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cc: Cathy R. Mays/OPD/EOP, Laura Emmett/WHO/EOP, Michelle Crisci/WHO/EOP, Melissa M. Murray/WHO/EOP

Subject: 4th Circuit Meeting

There will be a meeting tomorrow at 5:30pm in 211 on the upcoming 4th Circuit Court of Appeals decision on the FDA tobacco rule. Representatives from Justice, FDA, and HHS will brief us on their views on when a decision may be issued, what it might say, and how we might respond. Currently, and unlike the Greensboro District Court decision in April, we don't expect to receive advanced notice of the decision, or to be provided time to review the decision before it is made public.

As you know, in April the U.S. District Court in Greensboro ruled that FDA has jurisdiction over tobacco products, but that FDA exceeded its statutory authority in regulating advertising and promotion of tobacco products. The Court did not reach the First Amendment questions. Both the Government and the industry appealed the District Court ruling. A three-member panel of the Appeals Court heard oral arguments in August.

1/5/98 E. M.

*Office of the Assistant Secretary for Health
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FAX TRANSMISSION COVER SHEET

*Date: 11-17-97
To: BRUCE REED
Fax: 456-5542*

Please Deliver on Receipt!

*Re:
From: JIM O'HARA*

*YOU SHOULD RECEIVE 4 PAGE(S), INCLUDING THIS COVER SHEET.
IF YOU DO NOT RECEIVE ALL PAGES, PLEASE CALL 202.690.7694.*

Have a Healthy, Active Day!

20



① list of folks

faxes & phones

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Nov. 17, 1997

Note to Bruce Reed *BR*

From: Jim O'Hara *Jim*

Here is a document that can serve as basis for a meeting on the Fourth Circuit. Justice and HHS/FDA lawyers have all had opportunity to think about this and would be prepared to discuss. Please call me and let me know how you want to proceed. Thanks.

Tom/JRM -

*Looks good to me.
Could you call him
+ see whether we could
discuss this at next
tobacco mtg? Thanks
BR*

November 17, 1997

RE: Fourth Circuit Court of Appeals

Background

The 4th Circuit Court of Appeals is expected soon to rule on the case involving FDA's regulation to protect children from tobacco. The U.S. District Court in Greensboro ruled in April that FDA has jurisdiction over tobacco products; it ruled against the FDA with regard to advertising restrictions, opining that the Agency exceeded its statutory authority in regulating advertising and promotion of tobacco products. The Court did not reach the First Amendment questions. Both the Government and the industry appealed the District Court ruling, and a three-member panel of the Appeals Court heard oral arguments in August.

The Solicitor General and attorneys for the Departments of Justice and Health and Human Services will need to review the Appeals Court's ruling before the Administration can issue a statement. However, some broad outlines of possible statements can be sketched. They are as follows:

If Appeals Court upholds FDA jurisdiction:

This is another significant victory in our fight to protect our children from tobacco. We need to build on this, and Congress should take up comprehensive tobacco legislation -- based on the President's five key principles -- early next year.

If Appeals Court strikes down FDA jurisdiction:

We intend to seek further judicial review. The President is firmly committed to the FDA's rule and its role in protecting our children. We must have public health oversight of this industry and its products. Almost 3,000 young people become regular smokers each day, and that means nearly 1,000 of them will die prematurely from tobacco-related diseases. This is another reason why Congress should take up comprehensive tobacco legislation -- based on the President's five key principles -- early next year.

Other Considerations

Obviously, the Court of Appeals decision will be more complicated than the above responses indicate, but the general question from the media will be who won and who lost, and that question will turn on jurisdiction. Other nuances will need to be addressed at time of opinion, but here are some preliminary thoughts:

Split decision:

It is possible that the three-member Appeals Court panel will split 2-1 on the jurisdiction

What are the practical consequences?
July
Rush
D. G. St. J.
Rehman
S. G. St. J.

question. If the panel votes, for instance, 2-1 against jurisdiction and depending on the wording of the opinions, the Administration might want to say something like:

We intend to seek further judicial review. The President is firmly committed to FDA's rule and role in protecting our children. We have a very strong case as the District Court ruling and the dissenting opinion show. We must have public health oversight of this industry and its products. Almost 3,000 young people become regular smokers each day, and nearly 1,000 of them will die prematurely from tobacco-related disease. While we pursue our legal options, this is another reason for Congress to take up comprehensive tobacco legislation -- based on the President's five principles -- and act early next year.

Opinion that FDA must use drug authority

An opinion that gave FDA jurisdiction, but under the drug authorities of the Act, would be both a victory and a loss. It would reject the public health strategy chosen by the Agency while affirming the Agency's jurisdiction. In that case, the Administration might want to say something like:

This is an important victory for the public health, but substitutes a new regulatory framework for the one chosen by FDA to treat tobacco products as drug delivery devices. The Agency will review its regulatory options in light of the court's opinion. However, the Agency's assertion of jurisdiction based on the device regulations was aimed at providing the needed flexibility for protecting our children from tobacco-related diseases. We still believe it is the best public health strategy to follow. We intend to seek further judicial review.