

# **HISTORY OF THE U.S. FOOD AND DRUG ADMINISTRATION**

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FDA PUBLIC RELATIONS - 1929

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In May of 1929 I was working for the Merchants Trade Journal in Des Moines, Iowa. A magazine for the department store personnel; "The Magazine That Helps You Sell". I had been hired early in the year as the owner & publisher, Mr. Boreman, planned to buy a number of additional trade magazines and expand his operations. The editor, Arthur H. Brayton, was a very capable man and very easy to work with.

My normal routine was to spend about 2 weeks on the road visiting stores, getting acquainted with store management people, picking up ideas for business improvement and writing these up for publication in the magazine. Every store would have some new sales ideas of which it was proud. These usually made good copy and made the involved individuals feel good to see their name in print. The next two weeks I would be in the office completing the writing of my material and dummies up the book for the printer. As I was not married it was an ideal life and I was enjoying it. The atmosphere at the office was excellent and I felt I was learning a great deal about the business.

On a Sunday morning, toward the end of May, I was at

the printers doing some of the final work on the book before printing. Our production manager, Dick Vauter, came in to see how things were going and to visit. We had the sort of outfit where it was not uncommon for staff to work on a holiday especially just before the magazine was put to bed. He asked me if I had heard the latest news. Of course I hadn't. He said, "You know, of course, that the boss is down in New York City." I allowed as I had heard that Mr. Boreman was there to complete the deal for the new magazine he was buying. "Yes" said the Treasurer, "The news is that he is not buying."

I showed my surprise. "What Happened?"

"I understand", said the PM, "that the boss's astrologer called him last night and told him the stars were out of kilter, things didn't look right and he shouldn't buy anything." I was dumbfounded. "You mean that his astrologer is the one who decides how he runs his business?"

He answered, "She always has, she does now and I expect she always will run his business for him. You know what this means, don't you?"

Are you saying that it means I'm out?" I asked him.

"I wouldn't be surprised. You will know tomorrow morning."

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Sure enough on Monday morning Mr. Brayton called me in and told me that Mr. Boreman had decided not to buy the magazines, and as a result they would be over staffed and he would have to let me go. He had always been considerate and he was now. He told me that he would help me in any way he could to get me another job and the company would keep me on the payroll for two months but I was free to go anytime during that period if and when I found a job.

I immediately spread the news to all my friends and acquaintances in the media and asked them to keep me informed of anything that might come along.

A friend on the Wheat Grower magazine in Grand Forks, North Dakota sent me a notice of an examination for a job as assistant in Agricultural Information for the Food & Drug Administration in the Department of Agriculture in Washington. This was an unassembled examination that consisted of filling out a form giving education and experience and submitting with it my string. I knew the Government worked slowly so I did not expect to hear from them for several months. In the meantime, I heard from Phil Estes in Chicago, who was on Priters Ink, that there was a job available as Merchandise Editor on the Confectionary Buyer, a magazine "Devoted exclusively to problems of

candy distribution. Keynote: Bigger profits from better candy merchandising". He told me that he had talked with Mr. Allured, the publisher and was certain that I would get the job. He suggested that I come immediately to Chicago. It was about the last week in June that I went to Chicago and to the office of the Confectionary Buyer. The office manager, a Miss Walker, told me that Mr. Allured was at the printers putting the book together. I went down to the printers, the Western Newspaper Union and found Mr. Allured in his shirtsleeves working on the dummy. For perhaps five minutes while he completed the page he was working on we talked and it was agreed I would take the job and that he would pay me \$50 a week. With that settled, he asked me if I had ever dummied up a book. I admitted that I had numerous times. So he took his coat off the hook, put it on and said, "O.K. take over and finish up."

I saw Mr. Allured only once later. That was one evening quite late when I was at the office working. He came in, asked me what I was doing. I told him and then he said, "Do you have any money on you?" I said I had some, not very much. He said, "Lend me five bucks." Of course I lent him the five bucks. That was the last time I ever saw him. He walked out before I could propose to

talk business with him.

Miss Walker, the office manager, was Mr. Allured's wife. She knew her business very well, was very capable at it. She did not feel capable of being editor of the magazine and did not propose to try. I could understand her point of view. It put me in a very difficult position, however not being able to talk with the boss man to find out what ideas he had and how he wanted his magazine run. While there never was any criticism of my work or any suggestions of how I should handle it, I felt very unhappy at not having at least some rapport with the boss.

About the middle of July I got a letter from the Food & Drug Administration, asking me to go to their Chicago office to be interviewed by Jimmy Clark, the Central District Chief. In my unhappy frame of mind at the Confectionary Buyer I was very much delighted that here was another possible job. I did my best at the interview and felt that this really was a job more in the line of what I had in mind. A job that could be real science journalism.

Apparently Jimmy Clark was pleased with what he saw and the result was that I got a notice from Washington that I was hired and was to report for duty on the 3rd of September, which was Tuesday, the day after Labor Day in 1929.



I did not have a very high regard for Government employment, I had no real basis for forming an opinion but my thinking had been in the line of newspaper and magazine work. But at that time newspapers were not quite ready for science writers and science magazines were not very plentiful. My experience was entirely in ordinary newspaper work or on trade magazines. Not having any better opportunity, I decided to go with the Government for a year or two until I found some industry job more to my liking.

Having made up my mind I talked with Miss Walker who understood my problem, all too well. I felt bad that I could not give her a full months' notice. She seemed to think that the two weeks notice was sufficient. We parted friends.

I knew nothing about the Food & Drug Administration. I recalled asking my mother when I was very young, but able to read, what was meant on a label: "Registered with the Food & Drug Administration, No. 12345". She told me that the product had been examined by this government agency and found to be pure. Mother was fussy about what we ate. It was years before she would buy canned foods. There were frequent reports in the news about ptomain poisonings where canned foods were involved. However, she figured that any product registered with Food & Drug and

given a number must be safe.

So I arrived in Washington with a very general idea of the agencies' work. I was impressed that my appointment began the 3rd of the month, the first working day of that month so that my first salary check was for a month minus two days. I was told that the management of the Food & Drug Administration was very conservative.

I found that the Food and Drug Administration was one of the smallest units in USDA and was grouped with other regulatory agencies under Walter G. Campbell, trained as an attorney, who had started work with the government in 1906 as a Food and Drug Inspector when Dr. Harvey W. Wiley was in charge of the Bureau of Chemistry. While Campbell was listed as "In Charge", the actual day to day management was handled by Dr. Paul Dunbar, Assistant Chief, a chemist who had joined in 1908.

I was never certain but I strongly suspected that Food & Drug hired a writer, an "Information Specialist" because the Secretary of Agriculture told them to.

Dr. Harvey W. Wiley, "father" of the Food and Drug law had been a good public relations man. He had to be to get the laws passed in spite of the strong lobbies fighting him, especially the patent medicine lobby with its heavy financing by the industry. He had a flare for the dramatic and being a crusader sometimes let his enthusiasm

for consumer protection go unchecked, much to the dismay of some of the scientists who worked with him. The press loved it and at the turn of the century reported his consumer interest activities almost daily, such as his "Poison Squad" whose members ate a certain amount of sodium benzoate daily (at that time a common food preservative) to prove that it was harmful to health. Unquestionably Wiley deserved a great deal of credit for getting the Food & Drug Act of 1906 passed. In the public mind Food & Drug Administration was Wiley. While getting publicity for consumer protection laws and their enforcement he had also gotten publicity for Dr. Wiley. It probably couldn't have been done successfully in any other way.

When Wiley left the government his place was taken by a chemist without the inclination or the ability to dramatize. It became the policy of the Food & Drug Administration to give publicity to the Administration rather than to any individuals in it. In fact the pendulum swung so far that news neither of the Administration or the individuals got to the public.

It was not until 1929 that someone decided it was time to make some attempt to inform the consumer about the foods he ate daily and the drug he took when ailing, and what the government was doing to see that both were pure

and properly labeled. So it was that I came on deck on September 3, 1929, knowing essentially nothing about the past history but informed that it was my job to write press releases base on talks, papers research, regulatory actions, etc. to let the public know what was going on.

About 75% of the Food & Drug Administration personnel was scientifically trained. The No. 1 aim was accuracy. A scientist must have integrity. One who fudges, exaggerates or implies is soon out. In law enforcement it is all the more important as the scientist is expected to appear in court when necessary, and defend his results. Facts, facts, facts, - no room for guessing, surmising, or wishful thinking. When the defendant hasn't got a leg to stand on his attorney can only wait and watch for the prosecution to make a mistake.

Time after time I wrote a press release based on a talk, a report, or a paper prepared by a conscientious scientist and he would come to me with his paper and my proposed press release. He would explain to me that his whole paper had to be printed in order to accurately convey the facts. It just couldn't be abbreviated, digested and jazzed up to make it easy reading for the public. I understood their attitude built up by a lifetime of training but a newspaper won't print the whole paper, and if it did it would have few readers. Many a press release

did not go out because the scientist who did the work would not initial my proposed story.

And nothing went out without initials. First the person or people primarily involved, next the head of the unit and then at least 3 initials of top administrative people including PBD unless he was absent, which wasn't often. This was to prevent issuance of stories that might not be of suitable accuracy and -- dignity -- for an outfit such as the Food & Drug Administration. If I got the least bit gay or light hearted, the story was quashed or sometimes:

"Now Retz, this is excellent information presented so it is interesting reading but it just isn't a style that we can put out. Now, suppose you see if one of the newspaper reporters will take it and run it under his by line----?"

While essentially everyone tried to be helpful, although knowing less about the work than I did, it made me feel that I was part of the organization. I got the most help from the people in the USDA Office of Information. They usually had lunch at the same place every day and I joined them whenever I could. Milt Eisenhauer, who was an Assistant to the Secretary of Agriculture, came to find out what we knew and give us any enlightenment that he could.

I got to know Swann Harding, who was one of their better writers, and through Swann and his wife Mary I met many people of interest.

I had not been on the job long when a New York City importer by the name of Ambruster deliberately got a corner on Spanish ergot because the more desirable Hungarian ergot was a crop failure. On the average Spanish ergot was of a poor quality that did not meet the Pharmacopoeia standard and so was cheap. Ambruster figured that the short supply of Hungarian product would force the Government to permit the entry of the Spanish and he would make a killing. The potent extract of ergot was used in obstetrics to hasten the contraction of the uterus after childbirth, and for other medical purposes.

When Ambruster began offering the Spanish ergot for importation into this country it was detained at Customs at the insistence of the Food & Drug Administration because it failed to meet the standard. Ambruster stood to lose his shirt so let out mammoth wails of anguish. In the press--whenever he could get in and the media seems to love a noisy underdog---he accused the Food & Drug Administration of discrimination and illegal actions.

Dr. Dunbar wanted me to answer Ambruster's rantings. I objected saying our recognition of him would only give him more ammunition and he didn't have to stick to facts,

logic or even honesty. Our detentions stood because his product did not meet the Pharmacopoeia standard. By legislation the Pharmacopoeia was a part of the law. Whether the P standard was right or wrong was for the court to decide. Dr. Dunbar didn't like my attitude and told me so.

Ambruster succeeded in getting a hearing before a Senate Committee. I have forgotten who was the chairman, but I recall that Senator Wheeler of Montana was on the Committee and was present part of the first day and made some snide remarks that Mr. Campbell answered respectfully but firmly and made Wheeler sound like he didn't know what he was talking about. Wheeler didn't show up again at the hearing and we heard that he had taken off unexpectedly for Europe.

It was a pleasure hearing Walter Campbell answer Ambruster's charges and the questions of the few Senators that attended. He knew the law, he knew the Pharmacopoeia and he was gifted with the correct words. He answered all the questions raised and Ambruster got no where.

I proposed to put out a daily press release for the benefit of the papers but I was overruled. It might bring a charge that we were giving only one side of the picture. We got back again to the pure science view. So we had stenographers take down the hearing verbatim and

we mimeographed it with copies to whoever in the press wanted it. I wore out a number of stenographers - the press boys wouldn't read the whole transcript and we got no publicity except, of course, for the statements Ambruster gave the press telling how he was getting an unfair deal.

As a writer for the Food & Drug Administration, and the first one, I felt the people in charge were not exactly information minded. They didn't seem to know what they wanted and I am sure they thought I didn't know how to handle the job. Maybe not all of them felt that way.

I made mistakes, of course, I quickly learned not to tell a reporter anything you don't want printed. There was a story on spices that a news hawk wanted and I gave it to him. He knew that we detained spices at import for the presence of filth, and that we permitted the importer to clean out the extraneous material under our supervision. Sanitation in some of the countries producing spices definitely left much to be desired. If we did not permit the cleaning, we might be very short of some spices. He asked me if we had any tolerances for filth in spices. I wasn't able to lie my way out convincingly. Besides I thought I knew him well enough to tell him the facts of life and have him realize this was not something the public needed to know. We essentially grow few spices in this country and if you want spice you have to take



what you can get from the producer, over whom you have no control. You can refuse admission of contaminated lots and end up with short supply and high prices. This wouldn't please the consumer either.

