

Mercantile Agendas Versus Honest Public Policy

A research paper, "Estimating The Consequences Of Replacing Cigarettes With Nicotine Inhalers" by W. Sumner II, MD at Washington University, was recently published in the June 2003 edition of *Tobacco Control* [2003;12:124-132]. The paper also received review publicity in the research journal *Science Daily*. That research paper says:

Page 130: "For a wide range of plausible inputs, DEMANDS [an econometric model developed by the author] estimates that the health consequences of completely displacing cigarettes with a widely used, deeply inhaled, highly addictive, pharmaceutical grade nicotine inhaler are comparable or superior to reducing smoking prevalence to 12%. Public health advocates and pharmaceutical companies could adapt tobacco control techniques to encourage smokers to replace cigarettes with nicotine inhalers." (Underline, italic added.)

Page 129: "However, the same legislation should recognize that corporations can best anticipate, control, and manipulate perceptions of the harms inherent in their nicotine delivery systems." (Underline, italic added.)

The Washington University research paper describes efforts to reduce smoking prevalence as futile, and says that tobacco control goals to reduce adult smoking prevalence to 12 percent by 2010 are probably unattainable. The alternative described by the author is to substitute pharmaceutical nicotine products for cigarettes. The paper articulates a strategy whereby public law and policy would be applied to directly influence product selection behavior of consumers who *lawfully* consume *legal* tobacco products. The strategy is explicitly intended to give drug company nicotine products anti-competitive advantages. The paper describes a broad strategy for wide distribution of nicotine products acknowledged to be highly addictive and recognized by its author as to be inherently harmful.

The described strategy does not anticipate consumers using nicotine inhalers to quit smoking. Dr. Sumner says:

Page 125: "A deeply inhaled nicotine powder or aerosol could supply nicotine to the arterial circulation as efficiently as a cigarette, but would maintain nicotine dependency rather than facilitate smoking cessation." (Underline, italic added.)

Page 129: "Deeply inhaled nicotine may addict users just as efficiently as cigarettes."

The described nicotine inhaler marketing strategy does not limit its prospective customer base to smokers:

Page 129: "As with tobacco pipes and cigarette packages, the nicotine industry could produce myriad variation on the appearance of inhalers, so that users could select inhaler designs based on image. These images might even replicate successful smoking themes, such as rugged individuality, suave character, and pleasure. Pharmaceutical companies would then promote the images and real advantages of a modern nicotine inhaler to potential users, beginning with current smokers." (Italic, underline added.)

Page 130: "First, the inhaler could simply disappear from the market, leaving the prevalence of cigarette use and nicotine addiction unchanged or even increased. Second, the inhaler could recruit new users, but not replace enough cigarette smoking to offset the harms to the new users. However even this short term public health failure would create legislative opportunities to demand lower nicotine content in cigarettes while raising taxes aggressively.^{6,53} Relatively satisfying inhalers could then supplant expensive and unsatisfying cigarettes and provide an alternative to black market cigarette purchases.⁵⁴" (Underline, italic added.)

Page 124: "Reduced regulation of clean nicotine could lead to the development of delivery systems designed to establish or maintain nicotine addiction. If people believe these products are safer than cigarettes, then nicotine use may increase. Some smokers would switch nicotine sources rather than quit.^{6,8} Some ex-smokers and never smokers might become regular users, exposing those groups to the hazards of nicotine." (Underline, italic added.)

Beyond acknowledgment of the dangers of pharmaceutical nicotine and nicotine inhalers in the Washington University research paper, other credible research supports the conclusion that *nonsmoked* nicotine can be medically dangerous. Medical research also supports conclusions that nonsmoked nicotine is not effective for intended use as a smoking cessation aid, and that some of the dangerous effects reported are not observed in tobacco nicotine.

A September 11, 2002 *Journal of the American Medical Association* (JAMA) article (Vol. 288 No. 10) reported on three California studies about smoking cessation products that included more than 21,000 smokers. The article, "Impact Of Over-The Counter Sales On Effectiveness of Pharmaceutical Aids For Smoking Cessation," stated:

"Nicotine Replacement Therapy is heavily promoted to the general public by both the pharmaceutical industry and tobacco control advocates." and;

"Since becoming available over-the-counter, NRT appears no longer effective in increasing long-term successful-cessation in California smokers."

