Exhibit B

Edited Transcript of Presentation of
Jerome H. Heckman, SPI Counsel at
June 19, 1969 Meeting of SPI Food, Drug and Cosmetics
Packaging Materials Committee

Heckman

I'm glad to see all of you here. I see there are a number of new people here and I'll try to take that into account as best I can in the way of providing background on some of the subjects I'm going to discuss. I'll have to ask some of you who are not new to bear with me. Those of you who have not been at every meeting since the formation of this Committee in 1956 will have some difficulty in picking up the threads but we'll do our best.

I want to cover a couple of matters quickly before I get into the meat of current problems which, of course, relate to the National Conference on Indirect Food Additives "aftermath"--the name we've given this subject--and the so-called Ramsey proposal.

There have been some changes in the FDA Staff. Willard Orr, with whom some of you have probably had occasion to deal in the Petitions Control Branch, has now moved into the feed additives field, and is no longer available to help Bill Randolph with the handling of Food Additive Petitions.* Bill Randolph is, of course, feeling quite swamped and petition processing is suffering along as usual

Another in passing item which some of you may have been reading about is the fact that FDA is expecting

* Since the meeting, Mr. William H. Morgan has replaced Mr. Orr.

[illegible] very minimal requirements for [illegible]. Over the years, when Mr. Randolph gets [illegible] what is the food additive status for [illegible] of ABS or PVC resins, or whatever other resin it might be, he has followed the practice of sending the inquirer a copy of our Manual. We, of course, always supply extra copies of the manual whenever it requires them for that purpose.

One reason I mention this [illegible] is because Mr. Randolph has advised us that [illegible] asked FDA's Division of Chemistry and Food Technology to try to develop some sort of a protocol that could be passed out to those who are thinking about filing a petition relating to a stabilizer, an antioxidant, or some other adjuvant proposed for use with vinyl polymers, or at least with a broad spectrum of polymers rather than with a single one. There are times when someone comes to FDA, or come to us and say [illegible] stabilizer or antioxidant and we think it would be used to a degree of success with a number of polymers. How do we go about filing a petition? And a question that arises as to how much extraction work we do to be sure that in order to satisfy [illegible] will be safe to use with a polymer. That's the sort of question that has arisen with sufficient frequency lately so that Mr. Randolph has asked the Division of Chemistry and Food Technology to come up with a protocol that would be sufficient if you test this adjuvant with three different polymers, that ought to be enough testing to give us assurance so that we can give you authorization afterward.

Asking for such a protocol, and developing one are two vastly different things. It is not an easy job. I know that the Staff of the FDA has

come up with [illegible] of course, -- and that [illegible] with it because [illegible] Staff to work [illegible] if we would be [illegible] in connection with [illegible] that SRI would like [illegible] you would agree [illegible] be much better for us [illegible] make suggestions before [illegible] rather than to argue about [illegible]

The [illegible] stay in touch with [illegible] how this project is [illegible] and if they're [illegible] we can seek the [illegible] Subcommittee as [illegible] offer

One other [illegible] to mention to you is [illegible] gressional committee [illegible] Practices and Procedures Subcommittee [illegible] Committee -- generally [illegible] committee since [illegible] and, on February 21, [illegible] to almost all of the [illegible] them a number of broad [illegible] One of the agencies [illegible] of course, the [illegible] reported on [illegible] 969 so if some of you [illegible] look like you might [illegible]

Presumably [illegible] responded to the [illegible] whether

FDA has [illegible]
within two weeks [illegible]
that probe, [illegible]
answers to the [illegible]
public at [illegible]
made public, it [illegible] of
hearings that the S[illegible]
likely to proceed [illegible] FDA
would be one of [illegible] to be
heard on the sub[illegible] follow the
matter and try to keep [illegible] as

To give [illegible]
mention, here are [illegible]
asked. The first [illegible]
consumer-oriented [illegible] is:
To what extent, [illegible] there
an input into [illegible]
from private citiz[illegible]
agency encourage [illegible]
be greater? [illegible]

I suspect [illegible]
question will [illegible]
to give [illegible]
"Nader's Raiders" [illegible] of
you who might [illegible] their
another little [illegible]
going to find [illegible] this
summer in the [illegible]
Federal Trade Commission [illegible]

Another [illegible] sub-
committee is [illegible]
industry advisory [illegible] their
functions and [illegible] become
involved in any [illegible] decision-
making process? What [illegible] the

views of affected groups [illegible] might not become [illegible] own initiative.

