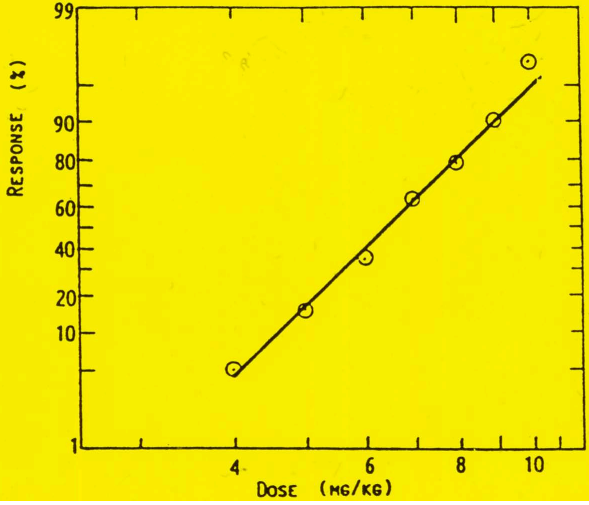
All substances toxic The dose makes the poison

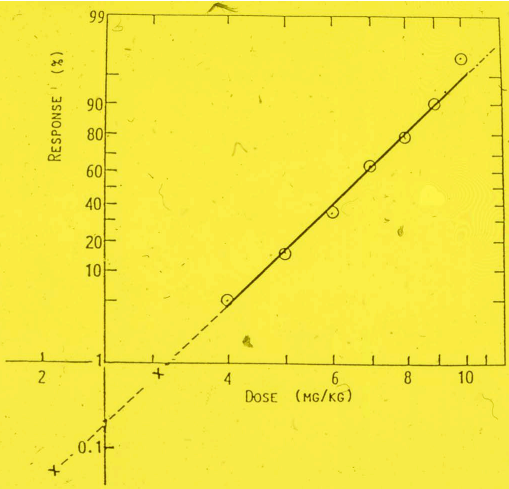
Firm answers are expected

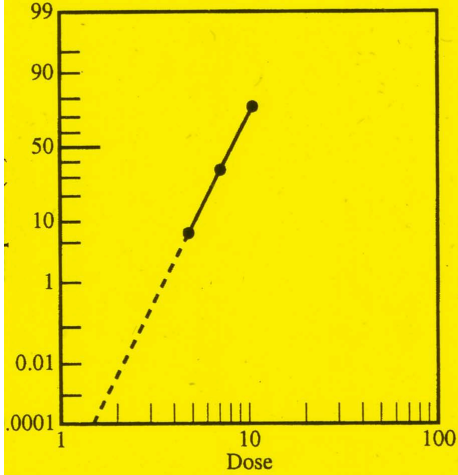
Toxicity data severely limited

Extrapolation animals --> humans

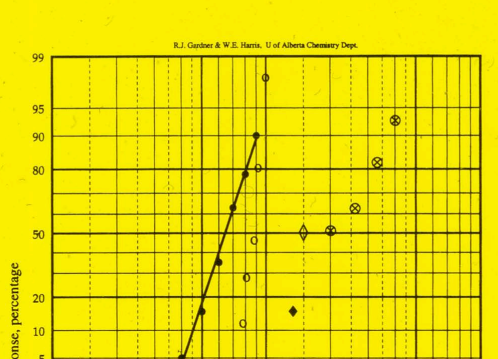
Target dose limit needs selection


RESPONSE (%)
99
90
80
60
40
20
10
1
4
6
8
10
DOSE (MG/KG)


99
90
80
60
40
20
10
1
0.1
RESPONSE (%)
2
4
6
8
10
DOSE (MG/KG)



Probability model


R.J. Gardner & W.E. Harris, U of Alberta Chemistry Dept.
Response, percentage
99
95
90
80
50
20
10
5
1
0.1
0.01
0.001
0.0001
1
2
3
4
5
6
7
8
9
10
20
30
40
50
60
70
100
Dose, mg/kg

