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Guidance Documents and Regulatory Beneficiaries

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By Nina A. Mendelson[1]

The World of Guidance Documents

Federal agencies rely heavily on guidance documents, and their volume is massive. The Environmental Protection Agency and the Occupational Safety and Health Administration recently catalogued over 2000 and 1600 such documents, respectively, issued between 1996 and 1999. These documents can range from routine matters, such as how employees should maintain correspondence files, to broad policies on program standards, implementation, and enforcement. Documents in the latter category include Education Department policies on Title IX implementation, Environmental Protection Agency policies on hazardous waste cleanup, the Food and Drug Administration's policies on food safety and broadcast advertising of pharmaceuticals, and many more. Although these documents often resemble informal rules, agencies generally avoid Administrative Procedure Act notice-and-comment requirements because guidance documents arguably qualify under the statutory exceptions for general policy statements, interpretative rules, or both.

These policies now typically are express in disclaiming any binding effect upon regulated entities or upon the agency itself, a response to some recent judicial decisions requiring notice-and-comment rulemaking for a guidance accorded binding effect, as well as to congressional concern about uncertainty. Nonetheless, a guidance document often evokes a significant change in behavior by those the agency regulates. And if the document includes an interpretation of law, that interpretation may also receive limited *Mead/Skidmore* deference in court. Finally, despite the lack of formal legal binding effect, agencies are increasingly stating they will usually conform to positions taken in guidance documents.

Consequently, a number of commentators have called for procedural reform of agency issuance of guidance documents. Over the years, the Administrative Conference has issued multiple recommendations, including calling generally for greater participation and for notice-and-comment for guidance documents with a "substantial impact." Other commentators, however, have guardedly defended the current state of affairs because of a desire not to deter the creation of guidance documents, which help agencies supervise low-level employees and supply valuable information to regulated entities regarding how an agency will implement a program. Moreover, they argue that a regulated entity at least retains a formal opportunity to challenge the agency's policy at the time an enforcement action is brought.

The Interests of Regulatory Beneficiaries

Thus far, however, the debate has largely ignored the distinct and substantial interests of those who might (inelegantly) be called indirect regulatory beneficiaries. These are people whose behavior is not directly regulated or who receive no government subsidy or payment, but nonetheless reasonably expect to benefit from government regulation of others – pharmaceutical consumers, women seeking opportunities in college athletics, environmental users, workers seeking safe workplaces, to name a few. Regulatory beneficiaries may have been specifically named in a statute or it may simply have been widely understood that the statute was meant to regulate one segment of the public to indirectly benefit another group. These latter groups have obvious and substantial interest in the way an administrative agency "fills in the blanks" of such a regulatory program.

Regulatory beneficiaries do sometimes benefit from agency guidance documents, if the guidance happens to be favorable in substance. Such a guidance can prompt useful changes in the behavior of regulated entities. Guidance document policies can certainly be unfavorable, however. For example, the FDA's 1999 guidance document advising that pharmaceutical companies may advertise prescription drugs to consumers without supplying detailed risk information prompted a significant and highly controversial increase in television advertising. The Education Department's 2005 "Dear Colleague letter" to universities suggesting that on-line surveys of students could be sufficient to document insufficient interest by the "underrepresented sex" in a varsity athletic team has also been controversial.

Generally, regulatory beneficiaries suffer distinct procedural losses when an agency issues policy in this way, inhibiting their ability to hold the agency accountable for its policy decisions. Regulatory beneficiaries lose access both to judicial review and to the process of agency decision making. First, with respect to judicial review, even if the regulatory beneficiary has standing, a guidance document may not be considered final agency action or ripe for review at the time it is issued, especially if the document expressly disclaims a binding effect. This obstacle, of course, plagues both regulated entities and regulatory beneficiaries. At least in theory, however, regulated entities can choose not to follow the guidance, wait for agency enforcement, and obtain judicial review of the agency's policy or statutory interpretation at that time. Unlike regulated beneficiaries, however, regulatory beneficiaries generally lack any such later opportunity to obtain judicial review. In many cases, the aspect of the policy of

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concern to a regulatory beneficiary will be realized through agency inaction. For example, in the food safety context, a Food and Drug Administration guidance saying that it will consider ready-to-eat food "adulterated" under the Federal, Food, Drug and Cosmetic Act if the food contains foreign objects of larger than 7 millimeters in maximum dimension will mean that the FDA is unlikely to bring an enforcement action against, say, a manufacturer selling baked beans or pickles with 5 millimeter foreign objects. Needless to say, challenging a decision not to file a particular enforcement action is very difficult. Meanwhile, a choice by a regulated entity to comply with a guidance – such as by sifting out sharp 7-millimeter long objects – will also foreclose enforcement actions and with that the prospect of judicial oversight. Even if there is enforcement litigation, a regulatory beneficiary will have a difficult time intervening for the purpose of arguing that the underlying policy should be more stringent, since a court generally will be able to resolve a particular enforcement action without reaching such arguments.

