Letter of Acting Secretary Dunlap to the President.

The President,

The White House.

Dear Mr. President:

I wish to acknowledge Mr. Sanders' letter of June 13 transmitting a communication addressed to you under date of June 3, 1925, by Dr. Harvey W. Wiley. Dr. Wiley alleges certain laxities in the enforcement of the Federal food and drugs act and encloses exhibits bearing on the charges which he has made. The substance of his allegations appears to be covered by the suggested executive order which is included in the concluding portion of his article entitled "A Job for the New Administration" published in the Good Housekeeping Magazine for June, 1925. That suggested order proposes the repeal of certain previous orders, regulations, food inspection decisions and other pronouncements which according to Dr. Wiley have permitted the continued use in foods of benzoate of soda, sulphur dioxide and sulphites, saccharin and alum and the continued traffic in bleached flour and Coca Cola, which Dr. Wiley holds to be violative of the food and drugs act.

The allegations which Dr. Wiley makes are serious. Because of his eminence as an advocate of the purity of the food and drug supply of the nation, and because of great service rendered by him in helping to bring about the enactment of the food and drugs act, one of the most beneficent pieces of legislation ever passed by Congress, his statements are deserving of the most careful and respectful attention. I have taken occasion since receipt of this communication to have made a careful review of the history of the enforcement work under the food and drugs act in so far as it

relates to the particular items mentioned by Dr. Wiley. I know that I am voicing the feeling of the Bureau of Chemistry as well as my own when I say that there is the utmost sympathy between the officials of that Bureau in charge of the enforcement of the food and drugs act and the higher administrative officers of this Department who are called upon to review in a general way, actionstaken in connection with the food and drugs act. It is not my purpose to hamper the Bureau of Chemistry by any restrictions which will prevent the literal application of the terms of the law to food and drug products brought within the jurisdiction of the act. The Department and the Bureau of Chemistry share Dr. Wiley's view that the use of substances such as benzoate of soda, sulphur dioxide and sulphites, saccharin, alum, chemical bleaches in flour and added caffein in beverages, is for the most part undesirable from the broad general standpoint of human health and nutrition. The elimination of these extraneous substances from the food supply is an object greatly to be desired. We differ from Dr. Wiley only in our view as to the adequacy of existing means which may be employed to attain these ends. Dr. Wiley's view appears to be that there is sufficient evidence now available to warrant the institution of proceedings under the food and drugs act looking to the elimination of all of these substances from the nation's food supply. A review of the Department's actions may demonstrate why the Department is obliged to differ with Dr. Wiley.

Legal action under the food and drugs act has been brought against Coca Cola, against bleached flour and against saccharin. No such action under the act has been instituted against benzoate of soda, alum, sulphur dioxide and sulphites.

In the action against Coca Cola, the principal cause for complaint was the presence in this product of the substance caffein, which the Department held to be an added deleterious ingredient. Expert testimony intended to establish the deleterious character of caffein was introduced by the Department in connection with a seizure instituted in the Eastern District of Tennessee in October, 1909. Contrary expert testimony was introduced by the claimant. The court, however, held as a matter of law that caffein in the product in question was not an added ingredient within the meaning of the statute and directed a verdict in favor of the claimant. The Government took an appeal in this case to the Circuit Court of Appeals for the 6th Circuit, which sustained the judgment of the district court. The case was then carried by the Government to the Supreme Court of the United States upon a writ of error. In a decision rendered May 22, 1916, (241 U. S. 265), the Supreme Court reversed the lower courts and remanded the case for retrial. The Supreme Court's decision substantially established that caffein in this product was an added ingredient and left for retrial in the lower court the question of fact whether the added ingredient was an added poisonous or deleterious ingredient which may render such article injurious to health. The respondent thereupon changed the formula for its product so as to reduce materially the amount of caffein in the finished article. Holding that a decision of the question at issue, in view of the reduction of the amount of caffein in the product, would not be conclusive in any future proceedings, the claimant withdrew its claim and all other pleadings and consented to the entry of a judgment in the case. There had in the meantime been handed down by the Supreme Court in February, 1914 (232 U. S. 399), a decision in the bleached flour case to the ef-

fect that the burden was on the Government, with reference to the section of the act relating to the addition of a poisonous or deleterious ingredient, of establishing, in order to prove adulteration, that there is a possibility, when the facts are reasonably considered that the food product by reason of the presence of the added poisonous ingredient in the amount found may injure the health of some consumer. Before this decision was rendered enforcing officials, including we believe Dr. Wiley, had assumed that it was necessary to establish only that the ingredient was added and was in itself of an injurious character in order to prove adulteration within the meaning of the law. By reason of the reduction of the amount of caffein in the formula, of the Supreme Court's decision in the bleached flour case, and because as will later be developed, of the difficulty of establishing harmful effect by expert testimony, the Department has never felt that it has had available sufficient evidence of the deleterious character of Coca Cola to warrant it in bringing action against the product as now manufactured on the charge that it is adulterated within the meaning of the food and drugs act, because of the presence of added caffein.

