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April 28, 2008

VIA HAND DELIVERY

CLIENT/MATTER NUMBER
045152-0101

Honorable Richard Niess
Dane County Circuit Court, Branch 9
215 South Hamilton Street, Room 5103
Madison, WI 53703-3289

Re: *State of Wisconsin v. Abbott Labs., et al.*
Case No. 04-CV-1709

Dear Judge Niess:

Enclosed for filing in the above referenced matter please find Defendants' Reply in Support of Their Joint Cross-Motion for Summary Judgment, with supporting exhibits.

All counsel of record have been served with a copy of the same via Lexis Nexis File & Serve.

Sincerely yours,

FOLEY & LARDNER LLP

Matthew D. Lee

Enclosures

- cc: Attorney Frank D. Remington (w/enclosures) (via Hand Delivery)
- Attorney Charles J. Barnhill, Jr. (w/enclosures) (via Hand Delivery)
- Attorney P. Jeffrey Archibald (w/enclosures) (via Hand Delivery)
- All Counsel of Record (w/enclosures) (via Lexis Nexis File & Serve)

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STATE OF WISCONSIN,

)

Plaintiff,

)

v.

)

Case No.: 04 CV 1709

)

ABBOTT LABORATORIES, *et. al.*,

)

Defendants.

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)

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**DEFENDANTS' REPLY IN SUPPORT OF THEIR
JOINT CROSS-MOTION FOR SUMMARY JUDGMENT**

Defendants are entitled to summary judgment as a matter of law on all of Plaintiff's claims.¹ Plaintiff has offered no relevant law contradicting Defendants' legal arguments. Nor has it offered any evidence contradicting the material facts upon which Defendants' Motion relies. Instead, Plaintiff's Response relies upon unsupported argument and baseless speculation, neither of which is sufficient to overcome Defendants' Motion.

First, with respect to Plaintiff's claims under Counts I and II (Wis. Stat. §100.18), Defendants demonstrated in its moving papers that §100.18 does not apply to prescription drugs because a separate statute covers deceptive trade practices related to prescription drugs and the legislative history of §100.18 shows that the Legislature did not intend for §100.18 to apply to prescription drugs. Plaintiff's arguments do not alter this analysis. This case simply is not appropriately maintained under §100.18.

Second, Plaintiff incorrectly applies the law with respect to its Wis. Stat. §100.18 claims. It argues that it does not have to prove Defendants' statements caused its losses—

¹ Defendants are cognizant of this Court's standing order limiting the argument section of a summary judgment reply to ten pages. However, and in accordance with Defendants' long-standing efforts to avoid bombarding this Court with unnecessary paper, this reply is being filed on behalf of *all* Defendants in this action. In so doing, Defendants have made every effort to be as succinct as possible.

an argument Plaintiff has made numerous times in its brief. Plaintiff is mistaken. It is seeking damages on its own behalf and therefore must prove that Defendants' statements materially induced its losses. Plaintiff has not and cannot show this.

Third, Plaintiff apparently concedes that Wis. Stat. §100.18(10)(b) does not create a cause of action separate from its §100.18(1) claim. However, and as Defendants demonstrated in their moving papers, even if §100.18(10)(b) were a separate cause of action, it does not apply to the conduct alleged here.

Fourth, Plaintiff attempts to dispute Defendants' Additional Proposed Undisputed Facts ("DAPUF") on inappropriate grounds. In so doing, it fails to present evidence that contradicts the material facts underlying Defendants' Motion showing that Plaintiff has known since at least 1975 that AWP did not represent an actual average of wholesale prices.

Fifth, with respect to the statute of limitations, Plaintiff does not dispute the facts proffered showing that it knew, or should have known, all of the facts underlying its Wis. Stat. §133.05, Wis. Stat. §49.49 and unjust enrichment claims well before June 3, 1998 (six years prior to the filing of Plaintiff's complaint). As such, its claims under Counts III, IV and V are barred by the applicable six-year statute of limitations.

Finally, with respect to the political question doctrine, Defendants showed that they are entitled to summary judgment because Plaintiff's lawsuit raises a non-justiciable political question addressing complex economic policy determinations made by the Wisconsin legislative and executive branches. Plaintiff does not (and cannot) dispute the factual record showing that the Wisconsin Legislature and Governor's office knowingly and intentionally chose to use an AWP-based reimbursement formula to carry out certain policy goals. Nor does it offer any evidence that a ruling by this Court requiring Defendants to report the average net prices for their drugs in the marketplace would not disrupt the deliberate policy decisions made by these branches of government.

ARGUMENT

I. Wis. Stat. §100.18 Does Not Apply To Drugs.

As Defendants explained in their Joint Brief, Defendants are entitled to summary judgment as a matter of law on Plaintiff's §100.18 claims because §100.182, not §100.18, exclusively applies to deceptive trade practices relating to prescription drugs.²

Plaintiff responds that §100.182 is an example of a narrower prohibition of a broader statute, §100.18.³ This argument was heard and rejected by the Court of Appeals in the *Gallego* case and should be rejected here for the same reasons.⁴ The Court in *Gallego* found that both §100.18 and §100.183 are “specific” statutes – “separate, different and non-overlapping.” The Court, considering the fact that both statutes provide for the same remedies, reasoned that the statutes must be “specific” and non-overlapping, because to conclude otherwise would mean that the Legislature had enacted a superfluous statute.⁵ The same is true of §100.18 and §100.182. Section 100.182 and §100.18 both provide the same remedies. If, as Plaintiff suggests, drugs are “merchandise” under §100.18, then §100.182 would have been superfluous, because a party could have sought identical civil remedies for the same conduct under §100.18.

Plaintiff also mistakenly asserts that drugs are “merchandise” under §100.18.

Prescription drugs are not commodities that can be bought and sold by typical merchants.

²See Defendants' Joint Response to Plaintiff's Partial Motions for Summary Judgment Against AstraZeneca, Johnson & Johnson, Novartis and Sandoz & Defendants' Joint Cross-Motion for Summary Judgment and Supporting Memorandum (“Defendants' Joint Br.”) at 74-76 (Jan. 15, 2008); see also *Gallego v. Wal Mart Stores East, Inc.*, 288 Wis.2d 229, 707 N.W.2d 539, 2005 WI App. 244 (Wis. Ct. App. 2005).

³ Plaintiff State of Wisconsin's Reply Brief In Support of Its Motions for Summary Judgment and Response Brief In Opposition to Defendants' Cross-Motions for Summary Judgment (“Plaintiff's Br.”) at 28 (Mar. 7, 2008).

⁴ See *Gallego*, 2005 WI App at ¶ 18 (noting that §100.18 and §100.183 are both “specific” statutes that are “separate, different and non-overlapping.”).

⁵ *Gallego*, 2005 WI App at ¶¶ 16-18.

Rather, prescription drugs must be prescribed to individual patients by licensed physicians and distributed by trained pharmacists. Moreover, “merchandise,” as defined when §100.18 was enacted, does not include items meant for immediate consumption.

Prescription drugs are prescribed by physicians for immediate consumption. The fact that a prescription may call for 30 pills to be taken over 30 days does not change this.

Physicians typically do not prescribe drugs with instructions to begin consumption at some date in the future. Rather, patients typically are instructed to begin taking them immediately. If anything, food items, which the *Gallego* court held were *not* merchandise for purposes of §100.18, are far more akin to “merchandise” than prescription drugs.⁶

Plaintiff’s suggestion that §100.182 could not possibly be the sole statute that covers deceptive trade practices relating to prescription drugs because it only concerns misrepresentations regarding the *effects* of prescription drugs is nonsense. It does not follow from the fact that the Legislature decided to regulate only certain conduct in §100.182 that §100.18 must therefore subsume all other types of conduct related to prescription drugs. Rather, it reflects the Legislature’s intent to regulate *only* conduct regarding the *effects* of prescription drugs. Wisconsin’s Deceptive Trade Practices Act

⁶ Plaintiff argues that food is *less* like “merchandise” (as defined when §100.18 was first enacted as not including items required for immediate consumption) than prescription drugs because “in 1910, with limited technology for refrigeration, [food] had to be eaten almost immediately after purchase.” See Plaintiff’s Br. at 27. In actuality, food preservation techniques such as canning, refrigeration and freezing were widely used in the nineteenth and early twentieth centuries. See *generally*, INTERNATIONAL INSTITUTE OF REFRIGERATION, A BRIEF HISTORY OF REFRIGERATION 3-4 (2008) (attached as Ex. A); *Food Preservation*, BRITANNICA ONLINE ENCYCLOPEDIA 4-7 (2008)(attached as Ex. B)

In a somewhat similar vein, Plaintiff also argues that motor fuel, in Plaintiff’s words, “is clearly closer to the category of “required for immediate consumption” than drugs...[and] under 100.18...*is* merchandise.” Plaintiff’s Br. at 27. However, the plain language of §100.18 reveals that motor fuel is *not*, in fact, considered “merchandise.” Rather, motor fuel is a separate item the Legislature chose to add to the enumerated list of items regulated by §100.18, a list which *includes* merchandise, as well as real estate, employment and services, among others. Given that motor fuel is frequently stored for later use, it also is far from clear that Plaintiff’s glib assumptions are correct.

“DTPA”) is a statutory scheme reflecting the legislature’s intent to govern only the conduct specifically provided for in the statutory language. If a type of conduct does not appear in that language, the presumption is *not* that such items are covered by the statute, but rather that the Legislature did not intend for it to be covered by the statute.⁷ This obviously does not preclude Plaintiff from asserting (as it has) common law claims or claims stemming from other statutory provisions. It merely means that its claims do not give rise to a cause of action under the DTPA.

II. Wis. Stat. §100.18 Does Not Apply To the Conduct Alleged.

Even if §100.18 could be construed to apply to misrepresentations related to prescription drugs, §100.18 does not apply to the conduct alleged here because Plaintiff has not shown – as it must – that it was induced to act differently by Defendants’ statements. Plaintiff has not and indeed cannot prove that it would have acted differently if AWP’s had been reported differently.

First, Plaintiff’s argument that it does not have to prove that it was induced to act differently is incorrect. The law is clear that to establish *liability* under §100.18, Plaintiff must prove, among other things, that Defendants’ statements caused its pecuniary losses.⁸ This element requires a showing that Defendants’ statements “materially induced” Plaintiff

⁷ See, e.g., *Perra v. Menomonee Mut. Ins. Co.*, 239 Wis.2d 26, 34-35, 619 N.W.2d 123, 127 (Wis. Ct. App. 2000) (holding a list of prohibited employments contained in an employment statute to be both exhaustive and exclusive, under the principle of statutory construction known as *expressio unius est exclusio alterius*); see also *In Interest of C.A.K.*, 154 Wis.2d 612, 621, 453 N.W.2d 897, 901(1990) (citing the “well-established principle[] of statutory construction that the “enumeration of specific alternatives in a statute is evidence of legislative intent that any alternative not specifically enumerated is to be excluded.”).

⁸ *K&S Tool & Die Corp. v. Perfection Machinery Sales, Inc.*, 301 Wis.2d 109, 121-22, 732 N.W.2d 792, 798, 2007 WI 70, ¶ 19 (Wis. 2007) (“To prevail on a claim [under §100.18], the plaintiff must prove three elements...[including] that the representation caused the plaintiff a pecuniary loss.”) (emphasis added).

to act differently.⁹ Plaintiff argues that it does not have to prove this element because it is seeking injunctive relief under §100.18(11)(d). However, Plaintiff is not seeking only injunctive relief in this case, but is, in fact, acting in its capacity as an allegedly injured party and seeking damages for its own losses.¹⁰ As such, Plaintiff's reliance on *State v. American TV & Appliance of Madison, Inc.* is misplaced.¹¹ Unlike here, in that case the State was acting purely in its enforcement capacity and seeking forfeitures on behalf of consumers.¹²

In order to recover damages under §100.18, the State may sue under either §100.18(11)(b)(2) or §100.18(11)(d), both of which require proof that Defendants' representations caused Plaintiff's pecuniary losses. Section 100.18(11)(b)(2) provides in relevant part:

“Any person suffering pecuniary loss *because of* a violation of this section by any other person may sue in a court of competent jurisdiction and shall recover such pecuniary loss . . .”¹³

Section 100.18(11)(d) provides in relevant part:

“The court may in its discretion, prior to entry of final judgment, make such orders or judgments as may be necessary to restore to any person any pecuniary loss suffered *because of* the acts or practices involved in the action, provided proof thereof is submitted to the satisfaction of the court.”¹⁴

⁹ See *id.* at ¶¶ 35-36 (internal citations omitted) (finding that “proving causation in the context of §100.18(1) requires a showing of material inducement” and explaining that “the test is whether (plaintiff) would have acted in [the misrepresentation's] absence.”) (quoting Wis. Jury Instr. 2418); see also *Werner v. Pittway Corp.*, 90 F. Supp.2d 1018, 1033-34 (W.D. Wis. 2000) (dismissing a §100.18 claim on the grounds that plaintiffs “did not rely on any statements from defendants regarding” a defective carbon monoxide detector); *Ball v. Sony Electronics, Inc.*, No. 05-C-307-S, 2005 WL 2406145 at *3 (W.D. Wis. Sept. 28, 2005) (plaintiff must demonstrate reliance to satisfy §100.18).

¹⁰ See Complaint at pp. 30-32; see also Reply of AstraZeneca Pharmaceuticals LP and AstraZeneca LP In Further Support of Cross-Motion for Partial Summary Judgment (“AstraZeneca Reply”) at 2-4 (Apr. 28, 2008), incorporated herein by reference.

¹¹ See Plaintiff's Br. at 8 (citing 146 Wis.2d 292 (Wis. 1988)).

¹² See *State v. American TV & Appliance*, 140 Wis.2d 353, 356, 410 N.W.2d 596, 597 (Wis. Ct. App. 1987).

¹³ Wis. Stat. §100.18(11)(b)(2) (emphasis added).

¹⁴ Wis. Stat. §100.18(11)(d) (emphasis added).

Wisconsin courts have construed the “because of” language that appears in §100.18(11)(b)(2) as requiring proof that a defendant’s statement caused the plaintiff’s loss.¹⁵ The same “because of” language also appears in §100.18(11)(d) and thus a similar analysis should apply.¹⁶ Accordingly, whether Plaintiff brings its claims for damages under §100.18(11)(b)(2) or §100.18(11)(d), it must prove that Defendants’ statements “materially induced” it to act in some way that resulted in its harm. Plaintiff not only has failed to produce any evidence that it was materially induced to act differently because of Defendants’ statements, it cannot make that showing, as Defendants demonstrated in their Joint Response. Plaintiff was not materially induced to act differently by reason of Defendants’ statements.¹⁷ Plaintiff offers no evidence to the contrary.

Plaintiff also mischaracterizes Judge Krueger’s prior decision in this case.¹⁸ Judge Krueger did not rule, as the Plaintiff now contends, that the State was excused from proving causation under §100.18, but instead ruled that Defendants had not presented her with adequate authority to find that causation is required.¹⁹ Here, Defendants have fully briefed the issue and the law is clear—Plaintiff must prove that Defendants’ statements caused its losses.

¹⁵ See, e.g., *Tim Torres Enterprises, Inc. v. Linscott, Inc. et al.*, 142 Wis. 2d 56, 70, 416 N.W.2d 670, 675 (Wis. Ct. App. 1987), *review denied*, 142 Wis. 2d 953 (1988).

¹⁶ In fact, in reaching its conclusion that the “because of” language in §100.18(11)(b)(2) requires proof of causation, the court in *Torres* relied upon a law review article which interpreted the “because of” language in §100.18(11)(d) as requiring a causal connection between the violation and the loss. *Id.*, citing James Jeffries, *Protection for Consumers Against Unfair and Deceptive Business*, 57 MARQ. L. REV. 559, 602 n.283 (1974)(§100.18(11)(d) requires a causal connection between the practices found illegal in the injunction portion of the litigation and the pecuniary losses suffered by the customer).

¹⁷ See Defendants’ Joint Br. at 87-91.

¹⁸ See Plaintiff’s Br. at 9-10.

¹⁹ See Partial Decision and Order at 14-15 (Apr. 3, 2006).

Plaintiff's argument that §100.18 *must* apply here because otherwise Plaintiff will be "unable to sue to stop a massive scheme" is meritless.²⁰ Not only does it assume its conclusion, it is wrong. Plaintiff has already brought a variety of claims in addition to its §100.18 claim for the same alleged conduct. This Court should not accept Plaintiff's invitation to shoehorn its allegations into a §100.18 claim when they do not fit.

III. Wis. Stat. §100.18(10)(b) Does Not Create a Separate Cause of Action and Does Not Apply to the Conduct Alleged.

Plaintiff apparently concedes that Wis. Stat. §100.18(10)(b) does not create a cause of action separate from its §100.18(1) claim²¹ and certainly offers nothing to rebut the Defendants' argument that it does not. Defendants, therefore, are entitled to summary judgment on Count II of the Second Amended Complaint.²² Even if §100.18(10)(b) did give rise to a separate cause of action, Defendants are entitled to summary judgment on this count because the arguments Defendants have made with respect to Plaintiff's §100.18(1) claim apply to its §100.18(10)(b) claim as well.

Moreover, §100.18(10)(b) does not apply to the conduct alleged here. It applies to merchandise, not prescription drugs. It also was enacted to prevent *retailers* (not manufacturers) from advertising the sale of merchandise to consumers at a wholesaler's price when the advertised price is actually higher than the "real" wholesale price. This

²⁰ Plaintiff's Br. at 30-31.

²¹ Plaintiff states: "First, defendants argue that §100.18(10)(b) is not a cause of action separate from §100.18(1), but merely defines one type of conduct that is deemed "deceptive" conduct under §108.18(1) [sic]. Hence, argue defendants, their defenses to liability under §100.18(1) also apply to the State's alleged violation of §108(10)(b) [sic]. The State agrees, and in fact so stated in its Motions." Plaintiff's Br. at 40 (internal citations omitted). It is unclear whether Plaintiff agrees that §100.18(10)(b) does not create a separate cause of action, or whether Plaintiff merely agrees that the same defenses apply.

²² Interestingly, in a similar suit brought by the State of Illinois (who is represented by the same outside counsel as Wisconsin) plaintiff did not oppose defendants' motion to dismiss a similar claim which the court then dismissed. *See Order, The People of the State of Illinois v. Abbott Laboratories, et al.*, No. 05-CH-2474 (Apr. 11, 2008) (dismissing Illinois' wholesale price advertising claim under 815 ILCS 505/2-CC); *see also* 815 ILCS §§505/2 and 505/2CC.

intent is shown in the statute's drafting record. Plaintiff suggests that the legislative intent demonstrated by the drafting record for §100.18(10)(b) should be ignored because it was not included in the final version of the bill. That position is baseless. Wisconsin statutes generally do not include explanatory drafting history; such language is routinely stricken from the final drafts of legislation.²³ The idea that "someone in the legislative process concluded that the original 'explanation' did not appropriately describe the amended bill," as Plaintiff suggests,²⁴ is unfounded conjecture.

IV. Plaintiff Does Not Properly Dispute Defendants' Proposed Undisputed Facts Regarding Its Knowledge and Fails to Put Forth Contrary Evidence.

Plaintiff presents *no* evidence to contradict the fact that it has known since at least 1975 that AWP did not represent an actual average of wholesale prices.²⁵ Instead, Plaintiff argues that Defendants' facts are "disputed" on one of the following four bases: (1) the fact is based on inadmissible evidence (presumably on relevancy grounds); (2) the fact is a "disputed inference"; (3) the fact is not supported by the record cite provided; or (4)

²³ See Wis. Leg. J.R. 59 (excerpt attached as Ex. C)(Explanative notes "shall appear in the original reproduced version of the proposal or amendment only, and shall not appear in the Wisconsin Acts or session law volumes unless the chief of the legislative reference bureau determines that including them is essential or in the statutes unless the revisor determines that including them is essential."). The drafting history of other amendments to §100.18 contain drafting language that was not included in the final bill as enacted by the Legislature. For example, a section entitled "Analysis by the Legislative Reference Bureau" discussing the intent behind the 1969 amendment is crossed out, and was not included in the final bill. Drafting Record, L. 1969, c.425, p. 13 of 21 (attached as Ex. D).

²⁴ Plaintiff's Br. at 42.

²⁵ Plaintiff has not shown that the few documents it presents as "contrary evidence" were ever received or reviewed by the State, much less considered by the State in formulating its reimbursement formula. In fact, copious evidence reflects the exact opposite – showing that the State's own understanding at all times relevant to this litigation was that AWP did not represent an actual average of wholesale prices. See, e.g., DAPUF ¶¶ 7, 10-12, 16, 18, 36, 105, 111-113, 122-24, 127-28, 142, 161-66, 168, 174; see also Defendants' Joint Br. at 103-105. Almost all of this evidence has been shown to be either directly authored, confirmed to have been received or, in most cases, specifically considered by the State agencies directly responsible for setting Wisconsin's reimbursement rate. See, e.g., DAPUF ¶¶ 11-12, 122-24, 142, 161-66, 168. Plaintiff's "evidence" does nothing to contradict these facts.

impermissible legal arguments.²⁶ Each of these purported grounds for disputing the Defendants' facts does not withstand scrutiny.

First, Plaintiff's objections to the admissibility of Defendants' evidence, which appear to be based solely on relevance grounds,²⁷ are improper. As demonstrated by the briefing before the Court, evidence of Plaintiff's knowledge is undeniably relevant — not only to statute of limitations and political question doctrine defenses, but also to the elements of Plaintiff's claims. Moreover, by invoking Plaintiff's own federal obligation to limit Medicaid payments to “estimated acquisition cost” as one of the “material facts on which [it] bases its motion[],” Plaintiff has put its knowledge directly at issue.²⁸ Examples of evidence Plaintiff disputes solely on admissibility grounds include DHFS, DOA and LFB budget reports,²⁹ letters and testimony from Wisconsin Medicaid providers and provider groups,³⁰ a federal government report specifically addressing Wisconsin's reimbursement methodology (as well as other federal government reports discussing Medicaid reimbursement),³¹ and State designee James Vavra's testimony that DHFS was aware that

²⁶ In an effort to reduce the volume of paper before the Court, Defendants have refrained from responding to each of Plaintiff's spurious disputations of Defendants' proposed undisputed facts. The fallacies of most of Plaintiff's responses to these facts are self-evident. Defendants have confined their reply to Plaintiff's Appendix B to just a few of the most prevalent categories of Plaintiff's bases for disputation.

²⁷ Notably, Plaintiff does not object to the admissibility of some of the exact same evidence when offered in support of facts that do not involve government knowledge or government choice. For example, Plaintiff does not dispute the admissibility of James Vavra's testimony as support for numerous facts, including the fact that DHFS took the federal access-to-care requirement seriously, *see* Plaintiff's Br., Appx. B ¶¶ 65-66; *see also Id.* at ¶¶ 1, 42-43, 45, 59-61, yet claims that the same testimony is inadmissible to show that it knew AWP did not represent an actual average of wholesale prices. *Id.* at ¶ 163.

²⁸ *See* Plaintiff's Br. at 3-4.

²⁹ *See, e.g.,* Plaintiff's Br., Appx. B ¶¶ 142, 149, 155, 168-71, 176-77, 180-82, 186.

³⁰ *See, e.g.,* Plaintiff's Br., Appx. B ¶¶ 143-46, 154, 156, 172, 178-79, 185.

³¹ *See, e.g.,* Plaintiff's Br., Appx. B ¶¶ 161-66, 174.

