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December 11, 2017

Via TrueFiling

California Supreme Court
Earl Warren Building
350 McAllister Street
San Francisco, Ca. 94102

Re: *Rosendez v. Green Pharmaceuticals Inc.* Case No: S244857
Amicus Letter in Support of the Petition for Review

To the California Supreme Court:

I am an attorney admitted to practice in California, New York and Texas. Pursuant to Rule 8.500 (g) of the California Rules of Court, I submit this amicus letter as a private practitioner in support of Green Pharmaceutical's Petition for Review of the Fourth Appellate District's unusual decision overturning the bench trial judge's defense verdict and ordering judgment for the plaintiff class members.

For the Court's information, for the past thirty plus years, I have specialized in representing health care practitioners and companies who use, develop or sell cutting-edge or non-conventional therapies and remedies. I have appeared in federal and state trial and appellate courts and/or state administrative agencies in most states in the United States. I spend much of my professional life dealing with the use and limitations of various types of scientific evidence in evaluating novel or unconventional modalities such as homeopathy.

I do not normally make any kind of court appearance without a client. However, I am making an exception for two reasons. First, I believe the decision will have a deleterious effect on all California consumers who utilize over-the-counter homeopathic remedies because it will likely make fewer of these remedies available in California because of the chilling effect that the decision will have on homeopathic manufacturers. The chilling effect is especially acute since, as will be discussed *infra*, the claim which is the basis of this case was supported by a published clinical trial of the actual product, which study followed the gold standard of clinical trials.

Second, and more importantly for the purposes of the Court's consideration of the Petition for Review, the lower court's decision is in direct conflict with a prior state appellate case (*National Council Against Healthcare Fraud v. King Bio Pharmaceuticals,*

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(2003) 107 Cal. App. 4th 1336) and a recent federal appellate case which concluded that *King Bio* was good law in California (*Kwan v. SanMedica International* 854 F.3d 1088 (9th Cir. 2017)). The conflict involves several critical legal determinations in all future cases such as this. If the Fourth Appellate District's decision stands, it will make it more difficult for practitioners such as myself to try these cases in the future. The decision will also make it more difficult to provide proper legal guidance advising clients like Green as to how to conform their actions to the law regarding claims and advertising. The conflict will also make it more difficult for trial judges to decide cases or write jury charges since they will have to choose whether to follow *King Bio* or the lower court's decision in this case.

For these reasons, I feel it is imperative that the Court accept this case and resolve these conflicts.

The Conflict

.

To practitioners in the field, *King Bio* contains two important principles which guide litigation and the advising of clients (both pre litigation and settlement discussions during litigation) First, *King Bio* establishes that causation and actual, detrimental reliance are necessary for false advertising and unfair competition. The continued viability of these requirements was recently acknowledged by the 9th Circuit in *Kwan v. SansMedica Int'l* 853 F.3d 1088, 1095 (9th Cir. 2017).

The appellate court's decision in this case ordered judgement for the plaintiffs without requiring proof of either element. Indeed, it held that for both false advertising and UCL claims, it is only necessary to show that "'members of the public are likely to be deceived.'" Opinion at page 17 quoting *Kasky v Nike, Inc.* (2003) 27 Cal. 4th 939, 950-951, and *Colgan v. Leatherman Tool Group, Inc.* (2006) 135 Cal. App. 4th 663, 679-680.

Kasky and *Colgan* are no longer good law**.** The UCL was amended in 2004 to impose limits on private enforcement actions. This Court held in 2009 that the statutory amendment imposed an actual reliance element in a UCL claim. *In re Tobacco II Cases,* 207 P.3d 20, 39 (2009). Thus, the lower court's decision is not only in conflict with *King Bio*, it is inconsistent with this Court's rule of law as to the elements of an UCL claim.

