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Using advanced scientific information to improve the timing and coverage of risk-based decisions

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Two areas of concern for today...

1. Thousands of compounds released throughout the life cycle; 200 assessed for risk (at best)
2. Poor understanding of multiple exposures of vulnerable populations (environmental justice)

Too many risk agents, too little time
(and resources)

Regulatory decisions have been based
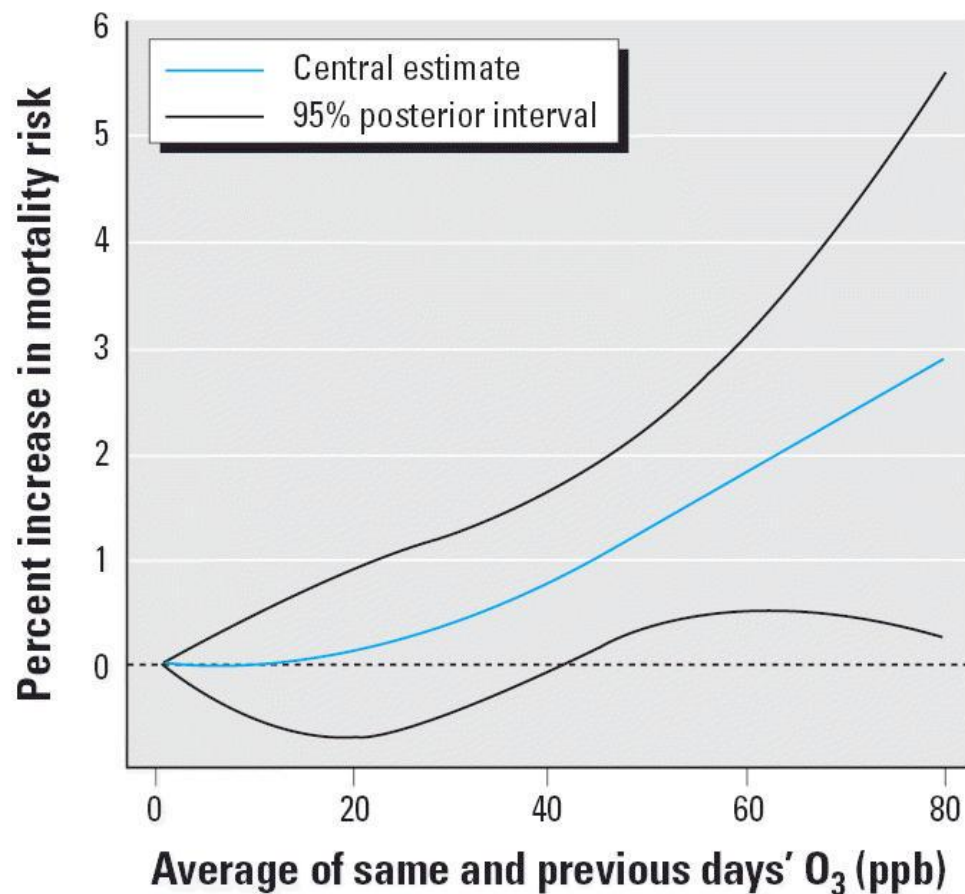on observable, adverse effects

If these data are not available in people…

...animal surrogates might
be used

These data are used to create exposure-response curves...

However, there are several problems...

- The data often are not in humans (the subjects of protection)
- The data are not necessarily from sensitive subpopulations
- The data do not examine all potential effects
- The data do not have statistical reliability below the level of exposure of regulatory interest

And so one develops Points of Departure…

- NOELs: No Observed Effects Level
- NOAELs: No Observed Adverse Effects Level
- LOELs: Lowest Observed Effects Level
- LOAELs: Lowest Observed Adverse Effects Level

…and applies margins of safety

The general framework of risk-based policy

Find a policy such that it will produce (i) an acceptable level of risk from energy production, (ii) in an acceptable fraction of the population, and (iii) do so with the desired level of confidence

Precaution appears to – or has been interpreted to – require significant margins of safety on the whole organism data. But can there be "too much" precaution?

