

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE ADJUDICATION AND HEARINGS

In the Matter of

AG WATERHOUSE, L.L.C.,
KLEIN-BECKER USA, L.L.C.,
NUTRASPORT LLC

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)

A.G. WATERHOUSE, L.L.C.,
KLEIN-BECKER USA, L.L.C.,
NUTRASPORT LLC

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Federal Trade Commission Dietary Supplement Advertising Cases

I. SUMMARY

The Federal Trade Commission (hereinafter FTC or the Commission) has charged the

limited liability companies Basic Research, L.L.C., A.G. Waterhouse, L.L.C., Klein Becker USA

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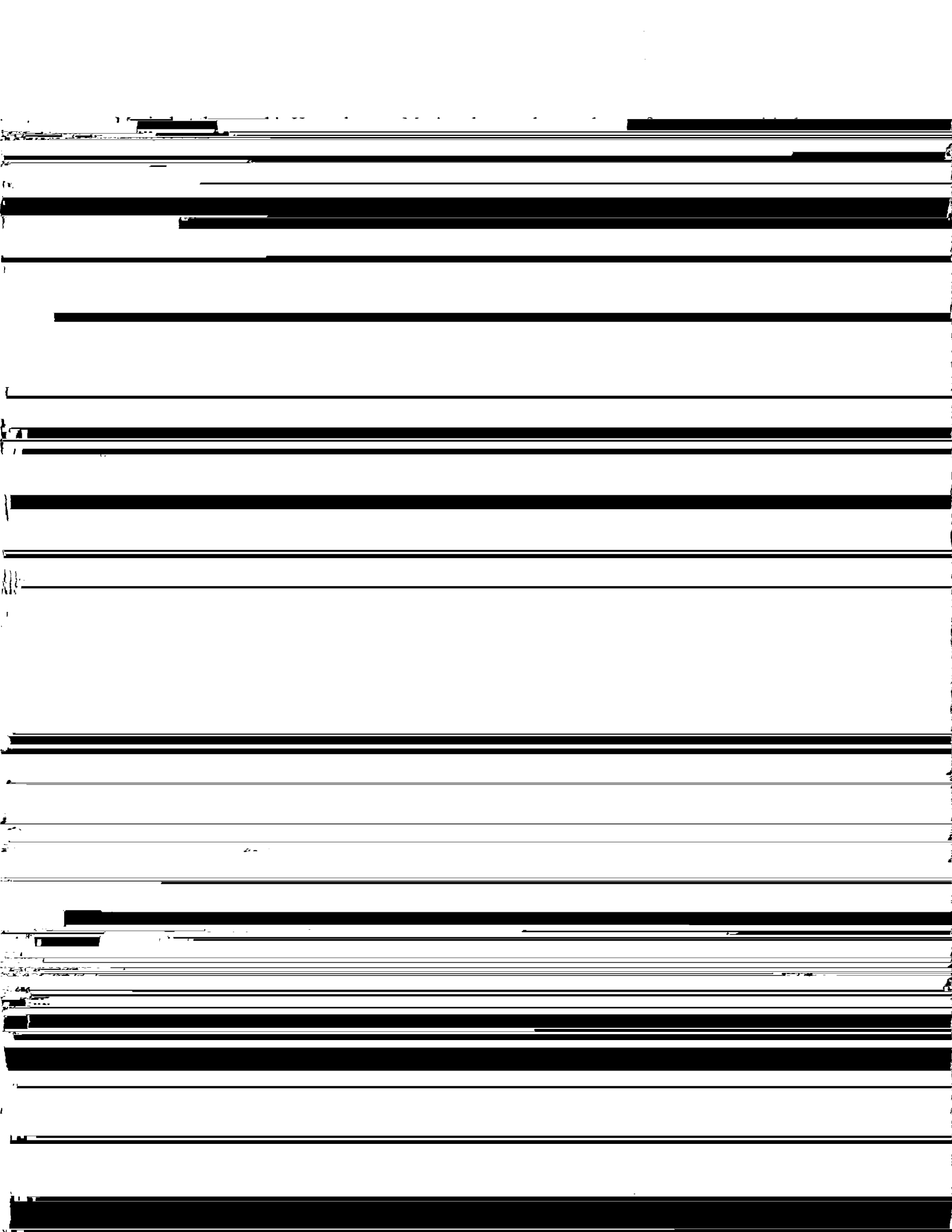
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FTC Counsel have failed to satisfy their burden of proof to justify the speech restrictions they seek. The products in issue perform as advertised. The totality of publicly available scientific evidence confirms that performance, indeed even to the extent of achieving the performance results alleged by FTC Counsel to be implied by the advertising. FTC Counsel have not a shred of empirical evidence (surveys or copy tests) to support its charge that consumers perceive the ads to carry the implications they allege. FTC market expert Mazis never performed such tests. Indeed, Mazis never evaluated the actual target audiences for the claims. He never took into account actual empirical evidence contrary to his assessment that

reveals a high degree of consumer skepticism about weight loss advertising. He bases his "facial analysis" on a fiction detached from empirical evidence.



claims [redacted] that the Commission must determine whether the [redacted] [redacted] that level of

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Even were one to presume, on faith, that the implied claims are the ones the target audiences perceived from viewing the actual claims, those implied claims are so ambiguously worded so subjective and imprecise that it is undoubtedly the case that the physiological effects

begot from the products are ones described by the implications alleged. [* * REDACTED * *]

Based on the scientific evidence, there is a reasonable basis for the actual claims made in Respondents' advertising (and for the claims FTC presumes are implied). If the Chief ALJ were to conclude otherwise, it is nevertheless legally impermissible to impose any restriction on Respondents' future advertising (such as the standard prohibition on future advertising of the same or similar claims unless and until Respondents possess "competent and reliable scientific

Neither the FTC nor the Chief ALJ has defined what a "Demand Letter" means.

to advertise across in the broadcast that there will not be a demand letter. 17-127

mandate of a qualification or disclaimer.⁸ Potentially misleading speech is that speech which can

~~avoid misleading communication that is not in the public interest.~~ 9

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II. PROPOSED FINDINGS OF FACT

A. THE COMMISSION HAS CHARGED RESPONDENTS WITH FALSE ADVERTISING UNDER THE FTCA

1. In its Complaint, the Commission has charged Respondents with making certain representations in commerce the implications of which are said to be "false or misleading." Complaint, CX 001 at ¶¶ 16, 19, 22, 24, 26, 30, 32, 34, 39, 41, 43. In its

claims. In its Complaint, the Commission has not charged Respondents with "unfairness" or "unfair acts or practices." See CX 001.

? In its Complaint, the Commission asks the ALJ to issue an order that prohibits Respondents

6. The Commission's Complaint does not charge Respondents with violating Section 5(n) of the FTC Act, *i.e.*, that the challenged advertisements resulted in a substantial risk of

injury to ordinary prudent consumers in the relevant market (but for any other factors)

likelihood of confusion) that could not be reasonably avoided under the circumstances (although ordinary prudent consumers were not misled and were given a 100% money-back guarantee), and that this risk of harm is not outweighed by other considerations

10. The Commission argues that Respondents' advertisements impliedly represent to consumers that:

1. Each Epidril Product "causes rapid and visually obvious

~~fat loss in excess of that which can be expected from a diet and exercise program."~~

2. Each ECA Product "causes loss of substantial, excess

~~fat in a period of time that is not consistent with a diet and exercise program."~~

14. FTC has an advertising guide for the dietary supplement industry that states that advertising substantiation must meet the competent and reliable scientific evidence standard. RX 015.¹¹ It mentions no other substantiation standard under the FTCA.¹²

15. FTC has a 1982 policy statement on substantiation for advertising. It discusses only the

competent and reliable scientific evidence standard and mentions no other standard that

21. Since 1938, the Commission has required advertisers to possess a reasonable basis before making an objective product claim. *See* "Annual Report of the Federal Trade Commission for the Fiscal Year ended June 30, 1939," 4-5 *available at* <http://www.ftc.gov/os/annualreports/ar1939.pdf> *as of* February 6, 2006. *See also* "A Brief History of the Federal Trade Commission," FTC 90th Anniversary Symposium Brochure *available at* http://www.ftc.gov/ftc/history/docs/90thAnniv_Program.pdf *as of* February 6, 2006.
22. The Commission has regulated weight loss claims in dietary supplement advertising for at least 80 years. *See* "Federal Trade Commission Advertising Cases Involving Weight Loss Products and Services" *available at* <http://www.ftc.gov/opa/1997/03/dietcase.htm> *as of* February 6, 2006.
23. FTC has engaged in a national public education campaign to inform consumers that advertising promoting dietary supplements for weight loss is false and misleading. RX 002. *See* "FTC Announces 'Operation Waistline'--A Law Enforcement and Consumer

26. FTC has not informed the Respondents of what level, degree, quality, or quantity of scientific evidence the FTC would require to support their advertising claims despite repeated requests for same. RX 131, RX 134, RX 137, RX 138.

27. FTC has not informed the Respondents of what kind of scientific evidence the FTC would require to support their advertising despite repeated requests for same. RX 131

28. FTC has not given Respondents and does not give any in the regulated class advisory opinions at their request concerning whether science in support of a health benefit claim is adequate support for a claim. RX 010 and RX 032.²⁰

E. FACTS CONCERNING FTC'S LACK OF FAIR NOTICE

"visually obvious" any objective meaning in their Expert Reports or deposition testimony and have no empirical evidence or any other form of credible evidence to support their interpretations of those terms. RX 050, RX 054, RX 075, RX 077, RX 086, RX 064, RX 036, RX 037, RX 067, RX 044, RX 055, RX 813.

