United States Court of Appeals
for the First Circuit

No. 00-2425

PHILIP MORRIS, INC., ET AL.,
Plaintiffs-Appellees,
v.
THOMAS F. REILLY, Attorney General of Massachusetts, et al.,
Defendants-Appellants.

No. 00-2449

UNITED STATES TOBACCO COMPANY, ET AL.,
Plaintiffs-Appellees,
v.
THOMAS F. REILLY, Attorney General of Massachusetts, et al.,
Defendants-Appellants.

On Appeal from the United States District Court for the District of Massachusetts

BRIEF AMICI CURIAE IN SUPPORT OF DEFENDANTS-APPELLANTS REQUESTING REVERSAL

SUBMITTED BY PUBLIC CITIZEN, INC., NATIONAL CENTER FOR TOBACCO-FREE KIDS, AMERICAN CANCER SOCIETY, AMERICAN COLLEGE OF CARDIOLOGY MASSACHUSETTS CHAPTER, AMERICAN COLLEGE OF CHEST PHYSICIANS, AMERICAN COLLEGE OF PHYSICIANS-AMERICAN SOCIETY OF INTERNAL MEDICINE, AMERICAN HEART ASSOCIATION, AMERICAN LUNG ASSOCIATION, AMERICAN MEDICAL ASSOCIATION, AMERICAN PUBLIC HEALTH ASSOCIATION, AMERICAN SCHOOL HEALTH ASSOCIATION, AMERICAN THORACIC SOCIETY, MASSACHUSETTS MEDICAL SOCIETY, AND THE NATIONAL ASSOCIATION OF LOCAL BOARDS OF HEALTH

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CORPORATE DISCLOSURE STATEMENT

The undersigned, counsel of record for Amici Curiae, states the following, in compliance with Federal Rule of Appellate Procedure 26.1:

(1) Parent Corporations of Amici Curiae: None.

(2) Publicly held companies that own 10 percent or more of the stock of Amici Curiae: None.

Date: February 8, 2001

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CERTIFICATE OF COMPLIANCE WITH RULE 32(a)(7)(B)

The following brief complies with the type volume limitation of Federal Rules of Appellate Procedure 29(d) and 32(a)(7)(B). According to the word-processing system used to prepare the brief (WordPerfect 7), the brief contains 6,966 words, exclusive of the table of contents, table of authorities, statement of identity and interest of amici curiae, and certificates of counsel.

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RULE 29(c)(3) STATEMENT OF IDENTITY AND INTEREST OF AMICI CURIAE

Each of the following Amici Curiae shares a common interest in supporting the Massachusetts ingredient disclosure requirement, Mass. Ann. Laws ch. 94, § 307B, in order to inform regulators, the scientific and public health communities, and consumers of the absolute risks of using tobacco products and the relative risks presented by specific tobacco brands. Amici have moved for leave to file this brief pursuant to Federal Rule of Appellate Procedure 29(b).

Amicus American Cancer Society (ACS) is the world's largest voluntary health organization with a membership of 2.2 million, including over 50,000 physicians, nearly all of the leading oncologists in the United States, and many victims of tobacco-caused cancer and their family members. ACS has representation in every state and 3,400 units located throughout the United States and is dedicated to the control and elimination of cancer through research, education, advocacy, and service. ACS has been a leader in research on the relationship between tobacco and cancer, and it devotes substantial resources to research, public education, and direct service to those suffering from cancer caused by tobacco. ACS joins this brief on behalf of the National Home Office of the American Cancer Society and its New England Division.

Amicus American College of Cardiology (ACC) Massachusetts Chapter is a professional society of 415 cardiovascular specialists. The mission of the Massachusetts Chapter of the ACC is to support quality cardiovascular care in Massachusetts, to become the voice of cardiology in the state, and to advance the interests of Massachusetts' cardiologists, their patients, and the community at large.

Amicus American College of Chest Physicians' (ACCP) mission is to promote the prevention and treatment of diseases of the chest through leadership, education, research, and communication. ACCP is the leading resource for the improvement in cardiopulmonary health and critical care worldwide. ACCP has nearly 15,000 members in over 100 countries worldwide who specialize in various multidisciplinary areas of chest medicine.

Amicus American College of Physicians-American Society of Internal Medicine (ACP-ASIM) is the nation's largest medical specialty organization and the

second largest physicians group. Its mission is to enhance the quality and effectiveness of health care by fostering excellence and professionalism in the practice of medicine. ACP-ASIM membership includes more than 115,000 internal medicine physicians and medical students.

Amicus American Heart Association (AHA) is the largest voluntary health organization fighting heart disease, stroke, and other cardiovascular diseases, which annually kill approximately 950,000 Americans. Nationwide, its organization has grown to include more than 22.5 million volunteers and supporters who carry out its mission in communities across the country. Tobacco use prevention remains a top priority for the Association. More than 400,000 people die each year from smoking-related diseases, nearly half of which are tobacco-related cardiovascular diseases.

Amicus American Lung Association (ALA) is the nation's oldest voluntary health organization, with over 400,000 volunteers and affiliates in all 50 states, the District of Columbia, Puerto Rico, and the Virgin Islands. Because cigarette smoking is a major cause of chronic obstructive lung disease, ALA has long been active in research, education and public policy advocacy on the adverse health effects of tobacco products.

Amicus American Medical Association (AMA), with a membership of more than 280,000 physicians, is the largest private nonprofit organization of physicians in the United States. The AMA's mission is to promote the science and art of medicine and the betterment of the public health. The AMA has long opposed tobacco use based on the massive body of scientific evidence that tobacco is

addictive and kills smokers. The AMA appears as a representative of the Litigation Center of the American Medical Association and the State Medical Societies. The Litigation Center is a coalition of the AMA and 50 state medical societies, organized to represent the interests of organized medicine in the courts.

Amicus American Public Health Association (APHA) is a national organization devoted to the promotion and protection of personal and environmental health. Founded in 1872, APHA is the largest public health organization in the world, representing over 50,000 public health professionals. It represents all disciplines and specialties in public health. APHA passed comprehensive policy calling for full authority of the Food and Drug Administration to regulate tobacco and all tobacco products. APHA continues to advocate for this and other national tobacco control measures to protect the public's health from the adverse effects of tobacco products.

