The Data Quality Act

A New Weapon to Defeat Junk Science

by Bruce R. Parker and Michele R. Kendus

Imagine yourself in a courtroom listening to the plaintiff's expert testify that a causal relationship exists between your client's product and the plaintiff's injury. The expert's opinion is largely based on an FDA risk assessment. The jury listens carefully to the expert describe the FDA's "thorough" analysis of the risks associated with your product. Among the risks identified by the FDA is a "probable" causal nexus between your client's product and the plaintiff's injury. Not surprisingly, the expert glosses over the fact that the FDA's "findings" are based on case reports and liberal use of default assumptions. While the testimony hurts your defense, it is not as bad as you had anticipated. Despite having lost a pre-trial *Daubert* challenge, you remain optimistic that your cross-examination will demonstrate the methodological weaknesses in the FDA's risk assessment. You are confident that your expert will offer a convincing explanation why the risk assessment cannot serve as a basis for a scientific conclusion on general causation.

First slowly, then with increasing velocity, your optimism drains as you hear the expert explain to the jury that federal law required the FDA's "study" to meet high standards of scientific quality. The jury is told that if your client felt that the risk assessment had not met Congressional-mandated levels of quality, procedures exist that would have allowed your client to force the FDA to correct the report. Where optimism once existed, you're now left feeling slightly dizzy as you hear the expert explain that your client made no effort to challenge the risk assessment. You mutter a feeble objection that the court quickly overrules. The expert continues to explain that the absence of a challenge entitled the FDA to conclude that its information met federal standards of high quality. As you stand to begin your cross-examination you first wonder why you ever wanted to be a trial lawyer, then why no one advised your client (or why it failed to listen) of the ability to challenge the report under the Data Quality Act.

Bruce R. Parker is a partner, and Michele R. Kendus is an associate, in the Baltimore law firm of Venable, Baetjer and Howard, LLP. Their practices focus on medical products liability and toxic tort litigation, with an emphasis on pharmaceuticals and medical devices, such as latex gloves. Mr. Parker has served on national trial teams, and Ms. Kendus has worked with industry to draft comments on proposed regulation. Both authors are members of DRI.

A Means to Weaken the Plaintiffs' Arsenal

The Data Quality Act provides the means by which the defendant in the above scenario might have successfully challenged the FDA's risk assessment long before the trial began. The DQA was enacted in December 2000 as part of the Treasury and General Government Appropriations Act for Fiscal Year 2001. Pub.L. 106–554, §515 (2000). Occupying a scant 38 lines in the Congressional Record, the DQA's potential impact far exceeds its diminutive size.

The DQA requires the Office of Management and Budget to issue government-wide policy and procedural guidelines for federal agencies to implement the DQA. In turn, the OMB Guidelines require each agency to issue guidelines to ensure compliance. The individual agency guidelines became effective October 1, 2002. See "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies," 66 Fed.Reg. 49718 (Sept. 28, 2001), *revised by* 67 Fed.Reg. 8452, 8458–60 (Feb. 22, 2002).

In the Fall 2002 issue of the DRI Drug and Medical Device Committee newsletter, available on DRI's Web site, the present authors provided a detailed analysis of the DQA and the OMB's Guidelines in "The Data Quality Act: Will it Daubertize Federal Agencies?" In the article, we raised several questions that emanate from ambiguities in the OMB Guidelines. We begin this article with a brief overview of the OMB Guidelines, but encourage the reader to refer to the earlier article for a more detailed discussion. The current article focuses on the FDA Guidelines and the procedural mechanisms for challenging information released by the FDA. Throughout our analysis, we comment on how defense counsel and their clients can use the DQA and FDA Guidelines to weaken plaintiffs' expert evidence and to strengthen a *Daubert* challenge at trial.

Overview of the OMB Guidelines on Information Dissemination

The OMB Guidelines require federal agencies to: 1) "ensure and maximize the quality, objectivity, utility, and integrity of information" that agencies disseminate; 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. Pub.L. 106–554, §515; 67 Fed.Reg. at 8459.

