

CHICLE DEVELOPMENT COMPANY

500 FIFTH AVENUE

NEW YORK

PLEASE ADDRESS ALL COMMUNICATIONS TO THE COMPANY

November 25th 1935.

Messrs. R.A. Kehoe, ✓
S.C. Prescott,
W.C. Arkell,
P.L. Becker,
Nelson Buck.

Gentlemen:-

I enclose herewith transcript
of the record of the November 20th hearing before the Food
and Drug Administration.

Very truly yours,

CHICLE DEVELOPMENT COMPANY,


S.S. Yates,
President

SSY-W

Encl.

KE-0006309

N 7564

Tr. DS

NEW YORK STATION HEARING

DATE: November 20, 1935.

SUBJECT: N.Y. 20113, Chicle.

PRESENT: Mr. Charles Wesley Dunn, Attorney,
Mr. S.S. Yates, President,
Dr. Samuel C. Prescott (Dean of Science,
Massachusetts Institute of Technology),
Scientific Consultant,
Dr. Robert A. Kehoe (University of Cincinnati),
Scientific Consultant,
Chicle Development Co.,
500 Fifth Ave.,
New York, N. Y.

Mr. W.R.M. Wharton, Chief, Eastern District,
Mr. E.L. Anderson, Acting Chief, New York Station,
Food & Drug Administration,
New York, N. Y.

Mr. Anderson: This hearing is in connection with an importation of chicle consigned to Chicle Development Co., 500 Fifth Ave., New York City, arriving on S.S. Panuco, entry No. 320018, entry date 10/9/35. The shipment was examined and part of it found to contain lead in excess of the tolerance of this Department. The portion so found is labeled MECAM/SN - 132 bags. This portion of the shipment was accordingly detained under the Food & Drugs Act as being adulterated, since it contained an added poisonous or deleterious ingredient, lead, which may render the article injurious to health. The purpose of the hearing is to give the importer an opportunity to find any fault or error in the government's findings.

Mr. Wharton: I think at this point we might amend and supplement the charge by adding the charge that it contains a substance, lead, which may be injurious to the health of the people of the United States.

Mr. Anderson: We will be glad to have any statements you care to offer.

Mr. Dunn: Mr. Anderson, I would like to have the privilege of making a brief and summary statement in behalf of the respondent at this proceeding. (Reads statement as follows:- "Re: Port No. NY 20113. This is an administrative hearing to the Chicle Development Co., located at 500 Fifth Avenue, New York City, upon the detention of an importation of 132 bags of chicle under the federal food and drugs act, consigned to the company. The official notice of October 24, 1935, to the company charges in effect that the inspection and analysis of a representative sample of this chicle indicates that it is adulterated in violation of the foregoing act 'Since it contains an added poisonous or deleterious ingredient, lead, which may render the article injurious to health.' The company has not been informed of the amount of lead officially found in this chicle; but it has been informed that this amount exceeds the maximum lead tolerance allowed

"In importing this and its other chicle the company is acting for large domestic manufacturers of chewing gum; it imports about 50 per cent. of the chicle imported into this country, and all of the chicle imported by it is used exclusively in the manufacture of chewing gum. In dealing with this detention the company is also representing another large domestic manufacturer of chewing gum, who imports about 40 per cent. of all the chicle imported into this country, which chicle is likewise used exclusively in the manufacture of chewing gum. Therefore the company in effect represents the importers of at least 90 per cent. of the total amount of chicle imported into this country, and if the chicle imported by them and others is used exclusively in the manufacture of chewing gum.

"This charge of chicle adulteration in violation of the act, by reason of the presence of lead, has greatly surprised and deeply concerned chewing gum manufacturers directly affected. Consequently and immediately upon receiving the notice of this charge these manufacturers, acting through the Chicle Development Co., acted for the institution of a comprehensive, authoritative and conclusive scientific investigation of the fundamental facts presented, which investigation is directed to secure a due settlement of the questions presented by this charge through constructive collaboration with the government. Such action may be broadly summarized as follows:

"(1) The company retained the following scientists to make this investigation: Dr. S.C. Prescott, Dean of Science of the Massachusetts Institute of Technology, who has done notable fundamental research in the field of food science; Dr. George R. Cowgill, Associate Professor in the Department of Physiological Chemistry at the Medical School of Yale University, who has done authoritative research upon fundamental nutrition problems and who is now investigating the scientific problem of lead in food; and Dr. Robert A. Kehoe, Associate Professor in the College of Medicine of the University of Cincinnati, who has done outstanding research into related lead problems and made authoritative publications upon this subject. This list of scientists may be extended as the investigation proceeds and such extension is indicated.

