From: Christopher Horner

To: Hyde, Timothy N.; Tompson, Randy

CC: BCC:

Subject: Federal Agency Science Date: 12/23/1996 1:56:01 PM

Attachments:

Gentlemen: The following is the document we discussed. Have a happy

holiday. CCH

MEMORANDUM

TO: Mr. Tim Hyde Mr. Randy Johnson RJ Reynolds Tobacco Company

FROM: Mr. Christopher C. Horner Bracewell & Patterson, L.L.P.

DATE: December 23, 1996

RE: Background and Proposed Program to Address Federal Agency Science

Per our earlier conversations, the following sets forth what needs to be done to reform agency science, focusing on the need based upon your interests, and how you are positioned to take a behind the scenes leadership position. It provides an overview of the issues relevant to this goal, and details a program taking advantage of the increasingly flagrant way regulators have perverted the scientific process, hiding behind a wall of selected scientists to essentially cow industry and Congress into accepting fringe scientific conclusions.

Summary

We propose creating, beginning with congressional oversight and a goal of enacting legislation, required review procedures which EPA and other federal agencies must follow in developing "extra-judicial" documents (i.e., those documents produced as guidance, science or other government products issued by regulatory agencies which are not necessarily at time of publication ripe for judicial review). This is important to your organization because, at some point in the near future, EPA will most likely be ordered to re-examine ETS. The only way to do

so on a level playing field is to construct explicit procedural hurdles the Agency must follow in issuing scientific reports.

Because there is virtually no chance of affecting change on this issue if the focus is ETS, our approach is one of addressing process as opposed to scientific substance, and global applicability to industry rather than focusing on any single industrial sector. Thus the examples of questionable science, to justify these standards. Congress must require those examples serve as the test cases.

Background

On the surface, now appears an opportune moment for addressing agency science head on, tackling the substance. This would seem the case because the first run at legislative attempts to reform the regulatory process failed and concerned Members are searching for a new mechanism to control EPA and other regulatory bodies. The landscape of the past year is littered with examples of persistent or newly-promoted "bad science," including the Mercury Report to Congress, MACT Hazardous Waste Combustion Rule, Methylene Chloride and the Dioxin Reassessment. Regarding the latter example, as you are likely aware, for the next round of EPA Science Advisory Board (SAB) review of the Dioxin Reassessment the Agency has removed any SAB members who were too vocal in their disagreement with the Agency. There will still be SAB review, but it will be an already-transparent group of "agreeable" scientists. So, in addition EPA is flagrantly "stacking the deck" with those whose conclusions are predetermined and in the Agency's favor.

Irrespective of this pattern, it is clear the 104th Congress was singularly unsuccessful in managing the Agency on a chemical-by-chemical or industry-by-industry basis. EPA actions demonstrate the it has taken measure of its legislative and industry adversaries, and decided upon aggressive campaigns on several of these issues to impose its policy-driven will upon scientific conclusions. The Agency helps create, and responds, to, the political winds, so you should anticipate no relief on re-evaluating ETS. EPA has of late played its public relations card very well, avoiding long news cycles for its proposals -- even timing them around holidays when readership is at its nadir -- while engaging the environmental press for the coming conflicts. EPA, helped by the backlash of the generally "pro-environment" public to a poorly implemented reg-reform agenda, has fostered an atmosphere where "industry" are reluctant to match the Agency's hardball tactics out of fear either that Congress would duck/mismanage the issue, or of Agency retribution. Thus, through a lack of industry support and unfavorable press, Congress has to date lacked the requisite support to effectively use the oversight powers of the legislative branch.

It is in this climate you will face a chastened but at least as aggressive EPA on re-evaluating the ETS study.

Project Approach

To improve the climate, and process, under which ETS and others are reviewed, we recommend initiating reforms by playing a strong role in molding and guiding Congress's oversight of EPA's latest Clean Air Act initiative (on PM 2.5/ozone). Such an effort would work toward requiring EPA to institute certain procedural changes to the pre-regulatory process. These would serve as a set of checks and balances to ensure a fair and equitable development and publication of scientific findings (i.e., reform the scientific process). It is that process, which is beyond the reach of the Administrative Procedure Act, which sets the stage for the rulemaking process. These procedures could then be subject to judicial review without the courts becoming involved in specific scientific issues (i.e., discern if EPA followed the requisite steps, rather than if it achieved the "right" answer).