TECHNICAL ESTIMATES

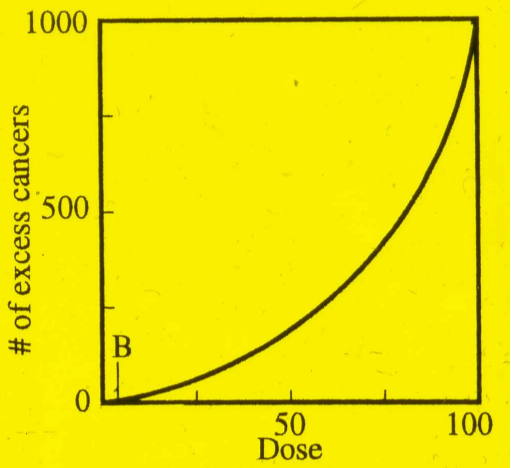
Estimate animal low-dose response
Extrapolate to humans at low doses
Underscore the uncertainties

UNCERTAINTIES

Extrapolations, threshold, human data, animal data, assumptions, dose, response, cumulative effects, human/rodent sensitivity, repair mechanisms, positive effects, delayed response.

EXTRAPOLATIONS

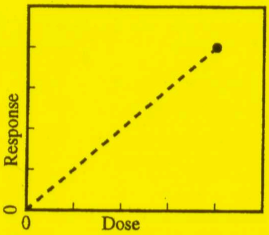
1- Speculative extension into the unknown
2- View with common sense skepticism
3- Should be logical extension of reality
4- Not all extrapolations are of equal validity
5- Extrapolations to modern detection limits no longer consistent with moderate extensions
6- Model hypothesis needs validation


1000
500
0
# of excess cancers
B
50
100
Dose

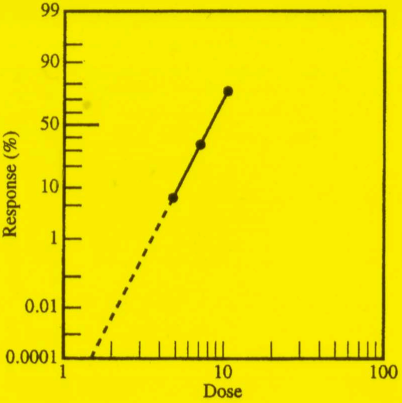
MODEL VALIDATION

Linear model does not recognize the linearity problem, does not give realistic extrapolations, and does not give results that are consistent with human expericence.

Probability model is consistent with normal distributions (normal biological variation), gives realistic extrapolations, and gives results that are consistent with human experience.



Linear model



Probabillity model

TOXICITIES

Substance	Dose	Response (rats)
Vinyl chloride	1.3 mg/kg	15% cancer
Methyl mercury	26 mg/kg	62% mortality
Alcohol	8.9 g/kg	50% mortality

Linear vs probability (realistic) dose estimates

Substance	Risk, %	Dose(mg/kg) for 0.0001% risk	
		Linear	Probability
Vinyl chloride	0.0001	0.000 0087	About 0.4
Methyl mercury	0.0001	0.000 042	About 5
Alcohol	0.0001	0.018	About 2000

For risks of 1 in a million, the linear model typically overestimates doses by factors of about 100 000.

ALCOHOL Linear vs probability

Linear model indicates a daily limit of about 0.001 ml of wine

Probability model indicates a daily limit of about 250 ml

The linear model is not consistent with human experience.

"Do not confuse politically motivated characterization of health risks with science."

"Assume that there are no disinterested parties."

S. Klaidman, *The stories behind the stories* Oxford U. Press, 1992

RISKS AND BENEFITS

Asbestos About $5 billion on removal activities. Deaths prevented?

Dioxin Huge amounts being spent to reduce the now negligible levels.

Vaccines Millions of lives could be saved by their wider use.

Resources are limited - reallocate them and focus on real problems.