33. The Commission has not defined through rulemaking what constitutes "a reasonable basis" for the alleged efficiency claims at issue. RX 050, RX 044

(d) What criteria does the FTC employ in determining whether a test, analysis, research, study or other evidence has been conducted and

evaluated in an objective manner? What criteria does FTC employ in determining whether a test, analysis, research, study or other evidence is adequately designed? How many subjects are required? Is there a minimum duration for a study or test?

(e) What factors does the FTC take into account to determine whether scientific evidence is accurate and results are reliable? To what extent

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H. DERMALIN, TUMMY FLATTENING GEL, AND CUTTING GEL

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I. PEDIALEAN

157. The sixth product at issue in this case is a dietary supplement with the tradename PediaLean. RX-697, 698.

158. The PediaLean ads are attached to the Complaint as Exhibit K-I. CY 001 at 15



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J. FACTS CONCERNING DR. DANIEL MOWREY AS THE CONSULTING SCIENTIST TO CORPORATE RESPONDENTS

214. Dr. Daniel Mowrey is the consulting scientist to Corporate Respondents. RX 051 at 303-311.

215. Dr. Daniel Mowrey has a Ph.D. in Experimental Psychology from Brigham Young University with an emphasis in psychopharmacology, which is the study of the relationship between drugs and behavior and involved an understanding of physiology and

biochemistry. Psychopharmacology also involves the study of the experimental analysis of behavior and emphasizing the design, conduct, and evaluation of experimental studies. RX 828 at 79, RX 051 Mowrey Depo. at 66-68.

216. Dr. Daniel Mowrey is trained in the scientific method, statistics, and the

217 Dr. Mowrey's Ph.D. dissertation concerned the effects of ginger root on motion

assess the totality of all publicly available scientific evidence and opinion pertaining to a specific nutrient and potential physiological effects to determine whether that nutrient

[** REDACTED **]

L. RESPONDENTS' REFUND POLICY


227. For all of their products Respondents offer a 30 day no questions asked refund guarantee. Complaint CX 002.

[** REDACTED **]

M. FACTS CONCERNING FTC'S LACK OF PROOF IN SUPPORT OF ITS COMPLAINT

244. Dr. Stephen B. Heymsfield is not an expert in statistics, and admits that he is not a statistician. Heymsfield Jan. Depo. at 227. RX 050.

245. ~~Heymsfield is not an expert in biostatistics, and admits that he is not a~~



biostatistician. Heymsfield Jan. Depo at 462. RX 050.

246. Heymsfield is not an expert in conducting power calculations or determining the number of study participants needed for a "valid" study. Heymsfield Aug. Depo at 537-538. RX 813.

247. Heymsfield admitted that he did not seek commentary or review from a qualified biostatistician to assess the validity of the data contained in the Daly study. Heymsfield Aug. Depo at 540-541. RX 813.

248. Heymsfield admitted that he did not seek commentary or review from a qualified biostatistician to assess the validity of the data contained in any of the additional

252. Heysmsfield testified that he is responsible to review the published literature of

the studies that he reviews. Heysmsfield Feb. Depo at 420. RX 054.

253. Heysmsfield testified that he has not researched the published literature to determine if there were written criticisms of the studies that he cited in his expert

265. Heymsfield admits that he rejects all scientific evidence on the subject except that

which comes in the form of prospective, large scale, randomized, double blind

placebo controlled clinical trials of over 2 months duration. Heymsfield Feb. Depo. at 381, RX 054; Heymsfield Expert Report at 13-25, RX 086.

266. Heymsfield lacks education, experience, and training in the area of statistics and is not adept at evaluating statistical significance. Heymsfield Feb. Depo. at 461, RX 054.
267. A study's sample size does not determine its power; yet Dr. Heymsfield makes that fundamental error. See Heymsfield Feb. Dep. at 464, RX 054; *see also* Daniel Mowrey's Expert Report, RX-828.
268. Heymsfield has admitted that he neglects to review entire articles in which he is listed as co-author and, oftentimes, has but a small part in the work leading to the ultimate published study. *See* Heymsfield Aug. Depo. at 455-459, RX 813.

292. Mazis did not include any of the marketing research documenting consumer skepticism of advertising and of weight loss advertising in particular, in his Expert Report. RX 036.

293. Mazis has cited Calfee and Binzold, "Consumer Skepticism and Advertising Regulation,"

What Do the Data Show? 15 Advances in Consumer Research 244-246 (1998): 1.

299. In his expert report, Mazis did not identify parents of overweight children and

adolescents as the target audience for PediaLean. RX 064.

300. In his expert report, Mazis did not identify body builders as the target audience for Cutting Gel. RX 064.

301. Mazis has not conducted any empirical research to determine how consumers and

consumers and parents of overweight children perceive weight loss product advertising

302. Mazis has not conducted any empirical research to determine how women who have excess fat on their stomachs and thighs perceive fat loss product advertising. RX 064.

significant amount of excess body weight...a success rate of 100% (Complaint Exhibit K, 5050054, 5050066). RX 067.

310. Nunberg used lexical analysis to attempt to determine what consumers might think about advertisements for *RediaL* and examined the word "significant" by

conducting searches of newspaper articles for its meaning, rather than conducting consumer survey research to ascertain what consumers actually thought about terms contained in advertisements. RX 067

311. Nunberg did not examine how the word "significant" was used in advertisements.

319. In forming his opinion, Solan relied on his knowledge of linguistic literature, and consulted various dictionaries, database searches of relevant expressions, and conducted term searches within the databases. RX 049 at 74.

688. In *United States v. Solan*, 2014 WL 1234567, the court stated: “[I]n *United States v. Solan*,”

“rapid decrease,” and “rapid increase,” “depend upon prior expectations about how much of a reduction, decrease or increase must occur within a time period for it to be considered

329. FTC has presented no evidence that it is impossible to define with specificity, through rulemaking, what constitutes a "reasonable basis" or "competent and reliable scientific evidence" for a weight or fat loss claim. BX 064, BX 067

330. FTC has not informed Respondents of the level, degree, quality, or quantity of scientific evidence it would accept or qualification or disclaimer FTC would accept as

and quantity of science the Defendants need to present the Defendants' advertising

disclaimers they might use as less speech restrictive alternatives to prosecution. RX-099,

III. PROPOSED CONCLUSIONS OF LAW

The products in question are of three essential kinds.

[* * REDACTED * *]

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Weight loss in excess of 4 pounds per month is considered significant by the Food and Drug

Administration. See http://www.fda.gov/medwatch/safety/2005/jul_PI/Meridia_PI.pdf, July 28,

higher weight loss in the scientific studies. Consider the following chart showing evidence of weight loss:

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FTC relies on no empirical evidence to suggest its view that the ads in question create an

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from deriving implications from weight loss advertising that weight loss is achievable in every case, weight loss product consumers are highly skeptical that weight loss is achievable. RX

828 ³⁵ Thus, FTC's speculation that significantly overweight consumers understand that they will

decision. FTC's assumptions of materiality are likewise wholly uncorroborated. Here, the FTC has presented no empirical evidence to establish that purchasing decisions were made based on any specific representations in the ad that consumers viewed as material. The only empirical evidence presented confirms that weight loss advertising resonates with its audience in the minds of

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field (ones with extensive publication histories involving their original research on weight loss effects⁴⁰) who cite to and rely upon that same evidence in their own reviews of the literature and assessment of original research. See (among Respondents' substantiation composites, JX 003

[* * REDACTED * *]

The government's designated expert on weight loss, Dr. Stephen Heymsfield, takes a view that is not representative of those who study the combination of ephedra, caffeine and aspirin. Dr. Heymsfield's peers look to the totality of publicly available scientific evidence, as indeed the FDA and FTC require of themselves,⁴¹ and give credence to weight loss studies that may lack placebo controls, experience variable drop out rates, and have a duration of 4 weeks or less. Those peers examine the totality of the evidence and derive their opinions from that totality.⁴² Dr. Heymsfield, by contrast, states unequivocally that he does not give credence to any study that lacks placebo controls, has drop-outs in excess of 20%, and has a duration of two

⁴⁰ Contrast that with FTC's expert, Heymsfield. He has but three publications bearing his name
on ephedra that concern ephedra and weight loss. In two of these he is the principal au

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makes that fundamental error. See Heymsfield Feb. Dep. at 464. See also Daniel Mowrey's

Witness Report, P.V. 229 at 40.⁴⁵ A scientist who cannot handle even admission across the

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the source data for the articles that bore his name and was, indeed, largely, if not completely, unaware of the content of those articles. *See* RX 813, Heymsfield Aug. Depo. at 460-590. He could not be a party in fact to the fraud, he argues, because he was oblivious to the content that made the articles fraudulent that despite the fact that he is listed as an author on each one. *See*

[REDACTED]

no promotions or opportunities.”⁴⁷ Now, years hence, he says he can neither admit nor deny having said the quoted lines. Heymsfield Aug. Depo. at 631-634. For one who regarded the event, and rightly so, as devastating, Dr. Heymsfield cannot be believed when he says he can neither admit nor deny having said the words. When an expert witness lacks credibility, the

proper response is to discount or exclude his testimony. See *Daubenton*, *Marshall*, *Daw*

Pharmaceuticals, Inc., 509 U.S. 579, 125 L. Ed. 2d 469, 113 S. Ct. 2786 (1993); *General Elec. Co. v. Joiner*, 522 U.S. 136, 118 S. Ct. 512, 517, 139 L. Ed. 2d 508 (1997). Giving that testimony any credence destroys the integrity of the truth-seeking process.

