In the
UNITED STATES DISTRICT COURT
for the SOUTHERN DISTRICT OF INDIANA,
INDIANAPOLIS DIVISION

NIGHTINGALE HOME HEALTHCARE, INC.,	)	
Plaintiff,	)	
vs.	)	**CAUSE NO. 1:06-cv-1435-SEB-WTL**
ANODYNE THERAPY, LLC,	)	
Defendant.	)	

E N T R Y

Defendant's Motion for Summary Judgment (doc. 126)

On September 18, 2008, the Court entered summary judgment against Plaintiff Nightingale Home Healthcare, Inc. on Counts 1 (Lanham Act) and 4 (product liability) of its four-count Amended Complaint. Count 2, a breach-of-contract claim under Florida law, and Count 3, a fraudulent-misrepresentation claim under Indiana law, survived to the extent that they allege that Defendant Anodyne Therapy, LLC represented that its infrared medical device was approved by the federal Food and Drug Administration ("FDA") for the treatment of peripheral neuropathy. Entry of September 18, 2008 (doc. 106), at 20; Entry and Order for January 7, 2009 (doc. 125).[1] At the final pretrial conference held on January 5 and 7, 2009, the trial date was continued and Anodyne was invited to submit a motion for summary judgment on the issue of damages. Entry and Order for January 7, 2009 (doc. 125). That motion is now before the Court.

[1] At the final pretrial conference, Nightingale formally dropped its claims based on Anodyne's representations regarding Medicare reimbursement for treatments with its device. Entry and Order for January 7, 2009 (doc. 125).

To better understand the instant rulings, we summarize the factual background from our previous Entry. Anodyne acquired the rights to an infrared lamp device that relieves pain and improves circulation through the use of infrared photo energy. The device consists of flexible pads containing light-emitting diodes that are placed in direct contact with a patient's skin at affected areas and infrared light is applied at different strengths and durations depending on the patient's particular condition. Anodyne marketed the professional model to health-care providers — physicians, nursing homes, physical-therapy clinics, and home health-care agencies — and the home model to individual consumers.

Anodyne's infrared lamp is a Class III medical device under the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360c, which requires premarket approval before, *inter alia*, being introduced or delivered for introduction into interstate commerce, or being received in interstate commerce, *id.*, §§ 331 and 360e. Prior to Anodyne's acquisition of the lamp, its inventor applied FDA for premarket approval and, in the application, described the device as intended "for relief of minor muscle and joint pain and improvement of superficial circulation." The FDA granted the application in 1994. Anodyne was formed in 2000 or 2001 and began marketing the device to health-care providers as a treatment for peripheral neuropathy, among other conditions, such as wound care.

Peripheral neuropathy is a degenerative condition of nerves extending from the central nervous system (the spinal cord and brain) that results in loss of sensation, weakness and atrophy of muscles, decreased deep reflexes, and decreased circulation. The disorder is usually manifested in the extremities and is often characterized by increasing motor deficiencies and

pain. Peripheral neuropathy can be caused by many conditions, including trauma, toxins, metabolic diseases such as diabetes, physical impingement of the nerves, infections such as Lyme disease, auto-immune reactions, and nutritional deficiencies. J. E. Schmidt, *Attorneys' Dictionary of Medicine and Word Finder* at –90, P-181 to P-182 (2007). Peripheral neuropathy is often a circular process: degeneration of the nerves that control the blood vessels cause the vessels to constrict, the decreased blood flow further irritates the nerves causing pain and further degeneration and constriction, resulting in more pain, numbness, and atrophy. *Id.*; Brar Deposition, pp. 53-54. Relying on studies and research showing circulatory benefits of infrared photo therapy, Anodyne promoted its infrared lamp as a means of increasing blood flow in the affected areas of the body and thus providing temporary relief of pain and numbness associated with peripheral neuropathy and improved nerve function.

In November 2004, Nightingale Home Healthcare, Inc., a provider of home health-care services, began purchasing professional models from Anodyne following an in-person demonstration of the device by Jody Conrad, an Anodyne sales representative, at Nightingale's facility. There is no dispute that Mr. Conrad represented and Anodyne's general marketing stated that Anodyne's infrared lamp is a treatment for peripheral neuropathy, among other conditions; that Nightingale could so market the device; and that the lamp was FDA-approved. The parties dispute whether Mr. Conrad further represented that the lamp was FDA-approved specifically for the treatment of peripheral neuropathy.