June 30, 2001 *The Associated Press* published "Questions Raised About Nicotine Patches." A Stanford study concluded *nonsmoked* nicotine stimulates growth of blood vessels, which can increase growth of tumors. That effect is opposite to *smoked* nicotine, which reduces circulation. AP quoted Dr. John Cooke at Stanford University School of Medicine:

"This [increased blood flow to tumors] was totally a shock to us. We expected just the opposite."

January 2, 2003 CBS News reported on National Cancer Institute studies about nicotine, quoting Dr. Phillip Dennis:

"The take-home point is that nicotine is clearly not harmless."

Dr. Dennis explained that people who nicotine replacement should do so short term only. The institute's research compared the effects of tars and nicotine on damaged cell behavior. The conclusion was that *both* tars and nicotine have a similar effect that can lead to cancer: DNA in damaged cells causes them to eliminate themselves, both tar and nicotine stop that process. As a result, more damaged cells remain in the body, causing "an important early event in the formation of cancer."

Dr. Sumner also cites additional studies in his footnotes, such as those by Eliasson in 1996 that associated long term use of nicotine gum with insulin resistance. He also refers to studies by Lee in 1996 that associated nicotine with heart disease.

Despite the fact that nonsmoked nicotine is not considered to be an effective smoking cessation aid, such products continue to be advertised by pharmaceutical companies for that intended use. Today there are more youth and adult smokers than in 1990 before tobacco control interventions began, yet policy advocates and public figures continue to promote tobacco control programs as highly successful. Nonsmoked nicotine products such as the Nicotrol inhaler are acknowledged to be highly addictive and inherently harmful, but public policy could now virtually mandate their wide public distribution. For more than a decade tobacco control advocates have strenuously objected to improprieties of tobacco company marketing tactics. Today many of the same advocates are informed in Dr. Sumner's paper how previously-successful tobacco marketing themes can be applied to sell pharmaceutical nicotine inhalers.

The described strategy could permit nonsmoked nicotine products to be promoted with fewer restrictions than tobacco:

Page 129: "As a special form of counter-advertising, legislation could permit promotion of clean nicotine delivery systems as an alternative to cigarettes, perhaps with fewer constraints than we apply to tobacco products."

Moreover, the Washington University research paper outlines a strategy whereby nonsmoked nicotine products would be widely distributed to the public without legal accountability for the harms those products could cause. The described strategy would allow drug companies to do what is allegedly improper about tobacco company marketing to sell their nicotine products, and to have no legal accountability for doing so:

Page 129: "Legislation could shield the nicotine and tobacco industries from liability for the health effects of nicotine use, on the theory that even addicted individuals bear some responsibility to weigh the known risks against the perceived benefits of nicotine,⁵¹ and in recognition of the historical futility of efforts to fully eradicate nicotine use.⁵²"

The described strategy to replace cigarettes with nonsmoked nicotine inhalers encourages the establishment of anti-competitive price advantages for those products through the use of discriminatory taxation:

Page 129: "Governments would then tax safer nicotine delivery devices at a lower rate than hazardous tobacco products.⁶

Page 129: "Taxation and product liability costs are already raising the price of cigarettes, and could create a significant price difference between cigarettes and less hazardous nicotine delivery systems."

The described strategy constrains free-market competition and restricts voluntary consumer choice. The strategy crafts a *coerced consumer choice* of pharmaceutical nicotine as a substitute for tobacco products. The stated purpose of the strategy is to secure a mercantile advantage for pharmaceutical nicotine products. Moreover, the study anticipates using public policy influence of tobacco control advocacy subsidized by public funds to realize pharmaceutical nicotine mercantile goals:

Page 129: "The first policy step would be to allow the pharmaceutical industry to privately develop and market increasingly clean *and fast acting* nicotine delivery systems. For example, adapting an existing metered dose powder inhaler or adopting the design patented by Rose [Prof. Jed E. Rose of Duke University] and colleagues. Policies to encourage substitution of nicotine inhalers for cigarettes would reflect established principles of community level tobacco control policy, such as raising tobacco product prices, informing customers of risks, counter advertising, restricting youth access and marketing, and limiting opportunities to smoke." (Italic, underline, brackets added.)