Each agency must adopt a basic standard of quality that it integrates in every step of in-

formation development, including creation, collection, maintenance, and dissemination. 67 Fed.Reg. at 8459. Thus, to the extent the FDA sponsors research, it is compelled to design the research in a manner that is consistent with the OMB Guidelines. The guidelines define "quality" as embracing the four statutory standards of quality, objectivity, utility, and integrity. *Id.* at 8459–60.

The two key statutory terms that trigger the DQA requirements are "information" and "dissemination." OMB defines information broadly as any communication or representation of knowledge in any medium or form, but excludes agency Web page hyperlinks to information that others disseminate and agency employee "opinions" that do not reflect the agency's views. *Id.* at 8460. Dissemination refers to any "agency initiated or sponsored distribution of information to the public," but excludes information that the agency distributes among government employees and agency contractors, inter-agency sharing of government information, responses to requests for information under the Freedom of Information Act, correspondence to individuals, press releases, archival records, and adjudicative processes.

The OMB Guidelines impose a higher standard of quality on "influential scientific, financial or statistical information." If an agency determines that the information in its possession is influential, it is to provide a "high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties." *Id.* When the public is not able to access data and methods due to privacy, trade secrets, and other confidential protections, agencies must provide "especially rigorous robustness checks to analytic results," and in all cases must disclose data sources, quantitative methods, and assumptions used in reaching analytic results. *Id.*

The OMB specifically identifies risk assessments as influential information and requires agencies to "adopt or adapt" the quality principles announced in the Safe Drinking Water Act Amendments of 1996 for risk analysis. *Id.* See 42 U.S.C. §300g-1(b)(3)(A)&(B). Information that has been subjected to "formal, independent, external peer review" enjoys a presumption of objectivity that can be rebutted. *Id.* at 8459. To establish the same presumption for information subjected to internal peer review, the OMB requires that the review meet criteria for "competent and credible peer review" used by OMB's Office of Information and Regulatory Affairs (OIRA) in its regulatory review process. *Id.* See "OMB-OIRA Memorandum for the President's Management Council (9/20/01), at http://www.whitehouse.gov/omb/inforeg/oira_review-process.html (last visited 6/9/03).

Though the Guidelines only require internal peer review to meet the OIRA criteria, counsel should scrutinize external peer review in the same manner when attempting to rebut the presumption of objectivity. It is not uncommon for an epidemiological study published in a peer-reviewed journal, for example, to have been reviewed by someone without expertise in epidemiology or statistics, or to have undisclosed funding or scientific bias. Additionally, investigation of an editor's peer review process may reveal that it is not performed in an open or rigorous manner.

The two key statutory terms that trigger the DQA requirements are "information" and "dissemination."

Agencies must have procedures in place that allow "affected persons" (those who may benefit or be harmed by disseminated information) to obtain timely correction of information "maintained and disseminated" by the agency that does not comply with the OMB or agency guidelines. 67 Fed.Reg. at 8458. By October 1, 2002, agencies were to implement procedures to ensure prospectively that information generated and disseminated met the requisite quality standards. Information disseminated before October 1, 2002 is subject to challenge provided it continues to be disseminated after that date. *Id.* Consequently, information found on an agency's Web site after October 1 that was first disseminated before October 1 can be challenged.

Both the OMB and FDA guidelines are unclear with respect to how to treat information that an agency disseminates in printed hard copy form. The interpretation most consistent with the letter and spirit of the DQA would allow parties to challenge printed information that the agencies published before October 1, 2002, and which remains available in print. Since such information remains available to the public, it presents precisely the type of problem the DQA is intended to address.

A change driven by the OMB Guidelines, equally important to improving the quality of information, is to increase the transparency of how the agencies reach their decisions. Some scientists have argued that increasing the transparency of agency decision making enhances the democratic process and gives research scientists a better understanding of how the agencies weigh different study methodologies. Increased transparency certainly provides increased opportunity to either validate the information or challenge the agency decisions when the underlying information does not comply with the mandates of the DQA and OMB guidelines.

