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DEEPER JUDICIAL SCRUTINY NEEDED FOR AGENCIES' USE OF SCIENCE

by

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A recent decision of the United States Court of Appeals for the District of Columbia Circuit may offer a potentially significant expansion of judicial review of regulatory science. The case involved the Department of Health and Human Services' (HHS) designation of dioxin as a "known" human carcinogen. The court's decision to review the Agency's scientific report under the Administrative Procedure Act was correct, but the opinion curiously omits discussion of a number of important reviewability precedents. The case is a salutary development regarding the availability of judicial review, but, upon reaching the merits, the court retreated to an excessively deferential stance. It is also one among many regulatory science cases which demonstrate that under the current doctrine of APA review of regulatory science, the degree of judicial scrutiny — i.e., the "hardness" of the look — is not applied in a consistent manner.

Background. *Tozzi v. United States HHS*, No. 00-5364, 2001 WL 1477786, -- F.3d -- (D.C. Cir. Nov. 23, 2001), arose out of a Department of Health and Human Services decision to upgrade the chemical dioxin from a "reasonably anticipated" to a "known" carcinogen. The 1978 amendments to the Public Health Service Act, Pub. L. No. 95-622, Tit. II § 262 (1978) (amending 42 U.S.C. § 241), require HHS to publish a list of suspected and known carcinogens in a biennial Report on Carcinogens. Though the Report does not trigger HHS—or EPA— regulation of included substances, the D.C. Circuit in *Tozzi* held that listing or reclassifying a substance is a reviewable agency action. *Tozzi*, 2001 WL 1477786, at *8.

The plaintiffs complained that HHS acted arbitrarily and capriciously in relying on mechanistic rather than epidemiological evidence to elevate dioxin to the status of a "known" carcinogen. *Id.* at *4. Mechanistic evidence focuses on the biochemical processes through which a substance can theoretically cause cancer. Epidemiological evidence, by contrast, provides empirical evidence of carcinogenicity, as it shows how often members of a population have actually been diagnosed with cancer from a particular cause. The quality of HHS' science — specifically, the level of scientific proof required before the Agency could list or reclassify a substance — was therefore implicated in *Tozzi*.

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Deference to Agency "Expertise." Regulatory agencies have been consistently criticized for the erratic quality of their science; commentators have called attention to agencies' reliance on inadequate information, use of flawed analyses, and manipulation of data and methodologies to justify desired policy outcomes. Courts have frequently compounded the problem by reflexively deferring to agencies on scientific matters, on the theory that agencies possess superior technical expertise. Given the documented criticisms of agency science, as well as the far-reaching effects of agencies' scientific decisions on the public's health, welfare, and pocketbook, agency action should not be insulated from meaningful judicial oversight. Though *Tozzi* is a positive step toward ensuring the availability of judicial review, the case is equally a sign that judicial progress in the direction of searching scrutiny and away from extreme deference has been uneven.

Reviewability. Reviewability of an agency action generally turns upon whether it is binding on the agency or regulated parties. HHS argued forcefully that its reclassification of dioxin was unreviewable, pointing out that the preamble to the Report on Carcinogens stated that the Report was "for informational purposes only," and noting that the final Report was never published in the Federal Register.

The court made strikingly short work of these arguments. With little analysis, the panel found HHS' action reviewable. Judge Tatel, writing for the court, distinguished certain D.C. Circuit precedents but cited no directly supporting authority. The court took into account that HHS did publish a notice proposing the upgrade as well as a summary of its final decision, and that HHS was required to undergo notice and comment procedures before removing or adding a substance with regard to either category. Most important to the court's conclusion was the fact that though listing a substance does not result in further HHS action, this action does trigger obligations under the rules of other regulatory bodies such as the Occupational Safety and Health Administration, the Department of Labor, and the states. 2001 WL 1477786, at *8. While the decision in favor of reviewability is ultimately correct as a matter of law and policy, it is not self-evidently so. Indeed, if the court had engaged in the more typical inquiry which begins with assessing whether an agency action is final and then proceeds to determine whether the action is also ripe for review, finding judicial review to a free-standing scientific report reviewable could have been downright controversial. *See Toilet Goods Ass'n v. Gardner*, 387 U.S. 158, 162-66 (1967) (setting forth the test for ripeness). It is thus surprising that the court did not draw upon key reviewability precedents that would have significantly bolstered its decision.

From a policy perspective, *Tozzi* is an important recognition that agency action short of actual regulation can have ramifications sufficient to justify judicial review. Administrative action that impacts public health and safety should be subject to careful, if not profound, judicial oversight. *Tozzi*'s holding is noteworthy but not entirely unprecedented; in particular, it finds substantial support in two Supreme Court cases omitted from the court's analysis.

