



Conflicting Scientific Judgments and Judicial Review

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Judicial Review 101

- ◆ Lots of deference or “weigh the evidence”?
 - ◇ Typically lots of deference
 - Courts do not weigh scientific evidence or resolve scientific disputes
 - Courts do not substitute their own judgment or what they think is best
- ◆ What is the “standard of review”?
 - ◇ Administrative Procedure Act (“APA”) 5 USC 706
 - Court must “hold unlawful and set aside agency action, findings, and conclusions found to be *arbitrary, capricious, an abuse of discretion...*”
 - ◇ Governing Statute
 - E.g., Toxic Substances Control Act (“TSCA”) 15 USC 2618(c)
 - Court must “hold unlawful and set aside such rule if the court finds that the order is not supported by *substantial evidence* in the record taken as a whole”

Judicial Review 101 (cont.)

- ◆ **What science does the court review?**
 - ◇ Typically limited to the “administrative record”
 - ◇ Court acting as an appellate reviewer of an agency decision
 - ◇ Court reviews science that was before agency at time of decision
 - ◇ Not a civil trial (i.e., no expert witnesses or expert reports)
- ◆ **Where does science come from?**
 - ◇ Public comments (trade associations, NGOs, companies, academics)
 - ◇ Agency’s own data and studies
 - ◇ Publicly available research cited by stakeholders or agency
 - ◇ Evidence submitted in administrative proceedings
- ◆ **Rarely can litigants supplement the record after the agency decision**

Levels of Deference – “Super” Deference

- ◆ *Baltimore Gas and Elec. v. NRDC (1983)*
 - ◇ “...a reviewing court must remember that the [Nuclear Regulatory Commission] is making predictions, within its area of special expertise, at the frontiers of science. When examining this kind of scientific determination, as opposed to simple findings of fact, a reviewing court must generally be at its most deferential.”
- ◆ Affirmed NRC’s “zero release” presumption in licensing proceedings
 - ◇ Administrative record had thousands of pages of testimony, data, etc.
 - ◇ NRC relied on various analyses of potential release scenarios
 - ◇ NRC made certain conservative assumptions
- ◆ Contrary evidence? Studies in support? Reasonable assumptions?

Basic Justifications for “Super” Deference



- ◆ Agency experts, not generalist judges, should be resolving complex scientific and technical questions
- ◆ Agency experts are in a better position to make predictive judgments where the science is uncertain
- ◆ Agency officials work for the President and thus are more accountable to the voting public than federal judges
- ◆ A high level of deference ensures judges do not weigh the evidence and impose their own biases and views
- ◆ Reduces incentive for agencies to needlessly overload administrative record with scientific explanations and data
 - ◆ APA Section 553 – “concise general statement of [the rule’s] basis and purpose”

Levels of Deference – “Hard Look” Doctrine



- ◆ *Motor Vehicle Mfrs. Ass’n v. State Farm (1983)*
 - ◆ “...the agency must examine the relevant data and articulate a satisfactory explanation for its action including a ‘rational connection between the facts found and the choice made...’ Normally an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress had not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.”
- ◆ Set aside NHTSA decision to rescind rule requiring passive restraints
 - ◆ Considered irrelevant factors (industry preference for detachable seat belts)
 - ◆ Ignored relevant information (air bags would be adequate alternative)
 - ◆ Failed to weigh contrary data (even detachable belts increased use)

Basic Justifications for Hard Look Doctrine



- ◆ Forces agencies to be more deliberate and transparent
- ◆ Prevents agencies from cherry-picking science and ignoring best science
- ◆ Decreases risk that judges will miss significant decision-making errors (e.g., agency failed to consider relevant factor required by statute)
- ◆ Guards against agencies cloaking “subjective” policy decisions as “objective” scientific judgments
- ◆ Promotes public participation because agency must acknowledge differing views and explain how it resolved public comments
- ◆ Ensures agencies adhere to the relevant statutory language (e.g., level of acceptable risk) and underlying purposes

Additional Factors Complicating Review

- ◆ Scientific Uncertainty
 - ◇ Agency must fill-in gaps with policy decisions
 - ◇ E.g., can we extrapolate from animal studies to humans and, if so, how?
 - ◇ E.g., how much conservatism is built into exposure number?
 - ◇ E.g., which absorption model is used and what are its limitations?
- ◆ Statutory Language Implicates Policy Issues
 - ◇ E.g., TSCA “unreasonable risk” determinations and “whole chemical” approach
- ◆ Policy Bias
 - ◇ Not all policy decisions are unlawful; in fact, statute may require it
 - ◇ But risk having agency cloak policy decisions falling outside statutory authority as a scientific decision that deserves deference

So What's Better? More or Less Deference?

- ◆ Hard look doctrine and red flags/danger signals
 - ◇ Unexplained or unsupported assumptions
 - ◇ No response or discussion of significant evidence or arguments
 - ◇ Sudden departure from past policies or approaches w/o explanation
 - ◇ No discussion or analysis of a selected model's limitations
 - ◇ Decision runs counter to well-established scientific principles
 - ◇ Significant data gaps forcing policy considerations that drive decision
 - ◇ High profile and controversial issue that has gone mainstream
- ◆ Court challenges do not focus on weight of the evidence
 - ◇ Rather, they challenge decision-making process (e.g., unexplained assumptions, cherry-picked studies, etc.)

FDA Example With Red Flags/Danger Signals



- ◆ Tobacco Control Act and Electronic Cigarettes
 - ◇ Requires pre-market review by FDA to determine if a given e-cigarette is “appropriate for the protection of the public health” (“APPH”)
 - The Tobacco Control Act has multiple goals – reducing harm from traditional cigarettes, guarding against underage use, and promoting reduced harm cessation products
 - ◇ APPH requires a comprehensive evaluation of each product, including tox data, public literature review, cessation efficacy, and underage use rates
 - APPH is a balancing approach based on all factors
 - Prior FDA regulations and guidance reflected this comprehensive approach
 - ◇ FDA overwhelmed with applications and Congressional pressure
 - Without any scientific review, FDA denies marketing approval for all non-tobacco flavored products (1.2 million products) based on internal “fatal flaw” approach



Thank You

Any questions?

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