Amicus American School Health Association (ASHA) unites the many professionals working in schools who are committed to safeguarding the health of school-aged children. The Association, a multi-disciplinary organization of administrators, counselors, dentists, health educators, physical educators, school nurses, and school physicians, advocates high-quality school health instruction and health services, and a healthful school environment.

Amicus American Thoracic Society (ATS), founded in 1905, is an independently incorporated, international professional and scientific society which focuses on respiratory and critical care medicine. The ATS has approximately 13,500 members. The Society's members help prevent and fight respiratory disease around the globe, through research, education, patient care and advocacy.

Amicus Massachusetts Medical Society (MMS), founded in 1781, is the oldest continuously operating medical association in America, with more than 17,000 physician and student members. It is purposed by its charter "to do all things as may be necessary and appropriate to advance medical knowledge, to develop and maintain the highest professional and ethical standards of medical practice and health care, and to promote medical institutions formed on liberal principles for the health, benefit and welfare of the citizens of the commonwealth." The Society, in the interest of patients and public health, has actively supported efforts to regulate tobacco.

Amicus National Association of Local Boards of Health (NALBOH) represents the interests of local boards of health throughout the United States and assists them in assuring the health of their communities. NALBOH is recognized as the national voice of local boards of health and an important partner in this country's public health system. NALBOH was developed to provide a national

voice for the concerns of local boards of health and to assist local boards of health in obtaining the knowledge, skills, and abilities necessary to protect and promote public health in their communities.

Amicus National Center for Tobacco-Free Kids (NCFTFK) works to protect minors from tobacco by raising awareness that tobacco is a pediatric disease, changing public policies to limit the marketing and sales of tobacco to children, and altering the environment in which tobacco use and policy decisions are made. NCFTFK has over 100 member organizations, including health, civic, corporate, youth, and religious groups dedicated to reducing children's use of tobacco products.

Amicus Public Citizen, Inc. is a consumer advocacy organization representing the interests of its approximately 150,000 members who believe that tobacco products should be subject to regulation, including a requirement that tobacco manufacturers disclose brand-specific information regarding their products' ingredients.

ARGUMENT

Approximately 50 million Americans smoke cigarettes and another six million use smokeless tobacco. Regulation of Cigarettes and Smokeless Tobacco Under the Federal Food, Drug, and Cosmetic Act, 61 Fed. Reg. 44,396, 44,398 (Aug. 28, 1996) (hereinafter "FDA Regulation"). Tobacco use is the single leading cause of preventable death in the United States. More than 400,000 people die each year from tobacco-related illnesses, such as cancer, respiratory illnesses, and heart disease. *Id.*

Of course, that cigarettes kill has been understood for more than thirty-five years. *See* U.S. Dep't of Health, Educ. & Welfare, Report of the Advisory Comm. to the Surgeon General, *Smoking and Health* (1964). What is less appreciated is how little the public knows about the ingredients that are added to cigarettes and smokeless tobacco and how these ingredients escape any form of oversight or regulation. Many of these additives, when burned, may lead to the formation of carcinogens or interact with nicotine to enhance addictiveness. U.S. Dep't of Health & Human Servs., *Reducing Tobacco Use: A Report of the Surgeon General* 182 (2000) (hereinafter "Surgeon General Report 2000"). Non-tobacco ingredients may be added to the tobacco blend or to the reconstituted tobacco sheet during manufacture, as well as to the cigarette paper and filter. John Slade, M.D. & Jack E. Henningfield, Ph.D., *Tobacco Product Regulation: Context and Issues,* 53 Food

& Drug L.J. 43, 47 (1998) (hereinafter "Slade & Henningfield"). Additives are used for a wide variety of purposes, not all of which are known by the general public. "They might prolong shelf life (humectants), make the smoke milder and easier to inhale (sugars and humectants), add flavor and aroma, improve the delivery of nicotine (ammonia compounds), and numb the throat (menthol and eugenol)." Stanton A. Glantz, et al., *The Cigarette Papers* 211 (1996) (hereinafter "*Cigarette Papers"*).

While every cookie, can of soup, or soft drink on a grocer's shelf includes ingredients approved as safe for use by the FDA and comes complete with a label detailing its ingredients in order of predominance, 21 U.S.C. § 343(i); 21 C.F.R. § 101.4, additives in tobacco products have not been subjected to a pre-market approval process, safety testing, or even the simple requirement of disclosure by product brand. Instead, federal law requires only disclosure to the Secretary of Health and Human Services of an aggregate list of all ingredients used in cigarettes and smokeless tobacco products, without differentiation by brand or company. 15 U.S.C. § 1335a; 15 U.S.C. § 4403. These aggregate lists, which the Secretary is prohibited from sharing with the public, § 1335a(b)(2)(a); § 4403(b)(2)(a), contain almost 600 possible ingredients. Even when periodically released to the public by the tobacco companies, the lists are of little use to scientists, legislators, and the

consuming public in determining which additives, or combinations of additives, are toxic when smoked or inhaled, interact with nicotine to increase the addictiveness of the product, or present other health hazards. The aggregate lists are notable for one reason only: they confirm that there is no "secret ingredient" the revelation of which is threatened by the Massachusetts law here.

What the Massachusetts law adds that is significant to the public is a requirement that the tobacco companies divulge *which* combinations of ingredients are included in *which* brands. Mass. Ann. Laws ch. 94, § 307B. Because, in contrast to foods and drugs, tobacco additives have undergone no scientific scrutiny, outside testing, or regulatory approval process to assure their safety, the Commonwealth's interest in promulgating this ingredient disclosure requirement is compelling.

