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The Ethics of Industry Experimentation Using Employees: The Case of Taste-Testing Pesticide-Treated Tobacco

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In the United States, companies that use their own funds to test consumer products on their employees are subject to few regulations. Using previously undisclosed tobacco industry documents, we reviewed the history of that industry's efforts to create internal guidelines on the conditions to be met before employee taste testers could evaluate cigarettes made from tobacco treated with experimental pesticides.

This history highlights 2 potential ethical issues raised by unregulated industrial research: conflict of interest and lack of informed consent. To ensure compliance with accepted ethical standards, an independent federal office should be established to oversee industrial research involving humans exposed to experimental or increased quantities of ingested, inhaled, or absorbed chemical agents. (*Am J Public Health.* 2006;96: 37–46. doi:10.2105/AJPH.2005.071969)

IN THE UNITED STATES, federally funded research involving human subjects must conform to ethical requirements that include obtaining participants' informed consent and oversight by an institutional review board (IRB). When these rules were first codified, however, political opposition to federal regulation in general resulted in exemptions for privately funded research involving humans, provided the research was not already subject to Food and Drug Administration (FDA) jurisdiction.[1(p172),2(p72)] Research conducted on employees is also not subject to federal or state Occupational Safety and Health Administration regulations (other than the general duty clause, which states that the workplace must be free of recognized hazards that are likely to cause death or serious physical harm). Thus, companies using their own funds to test consumer products on employees are largely left to regulate themselves.

Previously undisclosed tobacco industry documents provide an opportunity to evaluate one industry's attempts to create internal guidelines for research using its employees. In this study, we focus on one type of employee research conducted by the tobacco industry: taste tests (called "smoke panels" or "taste panels") of cigarettes treated with experimental pesticides. Although tobacco industry employees have also been regularly used to evaluate the impact on cigarette taste of additives, flavorings, and other product modifications,[3–9] we focus on pesticide-treated cigarettes because the industry saw this type of research as particularly vulnerable to lawsuits. It therefore developed guidelines stipulating that toxicological data be reviewed before employees smoked these cigarettes in experimental settings. We highlight the ethical issues raised by this research and propose extending, in certain instances, federal protection of human subjects to privately funded research.

METHODS

Data for this study came from previously undisclosed tobacco industry documents released publicly through litigation and from Web sites containing information on federal regulations regarding human subjects.[10–12] The tobacco documents include letters, memos, e-mails, and reports relating to tobacco marketing, manufacturing, research, and governmental and public relations. We accessed them primarily through the Legacy Tobacco

TABLE 1—Number of Documents Yielded by Tobacco Industry Document Searches, by Selected Key Words and Tobacco Company

Key Words[a]	Source					
	American Tobacco	Brown and Williamson	Lorillard	Philip Morris	RJ Reynolds	Tobacco Institute
Smoke panel	861	304	56	251	151	8
Taste panel	155	11	299	96	45	0
Flavor evaluation	106	102	53	243	300	1
Tobacco Pesticide Committee/TPC	18	26	36	1045	188	0
Informed consent	0	1	4	185	27	6
Consent form	0	4	7	52	162	5
Human Research Review Committee/HRRC	0	25	0	3	1962	0
Institutional review board/IRB	0	4	151	765	93	12
Human subject	1	14	118	362	164	3

Source. Documents were accessed through the Legacy Tobacco Documents Library (http://legacy.library.ucsf.edu).
[a]Including wild cards that allow any form of the word.

Documents Library (available at: http://legacy.library.ucsf.edu), an online database containing nearly 7 million documents from RJ Reynolds (RJR), Philip Morris (PM), American Tobacco Company (ATC), Brown and Williamson, Lorillard, and the Tobacco Institute.

Between July 2003 and January 2005, the first author retrieved documents by using a snowball sampling strategy, beginning with broad search terms (e.g., "smoke panel") and using retrieved documents to identify more specific search terms (e.g., "Tobacco Pesticide Committee") (Table 1). This process produced over 8400 documents. These documents' index entries were reviewed, and duplicates and irrelevant documents were excluded. The final sample size was approximately 1000 documents, spanning the years 1947 to 2000. All 3 authors iteratively reviewed successive collections of key documents while developing interpretations and analyses; the first author then assembled the data and analyses into a chronologically organized case study, a method common to sociology, political science, and anthropology.[13,14]

