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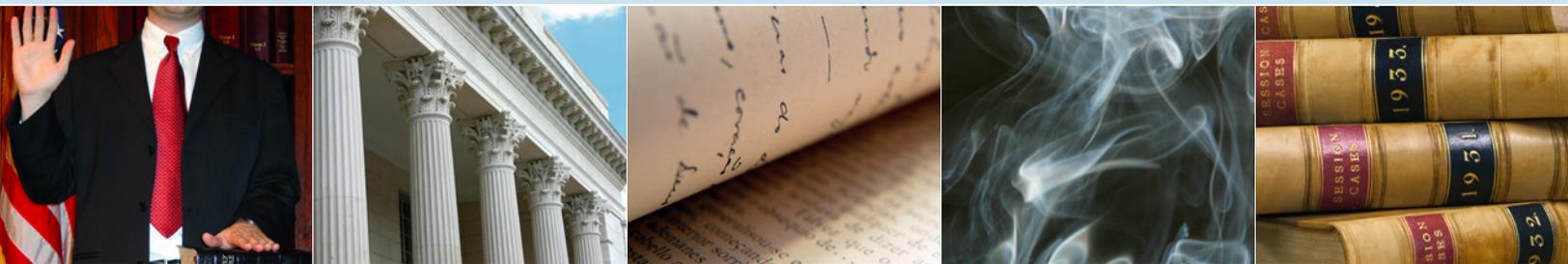
Racketeers at the Table

How the Tobacco Industry is Subverting the
Public Health Purpose of Tobacco Regulation

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Tobacco Control
Legal Consortium



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Racketeers at the Table

How the Tobacco Industry is Subverting the Public Health Purpose of Tobacco Regulation

Desmond Jenson

The Family Smoking Prevention and Tobacco Control Act of 2009 (Tobacco Control Act) grants the U.S. Food and Drug Administration (FDA) unprecedented authority to regulate tobacco products. This law mandates that the FDA act “for the protection of the public health.”¹ This unique mandate requires the FDA to consider tobacco’s broad impact on the health of our society in promulgating new regulations that will not just mitigate past damage but improve public health.

However, even with that clear mandate, the FDA has treated the tobacco companies the same way that it treats the public health community, as stakeholders in the regulatory process.² This approach may work with other regulated industries, but tobacco manufacturers are a different breed entirely. Tobacco manufacturers create and sell products that — when used as directed — cause illness and death in both the users and bystanders. This puts the industry at odds with the FDA’s mandate to protect public health. They cannot be considered good faith participants in a process meant to protect the public health when doing so goes against the industry’s interest in selling deadly products. This is especially clear given the amount of time, energy and money they have spent hiding the truth about their products and fighting regulations that have attempted to reduce the damage caused by tobacco.

It is important to remember that the nation’s largest tobacco companies have been found liable of violating federal racketeering statutes by engaging in a systematic, long-term strategy to mislead the public about the dangers of their products.³ In *U.S. v. Philip Morris*, the court identified seven pillars of fraud perpetuated against the American people. The industry was found to have deceived the public and the

Key Points

- The tobacco industry has a decades-long history of hiding the truth about the harmful effects of its products by attempting to cast doubt on scientific evidence linking tobacco use and disease and death, disseminating industry-sponsored junk science to rebut meaningful evidence, and concealing any internally conducted studies that could be harmful to its image and the sale of its products.
- When public health advocates push for stringent regulation of tobacco, the industry has responded by attempting to divide the public health community, attack sources of funding for advocacy groups, and portray advocates as greedy proponents of frivolous lawsuits.
- From the moment federal tobacco regulation became a possibility, the industry poured resources into fighting it. Once the Tobacco Control Act passed, the industry tried unsuccessfully to block the Act’s implementation and it has continued to contest all significant FDA action, while repeatedly attempting to use the Act as a weapon to fight local regulation.
- The FDA’s default position inadvertently provides more access to the regulatory process for the tobacco industry than for the public health community. While the Tobacco Control Act has tremendous potential to mitigate the damage caused by tobacco use, the FDA could be doing much more to engage the public health community.

government with respect to: industry marketing to youth, the health effects of smoking, the health effects of secondhand smoke, the addictive properties of nicotine, industry manipulation of nicotine levels, the invention and marketing of so-called “light” cigarettes, and the industry’s suppression of truthful information. By holding the tobacco companies liable for violating federal racketeering statutes due to their massive conspiracy to deceive the public, the tobacco companies have been forever branded as racketeers.

