UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PUBLIC CITIZEN HEALTH RESEARCH GROUP, Plaintiff, v. FOOD AND DRUG ADMINISTRATION, Defendant, and AGOURON PHARMACEUTICALS, ALZA CORPORATION, ALLERGAN INC., CHIRON CORPORATION, AND MERCK & COMPANY, INC. Intervenor-Defendants.	C.A. No. 99-2110 (RCL)

PLAINTIFF'S CROSS-MOTION FOR SUMMARY JUDGMENT

Pursuant to Rule 56 of the Federal Rules of Civil Procedure, Plaintiff Public Citizen Health Research Group hereby moves for summary judgment on the ground that there is no genuine issue of disputed material fact and that Plaintiff is entitled to judgment as a matter of law.

In support of this motion, plaintiff submits the accompanying (1) memorandum in support of Plaintiff's motion for summary judgment and in opposition to Defendant's and Intervenor-Defendants' motions for summary judgment; (2) statement of material facts as to which there is no genuine dispute; (3) response to Defendant's and Intervenor-Defendants' statements of material facts;

(4) declaration of Larry D. Sasich, Pharm.D., M.P.H., and (5) a proposed order.

Dated: June 9, 2000

_____
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ORDER

Upon consideration of Defendant's and Intervenor-Defendants' motions for summary judgment, the opposition thereto, Plaintiff's cross-motion for summary judgment, the oppositions thereto, and the entire record herein, it is, this __ day of _____, 2000,

ORDERED that Defendant's and Intervenor-Defendants' motions are DENIED. It is

FURTHER ORDERED that Plaintiff's motion is GRANTED. It is

FURTHER ORDERED that, within ten days of the date of this Order, the Food and Drug Administration will segregate and release to Plaintiff all descriptions of adverse experiences associated with the use of the drugs and biologics at issue from the information currently being withheld.

DATED: _____

_____
ROYCE C. LAMBERTH
UNITED STATES DISTRICT JUDGE

Copies to:

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PLAINTIFF'S MEMORANDUM IN SUPPORT OF ITS CROSS-MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO DEFENDANT'S AND INTERVENOR-DEFENDANTS' MOTIONS FOR SUMMARY JUDGMENT

In this case, Public Citizen Health Research Group ("HRG") seeks to compel the Food and Drug Administration ("FDA") to disclose under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, information concerning off-label, unapproved uses of previously approved drugs and biologics. The materials at issue were submitted to FDA pursuant to section 401 of the Food and Drug Administration Modernization Act of 1997, 21 U.S.C. § 360aaa, et seq. Under section 401, manufacturers that wish to promote off-label uses of their drugs, biologics, and medical devices submit to FDA their promotional materials and clinical data and other safety and effectiveness information about the off-label uses prior to disseminating the promotional materials, in return for

which FDA agrees not to bring an enforcement action against them for misbranding or adulteration based on their dissemination of the promotional materials. See generally Washington Legal Foundation v. Henney, 202 F.3d 331 (D.C. Cir. 2000).

Manufacturers must include in their section 401 submissions information about adverse experiences associated with their products. 21 U.S.C. § 360aaa(b)(4)(B). An "adverse drug experience" encompasses "[a]ny adverse event associated with the use of a drug in humans, whether or not considered drug related," including events occurring during commercial marketing and postmarketing clinical studies on the drug. 21 C.F.R. § 314.80(a) & (b). The definition is identical for adverse experiences associated with the use of biological products. 21 C.F.R. § 600.80(a) & (b). Without conceding its right to obtain access to the rest of the information in the section 401 submissions at issue in this case, HRG has narrowed its FOIA request and is now seeking only those portions of the section 401 submissions concerning adverse experiences associated with the use of the drugs and biological products that are the subject of those submissions.

FDA and the five manufacturers that have intervened to oppose disclosure of their section 401 submissions contend that adverse experience information is not subject to the ordinary rule of disclosure because it qualifies for withholding under exemption 4 of FOIA, 5 U.S.C. § 552(b)(4). However, because adverse experience data were required to be submitted to FDA in return for the benefit of evading an enforcement action by FDA, and because the manufacturers' competitors will not gain a competitive advantage from the disclosure of that information, adverse experience data cannot be withheld under exemption 4 of FOIA.

BACKGROUND

I. LEGAL AND REGULATORY BACKGROUND

A. FDA's Drug Approval Process and the Food and Drug Administration Modernization Act.

Under the Food, Drug, and Cosmetic Act of 1938 ("FDCA"), a new drug cannot be introduced into interstate commerce until the manufacturer submits a new drug application ("NDA") and receives FDA approval that the drug is safe and effective for its intended uses. See 21 U.S.C. § 355(a).[1] When FDA approves a drug, its approval applies only to those uses set out in the drug's approved labeling, which are referred to as the drug's "labeled" or "approved" uses. 65 Fed. Reg. 14286, 14286 (Mar. 16, 2000). "Unapproved" or "off-label" uses of the drug are uses that have not been approved as safe and effective by FDA. Id. Off-label uses include not only treating a condition not indicated on the label, but also treating the indicated condition with a different dosing regimen or in a different patient population. Once a drug is approved and on the market, a manufacturer can seek FDA approval for new uses of the drug by filing a supplemental NDA.

FDA does not prohibit physicians from prescribing approved drugs for off-label uses because FDA has not asserted authority to interfere with the traditional role of the States in regulating the physician-patient relationship. See 59 Fed. Reg. 59820, 59821 (Nov. 18, 1994). However, under the FDCA, manufacturers are prohibited from distributing drugs in interstate commerce with the intent that they be used off label. 21 U.S.C. §§ 331(d), 355(a). A drug that is marketed for a use for which it has not been approved is "misbranded" under the FDCA because its label would not include "adequate directions for use." 21 U.S.C. § 352(f). Misbranded drugs cannot legally be marketed in

[1] This case concerns information about both drugs and biological products. As used in this brief, the word "drug" includes biological products.

the United States, 21 U.S.C. § 331(a), and are subject to seizure and condemnation, 21 U.S.C. § 334. The government may pursue a criminal prosecution or civil suit against those responsible for marketing misbranded drugs. 21 U.S.C. §§ 332, 333.

FDA prohibits the marketing of drugs for off-label uses for the same reason that it prohibits the marketing of a drug that has never been approved by FDA for any use: untested drugs pose significant dangers to the public. See Brief of Appellant FDA, in Washington Legal Foundation v. Henney, 202 F.3d 331 (D.C. Cir. 2000), at 7. When FDA approves a drug for market, it is approving that drug only for those uses for which it has undergone clinical testing and been proved safe and effective. 21 U.S.C. § 355. The drug may not be effective for other uses, or it may prove dangerous for other uses.

One of the best known examples of the hazards of off-label prescription involves the diet drug combination popularly known as phen-fen. The drugs fenfluramine and phentermine were approved by FDA for treatment of obesity, but only for short term use (ten days), and were intended to be taken alone. Doctors prescribed the two drugs for use together and allowed patients to remain on the drugs for months. A few years after the commencement of off-label use, the drugs were discovered to cause serious damage to heart valves, in some cases resulting in the patient's death, in others requiring the patient to undergo a heart transplant. See Declaration of Larry D. Sasich, Pharm.D., M.P.H. ("Sasich Decl.") ¶ 10; see also Laurence Landow, M.D., "Off-Label Use of Approved Drugs," 113 Chest: The Cardiopulmonary and Critical Care Journal 589-91 (1999).

An intent to market a drug for an unapproved off-label use can be determined from, among other things, the promotional materials a drug manufacturer issues about its drug. See 21 C.F.R. § 201.128; 65 Fed. Reg. at 14286. Prior to passage of the Food and Drug Administration

Modernization Act of 1997 ("FDAMA"), Pub. L. No. 105-115, 111 Stat. 2296 (1997), FDA Guidance Documents provided that if a manufacturer publicly distributed materials concerning the off-label use of its drug, FDA could use those materials as evidence of misbranding. See Guidance to Industry on Dissemination of Reprints of Certain Published, Original Data, 61 Fed. Reg. 52800 (Oct. 8, 1996); Guidance for Industry Funded Dissemination of Reference Texts, 61 Fed. Reg. 52800 (Oct. 8, 1996). Section 401 of FDAMA, which supersedes those Guidance Documents, operates as a "safe harbor" that allows manufacturers who first obtain FDA approval under that section to distribute to doctors and health care organizations peer-reviewed medical and scientific journal articles discussing uses of their drugs that have not been approved as safe or effective without fear that those materials will be used as evidence of misbranding. See 21 U.S.C. §§ 360aaa(a) & (b); Washington Legal Foundation v. Henney, 202 F.3d at 335. Although failure to comply with section 401 is not an independent violation of the law, FDA may use the information disseminated by manufacturers who do not comply as evidence that their products are misbranded. 65 Fed. Reg. at 14287; Washington Legal Foundation, 202 F.3d at 335-37.[2]

To qualify for Section 401's safe harbor, a manufacturer must submit, in part, the following information to FDA at least sixty days before disseminating information to doctors and health care organizations:

(1) a copy of the journal article or medical textbook to be disseminated, 21 U.S.C. § 360aaa(b)(4)(A);

(2) a bibliography of other articles from scientific or medical journals that have been published about the use of the drug discussed in the information disseminated, 21 U.S.C. § 360aaa(b)(6)(B);

[2] Washington Legal Foundation leaves open the possibility that a manufacturer could raise the First Amendment as a defense against an enforcement action for misbranding.

