



Wisconsin's discovery dispute with AstraZeneca presents two issues fundamental to ongoing discovery in this case: 1) whether AstraZeneca can respond to wholly relevant discovery requests by producing what it sees fit, announce that the information produced is sufficient for Wisconsin to evaluate its claims, and refuse to produce additional responsive documents until the motion to dismiss is decided, and 2) whether AstraZeneca can respond to plaintiff's discovery requests by requiring plaintiff to search through hundreds of thousands of documents produced in a different case, 90% of which relate to a claim Wisconsin has already settled. Resolution of these two issues will obviously have a substantial impact on how expeditiously discovery proceeds in this case.

Plaintiff first addresses the issue of whether the pendency of a motion to dismiss permits defendant to limit its discovery responses (and defendant's companion argument that plaintiff's requests are burdensome at this stage of the litigation), and then addresses the issue of whether plaintiff has the burden of seeking the answers to its discovery in a collection of files produced in a different and much more narrow case. Finally, plaintiff addresses the responses of the defendant to the individual requests to the extent they are not resolved by resolution of these broader issues.

**I. AstraZeneca Should Respond Fully and Completely To Plaintiff's Discovery Requests.**

A. The Pendency of the Motion to Dismiss Does Not License Defendant to Selectively and Improperly Respond to Plaintiff's Discovery Requests.

The primary justification for defendant's abbreviated response to Wisconsin's discovery requests is that a motion to dismiss is pending. This argument should be rejected for three reasons. First, a stay request based on this appeal has already been rejected by Judge Krueger. Second, defendant cannot show that it has a substantial chance to succeed on its motion. And,

third, the standard that defendant AstraZeneca asks the Special Master to adopt, namely, that it has produced enough under the circumstances, is neither sanctioned by the law nor workable.

AstraZeneca's request that it be permitted a stay from responding fully to plaintiff's discovery requests is not supported by the rulings of Judge Krueger. Defendants initially sought a stay from Judge Krueger at the first court hearing on the very same grounds AstraZeneca is requesting here—the pendency of their motion to dismiss. Judge Krueger entered an order staying discovery until May 11, or further order of the Court, urged the parties to agree on a protective order (which they did) and requested that the plaintiff narrow its drug list (which it did shortly thereafter by limiting the list of drugs for which it was seeking discovery to those for which Wisconsin spent over \$100,000.) At the hearing on May 11, the protective order was presented to the Court and defendants represented to Judge Krueger that discovery would begin to flow. Defendants did not request any additional stay and, accordingly, there was no further order of the Court. Subsequently, Judge Krueger appointed Judge Eich to act as Special Discovery Master to resolve all discovery disputes. This chain of events clearly refutes AstraZeneca's claim that Judge Krueger intended for there to be a stay of discovery or that she wished discovery to proceed piecemeal while she considered the motion to dismiss.<sup>1</sup>

Moreover, defendants did not provide Judge Krueger with any grounds upon which she could have granted a stay. The most remarkable thing about this case is that because of recent federal hearings, and documents produced by a federal whistleblower in other litigation, we

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<sup>1</sup> Indeed, AstraZeneca's assertion that a stay is still in effect is premised only on their unbelievable interpretation of Judge Krueger's one line order that decided defendants' Motion for a Protective Order Staying Discovery Until the Court Rules on Defendants' Pending Motion to Dismiss: "IT IS ORDERED that discovery directed at the defendants, or any defendant, is STAYED until May 11, 2005, or until further order of the Court." Because the Court took no further action, the plain language of the order dictates that the stay expired on May 11, 2005. AstraZeneca, in its response, disingenuously interprets this order as requiring the Court to take affirmative action to lift the stay: "The Court did not issue an order lifting the stay of discovery on May 11, 2005. Nor did the Court lift the stay on any subsequent date." AZ Resp. at 22. This position is incomprehensible.

know that defendants did precisely what the complaint alleges they did. Defendants caused to be published inflated average wholesale prices, and secreted their real wholesale prices, knowing that the states were utilizing their fictional prices in connection with their Medicaid reimbursements and thereby overpaying for drugs by billions and billions of dollars. This applies with special force to defendant, AstraZeneca, who plead guilty to a felony in connection with this very conduct, and who later settled with the states over allegations that it manipulated the AWP for Zoladex. (See Appendix 1, attached hereto.) Causing to be published false, inflated wholesale prices is clearly in violation of Wisconsin's consumer protection law which, inter alia, makes it deceptive per se to publish wholesale prices which are greater than retailers are actually paying, Wis. Stats. § 110.18(10)(b), and Wisconsin's Medicaid Fraud statute which prohibits the making of "any false statement or representation of a material fact for use in determining rights to a benefit or payment." Wis. Stats. § 49.49 (4m)(a)(2).

Indeed, the primary refuge of defendants is their argument that because the federal government published studies indicating that certain of defendants' drugs had been discounted beyond the AWP, everyone knew what they were doing and they were thereby licensed to violate Wisconsin's consumer protection laws and its Medicaid fraud laws by continuing to publish phony prices and hide their true prices. The defendants term this their "government knowledge" defense; it is an apocryphal defense; no case supports it. As Judge Stearns put it:

In support of this argument, defendants cite a number of government reports acknowledging that the published AWPs for prescription drugs often exceed their acquisition cost. The argument is ultimately unpersuasive. There is a difference between a sticker price and a sucker price. If one were confronting a modest markup of the actual AWP for Lupron (which 300% is not), intended to make sale of the drug for the treatment of Medicare patients commercially viable (given the 95% of the AWP reimbursement rate), it is unlikely that there would have been a government investigation of TAP's marketing practices... Finally, the recognition on the part of government regulators of inefficiencies in the administration of

Medicare does not, as defendants' contend, amount to condonation of fraudulent conduct.

*In re Lupron Marketing and Sales Practices Litig.*, 295 F.Supp.2d 148, 168 n.19 (D.Mass. 2003).

Moreover, knowledge by state officials of some aspects of defendants' scheme would not exculpate the defendants. Defendants' "government knowledge" defense is nothing more than a claim that state officials were negligent in not suing the defendants earlier, and the law has been settled for almost two hundred years that "laches or neglect of duty on the part of officers of the Government is no defense to a suit by it to enforce a public right or protect a public interest."

*FTC v. The Crescent Publishing Group, Inc.*, 129 F.Supp. 311, 324 (S.D.N.Y. 2001). See *Nevada v. U.S.*, 463 U.S.C. 110 (1983); *U.S. v. Kirkpatrick*, 22 U.S. 720, 735 (1824).

Because the law clearly rejects defendants' defenses, they have lost all 15 attempts to obtain a substantive dismissal of an AWP based complaint, including many challenges which were brought in states with consumer protection laws far less robust than Wisconsin's.<sup>2</sup> Thus, there was no record upon which a stay of discovery could be justified.

Finally, the standard AstraZeneca asks the Court to apply in deciding plaintiff's motion, whether it has produced enough while a motion to dismiss is pending, is no standard at all. How is the Special Master to decide when enough is enough? Does this standard apply to everyone? And if it applies to everyone, will the Special Master have to decide whether each defendant's production is "enough" separately? In reality, the only workable standard to evaluate discovery requests is the one envisioned in the rules: whether plaintiff's discovery requests are relevant and whether AstraZeneca has fully complied.

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<sup>2</sup> Defendant quarrels with this accounting pointing out that several courts have granted motions to dismiss. But not a single one of these decisions was on substantive grounds ending the lawsuit. Instead the decisions merely required plaintiff to plead more specifically, see, e.g., *Alabama v. Abbott Labs., Inc.*, Civ. A. No. CV-05-219 (C.C. Ala. Montgomery County Oct. 13, 2005) where the Court simply required Alabama to specifically identify the drugs for which it was seeking relief. Every plaintiff who has been required to replead has done so successfully.