EMPLOYEE TASTE PANELS

American tobacco companies have conducted employee panels to evaluate pesticides' impact on cigarette flavor since at least 1947, when ATC employees smoked cigarettes made from tobacco grown in DDT-treated soil.[15] Typically, taste panels were conducted on pesticides not yet registered or officially permitted for tobacco use by the US Department of Agriculture (USDA) (in 1970, the Environmental Protection Agency [EPA] assumed responsibility for pesticide registrations). Pesticide-treated tobacco was grown at USDA and university agricultural experiment stations in the southern United States and delivered to tobacco companies for flavor evaluations.[15–22]

Tobacco companies recruited groups of 3 to 26 employees, smokers and nonsmokers, to taste-test cigarettes manufactured from pesticide-treated tobacco.[4,23–28] At ATC in the 1950s, some employees served on panels for at least 2 years.[26,29,30] The documents we located lack additional details on these early panelists; however, documents from the 1980s and 1990s reveal that some panelists worked in Research and Development at PM and RJR[27,31] and in the Flavor Development Department at PM.[31,32] Flavor Development employees regularly tested experimental cigarettes, including those containing new flavor additives and new pesticides.[31,33] We were unable to determine whether they received additional compensation for tasting work. At RJR in the 1980s, employee taste-testers were company-wide volunteers who served on panels 2 to 3 times per week.[23] They earned no additional pay, but received sweets after sessions.[23]

At ATC in the 1950s, each employee evaluated 3 cigarettes: 1 made from untreated tobacco and 2 made from pesticide-treated tobacco.[26] In the 1980s, panelists from ATC, Brown and Williamson, RJR, and PM smoked 3 to 12 cigarettes, some with tobacco treated with the pesticide at the maximum proposed use rate, some with tobacco treated with the pesticide at twice the maximum proposed use rate, and some with untreated tobacco.[34–36] At RJR in the 1980s, employee panelists smoked on company time (approximately 15 minutes per session) in individual booths.[23] Panelists scored cigarettes as "normal" or "off-taste."[26,37,38] Test results were communicated to pesticide manufacturers or to agricultural experiment station personnel, who would discourage pesticide manufacturers from registering pesticides rated unfavorably.[39,40]

EARLY SELF-REGULATION

In the 1970s, tobacco companies reassessed employee taste panel procedures. In April 1972, the Regional Tobacco Growth Regulator Committee—which was comprised of representatives of tobacco (ATC, Brown and Williamson, Lorillard, PM, and RJR) and chemical companies (e.g., Proctor and Gamble,

UniRoyal), the EPA, and the USDA—met to discuss the efficacy of various chemicals. Several members noted that tobacco companies typically lacked residue and toxicity data on experimental pesticides.[41] They agreed that "more attention should be paid" to obtaining this information from chemical companies before taste panels were conducted.[41]

Several months later, North Carolina State University's Coordination Committee for Manufacturing Cigarettes—which was apparently headed by T.J. Sheets, director of the university's pesticide residue research laboratory—developed a toxicological safety protocol (Table 2, second column). The protocol requested that pesticide manufacturers provide data on acute oral and inhalation toxicity (derived from animal tests), residue concentrations, and pesticide transfer into cigarette smoke.[42]

Soon after, in July 1972, the Associated Press broke the story of the Tuskegee syphilis study.[45(p1)] Public outcry over its unethical nature led Congress to pass the National Research Act in 1974.[46(p160)] It required that those applying for Department of Health, Education and Welfare funding for research involving human subjects provide evidence of oversight by an IRB.[47(p198)] It also stipulated that subjects be informed of any risks.[48(p188)]

SAFETY PROTOCOL DISSATISFACTION

It is unclear whether the safety protocol of the Coordination Committee for Manufacturing Cigarettes was widely used. In December 1975, RJR researcher W.B. James rejected the committee's conclusion that tobacco treated with 2 experimental pesticides (napropamide and pebulate) was safe for panelists to smoke.[49] James pointed out that "it is by no means clear that a *combination* of [the two] has been tested and judged to be safe."[49] He also claimed that 2 additional chemicals had been applied to the tobacco, raising questions about "the *combinations* of chemicals and possible synergistic effects . . . during pyrolysis [emphasis in original]."[49] Although RJR employees had already tested these cigarettes,[50] James recommended that no further taste tests be conducted without "objective" safety information.[49]

In March 1977, tobacco company representatives joined North Carolina State University researchers at the annual "Fate of Pesticide Residues on Tobacco" meeting.[51] Sheets solicited comments on the 1972 toxicological safety protocol.[52,53] RJR's James and PM's P.A. Eichorn recommended requiring more pyrolysis information.[53–55] Eichorn also suggested requiring more information on a pesticide's transfer into cigarette smoke.[55] Although such "stringent" requirements "could seriously limit a chemical company's interest in providing new compounds," Eichorn argued that they were necessary because of "the climate in which we work today."[52] Eichorn may have been referring to the litigious climate in which tobacco companies operated.