(3) any clinical trial information the manufacturer has relating to the safety and effectiveness of the new use, any reports of clinical experience pertinent to the safety of the new use, and a summary of such information, 21 U.S.C. § 360aaa(b)(4)(B); and

(4) one of the following:

(I) if the manufacturer has submitted a supplemental application for the new use, a cross-reference to that supplemental application, 21 U.S.C. §§ 360aaa(b)(5), 360aaa-3(a)(1)(A)**;** or

(ii) if the manufacturer has completed studies needed for the submission of a supplemental application for the new use, a copy of the protocol and a certification promising to submit the supplemental application within six months from the date of dissemination of the information, 21 U.S.C. § 360aaa-3(b); or

(iii) if the manufacturer has planned studies that will be needed for the submission of a supplemental application for new use, the proposed protocols and schedule for conducting the studies and a certification promising to complete the clinical studies necessary to submit a supplemental application within 36 months, 21 U.S.C. § 360aaa-3(c); or

(iv) an application for an exemption from the requirement of a supplemental application. 21 U.S.C. § 360aaa-3(d).

B. Reporting of Adverse Experiences

FDA requires manufacturers to report to the agency adverse experiences associated with the use of their drugs. 21 C.F.R. §§ 312.32 (sponsor of new drug must report adverse experiences that occur during pre-market testing of a drug to FDA); 314.80 (sponsor of an approved drug must report postmarketing adverse experiences to FDA); 600.80 (same requirement for sponsors of biological products). An adverse experience is defined as:

> Any adverse event associated with the use of a drug in humans, whether or not considered drug related, including the following: An adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and

any failure of expected pharmacological action.

21 C.F.R. §§ 314.80(a); 600.80(a). Because FDA's reporting regime differs slightly depending on the phase of development of the drug at issue, we now summarize that regime with respect to the two phases at issue in this case.

Investigational New Drug ("IND") Safety Reports: Under 21 C.F.R. § 312.32, the sponsor of a new drug application that has yet to be approved must notify FDA of "[a]ny adverse event associated with the use of the drug that is both serious and unexpected." 21 C.F.R. § 312.32(c)(1)(I)(A). Each written notification is to be made as soon as possible, but no later than 15 days after the sponsor's receipt of the information. Id. FDA must be notified of any unexpected fatal or life-threatening adverse event no later than 7 days after the sponsor learns of the event. 21 C.F.R. § 312.32(c)(2). The sponsor of the IND is also required to investigate the adverse events that it has reported and submit follow up information as soon as possible. 21 C.F.R. § 312.32(d).

Postmarketing Reporting of Adverse Drug Experiences. Manufacturers who obtain approval for their new drug applications must continue to inform FDA of adverse experiences associated with the use of the drug, whether those experiences arise from "commercial marketing experience, postmarketing clinical investigations, postmarketing epidemiological/surveillance studies, reports in the scientific literature, [or] unpublished scientific papers." 21 C.F.R. § 314.80(b). Manufacturers must report each adverse drug experience that is both "serious and unexpected" no later than 15 days from receipt of the information, and must investigate each experience and submit follow up reports. 21 C.F.R. §§ 314.80(c)(1)(I) & (ii). In addition, manufacturers must inform FDA of each adverse drug experience that was not previously reported in a quarterly safety report for three years following the date of approval of the new drug application, and then at annual intervals

thereafter. 21 C.F.R. § 314.80(c)(2)(I).

FDA requires manufacturers to report adverse experience information on FDA Form 3500A or in a narrative format that includes the same information. On many occasions, HRG has submitted FOIA requests for, and received, 3500A forms. Sasich Decl. ¶ 16. An exact copy of one such form is attached as Exhibit A. Id. Form 3500A requires manufacturers to report a significant amount of information about the patient, the event, and the medication suspected of causing the event, including 1) the patient's age at the time of the event, 2) the patient's sex; 3) the patient's weight, 4) the date of the event, 5) a description of the event or problem; 6) relevant tests and laboratory data; 7) other relevant patient history, including preexisting medical conditions; 8) the name of the suspect medication, 9) the dose, frequency, and route used, 10) the diagnosis that led to the prescription of the drug, and 11) whether the event abated after the patient went off the drug or was given a reduced dosage. See Exhibit A, attached. In addition, FDA has established a voluntary reporting program for health care professionals, who can report information about adverse experiences to FDA on FDA's Form 3500, which seeks the same information Form 3500A seeks from manufacturers. All these adverse experience reports are then compiled by FDA as part of MedWatch, the FDA's Medical Products Reporting Program.

As FDA has explained in regulatory commentary discussing these mandatory-reporting regulations, the agency relies heavily on postmarketing adverse event reports to ensure the safety and efficacy of medical products:

> Although preapproval testing provides significant information about the safety and efficacy of a product, not all potential safety problems can be identified in the preapproval stage when the number of subjects exposed to the product and the period of exposure are necessarily limited. For that reason, the receipt of postmarket reports of adverse events associated with a regulated product is critical to the agency's ability

to help protect the public health.

59 Fed. Reg. 3944, 3944 (Jan. 27, 1994).

C. FDA's Disclosure Practices And Policies

FDA has issued regulations and established practices regarding disclosure of information submitted by drug sponsors. All of the drugs at issue in this case have been approved by FDA for at least one intended use. Under FDA regulations, "[a]fter FDA sends an approval letter to the applicant" a great deal of information about the drug is "immediately available for public disclosure, unless the applicant shows that extraordinary circumstances exist." 21 C.F.R. § 314.430(e). For every approved drug, FDA will make available upon request an "approval package," consisting of FDA's review of the safety and efficacy of that drug, a summary of the safety and effectiveness data submitted with the new drug application, protocols, and all "[a]dverse reaction reports, product experience reports, consumer complaints, and other similar data and information . . . . " 21 C.F.R. § 314.430(e)(2), (3) & (4); see also Declaration of Roy Castle, attached to FDA's Motion for Summary Judgment ("Castle Decl.") ¶ 6. Accordingly, for all drugs, including the drugs at issue in this case, all adverse experiences reported during the pre-approval testing of the drugs are available to FOIA requesters after a drug is approved.[3]

Reports of postmarketing adverse experiences are also publicly available, whether those events arise from commercial use or during postmarketing clinical investigations. 21 C.F.R. § 314.80(b). FDA has established MedWatch, the FDA Medical Products Reporting Program, which keeps track of postmarketing adverse experiences reported by manufacturers and health care

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[3] If FDA receives three or more requests for a drug's approval package, it will then post that approval package on its web site. Sasich Decl. ¶ 15 & n.2.

professionals. These reports are input into FDA's MedWatch database, which is then made available to the public. As FDA has explained in its regulatory commentary discussing MedWatch, "the substantive content of adverse event reports is public information under the Freedom of Information Act, 5 U.S.C. § 552." 59 Fed. Reg. at 3944; see also Citizens Commission on Human Rights v. FDA, 45 F.3d 1325, 1329 (9th Cir. 1995) (FDA acknowledged that adverse event data must be disclosed under FOIA). In fact, the main purpose of FDA's MedWatch program is to inform the public about the adverse events associated with drugs. Id. According to FDA's web site, MedWatch is "designed" "to ensure that new safety information is rapidly communicated to the medical community thereby improving patient care." <http://www.fda.gov/medwatch/what.htm> (visited May 11, 2000). HRG has reviewed adverse event reports in the MedWatch database and has confirmed that the database contains recent adverse event reports about the five drugs at issue in this case. See Sasich Decl. ¶ 17.

In short, adverse events that occur before a drug is approved for any use are routinely disclosed upon that drug's approval, and adverse events that occur after the drug is on the market are routinely disclosed to the public soon after they occur.

Finally, FDA's disclosure regulations provide that even if a record is normally exempt from disclosure, that record must be made publicly available "to the extent that it contains data or information that have previously been disclosed in a lawful manner to any member of the public." 21 C.F.R. § 20.81(a).

II. FACTUAL BACKGROUND

Plaintiff Public Citizen Health Research Group ("HRG") has long been concerned about the

medical community's practice of prescribing drugs for off-label uses, that is, for use in treating indications for which the drugs had not been approved as safe and effective. See Sasich Decl. ¶¶ 8-10. With the passage of FDAMA, HRG became concerned that the promotional materials to be sent to doctors would not contain a balanced view of the risks and benefits of the off-label use. Id. ¶ 9. In particular, HRG worried that manufacturers would disseminate only the articles that claimed an off-label use is safe and effective, and would suppress research showing that its drug was not safe or effective for the off-label use. Id.

On December 9, 1998, HRG submitted a FOIA request to FDA seeking "[a]ny materials submitted by drug companies to the FDA requesting distribution of information on unapproved new uses for marketed drugs, biologics, and devices under Section 401 of FDAMA." Letter from HRG to FDA, Dec. 9, 1998, attached as Exhibit A to the Declaration of Les Weinstein, attached to FDA's Motion for Summary Judgment ("Weinstein Decl."). HRG submitted FOIA requests to FDA for the same materials on December 23, 1998 and again on February 2, 1999. See Letters from HRG to FDA, Dec. 23, 1998 and Feb. 2, 1999, attached as Exhibits B and C to the Weinstein Decl., submitted with FDA's Motion for Summary Judgment. On June 30, 1999, more than six months after its initial request, HRG received a letter from FDA stating that it had not responded to the request because it was "still waiting for a ruling from the General Counsel office [concerning] what we can release." Complaint ¶ 10 (filed Aug. 6, 1999). Because HRG had not received a substantive response to its FOIA requests within 20 working days, as FOIA requires, HRG filed a complaint requesting that the Court order FDA to disclose the requested records. See Complaint.