As you know, [illegible] the government-industry advisory committee to FDA [illegible] direct food additives. It has not [illegible] to establish such a committee but I don't think [illegible] is totally dead. FDA has other citizens advisory groups, and industry advisory groups, [illegible] formal basis than what we proposed. [illegible] interesting to see how the Agency answers the Kennedy [illegible]

This next question that [illegible] intrigues me no end. [illegible] skipping, by the [illegible] and not reading all of the questions [illegible] Do those [illegible] affected by the agency's activities know enough about it? How is citizen and industry awareness of the agency's functions, processes and decisions promoted? [illegible] the outward flow of information be improved. To what extent are agency records, [illegible]dings, [illegible] withheld from public view? What are the reasons for such withholding?

Some of you know that [illegible] our comments on the proposed [illegible] Procedural Regulations for food additive petitions [illegible] took part [illegible] FDA for not making its [illegible] known [illegible] additive field. We suggested that Advisory [illegible] type procedures similar to those of the Federal Trade Commission be used. So far that proposal [illegible] deaf ears for reasons [illegible] are [illegible] to me. I raised the question [illegible] at [illegible] FDA [illegible] meeting and received an answer [illegible] the [illegible] not really considering that [illegible] because it might lead to a lot of court [illegible] FDA Counsel's theory [illegible] opinions provides a basis for an appeal to the [illegible] question.

Another Kennedy Subcommittee inquiry many of you will be interested in is 'Do you belive that the agency's decision making procedures operate with reasonable speed, considering the interests and issues involved? Assuming that faster processing and decision making are desirable, how could they be achieved?" We've given FDA our views on this question many times so we would be interested in seeing how the agency answers the Kennedy question if we are ever able to determine the answer.

The last question that I think might be of some interest is one that asks: What procedures does the agency have for assessing the quality and efficiency of its own performance? How often and in what manner does the agency review the continuing relevance of its mission, goals, priorities, procedures and structure? In what ways could such review be stimulated?..."

Fascinating set of questions.

One sort of a separate type question posed is whether the staff quality is adequate to handle the complex and sophisticated issues presented to the agency. There's really only one answer FDA could give to that question if it's going to 'tell it like it is" but I doubt if that answer will be given.

Does anyone have a question up to this point in my report? We usually do this by simply allowing interruption whenever you see fit so those of you who are new, chime right in.

Question: Who is Bill Randolph?

Heckman: Bill is in the Petitions Control Branch of FDA and is technically titled a 'Food Additives Officer' which really doesnt' mean anything. From our

point of view, and as a practical matter, Bill Randolph is the staff man who handles all of the administrative processing of incidental food additives petitions. When he gets help there will be another man with him. They serve as what some might call coordinators in receiving petitions, circulating them within FDA and notifying petitioners regarding questions that arise, or petition status. Any letters you might receive on a petition would probably come from Mr. Randolph or his co-worker in the Petitions Control Branch.

Question: Isn't Mr. Buckley also working in this area?

Heckman: Right, but Buckley has been and still is working on direct food additives problems only.

Question. Do you have any indication at all when Spiher will be retiring? */

Heckman: No. Spiher, for those of you who don't know, has a position that's technical, just below McFarland who is over-all Chief of the Petitions Control Branch. McFarland is really on top of Buckley, Randolph, all of the people that work on petitions

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Now, let me get into this major situation that we really have to deal with. It relates to the Ramsey proposal but, for the sake of putting things in perspective, I want to take a few minutes to review the background.

Actually, I think it's fair to say that the genesis of the Ramsey proposal was probably an American Chemical Society meeting arranged by Ken Morgareidge way

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*/ Since this report was given, Mr Spiher has been on "special assignment" to the Consumer and Environmental Health Service, FDA's parent entity. He is, thus, not presently active on food additives matters. Whether he will return to basic FDA

back in 1966. At that meeting, somewhat to FDA's surprise, although I really don't know why, a number of papers were given that literally took the agency to task in depth on the indirect food additives question. It was perhaps the first time that there was an entire series of papers publicly indicating severe criticism of the way indirect food additives are regulated.