It is undisputed that submission of brand-specific ingredient information to the Massachusetts agency would effect no taking. In fact, the tobacco companies already provide the same information to the state of Texas. *See* Tex. Health & Safety Code § 161.352. The only question, as the district court acknowledged, is whether a taking would arise "when and if the DPH makes trade secret information available for public disclosure." *Philip Morris Inc. v. Reilly,* 113 F. Supp. 2d 129, 138 (D. Mass. 2000). While we do not yet know which ingredients the state

agency would release to the public—a gap that suggests this case is not ripe for disposition—it is the amici's view that even if the district court's assumption is correct that Massachusetts would disclose the ingredient information in its entirety, such disclosure would not constitute a compensable taking. By finding a taking in such circumstances, the district court subverts the principle recognized by the Supreme Court for more than eighty years, that "a manufacturer or vendor has no constitutional right to sell goods without giving to the purchaser fair information of what it is that is being sold." *Corn Prods. Refining Co. v. Eddy,* 249 U.S. 427, 431 (1919).

Whether or not a brand-specific list of ingredients in tobacco products is deemed a trade secret, the Commonwealth may exercise its police power to require disclosure to a state agency and, ultimately, to the public, to enable the scientific and public health communities to evaluate the risks presented by these ingredients and help the consuming public to make informed decisions regarding whether and what to smoke. The district court's decision not only invalidates a state statute that furthers the public health imperative favoring disclosure of the same information for tobacco that is supplied by every other manufacturer of an ingestable product, but the court's logic threatens to unravel decades of public health and safety laws that demand disclosure of product ingredients and other health and safety

information—regardless of alleged trade secret claims.

As this brief is filed on behalf of public health organizations, it will focus on the public health justifications for brand-specific ingredient disclosure and leave the more comprehensive legal argument to the Massachusetts Attorney General.

I. MASSACHUSETTS HAS AN IMPORTANT HEALTH AND SAFETY INTEREST IN REQUIRING THE DISCLOSURE OF BRAND-SPECIFIC TOBACCO INGREDIENT INFORMATION.

The district court seriously underestimated the full weight of the Commonwealth's interest in obtaining brand-specific ingredient information for cigarettes and smokeless tobacco products. *See* 113 F. Supp. 2d at 151. As its significance bears on the takings analysis that follows, amici will address here the Commonwealth's overwhelming interest in the submission and public disclosure of this ingredient information.[1]

A. The Absence of Information About Tobacco Product Ingredients

Just how little we know about the constituents of cigarettes is staggering, especially considering their deadliness. For twenty years, the Surgeon General has

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[1] This discussion is also relevant for purposes of determining whether, under the Commerce Clause, "the burden" imposed on tobacco manufacturers is "clearly excessive in relation to the putative local benefits" of the regulation. *See Pike v. Bruce Church, Inc.,* 397 U.S. 137, 142 (1970).

emphasized the need for information about cigarette additives so that the health community could evaluate their relative risks:

> A final question is unresolved, whether the new cigarettes being produced today introduce new risks through their design, filtering mechanisms, tobacco ingredients, or additives. The chief concern is additives. The Public Health Service has been unable to assess the relative risks of cigarette additives because information was not available from manufacturers as to what these additives are.

U.S. Dep't of Health & Human Servs., *The Health Consequences of Smoking: The Changing Cigarette: A Report of the Surgeon General* vi (1981) ("Surgeon General Report 1981"); *see also id.* at 17, 25, 52, 60 (expressing need to evaluate flavorings added to low tar, low nicotine cigarettes to determine the health effects of these additives).

Though twenty years have passed, the Surgeon General's "chief concern" is still unresolved. As discussed in the Surgeon General's most recent report, when consumers purchase a tobacco product, "they receive little information regarding the ingredients, additives, or chemical composition in the product." Surgeon General Report 2000, at 18. It remains the case that "[a]dditives to tobacco products are of uncertain safety when used in tobacco." *Id.* at 23. To make matters worse, the popularity of low tar and nicotine brands has shown that consumers may be misled by "the implied promise of reduced toxicity underlying the marketing of

these products." *Id.* at 18; *see also id.* at 23 ("Without information about toxic constituents in tobacco smoke, the use of terms such as 'light' and 'ultra light' on packaging and in advertising may be misleading to smokers."). Regrettably, the Surgeon General concludes, "[k]nowledge about the impact of additives is negligible and will remain so as long as *brand-specific information on the identity and quantity of additives is unavailable*." *Id.* (emphasis added).

The aggregate list of ingredients supplied by tobacco manufacturers is inadequate to inform either the public health community or consumers of the absolute risks of smoking and the relative risks presented by various tobacco brands. Cigarette manufacturers are not required to report or include on product labels brand-specific information about the presence, content, or levels of nicotine, ammonia, pesticide residues, heavy metals (such as lead, cadmium, mercury, or chromium), or sugar in the material added to tobacco, or the presence of known or suspected carcinogens, such as benzene or nitrosamines, in the smoke. *Id.* at 179.

B. Reasons for Requiring the Disclosure of Brand-Specific Ingredient Information

The Commonwealth has several important justifications for demanding brand-specific ingredient disclosures—interests that are not served by relying solely on aggregate ingredient lists.

First, disclosure of brand-specific ingredient information is necessary to enable the Commonwealth to evaluate (and disclose to the public) the toxicity of tobacco additives when burned and inhaled, particularly in combination with other additives in the brand. The burning of additives may lead to the formation of carcinogens. For example, amino acids commonly used as additives form compounds, when heated, that include genotoxic agents (known to damage DNA) and carcinogens. Surgeon General Report 2000, at 182; The American Health Foundation, *Comments on Tobacco Additives* 1 (1990) (hereinafter *"AHF Comments"*). Various plant extracts used as flavoring agents may form toxic or carcinogenic agents during smoking. Licorice root extract, for example, contains glycyrrhizin; both are used as cigarette additives. Glycyrrhizin produces carcinogenic byproducts when burned. The leukemia-producing agent benzene is a component of cigarette smoke that may be formed from the combustion of many cigarette additives. *AHF Comments,* at 2-3; Surgeon General Report 2000, at 182. Methyl salcylate, another additive, is teratogenic (causing defects in fetuses) when given to hamsters and rats. Menthol may accelerate the activation of tobacco carcinogens. *AHF Comments,* at 2.[2] *See generally Cigarette Papers,* at 211-25

[2] A quick search of the National Toxicology Program database, http://ntp-server.niehs.nih.gov/Main_Pages/Chem-HS.html (last visited Feb. 4, 2001), reveals that any number of the 599 cigarette additives can pose serious

(discussing tobacco industry's use and abandonment of various additives, many of which are toxic or carcinogenic).

