FOIA Number: 2008-1524-F

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Folder Title:
Tobacco Bills-Conrad, Hatch, Jeffords: Jeffords

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Provisions necessary to expressly acknowledge FDA's jurisdiction

A statement validating the regulations enacted by FDA--

> The regulations promulgated by the Secretary in the rule dated August 28, 1996 (Vol. 61, No. 168 F.R.), adding part 897 to title 21, Code of Federal Regulations, shall be deemed to have been properly promulgated under the Food, Drug and Cosmetic Act as amended by this title.

Amendments to the definitions of drug and device to specifically include nicotine in tobacco as a drug and tobacco products as devices--

> Drug-Section 201(g)(1) is amended by striking"; and (D)" and inserting ";(D) nicotine in tobacco products; and (E)"
>
> Devices- Section 201(h) is amended--in paragraph (2) by striking "or" at the end; in paragraph (3), by striking "and" at the end and inserting "or"; and by inserting after paragraph (3), "(4) a delivery component of a tobacco product; and"

In order to clarify the agency's authority amend section 520(e) as follows:

> Section 520(e)(1) is amended by striking "or use-" and inserting "or use, including restrictions on the access to and the advertising and promotion of, tobacco products-"

Codify the approach explained in the preamble to the FDA Tobacco Rule, 61 Fed. Reg. 44412-13:

> Section 513(a) is amended in paragraph (1)(B), by inserting after the first sentence "For a device which is a tobacco product, the assurance in the previous sentence need not be found if the Secretary finds that special controls achieve the best public health result."; and in paragraph (2) by redesignating subparagraphs (A), (B) and [C] as clauses (i), (ii), and (iii), respectively; by striking "(2) For" and inserting "(2)(A)For"; and by adding at the end "(B) For purposes of paragraph (1)(B), subsections (c)(2)(C),

(d)(2)(B), (e)(2)(A), (f)(3)(B)(i), and (f)(3)(C)(i), and sections 514, 519(a), 520(e), and 520(f), the safety and effectiveness of a device that is a tobacco product need not be found if the Secretary finds that the action to be taken under any such provision would achieve the best public health result. The finding as to whether the best public health result has been achieved shall be determined with respect to the risks and benefits to the population as a whole, including users and non-users of the tobacco product, and taking into account-[i] the increased or decreased likelihood that existing customers of tobacco products will stop using such products; and (ii) the increased or decreased likelihood that those who do not use tobacco products will start using such products."

Recall Authority: Section 518(e)(1) is amended by inserting after "adverse health consequences or death," the following, "and for tobacco products that the best public health result would be achieved,"

First Puff

Wednesday, March 11, 1998; Page A18

Editorial

Related Items

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THE SENATE Labor and Human Resources Committee is scheduled to start marking up a tobacco bill today. The legislation is an effort by Chairman James Jeffords to codify Food and Drug Administration authority to regulate the product. The effect, however, could be to weaken the regulatory authority that the FDA already claims to have. The administration, leading anti-smoking groups and leading committee Democrats are therefore opposed, and in our view rightly so.

There are two fundamental things that any tobacco bill must do -- if we are to have one. The first is to tax up the price of the product enough not just to discourage but to deter smoking, particularly on the part of kids who have not yet begun. The second is, at the very least, to affirm and preserve existing regulatory authority. That's the jurisdiction of the Labor Committee. Mr. Jeffords, in part on the theory that existing law wasn't meant to deal with tobacco and isn't a good fit, has tried to tidy it up. But this is a case in which power counts for more than tidiness. In tidying up, in the view of his critics, he would make the law less flexible. Part of his goal is to reduce the likelihood of future litigation. The critics argue that the likely effect of rewriting the law would be to set off a whole new round of litigation instead.

The FDA currently claims the authority to regulate on grounds that nicotine fits the body-altering definition of a drug and cigarettes are the instrument of its delivery. That's what Mr. Jeffords says doesn't fit. But the explicit authority with which he would replace it contains problems of its own. Enforcement would be spread among several agencies. The FDA, if it ordered cigarettes changed -- say, by reducing allowable nicotine levels -- would have to consider whether the new product was "commercially feasible," meaning in part whether people would buy it or turn to a black market for higher-potency cigarettes from abroad. Nor could the FDA take any action to eliminate nicotine or ban a tobacco product without concurrence in the form of an affirmative vote by Congress.

Those are hobbles. This seems to us not to be a time for hobbles.

These will be the first votes in either house on the tobacco legislation that both parties profess to want to pass this year. The first votes ought to send a different signal than this draft would. Mr. Jeffords is said to have marshaled all the committee Republicans behind this version. That's another form of tidiness that ought not be the test. Better no bill at all than a bill that needlessly yields ground to this lethal product and remorseless industry.

