UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA,
and THE STATE OF WISCONSIN,
ex rel. DR. TOBY TYLER WATSON,

Plaintiffs,

v. Case No. 11-CV-236

JENNIFER KING VASSEL,

Defendant.

DEFENDANT JENNIFER KING VASSEL'S BRIEF IN OPPOSITION TO THE PLAINTIFF'S MOTION TO COMPEL DR. KING TO PROVIDE PROPER RESPONSES TO DR. WATSON'S FIRST DISCOVERY REQUESTS AND SUPPLEMENT DR. KING'S INITIAL DISCLOSURES

The plaintiff wants to compel answers to fit his theory of the case, but Dr. King cannot be compelled to provide information she does not possess, nor provide answers to requests to admit that are not compliant with the law.[1] The plaintiff's motion must be denied. Defendant Jennifer King Vassel (Dr. King) respectfully submits this brief in opposition to the plaintiff's motion.

ARGUMENT

I. DR. KING HAS A FACTUAL AND LEGAL BASIS FOR HER ANSWERS TO THE PLAINTIFF'S DISCOVERY, AND THUS THE ANSWERS WERE NOT EVASIVE.

A. The Factual Basis.[2]

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[1]Although the plaintiff states this is a Civil L.R. 7(h) motion, it does not comply with any of the page limitations. Civil L.R. 7(h)(2) provides that the motion must not exceed three pages, excluding the caption and signature block. Thus, while every effort was made to comply with the three page limitation for this brief, it was very difficult to do so, in order to respond to the plaintiff's lengthy brief.

[2]It appears that the plaintiff is only disputing Dr. King's responses to his first and second set of requests to admit, interrogatories, and requests for production of documents. (Document 128, pp. 3-6).

The plaintiff's discovery was answered consistent with the facts known and the legal position asserted by Dr. King, as she stated in her emails with the plaintiff prior to the filing of this motion. As has been stated in recent briefs filed in support of her motion for a protective order (Document 118), brief in response to the plaintiff's motion in limine regarding false claims (Document 109), and brief in opposition to the plaintiff's motion for a protective order authorizing records custodians to obtain records (Document 130), Dr. King asserts that the statutes provide that "each state is to establish a formulary to apply to Medicaid drug coverage. The provisions clearly state that the compendia is only a factor that may be considered by the state board." *Dr. King's email responses in discussions about her discovery requests* (Document 129-3, p. 3).[3] Thus, the plaintiff's reference to the legal basis of false claims in the context of this case is disputed, and the opinions cited did not address these arguments. (Document 128, p. 2).

Dr. King's responses to the plaintiff's discovery reflect this position as well: "Dr. King wrote the prescriptions consistent with the formularies of the third party payors that paid for N.B.'s prescriptions, or for which Dr. King obtained prior authorization," and that the requests for production of documents assume that all prescriptions written by Dr. King were submitted to a pharmacy for fulfillment. (Document 128-3, p. 2). Now, in response to Dr. King's discovery requests, the plaintiff changed the focus of his discovery requests that are the subject of this motion and states that he does not assume all prescriptions written to N.B. were submitted to a pharmacy for fulfillment. (Document 128, p. 6). The plaintiff has created a moving target as to what he is requesting.

In an email before this motion was filed, Dr. King advised that further supplementation

[3]Although it is unknown why a discussion involving Dr. King's discovery is included with this motion.

would occur.[4] (Document 129-2, p. 1). That has been done. Dr. King disclosed an expert, Jacob Olson, on October 30, 2013. *Affidavit of Bradley S. Foley, Exhibit A,* Disclosure of Jacob Olson. Further, a Managed Health Services Formulary was disclosed on October 29, 2013. (Document 131, Exhibit A.) These documents and witness were disclosed as information became available, given the short time to discover information in this case once it returned to the trial court, and will continue to be done, pursuant to Fed. R. Civ. P. 26(e) and witness disclosure requirements. While Rule 37(a) authorizes a party to move to compel discovery, courts have denied such motions as moot when the disclosing party complies with the movant's discovery requests. ***Carrigan v. K2M, Inc.***, 2011 WL 1790423, *3 (C.D. Ill. 2011) (enclosed as it is unpublished, Civil L.R. 7.1(j)(2)).

B. The Legal Basis.

As shown in the October 23, 2013 response to the plaintiff, Dr. King elaborated on the legal issues involving the interrogatories.

> [T]he problem is the imprecise way the interrogatories are worked. Your email underscores the ambiguity by using the phrase "medically accepted indication" which is not a phrase defined or limited by the compendia nor the FDA as the FDA expressly acknowledges, and is inconsistent with the medically accepted use of that phrase.

(Document 129-2, p. 1).

Some context is needed to view the plaintiff's motion. The plaintiff admitted in the emails exchanged discussing Dr. King's discovery to him that "[w]e are not asserting any knowledge and reliance on the supposed applicable formularies." (Document 129-3, p. 1). Thus, the plaintiff acknowledges that he does possess any factual knowledge of the basis for his claim that the prescriptions written were not supported by a formulary. Moreover, the plaintiff admits that he "does

[4]In fact Dr. King is scheduled to be deposed on November 11, 2013 and the plaintiff can also make inquiries at that time as well.

not dispute that Wisconsin has been reimbursing prescriptions that are not for a medically accepted indication when a doctor such as the defendant here ignores Congress' coverage restriction to medically accepted indications. Whether such prescriptions may be legally reimbursed is a legal question, not a factual one." *Plaintiff's Opposition to Dr. King's Motion for a HIPAA Qualified Protective Order,* (Document 133, pp. 2-3).

The plaintiff makes the legal argument for the defense. The plaintiff does not dispute that Wisconsin reimburses prescriptions that may not meet his restrictive and incomplete reading of 42 U.S.C. § 1396r-8(d). If the plaintiff acknowledges this, then it cannot be said that Dr. King is providing evasive answers.

Further, the plaintiff cannot compel Dr. King to agree to an erroneous legal contention. "Requests to admit are proper when they are used to establish facts or the application of law to facts but not to establish legal conclusions. *See* 7 James W. Moore, Moore's Federal Practice § 36.10[8] (3d ed. 2006) [. . . .]***" U.S. S.E.C. v. Nutmeg Grp., LLC***, 285 F.R.D. 403, 405 (N.D. Ill. 2012). The plaintiff's requests to admit seek legal admissions to his incomplete reading of the statutes. "The purpose of Rule 36 is to allow parties to narrow the issues to be resolved at trial by effectively identifying and eliminating those matters on which the parties agree." ***United States v. Kasuboski,*** 834 F.2d 1345, 1350 (7th Cir.1987).

Moreover, the plaintiff's requests to admit present another problem. The requests to admit discuss restrictions on the use of medications and refer to a *use* approved under the Food, Drug, and Cosmetic Act (FDCA). The FDCA, however, does not restrict *use* or regulate a physician's prescription of a medication. The FDA itself, in its April 1982 Drug Bulletin, does not limit the use of a medication. "The FD&C Act does not, however, limit the manner in which a physician may use

an approved drug. Once a product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling. [. . .] [A]ccepted medical practice often includes drug use that is not reflected in approved drug labeling." *Affidavit of Bradley S. Foley, Exhibit B*, FDA Drug Bulletin, April 1982. "FDCA's legislative history expresses a specific intent to prohibit FDA from regulating physicians' practice of medicine." ***Chaney v. Heckler***, 718 F.2d 1174, 1179 (D.C. Cir. 1983).

This is further evidenced by the introduction to the Physicians' Desk Reference (PDR) and a statement by the publishers of the AHFS formulary. *Affidavit of Bradley S. Foley, Exhibit C*, PDR foreword to the 2007 edition ("The FDA has also recognized that the FD&C Act does not, however, limit the manner in which a physician may use an approved drug.") The publisher of one of the three components of the compendia, the AHFS formulary, is the American Society of Hospital or Health-System Pharmacists (ASHP). *Affidavit of Bradley S. Foley, Exhibit D*, ASHP 2006 formulary cover page. ASHP issued a statement in 1992 that "ASHP supports third-party reimbursement for FDA-approved drug products appropriately prescribed for unlabeled uses." *Affidavit of Bradley S. Foley, Exhibit E*, "ASHP Statement on the Use of Medications for Unlabeled Uses," p. 1. "In many clinical situations, unlabeled use represents the most appropriate therapy for patients." ***Id.*** This again demonstrates that the requests were improperly phrased for a meaningful denial.