"(2) These scientists have been directed to make a comprehensive scientific investigation which will conclusively establish the following basic facts: (1) what amount of lead, if any, is naturally present in the bark of the Achras Sapote tree and in the latex of that tree, for chicle is the latex from the young bark of that tree, solidified by boiling; (2) whether or to what extent lead externally enters chicle in the course of its production and subsequent handling; (3) what amount of lead, if any and in maximum range, is present in the chicle in question and in other chicle imported into the United States; (4) what amount of lead, if any and in maximum range, is present in chewing gum as a result of the use of chicle in its manufacture; and (5) whether any such lead in chewing gum may render such gum dangerous to health under the necessary and customary conditions of its use.

"At this point it should be noted that because chicle is used exclusively in the manufacture of chewing gum and because chicle is only consumed by the public in chewing gum, the question of the application of the federal food and drugs act to chicle, by reason of any lead content

must be determined upon the basis of its use in chewing gum and the resulting effect of such gum upon the health of the consuming public. In this connection it should be also noted that the maximum amount of chicle in chewing gum ranges from 20 to 30 per cent., wherefore the amount of any resulting lead in chewing gum is reduced proportionately; and that such gum is chewed and not swallowed, except accidentally on rare occasions. And it should be further noted that a preliminary investigation indicates that any lead in chicle is a natural and not an added ingredient; that the amount of any lead in chewing gum, added by chicle, is within the tolerance allowed under the act; that any such lead in chewing gum is only partially chewed out by the consumer; and that chewing gum is not actually or potentially injurious to health because of its chicle content.

"Having made this introductory statement the Chicle Development Co. now respectfully requests that this hearing be adjourned for six months. This request is based upon the advice of its aforesaid scientific experts and because such adjournment is necessary to make the scientific investigation required here. This is an original problem of food law application which requires an original research. Primary chicle materials must be brought from Mexico, chicle production and handling methods must be carefully checked, the methods of applicable analysis must be duly studied, extensive analyses must be made with respect to the primary materials, the imported chicle and the manufactured chewing gum, and the indicated biologic tests must be completed. Every effort will be made to expedite this investigation and the government will be informed of its progress, for the manufacturers have only the one purpose of duly solving all the questions here presented in constructive collaboration with the government. Their due solution is of vital importance to these manufacturers.

"The Chicle Development Co. also respectfully requests that all additional chicle detentions be suspended pending the completion of this investigation. This is the equitable procedure indicated here. For the investigation made in pursuance of the present detentions suffices as a basis to reach a conclusion of general application; such conclusion awaits the determination of this investigation, and the chewing gum manufacturers concerned ought not to be subjected to the danger of possible injury resulting from other detentions to which they are not in effect parties and which are therefore beyond their control and involve minor importers of chicle and minor manufacturers of chewing gum who are not positioned to make the required scientific investigation. It is too clear for argument that any premature and unfounded suspicion cast upon the healthful character of chewing gum will do an irreparable and wholly unwarranted injury to a great American industry.")

Now that completes my formal statement, and I will be glad to discuss it upon the basis of the questions which you may desire to ask.

Mr. Anderson: So far as the New York Station is concerned, I am sure that it would not be possible to grant any such request. The matter would have to be referred to the District and likely to the Administration.

Mr. Wharton: I will attempt to speak at this time on the subject of the viewpoint of the District. Before I do so, however, I would like to ask

some question, the first of which is have you considered, Mr. Dunn, the possibility of some process of lead removal from this material?

Mr. Dunn: Yes, we have that under consideration, and our scientific investigation will necessarily include any improvement in the process of gum manufacture and chicle treatment which will be effective to remove any added lead from chicle before the chicle is introduced into chewing gum.

Mr. Wharton: Have you made any studies as yet from the standpoint of a practical method of lead removal?

Mr. Dunn: I should say that the negative answer must be indicated to that question because this whole problem of lead in chicle is a novel one. It's a novel one under the Act and it's a novel one as to the manufacturer's effect, and we are attempting to duly solve that problem both from the standpoint of the Act and from the use of our product by the consuming public of the country.

Mr. Wharton: It appears to me that, while your objective is wholly constructive, there is indicated in your brief certain points wherein questions of controversial character enter which are involved in the question of the toxicity of lead, etc. It seems to me that, from the standpoint of the consumer based on the general knowledge that we possess at the present time, your clients might be expected first to undertake to find a method to remove any lead which may be in this material before using it in a food product. That seems to me to be a question that will be pertinent when we consider discontinuance of action over this long six months period.

Mr. Dunn: May I at this point give you the complete assurance of the three largest importers of chicle, who import over 90% of the chicle, and the three largest manufacturers of chewing gum, that they will give full attention to the problem that Mr. Wharton has just mentioned, and Mr. Wharton will be duly informed of the progress of that investigation.

Mr. Wharton: I can readily conceive that the Administration might agree to the importation of chicle containing lead if it was assured that that chicle was free from this lead before use in chewing gum or in the process of being used in the chewing gum.

Mr. Dunn: There are two problems presented there, Mr. Wharton. One is the problem of taking any lead out of this chicle that is used in chewing gum to the extent that is practical, and then the second problem is that, if there is a resulting amount of lead in chewing gum which falls within the tolerance established by the government, then of course there is no question about it.