Memo To: Jerry Mande, Cynthia Rice
From: Jon Gruber
Re: Comments on Jeffords & McCain lookback provisions

All of the comments below apply to both provisions, with the exception of the last two comments which apply only to McCain:

1) The penalties apply only to the industry, and not to individual companies. As we have emphasized, it is crucial to have a mix of industry and company-specific penalties, to provide both price and non-price insurance against missing youth targets. In particular, using only an industry penalty provides no incentives for individual companies to change their behavior, since the penalty can simply be passed on to price. We are happy to provide detailed specifications of a preferred structure for lookback penalties.

2) The penalties are too small. On a cents/pack basis, these penalties amount to only 0.3 cents-2.2 cents per percentage point for Jeffords, and only 0.3 cents for McCain. Since the penalties are on the entire industry and will be passed on to price, these levels are much too low. The level should be at least 3 cents (if deductible, or 2 cents if non-deductible) to start, and should rise from there.

3) The penalties apply to daily smoking, rather than 30 day smoking. At this point, administration consensus is that a 30 day measure is more appropriate for public health reasons (e.g. catching children who are experimenting with smoking), and does not raise larger measurement problems.

4) The penalties should be based on a new, 1999 survey done to be done by CDC (and there should be funding for such a survey). This will be required to do company-specific penalties. The Secretary should be empowered with proper authority to carry out and adjust this survey as necessary. This survey should cover all children age 12-17, as well as other age groups; this is as opposed to the Michigan survey, which covers only 8th, 10th, and 12th grades.

5) There should be no abatement process. This makes the entire penalty structure very uncertain and adds a degree of uncertainty to the penalties which greatly weakens the incentives for companies to reduce teen smoking. Moreover, after abatement the levels of the penalties are sufficiently low to provide little incentives for reductions in youth smoking, particularly when they can simply be passed on to price (as in the case of an industry penalty).

6) (McCain only) The penalty should be increasing, either at a point in time (for missing the targets more severely, as in Jeffords), or over time (multiplying if you miss the targets for a number of consecutive years). An advantage of the latter over the former is that, even at a given performance (e.g. missing targets by 10%), higher prices will be needed in later years to obtain a given reduction in youth smoking (since the youths who are still smoking after large price increases are less price sensitive).

7) (McCain only). The cap on industry penalties should not be at such a low level (NOTE: $2 billion is less than 10 cents/pack).

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FDA's authority to regulate tobacco products as contemplated in S. 1648

The President has stated that the Administration will support proposed tobacco legislation only if it affirms the FDA's full authority to regulate tobacco products. That means the authority must be as effective as FDA's authority over other drugs and devices, and must be sufficiently flexible to meet changing circumstances. S. 1648, if enacted, does not meet that standard. The bill has two problems. First, the bill deprives the FDA of needed elements of regulatory authority. Second, by creating a separate Chapter for tobacco products, the bill unnecessarily impinges on FDA's ability to exercise, in the most effective and efficient manner, its authority over tobacco products..

I. The separate Chapter created by S. 1648 to regulate tobacco product suffers from the following specific deficiencies:

A. Access. The bill deprives FDA or any other HHS agency of the ability to modify access requirements if the current access restrictions in the FDA rule are inadequate or require redirection (such as limiting the types of stores where tobacco products can be sold). The bill also bifurcates access and advertising regulatory authority, the former going to the Centers for Disease Control; the latter to FDA. That division of responsibility weakens both authorities.

B. Advertising. The bill deprives FDA of the authority to modify advertising restrictions if the ones in the current rule require amendment or supplementation.

C. Flexibility. The bill requires that both Houses of Congress act affirmatively – by enacting a law --to eliminate nicotine or to eliminate tobacco products (even if, in the distant future, a safer alternative to nicotine or the product is developed).

D. Product Safety. The bill limits FDA's authority to set standards pertaining to nicotine and other ingredients in tobacco products, and deprives FDA of the authority to require safer products through regulation of, for example, the filter, paper or tobacco leaf. In addition, the bill eliminates FDA's ability to require premarket approval and rigorous testing for new tobacco products.

E. Enforcement. The bill does not contain the following enforcement authorities that are in current law: civil money penalties; recall authority; authority to detain illegal products without a court order; and authority to seize products pursuant to a court order. Additionally, the bill eliminates FDA's current adulteration and misbranding authority for tobacco products – which is the authority to bring individual enforcement actions without issuing a regulation.

II. Even if all of the above elements of FDA authority were added to S. 1648, the creation of a separate Chapter for regulation of tobacco products creates unnecessary obstacles to the effective exercise of FDA authority. Three points illustrate this.

A. The inference that would be drawn from enactment of a new Chapter is that Congress intended to create a tobacco jurisdiction in FDA not only separate from but different than that

exercised over all other FDA-regulated products. The current statutory scheme that FDA has used to regulate tobacco has been interpreted in more than 20 years of regulations, guidances and judicial cases. Enactment of a new Chapter would replace all of that with a stand-alone, uninterpreted and unexplicated new jurisdiction, the full scope and extent of which would have to be re-built through agency action and judicial rulings.