In *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997), the Supreme Court found reviewable a biological opinion issued by the Fish and Wildlife Service which prescribed legally binding conditions to be followed in carrying out a project that threatened endangered fish. Last year in *Whitman v. American Trucking Associations, Inc.*, 531 U.S. 457 (2001), the Supreme Court considered the reviewability of an EPA implementation policy described in the preamble of an agency regulation. EPA had stated that this policy was merely preliminary and not binding on the states or the public. *See id.* at 477. With a nod to *Bennett*, the Supreme Court held the policy reviewable, finding that the necessary finality was supplied by the later publication of implementation procedures under the heading "Final decision." *Id.* at 477-79.[1]

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[1]In a case that preceded *Tozzi*, the Ninth Circuit reviewed administrative orders that EPA had issued to the Alaska Department of Environmental Conservation and the owner of an Alaskan mining facility. *Alaska v. United States EPA*, 244 F.3d 748 (9th Cir. 2001). The orders stated EPA's position that a permit had been improperly granted to a mining facility. *Id.* at 749. The court held that the orders were final agency action notwithstanding the fact that EPA had not commenced an enforcement action. *Id.* at 750-51. Though important, the court's ruling did not expand judicial review to the same extent as does *Tozzi*. The Ninth Circuit nonetheless relied heavily upon both *Bennett* and *American*

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American Trucking invited courts to hold agencies accountable for actions taken without "the conventional procedural accouterments of finality." *Id.* at 479. Without crediting *American Trucking* or *Bennett*, *Tozzi* accepted this invitation and went a step further, extending review to agency statements that lead to action by third party regulators. *Tozzi* did not break completely new ground, however. An important but too little remarked district court case actually prefigured *Tozzi*'s expansion of judicial review.

The* Flue-Cured Tobacco *Decision. In 1998, the United States District Court for the Middle District of North Carolina decided *Flue-Cured Tobacco Cooperative Stabilization Corp. v. United States EPA*, 4 F. Supp. 2d 435 (M.D.N.C. 1998). The court struck down EPA's scientific risk assessment designating "second-hand smoke" or environmental tobacco smoke (ETS) as a Group A carcinogen pursuant to the Radon Research Act, 42 U.S.C. § 7401 note (1994). *Flue-Cured Tobacco* is notable for its stinging indictment of EPA's glaringly unsound science and for its potentially dramatic departure in favor of expanded judicial review of agency science.

The Radon Research Act authorized EPA to establish a research program to study the effects of indoor air pollutants. The Act did not authorize EPA to regulate indoor air; indeed, the Act specifically *prohibited* EPA from regulating these pollutants. *See id.* at 439. EPA's dissemination of information on ETS had nonetheless spurred activities by independent groups that significantly impacted tobacco interests. The absence of formal regulation proved no bar to the district court's review. *See id.* at 443. *Flue-Cured Tobacco* thus laid the groundwork for *Tozzi*'s expansion of judicial review to agency activities that result in third party regulation. Though *Tozzi* makes no reference to *Flue-Cured Tobacco*, the D.C. Circuit's decision vindicates this carefully reasoned district court case that is currently stagnating in the Fourth Circuit since its appeal was heard in June of 1999.

Review of Agency Science. *Flue-Cured Tobacco* and *Tozzi* diverge when they reach the merits of the respective agencies' science. *Flue-Cured Tobacco* conducted an extensive analysis of EPA's scientific risk assessment and meticulously catalogued its many defects. 4 F. Supp. 2d at 449-66. The result was a credible indictment of EPA's flawed procedures, disregard of scientific principles, and elevation of policy over science. The court found ample evidence that EPA had "cherry picked" its data in order to confirm its a priori hypothesis. *Id.* at 460-62. In contrast to the close scrutiny applied in *Flue-Cured Tobacco*, the *Tozzi* court cast a comparatively furtive glance toward HHS's decision to reclassify dioxin based on mechanistic evidence, preferring a more "highly deferential" approach to review of agency science. 2001 WL 1477786, at *8.

The issue presented in *Tozzi* was whether HHS was permitted to rely on mechanistic evidence to classify a substance as a "known" carcinogen, or whether mechanistic evidence could only be used for the "reasonably anticipated" category. *Id.* Rather than grappling directly with the soundness of HHS's science and assessing the reliability of the two forms of evidence, the court framed the question as one of pure textual interpretation. The court reviewed the format of HHS's regulations and determined that the paragraph permitting reliance on mechanistic evidence could be read to modify both categories. These were sufficient grounds, in the court's view, for affirming the Agency's decision. *Id.* at 8-9.