Second, the *King Bio* Court refused to shift the burden of proof to the defendant in part because it acknowledged that federal law allows the marketing of homeopathic products listed on the Homeopathic Pharmacopoeia, which means that the general safety and efficacy has been established to the extent required by federal law. (*King Bio, supra,* at 107 Cal. Rptr. 2d. 216, 107 Cal.App. 4th 1348 (2003). The decision under review

chose not to follow this part of *King Bio* and supported its decision by adopting prior criticism of *King Bio's* analysis, (See opinion at pages 13-15 footnote 12). This conflict between *King Bio* and the lower court's decision should be resolved by this Court because these two opposing views require completely different trial strategies in future cases, and create uncertainty for the trial courts as to whether these types of claims are viable and what is required of the parties to prove and disprove these claims.

The reasonable reliance defense to a false advertising claim was ignored by the lower court

As reported by the lower court, at the bench trial, the plaintiffs' expert criticized a published clinical study (the Lipman study) which purported to show the efficacy of the actual product which was the subject of the lawsuit. I do not have access to the record in the case, and I do not know why the study was not admitted into evidence (per the lower court's opinion at footnote 3 page 13).

The appellate court noted that the trial court did not specifically cite the Lipman study as evidence contradicting plaintiffs' evidence that the product was ineffective, but "merely noted that Green relied on the study, which in the court's words 'purports to show that the product is effective as advertised [,] and that Willis gave testimony "indicating that he took issue with the results of the study." (Id.)

False Advertising (Bus. & Prof. Code, Section 17500) requires that the defendant knew or should have known that the statement was false (in the words of the statute, "which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading. . . .") My problem with the lower court's decision is that it omitted any discussion of Green's reasonable reliance on the study which would have been a defense to the false advertising claim.

And as indicated, it did so even though the appellate court specifically noted that the trial court found that Green relied on the study. Of course, the trial court also noted that plaintiffs' expert took issue with the study. But that still doesn't address the specific statutory reference to reasonable reliance.

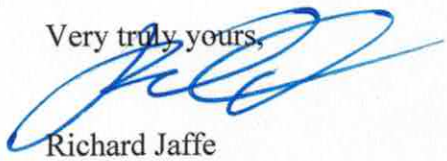
The fact that fifteen plus years after a study is published one expert witness criticizes the study's methodology is certainly not dispositive of whether Green's reliance on the study was unreasonable. Therefore, insofar as the lower court reversed the trial court without an express or even implied finding that the plaintiff carried its burden of proof that Green's actual reliance on the Lipman study was unreasonable, its decision does not follow the statutory elements of the claim.

Further, the Court should know that the Lipman study followed the gold standard of clinical studies in that it was placebo controlled and double blind. There are very few natural remedies or homeopathic products which are supported by that level of a published evidence. If a homeopathic manufacturer can't reasonably rely on a gold standard peer review published clinical study, then how is it safe for a manufacturer to say anything based on any study? (Because I am specifically addressing the Lipman study, I am attaching a copy of it to this letter pursuant to California Rules of Court 8.500 (g) and 805.4 (e) (C)).

My problem is that if a plaintiff can simply attack a published peer review study supporting an efficacy claim, and does not have to prove that the defendant's reliance was unreasonable – which basically rewrites the false advertising statute – then it really doesn't matter what scientific evidence supports the claim because almost any study can be attacked on some ground if you look hard enough. This issue itself may justify review by this Court.

Based on the foregoing, I would respectfully suggest that pursuant to Rule 8.500 (b) (1) review by this Court is necessary both to secure uniformity of decision and to settle important questions of law which impact how similar cases will be tried and evaluated on appeal.

Very truly yours,



Richard Jaffe
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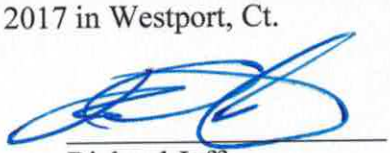
CERTIFICATE OF SERVICE

I am an attorney admitted to practice in the State of California.

I am serving a copy of this amicus letter and attachment on all counsel of record via True file as per the attached True file list of counsel which I incorporate herewith.

I declare under penalties of perjury that the forgoing is trued and correct and that I signed the original of this Certificate of Service on December 11, 2017 in Westport, Ct.