So against my better judgment I admitted it was necessary to have tolerances as no product of this type would be 100% clean, but I also explained why it was better not to talk tolerances to the consumer peppering his breakfast eggs.

You guessed it - he printed it all and played up the tolerance idea. Somehow a printed copy of the story got to someone in the Food & Drug who showed it to Dr. Dunbar. That didn't improve my standing with the Food & Drug. From then on I made sure not to have any "Classified" information when talking to a reporter. Only one exception to that rule occurred years later when I worked with a reporter whom I could confidently trust.

Up to this time my whole acquaintance with the Food & Drug was with the Washington office. I wanted to visit some of the field stations and learn first hand about the field work. On inquiry I found the idea was considered good but there was no money to pay my expenses. The entire budget was less than 5 million with 3/4 of this going for salaries.

During the summer I put in for 2 weeks vacation to

visit my home in North Dakota. With the Food & Drug's approval I arranged to visit the stations at Chicago, and Minneapolis on the way out and Denver, St. Louis and Cincinnati on the way back. I paid my own way, buying a rail excursion ticket to Yellowstone Park to get the most favorable rate. I was not required to take annual leave for the days I spend at the stations, but I got no per diem or expense money of any kind.

This gave me a better idea of how the Food & Drug operated, as I participated in a number of factory inspections, helped collect samples and write out reports, and observed chemists in the laboratories analyze the products. I also had the opportunity to get acquainted with some of the oldtimers, such as Jimmy Clark, head of the Central District in Chicago, Channing Harrison, Chief at Minneapolis, who was there because the job paid more money. His preference was to be in the lab, as a drug chemist at the bench. He came to Minneapolis from Baltimore where he had been Chief Chemist. At Cincinnati I was out with an inspector the whole day helping where I could. It was a hot July day. We came in sweaty and dirty. My train for Washington was to leave around 10 that night. Stuart Postal, the Cincy Chief took me home with him. He lived in a suburb on top, out of the valley where there was a breath of air. His wife was not home. Stuart

showed me the bathroom and I was in the bathtub when he brought me a tall Tom Collins. From then on I was always fond of Stuart. One of my regrets is that I never had a chance to work for him. He was a very capable administrator with excellent morale at his stations. He was one of the few men who became station chief that didn't have a college degree.

Jimmy Clark was very capable and I enjoyed working with him and getting an idea of the District operation. It was later that I learned he was not as conservative as the Washington boys and was inclined to call a spade when he saw one.

We worked Saturday mornings in those days. On a late Friday afternoon I got a carbon copy of a talk that Jimmy Clark proposed to give at a poultry meeting in some mid-western metropolis the following week. It was a good talk and he made good clear points - 1, 2, 3, etc. Of course I grabbed the points and played them up. I worked late Friday to have the story ready for Saturday morning because with the time limit if it didn't get out Saturday you might as well forget it. So on Saturday morning I sent it up for initialing. I sent the carbon copy of the talk with my release and in no time it was back with three or four initials including, to the best of my recollection; Charles Crawford, L. D. Elliott, F. B. Linton and

R. W. Balcom. It appeared that Dr. Dunbar had not come in on this Saturday morning and Charles Crawford was in charge. I sent the release over to the press bureau of USDA, happy that there had not been a change of any kind in the copy.

About midmorning, the following Monday, I was called up to Dr. Dunbar's office. There were, besides Dr. Dunbar, Charles Crawford, Elliott, Linton, Balcom, George Larrick and probably a few others. No one looked happy. I soon learned why.

Dr. Dunbar had a copy of the press release as it was issued on Saturday by the press bureau. Had I written it? Of course I had. Well, did I know that on Friday he had edited the talk and sent an edited copy to Jimmy Clark? No, I hadn't known that. Well, so he couldn't take a half day off to work in his garden without all hell breaking loose.

I couldn't figure this all out. I said, "I just picked out the important points in Mr. Clark's talk for the press release. Was that wrong?"

"Everyone of those points I cut out of that speech," emphatically stated Dr. Dunbar.

"Yes, Paul," said Charles Crawford, "You cut the heart out of that talk. You can't blame Retz for recognizing what's important. I thought he wrote a damn good press

release. But when I OK'd it I didn't know you had butchered the talk. All we had to go on was a carbon of the original."

That was the first time, but not the last, that Charles Crawford went to bat for me when he knew I was right. From then on I had the highest regard for Charley. You could make mistakes, if you made them in good faith Charles would back you against anyone. But if you cheated, he would be the first to condemn you.

A few weeks later Dr. Balcom who was head of Food Control, had a heart attack and died. He had initialed the press release and had sort of shivered through Dr. Dunbar's diatribe. I always hoped that my work was not the causes of his untimely death.

I don't think Dr. Dunbar was ever happy with me as a writer. From this point on I knew I was finished. My reaction was to quit and go out looking for another job but times were tough by then. This was the summer of 1930. After the October 29 crash there were no jobs available; capable, experienced men were selling apples on the street corners.

It was along in July that Bill Wharton, Chief of the Eastern District (office in New York City) was in Washington. He came to me and wanted to know if I would consider coming to New York City and be an inspector. I asked him

if he had word that I was out as a writer. He tactfully let me know that I had better be looking for another spot and he thought maybe he could find a place for me. I thanked him and said I would like to think it over and I would come up to New York City (at my own expense) to look it over. Bill was pleased. I think he liked the idea that I didn't immediately grab for the job at a time when offers just didn't exist.

I had wanted to be a science writer. I felt that I had prepared myself for that work. Now I hated to leave the field and become a Food & Drug Inspector, work that I certainly wasn't prepared for. Not that anyone was prepared for that job. The requirement at this time primarily was a degree in science, which I had. At one time there was an emphasis on selling experience, which I didn't have. There were many angles to the job. You had little authority under the Food & Drug Act of 1906 so you had to "sell" yourself to the factory owner - operator to get permission to make an inspection. You had to be a keen observer to find out what was going on in the plant. You had to report FACTS, not guesses, and be able to present a graphic picture in court if it became necessary.

Frankly, I preferred not to take the inspection job. I worked my friends hard and long to find something more in my line. THE USDA information bureau was full. I had

a friend who was an administrator in the Commerce Department and he (rather reluctantly) said he would look around to see if they had a job I could fit into. I didn't like that either so I gave up and on October 16, 1930 I reported to New York Station as a Food & Drug beginning inspector.

DR. HARVEY W. WILEY

I had not been in Washington long (late 1929 or early 1930) when the Food Standards Committee held its annual meeting which lasted for several weeks. The Committee was made up of a number of food enforcement officials from the various states plus a few food division scientists from FDA.

The idea of food standards was to define what was understood to be a standard product not only for the benefit of the consumer but also for the benefit of the producer. Standard products could be labelled with the standard name and did not require an ingredient statement unless certain optional permitted additives were placed in the product.

While I did not attend any of the meetings, I heard by the grapevine that they were attempting to define white flour. This would have to be done before a definition could be made for white bread. Someone jokingly told me that the men on the committee had spent several days trying to decide whether white flour was "the fine ground endosperm of wheat" or "the finely ground endosperm etc.". In any event writing a standard was not simple and required not only knowledge of food but considerable thought regarding the various possible meanings of words.



The definition was finally completed and as required by the law a hearing date was set up at which all interested people could attend and express their opinion of the proposed standard. As there were generally very few people that came to such a standards hearing, a room in the Olive building was used as a small auditorium. It seated perhaps a hundred people at the most. As this was a meeting that I could attend and wanted to attend in order to get a story, I was there probably 10 minutes early and was surprised to find Dr. Wiley and his wife already there sitting in the front row.

As this was late in 1929 or early in 1930 the Doctor must have been in his 80's. He was a large man I don't mean that he was over weight. But let us say that he was not as active as he once was, either physically or mentally.

I felt this was too good an opportunity to miss after all that I had heard about the great man so I immediately went over to them, introduced myself and sat down next to Dr. Wiley in the front row. Of course I talked with him and his wife until the hearing was called to order and found that while his wife was very cordial the Doctor treated me a bit coolly. I did not let this bother me as I assumed that his coolness was to FDA generally and not to me personally.

I have forgotten who chaired the hearing (I think it was a food chemist from South Dakota) but the meeting got under way with the chairman giving findings of fact on which the standard was based. He covered the history of wheat and wheat flours over the world and then got down to the final definition that had been written for white flour.

There was some discussion and questioning by members of the audience but no great objections developed. Some suggestions were made for the committees consideration.

During a lull I realized that Dr. Wiley was attempting to get to his feet. I noticed that Mrs. Wiley was trying to help him from her side, so I gave him a boost from my side and we got the Doctor to his feet.

Over the years Dr. Wiley had been a proponent of whole wheat bread and even went so far as to intimate that white flour and white bread were bad for ones health if not in fact poisonous. He considered that the chemicals used for bleaching and maturing certainly were poisonous.

The good Doctor spent no time at all on the standard for white flour. He quickly condemned the product as unworthy of consideration. He then told the virtues of whole wheat bread (and flour) as being good for ones health. He finished by recommending that white flour

and white bread should be made illegal under the law. Having made his point he sat down and the hearing was soon adjourned as there was little more to be said.

The next day I heard from one of my friends that there had been some criticism of my hobnobbing with Dr. Wiley and his wife. I, of course, was astounded as after all I felt that he was a very important person in the early development and passing of the Federal Food and Drugs Act of 1906. I soon learned that after Dr. Wiley left the Food and Drug Administration (or the Bureau of Chemistry as it was then called) he soon became very critical of the people who followed him in the enforcement of the law. In his crusade for the passage of the Food and Drug Act, Dr. Wiley had felt it necessary to be rather spectacular in order to get information into the news media. He played heavily on the word "poison" and as a matter of fact there were plenty of poisons being added to foods in those days and while he may have exaggerated in some cases, there was ample evidence to generally prove his statements. The people that followed Wiley realized that there had to be some give and take in law enforcement and that the ideal could not always be achieved. In the case of wheat flour they knew that the public in the U.S. would not be satisfied with the dark breads of Europe and would

in fact demand white flour and white bread. So the obvious course to take was to make white flour and white bread as pure as possible and limit the chemicals that could be added to those considered harmless to man. A part of this enforcement effort was to have reasonable standards for the food products to guide the producers.

I felt that this incident illustrated why Wiley was not particularly friendly with the people in FDA at this time in 1929-30. He had hired, trained and worked with most of these people and they knew his attitude on the production and consumption of the various foods and drugs. After the crusade he had put on over the years and with the success he had had in securing passage of the Food and Drug Act in spite of industry opposition, he probably felt that they were sabotaging his whole program of pure foods by officially recognizing such a vile product as white flour.

Allen T. Retzlaff

DOTTERWEICH CASE

It was a hot June 30, 1941 that we went into District Court in Rochester before Judge Burke charging Buffalo Pharmacal Co., Inc. of Buffalo, New York and Joseph H. Dotterweich, Secretary and General Manager with shipping adulterated and misbranded cascara compound tablets, digitalis tablets, and posterior pituitary solution in interstate commerce in violation of the Federal Food, Drug and Cosmetic Act.

The digitalis tablets were alleged to be adulterated in that they were found to contain about 1/2 the amount of digitalis that the label declared them to possess. The cascara compound tablets were alleged to be misbranded in that they contained strychnine sulfate, a drug which this product was not supposed to carry according to the National Formulary. The posterior pituitary solution was alleged to be adulterated and misbranded in that its potency was 50% more than it should have been according to the National Formulary.

The Assistant United States Attorney who handled the case for the Government was Joseph Doran of Rochester, New York, who later transferred to Washington with the Justice Department. Doran was a calm, persuasive individual who faced the opposition with facts and brought out the information in terms that any person could understand.

Sam Fleischman was attorney for Buffalo Pharmacal and

Joe Dotterweich. Fleischman was from Buffalo and had a good reputation there as a trial lawyer. Part of his strategy was to put on a good show for the customers and so get them in sympathy with his point of view. He rather fancied himself as a dramatist.

The defense first brought up the fact that Section 335, Title 21, U.S.C.A. (Section 305 of the Food, Drug and Cosmetic Act) provided for a hearing before a criminal action was brought against a person. In the instant case they argued, the hearing had been accorded the firm but not the individual Joe Dotterweich; although he had attended the hearing. As a result, they moved to have the case against the individual dismissed.

Just how it happened that the firm was cited to a hearing and that the owner and operator/manager, Joe Dotterweich was not included is difficult to determine. Certainly it had been our intention to cite both the firm and the individual. In fact, it was my opinion that both had been cited. However, Mr. Pappe, who was chief of the Buffalo station at that time knew that this had occurred by error but felt that a hearing of this type was not mandatory and would not invalidate the action. He had however secured an opinion from our General Counsel in Washington, who at that time was Mr. Dan Willis, and had been given a reference to a ruling of the Supreme Court in U.S. vs Morgan 222 U.S. 274 which was on a

similar section in the Federal Food, Drug Act of 1906 and to the effect generally that the hearing was a privilege and not necessarily a right.

