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Tobacco-Settlement: Notes & Memos [3]

Tob-mr -
Note memo

SEP 10 [illegible]

FDA Authority

The first priority of the Administration in considering tobacco legislation should be to confirm and protect the jurisdiction of the FDA to regulate tobacco products -- including through the reduction or elimination of nicotine or other constituents. This goal will necessitate substantial changes in the proposed settlement agreement.

Even as written, the settlement's provision on FDA jurisdiction had certain virtues. First, the provision specifically conferred jurisdiction to regulate tobacco products on the FDA, thereby removing the legal uncertainty now attending the FDA rule. (The Fourth Circuit panel sounds almost certain to rule against the FDA, and the Supreme Court may well uphold this decision.) Second, the provision established a "risk reduction" standard to guide the regulation of tobacco products in place of the "safety and efficacy" standard applicable to other drugs and devices. Because the former makes sense when applied to inherently dangerous products whereas the latter does not, the change in standard would facilitate the FDA's regulation of tobacco products.

This provision of the settlement, however, also contained several glaring weaknesses. First, as you noted in your first comments on the settlement, the FDA would have to prove a negative in order to reduce or eliminate nicotine -- i.e., that the action would not create a significant demand for contraband products. Second, the FDA could not eliminate nicotine for a period of 12 years. Third, the FDA could not take any action to modify tobacco products without surmounting a number of procedural hurdles -- e.g., formal rulemakings -- not usually applicable to administrative action.

The public health community will demand -- and we believe the industry will grudgingly accept -- a legislative proposal that corrects these weaknesses. This proposal would eliminate the 12-year waiting period and the special procedural hurdles in the current settlement. It also, and perhaps most important, would remove the necessity of the FDA's making a contraband finding. At one point, the industry proposed flipping the burden of proof on the contraband issue, so that the FDA could not take action if a party affirmatively demonstrated that doing so would create a significant contraband market. But even this approach puts too much weight on the contraband issue, which should be only one factor in the FDA's regulatory decisionmaking. The better approach is to authorize the FDA to order changes to tobacco products based on a simple finding that this change would reduce the risk of the product to the public and is technologically feasible, after consideration of the full range of consequences of the change, including the possible creation of a contraband market.

Penalties

The settlement sets ambitious targets for reductions in teen smoking of 30% in 5 years, 50% in 7 years, and 60% in 10 years. The most recent data show underage prevalence at 18.2% in 1996, which means approximately 3.5 million youths aged 13-17 are daily smokers. Because the settlement targets are based on youth prevalence over the past decade, which has averaged 15.2%, the declines from current levels necessary to comply with the agreement would have to

be 42% over 5 years, 58% over 7, and 67% over 10.

It is extremely difficult to predict how much teen smoking would decline under the settlement. While teen smokers are particularly sensitive to price -- Treasury has assumed that a price increase of 10% will reduce youth prevalence by 7% (compared to 2.6% for adults), and some studies suggest youth smoking will drop as much as 12% for every 10% increase in price -- we have never had a price shock of this magnitude. The Treasury Department estimates that the combined price rise from the current settlement and the 15-cent excise tax increase in the budget agreement would be about 80 cents by year 5, resulting in a 20-25% decrease from current youth smoking levels -- still well short of the settlement targets. Restrictions on access and advertising should reduce youth smoking still further, but no one can say how much.

Under the settlement, companies would have to pay $80 million for each percentage point they fall short, which is supposed to recapture the industry's projected profits from hooking that many young smokers. (The Treasury Department says a more accurate projection of profits would be $60 million a point, which is roughly equal to $80 million after taxes.) Public health groups have praised the idea of targets and penalties, but complain that the current scheme does not give companies sufficient incentive to stop hooking teenagers. The major criticisms against the current penalties are that they are tax-deductible, abatable, capped at $2 billion in a given year, and too small to serve as a deterrent.

The companies might accept penalties of $80 million a point that were not tax-deductible and could not be abated. They say they are unwilling to increase the price per point or to eliminate the $2 billion annual cap.

We recommend a two-tier system, with graduated penalties that get stiffer if the industry misses the targets by a substantial margin. For example, the first tier of penalties could require companies to pay $80 million per point if the industry missed the targets by less than 5 points in year 5, less than 10 points in year 7, and less than 15 points in year 10. This penalty would be non-deductible, could not be abated, and would reflect a company's share of the youth market. If the industry missed by a greater margin, companies would pay the full first-tier penalty, and a surcharge permanently added on to the price of a pack of cigarettes to reflect the remaining shortfall. This additional charge would be the equivalent of a non-deductible second-tier penalty representing a larger multiple of profits and rising over time -- e.g., $___ million a point in year 5, $___ million a point in year 7, $___ million a point in year 10. Because the charge would be locked in as a permanent price increase, it would help further reduce smoking by youth (and adults). Under this approach, the penalties could reach as high as __ cents a pack by year 10 if youth smoking failed to decline.

Marketing, Advertising, and Labeling

The advertising and marketing restrictions in the settlement are very strong. They include all the restrictions in the FDA rule -- most notably, requirements of black-on-white advertising and bans on tobacco brand names in non-tobacco merchandise. The district court struck down

these restrictions as inconsistent with the FDA's statutory authority. The Court of Appeals is highly unlikely to reverse this decision, and the Supreme Court probably will let it stand as well. The settlement also includes restrictions on advertising and marketing going far beyond the FDA rule, such as restrictions on point-of-sale advertising and bans on outdoor advertising, Internet advertising, the use of human images and cartoon characters, and payments for tobacco product placement in movies and other media. Congress could not enact such restrictions consistent with the First Amendment.

The Department of Justice believes that these restrictions on advertising should not be part of any legislation, but only of the consent decrees or other contracts entered into by the industry and Attorneys General. To the extent the restrictions are a part of the legislation -- or seen as a condition of the legislation -- serious constitutional issues will arise. To the extent the restrictions are a part only of the settlement agreements, they probably will be permissible as voluntary relinquishments of rights.

Assuming we follow the Justice Department's recommendation, serious questions relating to enforcement of the advertising restrictions arise. We know that each Attorney General will be able to enforce the restrictions in his or her state. But what of states in which there is no consent decree? Or what of states with inattentive Attorneys General? The proposed settlement agreement makes reference to a "national protocol" -- a contract designed to enhance enforcement of the advertising restrictions (and other provisions) in the consent decrees. But there is no consensus on precisely who will sign the protocol or how it will work in practice. We must keep a close eye on this scheme -- and on any legislative references to it -- to ensure that it provides an effective mechanism for enforcing the advertising restrictions while not increasing the vulnerability of the restrictions to constitutional challenge (by making their enforcement something other than a simple matter of contract law).

We also should insist on statutory confirmation of FDA authority over the advertising and marketing of tobacco products. This grant of authority is valuable even though the settlement agreements will go further than the FDA could, precisely because the FDA will have no authority to enforce the contracts between the industry and the states. With a specific grant of authority, the FDA itself could enforce the restrictions contained in its 1996 rule, as well as any other constitutionally permissible restrictions it might wish to impose in the future. Such a provision should be acceptable to all parties.

In addition to including restrictions on advertising, the settlement contains provisions to require "Canadian-style" warning labels -- i.e., strengthened warnings (such as "cigarettes cause cancer" and "smoking can kill you") that appear on 25% of the front or display panel of tobacco products, printed in alternating black-on-white or white-on-black type. These provisions would strengthen significantly the existing warning labels, both in the starkness of the message and in its size and placement on tobacco products. We do not recommend any changes to them.

Access and Licensing

The access and licensing provisions of the settlement significantly enhance the ability of the government to prevent youth access to tobacco products. The current FDA rule establishes 18 as the federal minimum age of sale, requires retailers to check photo identification of anyone under 27, and eliminates free samples and the sale of single cigarettes. The proposed settlement incorporates these access restrictions while also banning all cigarette vending machines and requiring tobacco products to be placed out of reach of consumers in any facility that children may enter. Even more important, the settlement would establish a retail licensing scheme to enforce these access restrictions. FDA and Treasury agree that such a system is necessary for adequate enforcement of youth access provisions. Assuming adequate funding, legislation creating a licensing system could count as one of the principal virtues of the settlement agreement.

As written, however, the licensing provision of the settlement contains some important ambiguities. Most critically, the settlement is vague as to who -- state authorities, federal authorities, or some combination of the two -- will administer the licensing scheme. We are not yet in a position to make a final recommendation on this question. FDA's current inclination is to give responsibility for running the scheme to the states, but to retain the power to revoke licenses. We are not yet sure whether such an approach would work (or even how it could be done); rather than recommending a specific scheme, we should commit only to working with Congress and the Attorneys General on this question.

The licensing provision also now contains an inadequate penalty structure. Most troublesome, the settlement provides for permanent license revocation only after a licensee's tenth offense within two years. Because licensing officials are unlikely to conduct ten compliance checks on a single retailer in a two-year time frame, this provision is essentially meaningless. We should insist on strengthening the penalty scheme -- including by making mandatory revocation a real weapon -- without getting into a level of detail unsuitable at this stage of the process.

These provisions are not particularly high-profile. They have not attracted much attention, and nothing we say about them will alter the politics of the deal in either direction. But the provisions, if strengthened and clarified along the lines suggested, could prove one of the great virtues of enacting tobacco legislation.

Documents

For decades, the tobacco industry has failed to disclose essential facts in its possession about the dangers and addictiveness of tobacco products. In particular, the industry has used both the attorney-client and the work product privileges to cloak scientific research and findings -- and possibly to shield evidence of criminal or fraudulent behavior. The Attorneys General attempted to address this issue through creation of a special court to resolve all privilege claims made by the industry. Although the proposed system has certain virtues, it also suffers from serious defects. The industry is willing to make certain minor changes in the proposed scheme, but will not accept changes recommended by the Justice Department and FDA. Even these

changes will not satisfy the harshest critics of the settlement, such as Skip Humphrey.

The settlement calls for a national document depository and a three-judge panel (appointed by the Judicial Conference of the United States) to provide expedited rulings on whether documents should remain privileged. The Attorneys General fought hard for this provision for two essential reasons. First, anyone -- not just a litigant, but any member of the public (including the New York Times or David Kessler) -- could ask the panel to review allegedly privileged documents. In this sense, the settlement establishes a Freedom of Information Act for tobacco documents. Second, the requester would not have to make the normal showing required in litigation for *in camera* review of a document: a *prima facie* case that the document is not privileged -- because, for example, it advanced a scheme of crime or fraud.