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ORIGINAL ARTICLE

A Randomized Double-Blind Placebo-Controlled Evaluation of the Safety and Efficacy of a Natural Over-The-Counter (OTC) Medication in the Management of Snoring

DEREK LIPMAN, M.D.,[1] GARY SEXTON, STATISTICIAN,[2] and JERRY SCHLESSER, N.D., D.C., C.N.S.[3]

ABSTRACT: *More than 40 million American adults snore. Habitual snoring afflicts 44% of adult males and 28% of females.[1] Uncomplicated snoring is generally due to vibration of the palatal soft tissues or the tongue base, causing intermittent airway obstruction. Loudness is correlated with the degree of vibration and/or obstruction. The tendency, frequency, duration, intensity, and sequelae of snoring are influenced by myriad structural, physiological, environmental and pharmacological factors. Uncomplicated, nonapneic snoring is treated in a wide variety of ways, ranging from self-help methods, such as positional therapy, to laser surgery. The purpose of this report is to evaluate the safety and efficacy of a natural medication for snoring in a randomized double-blind placebo-controlled trial. The treatment is significantly more effective than placebo. Neither side effects nor intolerance to the product was reported.*

KEYWORDS: snoring, naturopathic, homeopathic, Snore Stop

INTRODUCTION

Subjects (n = 100) from the Portland, Oregon metropolitan area were recruited to participate in a randomized double-blind placebo-controlled trial to evaluate the safety and efficacy of a natural medication as a treatment for chronic snoring. The objective was to ascertain whether a homeopathic medicine can influence the incidence and intensity of snoring, and whether the use of such a product effects the quality of sleep for the snorer and his/her sleepmate. The product tested (Snore Stop, The Green Pharmacy, Wilsonville, OR) is a tablet manufactured in accordance with the Homeopathic Pharmacopoeia of the United States (HPUS) containing the following natural substances: Nux vomica 4X & 6X, Belladonna 6X, Ephedra vulgaris 6X, Hydrastis canadensis 6X, Kali bichromicum 6X, Teucrium marum 6X, and Histaminum hydrochloricum 12X.

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METHODS

Randomization and Double Blinding

Study subjects were recruited from the Portland Oregon metropolitan area through newspaper advertising and submitted to a confidential medical history and screening examination (at no charge) by a local otolaryngologist. After suitable informed consent was obtained, qualified study participants received a bottle of study medication randomly numbered from 101 to 201. All containers and labels were identical with the exception of their assigned number. Each amber glass bottle contained 20 tablets, identical in color, odor, taste, shape, markings, and other physical characteristics. Both the active treatment and placebo tablets were prepared and packaged in sealed bottles in an FDA-registered manufacturing facility licensed to produce homeopathic medicines under GMP controls. Containers remained unopened until delivery to study participants. Neither the patient nor any persons having direct patient contact knew the identity of active and placebo containers. Codes were broken only at the conclusion of the study. The randomized placebo group (n = 46) comprised 32 men and 14 women, with a mean age of 47.6

TABLE 1. Subject Characteristics

Characteristic	Placebo		Treatment	
	n	*Mean (SD)*	*n*	*Mean (SD)*
Gender (% men)	46	69.5	44	79.5
Age (years)	46	47.6 (9.6)	44	49.3 (10.3)
Body Mass Index	36	29.5 (5.5)	34	29.7 (6.6)
Addiction[a] (% with addiction)	41	24.4	40	22.5
Allergies (% yes)	44	29.6	44	38.6
Surgery (% yes)	46	34.8	43	41.9
Number of years with chronic snoring	44	11.6 (10.2)	43	16.6 (12.8)*

[a]Addiction to cigarettes and/or alcohol.
*$p = 0.026$.

(SD 9.6) years. The treatment group ($n = 44$) contained 35 men and 9 women, with an average age of 49.3 (SD 10.3) years. The body mass index for the placebo and treatment groups were 29.5 (SD 5.5) and 29.7 (SD 6.6), respectively. Body mass indexes correlated with weights in the Metropolitan Life Tables. There were no significant differences between the treatment and placebo groups in subject characteristics (Table 1) or responses to the pretreatment Snoring Questionnaire (Table 2) with the exception of "Number of years snoring" in which the treatment group had experienced 16.6 ± 12.5 years of snoring as compared to 11.6 ± 10.2 years for the placebo group ($p = 0.026$).