At the April 1978 Fate of Pesticide Residues on Tobacco meeting, several tobacco company representatives reportedly stated that their

TABLE 2—Toxicological Data Required by Tobacco Companies Before Conducting Employee Taste Tests of Experimental Pesticide–Treated Cigarettes

Data Required by Safely Protocol	Safety Protocol Years		
	1972-1977[42]	1978-1983[43]	1984 -2000[44]
Oral LD_{50} and NOEL –pesticide	✓	✓	✓
Oral LD_{50} and NOEL–pesticide metabolites[a]	✓	✓	
Oral LD_{50} –pesticide pyrolytic products[b]	✓		
Dermal LD_{50} –pesticide		✓	
Inhalation LC_{50}–pesticide	✓	✓	✓
Inhalation LC_{50}–pesticide metabolites	✓		
Inhalation LC_{50}–pesticide pyrolytic products	✓		
Skin irritation–pesticide		✓	
Residue in cigarettes–pesticide	✓	✓	✓
Residue in cigarettes–pesticide metabolites	✓	✓	✓
Transfer into smoke–pesticide	If significant residue levels	If high degree of hazard	✓
Transfer into smoke–pesticide metabolites	If significant residue levels		
Identification of pesticide pyrolytic products		If high degree of hazard	✓
Smoke inhalation study (smoke from pesticide-treated tobacco)		If high degree of hazard	✓
Ames test–pesticide			✓
Ames test–pesticide metabolites			✓
Margin of safety calculated from toxicology data	Qualitative	Quantitative	Quantitative

Note. LD_{50} refers to the lethal dose required to kill 50% of a group of test animals; it is a measure of a pesticide's acute toxicity. NOEL (no-observed-effect level) is the maximum concentration of a pesticide in an animal test that produces no observed adverse effects.
[a]Pesticide metabolites are breakdown products that form when a pesticide is transformed inside a living organism.
[b]Pesticide pyrolytic products are the additional chemicals produced by burning the pesticide.

companies would no longer conduct employee taste panels without first reviewing pesticide toxicological data.[56] A Lorillard memo on this meeting indicated that

> [t]he concern was less that harm might be done from pyrolysis products of untested pesticides than from unfavorable publicity should a smoker from the taste panel choose to bring suit against a tobacco manufacturer claiming damages from smoking a cigarette containing an unapproved pesticide.[57]

Someone at the meeting proposed that pesticide manufacturers assume responsibility for conducting taste panels.[56,57]

The following month, North Carolina State University hosted a meeting between representatives of RJR, PM, and Imperial Tobacco and several chemical companies, including CIBA-Geigy, DuPont, Union Carbide, and Mobil.[58] An RJR memo described the chemical company representatives as initially "rather naïve about the entire process of smoking evaluations."[59] After discussions, "[t]hey now appreciate that safety considerations are a real and legitimate concern."[59] But for reasons not elaborated, chemical companies were unwilling to take responsibility for conducting taste panels. Instead, tobacco companies agreed to continue to do so, provided that chemical companies first supplied them with toxicological data.[59] Sheets revised the 1972 safety protocol to reflect the additional information requested by tobacco companies (Table 2, third column).[43]

This procedure appears to have been followed for several years.[60–62] However, an RJR review characterized it as unsuccessful.[63] Chemical companies often failed to supply toxicological information; when they did, tobacco companies lacked the expertise to evaluate it.[63(p139),64] At least 2 tobacco companies (RJR and PM) stated that if they lacked sufficient toxicological information, they did not permit employees to smoke experimental cigarettes.[63(p139),65,66] According to RJR, this "inhibited the development of new pesticides for use on tobacco,"[63(p121)] presumably because without early feedback from tobacco companies, chemical companies hesitated to commit resources to a pesticide that might later be rejected because it negatively affected taste.