There was also objection on the part of the defense to the counts on the cascara compound tablets and the posterior pituitary solution to the extent that the Assistant U.S. Attorney Doran moved that the adulteration count on the cascara compound and adulteration and misbranding counts on the posterior pituitary solution be nolle-prossed.

The trial was before a jury on which there were a few but not many women.

The Government began its case by presenting the testimony to show that the products had been shipped in interstate commerce from the state of New York into the states of Pennsylvania and Ohio where samples had been collected by Government agents and with proper identification delivered under seal to the Government laboratory where the assay was made. Chemists from the laboratory testified regarding their findings in the assay of the various products.

There was very little here that could be denied or disproved by the defense. In fact, the defense was not intending to deny that the firm had shipped the product and that the product was in violation. Previous to going into court, the regular attorney of the firm, a Mr. Whissel, came to see the chief of the Buffalo District of the Food and Drug

Administration, Mr. Pappe, and proposed to him that they would plead the company guilty to the charges if the Government would be willing to drop the case against the individual, Mr. Joseph H. Dotterweich.

It was the policy of the Department of Justice to encourage the naming of an individual defendant as well as a corporation or a company. Its theory was that there should be at least one definite individual who was responsible for the activities of the firm.

In this case there was no question in our minds but that Joe Dotterweich was the man responsible, the man who ran the Buffalo Pharmacal Co. very much in the manner of a dictator. We put on the stand inspectors who told about their efforts to make inspections of the Buffalo Pharmacal Co. and of their attempts to collect samples there. Inevitably nothing could be done unless Joe Dotterweich was there and accompanied them in whatever work they were doing. By Dotterweich's orders, no inspector was permitted to enter the plant during his absence.

I went to the Buffalo Pharmacal Co. myself on one occasion on an assignment. To enter the firm, one had to go up the steps to a second floor where there was a small landing, with a window behind which a girl sat who in addition to other work was a receptionist, and a door from the landing leading into the plant. The door of course was locked. I stated my business to the girl and she told me to wait a



moment and she would advise Mr. Dotterweich. Shortly he opened the door, came onto the landing and closed the door behind him. There was no place to sit down; we stood on the landing and I told him what my mission was. He informed me that he was entirely too busy to accompany me at the moment and couldn't I come back some other time, say in two weeks or a month. I advised Mr. Dotterweich that it would not be necessary for him to accompany me, that he could have anyone of his employees assigned to provide me with whatever I needed. He advised me that this was utterly impossible, that it was against his policy to let any inspector from the Government in his plant unless he himself accompanied the inspector and in view of the fact that he was too busy today to accompany me, it would be impossible for me to complete my mission. Argument was to no avail and Mr. Joe Dotterweich opened the door, went through it, closed the door, and left me locked out on the landing with nothing to do but descend the steps and go back to the office admitting a failure. I could return in two weeks from next Whitsuntide as far as Joe Dotterweich was concerned but I definitely was not going to get into his plant on this particular day.

In addition to our own people, we had located a few dissatisfied ex-employees. We placed the first ex-employee on the stand and he told how Mr. Joseph Dotterweich ran the Buffalo Pharmacal Co. and in no uncertain terms told that

nothing could be done there without Joe's knowledge, consent, and instruction. Apparently, Mr. Sam Fleischman, the attorney for Dotterweich, was not exactly prepared for this type of testimony from an ex-employee and he jumped up, ran his fingers through his long hair and said in a loud voice "I've been stabbed". Judge Burke stopped the taking of testimony immediately and stated "Mr. Fleischman, one more outburst such as that and I will find you in contempt of court". Fleischman sat down and the taking of testimony was resumed.

The Government had presented an air-tight case showing that the firm had shipped the products in interstate commerce bringing them under jurisdiction of the Federal Food, Drug and Cosmetic Act, that the samples had been collected by qualified inspectors and had been kept inviolate during transportation to the laboratory where qualified chemists had made the examination which found the products to be other than as labeled. The Government had also shown that Mr. Joseph Dotterweich was one of the main owners, was the Secretary and General Manager of the corporation and that he was not only active in the management of the corporation but that nothing could take place there without his consent and approval.

The defense had admittedly very little to work with and so after all the testimony had been taken which was on July 2, 1941, Joe Doran for the Government summarized this for the jury and asked that they find both the company and Mr. Dotterweich

guilty as charged. Sam Fleischman then made an appeal to the jury and being unable to give any adequate defense for either the firm or the individual, he gave the jury a sob story of how this firm employed some 30 odd people and a fine could put the company out of business and these 30 odd employees would be without jobs. In 1941 the effects of the depression were still being felt and there were not too many jobs available, so this was a reasonable argument with the jury.

The judge charged the jury and the jury retired.

The jury deliberated a respectable length of time but returned on the same day a verdict of guilty on all counts as to the individual defendant, Mr. Joe Dotterweich and reported a disagreement as to the guilt or innocence of the corporate defendant. Now this seemed to be rather illogical for if the individual manager of the corporation was guilty of an offense, it would seem that the corporation also would have to be guilty of the same offense. However, one of the jurors later explained to us that they had felt that Mr. Fleischman probably had an argument in claiming that the corporation would be put out of business if fined. They had therefore settled the question by seeing to it that the corporation itself would not be fined but that only the manager would be penalized. In this way, obviously, the corporation would not be put out of business and the 30 odd employees

on December 3, 1942 a decision was handed down reversing the judgment of the District Court.

Judge Swan in giving the decision of the Circuit called attention to the fact that the drugs were shipped through the mails by the Buffalo Pharmacal Co. in filling an order received from a physician who resided in a state other than New York. He called attention to the fact that Joe Dotterweich had no personal connection with the shipments but that he was in general charge of the corporation's business and had given general instructions to the employees to fill the orders received from physicians. He said "For some unexplainable reason, it (the jury) disagreed as to the corporation's guilt."

The Circuit agreed with Judge Burke that failure on the part of the Buffalo Station of the Food and Drug Administration to address the Notice of Hearing to the individual personally as well to the corporation was not a bar to prosecution.

Judge Swan stated that it was the opinion of the majority of the Circuit Court that they could find no basis in the statutory language for drawing a distinction between agents of high or low rank and so if the statute was applicable to the manager of the firm, it would also have to apply to, for instance, the shipping clerk or any other menial employee who was instrumental in actually causing the violative shipment. The majority did not feel that the manager was operating the

corporation as his "alter ego" or agent, and so they did not feel that he could be found guilty of the violation and so the Circuit reversed the decision of the District Court.

However, Judge Swan stated that while this was the view and the decision of the majority of the court, he was not in accord with it.

The Government felt that the decision of the Circuit Court was not correct and petitioned for a rehearing but this was denied by the Circuit Court of Appeals and so on February 8, 1943 a petition for a Writ of Certiorari was filed with the United States Supreme Court. The petition was granted on April 5, 1943 and on November 22, 1943 the Supreme Court rendered an opinion which reversed the judgment of the Circuit Court of Appeals. Felix Frankfurter, Associate Justice of the Supreme Court, gave the opinion of the majority. This was a 5 to 4 decision with Judges Murphy, Roberts, Reed, and Rutledge dissenting.

Frankfurter stated that there was no disagreement with the previous courts that the evidence was adequate to support the verdict. The Supreme Court further agreed that the opportunity of a hearing which was not accorded to the individual, Dotterwiech, was not a prerequisite to prosecution. The Court also found baseless the claim of Dotterweich that the jury could not find him guilty when it failed to find the corporation guilty. What the reasoning was on the part of

the jury was immaterial, the court stated, and "juries may indulge in precisely such motives or vagaries."

The Supreme Court then considered the one problem on which there appeared to be disagreement. The Circuit Court of Appeals had reversed the conviction on the ground that only the corporation was subject to prosecution unless the firm was a counterfeit corporation serving as a screen for the individual. It was felt that the Circuit Court had based its decision on the Guaranty section of the Act (Section 303 (c)). That Section provides that a receiver will not be prosecuted for shipping a violative product if he has a valid guarantee from the original manufacturer to the effect that the product is not in violation of the Federal Food, Drug and Cosmetic Act.

The Supreme Court stated "the guarantee clause cannot be read in isolation. The Food and Drugs Act of 1906 was an exertion of Congress by its power to keep impure and adulterated food and drugs out of the channels of commerce. By the Act of 1938, Congress extended the range of its control over illicit and noxious articles and stiffened the penalties for disobedience. The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a

working instrument of government and not merely as a collection of English words".

So the Dotterweich case settled a number of questions and gave the Food and Drug Administration guides to go by.

It said:

A hearing under Section 305 of the Act is not prerequisite to prosecution.

A jury can find a corporation innocent and an officer of the corporation guilty. The evidence is presented and the jury determines guilt.

A guaranty does not eliminate responsibility of those violating Section 301.

The purpose of the Act is to provide consumer protection and its interpretation should be strongly in this direction.

Ref: U.S. v. Buffalo Pharmacal Co. Inc. and J.H. Dotterweich  
U.S. Circuit Court of Appeals for the Second Circuit. No. 68  
Dec. 3, 1942 131 F. 2d. 500  
U.S. Supreme Court reversed. 320 U.S. 277. 64 S. Ct. 134. 88L.  
ed 48

Allen I. Retzlaff

## FEDERAL SECURITY AGENCY

### FOOD AND DRUG ADMINISTRATION

## NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

991-930

### DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

WATSON B. MILLER, *Acting Administrator, Federal Security Agency,*  
Washington, D. C., August 10, 1944.

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**DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS<sup>1</sup>**

917. Adulteration and misbranding of digitalis tablets, misbranding of cascara compound tablets, alleged adulteration of cascara compound tablets, and alleged adulteration and misbranding of posterior pituitary solution. *U. S. v. Buffalo Pharmaceutical Co., Inc., and Joseph H. Dotterweich*. Counts charging adulteration of cascara compound tablets and adulteration and misbranding of posterior pituitary solution *venie prosequi*. Pleas of not guilty. Tried to the court and jury. Verdict of guilty as to the individual defendant; disagreement as to the corporate defendant. Fine, \$500 on each of 3 counts against individual defendant; payment of fine on counts 2 and 3 suspended and the individual defendant placed on probation. Judgment reversed on appeal to the Circuit Court of Appeals. Petition for Writ of Certiorari granted and decision rendered by Supreme Court reversing the judgment of the Circuit Court of Appeals. (F. D. C. Nos. 951, 2087. Sample Nos. 78710-D, 78780-D, 78814-D.)

On April 29 and August 5, 1940, the United States attorney for the Western District of New York filed informations against the Buffalo Pharmaceutical Co., Inc., and Joseph H. Dotterweich, secretary and general manager of the corporation, alleging shipment on or about October 2, 1939, and January 8, 1940, from the State of New York into the States of Pennsylvania and Ohio of a quantity of digitalis tablets which were adulterated and misbranded, a quantity of cascara compound tablets which were misbranded and were alleged to be adulterated, and a quantity of posterior pituitary solution which was alleged to be adulterated and misbranded.

The digitalis tablets were alleged to be adulterated in that their strength differed from and their purity or quality fell below that which they purported or were represented to possess since each tablet was represented to possess a potency of one U. S. P. digitalis unit, whereas each tablet possessed a potency of not more than 0.48 U. S. P. digitalis unit per tablet. They were alleged to be misbranded in that the statement, "Tablets Digitalis 1½ Grs \* \* \* One USP Unit Represents (0.1 gram equals 1.543 grains) Powdered Digitalis," borne on the label attached to the bottle containing the article, were false and misleading in that the statements represented that each tablet possessed a potency of 1 U. S. P. digitalis unit, whereas each tablet did not possess such potency.

The cascara compound tablets were alleged to be misbranded in that the statement, "Tablets Cascara Compound \* \* \* (Hinkle)," borne on the bottle label, was false and misleading since it purported and represented that the article consisted of tablets of compound cascara (Hinkle), a drug the name of which, i. e., "Compound Pills of Cascara" and "Hinkle's Pills" is recognized in the National Formulary, whereas it did not consist of tablets of compound cascara (Hinkle) since it contained strychnine sulfate, an ingredient which is not included in the formula set forth as the standard for compound pills of cascara (Hinkle's Pills) in the National Formulary, official at the time of the investiga-

<sup>1</sup> See also Nos. 902, 908, 910, 914.

tion of the article. The Tablets Cascara Compound were also alleged to be adulterated on the ground that their strength and quality differed from the standard set forth in the National Formulary for Compressed Pills of Cascara, and Hinkle's Pills.

Adulteration and misbranding was also charged against a shipment of "Posterior Pituitary Solution" on the ground that its potency exceeded by 50 percent the potency of the product recognized under that name in the National Formulary.