After HRG filed suit, FDA identified thirty-three submissions of materials received by FDA pursuant to FDAMA section 401 through July 1999. Weinstein Decl. ¶ 7. Twenty submissions,

submitted by six different companies, were released in full because the manufacturers did not contest disclosure. Castle Decl. ¶ 14, Declaration of Frederick Sadler, attached to FDA's Motion for Summary Judgment ("Sadler Decl.") ¶ 11, Declaration of Margaret Curtsinger, attached to FDA's Motion for Summary Judgment ("Curtsinger Decl.") ¶ 10, Weinstein Decl. ¶ 15. One submission from Smithkline Beecham was released in part, and HRG did not contest the partial withholding. Nine manufacturers moved to intervene in the case. After intervening, two of the manufacturers, Berlex and R.W. Johnson Pharmaceutical Institute, also agreed to authorize release of their entire submissions to HRG. Weinstein Decl. ¶ 20, Castle Decl. ¶ 22; Motion of Berlex Laboratories, Inc. For Leave To Withdraw As Intervenor/Defendant (filed April 6, 2000); Stipulation of Dismissal of Action for Records Belonging to the R.W. Johnson Pharmaceutical Research Institute (filed April 14, 2000). Seven drug manufacturers filed motions for summary judgment, accompanied by declarations and Vaughn indexes on April 7, 2000. Since that date, two of the intervenor-defendants, Glaxo-Wellcome and Novartis, have agreed to disclose adverse event data in their Section 401 submissions in return for HRG's agreement to dismiss them from the case. See Stipulated Dismissal With Prejudice (Glaxo-Wellcome) (filed June 5, 2000); Settlement Agreement Between FDA, Novartis, and HRG (signed June 8, 2000). FDA continues to withhold some information submitted by five manufacturers -- ALZA Corporation ("ALZA"), Agouron Pharmaceuticals ("Agouron"), Allergan Incorporated ("Allergan"), Chiron Corporation ("Chiron"), and Merck & Company ("Merck") -- on the ground that disclosure would violate exemption 4 of FOIA.

FDA has released the titles, sources, and authors of all the published articles about the off-label uses that the manufacturers proposed to distribute to the medical community. FDA has also released the bibliographies of published articles about the off-label uses. FDA has withheld portions

of clinical studies, protocols, adverse event data, and the manufacturers' proposed schedule for submitting a supplemental new drug application. Although HRG believes FOIA entitles it to all of the withheld material, it is primarily interested in information about the adverse experiences suffered by individuals exposed to the drugs at issue, and thus is narrowing its request to information summarizing, describing, or reporting on adverse events associated with the drugs. HRG does not seek information that explains or analyzes the adverse event data beyond the information that would normally be included in FDA's 3500A and 3500 adverse experience reporting forms, which is the same information available to the public in FDA approval packages and in FDA's MedWatch database. Sasich Decl. ¶ 20.[4]

ARGUMENT

I. FDA AND THE MANUFACTURERS HAVE FAILED TO DEMONSTRATE THAT ADVERSE EVENT DATA IN THE SECTION 401 SUBMISSIONS ARE PROTECTED FROM DISCLOSURE UNDER EXEMPTION 4.

A. Legal Standard.

Under Rule 56(c) of the Federal Rules of Civil Procedure, summary judgment shall be granted when it can be shown "that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." See Washington Post v. HHS, 865 F.2d 320, 325 (D.C. Cir. 1989); National Ass'n of Governmental Employees v. Campbell, 593 F.2d 1023, 1027 (D.C. Cir. 1978). In a FOIA case, the agency and intervenors bear the burden of justifying nondisclosure, 5 U.S.C. § 552(a)(4)(B), and they are thus required to submit detailed declarations that identify the documents at issue and explain why they qualify for the claimed exemptions.

[4] However, HRG continues to seek the information that ALZA segregated from its section 401 submission and authorized FDA to release on April 7, 2000. Sasich Decl. ¶ 20.

See King v. United States Dep't of Justice, 830 F.2d 210, 217 (D.C. Cir. 1987); Vaughn v. Rosen, 484 F.2d 820, 826-28 (D.C. Cir. 1973). Declarations that are conclusory and nonspecific cannot support an agency's decision to withhold the requested records. See Public Citizen Health Research Group v. FDA, 185 F.3d 898, 906 (D.C. Cir. 1999); Voinche v. FBI, 940 F. Supp. 323, 327 (D.D.C. 1996), aff'd 1997 U.S. App. LEXIS 19089 (D.C. Cir. June 19, 1997). Moreover, courts must also give weight to rebuttal evidence submitted by the requester. See, e.g. Greenberg v. FDA, 803 F.2d 1213, 1217-18 (D.C. Cir. 1986).

FDA's declarations do not contain any specific explanation or justification for withholding adverse event data. The portions of the manufacturers' declarations alleging harm from disclosure of adverse event data are either vague and conclusory or discuss harm from adverse publicity or injury to reputation, neither of which is protected by exemption 4 of FOIA. Furthermore, the manufacturers' allegations of harm are undermined by FDA's policy of disclosing adverse event data, and by HRG's declarant, Larry D. Sasich, Pharm.D., M.P.H., who explains that adverse event data cannot be affirmatively used by a competitor to gain an advantage in the marketplace.

FOIA requires an agency to disclose a requested record unless it is exempt under one of the Act's nine narrow exemptions. See 5 U.S.C. § 552(a); Department of Justice v. Tax Analysts, 492 U.S. 136, 150-51 (1989). In this case, FDA and the manufacturers rely on exemption 4 of FOIA as the basis for withholding portions of the materials requested. "Like all FOIA exemptions, exemption 4 is to be read narrowly in light of the dominant disclosure motif expressed in the statute." Washington Post, 865 F.2d at 324 (citations omitted).

Exemption 4 excludes from disclosure only "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4); Public

Citizen Health Research Group v. FDA, 704 F.2d 1280, 1286 (D.C. Cir. 1983). HRG does not dispute that records concerning adverse events are "commercial," or that they were "obtained from a person," and defendants do not claim that the material is "privileged." Thus, the only issue for resolution by this Court is whether adverse event reports are "confidential" within the meaning of exemption 4.

In this Circuit, the standard for withholding information under exemption 4 varies depending on whether the information was provided voluntarily or whether the submitter was compelled to provide the agency with the information. In either case, the submitter must first show that the material is confidential because it is of a kind that the submitter would not customarily release to the public. National Parks and Conservation Ass'n v. Morton, 498 F.2d 765, 766-67 (D.C. Cir. 1974); Critical Mass Energy Project v. NRC, 975 F.2d 871, 880 (D.C. Cir. 1992) (en banc). If submitted voluntarily, the information can be withheld on this showing alone. Critical Mass, 975 F.2d at 881. If, however, the submission of the information was required by the government, then it must be disclosed unless the submitter can show that disclosure would result in either (1) impairment of the government's ability to obtain necessary information in the future or (2) substantial harm to the competitive position of the person from whom the information was obtained. National Parks, 498 F.2d at 770.

B. The Information Was Not Submitted "Voluntarily" Under Critical Mass.

The drug companies, but not FDA, argue that their section 401 submissions were "voluntary"

and thus qualify for the more lenient Critical Mass standard. However, "submissions that are required to realize the benefits of a voluntary program are to be considered mandatory." Lykes Bros SS Co. v. Pena, No. 92-2780, 1993 U.S. Dist. LEXIS 20279, at *13 n.4 (D.D.C. Sept. 2, 1993); see also Public Citizen Health Research Group v. FDA, 997 F. Supp. 56, 61 n.3 (D.D.C. 1998), aff'd in part, rev'd in part, 185 F.3d 898 (D.C. Cir. 1999) (information submitted in NDA not "volunteered" because submission is required to obtain the benefit of FDA approval); Public Citizen Health Research Group v. FDA, 964 F. Supp. 413, 414 n.1 (D.D.C. 1997). So, for example, even though a contractor is not compelled to submit a bid for a government contract, if it chooses to do so, its submission is not considered "voluntary" under Critical Mass because it is a prerequisite to being awarded a contract. McDonnell Douglas Corp. v. NASA, 895 F. Supp. 316, 318 (D.D.C. 1995), vacated as moot, 88 F.3d 1278 (D.C. Cir. 1996). As the court noted in McDonnell Douglas, a contractor is "not doing the government a favor by providing the most basic information in a contract" because submission of that information is necessary for the contractor to qualify for the benefit of "win[ning] lucrative government contracts." Id.

Drug manufacturers obtain a very significant benefit by submitting their section 401 materials to FDA before promoting off-label uses for their drugs: They qualify for a safe harbor from civil and criminal penalties for misbranding based on the dissemination of promotional materials. If a manufacturer does not comply with section 401, FDA may bring an enforcement action under the FDCA in which it can seek to use journal articles and reference texts disseminated by the manufacturer as evidence that the manufacturer intends to market the product for a use that has not been approved as safe and effective by FDA. See Washington Legal Foundation, 202 F.3d at 335; see also 65 Fed. Reg. at 14287. Because the submission of materials under section 401 is necessary

for drug manufacturers to obtain this immunity from an enforcement action, the submissions cannot be considered "voluntary" under Critical Mass.