Transparency is also a benefit to trial counsel attempting a *Daubert* challenge when DQA challenges were unsuccessful or not attempted. For example, consider the FDA risk assessment that caused our hypothetical attorney such problems. By regulation and/or guidelines the FDA is permitted to use certain "default assumptions" to reach its conclusions for a risk assessment when there are gaps or uncertainties in the scientific data. See National Research Council, *Science Judgment in Risk Assessment*, 85–91 (National Academy Press 1994). The DQA will not necessarily preclude the FDA from using default assumptions, as long as the risk assessment explicitly describes the data gaps and the assumptions used. With the uncertainties of the risk assessment made transparent, counsel in our hypothetical would have had a much better chance of winning the *Daubert* challenge to exclude the plaintiff's expert's opinions.

Using the Guidelines to Challenge Junk Science

The *FDA Guidelines for Ensuring the Quality of Information Disseminated to the Public* (FDA Guidelines), http://www.hhs.gov/infoquality/fda.html (last visited 6/9/2003), resonate the message that the FDA had procedures in place prior to the Data Quality Act to ensure that its information dissemination and decision-making processes were of high quality. Experienced drug and medical device defense attorneys faced with the FDA information used by plaintiffs' experts to support their claims of product defect might disagree. The FDA Guidelines describe the wide range of information disseminated by the FDA, most of which is sub-

ject to the DQA. Even for counsel who may never bring a DQA challenge, the guidelines offer an understanding of how the FDA operates to create and disseminate information. Defense counsel who understand FDA's processes are in a better position to bring a *Daubert* challenge to an expert who relies on FDA-disseminated information.

The FDA's DQA Guidelines describe the information released by the FDA in several broad categories. These are:

- public communications about risk
- rule making documents
- product approvals
- guidance in regulatory assistance
- reports
- citizen petitions and responses
- press items and publications

Almost all of these documents can be relied upon by experts, particularly in federal courts, provided a foundation is laid (which is often not difficult) that the information is authoritative and the type upon which other experts rely. See Rule 803(18) of the Federal Rules of Evidence. Thus, to the extent that such information is relevant to a medical product and does not meet the DQA quality standards, a manufacturer ought to consider a DQA challenge.

It is difficult to think of an example of a public communication about risk that would not be subject to the DQA. Examples of information routinely released by the FDA include Consumer Advising Fact Sheets, "Dear Health Care Professional" letters, Public Health and Safety Alerts, FDA Talk papers, and consumer brochures. See FDA Guidelines, para. III.A.

Information that the FDA publishes in the course of its rule-making is subject to the DQA. *Id.*, para. III.B. In the rule-making proceedings, the DQA can be a double-edged sword. Because the FDA is charged with generating information that complies with the DQA, information submitted to the agency in an effort to influence its rule-making by consumer groups and industry will be evaluated under the DQA/OMB quality standards. Where the FDA may previously have been apt to consider all comments to avoid a ruling that its decision was arbitrary and capricious, the DQA now provides a basis to disregard comments that are not founded on sound scientific principles.

Industry is advised to ensure that its own comments are based on sound science, and to monitor the quality of information submitted by consumer groups. If the information falls short of the requisite levels of quality, the FDA should be urged that, under the DQA, it ought not to consider the information.

Product approvals and related documents are subject to the DQA because the FDA disseminates them to the public via the Internet. See *id.*, para. III.C. Consumer groups and competing industry may now use the DQA in an effort to block the process of approval for products that they want to keep off the market by challenging the information a manufacturer submits to the FDA in support of its application.

Guidance documents and reports are clearly within the scope of the DQA. See *id.*, para. III.D. To the extent that reports include risk assessments, the information will have to satisfy the tougher quality principles promulgated as part of the Safe Drinking Water Act.