I gave one of those papers, Jack Frawley gave another. There were a series of other papers--George Ingle gave one--that were more technically oriented than critical. Don McCollister of Dow gave one, two men from Eastman discussed radioactive tracer data. It was at that time that the so-called Frawley Proposal" was first advanced. What Jack did was to comment on the fact that FDA was doing a very poor job on incidental additives by, in effect, over-regulating.' The net result was a waste of scientific time and expertise. As a means for delimiting petition filing he suggested that FDA eliminate the need for regulating components of packaging materials which were put into the package at a level of less than 0.2 percent, so that if you made a substance that was going to be used at a level of less than 0.2 percent in a food package, and the substance was not a heavy metal, a pesticide or a known carcinogen, FDA should permit its use without requiring the filing of a petition for issuance of a regulation

After 1966 and despite what had been said in these papers, nothing really changed, at least not right away. There was a lot of alleged internal discussion at FDA about the feasibility of the Frawley Approach , and generally about the feasibility of doing something about indirect food additives, but nothing really moved, because there wasn't enough effective pressure being brought to bear on the agency to make things move

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*/(Cont.) work again is unclear, as is the exact nature of his present work.

Thereafter, approximately in August of 1967, it was suggested to a Congressional Committee*/ that the indirect additives field was being badly mishandled. The reason that the situation was brought to the attention of that particular committee was because the Chairman of the Committee was and is Congressman John Dingell of Michigan. Congressman Dingell had been on the original committee**/ that handled all of the legislative work on the Food Additives Amendment, and had chaired many of the hearings.

The Congressman expressed an interest in the interpretation that FDA was giving to the Food Additives Amendment, particularly that portion of the statutory language which provided the basis for FDA's authority to regulate incidental additives, (i.e. any additive that "may reasonably be expected to become a component of foods"). So, at his request, a series of questions were prepared that were submitted to Dr James Goddard, then Commissioner of FDA, at a Congressional hearing. Dr. Goddard was asked to have answers to the questions within 30 days.

FDA set about attempting to prepare the answers to the questions, but had some difficulty, to say the least, because the questions were reasonably searching. Finally, because they couldn't really answer a lot of the questions without conceding that the incidental food additives situation was in a state of confusion, they advised Congressman Dingell that, as a partial response to the questions, FDA was going to call a national conference on indirect food additives and that the agency would report back to him within 30 days after the conference.

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*/ The House Select Small Business Subcommittee on Regulatory Agencies.

**/ The House Interstate and Foreign Commerce Committee.

Industry was given about a month's notice on the conference and we were totally unable to get any extension. Before anyone knew what was going to happen, FDA had sent out a meeting notice, and had laid out a program which was rather vague. On the one hand, FDA was counting on industry to participate, but on the other hand it had arranged things so that industry would have little, if any opportunity to make a strong, coherent presentation in opposition to the manner in which incidental additives were being regulated.

In any event, under the auspices of SPI, we got together representatives of the trade associations representing the main packaging industries that we knew had been called to come to the conference on indirect food additives. We had two pre-conference meetings and all agreed on the basic industry position that should be presented at the conference. As a result, contrary to some of FDA's expectations, we went into that conference fairly well prepared.

One of the things that we all recommended strongly was the establishment of a Government-Industry Advisory Committee. There was a great deal of debate on this subject at the conference, some of which became quite heated at times. There was some strong resistance to a Government-Industry Advisory Committee by FDA representatives which was not entirely clear. If nothing else, I think the conference served a useful purpose in putting "on the record" some of the points of view of industry. By the way, I mentioned this at the last two meetings but I will mention it again, I still have transcripts of the proceedings of the National Conference on Indirect Food Additives, so if any of you who have not yet requested and received one would like to have a complete transcript, which has a great deal of background information of value, generally, by all means drop me a note, and we will be happy to send you a copy.

In the mid-[illegible], on behalf of your Committee, a 69-page set of comments with FDA on some proposed Procedural Regulations that the agency had published. Those Procedural Regulations were drafted by Mr. Alan Spiher and we submitted extensive set of comments because, quite frankly, we were looking for anything at all that would provide us with a means to place industry's views about the indirect additive-regulatory situation in a formal record. The proposed regulations are still pending and we have been promised that they will not be finalized, if at all, until some of these other more substantive problems are resolved.

