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STATE OF WISCONSIN | CIRCUIT COURT Branch 9 | DANE COUNTY

STATE OF WISCONSIN, Plaintiff, v. ABBOTT LABORATORIES, et al., Defendants.	)	Case No. 04-CV-1709 Unclassified – Civil: 30703

PLAINTIFF'S TRIAL BRIEF AGAINST AVENTIS PHARMACEUTICALS INC.

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In this brief, the State will set forth the elements of its claims and generally summarize the evidence that fulfills each of those elements. The State will also set forth the relief to which it believes it is entitled.

I. Elements of the State's Claims.

A. Counts I & II: Deceptive Trade Practices Act, Wis. Stat. § 100.18(1) & 10(b).

There are two elements of an enforcement action under the Deceptive Trade Practices Act ("DTPA"), Wis. Stat. § 100.18: (1) a representation to the public with the intent to induce an obligation; (2) the representation was untrue, deceptive, or misleading. *Novell v. Migliaccio*, 2008 WI 44, ¶ 49, 309 Wis.2d 132, 151-52, 749 N.W.2d, 544, 553. It is not necessary to prove that Aventis Pharmaceuticals Inc. ("Aventis") caused any harm to establish a violation of § 100.18. As this Court has held, "the whole purpose for an enforcement action is to *forestall* any harm caused by the targeted conduct." (Decision and Order on Certain Defense Cross-Motions for Summary Judgment, July 29, 2008, at 4) (emphasis in original).

The statute also specifically provides that "[i]t is deceptive to represent the price of any merchandise as a ... wholesaler's price, or a price equal thereto, unless the price is not more than the price which retailers regularly pay for the merchandise." § 100.18 (10)(b).

B. Count IV: Medical Assistance Fraud statute, § 49.49(4m)(a)2.

The elements of a claim under the Medicaid fraud statute, Wis. Stat. § 49.49(4m)(a)2, are as follows: (1) making or causing to be made a statement or representation of a material fact, (2) the statement or representation was false when made, (3) the statement or representation was made or caused to be made knowingly; and the statement or representation was for use in determining rights to a benefit or payment in connection with medical assistance. Wis. Stat. § 49.49(4m)(a)2; *State v. Abbott Labs., et al.*, 2012 WI 62, ¶ 52, 341 Wis. 2d 510, 542, 816

N.W.2d 145, 161. Similarly, it is not necessary to prove that Aventis caused any harm to establish a violation of § 49.49(4m).

II. The State's evidence satisfies all elements of its claims.

A. "Publication" Element:

Both statutes require that Aventis either made or caused to be made a statement. Section 100.18 provides that Aventis shall not "make, publish, disseminate, circulate, or place before the public, *or cause, directly or indirectly*, to be made, published, disseminated, circulated, or placed before the public" any statement "which is untrue, deceptive or misleading." Wis. Stat. § 100.18(1) (emphasis added). Similarly, § 49.49(4m) provides that Aventis shall not "make or *cause to be made* any false statement." The State's evidence establishes that Aventis caused to be made statements—*i.e.*, their false AWPs—in pricing compendia, such as Red Book and First DataBank ("FDB").

Testimony and documents from Aventis (and its predecessor companies[1]) overwhelmingly establish this. Aventis knew that the pricing compendia, FDB and Red Book, published AWPs for its drugs and, during the relevant time period, Aventis actively participated in the process by supplying AWP and other pricing information for its drugs in order to make them available for third-party reimbursement. Aventis set its AWPs at either 20% or 25% above WAC, notwithstanding the fact that its AWPs did not reflect the average price paid by pharmacy providers for its drugs. Aventis expected that FDB and Red Book would publish AWPs identical to what Aventis reported. Aventis purchased FDB's pricing database, which contained the AWPs for its drugs, and understood that FDB, in fact, published the identical AWPs that Aventis

[1] Aventis was formed in December of 1999 as the result of a merger between Rhone-Poulenc Rorer and Hoechst Marion Roussel.

submitted. Additionally, FDB and the other pricing publishers asked Aventis to verify the AWPs for Aventis' drugs, and it did so.

