HB 274

<TARGET><BILL>HB 274</BILL><SUBJECT>HB 274</SUBJECT><COMM>SJUD27</COMM></TARGET>

Representatives
Lindsey Holmes
Kurt Olson

Capitol Room 405
465-4919
465-2137 fax

MEMORANDUM

Date: 21 February 2012

To: Sen. Hollis French,
Chair (S) JUD

From: Rep. Lindsey Holmes & Rep. Kurt Olson

RE: (S) JUD Scheduling Request for HB 274

We respectfully request that the Senate Judiciary committee schedule our bill, HB 274: "An Act relating to the exemption of certain acts and transactions from the provisions dealing with unfair methods of competition and unfair or deceptive acts or practices," for a hearing.

I have attached the only version of the bill, the sponsor statement, a copy of a relevant judicial order, and the fiscal note.

Please contact Rep. Holmes' aide James R. Waldo at james.waldo@legis.state.ak.us or 465.6597 if you have any questions.

Representative Lindsey Holmes

House Bill 274 Sponsor Statement

An Act relating to the exemption of certain acts and transactions from the provisions dealing with unfair methods of competition and unfair or deceptive acts or practices.

In 2010, the Department of Law filed suit against two pharmaceutical companies for committing violations of Alaska's Consumer Protection Act ("CPA") for engaging in misleading and deceptive marketing practices. The complaint alleges that Janssen Pharmaceutical Company and Astra Zenica Pharmaceuticals mislead and deceived doctors and others by promoting the antipsychotic drugs Risperdal and Seroques for uses not approved by the federal Food and Drug Administration ("FDA"). In many cases Alaska's Medicaid program paid for these off-label prescriptions.

In October of 2012, the federal court ruled that Alaska's Consumer Protection Act may not apply to the state's claims because the FDA regulates drug labeling. The court relied on AS 45.50.481 which exempts any act or transaction regulated by state or federal law from the CPA. Thus, even though the Food, Drug, and Cosmetic Act does not preempt state law, the court is concerned that AS 45.50.481 may prevent the state from pursuing these claims under the CPA. Although the state strongly disagrees with the court, and has argued against the court's reasoning, the court has suggested very strongly that the state's claims are exempt from the CPA. This creates a potential inadvertent loophole when federal laws may regulate conduct, but do not explicitly preempt state law.

Such a loophole could lead to situations, like the case of off-label prescriptions, where the federal government has a law regulating conduct but does not actually enforce the law to protect consumers. The state takes the position that when no effective enforcement by the federal agencies is taken, then these laws do not effectively "prohibit" the bad conduct, and the state should be allowed to bring CPA claims, even under the existing statute. However, to make the state's intention in AS 45.50.481 crystal clear, the legislature should take action.

House Bill 274 closes this potential loophole by removing the reference to federal law in AS 45.50.481. In cases where federal law preempts state law, the State will still be prevented from pursuing claims. This will, however, ensure the State's ability to defend Alaskan consumers where the federal government is not doing so.

Please join me in supporting HB 274 so that the State of Alaska can more effectively protect Alaskan consumers.

State Capitol, Juneau, Alaska 99801 · (907) 465-4919 · Fax: (907) 465-2137
Rep.Lindsey.Holmes@legis.state.ak.us

FISCAL NOTE

STATE OF ALASKA
2012 LEGISLATIVE SESSION

Bill Version: **HB 274**
Fiscal Note Number:
() Publish Date:

Identifier (file name): HB274-LAW-CIV-02-10-12
Title: An Act relating to unfair trade practices.
Sponsor: Representative(s) HOLMES, OLSON
Requester: (H) Labor & Commerce

Dept. Affected: Law
Appropriation: Civil
Allocation: Commercial and Fair Business
OMB Component Number: 2717

Expenditures/Revenues (Thousands of Dollars)

Note: Amounts do not include inflation unless otherwise noted below.