Now I've given you all of the basic background about the subject. After the [illegible] Conference, FDA set to work in an effort to come up with something that would at least be a palliative to packaging materials producers, and that's what led, ultimately, to the publication of the so-called Ramsey proposal.

While that was being done, I should mention one other important operative fact, -- a special committee, the Food Protection Committee of the National Academy of Sciences and the National Research Council, during the period between the National Conference on Indirect Food Additives and just prior to FDA's publication of the Ramsey proposal, began work on and completed a report that is entitled "Quantitative Guidelines for Toxicologically Insignificant Levels of Chemical Additives in Foods." Jack Fowler played a very significant part in the development of that report.

In essence, what the report says is that toxicologists have come to the conclusion that 0.1 ppm of anything in the diet, other than a known carcinogen, a pesticide, as defined in the Federal Poisons and Regulation Act, or heavy metals, may be considered toxicologically insignificant and therefore unworthy of the toxicologists'

time and attention to establish safety. That I think is an easy way to paraphrase what it means.

The problem, of course, as far as the food packaging industries are concerned, is in trying to convert 0.1 ppm in the diet to some meaningful figure in a package or a food. To analyze for such an amount, you would measure the daily intake of a given type or generic category of food and then determine how much of "X" substance will be in that total daily amount, because parts per million really is a relative mathematical concept.

Now at the last Committee meeting, in my report, I spelled out for you the basic concepts that we expected to be put forth in FDA's anticipated proposal. The FDA proposal, I advised, would be aimed at amending Section 121.2500 of the Food Additive Regulations, which, unfortunately, is often referred to as the "Good Manufacturing Practices" Regulation for incidental food additives. It's a loose term but the reason for that is that Section 121.2500 is a general regulation that precedes all of the specific Food Additive Regulations, and talks, in general terms, about what is deemed to be good manufacturing practice in the use of an incidental food additive. For example, that's the section that says you shall not use anything that will give a taste or odor problem in foods.

We advised at the last session that FDA would come up with a proposal to amend that Section and would use it as a means to exempt certain kinds of things from the necessity for the filing of food additive petitions. At our last meeting I told you about some of the details of the proposal and what they were supposed to be. What I told you was essentially correct except that FDA made two changes subsequent to my last report. The basic differences between what I told you and the "Ramsey

proposal," which has now been informally circulated to the packaging industries for comment, are two: (1) instead of using the "economic poisons" definition in the Proposal, paragraph (d)(5) says that certain specified substances, i.e. heavy metals and carcinogens, will not be exempt under any circumstances, and other substances that have been demonstrated to produce toxic reactions when present at levels of 40 ppm or less in the diet of man or animal will not be exempt and (2) the new "no migration" phraseology in the proposed paragraph (d)(5)(i) will make it clear that the figure used, i.e. less than 0.05 ppm can be determined by appropriate extraction tests or calculation (the previous language spoke only of no contribution greater than 0.05 ppm to food).

The language is a little confusing, but what they were really saying here is that if you have a component that's going to be used in an adhesive or in an article for repeated use, or if you can demonstrate that no more than 0.05 ppm will get into food, you don't have to file a food additive petition unless it's a heavy metal, a known carcinogen or a substance which has been demonstrated to be toxic at a level at less than 40 ppm. In effect, this means that if there isn't any data on a substance, you don't have to demonstrate that it's not toxic below 40 ppm. However, if it is known for a fact that a substance has been demonstrated to be toxic below 40 ppm it will not be exempt. You would have to file a petition for such a substance, or give up the use of the substance, which is the other alternative.

Question: The statement you made with respect to FDA's interpretation of the need for data on substances that have not been proven to be toxic in the 40 ppm or less, doesn't sound like FDA.

Heckman: I'm not telling you what they're going to accept, all I'm trying to tell you is that's what FDA had in mind when the proposal was written.

In other words, if FDA doesn't have any reason to belive that a substance is toxic it will assume

that it's not toxic. Obviously, the rule of reason has to come into play. If you have any reason to believe that a substance might be toxic then FDA might ask you to provide some data. It's not clear-cut at this point, and because of that it's one of the things we're going to have to work on very carefully.