Reference has been made to the bleached flour case. An action was instituted on or about April 1, 1910, against a shipment of bleached flour alleged to be adulterated and misbranded. Among the charges of adulteration was one alleging that "it contained added poisonous or other added deleterious ingredients, to wit, nitrites or nitrite reacting material, nitrogen peroxide gas and other poisonous and deleterious ingreidents and substances which may render said flour injurious to health." These ingredients

were present as a result of the treatment of the flour by an electrical bleaching process known as the Alsop process. The trial lasted for five weeks, during which the Government and the claimant introduced expert evidence on the physiological action of the various ingredients present as the result of the bleaching operation. There were two separate special verdicts; one that the flour was adulterated, and the other that it was misbranded. The claimants took the case to the Circuit Court of Appeals for the Eighth Circuit. That court found error in the instructions of the lower court to the jury as to the interpretation of the clause of the Act relating to deleterious ingredients. The Supreme Court on a writ of certiorari reviewed the decision of the Court of Appeals as to the construction of the clause of the statute which declares an article of food adulterated if it contains any added poisonous or deleterious ingredients, which may render it injurious to health. This was the sole question considered by the Supreme Court. It held that the instructions of the trial court with reference to this particular clause of the statute were erroneous or at least misleading and remanded the case for retrial. The Supreme Court's decision as already stated was that "if it can not by any possibility, when the facts are reasonably considered, injure the health of any consumer such flour, though having a small addition of poisonous or deleterious ingredients, may not be condemned under the Act." While the Department of Agriculture in the original trial of the bleached flour case was able to advance what it believed to be evidence of the deleterious character of the various bleaching agents found residual in the flour, it was forced to recognize that in the existing state of the science of toxicology, it would be

impossible to produce evidence to support the charge in court that the seized flour contained deleterious ingredients which might render it injurious to health, within the meaning of the statute as construed by the Supreme Court. It therefore advised the Department of Justice that in its opinion the charge that the flour contained an added deleterious ingredient which might render it injurious to health should be eliminated from the libel. The libel was amended in accordance with this recommendation. Thereupon the claimant withdrew its claim, answer and appearance and a decree was entered ordering that the amended libel be taken pro confesso, the cause heard ex parte and all the allegations of the amended libel found to be true. Thus the charges upon which the case was finally determined bore no relation whatever to the deleterious character of the added ingredients present as a result of bleaching. Following such termination the Bureau of Chemistry in a Service and Regulatory Announcement issued December 30, 1920, copy enclosed, (Items 350), announced that "no action would be taken at the present time on the ground that bleaching introduces into the flour a substance which may be injurious to health, provided as a result of bleaching there is not introduced such a quantity of the bleaching agent as may render the flour injurious as indicated in the decision of the Supreme Court. Should evidence later become available that the bleaching of flour introduces an ingredient in minute quantities which has the effect of rendering the article injurious to health, announcement of the fact will be made and appropriate action will be taken * * *." The last sentence of this announcement was based on the realization that under the existing methods of physiological experimentation sufficient evidence of the harmful character of the food product was

not attainable but with the thought that adequate methods of demonstrating harm might later be devised by some experimenter. To date neither the Bureau nor other experimenters have reported such findings.

The Department's attitude on saccharin is clearly shown by the enclosed Food Inspection Decision 142, approved February 29, 1912, by Secretary of Agriculture Wilson and Secretary of Commerce and Labor Nagel. The then Secretary of the Treasury dissented from this announcement. It was held in this decision that foods containing saccharin are adulterated because they contain an added deleterious ingredient and because the use of saccharin lowers the quality of the food. This decision was based upon the investigations made by the Referee Board of Consulting Scientific Experts referred to in Dr. Wiley's article as the Remsen Board. This Board was appointed at the direction of President Roosevelt after it had become evident that in the enforcement of the act repeated questions regarding the physiological action of various food ingredients were arising. The Board was presided over by Dr. Ira Remsen, a distinguished organic chemist, then President of John Hopkins University, and its personnel consisted of men almost universally recognized as the leading physiological chemists of the country, namely, Professor Russell H. Chittenden of Yale University, Professor John H. Long of Northwestern University, Dr. C. H. Herter of Columbia University and Professor Alonzo E. Taylor then of the University of California. The attitude expressed in Food Inspection Decision 142 represents the present attitude of the Department. It has nevertheless been unable to maintain this attitude in the courts. A criminal action under

