No. 02-575

IN THE

Supreme Court of the United States

NIKE, INC., *et al.*,
Petitioners,
v.
MARC KASKY,
Respondent.

On Writ of Certiorari to the Supreme Court of California

BRIEF OF *AMICUS CURIAE* PFIZER INC IN SUPPORT OF PETITIONERS

JEFFREY B. KINDLER
GEORGE W. EVANS
STEVEN C. KANY
ARNOLD I. FRIEDE
PFIZER INC
235 East 42nd Street
New York, NY 10017-5755
(212) 573-2323

BERT W. REIN
Counsel of Record
ROSEMARY C. HAROLD
WILEY REIN & FIELDING LLP
1776 K Street, N.W.
Washington, DC 20006-2304
(202) 719-7000

Counsel for *Amicus Curiae*

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INTEREST OF *AMICUS CURIAE*

Pfizer Inc ("Pfizer") is the world's leading research-based pharmaceutical company. Pfizer discovers, develops, and manufactures prescription drugs and other consumer health care products that are marketed worldwide.[1] Because Pfizer scientists and doctors operate at the cutting edge of knowledge in science and medicine, the company possesses a vast body of information relating to health care matters, including the characteristics of its products and the many health conditions they treat, as well as the scientific, economic, and political contexts in which issues surrounding them arise.

Pfizer exercises its First Amendment right to address the public—including physicians who prescribe and patients who use its products—in a number of different ways. The company is a substantial advertiser seeking to disseminate information to promote the sale of its products. Other Pfizer promotional material, such as the company's extensive website, provides considerable factual data on health conditions as well as commercial information about Pfizer products. When it advertises or promotes at its own initiative, Pfizer recognizes that the government has a legitimate interest in regulating the commercial marketplace to ensure that consumer decisions are not distorted by false or misleading commercial information.

Pfizer also speaks out on public health and policy issues that may relate, directly or indirectly, to the company's products and operations. For example, the company

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[1] Pursuant to Sup. Ct. R. 37.6 ("Rule"), Pfizer states that no counsel for a party has authored this brief in whole or in part, and no person or entity other than Pfizer has made a monetary contribution to the preparation or submission of the brief. Pursuant to Rule 37.3(a), Pfizer has obtained consent of the parties to the filing of this brief. The requisite consent letter from Respondent Marc Kasky was submitted to the Court on Feb. 14, 2003. Petitioners Nike Inc., *et al.*, filed a blanket consent letter in this docket on Feb. 3, 2003.

comments generally on broad public policy issues through its *Pfizer Forum* series of sponsored editorials and through public statements of its senior officers. In that capacity, Pfizer believes, as this Court held in *First National Bank of Boston v. Bellotti*, 435 U.S. 765 (1978), that it should be entitled to the same First Amendment protections as any other speaker.

In addition, Pfizer responds to matters of public concern, as Nike did in the case at bar, through vehicles such as media releases, interviews, and letters to the editor. These responses are not limited to abstract statements on political topics or societal trends but rather typically involve discussion of specific products in the context of news about scientific developments or consumer issues. In the last several months, for instance, mainstream media have tracked test developments concerning the long-term safety of hormone replacement therapy ("HRT") for women. The public discussion has included questions as to whether HRT products different from those tested in a recent groundbreaking study would produce different results. Drug effectiveness also is a matter of public discussion, especially within the scientific community and the specialty media that serve it. For example, the federal government recently published the results of a landmark study designed to compare three different types of drugs used to treat coronary heart disease, thereby touching off ongoing debate in both professional and consumer circles over the results. Pfizer manufactures both HRT products and one type of the heart disease drugs tested. In responding to these debates and protecting its commercial position, the company often enters into areas of scientific controversy involving competing priorities; balancing of risks, costs, and benefits; and other scientific and/or economic trade-offs in which what is "misleading" can be as much a matter of viewpoint as of knowledge.

Pfizer is significantly handicapped in its responses by the threat of action under state laws like the California statute at

issue.[2] The company believes that such handicaps, when applied as in this case, are antithetical to the First Amendment and to the public's interest in being fully informed on important health care issues. Pfizer thus views this case as an opportunity for this Court to secure the First Amendment rights of commercial speakers in addressing matters of public concern that involve their products and operations, subject only to the same governmental restrictions and reviews legitimately imposed on other participants in public debate. Pfizer urges that this Court either (a) adapt the existing commercial speech doctrine set forth in *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557 (1980), and its progeny, to give express recognition to a right of equal reply; or (b) clarify its *Central Hudson* criteria to recognize that the governmental interest in safeguarding the commercial marketplace from false and misleading statements is not an absolute exception to the need to examine the strength of that interest in specific circumstances, the means by which that interest is advanced, and the potential overbreadth of its intrusion into protected public debate.

SUMMARY OF ARGUMENT

This case presents a collision between the State of California's claimed interest in protecting its citizens from the adverse influence on commercial transactions of allegedly false and misleading statements and Nike's First Amendment

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[2] Pharmaceutical manufacturers also are subject to extensive regulation under the Food, Drugs & Cosmetics Act of 1906, as amended, with respect to their speech about drug products. *See* 21 U.S.C. § 301 *et seq.* In connection with an inquiry of the Food and Drug Administration concerning the application of existing constitutional principles to FDA speech regulation, Pfizer has recommended formal recognition of a protected right of response. *See* Letter of George W. Evans, Associate General Counsel, Pfizer Inc, to Dockets Management Branch, Food & Drug Admin., Docket No. 02N-0209 (dated Dec. 11, 2002) (attached).

interest in participating as an equal in ongoing public debate on "globalization" issues that potentially affect both its product sales and future governmental actions. The majority of the California Supreme Court sought to resolve this collision by determining whether Nike's speech should be classified as "commercial." Answering in the affirmative, the majority then treated California's regulatory interest as absolute and gave no further attention to Nike's speech rights or to the interests of California citizens in hearing both sides on this matter of public concern. The majority premised its analysis on what it understood—erroneously, Pfizer believes—to be this Court's teaching that states may ban or sanction "false or misleading" commercial speech without regard to the context in which the speech arises or the adverse impact of such state action on the marketplace of ideas.

The decision below leaves Nike, and similarly situated commercial entities, at a dual disadvantage in participating in public debate that involves their products or business operations. First, as a substantive matter, their speech—unlike that of other participants—is subject to liability under the California Business & Professions Code § 17200 *et. seq*. ("Code") if judged false or misleading, with consequent potential for significant economic and criminal penalties. Second, as a procedural matter, this judicial review of their statements under the Code can be triggered at the discretion of their critics. There can be little doubt of the adverse effect that these dual handicaps impose on business participation in the increasingly frequent public debate about products and business operations, and consequently on the process of debate itself. It is equally apparent that this outcome cannot be squared with fundamental First Amendment values or this Court's long endorsement of the process of robust collision of ideas through which truth emerges.

Although the record before this Court demonstrates broad business, media, and public interest group concurrence that the decision below must be reversed, there is far less

agreement on an appropriate rationale. Following the lower court's lead, the parties and most *amici* focused their attention at the *certiorari* stage on the issue of whether Nike's speech should be considered "commercial." They proposed that the Court either abolish the commercial speech category or narrow it in a way that would place Nike's speech outside of it. Pfizer, while not questioning that the commercial speech criteria might usefully be clarified, believes that a different analysis would better meet the issues presented in this case.

Accepting *arguendo* that the subject matter of Nike's speech might trigger a legitimate state interest in regulating the commercial marketplace, Pfizer urges the Court to hold that any such interest still must be weighed against the competing value of vigorous public debate. In order to decide the case on the narrowest basis, the Court should recognize an overriding "right of reply," which would permit commercial entities to meet their adversaries on an equal substantive and procedural footing in a discussion or debate over matters of public concern. This holding would require reversal of the decision below because the lower court, in applying the Code, reached the opposite result. A recognized right of reply would free a commercial entity to fairly protect its interests and inform the public decisional process whenever critics, or the independent editorial judgment of the media, subjected the entity's products, services, or business operations to public scrutiny.

On a broader basis, Pfizer believes that the facts of this case give the Court a unique opportunity to clarify its commercial speech precedents and to harmonize them with more general speech doctrine. The commercial speech label might best be viewed simply as a determination that the content could directly influence the conduct of commercial transactions and thus trigger a legitimate state interest in preventing false or misleading information from distorting those transactions. As with other state interests that the Court has identified in its commercial speech precedents, however, the

suppression of allegedly false or misleading information should not be a paramount interest that forecloses the full *Central Hudson* balancing analysis. Rather, that interest must be weighed, as *Central Hudson* instructs, against countervailing interests in free expression and the value of a clash of positions on matters of public concern. Where, as here, vigorous public debate already exists, the state has at best only an attenuated interest in making its courts—rather than the competition among ideas in that debate—the vehicle for preserving market integrity. Moreover, despite the assumed "hardiness" of the speech, based on the speakers' economic interests and their detailed knowledge of their own products and business operations, permitting an action to go forward under the Code also creates substantial risk of chilling speech which is neither false nor misleading. Application of the operative factors of the Court's *Central Hudson* test to challenged speech restraints in such cases would provide both a basis for reversal here and a better foundation for reconciling state interests in marketplace integrity and competing free expression values.

ARGUMENT

I. THE DECISION BELOW IMPERMISSIBLY FAILS TO ACCORD ANY WEIGHT TO THE PREEMINENT FIRST AMENDMENT VALUE OF FREE AND ROBUST DEBATE ON MATTERS OF PUBLIC CONCERN

The dispute here evolved in circumstances typical of those that often surround other high-profile matters of public controversy. Nike's critics began airing their views publicly in the mid-1990s, linking the company's alleged unfair foreign labor practices with the larger policy debate over "economic globalization." *Kasky v. Nike, Inc.*, 45 P.3d 243, 264 (Cal. 2002), *cert. granted*, 123 S. Ct. 817 (2003). Those criticisms led to a widespread series of media reports that cast a cloud over Nike's image—and fed into discussion about the

need for national or international policy initiatives to address globalization concerns. *Id*. Nike responded to the specific criticism of the company in several ways, including commissioning an independent assessment of its foreign subcontractors' labor practices and issuing press releases and other public statements to rebut its antagonists. *Id*. at 248. All the while, and up through the present day, public debate over globalization continues in "uninhibited, robust, and wide-open" fashion, *see New York Times Co. v. Sullivan*, 376 U.S. 254, 270 (1964), not only through the media but through demonstrations in the streets of many cities across both the nation and the globe.

Mr. Kasky, one of Nike's critics, took a step beyond the usual arenas for public debate by filing suit against the company under the "unfair business practices" and "false advertising" provisions of the Code. *Kasky*, 45 P.3d at 247. The relevant provisions, by their terms, are designed to prevent fraudulent transactions in the commercial marketplace. *See* Code §§ 17200, 17500; *see also Kasky*, 45 P.3d at 249 (recognizing the Code as a "consumer protection law"). Here, the California Supreme Court acknowledged the public debate in which the challenged speech arose but nonetheless focused its legal analysis solely on the question of whether the speech at issue was "commercial." *Id*. at 247. Relying principally on the so-called *Bolger* factors, the majority scrutinized Nike's identity as a business speaker, its economic interests in its products and the image behind them, and the potential customers in the audience toward which Nike's speech was aimed. *Id*. at 254-256 (citing *Bolger v. Youngs Drug Prods. Corp*, 463 U.S. 60 (1983)). The court concluded that Nike's speech was commercial and, as a consequence, subject to unconstrained false-or-misleading review under the Code. *Kasky*, 45 P.3d at 259. The court then terminated its review, without considering how any countervailing First Amendment concerns might weigh in the constitutional balance.