Inclusion Criteria

Adult snorers of both genders between the ages of 18 and 55 with uncomplicated medical histories and sleepmates whose sleep is adversely affected by their partner's snoring.

Exclusion Criteria

Sleep apnea, deviated septum, nasal polyps, and other structural conditions, alcoholism or other chemical depen-

TABLE 2. Snoring Questionnaire[a] (% Response)

Group	N	Score 1	2	3	4	5	Question No.
Placebo	46	0	0	4.4	39.1	56.5	1. How often?
Treatment	44	0	0	0	40.9	59.1	
Placebo	46	0	0	4.4	32.6	63.0	2. Disturb partner?
Treatment	44	0	0	2.0	29.6	68.2	
Placebo	44	20.5	29.6	22.7	22.7	4.6	3. Disturb others?
Treatment	42	16.7	19.1	40.5	16.7	7.1	
Placebo	45	15.6	11.1	20.2	40.0	13.3	4. Snore constantly?
Treatment	44	4.6	9.1	27.3	36.4	22.7	
Placebo	45	24.4	8.9	13.3	20.0	33.3	5. Snore on back?
Treatment	42	28.6	14.3	9.5	9.5	38.1	
Placebo	46	2.2	4.4	10.9	26.1	56.2	6. All positions?
Treatment	44	2.3	6.8	15.9	25.0	50.0	
Placebo	46	58.7	8.7	13.0	13.0	6.5	7. Stop breathing?
Treatment	44	43.2	9.1	22.7	20.5	4.6	
Placebo	45	24.4	20.0	35.6	17.8	2.2	8. Wake suddenly?
Treatment	41	22.0	22.0	39.0	12.2	4.9	
Placebo	46	13.0	15.2	21.7	23.9	26.1	9. Partner leave?
Treatment	43	9.3	18.6	27.9	20.9	23.3	
Placebo	46	30.4	19.6	26.1	10.9	13.0	10. Embarrassment?
Treatment	43	37.2	14.0	22.3	18.6	7.0	

[a]1 = Never; 2 = Very infrequently; 3 = Occasionally; 4 = Often; 5 = Always or almost always (Fisher's Exact test).

dency, COPD, concurrent medications and other factors predisposing to neuromuscular, postural or vascular-related airway/respiratory dysfunction which may complicate patient assessment were listed. Unwillingness or inability to adhere to the study protocol was also included.

Intervention

Over a 10-day period, study subjects were asked to consume two tablets, dissolved in the mouth before bedtime, taking care to avoid any food, beverages, or other factors that could confound the interpretation of product efficacy. Patients and their sleepmates were asked to faithfully and accurately maintain a nightly diary to record outcome measures. Study nurses conducted follow-up by telephone on days 3 and 7 to ensure compliance and answer questions.

Outcome Measures

On the case report forms for 10 consecutive nights, snorers were asked to assess their quality of sleep and daytime alertness, and sleep mates were asked to grade their partner's snoring on a scale of 1–5 for each night.

- 1 = snoring unchanged 0%
- 2 = snoring slightly reduced 25%
- 3 = snoring moderately reduced 50%
- 4 = snoring significantly reduced 75%
- 5 = snoring completely resolved 100%

Additional comments requested from the nonsnoring sleep partner included any noticeable changes in quality or frequency of their partner's snoring pattern, on which nights, and how the nonsnoring partner slept.

RESULTS

The first 5 nights of treatment were viewed as a run-in phase to allow for treatment effects to reach steady state. The last 5 nights were viewed as representing the steady-state treatment effect. In order to examine whether there was a change in snoring ratings, the average rating for the first 5 nights was compared to the average rating for the last 5 nights using a paired *t*-test for each group. There was no significant change in the placebo group ($p = 0.4665$). The treatment group showed an improvement in snoring score between the first and last part of the study ($p = 0.053$). We interpret this as indication that the steady state had not been completely attained within the first 5 days of the study. This is characteristic of the gentle and gradual therapeutic effect of homeopathic medicines.