Wisconsin pharmacists were purchasing drugs at well below AWP.³² Plaintiff's position is ill-founded; such evidence is both relevant and admissible.

Second, Plaintiff frequently improperly characterizes purely factual statements as “disputed inferences.” For example, Plaintiff claims that numerous federal government reports and private studies concluding that AWP does not represent an actual average of wholesale prices are “disputed inferences.”³³ In fact, a reading of the exhibits attached to Defendants’ Joint Response shows that these reports do not require that an inference be drawn – they set forth the exact facts for which Defendants offered them.

Third, the record provides ample and unambiguous support for the facts Plaintiff disputes as “not supported by the record cite provided.” For instance, the State argues that a letter to the federal government from Lieutenant Governor Martin Schreiber stating that pharmacists “must be allowed reasonable profits in their Medicaid business” does not support the fact that the Governor’s office stated that pharmacists participating in Wisconsin Medicaid are entitled to a reasonable profit.³⁴ Similarly, Plaintiff claims that its Wis. Stat. §804.05(2)(e) designees’ testimony does not support factual assertions about the State’s knowledge,³⁵ such as the fact that the State understood that discounts or rebates from WAC may be granted to wholesalers.³⁶ Yet Mr. Vavra testified *as the State’s designee* that the statement contained in the 1995 Department of Agriculture Report that “[r]ebates or discounts from WAC[] may be granted” was consistent with his, and thus the State’s, understanding of WAC.³⁷

³² See Plaintiff’s Br., Appx. B ¶ 163.

³³ See Plaintiff’s Br., Appx. B ¶¶ 7-8.

³⁴ Plaintiff’s Br., Appx. B ¶ 75.

³⁵ See, e.g., Plaintiff’s Br., Appx. B ¶¶ 17, 67.

³⁶ Plaintiff’s Br., Appx. B ¶ 48.

³⁷ DAPUF ¶¶ 47-48.

Finally, Plaintiff responds to a number of Defendants' Proposed Undisputed Facts with legal arguments that should have been included in the argument section of Plaintiff's brief rather than in an Appendix.³⁸ The Court has directed that "no argument is permitted" in the "Response to Proposed Undisputed Facts" section, and that "explanations for these responses belong in the 'Argument' section."³⁹ Plaintiff disregards the Court's directive and makes various inappropriate legal arguments in its attempts to dispute Defendants' facts, including, for example, citing legal opinions to challenge the admissibility of evidence⁴⁰ and presenting its unsupported argument that using ingredient cost reimbursement to cross-subsidize inadequate dispensing fees violates federal law as "contrary evidence" to facts showing that Wisconsin in fact knowingly and intentionally cross-subsidized.⁴¹ Plaintiff also improperly attempts to cite a judicial opinion rendered by Judge Saris in the multi-district AWP litigation ("MDL") as "contrary evidence" showing that "Congress intended that reported AWPs be real average wholesale prices."⁴² Not only does the cited opinion *not* support the proposition for which Plaintiff has offered it, but legal conclusions rendered by individual judges in other jurisdictions concerning the language of a statute not at issue here are not *factual* evidence that can be offered in support of or to dispute factual assertions. A legal conclusion is not an evidentiary "fact" and cannot serve to contradict facts proffered by the defendants. The proper place to address the applicability, weight and/or import of another court's conclusions of law is in the argument section of its brief.

³⁸ See, e.g., Plaintiff's Br., Appx. B ¶¶ 5, 7, 73, 80, 97, 104.

³⁹ Standing Order Regarding Contents of Motions for Summary Judgment, Responses to Motions for Summary Judgment, and Replies to Responses at 7-8.

⁴⁰ See Plaintiff's Br., Appx. B ¶¶ 5, 104.

⁴¹ See Plaintiff's Br., Appx. B ¶ 97, 104.

⁴² See, Plaintiff's Br., Appx. B ¶ 7.

V. Plaintiff's §133.05, §49.49 and Unjust Enrichment Claims Are Time-Barred.

Plaintiff's §133.05, §49.49 and unjust enrichment claims hinge on the assertion that AWP's were intended to reflect an actual average of marketplace prices. These claims are barred by the applicable six year statutes of limitation because the undisputed facts demonstrate that Plaintiff knew, or in the exercise of reasonable diligence should have known, that AWP's did not represent actual averages of wholesale prices long before June 1998. Although Plaintiff tries to chip away at the edges by criticizing select items of evidence, it does not (and indeed cannot) dispute the core truth that it was aware of the fundamental facts underlying its claims prior to 1998. Consequently, its claims are time-barred.

A. Defendants have shown as a matter of law that *all* of Plaintiff's non-DTPA claims are barred by the applicable six year statutes of limitation.

Plaintiff first attempts to rebut Defendants' evidence that the State knew or should have known of its claims before June 1998 by pointing to a single First DataBank document published in 1991 from which Plaintiff quotes a single paragraph out of context.⁴³ This document is insufficient to defeat Defendants' Motion for several reasons. First, Plaintiff provides *no evidence* that it ever received or reviewed this document, much less considered it when formulating its reimbursement rates.⁴⁴ Second, far from supporting Plaintiff's position, the document, if it was received and reviewed by the State, actually bolsters Defendants' argument that Wisconsin was on inquiry notice of the facts underlying its claims before 1998. The document identifies certain difficulties in determining AWP and notes that "Average Wholesale Price (AWP) is perhaps the most misunderstood concept in

⁴³ Plaintiff's Br. at 20, 72. The other documents cited by Plaintiff on pages 20-21 are irrelevant to the statute of limitations issue, because they are dated after June 3, 1998.

⁴⁴ By contrast, Defendants have submitted evidence that the reports cited in its Joint Cross-Motion were received, reviewed and considered by the State of Wisconsin in setting its reimbursement rates. *See, e.g.*, DAPUF ¶¶ 11-12, 122-24, 142, 161-66, 168.

the pharmaceutical industry.”⁴⁵ Assuming Plaintiff received the document, it undoubtedly should have put the State on inquiry notice that perhaps AWP was not an actual average of providers’ drug acquisition costs.

Plaintiff makes various other arguments that its claims are not barred by the applicable six year statutes of limitations, each of which is similarly meritless. First, Plaintiff argues that even if it had known that AWP did not represent an actual average of wholesale prices, it was not until recently that it understood Defendants’ role in the AWP reporting system. This assertion is belied by the undisputed evidence. A cause of action accrues when a party “kn[ows] the identity of the defendant, *or in the exercise of reasonable diligence, should have discovered the identity of the defendant.*”⁴⁶ The evidence demonstrates that Plaintiff, through the exercise of reasonable diligence, should have discovered the identity of Defendants long before 1998.⁴⁷ Plaintiff was armed with all the relevant facts: (1) Plaintiff knew that First DataBank’s AWP’s did not represent actual averages of wholesale prices;⁴⁸ (2) Plaintiff possessed documents⁴⁹ asserting that First DataBank’s AWP’s were derived, at least in part, from prices provided to First DataBank

⁴⁵ Plaintiff’s Br., Appx. H Tab 1.

⁴⁶ Plaintiff’s Br. at 72, *citing Spitler v. Dean*, 148 Wis.2d 630, 636, 436 N.W.2d 308, 310 (Wis. 1989) (emphasis added).

⁴⁷ *Spitler*, 148 Wis.2d at 638 (remanding to determine whether the plaintiff had exercised reasonable diligence in attempting to discovery the identity of the defendant).

⁴⁸ *See, e.g.* DAPUF ¶¶ 7, 10-12, 16, 18, 36, 105, 111-113, 122-24, 127-28, 142, 161-66, 168, 174; *see also* Defendants’ Joint Br. at 103-105.

⁴⁹ *See* Defendants’ Joint Br., Ex. 9 at WI-Prod-AWP-104241 (an OIG Report, Medicaid Pharmacy – Actual Acquisition Cost of Prescription Drug Products for Brand Name Drugs (Apr. 10, 1997) stating that “[t]he AWP is the price assigned to the drug by its manufacturer and is listed in either the Red Book, Medispan or the Blue Book – publications universally used in the pharmaceutical industry.”); *see also* Defendants’ Joint Br., Ex. 36 at 18 (a Department of Agriculture, Trade and Consumer Protection, Wholesale Pricing of Prescription Drugs in Wisconsin Report (July 28, 1995) stating that “[t]he AWP is published on an annual basis in the Red Book, an annual pharmacy guide, and other industry sources. The AWP is set by the manufacturer and provides a starting point for many of the price negotiations which are outlined later in this section.”)

from drug manufacturers;⁵⁰ and (3) Plaintiff knew which drug manufacturers' drugs were covered and reimbursed by its own Medicaid program. This is all the information Plaintiff would have needed to identify Defendants, and "Plaintiffs may not close their eyes to means of information reasonably accessible to them and must in good faith apply their attention to those particulars which may be inferred to be within their reach."⁵¹

Second, no new causes of action could have accrued once the State was aware, or, at the very least, was on inquiry notice, that AWP did not represent an actual average of wholesale prices. *Howard v. Philip Morris USA, Inc.* is instructive on this point.⁵² In *Howard*, the Seventh Circuit held that a smoker's Wisconsin state-law fraud claim for smoking-related injuries was barred by the applicable six-year statute of limitations.⁵³ The plaintiff claimed that he was misled by advertising for "Marlboro Lights" cigarettes that suggested they were "safer" than other cigarettes.⁵⁴ He was initially diagnosed with smoking-related injuries in 1995, yet continued to smoke and failed to bring suit until 2002, when he was diagnosed with additional smoking related injuries.⁵⁵ Despite the fact that the Marlboro Lights advertising continued to air during the interim between his first injuries and his decision to file suit, the court ruled that the statute of limitations began to run in 1995 when the plaintiff first discovered that smoking was causing him injury.⁵⁶

The same analysis applies here. The statute of limitations began to run when Plaintiff first discovered, or should have discovered, that AWP's did not represent actual averages of wholesale prices. The fact that First DataBank has continued to publish AWP's

⁵⁰ Defendants disagree with this underlying conclusion because First DataBank is an independent entity and the AWP's it publishes are its own. However, for purposes of inquiry notice, it is only important to observe that Plaintiff had access to this information prior to 1998.

⁵¹ *Id.* (citing *Kanack v. Kremski*, 96 Wis.2d 426, 432, 291 N.W.2d 864, 867 (1980)).

⁵² 98 Fed. Appx. 535, 538-39 (7th Cir. 2004).

⁵³ *Id.*

⁵⁴ *Id.* at 536.

⁵⁵ *Id.*

⁵⁶ *Id.* at 539-40.

for Defendants' drugs and that Plaintiff has continued to reimburse for pharmaceuticals based on AWP does not change the fact that Plaintiff was on notice of its causes of action well before 1998. The evidence submitted by Defendants makes this indisputably clear. For example, in a 2004 letter responding to a private attorney's solicitation for AWP litigation business – which outlined the alleged facts underlying a potential fraud claim against drug manufacturers – Plaintiff acknowledged that it had been aware of the issue since *at least 1997* and had “been discussing this issue with the Wisconsin Department of Justice for some time.”⁵⁷ Rather than providing evidence to dispute this knowledge, the State simply ignores it. Unfortunately for the Plaintiff, “the appearance of the first compensable injury starts the running for all claims based on the tortfeasor's single course of conduct, even for future injuries....”⁵⁸

Finally, there is no support for Plaintiff's argument that allowing the statute of limitations to bar its 30-year-old claims would lead to “outrageous results.” The two cases it cites in support of this proposition are inapplicable. Both cases involved discrimination claims where the courts held that the victims' claims were not time-barred under the “continuing violation” doctrine.⁵⁹ The “continuing violation” doctrine has only been applied in discrimination cases where the victims have no recourse other than to bring suit to enjoin the discriminatory practice.⁶⁰ It does not apply to actions alleging fraud or

⁵⁷ See DAPUF ¶ 22; see also Defendants' Joint Br. at 104-105.

⁵⁸ *Howard*, 98 Fed. Appx. at 539 (citing several Wisconsin cases).

⁵⁹ Plaintiff's Br. at 71. Plaintiff also cites a nuisance case, *Vogel v. Grant-Lafayette Electric Cooperative*, in support of its argument. 195 Wis.2d 198, 214, 536 N.W.2d 140, 146-47 (Wis. Ct. App. 1995). *Vogel*, however, has nothing to do with the “continuing violation” doctrine—it merely rejects an equitable argument to limit damages to a six-year period, and does not decide whether the “continuing violation” doctrine affected the limitations period for plaintiff's claims. *Id.*

⁶⁰ *Barry v. Maple Bluff Country Club*, 221 Wis.2d 707, 727, 586 N.W.2d 182, 190 (Wis. Ct. App. 1998) (“Under federal law, the continuing violation doctrine applies to express, openly espoused discriminatory policies that are systemic in nature....”); *Palmer v. Bd. of Educ. of Cmty. Unit Sch. Dist. 201-U*, 46 F.3d 682, 685-86 (7th Cir. 1995) (citing federal precedent applying the

misrepresentation like this one.⁶¹ Indeed, unlike individuals who are the victims of discriminatory practices, Plaintiff has the power in its own hands to remedy the situation by ceasing to use AWP as a basis for reimbursement (as it has for most generic and physician-administered drugs), and/or altering its reimbursement rate by discounting from AWP (as it has done since 1990 for all other drugs at issue in this case). It bears observing that courts in other jurisdictions have not balked at applying the statutes of limitations in similar AWP-based cases that allege fraud and misrepresentation.⁶² There is no reason for this Court to conclude differently, and Plaintiff has certainly presented none.

B. The six year statute of limitations period applies to Plaintiff's § 49.49 claim.

The six year statute of limitations also applies to Plaintiff's § 49.49 claim. Plaintiff argues that either (1) the ten year statute of limitations, Wis. Stat. § 893.87, rather than the six year statute of limitations applies; or (2) the State can not be bound by general statutes of limitation.⁶³ Neither argument is correct. First, the ten-year statute of limitations provided by Wis. Stat. § 893.87 only applies in the absence of another applicable statute of limitations. Here, there is another applicable statute of limitations, namely the

continuing violation theory in discrimination cases, and stressing the involvement of constitutional violations).

⁶¹ Judge Krueger also rejected other variations of Plaintiff's "continuing violation" argument. In an effort to refute Judge Krueger's order, Plaintiff relies on *Kolpin v. Pioneer Power & Light Co., Inc.*, an action for negligence, which did not involve a situation where there had been a continuing course of negligence, but merely concluded that the "continuum of negligence theory" did not apply because the plaintiffs' loss was attributable to a single act of negligence. 162 Wis.2d 1, 21-25, 469 N.W.2d 595, 603-04 (Wis. 1991). While Wisconsin Courts have recognized a doctrine of continuing negligence, this doctrine has never been expanded to include actions for fraud.

⁶² See, e.g., Memorandum Decision and Order On Defendants' Motion to Dismiss, *State of Idaho v. Aventis Pharmaceuticals, et al.*, Case No. CV OC 0710318 at 6-7 (Apr. 10, 2008) (attached as Ex. E) (rejecting plaintiff's continuing tort argument and dismissing all claims arising from conduct that occurred outside of the relevant limitations period); Order on Motions to Dismiss, *Commonwealth of Kentucky v. Alparma Inc., et al.*, Civil Action No. 04-C1-1487 at 1 (June 23, 2006) (attached as Ex. F)(dismissing all claims arising more than six years before the filing of the Complaint); *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 491 F.Supp. 20, 31-32, 78-79 (D.Mass. 2007) (same).

⁶³ See Plaintiff's Br. at 73-74.

six-year limitation applicable to fraud claims in § 893.93. Nowhere does Plaintiff dispute that its § 49.49 claim sounds in fraud, or that § 893.93 applies to claims that sound in fraud. Moreover, Judge Krueger has already ruled that the six year statute of limitations applies to Plaintiff's § 49.49 claim. Although Defendants did not specifically cite to §49.49 in their motion to dismiss briefing, they argued that “[e]ach of the remaining claims are governed by a six-year limitations period,” and cited the relevant supporting statutes and case law.⁶⁴ The language “[e]ach of the remaining claims” clearly included the State’s §49.49 claim. Judge Krueger, after reviewing the briefing from both sides, agreed with Defendants that the six year statute of limitations applied to “the balance of the claims.”⁶⁵

Second, Plaintiff provides no support for its assertion that the six year statute of limitations is a general statute of limitations that cannot be applied to Plaintiff. In order for a general statute of limitations not to apply, the Plaintiff must prove (under its own formulation of the standard) that it is “acting in protection of the public.”⁶⁶ It cannot make that showing here. Plaintiff's claim under §49.49 was not brought “in protection of the public.” It was brought on its own behalf.⁶⁷

⁶⁴ Defendant's Memorandum of Law In Support of Their Joint Motion to Dismiss the Amended Complaint at 42 (Jan. 20, 2005).

⁶⁵ See Remainder of the Decision and Order On Defendants' Motion to Dismiss at 6 (May 18, 2006).

⁶⁶ Plaintiff's Br. at 74, citing *State v. Josefsberg*, 275 Wis. 142, 81 N.W.2d 735 (Wis. 1957). The other cases cited by Plaintiff are inapplicable to the present case. *In re Allen's Estate* held that the State's statutory claim for recovery of the costs of care for a ward of the State was subject to the ten-year statutory period, because no other section of Chapter 893 provided an alternative limitations period for such a claim. 43 Wis.2d 260, 168 N.W.2d 869 (Wis. 1969). That is not the case here. Section 893.93 prescribes an alternative limitations period for actions sounding in fraud. Plaintiff also cites *John v. State* for the proposition that welfare fraud is a “continuing offense” for purposes of the criminal statute of limitations. Plaintiff's Br. at 74. The State has not brought criminal counts against any Defendant, and thus the application of criminal statutes of limitations is irrelevant to this litigation, and particularly has no bearing on the issue of whether the ten-year or six-year limitations period applies to Plaintiff's §49.49 claims.

⁶⁷ Indeed, Plaintiff's *only* requested remedies for the alleged violation of Wis. Stat. § 49.49 are damages, forfeitures, and litigation costs, not injunctive relief or penalties. See Complaint at pp. 34-35.

VI. The Court Should Abstain From Adjudicating This Case On Separation of Powers Grounds

Although Wisconsin courts have not had the opportunity to address (one way or the other) the issue of abstention in a case such as this, courts in other states have abstained from ruling where the party is seeking equitable relief that would upset a complex economic policy.⁶⁸ For example, in *Desert Healthcare*, the court abstained from ruling on a claim alleging that the defendant health care service plan had engaged in unfair competition.⁶⁹ In that case, defendant contracted with an intermediary physicians group who in turn contracted with plaintiff hospital for the provision of healthcare services to patients who subscribed to defendant's health care service plan.⁷⁰ The intermediary ultimately filed for bankruptcy, leaving plaintiff with unpaid claims for services provided to defendants' subscribers.⁷¹ The case involved a claim that defendant abused the health care capitation

⁶⁸ See *Desert Healthcare District v. Pacificare FHP, Inc.*, 94 Cal.App.4th 781 (Cal. Ct. App. 2001); *Shamisan v. Dept. of Conservation*, 136 Cal.App.4th 621, 626, 642 (2006) (affirming abstention from deciding a corporate fraud case for defendants' failure to offer convenient beverage container redemption for California consumers, stating that "to issue restitution and disgorgement orders against the corporate defendants would interfere with the department's administration of the act and regulation of beverage container recycling and potentially risk throwing the entire complex economic arrangement off balance."); *Cal. Grocers Ass'n, Inc. v. Bank of America, Nat'l Trust and Sav. Ass'n*, 22 Cal.App.4th 205, 218 (Cal. Ct. App. 1994) ("Judicial review of one service fee charged by one bank is an entirely inappropriate method of overseeing bank service fees.") The *Grocers Ass'n* court further noted that "[a]nother court, in a different context, pointed out the general preference for legislative or administrative regulation in the field of price control: '[T]he control of charges, if it be desirable, is better accomplished by statute or regulation authorized by statute than by *ad hoc* decisions of the courts. Legislative committees and an administrative officer charged with regulating an industry have better sources of gathering information and assessing its value than do courts in isolated cases." *Id.* at 218 (quoting *Lazzareschi Inv. Co. v. San Francisco Fed. Sav. & Loan Ass'n*, 22 Cal.App.3d 303, 311 (1971)); see also *Saxton v. Carey*, 378 N.E.2d 95, 98-99 (N.Y. 1978) (abstaining from deciding the sufficiency of itemization of the state budget because such a decision "is best left to the Legislature, for it is not something which can be accurately delineated by a court"); *Jones v. Beame*, 380 N.E.2d 277, 279-280 (N.Y. 1978) (declining to address the allocation of the state's resources because such issues raise "questions of broad legislative and administrative policy beyond the scope of judicial correction").

⁶⁹ 94 Cal.App.4th at 794-96.

⁷⁰ *Id.*

⁷¹ *Id.*

system by transferring too much risk to the intermediary without adequate oversight.⁷² The court abstained because it found that ruling on the case would have required it to make determinations regarding the appropriate levels of capitation and oversight in the healthcare finance industry.⁷³ The court noted that in cases involving complex economic policies “equitable abstention is appropriate” because “it is primarily a legislative and not a judicial function to determine the best economic policy.”⁷⁴

This case is similar. Plaintiff is asking the Court to impose a remedy that the State of Wisconsin’s executive and legislative branches themselves are free to, but have chosen not to, adopt. As in *Desert Healthcare*, doing so would “pull the court deep in the thicket of the health care finance industry, an economic arena that courts are ill-equipped to meddle in.”⁷⁵ Tellingly, Plaintiff presents *no evidence* contradicting this point. Although it makes a number of *unsupported assertions* about why and how it used AWP, it ultimately concedes that its AWP-based reimbursement formula was the result of a complex political process.⁷⁶ It offers no evidence that the Court has the necessary resources to reform the reimbursement system or manage the likely consequences of such a decision.

In contrast, Defendants have cited to evidence showing that Plaintiff chose to use an AWP-based reimbursement formula (despite having access to acquisition cost information) to carry out its goals of ensuring beneficiaries equal access to care and providing adequate provider reimbursement. The evidence submitted by Defendants shows that Plaintiff accomplished this goal by using AWP minus a percentage, which it understood represented more than a providers’ cost for a drug, to subsidize its low dispensing fees and provide pharmacies a reasonable profit on their Medicaid business.

⁷² *Id.*

⁷³ *Id.* at 795-96.

⁷⁴ *Id.*

⁷⁵ *Id.*

⁷⁶ Plaintiff’s Br., Appx. B ¶¶ 50-58.

Plaintiff's position that it would have been illegal for it to use AWP in this fashion is simply wrong. The *only* federal limit on the amount a State may reimburse under its Medicaid program for single-source and multi-source pharmaceuticals not subject to a federal upper limit ("FUL")⁷⁷ is that it cannot exceed *in the aggregate*, the lower of (1) the estimated acquisition cost and a reasonable dispensing fee, or (2) the provider's usual and customary charge. The application of the rules of statutory construction makes clear that this limitation is on the *total* amount paid to providers and does not prescribe any limit on either part of the total reimbursement (or, indeed, even require a state to separate out its EAC and dispensing fee components).⁷⁸ As long as the total amount paid does not exceed a State's best estimate of ingredient costs plus a reasonable dispensing fee, it is permissible under the federal regulations. Were there any doubt, Defendants have submitted an affidavit from Robert Helms, who chaired the task force responsible for drafting the regulation, who unequivocally confirms this interpretation.⁷⁹ Plaintiff, by contrast, has presented nothing to support its position beyond baseless, self-serving speculation.