Question: Would you tell what industry associations are involved in negotiations with FDA on the "Ramsey proposal," and how the negotiations are being handled?

Heckman: As you are probably aware, the subject proposal was sent out under cover of a letter from Les Ramsey to each individual trade association that had participated in the National Conference on Indirect Food Additives. We did not, of course, like the idea of anything in the nature of a divided industry approach, industry, by industry. So instead of responding immediately and arranging separate dates to meet with FDA, we conferred with our good friends in the American Paper Institute, they, having been in many ways the Secretariat at the earlier inter-industry meetings.

Einar Wulfsberg was good enough to call another inter-industry meeting which was held on June 3. From an SPI point of view we participated in that meeting under the authority given us by the resolution you passed at the last Committee meeting. Now, at the June 3 meeting of the inter-industry group, a committee of six was appointed to speak for the entire inter-industry group.

The inter-industry group includes, in addition to SPI, The National Flexible Packaging Association, the American Paper Institute, the American Petroleum Institute, The Soap and Detergent Manufacturers Association, the Can Manufacturers Institute, the Adhesives Manufacturers, and the Aluminum Association. This group, in a plenary session on June 3, appointed a committee of six to negotiate with

FDA as a whole, instead of separately. The mandate given to this committee of six, of which I now have the honor of being chairman, is to arrange for suitable meetings with FDA to discuss some of our mutual problems.

It is understood that the Inter-Industry Committee will not negotiate all issues. For example the Adhesives Manufacturers are free to negotiate with FDA on their own, as to whether or not the Adhesives List should remain in, or be eliminated from the Regulations. So too, SPI is free to have individual negotiations with FDA on matters of particular interest to us. And that is something I would like to see this committee discuss at length, as soon as I finish giving you what amounts to a background report.

After the June 3 meeting I called Mr Ramsey and he was very happy to hear that the Inter-Industry group had been able to appoint a committee of just six people to negotiate on behalf of all of the groups on what we consider to be central issues. The central issues that we have agreed to try to negotiate on are: (1) some means of better defining the 40 parts per million criterion that FDA is using, and (2) the desirability of substituting the language that was put forth at our Inter Industry meeting by Jack Frawley for sections (d)(5)(i) and (ii) of the Ramsey proposal.

The substitute language suggested by Jack Frawley for section (d)(5)(i) would read As components of food contact articles, provided any substance is present in the container or coating, or other food contact surface, at a level of 0.2% by weight, or less. Obviously that would be a more useful, workable concept because it would be much easier to establish whether a substance is present at a level of 0.2% by weight of the food contact surface

than it would be to analyze for parts per million in the food.

As regards our proposed substitute section (d)(5)(ii), this is both a backup position in a way, and it is also a position we should have anyway, at least in my opinion. The language we'll advance as a new section (d)(5)(ii) of the proposal reads: 'As components of food contact articles provided any substance so used contributes no more than 0.5 parts per million of additive to the contacted food, as determined by analysis of the food, or by appropriate extraction studies, or by calculation assuming 100% migration.' In other words, we will suggest that the 0.05 ppm criterion be changed to 0.5 ppm, a figure we believe to be much more helpful and realistic.

To date, we have had one meeting of the ad hoc committee of six. It was decided that, rather than rush into a meeting with Food and Drug, it would be better to delay such a meeting until we have had an opportunity to accumulate a special kind of background data. What we have in mind is a kind of market basket study in which the hundred or so foods used as an assumed 'market basket' by the Department of Agriculture will be purchased in various stores and, by evaluating those food purchases, an effort will be made to estimate how much food is packaged in all categories of packaging materials. Then an estimate will be made as to what might be the maximum percentage of foods packaged in each particular packaging material.

Jack Frawley made a preliminary estimate that 20 per cent of all foods are packaged in paper, and used this assumption, which is generally regarded to be a very high estimate, as the basis for his contention that 0.2 per cent of any component could be present in a package without presenting any safety problem.

Obviously, it is not going to be possible for us to do a truly definitive, scientific study. On the other hand, we hope to be able to come up with something that FDA can have for its files to justify a more liberal position on the 0.05 parts per million criteria set forth in the Ramsey proposal.

