legislation, or negotiated resolution). However achieved, the appropriate resolution would include both access restrictions and the modified approach to promotions and advertising set out above.

III. STRATEGY

Any strategy for the successful implementation of this policy objective must be built around its central goal: to make significant inroads into youth smoking while confirming the public's existing view that saving kids' lives -- far from being objectionable -- is a highly appropriate use of government power. Two themes must dominate:

* By focusing on "kids, kids, kids," we must inoculate ourselves at the outset from the charges that we are in any way intruding on adults' "right" to smoke.

* We must maximize the public's perception that the Administration, while unalterably committed to the goal of reducing tobacco use by children and teenagers, will pursue that objective in a balanced, minimally intrusive way. In particular, we would make clear that our first preference would be not to regulate at all, if the industry agreed to reform itself in concrete, substantive and enforceable ways (e.g., by supporting comprehensive kid's-oriented legislation.)

At the same time, an effective strategy must acknowledge and effectively minimize the following risks:

* An effort by pro-tobacco forces to enact legislation stripping the FDA of the power to regulate tobacco, e.g., a "no-funds" provision tied to a broader appropriations bill.

* A muddled resolution that succeeds in alienating everyone: strong enough to infuriate the tobacco industry but too weak to satisfy the "antis" or Kessler.

* Losing in court: While HHS/FDA lawyers are confident and Walter Dellinger is "bullish" based on OLC's preliminary review, FDA's jurisdiction will be furiously contested in litigation; thus, there is some risk of "firing a blank."

Proposed Strategy

We recommend that the Administration proceed along the following lines:

1. Assume leadership role on this issue with nationally televised presidential speech. In attendance would be all living Surgeon Generals, the head of the AMA, the head of various

children's groups (PTA, YWCA, Boy Scouts, etc.), the head of the Health Insurance Industry of America, and others. Speech would:

* Identify the problem (youth smoking) and explain the importance of doing something about it.

* Announce that the Administration is committed to reducing tobacco consumption among youths by at least 50%.

* Call on the industry to address the issue in a significant, enforceable way.

* Publicly commit to actively pursuing all legislative and administrative options to achieve the 50% goal if the industry does not make these reforms.

2. Determine, internally, that if significant, federally enforceable changes are not achieved in the realm of both access restrictions and curtailment of traditional efforts to boost demand among minors, the Administration will authorize the FDA to go forward with a rule along the lines recommended in Option 4. This strategy is guaranteed to fail if the Administration does not have an "end game" firmly in mind, and is committed to sticking with it.

3. Immediately initiate discussions with the tobacco industry, with the objective of securing their agreement to support a package of legislative reforms along the same lines. The discussions would be at the CEO level.

* The discussions would have a short, pre-determined time frame and clearly defined objectives (Option 4).

* There can be no wavering from an "irreducible minimum" of reforms or we will have the worst of both worlds: the wrath of the tobacco industry and its supporters and the searing criticism of constituencies (including the FDA) who would accuse us of having squandered an opportunity to save tens of thousands of lives.

* Any resolution must be enforceable. Because of antitrust concerns, we could not invite the companies to enter into a voluntary agreement, e.g., not to purchase billboard space. We could, however, secure their agreement to support legislation. In collaboration with the Hill, legislation would be drafted in advance.

* In exchange for industry support for and passage of legislation reflecting all of the items in Option 4, we would be prepared to agree to a statute expressly relinquishing FDA jurisdiction over tobacco. We would not

be prepared to give anything else, e.g., tort immunity or preemption of legitimate state regulatory efforts.

* We should anticipate the possibility of some division within the industry. To be acceptable, any negotiated resolution should have the support of all of the major companies.

4. Simultaneously engage the Hill. Any ultimate solution -- whether an industry-supported bill or the issuance of the rule outlined in Option 4 -- will require Hill support. While we do not map out the details of the Hill strategy, we recognize the need to identify supporters from tobacco states and Republican ranks to minimize the risk of a successful "no-funds" amendment or the failure of an industry-supported bill.

5. Energize existing grass roots and congressional support, to include Heart, Lung, and Cancer associations, PTA/NEA, senior citizens groups, Boy/Girl scouts, youth sports leagues, STATT (Stop Teenage Addiction to Tobacco), AMA, HIAA, and the Interreligious Coalition on Smoking and Health. Brief and enlist the aid of key congressional leaders before or on day of speech.

6. Authorize FDA to go forward only if negotiations fail to achieve predetermined policy objectives. Proposed rule should be pre-cleared even before negotiations begin.

