IN THE UNITED STATES DISTRICT COURT

FOR THE WESTERN DISTRICT OF WISCONSIN

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GEORGE H. PETERS,

Plaintiff,

v.

ASTRAZENECA, LP and
PROCTER & GAMBLE DISTRIBUTING
COMPANY,

Defendants.

OPINION and ORDER

05-C-649-C

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Plaintiff George H. Peters, an inmate at the New Lisbon Correctional Facility in New Lisbon, Wisconsin, contends that he lost his sense of taste after taking omperazole magnesium, a drug marketed and distributed by defendants Astrazeneca, LP and Procter & Gamble Distributing Co. under the brand name Prilosec OTC®. Plaintiff seeks compensatory and punitive damages based on state common law claims of strict liability and negligence for defective product design and failure to warn. Jurisdiction is present under 28 U.S.C. § 1332.

Now before the court is defendants' motion for summary judgment. Because plaintiff has come forward with no evidence from which a jury could conclude reasonably that

defendants' product caused the injury he alleges was caused by his consumption of omperazole magnesium, defendants' motion will be granted.

Before setting out the undisputed facts, I note that plaintiff has responded to a number of defendants' proposed findings of fact by alleging that he has not received the expert information he needs to dispute facts proposed by defendants. At the beginning of the preliminary pretrial conference held on December 6, 2005, the magistrate judge warned plaintiff of the importance of obtaining expert testimony in a timely fashion:

> First of all, it's going to be Mr. Peters' obligation to obtain an expert pretty darn quickly under the calendar that we're setting up . . . Now even if I were to stay discovery pending a decision on the dismissal motions, it would still behoove Mr. Peters to get his expert lined up. Mr. Peters, you don't have to tip your hand at this point if you don't want to but I would hope that you've already got an expert in mind before you even filed this lawsuit or it's going to be a pretty steep hill for you to climb to get where you need to get in this lawsuit . . . The point is that we're not going to postpone calendaring.

Dkt. #12, at 6:20-22; 6:25-7:6, 8. Later in the preliminary pretrial conference, the magistrate judge noted again:

> [T]his is a lawsuit that seems to be driven pretty strongly by expert opinions and the sooner you get on top of that, the better for your lawsuit. And again I'm not going to tell you what to do, but if the date [for disclosing experts] comes and goes, assuming we get that far, and you don't have an expert I cannot imagine this lawsuit going forward. So, again, it's something about which you need to be diligent.

Id. at 10:17-24. Plaintiff's deadline for disclosing his expert witnesses was March 6, 2006. Dkt. #3, at 5. On March 6, 2006, defendants received a notice from plaintiff indicating that

he "d[id] not expect to call" Dr. Jonathan S. Cooper, D.O. as a "non-testifying expert witness." Plaintiff submitted no report from Dr. Cooper. At his deposition held on April 11, 2006, plaintiff acknowledged that he has never spoken to or corresponded with Dr. Cooper (who is plaintiff's brother's physician) and that Cooper has not agreed to testify on plaintiff's behalf in this lawsuit. Despite plaintiff's continued hope that Cooper may agree to provide the expert testimony plaintiff needs in this lawsuit, the court will not delay ruling on defendants' motion on the off chance that an untimely designated expert will produce the evidence needed to keep plaintiff's case alive.

Moreover, to the extent that plaintiff contends defendants have failed to respond to his discovery requests, his complaints come too late. In the pretrial order, the parties were advised:

> If either side thinks the other side is not doing what it is supposed to do for discovery and they cannot work it out, then either plaintiff or the defendant quickly should file a motion with the court. If the parties do not bring discovery problems to the court's attention quickly, then they cannot complain that they ran out of time to get information that they needed for summary judgment.

If plaintiff believed that defendant was not forthcoming in producing discoverable documents, his remedy was to file a timely discovery motion. He did not do so. Therefore, where plaintiff has attempted to place facts into dispute solely by alleging that he lacks evidence with which to dispute facts proposed by defendants, the proposed facts will be

treated as undisputed.

From the parties' proposed findings of fact, I find the following to be material and undisputed.

UNDISPUTED FACTS

A. Parties

Plaintiff George H. Peters is an inmate of the New Lisbon Correctional Facility in New Lisbon, Wisconsin. Plaintiff is not a citizen of Delaware or Ohio.

Defendant Astrazenenca is a Delaware corporation with its principal place of business in Wilmington, Delaware. Defendant Procter & Gamble Distributing Co. is an Ohio corporation with its principal place of business in Cincinnati, Ohio. Defendants marketed and distributed a non-prescription version of the drug omperazole magnesium, which they market under the brand name Prilosec OTC®.

B. Plaintiff's Consumption of Prilosec®

At some time (the parties do not say when), plaintiff was incarcerated in Oklahoma. At that time, he began taking Prilosec OTC® to treat his acid indigestion. When plaintiff received the medication he "glanced" at the package insert but did not read its warnings in their entirety. Plaintiff did not report any adverse reactions to his doctor. (It is not clear

whether he did not report reactions because he did not experience any or because he did not associate any such reactions with his use of the medication.)

