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

Patricia A. McDaniel, PhD, Gina Solomon, MD, MPH, and Ruth E. Malone, PhD, RN, FAAN

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(p1 72),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
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.26 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 RJR27,31 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 taste-testing 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.

At ATC in the 1950s, each employee evaluated 3 cigarettes: 1 made from untreated tobacco and 2 made from pesticide-treated tobacco.34 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 untreated tobacco 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.

### 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. They agreed that “more attention should be paid” to obtaining this information from chemical companies before taste panels were conducted.

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.

Soon after, in July 1972, the Associated Press broke the story of the Tuskegee syphilis study. Public outcry over its unethical nature led Congress to pass the National Research Act in 1974. 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. It also stipulated that subjects be informed of any risks.

**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. James pointed out that “it is by no means clear that a combination of [the two] has been tested and judged to be safe.” 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].” Although RJR employees had already tested these cigarettes, James recommended that no further taste tests be conducted without “objective” safety information.

In March 1977, tobacco company representatives joined North Carolina State University researchers at the annual “Fate of Pesticide Residues on Tobacco” meeting. Sheets solicited comments on the 1972 toxicological safety protocol. RJR’s James and PM’s P.A. Eichorn recommended requiring more pyrolysis information. Eichorn also suggested requiring more information on a pesticide’s transfer into cigarette smoke. 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.”

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

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

<table>
<thead>
<tr>
<th>Data Required by Safety Protocol</th>
<th>Safety Protocol Years</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1972-1977&lt;sup&gt;42&lt;/sup&gt;</td>
</tr>
<tr>
<td>Oral LD&lt;sub&gt;50&lt;/sub&gt; and NOEL—pesticide</td>
<td>✓</td>
</tr>
<tr>
<td>Oral LD&lt;sub&gt;50&lt;/sub&gt; and NOEL—pesticide metabolites&lt;sup&gt;a&lt;/sup&gt;</td>
<td>✓</td>
</tr>
<tr>
<td>Oral LD&lt;sub&gt;50&lt;/sub&gt;—pesticide pyrolytic products&lt;sup&gt;b&lt;/sup&gt;</td>
<td>✓</td>
</tr>
<tr>
<td>Dermal LD&lt;sub&gt;50&lt;/sub&gt;—pesticide</td>
<td>✓</td>
</tr>
<tr>
<td>Inhalation LC&lt;sub&gt;50&lt;/sub&gt;—pesticide</td>
<td>✓</td>
</tr>
<tr>
<td>Inhalation LC&lt;sub&gt;50&lt;/sub&gt;—pesticide metabolites</td>
<td>✓</td>
</tr>
<tr>
<td>Inhalation LC&lt;sub&gt;50&lt;/sub&gt;—pesticide pyrolytic products</td>
<td>✓</td>
</tr>
<tr>
<td>Skin irritation—pesticide</td>
<td>✓</td>
</tr>
<tr>
<td>Residue in cigarettes—pesticide</td>
<td>✓</td>
</tr>
<tr>
<td>Residue in cigarettes—pesticide metabolites</td>
<td>✓</td>
</tr>
<tr>
<td>Transfer into smoke—pesticide</td>
<td>✓</td>
</tr>
<tr>
<td>Identification of pesticide pyrolytic products</td>
<td>✓</td>
</tr>
<tr>
<td>Smoke inhalation study (smoke from pesticide-treated tobacco)</td>
<td>✓</td>
</tr>
<tr>
<td>Ames test—pesticide</td>
<td>✓</td>
</tr>
<tr>
<td>Ames test—pesticide metabolites</td>
<td>✓</td>
</tr>
<tr>
<td>Margin of safety calculated from toxicity data</td>
<td>Qualitative</td>
</tr>
</tbody>
</table>

*Note. LD<sub>50</sub> 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.

<sup>a</sup>Pesticide metabolites are breakdown products that form when a pesticide is transformed inside a living organism.

<sup>b</sup>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

[italics added]."59 Ultimately, 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.72 This committee would make the decision on whether to proceed with taste panels.72 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.74 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].”76 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 Unryoyal 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.

Someone at the meeting proposed that pesticide manufacturers assume responsibility for conducting taste panels.36,57

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, “[they 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.93 Sheets revised the 1972 safety protocol to reflect the additional information requested by tobacco companies (Table 2, third column).53

This procedure appears to have been followed for several years.60–62 However, an RJR review characterized it as unsuccessful.59 Chemical companies often failed to supply toxicological information; when they did, tobacco companies lacked the expertise to evaluate it.53(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(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.57 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.65–71 In October 1982, the group agreed to hire an outside consultant to evaluate chemical company data on pesticide toxicity 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.72 This committee would make the decision on whether to proceed with taste panels.72 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)
of smoking tobacco containing experimental pesticides.83 One
member suggested having the chemical companies hire to-
bacco 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 representa-
tive highlighted the need for new tobacco pesticides given the
dangers of disease “wiping out” the crop, the committee agreed
to evaluate a synthetic pyrethroid insecticide.86 Each company
would decide whether to have its employees smoke the experi-
mental 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.” As
the next TPC meeting, ATC’s Eugene Glock suggested adding to
the protocol the following statement: “[the basis for deletion of
specific information as suggested below should be explained with
the submission of the informa-
tion to the toxicologist. Under
certain circumstances all the sug-
gested information . . . may not
be required [emphasis in origi-
nal].”87 Dale reported that he
had sent the protocol to a Shell
Development Company scientist88; 6 weeks later, after receiv-
ing 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 (Avail-
able documents do not reveal
whether data were received.)
Chemical manufacturers ap-
peared 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 com-
mittee did not approve taste pan-
els. For example, in April 1993,
when a chemical company de-
cided to register a Bacillus
thuringiensis–encapsulated endo-
toxin for use on tobacco without
conducting allergenicity testing,
the TPC advised against taste pan-
els.96,97 The documents do not in-
dicate whether individual compa-
nies 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 cre-
tated their own. Those of RJR were the most comprehensive.
In 1984, it created a Human Re-
search 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 evalua-
tions, required approval by the
committee, which was composed
of 9 RJR employees (with no ap-
parent outside members): 7 from
Research and Development and 1
each from the medical and
legal departments.98,99 The com-
nittee stipulated that study par-
ticipants sign consent forms, but
it apparently provided no guide-
lines for research involving hu-
man subjects.95 Rather than establish
“full responsibility” for it.

Unlike RJR, PM does not ap-
ppear to have created a human
research committee. In 1994, 2 company researchers
devised toxicity testing guide-
lines for research involving hu-
man subjects.105 The guidelines sug-
gested that a PM researcher
consider pyrolysis, smoke chem-
istry, and acute toxicity stud-
ies before conducting employee
testing of new cigarette compo-
nents.105 Rather than establish
an IRB, they recommended
that an expert approve the re-
search plan.105 Advice regarding
informed consent was brief:
“Informal consent can be a stan-
dard form (e.g., ‘this is a novel
substance, believed not to be

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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

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, 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.119(p274) 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. 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.

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. 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.

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. 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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