FDA Quality Assurance Policies and Standards

The FDA Guidelines provide a lengthy discussion of what the FDA does with respect to product review activities, food safety activities, research, and adverse event analyses for medical devices, drugs (human and animal), foods, dietary supplements and cosmetics. See *id.*, paras. IV–V. However, the guidelines do not do a great job of explaining how the FDA ensures that high-quality information is being developed in each of these endeavors.

The FDA defines "influential" information as that which, "results from or is used in support of agency actions that are expected to have an annual effect on the economy of $100,000,000 or more or will adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities." *Id.*, para. VII.A. The FDA asserts that its definition applies to the "information" and not to decisions that the information may support. One example of influential information is the rules issued in October 1997 for mammography. The FDA expected the regulations, which required replacing substandard mammography units, providing written results, testing, and training, would have an annual effect on the economy of over $100,000,000. Consequently, the FDA considers the information disseminated in support of this rule as influential and subject to a higher quality standard. *Id.*

The FDA's definition potentially raises the bar for the quality of information that must be submitted by a manufacturer seeking approval for a product that its economic analysts predict will have an effect on the economy of more than $100,000,000. Consumer groups and competing industry wishing to challenge the FDA's approval could argue that information supporting the product approval application must be held to the higher standard. Even if the proposed product's financial effect does not raise the bar, challengers might easily make a case that the product has the potential for adverse environmental, public health, or safety effects.

Submitting Complaints under the DQA

The Data Quality Act offers industry an opportunity to force the Food and Drug Administration to increase the quality of information that has a potentially significant effect on litigation. As the scenario at the beginning of this article demonstrated, failure to use this opportunity could damage a manufacturer's defenses against a product liability claim.

Had our hypothetical attorney and client been familiar with the DQA, they would have known there was no need to wait until trial to challenge the FDA's risk assessment. The FDA guidelines set out a plethora of procedures by which an affected person may challenge information. The FDA did not create new procedures, but lists those already available under certain parts of the Code of Federal Regulations. FDA Guidelines, para. VI.A.

The FDA promotes the use of informal procedures, such as the internal agency review of decisions available under 21 C.F.R. §10.75(a). This internal procedure would require the supervisor of an FDA employee to review a decision or action of the employee at the request of an affected person bringing a DQA challenge. If the supervisor's review does not address the concern, the affected person may request an additional internal review further up the supervisory chain, and the process may continue throughout the agency's chain of command to the Commissioner of the FDA. *Id.*, para. VI.B.

At first blush, this process seems potentially time-consuming and ineffective. The natural assumption is that a supervisor will be partial to the employee/department's decision and may delay review for an indefinite period, with an endless supply of supervisors to go through in the chain. Surprisingly, FDA's Center for Devices and Radiologic Health (CDRH) describes the internal agency review as the quickest and most efficient means of resolving a dispute or appeal in its guidance document,

Medical Devices Appeals and Complaints: Guidance on Dispute Resolution (February 1998), http://www.fda.gov/cdrh/modact/dispresl.pdf (last visited 6/9/03).

One particularly attractive process available to medical device manufacturers is a request for review by the Medical Devices Dispute Resolution Panel. The Panel was created as a forum to air scientific disputes in accordance with provisions of the Food, Drug & Cosmetics Act, 21 U.S.C. §§514, 515, 522 and 562. The CDRH has issued a guidance document that describes the Panel's purpose, its members, and the process for filing a request for review of a scientific dispute. See *Resolving Scientific Disputes Concerning the Regulation of Medical Devices, A Guide to Use of the Medical Devices Dispute Resolution Panel* (July 2, 2001) ("Panel Guide"), http://www.fda.gov/cdrh/resolvingdisputes/1121.html (last visited 6/9/03).

The Panel offers a number of advantages. Its members have general scientific expertise applicable to a broad range of scientific issues, including a member representing consumer interests and a member representing industry interests. One would therefore expect the overall review to be unbiased and scientifically sound. Additionally, the time frame for review is relatively short, taking about four months. See the Panel Guide, para. K, for a detailed explanation of the timeline for review. Appendix A of the document also lists suggested disputes involving scientific information that would be appropriate for review by the Panel, each of which would be appropriate for a challenge to scientific information under the DQA.