B. Plaintiff's Requests Are Not Burdensome; Plaintiff Has Limited The Scope Of Its Request As Judge Krueger Urged.

Defendant argues that plaintiff's discovery requests are overbroad and burdensome because plaintiff is seeking discovery in connection with 32 drugs even though—so defendant contends—plaintiff only mentioned one AstraZeneca drug in the complaint.<sup>3</sup> This argument simply ignores the complaint, and it ignores plaintiff's efforts to limit defendant's discovery burden by narrowing the list of drugs for which it is seeking discovery.

The Complaint alleges that defendants, including AstraZeneca, falsely inflated the prices of every one of its drugs. Paragraph 37 of the First Amended Complaint states unequivocally: "Defendants have illegally misrepresented the true AWP for virtually all of their drugs." As paragraph 41 of the Complaint makes clear, this allegation is not hyperbole: The U.S. Department of Health and Human Services concluded that: "[a] general conclusion reached in reviewing GAO and OIG data is that there is a level of overstatement in the listed AWP for all drugs." The complaint also identifies one AstraZeneca drug as an "example" of the overall scheme. (Plaintiff included the one example to satisfy the requirement of *K-S Pharmacies, Inc. v. Abbott Laboratories*, 1995 WL 1922010 at ¶ 5 (Dane County Circuit Court, 1995) that each defendant be given "one instance" of the claimed statutory violations.)

Although the Complaint sweeps in all of defendant's drugs, Judge Krueger asked plaintiff to provide the defendant with a narrower list of drugs for the first round of discovery. Plaintiff did that, listing only those drugs with respect to which Wisconsin spent more than \$100,000. This cutoff eliminated approximately half of the drugs AstraZeneca sold to Wisconsin.

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<sup>3</sup> Despite AstraZeneca's assertion to the contrary, it has waived its objections to the discovery requests by failing to timely object. As discussed in Footnote 1, it is beyond peradventure that the stay on discovery in this case expired on May 11, 2005. Further, on June 23, 2005, Wisconsin notified AstraZeneca that the responses were overdue as of June 12, 2005. See Ex. 9, attached to Wisconsin's opening brief.

Additionally, defendant's claim of burdensomeness needs to be evaluated in the context of this case and in light of the financial circumstances of the defendant. Over the last ten years AstraZeneca's companies have sold Wisconsin well over \$125 million of drugs. (AstraZeneca's operating profit for the first six months of this year was in excess of three billion dollars.) The cost to produce to Wisconsin the material Wisconsin needs to determine to what extent AstraZeneca has abused Wisconsin's Medicaid program is a small price to pay for the privilege of doing such a large volume of business here.

In sum, plaintiff's discovery is not overbroad both because it corresponds to the allegations in the complaint, and because plaintiff, at the request of the Court, has gone more than half way in meeting defendant's concerns about the breadth of the Complaint's undertaking.

## **II. Defendant's Document Dump Is Not A Proper Response To Plaintiff's Discovery Requests.**

### **A. AstraZeneca has not met its obligations under Wisconsin law regarding its proffered production**

As Wisconsin set forth in great detail in its opening brief, under Wisconsin law a dump of a massive amount of documents in response to a discovery request is not allowed. Further, it is only proper to respond to an interrogatory by producing business records when the burden of deriving the answer is "substantially the same for the party serving the interrogatory as for the party served," and the responding party must "specify" the records from which the answer may be derived. Wis. Stat. § 804.08(3). Additionally, if an answer is readily available in a more convenient form, the option to produce business records should not be used to avoid giving the ready information to a serving party. *See Daiflon, Inc. v. Allied Chemical Corp.*, 534 F.2d 221, 226 (10th Cir. 1976). With respect to document requests, the responsive production should include only designated documents. Wis. Stat. § 804.09(1). Document dumping is contrary to

both Wisconsin's general discovery principles and the presumption "that the responding party must bear the expense of complying with discovery requests ...." *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 358 (1978).<sup>4</sup>

AstraZeneca has offered nothing to contradict these discovery principles. Nonetheless, they still offer only the two MDL document sets that contain both responsive and non-responsive documents in response to Wisconsin's discovery requests and not a document more.

AstraZeneca has not designated the documents that are responsive nor specified the records from which the answer may be derived, as required under Wisconsin law. Wis. Stat. §§ 804.08(3), 804.09(1).

Further, AstraZeneca has made no attempt to establish that the burden of deriving the answer is "substantially the same" for Wisconsin as for AstraZeneca, as is necessary in order to utilize the option of producing business records in response to interrogatories. Wis. Stat. § 804.08(3). Instead, AstraZeneca unreasonably and incorrectly attempts to shift this burden to Wisconsin. AZ Resp. at 23. However, justification of the use of the business record option belongs with AstraZeneca, as the responding party: "A party *responding* to an interrogatory may not take advantage of [the option of producing business records] unless *it can show* that 'the burden of deriving or ascertaining the answer is substantially the same for the party serving the interrogatory as for the party served ....'" *In re Sulfuric Acid Antitrust Litig.*, 231 F.R.D. 351, 366 (N.D. Ill. 2005) (emphasis added) (citing *Magarl, LLC v. Crane Co.*, 2004 WL 2750252, \*7 (S.D. Ind. Sept. 29, 2004), and *Fresenius Medical Care Holding Inc. v. Baxter Intern., Inc.*, 224

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<sup>4</sup> These principles apply with special force here. The pace of discovery in this case will grind to a halt if defendants can dump hundreds of thousands of unrelated, unrequested documents on plaintiff in response to plaintiff's specific discovery demands. Plaintiff has sought to carefully tailor its discovery requests to seek information at this stage that goes only to the very heart of its case: the actual selling price of defendant's drugs; what defendant knew about the prices at which its drugs were selling; what role the defendant played in the publication of false wholesale prices; and how the spread between the real wholesale price and the fictitious price were used in marketing defendant's drugs. Plaintiff is entitled, and this case will be benefited by, requiring defendants to produce what plaintiff actually request and no more.

F.R.D. 644, 650 (N.D. Cal. 2004)). *See also U.S. S.E.C. v. Elfindepan, S.A.*, 206 F.R.D. 574, 577 (M.D.N.C. 2002) (“A [] burden imposed on the producing party is to justify the actual shifting of the perusal burden from it to the requesting party” with regard to the business record option. “[The responding party] has failed to show that it would be no more burdensome for [the requesting party] to go through voluminous documents to pull out answers than for [itself].”).

Moreover, contrary to AstraZeneca’s assertion, AZ resp. at 23, its allegation that the interrogatories are extremely broad does not fulfill its burden of justifying the use of the business records option, even if the interrogatories were not as narrowly tailored as they are here. *See Elfindepan, S.A.*, 206 F.R.D. at 577, n.4 (“defendants’ overly broad interrogatory requests do not, by themselves, show that it would be no less burdensome for defendants to extract the information than for plaintiff.”). Further, the burden of deriving the answers to the interrogatories is, in fact, substantially easier for AstraZeneca for many reasons, including the fact that AstraZeneca is much more familiar with its business practices and its own business records; and AstraZeneca has already reviewed the proffered documents when selecting them for production in the MDL. *See In re Sulfuric Acid Antitrust Litig.*, 231 F.R.D. 351, 366 (N.D. Ill. 2005).

Since AstraZeneca has not established that the burden of deriving the answer is “substantially the same” for Wisconsin as for AstraZeneca (and indeed it is not), it should not be allowed to produce business records in response to interrogatories.