	FY13 Appropriation Requested	Included in Governor's FY13 Request	Out-Year Cost Estimates				
OPERATING EXPENDITURES	**FY13**	**FY13**	**FY14**	**FY15**	**FY16**	**FY17**	**FY18**
Personal Services	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Travel							
Services							
Commodities							
Capital Outlay							
Grants, Benefits							
Miscellaneous							
TOTAL OPERATING	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**

FUND SOURCE		(Thousands of Dollars)						
1002	Federal Receipts							
1003	GF Match							
1004	GF							
1005	GF/Prgm (DGF)							
1037	GF/MH (UGF)							
1178	temp code (UGF)							
TOTAL		**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**

POSITIONS							
Full-time							
Part-time							
Temporary							

CHANGE IN REVENUES							

Estimated SUPPLEMENTAL (FY12) operating costs _____ *(separate supplemental appropriation required)*
(discuss reasons and fund source(s) in analysis section)

Estimated CAPITAL (FY13) costs _____ *(separate capital appropriation required)*
(discuss reasons and fund source(s) in analysis section)

Why this fiscal note differs from previous version (if initial version, please note as such)

Not applicable, initial version.

Prepared by: Eileen Donahue, Division Operations Manager
Phone: 465-5427
Division: Administrative Services
Date/Time: 2/10/12 10:00 AM
Approved by: Michael C. Geraghty, Attorney General
Department of Law
Date: 2/10/2012

(Revised 1/17/2012 OMB)

FISCAL NOTE

STATE OF ALASKA
2012 LEGISLATIVE SESSION

BILL NO. HB 274

Analysis

HB 274 amends Alaska's Consumer Protection Act ("CPA") by removing the exemption for conduct regulated and prohibited by federal law. Currently, the CPA does not apply to any conduct that is regulated and prohibited by state or federal law. The State of Alaska can control enforcement of state law, but is powerless to control the enforcement by federal regulators. Thus, the state cannot take enforcement action against a CPA violator if the conduct is "regulated" and "prohibited" under any federal statute or regulation, even if that conduct is not preempted by federal law. This bill would remove the exemption for conduct regulated by federal law, and would allow the state to pursue CPA violations as long as the conduct is not (1) regulated and prohibited by state law, or (2) preempted by federal law.

We anticipate no fiscal impact to the Department of Law from this bill.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ALASKA

STATE OF ALASKA, Plaintiff, vs. JANSSEN ORTHO LLC; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS INC.; and ASTRAZENECA PHARMACEUTICALS LP, Defendant.	Case No. 3:11-cv-0002-RRB **ORDER REGARDING DEFENDANTS' MOTION TO DISMISS, DISMISSING PLAINTIFF'S STRICT LIABILITY CLAIM, and REQUESTING FURTHER BRIEFING REGARDING THE SAFE HARBOR PROVISION**

I. INTRODUCTION

Defendants jointly move to dismiss both counts in the Amended Complaint pursuant to Federal Rule of Civil Procedure 12(b)(6) and the U.S. Supreme Court decisions in Bell Atlantic Corp. v. Twombly, 550 U.S. 544 (2007), and Ashcroft v. Iqbal, 556 U.S. 662, 129 S. Ct. 1937 (2009), arguing that Plaintiff has not alleged, and cannot allege, facts necessary to establish the claims against either Defendant. Moreover, they argue that Plaintiff's fraud-based claims fail because they are not alleged with the particularity required by Federal Rule of Civil Procedure 9(b).

Plaintiff has opposed the Motion to Dismiss, and Defendant has replied. This matter having been fully and adequately briefed, the

Court does not find that oral argument would be helpful at this time.

II. STANDARD OF REVIEW

A motion under Rule 12(b)(6) may be granted "only if it is clear that no relief could be granted under any set of facts that could be proven consistent with the allegations." In deciding this motion, not only must the Court accept all material allegations in the Complaint as true, but the Complaint must be construed, and all doubts resolved, in the light most favorable to the Plaintiff.

The United States Supreme court has recently and specifically addressed the pleading requirements in a civil action:

> Under Federal Rule of Civil Procedure 8(a)(2), a pleading must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." As the Court held in Twombly, . . . the pleading standard Rule 8 announces does not require "detailed factual allegations," but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation. . . . . A pleading that offers "labels and conclusions" or "a formulaic recitation of the elements of a cause of action will not do." . . . .
>
> To survive a motion to dismiss, a complaint must contain sufficient **factual matter**, accepted as true, to "state a claim to relief that is plausible on its face." . . . A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. . . .
>
> Two working principles underlie our decision in Twombly. First, the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. **Threadbare recitals of**

> **the elements of a cause of action, supported by mere conclusory statements, do not suffice**. . . . Second, only a complaint that states a plausible claim for relief survives a motion to dismiss. . . . Determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense. . . .[1]

Under Federal Rule of Civil Procedure 9(b), a claim for fraud must be pled with particularity, specifying "the who, what, when, where, and how" of the fraud.[2] Where a complaint asserts claims that are "grounded in fraud" or which "sound in fraud . . . the pleading as a whole must satisfy the particularity requirement of Rule 9(b)."[3] The parties disagree as to whether the Alaska UTPA claims alleging intentional misconduct must satisfy Rule 9(b).