It is also improper for the plaintiff to seek a change to a response to a request to admit, especially here where the denials meet the substance of the requested admission. Fed. R. Civ. P. 36 (a)(4).

> Dunlop has denied manufacturing, assembling, or selling metal woods having the structure described in the Raymont patent. Vardon is seemingly unhappy with Dunlop's denial and seeks to compel some other response. Nonetheless, we find that Dunlop's response fairly

> meets the substance of Vardon's request, **as Dunlop has denied each and every specific sub-part of the request to admit, and that is all that is needed.** *Cf.,* Charles A. Wright and Arthur A. Miller, Federal Practice & Procedure, § 2260 (1970) ("**A denial of a matter on which an admission has been requested must fairly meet the substance of the requested admission.**").

Vardon Golf Co., Inc. v. BBMG Golf Ltd., 156 F.R.D. 641, 653 (N.D. Ill. 1994)(emphasis added).

The party denying a request to admit may be exposed under limited circumstances to consequences if the contention is ultimately proven, but changing the answer is in reality a request for summary judgment. The plaintiff is in effect requesting a change that would lead to summary judgment on his legally deficient theory. The plaintiff's requested relief is therefore improper and must be denied.

CONCLUSION

Based on the foregoing arguments, defendant Jennifer King Vassel respectfully requests that the Court deny the plaintiff's motion.

Dated at Milwaukee, Wisconsin this 4th day of November, 2013.

GUTGLASS, ERICKSON,
BONVILLE & LARSON, S.C.

s/ Bradley S. Foley
Mark E. Larson (#1016423)
Bradley S. Foley (#1026871)
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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA,
and THE STATE OF WISCONSIN,
ex rel. DR. TOBY TYLER WATSON,

Plaintiffs,

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Defendant.

AFFIDAVIT OF BRADLEY S. FOLEY IN OPPOSITION TO THE PLAINTIFF'S MOTION TO COMPEL DR. KING TO PROVIDE PROPER RESPONSES TO DR. WATSON'S FIRST DISCOVERY REQUESTS AND SUPPLEMENT DR. KING'S INITIAL DISCLOSURES

STATE OF WISCONSIN)
) ss.
COUNTY OF MILWAUKEE)

BRADLEY S. FOLEY, being duly sworn under oath, deposes and states as follows:

1. I am one of the attorneys representing defendant Jennifer King Vassel in the above-referenced action and am authorized to make this affidavit on her behalf.

2. Attached as Exhibit A is a true and accurate copy of the October 30, 2013 letter disclosing Jacob Olson, an expert named on behalf of the defense.

3. Attached as Exhibit B is a true and accurate copy of the FDA Drug Bulletin, April 1982.

4. Attached as Exhibit C is a true and accurate copy of the 2007 edition of the Physicians' Desk Reference, first page of the Foreword.

5. Attached as Exhibit D is a true and accurate copy of the cover page of the 2006

AHFS drug formulary.

6. Attached as Exhibit E is a true and accurate copy of the ASHP Statement on the Use of Medications for Unlabeled Uses, copyright 1992.

s/Bradley S. Foley
Bradley S. Foley

Subscribed and sworn to before me
this 4th day of November, 2013.

s/Carrie Wentland
Notary Public, State of Wisconsin
My Commission expires: 1/19/14

Gutglass
Erickson
Bonville&Larson s.c.
A LIMITED LIABILITY ORGANIZATION

BRADLEY S. FOLEY
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writer's direct: 414-908-0240

October 30, 2013

Via email only
Attorney James B. Gottstein
Law Project for Psychiatric Rights
406 G Street, Suite 206
Anchorage, AK 99501

Re: Watson v. King-Vassel
Case No: 11-CV-236
Our File No: 911.19

Dear Mr. Gottstein:

Please find enclosed a copy of the report of an expert named on behalf of Dr. King, Jacob Olson, a copy of his Curriculum Vitae, and his publication list. Thank you.

Very truly yours,

Bradley S. Foley

Bradley S. Foley

BSF\cgw
Enclosures

cc:(w/encls.)(via email only): Attorney Rebecca L. Gietman

Skywalk RPHARMACY

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e-mail info@skywalkpharmacy.com
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October 30, 2013

Mr. Mark Larson
Gutglass, Erickson, Bonville & Larson, S.C.
735 N Water St Ste 1400
Milwaukee, WI 53202

Re. Watson v. King

Dear Mr. Larson:

I have reviewed the complaint in this case, the Encompass Effective Mental Health Services, Inc. records for patient N.B., and Dr. King's brief in support of summary judgment, filed in July 2012. I have also reviewed formularies for Managed Health Services for the period of time alleged in the complaint, and am familiar with the formularies of Medicaid and Managed Health Services based on my service on the pharmacy and therapeutics committee of MHS and the Medicaid drug utilization board. My opinions are also based on my education and experience practicing in Wisconsin.

The compendia is not used in writing prescriptions, as reimbursement for prescription medication is done pursuant to formularies and pre-authorizations. Reimbursement for prescription medication is not defined by the compendia. The writing of a prescription for medication for minors does not cause Medicaid coverage of fraudulent billings.

A copy of my CV is attached. I have not previously testified as an expert at trial or in a deposition. My publication list is attached. I charge $200 an hour.

The opinions expressed in this report are provided to a reasonable degree of pharmaceutical probability.

Very truly yours,

Jacob J. Olson, Pharm.D.

Curriculum Vitae

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Menomonee Falls, WI 53051
Phone: 262-754-0647
e-mail:jake@skywalkpharmacy.com

Jacob J. Olson, Pharm.D., RPh.

Professional Experience	**President/CEO**	**Skywalk Pharmacy** Located in the Children's Hospital of Wisconsin	**Dec. 2002 - Present**
	DUR Board Member P&T Committee	Wisconsin Medicaid Managed Health Services (Wisconsin T-19 HMO)	Sept. 2010 - Present July 2006 – January 2008
	Managing Diabetes for Life	Joint project with Independent Care (Wisconsin T-19 HMO) and Ye Olde Pharmacy	Oct. 2001 – Dec. 2002
	Clinical Director	Ye Olde Pharmacy	Dec. 2000 – Dec. 2002
	Junior Commissioned Officer Student Training Externship Program (JRCOSTEP)	Public Health Service Bureau of Prisons U.S.P. Leavenworth, KS	June 1997 – August 1997
Postdoctoral Residency	**First ASHP/APhA Accredited Community Pharmacy Practice Residency** Family PharmaCare Center, Inc. & Purdue University		July 1999 – July 2000
University Experience	Adjunct Faculty & Clinical Rotation Student Preceptor	Concordia University of Wisconsin St. Louis College of Pharmacy Creighton University Midwestern University	2010 - present 2010 - present 2006 - present 2004 – present
Professional Presentations & Exhibitions	"Topical Treatment of Pain Associated with Remodulin Therapy," United Therapeutics Investigator Meeting, July 27, 2002, Deer Valley, UT.		
Professional Associations	Pharmacy Society of Wisconsin (PSW)	Member	2001 - present
	Profession Compounding Centers of America (PCCA)	Member	1999 - present
	International Academy of Compounding Pharmacists (IACP)	Member	1999 – present
	American Pharmaceutical Association (APhA)	Member	1997 – present

Professional Education	University of Iowa Iowa City, IA	Doctor of Pharmacy	May 1999

Licensure

State of Wisconsin #13224-040

State of Indiana #26020025

References Available Upon Request

PUBLICATION LIST

Kate, *et al.*, "Quality-Control Analytical Methods: Aqua Pura: Water Purification Systems and United States Pharmacopeia Waters for the Compounding Pharmacy, Part 3: Testimonials and Comparisons," International Journal of Pharmaceutical Compounding, Volume 15, Number 5 (September/October 2011).