7. Follow up speech with rollout campaign, to include speeches by the Vice President, Cabinet Members, leaders of grass roots organizations, etc.

Pros:

* Gives you leadership role on issue that enjoys broad based support.

* Enhances likelihood that public will perceive the Administration's efforts as balanced and minimally intrusive -- even if the end result is FDA regulation.

* If negotiations succeed, diminishes litigation risks and attendant delays in implementing life-saving reforms.

* Even if negotiations fail (as they likely would), this approach would create a political environment inhospitable to the industry's predicted effort to disable the FDA through legislation.

* "Tobacco Democrats" may be persuaded to view the negotiation process as politically optimal solution to a complex problem.

Con:

The above strategy has one significant downside, the strength of which should not be underestimated. From the moment of your speech, the Administration will come under enormous pressure to accept a "deal" that falls short of the package of essential reforms that is necessary to achieve a political and substantive victory on this issue. The capacity of the industry to exert pressure through a well-orchestrated public relations campaign, political initiatives, calculated delay, or a negotiations strategy designed to change the focus of the debate should not be underestimated. If the end-result is a "compromise" that pleases nobody, this strategy will have been a failure.

Secondarily, some may view the above strategy as an affront to the institutional integrity of the FDA. If the FDA concludes that it has the statutory jurisdiction to regulate, the argument runs, it should be left alone to do so without any involvement by the White House.

Discussion: Anything short of simply allowing the FDA to go forward with its proposed rule carries with it the risk of getting "caught in the middle." While significant, this risk can be controlled if the Administration sticks with the tough negotiation strategy set out above. It would be optimal if the negotiations succeeded on the right terms. Under this approach, however, we "win" even if the negotiations fail -- by creating a political environment in which FDA regulation, which already appears to enjoy broad support, would be accepted even more readily. To the extent the negotiators can keep that premise firmly in mind, the pressure to accept a compromise less than the "irreducible minimum" of reforms should be diminished.

Nor should the "institutional-integrity" concern be controlling. At this juncture, no one is telling the FDA not to regulate. We are merely working with the FDA to find the optimal means of implementing crucial health-related reforms in a way that has the best chance of succeeding.

IV. RECOMMENDATION

We recommend that the Administration proceed along the lines set out in Part III.

Agree _____ Disagree ____ Let's Discuss ___

Goodey

III. STRATEGY

Any strategy for the successful implementation of this policy objective must be built around its central goal: to make significant inroads into youth smoking while confirming the public's existing view that saving kids' lives -- far from being objectionable -- is a highly appropriate use of government power. Two themes must dominate:

* By focusing on "kids, kids, kids," we must inoculate ourselves at the outset from the charges that we are in any way intruding on adults' "right" to smoke.

* We must maximize the public's perception that the Administration, while unalterably committed to the goal of reducing tobacco use by children and teenagers, will pursue that objective in a balanced, minimally intrusive way. In particular, we would make clear that our first preference would be not to regulate at all, if the industry agreed to reform itself in concrete, substantive and enforceable ways (e.g., by supporting comprehensive kid's-oriented legislation.)

At the same time, an effective strategy must acknowledge and effectively minimize the following risks:

* An effort by pro-tobacco forces to enact legislation stripping the FDA of the power to regulate tobacco, e.g., a "no-funds" provision tied to a broader appropriations bill.

* A muddled resolution that succeeds in alienating everyone: strong enough to infuriate the tobacco industry but too weak to satisfy the "antis" or Kessler.

* Losing in court: While HHS/FDA lawyers are confident and Walter Dellinger is "bullish" based on OLC's preliminary review, FDA's jurisdiction will be furiously contested in litigation; thus, there is some risk of "firing a blank."

Proposed Strategy: For the reasons discussed below, we recommend that the Administration's strategy proceed along the following lines:

1. Assume leadership role on this issue with nationally televised presidential speech. In attendance would be all living Surgeon Generals, the head of the AMA, the head of various children's groups (PTA, YWCA, Boy Scouts, etc.), the head of the Health Insurance Industry of America, and others. Speech would:

* Identify problem (kids only) and explain importance of doing something about it.

* Announce that the Administration is committed to reducing tobacco consumption among youths by at least 50%.

* Call on industry to address issue in a significant, enforceable way.

* Publicly commit to actively pursuing all legislative and administrative options to achieve goal if industry does not make these reforms.