B. The MDL documents and data are not responsive to Wisconsin’s requests

AstraZeneca attempts to rationalize its document dumping by arguing that the materials produced in the MDL are essentially what plaintiff is requesting here. This is simply not true. The MDL is a much different case. It is a class action brought by private parties purportedly on

behalf of a nationwide class of Medicare Part B participants (no class has yet been certified). Medicare Part B only pays for physician administered drugs and only those related to certain illnesses—*e.g.*, cancer, kidney failure. No party in the MDL is asserting Wisconsin’s Medicaid claim which is by far the biggest claim in this lawsuit. Thus, there are major differences between the two cases including:

a. **The Hundreds of Thousands of Zoladex Documents Have Limited**

**Application Here.** As Appendix 1 shows, Wisconsin has settled its claim over Zoladex, yet most of the documents defendant has offered to tender – over 400,000 – relate to that drug. Thus, these documents only apply directly to Wisconsin’s consumer claims.

b. **Different claims and issues.** The MDL is currently concerned with class certification which is not an issue in this case. Additionally, plaintiffs in the MDL are asserting a very complicated RICO claim, not present here. Conversely, Wisconsin asserts a Medicaid Fraud count and a consumer protection count completely different than any claim in the MDL.

c. **Different time periods.** The relevant time period in Wisconsin’s case is 1993 to the present, yet the Zoladex production runs only through 2002; the MDL AMP data is limited to 1997-2003; and AstraZeneca has failed to inform Wisconsin of the time parameters for the Price Strategy Group document production and the MDL national sales data.

Given these major differences in the cases, even if a document dump from another case were permissible (*which* it is not), the issues in the case would have to be much more closely aligned for it to be viewed as a fair discovery response.

C. The fact that the documents are in a text searchable format does not change the nature of the dumps.

AstraZeneca further attempts to excuse its production by pointing to the fact that the dumps they proffer are in a “text searchable format,” relying on *In re Lorazepam and*

*Clorazepate Antitrust Litig.*, 300 F.Supp.2d 43 (D.D.C. 2004) and *Zakre v. Norddeutsche Landesbank Girozentrale*, 2004 WL 764895 (S.D.N.Y. 2004). AZ Resp. at 11-12. These cases do not support defendants' response here.

In response to the plaintiffs' discovery requests in *In re Lorazepam and Clorazepate Antitrust Litigation*, the defendants provided unindexed, searchable CD-ROMs and certified that they had provided "everything that could possibly be responsive to the [plaintiffs'] discovery demands." 300 F.Supp.2d at 46. The court stated: "If, as I hope, the information on the CD-ROM's can be rendered readable and searchable quickly and cheaply, I expect that the problem of indexing the documents will be a non-issue." *Id.* at 47.

*Lorazepam*, rather than supporting AstraZeneca's position, highlights a major problem with its proffered dumps—they do not contain all responsive documents; indeed, most of the documents relate to the Zoladex claim Wisconsin has already settled. Even if Wisconsin agrees to search the 440,000 responsive and non-responsive documents produced for just one drug and finds *some* responsive documents, that does not resolve the problem. AstraZeneca is still obligated to supply *all* responsive documents and will eventually have to do what they are trying to avoid doing now: Fulfill its discovery obligations by searching for and producing all responsive documents. Further, contrary to the hopes of the court in *Lorazepam*, the task of searching and reviewing, even utilizing an electronic search, 440,000 responsive and non-responsive documents produced for just one drug cannot be done "quickly and cheaply."

Nor does *Zakre v. Norddeutsche Landesbank Girozentrale* support AstraZeneca's position. In *Zakre*, the defendant provided two CD's that contained the defendant's emails but the defendant did not review the emails to locate those responsive to the plaintiff's discovery requests. 2004 WL 764895, at \*1. The court held that pursuant to the rules of discovery, the

production was sufficient since the documents were produced “in as close a form as possible as they are kept in the usual course of business,” and thus the defendant had no obligation to further organize and label them to correspond with the plaintiffs’ discovery requests. *Id.* AstraZeneca, however, has not offered to produce documents as they are kept in the ordinary course of business. Instead, AstraZeneca proffers discovery requested by different parties in a very different case.

**III. The remaining responses and objections to the individual discovery requests are insubstantial.**

AstraZeneca’s remaining responses and objections to the individual discovery requests are easily resolved. However, before turning to them, Wisconsin briefly addresses the time limits in the discovery requests. In justifying its failure to respond to several requests, AstraZeneca complains that the requests have no time limitations. However, AstraZeneca has never before raised this objection—neither in its written response nor in subsequent discussions. Despite this, Wisconsin is willing to limit the requests to the time frame of the complaint—1993 to present—for Interrogatory Nos. 3 and 5 and for Document Request Nos. 3, 5 & 6.

**Interrogatory No. 1 (& related Document Request No. 4)**

The first interrogatory simply asks if AstraZeneca ever determined a price for any of its drugs net of discounts. This information is important for it will lead plaintiff to the real price of defendant’s drugs, and it will also show that defendant knows that the real selling prices of its drugs are significantly less than the wholesale prices it participates in publishing.

Defendant argues that it should not be required to produce this information first, because one such composite price—the average sales price (ASP) it must report to the federal government as a result of the recent changes in Medicare—has already been held to be too remote to be discoverable. AZ Resp. at 12-13, 17-18. And, second, defendant argues that the

plaintiff can calculate the actual price of its drugs from the national sales data it is producing (for some of its drugs). Neither response is adequate.

First, the ruling the defendant relies on to argue that the ASPs are too “attenuated” is no defense here. The court there refused to compel the production of the ASPs because they were all created after the events in the complaint transpired. AZ Ex. 11, at 19 (the requested ASPs corresponded to “quarters that [were] not at issue in the plaintiffs’ amend[ed] consolidated complaint ....” ). Wisconsin’s complaint, however, runs to the present, as do its damages, and thus include the time period of the requested ASPs.

Second, that plaintiff can calculate on its own the composite prices utilized by the defendant is not an adequate response for several reasons: There is no need for plaintiff to spend the time and money making these calculations if defendant has already done so. See Section II.A discussing the rule that a party must answer a discovery request unless it is at least as easy for the other party to determine the answer. In addition, if an answer is readily available in a more convenient form, the option to produce business records should not be used to avoid giving the ready information to a requesting party. See *Daiflon, Inc. v. Allied Chemical Corp.*, 534 F.2d 221, 226 (10th Cir. 1976) *Budget Rent-A-Car of Mo., Inc. v. Hertz Corp.*, 55 F.R.D. 354, 358 (W.D. Mo.1972); *Atlanta Fixture & Sales Co. v. Bituminous Fire & Marine Ins. Co.*, 51 F.R.D. 311, 312 (N.D. Ga. 1970).

Further, defendant’s calculation of these prices will prove, in easily understandable form, that defendant knew that the prices its drugs were selling for were substantially below the wholesale prices defendant was submitting to the medical compendiums. Defendants’ knowledge that its published wholesale prices are fictional is important since the defendants at

various points have suggested that they cannot be held accountable for the inflated prices because they did not know what the wholesale prices really were.

### **Interrogatory No. 2**

The second interrogatory asks AstraZeneca to identify each electronic database that contains a price for one of the 32 targeted drugs, and five specific features of each database. In response to this request, AstraZeneca says that it previously offered to produce a data expert informally to discuss the data it offered to produce. As an initial matter, plaintiff has no memory of, nor can find any record of, any such offer. Moreover, the offer, even at this stage, is apparently limited to the 15 drugs in the MDL, making it a piecemeal response at best. And in any event, the offer does no purport to provide the information actually requested by the interrogatory, i.e., the identification of all electronic databases that contain a price for an AstraZeneca drug, not simply an explanation of the data that AstraZeneca chooses to produce. Defendants assert for the first time in their opposition brief that data exists in multiple computer systems. Plaintiff is entitled to know the names of these systems and the other information sought in interrogatory number 2, including a description of each field in the database and the identities of the persons most knowledgeable about each system.

