IN THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT United States Cou

United States Court of Appeals Fifth Circuit

FILED May 24, 2012

No. 11-30812

Lyle W. Cayce Clerk

AKZO NOBEL INC.; GENERAL CHEMICAL CORP.; MISSISSIPPI LIME MANAGEMENT CO; MORTON INTERNATIONAL; OCI OF WYOMING; LONNY BADEAUX; JOSEPH VENDETTI; METHANE AWARENESS RESOURCE GROUP; DIESEL COALITION,

Plaintiffs-Appellees

v.

UNITED STATES OF AMERICA; KATHLEEN SEBELIUS, SECRETARY, DEPARTMENT OF HEALTH & HUMAN SERVICES; JOHN HOWARD, Director, National Institute for Occupational Safety and Health; HAROLD VARMUS, Director, National Cancer Institute,

Defendants-Appellants

Appeal from the United States District Court for the Western District of Louisiana (6:96-CV-2430)

Before BENAVIDES, PRADO and GRAVES, Circuit Judges. PER CURIAM: *

This appeal involves a Diesel Exhaust in Miners Study, commenced two decades ago in 1992 and conducted by the National Institute for Occupational

 $^{^{*}}$ Pursuant to 5TH CIR. R. 47.5, the court has determined that this opinion should not be published and is not precedent except under the limited circumstances set forth in 5TH CIR. R. 47.5.4.

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Safety and Health ("NIOSH")¹ and the National Cancer Institute ("NCI")² – two components of the United States Department of Health and Human Services (collectively, "HHS"). In this appeal – the third in a series of related appeals spanning thirteen years – HHS challenges the district court's order granting the motion for injunctive relief, civil contempt, and fees and expenses brought by the plaintiffs-appellees, Methane Awareness Resource Group ("MARG") and Lonny Badeaux (collectively "Plaintiffs").³ Once again, HHS's appeal is successful. We VACATE and REVERSE.

I. FACTUAL AND PROCEDURAL BACKGROUND

A. The Diesel Exhaust in Miners Study

Between 1992 and 1995, NIOSH and NCI developed a draft protocol for the study. In 1996, HHS decided to use a particular advisory committee, the NIOSH's Board of Scientific Counselors ("BSC"), to provide peer review for the draft protocol. In January, April and July 1997, BSC held public meetings to

¹ NIOSH is a component of HHS. 29 U.S.C. § 671(a). NIOSH conducts scientific research related to occupational safety and health. *Id.* §§ 669(a)(1). NIOSH's research is used, *inter alia*, to generate recommendations regarding permissible exposure levels for potentially harmful substances. *Id.* §§ 669(a)(3), 671(d). Congress has recognized a particular role for NIOSH in mine-related research. Federal Mine Safety and Health Act of 1977, 30 U.S.C. § 801. Congress directed NIOSH to improve and expand research programs to prevent occupational diseases in the mining industry. *Id.* U.S.C. §§ 801(g), 951(a)(9); *see also* 29 U.S.C. § 671. Congress declared that "there is an urgent need to provide more effective means and measures for improving the working conditions and practices in the Nation's coal or other mines in order to prevent death and serious physical harm, and in order to prevent occupational diseases originating in such mines." 30 U.S.C. § 801(c).

² NCI is another component of HHS. See 42 U.S.C. §§ 281(a), (b)(1); *id.* § 202. NCI conducts and supports research, information dissemination, and other activities related to "the cause, diagnosis, prevention, and treatment of cancer." *Id.* § 285. NCI is also authorized to coordinate its research activities with other public and private entities, such as NIOSH, that perform similar work. *See id.* § 284(c)(1).

³ MARG represents a majority of the mine operators with mines in the study. Current MARG company members include Cargill, Inc., Detroit Salt, Mossaic Potash (formerly IMC), Morton Salt, General Chemical (now Tata Chemicals, US), FMC Wyoming, and Navistar and Lonny Badeaux who is a plaintiff in his own personal capacity, as a former miner and subject of the study.