Even if federal regulations did prohibit Wisconsin from using the dispensing fee to cross-subsidize inadequate ingredient cost reimbursement (which they do not), Defendants have presented evidence that the State knew and embraced such cross-subsidization. Plaintiff's assertions to the contrary are neither supported by actual evidence nor accurately reflect what actually occurred,⁸⁰ and Plaintiff has presented no evidence to

⁷⁷ Drug reimbursement for multi-source drugs that are subject to a FUL must not exceed, in the aggregate, a reasonable dispensing fee plus the FUL established by the federal Centers for Medicare and Medicaid Services ("CMS"). See 42 C.F.R. § 447.512(a).

⁷⁸ For example, Wisconsin currently reimburses for physician-administrated vaccines on the basis of AWP+6%, and does not calculate or pay a separate dispensing fee. See Wisconsin Medicaid and BadgerCare Update, *Reimbursement Changes for Provider Administered Drug Codes* at 1 (Sept. 2005) (attached as Ex. G).

⁷⁹ DAPUF ¶ 104.

⁸⁰ Plaintiff's Opposition contains a number of supposed "statements of fact" that distort the record. For example, Plaintiff argues that Wisconsin was "unimpressed" by the complaints of

dispute the fact that Wisconsin knowingly used the profit on the ingredient cost portion of the reimbursement to cross-subsidize providers for demonstrably inadequate dispensing fees.

The Court should not be swayed by the vague and unsupported assertions made by Plaintiff.⁸¹ The *evidence* – not argument – shows that the Wisconsin legislative and executive branches deliberately continued reimbursing Medicaid providers based on a discounted AWP to carry out certain policy goals. As such, the Court should refrain from second-guessing the deliberate policy decisions made by the other branches of government and abstain from hearing this case.

pharmacists (Plaintiff's Br. at 45), despite evidence indicating the contrary (DAPUF ¶¶ 72, 98-99, 101-03, 137-141, 143-47, 150-52, 156-60, 178-86). Additionally, Plaintiff's statement that "Defendants' assertion that the federal government knows of and approves this practice is supported exclusively by the statement of one Reagan-era official," (Plaintiff's Br. at 45) completely ignores the testimony of Bruce Vladeck, Thomas Scully, Larry Reed and Linda Ragone, more recent CMS employees whose depositions were cross-noticed in this action (DAPUF ¶¶ 6, 80-81), and that CMS repeatedly approved Wisconsin's State Plan Amendments with full knowledge that Wisconsin's reimbursement formula overcompensated providers for the ingredient costs of drugs (DAPUF ¶¶ 6, 56-57, 60, 73, 80-81). Finally, Plaintiff contorts the testimony of State designee James Vavra. Mr. Vavra never said that "any profit the pharmacists would earn had to come through the dispensing fee." In fact, he stated, "[a]gain, most of the work we had done in setting pharmacy rates were based on the Federal principle of estimated acquisition cost close to what the pharmacist obtained the funds at plus a reasonable dispensing fee, according to this document, which included some profit margin, yes." Vavra Tr. at 77:9-14, Defendants' Joint Br., Ex. 1. This testimony, and the document which it concerns, show that Wisconsin intended its reimbursement, as a whole, to provide profit to pharmacists. Mr. Vavra's later testimony confirms this point, testifying that the Legislative Fiscal Bureau "look[ed] at reimbursement as a whole" when determining the adequacy of payments to pharmacists. Vavra Tr. at 336-37, Defendants' Joint Br., Ex. 1.

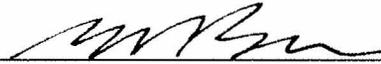
⁸¹ For example, Plaintiff asserts, without the benefit of any evidentiary support, that it could not abandon AWP because it was dependent on its computerized systems; it did not have access to acquisition cost information; and it believed its dispensing fees were too high. See Plaintiff's Br. at 44-45, 65-66.

CONCLUSION

For the foregoing reasons, Defendants are entitled to summary judgment as a matter of law on all of the claims contained in Plaintiff's Second Amended Complaint.

April 28, 2008

Respectfully submitted,



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CERTIFICATE OF SERVICE

I hereby certify that on April 28, 2008, a true and correct copy of the foregoing was served upon all counsel of record via electronic service pursuant to Case Management Order No. 1 by causing a copy to be sent to LexisNexis File & Serve for posting and notification.



EXHIBIT A



A Brief History of Refrigeration

1. Refrigeration in the pre-refrigerating-equipment era

Natural ice

People living in temperate zones soon realized that perishable foods kept much better in winter than in summer. The use of "natural refrigeration" began in the distant past and lasted a very long time: early in the 20th century, the natural-ice market was still bigger than the man-made ice market. Naturally produced ice (i.e. that produced without refrigerating equipment):

- originated in cold regions and was transported over large distances;
- or originated in rivers, lakes and ponds, where freezing took place during winter in temperature regions. Once harvested, this ice had to be stored in ice-storage facilities with thermally insulated walls.
- or was produced by man using natural cooling. In countries with clear skies, ice was produced in open ponds. Thermal radiation from the water made it possible, under certain atmospheric conditions, to achieve sufficient cooling to form ice.¹

Refrigerating mixtures

The chilling effects of the addition of certain salts to water was discovered, no doubt by accident, in the distant past. Ibn Abi Usaibia, an Arabic writer, appears to have been the first to mention the use of these type of mixtures in India during the 4th century.

An Italian physician called Zimara mentioned the use of water chilling using potassium nitrate in Padua in 1530 and Blas Villafranca, a Spanish physician, recorded similar practices in Rome in 1550. It was later demonstrated that by mixing snow and salts, even lower temperatures could be achieved. These phenomena were described by Battista Porta in 1589 and Tancredo in 1607.

2. Pioneers and scholars

In the 17th century, heat and cold fuelled reflections conducted by scholars and philosophers such as Robert Boyle (1627-1691) in England and Mikhail Lomonossov (1711-1765) in Russia. Over the same period, following Galileo's initial research, many studies were performed in the thermometry field by illustrious scholars: Guillaume Amontons (1663-1705) in France, Isaac Newton (1642-1727) in England, Daniel Fahrenheit (1686-1736), a German who worked in England and The Netherlands, René de Réaumur (1683-1757) in France and Anders Celsius (1701-1744) who invented the centesimal-scale thermometer in Sweden in 1742.

William Cullen (1710-1790) observed that when ethyl ether evaporated, it was accompanied by a fall in temperature. In 1755, he succeeded in obtaining a small quantity of ice by evaporating water under a bell jar. His disciple and successor, the Scotsman Joseph Black (1728-1799), clarified the notions of heat and temperature, and can be considered as being the founder of calorimetry. Several French scholars excelled in this domain: Pierre Simon de Laplace (1749-

¹ Using a suitably cautious approach, Professor Trombe was able to cool black surfaces exposed to a clear sky at temperatures of 30 - 35 K below the ambient temperature. During the the 5th century the Greek Protogoras reported that Nile-Valley Egyptians made ice in this way by placing containers on the roofs of their houses.

1827), Pierre Dulong (1785-1838) and Alexis Petit (1791-1820), Nicolas Clément-Desormes (1778-1841) and Victor Regnault (1810-1878).

Research conducted by the Scotsman James Watt (1736-1819) on the steam engine, research on gases performed by the physicists Boyle (in England), Edme Mariotte (1620-1684) then Jacques Charles (1746-1823) and Louis Joseph Gay-Lussac (1778-1850) (in France), and experimental work performed by the American Benjamin Thomson (1753-1814), paved the way to the emergence of thermodynamics. The Frenchman Sadi Carnot (1796-1832) was the first to enter the limelight, in 1824, when he published his famous treatise that was to prove to be the starting point for the second law of thermodynamics. During the 19th century, a great deal of research was devoted to various refrigerating systems, and thermodynamics was a fast-growing discipline thanks to studies performed by the following, among others: James Prescott Joule (1818-1889) in England, Julius von Mayer (1814-1878), Herman von Helmholtz (1821-1894), and Rudolph Clausius (1822-1888) in Germany, Ludwig Boltzmann (1844-1906) in Austria and William Thomson (Lord Kelvin) (1824-1907) in England. Other famous physicists were drivers of the development of thermodynamics during the 20th century.

3. The advent of refrigerating systems

Refrigerating systems fall into two main categories: those that require mechanical energy or its equivalent in order to operate (these are called *mechanical refrigerating systems*), and those consuming essentially thermal energy (these are called *thermal refrigerating systems*).

3.1. Mechanical refrigerating systems

These systems can be divided into two main categories:

- vapour-compression systems using liquefiable vapour,
- gas-cycle systems.

Vapour-compression systems

The working fluid of the refrigerating cycle, the *refrigerant*, vaporizes in an *evaporator*, producing useful cooling. The vapour produced is aspirated and compressed by a *mechanical compressor*. It then returns to the *condenser* where it is liquefied. The liquid formed returns to the evaporator via a *regulator* (or *expansion device*). This is by far the most widely used system.

The American Oliver Evans (1755-1819) was the first to describe this cycle, in 1805. However, it was Jacob Perkins (1766-1849), an American working in England, who first patented a machine based on this cycle (in 1835); the machine ran on ethyl ether. The first compression machines that proved to be successful on an industrial scale were developed by James Harrison (1816-1893), a Scotsman who had emigrated to Australia; Harrison patented his inventions in 1855, 1856 and 1857). Harrison's machines were manufactured in England, and were capable of producing ice or cooling brine (a *secondary refrigerant*). The refrigerant used was still ethyl ether.

Two new refrigerants then came into use:

- *dimethyl ether*: the Frenchman Charles Tellier (1828-1913) introduced this refrigerant.
- *carbon dioxide* (CO_2) was used by the American Thaddeus Lowe (1832-1913). It then fell into disuse, but is now experiencing a comeback.
- *ammonia* (NH_3), was first investigated by Tellier (in 1862), but it was the American David Boyle (1837-1891) and above all the German Carl von Linde (1842-1934) who were the first to apply it on a broad scale in the industrial field. It is still used.
- *sulphur dioxide* (SO_2) was first implemented by the Swiss physicist Raoul Pierre Pictet (1846-1929) and fell into disuse just before the Second World War.
- *methyl chloride* (CH_3Cl) was first employed by the Frenchman C. Vincent in 1878, and remained in use for many years: use ceased in the 1960s.
- *fluorocarbon refrigerants* were developed as safe (non-toxic and non-flammable) refrigerants; following research conducted by Swarts, (in 1893-1907) in Ghent, an American team at Frigidaire Corporation, headed by Thomas Midgley, developed the first

fluorocarbon refrigerants, in 1930. The first CFC, R12 (CF_2Cl_2) came onto the market in 1931, and was followed by the first HCFC, R22 (CHF_2Cl), in 1934, then in 1961, the first azeotropic mixture, R502 (R22/R115).

In 1974, two US Nobel prizewinners, F. S. Rowland and M. J. Molina, published disturbing findings: they suspected that the chlorine released by halogenated hydrocarbons was adversely affecting the ozone layer. This is why the Montreal Protocol (1987) on ozone-depleting substances and its subsequent amendments banned CFCs and HCFCs. Other halogenated (but not chlorinated) refrigerants are now used: these include pure HFCs such as R134a, HFC mixtures (R410A, R407C, R404A, etc.), these being refrigerants with varying global-warming impacts. "Natural" refrigerants, including ammonia, hydrocarbons, water and CO_2 , are being introduced or are making a comeback; use of these refrigerants involves more constraints but their global-warming impacts are non-existent or low.

Components of compression systems have also been considerably improved over the years. The heavy, slow and voluminous pistons used late in the 19th century have gradually given way to faster, lighter equipment. New types of compressors have been developed over the years: A. Lysholm developed a screw compressor with twin rotors in Sweden (1934), B. Zimmern developed a screw compressor with a single rotor in France in 1967, the scroll compressor was developed in the 1970s (this technology was patented by the Frenchman Léon Creux in 1905), and centrifugal compressors were developed (following fundamental research performed by the Frenchman Auguste Rateau in 1890, and that conducted by the American Willis Carrier in 1911).

Soon after these systems started to be used, ways of reducing refrigerant leakage were sought, and hermetic refrigerating units were developed in order to address this problem. The first unit of this type was a strange one invented by Father Audiffren in France, in 1905. Hermetic units are now widely used.

Heat exchangers (condensers and evaporators) have also been improved and are now much lighter.

Systems using gas cycles

In these systems, the working fluid does not undergo phase change during the refrigerating cycle: it remains in the gaseous phase. The compressed gas heats up, then is cooled under pressure down to the ambient temperature, then is expanded, leading to cooling.

The first open-cycle "air machine" was invented by John Gorrie (1803-1855), an American physician, in order to cool brine to a temperature of -7°C (Gorrie patented successive versions in 1850 and 1851). Based on the hot-air motor developed by the Scottish pastor Robert Stirling in 1837, Alexander Kirk (1830-1892), a Scottish mechanical engineer, developed a closed-cycle machine that produced, over a 10-year period starting in 1864, temperatures of -13°C . The German Franz Windhausen (1829-1904), the American Leicester Allen (1832-1912) and the Frenchman Paul Giffard (1837-1897) all played key roles in the development of this technology.

The development of these systems was hampered by their reduced efficiency (with respect to vapour-compression systems) in the refrigeration, freezing and air-conditioning fields. However, they are used in most cryogenic cycles in order to liquefy gases and produce low temperatures.

Thermoelectric systems

In 1834, the French physicist Jean Charles Peltier (1785-1845) discovered that the passage of continuous current through a junction of two metals triggered cooling in one metal and a temperature rise (through heat absorption) in the other junction. Thermoelectricity was for a long time considered as simply a scientific curiosity, but developed during the period ranging from the 1940s to the 1960s during which knowledge of semi-conductors expanded. However, although

this technology seemed promising initially, it has not achieved extensive penetration and is relatively little used today.

3.2. Thermal refrigerating systems

These refrigerating systems consume thermal energy and fall into the following categories:

- absorption systems,
- adsorption and thermochemical systems,
- ejection systems.

Absorption refrigerating systems

Although these systems are far less widely used than compression systems, they are the only thermal refrigerating systems that are currently encountering a degree of development. In these systems, instead of using a mechanical compressor to circulate the refrigerant, a pump is used to circulate an absorbent liquid, the quantity of which, in terms of absorbed refrigerant, depends on the temperature and the pressure. The mechanical work is very reduced; however, this system requires heat.

The "father" of these systems was the Frenchman Ferdinand Carré (1824-1900), who in 1859 patented the first continuous absorption machine using ammonia/water (with water as absorbent) as the working pair. These machines were almost immediately operational. It was only in 1913 when the German Edmund Altenkirch starting investigating them, that the thermodynamic properties of these systems began to be elucidated, and studies were performed throughout the first half of the 20th century. Work performed by the Italian Guido Maiuri on these systems, and studies performed by the Swedes von Platen and Munters on the absorption-diffusion cycle of pumpless absorption refrigerators (in 1920) are noteworthy. In the US during the 1940s, water-lithium bromide absorption systems, with water used as refrigerant, came into use; this type of system is based on a modified Carré cycle and has been widely used in the air-conditioning field.

Although discontinuous absorption refrigerating systems were among the first absorption systems to be developed (e.g. the water-chilling system invented by Edmond Carré² in 1866) but encountered very little success.

Adsorption and thermochemical adsorption systems

These systems were developed much later, essentially during the first half of the 20th century. The operating principle, based on the thermal effects accompanying the physical sorption or desorption of a gas on a solid (adsorption systems), or the forming or the breakdown of chemical compounds using a gas refrigerant (thermochemical systems), and is naturally discontinuous. These systems are little used but are being widely investigated.

Ejection refrigerating systems

Although water is not the only refrigerant that can be used, the first ejection systems, developed in 1908, operated on water (in the form of steam). The Frenchman Maurice Leblanc (1857-1923) was the inventor of this system.

This system operates using cooled water that changes into vapour at low pressure; the vapour is then aspirated using an ejector that is fed by a steam jet supplied by a boiler. The ejector comprises a combining nozzle – raising the flow rate of the jet reduces the pressure, enabling the desired degree of suction to take place – then a delivery nozzle – the gradual increase in diameter of the nozzle reduces the flow rate and the pressure is raised again. This system has specific application niches but is far from widely used.

² Ferdinand Carré's brother

4- A few salient dates in the gas liquefaction and very-low-temperature refrigeration fields – cryogenics

The cryogenic field is generally considered as comprising temperatures below 120 K (-153.15°C).³

- 1877: Louis Cailletet, in Paris, then Raoul Pictet, in Geneva, liquefied (in a transitory manner) oxygen.
- 1883: K. Olszewski and S. Wroblewski liquefied (durably), in Kraków, oxygen (boiling point $T_{eb} = 90$ K) and nitrogen ($T_{eb} = 77$ K).
- 1895: Carl von Linde, in Germany, obtained, using Joule-Thomson expansion (using a valve, without external work), 3 litres of liquid air per hour.
- 1898: Liquefaction of hydrogen ($T_{eb} = 20.4$ K), in London, by James Dewar.
- 1902: Georges Claude liquefied air using equipment with an expansion device, with external work.
- 1908: Helium liquefaction ($T_{eb} = 4.2$ K), in Leiden, by Heike Kamerlingh Onnes.
- 1911: Accidental discovery of mercury supraconductivity by Kamerlingh Onnes in Leiden; Kamerlingh Onnes began using the term "supraconductivity" in March 1913.
- 1926: Separate descriptions of a cooling process using adiabatic demagnetization by W. F. Giauque (Canada) and P. Debye (The Netherlands).
- 1931: Demonstration of the existence, in Leiden, of point λ (2.17 K) by W.H. Keesom and K. Clusius: – Helium I (normal) – Helium II (superfluid).
- 1933: First experiments on adiabatic demagnetization by Giauque in Berkeley (USA) (0.53 – 0.25 K).
- 1931 – 1938: Series of studies on helium superfluidity: Burton, A.D. Misener, H. Jones, P. Kapitza, J. G. Daunt, K. Mendelssohn, F. London, L. Tisza.
- 1956: Nuclear adiabatic demagnetization (13 μ K): Kurti, Robinson, Simon and Spohr (Oxford).
- 1965: Dilution cooling of ^3He in ^4He (2 mK): B.S. Neganov (USSR); De Bruyn Ouboter and K. W. Taconis (The Netherlands).
- 1983: Coolong of copper electrons (20 nK) by O. Lounasmaa (Finland)
- 1986: O. Lounasmaa: at around 1 nK, silver becomes a magnet.
- 1986: J. G. Bednorz and K. A. Muller discovered "high-temperature" superconductivity (35 K).

³ Note that 0°C = 273.15 K (K pour kelvin), temperature expressed using the Kelvin absolute scale.

EXHIBIT B

food preservation

 Encyclopædia Britannica Article

food preservation

any of a number of methods by which food is kept from spoilage after harvest or slaughter. Such practices date to prehistoric times. Among the oldest methods of preservation are drying, refrigeration, and fermentation. Modern methods include canning, pasteurization, freezing, irradiation, and the addition of chemicals. Advances in packaging materials have played an important role in modern food preservation.

Spoilage mechanisms

Food spoilage may be defined as any change that renders food unfit for human consumption. These changes may be caused by various factors, including contamination by microorganisms, infestation by insects, or degradation by endogenous enzymes (those present naturally in the food). In addition, physical and chemical changes, such as the tearing of plant or animal tissues or the oxidation of certain constituents of food, may promote food spoilage. Foods obtained from plant or animal sources begin to spoil soon after harvest or slaughter. The enzymes contained in the cells of plant and animal tissues may be released as a result of any mechanical damage inflicted during postharvest handling. These enzymes begin to break down the cellular material. The chemical reactions catalyzed by the enzymes result in the degradation of food quality, such as the development of off-flavours, the deterioration of texture, and the loss of nutrients. The typical microorganisms that cause food spoilage are bacteria (*e.g.*, *Lactobacillus*), yeasts (*e.g.*, *Saccharomyces*), and molds (*e.g.*, *Rhizopus*).

Microbial contamination

Bacteria and fungi (yeasts and molds) are the principal types of microorganisms that cause food spoilage and food-borne illnesses. Foods may be contaminated by microorganisms at any time during harvest, storage, processing, distribution, handling, or preparation. The primary sources of microbial contamination are soil, air, animal feed, animal hides and intestines, plant surfaces, sewage, and food processing machinery or utensils.

Bacteria

Bacteria are unicellular organisms that have a simple internal structure compared with the cells of other organisms. The increase in the number of bacteria in a population is commonly referred to as bacterial growth by microbiologists. This growth is the result of the division of one bacterial cell into two identical bacterial cells, a process called binary fission. Under optimal growth conditions, a bacterial cell may divide approximately every 20 minutes. Thus, a single cell can produce almost 70 billion cells in 12 hours. The factors that influence the growth of bacteria include nutrient availability, moisture, pH, oxygen levels, and the presence or absence of inhibiting substances (*e.g.*, antibiotics).

The nutritional requirements of most bacteria are chemical elements such as carbon, hydrogen, oxygen, nitrogen, phosphorus, sulfur, magnesium, potassium, sodium, calcium, and iron. The bacteria obtain these elements by utilizing gases in the atmosphere and by metabolizing certain food constituents such as carbohydrates and proteins.

Temperature and pH play a significant role in controlling the growth rates of bacteria.

Bacteria may be classified into three groups based on their temperature requirement for optimal growth: thermophiles (55°-75° C, or 130°-170° F), mesophiles (20°-45° C, or 70°-115° F), or psychrotrophs (10°-20° C, or 50°-70° F). In addition, most bacteria grow best in a neutral environment (pH equal to 7).

Bacteria also require a certain amount of available water for their growth. The availability of water is expressed as water activity and is defined by the ratio of the vapour pressure of water in the food to the vapour pressure of pure water at a specific temperature. Therefore, the water activity of any food product is always a value between 0 and 1, with 0 representing an absence of water and 1 representing pure water. Most bacteria do not grow in foods with a water activity below 0.91, although some halophilic bacteria (those able to tolerate high salt concentrations) can grow in foods with a water activity lower than 0.75. Growth may be controlled by lowering the water activity—either by adding solutes such as sugar, glycerol, and salt or by removing water through dehydration.

The oxygen requirements for optimal growth vary considerably for different bacteria. Some bacteria require the presence of free oxygen for growth and are called obligate aerobes, whereas other bacteria are poisoned by the presence of oxygen and are called obligate anaerobes. Facultative anaerobes are bacteria that can grow in both the presence or absence of oxygen. In addition to oxygen concentration, the oxygen reduction potential of the growth medium influences bacterial growth. The oxygen reduction potential is a relative measure of the oxidizing or reducing capacity of the growth medium.

When bacteria contaminate a food substrate, it takes some time before they start growing. This lag phase is the period when the bacteria are adjusting to the environment. Following the lag phase is the log phase, in which population grows in a logarithmic fashion. As the population grows, the bacteria consume available nutrients and produce waste products. When the nutrient supply is depleted, the growth rate enters a stationary phase in which the number of viable bacteria cells remains the same. During the stationary phase, the rate of bacterial cell growth is equal to the rate of bacterial cell death. When the rate of cell death becomes greater than the rate of cell growth, the population enters the decline phase.