Nightingale began using the units immediately and actively marketed and promoted the Anodyne lamp to its referral sources and the general public as a treatment for peripheral

neuropathy and other circulation-related conditions such as wound recovery. Nightingale noticed a positive effect on its clients who were referred with symptoms of peripheral neuropathy: treatments improved circulation in their extremities leading to temporary relief of pain, numbness, and nerve damage. Brar Dep., p. 102. Nightingale purchased 2 more devices in March, 2005; 1 more in July, 2005; 2 more in September, 2005; and 4 or 5 more in January, 2006. Turtzo Affidavit, ¶¶ 10-13.

In June and July, 2005, the FDA conducted a regular inspection of Anodyne's manufacturing facility in Florida. In December 2005, it sent a Warning Letter to Anodyne notifying it that its marketing and promotion of the infrared lamp "for use in the treatment of wounds and ulcers, loss of protective sensation, gait and balance impairment, and other Diabetic Peripheral Neuropathy conditions, as well as conditions associated with Non-diabetic Neuropathies" and for "the treatment of conditions including, but not limited to, soft tissue injuries, Carpal Tunnel Syndrome (CTS), and lymphedema" exceeded the device's premarket approval that was granted based on the description of the device's intended use for "relief of minor muscle and joint pain and improvement of superficial circulation." The letter stated that the promotion and introduction of the device into interstate commerce for those uncleared indications rendered the device "adulterated" under 21 U.S.C. § 351(f)(1)(B) and that the uncleared indications represented new uses that require a new application for premarket approval before being so marketed and promoted. Anodyne revised its marketing to eliminate mention of the uncleared uses for the lamp. It did not immediately inform Nightingale of the subject of the Warning Letter.

Sometime in February, 2006, Nightingale independently learned of the FDA's December 2005 Warning Letter and Anodyne's promotion of its lamp for uncleared uses — after it had already purchased or leased an additional 4 or 5 of the devices in January 2006 in response to a special promotion by Anodyne. Nightingale began revising its marketing and advertising to remove promotion of the Anodyne lamp as a treatment for peripheral neuropathy and other uncleared conditions and it contacted its referral sources to inform them of the revisions.

Nightingale claims that it was misled by Anodyne. Because of Anodyne's alleged misrepresentations about the approved uses of the lamps, Nightingale alleges that it aggressively promoted and used the lamps as a treatment for peripheral neuropathy at significant training and marketing costs and to the injury of its reputation among its referral clients when it had to backtrack following the Warning Letter. It contends that, rather than timely inform Nightingale of the Warning Letter when it was received in December, 2005, Anodyne ran a special promotion and allowed Nightingale to purchase an additional 4 or 5 units in January, 2006. At some point later in 2006, after Anodyne refused Nightingale's demands to buy back its lamps and reimburse its training and promotional costs, Nightingale stopped using the Anodyne devices, purchased and began using a similar number of a competitor's infrared lamps, and filed the present suit.

Anodyne's motion for summary judgment argues that Nightingale is unable to prove both liability and damages.[2] Summary judgment "should be rendered if the pleadings, the discovery

[2] Although Anodyne was invited to file a motion regarding only damages, Entry and Order for January 7, 2009 (doc. 125), Nightingale has not objected to Anodyne's motion regarding liability and it is expedient for us now to address the merits of a fully-argued motion

and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c).

Liability

1. Representation of FDA-approval. Anodyne contends that there is no qualified evidence that it represented to Nightingale that the FDA had approved its infrared lamp for the treatment of peripheral neuropathy or that Nightingale relied upon such a representation in deciding to purchase the devices. As mentioned above, there is no dispute that Anodyne marketed its infrared lamp generally, and specifically to Nightingale, as a treatment for peripheral neuropathy despite not having the requisite FDA approval to do so. There is also no dispute that Anodyne represented to Nightingale that it could promote its lamps as a treatment for peripheral neuropathy and thereby obtain additional business from its referral sources. Anodyne further concedes that it represented to Nightingale that its lamps were FDA-approved; it disputes, however, that it told Nightingale, or others, that its lamps were FDA-approved specifically for the treatment of peripheral neuropathy.