Mr. Wharton: Our information permits us to debate the question of the quantity of lead which may be expected at least to be found in chewing gum by reason of the results obtained on chicle. In some determinations we have made of lead content of chicle based on a dilution of four to one, there would still be many times the present tolerance for lead.

Mr. Dunn: May I ask, Mr. Wharton, are the government determinations to

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which you refer made on a wet basis?

Mr. Wharton: They are made on the as is basis.

Mr. Dunn: That's the wet basis really. When you say "as is", you refer to the chicle in the form it is imported. May I ask further the question which I asked in the similar tea inquiry, which you very fairly answered? How high did the amount of lead which you found in chicle go as a maximum? You answered that question in the tea case.

Mr. Wharton: Well, our figures on lead determinations on chicle are very limited, but we have a few high results. In this particular shipment, the larger part of the shipment contained a very small amount of lead and the part of the shipment that was detained contained a considerable amount of lead relatively. Other examinations we have made show that some chicle is practically free from lead and perhaps some parts of the same shipment may be very low in lead and other parts of the shipment quite high.

Mr. Dunn: Of course, that is readily explainable in theory at least from the standpoint that this chicle comes from different regions and from different parts of the same region. What the facts are, we will determine. We are quite sure, as a result of our preliminary investigation, that whatever lead there is in chicle is a natural ingredient, and it may be, and I presume it will be, found on our investigation that there may perhaps be some lead in chicle which comes from certain territories and perhaps no lead in chicle from other territories, and perhaps a smaller amount of lead as between the different territories, so that the situation which Mr. Wharton has stated is not surprising and probably explained upon that ground, but I would like to know whether you would be willing to inform us, so that we may have some intelligent basis of dealing with this situation, what was the maximum range of the amount of lead found in this chicle as a result of the limited investigations which the government has made.

Mr. Wharton: We will do that in approximate terms. We have we will say a maximum of roughly, in round figures, 22 parts per million or 0.150 grains per pound. It ranges from that down to practically none.

Mr. Dunn: That is a very fair answer and I appreciate it. It's a very frank response.

Mr. Anderson: Wouldn't it be possible that this contamination is due to individual gatherers? My understanding is that these natives go out and tap these trees and do their own boiling in their own receptacles. It seems to me that if one of these receptacles became damaged, it might be soldered and the native might still use this soldered receptacle.

Mr. Dunn: As to that, we are dealing altogether with a hypothetical situation which we will have to investigate.

Mr. Wharton: I think it is a more reasonable theory than that the lead is inherent in the product.

Mr. Dunn: We know it is a natural ingredient for the reason that we have examined the latex and we have examined the bark of the tree, and we have

found some small amount of lead as a result of these investigations, so that all of the indications are to the effect that lead is a natural and not an artificial ingredient. Now, as to whether lead is a contamination in this chicle is a matter of investigation, but apparently it is not. These natives gather this latex in canvas bags. So far as we know, there is no lead that can get in through that source. Then they boil this latex in iron pots. Whether there is any lead which can get in through these iron pots through soldering holes is a matter we will investigate, but whatever the facts are we assure you we will give them to you. We've got a problem here that has got to be answered on the basis of the facts and has got to be answered on a basis of not impairing the value of these vast businesses which are involved. In the grocery business of this country, from the standpoint of prosperity, there is probably no part of the business which is more important than this chewing gum. It's a tremendous business. It would not be at all to the service of the country at large, from the standpoint of the people who are employed in these businesses and the people who have money invested in these businesses, to have their value impaired unduly, so we are going to investigate, and whatever the facts indicate you will know them.

This Act has been in effect practically 30 years -- it will be 30 years June 30, 1936 -- and there has been no question raised under the Act heretofore as to the presence of lead in chewing gum or in chicle so far as we know. So far as we know, there is no available evidence of the damage to anyone from the use of chewing gum, so there isn't any real public emergency as we see it that demands the drastic action in the way of excluding this chicle that may ruinously impair these businesses. On the other hand, if this problem is going to be settled right, it can only be settled on the basis of such a scientific investigation as we are willing to make. If you name any chemist in the Department of Agriculture, we are perfectly willing to have your chemist work in cooperation with ours in this matter so that it will be a constructive undertaking on both sides. From the standpoint of the industry, it is an emergency problem. Let the slightest suspicion come out to the public mind that chewing gum may be injurious because of some lead in it and it would be disastrous. It's only the fair thing to do, on both sides, to follow the program which I have laid down of constructively working together to solve this problem. What more could we do than get together the most authoritative scientists in the United States and make the sort of investigation I have outlined? What more could we do than that?