A bacterial population is expressed either per gram or per square centimetre of surface area. Rarely does the total bacterial population exceed 10^{10} cells per gram. A population of less than 10^6 cells per gram does not cause any noticeable spoilage except in raw milk. Populations of between 10^6 and 10^7 cells per gram cause spoilage in some foods; for example, they can generate off-odours in vacuum-packaged meats. Populations of between 10^7 and 10^8 cells per gram produce off-odours in meats and some vegetables. At levels above 5×10^7 cells per gram, most foods exhibit some form of spoilage.

When the conditions for bacterial cell growth are unfavourable (e.g., low or high temperatures or low moisture content), several species of bacteria can produce resistant cells called endospores. Endospores are highly resistant to heat, chemicals, desiccation (drying out), and ultraviolet light. The endospores may remain dormant for long periods of time. When conditions become favourable for growth (e.g., thawing of meats), the endospores germinate and produce viable cells that can begin exponential growth.

Fungi

The two types of fungi that are important in food spoilage are yeasts and molds. Molds are multicellular fungi that reproduce by the formation of spores (single cells that can grow into a mature fungus). Spores are formed in large numbers and are easily dispersed through the

air. Once these spores land on a food substrate, they can grow and reproduce if conditions are favourable. Yeasts are unicellular fungi that are much larger than bacterial cells. They reproduce by cell division (binary fission) or budding.

The conditions affecting the growth of fungi are similar to those affecting bacteria. Both yeasts and molds are able to grow in an acidic environment (pH less than 7). The pH range for yeast growth is 3.5 to 4.5 and for molds is 3.5 to 8.0. The low pH of fruits is generally unfavourable for the growth of bacteria, but yeasts and molds can grow and cause spoilage in fruits. For example, species of the fungal genus *Colletotrichum* cause crown rot in bananas. Yeasts promote fermentation in fruits by breaking down sugars into alcohol and carbon dioxide. The amount of available water in a food product is also critical for the growth of fungi. Yeasts are unable to grow at a water activity of less than 0.9, and molds are unable to grow at a water activity below 0.8.

Control of microbial contamination

The most common methods used either to kill or to reduce the growth of microorganisms are the application of heat, the removal of water, the lowering of temperature during storage, the reduction of pH, the control of oxygen and carbon dioxide concentrations, and the removal of the nutrients needed for growth. The use of chemicals as preservatives is strictly regulated by governmental agencies such as the Food and Drug Administration (FDA) in the United States. Although a chemical may have preservative functions, its safety must be proved before it may be used in food products. To suppress yeast and mold growth in foods, a number of chemical preservatives are permitted. In the United States, the list of such chemicals, known as GRAS (Generally Recognized as Safe), includes compounds such as benzoic acid, sodium benzoate, propionic acid, sorbic acid, and sodium diacetate.

Chemical deterioration

Enzymatic reactions

Enzymes are large protein molecules that act as biological catalysts, accelerating chemical reactions without being consumed to any appreciable extent themselves. The activity of enzymes is specific for a certain set of chemical substrates, and it is dependent on both pH and temperature.



The living tissues of plants and animals maintain a balance of enzymatic activity. This balance is disrupted upon harvest or slaughter. In some cases, enzymes that play a useful role in living tissues may catalyze spoilage reactions following harvest or slaughter. For example, the enzyme pepsin is found in the stomach of all animals and is involved in the breakdown of proteins during the normal digestion process. However, soon after the slaughter of an animal, pepsin begins to break down the proteins of the organs, weakening the tissues and making them more susceptible to microbial contamination. After the harvesting of fruits, certain enzymes remain active within the cells of the plant tissues. These enzymes continue to catalyze the biochemical processes of ripening and may eventually lead to rotting, as can be observed in bananas. In addition, oxidative enzymes in fruits continue to carry out cellular respiration (the process of using oxygen to metabolize glucose for energy). This continued respiration decreases the shelf life of fresh fruits and may lead to spoilage. Respiration may be controlled by refrigerated storage or modified-atmosphere packaging. Table 1 lists a number of enzymes involved in the degradation of food quality.

Autoxidation

The unsaturated fatty acids present in the lipids of many foods are susceptible to chemical breakdown when exposed to oxygen. The oxidation of unsaturated fatty acids is autocatalytic; that is, it proceeds by a free-radical chain reaction. Free radicals contain an unpaired electron (represented by a dot in the molecular formula) and, therefore, are highly reactive chemical molecules. The basic mechanisms in a free-radical chain reaction involve initiation, propagation, and termination steps (Figure 1). Under certain conditions, in initiation a free-radical molecule ($X \cdot$) present in the food removes a hydrogen (H) atom from a lipid molecule, producing a lipid radical ($L \cdot$). This lipid radical reacts with molecular oxygen (O_2) to form a peroxy radical ($LOO \cdot$). The peroxy radical removes a hydrogen atom from another lipid molecule and the reaction starts over again (propagation). During the propagation steps, hydroperoxide molecules ($LOOH$) are formed that may break down into alkoxy ($LO \cdot$) and peroxy radicals plus water (H_2O). The lipid, alkoxy, and peroxy radicals may combine with one another (or other radicals) to form stable, nonpropagating products (termination). These products result in the development of rancid off-flavours. In addition to promoting rancidity, the free radicals and peroxides produced in these reactions may have other negative effects, such as the bleaching of food colour and the destruction of vitamins A, C, and E. This type of deterioration is prevalent in fried snacks, nuts, cooking oils, and margarine.

Maillard reaction

Another chemical reaction that causes major food spoilage is nonenzymatic browning, also known as the Maillard reaction. This reaction takes place between reducing sugars (simple monosaccharides capable of carrying out reduction reactions) and the amino group of proteins or amino acids present in foods. The products of the Maillard reaction lead to a darkening of colour, reduced solubility of proteins, development of bitter flavours, and reduced nutritional availability of certain amino acids such as lysine. The rate of this reaction is influenced by the water activity, temperature, and pH of the food product. Nonenzymatic browning causes spoilage during the storage of dry milk, dry whole eggs, and breakfast cereals.

Light-induced reactions

Light influences a number of chemical reactions that lead to spoilage of foods. These light-induced reactions include the destruction of chlorophyll (the photosynthetic pigment that gives plants their green colour), resulting in the bleaching of certain vegetables; the discoloration of fresh meats; the destruction of riboflavin in milk; and the oxidation of vitamin C and carotenoid pigments (a process called photosensitized oxidation). The use of packaging material that prevents exposure to light is one of the most effective means of preventing light-induced chemical spoilage.

Low-temperature preservation

Storage at low temperatures prolongs the shelf life of many foods. In general, low temperatures reduce the growth rates of microorganisms and slow many of the physical and chemical reactions that occur in foods.

Refrigeration

The life of many foods may be increased by storage at temperatures below 4° C (40° F). Commonly refrigerated foods include fresh fruits and vegetables, eggs, dairy products, and

meats. Some foods, such as tropical fruits (e.g., bananas), are damaged if exposed to low temperatures. Also, refrigeration cannot improve the quality of decayed food; it can only retard deterioration. One problem of modern mechanical refrigeration—that of dehydration of foods due to moisture condensation—has been overcome through humidity control mechanisms within the storage chamber and by appropriate packaging techniques.

Freezing

Freezing and frozen storage provide an excellent means of preserving the nutritional quality of foods. At subfreezing temperatures the nutrient loss is extremely slow for the typical storage period used in commercial trade.

History

Early freezing methods were based on the principle that mixing salt with ice results in temperatures well below 0° C (32° F). By the end of the 19th century, this method was being used commercially in the United States to freeze fish and poultry. By the 1920s Clarence Birdseye had developed two processes for freezing fish based on his quick freezing theory. His first patent, describing a method for preserving piscatorial products, involved placing food between two metal plates that were chilled by a calcium chloride solution to approximately -40° C (-40° F). The second process utilized two hollow metal plates that were cooled to -25° C (-13° F) by vaporization of ammonia. This freezing apparatus was the forerunner of the multiple plate freezer that is widely used in the modern food industry.

The freezing process

The freezing of food involves lowering its temperature below 0° C, resulting in the gradual conversion of water, present in the food, into ice. Freezing is a crystallization process that begins with a nucleus or a seed derived from either a nonaqueous particle or a cluster of water molecules (formed when the temperature is reduced below 0° C). This seed must be of a certain size to provide an adequate site for the crystal to begin to grow. If physical conditions are conducive to the presence of numerous seeds for crystallization, then a large number of small ice crystals will form. However, if only a few seeds are initially available, then a few ice crystals will form and each will grow to a large size. The size and the number of ice crystals influence the final quality of many frozen foods; for example, the smooth texture of ice cream indicates the presence of a large number of small ice crystals.

In pure water, the freezing process is initiated by lowering the temperature to slightly below 0° C, called supercooling. As ice crystals begin to grow, the temperature returns to the freezing point. During the conversion of liquid water to ice, the temperature of the system does not change. The heat removed during this step is called the latent heat of fusion (equivalent to 333 joules per gram of water). Once all the water is converted to ice, any additional removal of heat will result in a decrease in the temperature below 0° C.

The freezing of foods exhibits a number of important differences from the freezing of pure water. Foods do not freeze at 0° C. Instead, owing to the presence of different soluble particulates (solutes) in the water present in foods, most foods begin to freeze at a temperature between 0° and -5° C (32° and 23° F). In addition, the removal of latent heat in foods during freezing does not occur at a fixed temperature. As the water present in the food freezes into ice, the remaining water becomes more concentrated with solutes. As a result, the freezing point is further depressed. Therefore, foods have a zone of maximum ice crystal formation that typically extends from -1° to -4° C (30° to 25° F). Damage to food quality during freezing can be minimized if the temperature of the product is brought below this temperature range as quickly as possible.

Industrial freezers

The rate at which heat is removed from a food during freezing depends on how fast heat can travel within the food and how efficiently it can be liberated from the surface of the food into the surrounding atmosphere. Industrial freezers remove heat from the surface of a food as rapidly as possible. There are several types of industrial freezers, including air-blast tunnel freezers, belt freezers, fluidized-bed freezers, plate freezers, and cryogenic freezers.

In air-blast tunnel freezers and belt freezers, precooled air at approximately -40°C is blown over the food products. Packaged foods, such as fruits, vegetables, bakery goods, poultry, meats, and prepared meals, are usually frozen in air-blast tunnels. The packages are placed onto dollies or hand trucks and then rolled into the freezer tunnels. In a belt freezer, food is placed on a conveyor belt that moves through a freezing zone. Bakery goods, chicken parts, and meat patties are frozen using a belt freezer.

Fluidized-bed freezers are used to freeze particulate foods such as peas, cut corn, diced carrots, and strawberries. The foods are placed on a mesh conveyor belt and moved through a freezing zone in which cold air is directed upward through the mesh belt and the food particulates begin to tumble and float. This tumbling exposes all sides of the food to the cold air and minimizes the resistance to heat transfer at the surface of the food.

Plate freezers are used to freeze flat products, such as pastries, fish fillets, and beef patties, as well as irregular-shaped vegetables that are packaged in brick-shaped containers, such as asparagus, cauliflower, spinach, and broccoli. The food is firmly pressed between metal plates that are cooled to subfreezing temperatures by internally circulating refrigerants.

Cryogenic freezing is used to freeze food at an extremely fast rate. The food is moved through a spray of liquid nitrogen or directly immersed in liquid nitrogen. The liquid nitrogen boils around the food at a temperature of -196°C (-321°F) and extracts a large amount of heat.

Quality of frozen foods

Improper freezing or storage of foods may result in detrimental quality changes. When foods with high amounts of water are frozen slowly, they may experience a loss of fluid, called drip, upon thawing. This fluid loss causes dehydration and nutrient loss in frozen food products.

During frozen storage, the ice crystals present in foods may enlarge in size, producing undesirable changes in texture. This phenomenon is commonly observed when the storage temperature is allowed to fluctuate. For example, ice cream stored in an automatic defrosting domestic freezer becomes sandy in texture because the ice crystals increase in size as the temperature of the system fluctuates.

Improperly packaged frozen foods lose small amounts of moisture during storage, resulting in surface dehydration (commonly called freezer burn). Frozen meats with freezer burn have the appearance of brown paper and quickly become rancid. Freezer burn can be minimized by the use of tightly wrapped packages and the elimination of fluctuating temperatures during storage.

Thermal processing

Thermal processing is defined as the combination of temperature and time required to eliminate a desired number of microorganisms from a food product.

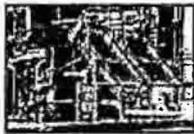
Canning

Nicolas Appert, a Parisian confectioner by trade, is credited with establishing the heat processing of foods as an industry. In 1810 he received official recognition for his process of enclosing food in bottles, corking the bottles, and placing the bottles in boiling water for various periods of time. In the same year Peter Durand received a British patent for the use of containers made of glass, pottery, tin, or other metals for the heat preservation of foods. In 1822 Ezra Daggett and Thomas Kensett announced the availability of preserved foods in tin cans in the United States. Tin-coated steel containers, made from 98.5 percent sheet steel with a thin coating of tin, soon became common. These cans had a double seamed top and bottom to provide an airtight seal and could be manufactured at high speeds.

The establishment of the canning process on a more scientific basis did not occur until 1896, when the microorganism *Clostridium botulinum*, with its lethal toxin causing botulism, was discovered by Émile van Ermengem.

Presterilization procedures

Selected crop varieties are grown specially for canning purposes. The harvesting schedules of the crops are carefully selected to conform to the cannery operations. A typical canning operation involves cleaning, filling, exhausting, can sealing, heat processing, cooking, labeling, casing, and storage. Most of these operations are performed using high-speed, automatic machines.



Spray washing of harvested tomatoes

prior to processing.

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Cleaning involves the use of shakers, rotary reel cleaners, air blasters, water sprayers (as shown in Figure 2), or immersion washers. Any inedible or extraneous material is removed before washing, and only potable water is used in the cleaning systems.

Automatic filling machines are used to place the cleaned food into cans or other containers, such as glass jars or plastic pouches. When foods containing trapped air, such as leafy vegetables, are canned, the air must be removed from the cans prior to closing and sealing the lids by a process called exhausting. Exhausting is accomplished using steam exhaust hoods or by creation of a vacuum.

Immediately after exhausting, the lids are placed on the cans and the cans are sealed. An airtight seal is achieved between the lid and the rim of the can using a thin layer of gasket or compound. The anaerobic conditions prevent the growth of oxygen-requiring microorganisms. In addition, many of the spores of anaerobic microorganisms are less resistant to heat and are easily destroyed during the heat treatment.

Sterilization

The time and temperature required for the sterilization of foods are influenced by several factors, including the type of microorganisms found on the food, the size of the container, the acidity or pH of the food, and the method of heating.

The thermal processes of canning are generally designed to destroy the spores of the bacterium *C. botulinum*. This microorganism can easily grow under anaerobic conditions, producing the deadly toxin that causes botulism. Sterilization requires heating to

temperatures greater than 100° C (212° F). However, *C. botulinum* is not viable in acidic foods that have a pH less than 4.6. These foods can be adequately processed by immersion in water at temperatures just below 100° C.

The sterilization of low-acid foods (pH greater than 4.6) is generally carried out in steam vessels called retorts at temperatures ranging from 116° to 129° C (240° to 265° F). The retorts are controlled by automatic devices, and detailed records are kept of the time and temperature treatments for each lot of processed cans. At the end of the heating cycle, the cans are cooled under water sprays or in water baths to approximately 38° C (100° F) and dried to prevent any surface rusting. The cans are then labeled, placed in fibreboard cases either by hand or machine, and stored in cool, dry warehouses.

Quality of canned foods

The sterilization process is designed to provide the required heat treatment to the slowest heating location inside the can, called the cold spot. The areas of food farthest from the cold spot get a more severe heat treatment that may result in overprocessing and impairment of the overall quality of the product. Flat, laminated pouches can reduce the heat damage caused by overprocessing.

A significant loss of nutrients, especially heat-labile vitamins, may occur during the canning process. In general, canning has no major effect on the carbohydrate, protein, or fat content of foods. Vitamins A and D and beta-carotene are resistant to the effects of heat. However, vitamin B₁ is sensitive to thermal treatment and the pH of the food. Although the anaerobic conditions of canned foods have a protective effect on the stability of vitamin C, it is destroyed during long heat treatments.

The ends of processed cans are slightly concave because of the internal vacuum created during sealing. Any bulging of the ends of a can may indicate a deterioration in quality due to mechanical, chemical, or physical factors. This bulging may lead to swelling and possible explosion of the can.

Pasteurization

Pasteurization is the application of heat to a food product in order to destroy pathogenic (disease-producing) microorganisms, to inactivate spoilage-causing enzymes, and to reduce or destroy spoilage microorganisms. The relatively mild heat treatment used in the pasteurization process causes minimal changes in the sensory and nutritional characteristics of foods compared to the severe heat treatments used in the sterilization process.

The temperature and time requirements of the pasteurization process are influenced by the pH of the food. When the pH is below 4.5, spoilage microorganisms and enzymes are the main targets of pasteurization. For example, the pasteurization process for fruit juices is aimed at inactivating certain enzymes such as pectinesterase and polygalacturonase. The typical processing conditions for the pasteurization of fruit juices include heating to 77° C (171° F) and holding for 1 minute, followed by rapid cooling to 7° C (45° F). In addition to inactivating enzymes, these conditions destroy any yeasts or molds that may lead to spoilage. Equivalent conditions capable of reducing spoilage microorganisms involve heating to 65° C (149° F) and holding for 30 minutes or heating to 88° C (190° F) and holding for 15 seconds.

When the pH of a food is greater than 4.5, the heat treatment must be severe enough to destroy pathogenic bacteria. In the pasteurization of milk, the time and temperature

conditions target the pathogenic bacteria *Mycobacterium tuberculosis*, *Coxiella burnetii*, and *Brucella abortus*. The typical heat treatment used for pasteurizing milk is 72° C (162° F) for 15 seconds, followed by rapid cooling to 7° C. Other equivalent heat treatments include heating to 63° C (145° F) for 30 minutes, 90° C (194° F) for 0.5 second, and 94° C (201° F) for 0.1 second. The high-temperature-short-time (HTST) treatments cause less damage to the nutrient composition and sensory characteristics of foods and therefore are preferred over the low-temperature-long-time (LTLT) treatments.

Since the heat treatment of pasteurization is not severe enough to render a product sterile, additional methods such as refrigeration, fermentation, or the addition of chemicals are often used to control microbial growth and to extend the shelf life of a product. For example, the pasteurization of milk does not kill thermoduric bacteria (those resistant to heat), such as *Lactobacillus* and *Streptococcus*, or thermophilic bacteria (those that grow at high temperatures), such as *Bacillus* and *Clostridium*. Therefore, pasteurized milk must be kept under refrigerated conditions.

Liquid foods such as milk, fruit juices, beers, wines, and liquid eggs are pasteurized using plate-type heat exchangers. Wine and fruit juices are normally deaerated prior to pasteurization in order to remove oxygen and minimize oxidative deterioration of the products. Plate-type heat exchangers consist of a large number of thin, vertical steel plates that are clamped together in a frame. The plates are separated by small gaskets that allow the liquid to flow between each successive plate. The liquid product and heating medium (e.g., hot water) are pumped through alternate channels, and the gaskets ensure that the liquid product and heating or cooling mediums are kept separate. Plate-type heat exchangers are effective in rapid heating and cooling applications. After the pasteurization process is completed, the product is packaged under aseptic conditions to prevent recontamination of the product.

Aseptic processing

The aseptic process involves placing a sterilized product into a sterilized package that is then sealed under sterile conditions. It began in 1914 with the development of sterile filters for use in the wine industry. However, because of unreliable machinery, it remained commercially unsuccessful until 1948 when William McKinley Martin helped develop the Martin system, which later became known as the Dole Aseptic Canning System. This system involved the sterilization of liquid foods by rapidly heating them in tubular heat exchangers, followed by holding and cooling steps. The cans and lids were sterilized with superheated steam, and the sterilized containers were filled with the sterile liquid food. The lids were then sealed in an atmosphere of superheated steam. By the 1980s hydrogen peroxide was being used throughout Europe and the United States for the sterilization of polyethylene surfaces.

Commercial sterility

In aseptic processing the thermal process is based on achieving commercial sterility—*i.e.*, no more than 1 nonsterile package for every 10,000 processed packages. The aseptic process uses the high-temperature-short-time (HTST) method in which foods are heated at a high temperature for a short period of time. The time and temperature conditions depend on several factors, such as size, shape, and type of food. The HTST method results in a higher retention of quality characteristics, such as vitamins, odour, flavour, and texture, while achieving the same level of sterility as the traditional canning process in which food is heated at a lower temperature for a longer period of time.

The heating and cooling of liquid foods can be performed using metal plate heat exchangers.

These heat exchangers have large surface areas that result in improved heating and cooling rates. Other types of heat exchangers involve surrounding the food with steam or directly injecting steam into the food. Products sterilized with steam are then pumped into a vacuum chamber, where they are cooled rapidly.

Liquid foods that contain large solid particles are heated in scraped-surface heat exchangers. These heat exchangers use blades to continuously scrape the inside surface of the heating chamber. The scraping action protects highly viscous foods from being burned on the heating surface.

An alternate method for heating foods, called ohmic heating, passes a low-frequency electric current of 50 to 60 hertz directly through the food. A liquid food containing solids, such as diced fruit, is pumped through a pipe surrounded by electrodes. The product is heated as long as the electrical conductivity of the food is uniform throughout the entire volume. This uniform rate of heating prevents the overprocessing of any individual region of the food. Ohmic heating yields a food product of higher quality than those processed using conventional systems.

Packaging aseptically processed products

The packaging containers used in aseptic processing are sterilized separately before they are used. The packaging machinery is sterilized using steam, sterile gases, or hydrogen peroxide. The sterilization process is generally monitored by culturing a test organism. For example, the remaining presence of the highly heat-resistant bacterium *Bacillus subtilis globigii* can be used as a marker to measure the completeness of sterilization.

Packages must be sealed under sterile conditions, usually using high-temperature sealing plates. Foods that are aseptically processed do not require refrigeration for storage.

Blanching

Blanching is a thermal process used mostly for vegetable tissues prior to freezing, drying, or canning. Before canning, blanching serves several purposes, including cleaning of the product, reducing the microbial load, removing any entrapped gases, and wilting the tissues of leafy vegetables so that they can be easily put into the containers. Blanching also inactivates enzymes that cause deterioration of foods during frozen storage.

Blanching is carried out at temperatures close to 100° C (212° F) for two to five minutes in either a water bath or a steam chamber. Because steam blanchers use a minimal amount of water, extra care must be taken to ensure that the product is uniformly exposed to the steam. Steam blanching leafy vegetables is especially difficult because they tend to clump together. The effectiveness of the blanching treatment is usually determined by measuring the residual activity of an enzyme called peroxidase.

Controlling water activity

Foods containing high concentrations of water are generally more susceptible to deterioration by microbial contamination and enzymatic activity. The water content of foods can be controlled by removing water through dehydration or by adding solutes to the food. In both cases the concentration of solutes in the food increases and the concentration of water decreases.

Dehydration

Dehydration, or drying, of foods has long been practiced commercially in the production of spaghetti and other starch products. As a result of advances made during World War II, the technique has been applied to a growing list of food products, including fruits, vegetables, skim milk, potatoes, soup mixes, and meats.

Pathogenic (toxin-producing) bacteria occasionally withstand the unfavourable environment of dried foods, causing food poisoning when the product is rehydrated and eaten. Control of bacterial contaminants in dried foods requires high-quality raw materials having low contamination, adequate sanitation in the processing plant, pasteurization before drying, and storage conditions that protect from infection by dust, insects, and rodents or other animals.