In releasing the aggregate list of 599 cigarette ingredients in 1994, the tobacco companies tried to mute safety concerns by suggesting that many additives, though by no means all, are "generally recognized as safe" ("GRAS") by the FDA, 21 U.S.C. § 321(s). The GRAS designation refers only to a food additive generally regarded as safe "under the conditions of its intended use," *id.*—that is, ingested as part of a food. Cigarette additives, of course, are burned and inhaled. As the Surgeon General warns, "that a material is regarded as safe when ingested in foods provides no assurance of its safety in a tobacco product, where it will be combined with other substances, heated to high temperatures, and may be inhaled into the lungs." Surgeon General Report 2000, at 182; *accord AHF Comments,* at 3.

The medical literature suggests that even the most seemingly innocuous food

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health risks when burned and inhaled. For example, valeric acid "is extremely destructive to the mucous membranes, upper respiratory tract, eyes and skin." "When heated to decomposition it emits toxic fumes." Benzaldehyde "causes central nervous system depression in small doses and convulsions in larger doses." "The vapor may cause lung injury." Argenine, when heated to decomposition, "emits toxic fumes." The chemical "3, 4-xylenol," a possible tumorigenic agent, "is highly toxic by inhalation, ingestion or skin absorption. It is corrosive and extremely destructive to tissue of the mucous membranes, upper respiratory tract, eyes and skin."

additives—cinnamon and nutmeg, for example, both of which are GRAS—can pose serious health hazards when smoked. According to a Center for Disease Control study, cinnamon and nutmeg contain alkenylbenzenes. The authors of the study were able to quantify several alkenylbenzenes and piperonal, another cigarette flavorant, in several U.S. cigarette tobaccos. Stephen B. Stanfill & David L. Ashley, *Quantitation of Flavor-Related Alkenylbenzenes in Tobacco Smoke Particulate by Selected Ion Monitoring Gas Chromatography—Mass Spectrometry,* 48 J. Agric. Food Chem. 1298, 1298-99 (2000). These compounds have acute toxic and carcinogenic properties. *Id.* at 1299.[3] Yet, the study observes, "[p]resently, very little is known about the extent to which alkenylbenzenes are transferred into mainstream cigarette smoke and the chronic health effects associated with their repetitive, long-term inhalation." *Id.* While reverse engineering a cigarette to determine its chemical constituents, as the authors did here, may be scientifically feasible (thereby undermining the tobacco companies' claims of trade secret protection), it is an inefficient and expensive way to determine the overall and relative health risks posed by tobacco products.

Second, the health community and the public need specific additive

[3] Significantly, the authors note that the toxic properties of eugenol, one type of alkenylbenzene, are 250 times greater in rodents when inhaled than when eaten. *Id.* at 1299.

information so that they can evaluate how tobacco product additives interact with nicotine to affect the "impact" and addictiveness of these products. "The use of additives may reinforce cigarette smoking by strengthening the addictive effects of nicotine." Surgeon General Report 2000, at 182. As is now well known, the tobacco industry uses ammonia to alter the pH of nicotine, converting it from a "bound" to a "freebase" form. Freebase nicotine more readily enters the smoke stream and has been predicted to cross lung and oral cavity membranes more quickly than nicotine in its bound form. *Id.* The FDA documented this manipulation of pH levels in its 1996 regulation, both for cigarettes, *see* FDA Regulation, at 44,946, 44,951, 44,966, 44,970-75, and smokeless tobacco, *see id.* at 45,108-09, 45,114; *see also The Control and Manipulation of Nicotine and Cigarettes: Hearing Before the Subcomm. on Health and the Environment, Committee on Energy and Commerce,* 103d Cong. (1994) (statement of Dr. David A. Kessler, FDA Commissioner). Indeed, the industry views ammonia technology as "the soul of Marlboro" and the "key factor" that "makes Marlboro a Marlboro." FDA Regulation, at 44,971.

Although ammonia has received the greatest attention, it is not the only culprit. Tobacco companies use other additives to enhance nicotine effects as well. *See* Clive Bates, et al., *Tobacco Additives: Cigarette Engineering and Nicotine*

Addiction, Action on Smoking and Health 11-14 (July 14, 1999), *at* http://www.ash.org.uk/html/regulation/html/additives.html (hereinafter "ASH") (discussing the pharmacological effects and synergistic interactions among acetaldehydes (produced by burning sugars), levulinic acid (cigarette additive), theobromine (contained in cocoa, a cigarette additive), glycyrrhizin (cigarette additive and found in licorice, another cigarette additive), and pyridine (cigarette additive)). State regulators and the consuming public alike are entitled to know which brands use additives to manipulate the intake and impact of nicotine.

Significantly, the FDA found, this "use of chemical manipulation to boost free nicotine levels may raise the amount of nicotine delivered to the smoker *without a corresponding increase in nicotine yield,* as measured by the FTC smoking machine. Thus, the actual nicotine delivery to the smoker from some brands may be higher than the FTC yield because of the addition of ammonia or similar compounds to increase free nicotine." *Id.* at 44,974 (emphasis added). Hence the district court's suggestion that Massachusetts does not need brand-specific ingredient information because consumers already can compare brands based on tar and nicotine labeling, 113 F. Supp. 2d at 151 n.37, falls wide of the

mark.[4] A recent study highlights the drawbacks in relying on tar and nicotine labeling alone. An international comparison of three major brands illustrates that it is the constituents of cigarettes or smoke that are *not* regulated or subject to public disclosure that may vary the most, presenting serious hidden health hazards.[5] Accordingly, "the tobacco industry argument that its ratings at least provide comparative information for making cigarette brand choices is flawed." Slade & Henningfield, at 50.