As a result, Nike now faces potential burdens that only it, but not its critics, must bear for airing its views in the public debate. Mr. Kasky is seeking a host of remedies, including, *inter alia*, disgorgement of "all monies" that Nike acquired through its alleged deception, Nike sponsorship of a "Court-approved public information campaign" to remedy the alleged misinformation, and, of course, attorneys' fees. *Id*. at 248. Moreover, because the Code lacks the usual procedural safeguard provided by traditional standing requirements, which ordinarily set actual injury as a condition for maintaining an action, see Code § 17204 (permitting action to be prosecuted by "any person acting for the interests of . . . general public"); Petition for Writ of Certiorari at 3, *Nike v. Kasky* (2002) (No. 02-575) ("Brief of Petitioner") (citing respondent's original complaint conceding no injury or "personal knowledge" of facts), it has, in effect, allowed Mr. Kasky to speak twice in the public debate—first by objecting as a private citizen to Nike's labor practices and then by cloaking himself in the garb of the state to chill the company's response. Nike, in contrast, may speak only once, and then only at the risk of severe sanction.

Were the Court to uphold the ruling below, the decision would severely retard, if not suppress entirely, the ability of any seller of products or services in California to respond to public criticism of its products, services, or business operations if its responses might affect its sales. In addition, because of California's prominence in the national economy, the decision below also would effectively retard speech by business speakers throughout the United States on many matters of public concern. These include the many political topics, societal trends, consumer issues, and scientific developments that affect the perception of product or service quality or of business integrity.

A. Business Speakers Such As Nike Make A Valuable Contribution To Discussion On Matters Of Public Concern That May Implicate Their Products, Services, Or Business Operations

The heart of the ruling below is the notion that the economic motivation of the speaker—in and of itself—is sufficient to determine whether Nike, or any business speaker, has equal freedom to participate with other speakers in debate over matters of public concern.[3] *Kasky*, 45 P.3d at 257. This case does not reprise the question of whether corporations have the same rights as others to speak generally on ballot issues or other broad policy controversies. *See Bellotti*, 435 U.S. 765; *Pacific Gas & Elec Co. v. Public Utils. Comm'n of Cal.* 475 U.S. 1, 8 (1986). Nor does this case call into question the speech rights of businesses in their self-initiated sales efforts. *See, e.g., Thompson v. Western States Med. Ctr.*, 122 S. Ct. 1497 (2002). The decision below actually raises a new question for this Court: Even assuming that a business entity's speech on a matter of public concern may affect its sales, should that foreclose a careful balancing of the government's consumer protection interest against the constitutional value of affording all "diverse and antagonistic sources," *Associated Press v. United States*, 326 U.S. 1, 20 (1945), equal First Amendment protection when that business entity is contributing to public debate?

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[3] Although the lower court articulates a new three-point definition of commercial speech and defends its rationale at length, *Kasky v. Nike, Inc.*, 45 P.3d 243, 256-259 (Cal. 2002), *cert. granted*, 123 S. Ct. 817 (2003), all elements of the new analysis reduce to economic motivation. This motivation identifies as commercial not only the "speaker" but also the "intended audience" and the "content" of essentially all of the speaker's messages—as well as the speaker's reasons for existing, and speaking, at all. In identifying economic motivation as the linchpin of its commercial speech definition, the lower court latched onto, and extended, one of the defining factors set forth in *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 66-67 (1983).

The California Supreme Court, struggling with the commercial speech definition, never even considered this question. The Constitution, however, requires it. So, too, does life in the real world. The Court already has been presented with many examples illustrating how business speakers may provide useful input on matters of public concern that involve their products, services, or business operations. *E.g.*, Brief of Amici Curiae of Council of Public Relations Firms, *et al*., at 5-6, 13-5, *Nike v. Kasky* (2002) (No. 02-575) ("Amicus Brief of Public Relations Firms") (citing, *e.g.,* agricultural products manufacturers' scientific arguments concerning genetic modification of crops, technology companies' opinions on immigration policy as it affects high-tech workers, energy companies' assessments of wind- and solar-power developments). The record also shows that business enterprises are important sources of information and viewpoints for media coverage of such issues, and that these sources may wither if the ruling below stands. Brief of Amici Curiae ABC, Inc., *et al*., at 4-11, *Nike v. Kasky* (2002) (No. 02-575) ("Amicus Brief of News Media") (noting business trade press warnings about speech liability risks post-*Nike*).

So many public debates today involve what might be considered "business" issues that unnecessary restraints on corporate speech relating to products, services, or business operations would deprive listeners of valuable information that can contribute both to their economic decisions and their understanding of the broader debate. *See, e.g*., *Pacific Gas & Elec*., 475 U.S. at 8. Journalists for decades have been trained specifically to use concrete factual examples to illustrate larger policy debates precisely because that approach is an effective device for explaining complex issues to an audience. *See, e.g*., The Missouri Group, *News Reporting and Writing*, at 265 (1980) ("Specific detail gathered by observant and questioning reporters always wins out over general description."); *id*. at 272 ("telling a story" by focusing on "part of the whole . . . makes large institutions, complex

issues and seven-digit numbers meaningful"). It is therefore nonsensical to suggest that either the media or their business sources can make the best possible contribution to public debate if corporate entities are free to speak only in generalities. *Kasky*, 45 P.3d at 260-261.

Pfizer, as a pharmaceutical manufacturer, is knowledgeable about and interested in many matters of public concern that touch upon the company's expertise. Health issues—including the identification of diseases and conditions, treatment options, research developments, and the cost and availability of health care—plainly are topics of public discussion and debate. To provide the Court with some indication of the scope of public concern over health matters that involve drugs or medical devices, Pfizer has compiled a brief appendix of selected media clippings gathered since October 2002, which cover topics ranging from potential new vaccines to prevent cancer caused by a widespread virus to ongoing disputes about alleged psychiatric side effects of a certain acne treatment. *See* App. at 22a, 25a.

As noted in the Interest of Amicus statement, *supra*, prescription drug products are often topics of intense public discussion. Certainly the scientific data released under the auspices of the National Institutes of Health in July 2002 concerning HRT therapy has evoked widespread discussion in consumer circles, as well as debate in the professional and scientific communities. *See, e.g.*, Gina Kolata & Melody Petersen, *Hormone Replacement Study A Shock to the Medical System*, N.Y. Times, Jul. 10, 2002, at A1; Ceci Connolly, *Doctors Working to Clear the Fog of Hormone Study*, Wash. Post Jul. 28, 2002, at A1; Regina McEnery, *Experts still disagree on wisdom of hormone therapy*, Cleveland Plain Dealer Oct. 8, 2002, at B4; Prithi Yelaja, *More HRT studies in the works*, Toronto Star, Jan. 16, 2003, at K4; Nancy Weaver Teichert, *Confusion persists over menopause care: Hormones or not? Women and doctors search for answers*,

Sacramento Bee, Jan. 29, 2003, at A1; *see also* App. at 9a, 18a. Manufacturers of various HRT products, who have developed and collected extensive data on women's health and the effects of their drugs, can make valuable contributions to that ongoing discussion. *See* Melody Petersen, *Wyeth Criticizes Media Coverage of Hormone Replacement Drugs*, New York Times, Jul. 24, 2002, at C8. Even though these manufacturers have an economic interest in their products, it would serve no constitutional purpose to discourage them from at least responding to, if not initiating, assertions or questions about the risks and benefits of the therapy options—such as weighing the benefits of treating menopausal symptoms and the relative risks of heart disease, cancer, osteoporosis, etc., implicated in the studies. *See, e.g.*, Teichert, *supra*.

The HRT issue also illuminates a significant weakness in the justification for applying lesser First Amendment protection to business speech on matters of public concern. The lower court in *Nike* dutifully recited the long-standing rationale for the greater restraints imposed on commercial speakers: the business speaker is best positioned to know the "truth" about its products and is more likely to persist, because of its economic motivation, in speaking out about them. Kasky, 45 P.3d at 253. Neither rationale works in the HRT context. There is yet no scientific consensus with respect to HRT therapy; scientists and other research professionals are now debating the implications of the 2002 data, while doctors and their patients are discussing whether HRT is advisable based each woman's needs and health profile. Given the ongoing therapeutic ferment, there is no reason to believe that HRT manufacturers would persist in airing their views on the topic in the face of Code sanctions—even though listeners would benefit from that information.

Scenarios like this are not uncommon with respect to other pharmaceutical products or, indeed, any product or service that may implicate evolving scientific developments. For

instance, medical researchers, physicians, and patients currently are discussing and debating the meaning of two head-to-head studies of different hypertension medications. In December 2002, researchers released the results of the largest clinical study of blood pressure treatments ever conducted in the United States. *See, e.g.*, News Release, National Institutes of Health, NHLBI Study Finds Traditional Diuretics Better Than Newer Medicines for Treating Hypertension, (Dec. 17, 2003), available at www.nhlbi.nih.gov/new/press/02-12-17.htm (announcing results of Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial, known as "ALLHAT"); David Brown, *Study Calls Diuretics Best Against Hypertension*, Wash. Post, Dec. 18, 2002 at A1. The study centered on comparisons of three alternative types of drugs, one of which Pfizer manufactures. More recently, however, a separate study came up with contrary results: "In what seems to be a classic whipsawing of medical news, a new Australian study appears to contradict conclusions from a recent U.S. trial that found older, inexpensive diuretic medications were just as good or better than costlier new drugs for treating high blood pressure." Ulysses Torassa, *Hypertension study findings in conflict; One says newer, costlier therapies better, the other says older treatments just as good*, S.F. Chron, Feb. 13, 2003 at A4. Professionals reacting to the studies noted that certain population groups seem to respond better to one alternative treatment or another—and made the indisputable observation that the matter is far from resolved. Torassa, *supra* (quoting epidemiologist stating, "I don't think we can sort this out immediately. We'll have to digest it and do some pooling of the data with different studies."); Scott Hensley, *Hypertension Report Disputes Earlier Study*, W.S. Journ., Feb. 13, 2003 (noting "backlash" among some doctors against U.S. study).

Denying full First Amendment protection to drug manufacturer speech on HRT and hypertension therapies would not

result in better consumer or regulatory decisions on the subjects. It would simply chill the prospects that business information and viewpoints would emerge publicly. This type of outcome, whatever the economic arena may be, would not simply hurt business speakers. Categorically reducing the First Amendment protection afforded to "economically motivated" speech in all instances would deprive listeners of data and opinions on issues that matter to them. It is also unnecessary, in a society that values its free enterprise system, to demean all business speech arising within a public debate simply because it could also redound to the speaker's financial benefit. Courts cannot assume that listeners, when determining for themselves the worth of a particular message, are incapable of taking both the content and the speaker's motivation into account—regardless of whether the situation is a commercial one or not. *See, e.g.*, *Bellotti*, 435 U.S. at 791 n.31 ("The First Amendment rejects the 'highly paternalistic' approach of statutes . . . which restrict what the people may hear.") (quoting *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748, 770 (1976).