By contrast, clarification in the Food Drug and Cosmetic Act of the definitions of "drug" and "device" to explicitly include tobacco products -- and clarification of FDA's statutory authority to place restrictions on medical device products to explicitly include tobacco advertising -- leaves in place this entire regulatory context. Should Congress so choose, the standard for safety and efficacy of new products could be amended to one that achieves an enhanced public health outcome.

B. New statutes require years to implement. A new Chapter will almost certainly require new rules, which will take years to implement, especially given the virtual certainty of legal challenges.

C. Finally, a new Chapter will almost certainly generate litigation over whether the FDA must scrap entirely its current regulation and re-start the regulatory process after new legislation is adopted.

3/5
1 p.m.

Provisions necessary to expressly acknowledge FDA's jurisdiction

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> The regulations promulgated by the Secretary in the rule dated August 28, 1996 (Vol. 61, No. 168 F.R.), adding part 897 to title 21, Code of Federal Regulations, shall be deemed to have been properly promulgated under the Food, Drug, and Cosmetic Act as amended by this title.

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In order to clarify the agency's authority, amend section 520(e) as follows:

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Codify the approach explained in the preamble to the FDA Tobacco Rule, 61 F.R. 44412-12:

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such products; and (ii) the increased or decreased likelihood that those who do not use tobacco products will start using such products."

Recall Authority: Section 518(e)(1) is amended by inserting after "adverse health consequences or death," the following, "and for tobacco products that the best public health result would be achieved,"

Text of Letter to Sen. Jeffords from Public Health Groups
U.S. Newswire
6 Mar 16:18

Text of Letter to Sen. Jeffords from Public Health Groups
To: National Desk, Health and Medical writers
Contact: Kathryn Kahler Vose, 202-296-5469
or Marjorie Tharp, 202-347-8600

WASHINGTON, March 6 /U.S. Newswire/ -- Following is the text of a letter to Sen. James Jeffords, chairman of the Senate Committee on Labor and Human Resources, from 29 public health groups:

March 5, 1998

Dear Sen. Jeffords,

We have had the opportunity to review the "Preventing Addiction to Smoking Among Teens Act." We want to thank you for your leadership on this vitally important issue. PAST contains many provisions that will contribute to the betterment of the nation's public health. We recognize and appreciate that changes made from the initial draft that was circulated for comment address a number of the concerns which were previously raised and that a number of provisions in the bill will move public policy forward significantly.

Nonetheless, the bill raises serious questions in several areas. Before we attempt to address other issues raised by the current bill, we felt it was critical to inform you of our view that the problems that remain with the provisions of PAST concerning the authority of the Food and Drug Administration are so fundamental and of such great concern that we could not support the bill if the bill is moved to mark-up in its current form.

FDA asserted jurisdiction over tobacco products after the emergence of a scientific consensus that cigarettes and smokeless tobacco cause addiction to nicotine. The entire public health community agrees that the FDA has rightly concluded that (1) nicotine in cigarettes and smokeless tobacco does "affect the structure and function of the body," and (2) these effects on the structure and function of the body are "intended" by the manufacturers. Every public health organization agrees that FDA's conclusion that the nicotine in cigarettes and smokeless tobacco is a drug, and that cigarettes and smokeless tobacco products are devices is one of the most significant advances in public health in recent history.

The benefits of FDA oversight of tobacco products are: it will be a coordinated, comprehensive approach to reduce tobacco use among children, it will encourage and assist adults to quit, and it will reduce the harm to the American public caused by the products that remain on the market. Unfortunately, as drafted, PAST will result in a curtailment of FDA's authority in a number of areas, and does not provide FDA with needed authority in others. Therefore, PAST will not give FDA the ability to do the job that is necessary.

The entire public health community is united in the conclusion that the following FDA related issues are critical:

-- Reaffirms the authority of FDA to treat Nicotine as a drug and Tobacco Products as Drug Delivery Devices. This is a power the FDA already possesses which should not be curtailed. The tobacco industry agreed to have its products treated as drugs and devices in its Agreement with the State Attorneys General. If the tobacco industry agreed to have its products treated as drugs and devices, there should be no reason to retreat from this sound position. There should not be a separate chapter in the FDCA just for tobacco in which tobacco is treated as neither a "drug" nor a "device". Any concern about the application of the "safety and efficacy" standard to tobacco products is misplaced and easily addressed. Section

513(a)(2) and Section 520(e) (Restricted Devices) already recognize that in certain instances devices require a more flexible public health standard than is generally attributed to the "safety and efficacy" standard. In addition, several sound proposals for an appropriate standard, including the standard contained in Section 903(C)(2)(A) in PAST, address this issue.

-- Does not abridge FDA's Authority to Be the Primary Federal Agency to Reduce the Ease With Which Children Obtain Tobacco Products: While PAST's youth access provisions have been strengthened since the discussion draft, PAST would strip FDA of its current authority over youth access to tobacco products and transfer that authority to the CDC. The CDC is not a regulatory enforcement agency, nor does it have rulemaking authority comparable to FDA. It is essential to have one agency with overall regulatory authority over the key components of any tobacco control plan and that agency must have the authority to enforce and revise its rules as loopholes in any regulatory plan are identified.