On March 11, 1941, the defendants were arraigned and pleas of not guilty were entered on their behalf. On March 15, 1941, the defendants filed motions to quash the informations on the grounds (1) that, with respect to the digitalis tablets and posterior pituitary solution, alleged guarantees that the products complied with the law had been received by the defendant company from the vendors, and that the products had been repacked and sold without change in strength and quality; (2) with respect to the cascara compound tablets that they were labeled "Tablets Cascara Compound No. 2 S. C. Pink. (Hinkle)," and were a different product than that recognized in the National Formulary under the name of "Compound Pills of Cascara" and "Hinkle's Pills" and that there is a distinction between pills and tablets; and (3) that the individual defendant was in no way involved in any alleged adulteration and misbranding as charged since his name did not appear in the labeling of the products.

On May 8, 1941, after arguments of counsel, the motions to quash were denied by the court on the basis that objections to the informations were matters of defense which should be brought up at the trial. Subsequently, on motion of the United States attorney, the counts charging adulteration of the cascara compound tablets and adulteration and misbranding of the posterior pituitary solution were nolle prossed. The two informations were consolidated for trial before a jury on June 30, 1941, on which date the trial commenced. The taking of testimony was concluded on July 2, 1941, the jury was charged and retired and, after deliberation, returned, on the same day, a verdict of guilty on all counts as to the individual defendant, and reported a disagreement as to the corporate defendant. The individual defendant appeared for sentence on September 8, 1941, and at that time presented an argument in support of a motion to set aside the verdict. Sentence was thereupon deferred for the purpose of considering the merits of the motion and on October 17, 1941, the following opinion in denial of the motion was handed down by Hon. Harold P. Burke, United States District Judge:

*BURKE, District Judge:* "The defendant, Joseph H. Dotterweh, moves to set aside the verdict of the jury upon the ground that it was against the law and against the weight of the evidence, that the verdict as to the defendant Dotterweh was inconsistent with the disagreement of the jury in regard to the corporate defendant and therefore an illegal verdict, and that the failure of the Government to prove notice to the defendant Dotterweh of an intended prosecution under the Food, Drug and Cosmetic Act, June 25, 1938, c. 675, 52 Stat. 1040 was a condition precedent to the commencement of a proceeding against him, without which there could be no valid proceeding.

"There was sufficient evidence upon which the jury could base a verdict of guilty. The verdict was not inconsistent with the jury's treatment of the corporate defendant as to which it reached no verdict. Notice pursuant to Section 335, Title 21, U. S. C. A. of a contemplated criminal proceeding was given to the corporate defendant. Dotterweh was the General Manager and had actual notice of the contemplated proceeding against the corporation. There is nothing in the statute limiting prosecutions to those cases that have been reported by the Secretary to the United States Attorney. Prosecution for violation of the statute arising independently of any report by the Secretary would require no preliminary notice. The absence of such a limitation indicates that the requirement for notice under Section 335 should be construed as an administrative provision imposing a duty upon the Secretary. The reasoning adopted by the Supreme Court in *United States vs. Morgan*, 222 U. S. 274, in construing a provision for preliminary notice under the former statute, Section 4, *Pure Food and Drug Act of June 30, 1906*, 34 Stat. L. 768 C. 3015, applies with equal force to the notice required under the present statute. It was there held that the requirement for notice was not jurisdictional. I think the same reasoning impels a like conclusion here.

"Motion denied."

On October 27, 1941, the individual defendant was sentenced to pay a fine of \$500 on count 1 of the consolidated information. Fines of \$500 were also imposed on such defendant with respect to the other 2 counts of the information, but payment thereof was suspended and the defendant was placed on probation for 60 days. The case was thereafter appealed to the United States Circuit Court of Appeals for the Second Circuit, and on December 3, 1942, the following decision was handed down reversing the judgment of the District Court:

SWAN, *Circuit Judge*: "The appellant was prosecuted, together with Buffalo Pharmacal Company, Inc., a New York corporation of which he was general manager, for violations of section 301 (a) of the Federal Food, Drug and Cosmetic Act, 21 U. S. C. A. §331 (a). Three counts of the informations were submitted to the jury. The first count was based on an interstate shipment on October 2, 1939 of a bottle of cascara compound which was charged to be misbranded, 21 U. S. C. A. §352 (a); the other two counts related to an interstate shipment on January 9, 1940 of a bottle of digitalis tablets, one of the counts charging adulteration, 21 U. S. C. A. §351 (c), and the other misbranding, 21 U. S. C. A. §352 (a). Each of the shipments was made in filling an order received through the mails by Buffalo Pharmacal Company from a physician resident in a state other than New York. The corporation had purchased the drugs from a wholesale manufacturer; it repackaged them for the shipments under attack. The appellant Dotterwetch had no personal connection with either shipment, but he was in general charge of the corporation's business and had given general instructions to its employees to fill orders received from physicians. The jury found guilty on all three counts. For some unexplainable reason it disagreed as to the corporation's guilt. The sentence imposed on the appellant was a fine of \$500 on each count, with payment suspended on the second and third counts, and probation for 60 days on each count to run concurrently.

"The bottle of cascara compound carried a label reading '1000 Tablets Cascara Compound \* \* \* (Hinkle),' followed by a list of the ingredients, one of which was strychnine sulphate. The charge of misbranding was based on the fact that this ingredient had been removed from the formula for Hinkle pills stated in the official National Formulary promulgated January 1, 1939. The issue left to the jury was whether the label was false and misleading in that it would lead the purchaser or the general public to believe that the tablets contained only the ingredients designated in the official formula for Hinkle pills. Since intention to violate the statute is immaterial in a charge of misbranding,\* we think the jury's finding that the label was false and misleading was not unsupported by the evidence.

"The label on the bottle of digitalis tablets represented that each tablet possessed a potency of one U. S. P. unit of digitalis, whereas in fact analysis proved that the tablets were less than one-half of the represented potency. This was so far below the standard that findings of adulteration and misbranding would seem to be inevitable, unless the deterioration occurred after the bottle of tablets was shipped. It was shipped on January 9, 1940 and its contents were analyzed by government chemists in March 1940. While cross examination brought out that digitalis tablets may deteriorate in potency by lapse of time if not properly stored, there was some testimony to indicate that the bottle in question had been properly cared for. We cannot say that the evidence was insufficient to support the verdict of adulteration and misbranding."

"Section 305 of the Act, set forth in the margin,\* provides that before the Administrator reports a violation to any United States attorney for prosecution, 'the person against whom such proceeding is contemplated' shall be given notice and a hearing. In the case at bar such notice was addressed only to the corporation. In response thereto the appellant appeared on behalf of the corpora-

\* See 21 U. S. C. A. §3321 (j) and (n).

\* See *Van Bremen v. United States*, 192 F. 904, 906 (C. C. A. 2), *Wicks v. United States*, 221 F. 64, 68 (C. C. A. 2), and *Strong, Cobb & Co. v. United States*, 103 F. 2d 671, 674 (C. C. A. 6) construing the Food and Drug Act of 1906. That intention is not necessarily an element of the offense under the existing Act is made very clear by section 303, 21 U. S. C. A. §333 (a) and (b) where different penalties are provided for simple violations and for violations "with intent to defraud or mislead."

\* 21 U. S. C. A. §335. Hearing before report of criminal violation. Before any violation of this chapter is reported by the Administrator to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding.

tion. He contends that a notice addressed to him personally was a condition precedent to his lawful prosecution. The district judge ruled that the provision for notice and a hearing was an administrative direction to the Administrator rather than a jurisdictional requirement for criminal proceedings. We agree with this conclusion. Such was the authoritative construction placed upon a similar provision in the Food and Drugs Act of 1906, 21 U. S. C. A. 811. *United States v. Morgan*, 222 U. S. 274; see also *United States v. King & Howe*, 78 F. 2d 693, 696 (C. C. A. 2). In our opinion the changes in phraseology introduced by the 1938 Act are not such as to render obsolete these decisions. This appears quite clearly from the Congressional debates. 83 Cong. Rec. pp. 7792, 7794, 75th Cong., 3d sess. Articles by certain commentators are cited as expressing the opposite view,<sup>1</sup> but we are constrained to disagree with them.

"The appellant further urges that the jury's failure to convict the corporation is so inconsistent with the finding of guilt on the part of the appellant that the verdict against him cannot stand. Assuming that the statute includes within its prohibitions an agent who acts for his employer in shipping in interstate commerce misbranded or adulterated articles, the contention is without merit. No authority has been cited in support of the argument that failure to convict the principal will avoid the conviction of an agent who has committed all the elements of a crime. We think the usual principle is applicable that error cannot be asserted for inconsistency in the jury's verdict. See *Dunn v. United States*, 284 U. S. 390; *United States v. Pandolfi*, 110 F. 2d 736 (C. C. A. 2).

"A more difficult question is presented by the appellant's contention that the statute is aimed only at punishment of the principal and not at punishment of an innocent agent who in good faith and in ignorance of the misbranding or adulteration takes part in an interstate shipment of food or drugs. Section 301, 21 U. S. C. A. 8331, prohibits 'the following acts and the causing thereof,' namely '(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.' Section 323 (a) of Title 21 declares that 'any person' who violates any of the provisions of section 331 shall be guilty of a misdemeanor and on conviction be subject to imprisonment or fine or both. The Act defines the term 'person' to include 'individual, partnership, corporation and association.' 21 U. S. C. A. 8321 (e). Who is the person causing 'the introduction or delivery for introduction' into interstate commerce of a misbranded drug? Is the clerk who innocently packs or ships it guilty of the offense, as well as the employer for whom he works? While the statutory language seems literally to include all who have any part in causing delivery for introduction into interstate commerce, there are serious objections to so construing it. Subsection (c) of 21 U. S. C. A. 8333 provides 'No person shall be subject to the penalties of subsection (a) of this section . . . for having violated section 331 (a) or (d), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in the case of an alleged violation of section 331 (a), that such article is not adulterated or misbranded within the meaning of this chapter designating this chapter . . . Obviously such a guaranty, if given, will be obtained by the drug dealer, not by his clerk who may later deliver the article for shipment in interstate commerce; nor is such clerk literally within the protection of the quoted section, since he is not the one who 'received' the article from the guarantor. It is difficult to believe that Congress expected anyone except the principal to get such a guaranty, or to make the guilt of an agent depend upon whether his employer had gotten one. The agent's guilt, like his principal's, must be independent of any scienter under section 331 (a). It would be extremely harsh to charge him criminally with the risks of the business as the drug dealer is himself charged. A majority of the court is of opinion that this cannot have been the congressional intent and that the statute must be construed to mean that only the drug dealer, whether corporation or individual, is the 'person' who causes the 'introduction or delivery for introduction' of misbranded or adulterated drugs into commerce. In support of this conclusion the appellant adverts to the omission from the present Act of a provision which appeared in the 1906 Act in 21 U. S. C. A. 84. This declared that in construing and enforcing the provisions of sections 1 to 15 of Title 21 'the act, omission, or failure of any officer, agent or other person acting for or employed by any corporation . . . within

<sup>1</sup>See "A Treatise on the Law of Food, Drugs and Cosmetics," 1942, p. 737; Law & Contemporary Problems, published by the School of Law of Duke University, 1939, Vol. 6, p. 74.

the scope of his employment or office, shall in every case be also deemed to be the act, omission or failure of such corporation . . . as well as that of the person.' In our opinion the omission of this provision adds nothing to the argument already developed; it was doubtless omitted as unnecessary because it states an obvious general principle of agency.

"The foregoing discussion has proceeded upon the assumption that if the statute is applicable to the appellant it must also apply to a shipping clerk or any menial employee who was instrumental in causing the forbidden shipment, for we can find no basis in the statutory language for drawing a distinction between agents of high or low rank. We are not, however, to be understood to hold that under no circumstances could an individual conducting a drug business in corporate form be subjected to the penalties of section 331 (a). If an individual operated a corporation as his 'alter ego' or agent he might be the principal; but the evidence hardly went so far as to establish that such was the relationship between the appellant and his corporation and in any event his guilt was not made to turn on any such issue. Accordingly his conviction must be reversed.

"The views above expressed in respect to the construction of the statute are those of a majority of the court. I am not in accord with them. I believe that the language of sections 331 (a) and 333 (a) is so inclusive as to render liable all persons who take part in causing a shipment in interstate commerce of misbranded or adulterated articles, and that any insufficiency in the protection afforded an agent by section 333 (c) is not an adequate reason for limiting the statutory prohibitions to the dealer. The possibility that a literal interpretation of the statute may lead to the prosecution of insignificant agents rather than their employers is not, I believe, a serious risk and is a matter Congress was willing to leave to the good sense of prosecuting officials and trial juries. See *United States v. Buffalo Cold Storage Co.*, 179 F. 865, 867 (D. C. W. D. N. Y.), where a warehouseman who innocently shipped pursuant to instructions was convicted under the 1906 Act; see also the charge given by Judge Grubb in *United States v. Mayfield*, 177 F. 765 (D. C. Ala.).

"Judgment reversed."