Finally, Dr. Heymsfield has no direct experience determining whether effects predicted in the science are borne out in the market. By contrast, Dr. Daniel B. Mowrey has 30 years of experience studying the scientific literature on the combination of ephedra, caffeine, and aspirin

and experience observing the clinical trial effects in the population of consumers. 1 1

the user population. See RX 828 at 32. He reports that ECA is designed for long term use, becomes safer with long term use, and overcomes at least in part the body's plateauing effect of weight loss. RX 828 at 32-33. He further confirms that weight loss in excess of the average is achievable in people with overweight to obese status as examples in the

placebo) is not infallible because one cannot "blind" for long an overweight subject who

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FTG contends that the claims regarding Respondent's advertising for PediaLean imply that

“PediaLean causes substantial weight loss in overweight or obese children” and that “clinical testing proves that PediaLean causes substantial weight loss in overweight or obese children.”

is not achievable in any process, weight loss product consumers have been shown to be highly

skeptical that weight loss is achievable at all. Thus, far from deriving from the ads implications of specific amounts of weight loss achievable, consumers likely question whether any loss of weight is achievable, yet the products perform and that performance likely exceeds their

trial in question are plainly revealed to the consumer. The consumer is also informed that
“individual results may vary.” RX 647.

[** REDACTED **]

[** REDACTED **]

from adipocytes, the adipocytes themselves reduce in size yielding an increase in quality of fat

reduction. See RX 317, 318, 319, United States Patent 4,588,724. Greenway, III et. al. Treatment for Selective Reduction of Regional Fat Deposits, filed January 11, 1985; patent granted May 13, 1986.

Dr. Robert Eckel, FTC's expert witness, does not dispute the effectiveness of aminophylline as a weight loss agent. See RX 055 at 12-13. Dr. Eckel frankly admits that he is not a dermatologist and, while aware of the scientific literature on the effectiveness of aminophylline as a weight loss agent, he is not versed in the science concerning the extent to which specific gels are effective delivery vehicles for the aminophylline. See RX 055 at 1.

[** REDACTED **]

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For the foregoing reasons, the Chief Administrative Law Judge should conclude that FTC

Counsel have not proven that Respondents lack a reasonable basis for the objective claims made

Accordingly, the Chief ALJ should dismiss and deny FTC Counsel's Complaint.

**B. THE FTC HAS NOT SATISFIED ITS BURDEN OF PROOF; THE
ADVERTISING IN QUESTION IS NOT DECEPTIVE UNDER SECTION 12 OF
THE FTCA**

Burden of Proof. Under the First Amendment to the United States Constitution (U.S.

Const. Amend. I) and under the FTCA, 15 U.S.C. Sec. 45(n)(1), the Federal Trade Commission

accused does not have the burden of proving that its advertising is non-deceptive, or otherwise protected speech. Rather, the burden remains squarely fixed from beginning to end on the government. *FTC v. Garvey*, 383 F.3d 891, 901 (9th Cir. 2004); *FTC v. Publishing Clearinghouse Inc.*, 104 F.3d 1168, 1170 (9th Cir. 1997)(citing *FTC v. American Standard Credit Sys.*, 874 F.Supp. 1080, 1087(C.D.Ca.1994)); See *Thomas v. Chi. Park Dist.*, 534 U.S. 316, 122 S. Ct. 775, 151 L. Ed. 2d 783 (2002), *United States v. Playboy Entm't Group, Inc.*, 529 U.S. 803, 120 S. Ct. 1878, 146 L. Ed. 2d 865 (2000) *Greater New Orleans Broadcasting Assn. Inc.*

v. United States, 527 U.S. 173, 183, 144 L. Ed. 2d 161, 119 S. Ct. 1923 (1999) ("The Government bears the burden of identifying a substantial interest and justifying the challenged restriction"); *Reno*, 521 U.S. at 879 ("The breadth of this content-based restriction of speech imposes an especially heavy burden on the Government to explain why a less restrictive

satisfies the burden of proof requirements prescribed in *Central Hudson* as modified by its progeny. In an unbroken line of precedent, applied from allegedly deceptive lawyer advertising

to dietary supplement and compounded drug claims, like the Supreme Court has consistently

held it the government's burden to justify restrictions on commercial speech and the Central Hudson four part test the unavoidable standard for decision. *See Peel*, 496 U.S. at 109; *Western States*, 535 U.S. 357; *Pearson*, 164 F.3d 650; *Bd. of Trs. v. Fox*, 492 U.S. 469 109 S. Ct. 3028; 106 L. Ed. 2d 388 (1989); *see, e.g., Central Hudson*, 447 U.S., at 566; *Metromedia, Inc. v. San Diego*, 453 U.S. 490, 507-508 (1981) (plurality opinion); *In re R. M. J.*, 455 U.S. 191, 203 (1982); *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 644 (1985); *Posadas de Puerto Rico Associates v. Tourism Company of Puerto Rico*, *supra*, at 343; *San Francisco Arts & Athletics, Inc. v. United States Olympic Committee*, 483 U.S. 522, 535 (1987); *Shapiro v. Kentucky Bar Assn.*, 486 U.S. 466, 472 (1988).

Moreover, the Supreme Court has demanded that speech regulation imposed after-the-fact avoid prohibiting the content in question if that speech can be rendered non-misleading

the First Amendment. See *Central Hudson Gas & Electric Co.*, 447 U.S. 564; 100 S. Ct. 2343; 65 L. Ed. 2d 341 (1980) (quoting “Even when advertising communicates only an incomplete version of the relevant facts, the First Amendment requires that some pertinent information be

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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without first establishing the absence of any reasonable qualification or disclaimer capable of eliminating the connotation FTC Counsel argues is implied. Under *Central Hudson's* direct

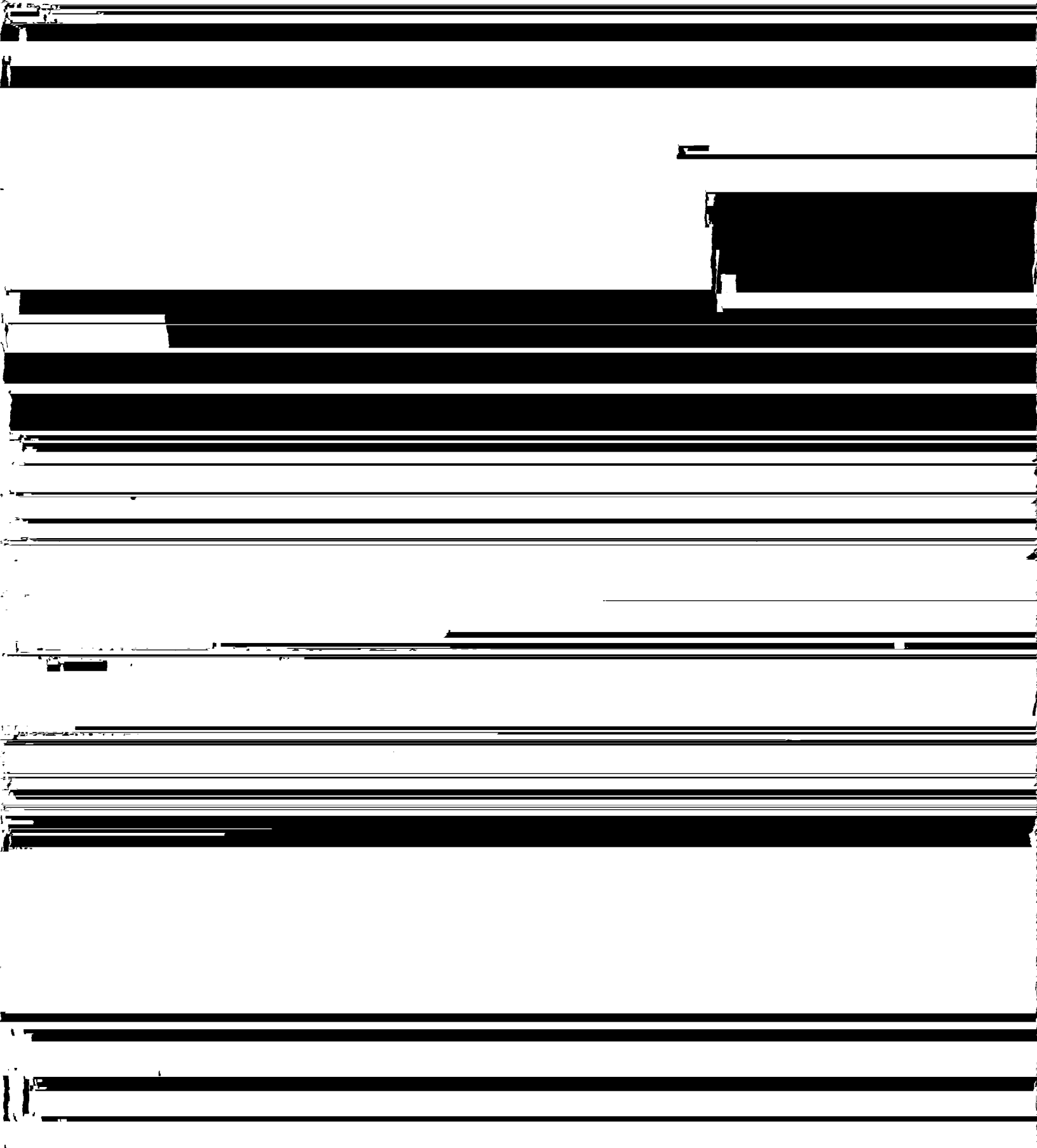
advancement prong, failure to do so denies the regulated sufficient information to discern what speech is fit to be safely communicated.⁶³ Under *Central Hudson's* first prong, failure to