The federal regulatory process allows for participation from all members of the public and this means that despite the decades of deception perpetuated by the industry, the FDA cannot prevent the industry racketeers from participating in the formal regulatory process. However, by

naming the tobacco industry a stakeholder and continually inviting the industry to participate in various formal and informal FDA activities, the FDA is deferring to the industry more than legally necessary. Elevating the tobacco industry to stakeholder status undermines the regulatory process and invites weak and ineffective regulations due to an overwhelming tobacco industry presence in the regulatory process.

The Tobacco Control Act provides tremendous potential to address the past and ongoing damage that the tobacco industry has done to public health. To maximize the potential benefits of the Tobacco Control Act, both the FDA and the public health community need to be aware of the industry’s tactics and take steps to minimize industry subversion of the regulatory process.

I. The Public Health Standard

The Food, Drug and Cosmetic Act provides established standards for the regulation of food, drugs, devices and other products over which the FDA has regulatory authority. The regulation of food and drugs focuses on ensuring that consumers receive the benefits of the products without being exposed to unnecessary and unregulated risks. For food, the FDA must ensure that food is safe, wholesome, sanitary, and properly labeled.⁴ For drugs, the FDA must ensure that drugs are safe and effective.⁵ Tobacco is different from food and drugs in that it is an inherently deadly product and thus clearly not safe. Cigarette smoking kills over 400,000 Americans each year,⁶ and is the single largest cause of preventable death and disease in the U.S.⁷ Nor is tobacco effective (other than at killing more than half of its users).⁸ Because tobacco is neither safe nor effective, and because it has no health benefits, only risks, federal food and drug standards simply will not work for the regulation of tobacco products.

Thus, Congress had to develop a new standard for FDA regulation of tobacco products, the

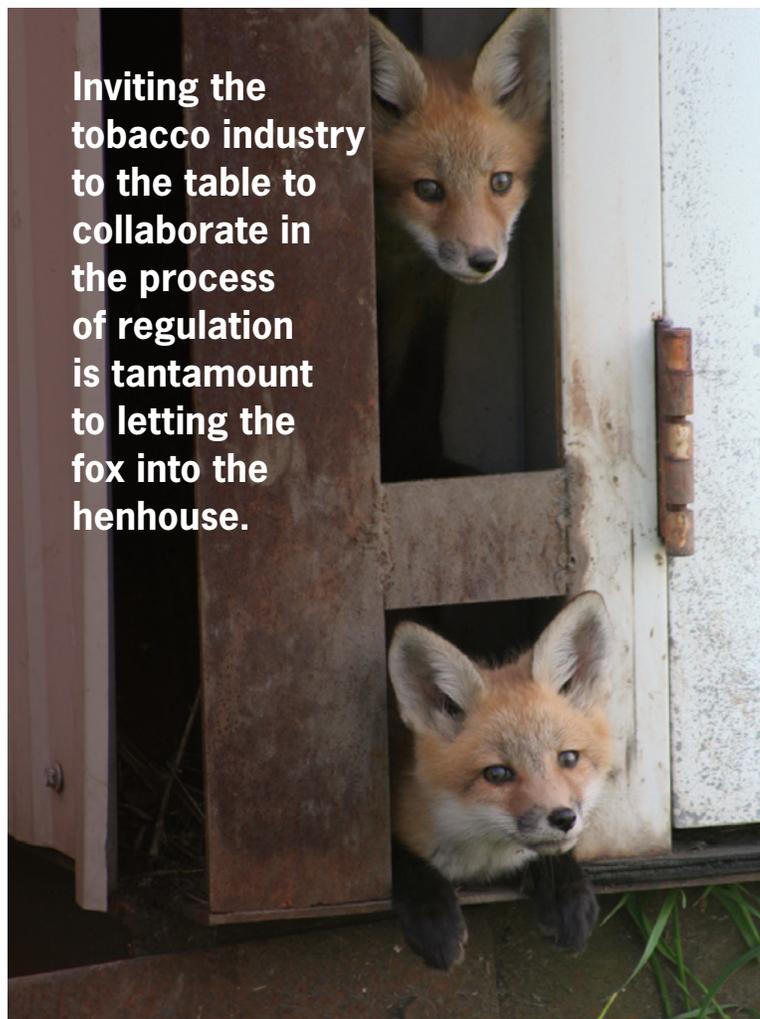
public health standard.⁹ Rather than focusing on the safety of the individual, Congress established a standard that focuses on tobacco’s effect on the entire population. Under this standard, the FDA must consider three factors when regulating tobacco: 1) the risks and benefits to the population as a whole, including users and nonusers of tobacco products; 2) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and 3) the increased or decreased likelihood that those who do not use tobacco products will start using such products.¹⁰ This comprehensive public health standard can be a very powerful tool for the FDA, permitting the agency to not just mitigate the ongoing damage caused by tobacco use, but also to prevent future harm. The FDA can implement stringent product and manufacturing standards and ensure that new products inflict less harm on the public’s health. The FDA is also empowered to promulgate regulations that prevent youth from starting smoking, help tobacco users quit tobacco, and protect non-users from health hazards like secondhand smoke.