THE TOBACCO-PESTICIDE WORKING GROUP

In 1981, Sheets suggested establishing the Tobacco-Pesticide Working Group.[67] Composed of 12 members drawn from tobacco and chemical companies, universities, and the USDA, its first meetings focused on modifying evaluation procedures for toxicological data on experimental pesticides.[68–71] In October 1982, the group agreed to hire an outside consultant to evaluate chemical company data on pesticide toxicology and advise the group whether to proceed with taste panels.[72]

In April 1983, after the Tobacco-Pesticide Working Group changed its name to the Tobacco Pesticide Committee (TPC), Sheets reported on a meeting he had with Duke University toxicologist Leon Golberg.[73,74] Golberg had outlined his view of the role he would assume as consultant: he would interpret chemical company pesticide data for a committee composed of "the public-at-large"—academics, lawyers, and industry representatives.[73] This committee would make the decision on whether to proceed with taste panels.[73] Golberg's proposed procedure was similar to the IRB policies established by the Department of Health and Human Services (formerly the Department of Health, Education and Welfare) in 1981, which required institutions receiving federal funding to establish IRBs composed of 5 members of varying backgrounds, including one outside member.[75(p60)]

The minutes of the meeting indicate that TPC members had not "expected Dr Goldberg to take this stand," of which they disapproved.[73] They commented that "the sole purpose for employing a toxicologist was for *him* to determine whether it would be safe for the general public to smoke cigarettes treated with a particular pesticide under study [italics added]."[73] Ultimately, Golberg chose not to work with the TPC, which identified another candidate, Lamar Dale, a private consultant (and former EPA toxicologist), who did not suggest forming an IRB.[76] In their initial negotiations, the committee asked Dale to prepare a draft safety protocol.[77,78]

When Dale discussed this protocol with committee members (Table 2, fourth column), they were concerned that some of the requested information would be unavailable, such as that on pyrolysis products and acute inhalation toxicity data.[78] A PM memo explained that "[c]hemical companies . . . would like to know whether or not [candidate pesticides] could pass an . . . evaluation by smoking panels before getting involved in . . . toxicological studies."[79] The memo also explained that the potential profit for tobacco pesticides was small and comprehensive toxicological testing expensive[79]; thus, chemical companies had little incentive to conduct tests early to satisfy tobacco companies. When a pesticide already had EPA approval for use on other crops, chemical companies would have fairly extensive toxicological data, but not pyrolysis data.[80]

Sheets discussed these problems with representatives of chemical companies Uniroyal and Union Carbide.[81] They apparently raised no objections to supplying the information, so TPC decided to proceed.[81] In April 1984, Sheets offered Dale the consulting toxicologist position.[34] Before assigning him any pesticide reviews, however, Sheets asked Tobacco Institute lawyers to review liability issues.[82]

LIABILITY ISSUES

At the January 1985 TPC meeting, Ed Beder, a Tobacco Institute lawyer, raised a major legal concern regarding employee taste panels: the possibility that a panelist might be (or allege to be) injured as a result

of smoking tobacco containing experimental pesticides.[83] One member suggested having the chemical companies hire tobacco company employees as taste panelists.[83] Beder argued that this would not necessarily let the tobacco companies "off the hook" because employees could claim that they were pressured to participate.[83] Ultimately, committee members made no decision about liability protections; instead, companies were to consider how to "make the planned procedures more creditable [*sic*]."[84,85] During this time, it does not appear that tobacco companies conducted any employee taste panels.

NEW PESTICIDES NEEDED

The TPC reconvened in April 1985. After an RJR representative highlighted the need for new tobacco pesticides given the dangers of disease "wip[ing] out" the crop, the committee agreed to evaluate a synthetic pyrethroid insecticide.[86] Each company would decide whether to have its employees smoke the experimental cigarettes on the basis of Dale's review.[86]

Some TPC members considered Dale's safety protocol too comprehensive. One argued that it was "really a suggested list of requirements and not a total commitment to all its parts."[86] At the next TPC meeting, ATC's Eugene Glock suggested adding to the protocol the following statement: "[t]he basis for deletion of specific information as *suggested* below should be explained with the submission of the information to the toxicologist. Under certain circumstances all the suggested information . . . may not be required [emphasis in original]."[87] Dale reported that he had sent the protocol to a Shell Development Company scientist[88]; 6 weeks later, after receiving no response, he wrote to Sheets, "I hope the 'requirements' did not frighten Shell away. I explained . . . [that they] were *suggested* and not to be taken as 'writ in stone' [emphasis in original]."[88]

