

Frameworks for Quantitative Risk Analysis, Uncertainty, & Precaution

~~RISK ANALYSIS
METHODS~~

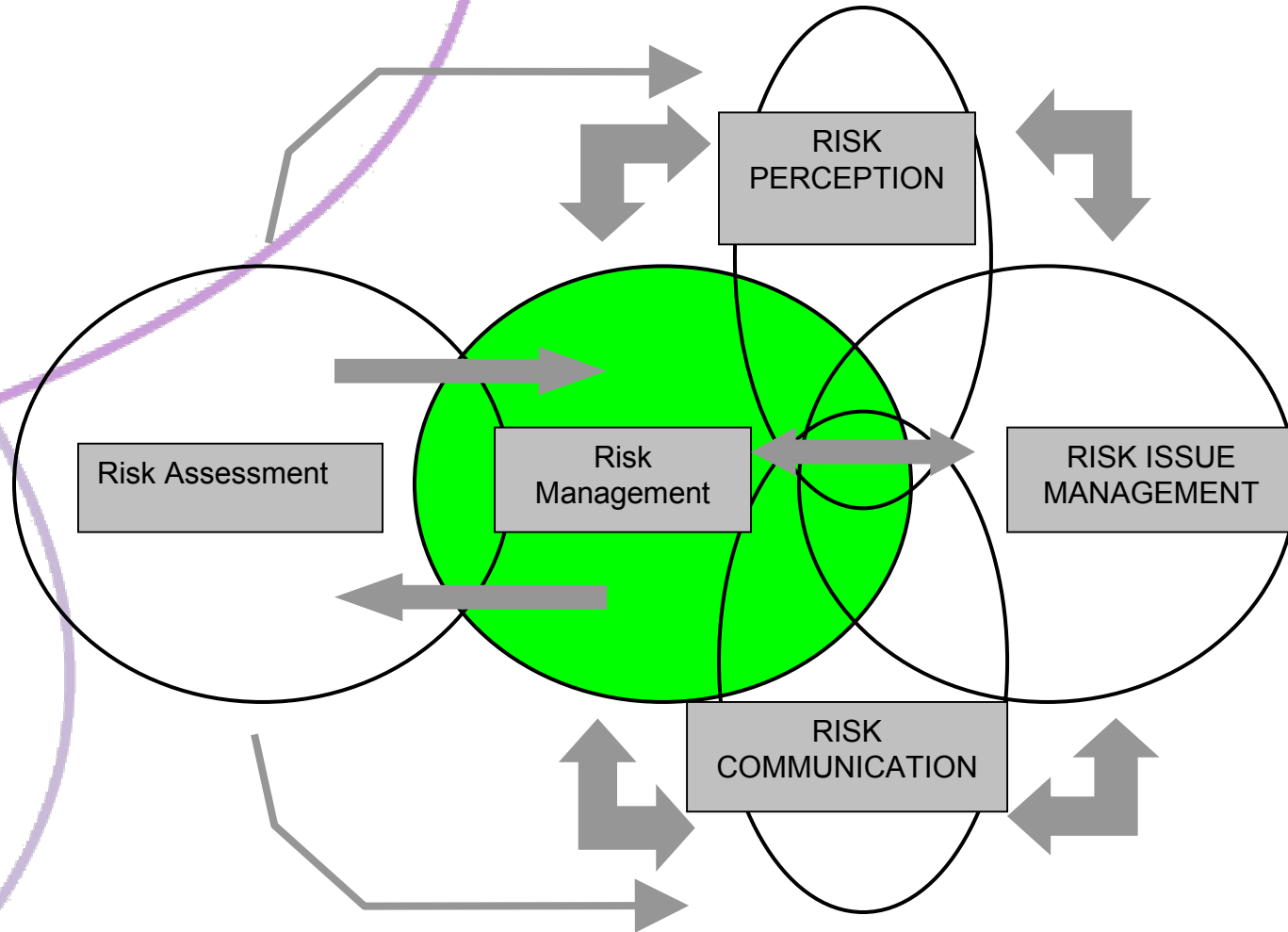
 **HealthRisk Strategies**

Washington, D.C.

