

A Legal Look at the Proposed Modifications to Circular A-110

At the behest of FASEB, Robert P. Charrow, Esp. was asked to review the proposed changes to OMB Circular A-110 that would allow third parties to sue for data produced under federal research grants. He analyzed the issue and its potential impact on the pursuit of biomedical research from a legal perspective.

According to Charrow, the provisions of the Freedom of Information Act are quite broad. FOIA requirements apply only to records in the possession of the Federal government and certain circumstances have been exempted from its purview – including those that jeopardize issues of privacy, proprietary information (i.e., trade secrets), and classified information. The proposed modifications – originally included in last year's Omnibus Appropriations Act as the result of an amendment sponsored by Senator Richard Shelby (R-AL) – seeks to open up the FOIA's reach into some of these areas which it had previously excluded.

In his analysis, Charrow notes that while the Shelby amendment applies only to *rules* put out by the Federal government, there is some question as to whether Federal *notices* will be subject to FOIA provisions. Notices often cite hundreds of studies and, if there is an FOIA request from an individual, the Federal agencies must produce the data.

What is the impact likely to be on research? Charrow believes that if it is limited to regulations, the impact is likely to be minimal to the community (but perhaps huge to an individual researcher). However, if its scope includes policies and general notices – the impact could be far greater. And even if a research study is not cited, an outsider can make a formal comment citing a study, and thereby make that study subject to FOIA provisions.

The following analysis prepared by Charrow makes it clear that there are still several ambiguities with the language of the proposed modification to Circular A-110 that could put research under the scope of the Freedom of Information Act, and could put scientific pursuits at great risk.

What is the Proposed Modification to Circular A-110?

The Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999, Pub. L. 105-277, § 117(d), 112 Stat. 1681-495 (Oct. 21, 1998), contained the following proviso, known as the Shelby Amendment:

Provided further that the Director of OMB amends Section --.36 of OMB Circular A-110 to require Federal awarding agencies to ensure that all data produced under an award will be made available to the public through the procedures established under the Freedom of Information Act: Provided, further, that if the agency obtaining the data does so solely at the request of a private party, the agency may authorize a reasonable user fee equaling the incremental costs of obtaining

the data.

The apparent purpose of the legislation was to ensure that if agencies (e.g., EPA, OSHA) relied on publicly funded studies to formulate government policy then the data underlying those studies should be available to the public. However, on its face, the legislation is not that narrowly drawn and could reach all data, whether the study is used to formulate policy or not.

How does the OMB proposal limit the scope of the legislation?

A private awardee would only be required to forward raw data to a government agency for ultimate production to a requester, if the

Data relat[es] to **published** research findings produced under an award that were **used** by the Federal Government in developing a **rule**....

Each term in bold face type has a special meaning that could limit the scope of the Circular's requirements.

1) The Term "Rules" Has A Narrow Meaning: The OMB proposal only applies to "rules." A rule is a formal legal mechanism by which an agency either makes law or interprets existing law. Most agencies use vehicles other than rules to announce a new policy. Thus, some very controversial scientific policies have been issued as notices, as opposed to rules, and the research cited in those Notices would not be subject to the OMB Circular. For example, chemicals newly classified as carcinogens or suspected carcinogens are published by the National Toxicology Program as Notices in the Federal Register and not as rules.

2) The Term "Used" Has A Narrow Meaning: To trigger release, the data at issue would have to have been used in developing a rule. Thus, according to the OMB preamble, an agency would have to affirmatively reference the study in the reference section to the proposed rule before the requirements of the Circular would be triggered. However, once triggered, an agency would have to move quickly enough so as to respond to the FOIA request before the comment period to the proposed rule (usually 60 or 90 days) closes.

How will the Circular impact the research community?

Whether the Circular will have a profound effect or no effect is difficult to gauge. One can argue that its impact will be modest given that it applies only to research actually used in developing rules. Each year, relatively few rules are issued which affirmatively rely on scientific studies. However, certain rules issued by certain agencies – e.g., EPA and OSHA – frequently cite to thousands of studies. A researcher could find his research the subject of a FOIA request merely because it is cited by a federal agency in its rulemaking. OSHA's permissible exposure limit rule of 1989, for instance, occupied over 500 pages in the Federal Register and cited to hundreds, perhaps thousands of studies. *See* 54 Fed. Reg. 2332 (Jan. 1,

1989). The rule could have a significant impact on any researcher whose work happens to be cited in such a rule.

What are the ambiguities in the current proposal?

1) What Does the Term "Data" Really Mean? The definition of "data" does not answer certain critical questions. For example, "data" includes "any raw underlying information necessary to validate researching findings." This definition is potentially so broad that it could easily encompass specimens and make them subject to FOIA to extent that they contain "information."

2) When is an Article Really "Published?" There is some question as to what the term "publication" means. Specifically, if a study has not been published in a peer-reviewed journal, but has been referenced in a proposed rule, does that mean that the data are subject to a FOIA request? The OMB proposal's language is not clear, but would appear to imply that in such a case, the data would be subject to FOIA

Are There Outstanding Legal Issues Worth Noting?

The Appropriations Act raises a host of legal issues – some constitutional and others statutory. One of the more intriguing such issues is whether the Shelby Amendment actually survives beyond this fiscal year. Specifically, provisions in an appropriations act normally are deemed to last for a single fiscal year unless the language of the act expressly notes the contrary. The language associated with the proviso under scrutiny contains no such language and therefore, one could argue that it dies on September 30, 1999. If a rulemaking is based solely on a statute that dies on September 30, one can argue that any rule would also die on that day.

Return to [August 1999 FASEB Newsletter Table of Contents](#)

Return to the [FASEB Office of Public Affairs](#) homepage