Section 2 of the food and drugs act was instituted in St. Louis against the Monsanto Chemical Co., one of the leading manufacturers of saccharin offered for use as a food sweetener. The product was labeled in part as positively harmless and the issue was practically narrowed by the court through the elimination of charges based on other statements upon the label to a determination whether the statement "positively harmless" was false and misleading and a misbranding under the food and drugs act. This restricted the issue to the establishment of the injuriousness to health of the substance saccharin. The Government presented what it considered to be, and still considers, satisfactory evidence of its deleterious character. The case was strongly contested and on two separate occasions resulted in a mistrial. It is understood that the juries in both trials divided seven to five in favor of the Government. The trials were extremely expensive. The first trial cost the Bureau of Chemistry $28,038.68, and the second, $8,278.19, both amounts being exclusive of the cost of general administrative overhead and preliminary laboratory work. The expense incurred by the Department of Justice is not known but was large, especially in the first trial owing to the employment of special counsel. Upon the failure to reach a definite conclusion after the second trial, conferences were had with the Department of Justice and it was determined that the Government could not hope to prevail in the trial of this issue upon the facts and under the conditions presented. The Department of Justice concluded the expenditure of additional public funds for the purpose of attempting to retry this case to be inadvisable and the action was dismissed.

The three cases just cited, namely, the Coca Cola case, the bleached flour case and the saccharin case, are illustrative of the extreme difficulty which is encountered in establishing by the introduction of technical scientific evidence that the addition of deleterious ingredients to food in the small amounts in which they are present may render the foods injurious to health. In contested actions such as those described it is always possible for the opponents of the Government to secure evidence of a kind almost if not quite as convincing as that procured by the Government and in opposition to it. The evidence is highly scientific and presents extreme difficulties for the average jury. The Government must, moreover, prove its case in criminal actions beyond a reasonable doubt and in civil cases by a preponderance of evidence.

In the case of benzoate of soda, sulphur dioxide and sulphites, investigations have been made both by the Bureau of Chemistry and by the above mentioned Referee Board of Consulting Scientific Experts for the purpose of determing whether these substances may be regarded, when used in foods, as added deleterious ingredients. Alum was studied by the Referee Board but not by the Bureau of Chemistry. The departmental orders relating to benzoate of soda and sulphur dioxide, to which Dr. Wiley refers as blocking action and which he asks be rescinded, are respectively Food Inspection Decision 104 and Food Inspection Decision 89 enclosed. The first named decision, based on the findings of the Referee Board of Consulting Scientific Experts, holds that sodium benzoate may be used in food products if its presence and amount are declared upon the label. The Referee Board found no evidence of physiological harm through the use of foods containing sodium benzoate.

Although these findings were at variance with those obtained by Dr. Wiley in the Bureau of Chemistry, they were sufficient to lead the Bureau of Chemistry to believe that it could not successfully maintain a case in the courts against a food containing sodium benzoate. Food Inspection Decision 104 stands as an expression of Departmental and Bureau opinion today and were it rescinded the Bureau of Chemistry would not be in a position to take successful legal action against sodium benzoate as an added deleterious ingredient which might render the food in which it is used injurious to health. The only pertinent portion of Food Inspection Decision 89 is the paragraph relating to sulphur dioxide, which permits the presence of this substance in the usual amounts in foods if its presence is declared on the label. The extensive physiological investigations of the Referee Board and of later investigators failed to demonstrate conclusively the adverse physiological action of sulphur dioxide or sulphites. We have recently had these reports reviewed by the United States Public Health Service, which confirms the conclusion reached by the Referee Board that there is no evidence that sulphur dioxide in the usual amounts is an added deleterious ingredient which may render the food injurious to health. As in the case of Food Inspection Decision 104, even were Food Inspection Decision 89 rescinded the Bureau of Chemistry would not be in a position to take successful action against food containing sulphur dioxide, and this is notwithstanding the fact that investigations carried on by the Bureau of Chemistry under Dr. Wiley's direction established to his satisfaction that sulphur dioxide was injurious.

No departmental order on alum has been issued, but Department Bulletin No. 103, enclosed, contains a summary of the results obtained on the study of this substance by the Referee Board. That Board did not find evidence establishing that foods containing added alum might be regarded as containing an added deleterious ingredient which might render them injurious to health. In view of the findings of that Board and because of the judicial decision in the bleached flour case, action against foods containing alum has not been instituted.

In conclusion it may be stated that the attitude of the Department is not based upon any favorable consideration of these substances but upon a recognized lack of power under this statute, as interpreted by the Supreme Court, to prevent their use in food. Since it is necessary to show that these products are not only themselves poisonous but that as ingredients in food they are present in sufficient quantity to make consumption of this food of possible injury to health, it is obvious that an attempt at prosecution with respect to the substances found by the Referee Board to be without adverse physiological action would result in defeat for the Government. This would be likely to stimulate more widespread use than now prevails. The Department's course in these matters is influenced by the limitations of existing methods of physiological experimentation. We are not convinced that deleterious results are not produced in some degree by the consumption of these extraneous substances. While we feel that from the broad standpoint of human health and nutrition their presence in foods is undesirable it will be impossible to compel their exclusion unless the future should develop refinements in methods of physiological experimenta-

tion greater than now exist, by which their possible injurious effect upon health may be established. In such circumstances their exclusion at this time can be effected by legislative action alone.

Respectfully,

(Signed) R. W. DUNLAP

Acting Secretary.