Even if the nicotine inhaler marketing strategy were to be effective in reducing risks to persons who smoke it would still be highly objectionable based on its restraint of trade, tobacco price-influencing, and coerced consumer choice aspects. Dr. Sumner is clear, however, that even the assumed benefits of using a nicotine inhaler versus smoking are uncertain:

Page 124: “Potential reduced exposure products (PREPS) are nicotine delivery systems designed to expose users to fewer toxins than cigarettes do. Examples include smokeless tobacco, heated tobacco devices, and pharmaceutical nicotine replacement therapies. The Institute of Medicine report, *Clearing the smoke: assessing the science base for tobacco harm reduction, described how little we know about the health consequences of PREPs in general*² . . . Furthermore, different PREP designs may have diverse health consequences.” (Underline, italic added.)

Page 125: “Although some observers might welcome a competitive market to supply chronic nicotine users,^{6 19-21} others have discouraged chronic nicotine use because of the health risks.^{22 23}” (Underline, italic added.)

Page 126: Referring to DEMANDS model risk attribution between correlates such as nicotine, carbon monoxide, and other smoke constituents: “There is no direct evidence for these risk fraction estimates. Therefore this analysis simply reports a range of possibilities relevant to regulation of a pulmonary inhaler delivering essentially pure nicotine.” (Underline, added.)

Washington University and other medical researchers admit how little they know about the health consequences of long term use of pharmaceutical nicotine inhalers that are acknowledged to be highly addictive, yet they would describe and promote an aggressive mercantile strategy to widely distribute those products to the public. And they would do so with legislation to protect pharmaceuticals from product liability for the harm those products may cause. Dr. Sumner’s nicotine research may be suitable and important as background for health professionals to conduct further analysis, but it is entirely inappropriate and improper as a basis for public policy or an aggressive pharmaceutical nicotine marketing campaign.

Is aggressively marketing nicotine products despite known significant health risks related to the fact that Washington University received a \$500,000 smoking cessation grant ending June 30, 2003 from the Robert Wood Johnson Foundation (see page 6 A.) and the publisher of the research paper, *Tobacco Control*, also received a \$200,000 grant from the foundation to support its operations (6 B.)? The RWJ Foundation is the largest single shareholder of Johnson & Johnson, reportedly owning 5.4 percent of the company’s stock (the present market value is about \$7 billion.)

According to *Value Line*, as of March 1999 Johnson & Johnson distributed Nicotrol Nicotine Replacement Therapy products through its McNeil Consumer Products subsidiary. Nicotrol products are now distributed by Pharmacia Consumer Care, and Johnson & Johnson may have or be developing a new fast acting nicotine inhaler as described by Dr. Sumner. Some may recall television advertisements in the late 1990s for then-Johnson & Johnson’s Nicotrol inhaler that featured a young man in a flashy convertible who inhaled deeply from a Nicotrol inhaler. The man in the advertisement was congratulated by an attractive young woman for his intelligent consumer choice. When he mentions using successful tobacco marketing themes to sell pharmaceutical nicotine products Dr. Sumner cannot be referring to future events only. What Dr. Sumner describes is also the application of such themes as employed by pharmaceuticals several years ago to sell nonsmoked nicotine products. That theme was employed by a company of which the foundation that provided Washington University’s \$500,000 grant was and is the largest single shareholder. Today we often observe Pharmacia’s advertisements for the Nicotrol nicotine inhaler on television. Grant records and joint cost sharing contributions for tobacco control projects also demonstrate that the Robert Wood Johnson Foundation has financial ties to other pharmaceutical nicotine distributors such as Pharmacia (now Nicotrol) and GlaxoSmithKline (Nicorette gum, NicoDerm CQ patches, and Commit lozenges.)