Mr. Wherton: Mr. Dunn and gentlemen, the Food & Drug Administration shares your purpose in its entirety. It wishes to be entirely constructive in the handling of this matter. It has no desire or intention of creating any unnecessary hardship or hazard for the chewing gum industry. It wishes only to secure a solution of the problem which appears to exist in this proposition. Now, having said that, I wish to be further constructive by saying that it seems to me you gentlemen should have a basis for approach to this problem which would present a reasonable basis for achieving the results that we are all aiming for. Frankly, the proposition as you put it, as persuasive as it is, in some of its phases is open to arguments. Those arguments I won't attempt to produce except to say, with respect to the emergency situation, that very naturally these particular matters develop by reason of the development of methods and of knowledge with respect to compositions of foods and with respect

to making progress in food control work, and even though 30 years have passed and no particular attention has been paid to this item from the lead standpoint, until very recently it was not possible to pay attention to it on account of lack of proper methods of estimation of lead content and for other reasons, and still we are confronted now not with a theory but with a degree of knowledge which directs attention not from the standpoint of what has gone before in comparison but what the situation is at present, and the Administration feels that obligation and is not influenced by the lapse of time previously.

Mr. Dunn: Let me say right there, Mr. Wharton, that I am in entire accord with what you have said. There is no implied criticism of the Administration when I say that this matter is now developing after 30 years because we all know that these scientific problems are being progressively developed. It is quite proper, from the standpoint both of the consuming public and the industry, that this matter should have developed right now -- this matter of whether there is lead in chicle and if so whether the use of that chicle in chewing gum may adversely affect the public health. All we are interested in doing is in seeing that that problem is duly solved.

Mr. Wharton: Again, from the standpoint of whether we can produce anyone who had been injured by chewing gum by reason of the lead content, probably we couldn't -- assuredly we couldn't -- but at the same time, if no individual can be produced who has been injured, that does not lessen the desirability, from the public health standpoint, of the removal of the lead from the product because of its possibility for cumulation and chronic manifestations. Now I will get back to my first proposition, and I assure you gentlemen that we wish to be helpful. On the basis of the proposition at present, without any showing of any prospect of solution, we are asked to delay action for six months time in order to permit a study. Nobody knows what the study will reveal. It does seem to me that if you could approach the Administration with a proposition -- and this is my own personal view of the matter -- that within lesser time an effort will be made to find a method whereby this lead can be taken out of any chicle in which it is contained -- that chicle can be made lead free by a commercial process -- if you can say to the Administration that you were going to do that, I think perhaps ---

Mr. Dunn: I am prepared to give you that assurance right now on behalf of the three largest manufacturers of chewing gum, who import over 90% of the chicle and produce at least 90% of the chewing gum in this country. We will make an immediate effort to develop a practical process to take any lead out of chicle and out of the chewing gum. Not only will we do that but we will advise you of the progress and the success that we have, and we will secure the best scientific talent in the United States, which as you know we have already secured, to assist us in this matter. Now, Mr. Wharton, could we do anything more than that?

Mr. Wharton: Let us say this. We are very much impressed, in our modesty, with the very high quality of talent that you have associated with you, Mr. Dunn. There is no doubt about it -- you have the best.

Mr. Dunn: Could I give you a greater assurance than I have on this score?

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Mr. Wharton: I don't think there is any question about it, but the whole question is the securing of an immediate or quick solution of the problem.

Mr. Dunn: As to the matter of a quick and immediate solution of this problem, I want to assure you that we are in entire accord with the government upon the value and necessity of that quick and immediate solution, and we are going to make every effort to secure it. When I say we need six months time, I am making that statement upon the advice of our scientific advisers. They say that time is required for their proper investigation and scientific research. Now if it develops that our results can be accomplished in a sooner period, we are very pleased to do it. I would even go a step further and say -- and I say this upon my own responsibility but for my clients and I am sure that they will support me in this position -- that if, in the course of your examination of imports of chicle during this period, you come across chicle which contains excessive amounts of lead as a result of your findings, we are perfectly willing to put those shipments aside and take them out of commerce entirely, and to let those shipments stay in abeyance until we can prove this investigation to the extent you suggest. With respect to any practical steps, of which this is one, to accomplish your purpose along with ours, we will be only too happy to cooperate with you.

Mr. Anderson: You mean by that that you have sufficient chicle on hand to last for six months?

Mr. Yates: No.

Mr. Wharton: That puts the burden on the government, too. What facilities does the industry for testing its own product for such segregation?

Mr. Yates: The industry has chemists as skilled in this research as can be obtained in these gentlemen here. At their suggestion, we can appoint a man whose only job will be to make these investigations.

Mr. Dunn: We will determine a plan for your approval which will develop the most effective control.

Mr. Wharton: That seems to me a practical proposition. You are giving a basis whereby the Administration may be able to leave this proposition for handling and solution with an industry that it can depend upon, but I won't attempt to commit the Administration at this point to that course.

Mr. Dunn: I will commit these manufacturers to the point that we are prepared to sit down with you and work out a control plan that will be satisfactory to you and to the industry.