DEPARTMENT OF
HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration, HFI-22
Rockville, Maryland 20857

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April 1982

Volume 12 Number 1

FDA Drug Bulletin

New Angina Drugs

Two calcium channel blockers, nifedipine and verapamil, have been approved for treatment of vasospastic and classical effort-associated angina. These drugs are also referred to as "calcium entry blockers" or "calcium antagonists."

Drugs of this pharmacologic class have some common properties but also have important differences in clinical use.

Both agents inhibit transmembrane reflux of extracellular calcium into cardiac and vascular smooth muscle, and produce, in isolated tissues, negative inotropic effects, depressed sino-atrial (SA) and atrio-ventricular (AV) node function, and vasodilation. At clinical doses in humans, however, the vascular effects are usually predominant, causing reduced peripheral vascular resistance and lower blood pressure and preventing or reversing coronary spasm. The effects on cardiac tissues are usually less prominent, probably because of afterload reduction and reflex sympathetic responses to vasodilation. In patients with normal cardiac function not on other negatively inotropic drugs, the negative inotropic effects of the drugs are not usually manifested.

In some cases, however, heart failure can be induced or worsened, and particular care must be paid to concomitant use of calcium channel blockers with beta blockers and to use in patients with aortic stenosis, where vasodilation would not be expected to produce significant afterload reduction.

Effects on AV and SA node function are also not prominent *in vivo* with nifedipine, although they can occur with verapamil.

Effectiveness

Verapamil, but not nifedipine, is an effective agent intravenously in interrupting supraventricular tachycardia and slowing the heart rate in atrial fibrillation.

Both drugs are effective in angina due to vasospasm and in chronic stable angina. Current labeling for nifedipine recommends it for use in stable angina only in patients "who remain symptomatic despite adequate doses of beta blockers and/or organic nitrates or who cannot tolerate those agents." This reservation is based on the limited long-term evidence of safety and effective-

FDA Drug Bulletin

Information of Importance To Physicians and Other Health Professionals

ness in people with stable angina.

Although the effectiveness of these agents in angina is documented, many aspects of their effectiveness remain to be defined. Uncontrolled reports[1] and studies in which these agents have been added to, or substituted for, organic nitrates that had proved insufficiently effective[2,3] in vasospastic angina seem to indicate a special ability of the calcium antagonists to prevent vasospastic angina. In two well-controlled studies comparing nifedipine with isosorbide dinitrate, however,[4,5] there was little difference between the two treatments. There are no similar direct comparisons of verapamil and organic nitrates.

Safety

The side-effect profile of these agents overlaps but is by no means identical. In general, nifedipine appears to have a somewhat greater tendency to decrease peripheral resistance and lower blood pressure than verapamil, and does not tend to inhibit SA or AV nodal conduction. There is often a small increase in heart rate, and typical symptoms and signs of vasodilation (dizziness, flushing, numbness and tingling of extremities, peripheral edema, or palpitations) are common but usually tolerable.

More serious reactions can also occur. Excessive hypotension occurs occasionally with the use of nifedipine, usually during the initial titration or at the time of upward dosage adjustment. It may be more likely in patients taking beta blockers concomitantly.

A few patients have developed increased frequency, duration, or severity of angina upon starting nifedipine or at the time of dosage increases.[6]

Nifedipine dosage should be titrated over a 7 to 14 day period, if possible, to enable the physician to assess response at each dose level and monitor blood pressure before proceeding to higher doses.

There are isolated reports of patients recently withdrawn from beta blockers who have developed marked worsening of angina and even infarction.[7]

If possible, it is advisable to taper beta blockers before stopping them and beginning nifedipine. It does not appear that nifedipine can treat the increased angina sometimes associated with beta blocker withdrawal.

Concomitant use of nifedipine and beta blockers is usually well tolerated. However, there is little controlled experience with the combination, which is known to increase the likelihood of congestive heart failure and severe hypotension.

In rare instances, patients have developed heart failure after beginning nifedipine, usually when the drug was added to a beta blocker.[8] Patients with tight aortic stenosis may also be at greater risk of developing heart failure with nifedipine.[9]

Nifedipine may be given concomitantly with nitrates, but there have been no controlled studies to assess the antianginal effectiveness of this combination.

Nifedipine has been reported to increase serum digoxin concentrations by about 50 percent and must be used with great caution with concomitant digoxin.[10]

Blood pressure falls with oral verapamil, but marked decreases appear unusual. There is usually a slight decrease in heart rate. Symptoms of vasodilation are not common. On the other hand, verapamil can inhibit SA node function and AV conduction, and cause sinus bradycardia, nodal escape rhythm, and/or AV block. It is, therefore, contraindicated in patients with pre-existing AV conduction abnormalities or sick sinus syndrome.

Verapamil has generally been avoided in patients with pre-existing

heart failure and is contraindicated in patients with severe left ventricular dysfunction because it can worsen heart failure.

There are few studies of verapamil given in combination with beta blockers, but it is clear that the combination can impair cardiac function in some patients,[11] even when cardiac function was initially good.[12]

Verapamil can cause constipation, which is usually mild.

In studies carried out in the United States, there were two reported instances of rechallenge-confirmed liver injury among the first 1,000 patients treated.[13] The patients had a picture of predominantly hepatocellular injury (transaminases in the 1,000 unit range), although there were no liver biopsies to confirm this; there was prompt resolution on discontinuation of the drug. In nearly 4,000 patients treated since that time, only isolated instances of enzyme abnormalities have been reported. The world literature does not include any reports of liver injury similar to the one previously cited.[13]

Patients on verapamil should have periodic liver function tests. The drug should be stopped if abnormalities are seen. Physicians can help define the frequency and severity of this adverse reaction by reporting observed cases promptly to FDA.

In patients with impaired liver or kidney function, verapamil should be administered only with great caution. (Verapamil is highly metabolized by the liver and 70 percent of an administered dose is excreted as metabolites in the urine.)

Verapamil increases serum digoxin levels in patients on chronic digoxin therapy and must be used with caution in such patients. Maintenance digoxin doses should be reduced and the patient should be carefully monitored to avoid over- or under-digitalization when verapamil is administered.

Disopyramide should not be given within 48 hours before or 24 hours after verapamil due to the combined negative inotropic effects of the two drugs.

Until further data are available, verapamil and quinidine should be used together cautiously, especially in patients with hypertrophic cardiomyopathy, because there have been a few reports of pulmonary edema in patients given the combination.[14]

As with nifedipine, verapamil may be given concomitantly with nitrates, although the effectiveness of the combination has not been evaluated.

More complete information for prescribing these drugs is available in the package inserts.

References:

1. Antman E, et al.: Nifedipine therapy for coronary-artery spasm. *N Engl J Med* 1980; 302: 1269-1273.
2. Waters DD, et al.: Provocative testing with ergonovine to assess the efficacy of treatment with nifedipine, diltiazem, and verapamil in variant angina. *Am J Cardiol* 1981; 48:123-130.
3. Johnson SM, et al.: A controlled trial of verapamil for Prinzmetal's variant angina. *N Engl J Med* 1981; 304: 862-866.
4. Hill JA, et al.: Randomized double-blind comparison of nifedipine and isosorbide dinitrate in patients with coronary arterial spasm. *Am J Cardiol* 1982; 49:431-438.
5. Ginsburg R, et al.: Randomized double-blind comparison of nifedipine and isosorbide dinitrate therapy in variant angina pectoris due to coronary artery spasm. *Am Heart J* 1982; 103:44-48.
6. Jariwalla AG, Anderson EG: Production of ischemic cardiac pain by nifedipine. *Brit Med J* 1978; 2:1181-1182.
7. Meinertz T, et al.: Beta blocker withdrawal syndrome. *Lancet* 1979; 1 (8110):270.
8. Robson RH, Vishwanath MC: Nifedipine and beta blockade as a cause of cardiac failure. *Brit Med J* 1982; 284:104.
9. Gillmer DJ, Kark P: Pulmonary edema precipitated by nifedipine. *Brit Med J* 1980; 284:1420-1421.
10. Belz GG, et al.: Digoxin plasma concentrations and nifedipine. *Lancet* 1981; 1:844.
11. Bala Subramanian V, et al.: Combined therapy with verapamil and propranolol in chronic stable angina. *Am J Cardiol* 1982; 49:125-132.
12. Chew C, et al.: Influence of severity of ventricular dysfunction on hemodynamic responses to intravenously administered verapamil in ischemic heart disease. *Am J Cardiol* 1981; 47:917-922.
13. Brodsky SJ, et al.: Hepatotoxicity due to treatment with verapamil. *Annals of Int Med* 1981; 94(4):490-491.
14. Epstein S, Rosing D: Verapamil: its potential for causing serious complications in patients with hypertrophic cardiomyopathy. *Circ* 1981; 64:437-441.