On January 3, 1943, a petition for a rehearing was denied by the Circuit Court of Appeals and on February 8, 1943, a petition for a Writ of Certiorari was filed with the United States Supreme Court. Such petition was granted on April 5, 1943, and on November 22, 1943, the Supreme Court rendered the following opinion, which reversed the judgment of the Circuit Court of Appeals:

FRANKFURTER, Associate Justice: This was a prosecution begun by two informations, consolidated for trial, charging Buffalo Pharmaceutical Company, Inc., and Dotterweich, its president and general manager, with violations of the Act of Congress of June, 1938, c. 675, 52 Stat. 1040, 21 U. S. C. §§ 301-302, known as the Federal Food, Drug, and Cosmetic Act. The Company, a jobber in drugs, purchased them from their manufacturers and shipped them, repacked under its own label, in interstate commerce. (No question is raised in this case regarding the implications that may properly arise when, although the manufacturer gives the jobber a guaranty, the latter through his own label makes representations.) The informations were based on § 301 of that Act (21 U. S. C. § 331), paragraph (a) of which prohibits 'The introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is adulterated or misbranded'. 'Any person' violating this provision is, by paragraph (a) of § 303 (21 U. S. C. § 333), made 'guilty of a misdemeanor'. Three counts were to the jury—two, for shipping misbranded drugs in interstate commerce, and a third, for so shipping an adulterated drug. The jury disagreed as to the corporation and found Dotterweich guilty on all three counts. We start with the finding of the Circuit Court of Appeals that the evidence was adequate to support the verdict of adulteration and misbranding. 131 F. 2d 500, 502.

Two other questions which the Circuit Court of Appeals decided against Dotterweich call only for summary disposition to clear the path for the main question before us. He invoked § 305 of the Act requiring the Administrator, before reporting a violation for prosecution by a United States attorney, to give the suspect an 'opportunity to present his views'. We agree with the Circuit Court of Appeals that the giving of such an opportunity, which was not accorded to Dotterweich, is not a prerequisite to prosecution. This Court so held in *United States v. Morgan*, 222 U. S. 274, in construing the Food and Drugs Act of 1906, 34 Stat. 768, and the legislative history to which the court below called attention abundantly proves that Congress, in the changed phraseology of 1938, did not intend to introduce a change of substance. 83 Cong. Rec. 7792-94. Equally base-

less is the claim of Dotterweich that, having failed to find the corporation guilty, the jury could not find him guilty. Whether the jury's verdict was the result of carelessness or compromise or a belief that the responsible individual should suffer the penalty instead of merely increasing, as it were, the cost of running the business of the corporation, is immaterial. Juries may indulge in precisely such motives or vagaries. *Dunn v. United States*, 284 U. S. 390.

"And so we are brought to our real problem. The Circuit Court of Appeals, one judge dissenting, reversed the conviction on the ground that only the corporation was the 'person' subject to prosecution unless, perchance, Buffalo Pharmaceutical was a counterfeit corporation serving as a screen for Dotterweich. On that issue, after rehearing, it remanded the cause for a new trial. We then brought the case here, on the Government's petition for certiorari, 318 U. S. 753, because this construction raised questions of importance in the enforcement of the Federal Food, Drug, and Cosmetic Act.

"The court below drew its conclusion not from the provisions defining the offenses on which this prosecution was based (§§ 301 (a) and 303 (a)), but from the terms of § 303 (c). That section affords immunity from prosecution if certain conditions are satisfied. The condition relevant to this case is a guaranty from the seller of the innocence of his product. So far as here relevant, the provision for an immunizing guaranty is as follows: 'No person shall be subject to the penalties of subsection (a) of this section . . . (2) for having violated section 301 (a) or (d), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 301 (a), that such article is not adulterated or misbranded, within the meaning of this Act, designating this Act

"The Circuit Court of Appeals found it 'difficult to believe that Congress expected anyone except the principal to get such a guaranty, or to make the guilt of an agent depend upon whether his employer had gotten one.' 131 F. 2d 500, 503. And so it cut down the scope of the penalizing provisions of the Act to the restrictive view, as a matter of language and policy, it took of the 'relieving effect of a guaranty.

"The guaranty clause cannot be read in isolation. The Food and Drugs Act of 1906 was an exertion by Congress of its power to keep impure and adulterated food and drugs out of the channels of commerce. By the Act of 1938, Congress extended the range of its control over illicit and noxious articles and stiffened the penalties for disobedience. The purposes of this legislation touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words. See *Hipolite Egg Co. v. United States*, 220 U. S. 45, 57, and *McDermott v. Wisconsin*, 228 U. S. 115, 128. The prosecution to which Dotterweich was subjected is based on a now familiar type of legislation whereby penalties serve as effective means of regulation. Such legislation dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger. *United States v. Balint*, 258 U. S. 250. And so it is clear that shipments like those now in issue are 'punished by the statute if the article is misbranded [or adulterated], and that the article may be misbranded [or adulterated] without any conscious fraud at all. It was natural enough to throw this risk on shippers with regard to the identity of their wares. . . .' *United States v. Johnson*, 221 U. S. 488, 497-98.

"The statute makes 'any person' who violates § 301(a) guilty of a 'misdemeanor'. It specifically defines 'person' to include 'corporation'. § 201(e). But the only way in which a corporation can act is through the individuals who act on its behalf. *New York Central R. R. v. United States*, 212 U. S. 481. And the historic conception of a 'misdemeanor' makes all those responsible for it equally guilty, *United States v. Mills*, 7 Pet. 138, 141, a doctrine given general application in § 332 of the Penal Code (18 U. S. C. § 550). If, then, Dotterweich is not subject to the Act, it must be solely on the ground that individuals are immune when the 'person' who violates § 301(a) is a corporation, although from the point of view of action the individuals are the corporation. As a matter of

legal development, it has taken time to establish criminal liability also for a corporation and not merely for its agents. See *New York Central R. R. v. United States*, *supra*. The history of federal food and drug legislation is a good illustration of the elaborate phrasing that was in earlier days deemed necessary to fasten criminal liability on corporations. Section 12 of the Food and Drugs Act of 1906 provided that, 'the act, omission, or failure of any officer, agent, or other person acting for or employed by any corporation, company, society, or association, within the scope of his employment or office, shall in every case be, also deemed to be the act, omission, or failure of such corporation, company, society, or association as well as that of the person.' By 1938, legal understanding and practice had rendered such statement of the obvious superfluous. Deletion of words—in the interest of brevity and good draftsmanship—superfluous for holding a corporation criminally liable can hardly be found ground for relieving from such liability the individual agents of the corporation. To hold that the Act of 1938 freed all individuals, except when proprietors, from the culpability under which the earlier legislation had placed them is to defeat the very object of the new Act. Nothing is clearer than that the later legislation was designed to enlarge and stiffen the penal net and not to narrow and loosen it. This purpose was unequivocally avowed by the two committees which reported the bills to the Congress. The House Committee reported that the Act 'seeks to set up effective provisions against abuses of consumer welfare growing out of inadequacies in the Food and Drugs Act of June 30, 1906'. (H. Rep. No. 2139, 75th Cong., 3d Sess., p. 1.) And the Senate Committee explicitly pointed out that the new legislation 'must not weaken the existing laws', but on the contrary 'it must strengthen and extend that law's protection of the consumer.' (S. Rep. No. 152, 75th Cong., 1st Sess., p. 1.) If the 1938 Act were construed as it was below, the penalties of the law could be imposed only in the rare case where the corporation is merely an individual's *alter ego*. Corporations carrying on an illicit trade would be subject only to what the House Committee described as a 'license fee for the conduct of an illegitimate business.'<sup>2</sup> A corporate officer, who even with 'intent to defraud or mislead' (§ 303b), introduced adulterated or misbranded drugs into interstate commerce could not be held culpable for conduct which was indubitably outlawed by the 1906 Act. See, e. g., *United States v. Mayfield*, 177 F. 705. This argument proves too much. It is not credible that Congress should by implication have exonerated what is probably a preponderant number of persons involved in acts of disobedience—for the number of noncorporate proprietors is relatively small. Congress, of course, could reverse the process and hold only the corporation and allow its agents to escape. In very exceptional circumstances it may have required this result. See *Sherman v. United States*, 282 U. S. 25. But the history of the present Act, its purposes, its terms, and extended practical construction lead away from such a result once we free our minds from the notion that criminal statutes must be construed by some artificial and conventional rule'. *United States v. Union Supply Co.*, 215 U. S. 50, 55.

The Act is concerned not with the proprietary relation to a misbranded or an adulterated drug but with its distribution. In the case of a corporation such distribution must be accomplished, and may be furthered, by persons standing in various relations to the incorporeal proprietor. If a guaranty immunizes shipments of course it immunizes all involved in the shipment. But simply because if there has been a guaranty it would have been received by the proprietor, whether corporate or individual, as a safeguard for the enterprise, the want of a guaranty does not cut down the scope of responsibility of all who are concerned with transactions forbidden by § 301. To be sure, that casts the risk that there is no guaranty upon all who according to settled doctrines of criminal law are responsible for the commission of a misdemeanor. To read the guaranty section, as did the court below, so as to restrict liability for penalties to the only person who normally would receive a guaranty—the proprietor—disregards the admonition that 'the meaning of a sentence is to be felt rather than to be proved'. *United States v. Johnson*, 221 U. S. 488, 496. It also reads an exception to an important provision safeguarding the public welfare with a

<sup>2</sup> 'The bill has been made shorter and less verbose than previous bills. That has been done without deleting any effective provisions.' S. Rep. No. 152, 75th Cong., 1st Sess., p. 2.

<sup>3</sup> In describing the penalty provisions of § 303, the House Committee reported that the bill 'increases substantially the criminal penalties which some manufacturers have regarded as substantially a license fee for the conduct of an illegitimate business.' H. Rep. No. 2139, 75th Cong., 3d Sess., p. 4.

liberality which more appropriately belongs to enforcement of the central purpose of the Act.

"The Circuit Court of Appeals was evidently tempted to make such a devitalizing use of the guaranty provision through fear that an enforcement of § 301(a) *as written might operate too harshly by sweeping within its condemnation any person however remotely entangled in the proscribed shipment. But that is not the way to read legislation. Literalism and evisceration are equally to be avoided. To speak with technical accuracy, under § 301 a corporation may commit an offense and all persons who aid and abet its commission are equally guilty. Whether an accused shares responsibility in the business process resulting in unlawful distribution depends on the evidence produced at the trial and its submission—assuming the evidence warrants it—to the jury under appropriate guidance. The offense is committed, unless the enterprise which they are serving enjoys the immunity of a guaranty, by all who do have such a responsible share in the furtherance of the transaction which the statute outlaws, namely to put into the stream of interstate commerce adulterated or misbranded drugs. Harshness there doubtless may be under a statute which thus penalizes the transaction though consciousness of wrongdoing be totally wanting. Balancing relative hardships, Congress has preferred to place it upon those who have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless.*

"*It would be too treacherous to define or even to indicate by way of illustration the class of employees which stands in such a responsible relation. To attempt a formula embracing the variety of conduct whereby persons may responsibly contribute in furthering a transaction forbidden by an Act of Congress, to wit, to send illicit goods across state lines, would be mischievous futility. In such matters the good sense of prosecutors, the wise guidance of trial judges, and the ultimate judgment of juries must be trusted. Our system of criminal justice necessarily depends on 'conscience and circumspection in prosecuting officers.'* *Nash v. United States*, 220 U. S. 272, 278 even when the consequences are far more drastic than they are under the provision of law before us. See *United States v. Balint, supra* (involving a maximum sentence of five years). For present purpose it suffices to say that in what the defense characterized as 'a very fair charge' the District Court properly left the question of the responsibility of Dotterwelch for the shipment to the jury, and there was sufficient evidence to support its verdict."

*Judgment reversed.*

MURPHY, Associate Justice, dissenting: "Our prime concern in this case is whether the criminal sanctions of the Federal Food, Drug, and Cosmetic Act of 1938 plainly and unmistakably apply to the respondent in his capacity as a corporate officer. He is charged with violating § 301(a) of the Act, which prohibits the introduction or delivery for introduction into interstate commerce of any adulterated or misbranded drug. There is no evidence in this case of any personal guilt on the part of the respondent. There is no proof or claim that he ever knew of the introduction into commerce of the adulterated drugs in question, much less that he actively participated in their introduction. Guilt is imputed to the respondent solely on the basis of his authority and responsibility as president and general manager of the corporation.

"It is a fundamental principle of Anglo-Saxon jurisprudence that guilt is personal and that it ought not lightly to be imputed to a citizen who, like the respondent, has no evil intention or consciousness of wrongdoing. It may be proper to charge him with responsibility to the corporation and the stockholders for negligence and mismanagement. But in the absence of clear statutory authorization it is inconsistent with established canons of criminal law to rest liability on an act in which the accused did not participate and of which he had no personal knowledge. Before we place the stigma of a criminal conviction upon any such citizen the legislative mandate must be clear and unambiguous. Accordingly that which Chief Justice Marshall has called 'the tenderness of the law for the rights of individuals'<sup>10</sup> entitles each person, regardless of economic or social status, to an unequivocal warning from the legislature as to whether he is within the class of persons subject to vicarious liability. Congress cannot be deemed to have intended to punish anyone who is not 'plainly and unmistakably'

<sup>10</sup> *United States v. Willberger*, 5 Wheat, 76, 85.



within the confines of the statute. *United States v. Lacher*, 134 U. S. 624, 628; *United States v. Gradwell*, 243 U. S. 470, 485.