Mr. Wharton: Of course, experience in other lines which we have had -- and we have had a great deal of it -- may throw some particular light on this problem. We found a great deal of lead in sardines. We found eventually that the chief reason was that the sardines were being packed in cans with exposed solder and that solder apparently was the part of the can that was made in the can factory where they used oleic acid as flux. A little of that acid remained behind and seemed to have an affinity for lead. It would dry on the bottom of the tins and the fish seemed to have an affinity for lead oleate or whatever the combination was, and they took

the lead up very promptly. The claim was made that this lead was inherent in the fish. There was another theory developed that the lead came from the grids on which the fish were cooked in oil. There were other theories developed and eventually this particular one. With the correction of the character of the container, the whole problem has been solved. It meant, for instance, in this country, junking a can manufacturing plant in Eastport, Maine, and using another one that would make another kind of can. I recite that experience because, if lead is inherent in the plant, then you've got to find a way to get it out of the chicle. If it isn't inherent in the plant, and my idea is that in quantities contained in some of those higher samples it isn't, then all you've got to do is find the place where it gets in and eliminate that entry and the problem is solved.

Mr. Dunn: That's what we will do. Another similar situation is the presence of lead in tea, which was due to the presence of these lead containers, and the problem was solved by putting a paper lining inside of these containers. I think that's only a partial answer. I think they used lead linings in harvesting the product, etc. We are going to follow this chicle right from the very beginning of its production, and we are going to uncover any sources of lead contamination. Those sources are going to be cured. They will have to be cured.

Mr. Wharton: This is a very unusual request which you have made of the Department and is one involving a matter of so much importance that I would prefer that it be decided in the Administration in Washington, and so we will undertake to send this record to the Administration very promptly with the request that they give us a definite answer to each of the requests that you have made.

Mr. Dunn: Now then, I would like to be informed of the transmission to Washington; that is, the time that it is transmitted, because I would then like to make application to Mr. Campbell for the privilege of a conference with him on the part of myself and my scientific associates to answer any questions which may be presented to him in the final decision of this matter.

Mr. Wharton: We can say to that that this record should go to the Administration by tomorrow night. (As a result of further discussion which later ensued off the record, respondent was informed that the record of hearing could not be forwarded to the Administration before Friday, November 22, 1935.)

Mr. Dunn: In that event, I will write immediately to Mr. Campbell and just state the fact of this hearing and the fact that I understand this record will be transmitted to him and will be considered by him for advice to you in New York, and we would like to have the privilege of a conference with him if that is agreeable to you.

Mr. Wharton: That is very satisfactory. In fact, I recommend that.

Mr. Dunn: As I understand, Mr. Wharton, in transmitting the record to Washington, whoever has charge of it here will make recommendations as to our requests for consideration in Washington.

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Mr. Wharton: Yes, we usually make some definite recommendation with respect to each issue we handle. Frankly, I am not prepared to state just what our recommendation will be. I have not formulated it in my mind as yet.

Mr. Dunn: I can understand you want to think this matter over. It is a very important matter, but may I add this further statement for the record; that, of course, you have your own problems of disposing of these applications of ours -- that is to say, questions of administrative procedure and regulations which control a situation of this sort. Now, whatever the administrative problems may be, I want to assure you that we would try in every practical way to fit ourselves into the solution of these problems in order to accomplish the ultimate purposes that we have in mind. I have presented this statement from the standpoint of the industry, and you have your problems in meeting the applications which I have presented, so if we can just have a common understanding of these problems and a common purpose of trying to solve them constructively from the standpoint of both sides, there is no doubt that we can reach a mutually agreeable conclusion.

Mr. Wharton: There is one thing that the record ought to have in it and that is the fact that the rule is that, for a detained product violative of the Federal Food & Drugs Act, there is a time limit of 90 days which is placed by the Customs for exportation, the rule being that if the product is not exported in 90 days, it shall thereafter be destroyed. However, it depends, I think, upon the estimation of the beginning date for determining the date when the 90 days expires, and that means, does it not Mr. Anderson, that the Customs begin to count the time after a final decision for exportation by this Department.

Mr. Anderson: In other words, if this hearing were adjourned now, we will say for the sake of argument, for a definite period, it would mean that the 90 day period would not begin to be effective until after the statement of conditions to be fulfilled was issued. After the statement specifies the conditions to be complied with, you will have 90 days to comply.

Mr. Dunn: I am trying to think of every point that would help us reach the common end. Would it perhaps be more agreeable to you and equally effective from our standpoint if the adjournment we will say was made at this time for three months instead of six months, and then the matter reconsidered upon the basis of the progress of our investigation at that time?

Mr. Wharton: I suggest that you ask for a transfer of the matter to Washington and let the matter of an adjournment continue there. That would be the logical sequence.