In view of the foregoing, it is apparent that the pharmaceutical nicotine marketing strategy set forth in Washington University’s research paper does not discuss distant future events, nor does it outline a prospective or alternative approach to selling pharmaceutical nicotine products. Today we also observe two other principal elements of the described strategy, aggressive increases in the cost of tobacco products through discriminatory taxation and promotion of smoking bans, currently being applied by tobacco control advocacy. What Dr. Sumner’s paper actually accomplishes is to clearly set forth an organized approach to wide distribution of pharmaceutical nicotine through application of current and already-in-use marketing themes, regulatory influence, and anticompetitive strategies. We are therefore able to understand the current research paper in its full context: a synthesis of past and present tobacco control strategies to sell pharmaceutical nicotine products into a consolidated model for future aggressive product marketing efforts. Unfortunately, such efforts are undertaken at the expense and medical risk of consumers who choose to use competitive tobacco nicotine products.

The described strategy also endorses and supports smoking bans for the express purpose of “limiting opportunities to smoke,” which is to say to limit consumers’ ability to use *competitive* nicotine products. The author states that employers could abolish outdoor smoking areas and smoking breaks. Smoking breaks and designated outdoor smoking areas could be abolished because “addicted” employees will be able to inhale nicotine indoors with the pharmaceutical product. For example, Dr. Sumner states in his research paper:

Page 129: “Local ordinances that curtail public smoking already create settings where a nicotine inhaler could be the most satisfying alternative for current smokers. Lacking a burning tip and side stream smoke, an inhaler should present no risk to bystanders, and requires no restriction on public use. Employers could even abolish outdoor smoking areas and smoking breaks if addicted employees could inhale nicotine indoors.” (Underline added.)

Stripped of a pretense that pharmaceutical nicotine is effective for its advertised use as a smoking cessation aid, such products are revealed by their own advocates to be a new, highly addictive, and medically dangerous *substitute* for tobacco products that consumers have used for centuries. Absent reduction in adult smoking prevalence under the auspices of tobacco control programs, anti-smoking campaigns now stand as ineffective special-interest interventions that did not accomplish their goals as advertised. Presuming discriminatory taxation of tobacco products to secure price advantages for nonsmoked nicotine delivery devices, the described strategy is an anti-competitive model of marketing through unfair competition. Seen in its true light, tobacco control advocacy is not a public health service it is a manipulative and deceptive mercantile strategy. The end results of that strategy are to stabilize, expand, and then exploit the market for drug company products that contain a substance its advocates acknowledge to be medically dangerous and proclaim to be highly addictive.

Based on the foregoing, I summarize several important issues below. I ask that you consider facts and policy as stated:

1. Product Safety: I believe that it is improper for state legislatures to pass any law that has the intended effect to increase distribution of any products that credible research says can be dangerous, and which its own advocates proclaim to be highly addictive. I believe that such pharmaceutical products could violate the U.S. Food and Drug Administration’s mandate to approve drugs that are safe and effective for use. In the case of pharmaceutical nicotine, credible research says that those products are neither safe for consumers to use nor effective for their advertised purpose of smoking-cessation.

a.) Do not permit pharmaceutical nicotine products to be advertised and promoted with less restrictions than tobacco nicotine products. Require that all pharmaceutical nicotine products contain health warning messages on their boxes and dispensers that accurately reflect the known health risks of *nonsmoked* nicotine. Such warnings must be as prominent and just as graphic as those required for cigarettes at any time. Those warnings are appropriate and necessary for products that June 2001 Stanford University School of Medicine research says could support or accelerate the growth of tumors, a property that the same research *does not attribute to smoked tobacco nicotine*.

b.) Support prohibiting the use of the word “medicine” in all advertisements and promotional or use literature when referring to *nonsmoked* nicotine. The same substance with the same properties—nicotine—cannot at once be “medicine” in a pharmaceutical dispenser but “a deadly drug” in a cigarette. Products that the National Cancer Institute has reported to be associated with “an important early event in the formation of cancer” cannot be construed as health-restoring “medicine.”

c.) Support policy to prohibit the promotion and sale of pharmaceutical nicotine products for intended use as a smoking cessation aid. That policy is not only supported by more than fifty studies dating back to the 1990s, it is also supported by statements in a paper published by the *Journal of the American Medical Association* September 2002. The policy is supported by Dr. Sumner’s statements to the effect that pharmaceutical nicotine products could establish and maintain addiction.

d.) Do not support special protections from product liability for drug company nicotine. Why should drug company nicotine distributors enjoy protection from liability that their advocates have stridently objected to for tobacco companies?