Sucralfate Approved for Duodenal Ulcer

Sucralfate (Carafate), a basic aluminum salt of polysulfated sucrose, has been approved for short-term (up to 8 weeks) treatment of duodenal ulcer. The drug is chemically unlike any other drug used for treatment of duodenal ulcer.

Sucralfate exerts its effect through local rather than systemic action, and there is little systemic absorption. Although the mechanism of sucralfate's anti-ulcer activity has not been fully defined, studies suggest that, with extracellular protein, it forms an ulcer-adherent complex that covers the ulcer site and protects it against further attack by acid, pepsin, and bile salts. The medication has negligible acid-neutralizing capacity and its anti-ulcer effects cannot be attributed to neutralization of gastric acid.

In two U.S. multicenter, placebo-controlled studies with endoscopic evaluation at 2 and 4 weeks, sucralfate was more effective than placebo in promoting complete healing, and statistically significantly better at 4 weeks. In the first study, the ulcer healing rate at 4 weeks was 75.2 percent for sucralfate and 63.6 percent for placebo. In the second study the 4-week ulcer healing rate was 92 percent for sucralfate and 58 percent for placebo.

The better result in the second study may be attributable to the dosage schedule used. In the first trial, sucralfate was given 2 hours after meals and at bedtime rather than as now recommended, 1 hour before meals and at bedtime. The latter regimen was used in several foreign studies and in the second U.S. study.

There are no known contraindications to the use of sucralfate. Adverse reactions in clinical trials involving more than 2,400 patients were minor and only rarely led to the discontinuation of the drug. The most frequent complaint was constipation, which was reported by 2.2 percent of patients. Other adverse effects reported in no

more than 1 of every 350 patients were diarrhea, nausea, gastric discomfort, indigestion, dry mouth, rash, pruritus, back pain, dizziness, sleepiness, and vertigo.

No long-term studies have been carried out and there is no recognized reason for long-term use of sucralfate. Specifically, it is not known whether sucralfate can prevent ulcer recurrence. Long-term studies will be needed to assess the possibility of adverse effects associated with long-term use, e.g., effects on absorption of fat-soluble vitamins.

The recommended adult dosage is 1 g four times a day on an empty stomach. Antacids may be prescribed as needed for relief of pain but should not be taken within 30 minutes before or after administration of sucralfate.

While healing with sucralfate may occur during the first week or two, treatment should be continued for 4 to 8 weeks unless healing has been confirmed by X-ray or endoscopy.

Ritodrine Update

Since the approval of ritodrine (Yutopar) for use in premature labor (see November 1980 and July 1981 *Drug Bulletins*), FDA has been monitoring several areas of concern about the drug's known cardiovascular effects. In light of a number of adverse reaction reports, the labeling of ritodrine has been updated to warn about:

- the need to monitor the patient's state of hydration;
- the possibility of pulmonary edema with or without the concomitant use of corticosteroids, many cases of which seem to be related to overhydration;
- the possible unmasking of occult cardiac disease, the first sign of which may be chest pain.

Ritodrine, a beta$_2$-sympathomimetic drug, may be useful in preterm labor in pregnancies of at least 20 weeks gestation when contraindications have been ruled out.

However, in pregnancies of more than 32 weeks, physicians should carefully weigh the risks and benefits before administering the drug.

When gestational age is in doubt, intrauterine growth retardation should be considered in the differential diagnosis of preterm labor. Among low birth weight infants, about 9 percent may be growth retarded for gestational age. Prolongation of labor beyond term will not correct the growth retardation of these babies.

Initial administration of ritodrine is intravenous. To minimize the risk of hypotension, the patient should be maintained in the left lateral position during infusion and careful attention should be given to her state of hydration. The amount of i.v. fluids administered should be monitored to avoid either circulatory fluid overload (overhydration) or inadequate hydration. An excess sodium load should be avoided in hydrating the patient.[1]

The boxed warning for ritodrine has been amended to read:

> Maternal pulmonary edema has been reported in patients treated with Yutopar, sometimes after delivery. While occurring infrequently, it has occurred more often when patients were treated concomitantly with corticosteroids. Maternal death from this condition has been reported with or without corticosteroids given concomitantly with drugs of this class.
>
> Patients so treated must be closely monitored in the hospital. The patient's state of hydration should be carefully monitored. (See Dosage and Administration.) If pulmonary edema develops during administration, the drug should be discontinued. Edema should be managed by conventional means.
>
> Because cardiovascular responses are common and more pronounced during intravenous administration of Yutopar, cardiovascular effects, including maternal pulse rate and blood pressure and fetal heart rate, should be closely monitored. Observe for premonitory or actual maternal signs and symptoms of pulmonary edema. A persistent high tachycardia (over 140 beats per minute) and/or persistent tachypnea (respiratory rate over 20 per minute) may be signs of impending pulmonary edema with drugs of this class.
>
> Occult cardiac disease may be unmasked with the use of Yutopar. If the patient complains of chest pain or tightness of chest, the drug should be temporarily discontinued and an ECG should be done as soon as possible.
>
> The drug should not be administered to patients with mild to moderate preeclampsia, hypertension, or diabetes unless the attending physician considers that the benefits clearly outweigh the risks.

Reference:

1. Philipsen T, et al.: Pulmonary edema following ritodrine-saline infusion in premature labor. *Ob Gyn* 1981; 58(3): 304-7.

Use of Approved Drugs for Unlabeled Indications

The appropriateness or the legality of prescribing approved drugs for uses not included in their official labeling is sometimes a cause of concern and confusion among practitioners.

Under the Federal Food, Drug, and Cosmetic (FD&C) Act, a drug approved for marketing may be labeled, promoted, and advertised by the manufacturer only for those uses for which the drug's safety and effectiveness have been established and which FDA has approved. These are commonly referred to as "approved uses." This means that adequate and well-controlled clinical trials have documented these uses, and the results of the trials have been reviewed and approved by FDA.

The FD&C Act does not, however, limit the manner in which a physician may use an approved drug. Once a product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling. Such "unapproved" or, more precisely, "unlabeled" uses may be appropriate and rational in certain circumstances, and may, in fact, reflect approaches to drug therapy that have been extensively reported in medical literature.

The term "unapproved uses" is, to some extent, misleading. It includes a variety of situations ranging from unstudied to thoroughly investigated drug uses. Valid new uses for drugs already on the market are often first discovered through serendipitous observations and therapeutic innovations, subsequently confirmed by well-planned and executed clinical investigations. Before such advances can be added to the approved labeling, however, data substantiating the effectiveness of a new use or regimen must be submitted by the manufacturer to FDA for evaluation. This may take time and, without the initiative of the drug manufacturer whose product is involved, may never occur. For that reason, accepted medical practice often includes drug use that is not reflected in approved drug labeling.

With respect to its role in medical practice, the package insert is informational only. FDA tries to assure that prescription drug information in the package insert accurately and fully reflects the data on safety and effectiveness on which drug approval is based.

Hepatitis B Vaccine for Use in Selected Populations

An inactivated hepatitis B vaccine (Heptavax-B) has been licensed for use in the United States. It is intended for selected populations at high risk of acquiring hepatitis B, one of three known forms of viral hepatitis. (The others are hepatitis A and non-A non-B hepatitis.)