In re R. M. J., 455 U.S. 191, 203 (1982); *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 644 (1985); *Posadas de Puerto Rico Associates v. Tourism Company of Puerto Rico*, *supra*, at 343; *San Francisco Arts & Athletics, Inc. v. United States Olympic Committee*, 483 U.S. 522, 535 (1987); *Shapero v. Kentucky Bar Assn.*, 486 U.S. 466, 472 (1988). But, in fact, the FTC's rule on point is a restraint imposed prior to publication of the ads in question. FTC requires that before advertiser publishes his or her health benefit ad, he or she possess in hand at the time the ad enters the market, competent and reliable scientific evidence corroborating the ad claims.⁶⁵ That documentation requirement just as surely works a prior restraint on speech that is no less absolute than FDA's ban on nutrient-disease claims

published without consultation by FDA that the same information will be available

Inc. v. United States, 527 U.S. 173, 183, 144 L. Ed. 2d 161, 119 S. Ct. 1923 (1999) ("The

Government bears the burden of identifying a substantial interest and justifying the



regulated class what is expected of them, and they must set those bounds constitutionally. See *FTC v. Garvey*, 383 F.3d 891, 901 (9th Cir. 2004); *FTC v. Publishing Clearinghouse Inc.*, 104 F.3d 1168, 1170 (9th Cir. 1997)(citing *FTC v. American Standard Credit Svs.*, 874 F.Supp. 1080.

1087(C.D.Ca.1994)); See *Thomas v. Chi. Park Dist.*, 534 U.S. 316, 122 S. Ct. 775, 151 L. Ed. 2d 783 (2002); *United States v. Playboy Entm't Group, Inc.* 529 U.S. 803, 120 S. Ct. 1878, 146 L.

Ed. 2d 865 (2000), *Greater New Orleans Broadcasting Assn., Inc. v. United States*, 527 U.S. 173, 183, 144 L. Ed. 2d 161, 119 S. Ct. 1923 (1999)

Despite this constitutional and statutory law, this agency, under its Rule 3.43(a), (16

FTC v. 3.43(a), effective with the First Amendment, 119 S. Ct. 1923, 144 L. Ed. 2d 161

need not prove the advertising false, just argue the support for the claims not enough. FTC Counsel believe they need only articulate one plausible yet uncorroborated interpretation of the ad that calls into question the proof relied upon by the accused and that alone suffices as support for a holding of deceptive advertising, regardless of the ultimate truth of the advertising statements. By contrast, FTC Counsel believe it is the duty of the accused to establish that there

the United States. 5 U.S.C. § 3331.⁶⁸ That oath is meaningless unless the First Amendment burden of proof, placed squarely on government to justify a restriction on speech, is honored in this case. FTC's Operating Manual Sec. 2.3. Under that burden, and under the Federal Trade

ads in question is inherently misleading (i.e., incapable of being rendered non-misleading

The Supreme Court has held commercial speech protected even if it conveys less than complete information so long as the information it does convey is, at worst, only potentially misleading. “Even when advertising communicates only an incomplete version of the relevant facts, the First Amendment requires that some accurate information is better than no

[REDACTED]

If he is to follow constitutional law, the Chief ALJ must discern that the Complaint rests on a charge of implied not literal deception,⁶⁹ he must realize that the implied claims are, at worst, only potentially misleading, and he must compel FTC to identify qualifications or disclaimers that will render the claims non-misleading rather than impose an unconstitutionally vague

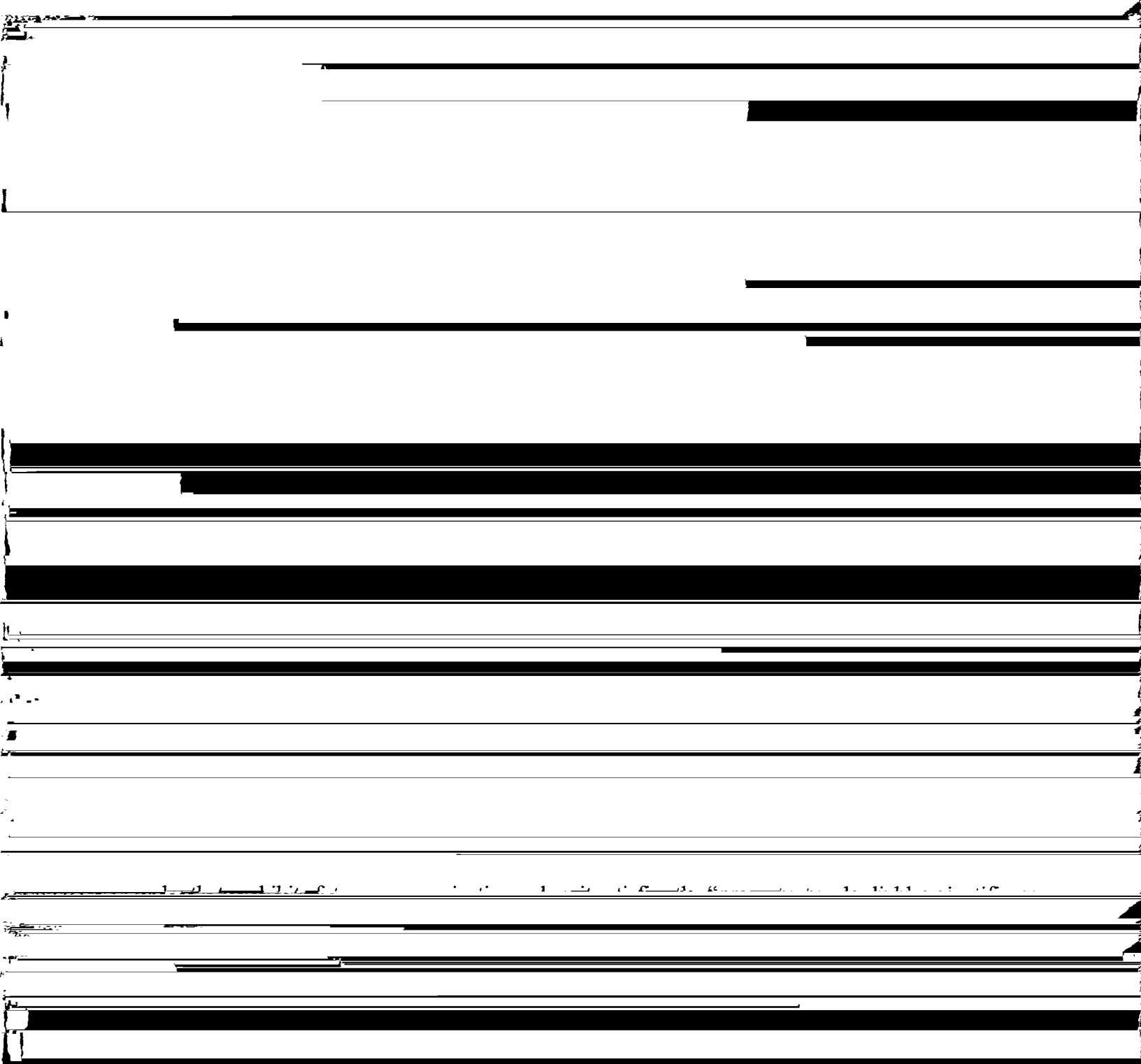
Amendment. See *City of Lakewood*, 486 U.S. 750, 782 (1988) ("Recognizing the explicit

protection afforded speech and the press in the text of the First Amendment, our cases have long