While the Panel is an attractive alternative, the Panel Guide explains that filing a request for review will not affect any ongoing or future regulatory action that FDA deems necessary to protect the public health. For example, FDA may issue a Warning Letter that orders a manufacturer to include new scientific information on its product label to indicate the potential for a serious health hazard. If the manufacturer does not change its label, it could face enforcement action. Despite requests by the manufacturer to stay the action due to a difference of opinion over the science, the FDA refuses. In such a case, the manufacturer will likely have grounds for and may choose to pursue judicial review. See *infra*.

The FDA Guidelines list several other informal procedures available for dispute resolution during the application review process. However, one should not assume that only the listed informal procedures are available. In fact, the FDA Guidelines refer the reader to four guidance documents, including the two discussed above, which were developed to assist the medical device industry in choosing informal processes or formal hearings to resolve disputes with the CDRH.

If a party chooses a formal hearing to dispute an FDA decision, it would be reasonable to challenge the scientific basis of the agency decision under the DQA within the course of that proceeding, particularly if the party has had no prior opportunity to bring a less formal challenge. Otherwise, the FDA faces the possibility that a party will challenge the scientific basis of an administrative decision during the hearing process and concurrently challenge the information under the DQA through the informal procedures. Such a situation could give rise to conflicting opinions where, for instance, the hearing officer rules in favor of the agency decision that is based on the challenged scientific evidence, while the same evidence is corrected or withdrawn through the informal request.

Once the FDA disseminates information, it immediately shapes public opinion. Mere withdrawal or correction of the already digested report may do little to sway the initial public response.

An administrative hearing currently pending before the FDA illustrates the point. In *In the Matter of: Enrofloxacin for Poultry: Withdrawal of Approval of Bayer Corporation's New Animal Drug Application (NADA) 140-828 (Baytril)*, FDA Docket 00N-1571, Bayer requested the hearing, joined by the Animal Health Institute (AHI), to challenge the Center for Veterinary Medicine's (CVM) proposed withdrawal of its new animal drug application approval for an antibiotic used in poultry. CVM based its decision on certain scientific evidence, including a risk assessment and several epidemiological studies that suggested the antibiotic caused an increased incidence of human infection with a resistant strain of bacteria.

In the course of the hearing, Bayer filed a motion to exclude CVM's scientific evidence, challenging it under the standards of both *Daubert* and the DQA. CVM's opposition motion argued that under the FDA Data Quality Guidelines, the hearing was not an appropriate place to bring a DQA challenge. CVM pointed out that the guidelines provided other informal processes, which AHI had pursued concurrent with the hearing proceedings. The administrative law judge ruled on the motions, admitting some of the challenged evidence without mention of the arguments concerning the DQA. Meanwhile, pending before the FDA is the AHI petition challenging the information under the DQA. The FDA's handling of the AHI challenge in this situation will signal how it intends to address future DQA challenges.

Judicial Review of a DQA Challenge

A manufacturer may wish to challenge the Food and Drug Administration's actions that involve violations of the Data Quality Act in court, either because it has exhausted its administrative remedies or it is facing administrative action for which an administrative remedy is ineffective. Judicial review may be a viable and effective way to challenge the agency, but the approach is not without risk. For example, a manufacturer may obtain judicial review and a court ruling that the challenged information meets the DQA quality standards. A plaintiff could then argue that the defendant is collaterally estopped to raise a *Daubert* challenge if the thrust of the challenge had been resolved in the DQA proceeding. Even if collateral estoppel were not applicable, the court's determination that the FDA information meets federal quality standards would provide ammunition to the plaintiff.

Another consideration is that a suit against the FDA takes time to adjudicate. After prolonged litigation, an appellate court could dismiss the suit for failing to exhaust administrative remedies or failure to comply with the Administrative Procedure Act (APA), 5 U.S.C. §§701–06. Because the DQA does not provide a statutory right to judicial review, jurisdiction to review an agency action under the DQA is governed by sections 702 and 704 of the APA.

