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Obligatory disclaimer: This is a statement of a problem. I'm not sure what I think about it yet, and I'm still kicking the tires of most of the arguments. I reserve the right to change my mind at any point.

## I. *Central Hudson*'s Other Problem

[The basic problem: For years, courts and commentators have assailed the Supreme Court's commercial speech jurisprudence as incoherent at best and anathema at worst. The controversy, however, has focused on the test for regulating truthful, nonmisleading commercial speech. There has been much less attention to false and misleading speech, and less still to the way that the two types of speech may constitutionally be distinguished. Discussions have often been sidetracked into how to formulate a disclaimer that would cure any misleading implications, as a less restrictive alternative to banning the speech at issue entirely. As the arguments in *Nike v. Kasky* show, the current version of false advertising law is incompatible with the current First Amendment. And now that advertising law has been recognized by the Supreme Court as problematic, the pressure to work the law pure through application of the First Amendment may be irresistible. The question is, then, what a purified advertising law would look like. The FDA, attempting to respond to recent court cases, has generated an extensive body of commentary on acceptable ways to determine truth; its well-established regulatory apparatus, full of experts on the relevant, limited field, may nonetheless have difficulty surviving the new First Amendment. While the FDA's mandate is limited, private lawsuits by competitors and consumers can cover any factual claim at all, generating even more disputes than drugs and supplements do, making it even more vulnerable to First Amendment challenges.]

False advertising law encompasses both private actions and direct government regulation; here I will mainly consider private actions by competitors under the federal Lanham Act, private actions by consumers under state law, and regulation by the Food and Drug Administration, which dictates what some of the world's biggest corporations can say to the public about matters of life and death. The appropriate First Amendment analysis of such laws would appear to come from the law of commercial speech, but, even assuming that law were coherent, the *Central Hudson* test for evaluating restrictions on commercial speech presupposes that the speech at issue is *truthful*. On the threshold issue of how one determines truth for constitutional purposes, the Supreme Court has been all but silent,[1] and the academic literature generally little better.[2]

In recent years, the Court of Appeals for the D.C. Circuit has joined the issue, aggressively striking down FDA regulations on First Amendment grounds related to the FDA's high standards for acceptable truth, and in 2002 the Supreme Court, in *Thompson v. Western States Medical Center*, invalidated a law prohibiting pharmacists from

[1] The Supreme Court has done the most work distinguishing truth from falsehood and misleading statements in the lawyer regulation cases. [Cites] The Court is probably more qualified to assess deceptiveness in legal services than in most other fields it is likely to encounter.

[2] But see Bevier.

advertising that they could compound drugs, creating individually tailored formulations, when compounding itself was legal. In response to the Supreme Court case, the FDA propounded a stunningly far-ranging series of questions for comment on the proper scope of its regulations. No longer is the FDA taking for granted that it can prohibit drug companies from claiming that their drugs work unless the FDA agrees with their interpretations of the evidence; in fact, the burden may be on the FDA to prove that health and efficacy claims are wrong before it can act. The numerous responses to the FDA's request for comments suggest that whatever consensus existed on regulation of drug claims may be breaking down, possibly because of growing competition from dietary supplements and so-called natural remedies.

Unfortunately for those hoping for some further guidance, the Supreme Court recently dismissed as improvidently granted *Nike v. Kasky*, a case in which a concerned citizen of California (or officious interloper, depending on how one sees Marc Kasky) sued Nike for allegedly making false statements about its contractors' labor practices in a variety of contexts, including letters to college presidents, press releases, and advertorials. Nike claimed that the complaint should have been dismissed because it was engaging in protected speech about matters of intense public interest. As with the fallout from *Thompson*, the volume of submissions to the Court, as well as their content, is evidence that false advertising law is extremely vulnerable to challenge under current First Amendment jurisprudence. The Court dismissed certiorari as improvidently granted because of concerns about the finality of the judgment, the standing of the parties, and the lack of clarity of the facts at this stage of the litigation, which had not progressed past a motion to dismiss. An examination of the many contested aspects of the case -- the facts that needed finding – shows just how uncomfortably the law fits within traditional First Amendment jurisprudence.