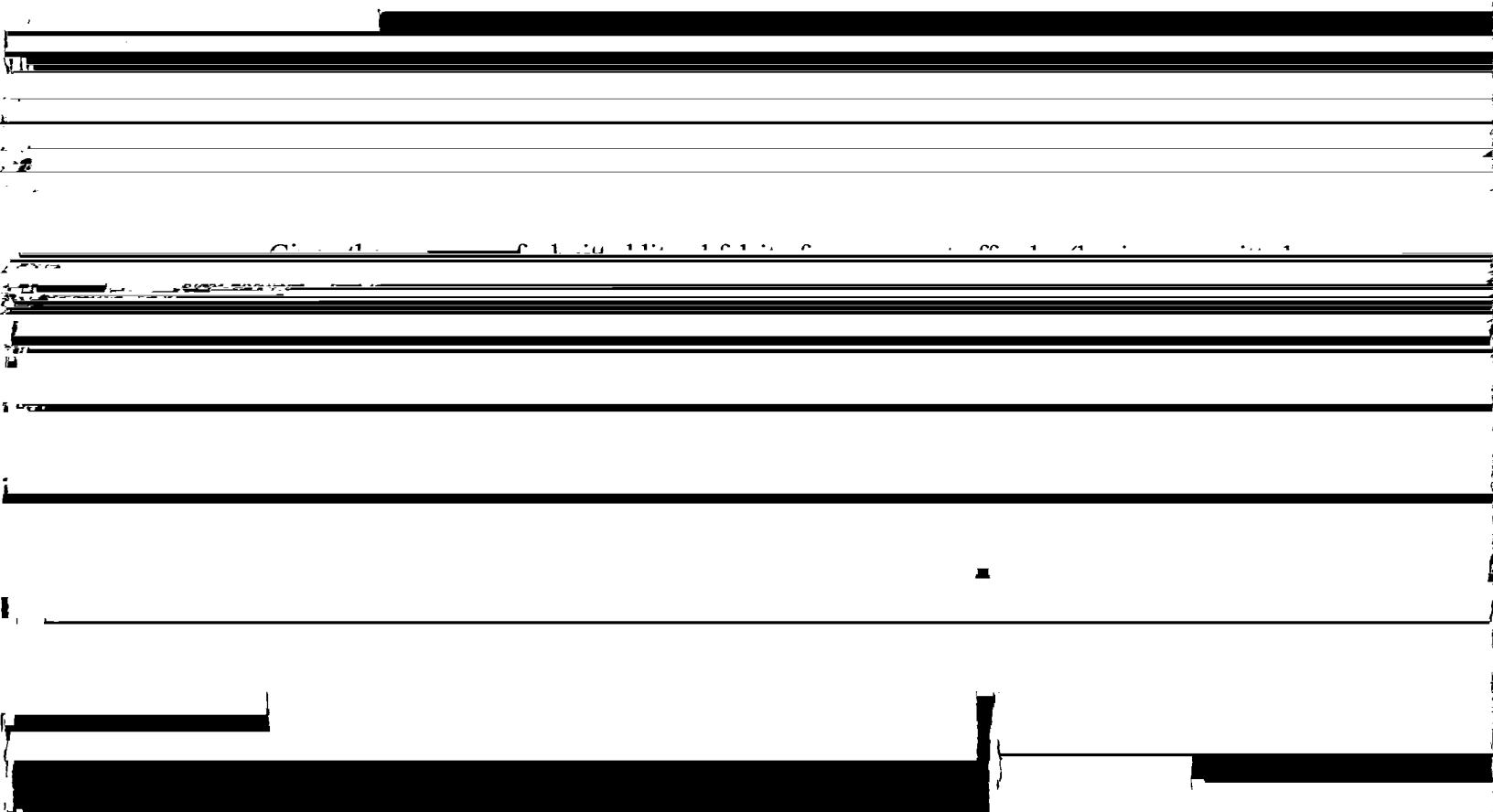
(1953) (The court recognized that when a statute is fairly susceptible to more than one interpretation, the interpretation most consistent with constitutionality should be adopted);

Crowell v. Benson, 285 U.S. 22, 62, 76 L. Ed. 598, 52 S. Ct. 285 (1932) (The court determined whether a constitutional construction of the ordinance is possible in order to avoid a question of

unconstitutional construction). In this case, 1941, 41 Cal. 2d 111, 257 P.2d 611, 15 A.L.R.2d 1001.

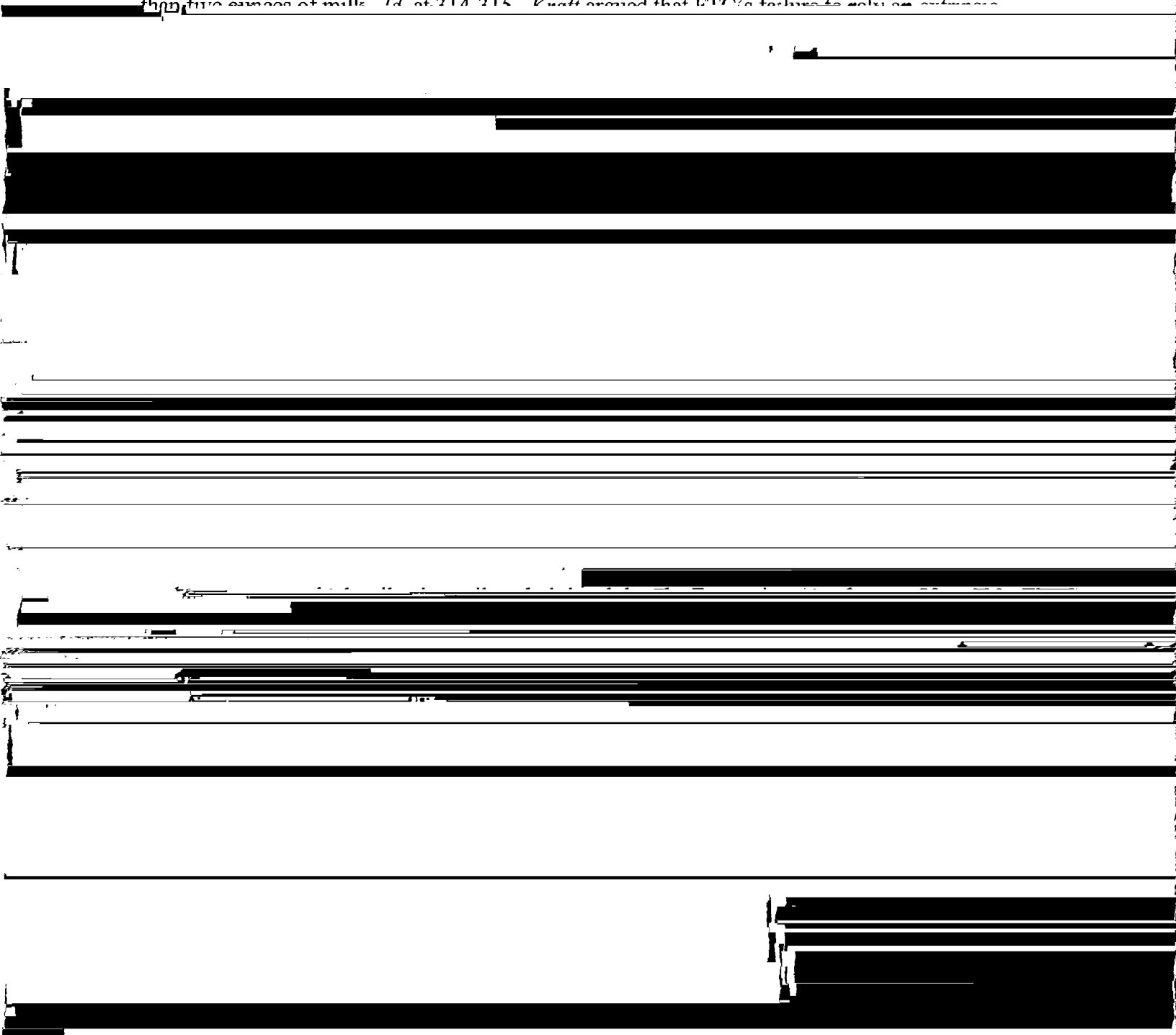


particular advertising claims before” the Court which were “wholly commercial in nature” containing “no material or comments having any relation directly or indirectly to any non-commercial First Amendment interests.” *Id.* at 399. The Court expressly limited its analysis “to advertisements of this nature” *Id.*



“flagrant violations of the Act repeated over a four year period, *id.* at 399-400), the Court found no justification for restricting the fencing in order and found no basis to permit a First Amendment challenge. *Id.* at 398-400. Here, by contrast, there is no claim of literal falsity; no admission of guilt; and speech that is imbued with and supported by a wealth of science. The

In *Kraft*, that company advertised that its imitation cheese singles had “five ounces [of milk] per slice” and equated the calcium in five ounces of milk with that in its imitation cheese single when cheese processing actually caused the imitation singles to have 30% less calcium than five ounces of milk. *Id.* at 214-215. *Kraft* argued that FTC’s failure to solve an intrinsic



juxtaposition of various phrases in the document, the nature of the claim and the nature of the transaction. *In re American Home Products*, 98 FTC 136, 374 (1981) aff'd 695 F2d. 681 (3d

Cir. 1982); *In re Women's Journal Co.*, 86 FTC 1208, 1480-00 (1975), aff'd 563 F.2d 1749

(D.C.Cir. 1977); cert. denied, 435 US 950 (1978); *In re Firestone Tire & Rubber Co.*, 81 FTC

398, 456 (1972) aff'd 481 F 2d 246 (6th Cir.) cert. denied 414 U.S. 1112 (1973). Under its own

precedent, FTC must establish the existence of an objective product claim i.e., one, that can be proven true or false. *In re Thompson Medical Center*, 104 FTC 648 (1984); *In re Removatron*. FTC precedent on implied claims acknowledges a significant limitation: when an implied claim is not obvious, extrinsic evidence is required. *In re Telebrands Corp.*, Docket No. 9313, Opinion of the Commission at 8 (Sept. 19, 2005)(unpublished opinion) (citing *Novartis Corp.*, 127 FTC 580, 680 (1999), aff'd 223 F.3d 783 (D.C.Cir. 2000)). Moreover, implied claims cannot be

descriptive if they contain contrary elements that effectively

timelines, 30 days or 19 days for when consumers can expect to see their results (or even 10

Empirical Evidence Contradicts FTC. There is empirical evidence directly contradicting the FTC's claimed deception. That evidence reveals consumers to be highly skeptical of weight loss

Exposure to Unrealistic Promises about Dieting: Are Unrealistic Expectations about Dieting Inspirational? *Int J Eat Disord* 2005; 37:142-149, RX 828, RX055. (RX-416, Dermalin APg Information Communication Study); see also Andrews JC, Netemeyer RG, Burton S. *Consumer*

Generalization of Nutrient Content Claims in Advertising. *Journal of Marketing* 62:62-75, Oct 1998.⁷² For decades the marketplace has been inundated with information from the FTC and the private sector, challenging the ability of any non-drug means for achieving weight loss. *See*

(D.C.Cir. 1999) (rejecting the Government's argument that consumers could not exercise judgment at the point of sale, stating: "It would be as if the consumers were asked to buy something while hypnotized and therefore they are bound to be misled. We think this

contention almost frivolous")(citing *Peel v. Attorney Registration and Disciplinary Comm'n of Illinois*, 496 U.S. 91, 105 (1990)(rejecting paternalistic assumption)); see also *Bates v. State Bar of Arizona*, 433 U.S. 350, 375 (1977)("We view as dubious any justification that is based on the benefits of public ignorance."); cf. *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503 (1996)(opinion of Stevens, J., Kennedy, J., and Ginsburg, J.)("The First Amendment directs us to be especially skeptical of regulations [of indisputably non-misleading information] that seek to keep people in the dark for what the government perceives to be their own good").