A FLEXIBLE APPROACH

In the years that followed, the TPC and the tobacco companies proved to be flexible about the safety protocol. The toxicologist sometimes recommended conducting taste panels despite the absence of pyrolysis data.[89–91] In at least 2 cases, it appears that these panels were conducted.[92–94] However, in 1988, an RJR scientist reviewing the toxicologist's favorable report on a synthetic pyrethroid insecticide recommended that the company delay employee testing until receiving pyrolysis data.[95] (Available documents do not reveal whether data were received.) Chemical manufacturers appeared to conduct pyrolysis tests late in the registration process, after favorable tobacco company employee taste testing.[92]

Sometimes, when insufficient information was available from chemical manufacturers, the committee did not approve taste panels. For example, in April 1993, when a chemical company decided to register a *Bacillus thuringiensis*–encapsulated endotoxin for use on tobacco without conducting allergenicity testing, the TPC advised against taste panels.[96,97] The documents do not indicate whether individual companies followed this advice or chose to purchase the treated tobacco.

INFORMED CONSENT POLICIES

The TPC apparently never established common informed consent procedures; instead, some individual companies created their own. Those of RJR were the most comprehensive. In 1984, it created a Human Research Review Committee to oversee the company's human subjects research, protect human subjects, and "guard against needless liability."[98] All human subjects experiments, including pesticide-treated tobacco evaluations, required approval by the committee, which was composed of 9 RJR employees (with no apparent outside members): 7 from Research and Development and 1 each from the medical and legal departments.[98,99] The committee stipulated that study participants sign consent forms, but it apparently provided no guidelines regarding form content.[99] At that time, Department of Health and Human Services requirements for informed consent included minimizing the possibility of coercion, assuring participants that participation was voluntary, explaining the purposes of the research, describing foreseeable risks and benefits, providing information on research subjects' rights and who to notify in case of injury, and avoiding the use of exculpatory language that appeared to release the institution from liability.[100(pp238–239)]

RJR consent forms for several employee taste panels conducted in 2000 that evaluated cigarettes made from tobacco treated with fungicides (o-ethyl phosphonate and azoxystrobin) and insecticides (emamectin benzoate and thiamethoxam) provided information on the nature of the test (evaluation of cigarettes containing a named pesticide about to be submitted to the EPA for approval) and the reason (taste appraisal).[101–104] They also assured employees that RJR toxicologists and an independent consultant had concluded that "there is no evidence for any potential adverse health effect from smoking cigarettes in this panel." By signing the consent form, employees affirmed that their participation was voluntary and took "full responsibility" for it.

Unlike RJR, PM does not appear to have created a human subjects research committee. In 1994, 2 company researchers devised toxicology testing guidelines for research involving humans.[105] The guidelines suggested that a PM researcher consider pyrolysis, smoke chemistry, and acute toxicology studies before conducting employee testing of new cigarette components.[105] Rather than establish an IRB, they recommended that an expert approve the research plan.[105] Advice regarding informed consent was brief: "Informed consent can be a standard form (e.g., 'this is a novel substance, believed not to be

harmful for intended use')."[105] In 1995, PM established a Scientific Research Review committee to approve the scientific and ethical basis of company research.[106] Although an early draft of its charter included subjective product evaluations under the committee's purview, this was dropped in all subsequent versions.[107–112]

In 1998, PM created an annual consent form to be signed by employee panelists.[113] It explained that participation was voluntary and that experimental cigarettes had been judged by PM to "not pose risks different from those associated with commercial cigarettes under these experimental conditions."[113,114] When PM employees participated in a panel, the taste evaluation form contained a small-print reminder of the voluntary nature of the test, but no other information.[115] (We were unable to determine whether employees testing pesticide-treated cigarettes were given information on the pesticide under consideration.)

DISCUSSION

This review of tobacco industry documents is, we believe, the first study to investigate industry research on employees, and it highlights several ethical issues. One is conflict of interest. In establishing employee taste panel procedures, tobacco companies' interest in protecting employees and reducing company liability clashed with their interest in maintaining a pipeline of tobacco pesticides. Performing rigorous toxicological testing *before* conducting employee panels represented a burden to pesticide manufacturers, who preferred to conduct such tests *after* they felt confident of a market. Because the potential profit from tobacco pesticides was relatively small, hurdles created by the tobacco industry might result in pesticide manufacturers abandoning the tobacco pesticide market. Tobacco companies thus had an incentive to limit the comprehensiveness of safety reviews or to follow guidelines selectively.