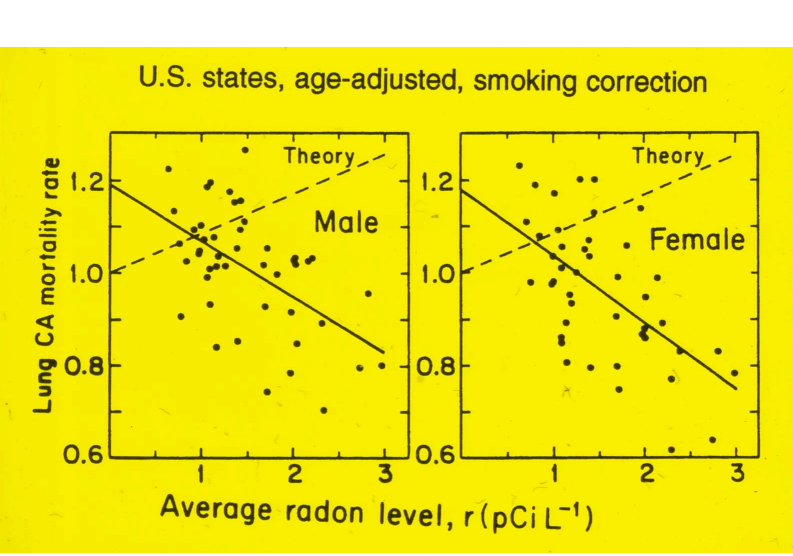
THE BOTTOM LINE

What is wrong with being extra safe?

1- Resources are limited.

2- Resources squandered with minimal or no societal benefit will not be available to be used to save real lives.

3- Gigantic risk and dose overestimates should be condemned.


U.S. states, age-adjusted, smoking correction
Theory
Male
Theory
Female
Lung CA mortality rate
1.2
1.0
0.8
0.6
1
2
3
Average radon level, r (pCi L⁻¹)

RADIOACTIVITY

High doses fatal

Regulators specify the linear model

Can hypothesize about the effects of low doses and low dose rates.

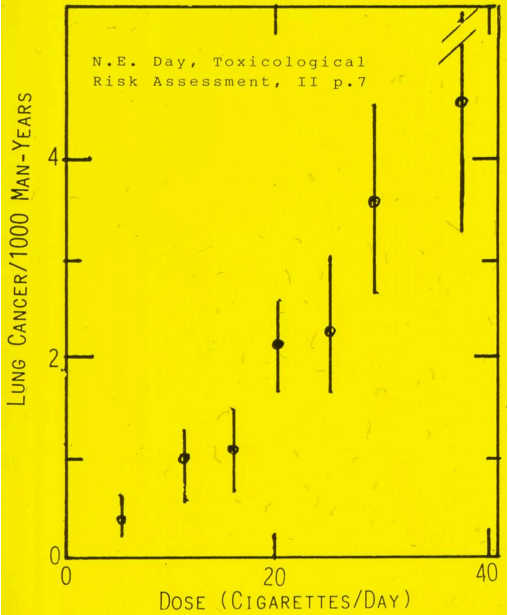
Real effect may be negative, zero or positive

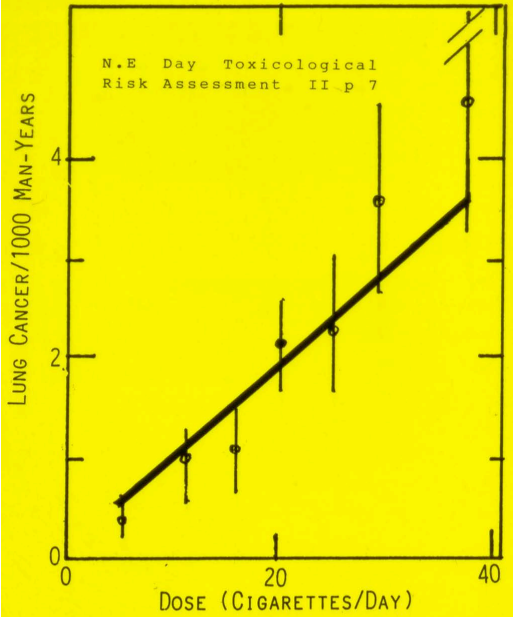
The no observable effect limit suggests that regulatory dose limits exaggerate risks by huge factors.