The markedly different approaches in *Flue-Cured Tobacco* and *Tozzi* trace a larger pattern among the federal courts. While in some cases courts recognize that safeguarding public health and safety necessitates meaningful review of agency science, in others courts respond with extreme deference whenever an agency's technical expertise is invoked. The D.C. Circuit itself has vacillated between probing review and excessive deference. In *Chlorine Chemistry Council v. EPA*, 206 F.3d 1286 (D.C. Cir. 2000), for example, the D.C. Circuit vacated EPA's maximum contaminant level goal for chloroform in drinking water because EPA did not use the best available science as required by the Safe Drinking Water Act, 42 U.S.C. § 300g-1 (Supp. II 1998). Five weeks later, the D.C. Circuit upheld EPA's decision not to add certain substances to a statutorily mandated list of hazardous wastes. *Environmental Defense Fund v. EPA*, 210 F.3d 396 (D.C. Cir. 2000). There, the court decided it was bound to show agencies "considerable deference" and subjected EPA's

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Trucking to support its reviewability finding. *Id.* at 750.

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decision to only "minimal standards of rationality." *Id.* at 400, 402. These disparate approaches strongly suggest the need for a framework to increase consistency, and to empower judges to engage in searching, albeit not overly intrusive, judicial review.

Incorporating* Daubert *Principles. In the tort context, *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 597 (1993), entrusted judges with a "gatekeeping role" to screen out expert testimony that is based on unsound science. The principles of *Daubert* could be usefully applied in the regulatory context. Judges reviewing agency science should perform a gatekeeping function to ensure that agencies use valid methodologies and procedures, rely on relevant evidence, and expose any scientific assumptions and uncertainties. These objectives find statutory support in the APA, which commands courts to invalidate agency actions that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706 (1994). Just as scientific evidence must be relevant and reliable under *Daubert*, 509 U.S. at 589, *Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile. Insurance Co.*, 463 U.S. 29, 43 (1983), the authoritative word on judicial review under the APA, makes clear that an agency rule is arbitrary and capricious if the agency has not considered all relevant factors, has relied on improper factors, or has "offered an explanation for its decision that runs counter to the evidence before the agency."

Courts should neither abandon all deference nor hold agency science to impossible standards. *Daubert* does not permit judges to substitute their own conclusions for those of the agency. 509 U.S. at 595. Courts should simply assess the validity of agencies' underlying scientific methodologies and principles. *See id.* In doing so, courts should apply consistent and coherent standards aimed at meaningful review of agency science. Indeed, one can question whether "minimal standards of rationality" are really good enough for courts to uphold agency decisions that govern major swathes of society's industrial activity where those decisions are ostensibly supposed to be grounded in objective science, rather than mere expressions of the regulators' policy preferences.

Quality of Information Guidelines. Since the decision in *Tozzi*, the Office of Management and Budget has issued new federal guidelines that require greater accountability for the quality of agencies' data. The Quality of Information Guidelines, which were published on January 3, direct each administrative agency to issue its own guidelines to ensure the quality of the information it disseminates.
Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, 67 Fed. Reg. 369, 369 (Jan. 3, 2002). The Guidelines seek to compel agencies to base their decisions on sound science. Agencies generating scientific information must adhere to the "best available science" standard set forth in the Safe Drinking Water Act. *See id.* at 375. They must also use sound statistical and research methods in developing data. *See id.* at 373.

The Guidelines have potentially significant implications for reviewability of agency action. Agencies must establish administrative mechanisms allowing affected parties to challenge and compel correction of agency information that does not comply with the Guidelines. *See id.* at 376. Thus, agency review can presumably be obtained before the agency issues a final regulation to obtain agency review. Whether an agency's refusal to correct information is subject to further challenge in the federal courts is an open question. *See OMB Guidelines on Quality of Information Seen as Having Profound Impact on Agencies*, REG., L. & ECON. (BNA) No. 09, at C-1 (Jan. 14, 2002).

If fully and conscientiously implemented, the Guidelines should increase the transparency of agency decisionmaking and the quality of agency science. A recent statement of John D. Graham, the director of OMB's regulatory review office, reveals that hard science is not OMB's sole focus. Referring to the role of precaution in scientific risk assessment, Graham noted that public concern about certain perceived hazards should also be taken into account in measuring risks. *See OMB's Graham Concedes Public Concerns, Science Both Relevant to Risk Assessments*, REG., L. & ECON. (BNA) No. 09, at A-27 (Jan. 14, 2002). Cautionary impulses should not excuse the obligation to base decisions on good science, however. Perhaps mindful of this fact, Graham emphasized the need to implement scientific and procedural safeguards where precautionary principles are adopted. *See id.* Though the exact effects of OMB's Guidelines remain to be seen, both the Guidelines and the *Tozzi* decision are an important recognition of the need for enhanced review of scientific decisions.

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Conclusions. Both those contesting and those defending agency action would benefit from greater consistency and predictability in judicial review. The larger public would likewise benefit from more probing review of agency science. In increasing the availability of judicial review, *Tozzi* took a valuable step. How courts will exercise these enhanced powers of review is a lingering question.

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