Foodstuffs may be dried in air, superheated steam, vacuum, or inert gas or by direct application of heat. Air is the most generally used drying medium, because it is plentiful and convenient and permits gradual drying, allowing sufficient control to avoid overheating that might result in scorching and discoloration. Air may be used both to transport heat to the food being dried and to carry away liberated moisture vapour. The use of other gases requires special moisture recovery systems.

Loss of moisture content produced by drying results in increased concentration of nutrients in the remaining food mass. The proteins, fats, and carbohydrates in dried foods are present in larger amounts per unit weight than in their fresh counterparts, and the nutrient value of most reconstituted or rehydrated foods is comparable to that of fresh items. The biological value of dried protein is dependent, however, on the method of drying. Prolonged exposure to high temperatures can render the protein less useful in the diet. Low-temperature treatment, on the other hand, may increase the digestibility of protein. Some vitamins are sensitive to the dehydration process. For example, in dried meats significant amounts of vitamin C and the B vitamins—riboflavin, thiamine, and niacin—are lost during dehydration.

Dried eggs, meat, milk, and vegetables are ordinarily packaged in tin or aluminum containers. Fibreboard or other types of material may be employed but are less satisfactory than metal, which offers protection against insects and moisture loss or gain and which permits packaging with an inert gas.

In-package desiccants (drying agents) improve storage stability of dehydrated white potatoes, sweet potatoes, cabbage, carrots, beets, and onions and give substantial protection against browning. Retention of ascorbic acid (vitamin C) is markedly improved by packaging at temperatures up to 49° C (120° F); the packaging gas may be either nitrogen or air.

A related technique, freeze-drying, employs high vacuum conditions, permitting establishment of specific temperature and pressure conditions. The raw food is frozen, and the low pressure conditions cause the ice in the food to sublime directly into vapour (*i.e.*, it does not transit through the liquid state). Adequate control of processing conditions contributes to satisfactory rehydration, with substantial retention of nutrient, colour, flavour, and texture characteristics.

Concentration of moist foods

Foods with substantial acidity, when concentrated to 65 percent or more soluble solids, may be preserved by mild heat treatments. High acid content is not a requirement for preserving foods concentrated to over 70 percent solids.

Fruit jelly and preserve manufacture, an important fruit by-product industry, is based on the high-solids-high-acid principle, with its moderate heat-treatment requirements. Fruits that possess excellent qualities but are visually unattractive may be preserved and utilized in the form of concentrates, which have a pleasing taste and substantial nutritive value.

Jellies and other fruit preserves are prepared from fruit by adding sugar and concentrating by evaporation to a point where microbial spoilage cannot occur. The prepared product can be stored without hermetic sealing, although such protection is useful to control mold growth, moisture loss, and oxidation. In modern practice, vacuum sealing has replaced the use of a paraffin cover.

The jelly-forming characteristics of fruits and their extracts are due to pectin, a substance present in varying amounts in all fruits. The essential ingredients in a fruit gel are pectin, acid, sugar, and water. Flavouring and colouring agents may be added, and additional pectin and acid may be added to overcome any deficiencies in the fruit itself.

Candied and glacéed fruits are made by slow impregnation of the fruit with syrup until the concentration of sugar in the tissue is sufficiently high to prevent growth of spoilage microorganisms. The candying process is conducted by treating fruits with syrups of progressively increasing sugar concentrations, so that the fruit does not soften into jam or become tough and leathery. After sugar impregnation the fruit is washed and dried. The resulting candied fruit may be packaged and marketed in this condition or may be dipped into syrup, becoming coated with a thin glazing of sugar (glacéed) and again dried.

Fermentation and pickling

Although microorganisms are usually thought of as causing spoilage, they are capable under certain conditions of producing desirable effects, including oxidative and alcoholic fermentation. The microorganisms that grow in a food product, and the changes they produce, are determined by acidity, available carbohydrates, oxygen, and temperature. An important food preservation method combines salting to control microorganisms selectively and fermentation to stabilize the treated tissues.

Pickled fruits and vegetables

Fresh fruits and vegetables soften after 24 hours in a watery solution and begin a slow, mixed fermentation-putrefaction. The addition of salt suppresses undesirable microbial activity, creating a favourable environment for the desired fermentation. Most green vegetables and fruit may be preserved by pickling.

When the pickling process is applied to a cucumber, its fermentable carbohydrate reserve is turned into acid, its colour changes from bright green to olive or yellow-green, and its tissue becomes translucent. The salt concentration is maintained at 8 to 10 percent during the first week and is increased 1 percent a week thereafter until the solution reaches 16 percent. Under properly controlled conditions the salted, fermented cucumber, called salt stock, may be held for several years.

Salt stock is not a consumer commodity. It must be freshened and prepared into consumer items. In cucumbers this is accomplished by leaching the salt from the cured cucumber with warm water (43°-54° C [110°-130° F]) for 10 to 14 hours. This process is repeated at least twice, and, in the final wash, alum may be added to firm the tissue and turmeric to improve the colour.

Pickled meat

Meat may be preserved by dry curing or with a pickling solution. The ingredients used in curing and pickling are sodium nitrate, sodium nitrite, sodium chloride, sugar, and citric acid or vinegar.

Various methods are used: the meat may be mixed with dry ingredients; it may be soaked in pickling solution; pickling solution may be pumped or injected into the flesh; or a combination of these methods may be used.

Curing may be combined with smoking. Smoke acts as a dehydrating agent and coats the meat surfaces with various chemicals, including small amounts of formaldehyde.

Deterioration of fermented and pickled products

Fermented foods and pickled products require protection against molds, which metabolize the acid developed and allow the advance of other microorganisms. Fermented and pickled food products placed in cool storage can be expected to remain stable for several months. Longer storage periods demand more complete protection, such as canning.

Nutrient retention in fermented and pickled products is about equal to retention for products preserved by other methods. Carbohydrates usually undergo conversion to acid or to alcohol, but these are also of nutritive value. In some instances, nutrient levels are increased because of the presence of yeasts.

Chemical preservation

Chemical food preservatives are substances which, under certain conditions, either delay the growth of microorganisms without necessarily destroying them or prevent deterioration of quality during manufacture and distribution. The former group includes some natural food constituents which, when added to foods, retard or prevent the growth of microorganisms. Sugar is used partly for this purpose in making jams, jellies, and marmalades and in candying fruit. The use of vinegar and salt in pickling and of alcohol in brandying also falls in this category. Some chemicals foreign to foods are added to prevent the growth of microorganisms. The latter group includes some natural food constituents such as ascorbic acid (vitamin C), which is added to frozen peaches to prevent browning, and a long list of chemical compounds foreign to foods and classified as antioxidants, bleaching agents, acidulants, neutralizers, stabilizers, firming agents, and humectants.

Organic chemical preservatives

Sodium benzoate and other benzoates are among the principal chemical preservatives. The use of benzoates in certain products in prescribed quantity (usually not exceeding 0.1 percent) is permitted in most countries, some of which require a declaration of its use on the label of the food container. Since free benzoic acid actually is the active agent, benzoates must be used in an acid medium in order to be effective. The ability of cranberries to resist rapid deterioration is attributed to their high benzoic acid content. Benzoic acid is more effective against yeasts than against molds and bacteria.

Other organic compounds used as preservatives include vanillic acid esters, monochloroacetic acid, propionates, sorbic acid, dehydroacetic acid, and glycols.

Inorganic chemical preservatives

Sulfur dioxide and sulfites are perhaps the most important inorganic chemical preservatives. Sulfites are more effective against molds than against yeasts and are widely used in the

preservation of fruits and vegetables. Sulfur compounds are extensively used in wine making and, as in most other instances when this preservative is used, much care has to be exercised to keep the concentrations low in order to avoid undesirable effects on flavour.

Oxidizing agents such as nitrates and nitrites are commonly used in the curing of meats.

Food irradiation

Food irradiation involves the use of either high-speed electron beams or high-energy radiation with wavelengths smaller than 200 nanometres, or 2000 angstroms (e.g., X rays and gamma rays). These rays contain sufficient energy to break chemical bonds and ionize molecules that lie in their path. The two most common sources of high-energy radiation used in the food industry are cobalt-60 (^{60}Co) and cesium-137 (^{137}Cs). For the same level of energy, gamma rays have a greater penetrating power into foods than high-speed electrons.

The unit of absorbed dose of radiation by a material is denoted as the gray (Gy), one gray being equal to the absorption of one joule of energy by one kilogram of food. The energy possessed by an electron is called an electron volt (eV). One eV is the amount of kinetic energy gained by an electron as it accelerates through an electric potential difference of one volt. It is usually more convenient to use a larger unit such as megaelectron volt (MeV), which is equal to one million electron volts.

Biological effects of irradiation

Irradiation has both direct and indirect effects on biological materials. The direct effects are due to the collision of radiation with atoms, resulting in an ejection of electrons from the atoms. The indirect effects are due to the formation of free radicals (unstable molecules carrying an extra electron) during the radiolysis (radiation-induced splitting) of water molecules. The radiolysis of water molecules produces hydroxyl radicals, highly reactive species that interact with the organic molecules present in foods. The products of these interactions cause many of the characteristics associated with the spoilage of food, such as off-flavours and off-odours.

Positive effects

The bactericidal (bacteria-killing) effect of ionizing radiation is due to damage of the biomolecules of bacterial cells. The free radicals produced during irradiation may destroy or change the structure of cellular membranes. In addition, radiation causes irreversible changes to the nucleic acid molecules (*i.e.*, DNA and RNA) of bacterial cells, inhibiting their ability to grow. Pathogenic bacteria that are unable to produce resistant endospores in foods such as poultry, meats, and seafood can be eliminated by radiation doses of 3 to 10 kilograys. If the dose of radiation is too low, then the damaged DNA can be repaired by specialized enzymes. If oxygen is present during irradiation, the bacteria are more readily damaged. Doses in the range of 0.2 to 0.36 kilograys are required to stop the reproduction of *Trichinella spiralis* (the parasitic worm that causes trichinosis) in pork, although much higher doses are necessary to eliminate it from the meat.

The dose of radiation used on food products is divided into three levels. Radappertization is a dose in the range of 20 to 30 kilograys, necessary to sterilize a food product. Radurization is a dose of 1 to 10 kilograys, that, like pasteurization, is useful for targeting specific pathogens. Radicidation involves doses of less than 1 kilogray for extending shelf life and inhibiting sprouting.

Negative effects

In the absence of oxygen, radiolysis of lipids leads to cleavage of the interatomic bonds in the fat molecules, producing compounds such as carbon dioxide, alkanes, alkenes, and aldehydes. In addition, lipids are highly vulnerable to oxidation by free radicals, a process that yields peroxides, carbonyl compounds, alcohols, and lactones. The consequent rancidity, resulting from the irradiation of high-fat foods, is highly destructive to their sensory quality. To minimize such harmful effects, fatty foods must be vacuum-packaged and held at subfreezing temperatures during irradiation.

Proteins are not significantly degraded at the low doses of radiation employed in the food industry. For this reason irradiation does not inactivate enzymes involved in food spoilage, as most enzymes survive doses of up to 10 kilograys. On the other hand, the large carbohydrate molecules that provide structure to foods are depolymerized (broken down) by irradiation. This depolymerization reduces the gelling power of the long chains of structural carbohydrates. However, in most foods some protection against these deleterious effects is provided by other food constituents. Vitamins A, E, and B₁ (thiamine) are also sensitive to irradiation. The nutritional losses of a food product are high if air is not excluded during irradiation.

Safety concerns

Based on the beneficial effects of irradiation on certain foods, several countries have permitted its use for specific purposes, such as the inhibition of sprouting of potatoes, onions, and garlic; the extension of shelf life of strawberries, mangoes, pears, grapes, cherries, red currants, and cod and haddock fillets; and the insect disinfection of pulses, peanuts, dried fruits, papayas, wheat, and ground-wheat products.

The processing room used for irradiation of foods is lined with lead or thick concrete walls to prevent radiation from escaping. The energy source, such as a radioactive element or a machine source of electrons, is located inside the room. (Radioactive elements such as ⁶⁰Co are contained in stainless steel tubes. Because an isotope cannot be switched on or off, when not in use it is lowered into a large reservoir of water.) Prior to the irradiation treatment, personnel vacate the room. The food to be irradiated is then conveyed by remote means into the room and exposed to the radiation source for a predetermined time. The time of exposure and the distance between the radiation source and the food material determine the irradiation treatment. After treatment, the irradiated food is conveyed out of the room, and the radioactive element is again lowered into the water reservoir.

Large-scale studies conducted around the world have concluded that irradiation does not cause harmful reactions in foods. In 1980 a joint committee of the Food and Agriculture Organization (FAO), the International Atomic Energy Agency (IAEA), and the World Health Organization (WHO) declared that an overall average dose of radiation of 10 kilograys was safe for food products. The maximum energy emitted by ⁶⁰Co and ¹³⁷Cs is too low to induce radioactivity in food. The energy output of electron-beam generators is carefully regulated, and the recommended energy outputs are too low to cause radioactivity in foods.

Packaging

Because packaging helps to control the immediate environment of a food product, it is useful in creating conditions that extend the storage life of a food. Packaging materials commonly used for foods may be classified as flexible (paper, thin laminates, and plastic film), semi-rigid (aluminum foil, laminates, paperboard, and thermoformed plastic), and rigid (metal, glass, and thick plastic). Plastic materials are widely used in food packaging because they are relatively cheap, lightweight, and easy to form into desired shapes.

The selective permeability of polymer-based materials to gases, such as carbon dioxide and oxygen, as well as light and moisture, has led to the development of modified-atmosphere packaging. If the barrier properties are carefully selected, a packaging material can maintain a modified atmosphere inside the package and thus extend the shelf life of the food product.

Dehydrated foods must be protected from moisture during storage. Packaging materials such as polyvinyl chloride, polyvinylidene chloride, and polypropylene offer low moisture permeability. Similarly, packaging materials with low gas permeability are used for fatty foods in order to minimize oxidation reactions. Because fresh fruits and vegetables respire, they require packaging materials, such as polyethylene, that have high permeability to gases.

Smart packages offer properties that meet the special needs of certain foods. For example, packages made with oxygen-absorbing materials remove oxygen from the inside of the package, thus protecting oxygen-sensitive products from oxidation. Temperature-sensitive films exhibit an abrupt change in gas permeability when they are subjected to a temperature above or below a set constant. These films change from a crystalline structure to an amorphous structure at a set temperature, causing the gas permeability to change substantially.

Storage

Food storage is an important component of food preservation. Many reactions that may deteriorate the quality of a food product occur during storage. The nutrient content of foods may be adversely affected by improper storage. For example, a significant amount of vitamin C and thiamine may be lost from foods during storage. Other undesirable quality changes that may occur during storage include changes in colour, development of off-flavours, and loss of texture. A properly designed food storage system allows fresh or processed foods to be stored for extended duration while maintaining quality.

The most important storage parameter is temperature. Most foods benefit from storage at a constant, low temperature where the rates of most reactions decrease and quality losses are minimized. In addition, foods containing high concentrations of water must be stored in high-humidity environments in order to prevent the excessive loss of moisture.

Careful control of atmospheric gases, such as oxygen, carbon dioxide, and ethylene, is important in extending the storage life of many products. For example, in the United States and Canada the apple industry utilizes controlled-atmosphere storage facilities in order to preserve the quality of the fruit. Use of controlled atmospheres to increase the shelf life of fruits was first shown in 1819 by Jacques-Étienne Berard, a professor at the School of Pharmacy at Montpellier, Fr. The commercial development of this technique occurred more than 100 years later with the pioneering work of Franklin Kidd and Cyril West at the Low Temperature Research Station at Cambridge, Eng.

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Additional Reading

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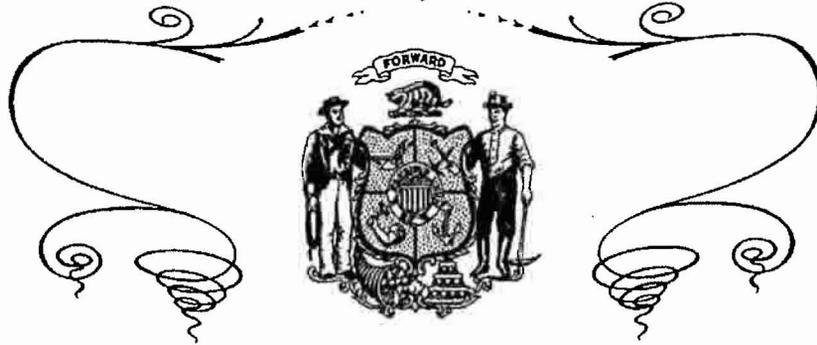
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EXHIBIT C

State of Wisconsin



JOINT RULES

As last affected by 2007 Senate Joint Resolution 1
Concurred in January 3, 2007

2007-2008 SESSION SCHEDULE AT A GLANCE Created by 2007 SJR-1, January 3, 2007

January 3, 2007	(Wednesday)	2007 Inauguration
January 9, 2007	(Tuesday)	Floorperiod
Jan. 30 to Feb. 1, 2007	(Tu - Th)	Floorperiod
February 13, 2007	(Tuesday)	Floorperiod
Feb. 20 to March 1, 2007	(Tu - Th)	Floorperiod
March 13 to 15, 2007	(Tu - Th)	Floorperiod
April 17 to 26, 2007	(Tu - Th)	Floorperiod
May 3, 2007	(Thursday)	Bills sent to Governor
May 8 to 17, 2007	(Tu - Th)	Floorperiod
May 29 to June 29, 2007, OR budget passage	(Tu - Fri)	Floorperiod
August 9, 2007	(Thursday)	Nonbudget Bills sent to Governor
August 9, 2007 (or later)	(Thursday)	Budget Bill sent to Governor
Sept. 18 to 20, 2007	(Tu - Th)	Floorperiod
Oct. 23 to Nov. 8, 2007	(Tu - Th)	Floorperiod
December 11 to 13, 2007	(Tu - Th)	Floorperiod
January 10, 2008	(Thursday)	Bills sent to Governor
Jan. 15 to 31, 2008	(Tu - Th)	Floorperiod
Feb. 19 to March 13, 2008	(Tu - Th)	Last general-business Floorperiod
April 3, 2008	(Thursday)	Bills sent to Governor
May 6 to 8, 2008	(Tu - Th)	Limited-business Floorperiod
May 15, 2008	(Thursday)	Bills sent to Governor
May 27 and 28, 2008	(Tu - W)	Veto Review Floorperiod
May 29, 2008, to Jan. 5, 2009	(Th - Mon)	Interim, committee work
June 11, 2008	(Wednesday)	Bills sent to Governor

January 5, 2009 (Monday) 2009 Inauguration

** A pamphlet of this type is printed within one week following final legislative concurrence in any joint resolution making significant changes in the joint rules.*

In the present pamphlet, the joint rules of the Wisconsin Legislature are printed as last reenacted by 1977 Assembly Joint Resolution 1 (enrolled as 1977 EJR-10), and subsequently modified by 1979 Assembly Joint Resolution 1 (EJR-1), 1981 Senate Joint Resolution 1 (EJR-1), 1981 Senate Joint Resolution 32 (EJR-26), 1987 Assembly Joint Resolution 1 (EJR-1), 1987 Senate Joint Resolution 48 (EJR-41), 1989 Assembly Joint Resolution 24 (EJR-15), 1991 Senate Joint Resolution 1 (EJR-1) and Assembly Joint Resolution 2 (EJR-10), 1993 Senate Joint Resolution 1, 1997 Assembly Joint Resolution 1, 1999 Assembly Joint Resolution 18, 2001 Assembly Joint Resolution 15, 2005 Senate Joint Resolution 1 (EJR-1), and 2007 Senate Joint Resolution 1.

All modifications made in the joint rules after their 1977 reenactment are indicated in the notes following the affected joint rules.

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JOINT RULES

As last affected by 2007 Senate Joint Resolution 1
(Concurred in January 3, 2007)

Chapter 1: JOINT PROCEDURES OF THE TWO HOUSES

JOINT RULE 1. **Joint convention.** Whenever there is a joint convention of the 2 houses, the president of the senate shall preside over the joint convention, if present, and the speaker of the assembly shall preside if the president is not present, and the chief clerk of the assembly shall act as clerk thereof, assisted by the chief clerk of the senate.

*[am. 1981 SJR-1]
[am. 2001 AJR-15]*

JOINT RULE 2. **Receding from position on amendment.** Whenever an amendment has been nonconcurred in by the other house, any member may move to recede from the amendment. If the motion prevails the amendment shall thereby be reconsidered and rejected and the bill or amendment to which the amendment had been adopted by the house shall thereby be passed or concurred in, as the case may be, so that further action is not required thereon in either house.

JOINT RULE 3. **Committee of conference.** (1) In all cases of disagreement between the senate and assembly on amendments, adopted by either house to a bill or joint resolution passed by the other house, a committee of conference consisting of 3 members from each house may be requested by either house, and the other house shall appoint a similar committee. At least one member from each house shall be a member of the minority party.

(a) The usual manner of procedure is as follows: If a bill of one house has been amended and passed by the other house, and has been returned to the house of origin and the house of origin has refused to concur in an amendment, the house of origin may appoint a committee of conference and notify the other house, which shall appoint a committee of conference unless it votes to recede from its amendment. Such committees shall be appointed as provided in the rules of each house. The joint committee shall meet and state to each other, orally or in writing, the reasons of their respective houses for or against the disagreement, and confer thereon, and shall report to their respective houses any agreement they arrive at by the vote of at least a majority of the members of the committee representing each house.

(b) When the committee of conference has reached agreement the report shall be first presented, if a senate bill or joint resolution, to the assembly and, if an assembly bill or joint resolution, to the senate. The vote by each house to approve the conference report constitutes final action on the proposal and may not be reconsidered.

(c) Approval of the conference report by a roll call vote in each house sufficient to constitute final passage of the proposal shall be final passage of the bill or final adoption and concurrence in the joint resolution in the form and with the changes proposed by the report.

(d) If the committee of conference is unable to agree, another committee of conference consisting of new members may be appointed as provided in the rules of each house and may proceed to further consideration of the proposal.

directs, an electronic copy of the memorandum shall be transmitted electronically to all legislators and to the legislative reference bureau.

*[am. 1987 SJR-48]
[am. 2001 AJR-15]*

JOINT RULE 48. Review of agency prepared fiscal estimates. (1) On the 6th working day after the legislative reference bureau transmits electronically a copy of a fiscal estimate for an introduced bill to the primary author, the bureau shall transmit electronically a copy of the fiscal estimate and any worksheet to the legislative fiscal bureau and to the chief clerk of the house of origin to be inserted in the bill jacket envelope and shall forthwith cause the estimate and any worksheet to be reproduced as are amendments.

(2) During the 5-day period under sub. (1), the primary author of an introduced bill may transmit electronically a request that an original fiscal estimate for the bill as affected by a proposed amendment or a proposed substitute amendment, whether offered for introduction or not, be prepared by the agency that prepared the fiscal estimate for the bill.

(3) The primary author of an introduced bill may transmit electronically a request that the legislative fiscal bureau or the department of administration prepare a supplemental fiscal estimate if the primary author disagrees with the fiscal estimate for the bill prepared by the state agency.

(4) During the 5-day period under sub. (1), the primary author of an introduced bill may transmit electronically a request that the agency that prepared the fiscal estimate rewrite its fiscal estimate. If the agency agrees to rewrite the estimate and the primary author agrees to a delay in the publication of the fiscal estimate, the agency shall immediately electronically notify the department of administration and the legislative reference bureau, and the rewritten fiscal estimate, notwithstanding sub. (1), shall be the only original estimate reproduced and inserted in the bill jacket envelope, but both the rewritten and the initial fiscal estimate shall be retained by the legislative reference bureau.