ALZA claims that the Critical Mass standard applies to its section 401 submission because the submission is not a "prerequisite" to engaging in the activity of distributing promotional materials. Memorandum of Points And Authorities In Support Of ALZA's Motion For Summary Judgment ("ALZA Mem.") at 18-19. As ALZA correctly points out, it could have disseminated promotional materials without complying with section 401. See id. However, ALZA fails to acknowledge that submitting materials under Section 401 is a prerequisite to obtaining the benefit of a safe harbor. If ALZA had not submitted the information required under section 401, ALZA would have been vulnerable to an enforcement action in which the promotional materials it disseminated could have been used against it. Insulation from an enforcement action is a government benefit just as being awarded a government contract or gaining approval to market a drug are benefits. See Public Citizen, 997 F. Supp. at 61 n.3; Lykes Bros., 1993 U.S. Dist. LEXIS 20279, at *13 n.4. Of course, ALZA and the other manufacturers were not required to seek the protection of section 401's safe harbor, any more than a contractor is required to bid for a government contract. Once the manufacturers chose to apply for that benefit, however, they were required by section 401 to submit adverse experience data. Accordingly, because submission of adverse experience data is a prerequisite to obtaining that benefit, the information is not "voluntarily" submitted.[5]

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[5] ALZA cites Cortez III Service Corp v. NASA, 921 F. Supp. 8 (D.D.C. 1996) to support its argument that information is submitted "voluntarily" if it is not a prerequisite to participating in an activity. In Cortez, the court held that rate ceilings submitted in a bid proposal were "voluntary" because contractors could still be awarded contracts even if they refused to submit rate ceilings. 921 F. Supp. at 12-13. Cortez only supports the conclusion that adverse event data

Furthermore, the policy concerns underlying the Critical Mass decision do not apply to submissions that are a prerequisite to obtaining a benefit. The court in Critical Mass reasoned that when information is voluntarily submitted the agency has an interest in ensuring the continued availability of that information, and thus held that FOIA should not operate to discourage the submitter from making future voluntary submissions. Critical Mass, 975 F.2d at 878. The purpose of establishing a more lenient disclosure standard for voluntarily provided information is to "encourage[] cooperation with the Government by persons having information useful to officials" in order to avoid hindering "the ability of the Government to make intelligent, well informed decisions." Id. For example, in Critical Mass, the Court feared that if FOIA required disclosure of safety reports that had been voluntarily submitted to the Nuclear Regulatory Commission by operators of nuclear power plants, the operators would cease to provide that information to the agency. However, when the submission is a pre-requisite to obtaining a significant benefit, as it is here, the agency need not fear that the submitter will cease its submissions. Unlike the nuclear power plant operators in Critical Mass, the drug manufacturers here were not "doing the government a favor" by providing the information, but rather advancing their own considerable interest in avoiding criminal and civil penalties for misbranding. McDonnell Douglas, 895 F. Supp. at 318.

Chiron argues that its submission was voluntary because it submitted its section 401 materials during the period when FDA was enjoined by court order from enforcing that provision. See Memorandum Of Points And Authorities In Support Of Chiron's Motion for Summary Judgment ("Chiron Mem.") at 20-22. However, just like submissions today, submissions of section 401

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in section 401 submissions should not be treated as voluntary under Critical Mass, because submission of adverse experience data to FDA is required to qualify for section 401's safe harbor. 21 U.S.C. § 360aaa(b)(4)(B).

material during the injunction were necessary to obtain immunity from an enforcement action based on the dissemination of those materials. Although the court injunction prevented FDA from bringing misbranding charges against drug manufacturers on the basis of their failure to comply with section 401, FDA still had authority to pursue them for misbranding based on the representations they made about their products in promotional materials. To protect itself against such charges, Chiron submitted the materials to FDA in return for the assurance that those materials would not be used against it in an enforcement action for misbranding, and thus its submission was not voluntary.

In any case, because the adverse experience data that HRG seeks are generally required to be submitted to FDA under other FDA regulations, see 21 C.F.R. §§ 312.32, 314.80, 600.80, FDA would be in no danger of being deprived of that information even if manufacturers ceased submitting those data under section 401. FDA's regulations require that manufacturers inform the agency of serious and unexpected adverse events and provide follow up information about those events. 21 C.F.R. §§ 312.32(c) & (d), 314.80(c)(1)(I) & (ii), 600.80(c)(1)(I) & (ii). In addition, manufacturers of all approved drugs must submit quarterly reports for three years following approval, and annual reports thereafter, detailing adverse events associated with use of the drug. 21 C.F.R. §§ 314.80(c)(2), 600.80(c)(2). At worst, FDA would have to gather adverse event data about drugs from these mandatory reports rather than rely on drug manufacturers to supply the information through section 401 submissions. See also Federal Defendant's Memorandum In Support of Its Motion For Summary Judgment ("FDA Mem.") at 12 n.6 (noting that information is required to be submitted to FDA under other statutes as well).

C. Adverse Event Data Is Customarily Released To The Public.

Even if this Court were to conclude that the information was submitted voluntarily, the

adverse event data in those submissions still do not qualify for withholding under exemption 4 because the information is "of a kind" that is "customarily release[d]" to the public. See Critical Mass, 975 F.2d at 880. Four of the manufacturers sought to disseminate articles containing discussions of adverse events. See Exhibits C, D, E & F attached. For example, ALZA sought FDA approval to distribute an article that included a two-page review of its drug's toxicity, and Allergan intended to distribute an article containing a chart detailing the number of patients who suffered from various complications, such as dysphagia, neck weakness, nausea, and diarrhea. See Exhibits C & E, attached. In addition, two of the drugs at issue in this case, Doxil and Viracept, have been approved for a supplemental new use, and thus a great deal of adverse event information is available in the label that accompanies the drug. 21 C.F.R. § 314.430(e). Moreover, adverse events that occur after a drug reaches the market must be reported to FDA, which maintains a database of such events that is routinely disclosed to the public. 21 C.F.R. §§ 312.32, 314.80, 600.80; 59 Fed. Reg. at 3944. Indeed, HRG has reviewed recent adverse event reports in that database for all five drugs at issue in this case. Sasich Decl. ¶ 17. Because adverse event information is of a kind that is customarily released to the public once a drug reaches the market, that information cannot qualify for withholding under exemption 4, even under the more lenient Critical Mass standard.

D. Disclosure of Adverse Event Data Would Neither Impair The Government's Ability To Obtain The Same Information In the Future Nor Cause The Manufacturers Substantial Competitive Harm.

The adverse experience data in the Section 401 submissions were not submitted "voluntarily," but instead to gain the benefit of a safe harbor from an enforcement action, and

therefore the data must be disclosed unless the information is of a kind that the manufacturers do not customarily disclose and disclosure would be "likely" either to (1) "impair the government's ability to obtain" the same quality of material in the future; or (2) "cause substantial harm to the competitive position of the person from whom the information was obtained." National Parks, 498 F.2d at 766-67, 770. For the reasons just discussed, supra II.C., the information at issue is of a kind that is customarily released by the manufacturers themselves, and thus does not even qualify as confidential information that can be withheld under exemption 4. National Parks, 498 F.2d at 766-67. Moreover, disclosure of adverse event data would not lead to either type of injury, and thus the data must be disclosed.

1. Disclosure Would Not Impair FDA's Ability To Obtain Adverse Event Information In The Future.

A few of the manufacturers argue that requiring disclosure "will result in a diminution of the 'reliability' or 'quality' of necessary future information" provided to FDA. Chiron Mem. at 23-25 (citing Critical Mass, 975 F.2d at 879); Agouron Mem. at 21-22. Courts withhold information under the impairment prong not to protect the submitter, but rather to "protect[] a government interest in administrative efficiency and effectiveness." Critical Mass, 975 F.2d at 879. It is significant, then, that FDA -- the agency whose interests are supposedly at risk in this case -- has not suggested that section 401 submissions will be of lower "quality" or less "reliable" if disclosure is required under FOIA. This court should defer to FDA's determination that disclosure will not impair its ability to gather the information in the future. See General Elec. Co v. NRC, 750 F.2d 1394, 1402 (7th Cir. 1984) (deferring to agency because there is not "much room for judicial review of the quintessentially managerial judgment" that disclosure will not impair ability to gather information);

AT&T Info. Sys. v. GSA, 627 F. Sup. 1396, 1401 (D.D.C. 1986) (agency "is in the best position to determine the effect of disclosure on its ability to obtain necessary technical information"); rev'd on other grounds, 810 F.2d 1233 (D.C. Cir. 1987); see also Hercules v. Marsh, 839 F.2d 1027, 1030 (4th Cir. 1988) (refusing to allow a submitter to make an impairment argument on agency's behalf).