So the points I've mentioned are the ones we will be discussing with FDA. We will not be arguing about whether FDA should give letters on "no migration" situations or any of those other questions, but one of the things I really want to know from this committee today is what other points you think should be argued, perhaps on behalf of SPI instead of or behalf of the food packaging industry as a whole.

Question: Could you please explain a little more about the basis for the position that no safety problems occur when most components are present in a package at a level of 0.2 per cent or less? Is there any data supporting that conclusion?

Heckman: I'd like Bob Miller, if he will, to explain some of the background behind this Frawley theory.

Miller: If anybody has any data on actual migrations of components or materials into foods we would certainly like to have it to include in this document we're going to give to FDA to support our position. In Jack Frawley's ACS paper, and subsequent rewrites, he used the data Hercules has on rosin paper migration into food, in addition to another one that Hercules had published several years ago on plasticizers for PVC, to show how the 0.2% of the total package material for a component limit could be used without safety concerns so long as the component was not a heavy metal, pesticide, or known carcinogen. The rosins and PVC data are all we have so if anyone has any more

or better data on actual migration to foods, we would certainly like to have it as back-up information.

Question: Do you think FDA will accept the 0.2 per cent level, or less, theory?

Heckman: This is a personal opinion, it s certainly not Jack Frawley's, and maybe not the opinion of our Inter-Industry Committee, and it certainly won't be reflected in our negotiations with FDA, but if I had to give odds I would say that our chances of getting the 0.2 per cent concept adopted are not as good as our chances of getting FDA to adopt the 0.5 ppm concept.

Question: What's the possibility of getting a revision of the generally understood list of heavy metals that will not be exempt from regulation under the Ramsey proposal?

Heckman: Not very good, due in part to the fact that heavy metals are naturally present in the diet already, so its no kind of argument with FDA at all to point out the unavoidable presence of substances in "natural" foods. What they say in response to that argument is "we agree that those things are present in the diet and there's nothing we can do about that, but we are not going to permit an increase to the dietary background of those metals and, therefore, the only way to get them cleared is by the petition route." In other words, heavy metals will not be exempt from regulation except in those generally accepted applications where no petitions would be required, such as in "repeated use" and "barrier" situations.

Question. Would you care to comment on what effect, if any, the Ramsey proposal will have on FDA's present policy of refusing to issue "no migration" letters?

Heckman: Well, that's a point we are going to try to clarify. I think, but I can't guarantee this, that if we end up with a proposal that's workable, then FDA will probably begin writing letters of concurrence that are worthwhile again. Thus, for example, if FDA accepts an 0.5 ppm criteria and you submit a set of data to FDA that shows that you have a test method that is sensitive to 0.5 parts per million, and that you have no migration at the level of the test method sensitivity, and it is therefore your conclusion that you don't have a food additive, I think that FDA would then send letters agreeing with such conclusions. However, I can't guarantee that, and I think the consensus is that we should not raise that subject with FDA at this time. That's a subject we can go back to at another time, after we've accomplished something substantial with regard to the proposal itself.

Question: Am I right in assuming that the Ramsey proposal implies that FDA is willing to agree that with certain specified exceptions, anything that is added to a food contact surface at a level of 0 05 ppm, or less, is safe?

Heckman: Not really, all FDA is really doing is agreeing not to ask you to demonstrate safety or anything else if you've got a material or component that is not going to get into food at any level higher than 0.05 parts per million. Disregard whether it is safe or not. FDA won't ask you to demonstrate that it's safe by means of a petition and ultimate regulation if you're dealing with something that you put into the food contact surface at a level of less than 0.05 parts per million.

We want them to raise that threshhold level to 0.5 parts per million but, in any event, it's not really a question of safety in the final analysis, it's a question of what you have to file petitions for.

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I must apologize for having spent so much of the Committee's time in discussing these matters, but I think you will agree that the subject matter is not the kind that lends itself to systematized preparation and discussion. In any event, I do hope you have found our "information exchange" of the past hour or so helpful and informative.

Thank you.

Editorial Note:

As lengthy as it is, all Committee members should understand that the foregoing "edited transcript" does not purport to cover the discussion at the meeting in full. This is due in part to our attempts to make the transcript reasonably coherent, and in part to the fact that some portions of the tapes made at the session were simply incomprehensible. You have our apologies if one of your questions, one of special concern to you is not reflected herein.

JEROME H. HECKMAN