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review the draft protocol, for which BSC provided notice and allowed for public comment. Plaintiffs offered their comments at the meeting. After the meetings, BSC voted to approve the protocol for the study.

Then in 1999, however, Plaintiffs sued, alleging that HHS had violated the Federal Advisory Committee Act ("FACA") by using BSC to review the draft protocol. Pursuant to FACA, the government must file the charter for an advisory committee (such as BSC) with a certain congressional standing committee, depending on the federal agency that the advisory committee advises. 5 U.S.C. Appx. § 2. HHS had mistakenly filed the charter for BSC with the House Committee on Commerce, rather than the House Committee on Education and the Workforce ("the House Committee"). On appeal, this court held that HHS had indeed made a mistake by filing BSC's charter with the wrong congressional committee. Cargill, Inc. v. United States, 173 F.3d 323, 334 (5th Cir. 1999). Although inadvertent, HHS's mistake required correction. To ensure proper congressional oversight of BSC, and to ensure that BSC's review of the draft protocol was valid, the appropriate congressional committee with the requisite expertise needed to be involved. This court further held that Plaintiffs had standing to compel HHS to refile the charter because the validity of the study protocol affected Plaintiffs' interests. Id. at 342. The study findings would form the basis for new administrative regulations. An invalid study protocol would generate an invalid study, which could lead to unnecessarily restrictive regulations on Plaintiffs. This court ultimately instructed the district court to fashion an injunction that promoted FACA's goals of ensuring public accountability and of reducing economic waste. *Id*.

On remand on March 13, 2000, the district court issued an injunctive order to remedy this FACA violation ("2000 Order"), which required HHS to provide study drafts and requested study data to the House Committee, and gave the

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House Committee veto power over the study. HHS appealed the order as overly broad, and this court agreed with HHS, instructing the district court to enter a narrower order, stating that there was "little reason for future injunctive relief" beyond refiling the charter with the correct House committee. *Akzo-Nobel, Inc.* v. United States, 2001 WL 34772206, at *2–*3 (5th Cir. 2001). "[A]n order requiring [House Committee] approval before the study can be released is not appropriate for HHS's inadvertent mistake in filing the [BSC's] charter with the wrong House committee." *Id.* at *2.

HHS did not hide from Congressional oversight. It tried to make itself accountable to the public. It unknowingly filed BSC's charter with the wrong House committee and filed it with the correct Senate committee. Plaintiffs and other interested parties had actual notice that the BSC was reviewing the study protocol and were informed of and invited to every meeting of the BSC panel.

Id. This court noted concern "that the [House] Committee should have sufficient time to examine the misfiled study data" and become familiar on the validity of the study protocol and BSC's corresponding advice. *Id.* at *3. Accordingly, we instructed the district court to "revise its order so that HHS will be barred from publicly releasing any of the information it sends to the [House] Committee until 90 days after its submission." *Id.*

On remand again in 2001, the district court issued a new two-part injunctive order ("2001 Order").⁴ In the first part of the order, the district court required HHS to submit BSC work product to the House Committee and to Plaintiffs. The last line of the first part states: "Defendants shall provide Plaintiffs with copies of all documents submitted to the Committee in compliance with this Order." In the second part of the order, the district court required HHS to submit to the House Committee (i) study data requested by the

⁴ Attached is a copy of the 2001 Order as appendix 1.

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Committee and (ii) study "draft reports, publications, and draft results or risk notification materials." The district court also barred HHS from publicly releasing information submitted to the House Committee until 90 days after submission. The second part of the order did not mention Plaintiffs.