B. First Amendment Principles Generally Applicable To Debates Over Matters Of Public Concern Support Nike's Right To Contribute To The Public Discussion

If the facts here had been assessed solely against the free speech principles that usually apply to discussion on "matters of public concern," *see, e.g.*, *Gertz v. Welch, Inc.*, 418 U.S. 323 (1974); *Bartnicki v. Vopper*, 532 U.S. 514 (2001), the case would not be before this Court now. There is no dispute here that this case arose within the context of a public debate initiated by others—and that the materials at issue are Nike's replies to its critics. *Kasky*, 45 P.3d at 263. In the normal course of public discussion, responses from interested parties are both expected and encouraged because the First Amend-

ment carries a presumption that truth will best emerge from the "collision" of ideas that results from open channels of communication. *See, e.g*., *New York Times,* 376 U.S. at 266, 269-271 & n.19 (even false statement contributes by bringing about a "clearer perception and livelier impression of truth, produced by its collision with error") (*citing* Mill*, On Liberty* (Oxford: Blackwell 1947), at 15). Should any speech uttered during the debate be false or misleading, the preferred constitutional remedy for exposing it is more speech, rather than less. *See, e.g., Whitney v. California,* 274 U.S. 357, 377 (1927) (Brandeis, J., concurring), overruled in part by *Brandenburg v. Ohio*, 395 U.S. 444 (1969).

The presumption carries particular force in settings such as *Nike*, where multiple speakers are engaged in the discussion. In protecting the conditions required for robust debate to flourish, the Court has repeatedly demonstrated a concern for the concept of the "level playing field." *See, e.g., Thornhill v. Alabama*, 310 U.S. 88 (1940); *Thomas v. Collins*, 323 U.S. 516 (1945); *Waters v. Churchill*, 511 U.S. 661 (1994) (termination improper when nurse spoke out on matter of "public concern" involving hospital). This overarching concern encompasses disapproval of discrimination on the basis of speaker identity or viewpoint. *See, e.g., Bellotti*, 435 U.S. at 776; *R.A.V. v. City of St. Paul, Minn.*, 505 U.S. 377 (1992) (improper restraint based on viewpoint); *cf. City of Ladue v. Gilleo,* 512 U.S. 43 (1994) (inequitable regulatory treatment of signs based on content); *Texas Monthly, Inc. v. Bullock*, 489 U.S. 1 (1989) (inequitable tax treatment of publications based on content); *Arkansas Writers' Project, Inc. v. Ragland*, 481 U.S. 221 (1987) (same). Accordingly, the Court has repeatedly acted to protect the ability of speakers—both corporate and individual—to discuss matters of public concern without having to confront either direct recrimination or indirect restraint. *See, e.g*., *Bellotti*, 435 U.S. at 776; *Consol. Edison Co. of N.Y. v. Pub. Serv. Comm'n of NY*, 447 U.S. 530 (1980) (utility allowed to provide bill

inserts on matters of public controversy); *Pacific Gas & Elec.,* 475 U.S. 1 (utility not obligated to carry counter-speech to political editorials inserted in gas bills); *Waters*, 511 U.S. 661; *DeBartolo Corp. v. Florida Gulf Coast Bldg. & Constr*., 485 U.S. 568 (1988) (peaceful handbilling by union permitted at shopping mall). The Court's precedent reflects an understanding that the give-and-take process of any dialogue benefits those who listen, as well as those who speak, especially when the debate occurs in a public arena. *Pacific Gas & Elec.*, 475 U.S. 1 (First Amendment "serves significant societal interests wholly apart from the speaker's interest in self-expression"); *Bellotti,* 435 U.S. at 776 ("The Constitution often protects interests broader than those of the party seeking their vindication.").

Under these general First Amendment principles, there is no justification for the state to suppress one side of the debate over Nike's labor practices abroad or the larger issue of globalization generally—although that is precisely what the Code, as applied by the court below, would permit. *Kasky v. Nike*, 79 Cal. App. 4th 165, 175 (2000) ("Though drafted in terms of commercial speech, the complaint in fact seeks judicial intervention in a public debate.") No one contends here that the Code was designed to police discussion on matters of public concern. Both sides have access to the public arena to air their views and the facts they offer to support those views. The public would benefit from exposure to robust debate on the issues. There is no reason to believe that listeners would be unable to take the interests of speakers, economic or otherwise, into account in evaluating for themselves the merit of the information and ideas being exchanged—which the Court has recognized they can do even when confronted with direct sales pitches. *Peel v. Attorney Registration and Disciplinary Comm'n*, 496 U.S. 91, 105 (1990) (rejecting notion that recipients of commercial speech "are no more discriminating than the audience for children's television"). There also is no reason to believe that

any arguably false or misleading information would be left unrebutted in the course of this ongoing debate, just as occurs in discussions of other matters of public concern. *See* Amicus Brief of News Media at 18-20 (news coverage calling certain Nike assertions into question). In short, from the public debate side of the collision of interests presented in this case, there is no justification for the State of California, or persons acting in its stead, to determine whether some speakers' assertions are so untrustworthy that they must be suppressed, or punished, while allowing other speech to flow freely. *See, e.g.*, *Riley v. Nat'l Fed'n of the Blind of N.C.*, 487 U.S. 781, 791 (1988) ("the government, even with the purest of motives, may not substitute its judgment as to how best to speak for that of speakers and listeners . . .").

II. THE COURT SHOULD RESOLVE THIS CASE BY ESTABLISHING A MEANS OF BALANCING THE GOVERNMENT INTEREST IN REGULATING THE COMMERCIAL MARKETPLACE AGAINST THE CONSTITUTIONAL VALUE OF ROBUST DEBATE ON MATTERS OF PUBLIC CONCERN

The potential chilling effect of the decision below has prompted a host of interested entities, including several that do not often find common cause, to combine in urging this Court to reverse the California Supreme Court's decision. Most follow that court's lead by focusing on the commercial speech definition but, in so doing, part company on how best to reach the desired outcome. *See, e.g.,* Brief of Amicus Curiae Center for the Advancement of Capitalism at 9-12, *Nike v. Kasky* (2002) (No. 02-575) (repudiate the commercial speech doctrine entirely); Amicus Brief of News Media at 12-15 (define commercial speech as only that which "does no more than propose a commercial transaction"); Brief of Petitioner at 21, 25 (suggest defining commercial speech as only that which refers to a specific product or service); Brief of

Amicus Curiae U.S. Chamber of Commerce at 10-11**,** *Nike v. Kasky* (2002) (No. 02-575) (distinguishing "business operations" from "product or service").

Pfizer recognizes that the harms to public debate arising from the decision below could be avoided by defining Nike's statements as something other than commercial, thus placing them constitutionally beyond the reach of the Code. Yet a narrowed definition, or outright rejection, of the state's interest in regulating commercial speech could also devalue California's legitimate interest in regulating commercial transactions. Pfizer recognizes that fair and honest commercial dealings are the foundation of a healthy free enterprise system, and the government has a role to play in policing that marketplace. Because consumer protection is a valid government concern, a failure to recognize the state interest in regulating commercial speech would not be warranted.

Further efforts to define commercial speech, however, would simply resurrect old problems or create new ones. The suggestions offered here illustrate that point by simply adding potential complications to the existing ambiguities. Defining commercial speech as that which does no more than "propose a commercial transaction" begs the question that has bedeviled the Court for years: What constitutes a proposal? Should it always require the use of the term "buy" or the inclusion of a price term? Does form matter, or context? The potential variants are daunting. Against that prospect, there may be some surface appeal to the idea of limiting the commercial speech label to only those communications that explicitly refer to a product or service. But that alternative sweeps too much high-value speech into diminished constitutional protection. Many legitimate matters of public concern do involve actual products and services. *See supra* Section I.A; Appendix. Furthermore, contrary to the conclusion of the court below, *Kasky*, 45 P.3d at 260-61, the public "concern" often cannot be discussed sensibly without reference to those products or services. *See, e.g.*, Amicus

Brief of Public Relations Firms at 11-13 (Tylenol/cyanide tampering incident and its subsequent impact on product packaging of many kinds). A similar infirmity infects the notion that discussion of "business operations" could somehow be easily segregated from discussion of products or services. Business operations that become a matter of public concern often may be bound up in the development of products or services, see Amicus Brief of News Media at 3, 6-7, such as the testing that leads to the creation of new foods or drugs. *See* App. at 25a, 32a. The distinction is too easily blurred to be definitive.

Pfizer believes that the decision below can be reversed without either attempting again to perfect the commercial speech definition or substantially overhauling the *Central Hudson* balancing test. Set forth below are two alternatives that share a common foundation: both recognize that cases such as *Nike* present competing interests that warrant a more careful balancing assessment than the California court undertook here. The government's interest in safeguarding the commercial marketplace from false and misleading statements cannot, in every circumstance, trump the competing value of vigorous public debate on matters of public concern. On the other hand, the government's consumer protection goals also are worthy of consideration in circumstances where a business speaker's messages may directly affect sales of its products or services. Weighing these interests under the facts presented by any particular case would better serve both interests.

Applying a balancing approach to cases such as *Nike*—whichever mechanism is chosen—would comport with much of the Court's *Central Hudson* precedent as well as other free speech jurisprudence. The weighing of competing interests is, of course, common in First Amendment law generally. *See, e.g.*, *Gertz*, 418 U.S. 323 (balance in defamation tips in favor of speech freedom when plaintiff thrust into matter of public controversy); *Dun & Bradstreet v.*

Greenmoss Builders, 472 U.S. 749 (1985) (balance in defamation tips back toward plaintiff in matters of only private concern); *San Francisco Arts & Athletics, Inc. v. United States Olympic Comm.*, 483 U.S. 522, n. 16 (1987) (characterizing commercial speech doctrine as one of several First Amendment balancing tests). Similar balancing is employed even in cases that pit the economic goals of otherwise valid government statutes against First Amendment rights. For example, the Court has determined that federal antitrust restraints must give way when they threaten to prevent the exercise of First Amendment rights to petition the government for redress of grievances. *See, e.g, E. R.R. Presidents Conference v. Noerr Motor Freight*, 365 U.S. 127 (1961), *Mine Workers v. Pennington*, 381 U.S. 657 (1965); *BE & K Constr. Co. v. NLRB*, 122 S. Ct. 2390 (2002). In such cases, though the antitrust restraints serve a valid government interest in ensuring the competitive operation of the commercial marketplace, the statutory regime cannot be used to bar persons from making coordinated efforts to lobby the legislature—even in pursuit of legislation that would hurt competitors—or pursuing good-faith court challenges to competitors. *Noerr*, 365 U.S. at 137 (Court will not "lightly impute to Congress an intent to invade . . . freedoms" protected by the Bill of Rights); *Pennington*, 381 U.S. at 664. Similarly, valid government concerns for personal privacy are not sufficient to foreclose completely any reasonable door-to-door efforts to engage in religious or political advocacy or to solicit charitable donations. *See Watchtower Bible & Tract Soc'y of N.Y., Inc. v. Vill. of Stratton*, 536 U.S. 150 (2002); *Hynes v. Oradell*, 425 U.S. 610 (1976); *Martin v. Struthers*, 319 U.S. 141 (1943). The government's interest in protecting the fairness of commercial transactions is, of course, valid, but it is not different in kind from these other interests that the Court has weighed against the constitutionally protected benefits of free speech.

A. The Court Should Recognize, At A Minimum, A Constitutional "Right Of Reply" That Would Allow Business Speakers To Respond To Criticism Of Their Products, Services, Or Business Operations Publicly Raised By Third Parties

A direct way to address the competing interests presented here would be to craft a specific mechanism to protect public discourse. Unnecessarily handicapping a business speaker from responding to public attacks on its products, services, or business operations encroaches on widely cherished notions of fundamental fairness in addition to the level playing field concept that underlies basic First Amendment principles. *See supra* Section I.B. Even if such responses might benefit the speaker's sales, that effect does not negate or outweigh the contribution that the speaker can make to public understanding of the issues under discussion. *See, e.g.*, *Bellotti*, 435 U.S. at 777 ("the inherent worth of the speech in terms of its capacity for informing the public does not depend on the identity of its source, whether corporation, association, union, or individual").

