Tobacco Mtg July 16, 1997
REGULATORY GROUP

I. Volume Restrictions indisputable
A. reduces their net to $284B
B. took acct of reductions in income taxes (related to the workers) and excise taxes. Will reduce revenues $103B more. Net ↑ for govt is $180B
C. Can't assume there will be any net GDP ↑ f. the sett.
D. Brings it ↓ to $116B present

E. If you assume 100% value discounted markup f. penalty excise tax - increase of $116B - that's why people feel the penalties aren't harsh enough.
II. Document Disclosure
A. Come up w/ a streamlined process to resolve disputes

generally govt would have to show the necessity of review — time consuming & burdensome for P's

B. In camera review applies to crime fraud — open up the wide use of this

C. Not really sure the process is effective & streamlined

1. accepts the status quo — lets the cos decide whether a docu. is privileged or not

D. Tob. Accountability Act of Waxman

E. We need details @ the proposal, like the tenure of the judges

F. Bill of attainder — the sett. could be characterized as this if it's seen as solely aimed to punish tob cos. This would fall away if the stat. lang. & legis. history make the public health objective clear

C. Tels. Cos. 6th A cts. to counsel in the most serious problem.

Tobacco Mtg. 2:00pm June 30, 1997

FDA can't predict knowledge & public will the in the future. Legally, FDA prob. had juris. to ban the prod. Any curtailment of that power is a plus for the industry. FDA hasn't chosen to demand lower levels of nicotine in the 1st phase.

- no one knows the level of nicotine below which cigs. aren't addictive
- avoid black market
- smokers compensate, so trying to wean them off might not work

*Reducing nicotine is a diff. approach than reducing what goes along w/it. Nicotine itself doesn't kill.

"Safer" cigs eliminate incentive to quit. + leads to attacks on FTS restrictions.

the challenge was ... it on the market, bec you don't want to create either mass withdrawal or a black market.

Regulating Nicotine
v. Reducing Harm
- FDA was able to prove "intent."
- how to reduce it?
  - device classification (require premarket approval for addictive levels of nicotine or any level of nicotine)
  - OR say it's injurious to the health as marketed

What Auth. does FDA lack that they should have?
- FDA has class flex. w/ prods., bec. all tob. prods. are put into one class. So no flex. to ask for data on reduced-risk prods. Are they really beneficial? → incentive to start or not to quit.

Tobacco Mtg. July 9, 1997

Regulatory Group

1. FDA doesn't intend to ban the product - we don't know what science will be in 20 yrs, so they don't want to cut off their future authority.

2. no one knows what the addicting level of nicotine is.

FDA has flex. now to V, X, ban to b.

① no reas. assurance of safety or

② nece. for public health

Gene thinks it would be easier to regulate cigs. under a different process/regimen than the current one. FDA needs some period of time (5 yrs) before they would even reduce to set up the process and let the science develop. - Limit the 5 year period to doing nothing w/ nicotine, not ~~you~~ other harmful components.

Procedural Hurdles/Considerations

1. Before taking action, FDA would go to an Advisory Committee
2. where is the burden of proof (FDA now makes the co. shoulder it.) Cos. say FDA has it where nic is concerned
3. standard of proof — FDA uses prep. (51%) for a factual quest before an admin law judge — but FDA doesn't bother w/ this for notice & comment. They go with arbitrary & capricious. For a ct. of review, says Gene, this isn't that distinguishable from substantial evid.
4. deference — what does that line on p. 18 about "agency expertise" mean? (Might hurt FDA when its trying to show that no black market will be created.)
5. Congressional review — 2 year ban on this. (You can have a rule in effect that is still subject to Cong. review).

6. black market petitions – let them petition only the health reduction finding.