*[(1) and (4) am. 1997 AJR-1]
[am. 2001 AJR-15]*

JOINT RULE 49. Bills not conforming. (1) Any member may at any time that a bill is before the house raise the issue that the bill requires a fiscal estimate, and if the presiding officer determines that the bill (not having the estimate) requires an estimate, the presiding officer shall direct the legislative reference bureau to secure the requisite estimate.

(2) Bills requiring fiscal estimates shall not be voted on by either house, and shall receive neither a public hearing nor be voted on by a standing committee, before the receipt of the original fiscal estimate for the bill.

(3) If the fiscal estimate for the bill has not been provided to the members when the vote on passage is taken, the chief clerk shall read the fiscal estimate at length before the vote.

[(3) am. 1999 AJR-18]

JOINT RULE 50. Waiver of requirement to transmit electronically. The president and speaker may jointly waive for a limited time any requirement under joint rules 41, 43, 45, 46, 47, and 48 for electronic transmission and permit, instead, transmission in paper form.

[cr. 2001 AJR-15]

Chapter 6: STYLE AND FORM OF PROPOSALS

JOINT RULE 51. Use of LRB legal services. No proposal may be introduced or offered unless it has been put in proper form by the legislative reference bureau. Only the persons authorized by this rule may

use the drafting services of the legislative reference bureau to have proposals prepared for introduction. Persons authorized to use the drafting services are:

(1) Any member or member-elect of the legislature and, on behalf of each committee thereof, the chairperson. The members and committees may authorize others to submit instructions for them, but for each draft prepared on such authorization the name of the member or committee authorizing the draft shall be made part of the record.

(2) Any agency, as defined in section 16.70 (1) of the statutes, created under chapter 13, 14, 15, or 758 of the statutes.

(3) The chief clerk of either house for drafting requests pertaining to the operation of the legislature.

(4) A party caucus of either house of the legislature.

*[(3) cr. 1987 SJR-48]
[(intro.) and (2) am.; (4) cr. 2001 AJR-15]*

JOINT RULE 52. Format; text display; structure of proposals. All bills shall be reproduced on paper 8-1/2 by 11 inches. Each bill shall have a title, an enacting clause, and subject matter disposed of in one or more sections and shall have the arrangement and wording prescribed by the following:

(1) The title of all bills shall state, in the fewest words practicable, the subject to which the bill relates and shall be drawn up in one of the following forms or a form similar to one of the following forms:

(a) AN ACT *to repeal*.... ; *to renumber*.... ; *to consolidate and renumber*.... ; *to renumber and amend*.... ; *to consolidate, renumber and amend*.... ; *to amend*.... ; *to repeal and recreate*.... ; and *to create*.... of the statutes; and *to affect* 19.. laws, chapter...., section.... [to 1981] and 19.. Wisconsin Act.... [starting 1983], section.... ; **relating to:**

(b) AN ACT **relating to:** (authorizing, providing, etc.)

(c) Any bill may include 2 or more types of actions and treat both general statutory law and nonstatutory law, but the various types of actions used shall be listed in the order shown in par. (a), and, if both statutory and nonstatutory law are treated in the same manner, the statutory law shall be cited first.

(d) The relating clause shall record any of the following:

1. Expressly granting rule-making authority, or providing an exemption from rule-making procedures, or providing an exemption from or extending the time limit for emergency rule procedures.

2. Requiring a referendum.

3. Expressly providing for a penalty.

4. Making, continuing, or renewing an appropriation.

(e) Executive budget bills under section 16.47 (1) of the statutes, other lengthy bills that encompass multiple subjects and that are to be introduced at the request of the governor or the committee on organization of either house, bills proposing bulk revision of one or more entire chapters of the statutes, reconciliation bills introduced by the committee on organization of either house, and revisor's correction and revisor's revision bills shall not be subject to the requirements of pars. (a) to (d), and instead may use a

descriptive title similar to the following example: "An Act to amend and revise chapter and to make diverse other changes in the statutes; **relating to:....**"

(2) The analysis by the legislative reference bureau shall follow the title.

(3) The enacting clause, required by section 17 (1) of article IV of the constitution, shall follow the analysis and shall read as follows: "The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:"

(4) The subject matter of the bill shall follow the enacting clause and be displayed in one or more sections that, except for budget bills or other bills of unusual length, shall be numbered consecutively. Substitute amendments may follow the section numbering of the bill. Each section shall begin in one of the following forms:

(a) SECTION.... (A designated part) of the statutes (or 19.. laws, chapter...., section.... [to 1981] and 19.. Wisconsin Act.... [starting 1983], section....) are (repealed) (renumbered....) (consolidated and renumbered....).

(b) SECTION.... (A designated part) of the statutes (or 19.. laws, chapter...., section.... [to 1981] and 19.. Wisconsin Act.... [starting 1983], section....) are (renumbered.... and amended) (consolidated, renumbered.... and amended) (amended) (repealed and recreated) (created) to read:

(c) SECTION (provisions of new, nonstatutory material).

(5) Any proposal, substitute amendment, or amendment that proposes to amend an existing law or legislative rule, and any joint resolution that proposes to amend a section of the state constitution, shall display the full text of the unit of the law, rule, or constitution that is being amended, with any matter to be stricken out typed with a line through the matter, and any new matter underscored. This requirement shall not apply to:

(a) Reconciliation bills introduced by the organization committee of either house and revisor's correction or revisor's revision bills.

(b) Appropriation sections that only increase or decrease the amount of an existing appropriation, which shall instead indicate the amount by which the applicable appropriation is to be increased or decreased, and the purpose of this increase or decrease.

(c) Proposals in which identical words are substituted for other words in existing law, if the laws in which the existing words occur are enumerated.

(6) All parts of the statutes and of other laws that are intended to be superseded or repealed should be specifically referred to, so far as practicable, and expressly superseded or repealed. This directive is not intended to affect judicial construction.

(7) Except as necessary to revise the relating clause of the affected proposal or substitute amendment, an amendment may not change the title of the proposal. When a substitute amendment or proposal is reproduced with all adopted amendments engrossed therein, or when the proposal is enrolled after passage, or adoption, and concurrence, the legislative reference bureau shall make the required changes in the title so that the title correctly lists all provisions affected by the proposal.

*[(intro.), (1) and (4) am.; (5) and (6) rn.am.; (7) cr. 1987 SJR-48]
[(5)(intro.) am. 1991 SJR-1]*

*[(1)(d)1. am. 1991 AJR-2]
[(1)(intro.), (b) and (e) and (7) am. 1997 AJR-1]
[(1)(a) v.rc. 1997 AJR-1]
[(1)(e), (5)(a) and (7) am. 2001 AJR-15]*

JOINT RULE 53. Incorporation of law into the statutes. (1) It is the policy of this state that law of continuing application shall be incorporated into the statutes. The assignment of statute numbering to any part of a bill is indicative of a legislative intent that this text be incorporated into the statutes.

(2) In general, provisions of the following types need not be incorporated into the statutes:

(a) An increase or decrease in the amount of an existing sum certain appropriation, but the dollar amount by which the existing appropriation is increased or decreased shall be reflected in the appropriation total as shown in the statutes in the schedule under section 20.005 (3) of the statutes.

(b) A conveyance of real property or of a real property right or interest to or from the state or its political subdivisions.

(c) A declaration of intent or purpose.

(d) A directive or request for a limited-term study.

(e) A creation of a committee as defined in section 15.01 (3) of the statutes.

(f) A ratification of a collective bargaining agreement for state employees.

(g) A change in the authorized state building program.

(h) A position authorization.

(i) A change in the authorized state trunk highway system.

(j) An amendment to an existing nonstatutory provision.

(k) A temporary transitional provision, not extending beyond July 1 of the even-numbered year of the legislature's next biennial session.

(L) A provision affecting the timing of a law's application or nonapplication, not extending beyond July 1 of the even-numbered year of the legislature's next biennial session.

(m) Any other provision that is narrow in scope and intended to be temporary.

*[cr. 1987 SJR-48]
[(1) and (2)(a) am. 1997 AJR-1]*

JOINT RULE 54. Approval and jacketing of drafts. (1) Before a proposal is jacketed for introduction, the legislative reference bureau shall submit a copy of the draft to the authorizing legislator, chief clerk, caucus, or state agency for approval, but substitute amendments or amendments shall be immediately prepared to be offered unless the authorizing legislator, chief clerk, caucus, or state agency requests prior submittal for approval.

(2) The legislative reference bureau, except as otherwise provided in sub. (2m), shall provide to the authorizing legislator, chief clerk, caucus, or state agency 4 copies of each proposal approved under sub. (1) and 6 copies of each amendment approved under sub. (1). One copy is for the use of the requester. The

other copies shall, if a proposal, be inserted in the jacket envelope or, if a substitute amendment or amendment, be attached to an amendment jacket.

(2m) (a) The chief of the legislative reference bureau and a chief clerk of either house may enter into a written agreement under this joint rule to have the chief clerk, when the chief clerk's house is in session, receive on the floor of the house copies of drafts of proposals, substitute amendments, and amendments transmitted electronically by the legislative reference bureau, and place the proposals in jacket envelopes and attach jacket cover sheets (stripes) to drafts of amendments and substitute amendments.

(b) The legislative reference bureau and the chief clerk may not act under this subsection until the legislative technology services bureau makes the computer programming changes and the legislative reference bureau and the chief clerk make the process changes necessary to permit the legislative reference bureau to transmit and the chief clerk to receive the drafts electronically in the chamber of the house, in a manner that ensures the confidentiality of the drafts, without changing the way the legislative reference bureau jackets proposals, substitute amendments, and amendments electronically.

(c) The legislative reference bureau and the chief clerk may not act under this subsection unless the chief clerk states in the agreement that the chief clerk and his or her employees:

1. Will comply with the requirements for confidentiality of drafts with which the legislative reference bureau must comply.

2. Provide, maintain, and supervise the equipment and the jackets for the electronic transmittal to the chief clerk as if the equipment and jackets were under the immediate supervision of the legislative reference bureau.

3. Submit directly to, and only to, the member any proposal in its jacket and any substitute amendment or amendment with its jacket attached.

(d) The legislative reference bureau may not transmit a draft of a proposal, substitute amendment, or amendment to the chief clerk under this rule unless the member requesting the draft waives confidentiality of the draft and requests the legislative reference bureau to transmit the draft under this rule.

(3) (a) Jacket envelopes for proposals, and amendment jackets for substitute amendments and amendments, shall be identified by red for proposals, substitute amendments, and amendments introduced or offered in the senate, and shall be identified by black for those introduced or offered in the assembly.

(b) Each amendment jacket shall contain blanks to identify the substitute amendment or amendment by number, to list the date it is offered, and to enter the name or names of the member, members, or committee of the house of origin that offered the substitute amendment or amendment. Each amendment jacket shall allow sufficient space to add, if appropriate, the name of the individual or organization requesting that it be offered.

(c) Each jacket envelope shall be large enough to hold the papers pertaining to the proposal without the papers being folded.

*[cr. 1987 SJR-48]
[(1), (2) and (3)(a) and (b) am. 1991 SJR-1]
[(2) and (3) am. 1997 AJR-1]
[am.; (2m) cr. 2001 AJR-15]*

JOINT RULE 55. Authors and cosponsors. (1) Any bill, joint resolution, or motion under joint rule 7 may have, following and separate from the names of the authors of the bill, joint resolution, or motion, the names of one or more cosponsors from the other house.

(2) When a proposal or amendment is introduced or offered by request, the name of the person requesting introduction or the offering of the proposal or offering of the amendment shall be made a part of the record of the proposal.

*[rn. from Jr.Rule 53; (2) am. 1987 SJR-48]
[am. 2001 AJR-15]*

JOINT RULE 56. Clerical corrections in legislative proposals and amendments. (1) The chief clerks and the legislative reference bureau shall correct all minor clerical errors found in any proposal or amendment. Any correction under this rule shall be entered by the chief clerk in the history file for the proposal of the house having possession of the proposal.

(2) The current edition of Webster's new international dictionary is the standard on questions of correct spelling, word usage, and proper grammar.

(3) Except as enumerated in pars. (a) to (e), corrections under this rule require in each instance the specific prior authorization of the presiding officer of the house having possession of the proposal. The following corrections do not require prior authorization:

(a) Inserting the enacting clause required for any bill by section 17 (1) of article IV of the constitution, or inserting the usual enabling clause in any resolution.

(b) Correcting the title of a proposal so that the enumeration of sections affected accurately reflects the statutes, session laws, Wisconsin Acts, sections of the constitution, or legislative rules treated in the proposal.

(c) Correcting the title of a bill so that the relating clause complies with joint rule 52 (1) (d).

(d) Correcting the text of the proposal so that it conforms to sub. (2).

(e) Correcting erroneous numeric references.

*[cr. 1987 SJR-48]
[(1) am. 1997 AJR-1]
[(title) and (1) am. 2001 AJR-15]*

JOINT RULE 57. Amendments to state constitution. (1) Every joint resolution proposing an amendment to the constitution introduced for the purpose of a first approval shall, in the closing paragraph, refer such proposed amendment to the legislature to be chosen at the next general election. Every joint resolution proposing the 2nd legislative approval of an amendment to the constitution shall, in the closing paragraph, provide for submission of the amendment to the people in accordance with section 1 of article XII of the constitution.

(2) The text of a proposed constitutional amendment is not subject to change when a joint resolution submits such text for "2nd consideration" after the joint resolution was adopted on "first consideration" by the last preceding legislature, unless appropriate changes are made to revert the status of the constitutional amendment to "first consideration."

(a) While the constitutional amendment has "2nd consideration" status, only the relating clause and those paragraphs of the joint resolution pertaining to the ballot question and to the date of submission to the voters may be changed by amendment.

(b) Because any change in the text of a proposed constitutional amendment before the senate or assembly for "2nd consideration" reverts that proposed amendment to "first consideration" status, any change shall be presented to the senate or assembly in the form of a substitute amendment that, in its title, its resolving clauses, and its instructions for transmittal to the next succeeding legislature, properly sets forth the resultant "first consideration" status of the proposed constitutional amendment.

*[rn. from Jt. Rule 55, 1987 SJR-48]
[(2)(intro.) and (b) am. 2001 AJR-15]*

JOINT RULE 58. Amendments to U.S. constitution. (1) Any amendment to the constitution of the United States, submitted to the legislatures of the several states for ratification, shall be considered in the form of a joint resolution.

(2) Every joint resolution to ratify an amendment to the constitution of the United States shall be given 3 readings in each house. The vote on adoption or concurrence shall be a roll call vote with the ayes and noes entered in the journal.

(3) That part of a joint resolution to ratify an amendment to the constitution of the United States which correctly sets forth the text of the proposed amendment may not be amended.

[cr. 1987 SJR-48]

JOINT RULE 59. Explanative notes. In addition to such notes as are required by law or joint rule, explanative notes may be included in revision and correction bills prepared by the revisor of statutes, in reconciliation bills introduced by the committee on organization of either house, and in proposals introduced or offered and in substitute amendments or amendments offered by the joint legislative council or its law revision committee, at the request of the judicial council, and by or at the request of any other official interim study or investigative group. The notes shall be prepared by the requester, shall be factual in nature, shall be as brief as may be and, where feasible, shall follow the section of the proposal or amendment to which they relate. Notes shall appear in the original reproduced version of the proposal or amendment only, and shall not appear in the Wisconsin Acts or session law volumes unless the chief of the legislative reference bureau determines that including them is essential or in the statutes unless the revisor determines that including them is essential. The notes constitute no part of the proposed act or engrossed or enrolled resolution.

*[rn. from Jt. Rule 56, 1987 SJR-48]
[am. 1997 AJR-1]
[am. 1999 AJR-18]
[am. 2001 AJR-15]*

JOINT RULE 60. Enrolled proposals. (1) Except as provided in sub. (2), immediately after the passage of any bill, or the adoption of and concurrence in any joint resolution amending the constitution, and in the case of a bill, before it is presented to the governor for approval, the legislative reference bureau shall prepare the number of enrolled copies of the proposal requested by the chief clerk of the house in which the proposal originated. One copy shall be used as the enrolled bill that is presented to the governor or the enrolled resolution that is deposited with the secretary of state. Four copies of the enrolled bill or resolution shall be delivered to the secretary of state. A sufficient number of copies of the enrolled bill or enrolled resolution shall be delivered to the revisor of statutes.

(2) Whenever the legislative reference bureau determines that the text of a proposal passed by the legislature cannot be properly enrolled because of unreconciled conflicts in adopted amendments, the bureau shall report the problem to the organization committee of the house in which the proposal originated. If the organization committee concurs with that determination: a) the committee shall

introduce a joint resolution recalling the proposal for further legislative action; and b) the bureau may not enroll the proposal until the legislature acts on the joint resolution recalling the proposal.

*[rn. from Jt. Rule 54, 1987 SJR-48]
[(1) rn.am.: (2) cr. 1989 AJR-24]
[(title) and (1) am. 2001 AJR-15]*

Chapter 7: REPRODUCTION OF PROPOSALS

JOINT RULE 62. Number of copies. (1) The joint committee on legislative organization shall determine the number of copies of each proposal and amendments thereto to be reproduced on a routine basis unless otherwise provided by joint resolution.

(2) Additional copies of a legislative proposal may be procured by the house in which the proposal originated, as provided in the rules of the house or upon authorization by the committee on organization or chief clerk of that house.

*[(title), (1) and (2) am. 1997 AJR-1]
[am. 2001 AJR-15]*

JOINT RULE 63. Reproduction of engrossed proposals and amendments. Upon the finding by the chief clerk of either house that a proposal or major amendment thereto has been amended in the house of origin to a considerable degree, the chief clerk may instruct the legislative reference bureau to prepare and have reproduced an engrossed copy of the proposal or amendment. In preparing engrossed copy for a proposal the legislative reference bureau shall, if time permits, provide it with a revised analysis. Upon receipt from the legislative reference bureau of the engrossed copy, the chief clerk shall enter that fact in the history file for the proposal. Any subsequent amendments to a proposal ordered reproduced with all adopted amendments engrossed therein shall be drafted to the reproduced engrossed text.

*[am. 1987 SJR-48]
[am. 1997 AJR-1]
[am. 2001 AJR-15]*

JOINT RULE 64. Display of text in amendatory proposals and acts. (1) Any proposal, substitute amendment, or amendment that proposes to amend an existing law or legislative rule, and any joint resolution that proposes to amend a section of the state constitution or joint rules, shall display the full text of the unit of the law, rule, or constitution that is being amended, with any matter to be stricken out displayed with a line through the matter, and any new matter displayed with underscoring. This requirement does not apply to:

(a) Reconciliation bills introduced by the organization committee of either house or revisor's correction or revisor's revision bills.

(b) Appropriation sections that only increase or decrease the amount of an existing appropriation, which shall instead indicate the amount by which the applicable appropriation is to be increased or decreased, and the purpose of the increase or decrease.

(c) Proposals in which identical words are substituted for other words in designated parts of existing law, if the designated parts in which the words occur are enumerated.

(2) In any official publication of any act or enrolled joint resolution, matter stricken out shall be shown with a line through the stricken matter and new matter shall be shown underscored.

*[am. 1987 SJR-48]
[(1)(intro.) and (2) am. 1991 SJR-1]*

EXHIBIT D

SECTION 19. 203.32 (14) of the statutes, as amended by chapter 337, laws of 1969, is repealed.

SECTION 20. 204.50 of the statutes, as amended by chapter 337, laws of 1969, is repealed.

SECTION 21. 208.38 of the statutes, as amended by chapter 337, laws of 1969, is amended to read:

208.38 Any person who knowingly or wilfully makes any false or fraudulent statement or representation in or with reference to any application for membership or in or with reference to any documentary or other record for the purpose of obtaining membership in or benefit from any such corporation, society, order or association, for himself or any other person, shall be fined not less than \$100 nor more than \$1,000, or imprisoned in the county jail not less than 3 months nor more than one year, or both; and any certificate of membership or policy so secured shall be absolutely void.

SECTION 22. 853.17 (2) of the statutes, as created by chapter 339, laws of 1969, is amended, effective July 1, 1971, by substituting "s. 701.09" for the reference to "s. 231.49".

SECTION 23. 853.23 of the statutes, as created by chapter 339, laws of 1969, is amended, effective July 1, 1971, by substituting "ss. 702.01 (1), 702.01 (4) and 702.09 (1) (b)" for references to "ss. 232.01 (1), 232.01 (4) and 232.09 (1) (b)", respectively.

SECTION 24. 861.05 (2) of the statutes, as created by chapter 339, laws of 1969, is amended, effective July 1, 1971, by substituting "s. 702.01 (5)" for the reference to "s. 232.01 (5)".

SECTION 25. 945.02 (3) of the statutes, as amended by chapter 252, laws of 1969, is amended to read:

945.02 (3) Conducts a lottery, or with intent to conduct a lottery, business facilities to do so.

SECTION 26. In the statutory sections listed in column "A" below, the cross references in column "B" are changed to the references shown in column "C".

A Statute sections	B Old cross references	C New cross references
54 (3) (as cr. by ch. 69)	14.77 (2) and (3)	14.76 (2) and (3)
370 (4) (a) (as cr. by ch. 154)	23.09 (7) (L)	23.09 (2) (L)
545 (1) (d) (as cr. by ch. 154)	27.30 (5)	22.40 (4)
42 (as cr. by ch. 276)	20.545 (2) (h)	20.545 (1) (h)
31 (1) (c) (as am. by ch. 233)	42.20 (14)	42.20 (21)
02 (12) (n) (as cr. by ch. 326)	41.155	38.155
9.04 (as cr. by ch. 45)	41.175	38.175
0.48 (1) (as am. by ch. 91)	14.90	66.77
1.19 (2) (as am. by ch. 141)	ch. 151	ch. 450
5.70 (1) (b) (as am. by ch. 252)	151.07	450.07
(1) (d) (as am. by ch. 252)	200.03 (11)	165.51
(2) (as am. by ch. 252)	200.19 to 200.25	165.55
7.07 (6) (f) (as renumbered)	200.19 to 200.25	165.55
1.02 (3) (g) (as cr. by ch. 71)	152.02 (2)	447.02 (2)
	ch. 136	ch. 452

SECTION 27. In the sections listed in Column "A" below, all as affected by chapter 353, laws of 1969, the cross references to the sections listed in Column "B" are changed to the references listed in Column "C":

A Statute sections	B Old cross references	C New cross references
16.08 (2) (j)	23.30	23.09 (23)
20.245 (1) (d)	44.02 (13)	44.02 (20)
20.370 (1) (d)	23.09 (7) (d)	23.09 (2) (d)
	3 and (18)	(3) and (10)
(1) (f)	23.09 (7) (m)	23.09 (2) (m)
(1) (fm)	23.09 (15)	23.09 (9)
(1) (fn)	23.09 (20)	23.09 (21)
20.370 (2) (d)	23.09 (7) (d)	23.09 (2) (d)
	1 and (16)	1 and (10)
(2) (e)	23.09 (17)	23.09 (11)
(3) (d)	23.09 (7) (d)	23.09 (2) (d)
	2 and (16)	2 and (10)
(3) (e)	23.09 (19)	23.09 (20)
(7) (a) (intro.)	20.395 (3) (a)	20.395 (2) (b)
(7) (a) 1	23.09 (19)	23.09 (20)
23.09 (24)	sub. (17) (c), (d) and (e)	sub. (11) (c), (d) and (e)
70.113 (1)	23.09 (7) (d)	23.09 (2)
	1 or 3	(d) 1 or 3
(2) (a)	23.09 (7) (d)	23.09 (2) (d)
144.21 (6) (b) and 1	20.866 (2) (tp)	20.866 (2) (tm)

SECTION 28. If Senate Bill 354 is enacted into law, the repeal and re-creation of section 15.191 (intro.) of the statutes by SECTION 2 of this bill shall supersede the amendment thereof by Senate Bill 354.