-- Retains the FDA's Authority to restrict Tobacco Advertising That Affects Children: PAST includes the advertising restrictions contained in the FDA Rule and the Agreement between the State Attorneys General and the Tobacco Industry, but does not retain the FDA as the enforcement agency for these restrictions and does not recognize the FDA's rulemaking authority to revise these important marketing restrictions if the current rules prove to be ineffective because of loopholes the tobacco industry identifies. If a coordinated effort is to succeed, one agency needs to have the authority to coordinate youth access, marketing, and product performance efforts.

-- Does Not Impose Substantive Burdens For Product Performance Standards That Exceed those Imposed On Other Products. PAST would require the FDA to consider whether a product is "commercially feasible" before imposing a product performance standard. This provision has been improved significantly from the discussion draft, but the "commercially feasible" criterion is one that is not imposed for other product performance standard and is a likely subject of abuse and delay because the tobacco industry is in a unique position to control the creation of any data on this topic.

-- Does Not Require Congressional Approval of FDA's Actions For Tobacco Products: PAST requires an affirmative vote of Congress before an FDA action eliminating nicotine or prohibiting a class of tobacco products takes effect.

This is tantamount to stripping FDA of the authority to take these actions. We do not support the prohibition of the sale of tobacco products to adults, but we also oppose requiring a level of Congressional approval for an FDA related tobacco action that would not be required if FDA took a comparable action with regard to any other product. It is significant that the restriction on the FDA in PAST goes beyond what even the tobacco industry demanded in its negotiations with the State Attorneys General.

We hope it will be possible to work with you and your staff before any mark-up to correct these critical problems and to address other aspects of PAST that we believe should be improved before the bill is acted upon by the Committee. We appreciate your concern for protecting our nation's children from tobacco and hope it will be possible to reach agreement on a bill that will meet all of our mutual goals.

Sincerely,

American Academy of Family Physicians
American Academy of Pediatrics
American Association of Physicians of Indian Origin
American Association for Respiratory
American Cancer Society
American College of Cardiology

American College of Chest Physicians
American College of Physicians
American College of Preventive Medicine
American Heart Association
American Medical Association
American Psychological Association
American School Health Association
American Society of Addiction Medicine
American Society of Internal Medicine
American Society of Clinical Oncology
Campaign for Tobacco-Free Kids
College on Problems of Drug Dependence
The HMO Group
Interreligious Coalition on Smoking or Health
Latino Council on Alcohol and Tobacco
National Association of Children's Hospitals
National Association of County and City Health Officials
National Hispanic Medical Association
Oncology Nursing Society
Partnership for Prevention
Society for Behavioral Medicine
Society for Research on Nicotine and Tobacco
Summit Health Group

cc: The Honorable Edward M. Kennedy, Ranking Minority Member
Senate Labor & Human Resources Committee

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/U.S. Newswire 202-347-2770/
03/06 16:18

First, the bill deprives FDA of needed elements of regulatory authority. Second, by creating a separate title for tobacco product, the bill unnecessarily impinges on the FDA's ability to exercise, in the most effective and efficient manner, its authority over tobacco products.

FDA's authority to regulate tobacco products as contemplated in S. 1648

The President has stated that the Administration will support proposed tobacco legislation only if it affirms the FDA's full authority to regulate tobacco products. That means the authority must be as effective as FDA's authority over other drugs and devices, and must be sufficiently flexible to meet changing circumstances. S. 1648, if enacted, does not meet that standard. The bill fails has two problems, ~~on two accounts. First, it does not include key elements of FDA's current authority. Second, even if a new enactment included each of those elements, the sum of the whole would be less than current FDA authority. We take these issues up in turn.~~

I. ~~S.1648 would create an entire new~~ The separate Chapter created by S.1648 to regulate tobacco products ~~The separate Chapter~~ suffers from the following specific deficiencies:

A. Access. The bill deprives FDA or any other HHS agency of the ability to ~~impose additional~~ modify current requirements if the access restrictions in the FDA rule are inadequate or require redirection (such as limiting the types of stores where tobacco products can be sold). The bill also bifurcates access and advertising regulatory authority, the former going to the Centers for Disease Control; the latter to FDA. That division of responsibility weakens both authorities.

B. Advertising. The bill ~~effectively eliminates~~ deprives FDA of the authority to ~~impose additional~~ modify advertising restrictions if the ones in the current rule require amendment or supplementation.

C. Flexibility. The bill requires that both Houses of Congress act affirmatively -- ~~to~~ by enacting a law --to eliminate nicotine or to eliminate tobacco products (even if, in the ~~distant~~ future, a safer alternative to nicotine or the product is developed). Under existing law Congress is would already provided an opportunity to review regulatory changes of this sort.