Second, when an agency issues a policy in a guidance document, regulatory beneficiaries are likely to have significantly less access to the agency decision making process. Assuming the guidance document qualifies for the APA exceptions to notice-and-comment rulemaking, the agency has no obligation to seek outside views, disclose data, or respond to comments. Some agencies indeed seek no public input at all on guidance documents. Especially when the guidance document announces a significant policy, however, an agency may well seek outside comment. The agency may hope to gather new information, identify significant feasibility problems, or flush out any political controversy early, to minimize later executive or legislative oversight. Indeed, agencies often claim greater legitimacy for these policies as a consequence of seeking public input.

A draft guidance might be posted on the Internet or published in the Federal Register for comment, but very often, agencies do not widely solicit comment. Instead, agency employees make ad hoc decisions regarding public outreach and to whom to "float" a guidance document. When this happens, regulatory beneficiaries can lose valuable opportunities to participate. Agency employees often try to include those who are frequent communicators with the agency. One agency reportedly uses as its starting point for public outreach lists of organizations that have commented on past rulemaking, or lists of contacts developed through agency meetings on other topics. Again, however, this process is often highly arbitrary. Among regulated entities, for example, a recent study of industry involvement in FDA guidance document development found that some industry representatives felt closed out of the process, finding it "opaque," while others found access to FDA staff to be easy, and the staff to be "very responsive."[2]

Turning to regulatory beneficiaries, agency participation decisions sometimes overtly advantage regulated entities. For example, the Federal Aviation Administration has explicitly adopted an exclusionary approach in its development of "advisory circulars," a major category of its guidance documents concerning aviation safety. The FAA has posted on the Internet an exclusive list of 17 associations, nearly all associations of regulated entities and related businesses, from which it welcomes comments on draft advisory circulars. The FAA's posting explains, "[W]e generally accept comments only from recognized industry organizations. If you would like to comment on a Draft Advisory Circular, please submit your comments to one of the organizations listed below, as appropriate."[3] The list includes no airplane passenger or consumer safety organizations. EPA's policy on circulating its small entity environmental regulatory compliance guides is to focus the circulation on small business representatives. Finally, the FDA has recently committed to seek public input in advance of issuing especially important guidance documents, except where those documents are presenting a "less burdensome policy that is consistent with public health."[4] Without suggesting any across-the-board criticism of the FDA, one could imagine that regulatory beneficiaries might sometimes have a comment on whether a less burdensome FDA policy remains consistent with public health.

Finally, without any conscious exclusivity whatsoever, agencies that consult ad hoc on draft guidance documents will tend to deemphasize participation by regulatory beneficiaries. Because of direct contact with regulated entities in permitting, licensing, inspection, and enforcement matters, an agency, as a rule, will know and have more regular relationships with regulated entity groups. Given time and resource constraints upon the agency, it is comparatively convenient and inexpensive to reach out to these same entities as a sounding board for policy development. The agency also may have a greater interest in a good long-term relationship with these entities, since it will want to procure their cooperation and compliance with the statutory regime. By contrast, the statute generally will not create any direct relationship between an agency and indirect regulatory beneficiaries such as food consumers, environmental users, or workers in hazardous workplaces. An agency official may have greater difficulty identifying the appropriate people to contact and less interest in maintaining a long term relationship. Moreover, regulated entities, in particular, are likely to have valuable information – often superior to that of the agency or of regulatory beneficiaries – regarding a new policy's cost and feasibility. Finally, regulatory beneficiaries are relatively diffuse and unorganized, compared with regulated entities, and thus will have fewer resources and less ability to find out about a guidance before it is finalized or to obtain executive or Congressional oversight. In short, unless the agency itself chooses to

[2] See Erica Seiguer & John Smith, Perception and Process at the Food and Drug Administration: Obligations and Trade-Offs in Rules and Guidances, 60 Food & Drug L.J. 17, 30 (2005).

[3] See "How do I comment on a Draft Advisory Circular?" posted at www.faa.gov/arp/publications/acs/draftacs.cfm#comment (Last visited Aug. 11, 2005).

[4] See 62 Fed. Reg. 8968 (Feb. 27, 1997) (noting that FDA will seek public input after issuance of these guidances); 65 Fed. Reg. 7321, 7324 (Feb. 14, 2000) (confirming same position).

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give public notice of a draft guidance or initiates contact with regulatory beneficiary groups, these groups are likely to have less of an opportunity to participate in guidance development.

