

IN THE MATTER OF

STERLING DRUG, INC., ET AL.

MODIFYING ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF SEC. 5
OF THE FEDERAL TRADE COMMISSION ACT*Docket 8899. Final Order, Oct. 1, 1974—Modifying Order, March 11, 1983*

This order reopens the proceeding and modifies the Commission's order issued on Oct. 1, 1974 (84 F.T.C. 547). The modified order permits respondents to make claims that environmental surfaces play a significant role in the transmission of viruses and bacteria associated with colds and that household disinfectants can reduce the incidence or prevent the spread of colds, if supported by competent and reliable scientific evidence.

ORDER REOPENING THE PROCEEDING AND
MODIFYING CEASE AND DESIST ORDER

On September 20, 1982, Sterling Drug, Inc. and SSC&B, Inc., respondents in the above-captioned matter, filed a petition pursuant to Rule 2.51 of the Commission's Rules of Practice to reopen the proceeding and modify the consent order entered therein. By letter dated January 17, 1983, respondents agreed to modify their original proposal.

The consent order, which was issued in 1974, applies to Lysol or any other household disinfectant products. Sterling Drug manufactures and markets Lysol Brand Disinfectants. SSC&B prepared and distributed the advertising for Lysol Brand Disinfectants which was challenged in the complaint. The advertising represented that Lysol Brand Disinfectants could be used to kill influenza viruses and other germs and viruses on environmental surfaces and in the air, and that such use would be of significant medical benefit in reducing the incidence or preventing the spread of colds, influenza, and other upper respiratory diseases within the home. However, the prevailing view among scientists at the time the advertising was disseminated was that airborne germs and viruses were the known cause of most colds, influenza, and other upper respiratory diseases, that germs and viruses on environmental surfaces did not play a significant role in the transmission of colds, influenza, and other upper respiratory diseases, and that Lysol Brand Disinfectants would not be of medical benefit in reducing the incidence or preventing the spread of these diseases. Consequently, paragraphs I.A and I.B of the consent order prohibited the following claims:

Modifying Order

101 F.T.C.

A. environmental surfaces play a significant role in the transmission of viruses or bacteria associated with influenza, colds, or streptococcal throat infection;

B. use of any household disinfectant product will be of medical benefit in reducing the incidence or preventing the spread of influenza, colds, or streptococcal throat infection.¹

In their petition, respondents allege that there has been a dramatic change in scientific opinion since the order was issued in 1974 with respect to the manner in which colds are transmitted. Consequently, they request a change in those provisions of paragraphs I.A. and I.B. of the order which relate to colds.² The request, as set forth in the letter of January 17, 1983, is that those paragraphs be changed to prohibit the following claims:

A. 1. environmental surfaces play a significant role in the transmission of viruses or bacteria associated with influenza or streptococcal throat infection;

2. environmental surfaces play a significant role in the transmission of viruses or bacteria associated with colds unless respondent[s] making such representation has [have] and relies [rely] on competent and reliable scientific evidence that environmental surfaces play a significant role in the transmission of viruses or bacteria associated with colds;

3. it has been established that environmental surfaces play a significant role in the transmission of viruses or bacteria associated with colds, unless such representation is true.

B. 1. use of any household disinfectant product will be of medical benefit in reducing the incidence or preventing the spread of influenza or streptococcal throat infection;

2. use of any household disinfectant product will be of medical benefit in reducing the incidence or preventing the spread of colds, unless respondent[s] making such representation has [have] and relies [rely] on competent and reliable scientific evidence that such use will be of medical benefit in reducing the incidence or preventing the spread of colds;

3. it has been established that use of any household disinfectant product will be of medical benefit in reducing the incidence or preventing the spread of colds, unless such representation is true.

Respondents presented impressive evidence indicating that most scientists no longer believe that "airborne germs and viruses are the known cause of most colds," as paragraph 9 of the complaint filed in

¹ The order also contains certain other provisions discussed below.

² In their petition, respondents also requested a change in order provisions relating to influenza and streptococcal throat infection. However, by letter dated January 17, 1983, they modified their request. As modified, the request does not seek a change in the existing prohibitions on claims relating to the role of environmental surfaces in the transmission of these diseases or the use of household disinfectants in reducing the incidence of preventing the spread of these diseases.

this matter indicates they did in 1974.³ Rather, there is mounting scientific evidence that, at least for rhinoviruses (which are the major cause of colds in adults), hand contamination with virus and subsequent self-inoculation with the virus may be a more important route of infection than the airborne route.⁴ Similar findings have been made for respiratory syncytial virus, the major cause of colds in children.