Nine years passed after the 2001 Order without any controversy. In 2002, BSC finished its oversight of the study protocol. Between 2002 and 2004, in compliance with the 2001 Order, HHS submitted study drafts and data to the House Committee. The submitted materials included final drafts of different parts of the study as they were completed, sample notification letters that were sent to individual miners, and a presentation that the agencies gave at a public meeting regarding the study's progress. Furthermore, in 2002, the House Committee wrote to HHS ("2002 Letter") to:

request that [NIOSH] provide all draft copies of all reports, notifications, recommendations, or alerts, related to or based on the [study], prior to the release or publication of such study, or portion thereof. The [House Committee] also requests submission of study data, in a format capable of being analyzed, as the data collection phase of each part of this study is completed, and preceding the drafting of any reports.

In 2003, the House Committee wrote to Defendants ("2003 Letter"), asking several questions about the study and requesting specific data sets. HHS complied with these letters; HHS also provided Plaintiffs with copies of the cover letters sent to the House Committee, but not the actual drafts and data. In 2004, the House Committee wrote to Defendants ("2004 Letter"), stating that NIOSH and NCI:

must submit any data requested by the Committee in accordance with certain confidentiality statutes and the terms specified in the order and must refrain from publicly releasing information submitted to the Committee until 90 days after the date of submission. We hereby request NIOSH and NCI to provide copies of any submissions that the agencies are required to make to this Committee under the District Court's order

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to a scientific reviewer designated by the United Steelworkers of America at the same time they make their submission to the Committee.

In response, HHS provided some data sets to Plaintiffs and answered Plaintiffs' questions about the data.

In or about 2009, HHS split the study into seven draft articles and decided to submit the draft articles to scientific journals for peer review. In November 2009, HHS submitted the first four draft articles to the *Annals of Occupational Hygiene* ("AOH"). HHS sent AOH a copy of the 2001 Order and asked the journal to "ensure that its staff and peer reviewers . . . maintain the confidentiality of the manuscripts" to "ensure that the [HHS] agencies remain in compliance with [the 2001 Order] during the journal's review process of these manuscripts." AOH agreed. In February 2010, AOH accepted the four articles for publication.

On March 1, 2010, HHS submitted the final drafts of these four articles to the House Committee. HHS also sent Plaintiffs a copy of the cover letter sent to the House Committee, but not the actual articles—similar to HHS's practice in 2002 and 2003. In April 2010, the Plaintiffs responded by filing two motions for contempt. First, Plaintiffs argued that HHS had violated the 2001 Order by submitting the final drafts of the four articles to the House Committee but not to Plaintiffs. Second, Plaintiffs argued that HHS had violated the 2001 Order by submitting the four articles to AOH before sending them to the House Committee and to Plaintiffs and then waiting 90 days. In its order ("2010 Order"), the district court denied the contempt motions.⁵ The 2010 Order required HHS to submit the final drafts of the four articles to the House Committee and Plaintiffs, and required HHS to wait 90 days before further distributing the study articles so that the House Committee and Plaintiffs would

⁵ Attached is a copy of the 2010 Order as appendix 2.

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have an opportunity to review the study articles. The district court further required HHS to prevent AOH from publishing the articles until the 90-day review period was complete. Lastly, the district court noted that Plaintiffs may not further disclose the articles during the 90-day period, but may make comments about the articles to HHS or to the House Committee. The district court did not resolve the issue of whether the submission of an article to a scientific journal for peer review constituted "public release" in violation of the 2001 Order. Furthermore, in a prior hearing, the district court had explained that it was not holding Defendants in contempt because "there is some language in [the 2001 Order] that I can see where they're coming from."

In September 2010, AOH published the four articles, after Plaintiffs and the House Committee had 90 days to review them. HHS only provided Plaintiffs and the House Committee with the final proofs of the articles. HHS did not provide Plaintiffs with the underlying study drafts or data. HHS indicated that it planned to produce data in the form of a "public use" dataset that resolved confidentiality problems.

By May 2011, the study's final three papers were almost ready for publication. One article was ready to be published in AOH, and the other two had been submitted to another peer-reviewed scientific journal and were undergoing peer review. HHS planned to provide the final drafts of these articles to the House Committee and Plaintiffs once they were accepted for publication, and then wait 90 days before publishing the articles. Accordingly, on May 31, 2011, HHS moved "for an order extending the provisions of the [2010 Order] to the last three papers remaining for publication in this action."