www.healthriskstrategies.com

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The Risk Labyrinth

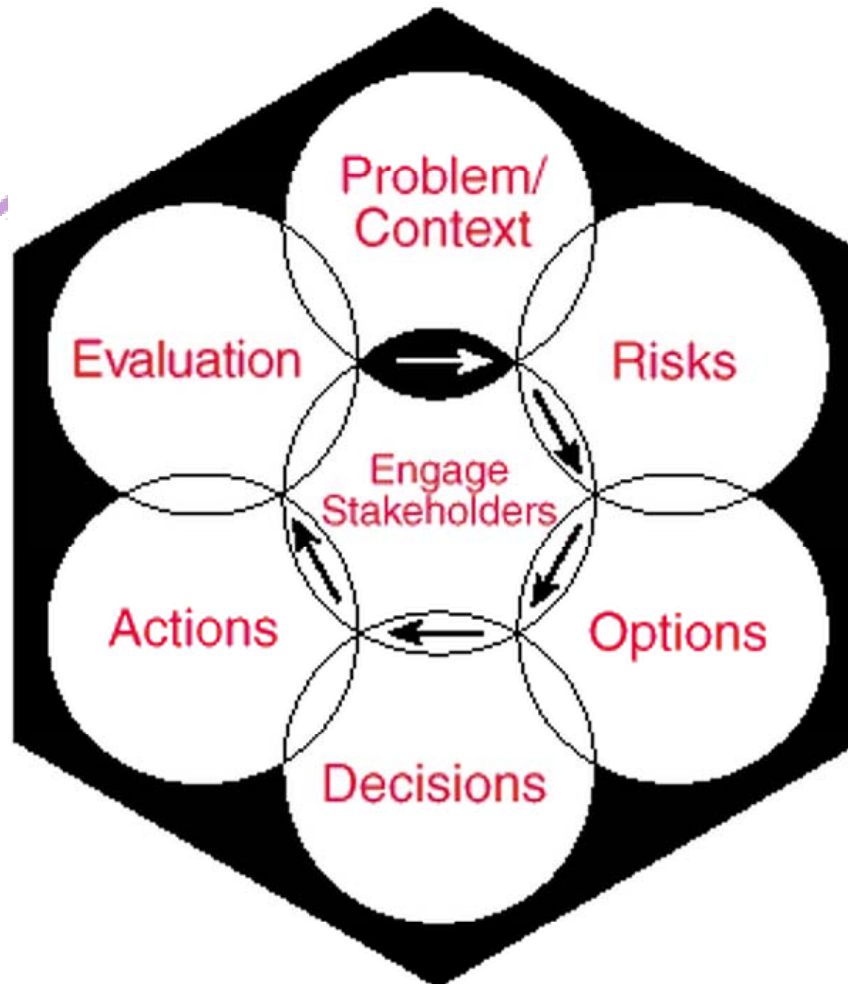


Risk Assessment

- “. . . a *decision-driven* activity, directed toward informing choices and solving problems . . . The purpose . . . is to enhance practical understanding and to illuminate practical choices.”

---*Understanding Risk*
National Academy of
Sciences (1996)

Framework for Risk Management Decision-Making



 **HealthRisk Strategies**

Quantitative Risk Assessment

- Evolved in response to the need to solve risk management problems
- Evolved to fulfill qualitative goals of health & environmental legislation
 - “ample margin of safety to protect public health” (CAA)
 - “reasonable certainty that no harm will result” (FQPA)
 - “adequate margin of safety” (SDWA)