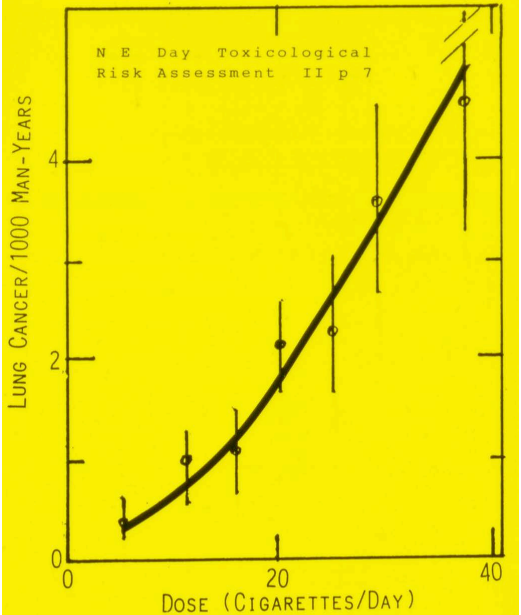
LINEAR MODEL- RADIOACTIVITY

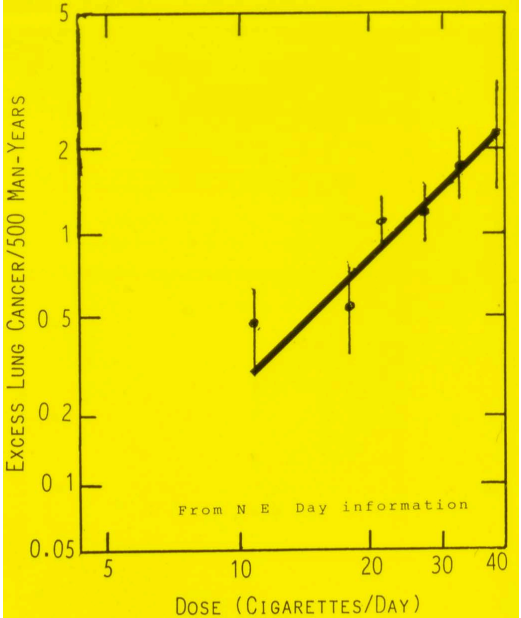
The model meets distressingly few challenges by scientists.
Why do risks continue to be so exaggerated.?
Scientists adopt the model unthinkingly.
Scientists do not challenge the underlying assumptions.
Scientists are more likely to attack challengers than to question the model itself.

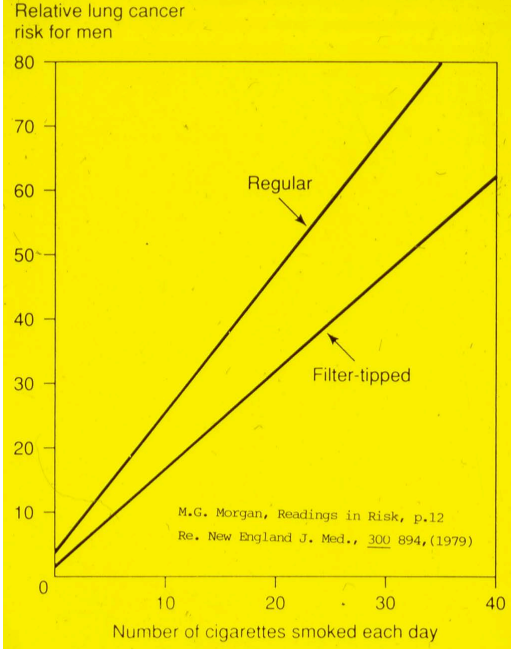
J. Jovanovich - *Physics in Canada* 245 - 265 (1994)


N.E. Day, Toxicological
Risk Assessment, II p.7
LUNG CANCER/1000 MAN-YEARS
0
2
4
0
20
40
DOSE (CIGARETTES/DAY)


N.E Day Toxicological
Risk Assessment II p 7
LUNG CANCER/1000 MAN-YEARS
4
2
0
0
20
40
DOSE (CIGARETTES/DAY)


N E Day Toxicological
Risk Assessment II p 7
LUNG CANCER/1000 MAN-YEARS
4
2
0
0
20
40
DOSE (CIGARETTES/DAY)


5
2
1
0 5
0 2
0 1
0.05
EXCESS LUNG CANCER/500 MAN-YEARS
From N E Day information
5
10
20
30
40
DOSE (CIGARETTES/DAY)


Relative lung cancer risk for men
80
70
60
50
40
30
20
10
0
Regular
Filter-tipped
M.G. Morgan, Readings in Risk, p.12
Re. New England J. Med., 300 894,(1979)
10
20
30
40
Number of cigarettes smoked each day

ASBESTOS

Regulatory driven by litigations
Workers of crocidolite type who smoke have high risk of cancer
Crysotile type low risk
Sociological Perceptions take precedence Vested interests
Regulatory Seem to ignore the fact that asbestos is of crysotile type
Technical We breathe in asbestos fibers every day. Is the problem real?