The Justice Department, however, believes that this scheme, adopted without change, would pose serious dangers. DOJ points out that no one knows whether or how this panel will work -- whether the judges (or special masters appointed by them) will be competent; whether they will be so swamped with document requests as to create an enormous backlog; whether they will favor one side over the other. DOJ also notes that this panel will have sole authority to rule on claims of privilege. While under the current system many courts may adjudicate a claim of privilege (with a finding of privilege in one court often not precluding the opposite finding in another), the special three-judge panel's decisions would be binding in all courts in all litigation in the United States. On top of these Justice Department concerns, the FDA would like access to all documents -- even those rightfully privileged -- to determine whether they contain scientific or other health-related information (for example, reflecting the industry's extensive research on nicotine addiction) relevant to the regulation of tobacco products.

To meet these agency concerns, we could strengthen the document provisions in two key ways. First, we could make the administrative disclosure process non-exclusive, so that a litigant could challenge a privilege claim in litigation even if the special panel had not completed review of the document in question or had ruled in favor of the company. (By contrast, a finding by the special panel that a document is not privileged would bind the company in all other proceedings.) Second, we could provide the FDA with access to all health-related documents, notwithstanding any claims of privilege.

The industry claims that it will not accept either of these changes, though it will not object to a scheme allowing courts to rule on a privilege claim if the special panel has not yet done so. The industry also proposes adding a provision to the settlement to require each company to identify and disclose all health-related information contained in privileged documents, without turning over the documents themselves. Under this proposal, the special panel could find that a company had failed to disclose such information and levy substantial penalties. Finally, the industry has expressed a willingness to consider a different scheme for selecting the people to sit on the special panel.

On the other side, some in Congress and the public health community will find even the changes recommended by the agencies to be inadequate. These changes do not broadly abrogate

the industry's attorney-client or work-product privileges. The Justice Department has expressed serious concerns about any such breach of the privilege, arguing that this approach would undermine the privilege generally and would enable a tobacco company official charged with criminal conduct to assert a violation of his Sixth Amendment right to effective assistance of counsel. But some will demand the complete abrogation of the companies' attorney-client privilege as a term of the settlement -- or, even more broadly, insist (as Sen. Leahy, Rep. Waxman, and Attorney General Skip Humphrey already have done) that the tobacco companies disclose all privileged documents before any consideration of a settlement takes place.

Environmental Tobacco Smoke

The best available scientific evidence indicates that environmental tobacco smoke (ETS) causes disease and death in non-smokers. The Environmental Protection Agency (EPA) classifies ETS as a Class A carcinogen and estimates that it is responsible for about 3,000 lung cancer deaths each year in non-smoking adults. The EPA also has found that ETS threatens the health of hundreds of thousands of children with asthma and other respiratory illnesses. Serious ETS restrictions, which ban smoking in public places or at work except in enclosed areas exhausted directly to the outside, reduce exposure to ETS and the harm it causes. At the same time, such restrictions lead many smokers to quit smoking entirely and many more to cut down. Indeed, among the many smoking cessation tools -- including substantial price increases -- ETS restrictions may well be the most effective.

All agree that the settlement's provision on ETS is extremely valuable, and needs few changes. The proposed legislation would broadly prohibit smoking in public places, without preempting even stricter state or local laws. The only question is whether to accept without change the settlement's exception for restaurants (but not fast food restaurants), bars, private clubs, hotel guest rooms, casinos, bingo parlors, and tobacco merchants. H.R. 3434, which the Administration supported, exempts restaurants (including fast food restaurants) and bars. The proposed rule on ETS that OSHA issued in 1994 does not include any exemption for the hospitality industry. (In a number of other ways, however, the settlement is more protective of public health than the OSHA rule, which in any event would face serious legal challenges if finally issued.) HHS would prefer to cut back on the exception in the settlement, noting that many of the exempted work places pose the greatest threat to non-smokers. The Department of Labor (OSHA) would keep the exemption essentially as is on the ground that trying to include restaurants, casinos, etc. would make the whole provision politically unsalable.

Liability and Other Legal Issues

The price of everything in the settlement agreement is, of course, protection from civil liability. The settlement limits total liability to $5 billion each year (with any unspent portion of a base $4 billion fund reverting to the government), prohibits class action and other joinder and consolidation devices, and eliminates punitive damage claims (but requires a payment of billions of dollars in punitive damages directly payable to the public). There is little doubt about the

value of these provisions to the tobacco companies.

On the other hand, it is not at all clear that these provisions harm public health interests. Instituting a comprehensive regulatory scheme, while keeping in place the possibility of $5 billion in annual compensatory damages ($5 billion more than the industry has ever paid before), should influence future corporate behavior at least as well as the litigation system usually manages to do. Moreover, making the companies pay a punitive damage award for past misconduct to the public (for use in health research, etc.) makes far more sense from a public health perspective than allowing such funds to go as windfalls to individual plaintiffs. Of course, these provisions do decrease the likelihood of bankrupting the tobacco companies. But as long as Americans are addicted to tobacco products, it is not clear how bankrupting the industry would serve the public health.

We should further advance public health interests by insisting on the removal of any limits on punitive damages for future misconduct. We would make clear that plaintiffs can seek such awards, and that these awards shall not count toward or be subject to yearly limits. The continued potential for unrestricted punitive damages will support the regulatory aspects of the legislation in deterring willful misconduct and otherwise changing corporate behavior. At the same time, this change will enable the legal system to punish the industry, over and above compensatory damages, for any future misbehavior. The industry can hardly argue against this change to the settlement agreement.

We also might consider whether to allow some consolidation of cases prior to trial for purposes of conducting discovery and adjudicating pre-trial motions. The Justice Department recommends this change, which would entail amendment of the current multidistrict litigation statute, to allow individual plaintiffs to share discovery materials and reduce discovery and other pre-trial costs. The industry apparently will resist any change to the provision on class actions, joinder, and consolidation. But given the cap on annual damages, it is hard to see why such changes matter so much to the industry. Moreover, the industry may see consolidation schemes of this kind as less threatening than mechanisms (whether class actions or joinder rules) that permanently tie many cases together, letting numerous "bad facts" cases ride in the wake of a couple of "good facts" cases all the way up to judgment.

The FTC and Antitrust Division of the Justice Department are both concerned about the breadth of the antitrust exemption contained in the proposed settlement agreement, noting that it might protect such activities as price-fixing, mergers to monopoly, predatory pricing, and agreements not to produce reduced-risk products. The FTC and Antitrust Division have not come to closure on exact language to include in legislation, but agree that the exemption should allow collusion only for the purpose of reducing youth smoking (by uniformly passing on the costs of the settlement and penalties and agreeing on advertising restrictions). We should insist on a narrowing of the antitrust exemption, but not yet propose specific language. The industry almost certainly will accept this change.

Finally, the preemption provisions of the proposed settlement are among its most baffling

aspects -- muddled, internally contradictory, and seemingly senseless. We should try to clarify them so that they preserve current FDA authority, while enabling states in appropriate circumstances to go beyond the provisions of the settlement agreement. More specifically, where existing law requires states to petition the FDA to regulate tobacco, states would remain under that obligation and the FDA would retain its current authority; where existing law allows states to regulate tobacco on their own, states could impose any regulations more stringent than the new federal standards. It is very difficult to know how much (if at all) this scheme deviates from what the drafters of the settlement intended. In any case, it is hard to imagine that the issue would drive any party from the table.

Farmers

We have made clear that tobacco farmers should receive protection in any legislative settlement, and that the Administration will work closely with members of Congress from tobacco states to forge a consensus. Secretary Glickman has traveled to tobacco markets in Virginia and North Carolina to express this commitment directly to farmers.

Farmers are primarily interested in continuation of the governmental tobacco program, guaranteed purchase at set levels of tobacco crops by cigarette companies, and some provision for buy out and transition to other crops, on a voluntary basis. Farm groups and tobacco state members have not yet coalesced around a consensus proposal. One plan put forward this month by Senators Ford and McConnell would require companies to buy a minimum amount of domestic tobacco over 25 years and would install penalties on companies that do not meet the stated goals for tobacco buying. The proposal would also create a "Tobacco Community Revitalization Fund" administered by USDA, but not subject to the appropriation process, which could spend up to $1 billion a year for 25 years from the settlement fund. This Revitalization Fund would cover costs related to the tobacco program such as administration and crop insurance, make supplemental payments of up to $500 million to producers whose income from tobacco drops substantially below the 1996 level, pay up to $100 million in benefits for displaced cigarette factory workers, and provide up to $250 million a year for rural economic development grants.

The best way to address this issue is to secure an agreement from the companies to maintain current purchases of domestic leaf, even if domestic consumption declines. Because of GATT, Congress cannot require companies to purchase a set level of domestic tobacco. However, a private contract between growers and the industry would probably not trigger a GATT violation.

Funding

Although the settlement is advertised at $368.5 billion, a variety of factors conspire to leave us with considerably less than that to spend on any new initiatives. The $368 billion is a 25-year number, and must be adjusted downward to reflect a projected drop in cigarette

consumption of about 15%. For scoring purposes, OMB adjusts the amount down still further to reflect lost business tax revenue and lost federal excise tax revenue from decreased consumption. Most of the rest of the money in the settlement is already spoken for, to pay for civil suits, cessation programs, counteradvertising, and the states' Medicaid claims.

At current funding levels, the main decision to be made is how best to spend the $25 billion research trust fund, which could serve as a 21st Century Research Fund dedicated to cancer and other tobacco-related research.

Additional funds could be raised by:

1) Eliminating the $50 billion tax credit in the budget agreement. This would increase the 25-year number from $368 billion to $430 billion, and free up about $2 billion a year for new initiatives. That money could be used to double tobacco-related illness research ($1.3 billion per year) and make targeted investments in tobacco-related public health initiatives such as school-based clinics, Healthy Start programs, cancer prevention, and substance abuse treatment. All your advisers support this option.