The evidence indicates that hands can become contaminated with virus in two ways—through contact with viruses on the skin of another person or through contact with viruses which have survived on environmental surfaces. Evidence has been presented which indicates that rhinoviruses can survive for as long as three or four days on environmental surfaces, and respiratory syncytial viruses for as long as six hours. The evidence indicates that most scientists are no longer certain that “germs and viruses on environmental surfaces do not play a significant role in the transmission of colds,” although paragraph 9 of the complaint indicates they did believe this proposition in 1974.⁵ Furthermore, while there is certainly controversy on the subject, some eminent scientists have taken the affirmative position that environmental surfaces probably do play some role in the transmission of colds.⁶ Finally, while some scientists still support the statement set forth in paragraph 9 of the complaint that disinfectants “will not be of significant medical benefit in reducing the incidence or preventing the spread of colds,” some eminent scientists have said that the use of disinfectants may be of benefit.⁷

Thus, we are presented with a change in scientific opinion with respect to issues on which the complaint and order in this matter were based. Most of these issues are now controversial, and there are reputable scientists on both sides of the controversy. We believe that an absolute ban on claims for which there may be reputable scientific support is inappropriate. On the other hand, we believe that such claims must not be made in such a way that they assert or imply that the propositions in question have been established to the satisfaction of the scientific community, unless such is the case.⁸ Consequently, we

³ See, *Sterling Drug, Inc.*, 84 F.T.C. 547, 551 (1974).

⁴ Indeed, the evidence indicates that experimenters have been unable to demonstrate that it is possible to transmit a rhinovirus cold via the airborne route.

⁵ 84 F.T.C. at 551.

⁶ See, e.g., letter of December 2, 1982 to Ernst Zander, M.D. from R. Gordon Douglas, Jr., M.D., Professor and Chairman, Department of Medicine, New York Hospital-Cornell Medical Center; letter of Jan. 7, 1983 to Ernst Zander, M.D., from Robert B. Couch, M.D., Professor of Microbiology and Immunology and Medicine, Baylor College of Medicine. It should be noted that Doctors Douglas and Couch were both designated by complaint counsel as witnesses in the trial scheduled in 1973 for this matter. (Neither testified since the matter was settled before trial.) Both have obviously changed their opinions on the relevant issues since that time.

⁷ *Id.*

⁸ See, e.g., *American Home Products Corporation*, D.8918 (Sept. 9, 1981), modified, No. 81-2920 (3rd Cir. Dec. 3, 1982); *National Commission on Egg Nutrition*, 88 F.T.C. 89 (1976), modified, 570 F.2d 157 (7th Cir. 1977), cert. denied, 439 U.S. 821 (1978).

have modified the order to allow claims that environmental surfaces play a significant role in the transmission of viruses or bacteria associated with colds to be made if they are supported by competent and reliable scientific evidence. Similarly, we have modified the order to allow claims that the use of a household disinfectant will be of medical benefit in reducing the incidence or preventing the spread of colds to be made if they are supported by competent and reliable scientific evidence. However, claims that either of these propositions have been established can only be made if it is true that the propositions have been established.

In addition, in the letter of January 17, 1983, respondents have requested that we modify section I.D. of the order "for uniformity of language" with sections I.A. and I.B., as modified. Paragraph D, as presently written, prohibits any representation that

D. use of any household disinfectant product kills germs associated with disease[s], unless such representation expressly mentions the name[s] of the disease[s]; the representation is true; and respondent[s] making such representation has [have] competent and reliable scientific evidence that such use reduces the incidence or prevents the spread of the named disease[s].

The change requires that a respondent can only make the claims listed in paragraph I.D. if it has and *relies on* competent and reliable scientific evidence for the claims. We believe this is a desirable change which will clarify the meaning of paragraph I.D. of the order.