Around August of 2001, Aventis discontinued reporting AWPs to FDB and Red Book. After Aventis stopped reporting AWPs to FDB and Red Book, it continued to report WACs knowing, expecting, and intending that FDB and Red Book would mark-up its WACs by 20% or 25% and publish an AWP for each of its NDCs. FDB and Red Book continued to publish AWPs for each of Aventis' NDCs throughout the relevant time period. Aventis knew this and internally tracked the AWPs FDB and Red Book continued to publish for its drugs.

In 2002, Aventis learned that FDB began publishing AWPs for some of Aventis' drugs that were 25% above the WACs Aventis submitted to FDB, even though Aventis had historically reported AWPs to First DataBank that were 20% above WAC. Aventis chose not to object to or oppose this bump-up, or to ask FDB to report different AWPs. In sum, Aventis caused the publication of its AWPs through the pricing compendia.

Although the Supreme Court in *K & S Tool & Die Corp. v. Perfection Machinery Sales, Inc.*, 301 Wis. 2d 109, 122, 732 N.W.2d 792, 799 (Wis. 2007), stated that the defendant's intent to induce an obligation was not a distinct element of § 100.18, the statute requires that the representation was made with the "intent to sell, distribute, increase the consumption of or in any wise dispose of ... any merchandise ..., directly or indirectly, to the public for ... use ... or with intent to induce the public in any manner to enter into any contract or obligation relating to the purchase, sale, hire, use or lease of any ... merchandise." Aventis' publication of its AWPs in the pricing compendia was clearly done with the intent to "sell, distribute, increase the consumption of or in [some way] dispose of" its drugs. Aventis published AWPs through the pricing compendia because it was necessary to ensure that its customers received reimbursement

from third-party payers, including state Medicaid programs. Aventis knew that state Medicaid programs such as Wisconsin used the AWPs to determine reimbursement to Medicaid providers such as retail pharmacies, and knew the specific formulas used by various programs, including Wisconsin Medicaid.

B. The "Untrue, Deceptive, or Misleading," or "False" Element:

Section 100.18 requires an "untrue, deceptive, or misleading" statement. Similarly, § 49.49(4m) requires a "false" statement. Through § 100.18(10)(b), the Legislature has established that *as a matter of law*, it is deceptive to publish a "wholesale price" that is more than the price which retailers regularly pay. Nothing and no one—except a change in the law—can make this behavior *not* deceptive. Thus, in addition to being untrue and misleading, Aventis' AWPs are deceptive as a matter of law.

The prices are also "false" under the Medicaid Fraud statute. Where a term is undefined, Wisconsin courts turn to the dictionary and apply the plain meaning of the term. *Jauquet Lumber Co. v. Kolbe & Kolbe Millwork Co.*, 164 Wis.2d 689, 698 (Wis. App. 1991). By publishing and causing to be published "average wholesale prices," Aventis represented that they were *prices;* that they were an *average* of prices; and that they were an average of prices at the *wholesale level.* Aventis' AWPs are false three different ways. Aventis' AWPs were not prices at all; they were not averages of anything; and they represented no reality at the wholesale level.

1. The State's evidence that Aventis' prices were deceptive/false is overwhelming.

According to the testimony of Aventis' own witnesses, its published AWPs were not averages of prices at which wholesalers sold the Aventis drugs to retailers. Nor were they prices that any retail pharmacy ever paid to acquire the drugs. The State's expert, Dr. Thomas DiPrete, confirmed this fact by analyzing wholesaler data on the prices at which they sold Aventis' drugs

to retailers. In short, the State's evidence makes clear that Aventis' AWPs were false and deceptive.

2. Aventis' assertion that AWP is simply a "list price" is legally incorrect.

As a matter of law, Aventis cannot avoid liability by arguing that its AWPs were merely "list prices" and therefore were not "false" or "untrue, deceptive, or misleading." As numerous courts have held, the "list price" argument is not a valid defense since a so-called "list price" is lawful only if "substantial sales" were made at the price. *Giant Food, Inc. v. FTC*, 322 F.2d 977, 981-82 (D.C. Cir. 1963); *In re George's Radio & Television Co., Inc.*, 60 F.T.C. 179 (1962) (advertising "manufacturer's suggested list prices" where no substantial sales were made at that price was unlawful); *Regina Corp. v. FTC*, 322 F.2d 765, 767-68 (3d Cir. 1963) (manufacturer's "suggested list price" was deceptive where it exceeded retailers' customary selling price); *In re Pharm. Indus. AWP Litig.*, 491 F. Supp. 2d 60, 104-05 (D. Mass. 2007); *In re Pharm. Indus. AWP Litig.*, 685 F. Supp. 2d 186, 200 (D. Mass. 2010) (applying substantial sales test to generic AWPs and WACs of various drug companies, and holding that they were not "true list prices"); *Illinois v. Abbott Labs.*, No. 05-CH-2474, Circuit Court of Cook County, Illinois, Transcript of March 20, 2012 Hearing, pp. 42-43, (applying substantial sales test to generic AWPs and rejecting "list price" defense).