II. The Tobacco Industry's Interests and Behavior Prevent Any Meaningful Participation in the Regulation of its Products

As part of its broad mandate to improve the regulatory process by collaborating with a variety of groups including the regulated industry,¹¹ the FDA has named the tobacco industry a stakeholder in tobacco regulation,¹² and in doing so has far exceeded the statutory mandate of collaboration. In the process of regulating food, drugs and devices, it is common practice for the FDA to include the regulated industry as a stakeholder. The food, drug, and device industries have a vested interest in creating products that are safe and effective; their businesses suffer from damaging publicity and litigation when their products harm the health of even a relatively small number of customers. As a result, these industries may have an interest in sharing valuable information with the FDA and a desire to collaborate with the FDA to create fair and efficient regulations that protect the health and safety of the users of regulated products.

The tobacco industry, however, is a different animal entirely, with interests that are inconsistent with the public health objectives the FDA must try to achieve. The tobacco industry's products are inherently harmful and the industry's ability to maintain a customer base depends both on the addictiveness of its products and its continued efforts to obscure the full scope of the adverse health effects associated with tobacco use. This means that the tobacco industry's interests are necessarily opposed to any tobacco product regulation that addresses the agency's public health goals of increasing cessation and decreasing initiation.

Moreover, the tobacco industry racketeers have demonstrated that their only interest in participating in the federal regulation of tobacco products is to minimize any decrease of their profits. This is evident from the tobacco industry's long record, described below, of defrauding the government and the public about the health effects and addictiveness of its products, as well as evading any meaningful regulation by weakening the tobacco control community and manipulating the regulatory process. Inviting the tobacco industry to the table to collaborate in the process of regulation is tantamount to letting the fox into the henhouse.



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A. Industry History of Deception Regarding Dangers of Smoking

The connection between smoking and cancer was known to the tobacco industry as early as 1953;¹³ however, as late as 2000, the industry still actively denied that smoking created any adverse health effects.¹⁴ Throughout the latter half of the 20th century, the industry “mounted a coordinated, well-financed, sophisticated public relations campaign to attack and distort the scientific evidence demonstrating the relationship between smoking and disease.”¹⁵

To deceive the public about the health effects of smoking, the tobacco industry had to ensure that its internal studies would never be seen by the public. Even as the industry was publicly denying any link between tobacco and disease, its scientists were well aware of the damage that tobacco causes. One tactic to suppress the truth was to use lawyers to oversee tobacco research studies¹⁶ and to scrub reports of any information that might be useful to opponents.¹⁷ By eliminating keywords like “cancer,” “safer,” “addictive,” or “disease,” and using code words like “zephyr” in place of “cancer,” the industry’s lawyers were able to prevent documents from being subject to legal discovery at trial.¹⁸ The use of lawyers to filter scientific documents also allowed the industry to justify nondisclosure by shielding the documents behind attorney-client privilege.¹⁹ Additionally, the tobacco industry regularly destroyed potentially damaging documents rather than allow them to be revealed in court.²⁰

In addition to preventing its own studies of the health effects of tobacco to be released, the tobacco industry also went to great effort to generate junk science to minimize the dangers of smoking and counter the public release of legitimate research documenting tobacco-related disease and death. In the 1970s, an internal memo by executives at the Tobacco Institute (TI), a front group created by the tobacco companies, proposed that TI actively generate

and advertise data that could be used to support industry-friendly hypotheses, in order to curb the decline in public opinion of tobacco products.²¹ Specifically, the memo proposed a new scientific study that could be reviewed by industry allies in the federal government and released, “hopefully [to be] published by a legitimate house.”²² The executives hoped that the conclusions of the industry-friendly study could then be marketed in magazines, television, radio and newspapers.²³ The industry believed that such exposure would have a positive effect because “it would only have to be seen — not read — to be believed.”²⁴