Pfizer therefore believes that, absent broader doctrinal changes, the Court should afford commercial speakers in these circumstances a constitutional "right of reply" that carries the same full First Amendment protection enjoyed by the noncommercial entities in the debate. This limited safeguard would serve the rights of both speakers and listeners. By guaranteeing that all speakers enjoy equal freedom to discuss the issues, the safeguard would properly resolve this case; the Code's liability standard would not automatically apply to Nike's rebuttals and effectively cut off the public debate prematurely. Instead, in this case and others like it, a right of reply would help foster the best possible dialogue on matters of public concern, thereby safeguarding the process of public debate upon which our government policymaking ultimately depends. *Id*. at 783; *Richmond Newspapers v. Virginia*, 448 U.S. 555, 587 (1980) ("the First

Amendment embodies more than a commitment to free expression and communicative interchange for their own sakes; it has a structural role to play in securing and fostering our republican system of self-government").

A right of reply would also dovetail with the First Amend ment value accorded to the process of dialogue generally, even in commercial speech cases. The "lesser" protection afforded to commercial speech is in some tension, as a conceptual matter, with situations that involve significant interchanges between two or more speakers. Advertising typically is perceived as one-way communication: the seller speaks to potential consumers. Government consumer protection policy is predicated on the premise of unlevel playing field; the power that sellers derive from their greater financial resources and knowledge about their wares, see *Kasky*, 45 P.3d at 257-58, supports the imposition of additional legal constraints upon them to protect consumers. Nearly all of the Court's commercial speech cases fit the "one-way speech" paradigm, whether the identified government interest was traditional consumer protection or not. *See, e.g., Bates v. State Bar of Ariz.,* 433 U.S. 350 (1977) (newspaper ads); *Bolger,* 463 U.S. 60 (direct-mail flyers); City of *Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410 (1993) (course catalogs); *Rubin v. Coors Brewing Co.,* 514 U.S. 476 (1995) (package labels); *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001) (placards and billboards); *United States v. Edge Broad.*, 509 U.S. 418 (1993) (broadcast commercials); *Greater New Orleans Broad. Ass'n. v. United States*, 527 U.S. 173 (1999) (same); *Virginia State Bd. of Pharmacy,* 425 U.S. 748 (unspecified form of "advertising"); *Cent. Hudson*, 447 U.S. 557 (same); *Ibanez v. Florida Dep't of Bus. & Prof'l Regulation Bd. of Accountancy*, 512 U.S. 136 (1994) (same); *Western States*, 122 S. Ct. 1497 (same). The few cases involving exchange of views, however, required a balancing of the state's asserted interest in marketplace integrity, *Ohralik v. Ohio State Bar Association*, 436 U.S. 447

(1978), or institutional integrity, *Board of Trustees of the State University of N.Y. v. Fox*, 492 U.S. 469 (1989), against the potential suppression of useful information. Indeed, in *Edenfield v. Fane*, the Court specifically acknowledged the ability of consumers to filter commercial communications and evaluate them in "rational and considered decision making." 507 U.S. 761, 775 (1993).

In broader public debates, a right of reply would enhance listeners' ability to obtain information useful to them both as consumers and citizens. Furthermore, because the right of reply would be triggered only when a third party criticizes a commercial entity, the potential seems negligible that a commercial speaker would induce criticism in order to launch a false or misleading response. The initial criticism of the business entity—as well as later critical rebuttals—creates a substantial commercial risk. In any event, the debate itself serves to alert consumers that certain issues involving the enterprise are in dispute, leaving them free to act as they see fit.

Recognition of a right of reply would not open the door to abuse. There should be no fear about the courts' ability to limit the safeguard by determining whether the response addresses legitimate matters of public concern; they already do so in other First Amendment contexts. *See e.g., Gertz*, 418 U.S. 323 (defamation legal standard turns on whether issue is private or public concern); *Bartnicki,* 532 U.S. 514 (media may publish surreptitious wiretap on matter of public concern). Courts also are quite capable of distinguishing a valid exercise of First Amendment reply rights from situations in which a speaker may attempt to use the safeguard, once triggered, to avoid valid consumer protection regulation. In analogous settings, the courts have successfully dealt with similar evasive or abusive use of the First Amendment as a defense against legitimate economic regulation. *See California Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508 (1972) (rejecting "sham" claim of *Noerr-Pennington*

protection of First Amendment right to petition); *BE & K Constr.,* 122 S. Ct. at 2396 ("while genuine petitioning is immune from antitrust liability, sham petitioning is not").

To assist lower courts in this task, the Court could specify consideration of several factors likely to be relevant in most, if not all, cases where a right of reply is asserted. In Pfizer's view, courts might properly review three principal factors. The first would be specificity, *i.e*., does the speech directly relate to the message to which the business speaker is responding. The second would be proximity, *i.e*., is the speech disseminated reasonably close in time to the initial message that prompted the response. The third would be proportionality, *i.e*., is the speech reasonably directed to the audience exposed to the initial criticism and does it exclude references to products, services, or business operations not germane to the identified public concern.

Recognition of a right of reply within the existing *Central Hudson* framework would level the playing field for all speakers participating in debates concerning important public issues. It also would help to eliminate the chill imposed by the mere threat of litigation under the Code, because it should allow many challenges to business participation in public debate to be dismissed on preliminary motion, in a manner similar to the use of the "public figure" defense in defamation actions. *See, e.g*., *id*. at 2401 (citing *New York Times*, 376 U.S. at 279, as example of procedural mechanism affording needed "breathing space" First Amendment requires). The right of reply therefore would serve fundamental First Amendment values both substantively and procedurally.

B. Alternatively, The Court Should Clarify That The Government Interest In Protecting the Fair Functioning of the Marketplace Is Subject To Complete *Central Hudson* Analysis Before Sanctions May Be Imposed On Commercial Speech Addressing Matters Of Public Concern

Should the Court wish to address larger doctrinal issues, this case offers an excellent opportunity to explain that determining that commercial speech is neither false nor misleading is not a predicate step to application of the full balancing analysis embodied in *Central Hudson*. In other words, allegations that the speech at issue is false or misleading should not create an absolute exception to the need to examine the strength of the government's consumer protection interest in the specific circumstances, the means by which that interest is advanced, the potential for less restrictive measures to alleviate any legitimate concerns about deception, and the countervailing risk of suppressing truthful speech of "public value." Restating *Central Hudson* to clarify that suppression of deceptive commercial speech is a legitimate government interest which must be weighed in the balance—like any other valid government interest—would do little more than describe how this Court, and subordinate ones, have been handling contentions that commercial speech can be sanctioned as false or misleading. *See, e.g.*, *Edenfield*, 507 U.S. 761; *Ibanez*, 512 U.S. 136; *Revo v. Disciplinary Bd. of the Sup. Ct. for the State of N.M.*, 106 F.3d 929 (11th Cir. 1997).

As demonstrated below, an accurate understanding of the essential teaching of *Central Hudson* and later precedent would have caused the California Supreme Court to affirm dismissal of Mr. Kasky's claims. The California court, however, simply took as a given that the state had plenary constitutional power to ban or sanction "false or misleading" commercial speech in all circumstances. It was than forced to

wrestle with the difficulties presented by the facts solely by analyzing the scope of "commercial speech." Kasky, 45 P.3d at 247. In seeking to extend that scope to preserve what it deemed the state's legitimate regulatory interest—*i.e.*, preserving the integrity of commercial transactions where a commercial speaker addressed its potential customers on issues affecting sales—the court below stopped short of even considering how application of the Code would affect the contribution of Nike's non-misleading speech to overall public debate and whether less restrictive means of protecting California's regulatory interests were available. The critical paradigm of *Central Hudson*, by contrast, requires a careful balancing of those competing values. *See, e.g., Ibanez*, 512 U.S. at 143 ("[t]he state's burden is not slight"); *Edenfield*, 507 U.S. at 768-69 (need to consider impact of restriction on protected speech).

While this Court has said that false or misleading speech plays no legitimate role in the commercial marketplace, it has never explained why pursuit of the regulatory objective of protecting consumers from deception should trump paramount First Amendment values. *See, e.g., Cent. Hudson*, 447 U.S. at 565; *Posadas de Puerto Rico v. Tourism Co.*, 478 U.S. 328, 350 (1986); *Edge Broad.,* 509 U.S. at 429. In *44 Liquormart, Inc. v. Rhode Island*, the Court declared that "the State's power to regulate commercial transactions justifies its concomitant power to regulate commercial speech that is 'linked inextricably' to those transactions." 517 U.S. 484, 499 (1996). Thus, regulation to guard against consumer deception plainly serves legitimate state interests, as do regulations to guard against intemperance (44 *Liquormart*, 517 U.S. 484; *Rubin v. Coors*, 514 U.S. 476); prevent unauthorized distribution of unapproved new drugs (*Western States*, 122 S. Ct. 1497); maintain professional relationships (*Ohralik*, 436 U.S. 447; *Edenfield*, 507 U.S. 761); and protect street safety and aesthetics (*Discovery Network*, 507 U.S. 410). Nothing in logic or this Court's precedent, however,

justifies elevating anti-deception interests above all other legitimate state interests for purposes of *Central Hudson* analysis.

Indeed, building upon the teaching in *Central Hudson* that the government may not "completely suppress information when narrower restrictions on expression would serve its interest as well", 447 U.S. at 565, this Court and lower courts have limited state power to act against speech which, while potentially misleading, could be made accurate by additional disclosure. *See In re R.M.J.*, 455 U.S. 191, 205 (1982) ("states may not place an absolute prohibition on certain types of potentially misleading information . . . if the information also may be presented in a way that it is not deceptive."); *see also Peel*, 496 U.S. 91; *Bates*, 433 U.S. 350; *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999); *cf. Shapero v. Kentucky Bar Assoc.,* 486 U.S. 466 (1988). In addition, claims of "false or misleading" speech have been rejected where challenged statements "were in fact easily verifiable . . .", *Zauderer v. Office of Disciplinary Counsel of the Sup. Ct.*, 471 U.S. 626, 645 (1985); see also *Edenfield*, 507 U.S. at 772, and the Court has further restricted state power to use the "paternalistic assumption that the recipients of [advertising] are no more discriminating then the audience for children's television." *Peel*, 496 U.S. at 105; *see also Ibanez*, 512 U.S. at 137. Finally, in *Edenfield*, the Court identified "ensuring the accuracy of commercial information in the marketplace" as a "substantial state interest" and expressly required that the state's assertion of that interest be weighed against other *Central Hudson* factors when the facts of the case indicated that "truthful and non-misleading expression will be snared along with the fraudulent or deceptive commercial speech." 507 U.S. at 768-69. Thus, any assumption that prohibiting deceptive commercial speech is an absolute constitutional value cannot be supported.

To recognize this evolving jurisprudence, the Court now should make plain that a determination or allegation that speech affecting commercial transactions is false or misleading constitutes the beginning, rather than the end, of the First Amendment analysis. The state's interest in preventing commercial deception must still be assessed, as *Central Hudson* teaches, for substantiality in the relevant circumstances and balanced against the competing free speech values of the dissemination of non-misleading information and the contributions of that information to vigorous public debate—while also taking into account the availability of less speech-restrictive means of advancing the state's interest. *See id*.; *Western States,* 122 S. Ct. at 1503. If competing values outweigh the relevant state interest, First Amendment jurisprudence makes clear that the tolerance of some deceptive information is a necessary price for the protection of greater interests. *New York Times,* 376 U.S. 254; *Gertz*, 418 U.S. 323*; cf. Philadelphia Newspapers v. Hepps*, 475 U.S. 767, 774 (1986) (even in "private figure" defamation, evidentiary burden placed on plaintiff because "constitutional requirement of fault supersedes . . . common law's presumptions as to fault and damages").