In response, Plaintiffs brought a new motion for contempt on June 10, 2011. Plaintiffs argued that HHS had been violating the 2001 Order since 2005,

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when it stopped submitting any study drafts or data to the House Committee and to Plaintiffs. They argued further that HHS had violated the 2001 Order by submitting the last three draft articles to outside journals before submitting them to Plaintiffs and the House Committee. Plaintiffs requested that study drafts and data be provided to the House Committee and to Plaintiffs, pursuant to the 2001 Order.

In July 2011, the House Committee wrote to HHS ("2011 Letter"), noting that under the 2001 Order, NIOSH and NCI:

must submit to this Committee and the MARG all data requested by the Committee as well as all draft reports, publications, and draft results or risk notification materials prepared in connection with the NIOSH/NCI Diesel study. The agencies must submit any data requested by the Committee in accordance with certain confidentiality statutes and the terms specified in the order, and must refrain from publicly releasing information submitted to the Committee until 90 days after the date of submission.

In August 2011, the district court held a hearing on the Plaintiffs' motion for contempt. In its order, the district court found HHS in contempt, and issued a broad injunctive remedy ("2011 Order"). First, the district court ordered HHS to immediately produce to Plaintiffs and the House Committee, "all nonconfidential documents, data, draft reports, publications, and draft results or risk notification materials," relating to the study. Second, the district court ordered HHS to "immediately inform all recipients, including journals, of the above described study draft reports, not yet published, that they are prohibited from further distribution of said drafts until at least 90 days after [HHS has] complied with this Order[.]" Third, the district court noted that Plaintiffs may not further disclose the articles during the 90-day period, but may make comments about the articles to HHS, the publishing journals, or the House

 $^{^6}$ Attached is a copy of the 2011 Order as appendix 3.

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Committee. Fourth, the district court awarded Plaintiffs attorneys' fees. On September 1, 2011, HHS appealed the 2011 Order.

II. STANDARD OF REVIEW

"We review contempt orders and sanctions imposed thereunder for an abuse of discretion." *Whitcraft v. Brown*, 570 F.3d 268, 271 (5th Cir. 2009). "We review the district court's underlying findings of fact for clear error and its underlying conclusions of law de novo." *Id*.

III. ANALYSIS

A. Whether the district court abused its discretion by holding HHS in contempt.

"[A] court abuses its discretion when it (1) relies on clearly erroneous factual findings, (2) relies on erroneous conclusions of law, or (3) misapplies its factual or legal conclusions." *Cargill, Inc. v. United States*, 173 F.3d 323, 341 (5th Cir. 1999) (citing *Peaches Entertainment Corp. v. Entertainment Repertoire Assocs.*, 62 F.3d 690, 693 (5th Cir. 1995)). Here, the district court made no findings, and likewise, made no conclusions of law. Hence, there is no way to determine what the district court either relied on or applied. Instead, the district court provided no specificity as to what action by HHS violated the 2001 Order.

First, the only finding made by the district court in its 2011 Order was that HHS was in contempt, but the district court does not provide any basis for that finding. The three preceding paragraphs of the 2011 Order are stand alone orders, not reasons for the finding of contempt. Second, a careful review of the hearing transcript regarding Plaintiffs' contempt motion further supports our conclusion, because it also reveals that the district court made no findings and made no conclusions of law. The district court did not specifically identify any

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violation of the 2001 Order, nor did the district court identify, or discuss with specificity, any part of the 2001 Order.

Nonetheless, the parties have briefed two grounds for the district court's contempt order. First, Plaintiffs urge, and HHS denies, that HHS violated the 2001 Order by submitting study articles to outside scientific journals for peer review before submitting the articles to Congress. Second, Plaintiffs urge, and HHS denies, that HHS violated the 2001 Order by failing to submit study drafts and requested study data to both Congress and to Plaintiffs. For the reasons stated below, even if we assume that the district court based its contempt order on these alleged violations, the contempt order constitutes an abuse of discretion.