To execute this new strategy, the tobacco companies needed a scientific hypothesis that would cast doubt on the inherent health dangers of cigarettes. Fred Panzer, a tobacco executive who was not a scientist, identified two possibilities. The first, the “Constitutional Hypothesis,” would claim that there were important differences between people who chose to smoke and people who did not, and these differences in “heredity, in constitutional makeup, in patterns of life, and in the pressure under which they live” were the cause of disease and death, not their use of tobacco.²⁵ The second hypothesis, the “Multifactorial Hypothesis,” would claim that new scientific advances identified sources of disease other than smoking, such as “air pollution, viruses, food additives, occupational hazards and stresses.”²⁶

The tobacco industry also formed multi-company research centers to further its agenda of casting doubt on the health effects of smoking under the guise of scientific study. In 1954, the tobacco industry formed the Tobacco Industry Research Committee (TIRC) with the stated purpose of funding independent scientific research to determine whether a link exists between smoking and cancer.²⁷ However, internal industry documents reveal that the actual purpose was to improve the public image of the tobacco companies.²⁸ In 1964, the year of the landmark Surgeon General’s Report on Smok-

ing and Health, TIRC changed its name to the Council for Tobacco Research (CTR). CTR awarded millions of dollars in research grants to fund scientists, creating a pool of candidates who could serve as industry witnesses in lawsuits or represent the industries' interests in the legislative process.²⁹

CTR also stepped in to fund a longitudinal study of the health effects of tobacco when the National Heart Institute and the American Medical Association discontinued funding in 1970.³⁰ The Framingham Study, as it came to be known, had provided a wealth of information on the connection between coronary heart disease and smoking. The study was only able to continue with funding from the tobacco companies but once they had control of the study, the tobacco companies conditioned the funding on producing results that were favorable to the tobacco companies.³¹ The tobacco companies also assigned their own scientists to review the study's data and question the results in various scientific journals. By the end of the study, tobacco company scientists had been able to cast enough doubt on the link between smoking and heart disease that the popular press reported on the controversy.³²

Additionally, the tobacco companies formed the Center for Indoor Air Research (CIAR) to study indoor air issues, including secondhand smoke.³³ However, CIAR spent more time and money focusing on non-tobacco indoor air pollutants to draw attention away from the dangers of secondhand smoke. The studies of secondhand smoke that were funded by CIAR focused on exposure to secondhand smoke rather than the damaging health effects.³⁴ These studies were used by the industry to argue that exposure levels of secondhand smoke are not enough to create a risk of disease even though the actual rates of disease were not studied.³⁵

As a part of the Master Settlement Agreement and individual state settlements that were signed in the late 1990s, the tobacco companies were

forced to stop industry-wide collaboration and disband CTR, TI, CIAR and other front groups. However, while this ended the overt collaboration within the industry, it did not end the tobacco industry's scientific misinformation campaign. Each company instead pursued its agenda separately. Philip Morris aligned itself with the Life Sciences Research Office (LSRO).³⁶ Originally established to research medical issues for the U.S. Army, LSRO began reviewing cigarette additives and potentially reduced-risk tobacco products in 2001.³⁷ LSRO created expert panels to study both of these topics. Of the panel members assigned to study cigarette additives, seven of fifteen had direct financial ties to Philip Morris and two additional members had indirect, non-financial ties.³⁸ A similar association was created between the Institute for Science and Health (IFSH) and British-American Tobacco and Brown & Williamson Tobacco (now a part of R.J. Reynolds).³⁹ Between 2002 and 2004, IFSH granted \$3.9 million to study biomarkers of tobacco smoke exposure, tobacco harm reduction and the toxicity of tobacco constituents.⁴⁰ In addition, 97% of all funds granted by IFSH between 2001 and 2005 supported tobacco industry research.⁴¹

The tobacco industry racketeers have an extensive, documented history of not only covering up damaging scientific data, but also of generating or soliciting data that would distract the public from the clear evidence that tobacco use causes disease and death.