D. Product Safety. The bill limits FDA's authority to set standards pertaining to nicotine and other ingredients in tobacco products, and deprives FDA of the authority to require safer products through regulation of, for example, the filter, paper or tobacco leaf. In addition, the bill eliminates FDA's ability to require premarket approval and rigorous testing for new tobacco products.

E. Enforcement. The bill does not contain the following enforcement authorities that are in current law: civil money penalties; recall authority; authority to detain illegal products without a court order; and authority to seize products pursuant to a court order. Additionally, the bill eliminates FDA's current adulteration and misbranding authority for tobacco products – which is the authority to bring individual enforcement actions without issuing a regulation.

II. ~~The sum of these parts, however, if enacted in a separate Chapter, will be less than the authority that currently exists to regulate and reduce youth tobacco use.~~ Three points illustrate the proposition.

A. The inference that would be drawn from enactment of a new Chapter is that Congress intended to create a tobacco jurisdiction in FDA not only separate from but different than that exercised over all other FDA-regulated products. The current ~~law on which~~ statutory scheme that FDA has ~~regulated~~ used to

Even if all of the above ~~authority~~ elements of FDA authority were added to S. 1648, the creation of a separate title for regulation of tobacco products ~~would~~ creates unnecessary obstacles to the ~~FDA's~~ effective exercise of its authority.

regulate

tobacco ~~contains a complex statutory structure that has~~ been interpreted in more than 20 years of regulations, guidances and judicial cases. Enactment of a new Chapter would replace all of that with a stand-alone, uninterpreted and unexplicated new jurisdiction, the full scope and extent of which would have to be re-built through agency action and judicial ~~intervention.~~ rulings.

By contrast, clarification in the Food Drug and Cosmetic Act of the definitions of "drug" and "device" to explicitly include tobacco products and of FDA's statutory authority to place restrictions on medical device products to explicitly include tobacco advertising, leaves in place ~~the context in which the law will operate going forward.~~ Should Congress so choose, the standard for safety and efficacy of new products could be amended to one that achieves an enhanced public health outcome.

this entire regulatory context.

B. New statutes require years to implement. A new Chapter ~~will inevitably require [illegible] will reconstruction of implementation (as noted above), an extremely and unnecessarily time-consuming enterprise. It is a virtual certainty that any additional regulations issued will be~~ challenged in court, leading to several additional years of delay.

almost certainly

C. Finally, ~~a new~~ Chapter ~~that forms the foundation for FDA regulation of these products~~ will ~~undoubtedly~~ generate litigation over whether FDA ~~need~~ scrap ~~entirely~~ its current regulation, ~~only to~~ re-start ~~that~~ process after new legislation is adopted. ~~Imperiling the FDA regulation that has been the platform on which the President's tobacco initiative has been built is not only destructive but cedes the authority that has carried the Administration to its current position of strength on this issue.~~

almost certainly

the

must

and

the regulatory

require new rules, which will take years to implement, especially given the virtual certainty of legal challenges.

TO JERRY MANDE:

WE INTEND TO GIVE ARTHUS ROSENFELD, OF SEN. JEFFORDS COMMITTEE STAFF THE FOLLOWING DOCUMENTS, WITH YOUR APPROVAL.

SHOULD I ALSO BE FAXING THIS TO ANYONE ELSE?

1. LIST OF INFORMATION AND STUDIES WHICH WILL HAVE TO BE PUT IN REOPENED RECORD TO DEMONSTRATE SIGNIFICANT RISK

2. SUGGESTED WORDING FOR SIGNIFICANT RISK AND FEASIBILITY FOR SEN JEFFORDS BILL

3. CURRENT STAFF REQUIREMENTS AND DETAILS ABOUT OUR "DOCKET" AND COMPUTER PROBLEMS

4. CURRENT REG PROCESS

5. PROJECTED STAFF REQUIREMENTS

6. PROJECTED REG PROCESS

Emily

David Baron
OLC
514-8713

LIST OF INFORMATION FOR WHICH OSHA WOULD NEED TO REOPEN THE RECORD IF NO CONGRESSIONAL FINDING OF SUBSTANTIAL BURDEN

1. Results of ETS Exposure workshop, help in September, 1997 (to be published in peer reviewed journal later this year)

2. Results of two additional workshops (ETS quantitative risk assessment; local exhaust ventilation for hospitality sector) to be held this calendar year (to be published in peer reviewed journal in near future)

3. List of new studies available since record closed, attached.

List of new information since 1996 closing of the record:

Ahluwalia, I., Grummer-Strawn, L, and Scanlon, K. Exposure to environmental tobacco smoke and birth outcome: increased effects on pregnant women aged 30 years or older. Am J Epidemiol. 146(1): 42-7, 1997.

Benowitz, Neal L.. Cotinine as a Biomarker of Environmental Tobacco Smoke Exposure. Epidemiologic Reviews. pp. 188-204 Vol.18 1996.

Bergman, T., Johnson, D., Boatright, D., et al. Occupational exposure of nonsmoking nightclub musicians to environmental tobacco smoke. Am. Ind. Hyg. Assoc. J. 57:746-752, 1996.