III. FACTS

This lawsuit involves two prescription medicines approved by the U.S. Food and Drug Administration ("FDA"): Seroquel®, marketed and sold by AstraZeneca, and Risperdal®, marketed and sold by Janssen. Both medications are approved by the FDA for the treatment

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[1] Ashcroft v. Iqbal, 129 S.Ct. 1937, 1949-50(2009) (emphasis added) (internal citations omitted); See also Bell Atlantic Corp. v. Twombly, 550 U.S. 544 (2007).

[2] See Kearns v. Ford Motor Co., 567 F.3d 1120, 1124 (9th Cir. 2009).

[3] Id.

of certain mental health conditions.[4] Plaintiff, the State of Alaska, has filed a two-count Amended Complaint against the Defendants - one count alleging violations of the Alaska Unfair Trade Practices and Consumer Protection Act ("UTPA"), AS 45.50.471, and the other captioned "Strict Liability - Failure To Warn." Plaintiff seeks: (1) damages for the value of all payments that Alaska allegedly expended through its Medicaid program for purchasing defendants' medicines for indications that were not "medically accepted" ("reimbursement costs"); (2) injunctive relief; (3) penalties of $25,000 for each separate violation of the Alaska UTPA; and (4) treble damages, punitive damages, interest, and costs and attorneys' fees.

The Complaint describes methods by which Defendants wrongfully marketed their drugs. These include allegedly deceiving physicians and consumers "regarding the comparative safety, efficacy, and superiority of Risperdal and Seroquel over traditional or other atypical antipsychotics . . . aggressive market[ing] and promot[ing] Risperdal and Seroquel for indications that are not approved by the FDA and for which the efficacy and safety of the drugs have never been established."[5]

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[4] See Docket 49 at ¶ 13.

[5] See Docket 49, ¶¶ 14- 23.

IV. DISCUSSION

A. The Requirements Of Iqbal/Twombly and Rule 9(b)

Defendants argue that the Amended Complaint contains only conclusory allegations that Defendants have "engaged in false and misleading marketing, advertising and sales campaigns," and is otherwise entirely devoid of facts amounting to fraud or deception, and therefore has failed to allege necessary facts under Twombly/Iqbal, and falls short of the specificity required by Rule 9(b).

1. Twombly/Iqbal

Plaintiff argues it is only required to provide "a short and plain statement of the claim" for relief under Fed. R. Civ. P. 8(a)(2), noting that in 2002, the Supreme Court reaffirmed the principle that "Rule 8(a)'s simplified pleading standard applies to all civil actions, with limited exceptions."[6] Plaintiff argues that Twombly and Iqbal do not require a departure from Rule 8(a)'s established requirements. Rather, the Supreme Court clarified the Rule 8(a) standard, stating that a complaint must contain "only enough facts to state a claim to relief that is plausible on its face."[7]

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[6] Swierkiewicz v. Sorema NA., 534 U.S. 506, 513 (2002).

[7] Twombly, 550 U.S. at 570; see also Iqbal, 129 S. Ct. 1937 (continued...)

The Ninth Circuit recently juxtaposed Swierkiewicz, Twombly, Iqbal, and two other Supreme Court cases that addressed Rule 8(a), and concluded that although the cases are "perplexing" when considered together, there are two common principles shared by all of them:

> First, to be entitled to the presumption of truth, allegations in a complaint or counterclaim **may not simply recite the elements of a cause of action**, but must contain sufficient allegations of underlying facts to give fair notice and to enable the opposing party to defend itself effectively. Second, the factual allegations that are taken as true must plausibly suggest an entitlement to relief, such that it is not unfair to require the opposing party to be subjected to the expense of discovery and continued litigation.[8]

Here, the Court agrees with Defendants that the Complaint lacks facts adequate to meet this standard. Generalized statements such as "the companies have engaged in false and misleading marketing, advertising and sales campaigns" and have "successfully deceived Alaskan physicians and Alaskan consumers," are inadequate. Use of the words "representing," "advertising," "engaging," "concealing," "suppressing," and "omitting" - without allegations of underlying facts which the Court can presume are true for

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[7](...continued)
(extending the standard articulated in Twombly to "all civil actions and proceedings in the United States district courts.")