B. Industry History of Attempting to Subvert the Tobacco Control Community

In the early 1990s, the tobacco companies realized that public knowledge of the dangers of tobacco use was not necessarily their greatest foe. As evidence of the health effects of tobacco use mounted, public attitudes had shifted and the industry could no longer fight the problem with junk science and deception. Philip Morris specifically recognized this transformation and it believed that this social norm change "may prove

our biggest challenge.”⁴² In order to curb the delegitimization of tobacco use, Philip Morris developed seven strategies, collectively known as “Project Sunrise.”⁴³ One strategy in particular, “Fair Play,” was intended to divide the tobacco control community into groups that would be willing to work with Philip Morris and those that would not, weakening the movement as a whole.⁴⁴

As part of this strategy, Philip Morris did extensive background research on the tobacco control community and began to identify groups that focused solely on restricting youth access to tobacco — groups that Philip Morris considered to be more moderate than groups that were working to limit tobacco use in other ways.⁴⁵ Offering to collaborate with tobacco control groups on restricting youth access was seen as a win-win situation: if the offer were accepted, Philip Morris could tout its cooperation in attacking a public health problem and if the offer were rejected, Philip Morris could publicly “question the true agenda of tobacco control advocates.”⁴⁶ Philip Morris hoped that this would be an opportunity to portray those in the tobacco control community opposed to working with Philip Morris as extremists and those that joined Philip Morris as reasonable — creating a rift in the community that would potentially turn tobacco control groups against one another.⁴⁷

Philip Morris also attempted to undermine the tobacco control community by attacking its funding sources. Philip Morris encouraged tobacco-friendly members of Congress to investigate tobacco control groups that received federal funding and provided them with evidence of what it viewed as wasteful spending.⁴⁸ This tactic was used against the Campaign for Tobacco-Free Kids in 1996 when Representative Harold Rogers pressed the Internal Revenue Service to investigate the organization’s tax exempt status.⁴⁹ Similarly, the American Stop Smoking Intervention Study was audited by the Department of Health and Human Services’

Inspector General at the request of Representatives Henry Bonilla and Ernest Istook.⁵⁰

Perhaps Philip Morris’s most egregious strategy was to publicly attack the credibility of public health groups focusing on tobacco control. The focus of this strategy was to paint tobacco control groups as prohibitionists motivated solely by financial gain.⁵¹ To carry out this strategy, the tobacco industry publicized links between tobacco control groups and tobacco trial lawyers. By asserting these links within the context of a greater discussion of tort reform, the tobacco industry simultaneously portrayed tobacco control organizations as greedy while at the same time it lobbied for restrictions that would make it more difficult for plaintiffs to sue the tobacco industry for injuries caused by tobacco.⁵² The industry also submitted opinion editorials to newspapers, making claims about the greedy tobacco control movement and its secret agenda of profiting from its work to limit individual freedom. This tactic helped the industry portray itself as the reasonable alternative, standing up for freedom of choice.⁵³ It is clear that the tobacco industry racketeers know no limits when it comes to preventing reasonable regulation of their products including attempting to divide and marginalize grassroots organizations whose only goal was to protect public health.

C. The Industry’s Manipulation of the Regulatory Process

Among its many strengths — aside from manufacturing and marketing a highly addictive and deadly product — is the tobacco industry’s mastery of the regulatory environment, which it deploys to fight existing tobacco control regulations and exploit every potential opportunity to prevent the adoption of new tobacco control regulations.

It is no secret that the tobacco industry has spent hundreds of millions of dollars over the last three decades lobbying legislative branches at the state and federal levels.⁵⁴ The industry’s



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manipulation of federal executive agencies is less visible, but just as critical to the industry's success. The tobacco industry has expended tremendous resources to track the actions and potential actions of executive agencies for the purpose of preventing and challenging unfavorable agency actions.

For example, on August 11, 1995, the FDA announced its intention to assert jurisdiction over cigarettes and smokeless tobacco.⁵⁵ Internal documents show that the tobacco companies were already well prepared to respond. In fact, Philip Morris had an "FDA Media Plan" devoted to thwarting any attempts by the FDA to regulate cigarettes.⁵⁶ This plan outlined strategies for several potential regulatory scenarios, including a notice of proposed rulemaking by the FDA, a leak of information from the FDA about a rule, or the issuance of a report that disparaged the industry. For each scenario,

Philip Morris was prepared with press statements,⁵⁷ press releases,⁵⁸ radio and television advertising scripts,⁵⁹ newspaper opinion editorials,⁶⁰ prepared speeches for industry-friendly congressional representatives,⁶¹ grassroots campaign information,⁶² and telephone contact lists for FDA employees.⁶³ This plan evolved into an "FDA Crisis Communication Plan," a minute-by-minute plan of the activities for a team of at least thirty-seven people who prepared for FDA action by running a "crisis simulation" on June 7, 1995.⁶⁴ This group was prepared for every step that FDA Commissioner David Kessler made — even disseminating rebuttals to speeches on the very day that Commissioner Kessler made them.⁶⁵