The danger in deciding *Nike* in Nike's favor, as it almost surely would have been, was that there were no convincing rationales that let Nike freely claim that its labor practices were sound without imperiling an enormous part of the modern regulatory state. The Court could have simply drawn a line: California's law goes too far by allowing Kasky to sue, but the traditional practices of the FDA, the SEC, and the FTC are fine. That this line would be illogical and unjustified is no practical barrier to drawing it.[3] One problem with this response is that the First Amendment is quite charismatic; once First Amendment analysis is applied instead of rejected, some regulations are going to fail a court's scrutiny. In other words, law is full of contradictions that somehow remain stable, but courts tend to want to work the law in any particular field pure, and Nike's success in defining the relevant field as First Amendment law risked destabilizing all regulation of the truth of commercial claims.[4]

## II. The FDA: "Who is to decide when doctors disagree?"[5]

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[3] *See* Eldred v. Ashcroft.

[4] Harry Kalven "celebrated the evolution of First Amendment doctrine over the course of the twentieth century as an example of the law working itself pure." OWEN M. FISS, THE IRONY OF FREE SPEECH 6 (1996) (citing Kalven's A Worthy Tradition). On the drive to work the law pure: Frank, J., concurring in Granz v. Harris, 198 F.2d 585 (2d Cir. 1952).

[5] P.T. Barnum adapted Alexander Pope's "Who shall decide when doctors disagree?" as part of his defense of the Fejee mermaid, one of his more notorious hoaxes. *See* PHILIP J. HILTS, PROTECTING AMERICA'S HEALTH: THE FDA, BUSINESS, AND ONE HUNDRED YEARS OF REGULATION 282 (2003)

The FDA oversees about $1 trillion worth of products each year, nearly a quarter of the American economy.[6] It is the most popular regulatory agency, routinely achieving seventy-five percent public approval since the 1970s, more popular than Presidents Reagan and George H.W. Bush.[7] Furthermore, the public expects and trusts that the FDA is looking out for its health. Studies show that Americans generally believe that the pills and medicines they can buy have been tested for safety and approved by the FDA, even when that is not the case, as with vitamins and herbal supplements.[8]

[*Western States*; *Washington Legal Fund v. Friedman*]

In *Pearson v. Shalala*, the DC Circuit invalidated the FDA's regulations for dietary supplement claims, particularly the requirement of "significant scientific agreement" before supplements were allowed to make health claims. The FDA was required to allow claims in most circumstances as long as the claims included a disclaimer. Then, after *Western States*, the FDA issued an expansive and perhaps alarming request for comments on First Amendment issues, covering essentially the FDA's entire jurisdiction:

> 1. Are there arguments for regulating speech about drugs more comprehensively than, for example, about dietary supplements? What must an administrative record contain to sustain such a position? In particular, could FDA sustain a position that certain promotional speech about drugs is inherently misleading, unless it complies with FDA requirements? ….
> 2. Is FDA's current position regarding direct-to-consumer and other advertisements consistent with empirical research on the effects of those advertisements, as well as with relevant legal authority? ….
> ….
> 6. What arguments or social science evidence, if any, can be used to support distinguishing between claims made in advertisements and those made on labels? Does the First Amendment and the relevant social science evidence afford the Government greater latitude over labels?
> 7. Would permitting speech by manufacturer, distributor, and marketer about off-label uses undermine the act's requirement that new uses must be approved by the FDA? If so, how? If not, why not? What is the extent of FDA's ability to regulate speech concerning off-label uses?
> 8. Do FDA's speech-related regulations advance the public health concerns they are designed to address? Are there other alternative approaches that FDA could pursue to accomplish those objectives with fewer restrictions on speech?

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[6] *See* HILTS, *supra* note --, at xiv.
[7] *See id.* at 295 (noting that the first President Bush was, during the first Gulf War, briefly more popular than the FDA).
[8] *See id.* at 290.

9. Are there any regulations, guidance, policies, and practices FDA should change, in light of governing First Amendment authority?[9]

The scope of the request can be explained in part by the ideological commitments of the FDA's current general counsel, Daniel Troy, who in private practice represented pharmaceutical and tobacco companies challenging, on First Amendment grounds, the FDA's right to regulate their offerings.[10]

This sequence of events is evidence of the corrosive power of the First Amendment in action. Though the scope of the request for comments reflects the current administration's attitude towards government regulation of business, it is also ruthlessly logical. If the FDA can't prohibit dietary supplement claims or advertising of compounded drugs, why can it prohibit drug companies from stating that a study showed that a drug was effective against breast cancer, regardless of whether the drug was approved for breast cancer? Conversely, if the FDA can't prohibit drug companies from advertising "off-label," unapproved uses for approved drugs, why does it have the power to regulate claims of safety and efficacy in the first place?[11]