2) Strengthening the penalties for failing to reduce teen smoking. The current penalties generate about $25 <ck> billion over 25 years, all of which goes to the states to expand anti-smoking efforts. A graduated penalty scheme could increase the 25-year number to $___ billion, which could be evenly divided between the states and the federal government. This would generate $__ billion a year beginning in year 5, which could be dedicated to additional research and/or coverage expansions, such as allowing people between ages 55 and 65 to buy into Medicare ($2-4 billion per year); covering workers between jobs ($2-3 billion per year) and Medicaid outreach ($500 million to $1 billion per year). DPC, HHS, NEC, and Treasury all support this approach.

3) Increasing the industry's up-front one-time payment, from $10 billion to $30 billion, and indexing the inflation adjuster to GDP rather than CPI (since GDP is more in line with medical cost growth). This would increase the 25-year number to $___ billion, and generate $_ billion a year, which could be used for any of the initiatives outlined above, other investments such as child care ($500 million to $1 billion per year) or medical education for doctors training in children's hospitals ($300 million per year), or deficit reduction (offsetting lost federal excise tax revenue from declining cigarette sales). Treasury supports this approach, although it would probably be a dealbreaker.

The industry will vehemently resist any effort to move beyond current funding levels. The most outspoken tobacco opponents, such as Senator Kennedy and Skip Humphrey, have called for a 25-year number in the range of $600-800 billion. Rep. Waxman and David Kessler would like to see a $1.50 a pack increase, which would require $900 billion over 25 years (although it could also be achieved by combining current base payments with enhanced penalties of about 90 cents a pack).

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Recommendation: Call for legislation with tough penalties of up to $a pack to reduce youth smoking

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The access and licensing provisions of the settlement significantly enhance the ability of the government to prevent youth access to tobacco products. The current FDA rule establishes 18 as the federal minimum age of sale, requires retailers to check photo identification of anyone under 27, and eliminates free samples and the sale of single cigarettes. The proposed settlement incorporates these access restrictions while also banning all cigarette vending machines and requiring tobacco products to be placed out of reach of consumers in any facility that children may enter. Even more important, the settlement would establish a retail licensing scheme to enforce these access restrictions. FDA and Treasury agree that such a system is necessary for adequate enforcement of youth access provisions. Assuming adequate funding, legislation creating a licensing system could count as one of the principal virtues of the settlement agreement.

As written, however, the licensing provision of the settlement contains some important ambiguities. Most critically, the settlement is vague as to who -- state authorities, federal authorities, or some combination of the two -- will administer the licensing scheme. We are not yet in a position to make a final recommendation on this question. FDA's current inclination is to give responsibility for running the scheme to the states, but to retain the power to revoke licenses. We are not yet sure whether such an approach would work (or even how it could be done); rather than recommending a specific scheme, we should commit only to working with Congress and the Attorneys General on this question.

The licensing provision also now contains an inadequate penalty structure. Most troublesome, the settlement provides for permanent license revocation only after a licensee's tenth offense within two years. Because licensing officials are unlikely to conduct ten compliance checks on a single retailer in a two-year time frame, this provision is essentially meaningless. We should insist on strengthening the penalty scheme -- including by making mandatory revocation a real weapon -- without getting into a level of detail unsuitable at this stage of the process.

These provisions are not particularly high-profile. They have not attracted much attention, and nothing we say about them will alter the politics of the deal in either direction. But the provisions, if strengthened and clarified along the lines suggested, could prove one of the great virtues of enacting tobacco legislation.

Documents

For decades, the tobacco industry has failed to disclose essential facts in its possession about the dangers and addictiveness of tobacco products. In particular, the industry has used both the attorney-client and the work product privileges to cloak scientific research and findings -- and possibly to shield evidence of criminal or fraudulent behavior. The Attorneys General attempted to address this issue through creation of a special court to resolve all privilege claims made by the industry. Although the proposed system has certain virtues, it also suffers from serious defects. The industry is willing to make certain minor changes in the proposed scheme, but will not accept changes recommended by the Justice Department and FDA. Even these

changes will not satisfy the harshest critics of the settlement, such as Skip Humphrey.

The settlement calls for a national document depository and a three-judge panel (appointed by the Judicial Conference of the United States) to provide expedited rulings on whether documents should remain privileged. The Attorneys General fought hard for this provision for two essential reasons. First, anyone -- not just a litigant, but any member of the public (including the New York Times or David Kessler) -- could ask the panel to review allegedly privileged documents. In this sense, the settlement establishes a Freedom of Information Act for tobacco documents. Second, the requester would not have to make the normal showing required in litigation for *in camera* review of a document: a *prima facie* case that the document is not privileged -- because, for example, it advanced a scheme of crime or fraud.

The Justice Department, however, believes that this scheme, adopted without change, would pose serious dangers. DOJ points out that no one knows whether or how this panel will work -- whether the judges (or special masters appointed by them) will be competent; whether they will be so swamped with document requests as to create an enormous backlog; whether they will favor one side over the other. DOJ also notes that this panel will have sole authority to rule on claims of privilege. While under the current system many courts may adjudicate a claim of privilege (with a finding of privilege in one court often not precluding the opposite finding in another), the special three-judge panel's decisions would be binding in all courts in all litigation in the United States. On top of these Justice Department concerns, the FDA would like access to all documents -- even those rightfully privileged -- to determine whether they contain scientific or other health-related information (for example, reflecting the industry's extensive research on nicotine addiction) relevant to the regulation of tobacco products.

To meet these agency concerns, we could strengthen the document provisions in two key ways. First, we could make the administrative disclosure process non-exclusive, so that a litigant could challenge a privilege claim in litigation even if the special panel had not completed review of the document in question or had ruled in favor of the company. (By contrast, a finding by the special panel that a document is not privileged would bind the company in all other proceedings.) Second, we could provide the FDA with access to all health-related documents, notwithstanding any claims of privilege.

The industry claims that it will not accept either of these changes, though it will not object to a scheme allowing courts to rule on a privilege claim if the special panel has not yet done so. The industry also proposes adding a provision to the settlement to require each company to identify and disclose all health-related information contained in privileged documents, without turning over the documents themselves. Under this proposal, the special panel could find that a company had failed to disclose such information and levy substantial penalties. Finally, the industry has expressed a willingness to consider a different scheme for selecting the people to sit on the special panel.

On the other side, some in Congress and the public health community will find even the changes recommended by the agencies to be inadequate. These changes do not broadly abrogate

the industry's attorney-client or work-product privileges. The Justice Department has expressed serious concerns about any such breach of the privilege, arguing that this approach would undermine the privilege generally and would enable a tobacco company official charged with criminal conduct to assert a violation of his Sixth Amendment right to effective assistance of counsel. But some will demand the complete abrogation of the companies' attorney-client privilege as a term of the settlement -- or, even more broadly, insist (as Sen. Leahy, Rep. Waxman, and Attorney General Skip Humphrey already have done) that the tobacco companies disclose all privileged documents before any consideration of a settlement takes place.

Environmental Tobacco Smoke

The best available scientific evidence indicates that environmental tobacco smoke (ETS) causes disease and death in non-smokers. The Environmental Protection Agency (EPA) classifies ETS as a Class A carcinogen and estimates that it is responsible for about 3,000 lung cancer deaths each year in non-smoking adults. The EPA also has found that ETS threatens the health of hundreds of thousands of children with asthma and other respiratory illnesses. Serious ETS restrictions, which ban smoking in public places or at work except in enclosed areas exhausted directly to the outside, reduce exposure to ETS and the harm it causes. At the same time, such restrictions lead many smokers to quit smoking entirely and many more to cut down. Indeed, among the many smoking cessation tools -- including substantial price increases -- ETS restrictions may well be the most effective.

All agree that the settlement's provision on ETS is extremely valuable, and needs few changes. The proposed legislation would broadly prohibit smoking in public places, without preempting even stricter state or local laws. The only question is whether to accept without change the settlement's exception for restaurants (but not fast food restaurants), bars, private clubs, hotel guest rooms, casinos, bingo parlors, and tobacco merchants. H.R. 3434, which the Administration supported, exempts restaurants (including fast food restaurants) and bars. The proposed rule on ETS that OSHA issued in 1994 does not include any exemption for the hospitality industry. (In a number of other ways, however, the settlement is more protective of public health than the OSHA rule, which in any event would face serious legal challenges if finally issued.) HHS would prefer to cut back on the exception in the settlement, noting that many of the exempted work places pose the greatest threat to non-smokers. The Department of Labor (OSHA) would keep the exemption essentially as is on the ground that trying to include restaurants, casinos, etc. would make the whole provision politically unsalable.

Liability and Other Legal Issues

The price of everything in the settlement agreement is, of course, protection from civil liability. The settlement limits total liability to $5 billion each year (with any unspent portion of a base $4 billion fund reverting to the government), prohibits class action and other joinder and consolidation devices, and eliminates punitive damage claims (but requires a payment of billions of dollars in punitive damages directly payable to the public). There is little doubt about the

value of these provisions to the tobacco companies.

On the other hand, it is not at all clear that these provisions harm public health interests. Instituting a comprehensive regulatory scheme, while keeping in place the possibility of $5 billion in annual compensatory damages ($5 billion more than the industry has ever paid before), should influence future corporate behavior at least as well as the litigation system usually manages to do. Moreover, making the companies pay a punitive damage award for past misconduct to the public (for use in health research, etc.) makes far more sense from a public health perspective than allowing such funds to go as windfalls to individual plaintiffs. Of course, these provisions do decrease the likelihood of bankrupting the tobacco companies. But as long as Americans are addicted to tobacco products, it is not clear how bankrupting the industry would serve the public health.

We should further advance public health interests by insisting on the removal of any limits on punitive damages for future misconduct. We would make clear that plaintiffs can seek such awards, and that these awards shall not count toward or be subject to yearly limits. The continued potential for unrestricted punitive damages will support the regulatory aspects of the legislation in deterring willful misconduct and otherwise changing corporate behavior. At the same time, this change will enable the legal system to punish the industry, over and above compensatory damages, for any future misbehavior. The industry can hardly argue against this change to the settlement agreement.