2. Determine, internally, that if industry leaders are not prepared to make significant changes in the realm of both access restrictions and curtailment of traditional efforts to boost demand among minors, the Administration will authorize the FDA to go forward with a rule along the lines recommended above. Strategy is guaranteed to fail if the Administration does not have an "end game" firmly in mind, and is committed to sticking with it.

3. Immediately initiate discussions with the tobacco industry, with the objective of securing their agreement to support a package of legislative reforms along the same lines. The discussions should be run from the White House and would be at the CEO level.

* The discussions would have a short, pre-determined time frame and clearly defined objectives (Option 4).

* There can be no wavering from an "irreducible minimum" of reforms or we will have the worst of both worlds: the wrath of the tobacco industry and their supporters and the searing criticism of constituencies (including the FDA) who would accuse us of having squandered an opportunity to save tens of thousands of lives.

* Any resolution must be enforceable. Because of antitrust concerns, we could not invite the companies to enter into a voluntary agreement, e.g., not to purchase billboard space. We could, however, secure their agreement to support legislation. Legislation would be drafted in advance.

* In exchange for industry support for and passage of legislation reflecting all of the items in Option 4, we would be prepared to agree to a statute expressly relinquishing FDA jurisdiction over tobacco. We would not be prepared to give anything else, e.g., tort immunity or preemption of legitimate state regulatory efforts.

* Our opening bid should ask for more than we would eventually settle for, e.g., text-only advertising in all media.

* We should anticipate the possibility of some division within the industry. To be acceptable, any negotiated resolution should have the support of RJR, Phillip Morris, the American Tobacco Co. and Brown and Williams.

4. Simultaneously energize existing grass roots and congressional support, to include Heart, Lung, and Cancer associations, PTA/NEA, senior citizens groups, Boy/Girl scouts, youth sports leagues, STATT (Stop Teenage Addiction to Tobacco), AMA, HIAA, and the Interreligious Coalition on Smoking and Health. Brief and enlist aid of key congressional leaders before or on day of speech.

5. Authorize FDA to go forward only if negotiations fail to achieve predetermined policy objectives. Proposed rule should be pre-cleared even before negotiations begin.

6. Follow up speech with rollout campaign, to include speech by VP, cabinet members, leaders of grass roots organizations, etc.

Pros:

* Gives you leadership role on issue that enjoys broad based support.

* Enhances likelihood that public will perceive Administration's efforts as balanced and minimally intrusive -- even if the end result is FDA regulation.

* If negotiations succeed, diminishes litigation risks and attendant delays in implementing life-saving reforms.

* Even if negotiations fail (as they likely would), this approach would create a political environment inhospitable to the industry's predicted effort to disable the FDA through legislation.

* "Tobacco democrats" may be persuaded to view the negotiation process as politically optimal solution to a complex problem.

Con:

The above strategy has one significant downside, the strength of which should not be underestimated. If the Administration does anything less than simply allowing the FDA to go forward with its proposed rule, the Administration will come under enormous pressure to accept a "deal" that falls short of the package of essential reforms that is necessary to achieve a political and substantive victory on this issue. The capacity of the industry to exert pressure through a well-orchestrated public