As we explained in our previous Entry, a Class III device, such as Anodyne's infrared lamp, is required to have an FDA-approved premarket application before the device may be introduced into interstate commerce. 21 U.S.C. §§ 360e(a), 331(a), and 351(f)(1)(B). While the application requires that the manufacturer submit all information regarding investigations into whether the device is safe and effective, 21 U.S.C. § 360e(c)(1)(A), it also requires "[a] general

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that might obviate the need for trial.

description of the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended", 21 C.F.R. § 814.20(b)(3)(i), and copies of the proposed labeling, including any information, literature, or advertising that constitutes labeling, 21 U.S.C. § 360e(c)(1)(F); 21 C.F.R. § 814.20(b)(10). A premarket application shall be denied if there is a lack of a showing of reasonable assurance that such device is safe and effective "under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof", 21 U.S.C. § 360e(d)(2), and "[a] device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA [premarket approval] order for the device", 21 C.F.R. § 814.80. FDA premarket clearance, therefore, is limited in scope to the indications and uses declared by the applicant in its application.

In this case, the premarket application for Anodyne's lamp declared that is was "for relief of minor muscle and joint pain and improvement of superficial circulation," which thus defined the permissible scope of Anodyne's promotion and marketing of its infrared lamp. Therefore, the December, 2005 FDA Warning Letter was based solely on the fact that Anodyne's marketing and promotion exceeded the bounds of its premarket clearance. While the premarket application process tends to ensure that only safe and effective devices are marketed for intended uses, Anodyne's violation was a marketing or promotional violation. The Food, Drug, and Cosmetic Act specifically does not "limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship." 21 U.S.C. § 396. Thus, the FDA does not comprehensively approve or disapprove the use, safety, or effectiveness of

medical devices for all possible treatments; it approves devices only to the extent of applicants' declared uses and conditions.

As we found in our previous Entry, Nightingale failed to show a genuine dispute about the fact that Anodyne's representation that its infrared lamp is a treatment for peripheral neuropathy was not false or misleading. In addition, Anodyne's representation that its lamp is FDA-approved was not false or, by itself, misleading. However, if Anodyne represented or warranted that its lamp was FDA-approved for the treatment of peripheral neuropathy, then that representation or warranty was false. The parties do not dispute that the only alleged occurrence of that specific representation was Jody Conrad's oral statements during a sales presentation to Nightingale's president, Dr. Dev Brar, and its Administrator, Piper Kirby, the two decision makers regarding Nightingale's purchases of the Anodyne devices. Anodyne argues that none of the depositions support that such a statement was made and that the only evidence of it is improper: the affidavits of Dr. Brar and Ms. Kirby that were made after their deposition testimony and that contradict that testimony.

There is no dispute that Anodyne generally marketed its infrared lamp — and Mr. Conrad specifically represented it to Nightingale — as "FDA approved," which it was, and as a "treatment" for peripheral neuropathy — which we previously found that it was, in the generally-accepted sense of providing symptomatic relief. However, there is no direct, unequivocal deposition testimony by Mr. Conrad, Dr. Brar, or Ms. Kirby connecting the two concepts: that Mr. Conrad either did or did not tell Nightingale that Anodyne's infrared lamp was approved by the FDA for the treatment of peripheral neuropathy. At most, there are a few

direct questions with imprecise answers:

> Q What representations were made to you by Jody Conrad regarding the either approval or nonapproval of the Anodyne system for the treatment of peripheral neuropathy?
>
> A Before we purchased it?
>
> Q Okay, let's focus on before purchase.
>
> A Jody told me that Anodyne is specifically for the treatment of peripheral neuropathy, numbness, and pain, and it is FDA approved, and the patients can be treated by a physical therapist, but after therapy is done the patients can keep the product themselves. * * *

Brar Deposition (doc. 68-2) at 4-5. It is unclear whether, in separating the facts that the lamps were "for the treatment of peripheral neuropathy" and that they were "FDA approved" in his answer, Dr. Brar meant to indicate that Mr. Conrad did not connect the two ideas or Mr. Brar affirmed the connection from the terms of the question. There was no focused follow-up question to clarify his meaning.

> Q What involvement does FDA have with approval of billing?
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> A I personally don't know whether FDA is what — is directly linked to billing, but CMS [Centers for Medicaid Services] has to get some kind of an approval for any program including home health, DME, or programs like Anodyne to be billed. So when we — the stress — we would not each have known any involvement of FDA until Jody had said that this is something that FDA has approved and there were certain aspect of the treatment that would be eventually billable.