In short, this case provides the Court an opportunity to establish the universality of the *Central Hudson* balancing approach across all commercial speech cases. In so doing, the Court also would harmonize its commercial speech doctrine with mainstream First Amendment analysis, where the weighing of asserted state interests against the values of free expression is commonplace. *See, e.g., Watchtower Bible*, 536 U.S. 150 (free speech and religious liberty v. privacy); *New York Times*, 376 U.S. 254 (personal reputation v. public debate); *Texas v. Johnson*, 491 U.S. 397 (1989) (patriotic symbolism v. criticism of government); *United States v. O'Brien*, 391 U.S. 367 (1968) (maintenance of military draft system v. criticism of government).

Applying the *Central Hudson* balancing analysis to the case at bar makes clear that the decision below must be reversed and the complaint dismissed on First Amendment grounds. Even assuming, as pleaded by Mr. Kasky, that Nike's descriptions of its foreign labor practices were false and misleading and therefore could deceptively induce consumers to buy the company's products, the state interest in suppressing this deception is attenuated for three important reasons. First, because there is ample counter-speech in the marketplace of ideas, which gives listeners a more sophisticated appreciation of the facts, the need for state interaction to "set the record straight" on their behalf is limited at best. Second, because the Nike statements at issue do not directly advocate purchase of the company's products and relate only remotely to consumer purchasing decisions, the state's consumer protection interests are further limited. Third, because the proceedings were initiated without regard to actual deception or consumer injury, the state interest is concomitantly reduced.

California's limited interest in suppressing Nike's allegedly deceptive speech is potentially advanced by the Code—via a number of draconian remedies, including injunction and orders for massive restitution. Yet while these remedies might be said to "directly advance" California's consumer protection interest, there is no basis for holding them to be appropriately tailored to First Amendment interests. *See, e.g., Western States,* 122 S. Ct. at 1507. First, in circumstances where counter-speech is readily available, First Amendment values counsel reliance on the collision of ideas and the good sense of listeners rather than the judgments of state officials to prevent deception. *See, e.g.*, *New York Times*, 376 U.S. at 270 (discussing "profound national commitment to the principle that debate on public issues should be uninhibited, robust, and wide-open"); *Riley*, 487 U.S. at 791 ("free and robust debate cannot thrive if directed by the government"). Second, when public controversy inevitably means that fact

statements, judgments, and policy views will be intertwined, there is a substantial risk that Code remedies will suppress the latter with the former, contrary to this Court's rejection of over-inclusive deception remedies. *See, e.g., Edenfield*, 507 U.S. 761. Third, actual cases of detrimental consumer deception could be dealt with under a better-tailored California conduct remedy. A more precisely framed statute would provide a cause of action to an injured consumer where the gravamen of the complaint would be an intentional attempt to market fraudulently by, *inter alia*, the knowing or reckless use of false or deceptive statements to affect consumer behavior. Requiring both actual consumer injury and the defrauding of consumers through intentionally false statements—two criteria which Mr. Kasky's complaint cannot meet—would adequately safeguard California's interest in protecting consumers against classic deceptive advertising and promotion while also giving public debate over business-related issues the breathing space it needs to flourish.

In addition, addressing *Nike* through this clarification would have essentially the same procedural effect as recognition of a constitutional right of reply proposed *supra* Section II.A. Disputes could often be resolved early in the adjudicatory process, thereby forestalling the additional chilling effect posed by the threat of prolonged litigation.

CONCLUSION

Pfizer believes that the facts of this case afford the Court an extraordinary opportunity to accommodate both general First Amendment principles and legitimate state interests in commercial regulation by recognizing a constitutional "right of reply" or by clarifying the universal application of the *Central Hudson* balancing analysis. For reasons set forth above, Pfizer respectfully requests this Court to reverse the judgment below and order that the complaint be dismissed.

Respectfully submitted,

JEFFREY B. KINDLER
Senior Vice President and
General Counsel
GEORGE W. EVANS
Associate General Counsel
and General Counsel to
Pfizer Pharmaceuticals Group
STEVEN C. KANY
Senior Assistant General
Counsel
ARNOLD I. FRIEDE
Senior Corporate Counsel
PFIZER INC
235 East 42nd Street
New York, NY 10017-5755
(212) 573-2323

February 28, 2003

BERT W. REIN
Counsel of Record
ROSEMARY C. HAROLD
WILEY REIN & FIELDING LLP
1776 K Street, N.W.
Washington, DC 20006-2304
(202) 719-7000

Counsel for *Amicus Curiae*

APPENDIX

Pfizer Inc
235 East 42nd Street
New York, NY 10017-5755

December 11, 2002

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

Re: First Amendment Issues
Docket No. 02N-0209.

Dear Sir or Madam:

Pfizer Inc ("Pfizer") hereby submits (Exhibit A) proposed regulations concerning one facet of the Food and Drug Administration's ("FDA's") First Amendment inquiry—a sponsor's right to respond to public statements by an independent third party concerning a drug that is subject to an approved or pending New Drug Application ("NDA") or Investigational New Drug ("IND") application. This is a particularly important and timely issue given the pending Supreme Court certiorari petition in *Nike v. Kasky,* 71 U.S.L.W. 3319 (Oct. 16, 2002). In that case, the petitioner seeks clarification of the circumstances in which a manufacturer's response to third-party attacks constitutes speech subject to strict scrutiny under the First Amendment, rather than commercial speech subject to intermediate scrutiny. Pfizer believes that providing FDA with specific proposed regulatory language safeguarding a manufacturer's right to respond to such third party attacks will assist the agency in considering whether and how to amend its regulations or guidances in order to conform with First Amendment principles. It will also demonstrate that

codification of First Amendment principles is a feasible and natural outgrowth of the agency's current constitutional review and should be aggressively pursued by FDA. Although Pfizer has illustrated its proposal in the form of draft regulations, it would be equally appropriate for FDA to incorporate these safeguards in the form of a guidance.

Pfizer observed in its initial comments that the First Amendment embodies a "presumption that truth will best emerge from the collision of ideas that results from open channels of communication" and that "more speech," rather than less, is the best remedy for exposing misleading speech. Comments of Pfizer Inc. at 44 & n.155 (Sept. 13, 2002) ("Pfizer Comments") (quoting *Whitney v. California,* 274 U.S. 357, 377 (1927), *overruled in part, Brandenburg v. Ohio,* 395 U.S. 444 (1969)). These principles apply with particular force to prescription drugs. "Given the benefit and risk calculus involved in the use of any drug, there is ample room for public debate over drug use and constitutional value in letting all speakers play an equal role in that debate." Pfizer Comments at 45. Thus, First Amendment interests are best served when all interested speakers are allowed an equal opportunity to debate publicly the merits and risks of a drug product. This is at least as important—perhaps even more important—than a debate about the ethics and legality of Nike's labor practices in third world countries at issue in the *Kasky vs. Nike* case.

As Pfizer stated in its initial comments, however, FDA's current regulations single out drug manufacturers as the only class of speakers who cannot join freely in this public debate. Instead, manufacturers are governed by "pervasive, extensive regulations that tightly control what manufacturers may say about their products and attempt to transmogrify advertising and other promotional communications into comprehensive instructional messages." *Id* at 111. "FDA, by requiring manufacturers to include an exhaustive list of a product's

risks as well as its benefits, . . . hampers drug manufacturers' ability to respond truthfully to attacks on their products." *Id.* at 113.

The agency's regulations appear to be premised on the concept that the manufacturer is the only speaker concerning its drug product and that regulating manufacturer speech is the sole means of ensuring that physicians and consumers are fully advised about drug benefits and risks. This is largely not the case. There are myriad speakers—from medical journals to patient advocacy groups to HMO benefits managers to dietary supplement manufacturers—each of whom has differing motivations in initiating public debate concerning various prescription drugs and different messages that they would like to convey *Id*. at 12-13. Once debate is initiated by an independent third party, the First Amendment commands reliance on the clash of conflicting views rather than government regulation to establish the truth. Thus, "[it] simply serves no public health purpose to inhibit a manufacturer, who is likely to be the most knowledgeable source of scientific data concerning a particular drug, from providing useful information about the drug when that drug's utility is thrown into public controversy by a third party." *Id*. at 115.

Pfizer's proposed regulations seek to level the playing field by affording manufacturers the right to respond to independent third party statements about their products without subjecting these responses to FDA's stringent prescription drug labeling and advertising requirements. Such speech is not properly characterized as labeling or advertising because physicians will not rely on it to ascertain the operative instructions for the safe and effective use of a product. *See id*. at 71-74. Nor can the speech be deemed commercial speech. Far from doing "no more than propose a commercial transaction," such speech constitutes the same type of scientific debate that others initiated concerning a

particular drug product. *See Pittsburgh Press Co. v Pittsburgh Comm'n on Human Relations*, 413 U.S. 376, 385 (1973). As neither labeling nor advertising, but rather scientific speech, such responses should benefit from full First Amendment protection.

Pfizer has carefully crafted its proposed regulations to ensure that manufacturers cannot evade FDA's requirements by characterizing statements as responsive, when they are not or when a response is knowingly or recklessly is false. For example, where a manufacturer knows that it is making a false statement or has serious doubts about its truth, that speech remains fully subject to FDA's otherwise applicable advertising and labeling requirements. Similarly, if the agency can establish that the speech at issue is not the type of responsive speech that the proposed regulation intends to cover because, *inter alia,* it does not respond to a specific statement made by another concerning a product, is not made in reasonable proximity to the time at which the need to respond to the public criticism of the drug arises, or is disproportionate in scope and in the extent of dissemination to the initial third party statement, FDA may subject that speech to its labeling and advertising regulations. These anti-evasion principles are borrowed from the law of self-defense, and would permit the manufacturer effectively to defend its products in the crucible of public debate on the same constitutional footing as the myriad other speakers in the marketplace.

Pfizer urges the agency to consider carefully the proposed regulations and to amend its regulations and guidances to reflect the approach taken in Pfizer's proposal. By so doing, FDA will remedy the inequity that currently exists between unregulated entities, who may attack drug products at will without being subject to any speech restrictions, and manufacturers, who are arguably in the best position to disseminate information concerning their products but who,

under current regulations may risk enforcement action if their response is not tightly controlled in ways that largely dilute the force of the communication without measurably enhancing the truthfulness of the message conveyed.

Respectfully submitted,

PFIZER INC

By: /s/ George W. Evans
George W. Evans
Associate General
Counsel, Pfizer Inc
General Counsel,
Pfizer Pharmaceuticals
Group

By: /s/ Arnold L. Friede
Arnold L. Friede
Senior Corporate Counsel

Exhibit A

Pfizer's Proposed Right of Response Regulation or Guidance

NDA and IND Holder's First Amendment Right of Response

Section 202.901. Constitutional Exemption for Sponsor Responses to Public Debate.

Where the sponsor of a pending or approved NDA or IND for a prescription drug disseminates statements in response to public statements disseminated by an independent third party which concern the nature, quality, utility or characteristics of that drug, including but not limited to safety or effectiveness, FDA shall not deem those statements to be labeling or advertising as defined, respectively, in 21 U.S.C. § 321(m) and Section 202.1(1)(2) of these regulations. FDA has determined that the First Amendment bars the agency from subjecting such responsive elements of public debate to any of the requirements governing prescription drug labeling or advertising under the Federal Food, Drug and Cosmetic Act or FDA's implementing regulations.

