Rx For The Defense

Fall 2002

The newsletter of the DRI Drug and Medical Device Committee

DRI
The Voice of the Defense Bar

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The Data Quality Act

Will It "Daubertize" Federal Agencies?

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Almost ten years have passed since the Supreme Court decided *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 469, 113 S.Ct. 2786 (1993), the watershed case that attempted to rid federal courtrooms of expert witness conjecture masquerading as scientific thought. At the time, commentators debated the effect *Daubert* would have on civil litigation. Now, few experienced trial lawyers question the tidal change in the admissibility of expert testimony in federal and state court decisions following *Daubert*.

While judges have used the *Daubert* rule to uncloak junk science disguised by an expert witness' testimony, *Daubert* has had no discernible effect on the release of scientific studies, data, and public health pronouncements by federal agencies. Some attorneys may question how the quality of data released by the government could affect civil litigation or undermine the principles of *Daubert*. These lawyers likely have been spared the difficulty of challenging an expert's causation opinion that is based on data generated by or for a federal agency. Federal agency reports present at least two significant problems for defense counsel. First, they may be admissible under Federal Rule of Evidence 803(8). Second, even if a report is inadmissible, experts can nonetheless rely upon the data. Challenging an expert's opinion based on government data has never been easy. Judges and jurors often cannot detect the unreliability of a

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biased expert's opinion if the expert can clothe the opinion in "objective evidence" from the federal government. Since the events of September 11, 2001, the task may have become more difficult if, as some believe, jurors are giving greater deference to federal agency decisions.

A risk assessment is one type of government report that can be particularly troublesome to a defendant in a products liability or toxic tort case. An experienced expert can make a risk assessment sound like a government decision on the precise causation issue in dispute at trial. The effect can be devastating. When this happens, defense counsel's task is no longer limited to impeaching a skilled expert's credibility. Defense counsel must now impeach the reliability of numerous government scientists, whom the jury will consider unbiased.

Many risk assessments suffer a common scientific weakness—a reliance upon "default assumptions." By regulation and/or guidelines, agencies are permitted to use certain default assumptions to reach their conclusions when gaps in the scientific data would otherwise preclude the same conclusion. For example, assume the question of whether a chemical, to which there is only low dose exposure, is a carcinogen. Assume also that there is *in vitro* evidence that the chemical is mutagenic at high concentrations in a particular animal cell line. Mutagenicity is viewed by some as evidence that a chemical may be a carcinogen. A conclusion, based on the *in vitro* evidence, that the chemical is carcinogenic to humans would be based on an assumption that it was mutagenic at low concentrations and in all human cell lines relevant to the cancer. Such an assumption is a "default assumption." While it is not unusual for agencies to embrace default assumptions to conclude that exposure causes disease, defense counsel would probably mount a successful *Daubert* challenge if an expert based his causation opinions on the same assumptions. Worse yet, in the world of regulatory science, default assumptions are assumed to be true absent compelling evidence to the contrary.[1]

Ironically, if plaintiff's experts were bold enough to admit that their opinions were based upon such a default assumption, defense counsel would have a shot at having the opinion excluded under *Daubert*. However, when the experts explain that their opinions are based upon a federal comprehensive risk assessment performed by an agency charged with protecting the public's health, it becomes much more difficult to convince the court that the opinion lacks a reliable basis.

Legislation enacted in late 2000 may offer some help to defense counsel and their clients who want to challenge the quality of scientific reports and assessments disseminated by federal agencies. Quietly passed during the waning days of the Clinton Administration, the Data Quality Act ("DQA") was tucked in as section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001.[2] Incredibly, it was passed with no debate and has no legislative history. Though the DQA occupies a mere 38 lines in the Congressional Record, its ambitious goal is to ensure that information disseminated by governmental agencies meets basic standards of quality.

We present an overview of what the DQA and the OMB Guidelines require. We then identify key issues that arise from both that will need to be resolved by the OMB and courts. Finally, we offer some practice pointers for in-house counsel and trial counsel for deriving litigation benefits from the DQA.

Agency Requirements under the DQA

To accomplish its ambitious goal, the DQA requires the Office of Management and Budget ("OMB") to issue government-wide policy and procedural guidelines that require federal agencies to: 1) "ensure and maximize the quality, objectivity, utility, and integrity of information... disseminated by the Federal agencies," 2) provide administrative mechanisms to allow affected persons to seek and obtain correction of information that does not comply with the OMB guidelines, and 3) report annually to the OMB Director regarding the number and nature of complaints received, and how they were handled.