Brar Dep. at 9. Without clarification of the antecedent of the "something" that Mr. Conrad said had FDA approval — whether the lamp by itself or the treatment of peripheral neuropathy with the lamp, both of which would be reasonable interpretations in the context — it is unclear whether Dr. Brar here intended to say that Mr. Conrad represented that the FDA gave premarket approval to the lamp for the treatment of peripheral neuropathy.

> Q Let's try to focus on FDA. And before you purchased from Anodyne, were

there problems that you think Anodyne had that they should have disclosed to you before your purchase?

A Yes.

Q What were those problems you think they should have disclosed?

A They should have told us that not like what we were told. And I will tell you what we were told and what they should have. Is that a fair way of saying it?

Q All right.

A We were told that this is an FDA-approved treatment for which we will be reimbursed, maybe not now but very soon. * * *

Brar Dep. at 22-23. As explained above, the Anodyne infrared lamp *was* an "FDA-approved treatment" for certain symptoms of peripheral neurology. Therefore, it is unclear whether this passage means that Mr. Conrad said only that "treatment" with Anodyne's lamp was FDA-approved, without further elaboration, or that he said treatment *for peripheral neuropathy* with the lamp was FDA-approved.

Q * * * It is my understanding that Nightingale initially purchased the Anodyne system based in part on Mr. Conrad's representations that the FDA had approved the Anodyne system for — as a form of treatment for peripheral neuropathy, and that Anodyne was working with Medicare trying to get Medicare billing approval; is that correct?

A Can you repeat the last part, the Medicare part?

Q That Anodyne was working with Medicare trying to get Medicare billing approval.

A That, plus the fact that patients would already be reimbursed for the usage. That part was already in place is what we were told.

Q Okay. So that's an accurate statement that I made?

A No, but you didn't say that the patient part.

Q But the first — the first part of the statement was accurate; is that correct?

A Yes.

Brar Deposition (doc. 68-3) at 91-92. In the last question, it is unclear whether the "first part of the statement," of which Dr. Brar confirms the accuracy, refers to the first part of the initial question — the fact of Mr. Conrad's representation regarding FDA approval — or the first part

of the clarifying question — the statement regarding Anodyne working to obtain Medicare billing approval.

> Q The question was: Did Mr. Conrad or any other representative of Anodyne ever indicate to you that the FDA recommended Anodyne Therapy for the treatment of neuropathy?
>
> A They promoted that it was FDA approved and requested that we — I believe there was a document back there where it even stated that they needed the diagnosis of peripheral neuropathy to apply for Medicare reimbursement. I think we went over that earlier. They highly recommended it for peripheral neuropathy.
>
> Q Anodyne recommended it for peripheral neuropathy?
>
> A Yes.
>
> Q But what at the time — again, before you made — before Nightingale made its purchase what was false about the statement that the FDA had approved Anodyne Therapy for the treatment of peripheral neuropathy?
>
> A They stated to us that it was FDA approved, that Anodyne was FDA approved.
>
> Q And what was false about that?
>
> A It was not intended for use with peripheral neuropathy.
>
> Q So it's your understanding that before Nightingale purchased its Anodyne Therapy system, the FDA had disapproved the use of Anodyne Therapy for the treatment of peripheral neuropathy?
>
> A I'm sorry, did you say prior to our purchase?
>
> Q Correct.
>
> A It's my understanding that they were FDA approved for the treatment of peripheral neuropathy prior to our purchase.
>
> Q They were approved?
>
> A Yes.

Kirby deposition (doc. 67-2) at 93-94. Similar to the ambiguity of Dr. Brar's testimony above, it is unclear in this passage whether Ms. Kirby's answer of "it was FDA approved" to the direct question about Mr. Conrad's representation was intended to indicate that Mr. Conrad did not connect the two ideas of FDA approval and treatment of peripheral neuropathy or meant that Ms.

Kirby was merely adopting the connection implicit in the question. In addition, in the last part of this passage, it is unclear whether Ms. Kirby's "understanding" that Anodyne's lamps were FDA-approved for the treatment of peripheral neuropathy resulted from a direct statement to that effect by Mr. Conrad or was inferred by her from ambiguous or incomplete statements by Mr. Conrad. Again, the record is devoid of any follow-up clarifying questions.

> Q * * * Other than what we've already talked about today, did you have any discussions with anyone from Anodyne regarding this claim of ability to promote the treatment and utilized the system and receive reimbursement form Medicare?
>
> A There was ongoing conversations. I mean, we had a relationship, so it wasn't just a "Sign on the line, here's your Anodyne machines" and they leave. It's an ongoing relationship that we have built together.
>
> Q Tell me about those conversations that you remember.
>
> A In various conversations, it was told to us many times that they were actively pursuing the Medicare reimbursement, that they were FDA approved and that they didn't foresee any reason why they wouldn't be. But that, yes, it would be a lengthy process for them as with anything with Medicare.