The vaccine is the first to be made from human blood. Noninfectious antigen is purified from the plasma of asymptomatic human carriers of hepatitis B. After a series of chemical treatments, followed by the addition of alum adjuvant, the vaccine is administered in three intramuscular injections over a 6-month period.

Vaccination is not intended for the general population, but is recommended for persons older than 3 months of age who are at increased risk of hepatitis B virus infection. These persons will include health care workers, institutionalized patients, laboratory workers, hemodialysis staff and patients, family contacts of carriers, some military personnel, and persons with numerous sexual partners.

There continues to be a dialogue among government agencies, industry, and the medical community about use of the vaccine in selected high-risk groups. The Advisory Committee on Immunization Practices (ACIP) of the U.S. Centers for Disease Control (CDC), with assistance from representatives of FDA, the National Institutes of Health, and the medical community, has met several times to discuss specifically which population groups should receive this vaccine. The ACIP will meet once more in May of this year to draft final guidelines for use of this vaccine.

Efficacy

In clinical trials, 85 to 96 percent of persons receiving three doses of either 20 mg or 40 mg of vaccine were immune to infection. The duration of protection is presently unknown. However, in clinical trials, vaccine-induced antibodies, shown to provide protection against infection, persisted for at least 24 months in those receiving all three doses and will probably last for at least 5 years. After this time, a booster may be necessary to maintain immunity.

Side effects have been mainly local, mild, and transitory.

Availability

Due to the complexity of the methods used for producing the vaccine, it will be summer or fall of 1982 before the product is generally available from Merck, Sharp & Dohme. This manufacturer can supply complete physician information.

Advice on Limiting Intake of Bonemeal

Due to the unknown but often substantial lead content of individual samples of bonemeal and dolomite, FDA advises practitioners that these substances should be used as little as possible in infants, young children, and pregnant or lactating women.

Bonemeal is used primarily as calcium and/or phosphorus supplements. Bonemeal supplements are usually composed of finely crushed, processed bone and are packaged in powder, capsule, tablet, or wafer form. The source of bone is usually cattle but sometimes also horses. Bone marrow may also be added to this product. All bonemeal products contain lead which originates primarily from the diet of the animals from which the bone is taken. Bone serves as a repository for lead in the body and, in general, the older the animal the more lead in its bones.

Dolomite is a mineral deposit, consisting of calcium-magnesium carbonate with traces of other elements, including lead. Dolomite is used as a calcium and magnesium supplement and, like bonemeal, may be purchased in powder, capsule, tablet, or wafer form.

While a large portion of the small amounts of dietary lead ingested by humans is excreted, some is deposited in the mineral fabric of bone and some goes into soft tissue. Infants and children tend to absorb lead more efficiently than adults. When it is consumed in excess, lead may produce toxic reactions including central nervous system damage, anemia, and abdominal pain. As in animals, the accumulation of lead in human bone increases with age. Additionally, studies with

adult volunteers have shown that over a long time, the accumulation of lead in the body is proportional to the level of intake.

FDA Surveys

FDA has undertaken limited surveys to identify the extent of lead contamination of bonemeal and to determine whether the problem is limited or industry-wide.

One survey by FDA's Division of Consumer Studies of approximately 3,000 persons, 16 years of age and older, determined that about 1 percent of the population surveyed consumed bonemeal as a calcium source. More than 90 percent of the individuals consuming bonemeal were women, 50 years of age or older. The available information suggests that the average intake of bonemeal does not usually exceed 10 g/day.

No reliable information is available on the use of bonemeal as a calcium source for young children or infants. However, it is possible that bonemeal has been used as a calcium supplement for infants who have an intolerance for milk.

Although levels are usually lower, FDA scientists have found some samples of bonemeal containing lead at concentrations as high as 17 to 20 parts per million (ppm). Comparably high levels of lead have also been detected in some samples of dolomite.

It is known that the consumption of bonemeal containing 5 to 10 ppm lead by infants and children may result in lead intakes that clearly exceed the FDA recommended tolerable or maximal daily intake from all sources. For the infant, lead intake should be as low as possible and less than 100 micrograms/day, and for children between 6 months and 2 years the intake of lead should be no more than 150 micrograms/day.

Special Risk

Individuals at special risk of lead toxicity from the consumption of bonemeal or dolomite include infants, children, women of childbearing age, and possibly the elderly. Others who ingest bonemeal at the recommended doses (usually not more than 5 to 10 grams/person/day) would not ordinarily exceed the WHO/FAO (World Health Organization/Food and Agriculture Organization) guideline for a tolerable daily adult intake of 430 micrograms of lead. However, individuals who consume more than two to three times the recommended dose would be at greater risk if the lead content of the bonemeal is high.

Pregnant or lactating women taking bonemeal or dolomite to meet increased calcium needs may have sufficient increased lead intake and absorption to present a health hazard to the developing fetus, via placental transfer of lead, or to the nursing infant from its mother's milk.

Bendectin PPI Available

A patient package insert (PPI) for Bendectin, an antiemetic combination of doxylamine and vitamin B_6 used in pregnancy, has been issued by the manufacturer, Merrell Dow Pharmaceuticals.

Pads of the PPIs are being distributed to retail pharmacies and physicians who are high prescribers of the drug, and are available to other health professionals from the manufacturer, upon request.

A Spanish language version of the PPI will be available upon request from the manufacturer.

In its summary section, the PPI explains: "Bendectin is used to treat the nausea and vomiting that may occur during the first few weeks of pregnancy. You should take this drug only if nausea and vomiting interfere with your eating or daily activities and if other treatments prescribed by your doctor do not relieve your symptoms. These other treatments include eating soda crackers or dry toast, or drinking hot or cold liquids as soon as you wake up in the morning.

"There is no way to prove that any substance taken by pregnant women does not cause birth defects on rare occasions. For this reason, no drug, including Bendectin, should be taken during pregnancy unless it is clearly necessary."

As was discussed in the March 1981 issue of the *Drug Bulletin*, the revised physician labeling for Bendectin cautions physicians that the drug should be used only when more conservative treatment for nausea and vomiting in pregnancy has failed and when symptoms are sufficiently distressing to require drug intervention.

Class I Recalls

As a special service to health professionals, the *Drug Bulletin* is publishing information on recent Class I recalls. The following products have been withdrawn voluntarily in firm-initiate Class I recalls because they pose serious health hazards:

Infant Formula

Nursoy Concentrated Liquid, 13-ounce cans, coded A26M, B2M, and B9M, and Nursoy Ready-to-Feed 32-ounce cans coded A28M and B11M. Codes may be preceded by a number such as 1,2, or 3, which can be ignored. Example: 2A26M. Formula lacks vitamin B_6, which can result in serious health effects ranging from irritability to convulsions. Cans may be returned to the retailer for refund or replacement. Recall date: March 3, 1982.

SMA powder and liquid with code numbers A25M through A31M, and B1M through B15M. Code numbers may be preceded by a number such as 1,2, or 3, which can be ignored. Example: 2A25M. Formula is deficient in vitamin B_6, which can result in serious health effects ranging from irritability to convulsions. Cans may be returned to the retailer for refund or replacement. Recall date: March 12, 1982.

Defibrillator

Safeguard 3, serial numbers 290, 374, 379, 380, 1001, 1002, 1006. The storage capacitor may fail, resulting in low discharge energy and consequent failure to defibrillate. The manufacturer, Safeguard Medical Systems, Inc., Beltsville, Md., will replace faulty condensors. Recall date: Dec. 14, 1981.

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FOREWORD TO THE 61st EDITION

PDR enters its 61st year offering a wider array of pharmaceutical reference options than ever before. Long available unabridged—in print, on CD-ROM, and via the Internet—*PDR* also provides essential prescribing information in other forms as well, detailed later in this foreword.