[8] Star v. Baca, 652 F.3d 1202, 1216 (9th Cir. 2011) (emphasis added).

purposes of considering a motion to dismiss - are inadequate under Iqbal/Twombly.

2. Rule 9(b)

While Fed. R. Civ. P. 8(a)(2) requires a party's pleading to contain "a short and plain statement of the claim showing that the pleader is entitled to relief," Fed. R. Civ. P. 9(b) requires that, when fraud is alleged, "a party must state with particularity the circumstances constituting fraud...." A plaintiff may allege a unified course of fraudulent conduct and rely entirely on that course of conduct as the basis of that claim. In that event, the claim is said to be "grounded in fraud" or to "sound in fraud," and the pleading, as a whole, must satisfy the particularity requirement of Rule 9(b).[9] "Fraud can be averred by specifically alleging fraud, or by alleging facts that necessarily constitute fraud (even if the word 'fraud' is not used)."[10] "Averments of fraud must be accompanied by the who, what, when, where, and how of the misconduct charged."[11]

Where fraud is not an essential element of a claim, only those allegations of a complaint which aver fraud are subject to Rule

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[9] Vess v. Ciba-Geigy Corp. USA, 317 F.3d 1097, 1103-04 (9th Cir. 2003).

[10] Id. at 1105.

[11] Id. at 1106.

9(b)'s heightened pleading standard.[12] Any averments which do not meet that standard should be "disregarded," or "stripped" from the claim for failure to satisfy Rule 9(b).[13] To the extent a party does not aver fraud, the party's allegations need only satisfy the requirements of Rule 8(a)(2).[14]

Rule 9(b)'s particularity requirement also applies to state law causes of action.[15] A state law statutory cause of action pled in federal court must satisfy Rule 9(b) when fraud is a "necessary element" of the claim under that statute or when the claim is "grounded in fraud" because it relies exclusively on a "unified course of fraudulent conduct."[16] Defendants assert that the Complaint must meet Rule 9(b)'s heightened pleading requirements because Plaintiff's claims are grounded in fraud. Plaintiff disagrees.

In order to determine whether a particular claim or allegation is tantamount to fraud, the Ninth Circuit refers to the elements of

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[12] Id. at 1105.

[13] Id.

[14] Id. For example, the heightened fraud pleading standards of Rule 9(b) apply only to "allegations of fraudulent conduct," not to "innocent or negligent misrepresentation." Id.

[15] Id. at 1103.

[16] Id. at 1103.

a state common law fraud claim.[17] In Alaska, common law fraud claims require a showing of (1) a false representation of fact; (2) knowledge of the falsity of the representation; (3) intention to induce reliance; (4) justifiable reliance; and (5) damages.[18] A review of the Alaska UTPA reveals that fraud is addressed specifically in AS 45.50.471(b)(1) and (12). The State makes claims under sections (b)(4), (6), (8), (11) and (12). Section (8) refers to intentional conduct, while sections (4), (6) and (11) could conceivably apply to both intentional and negligent conduct. The Amended Complaint suggests that Defendants routinely violated the UTPA by engaging in deceptive trade practices that involved "knowing and intentionally" engaging in certain activities.[19] While the Complaint may not be grounded in fraud, it bears a strong suggestion of averring fraud.

The Court finds that Plaintiff has failed to meet the requisite pleading standard under Twombly and Iqbal. Plaintiff requests leave to amend its Complaint. Courts are free to grant a party leave to amend whenever "justice so requires," Fed. R. Civ.

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[17] See Kearns v. Ford Motor Co., 567 F.3d 1120, 1127 (9th Cir. 2009).

[18] Shehata v. Salvation Army, 225 P.3d 1106, 1114 (Alaska 2010).

[19] Docket 49 at 10-11.

P. 15(a)(2), and requests for leave should be granted with "extreme liberality."[20]

Accordingly, Plaintiff shall be given leave to amend its Complaint to comply with the standard set by Twombly and Iqbal. In so doing, Plaintiff is cautioned to consider the requirements of Fed. R. Civ. P. 9(b) with regard to fraud. Any fraud claims which do not meet the requirements of Rule 9(b) will be subject to dismissal.