The DQA builds upon previous statutory and regulatory requirements for information dissemination and quality. The over-riding authority of the OMB to provide guidance and oversee the agencies' information dissemination activities stems from the Paperwork Reduction Act of 1995 ("PRA").[3] Section 3504 of the PRA provides authority to the Director of OMB to issue policies, principles, standards, and guidelines for agency dissemination of information. All federal agencies subject to the PRA must comply with OMB's issued guidelines.[4]

The OMB Guidelines became effective October 1, 2001.[5] Revisions became effective January 3, 2002.[6] Pursuant to the DQA and the OMB Guidelines, the individual agency guidelines become effective October 1, 2002.[7] Therefore, agency pre-dissemination review to ensure information meets the quality criteria applies to information *first* disseminated on or after October 1, 2002, while the administrative mechanisms to allow people to challenge information applies to infor-

mation disseminated on or after October 1, 2002, regardless of when the agency first disseminated the information.[8] Therefore, challenges can be brought under the DQA for information disseminated before October 1, 2002.

The OMB Guidelines provide the framework by which each agency must build its own system to ensure that the requirements of the DQA are met. While the OMB Guidelines provide certain requirements in accordance with the DQA that the agencies are not free to ignore, they are expressly drafted to allow agency flexibility to adapt to the wide range of information and agency administrative practices.

Quality, Objectivity, Utility, and Integrity of Government Disseminated Information is Required

OMB defines quality information as the over-riding principle, which encompasses objectivity, utility, and integrity.[9]

Objectivity is defined in terms of the presentation and the substance of information. Objective presentation is achieved when information is disseminated in an accurate, clear, complete, and unbiased manner. OMB considers the need to ensure the proper context of the disseminated information by including other information, and to identify sources of information and supporting data. Substantively, information is objective if the supporting data and analytical results are based on sound statistical and research methods. OMB considers peer review, reproducibility of results, and public availability of the data as measures of objectivity.

Utility refers to the usefulness of information to its intended users, including the public. OMB considers the need for reproducibility and transparency of information when they are relevant to assess the information's usefulness from the public's perspective.

Integrity refers to the security of information, to protect against unauthorized access or revision, corruption, or falsification.

"Quality" is used in the guidelines to collectively refer to the four statutory terms quality, objectivity, utility, and integrity. Agencies must adopt basic standards of quality and develop a process for reviewing the quality of information before it is disseminated.

OMB's Definitions and Provisions Provide a Flexible Framework for Individual Agency Guidelines

The OMB Guidelines direct agencies to adopt a basic standard of quality that must be integral to every step of the agency's development of information, including creation, collection, maintenance, and dissemination. The process must enable the agency to substantiate the quality of information through documentation "or other means appropriate to the agency."[10]

"Information" is defined as any communication or representation of knowledge such as facts or data, in any medium or form. The OMB Guidelines specifically include information disseminated from a web page, but excludes hyperlinks to information that others disseminate. The OMB Guidelines also excludes "opinions," where the agency makes it clear that what is being offered is someone's opinion rather than fact or the agency's views.[11] This will allow scientists working for an agency to publish their research and speak at professional meetings without a fear that by doing so their agency has disseminated information, provided the scientist makes it clear he or she is not speaking for the agency. The exception does not, however, immunize an agency's assessment of an issue that is dressed up to sound like an opinion.

The OMB Guidelines define dissemination as agency initiated or sponsored distribution of information to the public. Excluded are distributions limited to government employees or agency contractors or grantees, intra- or inter-agency use or sharing of government information, and responses to requests for agency records under the Freedom of Information Act, the Privacy Act, the Federal Advisory Committee Act, or other similar law. The OMB Guidelines also specifically exclude distribution limited to correspondence with individuals or persons, press releases, archival records, public filings, subpoenas, or adjudicative processes.[12]

OMB has recently responded to different approaches taken by two agencies whose guidelines exclude press releases from their definition of disseminated information. OMB supported the EPA in narrowing the exemption to information in press releases or other public notices if EPA has disseminated the same information elsewhere. Likewise, OMB denounced agency definitions that would exclude information in press releases (or congressional testimony) *that is not simultaneously distributed to the public.* In its June 10, 2002, review of information quality guidelines drafted by agencies,[13] the OIRA explained that the press release exception was not intended to provide a loophole for the release of information that would circumvent the information quality standards.