Section 202.902. Anti-Evasion Safeguards.

(a) The exemption in Section 202.901 for responses to third-party statements shall not be used to evade independent otherwise applicable labeling and advertising requirements. In determining whether a communication is a responsive communication protected by Section 202.901, the Commissioner shall take the following factors into account:

1. Specificity. Whether the communication addresses with specificity, by identifying time and place, and, if applicable, title or subject matter of the relevant publication or utterance,

the third party statements about the nature, quality, utility or characteristics of the sponsor's drug to which it responds.

2. Necessity. Whether the communication identifies with particularity the need to respond to the relevant third party statements for the benefit of the audience.

3. Immediacy. Whether the communication is disseminated in reasonably close proximity in time to the relevant third party statement given the nature of the media utilized in responding and the requirements for advance commitments for space and the like. The need to respond may arise, *inter alia,* (a) at the time a third party statement is disseminated; (b) at the time that the sponsor reasonably learned about the statement; or (c) at the time the statement becomes a matter of serious public importance due to, for example, greatly expanded public dissemination.

4. Proportionality. Whether the scope and dissemination of the communication is proportional to the dissemination of the relevant third patty statement to which it responds. The scope of the communication is proportional if it is reasonably tailored to address the representations in the third party statement. The dissemination of the communication is proportional to the dissemination of the public criticism if the audience reach and frequency of publication of the media used to respond is comparable to the audience reach and frequency of the media used to disseminate the criticism in the first instance.

(b) A statement shall not be deemed to be covered by Section 202.901 if the Commissioner establishes that the sponsor disseminated it with actual knowledge that a representation of fact was false or with substantial awareness of its probable falsity or a serious doubt about its truth.

Authority: United States Constitution, Amendment I.

THE NEW YORK TIMES, SUNDAY, NOVEMER 10, 2002

Menopause Without Pills: Rethinking Hot Flashes

This article was reported by Gina Kolata, Milt Freudenheim and Robin Marantz Henig and was written by Ms. Kolata.

In the few months since a study of a widely used hormone regimen found that its risks outweighed its benefits, the prevailing view of menopause has undergone a momentous shift.

For decades, women have been told that the symptoms of menopause—hot flashes and night sweats as well as vaginal dryness that could make sex a painful ordeal and libido a distant memory—were burdens they should not have to bear. With hormone therapy, they would feel like the clock was turned back. At the same time, they could protect themselves against osteoporosis, and probably even reduce their risk of heart attacks and strokes.

When the study, known as the Women's Health Initiative, was halted in July, many doctors changed their message. Try to live with your symptoms, these doctors now say. Or find other ways to deal with them. And forget about using hormones solely to protect yourself from diseases; there are other, better ways.

It is an almost unheard of transformation of the medical landscape, said Dr. Barbara J. Turner of the University of Pennsylvania, who studies the pace of innovation. Doctors "turned on a dime," she said.

But it is impossible to tell how many patients turned with them, and what happened when they did.

There is no obvious pattern of responses to the new reality. In interviews, gynecologists and internists say some patients have stopped taking hormones, only to resume their use when they find symptoms intolerable. Others say most women who

stop taking the pills have little or no trouble. They note that even before the study was halted last summer, more than half of the women who started hormone therapy stopped it on their own within a few years.

Still other doctors are devising their own methods of weaning women from the drugs—suggesting they wear estrogen patches and gradually trim them down to nothing, or increase the interval between pills. In this, however, they are acting on their own. There are no practice guidelines, no rigorous studies on what works best.

Eventually, the Women's Health Initiative will have data on how its participants fared when they were advised to stop taking their hormone pills. For now, the only data come from drug company sales figures, which show that many women taking Prempro, the hormone combination made by Wyeth that was tested In the study, have stopped, their number falling to 1.5 million from 2.7 million.

But in Wyeth's loss, other companies see an opportunity. For example, sales of Evista, made by Eli Lilly & Company, rose by 24 percent in September. Evista, which can actually elicit hot flashes but protects bone, has some estrogenlike properties, but the company emphasizes that it is not a hormone.

"There's this whole open market" said Valerie Layne, a nurse practitioner at Hightstown Medical Associates, a private practice in New Jersey where she says the Eli Lilly sales representative is now a frequent visitor. "They know our alternative now is their drug," Ms. Layne said. "Even though honnone therapy may be O.K., everyone is too afraid to continue."

The Burst Bubble

The study that caused this uproar, the Women's Health Initiative, involved 16,000 women who were randomly

assigned to take either Prempro, a popular combination of estrogens and progestin, or a placebo. The researchers halted the study prematurely when the accumulating data indicated that even though hormone therapy can reduce cholesterol 1evels, women who took Prempro had slightly more heart attacks, strokes and blood clots. They also had slightly more breast cancer. These risks exceeded the regimen's benefits, of slightly less colon cancer and slightly fewer fractures.

Women who were taking Prempro were advised to stop taking the pills immediately, and the scientists said there was no reason to believe that the findings applied only to Prempro. Until proven otherwise, they said, women and their doctors should assume that all hormone therapy that involved estrogen and progestin bears the same risks.

The study did not test other hormone regimens, but many researchers say it cannot be assumed that they are any safer.

At first, many doctors, gynecologists in particular, reacted with anger and denial.

"We have had a real love affair with hormone therapy," said Dr. Susan L Hendrix, a study investigator and gynecologist at Wayne State University in Detroit. When the study said it might not be a panacea, "it was like telling someone they have an ugly baby."

Dr. Isaac Schiff, who is the chairman of obstetrics and gynecology at Massachusetts General Hospital in Boston, said it was his impression that many gynecologists were upset because their own clinical experience had told them that the drugs were a boon to women. Internists, he added, who had been prescribing hormone therapy to prevent conditions like heart disease and osteoporosis, tended to be more accepting of the study's findings.

Dr. Schiff explained: "As a gynecologist, you have a patient who comes into your office who is troubled with hot

flashes or she has severe vaginal atrophy and she says sex is not pleasurable. You prescribe hormone therapy and she comes back four months later and says, ‘Oh, doctor, I feel so much better.’ An internist does not have someone come back and say, ‘Thank you, doctor, my heart feels better.’”

Yet many gynecologists, even those who say they think hormone therapy has been demonized, say they have changed their message.

“In the old days, I used to say, ‘Look, there’s no evidence that this in going to hurt you,’” said Dr. Andrew Good, a gynecologist at the Cleveland Clinic. “Now I can't say that with the same enthusiasm.”

Dr. Jan L Herr, a gynecologist at Kaiser Permanente Medical Group in San Rafael, Calif., said the new message has meant that women have had to change their expectations of life in their middle years. She asks women who find their symptoms of menopause unbearable to try the lowest possible dose of hormone therapy, which may not rid them of their symptoms.

“They have to be satisfied with feeling better, but not perfect,” Dr. Herr said. “They had always wanted to feel perfect,” with no hot flashes, no night sweats, no vaginal dryness. “They had always said, Why should I feel like I’m 55? 1 want to feel like I’m 30.’” Now, she said, women have to get used to feeling as if they are 55.

‘Honey, It’s the Hormones’

Iretta Taylor, a customer service adviser in Houston, said she tried to live without hormone therapy but decided she would rather not.

Ms. Taylor, 49, explained: “I went into menopause at a very early age, at about 40, and it was a very bad, very emotional time. I was edgy, depressed, I thought I was having a nervous breakdown. I had hot flashes, too, and a hollow, dry look, and dryness in the vaginal area, which was no fun.

"As soon as I started taking H.R.T, it all went away," she said, referring to hormone therapy by its old name, H.R.T., for hormone replacement therapy. "A co-worker told me, 'Your skin looks so fine.' It did; I had a real glow.

"When I heard all the horror stories last summer I stopped," She said. "I didn't even call my doctor; I just stopped. Right away I started to feel bad again. I thought at first that it was psychosomatic, but then I realized, 'Honey, it's the hormones.'

"I asked my doctor, 'Please put me back on H.R.T.,' and he did." Now, she said: "I feel like a woman is supposed to feel. If they ban this in the United States, I'll drive down to Mexico to get it. That's how much I need my H.R.T.

The question is, Are women like Ms. Taylor the exception or the rule?

"It's very clear that there is some proportion of women who did not react well to cold turkey," said Dr. Marcia L. Stefanick of Stanford University, who as principal investigator for the Women's Health Initiative lectures about the study and its results. "They are very vocal. But then I ask the audience, How many of you went cold turkey and had no problem whatsoever?" She is finding that "the vast majority of women are doing fine."

Dr. Herr turns to data from the days when she and others urged all women to take hormones. After two years, she said, 80 percent were not taking the drugs—they simply stopped filling their prescriptions. That tells her, she said, that many women are not bothered by severe symptoms, or choose to live with them. Doctors, she added, are more likely to hear from the women about their difficulties, which can skew their perspective.

They may not see women like Elizabeth Benney, who is 69 and runs a horse farm in Upton, Mass. She never had a hot

flash, never had a night sweat, but started taking hormones about 15 years ago to alleviate vaginal dryness and avert osteoporosis, worried because her mother had had the disease. She feared that if her bones thinned and she was thrown from a horse, they might fracture.

Last July, "when the news came out," she said, "I decided to stop." She did so with some reluctance, worried that the vaginal dryness would return and that her skin might age without the hormones. To her surprise, nothing happened. She feels and looks fine—no different, she says, from when she was taking the pills. Her bone density is fine, she added, so she does not appear to be at risk for fractures.

Doctors say some women are remaining on estrogen because they believe it keeps their skin looking young. The studies, so far, "are not nearly as well done as one would like," said Dr. Barbara A. Gilchrest, chairman of the dermatology department at Boston University School of Medicine. But, Dr. Gilchrest said, there is credible evidence that hormone therapy can thicken skin by increasing the amount of collagen, or prevent its loss. It is not clear when questions about these or other possible uses of hormone thereapy will be answered. Some studies, like ones asking if the therapy protects against Alzheimer's disease, are continuing. But given the findings so far, there is some question whether it would be ethical to conduct studies of cosmetic uses. Many women, however, are already convinced.

"You wouldn't believe how many women want to stay on estrogen for their skin," said D. Margaret M. Polaneczky, a gynecologist at the Iris Cantor Women's Health Center in New York. "You could have an hourlong intellectual discussion about all the risks and benefits of hormone replacement therapy, about how it might be better to consider some other drugs for, say osteoporosis prevention, and you think you've both agreed. But just as you're getting ready to

write a prescription for Fosomax, she'll say, "Wait a minute—I've changed my mind, I think the estrogen is making my skin look younger, I'm going to stay on it.'"

Some can wean themselves from hormones only gradually, using schemes their doctors invented. Some doctors ask women to try doing without hormones on weekends, gradually extending the hormone-free days into the week. Others advise taking a pill every other day for a few weeks, then every third day, gradually going down to no pills at all. Dr. Hendrix prescribes hormone patches and tells women to cut them each week, snipping them down until there is nothing left.

"Is there any science to this?" Dr. Hendrix asked, "absolutely not. We're on a rapid learning curve."

The Alzhelmer's Hypothesis

Dr. Rowan T. Chlebowski of the Harbor U.C.L.A. Research and Education Institute, an investigator with the Women's Health Initiative, has been spending time talking to doctors about what the study's data mean, and how to go on from here. His experience, he says, is a window on the lingering confusion. While the initial message is clear—that women should be asking themselves why they are taking hormones rather than why they are not taking them—it is overlaid with all sorts of what if's.

