UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

GLENN M. W. SCOTT,

Petitioner

v.

Nos. 82-3544
82-3759

FOOD AND DRUG ADMINISTRATION,

Respondent

(Petition for Review of orders of the Food and Drug Administration.)

BRIEF FOR PETITIONER

Filed by: Glenn M. W. Scott, P.O. Box 270, Owensboro, Ky. 42302.

Certificate of Service

I hereby certify that on the [illegible] day of May, 1983, I served the following BRIEF FOR PETITIONER by mailing copies, postage prepaid, to counsel for Respondent at the following addresses:

Hon. John J. Powers
Hon. Margaret G. Halpern
Attorneys, Antitrust Division (Room 3313)
Department of Justice
Washington, D.C. 20530

and

Hon. Donald Beers
Room 6-72
Office of Chief Counsel
Food and Drug Administration (GCF-1)
5600 Fishers Lane
Rockville, Maryland 20857

and to counsel for the amicus curiae Cosmetic, Toiletry, and Fragrance Association, Inc. at the following address:

Hon. Robert M. Sussman
Hon. Ellen J. Flannery
Covington & Burling
1201 Pennsylvania Avenue, N.W.
P.O. Box 7566
Washington, D.C. 20044

and to counsel for the amicus curiae Certified Color Manufacturers Association at the following address:

Hon. Daniel R. Thompson
Thompson & Middlekauff
900 17th Street, N.W.
Washington, D.C. 20006

Glenn M. W. Scott

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1. By permanently listing the color additive D&C Green No. 5, did the Food and Drug Administration (FDA) violate the Delaney Clause of the Food, Drug, and Cosmetic Act?

2. By permanently listing D&C Green No. 5, did the FDA violate the general safety clause of the Food, Drug, and Cosmetic Act?

STATEMENT OF THE CASE

Introduction

This issue in this case is whether a certain mixture of chemicals can legally be used to color drugs and cosmetics. The mixture involved in this case is classified as a "color additive", and is named D&C Green No. 5.

The problem with this particular mixture of chemicals is that it is carcinogenic, i.e., it causes cancer. The Food and Drug Administration (FDA), which regulates color additives, has taken the position that this particular mixture may legally be used. The FDA has issued certain orders allowing its use. I have taken the position that this mixture may not legally be used, and have filed petitions for review of the FDA's orders.

The Mixture

According to the Food and Drug Administration, "The color additive D&C Green No. 5 is principally the disodium salt of 2,2'-(9,10-dihydro-9,10-dioxo-1,4-anthracenediyl) diimino)bis-(5-methylbenezenesulfonic acid)." 47 Federal Register 24284 (June 4, 1982; emphasis added)(Appendix, p. ___). D&C Green No. 5 also contains several other chemicals, including one which is carcinogenic, namely p-toluidine. (Id.).

Historical Background

D&C Green No. 5 has been used in drugs and cosmetics for many years. Its legal status from 1960 up until late

1982 has been that of a "provisionally listed" color additive. 47 Fed. Reg. 24278-79 (June 4, 1982) (Appendix, pp. ___). Provisional listing is a status which has allowed D&C Green No. 5 to be used while its safety was being tested. (Id.). See 21 U.S.C. 376 note. For a discussion of provisional listing, see McIlwain v. Hayes, 690 F.2d 1041 (D.C. Cir. 1982).

The tests have now been completed and the FDA has decided to permanently list D&C Green No. 5. Permanent listing is a status which will permanently allow its use. See 21 U.S.C. 376. It is this decision by the FDA which I am challenging in the present case.

The Orders Under Review

On June 4, 1982, the FDA published an order which it called a "Final rule", in which it announced that it was permanently listing D&C Green No. 5. 47 Fed. Reg. 24278-85. (Appendix, pp. ___). The announcement of the rule invited persons to file objections, and I filed objections dated July 1, 1982. On September 1, 1982, I filed Case Number 82-3544, in which I asked the Court to review the June 4 order of the FDA. The petition for review was filed under 21 U.S.C. 371.

On September 3, 1982, the FDA published a stay of the effective date of the June 4 order. 47 Fed. Reg. 38883-84 (September 3, 1982). On November 2, 1982, the FDA published an order terminating the stay and confirming the original

effective date of the rule listing D&C Green No. 5. 47 Fed. Reg. 49628-32 (November 2, 1982)(Appendix, pp. ___). I filed Case No. 82-3759 on November 26, 1982, challenging the November 2 order.

This Court has ordered that cases 82-3544 and 82-3759 be consolidated, and it is the consolidated case which now comes before the Court for its decision.