Where, as here, *no* sales of Aventis drugs were made at AWP, much less "substantial sales," the "list price" defense is unavailable.

3. Aventis' "Term of Art" defense is unavailing.

To the extent Aventis argues that its AWPs were not "false" because AWP is a "term of art," the argument is unavailing for numerous reasons.

First, the Legislature has already determined that "it *is* deceptive" to publish a price as a "wholesale" price unless it is not more than the price regularly paid by retailers. Wis. Stat. § 100.18(10)(b) (emphasis added). There is no exception for wholesale prices that are "terms of art" or that the industry allegedly understands are inflated.

Second, to be a "term of art," a term must have a "specific, precise meaning in a given specialty." Black's Law Dictionary (9th ed. 2009). Here, Aventis cannot show a "specific, precise meaning" of "Average Wholesale Price" that is contrary to its plain meaning.

Third, to establish that an asserted term is a "term of art," a defendant must show more than that industry participants had knowledge of the falsity of the assertion. Nothing in Wisconsin law provides that a "false statement or representation for use in determining rights to" Medicaid payments is not "false" if Medicaid or those in the pharmaceutical industry understand that the statement is "false." Wisconsin law still prohibits the making of such statements, and as the Supreme Court ruled in the Pharmacia matter, even though Medicaid "knew the AWPs were inflated," the AWPs "harmed Medicaid" and caused damages. *Abbott Labs.*, 2012 WI 62, ¶ 78.

Fourth, there can be no established, settled meaning of AWP contrary to its plain meaning since market participants—including FDB, manufacturers, trade associations, and Congress—have continued to describe AWP as a real average price charged by wholesalers to retail customers. As Judge Peter Flynn noted, "as late as 2003, Congress itself, that is in a sense defendants' biggest customer for these purposes, asserted and understood that 'AWP is intended to represent the average price used by wholesalers to sell drugs to their customers.'" *Illinois v. Abbott Labs., et al.*, No. 05-CH-2474 (Cir. Ct. of Cook Cnty., Ill.) Transcript of March 20, 2012 Hearing, p. 34 (citing U.S. House of Representatives report). He continued, "[I]f your own biggest customer doesn't agree with your asserted meaning, it's pretty hard to argue that there is

a custom and usage." *Id.* at 35. Other courts addressing the issue have agreed. *In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F.Supp.2d 277, 278, 284-88 (D. Mass. 2006); *In re Pharm. Indus. Average Wholesale Price Litig.,* 582 F.3d 156, 168-72 (1st Cir. 2009); Order, 8/18/10, *Hawaii v. Abbott Labs, et al.*, (No. 06-1-0720-4), Minute Order, 8/23/10.

C. The Requirement of § 49.49 that the False Statements Were Caused to be Made *Knowingly* and that the Statements Were of *Material* Fact.

The Aventis evidence summarized in Section II.A above establishes that Aventis acted "knowingly," as required by Wis. Stat. § 49.49(4m). Aventis knew and expected that FDB would publish the AWPs for Aventis' drugs based on the pricing information that Aventis sent it. This, by itself, satisfies the "knowingly" element. *Abbott Labs.,* 2012 WI 62, ¶ 107 ("Pharmacia reported its AWPs to FDB so that FDB would in turn convey them to Medicaid. It therefore knowingly caused those statements to be made."). After 2001, when Aventis only reported WACs for its drugs, it knew, expected, and intended that FDB and Red Book would mark up those WACs by 20% or 25% and publish that figure as an AWP.