About This Book

Physicians' Desk Reference® is published by Thomson PDR in cooperation with participating manufacturers. The *PDR* contains Food and Drug Administration (FDA)-approved labeling for drugs as well as prescription information provided by manufacturers for grandfathered drugs and other drugs marketed without FDA approval under current FDA policies. Some dietary supplements and other products are also included. Each full-length entry provides you with an exact copy of the product's FDA-approved or other manufacturer-supplied labeling. Under the Federal Food, Drug and Cosmetic (FD&C) Act, a drug approved for marketing may be labeled, promoted, and advertised by the manufacturer for only those uses for which the drug's safety and effectiveness have been established. The Code of Federal Regulations Title 21 Section 201.100(d)(1) pertaining to labeling for prescription products requires that for *PDR* content "indications, effects, dosages, routes, methods, and frequency and duration of administration, and any relevant warnings, hazards, contraindications, side effects, and precautions" must be *"same in language and emphasis"* as the approved labeling for the products. The FDA regards the words *same in language and emphasis* as requiring VERBATIM use of the approved labeling providing such information. Furthermore, information that is emphasized in the approved labeling by the use of type set in a box, or in capitals, boldface, or italics, must be given the same emphasis in *PDR*.

The FDA has also recognized that the FD&C Act does not, however, limit the manner in which a physician may use an approved drug. Once a product has been approved for marketing, a physician may choose to prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling. The FDA also observes that accepted medical practice includes drug use that is not reflected in approved drug labeling. In the case of over-the-counter dietary supplements, it should be remembered that this information has not been evaluated by the Food and Drug Administration, and that such products are not intended to diagnose, treat, cure, or prevent any disease.

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ASHP Statement on the Use of Medications for Unlabeled Uses

The freedom and responsibility to make drug therapy decisions that are consistent with patient-care needs is a fundamental precept supported by ASHP. This activity is a professional duty of pharmacists not limited by language in Food and Drug Administration (FDA)-approved product labeling.

The prescribing, dispensing, and administration of FDA-approved drugs for uses, treatment regimens, or patient populations that are not reflected in FDA-approved product labeling often represent a therapeutic approach that has been extensively studied and reported in medical literature. Such uses are *not* indicative of inappropriate usage. Health-care professionals should appreciate the critical need for freedom in making drug therapy decisions and understand the implications of unlabeled uses. ASHP supports third-party reimbursement for FDA-approved drug products appropriately prescribed for unlabeled uses.

Definition of Unlabeled Use

The FDA approves drug products for marketing in the United States. Such a product approved for marketing is often termed an "FDA-approved drug." FDA also approves each drug product's labeling (container label, package insert, and certain advertising); the term "FDA-approved labeling" applies here. Drug uses that are not included in the indications or dosage regimens listed in the FDA-approved labeling are defined as "unlabeled uses." For purposes of this document, unlabeled use includes the use of a drug product in (1) doses, (2) patient populations, (3) indications, or (4) routes of administration that are not reflected in FDA-approved product labeling.

It is important to recognize that FDA cannot approve or disapprove physician prescribing practices of legally marketed drugs. FDA does regulate what manufacturers may recommend about uses in their products' labeling and what manufacturers can include in advertising and promotion.

The sometimes-used term "unapproved use" is a misnomer, implying that FDA regulates prescribing and dispensing activities. This term should be avoided.[1] Other terminology that is sometimes used to describe unlabeled use includes "off-label use," "out-of-label use," and "usage outside of labeling."

According to FDA, unlabeled use encompasses a range of situations that extend from inadequate to carefully conceived investigations, from hazardous to salutary uses, and from infrequent to widespread medical practice. Accepted medical practice often involves drug use that is not reflected in FDA-approved drug-product labeling.[2]

Health-Care Issues Related to Unlabeled Use

Access to Drug Therapies. The prescribing and dispensing of drugs for unlabeled uses are increasing.[3,4] In many clinical situations, unlabeled use represents the most appropriate therapy for patients. Failure to recognize this or, more importantly, regarding such use as "unapproved" or "experimental" may restrict access to necessary drug therapies.

Lack of Practice Standards. Well-defined medical practice standards that differentiate between experimental therapies and established practice will probably always be somewhat lacking, owing to the advancement of medical science and the dynamic nature of medical practice. Standards of practice for certain drug therapies, particularly biotechnologically produced drugs, cancer chemotherapy, and AIDS treatments, are continually evolving. The dynamic nature of these drug therapies makes it difficult for professional societies to review scientific data expediently and to develop standards that remain absolutely current.

Failure of Package Insert and FDA-Approved Labeling to Reflect Current Practice. For FDA-approved product labeling to be modified, scientific data must be submitted by a product's manufacturer to FDA to support any additional indication(s) and dosage regimen(s). Once they are submitted, FDA must review the data and make a decision to permit alteration of the package insert.

Knowing that unlabeled uses are permitted, and knowing that the accumulation and submission of scientific data to FDA to modify labeling is a time-consuming and often expensive process, some pharmaceutical manufacturers elect not to pursue labeling changes. Therefore, a product's labeling sometimes fails to represent the most current therapeutic information for a drug, and situations naturally occur when it is appropriate to prescribe drugs for unlabeled uses.

Pharmacist's Role

ASHP believes that pharmacists in organized health-care settings bear a significant responsibility for ensuring optimal outcomes from all drug therapy. With respect to unlabeled uses, the role of the pharmacist should be to

1. Fulfill the roles of patient advocate and drug information specialist.
2. Develop policies and procedures for evaluating drug orders (prescriptions) and dispensing drugs for unlabeled uses in their own work settings. Such policies and procedures might address the documentation of scientific support, adherence to accepted medical practice standards, or a description of medical necessity.
3. Develop proactive approaches to promote informed decisionmaking by third-party payers for health-care services.

Role of Drug Information Compendia

The Medicare Catastrophic Coverage Act of 1988 (now repealed) included the statements that "in carrying out the legislation, the Secretary [of Health and Human Services] shall establish standards for drug coverage. In establishing such standards, which are based on accepted medical practice, the Secretary shall incorporate standards from such current authoritative compendia as the Secretary may select."[5] Specific compendia recommended were the *AHFS Drug Information,*

AMA Drug Evaluations, and *USP Dispensing Information, Volume I.* Despite the repeal of the Act, some third-party payers have adopted guidelines that endorse these three compendia as authoritative information sources with respect to unlabeled uses for drug products.

Positions on Unlabeled Use

FDA Position. A statement entitled "Use of Approved Drugs for Unlabeled Indications" was published in the *FDA Drug Bulletin* in April 1982 to address the issues of appropriateness and legality of prescribing approved drugs for uses not included in FDA's approved labeling. This statement included the following:

> *The Food, Drug and Cosmetic Act does not limit the manner in which a physician may use an approved drug. Once a product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling. Such "unapproved" or, more precisely, "unlabeled" uses may be appropriate and rational in certain circumstances, and may, in fact, reflect approaches to drug therapy that have been extensively reported in medical literature.*[1]

Other Organizations. Other organizations that have published positions on the issue of unlabeled uses of drug products are the Health Care Financing Administration (HCFA),[6] the Blue Cross and Blue Shield Association of America (BC/BS),[7] and the Health Insurance Association of America (HIAA).[8]

The American Medical Association, American Society of Clinical Oncology, Association of American Cancer Institutes, Association of Community Cancer Centers, Candlelighters Childhood Cancer Foundation, Memorial Sloan Kettering Cancer Center, National Cancer Institute, and the National Institute of Allergy and Infectious Diseases jointly developed a consensus statement and recommendations regarding use and reimbursement of unlabeled uses of drug products.[9]

These statements are consistent with the ASHP position.

Reimbursement Issues

As a cost-containment measure, most third-party payers exclude coverage for experimental therapies. Drug therapy coverage decisions are complicated, because often it is difficult to differentiate among an accepted standard of practice, an evolving standard of practice, and investigational therapies. Data demonstrating medical necessity and improved patient outcome are often difficult to retrieve. Consequently, insurance carriers and managed care providers have sometimes elected to cover only those indications included in FDA-approved drug-product labeling and have frequently denied coverage for unlabeled uses of drug products.

ASHP believes that such coverage denials restrict patients from receiving medically necessary therapies that represent the best available treatment options. A growing number of insurance carriers are following the BC/BS and HIAA guidelines that encourage the use of the three authoritative drug compendia, peer-reviewed literature, and consultation with experts in research and clinical practice to make specific coverage decisions. ASHP supports informed decisionmaking that promotes third-party reimbursement for FDA-approved drug products appropriately prescribed for unlabeled uses.