1. Whether the district court properly held HHS in contempt for submitting study articles to outside scientific journals.

"A movant in a civil contempt proceeding bears the burden of establishing by clear and convincing evidence 1) that a court order was in effect, 2) that the order required certain conduct by the respondent, and 3) that the respondent failed to comply with the court's order." *Id.* It is undisputed that the 2001 Order was in effect. It is further undisputed that the 2001 Order required certain conduct by HHS. Therefore, the remaining question is whether HHS failed to comply with the 2001 Order.

The last sentence of the 2001 Order states that HHS "shall refrain from *publicly releasing* information submitted to the Committee until 90 days after it is submitted to the Committee." (Emphasis added.) Plaintiffs contend that HHS violated the 2001 Order when it provided draft copies of the study to AOH. HHS maintains that it did not violate the 2001 Order, because it provided the draft copies of the study to AOH (1) for the purpose of peer review, which does not qualify as a "public release" and (2) with a specific admonition that any manuscripts related to the study remain confidential.

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Documents involved in the peer review process are exempt from disclosure pursuant to the Freedom of Information Act ("FOIA") exemption that applies to "inter-agency or intra-agency memorandum or letters which would not be available by law to a party other than an agency in litigation with the agency." 5 U.S.C. § 552(b)(5). This FOIA exemption cannot be invoked for a document that has already been released publicly. *See Cooper v. Department of Navy*, 594 F.2d 484, 488-89 (5th Cir. 1979). Here, the 2001 Order does not define "publicly release," and the 2011 Order specifically exempts confidential documents from production. Therefore, a paper submitted for peer review cannot be deemed publicly released.

This court also recognized that "the government may deem it necessary to seek the objective opinion of outside experts rather than rely solely on the opinions of government" employees, and that documents prepared by these outside experts qualify as "intra-agency" memoranda not subject to disclosure pursuant to the relevant FOIA exemption. Hoover v. U.S. Dep't of the Interior, 611 F.2d 1132, 1138 (5th Cir. 1980). Additionally, in the aforementioned 2004 Letter, the House Committee recognized that "[w]e understand that the participation of the representatives of MARG and the Steelworkers will be dependent upon these representatives entering appropriate confidentiality agreements with the agencies." (Emphasis added.) Likewise, in 2005, the Executive Office of the President Office of Management and Budget issued its Final Information Quality Bulletin for Peer Review ("Peer Review Final Bulletin"), which are guidelines regarding peer review of scientific information disseminated by federal agencies. See Final Information Quality Bulletin for Peer Review, 70 Fed. Reg. 2,664, 2,665 (2005). The Peer Review Final Bulletin states, in relevant part:

Peer review should not be confused with public comment and other stakeholder processes. The selection of participants in a peer review is

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based on expertise, with due consideration of independence and conflict of interest. Furthermore, notice-and-comment procedures for agency rulemaking do not provide an adequate substitute for peer review, as *some* experts – especially those most knowledgeable in a field – may not file public comments with Federal agencies.

. . .

Peer review may take a variety of forms, depending upon the nature and importance of the product. For example, . . . the names of each reviewer may be disclosed publicly or may remain anonymous (e.g., to encourage candor) . . . For large, complex reports, different reviewers may be assigned to different chapters or topics. Such reports may be reviewed in stages, sometimes with confidential reviews that precede a public process of panel review. As part of government-sponsored peer review, there may be opportunity for written and/or oral public comments on the draft product.

. . .

Similarly, when a government agency sponsors peer review of its own draft documents, the peer review reports are an important factor in information dissemination decisions but rarely are the sole consideration. Agencies are not expected to cede their discretion with regard to dissemination or use of information to peer reviewers; accountable agency officials must make the final decisions.