Possible Solutions

The procedural costs imposed upon regulatory beneficiaries as well as upon regulated entities when agencies issue policies in guidance documents clearly call for greater regulation. Such regulation is unlikely to lead agencies to a world of "secret law," as some commentators have speculated. Even with more required procedures, agencies will have significant incentives to go public with their policies relating to compliance and enforcement. These incentives will range from a desire to provide regulated entities with some certainty regarding a program's implementation (a desire likely to be reinforced by members of Congress interested in certainty and compliance assistance) to a wish to avoid losing enforcement actions because the agency failed to provide "fair notice" of the requirements it is enforcing, following cases such as *General Electric v. EPA*, 53 F.3d 1324, 1332 (D.C. Cir. 1995).

Nonetheless, requiring notice-and-comment rulemaking for all guidance documents, which would include routine instructions to employees, is clearly overkill. Nor does a proposal to require guidance documents to have "precedential effect" – and to require an agency to give reasons for departing from a guidance document's policy – help the problems I am discussing here. While this approach would clearly reduce uncertainty for those dealing with an agency, it also implicitly presumes that the guidance itself is valid and has properly implemented the statute. It thus does comparatively little for regulatory beneficiaries, because it affords them no opportunity to argue, say, that the agency's choice is not adequately justified or that the agency should be more aggressively interpreting the statute.

Instead, some other intermediate solutions seem appropriate. Space and time constraints will permit me to briefly overview only three. One occasionally discussed solution is to amend the APA to require an agency to use notice-and-comment rulemaking for "important" interpretations or policy statements, or, in the words of the Administrative Conference, those with "substantial impacts." That would mean that a court could invalidate such a guidance document for failure to comply with the requirement. Moreover, regulatory beneficiaries could more fully engage an agency on a policy before it is finalized, which could in turn increase the information to the agency about public policy preferences and technical issues, and the final rule would be subject to judicial review. The major difficulty here is the burden on courts to distinguish the "important" policies from the others. Judges have typically shied away from this sort of decision because it requires so much programmatic expertise.

Agencies could also make procedures more inclusive as a matter of self-regulation. The FDA has done this to some degree in its "Good Guidance Practices," and the Office of Management and Budget has suggested it in its "Proposed Bulletin for Good Guidance Practices," posted on the Internet for comment in November, 2005. For a significant or controversial policy decision, an agency would give advance notice and collect public comment. Neither policy requires an agency to respond to comments, however, and neither appears to subject an agency's compliance with its policy to judicial review. What is thus unclear from these sorts of proposals is whether an agency will meaningfully engage the comments it gets. Comments from an entity with the clout to mobilize political oversight will, of course, receive attention, as such comments would in any event. Well-intentioned civil servants will undoubtedly try to read comments. However, agency resources and time would remain tight, and regulatory beneficiaries could invoke no new external controls in the event agencies do not fully consider their comments.

A third intermediate process-focused option would be a new right to petition to repeal or revise a guidance document that did not undergo notice-and-comment rulemaking. No court has so far construed the APA to afford such a right. A citizen petition could give substantive reasons for an agency to repeal or revise such a document; in response the agency could modify the guidance document or give reasons why the document should remain unchanged. (To avoid multiple successive petitions, an agency perhaps could publish a notice inviting the filing of all related petitions.) The agency's response to the petition would be subject to judicial review.

Any citizen, including a regulatory beneficiary, could thereby engage the agency on a guidance document's substance. By requiring an agency to supply crystallized reasons for its decision, this process would likely make judicial review more effective, and the inquiry on judicial review would be a familiar one: is the agency's decision arbitrary or capricious? Although it provides only a belated opportunity to engage the agency, it might prompt agencies to use a more thorough participatory process at the outset for significant or controversial policies.

On the other hand, depending on how many petitions are filed, the proposal does have the potential to impose significant costs on agencies. Those costs would surely be lower than requiring notice-and-comment rulemaking across-the-board, but it is unclear how the costs would compare to a more limited notice-and-comment requirement for "important" rules.

Conclusion

The debate over agency guidance documents has been incomplete because of the failure to adequately consider the interests of regulatory beneficiaries. When an agency chooses to issue a policy in a guidance document rather than a rule, indirect regulatory beneficiaries in particular can lose critical access to the agency decision making process and to judicial review. This is so even though the agency may be implementing statutes enacted in order to help those beneficiaries. While empirical research would surely be useful in documenting the extent of these costs, procedural reforms that would confer greater procedural rights on regulatory beneficiaries seems clearly worth considering. Such reform would also represent a significant step toward ensuring the agency procedures better recognize and incorporate the legitimate, immediate interests of regulatory beneficiaries in agency policy.