"Moreover, the fact that individual liability of corporate officers may be consistent with the policy and purpose of a public health and welfare measure does not authorize this Court to impose such liability where Congress has not clearly intended or actually done so. Congress alone has the power to define a crime and to specify the offenders. *United States v. Willberger*, 5 Wheat. 76, 95. It is not our function to supply any deficiencies in these respects, no matter how grave the consequences. Statutory policy and purpose are not constitutional substitutes for the requirement that the legislature specify with reasonable certainty those individuals it desires to place under the interdict of the Act. *United States v. Harris*, 177 U. S. 305; *Sarita v. United States*, 152 U. S. 570.

"Looking at the language actually used in this statute, we find a complete absence of any reference to corporate officers. There is merely a provision in § 303(a) to the effect that 'any person' inadvertently violating § 301(a) shall be guilty of a misdemeanor. Section 201(e) further defines 'person' as including an 'individual, partnership, corporation, and association.'<sup>11</sup> The fact that a corporate officer is both a 'person' and an 'individual' is not indicative of an intent to place vicarious liability on the officer. Such words must be read in light of their statutory environment.<sup>12</sup> Only if Congress has otherwise specified an intent to place corporate officers within the ambit of the Act can they be said to be embraced within the meaning of the words 'person' or 'individual' as here used.

Nor does the clear imposition of liability on corporations reveal the necessary intent to place criminal sanctions on their officers. A corporation is not the necessary and inevitable equivalent of its officers for all purposes.<sup>13</sup> In many respects it is desirable to distinguish the latter from the corporate entity and to impose liability only on the corporation. In this respect it is significant that this Court has never held the imposition of liability on a corporation sufficient, without more, to extend liability to its officers who have no consciousness of wrongdoing.<sup>14</sup> Indeed, in a closely analogous situation, we have held that the vicarious personal liability of receivers in actual charge and control of a corporation could not be predicated on the statutory liability of a 'company,' even when the policy and purpose of the enactment were consistent with personal liability. *United States v. Harris, supra*.<sup>15</sup> It follows that express statutory provisions are necessary to

<sup>11</sup> The normal and necessary meaning of such a definition of 'person' is to distinguish between individual enterprises and those enterprises that are incorporated or operated as a partnership or association, in order to subject them to the Act. This phrase cannot be considered as an attempt to distinguish between individual officers of a corporation and the corporate entity. See, 'Corporate Criminal Liability,' 28 Col. L. Rev. 1, 181, 190.

<sup>12</sup> Compare *United States v. Cooper Corp.*, 312 U. S. 600, 606, and *Davis v. Pringle*, 268 U. S. 315, 318, holding that the context and legislative history of the particular statutes there involved indicated that the words "any person" did not include the United States. But in *Georgia v. Evans*, 316 U. S. 159, and *Ohio v. Helvering*, 292 U. S. 360, these considerations led to the conclusion that 'any person' did include a state. See also 40 Stat. 1143, which specifically includes officers within the meaning of 'any person' as used in the Revenue Act of 1918.

<sup>13</sup> In *Park Bank v. Remsen*, 158 U. S. 337, 344, this Court said, 'It is the corporation which is given the powers and privileges and made subject to the liabilities. Does this carry with it an imposition of liability upon the trustee or other officer of the corporation? The officer is not the corporation; his liability is personal, and not that of the corporation, nor can it be counted among the powers and privileges of the corporation.'

<sup>14</sup> For an analysis of the confusion on this matter in the state and lower federal courts, see Lee, 'Corporate Criminal Liability,' 28 Col. L. Rev. 1, 181.

<sup>15</sup> In that case we had before us Rev. Stat. §§ 4386-4389, which penalized 'any company, owner or custodian of such animals' who failed to comply with the statutory requirements as to livestock transportation. A railroad company violated the statute and the government sought to impose liability on the receivers who were in actual charge of the company. It was argued that the word 'company' embraced the natural persons acting on behalf of the company and that to hold such officers and receivers liable was within the policy and purpose of so humane a statute. We rejected this contention in language peculiarly appropriate to this case (177 U. S. at 309):

'It must be admitted that, in order to hold the receivers, they must be regarded as included in the word 'company.' Only by a strained and artificial construction, based chiefly upon a consideration of the mischief which the legislature sought to remedy, can receivers be brought within the terms of the law. But can such a kind of construction be resorted to in enforcing a penal statute? Giving all proper force to the contention of counsel of the government, that there has been some relaxation on the part of the courts in applying the rule of strict construction to such statutes, it still remains that the intention of a penal statute must be found in the language actually used, interpreted according to its fair and obvious meaning. It is not permitted to courts, in this class of cases, to attribute inadvertence or oversight to the legislature when enumerating the classes of persons who are subjected to a penal enactment, nor to depart from the settled meaning of words or phrases in order to bring persons not named or distinctly described within the supposed purpose of the statute.'

satisfy the requirement that officers as individuals be given clear and unmistakable warning as to their vicarious personal liability. This Act gives no such warning.

"This fatal hiatus in the Act is further emphasized by the ability of Congress, demonstrated on many occasions, to apply statutes in no uncertain terms to corporate officers as distinct from corporations." The failure to mention officers specifically is thus some indication of a desire to exempt them from liability. In fact the history of federal food and drug legislation is itself illustrative of this capacity for specification and lends strong support to the conclusion that Congress did not intend to impose liability on corporate officers in this particular Act.

"Section 2 of the Federal Food and Drugs Act of 1906, as introduced and passed in the Senate, contained a provision to the effect that any violation of the Act by a corporation should be deemed to be the act of the officer responsible therefor and that such officer might be punished as though it were his personal act." This clear imposition of criminal responsibility on corporate officers, however, was not carried over into the statute as finally enacted. In its place appeared merely the provision that "when construing and enforcing the provisions of this Act, the act, omission, or failure of any officer, agent, or other person acting for or employed by any corporation . . . within the scope of his employment or office, shall in every case be also deemed to be the act, omission, or failure of such corporation . . . as well as that of the person."<sup>10</sup> This provision had the effect only of making corporations responsible for the illegal acts of their officers and proved unnecessary in view of the clarity of the law to that effect. *New York Central & H. R. R. Co. v. United States*, 212 U. S. 481.

"The framers of the 1938 Act were aware that the 1906 Act was deficient in that it failed to place responsibility properly upon corporate officers." In order to provide the additional scope necessary to prevent the use of the corporate form as a shield to individual wrongdoers,<sup>11</sup> these framers inserted a clear provision that "whenever a corporation or association violates any of the provisions of this Act, such violation shall also be deemed to be a violation of the individual directors, officers, or agents of such corporation or association who authorized, ordered, or did any of the acts constituting, in whole or in part, such violation."<sup>12</sup> This paragraph, however, was deleted from the final version of the Act.

<sup>10</sup> "Whenever a corporation shall violate any of the penal provisions of the antitrust laws, such violation shall be deemed to be also that of the individual directors, officers, or agents of such corporation who shall have authorized, ordered, or done any of the acts constituting in whole or in part such violation." 15 U. S. C. § 24.

"The courts of bankruptcy . . . are invested . . . with such jurisdiction at law and in equity as will enable them to . . . (4) arraign, try, and punish bankrupts, officers, and other persons, and the agents, officers, members of the board of directors or trustees, or other similar controlling bodies, of corporations for violations of the provisions contained in this title." 31 U. S. C. § 11.

"Any such common carrier, or any officer or agent thereof, requiring or permitting any employee to go, be, or remain on duty in violation of the next preceding section of this chapter shall be liable to a penalty . . ." 45 U. S. C. § 63.

"A mortgagor who, with intent to defraud, violates any provision of subsection E, section 924, and if the mortgagor is a corporation or association, the president or other principal executive officer of the corporation or association, shall upon conviction thereof be held guilty of a misdemeanor . . ." 46 U. S. C. § 941 (b).

<sup>11</sup> S. 88, 59th Cong., 1st Sess. Senator Heyburn, one of the sponsors of S. 88, stated that this was "a new feature in bills of this kind. It was intended to obviate the possibility of escape by officers of a corporation under a plea, which has been more than once made, that they did not know that this was being done on the credit of or on the responsibility of the corporation." 40 Cong. Rec. 894.

<sup>12</sup> 34 Stat. 772, 21 U. S. C. § 4.

<sup>13</sup> Senate Report No. 493, 73d Cong., 2d Sess., p. 21.

<sup>14</sup> *Ibid.*, p. 22. This report also stated that "it is not, however, the purpose of this paragraph to subject to liability those directors, officers, and employees, who merely authorize their subordinates to perform lawful duties and such subordinates, on their own initiative, perform those duties in a manner which violates the provisions of the law. However, if a director or officer personally orders his subordinate to do an act in violation of the law, there is no reason why he should be shielded from personal responsibility merely because the act was done by another and on behalf of a corporation."

<sup>15</sup> This provision appears in several of the early versions of the Act introduced in Congress. S. 1944, 73d Cong., 1st Sess., § 18(b); S. 2000, 73d Cong., 2d Sess., § 18(b); S. 2800, 73d Cong., 2d Sess., § 18(b); S. 5, 74th Cong., 1st Sess., § 709(b); S. 5, 74th Cong., 2d Sess., § 707(b), as reported to the House, which substituted the word "personally" for the word "authorized" in the last clause of the paragraph quoted above. A variation of this provision appeared in S. 5, 75th Cong., 1st Sess., § 2(f), and made a marked distinction between the use of the word "person" and the words "director, officer, employee, or agent acting for or employed by any person." All of these bills also contained the present definition of "person" as including "individual, partnership, corporation, and association."

"We cannot presume that this omission was inadvertent on the part of Congress. *United States v. Harris, supra* at 300. Even if it were, courts have no power to remedy so serious a defect, no matter how probable it otherwise may appear that Congress intended to include officers; 'probability is not a guide which a court, in construing a penal statute, can safely take.' *United States v. Wittberger, supra* at 105. But the framers of the 1938 Act had an intelligent comprehension of the inadequacies of the 1936 Act and, of the unsettled state of the law. They recognized the necessity of inserting clear and unmistakable language in order to impose liability on corporate officers. It is thus unreasonable to assume that the omission of such language was due to a belief that the Act as it now stands was sufficient to impose liability on corporate officers. Such deliberate deletion is consistent only with an intent to allow such officers to remain free from criminal liability. Thus to apply the sanctions of this Act to the respondent would be contrary to the intent of Congress as expressed in the statutory language and in the legislative history.

"The dangers inherent in any attempt to create liability without express Congressional intention or authorization are illustrated by this case. Without any legislative guides, we are confronted with the problem of determining precisely which officers, employees and agents of a corporation are to be subject to this Act by our fiat. To erect standards of responsibility is a difficult legislative task and the opinion of this Court admits that it is 'too treacherous' and a 'mischievous futility' for us to engage in such pursuits. But the only alternative is a blind resort to 'the good sense of prosecutors, the wise guidance of trial judges, and the ultimate judgment of juries.' Yet that situation is precisely what our constitutional system sought to avoid. Reliance on the legislature to define crimes and criminals distinguishes our form of jurisprudence from certain less desirable ones. The legislative power to restrain the liberty and to imperil the good reputation of citizens must not rest upon the variable attitudes and opinions of those charged with the duties of interpreting and enforcing the mandates of the law. I therefore cannot approve the decision of the Court in this case.

"Mr. Justice ROBERTS, Mr. Justice REED and Mr. Justice RUTLEDGE join in this dissent."

BOWMAN VS RETZLAFF

Some half a million bushels of Canadian wheat was shipped by rail in bond to Baltimore during the war and loaded onto the James J. Hill, a freighter operated by the Government, for shipment to the French Government at Casablanca, Morocco. Loaded, it left Baltimore on September 13, 1945 and when it reached Norfolk the following day it put in at Hampton Roads, Va., for survey because the ship was riding low at the bow.

Survey showed that the No. 1 hold was full of water. The Hill returned to Baltimore to unload the hold, repair the damage and refill the hold with dry wheat before again setting out.

The explanation was that the Hill had been in a Philadelphia shipyard where facilities were added so the boat could bring back prisoners from Europe. As the prisoners were to be carried in the holds, it was necessary to install toilets. When the boat was empty - as when carrying prisoners - the floor of the hold would be above the water line. The discharge from the toilets would be by gravity into the ocean, but when the boat was loaded the floor of the hold would be below the waterline and unless the toilets were valved off the hold would fill with water. Apparently the valves in No. 1 hold had not been closed before the boat was loaded.

The wheat in the top of No. 1 hold was dry and was unloaded into an elevator. The wet wheat, however, could not be handled thru the elevator's equipment and so was bucketed out of the hold and loaded onto railroad open gondola cars, hopper bottom. Approximately fifty thousand (actually 40,843) bushels of wet wheat was put on these cars. A representative of the Hill came to see me and made application to enter the wet wheat into the United States as chicken feed. Up to this time the entire cargo of Canadian wheat had been in bond just travelling thru the U.S. It was now proposed to enter the wet wheat into the U.S. as an import.