The goal of the reformers is clear: to cut back FDA regulatory power so that it is limited to addressing proven frauds[12] – not, notably, to avoid falsity, which is a broader category, or to keep claims off the market in the first place. The First Amendment arguments correspond with a resurgence of substantive due process claims that also attempt to limit the FDA's ability to restrain the pharmaceutical trade.[13] The assault on the FDA's authority is one of the starkest examples of the use of the First Amendment to prevent economic regulations.

## III. *Nike v. Kasky*: The Marketplace of Ideas and the Market for Shoes

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[9] 67 Fed. Reg. 34942-44 (May 16, 2002). Press coverage noted the extremely broad scope of the requests. *See, e.g.*, Chris Adams, *Looser Lips for Food and Drug Companies? Industries Pressure FDA To Relax Rules on Commercial Speech*, Sept. 17, 2002, at A4; William Castagnoli, *Rx Marketing Regulations Hang on First Amendment Debate*, MEDICAL MARKETING & MEDIA, Sept. 1, 2002, at 86 (comparing potential for change in FDA regulations to *Brown v. Board of Education* and *Roe v. Wade*).

[10] *See* Stacey Schultz, *Mr. Outside Moves Inside*, U.S. NEWS & WORLD REPORT, Mar. 24, 2003, at 63. *But see* Castagnoli, *supra* note [] (suggesting that the FDA may be collecting comments merely to make a record to defend current practices).

[11] *See* Castagnoli, *supra* note [] ("[The FDA] fears, more than anything else, that if unapproved products can be promoted, or new uses of approved products can be promoted without FDA approval, its authority to review new data submitted in manufacturer applications will be undermined.").

[12] *See, e.g., Free Speech and the FDA*, WALL ST. J., Sept. 20, 2002, at A10 (arguing that FDA's First Amendment review should lead it to cut back substantially on regulation, which would not "impair the government's ability to prosecute actual cases of fraud"); Castagnoli, *supra* note [] (suggesting that best outcome of FDA review would be to let manufacturers make claims and prosecute "lies or partial truths … after the fact," based on rules governing "fraud and deception").

[13] The Washington Legal Foundation, for example, has filed suit arguing that the FDA's restrictions on experimental drugs violate the Fifth and Fourteenth Amendment liberty and privacy rights of terminally ill patients. *See Abigail Alliance for Better Access to Developmental Drugs v. McClellan*, No. [] (D.D.C., complaint filed July 28, 2003) (available at http://www.wlf.org/upload/Abigail%20Alliance%20complaint.pdf).

"[I]f we reach the merits, and if we have to address it, we're going to have to know what commercial speech is, I suppose."[14]

[Facts/allegations: Beginning in 1996, Nike was targeted by protesters claiming that it (actually, its subcontractors) underpaid and abused workers in developing countries. Nike launched a public relations counteroffensive, including letters to the editor, press releases, letters to college presidents who controlled lucrative athletic contracts, and so on. Nike's communications discussed general issues of globalization, suggesting that what looked exploitative from outside was welcomed by workers in developing areas, and also specifically defended the treatment of its subcontractors' workers. Marc Kasky believed that Nike was not telling the truth in those claims, so he sued, as California law allowed him to do.]

Nike and its amici made a number of powerful arguments that the application of the California false advertising law to its conduct would violate the First Amendment. Unfortunately, some of the most intuitively persuasive arguments provide no distinction between Kasky's claims and those of any other false advertising plaintiff, or the government regulating drug claims or securities filings.

The easiest defense to grasp is that the government lacks an interest in regulating statements about the conditions under which a product is manufactured, as opposed to product characteristics. Regardless of how ill-fed and ill-housed (or well-fed and well-housed) Nike's subcontractors' workers were, the shoes are the same, so the government interest in consumer protection should not extend to statements such as Nike's.