SECTION 29. SECTIONS 5, 10 to 13, 17, 18 and 27 of this bill are to become effective only if Assembly Bill 416 becomes law [NOTE: became chapter 353, laws of 1969]. If any part of Assembly Bill 416 is vetoed by the Governor, any of the above sections which are based on that part shall not become effective unless the veto is overridden.

Approved February 11, 1970.

1969 Senate Bill 701

Date published:
February 28, 1970

CHAPTER 425, LAWS OF 1969

AN ACT to renumber 100.18 (7); and to create 100.18 (11) (b) to (e), 100.20 (6) and 100.26 (6) of the statutes, relating to fraudulent advertising and prescribing penalties.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 100.18 (7) of the statutes is renumbered 100.18 (11) (a).

SECTION 2. 100.18 (11) (b) to (e) of the statutes are created to read:

100.18 (11) (b) 1. The department of agriculture may request that the department of justice commence an action to enjoin a violation of this section, in which event the latter department shall proceed with the requested action within a reasonable period of time or provide the department of agriculture with a brief statement of its reasons for not proceeding. The department of justice shall further provide the department of agriculture with periodic summaries of all activity under this section.

2. Any person suffering pecuniary loss because of a violation by any other person of any injunction issued under this section may sue for damages therefor in any court of competent jurisdiction and shall recover

twice the amount of such pecuniary loss, together with costs, including a reasonable attorney's fee.

3. No action may be commenced under this section more than 3 years after the occurrence of the unlawful act or practice which is the subject of the action. No injunction may be issued under this section which would conflict with general or special orders of the department or any statute, rule or regulation of the United States or of this state.

(c) 1. Whenever the department has reason to believe that a person is in possession, custody or control of any information or documentary material relevant to the enforcement of this section it may require that person to submit a statement or report, under oath or otherwise, as to the facts and circumstances concerning any activity in the course of trade or commerce; examine under oath that person with respect to any activity in the course of trade or commerce; and execute in writing and cause to be served upon such person a civil investigative demand requiring the person to produce any relevant documentary material for inspection and copying.

2. The department, in exercising powers under this subsection, may issue subpoenas, administer oaths and conduct hearings to aid in any investigation.

3. Service of any notice by the department requiring a person to file a statement or report, or service of a subpoena upon a person, or service of a civil investigative demand shall be made in compliance with the rules of civil procedure of this state.

4. If a person fails to file any statement or report, or fails to comply with any civil investigative demand, or fails to obey any subpoena issued by the department, such person may be coerced as provided in s. 885.12, except that no person shall be required to furnish any testimony or evidence under this subsection which might tend to incriminate him.

(d) The department or the department of justice or any district attorney, upon informing the department of justice, may commence an action in circuit court in the name of the state to restrain by temporary or permanent injunction any violation of this section. The court may in its discretion, prior to entry of final judgment, make such orders or judgments as may be necessary to restore to any person any pecuniary loss suffered because of the acts or practices involved in the action, provided proof thereof is submitted to the satisfaction of the court. The department of justice may subpoena persons, require the production of books and other documents, and may request the department to exercise its authority under subsection (11) (c) to aid in the investigation of alleged violations of this section.

(e) In lieu of instituting or continuing an action pursuant to this section, the department or the department of justice may accept a written assurance of discontinuance of any act or practice alleged to be a violation of this section from the person who has engaged in such act or practice. The acceptance of such assurance by either the department or the department of justice shall be deemed acceptance by the other state officials enumerated in par. (d) if the terms of the assurance so provide. An assurance entered into pursuant to this section shall not be considered evidence of a violation of this section, provided that violation of such an assurance shall be treated as a violation of this section, and shall be subjected to all the penalties and remedies provided therefor.

SECTION 3. 100.20 (6) of the statutes is created to read:

100.20 (6) The department may commence an action in circuit court in the name of the state to restrain by temporary or permanent injunction the violation of any order issued under this section. The court may in its discretion, prior to entry of final judgment make such orders or judgments

as may be necessary to restore to any person any pecuniary loss suffered because of the uses or practices involved in the action, provided proof thereof is submitted to the satisfaction of the court. The department may use its authority in ss. 93.14 and 93.15 to investigate violations of any order issued under this section.

SECTION 4. 100.26 (6) of the statutes is created to read:

100.26 (6) The department of justice or any district attorney may commence an action in the name of the state to recover a civil forfeiture to the state of not less than \$100 nor more than \$10,000 for the violation of an injunction issued under s. 100.18 or an order issued under s. 100.20. Approved February 12, 1970.

1969 Assembly Bill 163

Date published:
March 11, 1970

CHAPTER 426, LAWS OF 1969

AN ACT to create 134.67 of the statutes, prohibiting the distribution, sale and use of the chemical compound DDT.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 134.67 of the statutes is created to read:

134.67 DISTRIBUTION AND SALE OF DDT PROHIBITED. No person shall distribute, sell, offer for sale or use the chemical compound DDT (dichlorodiphenyltrichlorethane) or any of its isomers except as provided in this section. In subs. (1) and (2) "DDT" includes compounds isomeric with DDT.

(1) For the purposes specified in sub. (2), the secretary of agriculture, the state health officer and the secretary of natural resources shall constitute a DDT emergency board, and any such officer may call a meeting of the emergency board to act under sub. (2).

(2) (a) In the event of the outbreak of an epidemic disease of humans or animals spread by insects which it is known can be controlled by DDT but cannot be adequately controlled by any other known pesticide, the emergency board may authorize the use of DDT in controlling the epidemic upon a finding that:

1. A serious epidemic disease of humans or animals exists;
2. The disease is likely to spread rapidly unless insects which spread the disease are controlled; and
3. The only effective means of control is DDT.

(b) In the event of the outbreak of a plant disease of epidemic proportions which threatens a significant portion of the affected crop and which is caused or spread by an insect which it is known can be controlled by DDT but cannot be adequately controlled by any other known pesticide, the emergency board may authorize the use of DDT in controlling the epidemic upon a finding that:

1. An epidemic plant disease exists;
2. The disease threatens a significant portion of the affected crop; and
3. The only effective means of control is DDT.

(c) The emergency board also may authorize the use of DDT or its isomers or metabolites for specified research by educational institutions if it finds that no ecologically significant residues of DDT or its isomers or metabolites will be allowed to escape into the environment.

1969 CHAPTER 425

PROPOSED LEGISLATION (DRAFT #3)

AN ACT to repeal and recreate 100.18 (1) and (7), to amend 100.18 (2) to (6) and (8) to (10) and to create 100.26 (6) of the Statutes, relating to false, misleading and deceptive practices.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 100.18 (1) of the Statutes is repealed and recreated to read:

100.18 (1) The department of justice or the several district attorneys, upon informing the department of justice, may commence an action in circuit court in the name of the state to restrain by temporary or permanent injunction the use of any false, misleading or deceptive act or practice in trade or commerce. The court may make such orders or judgments as may be necessary to restore to any person in interest any moneys or property, real or personal, which may have been expended or lost because of the use of any act or practice prohibited by this section.

SECTION 2. 100.18 (2) to (6) of the Statutes are amended to read:

100.18 (2) * * * it is a deceptive practice * * *.

(3) It shall be deemed a deceptive advertising practice, within the meaning of this section, * * *."

(4) It shall be deemed a deceptive advertising practice, within the meaning of this section, * * *."

(5) * * * It shall be deemed a deceptive practice, within the meaning of this section, to fail to comply with the foregoing requirements.

(6) * * * It shall be deemed a deceptive practice, within the meaning of this section, to fail to comply with the foregoing requirements.

SECTION 3. 100.18 (7) of the Statutes is repealed and recreated to read:

100.18 (7) (a) Whenever the department of justice has reason to believe that a person is in possession, custody, or control of any information or documentary material relevant to the enforcement of this section it may require that person to submit a statement or report, under oath or otherwise, as to the facts and circumstances concerning any activity in the course of trade or commerce; examine under oath that person with respect to any activity in the course of trade or commerce; and execute in writing and cause to be

served upon a person a civil investigative demand requiring the person to produce any relevant documentary material for inspection and copying.

(b) The department of justice, in exercising the power given by this subsection, may issue subpoenas, administer oaths and conduct hearings to aid in any investigation.

(c) Service of any notice by the department of justice requiring a person to file a statement or report, or service of a subpoena upon a person, or service of a civil investigative demand shall be made in compliance with the rules of civil procedure of this state.

(d) If a person fails to file any statement or report, or fails to comply with any civil investigative demand, or fails to obey any subpoena issued by the department of justice, such person may be coerced as provided in section 885.12; provided, however, that no person shall be required to furnish any testimony or evidence pursuant to this subsection which might tend to incriminate him.

SECTION 4. 100.18 (8) to (10) of the Statutes are amended to read:

100.18 (8) * * * It shall be deemed a deceptive advertising practice, within the meaning of this section, to fail to comply with the foregoing requirements or to advertise * * *."

(9) (a) It is deemed a deceptive advertising practice,
within the meaning of this section, * * *.

(9) (b) This subsection * * *.

(10) (a) It is a deceptive practice * * *.

(b) It is a deceptive practice * * *.

SECTION 5. 100.26 (6) of the Statutes is created to read:

100.26 (6) The department of justice or the several district attorneys may commence an action in the name of the state to recover a civil forfeiture to the state of not less than one hundred dollars nor more than ten thousand dollars for the violation of any injunction issued under section 100.18 or any order issued under section 100.20.

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STATE OF WISCONSIN

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° Analysis by the Legislative Reference Bureau °°

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This bill expands s. 100.18 from its present role as a statute
banning misleading advertising into a much broader measure prohibiting
false and misleading trade practices.
Emphasis is shifted to labeling prohibited acts as "deceptive
practices" under the enforcement wing of the department of justice.
Broad powers to investigate are vested in the department.
Penalties range from injunctions and orders for restoration of
costs to competitors to forfeitures of \$100 to \$10,000 for violation
of injunctions.

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The people of the state of Wisconsin, represented in senate
and assembly, do enact as follows:

SECTION 1. 100.18 (1) of the statutes is repealed and recreated
to read:

100.18 (1) The department of justice or any district
attorney, upon informing the department of justice, may commence
an action in circuit court in the name of the state to restrain by
temporary or permanent injunction the use of any false, misleading or
deceptive act or practice in trade or commerce. The court may make
such orders or judgments as may be necessary to restore to any person
in interest any moneys or property, real or personal, which may have
been expended or lost because of any act or practice prohibited by
this section.

SECTION 2. 100.18 (2) to (6) of the statutes are amended to read:

100.18 (2) In advertising or otherwise representing the sale or furnishing of
any property or services combined with or conditioned on the purchase of

stat.

SENATE AMENDMENT
TO 1969 SENATE BILL 701

Amend the bill as follows:

1. On page 1, line 1, after the semi-colon insert "to renumber 100.18(7) and 100.20(4) and (5);".

2. On page 1, line 2, delete "and (7)" and after "create" insert "100.18(7)(b) to (e), 100.18(11), 100.20(4) and".

3. Delete all of the material beginning with line 21 on page 1 and ending with line 5 on page 2 and insert

"100.18(1) No person shall engage in any false, misleading or deceptive act or practice in trade or commerce.

(a) As used in this section, 'false, misleading or deceptive act or practice in trade or commerce' means any act or practice, including those listed in 100.18(2) to (6) and (8) to (10), which may cause substantial detriment to consumers and which is deliberate, involves reckless conduct, or takes unfair advantage of the lack of knowledge, ability, experience, or capacity of consumers.

(b) As used in this section, 'consumer' means a natural person who is offered or supplied goods, services, interest in land or intangibles primarily for personal, family, household, or agricultural purposes.

(c) The department may commence an action in circuit court in the name of the state to restrain by temporary or permanent injunction the use of any false, misleading or deceptive act or practice. The department of justice, when requested by the

department, may assist in the prosecution of any action under this section and any action under s. 100.26(6).

(d) The court may, upon application prior to a final determination in an action under (c) of this subsection, make such orders or judgments as may be necessary to restore to any consumer who has suffered damages as a direct result of the acts or practices involved in the action, and who submits proof to the satisfaction of the court that he has in fact been so damaged, any losses sustained as a result of such acts or practices.

(e) No action under this section may be brought more than one year after the unlawful act or conduct which is the subject of the suit.

(f) In lieu of instituting or continuing an action pursuant to this section, the department may accept a written assurance of discontinuance of any act or practice alleged to be a violation of this section from the person or persons who have engaged in such act or practice. An assurance entered into pursuant to this section shall not be considered evidence of a violation of this section, provided, however, that violation of such an assurance shall be treated as a violation of this section, and shall be subjected to all the penalties and remedies provided therefor.

4. On page 5, line 3, delete "repealed and recreated" and substitute "renumbered 100.18(7)(a).

SECTION 3a, 100.18(7)(b) to (e) are created"

5. On page 5, line 5, change "(a)" to "(b)" and delete "of justice".

6. On page 5, line 10, after "commerce" insert "which relates to an alleged violation of this section".

7. On page 5, line 12, after "commerce" insert "which relates to said alleged violations".

8. On page 5, line 16, change "(b)" to "(c)" and delete "of justice".

9. On page 5, line 19, change "(c)" to "(d)" and delete "of justice".

10. On page 5, line 24, change "(d)" to "(e)".

11. On page 5, line 26, delete "of justice".

12. On page 7, line 21, after "station," insert "or advertising agency,"

13. On page 8, after line 6 insert:

"SECTION 4a. 100.18(11) is created to read:

100.18(11) In any action under this section, it shall be a complete defense to show that the challenged act or practice is subject to, and complies with, any federal or state statute, or any rule or regulation of a federal or state agency.

SECTION 4b. 100.20(4) and (5) of the statutes are renumbered 100.20(5) and (6) respectively.

SECTION 4c. 100.20(4) of the statutes is created to read:

100.20(4) The department may commence an action in circuit court in the name of the state to restrain by temporary or permanent injunction the violation of any general or special order issued under this section. The department of justice, when requested by the department, may assist in the prosecution of any action under this section and any action under s. 100.26(6)."

14. On page 8, line 8, delete "of justice or any district attorney".

15. On page 8, line 11, after "issued" insert ", or an assurance of discontinuance given,".

16. On page 8, line 12, after "order" insert "or injunction".

1969

STATE OF WISCONSIN

LRB-6994/1
JE:lg

Assy. Substitute Amendment

To 1969 SENATE BILL 701

October 10, 1969 - Introduced by Senators RASMUSEN, CIRALLI, McPARLAND,
BUSBY, KNOWLES, SOIK, SCHUELE and DEVITT; co-sponsored by
Assemblymen TREGONING and GREIDER. Referred to Committee on
Judiciary.

1 AN ACT to amend 100.18 (2) to (6) and (8) to (10); to repeal and
2 recreate 100.18 (1) and (7); and to create 100.18 (11) and
3 statutes, relating to false, misleading and deceptive practices, and
4 prescribing penalties.

5
6 Analysis by the Legislative Reference Bureau

7 This bill expands s. 100.18 from its present role as a statute
8 banning misleading advertising into a much broader measure
9 prohibiting false and misleading trade practices.

10 Emphasis is shifted to labeling prohibited acts as "deceptive
11 practices" under the enforcement wing of the department of justice.
12 Broad powers to investigate are vested in the department.

13 Penalties range from injunctions and orders for restoration of
14 costs to competitors to forfeitures of \$100 to \$10,000 for violation
15 of injunctions.

16
17 The people of the state of Wisconsin, represented in senate
18 and assembly, do enact as follows:

19 SECTION 1. 100.18 (1) of the statutes is repealed and
20 recreated to read:

21 100.18 (1) The department of justice or any district
22 attorney, upon informing the department of justice, may commence an
23 action in circuit court in the name of the state to restrain by
24 temporary or permanent injunction the use of any false, misleading

in its

discretion, prior to entry of final judgment, make such orders or judgments as may be necessary to restore to any person any pecuniary loss suffered because of the acts or practices involved in the action, provided proof thereof is submitted to the satisfaction of the court.

1 or deceptive act or practice in trade or commerce. The court may
2 take such orders or judgments as may be necessary to restore to any
3 person in interest any moneys or property, real or personal, which
4 may have been expended or lost because of any act or practice
5 prohibited by this section.

6 SECTION 2. 100.18 (2) to (6) of the statutes are amended to
7 read:

8 100.18 (2) In advertising or otherwise representing the sale
9 or furnishing of any property or services combined with or
10 conditioned on the purchase of any other property or services
11 described in such advertisement or other representation, it is a
12 deceptive practice to fail to state the price or amount which must
13 be paid for the property or services included in such sale, along
14 with any other requirement which is a condition to the receipt of
15 such property or services. The price or amount which must be paid
16 shall be set forth clearly, conspicuously and in such manner that
17 the total price or amount to be paid may be readily ascertained.

18 (3) It shall be deemed a deceptive advertising practice,
19 within the meaning of this section, for any person, firm or
20 corporation, engaged in the business of buying or selling new or
21 secondhand furs, wearing apparel, jewelry, furniture, pianos,
22 phonographs, or other musical instruments, motor vehicles, stocks,
23 or generally any form of property, real, personal or mixed, or in
24 the business of furnishing any kind of service or investment, to
25 advertise such articles, property or service for sale or purchase,
26 in any manner indicating that the sale or purchase is being made by

1 a private party or householder not engaged in such business. And
2 every such ~~firm, corporation or association~~ person, engaged in any
3 such business, in advertising goods, property or service for sale or
4 purchase, shall affirmatively and unmistakably indicate and state
5 that the seller or purchaser is a business concern and not a private
6 party.

7 (4) It ~~shall be~~ is deemed a deceptive ~~advertising practice,~~
8 within the meaning of this section, for any person, ~~firm or~~
9 ~~corporation~~ to take donations or sell merchandise or tickets of
10 admission or solicit programs or any other advertising when any part
11 of the proceeds will be donated to any organization or fund, unless
12 said advertising ~~shall contain~~ contains a correct statement of the
13 amount to be donated to any such organization or fund, set out
14 substantially in the following manner: (a) the minimum amount stated
15 in dollars; or (b) the minimum percentage of the gross income; or
16 (c) the minimum percentage of the net income. If the amount to be
17 donated is to be based on the net income such donor shall file with
18 the secretary or treasurer of the fund or organization receiving the
19 donation before commencing such advertising, an itemized statement,
20 under oath, setting forth the maximum amounts to be deducted from
21 gross income in determining the net income. Such statement shall be
22 open to examination by the public. If merchandise is to be received
23 and donated to such organization or fund, without change of form,
24 the advertising shall state what percentage of the total amount of
25 merchandise collected will be donated to such organization or fund.

1 (5) Any person, ~~firm, corporation or association~~ engaged in
2 any business mentioned in sub. (3), or in any other kind of
3 business, whether conducting such business in a store, business
4 block, residence or other building, shall at all times keep a
5 conspicuous sign posted on the outside of his establishment and
6 another conspicuous sign in the salesroom, which sign shall clearly
7 state the name of the ~~association, corporation or individual~~ person
8 who actually owns said merchandise, property or service which are
9 being offered to the public and not the name of any other person;
10 ~~provided, however, that the.~~ The exterior sign shall not be
11 required where the seller has no control over the exterior of the
12 premises where such business is conducted. It is deemed a deceptive
13 practice, within the meaning of this section, to fail to comply with
14 the foregoing requirements.

15 (6) All advertising which shows or in any manner relates to
16 the price at which motor fuel is offered for sale at retail, except
17 multiple gallon computers attached to or forming a part of any
18 dispensing equipment shall show only (a) the single gallon unit
19 price including all applicable taxes in one amount or (b) the single
20 gallon product price, the taxes applicable thereto, and the total
21 single gallon unit price including all applicable taxes. In any such
22 advertising, all numerals which represent either price or taxes
23 shall be of the same type and size except that fractions of a cent
24 shall be shown in figures one-half the height, width and prominence
25 of the whole numbers. It is deemed a deceptive practice, within the
26 meaning of this section, to fail to comply with the foregoing

1 requirements.

2 SECTION 5. 100.18 (7) of the statutes, as affected by chapter
3 —, laws of 1969 (^{repealed} ^{100.18} Senate Bill 355), is repealed and recreated to
4 read:

5 100.18 (7) (a) Whenever the department of justice has reason
6 to believe that a person is in possession, custody or control of any
7 information or documentary material relevant to the enforcement of
8 this section it may require that person to submit a statement or
9 report, under oath or otherwise, as to the facts and circumstances
10 concerning any activity in the course of trade or commerce; examine
11 under oath that person with respect to any activity in the course of
12 trade or commerce; and execute in writing and cause to be served
13 upon such person a civil investigative demand requiring the person
14 to produce any relevant documentary material for inspection and
15 copying.

16 (b) The department of justice, in exercising powers under
17 this subsection, may issue subpoenas, administer oaths and conduct
18 hearings to aid in any investigation.

19 (c) Service of any notice by the department of justice
20 requiring a person to file a statement or report, or service of a
21 subpoena upon a person, or service of a civil investigative demand
22 shall be made in compliance with the rules of civil procedure of
23 this state.

24 (d) If a person fails to file any statement or report, or
25 fails to comply with any civil investigative demand, or fails to
26 obey any subpoena issued by the department of justice, such person

1969 SENATE BILL 701

1 may be coerced as provided in s. 885.12, except that no person shall
2 be required to furnish any testimony or evidence under this
3 subsection which might tend to incriminate him.

4 SECTION 4. 100.18 (8) to (10) of the statutes are amended to
5 read:

6 100.18 (8) Every wholesaler and every other person selling or
7 distributing motor fuel in this state shall keep posted in a
8 conspicuous place, most accessible to the public at his place of
9 business, and on every pump from which delivery is made directly
10 into the fuel tank attached to a motor vehicle, a placard showing
11 the net selling price per gallon of all grades of motor fuel and the
12 amount of all taxes per gallon thereon. On pumps or other dispensing
13 equipment from which motor fuel is sold and delivered directly into
14 fuel supply tanks attached to motor vehicles, such posting shall be
15 in figures not less than one inch high, except that no such placard
16 shall be required on a computer pump whereon the total net selling
17 price per gallon including all taxes is legibly shown on its face.
18 All sales shall be made at the posted price and delivery slips shall
19 also show the net selling price per gallon of all grades of motor
20 fuel and the amount of all taxes per gallon thereon. If the
21 wholesaler or person has more than one place of business in this
22 state, the wholesaler or person shall post said placard at all of
23 his places of business. All prices posted shall remain in effect for
24 at least 24 hours after they are posted. It ~~shall be~~ is deemed a
25 deceptive ~~advertising practice, within the meaning of this section,~~
26 to fail to comply with the foregoing requirements or to advertise or

added
motor
fuel
section

represent in any manner the price of motor fuel offered for sale at retail to be less than the price so posted on each pump.