All of these efforts were in addition to the formal channels that the tobacco industry used to challenge the FDA's proposed rule. The FDA accepted public comments on the proposed rule

from August 11, 1995 until January 2, 1996, and for an additional 30 days starting on March 18, 1996.⁶⁶ During the public comment period, the industry mobilized tobacco retailers by providing them with form letters to send to the FDA,⁶⁷ and by sending out an “Action Alert” describing the FDA’s proposed regulation and outlining how retailers could get involved in the industry’s effort to defeat it.⁶⁸ The tobacco industry also placed petitions inside tobacco retail stores so that customers could object to the proposed rule.⁶⁹ Philip Morris solicited comments opposing the rule from its own employees by placing letter-writing booths outside employee cafeterias.⁷⁰ The tobacco industry also mobilized the advertising industry to respond negatively to the proposed rule by focusing on the rule’s limitations on tobacco advertising and how it might affect advertising agency revenues.⁷¹ This particular effort also included the provision of form letters for the advertising industry to send to the FDA.⁷² In total, the massive mobilization campaign yielded the largest response to a proposed rule in FDA history.⁷³ The agency “received more than 700,000 individual pieces of mail, representing the views of nearly 1 million individuals.”⁷⁴ This effort to overwhelm the FDA with comments illustrates how much energy the industry is willing to spend in order to utilize the formal legal processes to oppose regulation of its products. The notice-and-comment rulemaking process permits comments from the public but the tobacco industry’s domination of the process demonstrates its determination to avoid FDA regulation.

While the tobacco industry identified possible tactics to thwart the FDA’s efforts to regulate cigarettes and smokeless tobacco, such as lobbying Congress to limit the FDA’s enforcement ability by freezing its funding levels and/or forcing it to devote all of its employees to other tasks,⁷⁵ the industry ultimately resorted to the heaviest hammer in its toolbox: litigation. This

was another strategy for which the tobacco industry had been preparing long before the FDA proposed the cigarette and smokeless tobacco regulation. Complaints had been drafted in advance and were prepared to be filed with the courts. On August 10, 1995, five tobacco companies and one advertising agency filed suit against the FDA and Commissioner Kessler,⁷⁶ before the FDA even issued its final rule which was published on August 28, 1996.⁷⁷ After a protracted legal battle that was fought all the way to the U.S. Supreme Court, the FDA’s rule was struck down on March 21, 2000, in a decision finding that the agency had no power to regulate tobacco products without express authorization from Congress.⁷⁸ With the FDA’s attempt to regulate tobacco blocked, the industry returned its focus to Congress, monitoring and lobbying against any bill that could empower the FDA to regulate tobacco in the future.⁷⁹

After the Supreme Court struck down the FDA’s rule in 2000, it took nine years and several attempts⁸⁰ before Congress passed the Family Smoking Prevention and Tobacco Control Act, which President Obama signed into law on June 22, 2009.⁸¹ The Act finally granted the FDA the express authority to regulate tobacco products. However, this did not mark the end of the tobacco companies’ attempts to escape regulation. Before the FDA had exercised any meaningful authority and even before most of the statutory provisions of the Act had gone into effect, the tobacco industry filed a lawsuit challenging more than ten provisions within the Tobacco Control Act, including prohibitions on certain types of marketing activities directed toward youth and the Act’s provision mandating graphic warnings on cigarette packages.⁸² The industry later filed suit to challenge the FDA’s final rule implementing graphic warnings.⁸³ The industry was unsuccessful in removing the FDA’s authority to create graphic warnings, but blocked implementation of the first graphic warning rule, forcing the FDA to once again start that rule-making

process.⁸⁴ Additionally, the tobacco industry has tried to prevent regulation of menthol cigarettes and dissolvable tobacco products by way of a lawsuit challenging the composition of the Tobacco Products Scientific Advisory Committee (TPSAC),⁸⁵ which was formed pursuant to the Act to advise the FDA on safety and health issues, including those related to menthol cigarettes and dissolvable tobacco products. At the same time that it is working to limit the FDA's efforts to implement the Act, the industry has attempted to use the Act's narrow preemption provision to stamp out novel tobacco control policies at the local level, including two adopted by New York

City⁸⁶ and two enacted in Providence, RI.⁸⁷ The tobacco industry has also attempted to argue that the passage of the Tobacco Control Act deprives the courts of jurisdiction in *U.S. v. Philip Morris* because the tobacco industry will be forced to comply with the Act's and the FDA's comprehensive regulatory requirements and thus cannot commit future racketeering violations prohibited by the court's ruling.⁸⁸ At the very same time that the industry made this argument, as discussed above, it was attempting to overturn the Act by arguing to another court that the Act was unconstitutional. All of these actions demonstrate the industry's dedication to avoiding regulation.