Primary Analysis

Primary comparisons between the two groups were based on the average snoring score computed from the responses to the Snore Diary (Table 3) over the last 5 nights for each of group. The average score for the placebo group was 0.73 (SD = 0.94) indicating no significant change in

TABLE 3. Distribution (% Response) of Responses to the Snore Diary

		Rating[a]						
Group	*N*	*−1*	*0*	*1*	*2*	*3*	*4*	*Night*
Placebo	46	0	65.2	23.9	4.4	4.4	2.2	1
Treatment	44	2.3	40.9	25.0	11.4	13.6	6.8	
Placebo	46	2.2	54.4	26.1	10.9	4.4	2.2	2
Treatment	43	0	32.6	27.9	23.3	16.3	0	
Placebo	46	2.2	45.6	26.1	15.2	8.7	2.2	3
Treatment	44	0	29.6	22.7	13.6	27.3	6.8	
Placebo	45	2.2	50.0	30.4	13.0	4.4	0	4
Treatment	44	0	31.8	15.9	27.3	18.2	6.8	$p = 0.010$
Placebo	46	2.2	47.8	28.3	13.0	8.7	0	5
Treatment	44	0	29.6	15.9	22.7	22.7	9.1	$p = 0.019$
Placebo	45	0	48.9	28.9	8.9	11.1	2.2	6
Treatment	44	0	25.0	18.2	22.7	29.6	4.6	$p = 0.018$
Placebo	44	0	47.7	36.4	9.1	2.3	4.6	7
Treatment	43	0	25.6	20.9	18.6	30.2	4.7	$p = 0.001$
Placebo	46	2.2	56.5	21.7	8.7	8.7	2.2	8
Treatment	43	0	30.2	16.3	20.9	27.9	4.7	$p = 0.020$
Placebo	46	0	54.4	30.4	8.7	2.2	4.4	9
Treatment	43	0	39.5	18.6	9.3	20.9	11.6	$p = 0.025$
Placebo	44	2.3	59.1	20.5	13.6	2.3	2.3	10
Treatment	43	0	38.6	22.7	9.1	18.2	11.4	$p = 0.031$

[a]−1 = worse; 0 = no change; 1 = slightly reduced; 2 = moderately reduced; 3 = significantly reduced; 4 = completely resolved (*p*–values from Fisher's Exact test).

TABLE 4. Global Rating (%)

A. Rating

Rating	*Group*[a]			
	Placebo		*Treatment*	
	%	(n)	%	(n)
No change	54.4	(25)	20.5	(9)
Slightly reduced	23.9	(11)	18.2	(8)
Moderately reduced	6.5	(3)	18.2	(8)
Significantly reduced	10.9	(5)	27.3	(12)
Completely reduced	4.4	(2)	15.9	(7)
Totals		(46)		(44)

B. Summary Results

Rating	*Group*			
	Placebo		*Treatment*	
	%	(n)	%	(n)
No improvements	54.4	(25)	20.5	(9)
Improvements	45.6	(21)	79.5	(35)
Totals (44)		(46)		

[a]The groups are significantly different in their response, $p = 0.0024$ ($X^2 = 16.54$,4df).

snoring. The average for the treatment group was 1.58 (SD = 1.20) representing a noticeable reduction overall. These differences were statistically significant ($p = 0.0009$).

Secondary Analysis

Comparing "improvement" versus "no improvement" in the global assessment rating (Table 4), 79.5% of the treatment and 45.5% of the placebo group showed overall improvement in their snoring ($p = 0.0009$). In the treatment group, 61.4% reported moderate to excellent improvement versus 21.7% of the placebo group ($p = 0.0001$).

DISCUSSION

In this randomized, double-blind, placebo-controlled trial, the evaluating physician was also blinded to the responses in the patient diary when calculating the overall results and determining the global assessment (Table 4) of success or failure for each participant. In this rating the treatment group was significantly better ($p = 0.0024$).

Although the trial lasted a short period, it demonstrated a clear treatment effect for a chronic condition (mean 16.6 years for the treatment group). There is no consensus on the scientific basis for the mechanism of action of homeopathic medicines. Controlled trials have confirmed the efficacy of homeopathic medicines in the management of acute diarrhea[2] and influenza.[3] Similarly, this study suggests that a safe, inexpensive homeopathic treatment may be of benefit to socially disruptive snorers.

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SLEEP AND BREATHING

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