ARGUMENT

1. The Orders Of The FDA Violate The Delaney Clause.

Color additives are regulated under the Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq. This statute contains a very important clause, commonly known as the Delaney Clause, which states in part:

> A color additive (i) shall be deemed unsafe, and shall not be listed, for any use which will or may result in ingestion of all or part of such additive, if the additive is found by the Secretary to induce cancer when ingested by man or animal, or if it is found by the Secretary, after tests which are appropriate for the evaluation of the safety of additives for use in food, to induce cancer in man or animal, and (ii) shall be deemed unsafe, and shall not be listed, for any use which will not result in ingestion of any part of such additive, if, after tests which are appropriate for the evaluation of the safety of additives for such use, or after other relevant exposure of man or animal to such additive, it is found by the Secretary to induce cancer in man or animal ...
> [21 U.S.C. 376(b)(5)(B)]

There is no doubt that D&C Green No. 5 is a carcinogenic mixture. Adding D&C Green No. 5 to drugs and cosmetics means adding carcinogens to drugs and cosmetics. It means exposing consumers to the risk of cancer. This is undeniably true because D&C Green No. 5 contains p-toluidine as one of its components, and the FDA admits that p-toluidine is carcinogenic. 47 Fed. Reg. 24279 (June 4, 1982) (Appendix, p. ___).

Under the Delaney Clause a color additive must not be used if its use would expose consumers to the risk of cancer. It must not be used if its use would cause consumers to ingest carcinogens. Thus the listing of D&C

Green No. 5 is illegal.

The FDA has defended its action by arguing that p-toluidine is not a color additive. The FDA notes that under 21 U.S.C 321(t)(1) a color additive is a substance which is capable of imparting color. The FDA says p-toluidine does not impart color, and thus is not a color additive and is not subject to the Delaney Clause. 47 Fed. Reg. 24280 (June 4, 1982)(Appendix, p. ___).

The FDA's point is irrelevant. We are dealing here not with p-toluidine by itself, but rather with D&C Green No. 5. D&C Green No. 5 is a mixture of several chemicals. This mixture is capable of imparting color, is intended to impart color, and does impart color, and thus the mixture is undoubtedly a color additive. 21 U.S.C. 321(t)(1). Because the mixture contains a carcinogen, and use of the mixture will expose consumers to this carcinogen and the risk of ✓ cancer, the color additive cannot be legally listed.

My interpretation of the Delaney Clause is the only one which follows the established principles of statutory interpretation. The "natural way to interpret" a clause in a statute is "in light of the statutory purpose". Securities & Exchange Commission v. Ralston Purina Co., 346 U.S. 119, 124-125 (1953). This Court must follow "the well-accepted principle that remedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to

protect the public health..." United States v. An Article Of Drug ... Bacto-Unidisk, 394 U.S. 784, 798 (1968).

The purpose of the Delaney Clause is to protect consumers from cancer. To allow the use of D&C Green No. 5, knowing that it means exposing consumers to a carcinogen, would be to stand the Delaney Clause on its head.

The legislative history supports my interpretation of the Delaney Clause. The Delaney Clause was added to law governing color additives by the Color Additive Amendments of 1960. Pub. L. 86-618, 74 Stat. 397, July 12, 1960. The House Report on the bill which became law quotes with approval the testimony of the Secretary of Health, Education and Welfare, who asserted that the clause is "based on the simple fact that no one knows how to set a safe tolerance for substances in human foods when those substances are known to cause cancer when added to the diet of animals." H.R. Rept. 1761, 86th Cong., 2d Sess. (1960), at page 12. He also said that "no one can tell us with any assurance at all how to establish a safe dose of any cancer-producing substance." (Id., p. 13).

This indicates clearly that Congress did not intend to put the FDA into the business of setting "safe" tolerances for the carcinogen which is found in D&C Green No. 5. The FDA is now claiming the right to do that which Congress said could not be done.

The House Report also quotes with approval the following statement by the Secretary: "It is clear that if

we include in our diet substances that induce cancer when included in the diet of test animals, we are taking a risk. In the light of the rising number of cases of cancer, why should we take that risk? Why shouldn't the Government do everything possible to see to it that we do not involuntarily take that risk?" (Id., pp. 12-13).

Congress wanted a strong anticancer provision enacted into law. The House Committee rejected all proposals to change the clause, no matter how slightly, because "any of the proposals, if adopted, would weaken the present anticancer clause in the reported bill." (Id., p. 13)

Congress wrote a strong and tough anticancer clause, and now the FDA, by administrative decree, is trying to weaken it. I ask that this Court not allow the agency to undo what Congress has done.