Agencies are Required to Provide an Administrative Procedure to Challenge Disseminated Information that Does Not Comply with the Act or the Guidelines

To facilitate citizen review, OMB directs agencies to establish mechanisms allow-

ing affected persons[14] to seek and obtain, "where appropriate," timely correction of information "maintained and disseminated" by the agency that does not comply with the OMB or agency guidelines. This language suggests that agencies are free to leave aberrant information uncorrected in undefined situations where correction would be inappropriate. OMB explains in its preamble to the Guidelines that it does not intend to "burden agencies with frivolous claims."[15] An example of a frivolous claim was offered by the National Oceanic and Atmospheric Administration to the first draft OMB Guidelines. Such a claim would be a disseminated weather report that was later proven to be incorrect.[16]

Therefore, agencies, in determining whether to correct information, may reject claims made in bad faith or without justification, and are required to undertake only the degree of correction that they conclude is appropriate for the nature and timelines of the information involved. Agencies must explain any such practices in their annual fiscal year reports to OMB.[17]

"Influential Information" Requires a Higher Standard of Quality

The OMB Guidelines recognized that some information may need to meet higher or more specific information quality standards than other types. Therefore, the Guidelines require agencies to define influential information, to which a higher standard of quality is applied. OMB provides a loose definition of influential scientific, financial, or statistical information as information "the agency can reasonably determine... will have or does have a clear and substantial impact on important public policies or important private sector decisions."[18] OMB then authorizes each agency to define "influential" in ways appropriate for it "given the nature and multiplicity of issues for which the agency is responsible."[19]

OMB specifically recognizes a heightened need for objectivity of influential information, requiring additional quality checks beyond peer review. Influential information requires a high degree of "transparency about data and methods to facilitate the reproducibility of such information by qualified third parties."[20] Reproducibility means that the information is capable of being substantially reproduced, subject to an acceptable degree of imprecision. "Capable of being substantially reproduced" means that independent analysis of the original or supporting data using identical methods would generate similar analytic results, subject to an acceptable degree of imprecision or error.

Agencies must also provide "especially rigorous robustness checks to analytic results" when public access to data and methods is not feasible due to privacy, trade secrets, intellectual property, and other confidentiality protections.[21] Even if data cannot be disclosed due to privacy and confidentiality issues, in all cases agencies must disclose specific data sources, quantitative methods, and assumptions used in reaching analytic results.

With respect to risk assessments, agencies must "adopt or adapt" the quality principles announced in the Safe Drinking Water Act Amendments of 1996.[22] These principles require:

1. For agency actions based on science, the agency shall use:
   "(i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and
   (ii) data collected by accepted methods or best available methods (if the reliability of method and the nature of the decision justifies use of the data)."
2. When disseminating public information on the risk, the agency is to "ensure that the presentation of information on public health [risk] effects is comprehensive, informative, and understandable."
3. In documents made public that support a regulation, the agency shall specify to the extent practicable (i) each population addressed by any estimate; (ii) the expected risk or central estimate risk for the specific populations; (iii) each appropriate upper-bound or lower-bound estimate of risk; (iv) each significant uncertainty identified in the process of the assessment of effects and the studies that would assist in resolving the uncertainty; and (v) peer-reviewed studies known to the [agency] that support, are directly relevant to, or fail to support any estimate of effects and the methodology used to reconcile inconsistencies in the scientific data."[23]

The FDA's draft guidelines assert that for many of its product approval actions, supporting data submitted by the manufacturer is not peer reviewed except to the extent it is evaluated by scientific advisory committees. For such health assessments, the FDA guidelines provide that it will use the best available science including peer reviewed studies when they are available. If they are not available and if the product action is deemed "influential," the information will not enjoy the presumption of quality offered to peer reviewed (internal or external) studies.[24]

Key Issues

No one knows how the DQA will ultimately affect agency practice and, derivatively, civil litigation, any more than commentators knew how *Daubert* would affect civil litigation. There is no precedent for the statute, and it is presently unclear what degree of review the courts will give "affected persons" who challenge disseminated information. Despite its uncertainties, the importance of this legislation has not gone unnoticed in Washington. In March 2002, the prestigious National Academy of Science sponsored a two-day workshop during which legal scholars and numerous agency representatives debated the effect of the DQA on agency practice and tried to identify the key issues with the DQA. Several of these issues are identified below. We add our thoughts of how the issues may affect civil litigation.

Does the DQA apply to data generated by third parties for an agency?