Nor could FDA reasonably fear such a result. To obtain the benefit of a safe harbor for dissemination of such promotional materials, FDAMA requires that drug manufacturers submit the results of all clinical studies relevant to the off-label use of their products, including all adverse event data. 21 U.S.C. §§ 360aaa(a) & (b)(6)(B). Drug manufacturers can either choose to submit the information, thereby insulating themselves from misbranding charges based on the articles that they disseminate, or they can forego the benefits of the safe harbor and take their chances that an enforcement action will be brought against them. There is no middle ground. They cannot submit only some of the required information, or some lesser quality of information, and yet still gain the benefit of the safe harbor. Because manufacturers stand to gain such a significant benefit from compliance with section 401, and because section 401 requires a complete submission to obtain that benefit, FDA has no reason to fear diminution in the quality of future submissions. See, e.g., Lee v. FDIC, 923 F. Supp. 451, 454 (D.D.C. 1996).

2. Disclosure of Adverse Event Information Is Not Likely To Cause The Manufacturers Substantial Competitive Harm.

FDA and the manufacturers argue that disclosure of adverse event information is likely to cause the manufacturers substantial competitive harm. To prevail, FDA and the manufacturers must provide "adequate documentation of the specific, credible, and likely reasons why disclosure of the

documents would actually cause substantial competitive injury," Gulf & Western Industries v. United States, 615 F.2d 527, 530 (D.C. Cir. 1979); Lee, 923 F. Supp. at 455. They cannot rely on "conclusory and generalized allegations," but instead must explain with specificity why disclosure is likely to cause them substantial harm. Public Citizen, 185. F.3d at 906; Northwest Coalition for Alternatives to Pesticides v. Browner, 941 F. Supp. 197, 202 (D.D.C. 1996); see also Hercules, 839 F.2d at 1030 (claims regarding competitive injury rejected as "entirely conclusory or speculative").

Defendants have failed to meet their burden. Although the five manufacturers and FDA chose to write separate legal memoranda and submit separate declarations, they make similar arguments. Very little space -- just a few sentences in each declaration and memorandum -- is devoted to the purported harm from disclosure that is unique to the drug manufacturer and the drug at issue. In this portion of our memorandum we first respond to the general arguments that were made by all defendants. Then, in separate sections for each manufacturer, we show how their more specific arguments also fail to support withholding.

a. The Drugs At Issue Have All Been Approved For At Least One Indication, And Thus A Great Deal Of Information About Each Drug, Including Adverse Event Data, Is Already Publicly Available.

By definition, for every drug at issue in this lawsuit, FDA has approved an application to market the drug for the treatment of at least one indication, and thus the drug is available to consumers for both the approved on-label use and unapproved, off-label uses. Yet the manufacturers' arguments against disclosure are based on their mistaken assumption that they are in the same position as a manufacturer of a new drug that has not yet been approved for market for any indication. For example, four of the manufacturers cite to FDA regulations that prohibit

disclosing even the existence of a particular investigational new drug application ("IND"), NDA, or biological product file prior to approval if that application has not been publicly acknowledged by the drug's sponsor. See Chiron Mem. at 14 (citing 21 C.F.R. § 314.430(b)); Agouron Mem. at 11 (citing 21 C.F.R. § 314.430(b)); Allergan Mem. at 12 (citing 21 C.F.R. § 601.51(b)); Merck Mem. at 12 (citing 21 C.F.R. § 314.430). The manufacturers assume that these regulations support their argument that adverse event data in their section 401 submissions should be kept confidential. The regulations do not, because a great deal of information about these drugs, including adverse event information, is already publicly available.

None of the manufacturers have kept their future plans for developing their drugs confidential, as FDA's nondisclosure regulations require. 21 C.F.R. §§ 314.430(b), 601.51(b). For every drug at issue in the lawsuit, the manufacturer has disclosed the fact that it has either submitted a supplemental NDA or product license application, or else is conducting clinical trials on an unapproved new use and will submit an application in the near future. See Declaration of Edward F. Schnipper, M.D., attached to ALZA's Motion for Summary Judgment ("Schnipper Decl.") ¶ 11; Declaration of Michael A. Adam, Ph.D., attached to Agouron's Motion for Summary Judgment ("Adam Decl.") at ¶ 5; Declaration of Adelbert L. Stagg, Ph.D., attached to Allergan's Motion for Summary Judgment ("Stagg Decl.") ¶ 28; see Declaration of Mary O'Hara, attached to Chiron's Motion for Summary Judgment ("O'Hara Decl.") ¶ 11; Declaration of David W. Blois, Ph.D., attached to Merck's Motion for Summary Judgment ("Blois Decl.") ¶ 28. Moreover, all five manufacturers have actively sought to promote an unapproved, off-label use of their drug through distribution of published articles discussing the supplemental new use.

In addition, because the five drugs at issue in this case have been approved for market, a great

deal of information is now publicly available about those drugs, such as FDA's reviews of the drugs' safety and efficacy, a summary of clinical data, and reports of the adverse experiences that occurred during clinical testing of the drugs. 21 C.F.R. § 314.430(e). Indeed, two of the drugs, Doxil and Viracept, have received FDA approval for the supplemental new uses their manufacturers were seeking to promote, and thus the approval packages concerning those new uses are now available. Id.; see also infra 35, 36, 41. Furthermore, off-label use of the drugs at issue here have all been the subject of published articles. Accordingly, the manufacturers cannot argue that they are in the same position as the sponsor of a new drug that has kept the very existence of the drug confidential.

Of even greater significance is the fact that adverse event data, which are the only data HRG continues to seek in this lawsuit, are routinely available after a drug reaches the market. Adverse experiences that occur during clinical testing prior to the drug's approval for any indication must be reported to FDA and are publicly disclosed once a drug is approved as part of the approval package. 21 C.F.R. § 314.430(e)(4). In addition, every sponsor of an approved drug is required to report to FDA all serious and unexpected postmarketing adverse drug experiences, whether those experiences occur during approved or off-label uses of the drug, and whether they arise from "commercial marketing experience, postmarketing clinical investigations" or in "published or unpublished scientific papers." 21 C.F.R. §§ 314.80(b) & (c). The applicant is required to fill out FDA Form 3500A, or provide the same information in narrative form, and that information is then compiled by FDA as part of MedWatch, the FDA Medical Products Reporting Program. See Exhibit A. As FDA has previously stated, adverse event reports are public information under FOIA. 59 Fed. Reg. 3944; see also Citizens Commission, 45 F.3d at 1329 (FDA agrees that adverse event data must be disclosed under FOIA.). Put simply, once a drug is on the market -- as are all the drugs at issue in

this case -- reports of adverse events are routinely disclosed to the public and to the health care community.

The significance of this fact is two-fold. First, any adverse event information in the manufacturers' section 401 submissions that have previously been disclosed to the public cannot be withheld, regardless of whether that information would otherwise qualify for exemption 4. "Any [FDA] record that is otherwise exempt from public disclosure . . . is available for public disclosure to the extent that it contains data or information that have been previously disclosed in a lawful manner to any member of the public . . . ." 21 C.F.R. § 20.81(a); see also CNA Financial Corp. v. Donovan, 830 F.2d 1132, 1154 (D.C. Cir. 1987) ("To the extent that any data requested under FOIA are in the public domain, the submitter is unable to make any claim to confidentiality -- a sine quo non of Exemption 4."). Some, perhaps most, of the data in the section 401 submissions have already been disclosed to the public through MedWatch. Indeed, HRG has a yearly subscription to MedWatch, and it has already obtained recent adverse event data on all five drugs at issue in this case. See Sasich Decl. ¶¶ 16, 17. Adverse event data are also available in the labeling and approval packages for Doxil and Viracept, the two drugs whose supplemental NDAs have been approved. See infra 35-36, 41; see also Exhibit B, attached. Because a good portion of the adverse event data that HRG is seeking have been disclosed publicly through one or all of these sources, the data cannot be withheld under exemption 4.[6]

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[6] Despite HRG's ability to gather adverse event data from other sources, it remains interested in obtaining adverse event data from the section 401 submissions. HRG wishes to review the adverse event data in section 401 submissions to ensure that drug manufacturers are accurately reporting the number and type of adverse events to FDA when they are seeking FDA's approval to promote off-label uses of their drugs. Sasich Decl. ¶ 26. If it prevails in this litigation, HRG plans to compare the adverse event reports in the Section 401 materials with the reports in FDA's MedWatch database to determine whether drug manufacturers have been

Second, the fact that postmarketing adverse event data is routinely disclosed belies any claim by FDA and the drug manufacturers that disclosure of such data in this case will be likely to cause the manufacturers substantial competitive harm. To justify withholding adverse event information here, FDA and the manufacturers needed to explain why these data should be treated differently from the adverse event data for all other drugs -- an explanation they have failed to give.

Only one defendant, Allergan, has acknowledged the routine availability of adverse event data after a new drug is approved and comes onto the market. As Allergan's declarant, Adelbert Stagg, admits, "[a]dverse experiences are reported to FDA, collected in databases created for this purpose, and are available through FOIA requests." Stagg Decl. ¶ 40. Oddly, neither FDA nor the other four drug manufacturers address the fact that the information they are seeking to withhold is regularly made available to the public. Instead, they base their argument for nondisclosure on the general presumption of secrecy under FDA regulations that they claim protects all clinical data concerning unapproved new uses of drugs, ignoring the fact that once a drug is approved and on the market for any indication, adverse event data -- including data on off-label uses -- are publicly available.