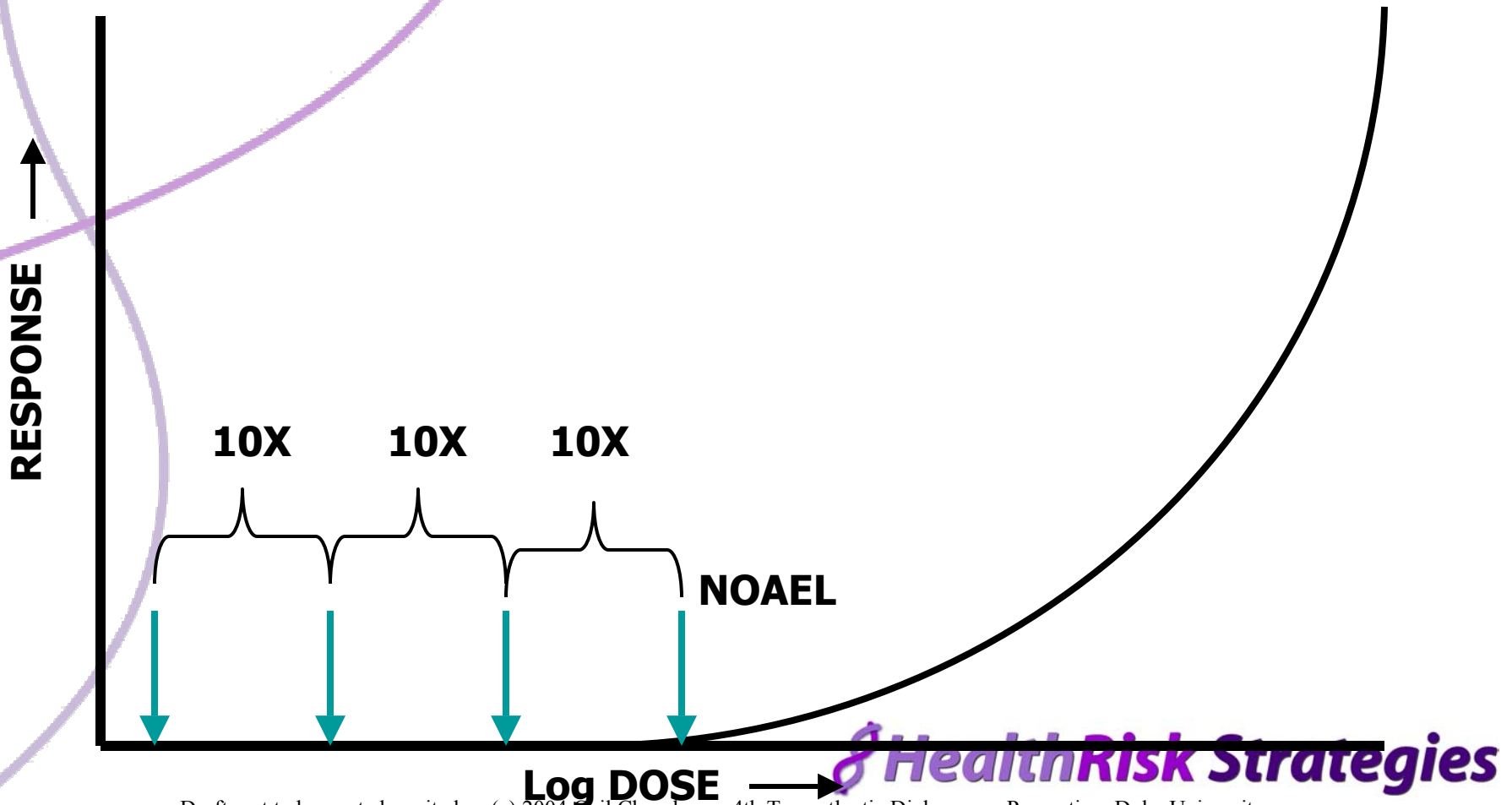
Quantitative Risk Assessment

- Evolved in response to Supreme Court's 1980 *Benzene* decision
 - “significant risk” standard
- Evolved in response to Administrative Procedure Act's requirement for a factual record supporting a risk management decision
 - avoid “arbitrary & capricious”