There are potential health costs of over protection…
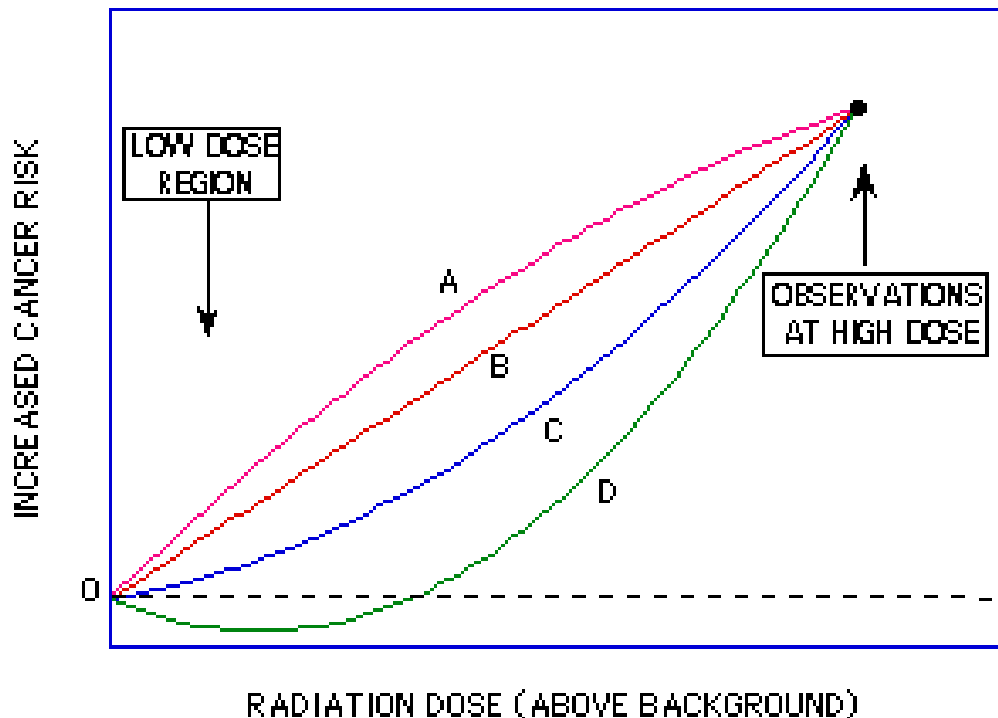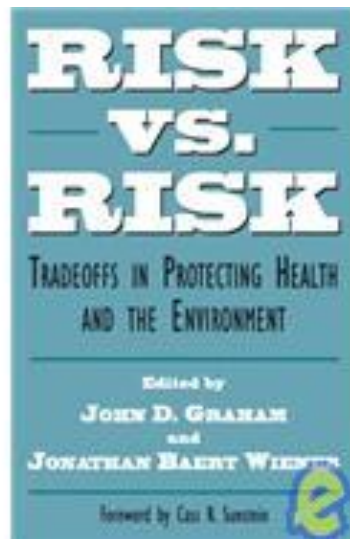
And due to "health poverty"…
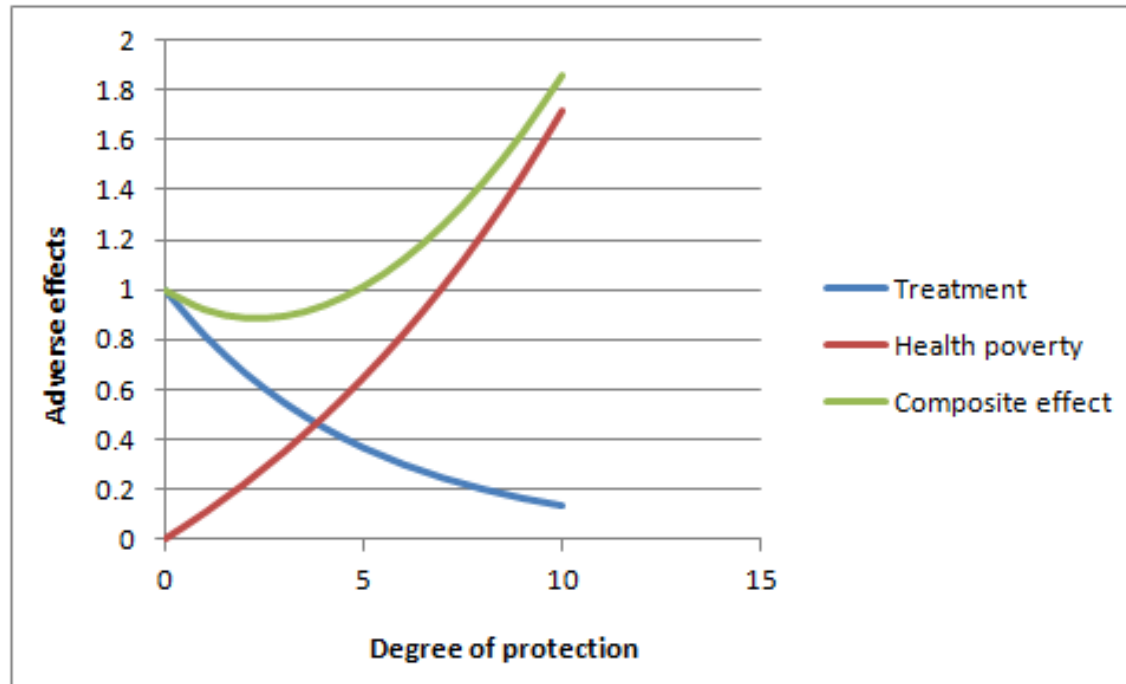
Enter advanced scientific data...

- Proteomics
- In vitro assays
- Structure-activity
- Inflammation response
- Gene regulation...

These are rapid; capable of examining thousands of compounds; much less expensive.

These allow us to...

- Look at much lower exposures
- Look at many, many more compounds
- Significantly reduce the time required for assessments

...but they are not direct observations of adverse effects

And so the challenge...

We understand (approximately) the margin of safety, degree of confidence, etc of traditional regulatory policy approaches of uncertainty factors, modifying factors, etc...

But we don't yet know the degree of protectiveness offered by the advanced methods, and they may be greatly overly protective if they simply become the new Points of Departure

Concern 2…

People are exposed to much more complex mixtures than we can possibly study, even for the <200 compounds we have examined

And these tend to be the most vulnerable subpopulations with historical claims to injustice

The same slide as Concern 1: These allow us to…

- Look at much lower exposures
- Look at many, many more mixtures of compounds
- Consider the sensitising effects of exposures

...but again, they are not direct observations of adverse effects

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And this leads to...

...the potential for regulatory limits on risk agent X being different in different contexts (e.g. Different geographic areas, or for different subpopulations)

Some key lessons…

- We understand the degree of protectiveness of the existing system of risk-based decisions

- Legal arguments can point to direct observation of adverse effects

- But this is too slow and too costly a process

- So either we live with a slow rate of approval for new energy sites, or we speed up the assessment process

- This is possible with scientific advances near to deployment

- However, we do not yet know the reliability of these methods or the Type I and Type II error rates, and hence the confidence that resulting decisions will provide a reasonable degree of confidence

- So, watch this space...