### **Interrogatory No. 3**

The third interrogatory asks for the identity of and information regarding each type of incentive AstraZeneca has offered in conjunction with the purchase of any Targeted Drug. At no time has AstraZeneca disputed the relevancy of the requested information.

AstraZeneca complains that the request is overbroad because it “requires detailed information regarding every single rebate and discount ....” AZ Resp. at 19. However, at the same time, AstraZeneca states that “much of the information the State is seeking” is contained in

the transactional sales data for 15 drugs that it intends to produce in response to the Wisconsin's first document request. *Id.* (See discussion below) If that is so, it should not be burdensome for AstraZeneca to cull the information regarding incentives from its own sales data and supplement it with the remaining requested data that is not in the sales data, for example, the description of the incentive, and the classes of trade eligible for the incentive, as requested in the interrogatory.

Further, AstraZeneca has offered no evidence, as indeed it cannot, that culling the incentive information from its own transactional sales data would be as easy for Wisconsin to do as it would be for AstraZeneca to do themselves. Such a requirement is necessary in order to respond to an interrogatory by producing business records under Wisconsin Statute Section 804.08 (3). See discussion under Section II.A, *supra*.

#### **Interrogatory No. 4**

The fourth interrogatory asks AstraZeneca to describe in detail how it determined each price it used in the ordinary course of business for each Targeted Drug and to identify the person most knowledgeable thereof. At no time has AstraZeneca disputed the relevancy of the requested information.

In response to this interrogatory, AstraZeneca offers a document dump with the tepid assurance that “[c]learly, information responsive to the State’s request would be located among the documents produced from these files.” AZ Resp. at 21. As discussed above, AstraZeneca has offered no reason or case law to overcome the fact that the proffered document dumps are unacceptable.

AstraZeneca also states that a deposition is a better format for answering the interrogatory, but the only justification for its position is that formulating prices is an “intricate process.” AZ Resp. at 20. However, the suggestion that the answer might be “intricate” weighs

in favor of written answers, not attempting a drawn-out explanation at an expensive and time-consuming deposition. The cases AstraZeneca relies on for its position are inapposite. *Duncan v. Paragon Pub., Inc.*, 204 F.R.D. 127 (S.D. Ind. 2001) (plaintiffs did not demonstrate particularized need for more than maximum interrogatories allowed by federal rule, and, thus, could not serve 99 interrogatories where they had opportunity to obtain information through depositions which had already been scheduled); *Spector Freight Systems, Inc. v. Home Indem. Co.*, 58 F.R.D. 162, 164 (N.D. Ill. 1973) (court did not compel further answers to interrogatories because requesting party had already taken extensive depositions and had audited plaintiff's claims and records; and the requesting party's knowledge of the facts was as extensive as the responding party's).

Further, despite AstraZeneca's suggestion of a deposition, it has refused to answer the second portion of the interrogatory requesting the identity of the person(s) most knowledgeable in making pricing determinations for each targeted drugs. Wisconsin is entitled to such information if a follow-up deposition is necessary.

**Interrogatory No. 5 (& related Document Request No. 3)**

The fifth interrogatory asks whether AstraZeneca has ever included in its marketing of a Targeted Drug reference to the difference (or spread) between a published price and the actual price; and the third document request asks for documents that discuss or comment on those spreads. At no time has AstraZeneca disputed the relevancy of these requests.

AstraZeneca responds to this request by again offering the unacceptable document dumps, with the unsettling assurance that "a large portion of these documents are responsive [not to this request but] to similar requests in the MDL proceeding." AZ Resp. at 11. See also, AZ Resp. at 21-22. As discussed above, this is unacceptable.

In an attempt to justify its failure to respond to these requests in a meaningful way, AstraZeneca offers the following puzzling argument: The problem of responding to these requests—which ask for information regarding whether they have acknowledged the spread between published and actual prices—is “exacerbated by the fact that AstraZeneca routinely provides volume discounts and rebates off of WAC to managed care customers ....” AZ Resp. at 10. However, if documents relating to these transactions refer to the spread between published and actual prices and demonstrate either that AstraZeneca had knowledge that its drugs do not actually sell for the published prices, and/or was marketing its drugs on the basis of its spread, these are exactly the sorts of documents we are requesting.

**Document Request Nos. 1 & 2**

The first two document requests ask for all national sales data and for Average Manufacturer Price (AMP) data for each Targeted Drug during the defined time period. At no time has AstraZeneca disputed the relevancy of these requests. Moreover, producing the AMP information is simple since the defendants must report this data to the federal government quarterly.

AstraZeneca responds to this request by offering to produce the “MDL data for 15 of the drugs on the State’s ‘targeted list.’” AstraZeneca’s Resp., at 14. This limited response is unacceptable for several reasons. First, as discussed above, there is no reason that AstraZeneca should refuse to respond with respect to over half of the 32 targeted drugs (which has already been narrowed from the original 62). Second, it is not clear what the “MDL data” is and how it differs from actually responding to the request. For example there is no time period given for the proffered MDL national sales data. Further, the AMP data from the MDL is unacceptably limited to 1997-2003, instead of the requested twelve-year period.

AstraZeneca also asserts that since “the State does not intend to analyze the case on a drug-by-drug basis,” information regarding less than half of the drugs “should be sufficient when a motion to dismiss with significant merit is still pending.” AstraZeneca’s Resp., at 15.

Wisconsin has never stated that it does not intend to analyze the case on a drug-by-drug basis. The citation to the record to which AstraZeneca points for this alleged position states an entirely different proposition: Although not every drug that defendants market in Wisconsin is reimbursed based on an AWP formula, “[f]alse AWP’s and WAC’s are part of a larger deceptive scheme, the purpose of which is to disguise the true cost of defendants’ drugs,” and which “interfere[s] with Wisconsin’s ability to set reasonable reimbursement rates for their drugs.” AZ Ex. 13, at 30. That AstraZeneca’s scheme obscured the true prices of all drugs only reinforces Wisconsin’s position that it is entitled to damages for each drug for which Wisconsin paid a price that did not reflect the actual cost, and thus it is entitled to discovery for each drug.

**Document Request No. 3** – Please see discussion for related Interrog. No. 5, *supra*.

**Document Request No. 4** – Please see discussion for related Interrog. No. 1, *supra*

**Document Request No. 5**

The fifth document request asks for documents sent to or received from the three main compendiums in which drug prices are disseminated to the public regarding the price of any Targeted Drug. These documents importantly will show AstraZeneca’s participation in the publication of the inflated prices for its drugs. At no time has AstraZeneca disputed the relevancy of the requested information. AstraZeneca responds to this request by offering the same two unacceptable document dumps. AZ Resp. at 13-14.

**Document Request No. 6**

The sixth document request asks for documents prepared by IMS Health regarding a Targeted Drug or competitor's drug regarding pricing, sales or market share. These documents to go AstraZeneca's knowledge of the falseness of its published AWP. At no time has AstraZeneca disputed the relevancy of the requested information.

AstraZeneca responds to this request by offering to produce any IMS data that it produces in the MDL. AZ Resp. at 16. Although AstraZeneca states in its brief that it has produced IMS data in the MDL for Zoladex and Pulmicort, id, the record AstraZeneca cites to support this states a contrary fact: "To date, there has been no IMS data produced in the MDL." AZ Ex. 8.