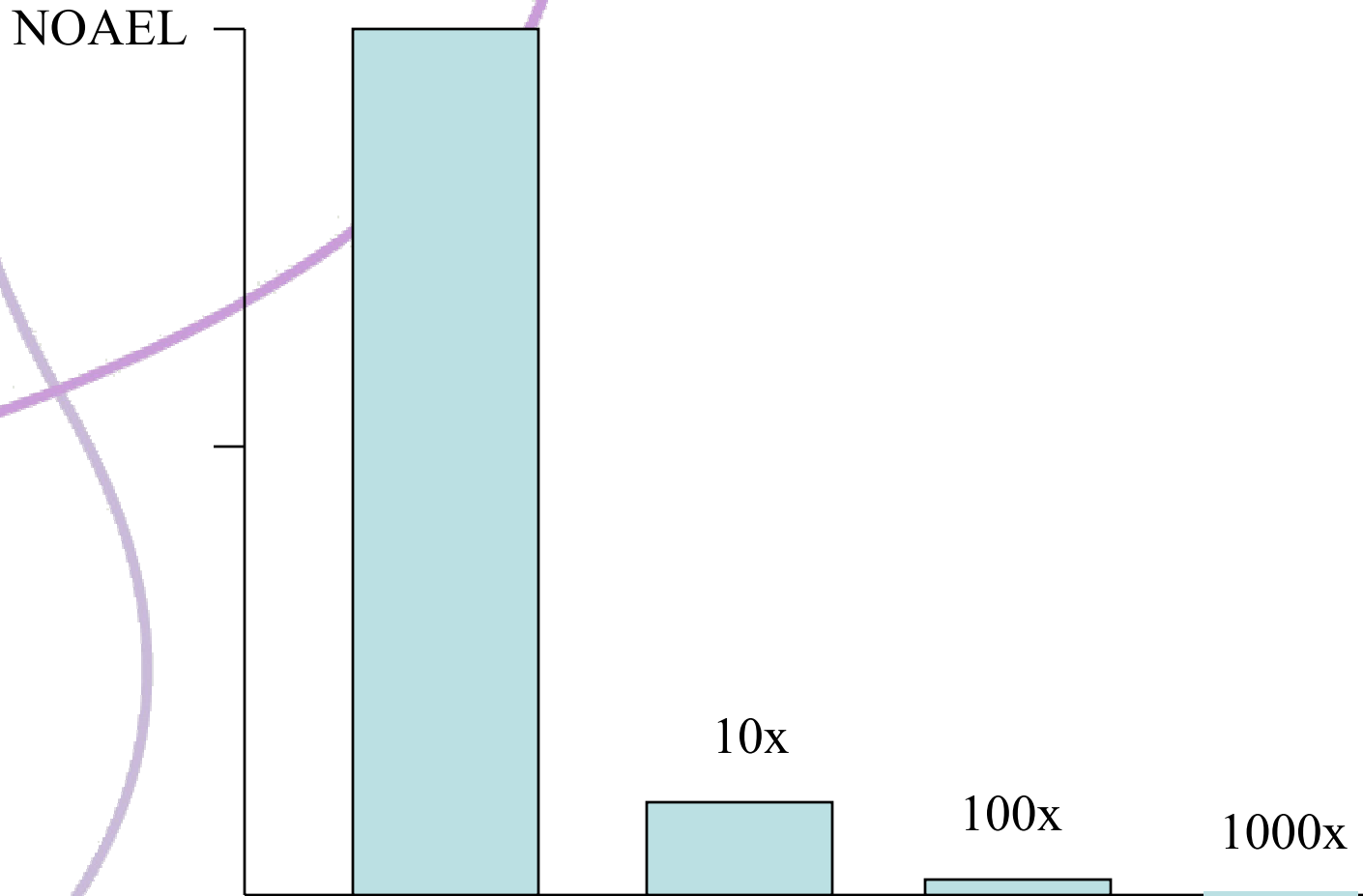
Precaution in Risk Analysis

- Precautionary Principle not explicitly embraced in US legislation and regulation
 - practiced nonetheless
- Relying on QRA \neq excluding precaution
- Standard-setting to limit chemical exposures
 - e.g., EPA, OSHA, FDA
 - includes both risk assessment & management components