Id. at 2,665-2,666 (emphasis added). In addition, the Peer Review Final Bulletin defines "dissemination" as "agency initiated or sponsored distribution of information to the public" but specifically excludes from this definition "information distributed for peer review in compliance with this Bulletin." Id. at 2,667. "Moreover, the National Academy of Sciences now discloses the names of its peer reviewers, without disclosing the substance of their comments." Id. at 2,670 (emphasis added).

Here, HHS submitted drafts of the study to AOH solely for peer-review purposes. When HHS submitted the final three papers for peer review, it transmitted a copy of the 2001 Order to the reviewing journals and admonished them to maintain the confidentiality of the papers during the review process. In a November 2, 2009 letter to AOH, HHS stated:

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NIOSH's and NCI's "actions regarding this study are the subject of a court order issued by the United States District Court of the Western District of Louisiana, and request your journal's assistance to ensure that the agencies remain in compliance with this order during the journal's review process of these manuscripts. I have enclosed a copy fo this order for your information. Paragraph 2 of the order directs the agencies, among other things, to submit draft reports and publications to a committee in the United States House of Representatives and to refrain from publicly releasing any information submitted to that committee until 90 days after it is submitted. . . . Therefore, both agencies are requesting that the Annals of Occupational Hygiene ensure that its staff and the peer reviewers it employs maintain the confidentiality of the manuscripts. It is my understanding, from your discussions with representatives of NCI, that the Annals of Occupational Hygiene requests that its reviewers maintain the confidentiality of any manuscript which they are asked to peer review as part of its normal peer review process. The agencies request, in addition to your normal procedures, that you inform your reviewers and staff, in writing, that this study is subject to a court order that requires the manuscripts and their content to remain confidential.

(Emphasis added.) HHS's specific confidentiality admonition supplemented the general rule that scientific journals – such as AOH – keep materials submitted for peer review confidential. For example, HHS stated – in a March 1, 2010 letter to the United States House of Representatives Committee on Education and Labor – that "[i]t is the policy of peer-reviewed scientific journals to refuse to publish papers if the information contained in them is disclosed prior to the scheduled publication date." NIOSH and NCI had followed this practice when HHS submitted the study's first four papers to AOH for peer review in 2009, and the House Committee never objected or indicated that it found this problematic. Accordingly, HHS did not violate the 2001 Order by submitting study articles to outside scientific journals. Even if submitting study articles to outside scientific journals is the basis for the contempt order, holding HHS in contempt for such submission constitutes an abuse of discretion.

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2. Whether HHS violated the 2001 Order by failing to produce requested study data and drafts to Plaintiffs and to the House Committee.

HHS argues on appeal that it has fully complied with the 2001 Order's mandate to submit to the House Committee: (1) study "data requested by the [House Committee]" and (2) "draft reports, publications, and draft results or risk notification materials" related to the study. Plaintiffs counter on appeal that HHS violated the 2001 Order by failing to provide: (1) Plaintiffs with study materials, (2) the House Committee with requested data from 2005 onward, and (3) the House Committee with study drafts from 2005 onward.

First, HHS did not violate the 2001 Order by failing to submit requested study data and study drafts to Plaintiffs. HHS routinely provided Plaintiffs with cover letters of the study materials sent to the House Committee. Although HHS did not always provide Plaintiffs with the actual study materials, the 2001 Order did not require HHS to do so. Part 1 of the 2001 Order required HHS to submit BSC's work product to the House Committee, and required Defendants to submit to Plaintiffs all the documentation that it submitted to the House Committee. That latter requirement was the last sentence of Part 1, which read: "[HHS] shall provide Plaintiffs with copies of all documents submitted to the Committee in compliance with this Order." Yet, in the entirely separate Part 2 - wherein HHS was ordered to submit to the House Committee: (1) study data that the House Committee requested and (2) study drafts – there was no mention of Plaintiffs. Part 2 includes no requirement that HHS submit this information – requested study data and study drafts – to Plaintiffs. Of course, Plaintiffs urge that the last line of Part 1 of the 2001 Order applies to the entire order. However, because the 2001 Order has been split into two separate parts, there is no reason to read the last sentence of Part 1 as also applying to Part 2, such that HHS would be required to submit requested study data and study