We also might consider whether to allow some consolidation of cases prior to trial for purposes of conducting discovery and adjudicating pre-trial motions. The Justice Department recommends this change, which would entail amendment of the current multidistrict litigation statute, to allow individual plaintiffs to share discovery materials and reduce discovery and other pre-trial costs. The industry apparently will resist any change to the provision on class actions, joinder, and consolidation. But given the cap on annual damages, it is hard to see why such changes matter so much to the industry. Moreover, the industry may see consolidation schemes of this kind as less threatening than mechanisms (whether class actions or joinder rules) that permanently tie many cases together, letting numerous "bad facts" cases ride in the wake of a couple of "good facts" cases all the way up to judgment.

The FTC and Antitrust Division of the Justice Department are both concerned about the breadth of the antitrust exemption contained in the proposed settlement agreement, noting that it might protect such activities as price-fixing, mergers to monopoly, predatory pricing, and agreements not to produce reduced-risk products. The FTC and Antitrust Division have not come to closure on exact language to include in legislation, but agree that the exemption should allow collusion only for the purpose of reducing youth smoking (by uniformly passing on the costs of the settlement and penalties and agreeing on advertising restrictions). We should insist on a narrowing of the antitrust exemption, but not yet propose specific language. The industry almost certainly will accept this change.

Finally, the preemption provisions of the proposed settlement are among its most baffling

aspects -- muddled, internally contradictory, and seemingly senseless. We should try to clarify them so that they preserve current FDA authority, while enabling states in appropriate circumstances to go beyond the provisions of the settlement agreement. More specifically, where existing law requires states to petition the FDA to regulate tobacco, states would remain under that obligation and the FDA would retain its current authority; where existing law allows states to regulate tobacco on their own, states could impose any regulations more stringent than the new federal standards. It is very difficult to know how much (if at all) this scheme deviates from what the drafters of the settlement intended. In any case, it is hard to imagine that the issue would drive any party from the table.

Farmers

We have made clear that tobacco farmers should receive protection in any legislative settlement, and that the Administration will work closely with members of Congress from tobacco states to forge a consensus. Secretary Glickman has traveled to tobacco markets in Virginia and North Carolina to express this commitment directly to farmers.

Farmers are primarily interested in continuation of the governmental tobacco program, guaranteed purchase at set levels of tobacco crops by cigarette companies, and some provision for buy out and transition to other crops, on a voluntary basis. Farm groups and tobacco state members have not yet coalesced around a consensus proposal. One plan put forward this month by Senators Ford and McConnell would require companies to buy a minimum amount of domestic tobacco over 25 years and would install penalties on companies that do not meet the stated goals for tobacco buying. The proposal would also create a "Tobacco Community Revitalization Fund" administered by USDA, but not subject to the appropriation process, which could spend up to $1 billion a year for 25 years from the settlement fund. This Revitalization Fund would cover costs related to the tobacco program such as administration and crop insurance, make supplemental payments of up to $500 million to producers whose income from tobacco drops substantially below the 1996 level, pay up to $100 million in benefits for displaced cigarette factory workers, and provide up to $250 million a year for rural economic development grants.

The best way to address this issue is to secure an agreement from the companies to maintain current purchases of domestic leaf, even if domestic consumption declines. Because of GATT, Congress cannot require companies to purchase a set level of domestic tobacco. However, a private contract between growers and the industry would probably not trigger a GATT violation.

Funding

Although the settlement is advertised at $368.5 billion, a variety of factors conspire to leave us with considerably less than that to spend on any new initiatives. The $368 billion is a 25-year number, and must be adjusted downward to reflect a projected drop in cigarette

consumption of about 15%. For scoring purposes, OMB adjusts the amount down still further to reflect lost business tax revenue and lost federal excise tax revenue from decreased consumption. Most of the rest of the money in the settlement is already spoken for, to pay for civil suits, cessation programs, counteradvertising, and the states' Medicaid claims.

At current funding levels, the main decision to be made is how best to spend the $25 billion research trust fund, which could serve as a 21st Century Research Fund dedicated to cancer and other tobacco-related research.

Additional funds could be raised by:

1) Eliminating the $50 billion tax credit in the budget agreement. This would increase the 25-year number from $368 billion to $430 billion, and free up about $2 billion a year for new initiatives. That money could be used to double tobacco-related illness research ($1.3 billion per year) and make targeted investments in tobacco-related public health initiatives such as school-based clinics, Healthy Start programs, cancer prevention, and substance abuse treatment. All your advisers support this option.

2) Strengthening the penalties for failing to reduce teen smoking. The current penalties generate about $25 <ck> billion over 25 years, all of which goes to the states to expand anti-smoking efforts. A graduated penalty scheme could increase the 25-year number to $___ billion, which could be evenly divided between the states and the federal government. This would generate $__ billion a year beginning in year 5, which could be dedicated to additional research and/or coverage expansions, such as allowing people between ages 55 and 65 to buy into Medicare ($2-4 billion per year); covering workers between jobs ($2-3 billion per year) and Medicaid outreach ($500 million to $1 billion per year). DPC, HHS, NEC, and Treasury all support this approach.

3) Increasing the industry's up-front one-time payment, from $10 billion to $30 billion, and indexing the inflation adjuster to GDP rather than CPI (since GDP is more in line with medical cost growth). This would increase the 25-year number to $___ billion, and generate $_ billion a year, which could be used for any of the initiatives outlined above, other investments such as child care ($500 million to $1 billion per year) or medical education for doctors training in children's hospitals ($300 million per year), or deficit reduction (offsetting lost federal excise tax revenue from declining cigarette sales). Treasury supports this approach, although it would probably be a dealbreaker.

The industry will vehemently resist any effort to move beyond current funding levels. The most outspoken tobacco opponents, such as Senator Kennedy and Skip Humphrey, have called for a 25-year number in the range of $600-800 billion. Rep. Waxman and David Kessler would like to see a $1.50 a pack increase, which would require $900 billion over 25 years (although it could also be achieved by combining current base payments with enhanced penalties of about 90 cents a pack).

tobacco - settlement - notes + memos

Key Issues in Tobacco Settlement

I. FDA Jurisdiction

The settlement would codify FDA's authority to regulate tobacco products, and enact into law the specific access and advertising restrictions contained in FDA's rule, ending the risk and delay of legal challenges to the rule, and the risk that a subsequent FDA Commissioner could conclude that FDA does not possess the authority to regulate tobacco under current law. However, the settlement would significantly alter FDA's current authority. The settlement takes the positive step of establishing a "risk reduction" standard for FDA to use in evaluating tobacco products -- a more logical and flexible standard for tobacco products than the Food, Drug and Cosmetic Act's required showing of safety and efficacy. But other provisions in the settlement place significant new substantive and procedural hurdles in the way of any FDA restrictions on cigarette and smokeless tobacco content, labeling, and marketing.

To modify tobacco products, including reducing or eliminating nicotine, FDA must make new substantive findings and meet new standards of evidence. FDA must show a required product modification will: 1) result in a significant reduction in health risk to tobacco users; 2) be technologically feasible; and, 3) not create a significant demand for contraband. FDA must also consider the number of dependent users, the availability and demonstrated market acceptance of alternate products, and the effectiveness of smoking cessation techniques before requiring product modifications.

Under the settlement, administrative courts would give the agency less deference in reviewing challenges to FDA's rules. Currently, courts uphold FDA's decisions as long as FDA's actions are not "arbitrary and capricious." Under the settlement, administrative courts would hold FDA to a "substantial evidence" standard in reviewing its actions to reduce nicotine, and to a "preponderance of evidence" standard for actions to eliminate nicotine. Further, the settlement specifies that the court's deference to the agency would depend on the "extent to which the matter at issue is then within the Agency's field of expertise."

The settlement places procedural hurdles before the agency as well. The FDA must use burdensome, trial-like formal rulemaking procedures in lieu of regular notice and comment procedures to mandate product modifications that reduce risk. Finally, the settlement bars FDA from eliminating nicotine or taking an equivalent action for 12 years, and from changing the access and advertising provisions for 5 years except under extraordinary circumstances.

To address these concerns, the settlement could be modified to codify FDA authority, consistent with FDA's final rule on tobacco, except changing the standard for tobacco products regulation from safe and effective to "reduced risk" and changing the required findings to facts the agency must consider. The new procedural hurdles, standards for review, and time constraints (particularly the 12 year prohibition on eliminating nicotine or taking equivalent action), could be dropped. These changes would affirm FDA's current authority rather than circumscribe it.

II. Look Back Provisions

The settlement embraces the Administration's goals of reducing underage use of tobacco products and seeks to eliminate industry profits from new youth smokers. The industry would be subject to monetary penalties if youth tobacco use fails to drop by 30 percent in 5 years, 50 percent in 7 years, and 60 percent in ten years. The penalty is set at about the estimated lifetime industry profits from addicting a new smoker -- $80 million per percentage point under the target. However, the penalty is capped at $2 billion annually (about 8 cents per pack), and is lowered by 75% if companies make a "good faith" effort to comply with the agreement.

As structured, the penalty does not provide a meaningful incentive for the industry to work to meet youth targets. Since it is easy to show "good faith," the actual penalties for recruiting new youth smokers will be at best 75% below industry profits from the new customers. Further, since the smoking reduction targets are based on industry-wide usage, individual firms will have financial incentives to keep selling to children because they will reap the full reward while bearing only part of any penalty.

Our goal should be to provide meaningful incentives to the industry to reduce youth smoking. Industry representatives have said that they do not believe youth targets will be met and have argued that the industry should not be held accountable as long as it complies with the settlement's access and advertising restrictions. We believe, however, that providing the industry with a strong incentive to reduce youth smoking is the only way to assure meaningful progress toward targets. Our bottom line must become the industry's bottom line.

To strengthen the penalties, we could:

- Levy the penalties on a firm-by-firm basis;
- Make the penalty substantially higher than foregone profits (e.g. 3x profits);
- Make the penalty higher further from the target (e.g. 2x profits if the 50% reduction target is missed by 10 percentage points; 3x profits it's missed by 20 percentage points);
- Remove the annual $2 billion cap;
- Classify the penalty payments as fines, making them non tax deductible;
- Eliminate the "good faith" offset and volume adjustment; and/or
- Consider non-economic incentives, such as raising the age of legal purchase to 19 or 21 if youth targets are not met.