What if a woman takes hormones for only a year or so and then stops? The answer is, no one knows, Dr. Chlebowski said. "lt is almost certain your risk will be reduced, but then it's a question of, well, what is the risk compared to the benefits?"

What if, doctors ask, they sit down with a woman and figure out what her risks are? They could suggest to women at risk of breast cancer or heart disease that they try to do without hormone therapy and advise that women at risk for colon cancer or osteoporosis take it.

If only it were so simple, Dr. Chlebowski said. One problem, he said, is that there is no reliable way to determine which women are at particular risk for specific diseases, whether it is breast cancer, heart disease, osteoporosis or colon cancer.

"There's a kind of assumption that a doctor can chat with you about your risk—Did your mother have a heart attack?—and that that would have an influence on what you're doing." The problem, he said, is that "our current methods don't do very well" in predicting risk.

Some doctors also wonder if there might be critical periods when estrogen might protect against heart disease, osteoporosis or Alzheimer's.

While there are drugs to protect against heart disease and osteoporosis, there is nothing yet to prevent Alzheimer's. So if the window-of-opportunity hypothesis has any urgency, it might be with that disease.

"I think it is the most compelling reason to take estrogen," said Dr. Stanley Birge, a gerontologist at Washington University in St. Louis.

But other experts say that at this point it is simply wishful thinking to say that estrogen therapy is protective, but only if it is started early. Nevertheless, some women say that for now they will accept hormone therapy's small excess risk in hopes that by starting therapy early they will gain a potentially large benefit.

The Alzheimer's hypothesis "is a supposition," said Dr. Deborah Grady, who directs the University of California San Francisco/Mount Zion Women's Health Clinical Research Center.

While some laboratory and animal studies have indicated that hormone therapy might protect brain cells, it is not clear what would be required to prevent Alzheimer's. In some

studies, like one published last week, women who were taking hormones had less Alzheimer's disease, but in others they did. Dr. Grady said that in several studies, women who took estrogen actually preformed worse on cognitive tests. But Dr. Stefanick said that until researchers completed rigorous studies asking if estrogen can protect against Alzheimer's disease, the question will linger.

THE WALL STREET JOURNAL

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HRT WORRIES GIVE HEADACHES TO DRUG MAKERS

By Vanessa Fuhrmans

IN JUST FOUR MONTHS, hormone-replacement therapy has turned from a growing business into a major headache for many drug makers.

Consider Schering AG. Just a few months ago, the German company, which had been a key player in pioneering the birth-control pill 40 years ago, had two new treatments for menopausal symptoms on course to be approved in the U.S. next year. And it was forging ahead in more experimental hormone markets, having recently acquired rights to a testosterone therapy for men.

But in July, the Women's Health Initiative, an ongoing federally funded study, announced a possible link between a popular hormone pill and heightened risk for breast cancer, heart attacks and stroke. The international storm that followed has buffeted Schering's stock price, and the company has lost more than a quarter of its market value.

In the past two weeks, the Food and Drug Administration has rejected two menopause treatments from Schering awaiting approval, setbacks that could force Schering (which isn't related to Schering-Plough Corp. of the U.S.) to conduct new studies.

"I don't want to play it down," says Schering Chief Executive Hubertus Erien. "It was a real surprise and a real disappointment."

The Women's Health Initiative study looked only at the most popular hormone replacement, Wyeth's Prempro, a drug once taken by as many as six million women. But news of possible health risks have raised questions about safety of a whole range hormone-replacement drugs. Some researchers warn that it isn't possible to rule out risks associated with short-term HRT.

This week, the U.S. Preventive Services Task Force, a medical panel that helps set federal government policy. recommended against the routine use of estrogen and progestin for the prevention of chronic post-menopausal symptoms, such as osteoporosis.

Yesterday, at a conference sponsored by the National Institutes of Health on hormone-replacement therapy, Wyeth executives called on regulators and health experts to clarify what the study's findings really mean for women in need of treatment for acute menopausal symptoms, such as hot flashes, night sweats and vaginal dryness. The company also presented data that it says show the hormone therapy's benefits outweigh the risks when it used as a short-term treatment.

"More than 85% of women who start hormone therapy seek relief from menopausal symptoms," says Victoria Kusiak, vice president of medical affairs for Wyeth. "They need to know what the results of WHI mean for them."

Other companies also have been affected by questions about health risks of hormone replacement therapy. Prescription orders for Prempro have fallen nearly 50% since July, according to NDC-Health, a health-care information-services company. Orders for Wyeth's estrogen pill, Premarin have tumbled 18%.

Many women have stopped filling prescriptions for other products too: Orders for Pfizer Inc.'s FemHRT have dropped by 13%, Solvay Pharmaceuticals' Estratest by 16% and Galen Holdings PLC's Estrace by 15%.

"Right now, everything is getting painted with the same broad brush stroke," says David Archer, professor of obstetrics and gynecology at Eastern Virginia Medical School in Norfolk, Va. Pfizer says its sales representatives have been pointing out to doctors that FemHRT wasn't used in the WHI study. Officials at Galen and Solvay couldn't be reached.

FDA also is taking a more-cautious approach to hormone-based treatments. At conference yesterday, FDA officials told drug and health-care industry officials that the WHI study would have implications for how new estrogen drugs are developed and tested.

Schering, a big player in women's health products, remains small in hormone-replacement treatments, deriving just 7% of its global sales from them. Angeliq, the Schering hormone-replacement pill that the FDA rejected last week, wasn't expected to be nearly as popular as Prempro in the U.S. market for menopausal treatments (Regulatory authorities in Europe are still reviewing it.)

Schering's popular birth-control pill, Yasmin, is based on the same kind of progestin as the one used in Angeliq. Worries that health risks could taint Yasmin have recently weighed down Schering's shares, which yesterday were trading about 30% below their 52-week high, reached June 28.

Schering won't say why the FDA withheld approval for Angeliq. But Werner-Karl Raff, head of Schering's fertility and hormone-therapy businesses, says, "It is understandable that it is difficult to assess new HRT preparations," in the new debate over such treatments. Schering says it will begin new talks with the FDA over how to address its concerns about the

hormone-replacement pill. The FDA refuses to discuss, or even acknowledge, decisions to reject new-drug applications.

Schering's Dr. Erien says despite the doubts now swirling around the safety of many hormone treatments, he is convinced hormone-replacement therapy remains a viable business, even for small players such as Schering. "Our strategy is unchanged," he says. "We want to have a greater share of that market."

Schering currently has just one hormone-replacement product on the U.S. market: Climara, an estrogen patch. This month, the FDA rejected a new version, Climara Pro, that also includes progestin, citing questions about the documentation of one of the main studies of the drug. prescriptions for Climara, with U.S. sales of $83 million, have fallen by roughly 14% in the U.S. since July.

In sales calls to doctors, Schering is stressing that its hormone products use plant-based molecules, in contrast to Wyeth's Prempro, which is derived from the urine of pregnant mares. Because HRT products made from nonanimal sources metabolize in the body differently, it's possible they contain less risk. But there aren't any studies to back up this theory.

THE STAR-LEDGER

THURSDAY, DECEMBER 12, 2002

LAWMAKERS BLAST ROCHE, FDA ABOUT ACCUTANE

By Jonathan Casiano
Star-Ledger Washington Bureau

WASHINGTON—The Food and Drug Administration and a New Jersey drug maker were sharply criticized by members of Congress yesterday for failing to tightly regulate use of the acne drug Accutane.

The medicine, produced by drug maker Hoffmann-La Roche, is known to cause birth defects and has been blamed for teenage suicides.

"The FDA's response to the birth defects and psychiatric events has been inadequate, irresponsible and unacceptable," Rep. Bart Stupak (D-Mich.) said during a hearing before the House Energy and Commerce subcommittee. "The drug manufacturer, Hoffmann-La Roche, has continued to put profits before people."

Stupak, who blames Accutane for his 17-year-old son's suicide in 2000, has led the fight against the hugely popular drug, prescribed to an average of 600,000 people each year.

Roche President and Chief Executive George Abercrombie told the congressional panel fewer prescriptions and sagging sales are evidence patients are increasingly aware of Accutane's risks.

"We have acted in a responsible manner by adopting precautionary measures to communicate psychiatric information to prescribers and patients," Abercrombie testified.

But Stupak was joined by other lawmakers expressing concern about misuse of the powerful medication.

"This drug is perhaps more dangerous to pregnant women than Thalidomide, yet women are still getting pregnant while taking it," said Rep. Peter Deutsh (D-Fla.), comparing Accutane with the notorious 1960s morning sickness pill that caused birth defects. "It's a tragedy."

Stupak claimed Accutane was the cause of more than 200 teen suicides—a figure disputed by Roche, which has its U.S. headquarters in Nutley—and at least 172 birth defects.

Along with Deutsh and other lawmakers, he called for new controls, including creation of a mandatory FDA registry that would require every patient taking Accutane and every doctor prescribing it to enter a national database so the side effects could be monitored.

Currently, participation in a pregnancy prevention and monitoring program for Accutane is voluntary. The program includes two pregnancy tests, a commitment to use contraception while on the drug, a signed letter of consent and follow-up surveys to monitor side effects. Only 43 percent of female users are fully participating in the program.

FDA officials defended their regulation of Accutane, arguing that clear warnings of possible birth defects and psychological side effects appear prominently on the front of Accutane packaging.

They also pointed out that scientific studies have yet to link Accutane to depression, suicidal thoughts or suicide.

"All the evidence (on suicides) is anecdotal," said Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research. "There is no scientific link to take this drug off the market."

Abercrombie, the Roche CEO, said his company has curtailed its aggressive advertising campaign for the drug and

distributed an extensive battery of literature for patients and doctors.

He added that Accutane is one of the few medications for any disease that requires signed consent by the patient before being prescribed.

Accutane, the brand name for isotretinonin, is the only proven treatment for very severe cases of acne, prompting many dermatologists to enthusiastically recommend it despite its side effects.

Since its inception in 1982, the drug has treated more than 13 million people and last year earned $750 million for Roche, making it one of the drug maker's top products.

During the hearing, the subcommittee also heard from patients who benefited from Accutane and from Cornell dermatologist Diane Berson, who called it a "life-changing" medicine.

"Accutane is an extremely valuable drug which I feel must remain available for dermatologists to prescribe to those patients who clearly need it," Berson said.

THE WALL STREET JOURNAL

THURSDAY, NOVEMBER 21, 2002

Tackling a Kil1er

Vaccine to Prevent Cervical Cancer Shows Promise

In Interim Test, Merck Product Blocks Key Forms of Virus That Can Lead to Tumors

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Unusual Marketing Challenges

By Gardiner Harris

Cervical cancer kills almost as many women world-wide as breast cancer. *A* vaccine under development has the potential to cut the toll steeply.

The vaccine is still in testing and wouldn't available until 2006. But a just-published study gives an indication of its power and the developer, Merck & Co., is already wrestling with tricky marketing questions the vaccine would present. They arise because for the vaccine to be most useful, politicians, bill-payers and the parents of millions of adolescent children would all need to sign on.

Most cervical cancer is caused by sexually transmitted strains of human papilloma virus, or HPV. This is an extremely common family of viruses that also causes warts on hands, feet and genitalia, in both sexes. Just two strains of HPV are believed responsible for 70% of cervical cancer. Merck's vaccine might prevent infection from those two strains.