B. Motion to Dismiss under Rule 12(b)(6) for Failure Establish Causation

Under Federal Medicaid law, states may implement a Medicaid program, and Alaska has chosen to do so.[21] Alaska's Medicaid program provides medical assistance, including a prescription drug program, to low-income state residents. Alaska's Department of Health and Human Services has created a Preferred Drug List ("PDL"), which informs consumers and providers about those medicines - the "Preferred Drugs" - for which Alaska Medicaid will provide reimbursement without restriction.[22] Seroquel and risperidone are listed as Preferred Drugs.

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[20] Owens v. Kaiser Found. Health Plan, Inc., 244 F.3d 708, 712 (9th Cir. 2001).

[21] See 42 U.S.C. §§ 1396-1-1396w-5.

[22] See 7 AAC 120.140.

Defendants argue that because Risperdal and Seroquel are on Alaska's PDL, and because Alaska continues to reimburse for non-medically accepted indications of Risperdal and Seroquel, Alaska cannot establish causation. But Plaintiff argues that its allegations are focused on the fact that, as a direct result of Defendants' actions, Alaska Medicaid has paid for prescriptions issued for indications that were non-medically accepted, FDA-approved, or supported by the compendia. It argues that Alaska Medicaid has paid tens of millions of dollars for prescriptions of Risperdal and Seroquel because "Janssen and AstraZeneca aggressively marketed and promoted Risperdal and Seroquel for indications that are not approved by the FDA and for which the efficacy and safety of the drugs have never been established." Plaintiff argues that "but for" Defendants' unlawful conduct, Alaska would not have reimbursed for Defendants' defective drugs because the prescriptions would never have been issued.

Defendants also argue that Plaintiff cannot establish "but for" causation because Alaska continues to reimburse for non-medically accepted indications. The State argues that it simply does not have a system in place to effectively monitor each and every prescription that is reimbursed. Furthermore, Defendants' proximate causation argument is based on the theory that Alaska physicians' independent medical judgment regarding whether to

prescribe Risperdal or Seroquel to a particular patient is the intervening cause that relieves Defendants from liability. Alaska notes that this argument has been squarely rejected at the pleading stage in similar cases.[23]

The Court is not persuaded that Plaintiff cannot show causation. Although Defendants argue that the lack of restrictions on reimbursement for Seroquel and Risperdal under the Alaska Medicaid program eliminates a causal connection between Defendants' supposed actions and the State's alleged harm, the possibility remains that the State could prove that but for Defendants' actions, a number of prescriptions for Seroquel and Risperdal would never have been issued in Alaska.[24] The Court further notes that the rationale of the Eleventh Circuit in the Ironworkers case is inapplicable here. In Ironworkers, the 11th Circuit reasoned that:

> The insurers, under the terms of the insurance policies, consciously exposed themselves to pay for all prescriptions of Seroquel, including those that were medically unnecessary or inappropriate-even if such prescription were birthed by fraud. In light of such broad exposure, conventionally a rational insurer would have charged its enrollees higher premiums than it would have if its policies offered more limited prescription drug coverage. These higher premiums, in turn, would compensate the insurer for this increased number of prescription payments, including payments for

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[23] See Docket 69 at 16.

[24] Whether or not that number is ultimately quantifiable is another issue entirely.

> prescriptions that were medically unnecessary or inappropriate. . . . [C]onsequently, the district court had to dismiss their claims because they failed to allege plausibly that Astrazeneca's false representations caused them to suffer economic injury.[25]

But Alaska Medicaid does not collect premiums, and adults are responsible for a $2.00 co-payment for each new or refilled prescription.[26] Accordingly, the pass-on argument is inapplicable here. The Motion to Dismiss on these grounds is denied.

C. Plaintiff's UTPA Claim & The "Safe Harbor" Provision

Defendants argue that the claims under the UTPA are barred because they fall within the UTPA's "safe harbor" provision. Alaska Statute 45.50.481(a)(1) exempts unfair acts and practices from the purview of the UTPA "where the business is both regulated elsewhere and the unfair acts and practices are therein prohibited."[27] The State argues that because its UTPA claims satisfy neither of these two requirements, Defendants' argument necessarily fails. In contrast, Defendants argue that allegations of unlawful off-label marketing are addressed and remedied, if

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[25] Ironworkers Local Union 68 et al. v. AstraZeneca Pharmaceuticals, LP, 634 F.3d 1352, 1360 (11th Cir. 2011).