Like Allergan, FDA and the other three drug manufacturers should have acknowledged that

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diligent in informing FDA in section 401 submissions of the number and type of adverse events that occurred while patients were using their drugs. Id. HRG also wishes to review the adverse event data to determine whether FDA is properly screening manufacturers' requests to promote off-label uses for their drugs. Id. For example, if a drug manufacturer is seeking to promote the new use of its drug in children -- a group for whom the drug has not yet been approved as safe and effective -- and if the adverse event data reveal that the drug causes death or serious health problems in children, then FDA should not approve the dissemination of promotional material and should pursue an enforcement action for misbranding if the manufacturer chooses to do so anyway. Id. Access to adverse event data in section 401 submissions is essential for HRG to review FDA's performance, but it provides no competitive advantage to other drug manufactures.

adverse experience data are routinely available. Once they do, perhaps they will then join Allergan in arguing that the information should be withheld under exemption 4 because it is recorded in a different format in the section 401 materials than it is in FDA's adverse event report data base. Allergan contends that disclosure of the adverse event information in its section 401 submission -- the same information that Allergan agrees is publicly available in FDA's database -- would likely cause it "substantial competitive harm" because the information in FDA's database is "comprehensive," while the summaries of adverse event data in its section 401 submission are "presented in abbreviated tabular form" and thus "could easily be misunderstood or misconstrued." Stagg. Decl. ¶ 40. Allergan claims that it "would suffer harm if this abbreviated information, carrying with it the inherent risk of being subject to misinterpretation, were released to the public." Id.; see also O'Hara Decl. ¶ 32 (Chiron also alleges public will misunderstand data in section 401 submission).

The argument that information should be withheld under exemption 4 because it is less comprehensive than publicly available information, or because it is reported in a different form, is frivolous. As a threshold matter, the fact that the public might misunderstand or misconstrue the adverse event data is not grounds for withholding information under exemption 4. As the D.C. Circuit has held, "competitive harm refers to harm flowing from the affirmative use of proprietary information by competitors," Public Citizen, 704 F.2d at 1291 n.30 (emphasis in original) (citations and quotations omitted), and does not protect submitters against injury resulting from "adverse public reaction" to disclosure. Public Citizen, 964 F. Supp. at 415 n.2; see also CNA Financial Corp., 830 F.2d at 1154 (holding that adverse publicity and customer and employee disgruntlement do not constitute "competitive harm" under exemption 4).

In any event, it makes no sense to argue that disclosure of less comprehensive summaries of adverse event data will confuse the public because the drug manufacturers can simply choose to release more data if they feel the need to correct any misconceptions. Moreover, it is more than a little ironic that drug manufacturers here contend that adverse event data should be withheld from disclosure because the data might confuse or mislead the public; the same argument, made by FDA in the Washington Legal Foundation case in support of its authority to limit off-label promotion, was vigorously opposed by the drug industry -- which claimed that dissemination of information about drugs would only enlighten, not confuse, the public -- and was emphatically rejected by this Court. See Washington Legal Foundation, 56 F. Supp. 2d at 86 (rejecting the government's "paternalistic assumption that [speech] restriction is necessary to protect the listener from ignorantly or inadvertently misusing the information"); see also Brief of the Pharmaceutical Research and Manufacturers of America as Amicus Curiae in Support of Appellee Washington Legal Foundation, in Washington Legal Foundation, 202 F.3d 31, at 17.

Adverse experience data have always been routinely available to FOIA requesters because such data do not provide competitors with information that they can put to "affirmative use" in developing competing drugs, and thus do not qualify for protection under exemption 4. See Public Citizen, 704 F.2d at 1291 n.30. In fact, adverse experience data provide little information other than the fact that an adverse event occurred. The data do not explain how the drug caused the event or even if the drug caused the event. Sasich Decl. ¶ 21. The data do not include a description of the drug's mechanism of action, or give insights into the manufacturer's future plans for developing the drug. Id. Adverse experience reports have nothing to say about the drug's efficacy, or its overall safety and effectiveness. Id.

Nor will the data provide a competitor with insight into whether the drug will be approved for a supplemental new use because even a drug with a large number of adverse events may be approved if it is effective in treating a lethal disease. Sasich Decl. ¶ 23. In any case, it is impossible to determine from adverse experience reports alone how many adverse events occurred per use of the drug, because consumers and health care professionals often do not report all adverse experiences that occur and because the reports do not provide information on how many people are taking the drug. Id.

In addition, one drug's adverse event information is of no use to a competitor seeking FDA approval of a different drug. Drugs in the same pharmacological class, defined as having similar chemical structures and the same mechanism of action, share, qualitatively, similar toxicities in those patients for whom the drug is approved. Sasich Decl. ¶ 22. However, the frequency and severity of these adverse reactions, quantitatively, may be quite dissimilar. Id. In other words, the safety of a particular drug is peculiar to its unique chemical structure, its unique final finished formulation, and to the population of patients who will be prescribed the drug, and therefore the adverse event data for one drug is not indicative of the number of adverse events, or the severity of adverse events, that might be caused by another drug. Id. In sum, adverse experience reports are only useful to the FDA, the public, the medical community, and public health watchdog groups such as HRG as a warning sign that a drug causes serious problems that were not caught in pre-market testing. 59 Fed. Reg. at 3944.

Having shown that the manufacturers' general competitive harm arguments have no merit, we now turn to the drug-specific arguments raised by each manufacturer.

b. The Manufacturers And FDA Failed To Give Any Specific

Reasons Why Disclosure Of The Adverse Event Data In This Case Would Be Likely To Cause The Manufacturers Substantial Competitive Harm.

Allergan. Allergan's biological drug, BOTOX, was approved by FDA for treatment of strabismus and blepharospasm in 1989. Stagg Decl. ¶ 16. In March 1999, Allergan submitted section 401 materials to FDA to obtain approval to promote BOTOX to treat cervical dystonia, id. ¶ 19, and in April 1999, Allergan submitted a second set of section 401 materials in anticipation of promoting BOTOX for the treatment of focal upper limb post-stroke spasticity -- both off-label uses of the drug. Id. ¶ 20. Allergan has filed a product license application for the cervical dystonia indication, but the FDA has yet to approve the drug for that use. Id. ¶ 28. Allergan is currently conducting Phase III clinical studies for the spasticity indication, but has not yet filed a PLA for that indication. Id.

Allergan is withholding a number of records that describe or discuss adverse events arising from the off-label use of BOTOX. Allergan's summaries of clinical information on the proposed new uses of the drug contain a discussion of adverse events that occurred during clinical trials, and postmarketing adverse events that occurred in the United States and abroad. Stagg Decl. ¶¶ 36, 39, 41. Allergan argues that reports of adverse events in Allergan's section 401 materials should be withheld -- despite their availability in FDA's database -- because the information is less "comprehensive" than the adverse event information in the FDA's database and thus could "be misunderstood or misconstrued." Stagg. Decl. ¶ 40. As discussed above, see supra 28-29, fear of being misunderstood is not a basis for withholding records under exemption 4. See, e.g., Public Citizen, 704 F.2d at 1291 n.30; CNA, 830 F.2d at 1154; Public Citizen, 964 F. Supp. at 415 n.2. In any case, Allergan has given no explanation of why less comprehensive adverse event data would

be likely to be misunderstood, nor has ALZA described what kind of misunderstandings would arise from disclosure of such data.

Allergan also fails to explain how disclosure of descriptions of adverse events that occurred during postmarketing clinical trials is likely to cause it substantial competitive harm. Allergan's only argument is that "[t]his information is protected from public disclosure before a new product or a new use is approved because it would reveal safety information from the clinical trials to competitors for their own use." Stagg Decl. ¶ 39. Such "[c]onclusory or generalized allegations of substantial competitive harm . . . cannot support an agency's decision to withhold requested documents." See Public Citizen, 185 F.3d at 906 (citations and quotations omitted). Allergan has provided no explanation of how a competitor would use Allergan's adverse reaction data for its own benefit, and, as discussed supra 29-30, such data do not provide helpful information to a competitor. In any case, Allergan fails to address the fact that adverse events are routinely disclosed to the public once a drug is on the market, even if those events occurred during the testing of a supplemental NDA that has not yet been approved. See 21 C.F.R. § 314.80(b) & (c).

Nor is it credible for Allergan to insist that its adverse event data remain secret when Allergan itself sought to disseminate published studies disclosing just such data. For example, one of the articles that Allergan intended to distribute to health care practitioners to promote the use of BOTOX to treat cervical dystonia contains a chart detailing the number of patients who suffered from various complications, such as dysphagia, neck weakness, nausea, and diarrhea, and notes the number of patients for whom these complications were serious enough to be "disabling." See J. Jankovic & K. Schwartz, "Botulinum Toxin Injections for Cervical Dystonia," 40 Neurology 277 (1990), attached as Exhibit C. The article also speculates on the cause of the complications, noting

that the mean total dosage received by the patients who suffered complications was the same as the mean total dosage received by patients without complications, leading the authors to conclude that factors such as the number of muscle injections, rather than dosage, may have been a cause. Id. at 279. Allergan cannot seek to promote BOTOX by disseminating articles discussing adverse events and yet claim at the same time that disclosure of its adverse event data alone will cause it "substantial competitive harm."

Of course, Allergan would rather health care practitioners learn about adverse event data from an article that promotes the use of BOTOX as an effective treatment for cervical dystonia, rather than from press releases or warning letters from concerned consumer organizations, but Allergan cannot credibly claim that it will be at a competitive disadvantage if it is forced to disclose adverse event data when Allergan itself has sought to disseminate such data when that served its own purposes.