Although imports come under the jurisdiction of the Customs Division of the Treasury Department the law provides that any products that come under the jurisdiction of the Federal Food, Drug and Cosmetic Act must be examined to determine if the product is legal and can be entered or if it is illegal and must be detained. The Treasury Department then acts on the basis of the FDA recommendation. To avoid duplication and to speed up the operation, the FDA fills out the forms and signs them as representatives of the Treasury Department and sends copies to the Customs Division. Each operation is joint between FDA and Treasury.

As this was an unusual case and as I was familiar with wheat and what happens to it when it gets wet, I handled the

application myself and made the decision to allow a conditional entry. The condition was that the wheat had to be dried within two weeks. My reason was that the wheat would sour and decompose, in time, and become unfit for even animal feed.

There was only one elevator in Baltimore that had drying facilities that could be used and the capacity of the drier was about 500 bushels a day. The wet wheat would not go thru the elevating machinery and so had to be bucketed up on the outside of the elevator. The drying was completed in February of 1946, - 6 months after the wheat became wet.

At this time an attorney by the name of Robert Williams, a brother of the Baltimore city Health Commissioner, representing the captain of the boat came to the office and wanted to complete the entry of the 40 odd thousand bushels of now dry decomposed wheat. We had secured a number of samples during the unloading and drying and I had sent samples to Washington to get the opinion of experts there on whether or not this grain was fit for chicken feed. The experts agreed with me that there was a risk involved and that we should not permit the importation for chicken feed. Mr. Williams, the attorney for Captain Bowman, came to see me several times and argued for the importation on the basis that the wheat had been fed to chickens without damage. I advised him that he had my decision in writing and that the wheat could not

be entered as a chicken feed. On his last visit he became extremely abusive and I was about to ask him to leave the office when it suddenly occurred to me that the only way this attorney could get the wheat entered into the country was to show that my decision was arbitrary and capricious and if I ordered him out of the office he would use this as an example to prove that I was being arbitrary. So instead of becoming angry with the fellow because of his abuse, I laughed at him and told him flattery would get him nowhere. He left in a huff and shortly after I was served with papers of a suit against me and the Collector of Customs to force us to permit entry of the decomposed wheat.

The suit in Federal Court was against me and the Collector of Customs in that order so I went to see the Collector to advise him of the situation. Mr. George T. Cromwell had very recently been appointed to the position. At that time the Collectors were political appointees and so had usually no experience whatever with the work of the Customs Division. This was the case with Mr. Cromwell. I explained to him how the Customs and FDA worked on importations that came under the Food & Drugs Act and what I had done in the present instance. I told him that our action was taken under the Treasury law but that all the work had been done by FDA so we would provide the facts needed as testimony in our case. I told him that I did not anticipate that we would

need any help from the Customs Division but if we did I would let him know. Mr. Cromwell asked me to keep him advised when a date was set for the trial so he could be present. I assured him I would do so but there was not any need for him to come to the trial unless he particularly wanted to. The Collector surprised me when he said, emphatically and with just a little irritation, "Look Retzlaff, I'm being sued too. I am going to be there every day." I told him I was delighted that he was interested in the case and that I would keep him advised and would like him to sit in on our conferences in preparation for the trial so that he would be fully informed about our plans of the presentation of evidence. Mr. Cromwell surprised me. He stuck with us from start to finish of the trial and I think he enjoyed every minute of it.

The case was called before Judge Chesnut in the U.S. District Court at Baltimore. I was pleased, as Judge Chesnut, in my opinion, was always very fair and impartial. He did not favor the government but on the other hand he did not discriminate against it. If you put on a good case before this Judge you had no problems. If you came in with a stinker he would quickly smell it and throw you out. He was very well informed. He kept up with the latest regulations of the Justice Department and with not only the decisions of the Supreme Court and the Courts of Appeal, but also



with the District Courts throughout the U.S. He was inclined to be just a little intolerant with any attorney who appeared before him and was unfamiliar with any of this essential information. Most FDA cases are before the Judge without a jury and it is the Judge who makes the final decision. Under those circumstances Judge Chesnut persisted in getting the full facts out of a witness. He did not hesitate to bore in and persist in getting all the facts that he thought the witness had available.

Normal procedure in a court case is for the plaintiff to state his complaint and then put on testimony to prove it. The defense then has an opportunity to state its position and present testimony. After this each side has an opportunity for rebuttal.

The plaintiffs in this case stated their position in that they had this quantity of wheat that had been damaged by water, had been dried and which they wished to bring into the U.S. to be sold as chicken feed. They put on testimony by a Dr. Briggs of the Department of Poultry Husbandry of the University of Maryland, to the effect that some of this wheat had been fed to chickens and baby chicks as a part of their diet for 3 weeks without any bad effects. They also put on testimony of a Dr. J.A. Brown, an Assistant Professor of Bacteriology at Johns Hopkins University, to the effect that grain damaged in this condition would have

only a remote possibility of causing damage to chickens. When our opportunity came I presented testimony from bacteriologists from our Washington office to the effect that grain damaged such as this and containing this and that bacteria, molds and spores, might have a deleterious effect on chickens to which it was fed.

Bacteriology is a very inexact science and any time that someone speaks up bacteriologically and says that something can't possibly happen there always appears someone to prove that it has happened. I felt that it was more important to present the attitude of a chicken grower who might be buying the feed in which this product had been incorporated. So I put on the stand Mr. Rieck, a chicken grower from the Eastern Shore of Maryland, who testified that he grew so many thousand chickens every 15 weeks and these chickens as "peeps" cost him so much a piece and he fed them the best feed he could possibly buy. He was shown a sample of the wheat. He looked at it, smelled it, and stated he would not feed this to his chickens if it were given to him as a gift. He handed the sample to the Judge and said, "Smell it, your Honor." Judge Chesnut smelled the sample and said, "Smells like a strong cheese, like limburger." I could see that the Judge was very much impressed by the testimony of the chicken grower, and he felt it would be a deception for this type of grain to be

put in a chicken feed mixed with molasses and other nutritive elements so that its character would be disguised. I think the opposition felt too that the decision at that point was going to be against them so they put on the stand a grain dealer who testified that he had a client who wanted to buy this grain and would pay a dollar bushel for it. The attorney indicated that he had finished questioning his witness and Judge Chesnut took over. He asked the witness who this client was who wanted to buy the grain. The witness hemmed and hawed a bit but on the Judge's insistence, he finally stated that his client was the U.S. Department of Agriculture. This was too much for the Judge and he exploded in a condemnation of government operations where one unit of the government was refusing to permit entry of the grain into the country, while another unit of the government wanted to use it as a feed. Suddenly the Judge stopped and turned to the witness and asked, "What was the USDA going to use this grain for? Chicken feed?" The witness beat around the bush but the Judge was on his neck. Finally the witness stated, "I got the idea they planned to add poison to it and ship it out west to kill grasshoppers." This answer brought down the house and even the Judge joined in the laughter. I was never sure whether I won the case with my chicken grower witness from the Eastern Shore or if the other side had thrown away the case with their salesman of grasshopper poison.

In any event the decision was in our favor and the grain was not permitted entry into this country. I heard it was shipped to Cuba and that the recipients there never paid for it but of this I am not certain.

Several months later the Baltimore agent for Lloyds of London was in to see me about something and incidentally congratulated me on the good case I had put on in connection with the wheat from the James J. Hill. I said, "Coming from you I particularly appreciate that as I expect you carried the insurance on the cargo and brought the suit." He looked at me in surprise, "It was a Maritime Commission boat," he said, "You know the Government never insures anything. We didn't sue you. I strongly suspect it was your Federal Government that did." I am sure my mouth sagged open. He was right, the Government to my knowledge never carried any insurance in connection with our work. I was astounded, I said, "Good Lord, I hope this information doesn't get to Judge Chesnut."

Ref: John T. Bowman, Master of the SS James J. Hill, v  
Allen T. Retzlaff, et al

U. S. District Court for the District of Maryland.  
No. 2894 - April 4, 1946. 65#F. Supp. 265

Allen T. Retzlaff

## FEDERAL SECURITY AGENCY

### FOOD AND DRUG ADMINISTRATION

## NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

10001-10200

### FOODS

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

MAURICE COLLINS, Acting Administrator, Federal Security Agency.

Washington, D. C., May 29, 1947.

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10070. Action to restrain the enforcement of an order for the exportation or destruction of adulterated wheat. John T. Bowman, Master of SS James J. Hill, v. Allen T. Retzlaff, Chief, Baltimore Station of Food and Drug Administration, and George T. Cromwell, Collector of Customs, Port of Baltimore. Tried to the court. Complaint dismissed.

On or about January 24, 1946, a complaint was filed in the United States District Court for the District of Maryland on behalf of John T. Bowman, Master of the SS James J. Hill, seeking to restrain the enforcement of an order directing the exportation or destruction of some 40,000 bushels of adulterated wheat. The facts upon which the complaint was based are given in the court opinion.

An answer to the complaint was filed on behalf of the defendants on February 13, 1946, and thereafter the case came on for trial before the court. At the conclusion of the trial, the matter was taken under advisement by the court, and, on April 4, 1946, the court handed down the following opinion:

*Cause No. District Judge:* "In this case the master of the SS 'James J. Hill' seeks an injunction against the enforcement of an order of Gilbert A. Dailey, Collector of the Port of Baltimore, which required that 40,843 bushels of Canadian wheat theretofore provisionally entered for importation into the United States 'must be exported, or destroyed, under custom supervision.' The respondents are George T. Cromwell, Collector of Customs (successor to Gilbert A. Dailey) and Allen T. Retzlaff, Chief of the Baltimore Station Food and Drug Administration of Federal Security Agency. They have answered justifying the order under section 801 of the Federal Food Drug & Cosmetic Act of 1938 (21 U.S.C.A. s. 381), which deals with imports and exports.

"Section 381 (so far as here material) provides that the Secretary of the Treasury shall deliver to the Federal Security Administrator samples of food offered for import into the United States, giving notice thereof to the owner or the consignee 'who may appear before the Federal Security Administrator and have the right to introduce testimony.' If it is found that the article is 'adulterated' then such article shall be refused admission and 'unless such article is exported by the consignee within three months, it must be destroyed.' By section 342 (a) 'food shall be deemed adulterated (3) if it consists in whole or in part of any filthy, putrid or decomposed substance or if it is otherwise unfit for food.' [Italics supplied.]

"The position of the respondents is that in due course they have administratively determined that the wheat was unfit for food. The complainant attacks this position on two grounds: (1) that there was no substantial evidence before the respondents that the wheat was unfit for food and that their action is therefore arbitrary and capricious; and (2) that the Federal Security Administrator did not afford the plaintiff a fair hearing. Extended testimony was heard in court upon these issues and the case taken under advisement. After consideration I have reached the conclusion that the injunction applied for must be denied and the complaint dismissed.

"I find the material facts to be as follows:

"1. Prior to September 13, 1945, about 40,000 bushels of Canadian wheat were shipped by rail from Canada to Baltimore and there transhipped to the SS 'James J. Hill,' a government owned vessel. The wheat was consigned to an agency of the French Government at Casablanca, Morocco. The 'Hill' sailed from Baltimore on September 13, 1945. The next morning it was discovered that there were ten feet of water in No. 1 hold, where the wheat was stowed, by reason, as it was later found, of an influx of water through a plumbing fixture which ought to have been blocked off when the vessel was not being used as a troop-carrier but which had been opened while the vessel was in port. The 'Hill' proceeded to Hampton Roads, Virginia, where it found sufficient port facilities unavailable and consequently returned to Baltimore,

arriving September 16, 1945. Discharge of all grain from the watered hold was immediately undertaken and the grain was entered at the Custom House at Baltimore by John F. Connor, a broker acting on behalf of the owner of the grain.

"2. On September 21, 1945, the Collector of Customs served on Connor an order requiring the wheat to be held intact pending analysis of samples and advising that failure of the goods to comply with the requirements of the Food and Drug Act would result in an order for its exportation or destruction. The next day the Chief of the Baltimore Station Food & Drug Administration notified Connor in writing that inspection and analysis of the samples showed the wheat to be adulterated within the meaning of section 402 (a) of the Food Drug & Cosmetic Act (21 USCA, s. 342 (a)) since it consisted in whole or in part of a filthy, putrid or decomposed substance, or was otherwise unfit for food. 'Product is water damaged; grains hot and sour.' The notice fixed a hearing date three days later 'at which time and place you may be present and submit testimony, or at or before which time you may file a statement in writing.'