Third, the tobacco manufacturers use additives to make it easier to start and more difficult to quit using their products. The industry uses flavorings like cocoa, sugars, and licorice to mask the bitterness or harshness of nicotine, *see* FDA Regulation, at 45,083-84, thereby making it easier to begin smoking cigarettes. Similarly, sweeteners and flavorings such as cherry juice concentrate, apple juice, chocolate liqueur, and honey are used in smokeless tobacco products to "increase palatability and . . . intensify use of smokeless tobacco, at least among novices."

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[4] For various other reasons, the FTC test is unable to measure effectively the actual consumption of tar and nicotine by smokers, and thus tar and nicotine labeling is of questionable use. *See Federal Trade Commission Report to Congress for 1998* 3-4 & n.4 (issued 2000); Surgeon General Report 2000, at 184.

[5] *See* Nigel Gray, et al., 9 Tobacco Control 351 (2000) (testing Camel, Lucky Strike, and Marlboro in 29 countries and finding consistent levels of tar and nicotine conforming to package labeling, but three-to-ninefold variations in the undisclosed carcinogenic nitrosamine yields).

Surgeon General Report 2000, at 183-84; *see also* ASH, at 3-4, 15.[6]

Additives make it more difficult to quit smoking by facilitating the manufacture of low tar, low nicotine cigarettes, which lure smokers—who might otherwise quit—into a false sense of security that they are using a safer product. Many low tar cigarettes contain flavoring agents and additives to replace the flavor lost by reducing tar levels. Federal Trade Commission, *Staff Report on the Cigarette Advertising Investigation* 1-54 (1981). The increased use of additives in these purportedly safer products may prove counterproductive. As the Surgeon General Report noted twenty years ago, "the increasing use of additives for tobacco processing or flavoring," some of which "are either known or suspect carcinogens or give rise to carcinogenic substances when burned," may "negate beneficial effects of the reduction of 'tar' yield, or might pose increased or new and different disease risks." Surgeon General Report 1981, at 8.

Additives are used to facilitate the illusion of a healthier product. "Available evidence indicates that smoking lower-tar and nicotine cigarettes only minimally reduces smokers' health risks." Slade & Henningfield, at 53. Nonetheless, it

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[6] Relatedly, additives are used to hide sidestream smoke, which may increase non-smokers' involuntary exposure to environmental tobacco smoke by reducing the normal warning signs of exposure to smoke toxins. Gregory N. Connolly, et al., *How Cigarette Additives are Used to Mask Environmental Tobacco Smoke,* 9 Tobacco Control 283, 290 (2000).

appears that many smokers of low-tar cigarettes have used these brands instead of quitting. *Id.*; Surgeon General Report 2000, at 184. As two commentators have observed: "The incentive of manufacturers is not to make their cigarettes safer . . . but to make their cigarettes *seem* safer." Jon D. Hanson & Kyle D. Logue, *The Costs of Cigarettes: The Economic Case for Ex Post Incentive-Based Regulation,* 107 Yale L.J. 1163, 1190 (1998) (emphasis added).

The required disclosure of ingredients in specific tobacco brands represents an important first step. Armed with ingredient information, Massachusetts could subject the new data to scientific evaluation and testing. The Commonwealth could begin with the most popular cigarette and smokeless tobacco brands, or those with the greatest appeal to underage users. Such testing could lead the state to work with the tobacco companies to eliminate certain toxic additives or additives that increase addictiveness, while setting tolerances for others. *See* Slade & Henningfield, at 67-68 (proposing possible additive controls to make cigarettes safer); Surgeon General Report 2000, at 182 (noting that the British government maintains a list of "permitted" or "approved" additives and specifies the maximum level permitted for each specific additive).

This is not to understate the Commonwealth's interest in making ingredient information available for public disclosure—the real issue in this case. As the

Supreme Court has recognized, "public disclosure can provide an effective check on the decisionmaking processes [of the regulatory agency] and allows members of the public to determine the likelihood of individualized risks peculiar to their use of the product." *See Ruckelshaus v. Monsanto Co.,* 467 U.S. 986, 1016 (1984). Now that it is clear that the FDA has no statutory authority to regulate tobacco or its additives, *see FDA v. Brown & Williamson Tobacco Corp.,* 529 U.S. 120 (2000), and that there is no federal preemption, *see Philip Morris Inc. v. Harshbarger,* 122 F.3d 58 (1st Cir. 1997), Massachusetts should be free to require the tobacco companies to disclose the ingredients that comprise their harmful products.

II. THE MASSACHUSETTS INGREDIENT DISCLOSURE REQUIREMENT DOES NOT EFFECT A "TAKING."

Even if brand-specific lists of tobacco additives were trade secrets under Massachusetts law before enactment of the ingredient disclosure requirement, there is no dispute that the Commonwealth is free to alter its trade secret laws, subject to any limitations that the United States Constitution may impose.[7] In this instance, the Takings Clause does not bar the Commonwealth's refinement of the protection it accords proprietary information. Regardless of whether the ingredient information merits trade secret protection, the Supreme Court's decision in *Monsanto* and eighty years of case law that preceded it establish that the disclosure requirement does not effect a taking.

A. The Ingredient Disclosure Requirement is Analogous to the Portions of FIFRA Upheld in *Ruckelshaus v. Monsanto*.

In *Monsanto,* the Court considered the constitutionality of the disclosure requirements imposed by the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") and the takings implications for health, safety, and environmental data

[7] We are skeptical regarding whether Massachusetts law—or any other law—affords trade secret protection to entire lists of brand-specific ingredients in hazardous consumer products, especially where, as here, disclosure of actual product formulas, the proportion of each ingredient to the others, the quantities of ingredients used, or the process by which a brand is manufactured is not required. Knowing the ingredients in a cake does not mean one knows how to bake a cake.

submitted by Monsanto to federal agencies during three different regulatory regimes. As is the case with the Massachusetts disclosure law, FIFRA imposed the various health and safety disclosure requirements as a condition of doing business.