III. Size of Settlement Payments

The industry agreed to an up-front lump sum cash payment of $10 billion, and $358.5 billion paid over 25 years as indicated below (dollars in billions):

Payment Year(s):	**1**	**2**	**3**	**4**	**5**	**6-8**	**9**	**10-25**
Base Amount:	$6	$7	$8	$10	$10	$12.5	$15	$15
Public Health Trust:	$2.5	$2.5	$3.5	$4	$5	$2.5	$0	$0
Total:	$8.5	$9.5	$11.5	$14	$15	$15	$15	$15

The annual payments are not fixed. They are indexed upward for inflation (3% floor), increased sales, and profit increases, and adjusted downward if adult sales decrease. All payments are tax deductible. The industry must pass the annual payment on to smokers in the form of increased prices. The payment therefore functions like an excise tax estimated at about 60 cents per pack, and is expected to reduce smoking among adults by 15% and among teens by about 20%.

Under the settlement, 33% of the base amount would be made available to pay individual liability awards. Any excess funds would go to the federal government. The settlement proposes a $25 billion 8-year Public Health Trust Fund for tobacco-related medical research and proposes designating $2-3 billion annually of the base amount for other public health investments (including $1.0-1.5 billion for smoking cessation, $0.5 billion for an anti-smoking media campaign, and $0.3 billion to fund FDA's regulatory effort). The remaining funds would be used to reimburse states and the federal government for Medicaid costs.

OMB estimates that the Federal revenue raised by the settlement will be substantially lower than $368.5 billion. OMB adjusts the payments downward to account for: 1) an expected drop in sales; 2) an "indirect business tax" (a standard accounting adjustment that decreases scorable revenues by 25%); and 3) the loss of federal excise tax revenue associated with the volume decrease. The 15 cent per pack tax just enacted will reduce the payments further by about [$50 billion].

So, for example, in year 4 the industry has agreed to pay $14 billion (assuming industry payments are not reduced by the new 15 cent tax). The volume adjustment reduces the payment by $4 billion, and federal revenue offsets reduce the net revenue by an additional 4 billion. Inflation increases the payment by $1 billion. That leave $7 billion to pay for compensation and public health investments. The settlement proposes $4 billion in spending for the public health trust fund, and earmarks $2 billion for individual compensation claims. That leaves $1 billion to spend on public health programs and state and federal Medicaid reimbursements -- substantially

less than the what was envisioned in the settlement.

There are at least three arguments for seeking an increase in the settlement payments. First, an increase will raise the price of cigarettes -- the most reliable way to decrease smoking, especially among kids. Leading public health advocates recommend a $1-$2 per pack price increase. Second, the proposed net revenues leave states with far less money to settle their suits than anticipated and potentially under-funds promised public health investments. Third, CEA and Treasury believe the industry will benefit significantly from the deal. They argue that the proposed payments simply leave too much surplus profit on the table given that the settlement will provide the industry unparalleled liability protection and will facilitate collusion.

Options for increasing revenue include: undoing the 15 cent excise tax offset; indexing the payments by health care costs increases rather than by the Consumer Price Index; eliminating the volume adjustment; and/or increasing payments to offset the loss of federal tax revenues. Treasury estimates that these changes together would bring industry payments to about $700 billion over 25 years.

IV. Document Disclosure

The settlement creates a public national depository of tobacco health and youth marketing documents in Washington, DC. A panel of three Article III judges would review all industry trade secret and attorney-client privilege claims. The panel would undertake in camera reviews of privilege claims without the traditional prima facie showing of evidence of crime or fraud. The panel's decision regarding privilege claims would be binding on federal and state courts. The panel does not appear to interfere with FDA's authority to request and inspect documents for regulatory purposes.

The proposal would provide a national resource for researchers, regulators, and litigants. But as structured it raises several concerns. First, it could slow litigation -- the 3-judge panel would have less of an incentive to review documents rapidly than trial judges hearing specific cases. Second, it raises fairness issues -- centralizing review would preclude trial judges from weighing privilege claims in the context of specific trials and would bind future litigants not party to the settlement.

Some have argued the settlement should alter substantively the requirements industry must meet to sustain a privilege claim for certain types of documents. For example, Congressman Waxman has proposed that certain health research-related documents should not be subject to any privilege claims. The Justice Department opposes abridging the attorney-client privilege, in part because doing so may compromise criminal cases.

The timing of, as well as the process for, document disclosure is also raising concerns. Senator Leahy, Congressman Waxman, Attorney General Humphrey, and key public health leaders have stated that the industry's health and youth marketing documents should be made

public prior to deciding about a settlement. The industry has apparently systematically misused the attorney client privilege to improperly conceal health and youth-related documents. Anti-tobacco advocates argue that the appropriateness of any settlement can only be accurately evaluated after such documents are in the public domain.

We should seek to facilitate document disclosure to the greatest extent possible. We could maintain and enhance current document disclosure procedures while adopting the best aspects of the settlement's proposed national depository. Specifically, we could establish a national depository with non-binding judicial review of privilege claims. Further, we could facilitate plaintiff's discovery in litigation by eliminating the need for plaintiffs to make a prima facie showing of crime or fraud prior to gaining judicial review of privilege claims.

V. Civil Liability

The settlement would resolve Attorney General actions and class action suits, prohibit future state suits and class actions; prohibit joining, consolidating, and aggregating individual suits; prohibit punitive damage awards for past actions. The settlement does not abridge the rights of individuals to sue, but it caps industry's total annual liability payments at about $5 billion (it designates 33% of the industry's "base payments" for a compensation fund and augments the fund with 20% industry copayments). If individual judgments exceed available funds in any year, no individual would receive more than $1 million in that year. If the compensation fund exceeds claims, the federal government receives the remainder.

The cap on liability payments, the prohibition on punitive damage awards, and the prohibition on class actions and consolidations are obviously significant concessions that must be balanced against the settlement's benefits. It is an especially high price given the troubling evidence revealed by FDA's investigation. The provisions potentially limit plaintiffs' abilities to recover damages, discourage plaintiffs' lawyers from suing, and lower the industry's incentive to avoid future harms. How much impact these provisions would have in part depends on what would happen absent a settlement. To date, the industry has lost only one liability case and settled one other, but some believe the recent disclosure of damaging industry documents -- and the impending disclosure of many more -- will tip the balance in future litigation toward plaintiffs. If that occurs, than the liability provisions will significantly impede recovery.

We could consider a number of modifications to this provision, including removing the cap on punitive damages for future misconduct; dropping the prohibition on class actions; and/or dropping the prohibitions on consolidations. It is unclear, given the proposed annual cap on liability and the requirement that unspent funds under the cap revert to the government, why the industry is seeking to prohibit class action suits and punitive damage awards. But changes to these provisions may be deal-breakers for the industry.

VI. Advertising Provisions / National Protocol

The settlement codifies the advertising restrictions in FDA's final rule and makes some significant additions, including banning all outdoor tobacco advertising and advertising on the Internet. More important, the settlement significantly increases the likelihood that the advertising restrictions would withstand legal challenge by incorporating the advertising and marketing provisions in a voluntary "protocol," implemented through consent orders signed by states and participating companies. At least theoretically, participating companies would be bound by the agreements regardless of whether non-signatories (e.g. the advertising industry) bring First Amendment challenges. However, placing the provisions in a protocol rather than in legislation may make the provisions unenforceable by the federal government. Hence, the innovative protocol is one of the most important but uncertain benefits of the settlement. We are exploring the best way to structure it to walk the delicate line between constitutionality and enforceability.

VII. Tobacco Farmers

The proposed settlement is silent on tobacco farmers and tobacco-dependent rural economies. Grower representatives were not invited to the negotiating table. We have worked with Secretary Glickman to reach out to farmer representatives and members of Congress from tobacco growing states to make it clear the Administration will insist on meeting the needs of small farmers and their tobacco-dependent communities.

We are consulting with farmers and their representatives about possible solutions. In a White House meeting, Gov. Jim Hunt set forth three possible objectives: maintain the current tobacco quota and price support program; require industry to use mostly U.S.-grown tobacco; and provide transition assistance as the demand for cigarettes falls. Fifty officials from 7 southern states and farm groups recently sent a draft proposal to tobacco-state Congressmen. It spelled out a 10-point plan that would cost tobacco companies $15 billion over 25 years. In our meeting with democratic members of Congress from tobacco growing states, members agreed to provide us with a plan based on this proposal.

VIII. Environmental Tobacco Smoke

The settlement would put in place the first national restrictions on environmental tobacco smoke. The ETS provisions, modeled on legislation sponsored by Representative Waxman, would restrict indoor smoking in "public facilities" -- defined as facilities ten or more people enter at least one day per week. The restrictions are similar to those you have placed on government buildings, permitting smoking indoors only in rooms ventilated directly to the outside. The provisions would affect most private and public workplaces and fast-food restaurants, but would exempt certain facilities, such as bars, clubs, prisons, and casinos.

The ETS provisions are a clear advance over the status quo and a major benefit of the

settlement. ETS restrictions have proven to be an effective means of motivating smokers to quit. The provisions could be strengthened, however. The broad exemption for the hospitality industry (a departure from your Executive Order and OSHA's proposed rule) leaves those workers most exposed to ETS unprotected.

IX. International Issues

As you know, the settlement does not address international sales of tobacco products. Public health groups are pushing for the US to take a leadership role in fighting tobacco's rapid global growth. Worldwide, there are 3 million tobacco-related deaths annually, and the World Health Organization expects that number to rise to 10 million by 2025, with 75 % of annual deaths occurring in developing countries.

We have begun an evaluation of the Administration's international tobacco policies in three areas -- trade policy, export and business facilitation, and public health.

- **Trade Policy** -- the US treats as presumptively valid any foreign country's non-discriminatory health-based tobacco control measures. To ensure the health implications of trade actions are well considered, HHS participates with USTR in trade negotiations. Consistent with free trade principles, USTR's policy is to fight discriminatory barriers on behalf of all industries, including tobacco. Some believe USTR should not provide such assistance to tobacco companies, however, since the entry of US tobacco companies into foreign countries has arguably increased tobacco consumption. We are continuing to review this issue.