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drafts to both Plaintiffs and the House Committee. Furthermore, to the extent that HHS submitted any materials to Plaintiffs – such as the materials submitted in 2004 – HHS did so out of an abundance of courtesy. Lastly, the House Committee itself read the 2001 Order as requiring HHS to submit study materials to the House Committee, but not to Plaintiffs. In the 2004 Letter, the House Committee indicated that the 2001 Order obligated HHS to submit study materials to the House Committee. The letter then proceeded to request HHS to produce to Plaintiffs' reviewer study materials that had been submitted to the House Committee. HHS provided the reviewer with certain study data. If the 2001 Order on its face required HHS to produce study materials to Plaintiffs, then the House Committee would not have had to request HHS to produce study materials to Plaintiffs. Later, in the 2011 Letter, the House Committee indicated that the 2001 Order obligated HHS to submit study materials "to this Committee and to MARG," one of the Plaintiffs. It appears that the House Committee about faced because of the instant litigation. The absence of "MARG" in the 2004 Letter, compared to the 2011 Letter, demonstrates that the original understanding of the 2001 Order was that HHS was not required to produce study materials to Plaintiffs. Therefore, HHS did not violate the 2001 Order by failing to submit study materials to Plaintiffs.

To be sure, Plaintiffs also argue that HHS violated the 2001 Order by failing to provide the House Committee with requested data and study drafts from 2005 onward. Regardless of the soundness of Plaintiffs' argument, however, the 2001 Order was ambiguous. It is well-settled that the "judicial contempt power"—a "potent weapon"—"should not be used if the court's order upon which the contempt was founded is vague or ambiguous." *Piggly Wiggly Clarksville, Inc. v. Mrs. Baird's Bakeries*, 177 F.3d 380, 383 (5th Cir. 1999) (internal quotation marks omitted). Thus, even if the district court based its contempt order on HHS's failure to provide Plaintiffs and Congress with certain

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study materials—including the failure to provide Congress with study drafts and requested study data from 2005 onward—holding HHS in contempt for such a failure constitutes an abuse of discretion.

We have concluded that there was no basis for the district court to hold HHS in contempt. In any event, the district court's entire record is completely devoid of any stated reason for the contempt order. The district court made no factual findings or legal conclusions related to the 2011 Order. We therefore hold that the district court abused its discretion in holding HHS in contempt.

B. Whether the district court abused its discretion in issuing a broad injunctive remedy to ensure compliance with the 2001 Order.

In the 2011 Order, the district court required HHS to "immediately produce to Plaintiffs and [the House Committee] all non-confidential documents, data, draft reports, publications, and draft results or risk notification materials" related to the seven published or publish-ready articles. The district court also required HHS to warn the journals not to publish the study materials, and required Plaintiffs not to further disseminate the study materials. The district court also noted that Plaintiffs are permitted to make comments about the articles to HHS, the publishing journals, or the House Committee.

We hold that the district court abused its discretion by fashioning a new, broader order in 2011 that went beyond what it had ordered in 2001. Remedial injunctions must be narrowly drawn and precise, and the relief granted must be tailored to fit the nature and extent of the established violation. See, e.g., Haitian Refugee Center v. Smith, 676 F.2d 1023, 1041 (5th Cir. 1982); Fiber Systems Int'l v. Roehrs, 470 F.3d 1150, 1159 (5th Cir. 2006) ("An injunction must be narrowly tailored to remedy the specific action necessitating the injunction."). The 2011 Order purported to restate HHS's obligations pursuant to the 2001 Order, which remedied a specific violation: the minor FACA violation. Because the 2001 Order was issued to remedy the FACA mistake, and the 2011 Order

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was issued to ensure compliance with the 2001 Order, the 2011 Order should have been narrowly tailored to fit the minor administrative mishap. By requiring production of all non-confidential study drafts and data to the House Committee and to Plaintiffs, however, the 2011 Order is not so narrowly drawn.