2. Cigarette Taxes: Taxation for the intended purpose of discriminating against any class of citizens who *lawfully* consume any legal product is unacceptable. Discriminatory taxation of “Target Group” consumers is reprehensible in our post-September 11 culture of “United We Stand.” Discriminatory taxation of “Target Group” citizens for the express purpose of crafting a mercantile price advantage for products of politically influential pharmaceutical special-interests is despicable.

a.) Support legislation that taxes pharmaceutical nicotine products at the same rates, level, mils, or dollar amount as tobacco nicotine. Price advantages and subsidy supports for medically dangerous products that according to the *Journal of the American Medical Association* are not effective for intended use is not justified under any circumstance.

b.) Support or vote for legislation that prohibits appropriation of any tobacco or nicotine-based tax revenues for any purpose, such as financing tobacco control advocacy, other than the budgetary General Fund. Reimbursements for alleged medical costs incurred by the state should and must be subject to the deliberative process of the entire legislature.

c.) Do not support or vote for new tobacco taxes. Dr. Sumner’s strategy description reveals discriminatory tobacco taxes to be part of a pharmaceutical nicotine marketing scheme. I will vote against any new tobacco taxes on a ballot. I will also vote against, and encourage my friends and associates to vote against, any politician who supports new taxes on cigarettes.

3. Smoking Bans: July 17, 1998 Judge William L. Osteen ordered that Chapters 1 to 6 and Appendices of the December 1992 Environmental Protection Agency's report on secondhand smoke *be vacated* (7 A.) Judge Osteen's order included a 90-plus page scathing Memorandum Opinion that reviewed EPA's statistical methodologies. Included among Judge Osteen's findings were that a secondhand smoke risk factor of 1.19 was a very weak association that could not sustain EPA contentions secondhand smoke is a Group A carcinogen and that it is responsible for lung cancer deaths of 3,000 nonsmokers each year.

The 4th Circuit Court of Appeals vacated Judge Osteen's order December 2002, finding on a technical point that the court did not have authority to review the EPA report on secondhand smoke. In its order the 4th Circuit Court of Appeals stated that it was not ruling on the merits of the case. The appeals court also affirmed the importance of issues regarding the EPA report. Rather than vindicating EPA or supporting claims about secondhand smoke, the court was clear that important issues about EPA methodologies remained open (7 B.) The 4th circuit did not question Judge Osteen's conclusion that:

"EPA's conduct raises several concerns besides whether a relative risk of 1.19 is credible evidence supporting a Group A classification. First, with such a weak showing, if even a fraction of Plaintiff's allegations regarding study selection or methodology is true, EPA cannot show a statistically significant association between ETS and lung cancer."

A review of 58 studies on cancer and secondhand smoke conducted by the International Agency for Research on Cancer concluded that secondhand smoke increases the risks of lung cancer death in women by 22 percent and men by 36 percent. In context of Judge Osteen's order to vacate, the 58 studies reviewed by the agency tend to prove the *opposite* of what tobacco control claims. EPA conclusions were based on a weak relative risk of 1.19. The 58 studies reviewed by the agency showed relative risks of 1.22 and 1.36, averaging 1.29. Those risks are statistically the same as those in the EPA report, the risk factors have not materially changed from EPA's 1992 data. EPA's 1992 secondhand smoke statistics are still insufficient when reviewed by the International Agency for Research on Cancer in 2002. They will continue to be so regardless of how craftily they are stirred or how often they are proclaimed.