7. p. 19 ff. F., bullet 2 —

~~Elena's Summary~~:

1st Order Issues (all hate) — 2nd Order (some hate)

* – contraband proc.
* – deference
– formal rulemaking →
– initial per. is 12 → years
– standards of proof → imp. to FDA, but not DoJ practically
* – health standards → technological feasibility
(can't take into acct. future smokers + nonsmokers)

3rd Order (apathy)

~~Action~~

Key Prob. Provisions (Regulatory)

1. FDA can only reduce/elim. nic. levels thru performance standards mechanism. (why?)
   - → FDA loses arbitrary & capricious standard of judicial review.
   - → slower to implement

2. FDA, to reduce/elim. nic., also has to find that:
   - ① big ↓ in health risks will results (might clash w/ what has been said @ far.)
   - ② is technologically feasible
   - ③ will not results in a black market for stronger cigarettes.
     - → easy to challenge these findings
     - → FDA is limited to considering these issues to make its decision

3. FDA can pursue nicotine reduction thru formal rule-making only
   - time consuming compared to notice & comment rule-making.
4. Industry can make a black market petition to show that such a market would be created.
   → its only value seems to be as a delay tactic for the industry.
5. To eliminate nicotine, FDA has to consider the demonstrated market acceptance of alternate products then on the market."
(?) This applies even where FDA undertakes "such other action that would have an effect comparable to the elim of nic.
(make it clear that elim means 0, not reducing it to nonaddictive levels)

— hearing is created + FDA has burden of proof.
— Cong. review is 2 yrs. (not typical 60 dys.)
applies to { — judicial review standard is "substantial evid.," for Reduction/+ "prep. for elim." NOT arbitrary + capricious.

6. Ingredient Safety — scope is a problem. Requirements apply only to non-tobacco ingredients.
— FDA can't require a showing of safety for 5 years and can't require testing to determine an ingredient's safety. And then FDA has only 90 days to approve or disapprove. (Timing of submission should be staggered depending on the ingredient.)
— nic. doesn't have to be listed.
— ingredients aren't listed in quantitative order.
+ you don't have to say you've altered the tob. to contain a larger amt. of nic.

7. Reduced Risk Tobacco Products
— FDA can't require premarket approval
— industry can put health claims on the products
— exceptions from advertising restrictions need to be spelled out.
— make sure agency can recall prods. if necessary and whether requiring FDA to est. a perf. stand. means it can't call for additional special controls like postmarket surveillance.

8. Keep GMP requirements for manus. of finished devices for tob. cos.

9. settlement doesn't ban brand sponsorship of centers or teams in events.

10. find out whether the courts accepts FDA's broad definition of advertising (also "tobacco prod. adv." v. "adv.")

11. What authority does FDA have over the content of the ads? Does it have concurrent juris. with FTC?
12. Should we fight the label advantage given to cos. w/ more than 25% of the market (PM + RJR)?
13. Should we ban brand adv. on items (clocks) + services (Euro travel agencies, CD offers).
14. 12 mg. tar v. no tar
15. Should package comnt. of "Nicotine Delivery Device" include the age proscription?
16. Should warnings be added to the front of conuff can lids?
17. No hearing to change warnings.
18. There should be express language stating that manus have to remove ads + other violative articles.
19. Stronger sanctions for violations of retailer licensing system. (comparable to ones in Act)

20. Education Program

FDA may not be able to require cos. to fund education program after 8 years. Also, FDA may not be able to start the program until 5 yrs. have passed.

21. Should the FDA have a hand in controlling/appting members of the independent non-profit agency that will be formed to establish the public education program?

22. Should FDA retain the right to increase the minimum age of sale whenever it deems it necessary - even w/i the 1st 5 years (freeze on regs.)? Would the need to do so qualify as "extraordinary circumstances?"

* get Ashes to Ashes ~~for~~ Bruce.
* Elena – q's for women's group. – also GSA –
(–) (+) (new wishes)

7 6/30

– Access / Ad / Labeling / Ingredients –

Bill 50% in 7 years
Key is residual authority
– do more if not met –
– raise the age? [^com^ do under District Court's decision]
– concerned that companies will be very successful ~~at~~ hooking 18 – 19 year olds.

– other side – compared to District Ct's opinion –
huge advantages in terms of advertising.
– our statute
– first amendment.
having companies agree by contract / consent decree. has advantages
(but retailers not ~~tooth~~ locked in — Legal group looking at that).

Access → * significant ban on vending machines
– self-service displays – same
(reasons for that – special product
– enforcement)
– allowed in bars only

Compliance = strong FDA program – $300 million program
can enforce access provisions.

who's responsible – we drew clear lines –
– ability to revoke license great lever

penalties – under FDCA, penalties range for

enforcement / $

Criminal vs civil through admin action. under sett. — work for ind. retailers but not for chain stores. Limits to penalty violation.

summary Ent.