(9) (a) It is deemed a deceptive advertising practice, within the meaning of this section, for any person or any agent or employe thereof to make, publish, disseminate, circulate or place before the public in this state in a newspaper or other publication or in the form of book, notice, handbill, poster, bill, circular, pamphlet, letter, sign, placard, card, label or over any radio or television station or in any other way similar or dissimilar to the foregoing, an advertisement, announcement, statement or representation of any kind to the public relating to the purchase, sale, hire, use or lease of real estate, merchandise, securities, service or employment or to the terms or conditions thereof which advertisement, announcement, statement or representation is part of a plan or scheme the purpose or effect of which is not to sell, purchase, hire, use or lease the real estate, merchandise, securities, service or employment as advertised.

(b) This ~~subsection~~ section does not apply to the owner, publisher, printer, agent or employe of a newspaper or other publication, periodical or circular, or of a radio or television station, who in good faith and without knowledge of the falsity or deceptive character thereof, publishes, causes to be published or takes part in the publication of such advertisement.

(10) (a) It is a deceptive practice to misrepresent the nature of any business by use of the words manufacturer, factory, mill, importer, wholesaler or words of similar meaning, in a corporate or

Insert A

15

SECTION 100.18(11) ~~(a) to (c)~~ of the statutes are created to read:

100.18(11)(a) The department ^{(a) (b) (c) (d) (e) (f) (g) (h) (i) (j) (k) (l) (m) (n) (o) (p) (q) (r) (s) (t) (u) (v) (w) (x) (y) (z)} may request that the department of justice commence an action to enjoin an alleged false, misleading or deceptive practice, in which event the ^{Call to} department ~~of justice~~ shall proceed with the requested action within a reasonable period of time or provide the department ^{(a) (b) (c) (d) (e) (f) (g) (h) (i) (j) (k) (l) (m) (n) (o) (p) (q) (r) (s) (t) (u) (v) (w) (x) (y) (z)} with a brief statement of its reasons for not proceeding. The department of justice shall further provide the department ^{(a) (b) (c) (d) (e) (f) (g) (h) (i) (j) (k) (l) (m) (n) (o) (p) (q) (r) (s) (t) (u) (v) (w) (x) (y) (z)} with periodic summaries of all activity under this section.

(b) Any person suffering pecuniary loss because of a violation by any other person of any injunction issued under this section may

sue for damages therefor in any court of competent jurisdiction and shall recover twice the amount of such pecuniary loss, together with costs, including a reasonable attorney's fee.

(c) No action may be commenced under this section more than three years after the occurrence of the unlawful act or practice which is the subject of the action. No injunction may be issued under this section which would conflict with general or special orders of the department ^{(a) (b) (c) (d) (e) (f) (g) (h) (i) (j) (k) (l) (m) (n) (o) (p) (q) (r) (s) (t) (u) (v) (w) (x) (y) (z)} or any statute, rule or regulation of the United States or this state.

END - Insert A

1 trade name or otherwise.

2 (b) It is a deceptive practice to represent the price of any
3 merchandise as a manufacturer's or wholesaler's price, or a price
4 equal thereto, unless such price is not more than the price which
5 retailers regularly pay for such merchandise. ~~The effective date of
6 this act shall be January 1, 1962.~~

Insert
A

7 SECTION ¹⁶¹ 100.26 (b) of the statutes is created to read:

8 100.26 (6) The department of justice or any district attorney
9 may commence an action in the name of the state to recover a civil
10 forfeiture to the state of not less than \$100 nor more than \$10,000
11 for the violation of an injunction issued under s. 100.18 or an
12 order issued under s. 100.20.

13 (End)

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EXHIBIT E

NO. _____ FILED _____
A.M. 11:20 P.M. _____

APR 11 2008



J. DAVID NAVARRO, CLERK
By _____ INGA JOHNSON
DEPUTY

1 IN THE DISTRICT COURT OF THE FOURTH JUDICIAL DISTRICT OF
2 THE STATE OF IDAHO, IN AND FOR THE COUNTY OF ADA

3
4 STATE OF IDAHO

5 Plaintiff,

6
7 vs.

8
9 AVENTIS PHARMACEUTICALS
10 INC.; FOREST LABORATORIES,
11 INC.; MYLAN LABORATORIES,
12 INC.; MYLAN PHARMACEUTICALS,
13 INC.; NOVARTIS
14 PHARMACEUTICALS CORP.;
15 PFIZER INC.; PHARMACIA CORP.;
16 SCHERING-PLOUGH CORP.;
17 SMITHKLINE BEECHAM CORP.,
18 d/b/a GLAXOSMITHKLINE;
19 WARRICK PHARMACEUTICALS
20 CORPORATION,

21 Defendants.

Case No. CV OC 0710318

MEMORANDUM DECISION
AND ORDER ON THE
DEFENDANTS' MOTIONS TO
DISMISS

22 This matter comes before the Court on the defendant pharmaceutical companies' various
23 motions to dismiss the Plaintiff's Complaint pursuant to Idaho Rule of Civil Procedure 12(b)(6).
24 The motions include the Defendants' joint motion to dismiss, in which all defendants joined. Mr.
25 William Fuhrman argued on behalf of Aventis Pharmaceuticals in favor of this motion. Also before
26 the Court is the Certain Defendants motion to dismiss the Plaintiff's Complaint, submitted by the
generic defendants Mylan Laboratories, Inc., Mylan Pharmaceuticals, Inc., Pharmacia Corporation,
and Warrick Pharmaceuticals Corporation. Mr. William Dryden argued on behalf of the generic
defendants' motion.

1 In addition to the multi-defendant motions, three defendants filed independent motions to
2 dismiss the Complaint as it applies to them. In regard to these separate motions, Mr. John Bueker
3 argued on behalf of Warrick Pharmaceuticals Corporation in favor of its motion to dismiss, Mr.
4 John Burke argued on behalf of Novartis Pharmaceuticals in favor of its motion, and Ms. Erica
5 Smith-Klosak argued on behalf of Pfizer, Inc. in favor of its separate motion. Brett DeLange
6 argued against all motions on behalf of the State of Idaho.

7 The Court took all the various motions to dismiss under advisement on March 7, 2008.

8 BACKGROUND

9
10 In this case, the State of Idaho alleges that the defendant pharmaceutical companies violated
11 the Idaho Consumer Protection Act (ICPA or the Act) by inflating the price the State reimburses for
12 Medicaid prescription drugs. This case has three companion cases, two before the Honorable
13 Kathryn A. Sticklen called *State v. Abbott Laboratories, et al.* and *State v. Alpharma USPD, Inc. et*
14 *al.* and a third case before this Court called *State v. Ben Venue, et al.* Recently, this Court issued a
15 decision regarding similar motions to dismiss submitted by the *Ben Venue* defendants.

16 In broad strokes, the motions to dismiss concern issues of whether the State's Complaint
17 properly pled its requests for relief against the Defendants, whether the State can bring any of its
18 ICPA claims, whether the Complaint is fatally flawed because of a contradictory Idaho Regulation,
19 and whether the claims are barred by the statute of limitations.
20

21 ANALYSIS

22
23 Many of the issues set forth in the various motions overlap, thus the Court will take up one
24 issue at a time.
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1. Regarding the motion to dismiss the claim for equitable relief

The Idaho Rules of Civil Procedure and accompanying case law have authorized a litigant to plead alternative theories within a complaint. Rule 8(a)(1) specifically states that "relief in the alternative or of several different types may be demanded" and modern case law supports that a party may pursue a remedy at law and an alternative equitable remedy. See, *M.K. Transp, Inc. v. Gover*, 101 Idaho 345, 612 P.2d 1192 (1980). The State concedes that if it prevails on its Consumer Protection Act claim, the State has an adequate remedy at law that bars equitable relief. But if the ICPA claim fails, the State should be free to pursue the alternative theory of unjust enrichment.

An analysis of the State's Idaho Consumer Protection Act claim and the unjust enrichment claim show that the State has pled all the necessary elements to survive a 12(b)(6) motion to dismiss.

2. Regarding the claim that the Complaint fails to set forth the elements of an unjust enrichment cause of action

As stated above, the State may plead alternative theories. The State has alleged unjust enrichment as an alternative, equitable cause of action. To plead unjust enrichment properly, the State must set forth three elements, (1) the State conferred a benefit upon the Defendants; (2) the Defendants appreciated such benefit; and (3) it was inequitable for the Defendants to keep the benefit without compensating the State. See, Pl.'s Compl., ¶ 73-76 (June 8, 2007); *Aberdeen-Springfield Canal Co. v. Peiper*, 133 Idaho 82, 88, 982 P.2d 917, 923 (1999). The Defendants contend that the Complaint failed to allege that the State conferred a benefit upon the Defendants. However, the State satisfied this element because it alleged that its overpayment to providers resulted in increased market share and profit to the Defendants. Pl.'s Compl., ¶ 2, ¶ 75 (June 8, 2007). The Court does not find that the profit is too attenuated or remote to dismiss the claim.

1
2 **3. Regarding the motion to dismiss the claim for Injunctive Relief**

3 Certain Defendants argue that the State has not alleged any conduct for which the Court can
4 grant injunctive relief because they have not reported AWP information since 2005. The Idaho
5 Consumer Protection Act empowers the Attorney General to bring an action in the name of the State
6 to enjoin any practices that violate the Act whenever “the Attorney General has reason to believe
7 that any person is using, has used, or is about to use” such unlawful practices. I.C. § 48-606(1)(b).

8 In this case, the Attorney General asserts he has reason to believe the Defendant “has used”
9 an unlawful practice, to wit, inflating its AWP information. Regardless of whether such Defendants
10 continue to report AWPs, the Attorney General has reason to believe the Defendants did so in the
11 past. Accordingly, the claim for injunctive relief survives a motion to dismiss.
12

13
14 **4. Regarding Pfizer’s claim that the Complaint does not set forth a claim against it**
15 **because it has never reported average wholesale price information to First DataBank**
16 **nor to anyone else**

17 Pfizer raised the issue of whether the pleadings set forth any cause of action against it.
18 Ultimately, Pfizer may show that the State’s allegations are not true, but the standard the Court
19 applies to a motion to dismiss is simply whether the pleadings, if true, state a cause of action. *Young*
20 *v. City of Ketchum*, 137 Idaho 102, 104, 44 P.3d 1157, 1159 (2002). Even if the Court were to
21 consider affidavits or other material outside of the pleadings and treat this as a motion for summary
22 judgment, the Court would not consider the Defendant’s unsupported assertions in its memorandum.

23 The State’s Complaint contends that Pfizer inflated reports of average wholesale acquisition
24 costs caused false calculation of AWP and that is a sufficient allegation to survive a motion to
25 dismiss. Pl.’s Compl., ¶ 35, ¶ 45, and ¶ 46 (June 8, 2007).
26

1
2 **5. Regarding the claim that the spread between the true wholesale price and the average**
3 **wholesale price is within industry standards and therefore not a violation of ICPA**

4 The Defendants argued prematurely that the price spreads are within industry standards and
5 so their conduct was not deceptive as a matter of law. The thrust of this argument is whether the
6 Complaint states a valid claim. The questions of whether a price differential is within the industry
7 standard, and if so, whether such a finding would provide a legal defense to either the ICPA claim or
8 the unjust enrichment claim, will have to involve factual findings. Factual findings are inappropriate
9 at this stage of the litigation, thus the motion to dismiss based on this argument is denied.
10

11
12 **6. Regarding the claim that the State is not a Consumer or Purchaser injured by the**
13 **alleged conduct**

14 The Court entertained the same argument in *State v. Ben Venue*, and rejected it. The Court
15 rejects it here for the same reasons. The State pays for the goods in question; therefore, the State is a
16 consumer within the meaning of the ICPA.
17

18 **7. Regarding the claim that the Complaint fails to allege fraud with particularity**

19 The defendants in *State v. Ben Venue* also argued that the State failed to allege fraud with
20 particularity and the Court rejected such argument. The Idaho Consumer Protection Act and IRCP
21 9(b) both require a Complaint contain sufficient particularity to advise the Defendant what conduct
22 allegedly violates the Act. Similar to the *Ben Venue* ruling, the Court holds that the State's
23 Complaint contains sufficient allegations for the Defendants to frame their defenses and proceed in
24 this litigation, so it withstands a motion to dismiss.
25
26

1
2 **8. Regarding the claim that the Complaint is contrary to an Idaho Regulation that allows**
3 **the State to reimburse with a profit to the providers**

4 The Idaho Medicaid Plan is a contract between the State of Idaho and the Federal
5 Government that, *inter alia*, sets the reimbursement rate, which is largely based on reported AWP.
6 The issue in this case is whether the Defendants deceptively reported inflated AWP. Thus, the
7 Idaho Regulation cited by the Defendants does not alter the terms of the Idaho Medicaid Plan, to
8 include the reimbursement rate based on AWP information.

9
10
11 **9. Regarding the claim that the Idaho Administrative Regulation § 16.03.09.665.02(d)(iii),**
12 **defining “estimated acquisition cost” (EAC), controls the definition of AWP and allows**
13 **a profit**

14 Even if the Court accepted the Idaho Administrative Regulation definition of estimated
15 acquisition cost as net cost plus reasonable operating margin plus dispensing fee, the Court must still
16 consider the definition in the Medicaid Plan that the EAC is the “AWP minus 12%.” Pl.’s Compl., ¶
17 27 and ¶ 54 (June 8, 2007). The Idaho Regulation cannot be interpreted in a manner inconsistent
18 with the Medicaid Plan. Therefore, the motion to dismiss based on this argument is denied.

19
20 **10. Regarding the claim that the statute of limitations in I.C. §§ 5-217 and 5-224 bar any**
21 **claims that accrued more than four years prior to the filing of the lawsuit**

22 The defendants in *State v. Ben Venue* also argued this point and the Court held that the four
23 year statute of limitations applied. In doing so, the Court rejected the State’s contention that the
24

1 conduct complained of constituted a continuing tort and that the statute of limitations did not apply
2 to the State's ICPA claim.

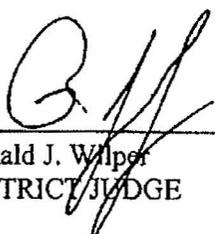
3 The parties in *Ben Venue* submitted a stipulation and order that agreed upon the date of the
4 limitation of the action given the court's decision that I.C. §§ 5-217 and 5-224 applied. The same
5 reasoning regarding the statute of limitations the Court employed in *Ben Venue* applies in this case.
6 The Court is not aware of whether the parties in this case have a similar stipulation that would set the
7 date more than four years before the Complaint. Without such a stipulation, the Court grants the
8 motion to dismiss to the extent that the Complaint made any claims for alleged conduct that accrued
9 fours years prior to the commencement of this action on June 8, 2007.
10

11
12 CONCLUSION

13 With respect to the joint motion to dismiss, the Court hereby denies the motion except to the
14 extent that the Chapter 5 statutes of limitations apply. Claims for alleged conduct accruing fours
15 years prior to the commencement of this action are dismissed. As to the Certain Defendant's Motion
16 to Dismiss, the Court denies it in its entirety. And last, the Court denies each separate motion to
17 dismiss submitted by Novartis, Warrick, and Pfizer.
18

19 IT IS SO ORDERED.

20 Dated this 10th day of April 2008.

21
22 
23 _____
24 Ronald J. Wilper
25 DISTRICT JUDGE
26

CERTIFICATE OF MAILING

I, HEREBY CERTIFY that on the 11 day of April 2008, I caused a true and correct copy of the foregoing MEMORANDUM DECISION AND ORDER to be served by the method indicated below, and addressed to the following:

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6 J. DAVID NAVARRO
7 Clerk of the District Court
Ada County, Idaho

8 By INGA JOHNSON
9 Deputy Clerk

EXHIBIT F

ENTERED

COMMONWEALTH OF KENTUCKY
FRANKLIN CIRCUIT COURT - DIV. 1
CIVIL ACTION NO. 04-C1-1487

JUN 23 2006
FRANKLIN CIRCUIT COURT
CLERK

COMMONWEALTH OF KENTUCKY
ex rel. GREGORY D. STUMBO, ATTORNEY GENERAL

PLAINTIFF

v.

ALPHARMA, INC., *et al.*

DEFENDANTS

ORDER
ON MOTIONS TO DISMISS

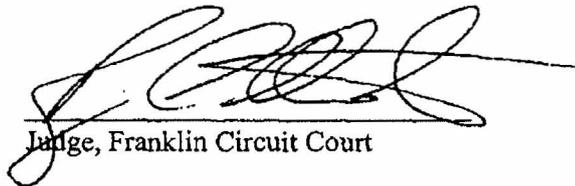
The matter came before the Court on June 6, 2006, for oral arguments on the defendants' joint motion to dismiss the Commonwealth's First Amended Complaint pursuant to CR 12.02 and CR 9.02, and certain motions to dismiss filed by individual defendants. Having read the memoranda filed by the parties and having heard the arguments of counsel, and for the reasons stated by the Court at the June 6, 2006 hearing, **IT IS HEREBY ORDERED**, as follows:

1. The joint Defendants' Motion to Dismiss the Commonwealth's Complaint filed by all of the defendants be and is **DENIED** in all respects except as follows: (a) the Target Drug List filed by the Commonwealth is imposed as an amendment to the Commonwealth's First Amended Complaint and identifies all those drugs for which the Commonwealth claims it or its citizens have overpaid; and (b) all claims arising prior to November 4, 1999 are hereby barred by the applicable statute of limitations set forth in KRS 413.120(2).

2. The individual Motions to Dismiss by AstraZeneca Pharmaceuticals LP and TAP Pharmaceutical Products, Inc. be and are **DENIED** as moot in light of the Commonwealth's voluntary dismissal, with prejudice, of claims against (a) AstraZeneca Pharmaceuticals LP

relating to the cancer drug Zoladex and (b) TAP Pharmaceutical Products, Inc. relating to Lupron.

3. The defendants shall have until July 19, 2006 in which to file their respective Answers.



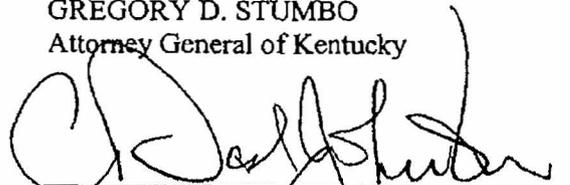
Judge, Franklin Circuit Court

June 23, 2006
Date

TENDERED BY:

GREGORY D. STUMBO
Attorney General of Kentucky

By:



C. David Johnstone
Assistant Attorney General

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Counsel for Plaintiff,
Commonwealth of Kentucky

Distribution to: All Counsel of Record

EXHIBIT G

To:

- Federally Qualified Health Centers
- Nurse Midwives
- Nurse Practitioners
- Physician Assistants
- Physician Clinics
- Physicians
- Rural Health Clinics
- HMOs and Other Managed Care Programs

Reimbursement Changes for Provider-Administered Drug Codes

Effective for dates of service on and after October 1, 2005, Wisconsin Medicaid will adopt a new reimbursement methodology for provider-administered drugs. Separate reimbursement will be allowed for administering drugs.

Reimbursement Changes

Effective for dates of service (DOS) on and after October 1, 2005, Wisconsin Medicaid will adopt a new reimbursement methodology for provider-administered drugs. The new reimbursement rates for single-source (brand name) drugs will be based on the average sales price. Reimbursement rates for multiple-source (generic) drugs will be based on the maximum allowed cost for the drug. Previously, Wisconsin Medicaid based reimbursement rates for provider-administered drugs on average wholesale price methodology.

Provider-Administered Drug Procedure Codes

The physician maximum allowable fee schedule contains the most current allowable provider-administered drug procedure codes. Providers may refer to the Medicaid Web site at dhfs.wisconsin.gov/medicaid/ for the most current fee schedule or call Provider Services at (800) 947-9627 or (608) 221-9883 for coverage information.

Reimbursement for Administration Component

Previously, reimbursement for provider-administered drugs included reimbursement for administering the drug. The new reimbursement methodology allows separate reimbursement for the administration component, except for vaccines. Effective for DOS on and after October 1, 2005, providers should use the appropriate administration procedure code from the list in the Attachment of this *Wisconsin Medicaid and BadgerCare Update* for provider-administered drugs. The procedure codes in the Attachment replace *Current Procedural Terminology* administration procedure codes 90780-90782, 90784, and 96400-96414.

Administration of a drug may only be reimbursed once per drug, unless otherwise noted in the procedure code description.

Note: Separate reimbursement for the procedure codes related to the administration component does not apply to vaccines. Reimbursement for vaccine procedure codes will continue to include reimbursement for the vaccine component, when applicable, *and* the administration component. Refer to the Physician Services Handbook for more information on immunizations.

Information Regarding Medicaid HMOs

This *Update* contains Medicaid fee-for-service policy and applies to providers of services to recipients on fee-for-service Medicaid only. For Medicaid HMO or managed care policy, contact the appropriate managed care organization. Wisconsin Medicaid HMOs are required to provide at least the same benefits as those provided under fee-for-service arrangements.

The *Wisconsin Medicaid and BadgerCare Update* is the first source of program policy and billing information for providers.

Although the *Update* refers to Medicaid recipients, all information applies to BadgerCare recipients also.

Wisconsin Medicaid and BadgerCare are administered by the Division of Health Care Financing, Wisconsin Department of Health and Family Services, P.O. Box 309, Madison, WI 53701-0309.

For questions, call Provider Services at (800) 947-9627 or (608) 221-9883 or visit our Web site at dhfs.wisconsin.gov/medicaid/.

PHC 1250

ATTACHMENT

Drug Administration Procedure Codes

The following is a list of drug administration procedure codes. Refer to the physician maximum allowable fee schedule for the most current allowable codes.

Note: For vaccines, reimbursement for the vaccine procedure code continues to include reimbursement for the vaccine component, when applicable, *and* the administration component. Providers will not be separately reimbursed for administration of vaccines.

Procedure Code	Description	Add-On Code?
G0345	Intravenous infusion, hydration; initial, up to one hour	
G0346	Each additional hour, up to eight (8) hours (list separately in addition to code for primary procedure)	Yes
G0347	Intravenous infusion, for therapeutic/diagnostic (specify substance or drug); Initial, up to one hour	
G0348	Each additional hour, up to eight (8) hours (list separately in addition to code for primary procedure and report in conjunction with G0347)	Yes
G0349	Additional sequential infusion, up to one hour (list separately in addition to code for primary procedure)	Yes
G0350	Concurrent infusion (list separately in addition to code for primary procedure) report only once per substance/drug regardless of duration, report G0350 in conjunction with G0345	Yes
G0351	Therapeutic or diagnostic injection (specify substance or drug); subcutaneous or intramuscular	
G0353	Intravenous push, single or initial substance/drug	
G0354	Each additional sequential intravenous push (list separately in addition to code for primary procedure)	Yes
G0355	Chemotherapy administration, subcutaneous or intramuscular non-hormonal antineoplastic	
G0356	Hormonal antineoplastic	
G0357	Intravenous, push technique, single or initial substance/drug	
G0358	Intravenous, push technique, each additional substance/drug (list separately in addition to code for primary procedure)	Yes
G0359	Chemotherapy administration, intravenous infusion technique; up to one hour, single or initial substance/drug	
G0360	Each additional hour, one to eight (8) hours (list separately in addition to code for primary procedure) use G0360 in conjunction with G0359	Yes
G0361	Initiation of prolonged chemotherapy infusion (more than eight hours), requiring use of a portable or implantable pump	
G0362	Each additional sequential infusion (different substance/drug), up to one hour (use with G0359)	Yes
G0363	Irrigation of implanted venous access device for drug delivery systems (do not report G0363 if an injection or infusion is provided on the same day)	