Chiron. Chiron manufactures the biological drug Proleukin, which has been approved by FDA for the treatment of advanced kidney cancer and advanced skin cancer. See O'Hara Decl. ¶ 6. Chiron has begun a clinical trial to study the effectiveness of Proleukin for use in treating Human Immunodeficiency Virus ("HIV"), but has not yet submitted a supplemental biologics license application to obtain FDA approval for that indication. Id. ¶ 11. Nonetheless, Chiron sought to promote Proleukin for the treatment of HIV. On November 21, 1998, and again on July 12, 1999, Chiron submitted to FDA articles it intended to disseminate about Proleukin, accompanied by the clinical data and other information about the use of the drug in the treatment of HIV, as required by Section 401 of FDAMA. Id. ¶¶ 13, 16. Among the materials submitted to FDA were "raw adverse event data generated in the ongoing clinical trials." Id. ¶ 21. Possibly, Chiron's section 401

submission also includes adverse event data generated from off-label prescription of the drug for treatment of HIV, although Chiron does not identify such data.

Like Allergan, Chiron argues that the release of data "that has not been fully analyzed could cause significant misunderstandings in the medical community if it were released prematurely." O'Hara Decl. ¶ 32. As previously discussed, see supra 28-29, even assuming that "misunderstandings" would result from disclosure, Chiron has failed to claim an injury that justifies withholding information under exemption 4. Public confusion resulting from disclosure, even if that confusion damages Chiron's reputation, is not the kind of "competitive" injury which exemption 4 protects against. See, e.g., Public Citizen, 704 F.2d at 1291 n.3; CNA Financial Corp., 830 F.2d at 1154; Public Citizen, 964 F. Supp. at 415 n.2. In any case, this Court should not credit Chiron's self-serving claim that the medical community will "misunderstand" factual data about the number, type and severity of adverse reactions to Chiron's drugs without Chiron's accompanying analysis of that data.

Finally, Chiron's claim that it would suffer competitive harm from disclosure of adverse event data is also not credible in light of the fact that Chiron itself sought to disseminate an article discussing adverse experiences. See Andrew Carr, et al., "Outpatient Continuous Intravenous Interleukin-2 or Subcutaneous, Polythylene Glycol-Modified Interleukin-2 in Human Immunodeficiency Virus-Infected Patients: A Randomized, Controlled, Multicenter Study," 113 The Journal of Infectious Diseases 992, attached as Exhibit D (discussing toxicity withdrawal rates).

ALZA. ALZA's drug, Doxil, was approved by FDA in 1995 for treating Kaposi's Sarcoma in AIDS patients. Seeking to promote Doxil for treating ovarian cancer -- an unapproved, off-label use -- ALZA submitted its section 401 materials to FDA in November of 1998. Schnipper Decl.

¶ 11. Specifically, ALZA sought to disseminate to health care practitioners a journal article discussing a Phase II study that it had conducted in patients with ovarian cancer. Id. ALZA and FDA have released every item in its Section 401 submission except the Final Report of the Phase II study that is described, in detail, in the published journal article. Id. ¶ 7. The Final Report includes descriptions of adverse events and follow-up information about those events. Id. ¶ 37.

On December 23, 1998, ALZA submitted a supplemental NDA seeking FDA approval of Doxil for the treatment of refractory ovarian cancer, the off-label use it had been seeking to promote. Schnipper Decl. ¶ 27. FDA approved the supplemental NDA on June 28, 1999. Id. As a result, a great deal of the adverse event data ALZA is seeking to withhold are automatically available to the public, giving ALZA even less ground to argue that disclosure of that data, or similar data, would be likely to cause it substantial competitive harm.

For instance, because Doxil has been determined to be safe and effective for treating ovarian cancer, FDA has permitted ALZA to alter the labeling for Doxil to reflect this new use. The labeling takes the form of a package insert that is included with the drug when it is shipped to pharmacies and medical clinics, and thus is available to doctors, nurses, and interested members of the public. HRG has printed this package insert off of FDA's web site, and it is attached to this brief as Exhibit B. Significantly, the package insert for Doxil contains a detailed description of adverse experiences associated with use of the drug. The package insert explains that all but 2 of the 361 patients treated with Doxil in its clinical studies suffered at least one adverse event and lists 22 different adverse reactions experienced by more than 5% of the ovarian cancer patients treated with the drug. See Exhibit B at 20, attached. For example, the labeling states that 37.7% of the patients on Doxil reported nausea, 10% suffered from diarrhea, and 8% experienced abdominal pain. Id. at 21. In light

of the extensive adverse event data available in Doxil's package insert, this Court should not credit ALZA's claim that disclosure of the same data submitted as part of its Final Report would be likely to cause ALZA substantial competitive harm.

ALZA's adverse event information is also available from two other sources. First, adverse event data is available through FDA's MedWatch database, which includes reports of adverse experiences that occurred during commercial use and during postmarketing clinical testing. See 21 C.F.R. § 314.80; 59 Fed. Reg. at 3944. The same data is also disclosed as part of the FDA's approval package for the supplemental new use, because FDA regulations provide that once a drug is approved, the drug approval package (which includes adverse event data) should be publicly disclosed absent "extraordinary circumstances." 21 C.F.R. § 314.430(e)(4). Indeed, if FDA receives three or more FOIA requests for the same drug's approval package, it will post that package on its web site so that it is available without the need for further requests.[7] Sasich Decl. ¶ 9 & n.2.

ALZA has not even attempted to argue that its situation is "extraordinary," but instead makes routine arguments that it would suffer competitive harm if the information were disclosed. As discussed in detail below, these arguments are not credible, but in any case, they fail to distinguish ALZA's situation from that of any other drug manufacturer. FDA cannot justify withholding ALZA's adverse event data unless it can explain why ALZA's data are different from the adverse event data about any other drug that are normally disclosed once the drug is approved.

ALZA makes two arguments for withholding adverse event data: First, ALZA argues that its adverse event data could be "unfairly appropriated and submitted by a competitor in support of

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[7] HRG submitted a FOIA request for the adverse event data in ALZA's supplemental NDA for Doxil on May 3, 2000, but has not yet received a substantive response from FDA. Sasich Decl. ¶ 24.

its own IND or NDA"; and second, ALZA contends that the data "represent valuable information suggesting additional lines of research and potential ways to circumvent ALZA's orphan drug exclusivity." ALZA's Vaughn Index, attached to Schnipper Declaration, Doc. # 13. Neither argument withstands scrutiny.

1. A Competitor Cannot Submit ALZA's Data To Support Its Own IND or NDA.

ALZA's contention that a competitor will seek to submit ALZA's adverse event data to support its own NDA is not credible. As ALZA itself acknowledges, Doxil has been granted "orphan drug exclusivity," and thus is entitled to seven years of market exclusivity. ALZA Mem. at 6 (citing 21 U.S.C. § 360cc(a)). As a result, ALZA's competitors cannot submit an NDA or abbreviated NDA for the "same drug" indicated to treat the same rare disease or condition unless they can show that the drug is "clinically superior" to ALZA's drug. ALZA Mem. at 6 (citing 21 C.F.R. § 316.31). To be "clinically superior," the drug must be safer and more effective than Doxil for treating ovarian cancer. Doxil's adverse event data cannot be used to establish the superiority of another drug. Adverse experience data are not an accurate record of the total number of adverse events experienced by persons taking Doxil because many events may have gone unreported by patients and health care professionals, nor does the data enable the competitor to determine the number of adverse events per patient. Sasich Decl. ¶ 23. Thus, Doxil's data cannot provide a baseline against which a competing manufacturer can compare the safety and effectiveness of its drug.

ALZA also asserts that a competitor will attempt to obtain approval for a drug that contains different, but related active moieties, and suggests that a competitor could submit ALZA's adverse reaction data to support its application for a new drug. ALZA Mem. at 6. ALZA's claim ignores the fact that the withheld data concern the adverse reactions caused by a specific drug, Doxil, and are

useful only for determining the safety of that drug. See Sasich Decl. ¶ 21. The fact that Doxil may have caused certain adverse events in those exposed to it has no bearing on whether a related drug would cause events of the same severity or with the same frequency, and thus could not be used to support the application of a drug with a formula different from Doxil. See Sasich Decl. 22.

2. ALZA's Adverse Event Data Will Not Assist A Competitor's Research.

ALZA's second fear is that a competitor will use ALZA's adverse event data to "develop additional lines of research and potential ways to circumvent ALZA's orphan drug exclusivity." ALZA does not explain how its adverse event data could assist a competitor in "develop[ing] additional lines of research," yet an explanation is certainly needed. How can a competitor gain any significant insight into new lines of research from a report of patient illness or death associated with using the drug? Although competitors might hope to develop a drug that did not cause similar illness or death, nothing in the adverse reaction report would give ALZA's competitors insights into how to do so. See Sasich Decl. ¶ 21.