SOCIETAL

Many concerns - asbestos, PCB, mercury, radioactivity
Acceptability of risks assessed in terms level of anxiety
The public believes in zero risk - not a reasonable goal
Complacency about familiar risks
Media - main information source - far from unbiased
Snowball effects from interactions of scientists, regulators, politicians, journalists. Each have their own agenda.

REGULATORY

Responsibility re public welfare
Aim for high level of safety
Conservative assumptions piled on
Socio/political/tech conclusion
Presented with an air of certainty

"Risk analysis is a kind of pretense, to avoid paralysis of protective action that would result from waiting for 'definitive' data, we assume that we have greater knowledge than scientists actually possess and make decisions based on those assumptions."

Ruckelhaus, Head EPA

TECHNICAl

Must recognize normal biological variation

Probability intuitively perplexing

Probability model estimates - accurate but not precise

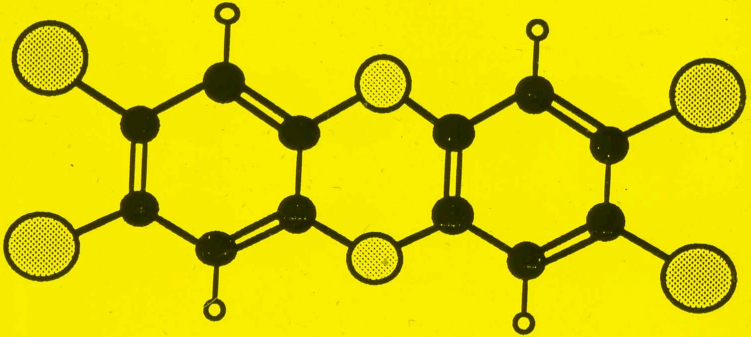
(The uncertainties are not so big that we can conclude that 6.4 makes sense when a realistic estimate is in the range of 3 or 4 million)

Communication is a problem

4 stages in acceptance of an idea

1- This is worthless nonsense
2- This is an interesting but perverse point of view
3- This is true but unimportant
4- I always said so

J.B.S. Haldane, 1963



2,3,7,8-tetrachlorodibenzo-p-dioxin

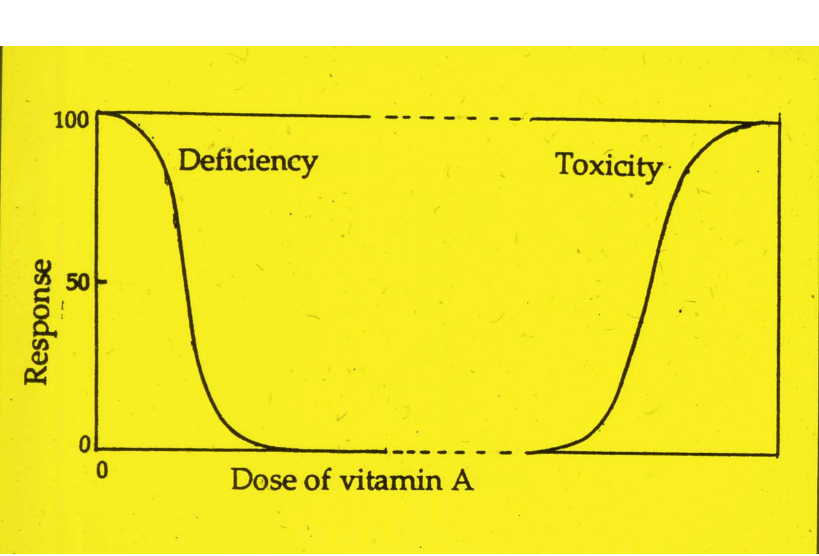
DIOXINS

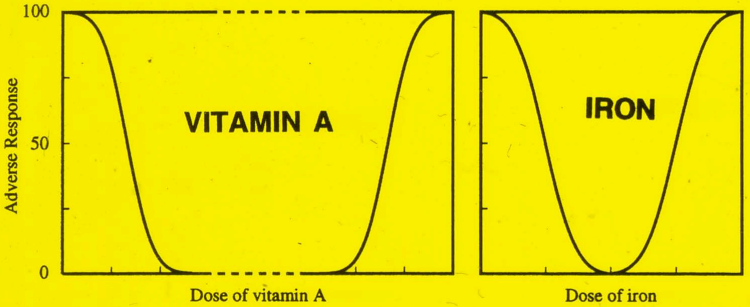
Past high exposures caused chloracne problems
Many have benefited
- Analytical chemists - identified and measured
- Cell biologists - research proposals support
- Lawyers - litigation
- Regulators - financial support for their work
- Reporters - entertaining news stories
- Sociologists, politicians, activists have roles