[26] Alaska Medicaid Recipient Services Handbook, (October 27, 2011), http://hss.state.ak.us/dhcs/PDF/MedicaidRecipientHandbook.pdf.

[27] State v. O'Neill Investigations, Inc., 609 P.2d 520, 528 (Alaska 1980).

necessary, by the FDA, acting within its comprehensive regulatory and enforcement scheme, and not by the states or private litigants. Defendants argue that the purported practices at issue here are expressly prohibited by the FDCA and FDA regulations, and note that other courts have found these types of claims are barred by the safe harbor provision.[28] This Court, however, notes that not all "safe harbor" provisions are created equally. Accordingly, decisions from other jurisdictions are not particularly helpful in this analysis.

1. Is the Conduct "Regulated Elsewhere"?

The State complains that Defendants carried out their misconduct by marketing Risperdal and Seroquel to Alaska physicians for the treatment of various conditions or symptoms which have not received FDA-approval. It is unlawful, under Alaska law, for Defendants to market their drugs for such indications. The State argues that Defendants have not shown, nor can they, that the FDA regulates the content of the communications from Defendants' sales representatives to Alaska physicians.

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[28] See, e.g., State of New Mexico v. AstraZeneca and State of New Mexico v. Janssen, LP, Nos. D-101-cv-2009-00652 and D-101-cv-2008-01144, Tr. at 73-76 (N.M. First Judicial Ct. July 22, 2011); McDaniel v. AstraZeneca, No. CV-2008-5448, Tr. at 28-29 (Ark. Cir. Ct. July 18, 2011); McDaniel v. AstraZeneca, No. CV-2008-544 (Ark. Cir. Ct. July 21, 2011). Defendant has provided the Court with copies of these opinions.

In response, Defendants allege that the Federal Food Drug and Cosmetic Act ("FDCA"),[29] and the FDA's regulations promulgated thereunder, expressly apply to such interactions, and heavily regulate this conduct.[30] FDA regulations provide that advertising of an FDA-approved prescription drug must be "consistent with and not contrary to" the drug's FDA approved labeling.[31] They further argue that any promotional material distributed by sales representatives constitutes "labeling" and its content is extensively regulated under the FDCA.[32]

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[29] 21 U.S.C. §§ 301-399(d).

[30] See 21 C.F.R. § 314.81(b)(3)(i) (requiring an applicant to "submit [to the FDA] specimens of mailing pieces and any other labeling or advertising devised for promotion of the drug product at the time of initial dissemination of the labeling and at the time of initial publication of the advertisement for a prescription drug product").

[31] See 21 C.F.R. § 201.100(d)(1) ("Any labeling . . . whether or not it is on or within a package from which the drug is to be dispensed, distributed by or on behalf of the manufacturer . . . [must be] consistent with and not contrary to such approved or permitted labeling."); Professional Product Labeling, Public Meeting, 60 Fed. Reg. 52,196-02 (Oct. 5, 1995) (a drug's approved labeling "serves as the basis for product promotion. FDA regulations specify that all advertising claims made about a product be consistent with its approved labeling (21 C.F.R. § 202.1(e)(4))").

[32] See 21 C.F.R. § 202.1(l)(2) (stating that labeling includes, inter alia, "[b]rochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs . . . letters . . . film strips . . . sound recordings, exhibits, literature, and reprints and similar pieces of printed,

(continued...)

Assuming that Defendants' conduct is regulated by the FDA, the Court turns to the second prong.

2. Does the Regulation Prohibit the Unfair Acts and Practices Alleged?

The State alleges that Defendants have failed to identify a single statute—other than the UTPA—prohibiting Defendants, through their sales representatives or otherwise, from making false statements or misrepresentations to Alaska physicians. To the contrary, Defendants argue, the FDCA prohibits manufacturers from "misbranding" a drug by including a description in the labeling, promoting, or advertising of an intended use of that drug that has not been approved by the FDA.[33] The FDCA also prohibits manufacturers from advertising or promoting a drug in a manner that is inconsistent with the drug's approved labeling.[34] The FDCA prohibits a manufacturer from distributing any promotional labeling or advertising to healthcare professionals or to consumers that is false or misleading, or lacking in fair balance. Accordingly, the

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[32](...continued)
audio,or visual matter descriptive of a drug and references published . . . for use by medical practitioners, pharmacists, or nurses, containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor . . . .").