In January 2004, plaintiff was transferred to the Columbia Correctional Institution in Portage, Wisconsin. While there, he took Prilosec OTC® every day for approximately one year, as directed by the prison physician. During that time, plaintiff was transferred to the New Lisbon Correctional Institution, where he remains incarcerated. In accordance with prison procedure at both the Columbia Correctional Institution and the New Lisbon Correctional Institution, plaintiff received his medication directly from the prison health services office. Each dose was accompanied by a list of warnings and directions produced by the health services unit. The medication was not accompanied by the manufacturer's packaging or package insert.

C. Side Effects of Prilosec®

Although plaintiff consumed only the over-the-counter version of Prilosec®, the medication comes in a prescription version as well. The package insert for the prescription version of Prilosec® contains the following information:

> Additional adverse experiences occurring in <1% of patients or subjects of domestic and/or international trials, or occurring since the drug was marketed, are shown below within each body system. In many instances, the relationship with Prilosec® was unclear.

Among the "adverse experiences" listed is "special senses damage." (Special senses are defined as "any of the five senses related to the organs of sight, hearing, smell, taste, and touch." American Heritage Stedman's Medical Dictionary (2002)). The same information is printed in the Physicians' Desk Reference entry for the prescription version of Prilosec®. (The Physicians' Desk Reference is a commercially published compilation of manufacturers' prescribing information on prescription drugs, updated annually. Wikipedia, http://en.wikipedia.org/wiki/Physician's_Desk_Reference.)

The product insert for Prilosec OTC® does not list special senses damage as a potential side effect.

In late 2004, plaintiff asked the Food and Drug Administration (FDA) to provide him with a list of side effects reported to the FDA by users of prescription Prilosec®. The FDA sent plaintiff a report listing all side effects that had been reported since 1997. The report contained a disclaimer stating that "the information [provided in the report] has not been scientifically or otherwise verified as to a cause and effect relationship and cannot be used to estimate the incidence of adverse drug reactions." The report listed more than 25,000 reported adverse reactions, including aguesia, the absence or impairment of the sense of taste. An adverse event report does not mean necessarily that a reported adverse event was caused by a drug; it means merely that the adverse event was reported by someone who experienced the adverse event while taking the drug.

Dr. Douglas Bierer was defendant Procter & Gamble's Director of Clinical and Regulatory Development during the period in which the Food & Drug Administration was determining whether to approve Prilosec® for sale over the counter. Bierer served also as Team Leader of the joint effort between defendants to develop Prilosec OTC®. During the course of the FDA approval process, defendant Procter & Gamble conducted clinical tests on more than 10,000 consumers, examining the potential adverse effects of omperazole magnesium (the active drug in both Prilosec® and Prilosec OTC®) and consumer reactions to various package labels. No patients in any of these studies reported aguesia or any other change in taste perception.

In addition to conducting his own studies, Bierer reviewed reports on the 380 million cases worldwide in which patients had been treated with Prilosec® or its equivalent. From his review of these studies, Bierer concluded:

> In the total omeprazole global safety database, there have been few adverse events in which there was no other explanation for the adverse event but the use of the drug, or use of the drug was a possible explanation. To my knowledge, no positive association of omeprazole and aguesia or other taste-perception changes has been found in the extensive global safety databases for omeprazole or omeprazole magnesium [Prilosec OTC®].

Moreover, Bierer concluded from his research that omeprazole may actually help treat taste dysfunction.

OPINION

In his complaint in this lawsuit, plaintiff asserted that defendants Astrazeneca, LP and Procter & Gamble Distributing Co. should be held liable for injuries he sustained to his "special senses" when he consumed Prilosec OTC®. Although the deficiencies in plaintiff's proof are legion, two omissions are dispositive: (1) plaintiff has failed to propose as fact that he suffered any damage to his sense of taste or to any other of his "special senses" and (2) plaintiff has adduced no evidence from which it may be inferred that Prilosec OTC® causes the damage to "special senses."

The undisputed facts reveal that a minuscule percentage of users of the prescription version of Prilosec have reported to the FDA that they experienced some loss of taste during the time they were consuming Prilosec®. No scientific studies have established a causal link between reports of loss of taste and the consumption of Prilosec®. Moreover, the facts reveal that plaintiff has never taken the prescription version of Prilosec®. Instead, he has taken Prilosec OTC®. Extensive clinical studies conducted by the manufacturer of Prilosec® OTC® did not reveal even a single report of loss of taste among the more than 10,000 participants in the clinical trials. Without some indication that defendants' product may cause the side effect of which plaintiff complains, defendants did not act improperly by failing to list special senses damage as a side effect in the Prilosec OTC® package insert.

The Court of Appeals for the Seventh Circuit has stated repeatedly that summary

judgment is the "put up or shut up" moment in a lawsuit. A party's failure to show what evidence he has to convince a trier of fact to accept his version of the facts entitles the opposing party to summary judgment in its favor. Fed. R. Civ. P. 56(e); Johnson v. Cambridge Industries, Inc., 325 F.3d 892, 901 (7th Cir. 2003); Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986); Matsushita Electric Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986). Therefore, because plaintiff has offered no evidence to show that Prilosec OTC® may cause loss of special senses damage or even that he has sustained damage to his special senses, defendants' motion for summary judgment must be granted.

ORDER

IT IS ORDERED that the motion for summary judgment of defendants Astrazeneca, LP and Procter & Gamble Distributing Co. is GRANTED. The clerk of court is directed to enter judgment in favor of defendants and close this case.

Entered this 12th day of June, 2006.

BY THE COURT:
/s/
BARBARA B. CRABB
District Judge