Kirby Dep. at 106-07. Neither Mr. Conrad's deposition (doc. 80) nor his affidavit (doc. 72-2) contains any statement regarding his representations to Nightingale about FDA approval.[3]

In support of its response to Anodyne's first motion for summary judgment, Nightingale submitted the affidavits of Dr. Brar and Ms. Kirby, both of which were made after their depositions were taken and which contained identical averments that Mr. Conrad represented to them that the FDA had approved the marketing of Anodyne's infrared lamp as a treatment for

[3] Nightingale cites additional parts of the depositions of Dr. Brar (pp. 29, 95, and 154-55), Mr. Conrad (pp. 67-68), Craig Turtzo (Anodyne's President) (doc. 79-2) (pp. 27-28), and Pamela Kissel (a patient advocate with Nightingale) (doc. 134-2) (pp. 15-16 and 18-20) in support of its assertion that Mr. Conrad or Anodyne represented that Anodyne's infrared lamp was FDA approved for the treatment of peripheral neuropathy, (Response (doc. 131) at 2-3), but we find no such testimony on those pages.

peripheral neuropathy and that Nightingale had relied thereon:

> Jody Conrad represented to me on behalf of his employer Anodyne Therapy, LLD, in discussions leading up to Nightingale's initial purchase of the Anodyne Therapy Professional Units (Model 480), that these units were approved by the Food and Drug Administration ("FDA") to treat peripheral neuropathy.
>
> In the discussions preceding Nightingale's initial purchase of the Anodyne Therapy Professional Unit (Model 480), Jody Conrad affirmatively represented that these units were FDA approved for peripheral neuropathy, when in fact they were not approved by the FDA for peripheral neuropathy.
>
> The above representations concerning the FDA approval of the Anodyne Therapy units as treatment for peripheral neuropathy, the ability of the Anodyne units to be marketed as a treatment for peripheral neuropathy, and the Medicare coverage the Anodyne treatment were crucial considerations in my initial and continuing decisions to purchase the Anodyne Therapy Professional Units (Model 480) and foster a working relationship with Anodyne Therapy, LLC.

Brar Affidavit (doc. 77-2) ¶¶ 6, 14, and 15; Kirby Affidavit (doc. 78-2) ¶¶ 6, 11, and 12.

Anodyne argues that Dr. Brar's and Ms. Kirby's affidavits cannot create a triable issue of fact about Mr. Conrad's alleged statement regarding the FDA's approval of Anodyne's lamp as a treatment for peripheral neuropathy. While Anodyne is correct that a party may not fend off summary judgment by creating factual disputes by submitting affidavits that contradict prior deposition testimony, unless a plausible explanation for the discrepancy is offered in the deposition itself, *Velez v. City of Chicago*, 442 F.3d 1043, 1049 (7th Cir. 2006); *Beckel v. Wal-Mart Associates, Inc.*, 301 F.3d 621, 623 (7th Cir. 2002), there is no contradiction in this case between the affidavits and the depositions. As the relevant excerpts above show, Dr. Brar's and Ms. Kirby's testimonies are, at best, imprecise or ambiguous and there are no instances, as in *Beckel*, where the deponents were asked "anything else" type questions to which they gave unequivocal answers. Therefore, the affidavits are proper evidence and suffice to create a

genuine dispute of fact about whether Anodyne represented to Nightingale that the FDA had approved use of its infrared lamps for the treatment of peripheral neuropathy.