In addition, the alleged relationship between secondhand smoke and heart disease is not confirmed by credible research. A study about heart disease and secondhand smoke was reported in the July 2001 edition of the *Journal of the American Medical Association*. That study (see abstract, 8 A.) concluded that secondhand smoke may cause coronary circulation problems in nonsmokers, despite two of three measures showing no effect. Peer comments on that study (8 B.) published in JAMA January 2002 established that no record of secondhand smoke exposure was provided and that ventilation systems were not described. Consequently, it is open to question whether secondhand smoke even caused the effects observed.

a.) Please consider that the alleged dangers of secondhand smoke are not supported by credible science or research.

b.) Do not support smoking bans to protect public health, because credible science does not support the proposition that secondhand smoke is a material risk. Should you support smoking bans in the future, please at the least acknowledge that by doing you choose to support a pharmaceutical scheme to aggressively market dangerous and highly addictive products.

I reasonably expect that those who sponsor, vote for, or support tobacco control legislation and policy are competently informed on the issues. Please consider this paper to be a contribution toward assuring that you are so informed.

I mention in closing that there are not only two views to tobacco issues, those of pro-tobacco and anti-tobacco. Defining policy discussion in terms of two groups is at once self-serving to the vested interests of tobacco companies and tobacco control and exclusionary as to the legitimate interests of those effected. There is a third party to the tobacco debate: those who lawfully consume legal tobacco products. To presume the only material parties are tobacco companies and tobacco control is to put self-serving blinders on, to avoid looking in the eye those whom advocates regard as their "Target Group" of choice.

Today there about 48 million people in that third tobacco policy debate group, 2 million *more* than there were in 1990 before tobacco control's Project ASSIST began. Those consumers now understand from the 1998 tobacco settlement that the other two groups will sit down at the bargaining table and decide how much of the third group's money they will spend to satisfy their mutual interests. That third group has also felt the sting of being ostracized as "social pariahs," according to New York Times columnist Jane Brody. And that group is accustomed to bearing the brunt of discriminatory taxation, to being the duty cash cow for politicians' and special-interest projects of the year. Considering that—due in no small part to the efforts of allegedly anti-tobacco activists to serve their pharmaceutical sponsor's marketing needs—tobacco consumers are a growing population, you may expect that the third discussion group will organize its memmbers into expanding political influence. The foregoing therefore becomes more of an opening statement of that third group's entry into the debate than a whimper of protest by an individual. You will be hearing from tobacco consumers with increasing frequency and volume in the future. We respectfully recommend that you begin to listen to those views, and that you take the time to become informed on tobacco issues from the standpoint of those effected by tobacco control policy, lawful consumers of legal tobacco products.

A. \$500,000 Washington University RWJ Foundation Smoking Cessation Grant

Grants

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PROJECT
Linking peer- and neighborhood-based smoking cessation with clinic-based services for low-income African Americans

GRANTEE
Washington University
 Campus Box 1089, 1 Brookings Drive
 Saint Louis, MO 63130-4899

GRANT DETAIL
\$500,000 (49 months, awarded on 05/25/1999, starting 06/01/1999 ending 06/30/2003) ID# 0

CONTACT INFORMATION
 Edwin Fisher Ph.D. (Project Director)
 efisher@jim.wustl.edu
 314-286-1900

SUMMARY

The Robert Wood Johnson Foundation's program, Addressing Tobacco in Managed Care, is integrate effective tobacco intervention into the basic health care provided by managed care program will fund a series of grants to evaluate systems changes aimed at reducing rates of cessation provided by neighborhood health centers with those provided by neighborhood-based program services targeted to a low-income, predominantly African-American population. Syst be implemented in two organizations—Care Partners, a Medicaid Managed Care organization health and social service agency—and will include: (1) a patient tracking system to facilitate co smoking cessation services across organizations; and (2) strategies to promote a participator involves professionals, staff, and volunteers in program planning and development. The proje the implementation of proposed system changes, and assess the impact of those changes or cessation services offered, the level of patients' awareness of services, and patients' smoking

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B. \$200,000 RWJ Foundation Grant To Support Tobacco Control Journal

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PROJECT
Support for Tobacco Control Journal

GRANTEE
Health Research, Inc.
 Elm and Carlton Streets
 Buffalo, NY 14263-0001
 716-845-3010