When EPA announced its proposal to regulate particulate matter and tropospheric ozone, despite their news cycle management, the set the predicate for procedural change. These proposed regulations, based on questionable science, are not focused on those industries that comprise EPA's "usual suspects", but rather all industries including small businesses. Congress is expected to conduct heavy oversight of this process, with most leaders expressing that the actions are unnecessary and unrealistic. EPA has already signaled a desire to compromise as the process moves forward, and will start airing its options in the January 14-15 initial public hearings. It is critical to our overall goal that EPA not be allowed to change the forum into an industry-by-industry examination. Equally important, the process should not devolve into "outdoor air" interest seeking to shift the focus to "indoor air" interests. Instead, the efforts we envision focus on the process by which EPA arrived at its scientific conclusions, avoiding to the extent possible specific scientific issues, contaminants, or industries.

While some will approach these hearings as regulation-specific, as you can appreciate, from our perspective the greater problem is EPA (and OSHA) "science," encompassing all the scientific reports, studies, guidance documents and procedures produced by the nonregulatory offices of these agencies. None of these products are subject to timely challenge. In some instances, industry must wait years before regulations are promulgated, thus allowing industry to sue. Then, when industry has that opportunity, the court is faced with the ramifications of overturning years of EPA actions and policies based on this scientific document. Moreover, industry face mindsets such as "how can a

document which has been around for so long be wrong?" (the "historical credibility" argument). Finally, once industry's hands are tied in Washington, EPA or OSHA has distributed the documents or guidance to the press or states, forcing industry to face a public relations nightmare.

Thus, as we seek to create a regime where this cycle is a thing of the past while highlighting problems with contemporary studies. These studies will be the first "test cases" for the reformed process. This requires developing (1) overall criteria for a "sound science" process, and (2) a record, through congressional oversight, on how the Agency typically does not meet those criteria.

To illustrate, criteria could be as follows:

"Sound Science" Criteria - any government scientific program must have four components:

Inclusive - The scientific community, the public, Congress, and other Executive Branch agencies are given fair and timely access to review and affect change in the development of the science/document.

Transparency - the public can follow the developmental process the steps followed to develop the final science/document.

Able to be reproduced - Can the answer be reproduced from the record?

Algorithm - Given the set of all available scientific knowledge on the subject would independent groups arrive at the same answer?

[a possible fifth component which could be included as a deal closer could be:

Not judicially reviewable - This may seem counterintuitive, but one of the aspects of reg-reform which its opponents exploited to bring it down was the belief that everything would be litigated. Thus, it may be possible to achieve reforms through the principle that the scientific portions of a successful program should not be easily placed before the courts. Instead, the courts should be able to easily look at procedures followed (e.g., did the Agency follow its own procedures).]

We envision these new steps being "field tested" on, e.g., the methylene chloride study, ETS, etc. which, having been used as justification for reform would be held and reviewed under the new procedures. To ensure Agency compliance Congressional oversight is also required. This at worst builds a record for judicial review and at best sets in

motion a set of enforceable procedures. We intend to develop for the Hill a set of scientific and procedural questions on scientific issues which different committees could then use. This requires:

Written Record - Submit lengthy, detailed questions to the agency requiring written responses. This creates a written record which the Agency often seeks to avoid, because it otherwise is permitted to develop scientific documents without responding explicitly (unlike the proposal/promulgation process) to public concerns.

Followup Hearings - Once the Agency has responded use this record both within and across an issue in oversight on how the Agency develops science. (e.g., this is an ideal place to inquire into risk assessment default values and risk criteria, which seem to change from office to office).

We envision the end results of the oversight hearings to be: (1) EPA publication in the Federal Register of a formal process for handling "extra-judicial" documents; (2) new legislation; and/or (3) inclusion in environmental or regulatory reform legislation which appears moving in the 105th Congress.

This approach merely ensures a fair hearing, but that is typically all the situations require to avoid the skewed result the federal agency prescribes. Critically, this approach also circumvents the tenuous situation you otherwise likely will face, of seeking after-the-fact, RJR-specific congressional support to undo the Agency's work.

What makes the National Association of Manufacturers a strong base for the above work is NAM's broad, yet non-specific, business base. Its one of a small handful, at best, of broad based associations not associated with particular industries. Thus, their lead on this general issue will not bog the hearings down in "anti-environmental," industry-specific rhetoric, nor create an environment where specific industries can legitimately fear Agency retaliation.

Conclusion

We envision a program, using contemporary studies and reports to illustrate how the Agency skews its results in the pre-regulation stage, to create set, reviewable science procedures. That process and its criteria will first be tested on those current examples of Agency misfeasance, which obviously must be sent back to the Agency or otherwise placed on hold in the interim. We need to meet again with you to discuss this proposal and how to best implement it, specifically beginning with the audiences with NAM and NFIB we discussed. We need another meeting, to hammer out the presentation to the two

referenced audiences, and reach consensus with you on the issues and approach we intend to pursue. Until we speak with you on this further, Happy Holidays.

CCH

/cch