In addition, there is undisputed evidence that Anodyne represented to Nightingale (through Mr. Conrad and its general marketing material) that its infrared lamp device was an effective treatment for peripheral neuropathy, see *e.g.*, Brar Dep. at 5 and 154; Craig Turtzo Affidavit (doc. 71-2) ¶ 14; Conrad Deposition (doc. 80) at 67-68, and that Nightingale could promote the lamp to its referral sources and clients as a treatment for peripheral neuropathy in order to increase their sales, Conrad Dep. at 67-68; Brar Affidavit ¶¶ 12, 13, and 15; Kirby Affidavit ¶¶ 9, 10, and 12; Kissel Affidavit (doc. 76-2) ¶ 5. In addition, there is undisputed evidence that Nightingale was looking for latest-technology treatments to promote its business and stay ahead of the competition, *e.g.*, Brar Dep. at 29, 93, 94-96, specifically new means to treat its peripheral-neuropathy patients, and that its ability to promote Anodyne's lamp as just such a treatment was an important consideration in Nightingale's decision to purchase Anodyne's lamps. Given that, under long-standing law, Anodyne's infrared lamp was required to have an approved application for premarket approval that specified its permissible marketing purposes, it would have been a reasonable and justified assumption by Nightingale that, if Anodyne promoted its lamp as a treatment for peripheral neuropathy and represented that Nightingale could promote the lamp itself as a treatment for peripheral neuropathy, then the FDA had so approved it.

We conclude, therefore, that Anodyne has failed to establish the absence of a genuine dispute about whether Anodyne represented to Nightingale that its infrared lamp was approved

by the FDA for the treatment of peripheral neuropathy and could be so promoted.

2. Disclaimer of warranties. Anodyne contends that there is no genuine dispute that it effectively disclaimed all warranties and, in particular, any warranties regarding FDA approval of its lamp, and Nightingale's ability to market its lamp, for the treatment of peripheral neuropathy. It alleges that the operating manuals that were provided to Nightingale with each lamp contained a disclaimer, which read, in part:

> Anodyne Therapy, LLC ("Manufacturer") warrants the Anodyne Therapy System® ("The Product") to the immediate purchaser as follows:
>
> **Limited Warranty**
> Manufacturer warrants that The Product sold hereunder will be free from defects in material and workmanship for a period of one (1) year from the date of purchase with normal use. If the defects are of such type and nature as to be covered by this warranty, **Manufacturer shall, at its option, either repair or replace the damaged product at its sole expense.** This warranty does not cover any Products that have been abused, misused, or tampered with in any way.
>
> THIS WARRANTY IS IN LIEU OF OTHER WARRANTIES INCLUDING WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR USE, WHICH ARE HEREBY SPECIFICALLY DISCLAIMED.
>
> This limited warranty gives you specific legal rights. You may have other rights, which vary from state to state. To the extent allowed by applicable law, in no event shall manufacturer be liable for any incidental, consequential, special, indirect, punitive or exemplary damages or lost profits from any breach of warranty.

Anodyne Therapy Professional System, Model 480, Important Safety Information and Instructions, p. 11, attached as Exhibit F to Declaration of Robert E. Johnson (doc. 127). Because these disclaimers were conspicuously printed in the manuals and each lamp was provided to Nightingale on a sixty-day trial period, Nightingale had ample opportunity to review the disclaimers and decide whether to accept each lamp and the accompanying disclaimer.

Because Nightingale did not object to the disclaimers or return the lamps within the trial periods, Anodyne argues that all warranties were excluded and Nightingale cannot prevail on its breach-of-warranty claim.

Anodyne supported its argument with citations to Florida law holding that public policy protects the rights of sellers to exclude warranties, *Desandolo v. F & C Tractor & Equipment Co.*, 211 So.2d 576 (Fla. Dist. Ct. App. 1968); conspicuous disclaimers are effective, Fla. Stat. Ann. § 672.316; *Earman Oil Co., Inc. v. Burroughs Corp.*, 625 F.2d 1291 (5th Cir. 1980); warranty disclaimers are part of a bargain when included in a manual of directions for use, *Monsanto Agriculture Products Co. v. Edenfield*, 426 So.2d 574 (Fla. Dist. Ct. App.1982); and boldface disclaimers in all capital letters are conspicuous and effective under Florida law, *Lennar Homes, Inc. v. Masonite Corp.*, 32 F.Supp.2d 396 (E.D. La. 1998). (Motion Brief (doc. 126) at 26; Reply (doc. 135) at 3-4).