GRANT DETAIL
\$200,000 (3 years, awarded on 01/29/2002, starting 04/01/2002 ending 03/31/2005) DF# 044

CONTACT INFORMATION
 K. Cummings Ph.D., M.P.H. (Project Director)
 michael.cummings@roswellpark.org
 716-845-8456

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A. Judge Osteen's July 17, 1998 Ruling On
December 1992 EPA Report On Secondhand Smoke

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA WINSTON-SALEM DIVISION

FLUE-CURED TOBACCO COOPERATIVE STABILIZATION CORPORATION,
THE COUNCIL FOR BURLEY TOBACCO INC., UNIVERSAL LEAF
TOBACCO COMPANY INCORPORATED, PHILIP MORRIS INCORPORATED,
R.J. REYNOLDS TOBACCO COMPANY,
and GALLINS VENDING COMPANY,

Plaintiffs,

V.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, and CAROL BROWNER,
Administrator, Environmental Protection Agency,

Defendants.

6:93CV00370

ORDER AND JUDGMENT

OSTEEN, District Judge

For the reasons set forth in the memorandum opinion
entered contemporaneously herewith,

IT IS ORDERED AND ADJUDGED that Plaintiffs' Motion for Partial Summary
Judgment is granted [1171.

IT IS FURTHER ORDERED AND ADJUDGED that Defendants' Cross Motion for
Summary Judgment is denied [1261. The court vacates Chapters 1-6 of and
the Appendices to EPA's Respiratory Health Effects of Passive
Smoking: Lung Cancer and other Disorders, </underline>EPA/600/6-90/006F
(December 1992). To ripen its judgment for purposes of appellate review,
pursuant to Federal Rule of Civil Procedure 54(b), the court finds there
is no just reason for delaying entry of judgment.

IT IS FURTHER ORDERED AND ADJUDGED that Plaintiffs, Motion for Leave to
File Supplement Pleading under Rule 15(d) is granted (1201).

This the 17th day July, 1998.

[signed William L. Osteen]

United States District Judge

B. 4th Circuit Court of Appeals Order Regarding
EPA Report On Secondhand Smoke

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long and as much, or more. In context, that is about the same period
of time that the Plantagenets and Tudors ruled England. North Caro-
lina is the nation's largest producer, and North Carolina, Virginia and
South Carolina together produce more than half the nation's tobacco
crop. So the importance of the decision of the EPA at issue here may
not be over-emphasized. Nevertheless, exclusion by the EPA of any
meaningful tobacco industry representative from the advisory com-
mittee mentioned in the Radon Statute is unexplained. But these facts
do not affect our lack of jurisdiction under the APA to review the
report at issue in this case. The legal questions in the case are substan-
tial. The practical consequences of the EPA Report are great and
affect the livelihood of thousands.

On that account, we stay the issuance of the mandate upon our
decision for a period of 30 days after it has become final in order that
the plaintiffs may file a petition for certiorari in the Supreme Court
of the United States and seek a stay from that Court in connection
with such filing. See *Reamer v. Beall*, 506 F.2d 1345, 1346 (4th Cir.
1974); *Rich v. Naviera Vacuba, S.A.*, 295 F.2d 24, 26 (4th Cir. 1961).
V.

The judgment of the district court is accordingly vacated and the
case remanded for dismissal for want of subject matter jurisdiction.
VACATED AND REMANDED WITH INSTRUCTIONS

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12/14/200

A. JAMA Secondhand Smoke Study Abstract

JAMA -- Abstracts: Otsuka et al. 286 (4): 436

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The Journal of the American Medical Association — To Promote the Science and Art of Medicine and the Betterment of the Public Health

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Acute Effects of Passive Smoking on the Coronary Circulation in Healthy Young Adults

Ryo Otsuka, MD; Hiroyuki Watanabe, MD; Kumiko Hirata, MD; Kotaro Tokai, MD; Takashi Muro, MD; Minoru Yoshiyama, MD; Kazuhide Takeuchi, MD; Junichi Yoshikawa, MD

JAMA. 2001;286:436-441.