The FDA says that the use of D&C No. 5 will only expose consumers to a small amount of carcinogen. The FDA has done a statistical study which allegedly proves that the risk from this level of exposure is very small. 47 Fed. Reg. 24283-84 (June 4, 1982)(Appendix, pp.___). The answer to the FDA's claim is contained in the legislative history quoted above, and in the following additional quote from the House Report: "No one at this time can tell how much or how little of a carcinogen would be required to produce cancer in any human being, or how long it would take the cancer to develop." (H.R. Rept. 1761, 86th Cong., 2d Sess. (1960) p.

12).

The FDA apparently believes that there is some sort of de minimus exception to the law, and the agency cites Monsanto v. Kennedy, 613 F. 2d 947 (D.C. Cir. 1979) in support of its position. The FDA is mistaken. Monsanto v. Kennedy has nothing to do with the definition of a color additive or the interpretation of the Delaney Clause. Nothing in Monsanto authorizes the FDA to disregard the Delaney Clause.

There is language in Monsanto which suggests that there is a de minimus exception to the definition of a food additive. 613 F. 2d at 955. The FDA cites this language in support of its position in the present case. However, that language has nothing to do with the Delaney Clause or color additives.

The notion that the FDA can disregard a statute, even in de minimus cases, is a very dangerous notion. It amounts to letting an administrative agency disregard the policy chosen by the Congress. For this reason, the language in Monsanto is probably in error. Even if Monsanto was correctly decided, the holding must be strictly limited to the facts of Monsanto.

We must remember the recent case of TVA v. Hill, 437 U.S. 153, 194 (1978), in which the Supreme Court said that it is emphatically the province of the Congress to formulate legislative policies and mandate programs. Once Congress, exercising its delegated powers, has decided the order of

priorities in a given area, it is for the Executive to administer the laws. (Id.). Congress, in the Delaney Clause, has declared that avoiding cancer has a higher priority than adding carcinogens to foods, drugs or cosmetics. The FDA has no choice but to follow this order of priorities.

If Congress had wanted to make a de minimus exception to the law, it would have written one into the statute. It did not do so. The legislative history indicates rather clearly that Congress did not want the FDA to alter the policy which the Congress established. The House Report quotes with approval from the testimony of the Secretary of Health, Education and Welfare, as follows: "Unless and until there is a sound scientific basis for the establishment of tolerances for carcinogens, I believe the Government has a duty to make clear - in law as well as in administrative policy - that it will do everything possible to put persons in a position where they will not unnecessarily be adding residues of carcinogens to their diet... Whenever a sound scientific basis is developed for the establishment of tolerances for carcinogens, we will request the Congress to give us that authority. We believe, however, that the issue is so important that the elected representatives of the people should have the opportunity of examining the evidence and determining whether or not the authority should be granted." (Id., emphasis added).

2. The Orders Of The FDA Also Violate The General Safety Clause.

In addition to the Delaney Clause, the statute which governs color additives contains a clause known as the "general safety clause", which states in part:

> The Secretary shall not list a color additive under this section for a proposed use unless the data before him establish that such use, under the conditions of use specified in the regulations, will be safe ... [21 U.S.C. 376(b)(4)]

The FDA apparently believes that it has the power to establish a "safe" level of exposure to a carcinogen under this clause. Again the FDA is mistaken.

The legislative history indicates that Congress did not believe it was possible to establish a safe level of exposure to a carcinogen. It is worth repeating some of the statements contained in the House Report on the Color Additive Amendments of 1960. The Secretary of Health, Education and Welfare was quoted with approval as saying "No one at this time can tell how much or how little of a carcinogen would be required to produce cancer in any human being, or how long it would take the cancer to develop." H.R. Rept. 1761, 86th Cong., 2d Sess. (1960), at page 12.

Congress did not give the FDA any discretion to set tolerances for carcinogens. The House Report goes on to quote the Secretary as saying "Whenever a sound scientific basis is developed for the establishment of tolerances for carcinogens, we will request the Congress to give us that

authority. We believe, however, that the issue is so important that the elected representatives of the people should have the opportunity of examining the evidence and determining whether or not the authority should be granted." (Id.) The FDA is trying to take power which the elected representatives of the people did not choose to give it.

CONCLUSION

For the above reasons, this Court should hold that the actions of the FDA are contrary to law.

Respectfully submitted,

Glenn M. W. Scott
P.O. Box 270
Owensboro, Ky. 42302