In its response, Nightingale chose to ignore Anodyne's disclaimer argument. Failure to respond may subject an argument to summary ruling, *cf.* S. D. Ind. L. R. 7.1(b), and failure to legally and factually develop a response to, let alone mention, an argument results in forfeiture of any defense thereto. We won't do Nightingale's legal research, review the record for favorable evidence, or make its arguments for it. We are entitled to assume, in short, that, if Nightingale had any plausible grounds to counter Anodyne's argument, then it would have presented them; therefore, we must conclude that it has no factual or legal defense to Anodyne's

disclaimer of warranties.[4]

We have reviewed Anodyne's legal support and find it applicable and controlling. Express, as well as implied, warranties can be disclaimed or excluded. *Belle Plaza Condominium Assoc., Inc. v. B. C. E. Development, Inc.*, 543 So. 2d 239 (Fla. Dist. Ct. App. 1989); *Family Boating & Marine Centers of Florida, Inc. v. Bell*, 779 So.2d 402 (Fla. Dist. Ct. App. 2000). Effective disclaimers can be included in instruction manuals accompanying a product. *Monsanto, supra*. *Cf., LWT, Inc. v. Childers*, 19 F.3d 539 (10th Cir. 1994) (disclaimer in catalog is effective).[5] We find and conclude, therefore, that there is no genuine dispute that Anodyne disclaimed and excluded any warranties regarding FDA approval of its lamps for the treatment of peripheral neuropathy or Nightingale's ability to promote the lamps for the treatment of peripheral neuropathy. It follows that Anodyne is due judgment as a matter of law on Nightingale's Count 2 claim for breach of warranties.

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[4] "In our adversary system, in both civil and criminal cases, in the first instance and on appeal, we follow the principle of party presentation. That is, we rely on the parties to frame the issues for decision and assign to courts the role of neutral arbiter of matters the parties present. * * * [A]s a general rule, '[o]ur adversary system is designed around the premise that the parties know what is best for them, and are responsible for advancing the facts and arguments entitling them to relief.'" *Greenlaw v. United States*, 128 S.Ct. 2559, 2564,171 L.Ed.2d 399 (2008).

[5] We note that, while disclaimers that are included in literature that is delivered only after a sale is completed are generally ineffective because they did not become a part of the bargain, *Bowdoin v. Showell Growers, Inc.*, 817 F.2d 1543 (11th Cir. 1987), in this case, Nightingale did not contest Anodyne's assertion that each sale of its lamps to Nightingale was on a sixty-day evaluation period (a preliminary lease, in effect) which ripened into a sale only if and when Nightingale retained the devices after the sixty days. Nightingale likewise did not contest that an effective disclaimer accompanied each device that was delivered. Further, Nightingale did not claim, or provide an apportionment of, damages that were incurred only during the initial sixty-day trial periods.

Citing Florida law, *Giallo v. New Piper Aircraft, Inc.*, 855 So.2d 1273 (Fla. Dist. Ct. App.), *cause dismissed*, 869 So.2d 539 (Fla. 2003), Anodyne argues that Nightingale's Count 3 fraud claim also fails because the representations on which it is based are the ones disclaimed in Anodyne's effective exclusion of warranties. Again, Nightingale offered no response. It did not offer any Indiana or other Florida law showing whether, and under what circumstances, a fraudulent-misrepresentation claim based on a seller's warranties could survive an effective disclaimer of those warranties, and it made no argument that it does in this case. We find and conclude, therefore, that Anodyne is due judgment in its favor on Nightingale's Count 3 fraudulent-misrepresentation claim.

Damages

Although Anodyne makes several arguments against the sustainability of Nightingale's damages, we address only the more salient ones in light of our disposal of Nightingale's liability claims above.

As part of its discovery responses and its response to the present motion, Nightingale produced a summary of the damages that it is seeking. Johnson Declaration, Exhibits B and G; Brar Supplemental Affidavit (doc. 133-2). In short, it seeks full reimbursement of the purchase/lease payments it has made for the Anodyne lamps; reimbursement for all advertising it made promoting the Anodyne lamps, including television broadcasting, a billboard, brochures, displays, and graphics; the costs of training its employees on the MedX system which it purchased to replace the Anodyne lamps; the opportunity costs of the employees during training, *i.e.*, the revenue they could have generated serving patients; and loss of Nightingale's goodwill

and reputation. In all, it seeks at least $336,818.49, plus whatever value is place on lost goodwill and reputation. Nightingale contends that it is entitled to one of two types of remedies, at its option: either (1) a refund of the full purchase price of the Anodyne devices in exchange for returning the units to Anodyne, returning any other benefits, in effect a restoration of the *status quo ante*, or (2) the difference in value between the Anodyne lamps as delivered and their value had they been as represented (which Nightingale measures as the difference between what it paid for the Anodyne units and what it paid for the replacement MedX units) plus any consequential and incidental damages proximately cause by Anodyne's misrepresentations.