Mr. Dunn: Of course it would be, but it's just a matter of modus operandi I had in mind in the first instance of proceeding on the basis of simply asking for a hearing by the Department upon the basis of your report. If, on the other hand, it is more advisable for you to make formal application at this time to transfer this whole hearing to Washington, I will be very glad to do that. I submit to your decision as to which would be the better procedure from your standpoint.

Mr. Wharton: I think, in effect, that is what's going to happen in the matter, and I think it would be proper to handle it on that basis. Then we haven't the indefinite request left in our record for a time limit, because after all it will be properly settled on that issue in Washington anyway.

Mr. Dunn: Would you suggest, then, that I make a formal request upon the record of this hearing to transfer it to Washington for final consideration? Is that your suggestion?

Mr. Wharton: Yes.

Mr. Dunn: Then I make that request at this time -- that this hearing be now adjourned and that it be continued before the officials of the Food & Drug Administration in Washington at some date to be fixed by them.

Mr. Wharton: We will notify the Administration of this adjournment of the hearing to Washington and tell the Administration that Mr. Dunn will communicate with Mr. Campbell seeking a definite appointment.

Mr. Dunn: Let me be perfectly clear in one point; that this request that I have made for a transfer of this hearing to Washington will not in any way preclude the transmission of your recommendations based upon the record of this hearing as to the final disposition of this matter.

Mr. Anderson: That is understood. Is there anything further?

Mr. Yates: I would like to ask one question about this lot. Did you find that representative samples taken from the entire lot which you have held were in excess of the government specifications on lead?

Mr. Anderson: What do you mean by representative of the entire lot?

Mr. Yates: Have you taken a sample out of one bag and said that, as long as that is high, we are going to hold all?

Mr. Anderson: We don't take a portion of each bag in the shipment.

Mr. Dunn: That raises a very important question in my mind. As I understand it, this chicle is in blocks.

Mr. Yates: Each block is made by an individual workman. That shipment may represent 100 or 200 different workmen scattered over a territory of 100 miles. Each block weighs 12 to 20 pounds. There are 150 pounds in a bag, so roughly there would be 10 blocks in a bag.

Mr. Dunn: When you come to sampling this chicle, how do you do it? If a bag contains 12 to 15 blocks, do you sample every block in that bag?

Mr. Anderson: No, I am quite sure they wouldn't. They might examine one or two blocks from a number of different bags but they wouldn't examine each block from each bag.

Mr. Dunn: In that event and in view of the fact that these blocks are separate entities and represent a composite of production and may

represent different localities of production and certainly different trees of production, would such a method of sampling be representative as to the entire bag?

Mr. Wharton: Very often it is desirable to take a sample that represents the average content of a shipment. That is to say, if you want to determine what the average lead content of a shipment of chicle is, then you would undertake to sample it in such a representative fashion that your sample would likely represent a fair average of the amount of lead in the entire shipment. We are not so much concerned, however, with getting representative samples of a product of that sort. We think in general it is sufficient to determine that there is in a shipment a quantity of material which contains an excess of the objectionable constituent. That is best illustrated with any poisonous material since there is no assurance that any one shipment is going to remain intact and the average distributed throughout that entire shipment. The application is to the product as we find it, presuming that it may be used as it is separately.

Mr. Dunn: Is it a fair statement, then, to say that the method of sampling is this:- Where a bag containing approximately 12 or 15 blocks of chicle is presented for examination, and if one of those blocks in that bag shows an excessive amount of lead beyond the tolerance allowed under the Act, then the whole bag is held up and detained -- is that right?

Mr. Anderson: If there is only one bag in the shipment. If there were more than one bag in the shipment, the sample would consist of a composite of a representative number of bags, so that our analysis would be on a number of bags in the shipment.

Mr. Dunn: We have 132 bags. That number of bags is a portion of the total shipment. We have a total importation of many more bags. I assume from what Mr. Wharton has said that those 132 bags are held up for the reason that at least one block in each of those 132 bags has been examined and found to contain an amount of lead in excess of the tolerance.

Mr. Anderson: No, that is not so. The situation is that a part of a block from one bag and a part of a block from another bag and so on until you get a representative number of blocks are all mixed together and ground up and sub-divided and a portion of that taken for analysis, and that analysis shows high lead.

Mr. Dunn: In other words, if we had a shipment of 132 bags and you picked out what you would fairly think would be a representative number of blocks and a representative number of bags and took a part of those blocks and then ground the whole pieces together in one mass, you then would have your representative sample which you analyze?

Mr. Anderson: Yes, that's right. That is supposed to represent the entire shipment.

Mr. Wharton: My remarks were not with regard to the specific instance of this case but to general considerations, and they apply in a way to this case because we don't want it to be understood that we have taken each bag in the shipment. If there were any bags in the shipment which you, by your own tests, find contain lead less than the tolerance, we, on checking that result, will release those bags.

Mr. Dunn: Let's take those 132 bags. As the situation now stands, the probability is that only a certain number of those bags have been subjected to an examination.