Further, when an advertisement is targeted to a specific audience, the Commission must

DL 4-1-78 11 576.F.2d 304 301 (D.D.C. 1992) v. D. C. 110 1100

542 F.2d 611, 617 (3rd Cir. 1976) cert. denied 430 U.S. 983 (1977); *Murray Space Shoe Corp. v. FTC*, 304 F.2d 270, 272 (2d Cir. 1962)). That standard contrasts sharply with the cursory analyses offered by FTC witnesses Drs. Mazis and Nunberg. Both weigh and analyze words selectively, in a hypothetical construct never tested in the real world, outside of the context of the entirety of the advertisements (in which they do not appear but are implied).

In contrast to the FTC policy of evaluating advertising as a whole and claims in context, FTC's witness Mazis gleans certain statements from the ads in his expert report, making no reference to their context and uses them to find implied claims and deceptive advertising. *FTC v.*

Moreover, this is not a case of fine print or *pro forma* disclaimers. This is not a case where consumers would not take the time or care to read the “fine print disclaimer.” *Cf. In re Giant Food, Inc.*, 61 FTC 326, 348 (1962). Nor is this a case where repetitive and all too familiar disclaimer language is proffered as curative of deceptive claims. *Warner Lambert*, 86 FTC 1398, 1414 (1975) *aff’d* 562 F.2d 749 (D.C.Cir. 1977). In bold and large print is the statement in the Dermalin, Cutting Gel, and Tummy Flattening Gel advertisements, “So What’s the Catch?” Immediately after that consumers are told: that they need to exercise while using the gels so that the fat that is released is not redeposited and that consumers can’t rub the gel all over their bodies at the same time because it would not be effective. CX-001 at 7. *See also* Trottier, K, Polivy, J, Herman, P. Effects of Exposure to Unrealistic Promises about Dieting: Are Unrealistic Expectations about Dieting Inspirational? *Int J Eat Disord* 2005; 37:142-149.

The Commission’s ponderings of *Porter & Dietsch*, 90 FTC 770, 864-865 (1977) *aff’d* 605 F.2d 294 (7th Cir. 1979) *cert. denied* 445 US 950 (1980) are outdated in this marketplace 20 years later where years of FTC awareness efforts and inundation with weight loss product advertising has left the reasonable consumer skeptical and unimpressed with weight loss advertising claims. Moreover, any analysis of the disclaimers present in Respondents advertising must be evaluated under the recent Supreme Court precedent recognizing the importance of disclaimers in commercial speech for curing potential misleading speech. *See also, Pearson v. Shalala*, 164 F.3d at 567; *Bates v. State Bar of Arizona*, 433 U.S. 350, 376 (1977); *see also Peel v. Att’y Registration and Disciplinary Comm’n*, 496 U.S. 91, 110 (1990), *In re R.M.J.*, 455 U.S.191, 206 n.20 (1982); *Shapiro v. Kentucky Bar Ass’n*, 486 U.S. 466, 478 (1988). FTC’s prior history of largely ignoring disclaimers or minimizing their effectiveness is based on case law pre-dating the current position of the Supreme Court and is based on conjecture rather than

actual study of consumers views of disclaimers. The most recent decisions of the Supreme Court

on commercial speech make it clear that if the "Government can achieve its interest in a manner

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

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[REDACTED]

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decision. While FTC ordinarily presumes without evidence that the presence of a money back guarantee makes no difference to consumers in purchasing decisions, in this case Respondents have produced a mall study showing exactly the opposite. RX-416.⁷³ Moreover, the money back guarantee makes the injury reasonably avoidable so consumers can recoup their cost for a product that does not perform as expected. Section 5(n). Respondents' records show that, in fact numerous consumers for whatever reason sought a refund under that guarantee and received

the act caused unjustified consumer injury. Unjustified consumer injury is a three part test: (1)

actually are based on the scientific evidence.

Respondents Had a Reasonable Basis for the Allegedly Implied Claims. Section 5 requires a manufacturer to have a ‘reasonable basis’ for any affirmative performance claims for a product. *Pfizer, Inc.*, 82 FTC 23, 62 (1972); *see also PharmTech*, 576 F.Supp. at 302 (citations omitted). Without a reasonable basis⁷⁴ the advertising is unfair. *Id.* In *Pfizer* the FTC found that the tests that form the reasonable basis for an advertiser’s performance claims must have been conducted prior to, and actually relied upon in connection with, the marketing of the product in question. 81 FTC 23 (1972). That “prior substantiation doctrine” has not been applied to exclude exculpatory evidence that confirms pre-claim evidence to be true. That doctrine also predates the commercial speech precedent that is controlling law now. *See Central Hudson*, 447 U.S. 557 (1984)(12 years after *Pfizer*); *see also, In re R.M.J.*, 455 U.S. 191, *Bolger v. Youngs*

In contrast to the commercial speech precedent above, the Commission states that it limits its consideration of post-claim substantiation to the following circumstances: (1) to determine whether a public interest exists in proceeding against the advertiser; (2) to assess the adequacy of the pre-claim substantiation that the advertiser had; and (3) to determine the appropriate scope of an order to be entered against a firm lacking adequate substantiation.

Substantiation Policy Statement, BY 005 at 2. FTC states in its policy statement in direct

contrast to the position the Chief ALJ has proof confirming the adequacy of pre-claim

substantiation is substantiated and confirmed. FTC states in its policy statement in direct

37:142-149.⁷⁶ For decades the marketplace has been saturated both from the FTC and the private sector with information challenging the ability of any non-drug means for achieving weight loss. See United States, Mexico, Canada (MUCH) Combat Weight Loss Fraud;

<http://www.ftc.gov/opa/2005/10/much.htm> October 24, 2005. The information is contained in the

the Commission's presumption that consumers expect dietary supplements for weight loss to work, and that consumers expect dietary supplements, for weight loss to work to a degree that

the Commission claims has been promoted and advertised here.

~~While the reasonable consumer is a skeptic the empirical data tells us the scientific~~

Respondents claims true to Dr. Heymsfield's satisfaction. No dietary supplement company

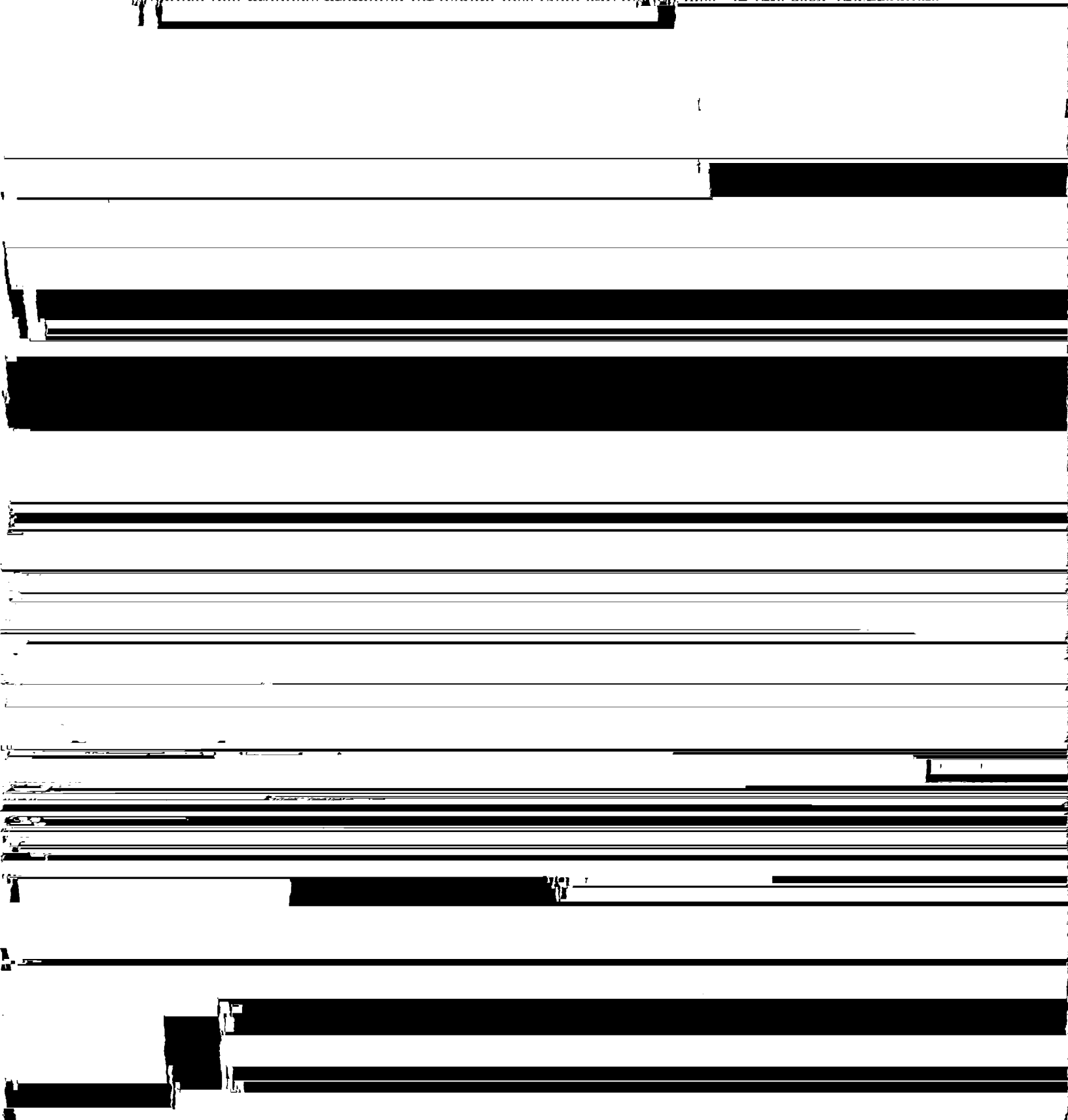
could afford that. Only pharmaceutical companies such as Dr. Heymsfield's employer, Merck,