California Environmental Protection Agency. Health Effects of Exposure to Environmental Tobacco Smoke. California Environmental Protection Agency, Office of Environmental Health Hazard Assessment. 1997.

Cardenas, Victor M. Environmental tobacco smoke and lung cancer mortality in the American Cancer Society's Cancer Prevention Study II. Cancer Causes and Control. pp. 57-64 Vol. 8, 1997.

Comstock, George W.. MD. Parental smoking and perinatal mortality. Am. J. Obs. &Gynec. pp. 708-718 July 1, 1967.

Coultas, David B. Variability of Measures of Exposure to Environmental Tabacco Smoke in the Home. pp. 602-608, 1990.

Deanfield, J. Passive smoking and early arterial damage. European Heart Journal 17:645-646, 1996.

Dobson, Annette J. Passive smoking and the risk of heart attack or coronary death. The Medical Journal of Australia Vol. 154 pp. 793-797. June 17, 1991.

Fotier, Isabel Passive Smoking during Pregnancy and Risk of Delivering a Small-for-Gestational-Age Infant. American Journal of Epidemiology. Vol 139. No 3 pp. 294-301. 1994.

Gerlach. K., Shopland, D., Hartman, A., et al. Workplace smoking policies in the United States: results from a national survey of more than 100,000 workers. Tobacco Control 6:199-206, 1997.

Glantz, Stanton A. Passive Smoking and Heart Disease Epidemiology, Physiology, and Biochemistry. Clinical progress series. pp 1-112 Vol. 83 , January 1991.

Glantz, S. and Parmley, W. Passive and Active Smoking: A problem for adults. Circulation 94(4):596-598, 1996.

Greer, Jonathan R. MD, MPH Asthma Related to Occupational and Ambient Air Pollutants in

Nonsmokers JOM Vol. 35, Number 9 pp 909-915 Sept. 1993.

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SUGGESTED WORDING

1. Significant Risk

Congress finds that lung cancer, heart disease, and other adverse health effects arising from exposure to environmental tobacco smoke in the workplace impose a substantial burden upon and are a hindrance to, interstate commerce in terms of lost production, wage loss, medical expenses and disability compensation payments.

All exposure to environmental tobacco smoke in workplaces, public buildings, and facilities poses an unacceptable risk of adverse health effects. Restricting smoking in these facilities will substantially reduce or eliminate that risk.

Congress finds that the Occupational Safety and Health Administration (OSHA) shall issue a final rule on involuntary exposure to tobacco smoke in agreement with the intent in Title III, Standards to Reduce involuntary exposure to tobacco smoke, of the 'Preventing Addiction to Smoking among Teens Act" or the "PAST Act" [S.1648].

2. Feasibility

Congress specifically requires that OSHA:

1) No later than 365 days after enactment of this legislation, the Secretary of Labor must issue a standard under the OSH Act to reduce involuntary exposure to tobacco smoke.

2) The standard must apply to all indoor and enclosed workplaces, ~~public buildings, and facilities~~.

3) The standard is to take effect upon "issuance," except that the standard may include a reasonable delay in the implementation date.

~~(4) The standard will have the effect of an OSH Act standard.~~

(5) Nothing in this statute or any regulation promulgated pursuant to it shall preempt any existing or future federal, State or local law or regulation that is at least as effective as the Federal OSHA standard in reducing involuntary exposure to tobacco smoke.

CURRENT STAFF AND RESOURCE REQUIREMENTS FOR COMPREHENSIVE IAQ STANDARD AND FOR SEPARATE FINAL ETS STANDARD

- Final will take substantially longer than 12 months
- Limited/focused reopening of record for information: (1) from workshops (which responds to portions of record, reducing our burden, if no Congressional finding); and, (2) on data gaps which, without Congressional finding, is needed by OSHA to sustain court challenge
- Draft regulatory text and preamble, modified on existing docket plus new information in docket from limited reopening
- Modify risk assessment, based upon existing and new docket information
- Current staff: For ETS final only,* with reopening of record, 5 and ½ FTE each year for 2-3 years from HSP/ORA/SOL/DTS (and docket) plus 1 additional FTE for DTS (docket)** for reopening; primarily non-GS-14-15; plus current contractor support ($0.2 M already budgeted) and additional $0.25 M for record analysis
- Make decision regarding scope: and restaurants other than fast food based on complete review of new information (to docket through limited reopening) collected from workshop on local exhaust capture ventilation; results of analysis determines, in part, and OSHA's ability address regulatory issues.

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*For comprehensive IAQ standard, with reopening of record, ETS final first, non-ETS final later, 6 FTE each year for 3-4 years from HSP/ORA/SOL/DTS (and docket) plus one additional FTE for DTS (docket)** for reopening; primarily non-GS-14-15; plus contractor support ($0.2 M already budgeted) and additional $0.25 M for record analysis

**Additional support for DTS not needed if record not reopened; legal vulnerability an issue if not reopen

DEVELOPMENT OF ORACLE DOCKET ANALYSIS DATABASE:

The massive size of the IAQ docket necessitated the development of an electronic tool to manage and analyze the information submitted to the IAQ record. It is a document management system intended to be used for all future OSHA rulemakings.