The two issues that determine whether a court has jurisdiction under the APA are whether the agency action marks the consummation of the agency decision-making process, and whether the action is one that determines the rights or obligations of the parties, or from

which legal consequences flow. *Bennett v. Spear*, 520 U.S. 154, 177–88 (1997). Additionally, to show standing, a plaintiff must demonstrate a redressable actual or immediate injury that is fairly traceable to the challenged conduct of the agency, and that the plaintiff's interest is one sought to be protected by the relevant statute. *Bennett, supra*, 520 U.S. at 167; *Tozzi v. United States Department of Health and Human Services*, 271 F.3d 301, 307 (D.C.Cir. 2001).

The following discussion of two federal court cases challenging agency actions that may have been brought under the DQA had it been available illustrates the situations in which a plaintiff may gain judicial review, and the risks involved.

Actions with legal consequences may be reviewed

A recent decision that reviewed a challenge to the Department of Health and Human Services' listing of dioxin as a known carcinogen in its "Report on Carcinogens" sets the stage for judicial review of claims brought to challenge FDA actions under the DQA. In *Tozzi v. HHS, supra,* the court granted judicial review, despite the report's statement in the preamble that it was "for informational purposes only," because the dissemination had direct legal consequences. 271 F.3d at 310–11. Dioxin is a chemical that is released when polyvinyl chloride products are incinerated. Jim Tozzi, a "regulatory consultant," sued HHS, along with a medical products manufacturer and two restaurant industry plaintiffs.

The court first granted the plaintiffs standing. It explained that the manufacturer demonstrated "actual or immediate injury-in-fact" that was "fairly traceable" to the agency action because listing dioxin as a carcinogen resulted in various municipality and industry efforts to decrease use of polyvinyl chloride products. *Id.* at 308–09. The court next granted judicial review under the APA because the HHS listing of dioxin as a known human carcinogen had legal effect. The court explained that the listing triggered industry obligations under OSHA, Department of Labor, and state regulations. *Id.* at 310. Additionally, the court found evidence of the listing's legal effect in the fact that to remove a substance from either category, HHS must undertake the same elaborate procedure used to list it, including scientific review, notice, and comment. *Id.*

While *Tozzi v. HHS* was a victory for achieving judicial review, the court's decision on the merits gave "substantial deference" to the agency. Under this standard, it held that the agency did not act arbitrarily and capriciously in relying on mechanistic rather than epidemiological evidence to elevate dioxin to the status of a "known" human carcinogen. *Id.* at 311–12. However, the court did not evaluate the scientific basis of the agency's decision in detail because the plaintiffs' challenge was whether the agency correctly interpreted its criteria to list a substance, not whether the scientific information underlying the decision was faulty. *Id.* at 311. Had the DQA been available and the plaintiffs framed the challenge to attack the scientific basis for the agency's decision, the outcome may have been different.

In fact, prior to filing suit, Tozzi had written a letter to the director of HHS' National Toxicology Program (NTP), which prepared the report on carcinogens, stating that HHS may not list substances in the known category without "sufficient" evidence from epidemiological studies. Tozzi also pointed out that "[too] much was crammed into too little time" and that the NTP failed to provide certain "key documents" to the public. *Id.* at 307.

The excerpts of Tozzi's letter recited in the court's opinion suggest deficiencies in the agency's evaluation and dissemination of the scientific information that would violate the mandates of the DQA and the OMB Guidelines, including lack of objectivity and transparency. In response to Tozzi's letter the NTP director conceded that the scientific review was inadequate, but that the HHS criteria had nonetheless been correctly applied. *Id.* The NTP director initiated another review that resulted in an agency scientific board's vote against the upgraded listing. However, NTP approved the listing despite the board's opinion.