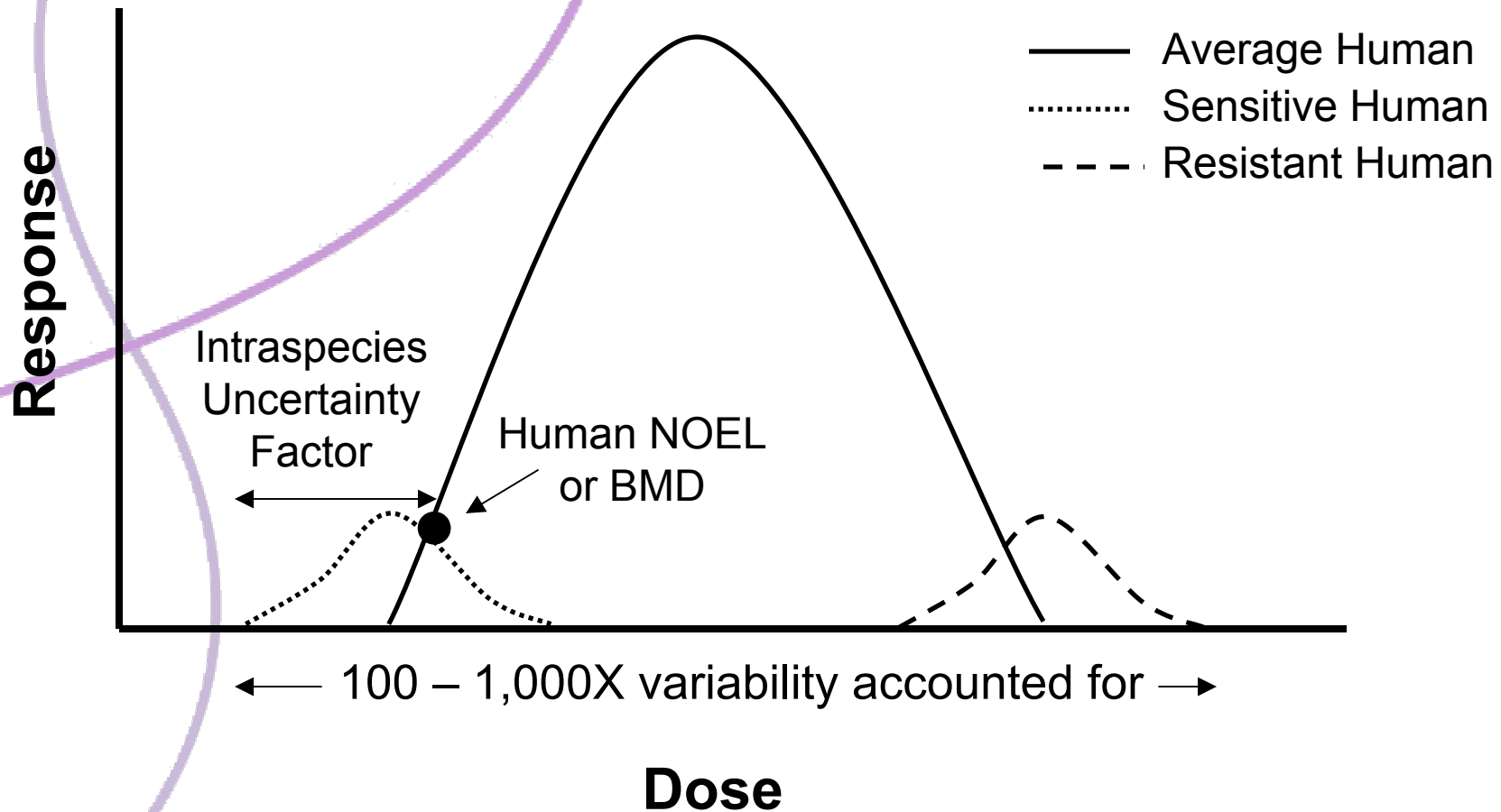
Setting chemical exposure limits



Setting chemical exposure limits



Response as a function of dose for humans of different sensitivities



Clean Air Act: Regulation of Hazardous Air Pollutants

- 18 years of relying on a risk-based approach produced standards for only 7 substances
- Title III = regulation by legislative fiat
 - Congress listed 189 pollutants to be regulated
 - Technology-based standards required
 - Success measured by tons of pollutants reduced
 - no knowledge of impact on reducing risk or improving public health

Conclusions

- Neither a purely risk-based nor precaution-based approach to limiting risks is ideal
- US links precautionary and quantitative approaches to risk management
- Finding appropriate balance between risk & precaution is a continuing challenge