- **Export promotion and commercial facilitation** -- State and Commerce are working with HHS to develop new guidelines limiting the involvement of U.S. ambassadors and their Foreign and Commercial Services staffs in tobacco marketing and export promotion activities.

- **International Public Health Initiatives** -- There is a general consensus we should strengthen the Administration's leadership role in global and bi-lateral efforts to reduce smoking. HHS is developing a proposed action plan for consideration in the context of -- or separate from -- the settlement.

Additional Considerations
other claimants (e.g. asbestos)
bankruptcy protections
reduced risk products
licensing
non-participating tobacco manufacturers (smokeless, Liggett)
state preemption
fire-safe cigarettes

Tobacco ~~settlement~~ - notes HUMANS

8/13/97 Tobacco mtg - Moore / Scruggs etc.

Penalties -

Ind willing to say non-deductible - not much more

~~[illegible]~~

Conf call

1. Lookback

a. Double counting p. 54 ¶ 3 — 50% red

30% red Yr 5	Yr 6	Yr 7
10% ↓	10% ↓	10% ↓
20 pt miss	20 pt miss	40 pt miss
× 80 m	paid for all in grades 8, 9, 10, 11 new grade 8	pay for gr 8 totally (40 pts)
1.6b	pay for this new grade	and 20 pts on gr 9-12
	1/5 of 1.6 = .3	
	(disadvan bec fewer smokers in gr. 8 than in gr 12 - but still paying 1/5)	

gcr new language from Bruce
"demonstrated mkt acceptance" -
phase-in language
contraband demand.
petition -
"fair eval. on the record"

All docs to be produced
Then priv claim process starts
complete neutrality - burden is not on anyone
only lab research - doesn't mean much.

industry's de novo review finished by time of legislation

tobacco - settlement - notes and memos

10-8-11 Tobacco mtg w/ Durbin Staff

1. For purposes - raise the price.

2. Fix FDA/strengthen penalties/take care of farmers/do something more on docs - though not so easy to solve.

3. Lippert - Pres probably won't say anything.
We'll be fine whatever you end up doing.

4. Don't want to draft - just outline guidance so everyone knows where we are. Stake out some of higher profile issues. Don't want to get lost in trees right off bat.

Stein - Lautenberg/Durbin/Kennedy - vehicle -
Unique Demo op. → Ford - farmers
Vast range in middle -
Is Breaux drafting legislation?

5. Pol benefit to us is to be on top of it throughout - call Repubs on it whenever they try to pull a fast one.

6. Should persuade all Dems that this is good issue for us - has even partisan benefit.

Stein - *if* we push envelope + try to get as much out of them as we can.
Golden op to extract some $ - for these things/others.
Anyone doing industry analysis?

Stein: In spectrum, we had 1st Boston et al to do industry analysis.

BR-We're trying to do ourselves. But we could do by an indep. company. Have to make sure #s aren't so high that they drive people away from barg. table.

Stein-Knit together ~~kitt~~ coalition for good policy. Push what Conrad wants too.

Apprise Dems senators in advance - try to find ways - talk to caucus. Maybe same day but in advance of press conf. Process very imp to these guys.

Tobacco settlement—notes + memos

FDA Jurisdiction

Settlement unacceptable in numerous counts, relating to nico. reg.

- makes ag. make difficult or imposs. findings e.g., black mkt
- sets up a series of proced. hurdles + rules that ag doesn't normally have
    - formal rulemaking
    - stds of proof / burdens of proof / stds of review
- sets up 12-year period

All agree we should insist that ag. has ability to reg. nicotine in accordance w/ procedures provided for in FDCA when would reduce risk to public

That would be btr than now —
- give clear stat auth
- make std "reduction of risk" rather than "promotion of safety + efficacy"

Document Disclosure

Proposal sets up special ct, w/ determs binding

All who've reviewed think this may lead not to expedition, but to delay

- no p.f. case — good.
- but who knows.

Proposal to have this operate in addition to litig syst —

effectively gives claimant 2 bites at apple.

- also, provide for no p.f. case

More?? Insist on waiver or breach priv? (as in Waxman bill)

- Unlikely tob. ind would agree to waive in consent decrees.
- Legislation breaching — bad precedent?

const probs?

interfere w/ crim prosecutions?

Working to see if any altern proposals —

e.g. use of presumptions.

Mt disclosure to FDA, if we give non-waiver ag.

8-7-97 DPC Meeting

Shalala: Settlement in fund. Flawed from pub health point of view
- hobbles FDA
- farmers (int'l
- documents
- want to hear from economists/budget types.

Bill S. FDA - reg of nicotine
- colloquy = Bruce L / Bill S - overruling state law re age to buy cigarettes.

DOJ: Punitive damages very sound approach
- future punitives - outside cap
Documents - legit concern re admin proc - not really $ cost in context
Class actions - major reservations about that
- BL challenges

6-8 - Q - abt cost of advert.
My answer - greatly ↑ my likelihood of being able to do this.

Frank - Budgetary. How many additional dollars?

Receipts	2002	1998-03	
Base Pay	14b	69	
Adjustments (ex volume)	-8	-28	volume consumed ↓ also:
Net Payments	6	41	
Tax offsets	-4	-18	
Net Add'l receipts	3	22	

Potential Uses / Changes	2002	1998-03
State A-6 proposals, total	7	33
Other reductions in st excise taxes	2	8
Eliminate credit for BBA excise taxes	-3	-9
Potential ↑ in fed Medicaid match	2	11
	8	43

Bruce says: should be 6 31 (not 3 22)
because we are not
offsetting the excise tax.

Yellen: Attraction of settlement from standpoint of industry
need for restructure — relief from uncertainty
payments per passed on.
Wall St perspective
Penalties are insufficient

Summers: Real advance in doing global deal—
can extract real benefits in exchange for giving
the industry certainty.
But division of surplus is not what it ought to
be—industry getting off too easily.
BS—exactly right that we need to have principled way of
making upward adjustments—
a) penalties - strengthen
b) funding budget as
c) index as by health care costs - or perhaps
by overall growth in economy.
d) elim. of volume adjustment

368 → 700 (even w/out penalties)

- e) ad hoc adjustment for reduction in other tax collection

Then - quite substantially change present value of total collection -

Rainer - modify one of Ron -

This is about reducing comp. So - should have fallback - adjustment up if things don't work out - if they make more profits, we get more.

BL - You should talk to Reynolds - They plead poverty - but might see if we can work through this.

International - DT

Issues that should be looked on separate from settlement

- tariffs
- trade facilitation -
- Int assistance to anti-smoking campaigns

2 things that not be related -

1) Additional limits to WHO etc. - target to youth smoking
2) Same restraints on advert abroad

no internal support

Tobacco - settlement - notes + memos

Bill's List 8/1 - FYI (from Jerry)

Tobacco - Major Issues 8/1

1. FDA
2. Look Backs
3. Documents
4. Budget
5. Farmers
6. Antitrust
7. Liability
8. Misc. Issues

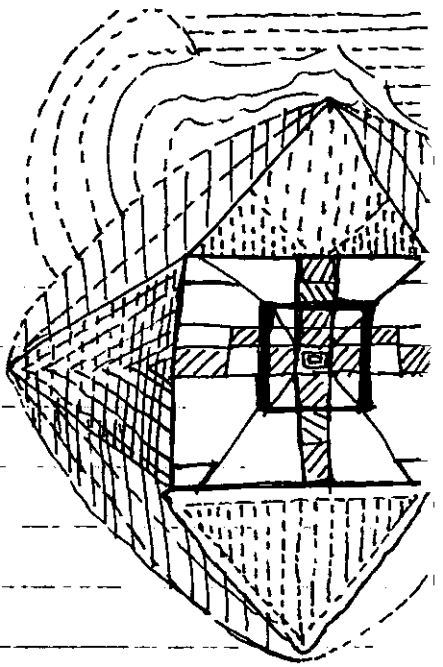
1) Liggett
2) Asbestos
3) Abrogation/unions
4) Cigars
5) Intl.
6) Bankruptcy
7) Preemption
8) Tax Fix
9) Smokeless
10) Scientific Research/Risk Reduction
11) Licensing/Compliance/Minors
12) Protocol
13) Minorities

Reduced Risk

VA / RECA / other gov't/unions

Tobacco – settlement –

notes + memos



ENVIR.

ADVERTISING

PUNITIVES

DOCUMENT DISCLOSURE

LICENSING

FDA
Ads
ETS

Incentives/penalties/rollbacks
Reduced risk incentives
Budgeting: 1) Harm red. & 2) Research 3) Cessation 4) Kids Health / 50% of county school health
Intl. – WHO 5) Appropriations + MOE 6) Farmers

- LIABILITY / PUNITIVES
- DOCUMENTS
- # OF YRS. on NICOTINE

tobacco - settlement - notes + memos

Tobacco Mtg - Matt Myers / Bruce L. / Novelli

Products ~~etc~~

Plug in Section 514 ??

to separately?

elim of nicotine not tantamount to ban.

Re reduced risk —

OK to go back to agency's general authority.

2Hs in ag that talk abt this (p. 14/ p. 9) - neither side would go crazy

but would lose protection of light/low Tar - but also would gain abil to challenge any ag action.

Untested auth here.

Reduction in risk - e.g. of overall v. smokers - a real issue for ind.

But they agreed for the after 12 yrs.

Not an easy give - but not end of discussion issue

Deference - subject of big fight.

clearly meant to interact w/ black mkt piece - today, ag has no deference on that

in combo w/ black mkt ← Drop dead issue for B&W.

How mins this is depends on contraband issue

Black mkt - meant to prevent FDA from getting ahead of the science. Need constant level on this from overall ag.

? Perhaps section 514 - 1 yr lag - is sufficient level of protection

Formal rulemaking -
Need elab proc. for total elimination of nicotine
.. Critical
For removal of others + ~~[illegible]~~ reduction of nicotine - could dispense w/ hearing. Section 514 proces - n+c rulemaking OK

If combined w/ ~~arb + cap.~~ (std of review)
dispensing w/ hearing
will make a diff.
Can't do both

Std of proof for total elimination of nic.
Very hard to ~~to~~ change this - make it less onerous. Maybe if they got a hearing.

Special Procedures most imp for elim of nico -
somewhat imp for reduction.

"comparable" language - p. 17. - [Is it real elim or reduc. below addiction level.]

