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Who Makes Agency Decisions?

The Food and Drug Administration (FDA) recently decided to make the Plan B (the "morning after pill") available over the counter without age restrictions to young teen girls. The recent Plan B decision is illustrative of the diminished policy role of agencies in this age of increased centralization of federal executive power. The Plan B decision is, therefore, instructive for those seeking to influence the direction of agency actions and for those contemplating legal challenges to agency actions.

Human Health Services' (HHS) Secretary Kathleen Sebelius overruled the decision of FDA Commissioner Dr. Margaret Hamburg to permit young women/girls below the age of 17 to obtain the Plan B contraceptive pill without a prescription. Research performed by FDA concluded the drug is safe and effective for nonprescription use and without the guidance of a healthcare provider. The Food, Drug, and Cosmetic Act authorizes the Secretary, "through the Commissioner," to execute the provisions of the Act. 21 U.S.C. § 393(d)(2). The Secretary thus exercised her power to trump the agency's medical and scientific expertise.

Following the Secretary's decision on Plan B, FDA's spokesperson stated that no Secretary had ever previously exercised this authority to overrule the Commissioner in the context of a drug approval decision. It would be a mistake, however, to conclude from that statement that FDA's decisions in other matters have been or are immune from the influence of the HHS Secretary or of persons above her in the government.

FDA makes many types of decisions in addition to approving or disapproving medical products. For example, FDA issues regulations, guidance documents, and Federal Register notices. The vast majority of these documents reflect policy judgments and choices. Except for truly mundane matters (e.g., scheduling notices), these documents and the policy judgments reflected in them are subject to a multi-step internal government "clearance process" before the documents are released.

The documents are reviewed, commented upon, and approved (or not) by HHS and then beyond HHS at the White House, specifically by the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget (OMB). The power of offices outside of FDA to review and to approve (or not) a document carries with it the power to approve (or not) the policy choices reflected in the document. Other agencies involved in domestic policy matters are subject to a similar policy review structure.

A well-publicized non-FDA example illustrates how review authority equals approval authority. On September 2, 2011, President Obama announced that he had decided to ask the Administrator of the Environmental Protection Agency (EPA) to withdraw a draft final ozone air quality rule. On the same day, OIRA Administrator Cass Sunstein sent a memorandum to the EPA Administrator setting forth the White House's reasons for this action. That memorandum makes clear that OIRA's review of EPA's rule (as well as OIRA's review of the rules of other agencies) is not limited to questions such as the agency's legal authority to promulgate the rule and includes the review of substantive policy matters.

The Sunstein memorandum and the statement of Secretary Sebelius rejecting FDA's decision on Plan B have much in common. Neither document gives much weight to the expert judgment of the agency involved. Similarly, both documents articulate a robust view of the appropriateness of non-experts outside the agency deciding policy matters even when those matters necessarily involve technical information.

The memorandum of Secretary Sebelius rejecting FDA's Plan B decision, for example, states explicitly that she reached a different decision than FDA because she substituted her judgment for that of the agency ("Based on my review, I have concluded that the data submitted for this product do not establish that prescription dispensing requirements should be eliminated for all ages.").

The point here is not whether HHS or OMB/OIRA should be making the key policy calls. The point is the factual one that the nominally responsible agencies are not making the key policy calls and persons outside the agencies are. While this practice played out in a very public fashion recently with FDA and EPA, there is no reason to believe that other domestic agencies are not undergoing comparable executive branch review and second guessing of their respective policy judgments.

At least two implications flow from the fact that the power of domestic agencies has been diminished in favor of concentrating power higher up the bureaucratic chain:

First, given that persons outside an agency with review authority will ultimately decide whether or in what

form an agency proposal will see the light of day, those seeking to have input on agency rules and policies must pay as much attention to those persons as to those inside the agency; and

Second, the increasingly transparent role of non-experts outside of agencies in making key policy decisions should cast a new and quite different light on the notion of judicial deference to agency decisions. The doctrine of judicial deference in administrative law is based on two closely related premises. The first premise is that agencies have expertise. The second premise is that the agencies are actually making the decisions. The factual basis for that second premise is ripe for scrutiny.

In cases challenging an agency action or rule, one can anticipate that the government will raise objections to efforts to develop the record of how and by whom key decisions were made. The counter arguments to overcome those objections are strengthened by the government's willingness to reveal, as it did in the cases of Plan B and the EPA rule, that those outside of an agency are, in fact, the ones making the final decisions.

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