However, Aventis knew even more: Aventis knew that its AWPs were not averages of wholesale prices, nor reasonable estimates of such prices. Aventis officials knew and intended that payers, including state Medicaid agencies, would rely on their AWPs in order to reimburse pharmacies that dispensed Aventis' drugs. Furthermore, Aventis knew that the government disapproved of its AWP-related practices.[2]

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[2] In any event, knowledge of Medicaid's rules and requirements should be imputed to Aventis. As Judge Saris ruled:

> [H]aving entered into the rebate agreements, the defendants were required, as a matter of law, to familiarize themselves with the legal requirements, standards and procedures of the Medicaid program. *Heckler v. Community Health Servs.*, 467 U.S. 51, 63-65 (1984). These include the procedures and legal requirements applicable to reimbursements. *United States v. Mackby*, 261 F.3d 821, 828 (9th Cir. 2001). The defendants were required to know that the Commonwealth's EAC was "the agency's best estimate of the price generally and currently paid by providers."

Massachusetts v. Mylan Labs., et al., 608 F. Supp.2d 127, 154 (D. Mass. 2008).

Further, Aventis' false statements were material. *See Neder v. United States*, 527 U.S. 1, 16 (1999) ("In general, a false statement is material if it has 'a natural tendency to influence, or [is] capable of influencing, the decision of the decision making body to which it was addressed"). Wisconsin Medicaid used Aventis' AWPs in it reimbursement process. And Aventis' AWPs caused the State damage. Cases decided under the Federal Trade Commission Act support this conclusion.[3] *See also FTC v. Windward Mktg. Ltd.*, 1997 WL 33642380 at 9 (N.D. Ga. 1997) ("any representations concerning the price of a product or service are presumptively material."); *FTC v. The Crescent Publ'g Group, Inc.*, 129 F. Supp. 2d 311, 321 (S.D.N.Y. 2001) ("Information concerning prices or charges for goods or services is material").

D. The Causation Element.

The State's evidence establishes that Aventis' inflated AWPs *caused* the State a pecuniary loss. The Court is familiar with the State's reimbursement methodology from the evidence presented at the Pharmacia trial. When determining reimbursement for a brand-name drug, the State compares and pays the lower of (1) the published AWP minus a percentage ("discounted AWP") plus the dispensing fee, or (2) the usual and customary ("U&C") amount submitted by the pharmacy. The State's evidence will demonstrate, as it did at the Pharmacia trial, that had Aventis reported and published a true AWP for its drugs, the State would have used that AWP as the ingredient cost portion of reimbursement. Hence, Aventis' practice of causing the publication of false AWPs caused damage to the State by causing the State to reimburse pharmacies a higher level than it otherwise would have with true AWPs.

This Court ruled during the Pharmacia trial that even where the State's reimbursement payment was based on a metric other than AWP, such as the U&C (or, where one is in place for

[3] Using FTC precedent is endorsed in Wisconsin case law. *See Tim Torres Enter., Inc. v. Linscott*, 142 Wis. 2d 56, 66, 416 N.W.2d 670, 674 (Wis. App. 1987).

a drug with generic equivalents, a Maximum Allowable Cost), a jury nevertheless could find that "the misrepresented AWP nonetheless caused a pecuniary loss because the state was required to jettison the unreliable AWP as the standard, and had to employ a different benchmark which set a higher reimbursement rate than would have been the case had the true AWP been represented." January 21, 2009, Decision at 1. The Supreme Court affirmed:

> The jury did not impermissibly speculate as to the damage award with respect to brand name drugs because the jury received credible evidence supporting a reasonable inference that, had actual wholesale prices been provided, the legislature would have used them to reimburse pharmacies for brand name drugs
>
> ...
>
> With brand drugs as well as generics, the State never contended that Medicaid paid ...the amounts Pharmacia supplied in its AWPs; [the State] contended that Medicaid *estimated* what pharmacies paid to wholesalers because it knew the AWPs were inflated, but did not know by how much. Thus, in both contexts, the reporting of inflated AWPs harmed Medicaid and in both the reporting of accurate AWPs would have saved Medicaid money. *See In re Pharm. Indus. AWP Litig.*, 582 F.3d 156, 190 (1st Cir. 2009) (affirming damages in AWP litigation as non-speculative where expert testimony established "that had the AWPs not been inflated, the plaintiffs would not have paid as much as they did"), *petition for cert. dismissed*, 561 U.S. __, 131 S.Ct. 60, 177 L.Ed.2d 1150 (2010).