In 1996 OSHA awarded a contract to Automated Systems and Programming, Inc. (ASPI) to develop the Docket Analysis Database. This is an electronic document management system that has the following features: It is a relational database management system which provides the user with the ability to retrieve, view, and edit documents. It is an ORACLE 7.3 database, linked to the PDF(i.e. text searchable) files of the IAQ record, designed to be used on the OSHA net and from remote access. The purpose of this application is to query, browse, edit and add database records related to OSHA documents, in addition to viewing images of all documents submitted to the record.

Status of project:

Database development began in September 1996. Twelve tapes containing the entire IAQ docket (H122) in TIFF image format were obtained from the docket office between October 1996 and February 1997. Significant work had to be done in order to convert and transfer data from the tapes to the current PDF environment which allows text seachable access. Collating the data into documents is nearly complete. 95% of the IAQ record is currently in text searchable format and is being used by IAQ team members to review and analyze the docket. The remaining documents are expected to be completed within 2 months. However, team access to these files is depended upon OMDS support which has been less than anticipated.

In addition, further enhancement of the ORACLE database by HSP is completely depended upon OMDS support.

Problems encountered:

1. One of the main problems that has resulted in the delayed development and implementation of the ORACLE database is the fact that this project has never been a stated priority with the Agency and therefore OMDS has been unable to provide full and timely response to HSP requests.

2. Communication problems have resulted in further delays. There is not a clear chain of command or defined area of

responsibility in how different sections of OMDS respond to requests for IT support on user applications development work.

3. OSHA net reconfiguration and changes in the architecture of the network, necessitated changes to previously completed and fully operational programs in order to conform to the new network configuration. This activity required an extensive amount of programmer time and was completely out of HSP's control.

4. Some delays in response can be directly attributed to situations outside of OMDS staff control (e.g., moving, upgrading equipment, and training associated with new products).

5. Delays in installing ORACLE Context on the server by OMDS. ORACLE Context is a crucial module of the database application, which will provide full text searching capabilities and the ability to use artificial intelligence and boolean logic to conduct document summaries. HSP has make repeated requests to OMDS for the installation of this IT tool on the server. Over a year later, OMDS has not made ORACLE Context available and there is no specific date by which this will be made available to HSP's programming staff yet.

Issues to be resolved:

1. SOL access to OSHA net. It is imperative that SOL be given access to the docket analysis database and all other internal team documents. Efforts to resolve this issue have been hampered by departmental conflicts (i.e. disagreements between OASAM vs. OMDS over network access issues), and project priorities (i.e. this has never been a priority issue for OMDS, therefore it has never received their full attention).

2. Granting remote access to the IAQ team members. This is not to accommodate flexiplace. The team will be working from home evenings and weekends and needs to access the files remotely.

3. Full cooperation from OMDS. We request at least one person from the ORACLE development team be assigned to this project full-time.

4. Additional funds to support further development of the database (including ORACLE context into the database architecture). We estimate $250,000.

Current Regulatory Development Process: ETS FINAL STANDARD
Not Comprehensive IAQ Standard; No Congressional Finding of Substantial Burden; With record reopening

Action
(1) Complete OSHA's workshops on quantitative risk assessment and local exhaust capture ventilation
(2) Draft Reg. Text
(3) Health standards and legal analysis of Reg. Text for legal sufficiency
(4) Respond to any comments and integrate new comments into Reg. Text, as needed
(5) Draft Summary and Explanation section
(6) Health standards and legal analysis of Sum&Ex for legal sufficiency
(7) Respond to comments and integrate into new Sum&Ex
(8) Draft Introduction/Paperwork/Federalism/Exec.Order 13045 sections of Preamble
(9) Health standards and legal analysis for legal sufficiency
(10) Respond to any comments and integrate new comments as needed
(11) Draft section: Events leading to final standard, including advisory committee response
(12) Health and legal analysis for legal sufficiency; respond to comments
(13) Limited and focused reopening of docket
(14) Close record
(15) Analyze new information and comments to record
(16) Draft Health Effects section of Preamble
(17)Health and legal analysis of legal sufficiency; respond to comments
(18) Draft revised quantitative risk assessment (QRA)
(19) Health and legal analysis of legal sufficiency; respond to comments

