

Comment by Jeff Lubbers on the Revised Recommendation on Agency Guidance

I support Ron Levin's proposals to reinstate the language of former paragraph 1 and to include interpretive rules within the scope of the recommendation. But I also have several concerns about the preamble. First I think it downplays too much the beneficial aspects of guidance documents. Although the first paragraph of the preamble does emphasize the beneficial aspects of guidance to agencies in their administration of programs it doesn't mention the beneficial aspects to the public. Moreover 6 of the 7 pages in the preamble accentuate the perceived problems or potential abuses of guidance. Even the lead-in to the recommendation is grudging: "The Administrative Conference recognizes that many agencies consider guidance to be a useful tool to be employed in appropriate circumstances."

I think this emphasis is unfortunate. As Peter Strauss has reminded us, the regulated public often wants more guidance, not less. I think Recommendation 92-2, short paragraph states this quite well:

Policy statements that inform agency staff and the public regarding agency policy are beneficial to both. While they do not have the force of law (as do legislative rules) and therefore can be challenged within the agency, they nonetheless are important tools for guiding administration and enforcement of agency statutes and for advising the public of agency policy.

This brings me to my institutional concern about the need to frame this new recommendation in the context of Recommendation 92-2. I am a fan of that recommendation. It is worded in a very concise way and is quite understandable to all who read it (including my students). I recognize that in the ensuing 25 years developments at OMB, the FDA, and the courts have informed us more fully as to the issues surrounding guidance, and Professor Parrillo's research has added a lot, as has Ron Levin's recent article. Moreover I think there is value in broadening 92-2's focus to include interpretive rules and, as Professor Parrillo argues, in broadening the concern about guidance beyond agency's intentional attempts to circumvent notice-and-comment.

In my view it might have been better to frame this project as an amendment to Recommendation 92-2, but it's a little late to suggest that. If we are going to continue down the road of the new recommendation, I would propose a new opening paragraph to put 92-2 in proper context. Something like this:

In 1992 the Administrative Conference issued Recommendation 92-2, "Agency Policy Statements."¹ This recommendation recognized the value of agency statements that inform agency staff and the public regarding agency policy, but also expressed concern "about situations where agencies issue policy statements which they treat or which are reasonably regarded by the public

as binding and dispositive of the issues they address.” It proposed that agencies should (1) decide whether to issue the policy as a legislative rule, in a form that binds affected persons, or as a nonbinding policy statement, and (2) that agencies establish informal and flexible procedures that allow an opportunity to challenge policy statements. This recommendation has been influential. It helped provide the foundation for Congress in 1997 when it required that the FDA develop a comprehensive regulation on “good guidance practices,”² and to OMB, which cited it prominently in its 2007 Bulletin on Good Guidance Practices (which is still in effect).³

In the ensuing 25 years, there have been numerous court decisions attempting to delineate between proper and improper agency use of agency guidance documents (including both policy statements and interpretive rules, both of which are exempt from notice and comment under the Administrative Procedure Act). The Conference determined it was a good time to update Recommendation 92-2 and commissioned a study that resulted in 135 interviews with agency officials, and industry and NGO representatives which “sought to assess guidance’s essential role and its sometime pathologies from the worm’s eye view.”⁴ This recommendation is the result of that study and also attempts a wider scope—including in its definition of guidance both policy statements and interpretive rules.

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