The DQA imposes the responsibility on agencies to ensure that information disseminated, regardless of its source, meets defined quality standards. Therefore, if the FDA were to disseminate a study generated by third parties on the FDA web site, the information would be subject to the DQA. Similarly, if the agency relies upon third-party data in reaching a decision that is disseminated, the decision and the third-party data relied upon are subject to challenge under the DQA and the OMB Guidelines.

While the prospect of challenging the quality of information disseminated by the FDA has definite appeal, the DQA may turn out to be more of a curse than blessing to parties that submit data to federal agencies in support of a request for government action.

For example, the FDA's approval of a new drug or medical device application is based upon data generated by third parties. The dissemination of its decision constitutes information that is subject to the DQA. The FDA could conclude that it cannot reach a decision on an application unless the supporting data meet the OMB Guidelines. One can reasonably expect that consumer groups will try to use the DQA to challenge the FDA's drug and/or medical device approvals. It is unclear which remedy will be afforded "affected persons" if the data supporting the application is shown not to meet the OMB Guidelines. As discussed below, the OMB Guidelines require only that information that does not comply with the Guidelines be corrected. Consumer groups will certainly argue that revocation of the approval is the only way to "correct" the information.

Can an agency disseminate information if it does not have access to the original data?

The OMB Guidelines do not expressly require that agencies obtain original data before disseminating a study, especially when the information will not have a "clear and substantial impact on important public policies or important private sector decisions."[25] If information is not influential and has been subject to "...formal, independent, external peer review, ...(it) may generally be presumed to be of acceptable objectivity."[26] While this presumption is rebuttable, the burden is on the affected person.

Certain standards must be met before peer reviewed data can enjoy the rebuttable presumption when the peer review is agency sponsored. The applicable standards, derived from general criteria for competent and credible peer review recommended by OMB-OIRA to the President's Management Council, include: 1) demonstrating that peer reviewers were selected primarily on the basis of their technical expertise, 2) disclosing the nature of prior technical/policy positions the reviewers may have taken on the relevant issues, 3) identifying personal and institutional funding (whether private or public), and 4) that the peer review be conducted "in an open and rigorous manner."[27] The recommendations are vague as to what it means to conduct a peer review in an "open manner." This will be a fertile source of litigation.

For influential information, OMB requires additional quality checks beyond peer review. In such cases, access to original data might be required. In describing the heightened quality standards required for influential information, OMB Guidelines distinguish between "original and supporting data" and "analytic results."

OMB does not require agencies to subject all disseminated original and supporting data to the reproducibility requirement.[28] Rather, agencies may identify, "in consultation with the relevant scientific and technical communities, those particular types of data that can practicably be subjected to a reproducibility requirement." However, even though a "replication exercise" is not required prior to each dissemination, the agency must provide transparency regarding the data and methods. For example, consider a study performed by the FDA on the efficacy of a certain medication, using human volunteers, that shows the medication is not effective for its stated purpose. The FDA could reasonably claim that it is impractical, and perhaps unethical, to replicate the study, particularly if alternative effective treatment is available, because that would require the research subjects to ingest a medication with no expected benefit. The FDA

could then disseminate the study results without actually establishing reproducibility. However, the FDA would also have to provide transparency regarding the data and methods. Sufficient transparency of the data and methods provides opportunity to evaluate the study, without actual replication, to determine whether the study design introduced reporting bias, for example, which would account for the lack of measured effect. The interested pharmaceutical company could then challenge the data based on the flawed methodology.

With regard to analytic results, OMB requires sufficient transparency about the underlying data and methods so that an independent re-analysis could be undertaken by a qualified third party.[29] However, when privacy and confidentiality concerns prohibit the disclosure of underlying data, agencies must perform and document robustness checks to ensure the data are reproducible. OMB does not define "robustness checks," but authorizes each agency to define the type of check and level of detail for documentation. This provides a particular opportunity for agencies to create a loophole through which faulty data can be protected from review, while their claimed robustness check validates the data for purposes of the DQA. It would be difficult indeed for a third party to successfully challenge the quality of data that are protected from external review, and that the agency claims has been validated through the agency's procedures.

If a qualified scientist attempts to replicate disseminated information and is unable to reproduce the results, must the information be corrected?

While information need not be replicated to satisfy the requirement of reproducibility, it is unclear what the consequences are if replication is attempted and reproducibility is not achieved. One can argue that the OMB Guidelines are satisfied solely by demonstrating transparency. Such a limited interpretation of the DQA and OMB Guidelines elevates form over substance. The goal of the DQA is to improve the quality of disseminated information. To achieve this, goal correction must be available if an affected person can show information is not correct. If information is not reproducible, by definition, it fails to meet the OMB quality standards.