After HHS had filed BSC's charter with the wrong congressional committee, this court instructed the district court to require HHS to file BSC's charter with the correct congressional committee. Cargill, 173 F.3d at 342. BSC was tasked with advising HHS on the research protocol for the study. The charter needed to be filed with the correct congressional committee to ensure proper congressional oversight of BSC's review. Other than ordering HHS to refile the charter, however, we noted that "there was little reason for further injunctive relief." Akzo-Nobel, 2001 WL 34772206, at *2. We also noted that the new House Committee would require some time to become familiar with the study protocol and examine the misfiled study protocol data. Id. We thus instructed the district court to revise its order to bar HHS from publicly releasing any information it sends to the House Committee until 90 days after its submission. Id. In response, the district court fashioned the 2001 Order to require HHS to submit study drafts and requested study data to the House Committee.

Because the 2001 Order was issued to remedy such a trivial FACA violation, the 2001 Order should be read narrowly. The violation only concerned BSC, which was tasked with a small role: advising HHS on the research protocol. Despite the erroneous filing, Plaintiffs had actual notice that BSC was reviewing the study protocol, were informed of and invited to every BSC meeting, and attended each BSC meeting and provided oral and written comments. Also, filing the charter with the correct committee was important merely to enable the House Committee's oversight regarding the research protocol, as opposed to the entire study itself.

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The 2011 Order is overly broad and demands much more than the properly-construed 2001 Order. First, although the 2001 Order only requires HHS to produce study materials to the House Committee, the 2011 Order requires HHS to produce study materials to the House Committee and to Plaintiffs. Second, although the 2001 Order requires HHS to submit to the House Committee data that the House Committee requests, the 2011 Order requires HHS to produce all non-confidential data to the House Committee and to Plaintiffs. Third, although the 2001 Order requires HHS to submit to the House Committee "draft reports, publications, and draft results or risk notification materials," the 2011 Order requires HHS to submit all "documents" to House Committee and to Plaintiffs, in addition to draft reports, publications, draft results or risk notification materials.

Because the 2011 Order was issued to ensure compliance with the 2001 Order, the 2011 Order must be as narrowly drawn and precise as the 2001 Order, which was narrowly tailored to remedy the inadvertent FACA mistake. By going beyond the 2001 Order, however, the 2011 Order becomes untethered from the underlying FACA violation to which it must be narrowly fit. As HHS argues: "Ordering the disclosure of information completely unrelated to an advisory board and that [P]laintiffs never could have obtained had FACA been complied with goes far beyond FACA's purpose to regulate boards and committees established to advise the executive branch."

Plaintiffs have no free-standing right to HHS's study materials. For the district court to issue an injunction to grant Plaintiffs access to HHS's study materials, Plaintiffs must identify a specific violation that the injunction would remedy. Neither Plaintiffs nor the district court has identified any violation that the 2011 Order was issued to remedy except for the FACA mistake, which HHS remedied a decade ago. More precisely, the 2011 Order was issued to bring HHS into compliance with the 2001 Order, which was issued to remedy the FACA

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mistake. However, neither Plaintiffs nor the district court has identified some other "violation," besides the FACA mistake, that HHS committed that would justify issuing a broader injunctive remedy. Consequently, there are no grounds for expanding the scope of the 2011 Order beyond the scope of the 2001 Order.

Because the underlying FACA mistake was, at most, administrative, we should narrowly construe the 2001 Order, and we should be wary of any provision of the 2011 Order that goes beyond the 2001 Order. The overly broad injunctive remedy in the 2011 Order – requiring production of all study drafts and data to the House Committee and to Plaintiffs – is an abuse of discretion.

IV. CONCLUSION

For the foregoing reasons, we hold that the district court abused its discretion by holding HHS in contempt and by fashioning an overly broad injunctive remedy. With respect to the 2011 Order, therefore, we VACATE in part and REVERSE in part.