Mr. Anderson: Not any one individually.

Mr. Dunn: There are a certain number of bags from which no sample was taken -- by far the greater number. Is there any feasible or allowable way in which our chemists, in conjunction with your chemists, might analyze the chicle in the bags which have not yet been analyzed in order that, if any of that chicle is free from lead or contains lead below the tolerance, it may be released? In other words, I assume you don't want to hold any of these bags if the chicle in them is all right. Would you be willing to work out some plan of joint analysis with our chemists as to those other bags?

Mr. Anderson: It seems to me that the responsibility for that segregation should be yours. If there is any way you can devise to make that segregation and the analysis, we will be glad to check it.

Mr. Yates: The 132 bags are in our hands.

Mr. Dunn: They are under our control, and I assume that you can identify the bags in that 132 from which samples can be taken.

Mr. Yates: No, because the government comes on the pier and takes samples without our knowledge.

Mr. Dunn: Were these samples taken from those 132 bags before the deliveries were made to you?

Mr. Yates: No. Delivery is made to the Chicle Development Co. in Mexico. Then we deliver to the manufacturing companies, but it is in our name when the samples are taken.

Mr. Dunn: These samples were taken on the pier or in the warehouse. Now, what I am trying to get at is to establish by a proper analysis the character from the standpoint of the Act and the point we are considering of the chicle in those bags which have not yet been examined by the government. Would you be willing to work with our chemists? Suppose we have Dr. Prescott come down and see your chemist. Would you be willing to work out some plan by virtue of which Dr. Prescott and your chemist would take samples from these other bags and work out an analysis?

Mr. Anderson: We will be glad to **check your** analysis if you take the samples yourself.

Mr. Dunn: If we go out and take the sample and bring you a pound of chicle and say that it comes from certain bags, you won't take that sample?

Mr. Anderson: No, but we will take your word for it that you had that sample if you have the analysis made. Then we will take samples from these same bags and run another analysis.

Mr. Wharton: We can't undertake joint examination with your chemists. If

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we undertook that procedure with respect to all products, we would be swamped. There may be 500,000 bags of cocoa coming in on one boat, and if some importer wants us to help examine each one of those bags, we can't do it. If you undertake to separate, by chemical test, the chicle that is below the tolerance in that shipment, if any, in one pile, and the chicle that is above the tolerance in another pile, then we will go and take a sample from the lot that you set aside as good and test it. If it is good by our test, we will release it.

Mr. Dunn: Then you have no objection, in the case of these 132 bags, for us to have our scientific experts take proper samples, have them analyzed and bring you the results, and if they show no violation, you will make check analyses and if your analyses confirm ours, you will release it.

Mr. Wharton: That's right, but you should make application for that to Mr. Anderson on the regular form which we have for that purpose.

Mr. Yates: The limit for lead is roughly $2\frac{1}{2}$ parts per million. Suppose that two lots come in that are practically lead free. Another lot may have 5 parts per million. If we could show you that we never made chewing gum without a blending, could we blend the high with the low to get an average?

Mr. Wharton: No, for this reason. The Administration has uniformly taken the position that it multiplies the distribution of the poisonous ingredient to mix a product that is free from the objectionable material with one that has an excess. You can see it just simply adulterates a larger amount of material and spreads it in a wider fashion. The Administration, I am sure, would not agree to any such procedure. It has been proposed many times.

Dr. Kehoe: That is precisely what happens when you take a sample which is composite.

Mr. Wharton: That is more or less true, and for that reason, Doctor, we very often undertake to sample products by individual packages and then, when we find a material amount of objectionable material, even though the majority is unobjectionable we detain the whole shipment and place the burden on the importer to make a separation.

Mr. Dunn: When you take a sample, Mr. Anderson, from these chicle blocks, just how do you take that sample? You cut it off? If you cut or chop it off, what instrument do you use and how much do you take out of these blocks for your examination?

Mr. Anderson: It would depend entirely on the amount necessary. I would say -- this is just my opinion -- that likely a two pound sample might be brought into the laboratory. You might have eight or ten bags examined to get that pound or two pounds.

Mr. Dunn: You take a piece off of each block, which in the aggregate amounts to the two pound sample? What instrument do you use to take it out?

Mr. Anderson: They have a number of instruments. I don't know which one they would use on chicle.

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Mr. Dunn: Is there any instrument you use that would contain lead in itself?

Mr. Wharton: I would say assuredly not.

Mr. Dunn: I don't suggest for a minute that you do that but I remember that when we had the tea consideration, the fact developed that when these samples were taken from tea, there was a possibility when the lead container was broken of some of those lead scraps getting down into the tea.

Mr. Wharton: That was a misapprehension on your part, Mr. Dunn. I recall the incident because you confused the sampling of tea when testing for quality with the sampling of tea when testing for lead. In all cases where we were testing for lead, we removed the lid of the case and carefully cut the lead lining.