Ancient History or Current News?

INDUSTRY TACTIC	PAST	PRESENT
Lobbying	Lobbying against FDA authority over tobacco products, ⁸⁹ lobbying against tax increases for tobacco products ⁹⁰	Lobbying against tax increases for tobacco products ⁹¹
Soliciting Comments	Soliciting comments to tobacco regulatory dockets from third parties including tobacco retailers, advertisers and even tobacco product consumers ⁹²	Soliciting comments to tobacco regulatory dockets from third parties including tobacco advertisers, manufacturers of tobacco product components, tobacco distributors and retailers, and even tobacco product consumers ⁹³
Opposition Documents	Rebuttals to reports from the Surgeon General ⁹⁴	Rebuttals to reports from TPSAC ⁹⁵
Misrepresentation of Science	Commissioning and disseminating junk-science and hiding evidence linking tobacco and disease ⁹⁶	Ignoring the public health standard and asserting a higher standard of scientific evidence for FDA action ⁹⁷
Health Fraud	Creation and marketing of "Light"/"Low Tar" cigarettes and "potentially reduced exposure products" known to be just as harmful as "full flavored" cigarettes ⁹⁸	Color-coding cigarette packages to perpetuate the "Light"/"Low Tar" myth, ⁹⁹ advocacy to change smokeless tobacco warning labels to establish a modified risk claim ¹⁰⁰
Lawsuits	Lawsuits to prevent FDA from asserting jurisdiction over tobacco products, ¹⁰¹ lawsuits to prevent state and local tobacco regulation ¹⁰²	Lawsuits to challenge FDA authority over tobacco products, ¹⁰³ lawsuits to prevent the FDA from implementing new regulations, ¹⁰⁴ lawsuits to prevent the FDA from relying on TPSAC reports, ¹⁰⁵ lawsuits to prevent state and local tobacco regulation ¹⁰⁶

In short, the tobacco industry racketeers have the resources and are prepared to block health-protective tobacco regulations at every stage of the regulatory process: both pre-rule (through public comment, mobilization, and Congress-

sional influence) and post-rule (largely through litigation but also Congressional influence). This is not ancient history; the industry's recent efforts to undermine FDA actions show that the tobacco companies have not changed their ways.

III. Steps the FDA Can Take to Counter Tobacco Industry Subversion

There is no question that the industry will continue to use its stakeholder status with the FDA to resist meaningful regulation of its products. With the vast resources available to the tobacco companies and the industry's history of using such resources to obscure the effects of its products and subvert efforts to protect the public health, the FDA must ensure that public health advocates and professionals have equal opportunities to weigh in on regulatory decisions.

The FDA can take a number of steps to do this. First, the FDA must work to increase transparency in the regulatory process. For example, the agency could (1) disclose all public comments on FDA dockets; and (2) provide minutes of meetings and copies of communications between the FDA and industry representatives. The FDA should also make a concerted effort to ensure that public health professionals and advocates have opportunities to engage in the regulatory process beyond commenting on pro-

posed regulations. For example, the FDA should provide more opportunities for the public to testify at both informal and formal hearings and it should hold some of those hearings outside of the Washington D.C. area. The FDA could also permit members of the public to provide testimony remotely — via phone, the internet, or other communications technology — as part of formal hearings held in Washington D.C. Finally, given the wealth of information that the public health community could be sharing with the FDA, the FDA needs to provide more opportunities to share information and be clear about the types of information that will be most useful to inform the regulatory process. State and local survey data could be very useful in the creation of future federal tobacco product regulation. The FDA can also be working to ensure that retailers who violate state and local tobacco control laws are also reported for violations of federal law.

IV. Steps the Public Health Community Can Take to Prevent Industry Subversion

Public health professionals and advocates can work to prevent the tobacco industry from subverting the regulation of tobacco products by engaging in the regulatory process. Members of the public health community are critical stakeholders with a wealth of information on the science of tobacco products, as well as the impact of tobacco on their communities. To balance the outsized resources and influence of the tobacco

industry, the public health community must make a concerted effort to press the FDA to adopt strong tobacco product regulations that protect public health.

The public health community can engage with the FDA through multiple channels, both formal and informal.