Only with respect to data submitted during the one time period, 1972-1978, during which the federal government had made an "explicit governmental guarantee" of confidential treatment for the data, did the Court find a taking, because that guarantee had formed the basis of a reasonable investment-backed expectation of confidentiality. *Monsanto,* 467 U.S. at 1010-11. For the pre-1972 period, when FIFRA was silent with respect to public disclosure, *id.* at 991, and the post-1978 period, when FIFRA provided for the disclosure of all health, safety, and environment data to qualified requesters *notwithstanding* the statute's general prohibition against disclosure of trade secrets, *id.* at 995-96, the Court found no taking. During those periods, Monsanto could have had no reasonable expectation that submitted data would remain confidential. *Id.* at 1006-09.

The *Monsanto* Court accepted as a given the power of government "to regulate the marketing and use of pesticides," for "such restrictions are the burdens we all must bear in exchange for 'the advantages of living and doing business in a civilized community.'" *Id.* at 1007 (quoting *Andrus v. Allard,* 444 U.S. 51, 67 (1979)) (citation and internal quotation marks omitted). The Court found this to be

"particularly true in an area, such as pesticide sale and use, that has long been the source of public concern and the subject of government regulation." *Id.*[8] Accordingly, the Court concluded:

> as long as Monsanto is aware of the conditions under which the data are submitted, and the conditions are rationally related to a legitimate Government interest, a voluntary submission of data by an applicant in exchange for the economic advantages of a registration can hardly be called a taking.

Id.[9]

Like Monsanto, the tobacco companies are now on notice of the conditions under which they continue to market and sell their brands in Massachusetts. The state's interest in obtaining the information is plainly legitimate. *See Philip Morris*

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[8] The Court's recognition that the police power extends to public disclosure of health and safety data alleged to enjoy trade secret protection is not new. In a long line of cases, the Court has recognized that "[t]he right of a manufacturer to maintain secrecy as to his compounds and process must be held subject to the right of the state, in the exercise of its police power . . . to require that the nature of the product be fairly set forth." *Corn Prods. Refining Co. v. Eddy,* 249 U.S. 427, 431 (1919) (upholding state law requiring labeling of the percentage of each ingredient of table syrup), *cited with approval in Monsanto,* 467 U.S. at 1007; *accord National Fertilizer Ass'n v. Bradley,* 301 U.S. 178, 182 (1937) (upholding state law that required labeling identifying each material, and the amount, used in the manufacture of fertilizer mixtures); *see also Savage v. Jones,* 225 U.S. 501 (1912).

[9] Significantly, the 1978 disclosure requirement applied to data with respect to any "registered or previously registered pesticide." 7 U.S.C. § 136h(d). Hence, the prospective disclosure requirements the Court upheld governed not only to new products, but to those that had been previously marketed.

Inc. v. Harshbarger, 122 F.3d 58, 67 (1st Cir. 1997) (recognizing that the Massachusetts Disclosure Act "comfortably falls within the 'health and safety' realm of traditional state police powers").

B. Application of the Particular Factors Identified in *Monsanto* Demonstrates That There is No Taking Here.

Apart from the obvious comparison to the 1978 FIFRA amendments, consideration of the three factors identified in *Monsanto,* "the character of the governmental action, its economic impact, and its interference with reasonable investment-backed expectations," 467 U.S. at 1005; *see also Penn Central Transp. Co. v. City of New York,* 438 U.S. 104, 124 (1978), demonstrates that the ingredient disclosure law here falls comfortably within the state's police powers and does not constitute a compensable taking.[10]

1. The Character of the Governmental Action

The powerful health and safety justifications for requiring disclosure of

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[10] As discussed in the Massachusetts Attorney General's brief and the amicus brief submitted on behalf of Environmental Defense *et al.*, the Court's subsequent land use decisions in *Dolan v. City of Tigard,* 512 U.S. 374 (1994), *Lucas v. South Carolina Coastal Council,* 505 U.S. 1003 (1992), and *Nollan v. California Coastal Comm'n,* 483 U.S. 825 (1987), do not affect the continued vitality of the *Monsanto* analysis as it applies to government-mandated disclosure of trade secrets.

brand-specific ingredient information are set forth above in Part I. As the Supreme Court has recognized, a taking may more readily be found when the interference with property "can be characterized as a physical invasion by government, than when interference arises from some public program adjusting the benefits and burdens of economic life to promote the common good." *Penn Central,* 438 U.S. at 124. Here, of course, there is no physical invasion; the Commonwealth "has taken nothing for its own use." *Connolly v. Pension Benefit Guar. Corp.,* 475 U.S. 211, 224 (1986). Instead, the Commonwealth has undertaken to regulate in a modest way an undisputedly unsafe product marketed to its citizens. *See Keystone Coal Ass'n v. DeBenedictis,* 480 U.S. 470, 488 (1987) (no taking where Pennsylvania acted "to protect the public interest in health, the environment, and the fiscal integrity of the area"); *Mugler v. Kansas,* 123 U.S. 623, 669 (1887) (power of the States to regulate to protect "the health, the morals, or the safety or the public" cannot be "burdened with the condition that the State must compensate . . . individual owners" for the loss of the ability to make "a noxious use of their property").

To require compensation in circumstances such as these, where the government seeks to regulate a consumer product that is demonstrably unhealthful, "would effectively compel the government to regulate by *purchase.*" *Andrus v.*

Allard, 444 U.S. 51, 65 (1979) (rejecting takings challenge to a ban on the sale of parts of certain birds).

2. Reasonable, Investment-Backed Expectations

The district court erred in concluding that the tobacco companies had a reasonable, investment-backed expectation in the perpetual secrecy of their products' ingredients. *See* 113 F. Supp. 2d at 144. Instead, here, as in *Monsanto,* the tobacco companies' lack of reasonable investment-backed expectations of secrecy for their ingredients conclusively disposes of their takings claim.

In contrast to the intervening 1972-1978 period under FIFRA, Massachusetts law has *never* guaranteed confidential treatment for information regarding the constituents of tobacco products. The period preceding the enactment of the ingredient disclosure law in 1996 resembled the pre-1972 period under FIFRA: in both instances, the law was silent regarding the treatment of health-related data concerning the products.