In addition to making this empty promise, AstraZeneca complains that Wisconsin could purchase the information that they themselves already have, and characterize Wisconsin's unwillingness to do so as "shift[ing] the costs" of discovery to AstraZeneca. AZ Resp. at 16. That argument makes no sense. Wisconsin is not asking AstraZeneca to purchase materials it has not already purchased. Wisconsin only wants copies of the IMS data AstraZeneca has already purchased for its own use. Further, Wisconsin has reason to know that such data runs in the tens of thousands of dollars, disproving AstraZeneca's statement that Wisconsin can "easily" obtain the data. AZ Resp. at 16. AstraZeneca has provided no legitimate basis not to produce the IMS data, and thus it should be compelled to do so.

#### **IV. Conclusion**

AstraZeneca has not offered to produce *anything* that was not already produced in the MDL, and most of what was produced in the MDL relates to a claim Wisconsin's Medicaid program has already settled. Apparently it is treating Wisconsin's case as if it were *de facto* part of the MDL. This is improper, given its two previous failed attempts at forcing this case to be *officially* part of the MDL. (Defendants twice removed Wisconsin's case and attempted to

consolidate it with the MDL, only to have it twice remanded back to state court.) It is time that AstraZeneca take Wisconsin's case and their discovery requests seriously.

For the foregoing reasons, Wisconsin respectfully asks this Court to compel full responses to their discovery requests and to award Wisconsin the costs and fees associated with bringing this motion.

Dated this 27<sup>th</sup> day of December, 2005.

Respectfully submitted,



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One of Plaintiff's Attorneys

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# APPENDIX 1

## SETTLEMENT AGREEMENT AND RELEASE

### I. PARTIES

This Settlement Agreement ("Agreement") is entered into this \_\_\_\_ day of \_\_\_\_\_, 2003. The parties to the Agreement are the state of Wisconsin and Zeneca Inc. and AstraZeneca Pharmaceuticals LP (collectively and hereinafter referred to as "Zeneca"), which has its headquarters in Wilmington, Delaware, and is a successor to the pharmaceutical business of Zeneca, Inc., and are collectively referred to as the parties. The Parties now agree as follows:

### II. PREAMBLE

A. WHEREAS, Zeneca is entering into a civil settlement with the United States of America, acting through and/or on behalf of its Department of Justice and the United States Attorney's Office for the District of Delaware, and the Office of the Inspector General of the United States Department of Health and Human Services ("HHS-OIG"); TRICARE Management Activity ("TMA") (formerly known as the Office of the Civilian Health and Medical Program of the Uniformed Services), a field activity of the Office of the Secretary of Defense; the Defense Supply Center Philadelphia, of the Defense Logistics Agency, the United States Department of Defense ("DSCP"); the Railroad Retirement Board ("RRB") (the "Federal Settlement"), and relator in a certain federal False Claims Act lawsuit, as well as settlement agreements with the state of Wisconsin and numerous other states (hereinafter the "Participating States"), all of which are intended to resolve civil claims for the conduct alleged in Preamble Paragraph F below;

B. WHEREAS, this Agreement addresses the state of Wisconsin's claims against Zeneca for the conduct alleged in Preamble Paragraph F below;

C. WHEREAS, on such date as may be determined by the Court, Zeneca will enter a plea of guilty pursuant to Fed. R. Crim. P. 11(c)(1)(C) to a one count Information alleging a violation of Title 18, United States Code, Section 371, namely, a conspiracy to violate the Prescription Drug Marketing Act, 21 U.S.C. §§ 333(b) and 331(t) by causing the billing of free drug samples (hereinafter the "Criminal Action");

D. WHEREAS, at all relevant times, Zeneca marketed and sold the drug Zoladex in various dosages to physicians, health maintenance organizations, hospitals, wholesalers, and others for use in treatment of prostate cancer;

E. WHEREAS, the state of Wisconsin alleges that Zeneca caused to be submitted claims for payment for Zoladex to the state's Medical Assistance Program ("Medicaid") established pursuant to Title XIX of the Social Security Act;

F. WHEREAS, the state of Wisconsin contends that it has Medicaid-related civil claims against Zeneca under various statutes and the common law for engaging in the following alleged conduct from January 1991 through the present, involving the marketing, sale and pricing of Zoladex for treatment of prostate cancer;

(i) The state of Wisconsin contends that certain employees of Zeneca provided free samples of the drug Zoladex to certain physicians, knowing and expecting that those physicians would prescribe and administer the free drug samples to their patients and thereafter illegally bill those free samples to its Medicaid program;

(ii) The state of Wisconsin contends that Zeneca knowingly and willfully offered and paid illegal remuneration to certain physicians, physicians' practices, and others in various forms including, for example, free Zoladex, unrestricted educational grants, business assistance grants and

services, travel and entertainment, consulting and audit services, and honoraria, to obtain unlawfully orders to purchase the drug Zoladex for treatment of prostate cancer from Zeneca, knowing that reimbursement for the drug would be made by the state's Medicaid program;

(iii) The state of Wisconsin contends that Zeneca knowingly and willfully offered and paid illegal remuneration to physicians by marketing Zeneca's "Return-to-Practice" program to physicians to unlawfully induce orders to purchase the drug Zoladex for treatment of prostate cancer, knowing that reimbursement for the drug would be made by the state's Medicaid program. The state of Wisconsin further contends that Zeneca's Return-to-Practice program consisted of inflating the Average Wholesale Price ("AWP") used by Medicaid and others for reimbursement of the drug, deeply discounting the price paid by physicians to Zeneca for the drug ("the discounted price"), and marketing the spread between the AWP and the discounted price to physicians as additional profit to be returned to the physician's practice from Medicaid's reimbursements for Zoladex. The state of Wisconsin further contends that Zeneca falsely advised physicians that the discounted price could not and should not be reported to Medicaid;

(iv) The state of Wisconsin contends that Zeneca engaged in a marketing scheme where it set an AWP for Zoladex at levels far higher than the majority of its physician customers actually paid for the drug when purchasing from Zeneca. As a result, the state of Wisconsin contends that Zeneca's customers received reimbursement from the state of Wisconsin's Medicaid program at levels significantly higher than the physicians' actual costs or the wholesalers' average price;

(v) The state of Wisconsin contends that Zeneca knowingly misreported and underpaid its Medicaid rebates for Zoladex used for treatment of prostate cancer, i.e., the amounts

that it owed to the states under the federal Medicaid Rebate Program, 42 U.S.C. § 1396r-8. The state of Wisconsin further contends that Zeneca was generally required on a quarterly basis to rebate to each state Medicaid program the difference between the Average Manufacturer Price ("AMP") and its "Best Price," as defined by 42 U.S.C. §§ 1396r-8(k)(1) and 1396r-8(c)(1)(C). The state of Wisconsin alleges that Zeneca falsely reported to the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration) its Best Price for Zoladex used for treatment of prostate cancer because Zeneca calculated its Best Prices for Zoladex without accounting for off invoice price concessions provided in various forms including, for example, cash discounts in the form of grants, services, free goods contingent on any purchase requirement, volume discounts and rebates. As a result, the state of Wisconsin contends that Zeneca misreported and underpaid its Medicaid rebates to the states under the Medicaid Rebate Program.

Zeneca's conduct alleged in Preamble Paragraph F is hereinafter referred to as the "Covered Conduct." The state of Wisconsin contends that its Medicaid program was damaged as a result of the Covered Conduct;

G. WHEREAS, the state of Wisconsin contends that it has administrative and civil claims against Zeneca for administrative and monetary penalties under state and federal law for the Covered Conduct;

H. WHEREAS, other than such admissions as Zeneca makes in connection with its plea in the Criminal Action, Zeneca denies the remaining allegations of the state of Wisconsin as set forth herein and in any civil action filed by the state of Wisconsin;

I. WHEREAS, to avoid the delay, expense, inconvenience and uncertainty of protracted litigation of these claims, the Parties mutually desire to reach a full and final settlement as set forth below.