State v. Abbott Labs., 2012 WI 62, ¶¶ 60, 78 (emphasis in original).

III. Relief to Which the State Is Entitled.

A. Enforcement Relief.

The State seeks two forms of relief in its enforcement capacity—forfeitures and an injunction. As this Court has already held, "causation arguments are not a defense to enforcement actions under §100.18 (11)(d)." Decision and Order on Certain Defense Cross-Motions for Summary Judgment, July 29, 2008, at 4. The same is true for violations of § 49.49(4m). Nor are causation arguments a defense to the State's claims for forfeitures, as both an injunction and forfeitures require only a "violation" of a statute, and do not require any proof of resulting harm. *See id.* ("[T]he whole purpose for an enforcement action is to *forestall* any

harm caused by the targeted conduct.") (emphasis in original); *see also Varljen v. Cleveland Gear*, 250 F.3d 426, 429-30 (6th Cir. 2001) ("Recovery under the FCA is not dependent upon the government's sustaining monetary damages"); *United States ex. rel. Schwedt v. Planning Research Corp.*, 59 F.3d 196, 199 (D.C. Cir. 1995) (holding that "regardless whether the submission of the claim actually causes the government any damages . . . its very submission is a basis for liability"); *United States ex. rel. Hagood v. Sonoma County Water Agency*, 929 F.2d 1416, 1421 (9th Cir. 1991) (holding that the government need not show damages in order to recover civil penalties under the FCA).

1. Forfeitures.

The State seeks forfeitures under both § 100.18 and § 49.49(4m). In the event that the jury finds Aventis committed any violations of either statute, the jury must determine *how many* violations have occurred based upon a standard that is now well-settled by prior rulings. The Court must then determine the amount of forfeitures to be imposed for each violation.

a. Forfeitures under the Medicaid Fraud statute

Section 49.49(4m)(b) provides that a person who violates the statute "may be required to forfeit not less than $100 nor more than $15,000 for each statement, representation, concealment or failure."

The Supreme Court affirmed that a § 49.49(4m) violation occurred each time "FDB transmitted an inflated AWP for [an NDC] to Medicaid, and Medicaid then relied upon it at least once in the reimbursement process." *Abbott Labs.*, 2012 WI 62, ¶ 109. This Court counted as a violation in the Pharmacia trial each time the State relied on an AWP in the reimbursement process—*i.e.*, each time it compared the AWP to the other pricing metrics and paid the lowest amount—regardless of whether the ultimate reimbursement was at the discounted AWP, the

MAC, or the U&C. These violations also include an "implicit affirmative representation" that an "AWP remained as previously represented" where "a drug was not updated" in a subsequent update.[4]

The State's economic damages expert, Dr. Thomas DiPrete, performed calculations in accordance with this standard. Specifically, Dr. DiPrete determined the number of NDCs for Aventis drugs that were reimbursed by the Wisconsin Medicaid or Senior Care programs at least once during each FDB reporting period during the damages period. FDB reported AWPs to Wisconsin Medicaid once a month through 1995, then twice a month through 2005, and then once a week thereafter. Based on Dr. DiPrete's calculations, during the relevant time period for the § 49.49(4m) claim (*i.e.*, November 1, 1994 to December 31, 2008), Aventis caused 18,382 AWPs to be sent to Medicaid, which Medicaid then relied upon at least once.

b. Forfeitures under the Deceptive Trade Practices Act

Section 100.26(4) provides that any "person who violates s. 100.18 ... is subject to a civil forfeiture of not less than $50 nor more than $200 for each violation." The controlling case on counting forfeitures under § 100.26 is *State v. Menard, Inc.*, 121 Wis.2d 199, 121 Wis.2d 199, 358 N.W.2d 813 (Wis. App. 1984), which explained that under § 100.26, a violation "occurred each time an improper advertisement was published, and that each newspaper edition ... constituted a separate publication." *Abbott Labs.*, 2012 WI 62, ¶ 98 (citing *Menard,* 121 Wis.2d at 201, 358 N.W.2d 813). The Supreme Court likened "each newspaper edition" to "each time ... updates were purchased by Wisconsin for each drug." *Id.* ¶ 86.