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- **File a citizen petition:** The public health community can proactively urge the FDA to take an action (or refrain from taking an action) through citizen petitions — formal documents that state the proposed action and the grounds for the action, to which the FDA must respond.¹⁰⁷
- **Submit a comment on an FDA docket:** Organizations and individuals can also indicate support for or opposition to proposed FDA actions (e.g., rules, guidance documents) or other entities' citizen petitions by commenting on an open FDA docket. A docket is a collection of all of the information for a particular regulatory action and all FDA dockets can be found at www.regulations.gov. Comments do not have to be long or detailed; they merely have to convey why the issue is important to the individual or organization, or provide information or a perspective that would help the FDA make effective, health-protective tobacco regulations. Comments that include evidence about how the subject tobacco product has impacted health in states and communities are especially helpful to the FDA. Commenting not only helps guide the

FDA's decision-making, but also provides a factual record for the FDA to rely on should a regulation be challenged in a lawsuit.

- **Contact the FDA:** The public health community can also engage informally with the FDA by requesting a meeting, inviting FDA staff to speak at local events, and calling or emailing staff at the FDA's Center for Tobacco Products.

The Tobacco Control Legal Consortium's [FDA Tobacco Action Center](http://www.fda.gov/oc/tobaccoactioncenter), located on its website at www.publichealthlawcenter.org, provides information about how to submit comments to the FDA. The website also includes resources, including materials and links related to opportunities to comment on proposed regulations and citizen petitions.

Please note that although engaging with a federal agency regarding regulations does not traditionally constitute lobbying, each organization must consider its own limitations based on its legal structure, funding sources and relevant law. If you have any questions regarding what activities are permitted for your organization, please contact your funder or an attorney licensed in your jurisdiction.

Endnotes

- 1 The Tobacco Control Act contains thirty-three references to the FDA's mandate to protect public health. 21 U.S.C. § 387(21)(C); § 387c(a)(8)(B)(ii); § 387e(j)(3)(A)(ii); § 387f(d)(1); § 387f(d)(3)(B); § 387f(e)(1)(A); § 387g(a)(3)(A); § 387g(a)(3)(B)(ii); § 387g(a)(4)(A); § 387g(a)(4)(B); § 387g(c)(2)(A); § 387g(c)(3); § 387g(d)(1)(A); § 387g(d)(2); § 387g(e)(1); § 387g(f)(1); 387h(a)(1); 387i(a), (a)(3); § 387i(a)(6); 387j(3)(A)(ii); § 387j(c)(2)(A); § 387j(c)(4); § 387j(c)(5)(A); § 387j(d)(1)(A); § 387k(g)(2)(A)(i); § 387k(i)(2); § 387k(j)(3)(C); 387o(b)(1); §387o(b)(2); 387r(b)(1).
- 2 *See, e.g.*, U.S. Food and Drug Administration Center for Tobacco Products Stake Holder Discussion Series, <http://www.fda.gov/TobaccoProducts/NewsEvents/ucm221040.htm>.
- 3 United States v. Philip Morris USA, Inc., 449 F.Supp.2d 1 (D.D.C. 2006). For an overview of industry practices from the findings section of the case, *see* TOBACCO CONTROL LEGAL CONSORTIUM, THE VERDICT IS IN: FINDINGS FROM UNITED STATES V. PHILIP MORRIS (2006) available at <http://publichealthlawcenter.org/sites/default/files/resources/tclc-verdict-is-in.pdf>.
- 4 U.S.C. § 393(b)(2)(A).
- 5 U.S.C. § 393(b)(2)(B).
- 6 Centers for Disease Control and Prevention, *Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses — United States, 2000–2004*, 57 MORBIDITY & MORTALITY WKLY. REP. 1226, 1226–28 (2008), available at <http://www.cdc.gov/mmwr/PDF/wk/mm5745.pdf>.
- 7 *Id.*
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About the Tobacco Control Legal Consortium

The Tobacco Control Legal Consortium is a network of legal programs supporting tobacco control policy change throughout the United States. Drawing on the expertise of its collaborating legal centers, the Consortium works to assist communities with urgent legal needs and to increase the legal resources available to the tobacco control movement. The Consortium's coordinating office, located at William Mitchell College of Law in St. Paul, Minnesota, fields requests for legal technical assistance and coordinates the delivery of services by the collaborating legal resource centers. Our legal technical assistance includes help with legislative drafting; legal research, analysis and strategy; training and presentations; preparation of friend-of-the-court legal briefs; and litigation support.