If an agency web site contains hyperlinks to information in third-party web sites, is the referenced information subject to the DQA?

Conceptually, information in a third-party web site that is hyperlinked from an agency's web site is being disseminated and ought to be subject to the OMB Guidelines. However, OMB Guidelines exclude from the definition of "Information" material disseminated by a third-party web site to which an agency provides a hyperlink. Conceivably agencies can collaborate with third-party web sites to publish information via a hyperlink and thereby avoid satisfying the OMB Guidelines. Allowing the agency to disseminate information through a third-party web site by use of a hyperlink violates the clear language of the DQA. There is no language in the DQA to support the OMB's exclusion for hyperlinks.

How have the agencies defined "influential"?

The latitude left for agencies to define influential information has led to very different approaches. The FDA and other agencies chose a purely economical definition of influential. They apparently derived the definition from the several statutes that require special review processes for proposed agency rules that may have an annual economic impact of $100 million or more.[30] This raises an interesting question about whether financial analysts' forecasts or manufacturers' predictions of the annual sales expected to be generated by approval of a product under review by the FDA is evidence that its anticipated decision is influential. Ironically, labeling the approval "influential" may not help the applicant because it means the data it has submitted to the FDA may be held to higher standards of quality.

In contrast, the EPA defines influential information in accordance with the OMB definition, and identifies classes of information that should adhere to a higher standard of quality. In addition to "economically significant" class defined above, the EPA identifies information supporting "top" agency actions, highly controversial issues, work product undergoing peer review, and information determined to be influential by the EPA on a case-by-case basis.[31]

Despite the discrepancies, individual agency definitions of "influential" do not abrogate the OMB definition. Therefore, if a petitioner can show that the information will have a clear and substantial impact on important public policies or important private section decisions, it will be considered influential.

What must be shown to satisfy the requirement that information subject to challenge be "maintained and disseminated"?

The DQA goal is to ensure the quality of information disseminated by federal agencies. This directive is not qualified by having to demonstrate that the agency also maintains the information. The qualification that the information be "maintained and disseminated" only appears in the DQA mandate that agencies

establish administrative procedures to allow "affected persons" to request correction of the information.[32]

Unfortunately, neither the DQA nor OMB Guidelines explain what, if any, additional burden is placed upon an affected person challenging disseminated information to show that it is also maintained by the agency. This ambiguity raises a number of issues that will need to be addressed by the OMB and/or courts. These include:

1) Can one challenge information only when the agency has actual possession of the data?
2) Is continued publication of a study on an agency's web site "maintaining" the information?
3) If material is disseminated on an agency's web site and later removed but is not replaced by corrected data, is the information that was previously disseminated still being "maintained"? Is "maintained" satisfied if the dissemination was accomplished by printing the material in hard copy?
4) If the information was derived from a publicly funded study performed by independent scientists, but is not possessed by the agency, would the funding alone satisfy the "maintain" requirement?
5) Is the DQA applicable if the information is maintained by one agency and disseminated by another?

Does the agency have a duty to update the information it disseminates after October 1, 2002?

The OMB Guidelines do not directly speak to this issue. Paragraph III.2. of the OMB Guidelines impose a requirement that agencies develop processes to ensure information quality in the information it maintains. In addition, the DQA does not place a time limit on the period between which information is disseminated and a challenge is permitted. Because previously disseminated data can be corrected by subsequently generated data, this imposes a *de facto* duty to update information disseminated after October 2002. Therefore, the better view, as articulated by several presenters at the NAS workshop, is that a prospective duty to update information is imposed by the DQA.

Given their limited resources, it is hard to imagine that agencies will devote much energy to updating their disseminated information. It seems more likely that agencies will rely upon "affected persons" to bring to their attention information that needs to be supplemented to reflect new scientific developments.

If disseminated information is found not to be in compliance with the DQA, must the information be expunged?

The OMB Guidelines are vague with respect to the precise nature of the remedy available to affected persons who are able to demonstrate that disseminated information does not meet the DQA standards. The OMB Guidelines provide that administrative mechanisms must be created that allow affected persons to obtain, "...where appropriate, timely correction of information... that does not comply with the OMB agency or guidelines."[33]

If a party has demonstrated that it is entitled to relief, the agency must correct the data. A reasonable interpretation of this directive is that the agency must withdraw the incorrect information and disseminate correct information. Alternatively, the OMB Guidelines would seemingly permit an agency to publish the correct information without withdrawing the incorrect data. One could argue that this is the preferred remedy in light of the restrictions on federal agencies destroying government information.