[33] See 21 U.S.C. § 331(a).

[34] See 21 C.F.R. § 201.100(d)(1).

FDCA and its regulations clearly prohibit any alleged promotion that is inconsistent with a drug's approved labeling or that is false or misleading, and Alaska may not use the UTPA to create a private right of action to enforce the FDCA.[35]

Certainly, Defendants have made a strong case that their actions fall under the safe harbor provision of the Alaska UTPA.

3. Certification to the Alaska Supreme Court

Plaintiff complains that a finding that Defendants' actions fall under the safe harbor provision would render the UTPA superfluous and leave the State without a remedy. This is so because the FDCA does not provide a private right of action under federal law for the claims asserted in Count I of the Complaint. Consequently, Plaintiff argues, if the Court were to find Alaska's UTPA claims exempted, the end result is a finding that the UTPA's safe harbor provision provides Defendants with complete preemption, and thus complete immunity – something that is neither required by federal law nor intended by the Alaska legislature. In that event, Plaintiff requests that this Court certify this issue to the Alaska Supreme Court for a final determination of whether Alaska's UTPA claims are exempted under section 45.50.481 – that is, whether

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[35] See 21 U.S.C. § 337(a) ("[A]ll such proceedings for enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States.")

Defendants' alleged unfair acts and practices are regulated elsewhere and therein prohibited.

However, regardless of the intent of the Alaska legislature, or the patent unfairness of leaving the State without a remedy, this Court concludes that the Alaska Supreme Court is in no better position than this Court to determine whether Defendants' "business is both regulated elsewhere and the unfair acts and practices are therein prohibited."[36] Indeed, the question appears to turn on the interpretation of Federal law as much, or more, than Alaska law.

Furthermore, this Court is troubled by the Alaska Supreme Court's holding that Alaska Statute 45.50.481(a)(1) "exempts only those acts or transactions **which are the subject of ongoing, careful regulation.**"[37] The Alaska Supreme Court found in Matanuska Maid that to define "regulate" as merely "subject to any prohibitory law" would severely limit the applicability of the UTPA.[38] In other words, a prohibition on certain conduct, without more, cannot satisfy the requirements of AS 45.50.481. The question remains, therefore, whether the existing regulatory scheme

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[36] O'Neill, 609 P.2d at 528.

[37] Matanuska Maid, Inc. v. Alaska, 620 P.2d 182, 186 (Alaska. 1980) (emphasis added).

[38] Id.

governing Defendants' actions actually has any teeth. Further briefing on this issue appears warranted.

D. Plaintiff's Strict Liability Failure To Warn Claim

Defendants also urge the Court to dismiss Alaska's strict liability claim. Defendants assert two grounds for dismissal: (1) Alaska lacks standing to assert the claim; and (2) Alaska's strict liability claim is barred by the economic loss rule.

Regarding the economic loss rule, Defendants argue that Plaintiff's strict liability claim fails because there is no plausible nexus between the alleged failure to warn and Plaintiff's alleged damages, as required under Alaska's intermediate approach to the economic loss rule. As noted by the Alaska Supreme Court, "if the dangerous defect did not cause the loss, the seller of a dangerously defective product can avoid a strict liability claim."[39] Defendants seem to argue, therefore, that Alaska's strict liability claim is barred by the economic loss rule because the State's alleged damages are not tied to any physical injury or harm.

Plaintiff argues that no such requirement exists. Instead, "[w]hen a defective product creates a situation potentially dangerous to persons or other property, and loss occurs as a result of that danger, strict liability is an appropriate theory of

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[39] N. Power & Eng'g v. Caterpillar Tractor Co., 623 P.2d 324, 330 n.10 (Alaska 1981).

recovery[.]"[40] Plaintiff argues that "[w]hen used off-label, Defendants' drugs can and do have serious side effects." Thus, when Alaska physicians prescribe Risperdal and Seroquel for indications not approved by the FDA, the products create a situation potentially dangerous to persons – here, Alaska Medicaid subscribers. The Complaint specifically pleads that Defendants' drugs have created a situation dangerous to Alaska consumers.[41] Accordingly, Plaintiff argues, the required loss occurred when Alaska Medicaid provided reimbursement for non-medically accepted indications of Risperdal and Seroquel—a loss Alaska would not have incurred absent Defendants' illegal off-label marketing of their drugs. Thus, the loss occurred as a result of the danger manufactured by Defendants.