Another ethical issue is informed consent. While some have argued for an even more robust notion of informed consent,[116] at minimum, it requires that the following conditions be met: disclosure, comprehension, voluntariness, and competence.[117(p274)] Disclosure generally consists of statements indicating that the subject is being asked to participate in research, the purpose of the research, a description of the procedures, and alternatives to participation.[118] Disclosure also includes a description of foreseeable risks of participation, and any individual or societal benefits.[118] PM's and RJR's consent forms were a patchwork of disclosure. Neither explicitly indicated that the employee was being asked to participate in research; rather, the employee would be involved in "evaluating" cigarettes. PM's form also left out important details, possibly including information on the pesticide being evaluated; it did, however, state that employees were free to discontinue participation at any time, information that was lacking on RJR's consent form. Neither PM nor RJR informed employees of possible risks or benefits, but instead provided reassuring statements regarding safety.

It is unclear whether tobacco industry employees understood the limited written information provided and were given sufficient time to decide whether to participate. While PM's consent form indicated that employee panelists were free to ask questions, the context in which this communication took place is unknown, including when and how questions were asked and answered, and by whom.

It is also unclear if participation by tobacco company employees was truly voluntary. Employees may be in an "implicitly coercive" research environment because to refuse participation could threaten their careers.[119] Federal regulations recognize that research on special populations requires particular attention to ethical issues.[120] Yet the TPC apparently never discussed ways to minimize coercion and ensure respect for employees' autonomy, a key ingredient of the competence required to grant consent.[116(p288)] Voluntary participation also depends on one's ability to weigh the risks of participation without being unduly influenced by potential benefits. Although the tobacco industry does not appear to have offered many rewards to its employee taste panelists, other industries might.

While both the extent to which other industries conduct research using employees and the risks involved remain unknown, there is nothing in the employer–employee relationship that would provide ethical justification for conducting such research outside accepted standards. To ensure compliance with these standards, the tobacco industry and other industries, when conducting certain types of research, should be subject to the same federal regulations regarding human subjects that govern publicly funded research and FDA products research.

Specifically, industrial research involving experimental or increased quantities of ingested, inhaled, or absorbed chemical agents should be regulated. Some of this research is already subject to regulation. For example, the FDA requires that taste tests involving certain food ingredients above an FDA-established safety level or food-use pesticides unapproved by the EPA conform to its regulations regarding human subjects, which include IRB oversight and informed consent. Companies not subject to the FDA approval process should be required to adhere to federal requirements regarding human subjects before conducting flavor, inhalation, absorption, or toxicity tests in humans. (Exceptions could be made for taste tests of foods with increased levels of ingredients that are generally recognized as safe.) Just as industry should meet data quality standards recently instituted for publicly funded studies,[121] so should it meet, in particular circumstances, the same ethical requirements as publicly funded research.

The National Bioethics Advisory Committee recommended in 2001 that an independent office be established to oversee

research using human subjects in all segments of the federal government as well as the private sector.[122(p6)] This office could be charged with ensuring industry compliance with IRB and informed consent regulations, and with addressing flaws in the current IRB system, such as overwork, inadequate expertise, and conflicts of interest.[122(p3),123]

Managing conflicts of interest is particularly important in the context of industrial research, because internal reviewers might have for-profit incentives to approve research. One remedy proposed by the National Bioethics Advisory Committee is to ensure that at least 25% of the IRB is composed of individuals who represent participants' perspectives, have no institutional affiliation, or have nonscientific interests.[122(p12)] Another option is to encourage companies to seek research approval from independent review boards—entities with no ties to the institution conducting research—that are structured, like those in France and Denmark, so that they have exclusive, mandatory regional jurisdiction and accredited members, and are financed by fees paid by companies submitting protocols for review.[124,125]

Recently, in response to concerns raised by pesticide toxicity tests conducted on humans by pesticide manufacturers, Congress barred the EPA from evaluating such data until the agency establishes comprehensive ethical guidelines, including establishing an independent human subjects review board.[126–131] Thus, an additional category of privately funded research involving human subjects will be subject to some form of federal regulation. This appears to be an opportune time for public health professionals to encourage policymakers to treat other industrial research in a similar fashion. ■

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Contributors

All authors originated the study. P.A. McDaniel conducted the tobacco industry document searches, analyzed documents, wrote the first draft, and revised successive drafts. G. Solomon and R.E. Malone analyzed documents and reviewed, edited, and revised all drafts.

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