One could, of course, dispute the factual premise. Perhaps shoes made by distressed workers are more likely to be defective than shoes made by content workers. More significantly, this distinction is inconsistent with the basic premise of advertising regulation, which is that consumers should be able to fulfill their preferences, or have their preferences changed, and not be deceived. Giving the consumer a satisfactory product doesn't make up for deceiving her to close the sale, as the Supreme Court explained with reference to the link between trademark and general false advertising law:

> [T]he seller has used a misrepresentation to break down what he regards to be an annoying or irrational habit of the buying public – the preference for particular manufacturers or known brands regardless of a product's actual qualities, the prejudice against reprocessed goods, and the desire for verification of a product claim. In each case the seller reasons that when the habit is broken the buyer will be satisfied with the performance of the product he receives. Yet, a misrepresentation has been used to break the habit and … a misrepresentation for such an end is not permitted.[15]

Consumer protection is about more than consumer health, safety, or even pocketbooks. It includes the consumer's interest in getting what she paid for, whether that was cruelty-free beauty or low-calorie ice cream, whether or not her preferences are rational. Or, if that is not a sufficient government interest to suppress speech, we will have to get rid of rather a lot of regulation, including a healthy chunk of trademark law

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[14] Oral argument transcript at 57, *Nike, Inc. v. Kasky*, 123 S. Ct. 2554 (2003) (No. 02-575).
[15] Federal Trade Comm'n v. Colgate-Palmolive Co., 380 U.S. 374, 389 (1965).

(for goods of equivalent quality). Conditions of product production that make a difference to consumers include "Made in America,"[16] "EPA approved,"[17] "dolphin-safe tuna," "Union Made," "shade-grown coffee," and many others. The FTC regulates product endorsements by celebrities and other authorities, even though they often have no connection with product characteristics, because consumers think that endorsement matters. Courts will enjoin commercials that falsely claim that one soda beat another in a taste test, again no matter how tasty the soda is.

Getting rid of those cases might be satisfactory to believers in a strong, libertarian First Amendment. But for them, the product characteristics/conditions of production division makes even less sense. What is a product characteristic? Consumers are probably better suited to determining that than courts; if a consumer finds information relevant to her purchase decision, then there is no non-paternalistic reason not to respect her preferences. Ironically, the distinction proposed by Nike and some of its *amici*, while superficially attractive, is far more regulatory at heart than a blanket prohibition on misleading consumers, since it requires government to decide what consumers should legitimately care about.

Relatedly, Nike suggested that product characteristics are more readily verifiable by an advertiser than conditions of manufacture in our modern, subcontractor economy. This, too, cannot be the law. Some product characteristics are almost impossible to verify, such as the relative performance of one analgesic compared to another, a topic that generated decades of litigation among the competitors and the FTC.[18] Some conditions of manufacture are simple to verify.

Justice Breyer noted that the materials at issue in *Nike* appeared outside of a traditional advertising format, focusing on a letter sent to numerous college presidents. The letter was, as he pointed out, different from a newspaper or television ad. But then, it was directed to a much smaller audience than a newspaper or television show: people who controlled college athletic budgets. False advertising law has had no difficulty

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[16] Research suggests that this claim influences a substantial number of purchasers. See C. Min Han, *The Role of Consumer Patriotism in the Choice of Domestic Versus Foreign Products*, 28 J. ADVERTISING RES. 25 (1988).

[17] Performance Indust. Inc. v. Koos Inc., 18 U.SP.Q.2d 1767, 1771 (E.D. Pa. 1990) ("In today's environmentally conscious world, [false claims regarding EPA approval] are serious misrepresentations. Consumers these days seem to favor products that are environmentally benign and to disdain those that are environmentally harsh.").