With this scenario in mind, one can envision how a challenge under the DQA may have changed the outcome at the agency level, or provided an additional avenue to challenge the agency's second decision, which was inconsistent with the board's evaluation of dioxin.

Actions "for informational purposes only" not subject to judicial review

Good arguments can be made that agency dissemination of information absent any regulation or rule-making can have a severe impact on parties. Courts, however, do not typically consider actions taken for informational purposes only to be final agency actions subject to judicial review.

In a remarkable case that sought to expand the limits of the court's jurisdiction under the APA, a federal court in North Carolina granted review of a tobacco trade association's challenge to an Environmental Protection Agency risk assessment that designated environmental tobacco smoke (ETS) as a Group A carcinogen. See *Flue-Cured Tobacco Cooperative Stabilization Corp. v. United States Environmental Protection Association,* 857 F.Supp. 1137 (M.D.N.C. 1994) (denying EPA's motion to dismiss for lack of jurisdiction and standing); 4 F.Supp.2d 435 (M.D.N.C. 1998) (decision on the merits vacating the EPA risk assessment). At the trial level, the district court granted judicial review despite the fact that the risk assessment did not require regulation of ETS. In fact, the Radon Research Act, 42 U.S.C. §740, which granted the EPA authority to research ETS, prohibited the research from having any regulatory effect. The court deemed the risk assessment influential enough to constitute "*de facto* regulatory activity" because of its practical and persuasive consequences. It pointed to regulations issued by the General Service Administration that relied in part on the risk assessment to ban smoking in GSA motor vehicles, and the "general public's tendency to panic at the slightest association of any product with cancer" to conclude that the risk assessment would have "far-reaching consequences," including an impact on tobacco interests. 857 F.Supp. at 1143.

On appeal some eight years later, the Fourth Circuit vacated the district court's grant of judicial review. *Flue-Cured Tobacco*, 313 F.3d 852 (4th Cir. 2002). The circuit court reasoned that information and recommendations from agencies that carry no *direct* consequences are not subject to review under the APA. The consequences in this case, like those that provided standing for the *Tozzi* plaintiffs, were due to independent actions taken by third parties free to either embrace or disregard the report. 313 F.3d at 858–60. Unlike the *Tozzi* plaintiffs, the *Flue-Cured Tobacco* plaintiffs did not show that the report triggered any legal obligations. The circuit court cautioned that holding the risk assessment subject to review under the APA would expose "various results of controversial governmental research" to immediate court review "as soon as published but before they are given regulatory effect." *Id.* at 862.

The Fourth Circuit's narrow interpretation of the requirements for judicial review demonstrates the risk for industry wishing to bring a

DQA challenge in court. It is noteworthy that the district court initially struck down the EPA risk assessment with scathing comments regarding the EPA's manipulation of scientific evidence to support its *a priori* hypothesis. See 4 F.Supp.2d at 456–63. Given the district court's assessment, there can be little doubt that the risk assessment would not have passed muster under the DQA. Had the DQA been available, a strong argument to gain judicial review might have been that the agency's violation of the statutory mandates caused the exact harm that the DQA was intended to prevent.

Remedy—What Does the DQA Offer?

Long before the advent of the information age, Abraham Lincoln recognized that "a universal feeling, whether founded or ill-founded, cannot be safely disregarded." Humes, *The Wit and Wisdom of Abraham Lincoln* (Gramercy Books 1999) (Harper-Collins 1996). The danger of generating ill-founded universal feeling has never been so great as now with the ability to quickly disseminate information to people of all societal sectors through the media and the Internet. While it is just that danger that may have contributed to the impetus behind the Data Quality Act, it is unclear how effective the available remedies will be. The obvious remedy under the DQA, withdrawal or correction of flawed information, may not be enough.

In fact, the agency's ability to expunge disseminated information is restricted by the Federal Records Act, which dictates the process by which the agency may either archive or destroy the information it possesses. See 44 U.S.C. §§3101–07, 3301–24. Even if agencies could simply "erase" the information, once it is disseminated the slate is anything but clean. Additionally, information disseminated by agencies may not be subject to the DQA if it is not "maintained" by the agency.