The Federal Records Act sets the standards for agency records management and preservation.[34] Under the Federal Records Act, records in the custody of an agency are not to be destroyed except as authorized by the National Archivist. The OMB Guidelines specifically exclude archived information from information that is disseminated by the agency. Therefore, the agency could either archive challenged information to take it out of public dissemination, or destroy it in accordance with 44 U.S.C. §3303a.

Not all disseminated information is subject to the Federal Records Act. The Act defines "records" to mean materials "made or received by an agency... under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency... as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the Government or because of the informational value of data in them."[35] Arguably, information challenged and shown to not conform to quality standards is of no informational value. If the disseminated information did not support any agency action, policy or decision, it could be expunged.

To what extent will there be judicial review of an agency's decision on a challenge?

The DQA and the OMB Guidelines are silent as to whether affected persons are entitled to judicial review of an agency's rejection of an affected person's demand for correction. Several presenters at the NAS workshop opined that despite the absence of a jurisdictional grant in the DQA, agencies' decisions will be reviewable under the Administrative Procedure Act.[36] A detailed analysis of the jurisprudence of judicial review under the APA is

beyond the scope of this newsletter. Simply stated, judicial review is dependent upon a showing that the agency's decision sought to be reviewed is final and that the decision affects the rights of the person seeking review.

Well-defined procedural mechanisms for FDA administrative hearings are published in 21 C.F.R. §10 *et seq.* These include relatively informal procedures for the review of internal agency decisions.[37] In its DQA draft guidelines, the FDA announced its intent to use existing procedures including those described in 21 C.F.R. §10.75. However, this approach contemplates having a challenge first considered by the supervisor of the employee whose decision is being challenged. As public dissemination of information is ordinarily not done without approval of a senior level employee of the FDA, it's not clear who will hear the challenge. In addition, allowing the supervisor of the employee who decided to release the challenged information to adjudicate the challenge falls short of the objective review process contemplated by the OMB.[38]

If judicial review is permitted, several procedural issues will have to be resolved, including the following:

1) Must an agency's appeal officer have been uninvolved with the dissemination of the information being challenged?
2) Are *ex parte* communications permissible between the agency employees responsible for disseminating the challenged information and the appeal officer responsible for resolving a challenge under the DQA?
3) Will agencies be required to create appeal mechanisms that allow affected persons the right to present evidence at a formal hearing? Will examination of witnesses be provided?
4) If an agency's decision on a challenge is appealed to the courts, will the appeal be limited to the record generated before the agency or will there be opportunity in the appeal for discovery and submission of evidence?
5) Must affected persons demonstrate they have standing? What degree of legal harm will be necessary to have standing to challenge information?

Practice Pointers

Although it makes sense for lawyers who practice before the FDA to work closely with trial lawyers defending FDA regulated products, in practice this is not accomplished very often. The potential benefit that the DQA may offer trial lawyers is another reason for both to develop a stronger collaboration.

In typical situations, trial lawyers are called upon to defend a manufacturer long after the FDA has disseminated critical and damaging information. There are at least two distinct periods when the DQA may be a tool to help reduce the potential for the FDA to release poor quality information.

The first period is when the FDA requests interested parties to submit comments on proposed agency action. Interested parties ought, at this early opportunity, to build a record that demonstrates that the proposed action does not meet the OMB Guidelines. It is unclear whether a party that chooses not to submit comments will be permitted to build a record after the comment period closes and the information is disseminated. Nothing in the OMB Guidelines expressly permits an affected person to submit supplemental information to the agency during the course of a challenge or administrative appeal of the decision on the challenge. Because courts will probably use a deference standard for reviewing challenges under the DQA, it will be difficult to demonstrate that the agency erred in refusing to correct disseminated information when the agency sought and considered public comment prior to dissemination. One's chances of succeeding in a challenge are greater if a strong record is made during the comment period.

If trial counsel are not called upon for advice during the comment period, it will fall upon in-house counsel and FDA counsel to address the DQA issues. Preferably, trial counsel will be brought in at this early stage to help assess the effect (positive or negative) the information is likely to have in potential products liability litigation.

The second period of time occurs after information has been disseminated and litigation has begun. As the time lag between filing a challenge and getting court ordered relief under the DQA is uncertain, trial counsel have even more reason to immediately upon their retention investigate the relevant information that the FDA has released. If disseminated information does not meet the DQA quality standards and is damaging to one's case, serious consideration ought to be given to challenging the information. If the data are not challenged, opposing experts will have even stronger reasons to argue that the information disseminated by the agency is reliable and correct.