[4] This Court held that even if monthly/weekly AWP updates from FDB to Medicaid included only the AWPs that changed from the previous update, such updates "constitute an implicit affirmative representation, condoned by [the manufacturer], that were a drug was not updated, its AWP remained as previously represented." September 30, 2009, Decision and Order on Remaining Forfeiture Issues, at 4.

The forfeitures at issue in *Menard* were those under § 100.26—the same statute at issue here for § 100.18 violations. Given the broad scope of the Deceptive Trade Practices Act, *Menard* holds that a "violation occurs each time [a deceptive price] is published," as discussed above, with no reliance requirement. *Menard,* 121 Wis.2d at 201.

100.18 Forfeitures Based on FDB AWPs

The State will ask the jury to count as a § 100.18 violation each time Aventis caused a false AWP for each of its NDCs to be transmitted from FDB to Wisconsin Medicaid. Although there is no reliance requirement for § 100.18 forfeitures, for this trial the State will voluntarily limit the FDB counts to AWPs that were used by the State at least once during a FDB reporting period. The State used an AWP for an NDC during a reporting if it paid a reimbursement for the NDC, regardless of whether the discounted AWP, the MAC, or the U&C was the lowest figure and thus the amount paid. From November 1, 2001, to December 31, 2008, at least 8,081 of Aventis' AWPs were reported by FDB to the State and used at least once for reimbursement.

100.18 Forfeitures Based on Red Book AWPs

The State will also ask the jury to count as a violation each time Aventis caused the AWP for each of its NDCs to be published in the annual and monthly editions of Red Book from November 2001 to December 2008. The State intends to present evidence that the Aventis AWPs were reported in Red Book editions that were received by the UW School of Pharmacy. From November 1, 2001, to December 31, 2008, at least 2,338 of Aventis' AWPs were reported in monthly Red Book editions that were received by the Ebling Library at the UW School of Pharmacy.

Additionally, Wis. Stat. § 100.261 requires that a mandatory 25% consumer protection surcharge be added for every forfeiture imposed for a violation of Wis. Stat. § 100.18, as well as other surcharges.

2. Injunction.

Upon a verdict for the plaintiff, Wisconsin requests that the same injunctive order be entered against Aventis that was previously entered against Pharmacia in this litigation.

B. Civil Damages.

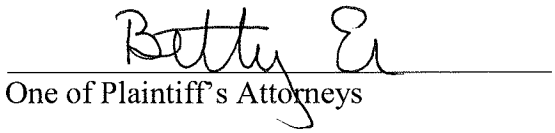
The State also seeks damages under §§ 100.18(11)(b)2 and 100.263, and under § 49.49(6). In addition to the elements required under the State's enforcement action, the element of causation of damages, as discussed above, is necessary. The State's damages expert, Dr. DiPrete, will present evidence and opinion regarding the State's economic damages using the same sources of information and basic methodology that were relied upon by the State in the Pharmacia trial, which was ultimately endorsed by the Supreme Court. *Abbott Labs.*, 2012 WI ¶ 57, 66. Specifically, Dr. DiPrete has estimated the amount of money Wisconsin Medicaid would have saved had it received, and used, true average wholesale prices. His calculations are based upon the difference between what Medicaid reimbursed pharmacies and the average of the prices actually paid by the pharmacies to wholesalers based on data subpoenaed from two national wholesalers, Cardinal Health and McKesson Corporation.

Dr. DiPrete has calculated that the damages for both Wisconsin Medicaid and Wisconsin Senior Care claims for Aventis' drugs for the entire damages period (1994-2008) are $7,246,483 using national wholesale sales data, and $7,137,808 using Wisconsin-only wholesale sales data. The State will seek the present value of these damages, which Dr. DiPrete calculated to be

$12,652,392 using national wholesale sales data and $12,292,008 using Wisconsin-only wholesale sales data.

Dated this 9th day of March, 2015.

Respectfully submitted,



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CERTIFICATE OF SERVICE

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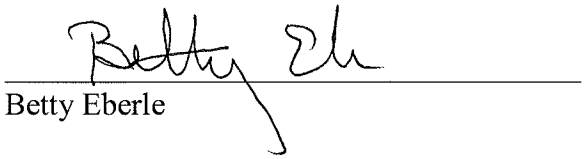

Betty Eberle