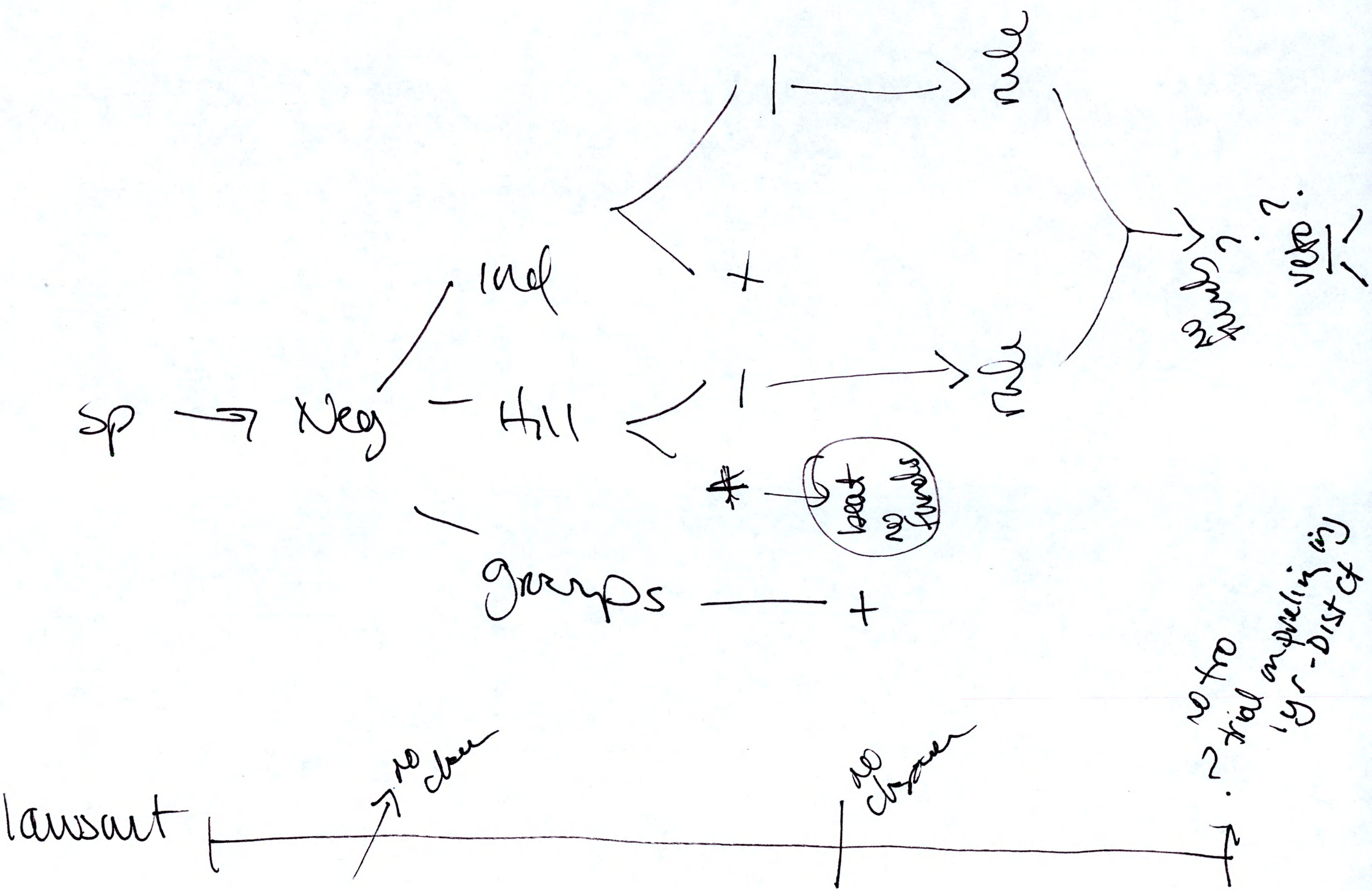
relations campaign, political initiatives, calculated delay, or a negotiations strategy designed to change the focus of the debate should not be underestimated. If the end-result is a "compromise" that pleases nobody, this strategy will have been a colossal failure.

Discussion: While this is a significant risk, it can be controlled if the Administration sticks with the tough negotiation strategy set out above. Obviously, it would be optimal if the negotiations succeeded on the right terms. Under the proposed strategy, however, we "win" even if the negotiations fail -- by creating a political environment in which FDA regulation, which already appears to enjoy broad support, would be accepted even more readily. To the extent the negotiators can keep that premise firmly in mind, the pressure to accept a compromise less than the "irreducible minimum" of reforms should be diminished.

IV. RECOMMENDATION

We recommend that the Administration proceed along the lines set out in Part III.

Agree ____ Disagree ____ Let's Discuss ___


sp
Neg
Ind
Hill
groups
rule
rule
funds?
veto?
lawsuit

3:30 Fri Simon's office

A) GOALS: To get a deal or, if industry won't deal, engage in a win/win battle on behalf of kids

1. focused on kids, kids, kids -- both substance and with finely tuned message
2. be reasonable; don't overreach substantively and don't appear to be "big" government
(don't build the negative coalition)
3. work with the Hill
(build consensus and avoid all out charge against FDA)
4. build grassroots/public support
(create appropriate expectations; don't oversell)
5. positive public health message/impact without longrange and extended downsides

B) THE STRATEGY

1. To achieve either of the broad goals, we need: to engage the industry and its Hill supporters; and sufficient description and sign-off on conception of our proposal

- what we know about prior Administration efforts (e.g., delay works for the industry), a voluntary deal won't happen and there will be no movement unless the threat of FDA jurisdiction is real

- that's why we need clearance/agreement on components of a rule and our willingness to publish it before starting down the road of implementing a strategy

2. Strategy Options

a. POTUS speech; negotiations; if fail, rule

b. grassroots building; rule; negotiations

c. other?