Finally, ALZA's claim that disclosure of adverse event data would cause it substantial competitive harm is not credible considering that the very article that ALZA itself disseminated to promote the use of Doxil in ovarian patients contains a detailed discussion of the adverse events suffered by the patients who participated in ALZA's phase II study. Franco M. Muggia, et al., "Phase II Study of Liposomal Doxorubicin in Refractory Ovarian Cancer: Antitumor Activity and Toxicity Modification by Liposomal Encapsulation," 15 Journal of Clinical Oncology 987 (1997), attached as Exhibit E. In a two-page review of the drug's toxicity, the article explains that patients suffered nuetropenia, stomatitis, skin toxicities, nausea, and vomiting. See id. at 989-91. ALZA has failed to explain how disclosure of adverse event data could cause it competitive injury when ALZA itself

has disseminated such information to doctors and health care practitioners. Perhaps ALZA does not object to disclosure of such data in the context of an article that generally praises the use of its drug for treating ovarian cancer, but would prefer not to suffer the negative publicity that might result were the data publicly disclosed without any positive analysis. However, ALZA cannot pick and choose when, and in what context, it wishes information on its drugs to be disclosed. If the information does not cause it competitive harm when published in an article, then it also cannot cause it competitive harm when disclosed to a requester under FOIA.

Agouron. Agouron manufactures the drug Viracept, for which FDA granted accelerated approval for treatment of HIV in 1997. FDA's accelerated approval regulations allow marketing of a new drug for the treatment of serious or life-threatening illnesses on the basis of studies showing the drug has some therapeutic benefit, even if those studies are not sufficient to fulfill the requirements of FDA's normal approval process. The sponsor of such a drug is permitted to market the drug, but must continue conducting clinical tests on the drug, 21 C.F.R. § 314.510, and in some cases can only distribute the drug to certain facilities or physicians with special training or expertise. In addition, the sponsor must obtain FDA approval before disseminating promotional materials. See 21 C.F.R. § 314.550.[8]

On January 26, 1999, Agouron submitted a supplemental NDA to gain traditional, full approval for Viracept that would allow it to escape the restrictions on marketing and promoting of the drug. Adam Decl. ¶ 5. While that supplemental NDA was pending, Agouron filed its section 401 submission with FDA to gain FDA's imprimatur to promote Viracept for use in combating HIV.

[8] Although this regulation was not at issue in the Washington Legal Foundation litigation, it is possible that FDA would now also interpret this regulation as a "safe harbor" rather than as an independent requirement.

Id. ¶ 6. Unlike other drug manufacturers, Agouron sought to promote the drug for the same use for which it had received accelerated approval, and not a new use that had never been reviewed by FDA. On June 5, 2000, Agouron's counsel informed HRG that Agouron's supplemental NDA had been approved by FDA.

Unfortunately, Agouron alone has not provided a Vaughn index describing the documents withheld, and Agouron's declarant, Michael A. Adam, does not address adverse event data specifically. However, Agouron's supplemental NDA for Viracept presumably includes descriptions of adverse events that occurred during the clinical trials. 21 U.S.C. § 360aaa(b)(4)(B). Agouron's section 401 submission should also include discussions of adverse events reported to Agouron from consumers and health care practitioners. Id.

Agouron's adverse event data should be disclosed for a number of reasons. First, Agouron has given no explanation for withholding that data, and thus has failed to carry its burden of justifying withholding under exemption 4. 5 U.S.C. § 552(a)(4)(B). Second, even before Viracept's supplemental NDA was approved, much of the adverse event data would be available through FDA's MedWatch database, and thus it is simply not credible for ALZA to argue that it would suffer substantial competitive harm from release of that same data. 59 Fed. Reg. at 3944; see also Citizens Commission on Human Rights, 45 F.3d at 1329. Third, because the supplemental NDA has been approved, the adverse event data will also soon be available in Viracept's approval package and in the new labeling for Viracept, just as it is for ALZA's drug Doxil. 21 C.F.R. § 314.430(e). As a result, the adverse event data will be even easier for the public to obtain, because the labeling will be available on FDA's web site and will be distributed along with the drug, and because the approval package may be posted on FDA's web site if more than three individuals request it. Thus, Agouron

has no grounds for arguing against disclosure of that same data in its section 401 submission.

Furthermore, Agouron itself sought to disseminate an article containing discussions of adverse events, further undermining its claims that disclosure of such events would cause it competitive harm. See Pablo Tebas, "Virologic responses to a ritonavir-saquinvair-containing regimen in patients who had previously failed nelfinavir," 13 AIDS F23 (1999) (explaining that 2 of the 26 patients in the study discontinued the therapy due to grastrointestingal intollerance) attached as Exhibit F.

Merck. Merck's drug, PROSCAR, was first approved for market in June 1992 for the treatment of benign prostatic hyperplasia ("BPH") in men with an enlarged prostate. Declaration of David W. Blois, Ph.D. ("Blois Decl.") ¶ 20. On June 9, 1999 Merck notified FDA that it intended to promote PROSCAR for an off-label use by disseminating to health care practitioners an article from the journal Urology that identified a subset of BPH patients likely to benefit from PROSCAR. Blois Decl. ¶ 24. In accordance with section 401, Merck submitted to FDA the Urology article that it intended to disseminate about Proleukin, accompanied by the clinical data and additional information required to satisfy section 401. Id.

Portions of Merck's materials "contain information on clinical observations of patients participating in unpublished clinical trials of PROSCAR (finasteride). The materials include descriptions of adverse events, analyses of similar experiences and their significance and follow-up information." Blois Decl. ¶ 18. HRG seeks the disclosure of the descriptions of adverse events and experiences and follow-up information about those events, but does not seek Merck's analyses of the events or Merck's conclusions regarding their significance. See Sasich Decl. ¶ 20. As HRG has previously explained, the information it seeks is the same information that would be provided to

FDA in adverse experience reports -- information that is routinely disclosed to the public.

Merck's memorandum in support of its motion for summary judgment contains no discussion of how disclosure of adverse event data would cause it competitive harm. Merck's declarant, Dr. David Blois, gives only a one-sentence justification for withholding the data. According to Dr. Blois, "[t]his information is protected from public disclosure prior to new drug approval because it would reveal safety information from the clinical trials to competitors for their own use." Blois Decl. ¶ 35. This statement is vague and conclusory, and thus insufficient to justify withholding the information. See Public Citizen, 185 F.3d at 906; Northwest Coalition for Alternatives to Pesticides, 941 F. Supp. at 202.

Merck fails to explain how a competitor could use the adverse event data for its own benefit, nor is such an explanation possible. Even drugs having similar chemical structures and the same mechanism of action differ in the frequency and severity of adverse reactions they cause. See Sasich Decl. ¶ 22. In other words, the safety of a particular drug is peculiar to its unique chemical structure, its unique final finished formulation, and to the population of patients who will be prescribed the drug. Id. Thus, adverse event data for Merck's drug will not provide a competitor manufacturing even a very similar drug with information that will aid in the development of its own drug. Id.

FDA

FDA makes no specific arguments justifying withholding adverse event data in this case, and a justification is needed considering FDA's policy of routinely disclosing adverse event data once a drug is on the market.

In its memorandum in support of its Motion for Summary Judgment, FDA has only two paragraphs of argument justifying its nondisclosure of clinical data generally. See FDA Mem. at 14-

15. FDA argues that a "drug sponsor's clinical data could be used to assess which research techniques, study protocols and study parameters best produce useful information and results concerning a drug's chemical and biological properties and toxicity." FDA Mem. at 14 (citing Castle Decl. ¶ 24). As previously explained, adverse experience information would not give competitors any insight into a company's "research techniques," "study protocols," or "study parameters," because the data does nothing more than tell a competitor the number and type of adverse events experienced while taking the drug. Sasich Decl. ¶¶ 20-23. FDA also argues, without any explanation, that disclosure of "[r]aw data can show competitors which avenues of research the sponsor has pursued and may continue to pursue in search of possible uses of the compound or related compounds." Id. Some adverse event information may be reported as "raw" data -- that is, data that is not summarized or tabulated. Other adverse event information will be presented in summary form, and thus would not qualify as raw data. Either way, describing the number and type of adverse reactions suffered would not inform a competitor of a sponsor's research decisions or its plans for future development of the drug or related drugs.

Finally, FDA mistakenly concludes that this Court should grant deference to its determination to withhold documents. FDA Mem. at 16. FOIA is a statute of general applicability, and it has not been entrusted to one agency's interpretations. See, e.g., Public Citizen, 704 F.2d at 1287. Congress certainly did not intend courts to defer to FDA's interpretation of FOIA's disclosure obligations as they should FDA's construction of provisions in the FDCA, FDA's governing statute. To the contrary, because Congress recognized that agencies have incentives to fight disclosure under FOIA, Congress required de novo review by courts of an agency's disclosure determinations.

CONCLUSION

For the foregoing reasons, plaintiff HRG's motion for summary judgment should be granted, and the Court should order that the adverse experience data in the manufacturers' Section 401 submissions be released to HRG.

Respectfully submitted,

DATED: June 9, 2000

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CERTIFICATE OF SERVICE

I hereby certify that on this 9th day of June, 2000, I served the foregoing Plaintiff's Cross-Motion for Summary Judgment, Memorandum in Support of Plaintiff's Cross-Motion for Summary Judgment and In Opposition to Defendant's and Intervenor-Defendants' Motions for Summary Judgment and exhibits, proposed order, declaration of Larry D. Sasich, Pharm.D., M.P.H., Plaintiff's Statement of Material Facts, and Plaintiff's Response to Defendant's and Intervenor-Defendants' Statement of Material Facts on the parties listed below by causing a true and correct copy thereof to be placed in the U.S. mail, postage prepaid, and addressed as follows:

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