The 1996 Massachusetts disclosure law ended that silence, requiring the prospective disclosure of tobacco ingredient information for brands sold in the state. After enactment, the tobacco companies, like Monsanto after 1978, can claim no reasonable expectation that the state would accord confidential treatment

to tobacco product ingredient information. *Id.* at 1006; *accord New Jersey State Chamber of Commerce v. Hughey,* 600 F. Supp. 606, 627-28 (D.N.J.) (mandated disclosure of trade secrets under the Right to Know Act effected no taking because "there has been no antecedent period of disclosure during which the state committed itself to protecting trade secrets"), *aff'd in relevant part,* 774 F.2d 587 (3d Cir. 1985).

The district court reasoned, however, that unlike the regulatory scheme addressed by *Monsanto,* the Massachusetts disclosure law conferred no benefit on tobacco manufacturers and imposed "only burden." 113 F. Supp. 2d at 144. That logic is flawed. Both the post-1978 FIFRA and the disclosure requirement here provide the same "benefit" to manufacturers—the right to continue to do business in the jurisdiction. More to the point, *Monsanto* did not uphold the 1978 FIFRA amendments because they offered some quid pro quo to pesticide manufacturers, but because the burden to disclose previously secret health and safety data was an appropriate one to "bear in exchange for 'the advantage of living and doing business in a civilized community.'" *Monsanto,* 467 U.S. at 1007 (citations and internal quotation marks omitted).

It is difficult to see how the manufacturers of a deadly consumer product can claim any reliance interest in the continued confidentiality of their brands'

ingredients. That numerous federal laws require disclosure of ingredients in food, alcohol, drugs, and hazardous products is potent evidence that the mandated disclosure of the same information for tobacco products, whether trade secrets or not, does not give rise to a compensable taking. *See, e.g.,* Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 343(i) (requiring labeling of ingredients in food), § 352(e) (same for drugs); Federal Meat Inspection Act, 21 U.S.C. § 601(n)(9) (same for meat); Poultry Products Inspection Act, 21 U.S.C. § 453(h)(9) (same for poultry); Federal Alcohol Administration Act, 27 U.S.C. § 205(e) (requiring labeling regarding "the identity and quality of the products," alcoholic content, and "net contents of the package"); *see also Northwest Coalition for Alternatives to Pesticides v. Browner,* 941 F. Supp. 197 (D.D.C. 1996) (rejecting takings claim based on trade secrets and ordering EPA to identify ingredients of six pesticides, including inert ingredients).[11]

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[11] In addition, myriad federal laws require or authorize the public disclosure of trade secrets when health and safety concerns are at stake. *See, e.g.,* 15 U.S.C. § 2217(4) (authorizing Secretary of Commerce to disclose trade secrets regarding fire safety and prevention to the public when "necessary in order to protect health and safety"); 49 U.S.C. § 1114(b) (authorizing the National Transportation Safety Board to disclose trade secrets relating to its crash investigations "to protect health and safety"); 15 U.S.C. § 2613(a)(3) & (b) (requiring public disclosure of trade secrets regarding toxic substances when "necessary to protect health or the environment against an unreasonable risk of injury to health or the environment," while treating a broad range of health and safety data as presumptively subject to disclosure).

The tobacco companies point out, however, that the FDCA exempts "flavorings" and "spices" from the food labeling requirement, *see* 21 U.S.C. § 343(i), as if to suggest that federal law protects the identity of "flavorings" in food, and thus state law should similarly protect tobacco additives. The comparison is misleading. While Congress saw no need to require their identification on food labels, Congress did not exempt flavorings and spices from the rigorous pre-market approval regime that governs all foods. No flavoring or spice that is a "food additive," 21 U.S.C. § 321(s), may be used in food until its use or intended use has been approved by the FDA, *see* 21 U.S.C. § 348, or demonstrated to be "generally recognized . . . to be safe under the conditions of its intended use." § 321(s). The pre-market approval process for food additives and the standards governing substances "generally recognized as safe" are the subject of extensive regulation. *See* 21 C.F.R. parts 170-180 (food additives), parts 182, 184, 186 (GRAS).[12] The absence of similar regulatory oversight for tobacco constituents is all the more justification for the Massachusetts requirement that the tobacco companies at least disclose the ingredients comprising a particular

[12] Similarly, the FDCA requires the disclosure of "active" and "inactive" ingredients on drug labels, but exempts from disclosure certain "inactive" ingredients that are trade secrets. 21 U.S.C. § 352(e)(1)(A). Nevertheless, new drugs undergo a rigorous pre-market testing and approval process that requires disclosure of all components of the proposed new drug. 21 U.S.C. § 355(b).

cigarette brand.

The tobacco companies also argued in the district court that many federal health and safety disclosure statutes, including the FDCA, protect trade secrets from disclosure, and hence the Massachusetts ingredient disclosure law goes too far. Yet even those health and safety federal statutes that include protection for trade secrets define confidential information narrowly so as either to mandate disclosure when health and safety are at risk or to protect only manufacturing "methods," "processes," or "formulas."[13] Ingredients are not "methods" or "processes," and the Massachusetts law requires no submission of brand formulas.

Finally, the federal government regulates several facets of the tobacco industry, undermining still further any expectation by the tobacco companies that they may continue to market their deadly products without any increase in their

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[13] *See, e.g.,* FDCA, 21 U.S.C. § 331(j) (barring disclosure of "any method or process" entitled to trade secret protection); Toxic Substances Control Act, 15 U.S.C. § 2613(b) (protecting manufacturing "processes" and data disclosing the "portion" of the mixture comprised by any of the mixture's chemical substances); FIFRA, 7 U.S.C. § 136h(d)(1) (protecting manufacturing and quality control processes, unless disclosure is "necessary to protect against an unreasonable risk of injury to health or the environment"); Clean Water Act, 33 U.S.C. § 1318(b) (making effluent data public unless it would divulge "methods or processes" entitled to trade secret protection); National Safe Drinking Water Act, 42 U.S.C. § 300j-4(d)(2) (requiring disclosure of the level of contaminants in drinking water notwithstanding the statute's general protection of trade secrets); Clean Air Act, 42 U.S.C. § 7414(c) (making pollution information public unless it would divulge "methods or processes" entitled to trade secret protection).