Assume your opposing expert has relied heavily upon a federal agency's risk assessment that addresses a key causation issue in your case. In his or her direct examination of the expert, plaintiffs' counsel will ask the expert to explain how federal law allows corporations to challenge information disseminated by agencies that they feel is not reliable. The expert will explain all of the steps that the agency must go through to ensure

that its information is of high quality. He will conclude this portion of his examination by explaining that the defendant chose not to challenge the information. When you begin your cross-examination of the expert, each time you question the validity of the agency's risk assessment you will be reminded by the expert that if your client really thought the information was unreliable, it would surely have challenged the information. This theme will be repeated later when plaintiff's counsel cross-examines your expert who has tried to explain to the jury why the government's information is unreliable.

The OMB Guidelines require that agencies establish time limitations governing the disposition of challenges and appeals. Seeking judicial review of an agency's refusal to correct information will take months. When defending products liability claims, defense counsel rarely have the luxury of time. Much damage can be inflicted upon a manufacturer very quickly by a plaintiffs' expert effectively using poorly developed government information. Therefore, defense counsel need to think creatively about how to obtain benefits from DQA if their clients failed to challenge information before litigation began. One approach to circumvent a prolonged and probably futile challenge before an agency may be to argue that the act of disseminating the information was final agency action that is reviewable immediately by the courts. The danger of this approach is that months could pass before the court dismissed the challenge for failing to exhaust administrative remedies.

If the FDA did not implement or follow the required procedures under Para. III.2. of the OMB Guidelines for reviewing information before it was disseminated, a *Daubert* motion challenging an expert who has relied upon the faulty government study ought to include an argument under the DQA. In many cases, litigants won't know whether the FDA followed its internal procedures for ensuring information quality. Pursuant to 21 C.F.R. §20.1, depositions of FDA employees are not permitted unless the Commissioner determines the testimony is in the public interest and promotes the objectives of the FDA Act. Rarely have courts refused to give deference to the Commissioner's decisions in this area.

Conclusion

Many litigants have experienced the frustration of courts allowing experts, notwithstanding *Daubert*, to offer opinions based on government disseminated reports that are replete with unsubstantiated assumptions. The DQA imposes the responsibility upon federal agencies to develop procedures to ensure that information they disseminate meets standards of quality, objectivity, utility, and integrity. The DQA will not prevent agencies from relying upon assumptions to reach conclusions on public health and safety. However, the requirement that such decisions be transparent will allow litigants to more easily demonstrate that the agencies' reports on which plaintiffs' experts rely are as scientifically weak as the proverbial house of cards. While it may not provide all the guarantees of *Daubert*, the DQA should help to improve the quality of scientific data disseminated by federal agencies that is later used in civil litigation.

Endnotes

[1] National Research Council, *Science Judgment in Risk Assessment*, 85-91 (National Academy Press 1994).

[2] Pub. L. 106-554.

[3] 44 U.S.C. §§3501–3516.

[4] 44 U.S.C. §§3504(d)(1); 3506(a)(1)(B).

[5] Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, 66 Fed.Reg. 49718 (Office of Budget and Management, Sept. 29, 2001).

[6] Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, published in corrected form at 67 Fed.Reg. 8452, 8458-60. (Office of Budget and Management, Feb. 22, 2002) (hereinafter "OMB Guidelines").

[7] Data Quality Act, Pub. L. 106-554, section 515(b)(2)(A); 67 Fed.Reg. 8452 (Summary of OMB Guidelines setting Oct. 1, 2002 as the date by which agencies must issue guidelines).

[8] OMB Guidelines, para. III.4, 67 Fed.Reg. at 8459.

[9] *Id.*, para. V. 1-4, at 8459-60.

[10] *Id.*, para. III.2, at 8459.

[11] *Id.*, para. V.5., at 8460.

[12] *Id.*, para. V.8.

[13] The review was attached to OMB's June 10, 2002, Memorandum to the President's Management Council ("PMC"), both published in a June 11, 2002, OMB press release no. 2002-33. The PMC is comprised of the Chief Operating Officer from each federal department and chaired by the Deputy Director for Management at the OMB.

[14] The preamble to the September 28, 2001, published rules broadly defined "affected persons" as people who may benefit or be harmed by the disseminated information. 66 Fed.Reg.at 49721.