For Vietnam veterans - focus for the bitterness

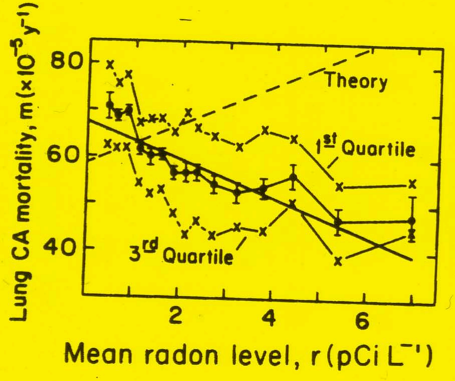
CAFFEIC ACID

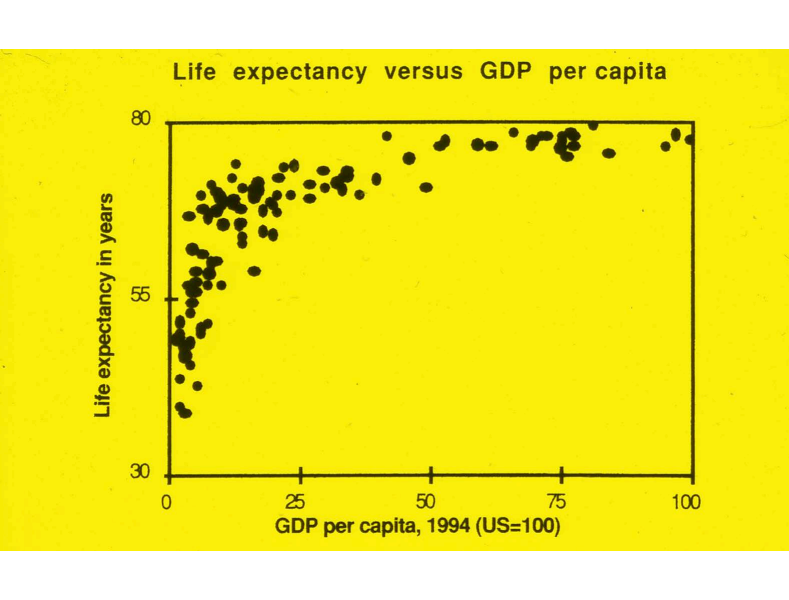
No sociological or regulatory complications
No public or political concern
Sociological If it were an additive it would be viewed with alarm
Regulatory If regulated by LNT extrapolation our intake would have to be reduced at least 1000 X
Technical LPNT extrapolation indicates risk far below baseline risk.

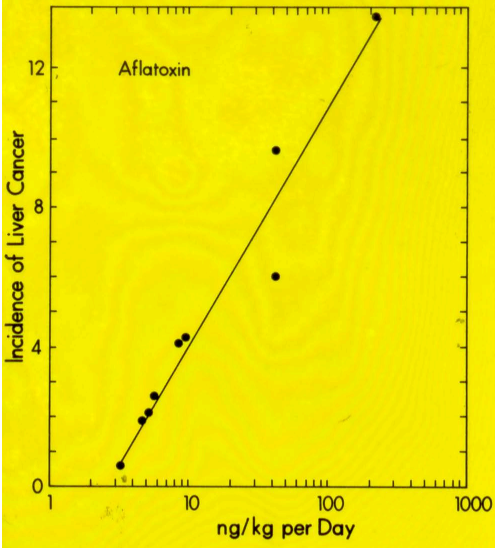

100
Deficiency
Toxicity
Response
50
0
0
Dose of vitamin A


100
50
0
Adverse Response
VITAMIN A
Dose of vitamin A
IRON
Dose of iron

900 U.S. counties, age-adjusted, smoking correction




Life expectancy versus GDP per capita
80
55
30
Life expectancy in years
0
25
50
75
100
GDP per capita, 1994 (US=100)


Aflatoxin
Incidence of Liver Cancer
0
4
8
12
1
10
100
1000
ng/kg per Day