In response, Defendants note that Plaintiff nowhere alleges that any individuals suffered the supposed side effects. Furthermore, the State consistently alleges that its damages claim derives from "Defendants illegal off label marketing of their

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[40] Pratt & Whitney Canada, Inc. v. Sheehan, 852 P.2d 1173, 1177 (Alaska 1993).

[41] See Docket 49 at ¶ 12 ("Janssen and AstraZeneca knew or should have known but failed to warn—and affirmatively misled—Alaska, Alaskan physicians, and Alaskan consumers regarding Risperdal's and Seroquel's association with the development of diabetes, diabetes-related conditions, including weight gain, and other serious, even life threatening medical conditions.").

drugs," not from a failure to disclose side effects. Because the State's alleged loss did not result from the alleged defective condition, Defendants argue, the failure to warn claim should be dismissed.

The Court agrees with Defendants on this issue, and finds support even in the Alaska Supreme Court case cited by the State. In Pratt & Whitney, The Alaska Supreme Court summarized the history of strict liability law in Alaska, and the evolution of the law as it applies to purely economic losses.[42] The application of strict liability originally applied only to those cases where injury to a human being resulted from a defective product.[43] Eventually, the law evolved to include recovery for injury solely to the product itself.[44] "When a defective product creates a situation potentially dangerous to persons or other property, and loss occurs as a result of that danger, strict liability in tort is an appropriate theory of recovery, even though the damage is confined to the product itself."[45] Furthermore, "the requirement that the loss occur under

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[42] Id. at 1176-78.

[43] Id. at 1176, citing Clary v. Fifth Avenue Chrysler Center, 454 P.2d 244 (Alaska 1969).

[44] Id. at 1177, citing Northern Power & Engineering Corp. v. Caterpillar Tractor, Co., 623 P.2d 324 (Alaska 1981).

[45] Id., citing Northern Power.

dangerous circumstances is necessary because . . . allowing recovery solely on proof that a defect *could* endanger persons or property is too speculative."[46]

Plaintiff asks this Court to take the Alaska Supreme Court's guidance regarding strict liability to an unprecedented level, and allow a claim for strict liability to lie where the losses are purely economic, and no physical harm has occurred. The "loss" contemplated by the Alaska Supreme Court simply did not include the type of economic losses Plaintiff claims here.[47] Having so concluded, the Court does not reach Defendants' standing argument.

Plaintiff's claim for strict liability is accordingly **DISMISSED.**

V. CONCLUSION

In light of the foregoing, the Court **DENIES** Defendants' Motion to Dismiss with respect to the arguments discussed in sections A and B of this Order. Plaintiff may be permitted to amend its

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[46] Id., citing Northern Power, 623 P.2d at 329 n. 11 (emphasis original).

[47] The Court is not persuaded by the State's argument that it should follow Judge Ridner's findings in the Zyprexa litigation in Alaska Superior Court. Judge Ridner found that the economic loss rule allowed a claim for strict liability in the Zyprexa litigation. However, Judge Ridner specifically relied on the fact that physical injuries to persons were alleged. No physical injuries have been alleged in this case.

Complaint pending resolution of the Safe Harbor argument (Section C).

The Court **GRANTS** Defendants' Motion to Dismiss Plaintiff's claim regarding Strict Liability (Section D).

With respect to the Safe Harbor Provision argument (Section C), further briefing is required. Plaintiff shall file a Sur-Reply to Defendants' Reply regarding this issue on or before **November 21, 2011**. Defendants shall file additional responsive briefing on or before **December 5, 2011**. All parties should address what enforcement, if any, exists as to the applicable Federal regulations.

Upon receipt of the further briefing, this Court will issue a further order regarding the Motion to Dismiss. If the matter is not completely dismissed, the Court will at that time set a deadline for the filing of Plaintiff's Second Amended Complaint.

IT IS SO ORDERED.

ENTERED this 31st day of October, 2011.

S/RALPH R. BEISTLINE
UNITED STATES DISTRICT JUDGE