In the study published today, about 2,400 women aged 16 to 23 who had had five or fewer sexual partners received a version of the vaccine, while others got a placebo. Seventeen

months later, 41 women who received placebos had become infected with a strain of HPV that can lead to cervical cancer. None of those who got the vaccine were infected. An accompanying editorial in the New England Journal of Medicine, which published the Merck study, said it demonstrated that "cervical HPV infection—and, by association, cervical cancer—can be prevented by vaccination."

The study was an interim one. Merck is now doing a final "Phase III" study that, if it proves both effectiveness and safety, could lead to marketing approval. Food and Drug Administration officials have told the company they want to know not only whether the vaccine blocks viral infection but also if it prevents precancerous lesions on the cervix, the kind detected by Pap tests. Meanwhile, two other groups, including the National Cancer Institute, are developing competing vaccines.

Cervical cancer kills at least 4,000 U.S. women annually and about 230,000 world-wide. The vaccines won't end the disease, not only because many women already are infected with a form of HPV that can cause cancer but also because vaccine distribution is apt to be spotty in developing countries. More than 80% of the 470,000 annual cases of cervical cancer occur in those countries. Once an HPV infection takes hold, any resulting cancer can be treated, but the viral infection itself can't be eliminated.

"Is this the end? It is not," says Martin Kast, a researcher at Loyola University in Chicago. Dr. Kast leads one of nearly 20 groups across the world that are working to create an HPV vaccine that would help those who already have cancer. Such a vaccine is many years away, Dr. Kast says.

To be most effective, an HPV vaccine would have to be given to girls before they had been exposed to the virus through sex. Thus, from a marketing perspective, the vaccine's maker could face a delicate task in persuading

parents to vaccinate their young daughters against a virus that they wouldn't be subject to until they became sexually active.

Although boys obviously aren't subject to cervical cancer, a vaccine would have greater impact if it were also given to boys, since they do get HPV and can pass it along. Most boys infected with HPV have no symptoms at all, not even genital warts. Hence another marketing challenge: Merck is concerned that it might not be easy to persuade parents to have their 10- or 12-year-old sons vaccinated.

Potential Hurdle

Even politics could pose a hurdle, some within Merck believe. Assuming marketing approval, the company would hope to get the U.S. government to pay for the vaccine as part of an existing program that now pays for half of childhood vaccines. But marketers are concerned that some conservative politicians might challenge the use of tax dollars for a vaccine that would essentially make sex safer.

HPV infection by no means dooms a woman to develop cervical cancer. It's estimated that less than 1% of women who become infected with the cancer-causing forms of the virus develop cervical cancer or a worrisome condition called "severe dysplasia." Years or decades may pass between infection and disease.

Infection is very common. One study of female students at Rutgers University in New Jersey found that 26% were already infected with HPV when they arrived as freshmen. The rate was 60% after three years of college.

Other studies have indicated that women have a 20% chance of getting an HPV infection with their first intercourse. Condoms help prevent transmission but aren't a guarantee. The virus can also be passed by simple touching.

Merck has a track record of successfully running "educational" marketing programs that boost awareness of medi-

cal problems, such as high cholesterol and osteoporosis, and then promote a Merck product as the solution. But the many questions surrounding the distribution and use of an HPV vaccine initially led some Merck executives to debate whether investing in the project made economic sense.

Having gone ahead and shown great progress, Merck now is gearing up its enormous marketing muscle to promote the HPV vaccine as a life-saver. Its thousands of salespeople would first visit pediatricians, OB-GYNs and family-practice doctors to convince them of the vaccine's importance. Then the company might begin a large advertising campaign. It would aim to see the vaccine used not only in young people, both girls and boys, but also in mature, sexually active women.

Its usefulness in such women would be less clear. Researchers have focused on four common strains of sexually transmitted HPV. Only two can lead to cervical cancer. If a woman was already infected with both, the vaccine might not help—it doesn't kill the virus. If she was infected with one of the two, vaccination could still help lower her odds of getting cancer.

Merck is formulating the vaccine to block all four of these HPV strains, partly as a way to make vaccination easier to sell to parents of young boys. Merck has indications the vaccine might be 90% effective in preventing genital warts when given to people not yet exposed.

Merck's marketing plans concern one top researcher at the National Cancer Institute. John Schiller, a senior investigator there, frets that if Merck over-sold the benefits, some women might become less vigilant about getting Pap tests, leading to missed opportunities for diagnosis. "If companies are driving the public-relations campaign, it may be difficult to point out that this vaccine is only 70% protective against cancer," Dr. Schiller says.

Working Feverishly

Merck has been working feverishly on its vaccine since 1993, two years after a researcher in Australia figured out how to construct tiny shells of the virus that would fool the body into attacking the virus. By then, teams from the National Cancer Institute and MedImmune Inc., a Maryland biotechnology company, were already working to develop HPV vaccines.

The study published today shows Merck has leapfrogged both competitors. Dr. Schiller estimates that Merck is at least a year ahead of his effort and that of MedImmune. GlaxoSmithKline PLC, which licensed the MedImmune program, declines to comment except to say its vaccine is in Phase II trials, which gauge dosage and give some indication of effectiveness. Though the study published today was also a Phase II study, Merck is now well along in the final Phase III efficacy test needed for marketing approval.

Researchers observed more than 100 years ago that prostitutes had very high rates of cervical cancer, leading to speculation that a sexually transmitted virus caused it. In the mid-1970s, a German researcher isolated HPV in cancerous tissue.

Merck had no plan to use the HPV virus itself in a vaccine. Not only can even a killed virus occasionally prove dangerous, but this virus is all but impossible to grow in a test tube. Researchers have found that the shell of a virus will do just as well in gearing up the immune system for a fight.

A researcher named Kathrin Jansen began Merck's program in early 1993, surreptitiously working on HPV because she was discouraged with her other work. "It really got started under the radar," she says. She asked a Merck yeast expert, Loren Schultz, if he could coax yeast into making HPV shells.

The decision to use yeast would prove crucial. MedImmune and the NCI both used host cells derived from butterfly caterpillars. While those were easier to use in small quantities, they are very hard to use in large-scale manufacturing.

The two scientists picked apart the genetic code of HPV-11, a strain that commonly causes genital warts. Using the Australian work as a guide, they figured out that a particular sequence of the code created the virus's protein shell. They stuck that sequence onto the genetic code of baker's yeast, added sugar and waited.

Nothing happened. "We might have gotten discouraged at that point if we hadn't had a lot of experience with yeast," said Dr. Schultz.

But Merck has a library of many strains of baker's yeast, developed over decades and used by the company to make a hepatitis-B vaccine. Dr. Schultz knew that yeast strains all behave differently. The huge yeast library would prove a boon to Merck's effort.

Dr. Jansen also needed to choose what forms of HPV to tackle. There are nearly 100 strains in all, a third of which can be sexually transmitted. Researchers had discovered that HPV-16 and HPV-18 were the most common causes of cervical cancer. Two others, HPV-6 and HPV-1I, were thought to cause most genital warts.

Dr. Schultz now struggled to coax his yeast into growing the shells of all four strains—hitting a brick wall with one strain. Meanwhile, Dr. Jansen wanted to do a quickie test to see if an HPV vaccine could work, so she tried vaccinating cottontail rabbits against an HPV-like wart. The rabbits didn't get warts.

It was time to decide whether to start tests in humans—a hugely expensive undertaking. She brought her results to

Edward Scolnick, Merck's chief of research. He figured the science made sense and Dr. Jansen had the grit to get the project done, so he approved spending the money.

Now Merck's yeast experts had to figure out a way to grow huge quantities of HPV shells. That proved another big technical hurdle, which another Merck yeast expert, Hugh George, finally solved. Even when he did, shells for three of the four HPV strains came out mangled, "like goofed-up balls" instead of geometric gems, as one researcher put it. Only when they applied salt and acid did the balls, made up of 72 different proteins, reorganize themselves into the proper shape.

Merck believes its vaccine can not only block cervical cancer but also prevent genital warts in boys. But it hasn't yet figured out how to prove this, because of the difficulty of collecting tissue samples. For girls, a Pap test is enough. In boys, Merck found it has to use something akin to a nail file to get enough skin cells for a proper lab sample. "We had a team meeting and I asked everybody how we could get good samples from men, and the room cleared out pretty quickly, " says Dr. Jansen. "I gave my husband some tools. He never could get a good sample, and he wouldn't let me try."

THE WALL STREET JOURNAL

WEDNESDAY, NOVEMBER 20, 2002

Stents May Become Useful Tool In the Prevention of Strokes

Procedure That Catches Loosened Plaque Is Crucial To the Carotid Treatment

By RON WINSLOW

CHICAGO—Stents, the tiny metal devices that have transformed treatment of heart patients, could become an important tool in preventing strokes, a new study suggests. But the study points up the importance of using tiny filterlike devices in conjunction with the stents in stroke prevention.

Currently, about 200,000 patients a year undergo a surgical procedure on neck arteries called carotid endarterectomy. The procedure aims to avert a potential stroke by clearing out obstructions in the artery that transports blood to the brain. But the operation itself comes with significant risk of complications, and researchers have been seeking safer and more effective ways to remove the blockages.

In the new study, headed by Jay S. Yadav, of the Cleveland Clinic, 307 patients with severe blockage in their carotid arteries were randomly assigned to getting the experimental stent procedure or the operation. The patients had additional health problems that significantly increased their risk of complications from either procedure.

Importantly, the stent, a wire-mesh scaffold that resembles a ballpoint pen spring, was combined with a small, umbrella-like filter device that doctors deployed downstream of the blockage to capture any debris that became dislodged during the placement of the stent.

In both the surgical and stent procedures, the effort to treat the artery can cause small particles of disease-causing plaque to break off and get carried with the blood into the brain where they can cause strokes and other problems.

The study found that after 30 days, nine, or 5.8% of the 156 patients assigned to the stent and filter device either died or suffered a heart attack or stroke. That compared with 19, or 13%, of the 151 patients who had the surgery, a relative reduction of 54%.

Dr. Yadav presented the results at the annual scientific meeting of the American Heart Association here. Johnson & Johnson's Cordis unit, which markets a variety of stents and is developing a filter called Angioguard, sponsored the study. Angioguard isn't yet on the market. Several other companies, including Guidant Corp. are developing similar devices for use in the carotid arteries.

In the experimental procedure, the filter is deployed first, threaded into the carotid artery in a closed position past the blockage and then opened. Subsequent placement of the stent often causes a "cheese-grater" effect that can dislodge bits of the plaque. That is what the filter basket is intended to capture. "We saw visible particles in 80% of these filters," Dr. Yadav said. While that raises the possibility that a clogged filter could block or slow necessary blood flow to the brain during the procedure, Dr. Yadav said that wouldn't likely cause a major problem. Deploying the stent—the step that is most likely to lead to the debris breaking off—comes at the end of the procedure, so the doctor can quickly retrieve the basket and restore normal blood flow with little risk of adverse consequences, he said,

"The contribution of the protection device would appear to be an important part of the study," said Sidney Smith, cardiologist at University of North Carolina at Chapel Hill and chief science officer of the American Heart Association.

The results were "impressive," he added, but said both longer follow-up data from this trial and other studies of lower-risk patients are needed to determine how widely the technique might be used.

Dr. Yadav described the 30-day findings as preliminary and said the plan is to follow patients for one year. The type of high-risk patients included in the study account for about one-third of those who undergo carotid endarterectomy each year. Other studies, including one sponsored by Guidant, are exploring whether carotid stenting will prove beneficial for lower-risk patients.