Context Recent studies have shown that **passive smoking** is a risk factor for ischemic heart disease and may be associated with vascular endothelial dysfunction. The **acute effects of passive smoking** on coronary circulation in nonsmokers are not known.

Objective To determine the **acute effects of passive smoking** on coronary circulation using coronary flow velocity reserve (CFVR), assessed by noninvasive transthoracic Doppler echocardiography.

Design, Setting, and Participants Cross-sectional study conducted from

September 2000 to November 2000 among 30 Japanese men (mean age, 27 years; 15 healthy nonsmokers and 15 asymptomatic active smokers) without history of hypertension, diabetes mellitus, or hyperlipidemia.

Main Outcome Measures Coronary flow velocity reserve, calculated as the ratio of hyperemic coronary flow velocity induced by intravenous infusion of adenosine triphosphate and measured participant before and after a 30-minute exposure to environmental tobacco smoke.

Results Heart rate and blood pressure responses to adenosine triphosphate infusion were not significantly different between groups. **Passive smoking** exposure had no effect on basal coronary flow velocity in either group. Mean (SD) CFVR in nonsmokers was significantly higher than that in smokers before **passive smoking** exposure (4.4 [0.91] vs 3.6 [0.88], respectively; $P = .02$), whereas after **passive smoking** exposure did not differ between groups ($P = .83$). **Passive smoking** exposure significantly reduced mean (SD) CFVR in nonsmokers (4.4 [0.91] vs 3.4 [0.73], respectively; $P < .001$).

Conclusions **Passive smoking** substantially reduced CFVR in healthy nonsmokers. This finding directly evidence that **passive smoking** may cause endothelial dysfunction of the coronary circulation in nonsmokers.

http://jama.ama-assn.org/cgi/content/abstract/286/4/436?maxtoshow=&HITS=10&hits=10&... 6/5/2003

B. JAMA Secondhand Smoke Study Peer Comments

JAMA -- Lam et al. 287 (3): 316

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Vol. 287 No. 3, January 16, 2002

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Effects of Passive Smoking on Coronary Circulation

To the Editor: Dr Otsuka and colleagues¹ found that passive smoking has harmful effects on the coronary endothelial function in healthy young nonsmoking adults after exposure was not more clearly quantified. Apart from describing the size of the smoking room and the fact that some individuals were smoking, the authors did not estimate the amount of exposure to environmental tobacco smoke. They did not describe the number of smokers or the number of cigarettes smoked in the room before or when the subjects were exposed. They similarly gave no information about the ventilation system.

Furthermore, only air concentrations of carbon monoxide, not nicotine or particulate levels, were measured. To gauge the bioavailability of environmental tobacco smoke compounds, the authors measured the subjects' plasma carboxyhemoglobin level. Measuring other biomarkers such as nicotine could have provided additional useful information. In terms of public policy, it would be know how typical these exposures and results are.

Otsuka et al also found an apparent lack of effect of **secondhand smoke** on the endothelial function in smokers. Does this imply that passive smoking is not harmful to active smokers and that they safely accommodated in designated smoking rooms? More sensitive measures of vascular effect passive smoking in active smokers are needed. **Secondhand smoke** is a confirmed human carcinogen with no safe level of exposure for either smokers or nonsmokers.

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1. Otsuka R, Watanabe H, Hirata K, et al. Acute effects of passive smoking on the coronary circulation in nonsmokers. *JAMA*. 2001;286:436-441. ABSTRACT/FULL TEXT

To the Editor: Dr Otsuka and colleagues¹ showed that exposure to **secondhand smoke** with carbon monoxide (SSCO) levels of 6.02 ppm for 30 minutes induces endothelial dysfunction of the coronary circulation in nonsmokers. This exposure level can be related to actual **secondhand smoke** exposure by an equation relating SSCO to **secondhand smoke** respirable particulate matter (SSRSP)²:
 $SSRSP = 0.0001 \times SSCO + 0.0001 \times SSCO^2$
http://jama.ama-assn.org/cgi/content/full/287/3/316?maxtoshow=&HITS=10&hits=10&RES... 6/5/2003