Disseminated information can cause irreparable harm

Once the FDA disseminates information, it immediately shapes public opinion. Mere withdrawal or correction of the already digested report may do little to sway the initial public response. In *Tozzi v. HHS, supra,* the court recognized this conundrum when it addressed the HHS argument that the court could not redress the medical device manufacturer's injury. The D.C. Circuit agreed that striking the dioxin risk assessment from the report would not likely reverse decisions to limit polyvinyl chloride use. Nonetheless, the court found that future harm could be redressed, aptly predicting that if the court "set aside the Secretary's upgrade decision, dioxin activists could no longer point to an authoritative determination by the United States government that dioxin is 'known' to cause cancer in humans." 271 F.3d at 309–10.

Information not "maintained" by the agency is not subject to challenge

Section 515(b)(2)(A) of the Data Quality Act mandates that federal agencies create guidelines

The DQA can prevent the FDA from disseminating poor quality information that junk science proponents can use.

to ensure and maximize the quality of information that the agency disseminates. However, Section 515(b)(2)(B), which mandates that agencies establish procedures to allow "affected persons to challenge the information," is limited to information "maintained and disseminated" by the agency. This same language appears in section II.2. and III.3. of the OMB Guidelines. Interestingly, the summary in OMB's preamble to its guidelines leaves out the word "maintains" when it describes the directive to establish administrative mechanisms for correction of information. 67 Fed.Reg. at 8453.

At first blush, it would seem obvious that information correction can only occur if the agency possesses or maintains the data. Such a conclusion defines "information" too narrowly. Consider a statement made by the former FDA Commissioner, David Kessler, expressing a "heightened concern" about the safety of breast implants, referring to painful hardening in "10 to 70 percent of patients" and "increasing number of autoimmune disorders among breast implant patients." http://www.fda.gov/bbs/topics/SPEECH/SPE00012.htm (last visited 6/9/03). Once the FDA released the statement, it was picked up by various media sources, as Dr. Kessler may have intended. Had the DQA been available in 1992 when Dr. Kessler's statement was issued, an affected person may have brought a challenge. In response to the DQA challenge, the FDA might have simply removed the statement from its Web site and refused to take any action to correct reprints of the statement in the media by arguing that it does not "maintain" that information.

Proper remedy may include forcing agencies to update information

If the goals of the DQA to ensure that the federal agencies develop, disseminate, and maintain information that meets the Congressionally mandated levels of quality are to be accomplished, the information must be updated to account for newly developed data. However, the OMB Guidelines do not address the responsibility of agencies to update disseminated information. With its limited resources it will not be surprising if the FDA elects to wait for "affected persons" to bring its attention to disseminated information that needs to be updated.

While the remedy for harm done by disseminated information is difficult to achieve, withdrawal or correction of flawed information takes that information out of the hands of activists and plaintiffs' attorneys alike. Additionally, affected persons can request that an agency disseminate announcements of the corrections made or information withdrawn in the same manner that the original information was disseminated, to make sure the intended audience is alerted. Interested parties should also be vigilant to petition agencies to update outdated information. It is then up to industry to use information resources in an effort to keep ill-founded public opinion in check.

Conclusion

The Data Quality Act can be an effective weapon to fight junk science. Used as sword and shield the DQA can prevent the Food and Drug Administration from disseminating poor quality information that junk science proponents can use. Effective use of the DQA to challenge FDA-disseminated information that does not meet Congressional mandated levels of quality can also prevent plaintiffs' counsel from weakening an otherwise strong *Daubert* challenge. A manufacturer that fails to bring a DQA challenge may find itself at the tip of the DQA sword, as our hypothetical attorney at the beginning of this article learned.

Like all weapons, the DQA must be used with discretion until we know more about how it works, and how it can be turned against us. Drug and medical device manufacturers cannot afford to ignore this legislation and should consider it throughout all stages of its dealings with the FDA. **FD**