12-yr time period. -
Ind. wanted 25 yrs.
Benowitz/Henningfield say would take 10 yrs. anyway.
Zero is imposs - could be somewhat less than 12.

Further away from goal, higher the penalties (2-tier system)
penalty

Company by company — ind wouldn't scream.
Nor clear you have a good measurement tool.
MT make sense for this to kick in later

Gradual ↑ of penalties - decent idea

FOR - Do a study - how many lives saved.

Document disclosure -

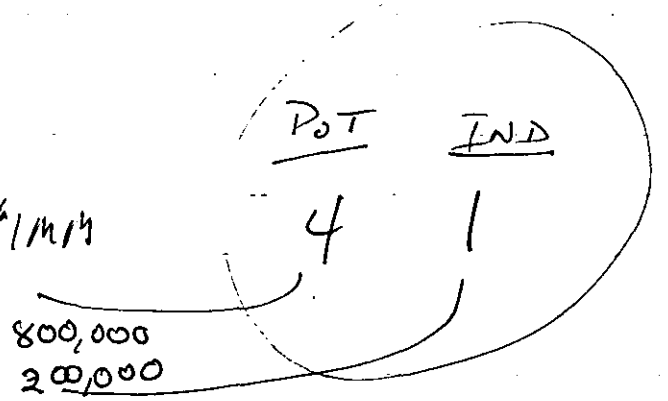
1) Aggregate privs as to relating to...
   a) narrowly defined cases ←
   b) not direct litigation preparation
Take it back x # of yrs...

Ch this

Also - OK to give litigants the ability to litigate these q's in the context of their litigation.

All Abs can legislatively settled.
Cuts get through Cong w/out judge ruling.
on privilege.
Support on appeal when Cong. extinguishes the litigation

Industry oversight -
Ex officio cmte on board?
OR - comes down to $$?
Ind didn't seem opposed.



2 MM

2 MM
1,600,000
400,000

when pot exhausted. it is exhausted as to both

Punishing for future misconduct – same rules apply.
Why should they??

BL-cm's to be a deal breaker.
Entirely w/in ind's control.

tobacco settlement —
notes + memos

7/31 Tobacco meeting

Moore / Cregoire / Myers / Scruggs

AMA shut excellent today

CG: Prepared to do anything but put in more $.

MMoo: But to tack on extra $ at end — not in the ramp up.

MMyers: But can raise price more than a buck + they'll pass it on. Liable to

All economists say this.

True, Reynolds is a drag - but ...

agreement requires that this be passed on.

This prevents PM from keeping price down + creating monopoly

24 billion packs

$1 a pack = ??

$24 billion - $6 billion (25% demand drop) =

$18 billion

BR - Our econ people worried may try to raise price even more now that they're officially sanctioned oligopoly

MMy: They've always moved in lockstep.

MMo: Lockpack provision - problem: cannot go if you fine someone for actions of other people (e.g. retailers) - need to ensure they're violating a law before we can fine them to this extent.
Has to be rational relation btw their conduct + fine:
Disgorgement of profits meets this test.
Anything else you impose must also.

BR: Company by company vs. industry?
Just in doing it individually, but uncertainty about whether we can do data collection to make it stick.
Abatement?

Scruggs: Also non-market pieces - plain packaging - other advert etc.

"x mit reduction" to public health
↳ use other word?

Section 514 –
use rulemaking
1-yr delay to make manufac changes
re q appeal.

Section
Why isn't this used more often?

CG: ought to track FDA as much as poss.
flip burden on cessation?
BL: Reads his
Myers: 1st part of 514 is good.
Then – "In tob. prods, std shall be
'reduction in risk / tech feas.
In mking determ, consider following factors.
THE END.
Let them come back + say elim is diff.
517 – user subst ev. std on review.

1-sentence change ← on 514.

BL: Ind doesn't seem to care if same std is used for reduc/elim.
Just give them 2-yr period to make their case to Congress on elimination.

My: P. 9/14 – light + low tar – Kessler doesn't like this. While backed
→ take this sentence out, so there's no uncertainty that
FDA could prevent use of these terms (like etc) altogether.

Myers: Pres needs to call Dr Koop – meet w/ him by himself.
Pres also has to call Kessler. Count on his loyalty.
Talk to small public health SP before announcement too

7-31-97 FDA Meeting w/ Myers

Myers: FDA can regulate cigars unimpeded.

Myers: Leg. would take wording of rule to greatest extent. Any diffs are unintentional. Industry will commit to this.

" : AGs have hired law firm to do leg drafting. Not public yet.

Zelko: "Vague terms"

a. "scientifically based health claims": p.14 - 3rd bull

"less hazardous tobacco product" - p.14

Myers: would leave it to FDA to set stds - this said specifically "significant demand"

Myers - harder. No one ever defined it. FDA, then advis cmte or other process, would spell out impact - prob just have it like that

"unduly burden," p. 33, bull 2 - 1st

Myers - straight from your statute. I'll check.

"based on" statute's pens: p. 26 --

MM - except where specific change, your auth would be retained. All crafted on to your statute.

— : P. 18 - std of review - exception

MM - arose around contraband issue.

pretty black letter law

This provision would be litigated - as have exception or not?

Applies to both reduction + elim (??)

Schultz: "signif demand" on contraband - not really a pub. health issue

What is signif? Not a scientific issue - just a mtr of stat interp - what this means.

MM - Undefined. You may be right.

Zeller: In yr 4, do we have auth to ~~[illegible]~~ do stuff?

MM: What was for you to retain all auth.

Express reservation of auth - would be fine.

Zeller: Classif as Class 2. Can we reclassify?

No.

Zeller: Can we do anything w/in Class?

Yes - even if not explicitly mentioned.

Zeller: Lite/low tar. Can we ban lite/low tar?

Lang of agr not entirely clear. Tension btw 2 provisions.

People did end up dancing a bit.

Ind. was concerned abt brand lines - e.g. Marlboro Light.

But lang always went beyond there.

Could prevent them from doing this for new brands - sort of a grandfather clauses.

__: FTC current method - 12 mg.

If you were going to do in this timeframe, needed to use this method.

__: Prob - may encourage ppl to think this is safe product.

Take it out if you want - ind won't give a damn.

__: What abt light products they've trademarked? Or what if they change product?

Kept be area of concern. Not discussed.

Zeller: P. 14 - reduced risk. "obj was consumer"

That could go - no problem.

__: Ingredient disclosure

Must give FDA total list

Public - like food - can use "flavors" etc.

90 day - will have to be changed.

In fact, never done this. Very careful about trade secrets - prob wouldn't go all way here

each ingred / formula

FDA can req pub. ↑

*] __ : Provisions supersedes current law - on ingred disclosure. 502(r)

Yes.

Zeller: What's the protocol?

Designed to give ① enf auth over

(1) advert/marketing - protection agt. inconsist

(2) also - a mech to remove ~~state AGs~~ provisions could be weakened by Cong^ | or FDA and give AGs abil to go into ongoing enf auth ← ct + get sanctions for viol of agt.

Debate over which provisions in agt needed protection - This never got fully + finally resolved.

K between AGs + tobacco cos - Then incorporated into st. consent decrees.

No discussion abt whether protocol would be attached to anything else - so fed govt can come in - and get nationwide effect. Must talk about this further.

Zeller: If targets not met, could FDA use reg. auth to punish after 5 yrs? In other, greater ways

YES

Zeller: Not all research docs excepted from priv - only cert research

You're right - long is unanswered. Not sure whether This would be point of contention. Never came up. Have to see if there's a contour when we reduce to leg lang.

__ : What abt our current auth to get docs?

Whatever auth you had to get docs would remain intact. Not in dispute. Same Thing on inspection authority.

⇒ We don't have subpoena auth now.

Zeller: What would happen to MN doc warehouses?

Go to Washington.

Zeller: Ruling in mid-Autumn / appealed. To no disclosure.

Have to deal w/ that.

Licensing

Zeller: Who admin licensing prog – fed govt / states

CG say states admin / fed govt sets stds.

Judy: Then can we yank the license?

Culturing.

If you have thoughtful game plan about how to do it, you will be ask to do this.

Zeller: Your pen structure is weaker than our maximum fines $2 ~~$10~~

I Didn't participate in these discussions. Don't know where they would limit your auth?

Preemptic – no preemptic of st + local youth access laws.

So youth access laws are not covered by p.26 restrict – on penalties.

St could have own penalties.

Schultz: ~~Not~~ What's not preempted?

Eg. labelling act remains in effect.

Some provisions on product modificati-

ingred. labelling is not preempted.

Participating companies –

Zeller: Could Morris or Reynolds become a non-partic company? As by process moves along.

If happened, deal would crater + lawsuits would continue.

tobacco settlement – notes + musings

9/3 Tobacco mtg w/ BLindsay + BReed

1. Jurisdiction

Keep std of reduced risk; switch req'd findings to considerations

Eliminate separate timeframes; discard ~~deference~~ revised deference + review standards – formal rulemaking + change proof burdens –

Replace settlement procedures w/ or of procedures pursuant to FDCA and/or representing what FDA would in any event do

2. Lookbacks

Eliminate cap

Remove tax deductability

Strengthen penalties on smokeless products?

- a profit if co misses targets by more than or amt:
  - at 30% / if miss by 5
  - at 50% / by 10
  - at 60% / 15
  - on the excess
  - (another tier??)

Reduce abatable portion – now 75%. solution – abate the multiple – go back to 1x profits

Firm by firm. ~~(=)~~ change to Basis is what share at time of penalty – not industry wide average

3. Document disclosure

Two-track deal – 3-judge panel // and litigation system.

No prima facie case needed

extra presumptions? (in particular categories)

Agree not to appeal in Humphrey case if companies lose

→ • Give even priv'ed docs to FDA??

4. Advertising

Like what's there

Eventually, have to figure out how to balance const q's w/ enforcement

5. ETS

Excellent

Only ? is hospitality exemption - probably leave alone

6. Liability

Accept basic scheme

Insist on punitives for future misconduct

Class action ban?? too broad? - (but then more $ to indivs, less to att?)