can compete in such a marketplace. Not only did Respondents comb the literature that was

publicly available for the design of their products. 111

foolish or feeble-minded); *Heinz W. Kirchner*, 63 F.T.C. 1282, 1290 (1963).⁷⁸ As explained *supra*, the empirical evidence reveals the audience for weight loss advertising to be highly

apt that products promoted for weight loss yield any weight loss. In this case, the products



In every case brought by the FTC against an advertiser of weight-loss products pursuant to Sections 5 and 12 of the FTCA, the Commission and the Chief Administrative Law Judge, in the advent of *Sterling Drug v. FTC*, hold that an advertiser deemed to have advertised without “competent and reliable scientific evidence” has violated Section 5 and 12 of the FTCA. See *Sterling Drug, Inc. v. FTC*, 741 F.2d 1146, 741 F.2d 1146; 1984 U.S. App. LEXIS 19141 (9th Cir. 1984); *Jerome Milton, Inc. v. FTC*, 734 F. Supp. 1416 734 F. Supp. 1416; 1990 U.S. Dist. LEXIS 2736 (N.D. Il. 1990); *Bristol-Myers Co. v. FTC*, 102 F.T.C. 21, 321, affd, 738 F.2d 554 (2d Cir. 1984), cert. denied, 469 U.S. 1189, 105 S. Ct. 960, 83 L. Ed. 2d 966 (1985); *In re Pfizer*

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comply with the guides may result in corrective action by the commission under applicable statutory provisions”).

All rules of general applicability wrought by administrative agencies cannot – consistent with the APA, 5 U.S.C.S. § 553(b) – be applied unless and until they have been adopted following notice to the public in the Federal Register of the agency’s intent to adopt the rule and opportunity for comment. For a rule to be considered valid, an agency must provide notice in the Federal Register of its intentions to create such a rule and an opportunity for interested parties to comment on it. *See e.g., U.S. v. Seward*, 1981 U.S. App. LEXIS 21300 (10th Cir. 1981)(citations omitted).

There is nothing unique about weight loss and fat loss claims among that category of products. FDA has defined claims for low calorie, high vitamin C, and low tar in rule-making; there is nothing preventing FTC from defining in rule-making the substantiation necessary for specific weight loss claims. The statutory language in section 12 of the FTCA is

~~It shall be unlawful for any person, partnership, or corporation to disseminate or cause to~~

be disseminated, any false advertisement...

False advertisement is defined in Section 15 as

an advertisement, other than labeling, which is misleading in a material respect; and in determining whether any advertisement is misleading, there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound or any combinations thereof, but also the extent to which the advertisement fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the commodity to which

standard for substantiation that does not appear in the FTCA or in rulemaking, a standard that is, in reality, impossible to pin down – so inexact as to evade the grasp of a reasonable mind.

The APA states, in pertinent part, that prior to the issuance of a substantive rule,⁸⁰ an agency such as FTC shall provide notice of its rulemaking intentions, and such notice shall be published in the Federal Register. 5 U.S.C. § 553.⁸¹ The APA also requires an opportunity for public participation in the rulemaking process and publication of the final rule, including a concise statement of its basis and purpose, thirty days before its effective date. 5 U.S.C. 553(d)

(d); see also: *North American Coal Corporation v. Director, Office of Workers' Compensation Programs*, 854 F.2d 386, 388 (10th Cir. 1988).

The Commission's competent and reliable scientific evidence standard is a substantive rule. It establishes a standard of conduct that has the force of law. It is a separate obligation owed by the regulated class. In addition to conveying messages that are truthful and non-

Respondents of what is required. Respondents have asked repeatedly for an advisory opinion and have been informed that the FTC will not provide it. That failure to provide any means to elucidate the meaning of the standard in any particular case violates the APA. It reveals the standard to be wholly subjective, subject to whim and caprice, to unbridled discretion. something

forbidden of speech regulators. *Lakewood v. Plain Dealer Publishing Co.*, 486 U.S. 750, 769-772 (1988) (4-to-3 decision); *Heffron v. International Society for Krishna Consciousness, Inc.*, *supra*, at 649; *Freedman v. Maryland*, 380 U.S. 51, 56 (1965); *Thornhill v. Alabama*, 310 U.S. 88, 97 (1940). The APA compels the FTC to make clear its standard either through rulemaking or on a case by case basis. The FTC has violated every part of the APA governing adoption of rules or decisions by imposing an undefined rule on the regulated class, and on Respondents in this proceeding, without even attempting to satisfy the APA requirements in any respect.

For the foregoing reasons, the Chief Administrative Law Judge may not rely upon the “competent and reliable scientific evidence” standard in this case and may not include it in any ultimate order without violating the law. The relief requested by FTC Counsel is barred by operation of law and the APA.

D. THE “COMPETENT AND RELIABLE SCIENTIFIC EVIDENCE” STANDARD VIOLATES THE FIFTH AMENDMENT: IT IS VOID FOR VAGUENESS

The commercial speech here in issue is, at worst, potentially misleading. As explained above, potentially misleading commercial speech is protected under the First Amendment to the United States Constitution. *See Central Hudson Gas & Electric Corp. v. Public Serv. Comm’n.*, 447 U.S. 557; 100 S. Ct. 2343; 65 L. Ed. 2d 341 (1980); *Pearson v. Shalala*, 334 U.S. App. D.C.

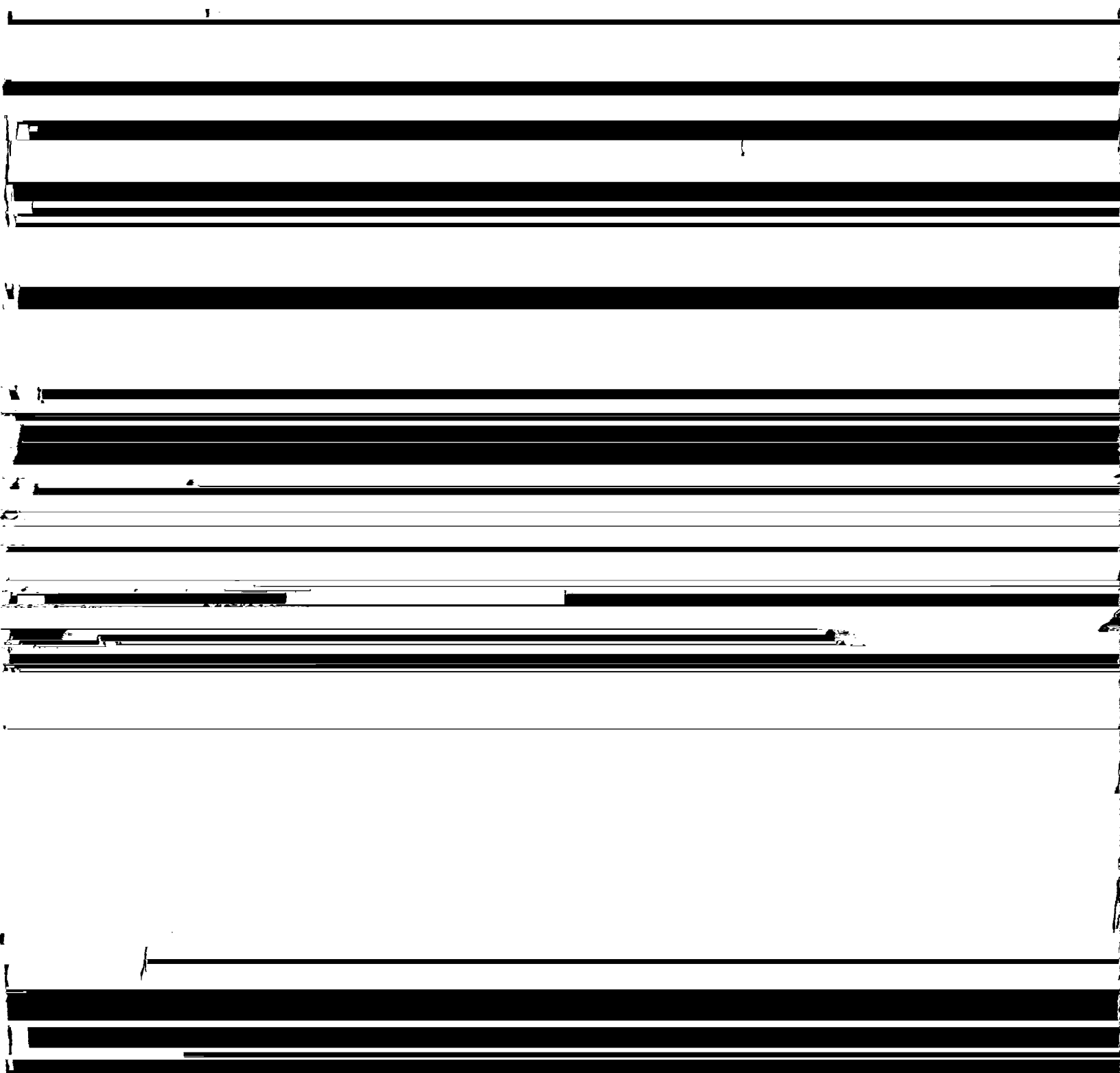
71, 164 F.3d 650; 1999 U.S. App. LEXIS 464 (1999).⁸² The right to advertise is a liberty right under the Fifth Amendment to the United States Constitution. *See Thompson Medical Company, Inc., v. FTC*, 791 F.2d 189 (D.C. Cir. 1986) (after stating the Court's preference for FTC orders that are "unequivocally legal," the D.C. Circuit expressly noted that the FTC's use of vague standards to regulate commercial speech are repeatedly "attacked on vagueness grounds" and often force the FTC to go through a lengthy and uncertain appellate process [...]"). *Id.* at 195-96.