burdens of disclosure. Indeed, in urging the Supreme Court to reject the FDA's assertion of regulatory authority, the industry cited the wealth of tobacco-specific statutes as evidence that Congress did not provide a role for the FDA. *See, e.g.,* Brief for Respondent R.J. Reynolds Tobacco Co. at 35-37, *FDA v. Brown & Williamson,* 529 U.S. 120 (2000) (No. 98-1152); *see also* Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92; Public Health Cigarette Smoking Act of 1969, Pub. No. 91-222; Comprehensive Smoking Education Act, Pub. L. No. 98-474; Comprehensive Smokeless Tobacco Health Education Act of 1986, Pub. L. No. 99-252. That Congress, to date, has not enacted a brand-specific ingredient disclosure law for tobacco products does not give the tobacco companies an entitlement to continued immunity from the obligations imposed on every other purveyor of consumer products. *See Keystone Coal Ass'n v. DeBenedictis,* 480 U.S. 470, 488 (1987) ("The Subsidence Act is a prime example that 'circumstances may so change in time . . . as to clothe with such a [public] interest what at other times . . . would be a matter of purely private concern.'") (citation omitted). Instead, Congress's failure to impose such a requirement is all the more reason for this Court to permit the Massachusetts program to go forward.

Because both the federal government and the states are governed by the Takings Clause, the district court's determination that the Massachusetts ingredient

disclosure law effects a taking is particularly troubling because it threatens to unravel most, if not all, federal (not to mention state) health and safety disclosure regimes, such as those cited above. All of these regulatory schemes "involve[] the adjustment of rights for the public good," *Andrus v. Allard,* 444 U.S. 51, 65 (1979), and impose burdens "in exchange for the ability to market" consumer products, *Monsanto,* 467 U.S. at 1007, with no other benefit to the manufacturer. The district court's ruling is tantamount to a declaration that all federal and state laws regulating foods, drugs, and hazardous products effect a taking because they mandate the disclosure of trade secrets without a quid pro quo for the manufacturers. The ruling cannot stand.

3. The Economic Impact of the Governmental Action

The district court erred again when it determined that the economic impact of the Commonwealth's ingredient disclosure law compelled a finding of a compensable taking. *See* 113 F. Supp. 2d at 143-44. At most, however, the disclosure law forces the companies to part with "one strand"—if that—of their bundle of property rights involving the manufacture and sale of tobacco products.

We are skeptical regarding the apocryphal picture the tobacco companies paint as to the likely economic impact of the ingredient disclosure requirement.

Not only does the demand for cigarettes and other tobacco products remain high because smokers are by and large addicted to nicotine, but three companies control the bulk of the market. At most, competitive pressures may persuade the tobacco companies to reformulate their products to remove the most noxious additives. That result would be to the public good.

The tobacco companies cannot evade the state's established authority to regulate or remove particular strands in a bundle of property rights, in the interests of health and safety, by depicting the companies' alleged right of secrecy in their ingredient information not as a single strand, but as their entire bundle of rights. The Supreme Court's decision in *Allard* refutes that characterization of the deprivation. There the Court upheld a ban on the sale of parts of birds protected by federal statutes, even with respect to birds killed before they came under the protection of federal law. In finding no taking, the Court reasoned that the challenged regulations did not "compel the surrender" of the bird parts themselves and involved "no physical invasion or restraint upon them." 444 U.S. at 65. Though it was undeniable that the regulations prevented "the most profitable use" of the challengers' property, that consideration was not dispositive. The Court concluded that "[a]t any rate, loss of future profits—unaccompanied by any physical property restriction—provides a slender reed upon which to rest a takings

claim." *Id.* at 66.

Similarly, the Massachusetts law does not restrain the tobacco manufacturers from making use of the ingredient information; the companies can and undoubtedly will continue to market their brands even after disclosing the ingredients. As the Court recognized, "At least where an owner possesses a full 'bundle' of property rights, the destruction of one 'strand' of the bundle is not a taking, because the aggregate must be viewed in its entirety." *Id.* at 65-66; *see also Keystone,* 480 U.S. at 496-97 (rejecting effort by coal mine operators to "narrowly define certain segments of their property" and then assert that the Subsidence Act denied them economically viable use of those segments) (citing *Penn Central Transp. v. City of New York,* 438 U.S. 104, 130-31 (1978)).

But even if state regulation enacted to protect the health and safety of the public rendered the tobacco companies' brands worthless—certainly not the case here—such a regulation would not amount to a taking. *See Lucas v. South Carolina Coastal Council,* 505 U.S. 1003, 1027-28 (1992) ("'And in the case of personal property . . . [the property owner] ought to be aware of the possibility that new regulation might even render his property economically worthless . . . ."); *Mugler v. Kansas,* 123 U.S. 623 (1887) (upholding Kansas' alcohol prohibition law even though it substantially diminished the value of the beer manufacturers'

breweries). As one court has recognized, "a regulation requiring the disclosure even of formula or process information as a precondition for the sale of hazardous products . . . would be valid." *United Steelworkers of Am. v. Auchter,* 763 F.2d 728, 741 (3d Cir. 1985).

* * *

In short, the Takings Clause poses no obstacle to the Commonwealth's exercise of its police power to do what states traditionally do—protect the health and safety of its citizens through appropriate regulation. The absence of federal preemption and FDA regulatory authority is all the more reason to permit Massachusetts the flexibility to demand the same ingredient information furnished by every other manufacturer of a food, drug, or dangerous consumer product.[14]

[14] At the very least, the district court's injunction is overbroad because it forbids the transmittal of the ingredient information to the Commonwealth itself and assumes that every conceivable future public disclosure by the Commonwealth would involve trade secrets. Under any standard, the district court's injunction cannot be sustained.

CONCLUSION

For the reasons stated above, and by the Massachusetts Attorney General in his brief, this Court should reverse the judgment of the district court.

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that on this 8th day of February, 2001, she caused to be served two copies of the foregoing "Brief Amici Curiae in Support of Defendants-Appellants Requesting Reversal" by United States first-class mail upon the following counsel for the parties in the case:

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