1. Revenue generated by use of Anodyne lamps. Anodyne alleges that Nightingale has never complied with its discovery requests for documents, logs, and any other evidence showing the revenue and profits that Nightingale generated through its use of Anodyne's lamps. Because such profits must be set off against Nightingale's alleged incidental and consequential damages in order to return the parties to the *status quo ante*, Nightingale's failure and refusal to produce such crucial evidence disqualifies it from recovering any damages for Anodyne's alleged breaches and fraud. Again, Nightingale did not respond to Anodyne's arguments and supporting evidence on this point. It did not even deny that such evidence exists and it would be unreasonable for us to assume that there would be no such evidence. Dr. Brar's, Ms. Kirby's, and Ms. Griffin's depositions show that Nightingale used Anodyne's lamps, had success treating its patients with them, and that revenues were generated. Nightingale cannot withhold evidence of its offsetting profits and thus obtain excessive damages.

2. Training costs. Nightingale seeks reimbursement of its costs in training its physical

therapists and marketing personnel in the use and marketing of the MedX devices which it purchased to replace the Anodyne devices. It failed to produce any documentation supporting these costs, however. More important, however, is the fact that Nightingale is currently using the MedX system and therefore is benefitting from the necessary training of its therapists and marketers in that system. The training costs for the MedX system are irrelevant: if it seeks to recover incidental and consequential expenses and costs lost due to its use of the Anodyne system, and return to the *status quo ante*, it wants the costs associated with training its personnel for the Anodyne system, not MedX. It presented no summary, let alone evidence, of those costs and there is no basis for assuming that the costs would be the same as for the MedX system.

3. Loss of reputation and goodwill. Nightingale presented no evidence, factual or opinion, lay or expert, to support the award of any amount of damages for its alleged loss of goodwill and reputation caused by its retraction of marketing that promoted the Anodyne system as a treatment for peripheral neuropathy. There is no evidence in the depositions of Nightingale's personnel or produced in discovery that indicates the existence of *any* lost referrals or sales due to its inability to promote the Anodyne lamps for the treatment of peripheral neuropathy directly, rather than the symptoms of peripheral neuropathy, as it is doing now with the replacement MedX units. While there are several assertions by Dr. Brar and other Nightingale personnel that the ability to promote the use of infrared therapy for the treatment of peripheral neuropathy itself, rather than its symptoms, was a major selling point in Nightingale's decision to purchase the Anodyne system, it produced no evidence — scientific or anecdotal — that such a difference in approach had any actual significant effect among its referral sources or clients, resulting in loss of any current or future business. The undisputed evidence shows that

Nightingale is continuing to successfully use infrared photo therapy with MedX units as it did with Anodyne units. While Nightingale might have wanted, and paid for what it thought was, a new technology that it could promote in a new way in order to generate additional business and gain a competitive advantage, it would be mere speculation and guess to award any damages without evidence that Nightingale likely lost any business as a result of its inability to promote the new technology as intended.

4. Advertising. Nightingale seeks to recover all advertising costs associated with the Anodyne system. In addition to the absence of any evidence supporting its calculation of the amounts sought and the amount of any offsetting profits generated from that advertising, Nightingale has failed to apportion what costs were actually necessitated by Anodyne's alleged misrepresentations as opposed to its unilateral decision to stop using the Anodyne lamps entirely. Nightingale alleges that Anodyne misrepresented that its lamps were FDA-approved for the treatment of peripheral neuropathy and, accordingly, that Nightingale itself could promote the lamps for that purpose as well. Anodyne has shown that much of Nightingale's marketing material did not mention FDA approval, much of it did not even mention peripheral neuropathy (*e.g.*, the billboard), and much of it combined with promotion of other products or services. Correction of its marketing required Nightingale to remove only statements regarding use of Anodyne therapy as a treatment for peripheral neuropathy; it could still use and promote treatment of the symptoms of peripheral neuropathy. (There is no evidence in the record that this difference in wording had or would have had any effect either on Nightingale's actual use of the lamps or on its ability to sell the treatment.) However, Nightingale asked only for the entire costs of its Anodyne advertising; it failed to provide a breakdown of the costs related only to

removing statements regarding the treatment of peripheral neuropathy. As such, only speculation could support an award of damages for lost advertising costs.

Conclusion

Anodyne's motion is **GRANTED**. Final judgment will be entered against Nightingale and in favor of Anodyne on all counts of the Amended Complaint.

Date: 05/15/2009

SARAH EVANS BARKER, JUDGE
United States District Court
Southern District of Indiana

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