### III. TERMS AND CONDITIONS

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants, and obligations in this Agreement, and for good and valuable consideration, receipt of which is hereby acknowledged, the Parties agree as follows:

1. Zeneca agrees to pay to the United States and the Participating States, collectively, the sum of two hundred ninety one million, twenty-seven thousand, eight hundred forty-four dollars (\$291,027,844), as set forth below ("Settlement Amount"). This sum shall constitute a debt immediately due and owing to the United States and the Participating States on the effective date of this Agreement. This debt is to be discharged by payments to the United States and the Participating States, under the following terms and conditions:

A. Zeneca shall pay to the United States the sum of two hundred seventy nine million, eight hundred twenty-two thousand, eight hundred forty dollars (\$279,822,844), plus simple interest at the rate of 6% in an amount of (\$45,998.28) for each day following the effective date of this Agreement before complete payment is made (the "Federal Settlement Amount"). The Federal Settlement Amount shall be paid pursuant to the civil settlement agreement entered between Zeneca and the United States (the "Federal Agreement").

B. Zeneca shall pay to the Participating State Medicaid programs the sum of eleven million, two hundred five thousand dollars (\$11,205,000), plus simple interest at the rate of 6% in an amount of (\$1,841.92) for each day following the effective date of the Federal Agreement

until complete payment is made (the "State Settlement Amount"). This State Settlement Amount shall be paid to an escrow account pursuant to the State Settlement Agreement no later than seven business days after Zeneca receives written payment instructions from the negotiating team for the Participating States and following the latest date on which the following occurs: (1) the Federal Agreement is fully executed by the Parties and delivered to Zeneca's attorneys, (2) the stipulated dismissals described in the Federal Agreement are filed and copies provided to Zeneca's attorneys, or (3) the Court accepts the Fed. R. Crim. P. 11(c)(1)(C) guilty plea in connection with the Criminal Action as described in Preamble Paragraph C and imposes the agreed-upon sentence. The escrow account into which Zeneca shall deposit the State Settlement Amount shall be an account under the custody and control of a Medicaid Fraud Control Unit, which shall be designated by the state negotiating team. This Medicaid Fraud Control Unit shall act as Escrow Agent and shall retain such funds until their release in accordance with the payment terms set forth in subparagraph D below.

C. The total portion of the Settlement Amount paid by Zeneca in settlement for alleged injury to the Medicaid program for the state of Wisconsin is \$224,050.16, consisting of a portion paid to the state of Wisconsin under this agreement and another portion paid to the federal government as part of the Federal Settlement Agreement. The individual portion of the State Settlement Amount allocable to the state of Wisconsin, and which may be withdrawn by the state of Wisconsin from escrow pursuant to this Agreement is \$94,811.38 (the "Individual State Settlement Amount"), plus any accrued interest on that portion of the State Settlement Amount. The portion of the Federal Settlement Amount allocable to the state of Wisconsin is \$129,238.78.

D. The state of Wisconsin shall be entitled to disbursement of its Individual State Settlement Amount from the escrow account ten days after the Escrow Agent has received fully

executed state settlement agreements from all of the participating states, or, in the alternative, when the state negotiating team and Zeneca agree that the Individual State Settlement Amounts shall be disbursed.

E. If Zeneca's agreed upon guilty plea pursuant to Fed. R. Crim. P. 11(c)(1)(C) in the Criminal Action described in Preamble Paragraph C is not accepted by the Court or the Court does not impose the agreed upon sentence for whatever reason, this Agreement shall be null and void at the option of either the state of Wisconsin or Zeneca. If either the state of Wisconsin or Zeneca exercises this option, which option shall be exercised by notifying all Parties, through counsel, in writing within ten business days of the date on which the party receives actual notice of the Court's decision, the Parties will not object and this Agreement will be rescinded. If this Agreement is rescinded, Zeneca agrees that the period of time between January 10, 2003, and thirty days after rescission of this Agreement shall be excluded for the purpose of considering any time-related defenses, including but not limited to those defenses based in whole or in part on a statute of limitation or on a theory of laches.

2. In consideration of this Agreement and payment set forth herein and subject to the exceptions from release set forth in Paragraph 3, the state of Wisconsin, on behalf of itself, and its officers, agents, agencies, and departments, releases and discharges Zeneca, its predecessors, successors, subsidiaries, partners, joint venture owners, and their corporate parents and affiliates, predecessors, successors and assigns, and their current and former directors, officers and employees from any civil or administrative claims for Medicaid damages or penalties that the state of Wisconsin has or may have relating to the Covered Conduct as defined in Preamble Paragraph F. The payment

of the Settlement Amount fully discharges Zeneca from any obligation to pay Medicaid-related restitution, damages, and/or any fine or penalty to the state of Wisconsin for the Covered Conduct.

3. Notwithstanding any term of this Agreement, the state of Wisconsin specifically does not herein release any person or entity, including Zeneca, its predecessors, successors, subsidiaries, partners, joint venture owners, and their corporate parents and affiliates, predecessors, successors and assigns, and their current and former directors, officers, and employees from any and all of the following: (a) any criminal, civil or administrative claims arising under state of Wisconsin revenue codes; (b) any criminal liability not specifically released by this Agreement; (c) any liability to the state of Wisconsin (or any agencies thereof) for any conduct other than the Covered Conduct; (d) any claims based upon obligations created by this Agreement; (e) except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs; (f) any express or implied warranty claims or other claims for defective or deficient products and services provided by Zeneca; (g) any claims for personal injury or property damage or for other consequential damages arising from the Covered Conduct; (h) any claim based on a failure to deliver items or services due; or (i) any civil or administrative claims against individuals, including current and former directors, officers, and employees of Zeneca, its predecessors, subsidiaries, partners, joint venture owners, and their corporate parents and affiliates, who, related to the Covered Conduct, receive written notification that they are the target of a criminal investigation, are criminally indicted or charged, or are convicted, or who enter into a criminal plea agreement; or (j) any reporting of AWP for Zolodex to First Data Bank or any other national reporting service for use in Medicaid reimbursement submitted subsequent to the effective date of this Agreement.

4. In consideration of the obligations of Zeneca set forth in this Agreement and conditioned upon Zeneca's payment in full of the Settlement Amount, the state of Wisconsin agrees to release and refrain from instituting, directing, recommending or maintaining any administrative claim or any action seeking exclusion from the state of Wisconsin's Medicaid program against Zeneca, its predecessors, successors, subsidiaries, partners, joint venture owners, their corporate parents and affiliates, predecessors, successors and assigns for the Covered Conduct or for Zeneca's conviction in the Criminal Action. Nothing in this Paragraph precludes the state of Wisconsin from taking action against Zeneca in the event that Zeneca is excluded by the federal government, or for conduct and practices other than the Covered Conduct or the conviction in the Criminal Action. Zeneca acknowledges that the state of Wisconsin does not have the authority to release Zeneca from any claims or actions which may be asserted by private payors or insurers, including those that are paid on a capitated basis for providing health care to the state's Medicaid program.

5. This agreement is expressly conditioned upon resolution of the Criminal Action. In consideration of the Criminal Action, the Medicaid Fraud Control Unit of the state of Wisconsin agrees that it shall not prosecute or refer for investigation or prosecution to any agency Zeneca, its predecessors, successors, subsidiaries, partners, joint venture owners, and their corporate parents and affiliates, predecessors, successors and assigns for the Covered Conduct.

6. Zeneca fully and finally releases the state of Wisconsin, its agencies, employees, servants, and agents from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) which Zeneca has asserted, could have asserted, or may assert in the future against the state of Wisconsin, its agencies, employees, servants, and agents, related to or

arising from the investigation and prosecution of Covered Conduct up to the effective date of this Agreement.