3. POTUS speech strategy:

a. context is federal government's role in protecting health and safety of citizens; POTUS describes:

1. the nature and extent of the public health problem (big)
2. the outline of a solution - the message
- describe focus on kids with one overarching aim and two more limited means -- decreasing teenage smoking by 50% by decreasing access and appeal

3. say what it's not: resticting access for adults, big government intrusion, etc.
4. prepared to move forward but want to give Hill/industry opportunity to work together in interest of our children
   - but solution must have teeth

b. Brief Hill and leadership of grassroots networks and prepare press strategy (to ensure sufficient days one through five validation and support)

c. Post speech, public support activated fully

1. involve broad coalition of groups
- Cancer Society, Lung Assn., Heart Assn., AMA, AAP, other medical groups,
- Little League, PTA, Boy Scouts/Girl Scouts, professional sports leagues,
- individuals: Harvey Sloane, C. Everett Koop,
- govt.: Donna Shalala, Phil Lee, David Satcher, governors, state AGs,

d. The Hill

1. pre-speech meetings/briefings?
2. post-speech meetings/briefings?
3. preparation for hearing/document/other requests

4. Sixty to ninety days following speech

a. maintaining/increasing public support
   - widening spectrum of groups
   - getting groups to carry water independently

b. keeping focus on kids/staying on message

c. press strategy
   - ed. bds, columnists, etc.

d. alternative Admin. public spokespersons (i.e., keep D. Kessler inside for a period)?
   - VPOTUS, Sec. Shalala, Asst. Sec. P. Lee
   - use other Admin. surrogates (D. Satcher, L. Brown)

e. negotiations -- initiate high-level negotiations among Admin., industry (or representatives of one or more of the companies), and, perhaps, major Hill players
   - suggestion: co-leads, HHS and White House

TO BE CONTINUED

I. Recognize political benefits and risks of moving on tobacco -- particularly in context of 1996 election

A. That's why we need to focus on kids
   1. limiting access of kids to cigarettes
   2. limiting appeal of cigarettes for kids

B. That's why we need to fight this battle on our terms quickly -- get out our message and appear reasonable
   1. put out clear statement of what we're interested in and what we're not (not restricting access for adults or banning)-- POTUS speech
   2. avoid having industry mischaracterize efforts
   3. calm political nerves

II. Political upside

A. President/Administration showing leadership by standing up for kids (leadership is a White House theme)
   1. create a win-win dynamic on presidential leadership -- Pres. standing up for the people/kids against other interests
   2. polling data (RWJohnson; others) suggests broad-based support, even among smokers, for government efforts to decrease kids smoking
   3. will appear reasonable given wide-eyed speculation about possible FDA steps

B. Significant grassroots network can be activated on this with likely spillover on local level for 1996
   1. typical groups (Heart, Lung, Cancer, AMA, AAP)
   2. non-traditional groups are involved but would have level of activity elevated (e.g., senior citizen groups, religious, PTA/NEA, youth sports leagues, STATT (Stop Teenage Addiction to Tobacco)

C. Fits with the momentum on related issues --
   1. repositioning of ads at sports arenas
   2. suits by state attorneys generals
   3. cigarette recalls
   4. evidence of manipulation of nicotine levels
   5. research on extent and impact of teenage smoking

D. November 1994 experience in some states
   1. California ballot initiative failed (about 65-35%) despite over $20 million spent by industry
      -- exposed weakness of industry
      -- occurred in context of Prop. 187 results
   2. Arizona passed increase in cigarette tax (Colorado voted one down)

III. Understand potential political risks

A. 1996 - impact on some southern states (e.g., Tenn; KY; North Carolina, Georgia)
   1. Democratic governors feeling heat (Hunt)

B. Hill implications -- depending on how rolls out:
   1. southern Democrats in House and Senate
   3. potential "no funds" amendment on the floor of either chamber which we might lose
   3. implications for support on other Administration business

C. Potential risks of <u>not</u> moving forward
   1. information will get out and we'll be seen as following, not leading
   2. disappointment/outrage among natural constituencies

IV. Other random thoughts

A. Negotiations without explicit clearance of a proposed rule won't work because we won't have any leverage; the Ab Mikva-industry experience is illustrative
   1. can't negotiate until we know we'll win

B. Anything other than a strong step gives industry upper hand in framing the debate and locks Admin. into a losing strategy and endgame

C. Optimal timing may be just before or at beginning of August recess