Mr. Dunn: I am very glad to be corrected on that. I was under that misapprehension. I presume, Mr. Anderson, you would have no objection to telling us the details of this operation.

Mr. Anderson: I couldn't tell you the exact details because I haven't been out with them.

Mr. Dunn: I presume you would have no objection to one of our experts talking with your examiner about that.

Mr. Anderson: No, there would be no objection.

Mr. Dunn: I am simply trying to get all the facts that are pertinent to this inquiry.

Mr. Wharton: I think you can assume that we have had enough experience in sampling, and when you talk about an inspector's equipment for sampling, I believe we have 100 instruments out there for various specific purposes. They are all made to order for a specific purpose. I think you can assume that the samples are properly taken and that there is no contamination possible.

Mr. Anderson: I think if you ever have a contamination by the instrument which you are using for sampling, the amount of lead would be so great that there would be no question as to its source.

Mr. Dunn: That is a matter that we could learn through contact of the mutual chemists. As far as I know, that's about all I want to say.

Dr. Prescott: There is one thing, if I may mention it, which should be brought out. That is on the question of method of analysis. Of course, this matter has only been brought to my attention within a comparatively short time -- two weeks or something like that. Dr. Kehoe has been engaged in the examination of the materials with small quantities of lead for a longer time. These methods of analysis are extremely slow methods -- very time-consuming operations. If the thing is done right, it involves the greatest delicacy of technique. It seems to me it would be

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should try first of all -- if we can carry out this highly desirable method of cooperative investigation of this problem, that's what we ought to do -- we ought to make first of all a very careful study of the methods which are likely to yield us the most accurate results in these examinations. From my study of the methods thus far, I don't feel that there is any method that has been published which gives us absolute figures. Do you?

Mr. Anderson: We can say this about our method. We are quite sure that the results are not any more than is present. The tendency would be to be just slightly below the amount that we know is in there. That is from adding definite amounts and recovering them. I mean the error is favoring the manufacturer, if there be any error.

Dr. Prescott: Is your method the one devised for the examination of sardines by electrolysis, etc.?

Mr. Anderson: Yes.

Dr. Prescott: Well, of course we have undertaken a study of methods since this matter came up two weeks ago. Three laboratories will be making studies of methods, and it was my hope, and my colleagues agree with me, that there would be four laboratories studying the method, because the government laboratory is quite as interested as we are and it seems to me that a very close cooperation and comparison of methods and results there is desirable.

Mr. Wharton: It would be. I think the proper place to make that suggestion would be at Dr. White's laboratory in Washington. You see, Dr. Prescott, in the field we are engaged in productive operations from the enforcement standpoint and not so much with the tools of operation. The tools presumably are furnished to us from Washington. They study the methods. While we do some of it through sheer necessity and often our men participate, that is all done under Dr. White's supervision. I am very sure he would be delighted to collaborate with you gentlemen.

Mr. Dunn: May I express the hope on the record that Dr. White will attend the further hearing on this matter at Washington.

Dr. Prescott: I brought that matter up because it seems to me that the problem of methods is one of the first things which ought to be considered. I don't know whether Dr. Kehoe will quite agree with me on that or not but from the amount of study I have been able to give this thing in a comparatively short time and the work which we have carried out in our laboratory on these methods in that short time, it seems to me we ought to be able to talk a common language on the question of methods as soon as possible.

Mr. Wharton: I think you are very correct, Doctor. The Food & Drug Administration has, by reason of necessity, had to develop methods for lead determination; arsenic, fluorine, mercury, etc., and the Administration has put in a great deal of time on the development of those methods. Now there are two objectives. You hinted at one when you spoke of the time it would take to examine 132 bags. The time element is important when you are dealing with questions of detentions of property and the rights of citizens, and so we must be expeditious.

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Dr. Prescott: Some of these methods require two days before you can get your results, and trying to do 132 samples in two days a piece, you are not going to get your stuff out.

Mr. Wharton: The point of that is, from the practical side, probably you would spend more time at analysis than your product would be worth.

Dr. Prescott: Of course, you wouldn't do them one at a time.

Mr. Wharton: You know, we have been studying this sampling business for thirty years, and it is one of the most difficult things there is because your result on your sample is no better than the sample you've got.

Mr. Dunn: That's the reason I asked those questions about the sample.

Mr. Wharton: You may be looking for the average composition or you may be looking for even an isolated occurrence as we do with respect to canned goods containing B. botulinus toxin. If we find a shipment of canned goods containing one can affected with B. botulinus toxin, we will seize the whole shipment. We do it frequently.

Dr. Prescott: You have a little different situation than you have in the chicle, but we can understand it.

Mr. Dunn: Mr. Anderson, we would like to obtain seven copies of the record of this hearing, and we are very glad to take care of whatever expense is involved.

Mr. Anderson: Very well. If there is nothing further to be added, we will consider the hearing adjourned.