7. Zeneca waives and will not assert any defenses it may have to any criminal prosecution or administrative action relating to the Covered Conduct which defenses may be based in whole or in part on a contention that, under the Double Jeopardy Clause of the Fifth Amendment of the Constitution or Excessive Fines Clause of the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Zeneca agrees that this Agreement is not punitive in purpose or effect.

8. The Settlement Amount that Zeneca must pay pursuant to Paragraph 1 above will not be decreased as a result of the denial of claims for payment now being withheld from payment by the state of Wisconsin's Medicaid program where such denial resulted from the Covered Conduct. If applicable, Zeneca agrees not to resubmit to the state of Wisconsin's Medicaid program any previously denied claims, which denials were based on the Covered Conduct and agrees not to appeal any such denials of claims.

9. Zeneca agrees to the following:

(a) Unallowable Costs Defined: that all costs (as defined in the Federal Acquisition Regulations (FAR) § 31.205-47 and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395ggg and 1396-1396v, and the regulations and official program directives promulgated thereunder) incurred by or on behalf on Zeneca, its present or former officers, directors, employees, shareholders, and agents in connection with: (1) the matters covered by this Agreement and the related plea agreement; (2) the United States' and the state of Wisconsin's audit and civil and criminal investigation of the matters covered by this Agreement; (3) Zeneca's investigation, defense,

and any corrective actions undertaken in direct response to the United States' and the state of Wisconsin's audit and civil and criminal investigation in connection with the matters covered by this Agreement (including attorney's fees); (4) the negotiation and performance of this Agreement and the plea agreement; (5) the payment Zeneca makes to the United States and the Participating States pursuant to this Agreement and any payments that Zeneca may make to relators; (6) the negotiation of the Corporate Integrity Agreement (CIA), and the obligations undertaken pursuant to the CIA to: (i) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and (ii) prepare and submit reports to the HHS-OIG, are unallowable costs on Government contracts and under the Medicare Program, Medicaid Program, Railroad Retirement, TRICARE, DOD, and Federal Employees Health Benefits Program (FEHBP). However, nothing in this paragraph affects the status of costs that are not allowable based on any other authority applicable to Zeneca. (All costs described or set forth in this Paragraph 9(a) are hereafter, "unallowable costs").

(b) Future Treatment of Unallowable Costs: If applicable, these unallowable costs will be separately estimated and accounted for by Zeneca, and Zeneca will not charge such unallowable costs directly or indirectly to any contracts with the United States or any State Medicaid Program, or seek payment for such unallowable costs through any cost report, cost statement, information statement, or payment request submitted by Zeneca or any of its subsidiaries to the Medicare, Medicaid, TRICARE, DOD, Railroad Retirement or FEHBP Programs.

(c) Treatment of Unallowable Costs Previously Submitted for Payment: If applicable, Zeneca further agrees that within 60 days of the effective date of this Agreement, it will identify to applicable Medicare, Railroad Retirement and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid, DOD, VA and FEHBP fiscal agents, any unallowable costs (as

defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid Program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Zeneca or any of its subsidiaries, and will request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. Zeneca agrees that the United States and the state of Wisconsin, at a minimum, will be entitled to recoup from Zeneca any overpayment plus applicable interest as a result of the inclusion of such unallowable costs on previously-submitted cost reports, information reports, cost statements, or requests for payment. Any payment due after the adjustments have been made shall be paid to the United States or the state of Wisconsin pursuant to the direction of the Department of Justice, and/or the affected agencies. The state of Wisconsin reserves its rights to disagree with any calculations submitted by Zeneca or any of its subsidiaries on the effect of inclusion of unallowable costs (as defined in this Paragraph) on Zeneca or any of its subsidiaries' cost reports, cost statements, or information reports. Nothing in this Agreement shall constitute a waiver of the rights of the United States or the state of Wisconsin to examine or reexamine the unallowable costs described in this Paragraph.

10. If applicable, Zeneca agrees that it will not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents or sponsors. Zeneca waives any causes of action against these beneficiaries or their parents or sponsors based upon the claims for payment covered by this Agreement.

11. Zeneca expressly warrants that it has reviewed its financial situation and that it currently is solvent within the meaning of 11 U.S.C. Section 547(b)(3), and will remain solvent

following its payment to the state of Wisconsin hereunder. Further, the Parties expressly warrant that, in evaluating whether to execute this Agreement, the Parties (i) have intended that the mutual promises, covenants and obligations set forth herein constitute a contemporaneous exchange for new value given to Zeneca, within the meaning of 11 U.S.C. Section 547(c)(1), and (2) have concluded that these mutual promises, covenants and obligations do, in fact, constitute such a contemporaneous exchange.

12. This Agreement is intended to be for the benefit of the Parties only, and by this instrument the Parties do not release any claims against any other person or entity, including but not limited to any individual or entity that purchased Zoladex from Zeneca.

13. Nothing in any provision of this Agreement constitutes an agreement by the state of Wisconsin concerning the characterization of the Settlement Amount for purposes of state internal revenue codes or the United States Internal Revenue Code.

14. In addition to all other payments and responsibilities under this agreement, Zeneca agrees to pay all reasonable travel costs and expenses (including distribution costs) of the state negotiating team. Zeneca will pay this amount by separate check or wire transfer made payable to the National Association of Medicaid Fraud Control Units after all Participating States execute this Agreement, or as otherwise agreed upon by the state negotiating team and Zeneca.

15. Zeneca agrees to cooperate completely and truthfully with the state of Wisconsin's ongoing investigation of third parties for alleged violations of state and federal law arising out of its investigation. Zeneca understands and agrees that such cooperation shall include the following:

(a) prompt production of any non-privileged document or record in the possession, custody or control of Zeneca relating to the subject matter of the investigation. In

connection with this, Zeneca shall provide such technical assistance as is necessary and reasonable to facilitate the state of Wisconsin's access to any non-privileged computerized information covered by this subparagraph:

(b) taking all reasonable measures available to Zeneca to ensure that present and former officers, directors, agents and employees of Zeneca cooperate truthfully and completely in connection with the on-going investigation; and

(c) taking all reasonable measures available to Zeneca to make all present and former employees of Zeneca available for interviews by law enforcement personnel, upon reasonable notice.

Provided, however, notwithstanding any provision of this Agreement, that Zeneca is not required to request of its present or former employees or agents that they forego seeking the advice of an attorney nor that they act contrary to that advice, and that Zeneca is not and will not be required to waive the attorney-client privilege, the protection of the work product doctrine, or any other privilege or protection from disclosure.

16. Zeneca represents that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

17. Zeneca has entered into a CIA with HHS-OIG. Zeneca acknowledges that the state of Wisconsin may gain access to and use pricing information provided by Zeneca under the CIA, provided that the state of Wisconsin meets its obligations relating to the use and confidentiality of that information as set forth in this Agreement. Zeneca acknowledges that the CIA does not preclude the state from taking any appropriate action against Zeneca for future conduct under the state of Wisconsin's laws. The state of Wisconsin hereby agrees to abide by all confidentiality provisions

and restrictions contained in the CIA as allowed by state law and afford all such information the maximum degree of confidentiality permitted by law.

18. Zeneca shall report directly to the Medicaid Program for the state of Wisconsin the average sale price, as defined below, for the following currently marketed drugs: Cefotan, Elavil Injection<sup>1</sup>, Faslodex, Foscavir, Merrem, Tenormin Injection, Xylocaine Injection, Zolodex, and all other newly developed injectible products which are primarily marketed and sold by Zeneca to individual medical practitioners/clinics for in-office administration and directly billed by the practitioner/clinic to health care insurers, including federal health care programs (hereinafter "Covered Products").