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Approved by the ASHP Board of Directors, November 20, 1991, and by the ASHP House of Delegates, June 1, 1992. Developed by the Council on Professional Affairs.

The bibliographic citation for this document is as follows: American Society of Hospital Pharmacists. ASHP statement on the use of medications for unlabeled uses. *Am J Hosp Pharm.* 1992; 49:2006–8.

2011 WL 1790423
Only the Westlaw citation is currently available.
United States District Court, C.D. Illinois.

Randal W. CARRIGAN and
Sherry Carrigan, Plaintiffs,
v.
K2M, INC., Defendant.

No. 09–CV–3149. | May 10, 2011.

Attorneys and Law Firms

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Carmel Cosgrave, Colin Patrick Gainer, Donna E. Fernandez, Smith Amundsen LLC, Chicago, IL, for Defendant.

Opinion

OPINION

BYRON G. CUDMORE, United States Magistrate Judge:

***1** This matter comes before the Court on Plaintiffs Randal W. Carrigan and Sherry Carrigan's (collectively Carrigans) Second Amended Motion to Compel Discovery and Application to Take the Deposition of Mike Barrus Out of Time (d/e 51) (Motion to Compel); Plaintiffs' Motion for a Sixty Day Extension of Time on All Scheduling Order Deadlines to Allow a Ruling on Plaintiffs' Motion to Compel (Document Number 51) and Allow Further Testing and Examination of the Subject Product and Allow Plaintiffs' Experts to Supplement Their Rule 26 Expert Reports (d/e 58) (Motion for Extension) (collectively Carrigan Motions); and Defendant K2M, Inc.'s (K2M) Emergency Motion to Compel K2M Hardware for Non–Destructive Inspection (d/e 60) (K2M Motion). The parties have certified that they have attempted in good faith to resolve these matters without court action. Fed.R.Civ.P. 37(a)(1). For the reasons set forth below, the Carrigan Motions and the K2M Motion are ALLOWED in part.

BACKGROUND

The Carrigans allege products liability claims against K2M arising from screws that fractured in a Mesa Spinal System designed and distributed by K2M that had been implanted into Randal Carrigan's spine. Specifically, the threads in the screws fractured. The threads on the screws were based on the "thread form and geometry" of the screws used in the Denali Spinal System, also designed and distributed by K2M. *Motion to Compel,* Exhibit 7, *Excerpt of the 510k Application to Food and Drug Administration; Deposition of Richard Woods,* at 183 (both exhibits filed under seal at d/e 54). The Carrigans have requested documents from K2M related to the Denali Spinal System, but K2M has objected based on relevance and undue hardship. *Motion to Compel,* Exhibit 6, *Defendant's Response to Plaintiffs' Fourth Request to Produce.* The Carrigans now ask this Court to compel production of these documents.

The Carrigans also ask the Court to compel K2M to compel an unredacted copy of the meeting minutes of the Board of Scientific Advisors. K2M produced a redacted copy that redacted a portion of the minutes that discuss the Denali Spinal System. The Carrigans want these minutes produced in discovery. K2M objects on the same grounds of relevance and undue burden.

The Carrigans also ask for permission to take the deposition of K2M employee Mike Barrus out of time. The Carrigans submitted a interrogatory to K2M for the identity of, "Defendant's 30(b)(6) witness most knowledgeable regarding the specifications for manufacturing of the subject product, including screws." *Motion to Compel,* Exhibit 1, *Defendant's Answers to Plaintiffs' Interrogatories,* ¶ 17. K2M responded, "*ANSWER:* Rich Woods, Senior Vice President of Engineering, K2M, Inc., ..." *Id.* (emphasis in the original). The Carrigans then noticed Woods' deposition under Rule 30(b)(1). Woods' deposition was taken on November 9, 2010. *Motion to Compel,* Exhibit 2, *Woods Deposition,* at 1. During the deposition, Woods discussed the fact that the Mesa Spinal System was manufactured for K2M by Hammill Manufacturing Company. *Id.* at 85. Woods was asked about the number of cutting movements used to cut the screws at issue. Woods said, "I don't know the answer to that." *Id.* Woods then said that Mike Barrus might know. Woods stated that Barrus, "is the engineer who designed the screw, and he has been to Hammill more often than the rest of us have." *Id.*

***2** On January 7, 2011, the Carrigans' counsel sent a letter to K2M's counsel requesting the deposition of Barrus. *Motion to Compel,* Exhibit 3, *Letter from Thomas J. Steece to Donna*

Fernandez dated January 7, 2011. K2M's counsel responded by letter dated January 11, 2011. *Motion to Compel,* Exhibit 4, *Letter from Carmel M. Cosgrave to Thomas J. Steece, dated January 11, 2011.* K2M's counsel did not object to the deposition as long as it was taken in Leesburg, Virginia, where K2M's offices are located. On January 13, 2011, the Carrigans' counsel told K2M's counsel that the Carrigans no longer wanted to take Barrus's deposition. *Motion to Compel,* Exhibit 5, *Letter from Thomas J. Steece to Carmel Cosgrave dated January 7, 2011.*

On January 20, 2011, K2M's counsel renewed the request for the deposition of Barrus. On January 21, 2011, counsel for K2M again agreed to the deposition of Barrus, but only if: (1) the Carrigans provided a list of topics to be covered in the deposition; (2) the Carrigans held the deposition in Virginia; and (3) the Carrigans do not seek to recover the costs of the deposition. The Carrigans refused the last condition. They stated that they would seek costs if they were the prevailing party in this matter. *Defendant's Response to Plaintiffs' Motion to Compel,* Exhibit 3, *Email from Michael Velez to Donna Fernandez dated January 25, 2011.* The deadline for fact discovery passed on January 31, 2011, without the parties resolving their dispute of the costs of the deposition. *See Text Order entered October 7, 2010.* The Carrigans now ask the Court to allow them to take the deposition of Barrus after the deadline.

The parties have conducted two destructive tests on the Mesa Spinal System screws at issue. The parties failed to properly complete the agreed upon testing protocol at both of the tests. The Carrigans' experts want to conduct additional destructive testing. The Carrigans ask for an additional sixty days to complete another destructive test. K2M objects on the grounds that the Carrigans could have completed the testing before the deadline for such testing ran on March 31, 2011.

The K2M Motion asks for an order compelling the Carrigans to allow K2M's expert to conduct a non-destructive inspection of the screws and hardware from the Mesa Spinal System at issue. The screws and hardware are currently in the possession of the Carrigans' attorney in Oklahoma City, Oklahoma. K2M's expert wants to conduct the inspection at the expert's laboratory in Fairfield, Ohio. The Carrigans have stated that they will allow the transportation of the screws and hardware to Fairfield, Ohio, only if: (1) the Defendant or Defendant's counsel personally transport the screws and hardware from the Carrigans' counsel Oklahoma City to Fairfield and personally return them to the Carrigans' counsel; or (2) K2M insures the screws for $3,000,000.00 against loss during transit. K2M would not agree to either condition. *See K2M Motion,* Exhibits C–J, *Correspondence between Thomas J. Steece and Carmel M. Cosgrave.* K2M asks for an order to compel the Carrigans to produce the screws and hardware for non-destructive inspection without these preconditions.

ANALYSIS

***3** The Carrigan Motions raise three issues: (1) the request to compel production of information related to the Denali Spinal System; (3) the request to depose Mike Barrus; and (3) the request for an extension of deadlines to conduct additional destructive testing of the screws. K2M indicates that it has provided other discovery that the Carrigans sought in the Motion to Compel. Those portions of the Motion to Compel are denied as moot. The Court will address the three remaining matters as follows. The Court will thereafter address the request for inspection of the screws and hardware set forth in the K2M Motion.