"3. It seems to have been conceded at that hearing as at the hearing in this court that the wheat in its then condition was unfit for importation. On September 27, 1945, Connor made application for the release of 5,000 bags of wheat found to be undamaged by water and also for permission to re-condition the damaged wheat by blowing, cleaning and drying and thus stopping further decomposition and deterioration. This permission was granted but with the following condition: 'However, before issuing conditional release providing for final re-conditioning and disposition of the damaged wheat it must be clearly understood just how you plan to accomplish this, for which purpose we are enclosing another blank application in duplicate. On receipt of this application stating the purpose to which the wheat is to be put after re-conditioning and also outlining the method to be used in re-conditioning, we shall issue the conditional release.'

"4. Regulations have been published for administration of the Act. No. 2309 provides for relabelling or re-conditioning an article to bring it within compliance with the Act. It provides that the owner or consignee may make request in writing for such re-conditioning or other action to render the article not a food within the meaning of the Act. 'Such request shall propose the labelling to be used and any other act to be done for such purpose and shall specify the time and place when such labelling or other act is to be done.' If and when it has been done and in its changed condition approved by the Administrator the article may be released from detention.

"5. It appears that the owner or consignee in this case did not make formal written application but did informally and by correspondence with the Administrator request the release of the wheat, then in process of being dried out, for use as poultry food, and submitting an offer for the purchase of the dried wheat from a dealer in poultry foods on November 16, 1945; and on November 27, 1945 attorneys for the owner requested a hearing by the Administrator with an opportunity to submit testimony 'as to the present condition of the damaged wheat, and particularly on the question of the fitness of said wheat for animal food'; and stating that they had consulted the Department of Poultry Husbandry at the University of Maryland, College Park, Maryland, and submitted samples of the re-conditioned grain in order that it could be carefully examined and tested to determine its availability as poultry food; and that this proposed test would cover a period of two or three weeks at which time the results of the test would be submitted. The Administrator replied on November 30, 1945 that a hearing under the Act had already been given and that the request for the use of the wheat as poultry feed was denied and declining to accept the invitation to participate in the controlled feeding tests.

"6. On December 11, 1945 the Collector of Customs passed the formal order for the destruction or exportation of the damaged wheat to be complied with in three months. The notice stated 'part of the lot has been dried since detention. Examination of the dried portion of this lot indicates it to be unfit for food of any kind. Undried portion is decomposed or hot and sour.'

"7. Some further informal negotiations or consultation ensued between the parties with a final letter from Mr. L. D. Elliott, Assistant Commissioner of Food and Drugs at Washington, dated January 9, 1946, which stated in part:

As was further pointed out to him (Mr. Robert Williams, attorney for the owners) this Administration cannot agree to the release of this damaged grain for poultry feed purposes irrespective of the outcome of the experiments you plan, nor are we in a position to participate in them. It has been our consistent policy to refuse to acquiesce in the use of moldy material in poultry feed in connection with salvage operations under the seizure section of the Act as well as under its import provisions. This policy is based upon the consensus of opinion among the authorities in the field of Veterinary Medicine who cannot assure us that the feeding of moldy material to poultry would be free of any possibility of adversely affecting the health of the birds. The outcome of any brief tests using some part of the 40,000 bushels involved here would not alter the applicability of our policy based on the consensus above. We have no disposition to close the door to the consideration of any proposals you may wish to make for some other use of this material which will in no way jeopardize public interests. Although there is no provision for an appeal under the import regulations of the Act, you are of course welcome to call at the Administration at any time for a discussion of your problem in connection with the proper disposal of this grain, having in mind the time limit prescribed by the order above.

"S. At the hearing in court the respective parties submitted interesting scientific testimony with respect to the suitability of the dried out grain for use as poultry feed. It was not controverted that the water damaged grain before being dried out was unsuitable for either human or animal food. Dr. Briggs, an expert poultry nutritionist at the University of Maryland testified to the results of experiments over a period of three weeks on chickens and baby chicks to which portions of the dried wheat had been fed. He said the chickens had thrived on the wheat which was mixed with other food, and expressed his opinion that it could be safely used generally for poultry feed. Dr. J. H. Brown, Assistant Professor of Bacteriology at the Johns Hopkins University, an expert in his field, after giving extended testimony upon the general subject expressed the opinion that any danger to the poultry from the use of the dried wheat would be 'remote.' On the other hand, witnesses for the respondents, and particularly Dr. Elliott, Assistant Commissioner of Food & Drugs, also an expert upon the subject, after likewise detailed testimony expressed the opinion that the danger was more than remote. The practical viewpoint upon the subject was expressed by the witness Rieck, extensively engaged in poultry farming on the Eastern Shore of Maryland. He said that in his business he would not take the chance of loss and damage to growing chickens by the use of such damaged wheat, as the saving in cost for the food would not justify the risk of damage that might occur.

"The scientific testimony was to the effect that not all moldy material was necessarily injurious to health. As for instance, the drug penicillin is itself a mold. Various articles of cheese are to some extent decomposed or moldy and are yet edible. But the particular contention of the respondents is that this particular damaged wheat contained a certain amount of aspergillus mold which is generally recognized by standard authorities to be damaging to chickens if the spores are inhaled. Dr. Brown thought it quite unlikely that there would be any such inhalation in the ordinary way in which the wheat mixed with other articles is fed to poultry; but experts for the respondents were of a contrary opinion.

"On these facts the plaintiff contends that the administrative action was arbitrary and capricious and should be enjoined. Consideration of this contention must be related to the particular situation giving rise to the controversy. If the order of the Collector for exportation or destruction was not within the grant of statutory power it should of course be enjoined, even though the statute does not provide for judicial review. *Waite v. Macy*, 246 U. S. 606; *Hannegan, Postmaster General, v. Esquire*, U. S. Sp. Ct. Feb. 4, 1946. By section 381 the Collector of Customs was authorized to refuse admission if the article was 'adulterated.' By section 342 (a) 'food shall be deemed to be adulterated—(3) if it consists in whole or in part of any filthy, putrid or decomposed substance, or if it is otherwise unfit for food.' We may put aside in this case the words filthy and putrid, but it is the contention of the government that the damaged wheat was decomposed and otherwise unfit for food. There was substantial evidence, and indeed it is not disputed by the plaintiff, that there was some decomposition in the wet wheat and to some extent at least it was fermented and moldy. The evidence is in conflict as to the extent of this fermentation and also in conflict as to whether the drying of the grain had arrested or merely retarded the process of fermentation. The ultimate question here is, I think, whether the decomposition was so extensive as to



render the grain unfit for food. *Andersen v. United States*, 294 F. 542, 544; *United States v. 200 Cases of Catsup*, 211 F. 780.

"And it is important here to distinguish between the condition of the grain when first offered for importation, and its condition after it had been dried. And it is also very important in this connection to note that there is really no controversy between the parties whether the wet grain before the drying was unfit for food of any kind, animal or human. In its original wet condition it was practically conceded that it was so unfit for any kind of food. The controversy as to its fitness for food is thus limited to the question as to whether after being dried it was fit for poultry feed. And here again on the evidence in the case taken in court the expert testimony was fairly evenly balanced. In my opinion, therefore, it cannot be said that the determination of the Food Administrator is not supported by substantial evidence. The plaintiff's particular contention to the contrary is that the decision of the Administrator was based on only a so-called organoleptic test, that is, by appearance, taste, texture, solubility, viscosity and color. See *Knapp v. Calloway* (D. C. N. Y.) 52 F. 2d, 467, 477. It may be noted, however, that subsequently and in preparation for trial of the case in court, the Food Administrator had expert bacteriological examinations made and submitted evidence therefrom tending to support his decision based on the previous organoleptic tests.

"It is also very important in this case to note that the administrative action was taken in the field of *importation* in which the power of Congress is *exclusive and absolute*. *Buttsfield v. Stranahan*, 192 U. S. 470, 493. The rights of the importer are, therefore, only those given in the Act of Congress in this case, 21 USCA, s. 381. And it will be noted that the statute itself deals only with the condition of the article when first offered for importation and its admission or rejection is to be determined by the Collector of Customs on the basis of advice from the Federal Security Administrator whether the samples show that the article offered for import is adulterated. In this case the Administrator did advise the Collector that the article was adulterated (within the meaning of the Act) and it is therefore clear enough that the Collector was authorized to refuse admission to the wheat in its originally tendered condition.

"The plaintiff does not contend to the contrary but bases its present position on subsection (b) of section 381 and on a regulation (2.300) providing under some circumstances for the reconditioning of the article offered for import in order to bring it within compliance with the Act, or to take such action as may be necessary to render it not a food product. Section 381 (b) provides that the Secretary of the Treasury may deliver the article to the consignee 'pending examination and decision in the matter on execution of a bond.' Section 2.300 of the regulations provides that the owner may request the Food Administrator in writing to permit the relabelling or other act with respect to the article necessary to bring it into compliance with the provisions of the Act or to render it not a food, and 'such request shall propose the labelling to be used and any other act to be done for such purpose, and shall specify the time and place at which such proposed labelling or other act is to be done.'

"As we have seen, the Secretary, acting through the Collector, did permit delivery of the grain to the owner before passing his final order of December 11, 1945; but this was only for the limited purpose of drying the grain to prevent further spoilage. And thereafter the owner did not formally request permission to do anything with the grain (except dry it) to render it not a food. Instead thereof what the owner did request was permission to sell the dried grain as poultry feed. And this the Administrator refused to permit because in his expert opinion, based on generally accepted standards and information, it would not be safe for poultry growers to use even the dried grain for chicken feed. It is this action of the Food Administrator that is here attacked as arbitrary and capricious. As I have said, the scientific question presented is a nicely balanced one not free from doubt, but I conclude that the decision of the Food Administrator was not arbitrary or capricious. The plaintiff contends that it should be regarded as arbitrary and capricious because on the evidence injurious effects in poultry raising from the use of this damaged grain are not certain but only possible or conjectural. But I cannot accept this view as established by the preponderance of the evidence, and in

any event it is my opinion that the decision of the Food Administrator on the basis of present scientific knowledge on the subject was not arbitrary or capricious.

Plaintiff also contends that under the evidence the Administrator did not accord him a fair hearing on this question. As heretofore stated, we are dealing with a subject matter of importation into the United States of articles where the power of Congress is absolute and the rights accorded the importer are only those given by the statute. The statute (s. 381) accords a hearing only after notice to the importer with respect to the samples taken from the bulk of the commodity to determine whether it is properly importable. At the hearing upon notice the only right accorded to the importer is 'to introduce testimony.' Presumably this testimony should be relevant to whether the samples are fairly illustrative of the bulk product, and if so whether the bulk product is properly importable. In the particular case the notice was duly given and the opportunity was afforded the importer to introduce testimony at the appointed time and place. Apparently the right was waived because it was practically conceded that the samples were fairly taken and the bulk product in its then condition was not importable under the Act. The plaintiff's complaint here is not lack of a fair hearing with regard to the samples of the wet grain but to the refusal of the Food Administrator to give a further hearing with respect to the availability of the dried grain for use as poultry feed. The statute does not provide for such a further hearing. Indeed the provision of the regulation referred to is not expressly provided for in the statute itself; but it is in the nature of an act of grace to the importer to recondition the article so that it will not be violative of the Act as a food product but may be used for other proper purposes not inconsistent with the Act, and thus possibly avoid unnecessary monetary loss.

It is also to be noted that the statute does not provide for judicial review. In this respect the procedure under section 381 is quite different from that taken under other sections of the Food & Drug Act of 1938 relating to domestic commerce, where proceedings for condemnation require judicial procedure. And section 381 as it now stands is an amendment of the prior Act of 1906 (21 U.S.C.A. s. 14) in relation to importation, which also required judicial procedure for condemnation. See *Ambruster v. Mellon* (U. S. D. C.) 41 F. 2d. 430, where it was held, under the earlier Act, that the action of the Secretary of the Treasury in *admitting* a certain importation was not subject to judicial review unless capricious or arbitrary. While there is no recorded case of an attack on the Secretary's action under the new Act, it is clear that in the present case the statute makes no provision for judicial review and creates no personal federal rights as the basis for judicial review, so long as the Secretary acted within the scope of his authority under the Act. See *Stark v. Wickard*, 321 U. S. 288.

We must also bear in mind that the case does not present a question of confiscation by the government of a property right. Indeed the order here sought to be enjoined is merely in the alternative, that is, for exportation or destruction within three months. That period has now passed, but it was understood at the hearing here that the damaged wheat would not be destroyed pending decision of this case. And it appeared further in the evidence that the Administrator was still willing to consider any reasonable proposal from the importer to allow importation of the wheat if effective measures could be taken to use it for purposes other than food. It appears that the importer had an offer for the purchase of the remainder of the dried wheat (about 32,000 bushels) at the price of \$1.40 per bushel for use as poultry feed, and also another provisional offer for the wheat at \$1.00 per bushel for use for purposes other than a food product.

"On the whole case I conclude that the complaint must be dismissed with taxable court costs allowed to the defendants. Counsel may present the appropriate order in due course."

On April 22, 1946, a decree was entered in accordance with the above opinion, ordering that the complaint be dismissed and that the plaintiff or his assigns, as owners of the wheat in question, proceed with its exportation under customs supervision within 30 days from the date of the decree.