[15] Preamble to OMB Guidelines, 67 Fed.Reg. at 8458 (Feb. 22, 2002).

[16] 66 Fed.Reg. at 49721.

[17] 67 Fed.Reg. at 8458.

[18] OMB Guidelines, para. V.9., 67 Fed.Reg. at 8460.

[19] *Id.*

[20] *Id.*, para. V.3.b.ii.

[21] *Id.*, para. V.3.b.ii.B.ii.

[22] See *id.*, para. V.3.b.ii.C.

[23] Safe Drinking Water Act, 42 U.S.C. 300g-1(b)(3)(A)&(B).

[24] Food and Drug Administration Draft Guidance on Ensuring the Quality of Information Disseminated to the Public, available at http://www.hhs.gov/infoquality/fda.htm.

[25] Preamble to OMB Guidelines, 67 Fed.Reg. at 8455.

[26] *Id.* at 8454.

[27] OMB Guidelines, para. V.3.b.i, 67 Fed.Reg. at 8459, citing OMB-OIRA Recommendations to the President's Management Council

(9/20/01) (http://www.whitehouse.gov/omb/inforeg/oira_review-process.html).

[28] *Id.*, para. V.b.ii.A. at 8460.

[29] Under the Information Release Act ("IRA"; Pub. L. 105-277), data relating to published research findings funded by the federal government and used to develop federal policy or rules can be obtained in response to a Freedom of Information Act ("FOIA") request. Information obtained through a FOIA request is not disseminated information for purposes of the Data Quality Act, so the data itself cannot be challenged. However, the published findings and agency analytical conclusions based on those findings can be challenged under the Data Quality Act if the underlying data obtained pursuant to the IRA and FOIA are flawed.

[30] *See* Congressional Review Act definition of "major rule," 5 U.S.C. 804; Unfunded Mandates Reform Act definition of proposed and final rule that triggers a benefit-cost analysis, Pub. L. 104-4, section 202 (March 22, 1995); and Exec. Order No. 12866 definition of "significant regulatory action," 58 Fed.Reg. 51735 (Oct. 4, 1993).

[31] Environmental Protection Agency Draft Information Quality Guidelines available at http://www.epa.gov/oei/qualityguidelines/iqg-draft1.htm.

[32] Data Quality Act, section 515(b)(2)(B).

[33] OMB Guidelines, para. III.3 at 8459.

[34] Federal Records Act, 44 U.S.C. §§ 3101-07, 3301-3324 (1991).

[35] 44 U.S.C. §3301.

[36] *See* 5 U.S.C. §554 (1994).

[37] *See* 21 C.F.R. §10.75.

[38] Preamble to OMB Guidelines, 67 Fed.Reg. at 8458.

Industry Gifts to Physicians—The New Frontier?

W. Kennedy Simpson

Products liability claims involving pharmaceutical drugs and medical devices traditionally focused on failure to warn. As drug and device litigation exploded into big business for the plaintiffs' bar, theories of recovery rapidly expanded into new areas, including "design" defects, negligence *per se* (violation of FDA regulations), fraud on the FDA, off-label promotion, and clinical trial liability. Although over-promotion claims are not new, the diet drug litigation signaled a new focus on industry gifts to physicians. This article will outline recent guidelines issued by national pharmaceutical and physician organizations that could affect over-promotion claims.

On July 1, 2002, the Pharmaceutical Research and Manufacturers of America's ("PhRMA") voluntary code on relationships with health care professionals became effective. *PhRMA Code on Interactions with Healthcare Professionals*, http://www.phrma.org/publications/2002-04-19.391.pdf. The pertinent parts of the code include:

1) Informational Presentations—Permits occasional meals which are "modest" and occur in a "venue and manner" conducive to informational communication and that "provide[ ] scientific or educational value." Entertainment, recreational events, inclusion of spouses or guests, and take-out meals without the presence of a company representative ("dine & dash") prohibited.
2) CME Meetings—Financial support to conference sponsor permitted. Direct payment to nonfaculty health care professional attendees, including costs of travel, lodging, or personal expenses, prohibited.
3) Consultants—Compensation for consulting services and reimbursement for travel, lodging, and meal expenses permitted for consultants with "bona fide consulting arrangements."
4) Speaker Training Meetings—Compensation for services and reimbursement for expenses for participation in programs intended to recruit and train speakers for company-sponsored bureaus permitted if participants receive extensive training on drug products and compliance with FDA regulations which result in provision of valuable service to company.
5) Scholarships and Educational Funds—Financial assistance to medical students, residents, fellows, and other

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