A. *Documents Related to the Denali Spinal System*

Federal Rule of Civil Procedure 26(b)(1) allows parties to obtain discovery regarding any matter, not privileged, which is relevant to the claim or defense of any party. Relevant information need not be admissible at trial if the discovery appears to be reasonably calculated to lead to the discovery of admissible evidence. The rule gives the district courts broad discretion in matters relating to discovery. *See Brown–Bey v. United States,* 720 F.2d 467, 470–71 (7th Cir.1983); *Eggleston v. Chicago Journeymen Plumbers' Local Union 130,* 657 F.2d 890, 902 (7th Cir.1981); *see also, Indianapolis Colts v. Mayor and City Council of Baltimore,* 775 F.2d 177, 183 (7th Cir.1985) (on review, courts of appeal will only reverse a decision of a district court relating to discovery upon a clear showing of an abuse of discretion). "[I]f there is an objection the discovery goes beyond material relevant to the parties' claims or defenses, the Court would become involved to determine whether the discovery is relevant to the claims or defenses and, if not, whether good cause exists for authorizing it so long as it is relevant to the subject matter of the action. The good-cause standard warranting broader discovery is meant to be flexible." Fed.R.Civ.P. 26(b)(1) Advisory Committee Notes, 2000 Amendment.

The federal discovery rules are to be construed broadly and liberally. *Herbert v. Lando,* 441 U.S. 153, 177 (1979); *Jeffries v. LRP Publications, Inc.,* 184 F.R.D. 262, 263 (E.D.Pa.1999). Federal Rule of Civil Procedure 26(b)(1) provides that the "[p]arties may obtain discovery regarding any matter, not privileged, that is relevant to the claim or defense of any party ...," but "[f]or good cause, the court may order discovery of any matter relevant to the subject matter involved in the action." *Id.* The party opposing discovery has the burden of proving that the requested discovery should be disallowed. *Etienne v. Wolverine Tube, Inc.,* 185 F.R.D. 653, 656 (D.Kan.1999); *Golden Valley Microwave Foods, Inc. v. Weaver Popcorn Co.,* 132 F.R.D. 204, 207 (N.D.Ind.1990); *Flag Fables, Inc. v. Jean Ann's Country Flags and Crafts, Inc.,* 730 F.Supp. 1165, 1186 (D.Mass.1989).

District Courts have broad discretion in discovery matters. *Packman v. Chicago Tribune Co.,* 267 F.3d 628, 646 (7th Cir., 2001). A party must be diligent in pursuing the perceived inadequacies in discovery and the trial court does not abuse its discretion if a party untimely seeks to compel inadequate discovery responses. *Id.* at 647. However, even an untimely filed motion to compel may still be allowed if the party demonstrates actual and substantial prejudice resulting from the denial of discovery. *Id.* Remember, we are talking discovery, not admissibility at trial.

***4** In light of these principles, the unprivileged documents requested by the Carrigans that relate to the Denali Spinal System should be produced, including the unredacted minutes of the Board of Scientific Advisors discussing the Denali Spinal System. The threads on the screws in Randal Carrigan's back fractured. The threads on those screws were based on the design of the Denali Spinal System screws. Information related to the Denali Spinal System, therefore, is relevant or is reasonably calculated to lead to admissible evidence. K2M may invoke the provisions of the Agreed Protective Order (d/e 38) to limit disclosure of confidential information.

K2M argues that the screws in the Denali Spinal System are not relevant because the Denali and Mesa Spinal Systems have different designs and use different materials. *See Defendant's Response to Plaintiffs' Second Amended Motion to Compel (d/e 57),* Exhibit 3, *Affidavit of Rich Woods,* ¶¶ 3--5. That may be true, but it is also clear that the threads on the screws in Randal Carrigan's back fractured, and those threads were based on the Denali Spinal System design. The design of the Denali Spinal System screws may lead to relevant evidence to this case and information is discoverable. The Carrigan's motion to compel production of these documents is allowed. K2M is directed to produce the requested unprivileged documents by June 11, 2011.

B. *Deposition of Mike Barrus*

The Court will allow the deposition of Mike Barrus on the condition that the Carrigans serve a proper Rule 30(b)(6) notice on K2M and the deposition be conducted in Leesburg, Virginia. The Carrigans complain that K2M should have disclosed Barrus initially as the person who had the most knowledge of the Mesa Spinal System for purposes of Rule 30(b)(6). The record does not demonstrate that K2M acted improperly in identifying Rich Woods in answer to the Carrigans' interrogatory. The interrogatory asks for the person most knowledgeable about he product, including the screws. There is no evidence that Barrus knows more that Woods knows about the product, the Mesa Spinal System. Woods stated in his deposition that Barrus designed the screws, but Woods did not say that Barrus designed the entire Mesa Spinal System. Thus, the evidence does not indicate that the answer to the interrogatory was incorrect.

Furthermore, the Carrigans did not conduct a Rule 30(b)(6) deposition of Woods. The Carrigans noticed him for an individual discovery deposition under Rule 30(b)(1). K2M properly produced Woods since he was the person noticed for the deposition. K2M did nothing improper with respect to this deposition. The Court also recognizes that the Carrigans acted indecisively, first requesting the deposition of Mike Barrus, then withdrawing the request, then renewing the request. K2M, understandably, was frustrated with such indecisiveness.

Nevertheless, the Carrigans ultimately requested the deposition of Barrus before the time for fact discovery closed. K2M had no basis to condition that deposition on the waiver of a claim for costs in the event that the Carrigans ultimately prevails in the case. The prevailing party generally may be entitled to certain costs associated with depositions. 28 U.S.C. § 1920; Fed.R.Civ.P. 54(d). Because the Carrigans made a timely request on January 20, 2011, the Court will allow the deposition. The Carrigans are directed to serve a proper Rule 30(b)(6) notice on K2M for the deposition and the deposition will be conducted in Leesburg, Virginia. The Carrigans will complete the deposition by June 30, 2011.

C. *Request for Additional Testing and Extension of Time*

*5 In light of the delay necessitated by the deposition of Barrus, the Court will allow one additional destructive test of the Mesa Spinal System screw as requested by the Carrigans. The parties agree that the two previous tests were not completed properly in accordance with the agreed protocol. The parties are given until June 30, 2011, to complete one more test. The testing is to be done after the completion of the non-destructive inspection requested in the K2M Motion, discussed below. The Court, however, will not allow a sixty day extension of all deadlines. The parties' experts can file supplemental reports. The parties further may request extensions on expert depositions if necessary. At this time, however, the Court will not extend all deadlines.

D. *K2M Motion*

K2M's request for a non-destructive inspection of the screws and hardware at issue is allowed in part. The parties agree that K2M's expert may inspect the screws and hardware. The parties only disagree on the conditions for the transportation of the screws and hardware. The Court has reviewed the cases cited by the Carrigans, and conducted an independent review of the case law, and finds no examples of any court imposing the kind of conditions, financial or otherwise, requested by the Carrigans for the transportation of physical evidence for inspection by the opposing party or designated experts. The Court will not require such precautions.

The Defendant's non-destructive inspection and the Plaintiffs' third destructive testing must be coordinated. The non-destructive inspection should be conducted before the destructive testing is performed. K2M's expert may also want to attend the third destructive testing. The Court, therefore, directs the parties to meet and confer to develop an agreed protocol for transporting the screws and hardware in order to effectuate both the non-destructive inspection and the third destructive testing. The parties are directed to present to the Court by June 3, 2011, an agreed protocol for transporting the screws and hardware to effectuate the nondestructive inspection and the destructive testing. If the parties cannot agree, then each party should submit a proposed protocol by that date, and the Court will decide the matter.

WHEREFORE, Plaintiffs Randal W. Carrigan and Sherry Carrigan's Second Amended Motion to Compel Discovery and Application to Take the Deposition of Mike Barrus Out of Time (d/e 51); Plaintiffs' Motion for a Sixty Day Extension of Time on All Scheduling Order Deadlines to Allow a Ruling on Plaintiffs' Motion to Compel (Document Number 51) and Allow Further Testing and Examination of the Subject Product and Allow Plaintiffs' Experts to Supplement Their Rule 26 Expert Reports (d/e 58); and Defendant K2M, Inc.'s (K2M) Emergency Motion to Compel K2M Hardware for Non–Destructive Inspection (d/e 60) (K2M Motion) are ALLOWED IN PART as set forth above in this Opinion.

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