(+) / licensure budget

(−) NOT FOCA authorities

licensure — 10th amendment issues.
— enormous # of establishments. (firearms 110,000?)

SAMSHA — overlap w/Eynar; who has review authority

Mirch — p. 26. — states can't impose more restrictive access
Gene T. — now - system is essentially non-preemptive.
— we already preempt "comparable" provision.
— but states can ~~not~~ ask for ~~exemption~~ exception.

Elena — Separate mtg on state preemption.
now / agreement / where assignors

Access

More — self-service displays

Bill – Advertising Provisions are fairly aggressive.

- IOM study basis
- starting pt. is black & white text ads. —

Point of Sale
Bkw

Sponsorship / Trinkets and trash

FDA
events / teams / entries –? Agreement just event?

Ads

+? List of permissable ads only media that is permitted.

+ Bans billboards

+ Warnings on ads

±? Low tar & light ads
- problematic if there is no benefit
- can disclaimers remedy? does deal cement light?

low/high tar - are they making a decision for us.

(+) human cartoon
not much - symbolic.

informal agreement w/FTC they won't pay directly.

prohibiting payments to glamorize tob (direct or indirect)
— we would need compulsory process
↳ what's "glamorize"
"appealing to youth"
"payments."

highs

low/tar move to products — preserve our reg authority?

Labeling

FDA

Labels

There is rule
— reg. by statute - mostly there for that reason

wish list
- just BiW ads, labeling. -
- plain package - pkg. as a badge.
-

~~bad - Theyre added~~

education — Sharan Natarshut, —

Our proposal
still pending

(+) 500 million
start now
no conditions.

(—) Funding ends after
year 8?

(?) Kick back into
notification effort?

Coordinated by govt

? Coordinated by non-
profit (?) confusing
Secty's authority limited

DoJ [Wilcox case upheld sales]
-but here we would have govt speech.

Next entry
①
- Preemption rules
- penalties (including licensing)
Paper by Wed. a.m.

catalogue / how it differs from
what exists now.

FDA Product Regulation 6/30

— 12 year limit on authority
To big questions — ① limit
€ — ② covering cigars

Schmitt — Impossible to know or project what thinking is, will of the country is re. product. We got jurisdiction to ban the product.

Jenny — but researchers haven't done much work yet — with true/focus tools may rapidly make progress

Ann Witt — did social searching on whether to wean people by ↓ addictions. Two q's that answers: ① what is non-addictive nicotine level. ② What would happen — people would smoke more and more.

Jenny — NIH — convened a meeting but haven't made progress — scientists working ~~about thinking~~ on it think they can answer in more than 3 years.

Mitch — have to know relationship btw nicotine and other agreements — that affect delivery

Eclipse — RJR product — smokeless cigarette test marketed now.

- Money

- Safer cig / document

< Safer products — history make you worse off
Eclipse — ↓ incentive to quit

Schmitz NICOTINE —
- Takes policy element out
- decides what factual questions are
- puts burden on FDA (we typically put it on industry).

Arm with Tests Now - "injurious to health as labeled"

- (device classification process) — required to do now
  class III requires premarket approval
  - requires showing of safe and effective before marketing
    "reasonable assurance of safety & efficacy"

Given dangers associated w/ product, easy to take it off the market
"tech. feasibility."
"significant ↓ in risk"

Safety → risk/benefit analysis.

FDA has already made a finding black market is likely to occur — we'd have to make findings to work 4 occat.

other findings "demonstrated market acceptance."

- elimination / or action w/effect comparable to elimination of nicotine

After 12 years - findings on "preponderance of evidence"

petition allows them to come back in and challenge. When black-market occurs.

Reduced risk authority

Cath Loraine - Reg one at a time
- classify
- flexibility.

Because regulated as a class, have less flexibility. -

Product like eclipse - may treat as class 3 device (looks like cigarette, but v. different)

- How much info. can we require from each producer.

Ann - Public health community is split on red. risk products.

We wouldn't necessarily put ?ish products under cigarettes - but would handle it class III devices

Elena – assignats - rewrite it – leave as much of broad structure intact if you can

Mitch – but some want to fix this section and move this forward.

– write up bargain