(a) Average Sale Price Definition: For purposes of this Agreement, "Average Sale Price" means, with respect to each dosage form, strength and volume of the Covered Products (without regard to any special packaging, labeling, or identifiers on the dosage form or product or package) the average of all final sales prices charged by Zeneca for the product in the United States to all purchasers, excluding those sales exempt from inclusion in the calculation of "Best Price" for Medicaid Drug Rebate purposes, pursuant to 42 U.S.C. § 1396r-8, and excluding identifiable direct sales to hospitals. (Those purchasers for which the sales are included in the calculation of Average Sale Price are hereafter referred to as the "Relevant Purchasers.") The prices identified in the calculation of the Average Sale Price should be net of all the following: volume discounts; prompt pay discounts; cash discounts; charge backs; short-dated product discounts; free goods; rebates<sup>2</sup>; and all other price concessions provided by Zeneca to any Relevant Purchaser that result in a reduction of

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<sup>1</sup> As of February 2003, AstraZeneca no longer makes or sells Elavil injection. Consequently, AstraZeneca may be limited or unable to report average sale price for this product in the future.

the ultimate cost to the purchaser. Notwithstanding the foregoing, the Average Sale Price shall not include the value of bona fide charity care or bona fide grants.

Zeneca shall report the Average Sale Price by National Drug Code ("NDC") for each Covered Product identified by Zeneca's NDC. The Average Sale Price reported shall be properly weighted to reflect the volume of sales at each sale price, *i.e.*, for each NDC, the price reported shall be an average per unit price determined by dividing the sum of all final prices charged by Zeneca to a Relevant Purchaser, net of all price reductions identified above, for a Covered Product in a quarter by the total number of units of that product sold in that quarter.

(b) Time Frame: Except as otherwise noted below, forty five (45) days after the last day of each calendar quarter, Zeneca shall report, in accordance with section 18(a) above, the average sale prices of each of its Covered Products identified by Zeneca's NDC to: (1) the Medicaid programs of those States who have executed a State Settlement Agreement with Zeneca; and (2) First DataBank Inc.<sup>3</sup> solely for the purpose of reporting pricing information based on those Average Sale Prices to the Medicaid Programs of those States that have executed a state settlement agreement. The first such report of Average Sale Prices shall be made no later than 45 days after the end of the first full calendar quarter following the Effective Date of the CIA. The Average Sale Price reporting obligations under this agreement may be subject to modification consistent with a change in federal

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<sup>2</sup> The term "rebate" as used in this paragraph does not include any payments made by Zeneca to the States pursuant to the Medicaid Drug Rebate Program (42 U.S.C. § 1396r-8).

<sup>3</sup> If appropriate to reflect changes in the sources from which the Medicaid programs for the Participating States receive pricing information, Zeneca agrees that, upon the receipt of a written request by any of the Participating States, Zeneca will report the required information to a drug pricing reporting source other than, and in addition to, FirstDataBank, provided that the price reporting source agrees to protect the confidentiality of Zeneca's pricing information in a written agreement containing reasonable provisions equivalent to the confidentiality provisions governing the submission of pricing information to First DataBank.

or state statutory or regulatory requirements for the submission of price information by pharmaceutical manufacturers.

(c) Certification: With each report of Average Sales Price information Zeneca sends to the Medicaid Program for the state of Wisconsin, an appropriate employee or agent of Zeneca will certify that price information reported has been reported to First DataBank, or any successor or alternative reporting agency, and that the information has been calculated in accordance with the methodology described in this Agreement. Said certification shall be in the form annexed to this Agreement as Exhibit "A." Zeneca agrees that this certification by an appropriate employee or agent of Zeneca constitutes a certification by Zeneca.

(d) Document Retention: Zeneca shall retain all supporting work papers and documentation relating to the average sale price of its Covered Products for six years after the effective date of the CIA, and, to the extent not protected by appropriately asserted privileges, shall make such documentation available for inspection by the MFCU for the state of Wisconsin, or a duly authorized representative of the MFCU, pursuant to the confidentiality provisions set forth in paragraph 20 below.

(e) Time Period: Zeneca agrees to submit Average Sale Price in accordance with this Agreement for a period of five years from the effective date of the CIA.

19. (a) Zeneca and the state of Wisconsin acknowledge that Zeneca considers the pricing information provided by Zeneca to be confidential commercial information and proprietary trade secrets that if disclosed may cause substantial injury to the competitive position of Zeneca. It is further understood that all information provided by Zeneca shall be made available to the state of

Wisconsin's MFCU upon request. The state of Wisconsin hereby agrees to afford to the pricing information disclosed by Zeneca the maximum degree of confidentiality permitted by law.

(b) The Medicaid Program of the state of Wisconsin has been advised by the MFCU of the purpose and use of this information. Without surrendering any legal right to contest the use of this information, Zeneca acknowledges that this information may be relied upon by the state of Wisconsin in establishing reimbursement rates for Zeneca's products, provided however the state of Wisconsin will not change reimbursement rates for any Zeneca product based on this information without conducting meaningful review for all government-reimbursed therapeutically similar products.

20. Unless otherwise stated in writing subsequent to the execution of this Agreement, all notifications and communications made pursuant to this Agreement shall be submitted to the entities listed below:

**STATE PHARMACY MANAGER  
[For the submission of Average Sale Price Data]:**

Division of Health Care Financing  
P.O. Box 309  
Madison, WI 53701-0309

**STATE MEDICAID FRAUD CONTROL UNIT  
[For legal notices and other purposes]:**

MFCU of Wisconsin  
Office of the Attorney General  
P.O. Box 7857  
Madison, WI 53707-7857

**ZENECA**

Glenn Engelmann

Vice President, General Counsel  
And Secretary  
Zeneca, Inc.

21. This Agreement is governed by the laws of the state of Wisconsin. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Agreement will be the appropriate court having jurisdiction and venue in the state of Wisconsin.

22. The undersigned Zeneca signatory represents and warrants that he is authorized by the Board of Directors of AstraZeneca PLC, the parent corporation of AstraZeneca Pharmaceuticals, LP, to execute this Agreement. The undersigned state of Wisconsin signatories represent that they are signing this Agreement in their official capacities and they are authorized to execute this Agreement on behalf of the state of Wisconsin through their respective agencies and departments.

23. This Agreement is effective on the date of signature of the last signatory to the Agreement.

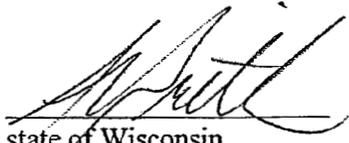
24. This Agreement shall be binding on all successors, transferees, heirs and assigns of the Parties.

25. This Agreement constitutes the complete agreement between the Parties with regard to the Covered Conduct. This Agreement may not be amended except by written consent of the Parties.

26. This Agreement may be executed in counterparts, each of which shall constitute an original and all of which shall constitute one and the same Agreement.

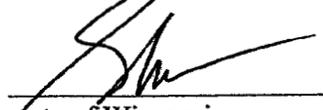
THE STATE OF WISCONSIN

DATED: 6/24/03

  
state of Wisconsin  
Office of the Attorney General  
Medicaid Fraud Control Unit

BY: Amy R. Smith  
Title: Director and Assistant Attorney General

DATED: 6-24-2003

  
state of Wisconsin  
Medicaid Program

BY: Alan S. White  
Title: Director, Program Integrity

**ASTRAZENECA PHARMACEUTICALS LP**

By: \_\_\_\_\_  
Glenn Engelmann  
Vice President, General Counsel  
And Compliance Officer  
AstraZeneca Pharmaceuticals LP

Dated: \_\_\_\_\_

By: \_\_\_\_\_  
JOHN C. DODDS  
Morris, Lewis & Bockius LLP  
1701 Market Street  
Philadelphia, PA 19103-2921  
Counsel to AstraZeneca Pharmaceuticals, LP

Dated: \_\_\_\_\_