Under the Fifth Amendment, the right to liberty cannot be deprived without due process

of law. *See* U.S. Const. Amend. V. A decision from the Chief Administrative Law Judge that has the effect of depriving Respondents of their liberty right to communicate future protected speech issue free from fear of prosecution under a vague standard thus constitutes a deprivation of a liberty right. It chills protected speech; through vagueness it sweeps within the ambit of [deception speech that is constitutionally protected. "It is established that a law fails to meet the

that if a statute is unconstitutionally vague, issuance of a warning or notice of a violation does not cure that vagueness. *City of Chicago v. Morales*, 527 U.S. 41, 56 (1999):

If the [conduct sought to be restricted] is in fact harmless and innocent, the dispersal order itself is an unjustified impairment of liberty...Because an officer may issue an order only after prohibited conduct has already occurred, it cannot provide the kind of advance notice that will protect the putative loiterer from being ordered to disperse. Such



476, 481-482, 115 S. Ct. 1585, 1589, 131 L. Ed. 2d 532 (1995) (quoting *Virginia Bd. of Pharm.*
v. Va. Citizens Consumer Council, Inc., 425 U.S. 748, 763, 96 S. Ct. 1817, 1826, 48 L. Ed. 2d

246 [10767]). *United States v. Blumberg, Entek Corp., Inc.*, 520 U.S. 902, 912, 120 S. Ct. 1979

to which they are entitled if their First and Fifth Amendment rights are to be protected.

Under the Fifth Amendment, when a liberty right is in issue, due process requires at a

minimum that any standard applied to assess the conviction of a defendant must be

assumption that it does, never knowing for sure what FTC will or will not regard as permitted speech under the FTCA.

Time and time again Respondents have been denied their due process rights associated

determine the substantiation necessary for their advertising and were left nearly clueless - with

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evidence under the APA. 5 U.S.C. § 706; see also *Ingalls Shipbuilding, Inc. v. Director, Office of Workers' Comp. Programs*, 991 F.2d 163, 165 (5th Cir. 1993); quoting *NLRB v. Columbian*

~~_____~~

E. THE "COMPETENT AND RELIABLE SCIENTIFIC EVIDENCE" STANDARD VIOLATES THE APA: IT FAILS TO GIVE THE REGULATED CLASS

~~_____~~

~~_____~~
APPLICATION OF IT RESULTS IN ARBITRARY AND CAPRICIOUS
~~_____~~

(1999) (quoting *Giacco v. Pennsylvania*, 382 U.S. 399, 402-403 (1966)). Under the APA, agency rules are “unlawful,” and hence void, if they are “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 7-6(2)(A). Whether an agency acted in an arbitrary and capricious manner is determined by whether the agency’s decision was based on a

consideration of the relevant factors and whether it has made a clear error of judgment. *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). An agency decision will be

[REDACTED]

Illinois v. Board of Directors of the Fed. Reserve Sys., 371 U.S. 175 (1962), *cert. den.*

[REDACTED]

[REDACTED]

To the extent that the competent and reliable scientific evidence standard is considered an interpretation by FTC of the FTCA, it is entitled to no deference because it is unconstitutional.⁸⁵

Here, the definition given for "competent and reliable scientific evidence" is not

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

reasonable certainty what level, degree, quality or quantity of scientific evidence will satisfy the

Federal Trade Commission Act. See *Village v. Hoffman Estates, Inc.*, 455 U.S. 489, 499 (1982);
Cohen v. California, 403 U.S. 15 (1971) (“We cannot indulge the facile assumption that one

process. Indeed, government might soon seize upon the censorship of particular words as a
convenient guise for banning the expression of unpopular views. We have been able [to] discern

In this case, Defendants possessed substantial scientific evidence that aminocaprolic

was an effective localized fat reducing agent, as explained above. See Daniel B. Mowrey's

Expert Report (DX-928). They also knew that the real therapeutic use of the Compound was to reduce

Civ. P. 26. Rule 26(b)(1).⁸⁸ Section 556(d) of the Administrative Procedure Act governs cross examination in administrative hearings. *Central Freight Lines, Inc. v. United States*, 669 F.2d

1062, 1068 (1982); 5 U.S.C. 556(d). That subsection states:

Except as otherwise provided by statute, the proponent of a rule or order has the burden

United States, 304 U.S. 1, 18 (1938)). “Implicit in this concept [of a right to a hearing] is the ‘traditional right of confrontation and cross-examination’ in furtherance of fundamental

Smith v. Maryland, 449 U.S. 161, 174 (1980) (“[I]n *Smith*”

304 U.S. 1, 18 (1938) (“[I]n *Smith*”

Law Judge and, then, ultimately the Commission will say whether the standard is satisfied but in

Administrative Code, Section 24.1, Administrative Code, Section 24.1, Administrative Code, Section 24.1

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

The Chief Administrative Law Judge has denied Respondents the right to present eight

expert rebuttal witnesses. Those witnesses were identified at the time set, post-case stay, for witness identification. See Respondents' Revised Witness List submitted November 8, 2005. Nevertheless, with fully four and a half months to go before the trial, the Chief Administrative Law Judge determined that allowance of the witnesses would violate the procedural rules and

to make such a determination. Moreover, the Complaint in this action did not give Respondents fair notice of the charges against them.

Section 5(b) of the FTCA requires that the Commission make a determination that there is a reason to believe that unfair or deceptive acts or practices have occurred. 15 U.S.C. §45(b). Without that check the prosecutorial discretion of the agency is unlimited. There would be no check or balance against the enforcement arm of the FTC in prosecuting advertisers where the

Without the Commission satisfying the reasonable belief requirement of the FTCA the

~~potential abuse of the FTCA for political purposes is not. The FTCA has and remains~~

investigative and enforcement power against any party that advertises in interstate commerce in the United States. Those parties are not without rights under the FTCA, the APA, and the Constitution. Without a check to that power before an enforcement action is begun, companies

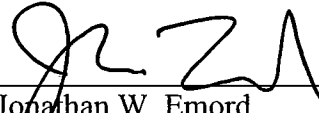
~~that are disfavored by the political climate could be subject to baseless prosecutions. The check-~~

course of the defense of their rights before the agency. The Chief ALJ has ruled that the

claims not included in the Complaint and for advertising not attached to it. See Order dated July 20, 2004 at 3. Respondents thus completely lack fair notice of the allegations against them and are not afforded an adequate basis for mounting their defense.

In this case, there is no evidence that the Commission has satisfied the FTCA's requirement that it make a reasonable belief determination. There is no definition for the terms against which that determination would be made rendering that determination impossible. Moreover, the Complaint is so vague and has been ruled to be merely a framework upon which

Respectfully submitted,



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Date: February 17, 2006

**UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES
WASHINGTON, D.C.**

In the Matter of

**BASIC RESEARCH, LLC
A.C. WATERHOUSE, LLC**

**KLEIN-BECKER USA, LLC
NUTRASPORT, LLC**

**BAN LLC d/b/a BASIC RESEARCH LLC
OLD BASIC RESEARCH, LLC**

The Hon. Stephen J. McGuire

Chief of Administrative Law Judge

U.S. Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Room H-112
Washington, D.C. 20580

2) one paper copy by first class U.S. Mail to:

James Kohm
Associate Director, Enforcement
U.S. Federal Trade Commission
601 New Jersey Avenue, N.W.
Washington, D.C. 20001

3) one paper copy by first class U.S. mail and one electronic copy in PDF format
by electronic mail to:

Laureen Kapin

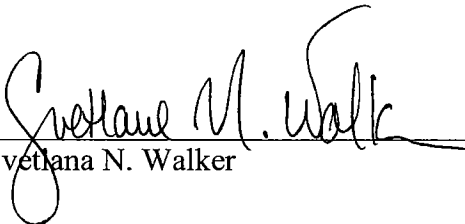
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In the Matter of

BASIC RESEARCH, LLC
A.G. WATERHOUSE, LLC
KLEIN-BECKER USA, LLC
NUTRASPORT, LLC
SOVAGE DERMALOGIC LABORATORIES, LLC
BAN LLC d/b/a BASIC RESEARCH LLC
OLD BASIC RESEARCH, LLC

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