Settlement issues - need everyone?? Must make sure

→ [struck-through word] [Lower level issue - non-subrogation claims to be considered by commission - e.g. labor union suits - limit to parties that could not raise premiums, e.g. had to absorb costs]

7. Farmers

Side agreement by companies to buy domestic

Some %age of $? Buy their allotments?

8. Antitrust

→ Pass along costs of this - but over + above not raise prices?

Talk to Joel Klein

9. Funding

A black hole

tobacco settlement —
notes + memos

8-5 Liggett meeting

Docs show: smoking is addictive
smoking causes cancer

Now in 25 cts around country.
Judges have said these show crime/fraud

Liggett has agts w/ 25 AGs (70% of Medicaid)
22.5% of pre-tax profit to states
agreed to unfettered FDA juris
coop. w/ AGs agt rest of ind
turn over all docs
waive all a-c / pt defense / any other immunity.
" " confidentiality agts ← how to this?
disclosing all ingreds in cigs.

→ Other cos have sued for agreeing to turn over pt defense docs

3 categs of docs
1. Non-privileged
2. waive its AC priv (Liggett only)
re a. demo that cos have talked to feds
b. " " ingreds haven't been disclosed – radioactive materials
3. To defense priv docs
other cos had asserted privs
so L turned over for ct determs – privileged?
5 states cts have found crime/fraud – make public.

If settlement goes through – their stock value will triple –
become largest co. in world

Pam L will go background —
but we're a nonparticipating co. - can't tear up existing agts; anyhow

Tob cos just want revenge: it's not right: we stepped up to the plate, acted in gd faith

We negotiated agts to give us a comp advan. If we became a partic. co, we would not get the benefit of our bargain — if you take away comp advan, we will go bankrupt.

AG letters coming — Liggett should be protected

survival mech / not get rich mech

Willing to raise prices outside of terms of settlement.
Do everything except make payments provided for in settlement.

Documents -

Hide them Amer cos - known facts about health.
Conduct of all players - consistent w/ idea that there's something very damaging.

Our priv'ed docs -

making to kids
manip of nicotine

Tobacco settlement —
notes + memos

8-3 Tobacco mtg w/ Donna Shalala / HHS etc.

Radio address — do exec order and appropriations

Pres to do pres' plan, building on his accomps.
Calibrate so no one walks away. (Emp on pub health)
Lean some things vague.

1. FDA jurisdiction
   Basic principle - not undercut basic authority
   On reduced risk - up to FDA.

2. Disclosure (except on limits on liab)
   If we find out more, price will go up...
   Expand, not constrict access
   Forcash Ac priv?? DOT concern
   Leahy: full disclosure for immunity
   Odd to make deal before know docs exist?

3. Liability
   Try to keep some room
   Future misconduct - keep punitives

4. Preemption
   Not part of P's plan; but must make sure

5. International
   Restrictions here should guide our reps. at international level.
   Should put down a placeholder.
   So-progress in area via admin policies - not legislation

6. Funding

Principles - Things we want to do need to be fully funded

Additive of tax + other approps.

Doesn't cost general taxpayers (???)

7. Lookbacks

Non deductible; no cap; graduated (so it miss by lots, a multiple of profits) - creates real incentive to produce; induce amt they can abate; company-by-company.

8. Farmers

Have to take care of them - add on to price of settlement.

Take credit for bringing them in. "Companies didn't want them at table."

Don't need specific solution

9. Advertising restriction

Op to push ball forward

building on what we've done

giving some credit to AGs

→ Also, on ETS.

10. Cessation ↗

HHS: Gets us into adult area

FDA: Shouldn't lead w/ reducing adult smoking, but shouldn't run away - expect it just helping p. to quit (even ETS - we're jumping off that bridge this weekend)

11. Access restrictions // licensing too
As strong as strongest state rule

12. Cybersecurity
Need to; to whom targeted

Overall principles - (Thune)
Industry accountability -
wraps into lookback
States also need to be accountable as partners in each.
Flexibility
goes back to FDA reg.
don't want to freeze - retain flexibility - gov't continue to make progress

Next steps - When meet w/President? Push back until after...
Principals meeting (T, W, Th)
Strategy for Aug/Sept - who we tell when about what.

Speech; anything else?
a definite plan?
or just extensive Q+A?
↑
leaning toward this
but in some areas, he should be very specific in his speech.

Tobacco - settlement - notes + memos

TOBACCO SETTLEMENT ISSUES FOR DISCUSSION
8/4/97

I. FDA Jurisdiction

Strengths -- codifies FDA authority; sets explicit risk reduction standard for tobacco products.
Weaknesses--FDA must make new findings, overcome new procedural hurdles, meet new standard of proof, is given reduced deference, and can't act within certain time frames.
Possible Objectives-- No change to FDCA; set risk reduction standard (modified); require more than notice and comment rulemaking

A. New Findings

1) To reduce or eliminate nicotine, FDA must find that product modification will:
   a) result in significant reduction in health risk;
   *modify to address risk to entire public, not just smokers
   *drop "significant" and/or drop as finding
   b) be technologically feasible;
   *drop as finding, leave as factor FDA must consider
   c) not create a black market.
   *drop as finding, leave as factor FDA must consider.
2) To eliminate nicotine or take "equivalent" action, FDA must consider number of dependent users, availability and demonstrated market acceptance of alternate products.
*drop or modify

B. Time Restrictions

1) FDA can make no changes to access provisions for 5 years.
2) FDA must wait 12 years, and phase in over at least two years.
*drop or modify (1) and/or (2)

C. New Procedural Hurdles

1) Formal rulemaking required to reduce nicotine
2) Formal rulemaking or Part 12 hearing (at industry's option) to eliminate nicotine or take equivalent action.
*Maintain FDCA procedures, require formal rulemaking, or adopt intermediate procedure

D. New Standard of Evidence / Reduced Deference--

1)"substantial evidence" for reducing nicotine;
2) "preponderance of evidence" for eliminating nicotine or equivalent action:
3) deference in judicial review depends on "Agency expertise."
*delete deference provision
*drop standards

II. Look Back Provisions

Strengths -- embraces Administration's youth reduction goals
Limitations --Maximum impact estimated at 8 cents per pack; 2 cents after 75% abatement for companies making "good faith" effort to comply; penalty is lowered if sales decline; applying penalty industry wide reduces each company's incentive to meet targets ("free-rider" problem)
Objective -- provide meaningful incentive for companies to meet targets.

A. Level of Penalty

*Make penalty substantially higher than foregone profits (e.g. 3x profits)
*Make non-linear (pay higher penalties further from the target)
*Remove annual $2 billion cap
*Remove tax deductibility (reiterate these payments are fines)
*Remove volume adjustment
*Eliminate double counting provision
*Consider non-economic incentives, e.g. raising age to 21

B. Free Rider Problem

*Assess penalties firm-by-firm
- collect data (e.g. expand Michigan survey to collect brand information)
- use base number of teens that smoked each firm's product

C. Abatement for "Good Faith"

* Make only limited part of penalty eligible for abatement for good faith or drop

III. Document Disclosure

Strengths-- establishes a national tobacco document depository of existing documents discussing health research/marketing to youth (a 3-judge panel reviews trade secret and privilege claims); any member of the public can challenge claim; authorizes in camera review of privileged documents by 3-judge panel without prima facie showing of evidence of crime or fraud

Limitations -- decisions binding on [federal and] state courts; binds all future litigants not party to the settlement; panel does not have same incentive as trial judges to resolve privilege disputes in a timely matter, leading to delay; industry can still assert full privilege claim

Possible Objectives -- Centralize documents but preserve and enhance plaintiffs's discovery in litigation

A. **Preemption of current/future litigants**
*create national depository but one in which panel decisions do not bind (state?) litigants;

B. **Ease discovery in litigation**
* eliminate procedural hurdle of prima facie showing prior to in camera review (apply document depository provision)
*alter substantively the requirements industry must meet to sustain a privilege claim for certain types of documents (e.g. health research) in court or in national depository

IV. FUNDING

Strengths -- Substantial sum

Limitations -- Net estimated to be less than half of gross revenues; minimally negative to positive effect on shareholders, profits.

Possible Objectives --

A. **Level of Funding** -- How much pain is enough for liability protections, antitrust ~~predictions?~~ protections?
1) Annual payment functions like an excise tax estimated at about 60 cents and is expected to reduce smoking among adults by 15% and among teens by 22%
2) Payment expected to reduce profits by at most 10% and could lead to a rise in stocks and profits.
3) Actual federal and state revenues expected to be less than half of gross payments due to offsetting effects (e.g. decreased excise tax; CPI adjustment; indirect business tax offset) .
*increase the annual payment amount (raises price of cigarettes)
*increase the initial payment (borne by shareholders)
*increase excess profits tax
*replace industry payments with Federal excise tax ($1 raises about $15 billion/yr)

B. How funds are spent – TBD

1) Trust fund -- tobacco-related research
2) Earmarked smoking cessation and education
3) Health care investments (size?)

V. Immunity from Class Actions and Punitive Damage Awards

Strengths -- Industry incentive to settle.
Weaknesses -- Arguably removes only real fiscal deterrent to harmful behavior
Objectives -- ?

A. Constraints on class actions.

*drop prohibition but let fall under cap
*remove prohibition on joining, consolidating, aggregating individual suits

B. Disincentives for future misconduct

*No prohibition on punitives for future misconduct; cap does not apply

VI. Farmers

Strengths – N/A
Weaknesses – excludes farmers
Objectives -- include in settlement; consider Democratic members' proposal, possibly 2% of settlement funds dedicated to assistance.

VII. Environmental Tobacco Smoke (ETS)

Strengths–More certain and in some ways stronger than OSHA standard (e.g. covers some businesses with fewer than 10 employees; does not preempt state and local coverage)
Weaknesses -- Broad exemption for hospitality industry leaving those workers at greatest risk unprotected and may preempt OSHA's ability to act in hospitality industry.
Objectives -- support provision and(?) seek to narrow exemption.

ADVERTISING

Additional Issues

- Advertising/protocol
- Other claimants (asbestos, pension plans/unions, VA, RECA fund)
- International
- Bankruptcy
- Reduced risk products
- Licensing
- Other regulate tobacco (smokeless, Liggett)
- Cigars
- Licensing/compliance/minors
- minorities
- fire safe cigarette
- preempt regime
- antitrust