[18] *See, e.g.*, Sterling Drug, Inc. v. Federal Trade Comm'n, 741 F.2d 1146 (9th Cir. 1984); American Home Prods. Corp. v. Federal Trade Comm'n, 695 F.2d 681 (3d Cir. 1982); In re Novartis Corp., No. 9279, 1999 WL 353248 (F.T.C. May 13, 1999), *aff'd*, 223 F.3d 783 (D.C. Cir. 2000); Am. Home Prods. Corp. v. Procter & Gamble Co., 871 F.Supp. 739, 761-62 (D.N.J.1994); American Home Prods. Corp. v. Johnson & Johnson, 654 F. Supp. 568 (S.D.N.Y. 1987); Upjohn Co. v. American Home Prods. Corp., 598 F. Supp. 550 (S.D.N.Y. 1984); American Home Prods. Corp. v. Abbott Labs., 522 F. Supp. 1035 (S.D.N.Y. 1981); McNeilab, Inc. v. American Home Prods. Corp., 501 F. Supp. 517 (S.D.N.Y. 1980); F.T.C. v. Sterling Drug, Inc., 215 F. Supp. 327 (S.D.N.Y. 1963). Litigation over the best treatment for heartburn has likewise produced an entire subfield of false advertising law. *See, e.g.*, Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharmaceuticals Co., 290 F.3d 578 (3d Cir. 2002); Johnson & Johnson-Merck Consumer Pharmaceuticals Co. v. Procter & Gamble Co., 285 F.Supp. 2d 389 (S.D.N.Y. 2003); Glaxo Warner-Lambert OTC G.P. v. Johnson & Johnson Merck Consumer Pharmaceuticals Co., 935 F.Supp. 327 (S.D.N.Y. 1996); SmithKline Beecham Consumer Healthcare, L.P. v. Johnson & Johnson-Merck Consumer Pharmaceuticals Co., 906 F.Supp. 178 (S.D.N.Y. 1995), *aff'd*, 100 F.3d 943 (2d Cir. 1996) (table).

finding similar letters to be commercial speech when they targeted small, specialized markets, and this makes perfect sense. Justice Breyer offers no reason to have a small-market exception to the law. Nor is Justice Breyer's general attention to format appropriate, especially in a world in which advertising can take any form we can conceive and probably some we can't.[19] The press releases that form part of the challenged materials in *Nike* are increasingly standard means of communicating directly with consumers, as companies know that material in their press releases will often be passed on without alteration by reporters, or even read directly by consumers.

[Other aspects of California false advertising law combined to make Kasky's claim especially weak. California law, like the federal Lanham Act and most state consumer protection laws, lacks any scienter requirement. Perfectly good-faith errors, if false, can lead to liability. In addition, California's standing requirement for consumer suits is minimal at best. Kasky had never bought a pair of Nike shoes, which does make his harm from Nike's alleged misstatements a bit hard to identify.]

The government's theory was an interesting one: It wasn't that there was anything (much) wrong with the substantive cause of action; the problem was that, under California law, any officious intermeddler could appoint herself a private attorney general and bring a false advertising action against a company, regardless of whether she herself had suffered any damage from the false advertising. The theory has some appeal, at least as an enhancer of the free speech risks of the cause of action; as a practical matter, we can expect more litigation, and thus more of a speech-deterrent effect, when anyone with a grudge and a willingness to risk the expense can litigate rather than forcing the government, with its always limited resources, to pick and choose what advertising to assail. But, as the Court pointed out at oral argument, by First Amendment logic a cause of action unsound in private hands is at least equally so in government hands. The Solicitor General suggested that the government was more to be trusted -- "I'm from the government and I'm here to help you" -- but, unsurprisingly, found little support in the case law for this proposition.

[Scienter/strict liability as a serious problem, both for the Lanham Act and the FDA. No matter how strong the First Amendment gets, we wouldn't expect fraud law to disappear, but there is a big difference between good-faith mistake and deliberate deception, one that has made a First Amendment difference in other contexts. Why wouldn't it do so here? Even a negligence standard, urged by a number of the *Nike* briefs, would have immense consequences in false advertising law generally. Not to mention the potential consequences for the FDA, the SEC, et cetera, where the logic would apply equally.]

[False advertising law may be particularly vulnerable because it, unlike copyright and trademark, has no well-recognized property interest to which it can appeal as a counterweight to a free speech claim. *Eldred* shows the potential of defining an intangible interest as a property right – it magically moves from part of the marketplace

[19] Kozinski, Who's Afraid of Commercial Speech; product placement; NYT article on "Pass the Courvoisier."

of ideas to the actual marketplace, where it's all right to deny access to those who can't pay. Trademark law has self-consciously moved in the direction of property right, instead of consumer protection device, for decades. Notably, the EU defines a business's property right in its reputation to include the right not to be spoken of at all, even truthfully. We could define Kasky's interest in not being deceived as a property right, though it's a little harder; we could with less strain define Converse's interest in competing against Nike on the merits as a property interest, part of its goodwill being its comparative position. But that has not been done, and false advertising law therefore lacks one of the most powerful rhetorical countermoves to a free speech claim.]

*Pearson* and the FDA's comprehensive rethinking of its role may herald the future of much regulation of commercial speech.