Action
(20) Peer review of QRA
(21) Negotiate resolution of any remaining issues
(22)Incorporate relevant comments into new QRA
(23)Draft Significance of Risk section of preamble
(24) Health and legal analysis of legal sufficiency of Sig. Risk section
(25) Respond to comments on Sig. Risk section and incorporate as needed
(26) Draft SBREFA analysis
(27)Draft Unfunded mandates (UMRA)section
(28)Draft Regulatory Impact Analysis (RIA)
(29)Draft Environmental Impact Analysis (EIA)
(30)Legal and Policy analysis of SBREFA/UMRA/RIA/EIA sections for legal/policy sufficiency
(31)Respond to comments on SBREFA/UMRA/RIA/EIA sections; integrate into new sections as needed
(32)Departmental economist analysis of policy/legal issues of SBREFA/UMRA/RIA/EIA section
(33)Respond to comments on SBREFA/UMRA/RIA/EIA sections; integrate into new sections as needed
(34) Incorporate Reg.Text, Sum&Ex, Introduction, Paperwork, Health Effects, QRA, Sig. Risk, RIA (SBREFA/UMRA/EIA/RIA) sections into draft standard
(35) Prepare briefing materials for Assistant Secretary, ASP, and Secretary of Labor analysis and review of draft standard
(36)Respond to comments and integrate into draft standard
(37) Departmental internal analysis by Policy, SOL, ASP for legal/policy sufficiency
(38)Respond to comments; integrate comments into draft final standard
(39) Provide draft final standard to Assistant Secretary for review
(40) Incorporate changes as needed
(41) Provide draft final standard to DOL for policy/legal analysis

Action
(42)Incorporate changes as needed
(43) Prepare standard in proper FR format
(44) OMB analysis and review
(45)Develop responses to OMB issues; negotiate resolution of issues
(46) Transmit final standard to FR for Publication
(47) Respond to FR request for revisions
(48) Publication of final in FR

PROJECTED STAFF AND RESOURCE REQUIREMENTS TO IMPLEMENT FINAL ETS RULE GIVEN CONGRESSIONAL FINDING OF SUBSTANTIAL BURDEN AND UNACCEPTABLE RISK AND APPLICATION

- No reopening of record; final in 12 months
- Complete analysis of existing record
- Draft regulatory text
- Draft modified preamble based on existing docket
- Draft risk assessment using Congressional finding
- Estimated total resources and staff required to complete in 1 year: 11 FTE - OSHA and 2.5 FTE - SOL; includes additional GS-14/15 level support from HSP/SOL/ORA; plus additional contractor support ($0.55 M - this includes two additional FTE contract support) beyond $0.2 M already budgeted
- Regulation of bars, hotels and casinos, and restaurants other than fast food establishments held in abeyance; final non-ETS standard completed later

Projected Regulatory Development Process: ETS FINAL STANDARD (one year)

Congressional Finding of Substantial Burden; no reopening

Action
(1) Draft Reg. Text
(2) Health standards and legal analysis of Reg. Text for legal sufficiency
(3) Respond to any comments and integrate new comments into Reg. Text, as needed
(4) Draft Summary and Explanation section
(5) Health standards and legal analysis of Sum&Ex for legal sufficiency
(6) Respond to comments and integrate into new Sum&Ex
(7) Draft Introduction/Paperwork/Federalism/Exec.Order 13045 sections of Preamble
(8) Health and legal analysis for legal sufficiency
(9) Respond to any comments and integrate new comments as needed
(10) Draft section: Events leading to final standard, including advisory committee response
(11) Health and legal analysis for legal sufficiency; respond to comments
(12) Draft Health Effects section of Preamble*
(13) Health and legal analysis of legal sufficiency; respond to comments
(14) Draft SBREFA analysis
(15)Draft Unfunded mandates (UMRA)section

Action
(16)Draft Regulatory Impact Analysis (RIA)
(17)Draft Environmental Impact Analysis (EIA)
(18)Legal and Policy analysis of SBREFA/UMRA/RIA/EIA sections for legal/policy sufficiency
(19)Respond to comments on SBREFA/UMRA/RIA/EIA sections; integrate into new sections as needed
(20)Departmental economist analysis of policy/legal issues of SBREFA/UMRA/RIA/EIA section
(21)Respond to comments on SBREFA/UMRA/RIA/EIA sections; integrate into new sections as needed
(22) Incorporate Reg.Text, Sum&Ex, Introduction, Paperwork, Health Effects, QRA, Sig. Risk, RIA (SBREFA/UMRA/EIA/RIA) sections into draft standard
(23) Prepare briefing materials for Assistant Secretary, ASP, and Secretary of Labor analysis and review of draft standard
(24)Respond to comments and integrate into draft standard
(25) Departmental internal analysis by Policy, SOL, ASP for legal/policy sufficiency
(26)Respond to comments; integrate comments into draft final standard
(27) Provide draft final standard to Assistant Secretary for review
(28) Incorporate changes as needed
(29) Provide draft final standard to DOL for policy/legal analysis
(30)Incorporate changes as needed
(31) Prepare standard in proper FR format
(32) OMB analysis and review

Action
(33)Develop responses to OMB issues; negotiate resolution of issues
(34) Transmit final standard to FR for Publication
(35) Respond to FR request for revisions
(36) Publication of final in FR

*assumes preamble does not have to address comments to record on ETS quantitative risk assessment; no Sig. Risk section required.

Jeffords staff

Jay Hawkins
Mark Powton (sp?)

Karen