Finally, respondents requested in their petition that paragraph I.E. of the order be modified to eliminate the requirement that any representation that "use of any household disinfectant kills viruses associated with influenza, colds, streptococcal infection, staphylococcal infection, or other respiratory diseases" must be accompanied by a statement that "there is no evidence that the product portrayed will protect the family against flu or strep throat." (This request is unchanged by the letter of January 17, 1983). Respondents point out that paragraph I.D. of the order guarantees that no representation that a product kills cold viruses will be made unless there is scientific evidence that the product is of benefit in preventing the spread or reducing the incidence of colds. Respondents contend that "[s]uch a well-founded and substantiated statement about *colds* would be confused, not clarified, by a disclaimer directed to other more serious diseases," and that the existing I.E. "would impose an unwarranted and confusing burden upon valid and useful statements reflecting the new scientific knowledge and opinion on colds." Petition, p.20. We agree that the disclosure required by I.E. is not necessary in advertisements relating only to colds. Consequently, we have modified I.E. so as to delete this requirement.

It is therefore ordered, That the proceeding is hereby reopened and the Decision and Order issued October 1, 1974 in Docket No. 8899 is hereby modified to read as follows:

ORDER

I

It is ordered, That respondents Sterling Drug Inc., a corporation, and SSC&B, Inc., a corporation, their successors and assigns and their officers, agents, representatives and employees, directly or through any corporation, subsidiary, division, or other device, in connection with the advertising, offering for sale, sale or distribution of Lysol Brand Products or any household disinfectant product, shall forthwith cease and desist from representing, directly or by implication, that:

A. 1. environmental surfaces play a significant role in the transmission of viruses or bacteria associated with influenza or streptococcal throat infection;

2. environmental surfaces play a significant role in the transmission of viruses or bacteria associated with colds unless respondent[s] making such representation has [have] and relies [rely] on competent and reliable scientific evidence that environmental surfaces play a significant role in the transmission of viruses or bacteria associated with colds;

3. it has been established that environmental surfaces play a significant role in the transmission of viruses or bacteria associated with colds, unless such representation is true.

B. 1. use of any household disinfectant product will be of medical benefit in reducing the incidence or preventing the spread of influenza or streptococcal throat infection;

2. use of any household disinfectant product will be of medical benefit in reducing the incidence or preventing the spread of colds, unless respondent[s] making such representation has [have] and relies [rely] on competent and reliable scientific evidence that such use will be of medical benefit in reducing the incidence or preventing the spread of colds.

3. it has been established that use of any household disinfectant product will be of medical benefit in reducing the incidence or preventing the spread of colds, unless such representation is true.

C. use of any household disinfectant product kills airborne viruses or bacteria associated with influenza, colds, streptococcal throat infection, or other upper respiratory disease, *provided*, that nothing in this

subparagraph shall be construed to otherwise restrain demonstrations of aerosol products as room deodorizers or air fresheners;

D. use of any household disinfectant product kills germs associated with disease[s], unless such representation expressly mentions the name[s] of the disease[s]; the representation is true; and respondent[s] making such representation has [have] and relies [rely] on competent and reliable scientific evidence that such use reduces the incidence or prevents the spread of the named disease[s];

E. use of any household disinfectant product kills viruses or bacteria associated with influenza, streptococcal infection, staphylococcal infection, or other upper respiratory diseases other than colds, unless the advertisement in which such representation appears clearly and conspicuously discloses that there is no evidence that the product portrayed will protect the family against flu or strep throat, *provided*, that nothing in this subparagraph shall be construed to apply to a representation that Lysol Brand Disinfectants kill bacteria which cause streptococcal or staphylococcal skin infections.

II

It is further ordered, That nothing herein contained shall be construed to require any alteration of, or deletion from the labeling of any of Sterling's household disinfectant products of legends, claims or information heretofore specifically accepted by the Environmental Protection Agency or its predecessor agency pursuant to the Federal Insecticide, Fungicide and Rodenticide Acts, as amended, 7 U.S.C. 135, *et seq.*

III

It is further ordered, That respondents notify the Commission at least 30 days prior to any proposed change in the corporate respondent such as dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change in the corporation which may affect compliance obligations arising out of this order.

It is further ordered, That respondents forthwith distribute a copy of this order to each of its operating divisions or subsidiaries involved in the advertising, promotion, distribution or sale of Lysol Brand Disinfectants.

It is further ordered, That the foregoing modification shall become effective upon service of this order.

SEPARATE STATEMENT OF CHAIRMAN JAMES C. MILLER III

I concur in the Commission's unanimous decision to modify the existing order in this matter and require a reasonable basis for Sterling's advertising claims for Lysol. Sterling will now be permitted to make truthful claims, subject to proper substantiation, that environmental surfaces can play a significant role in transmitting colds and that using a household disinfectant may reduce the incidence or prevent the spread of colds.

Sterling has presented to the Commission a significant amount of new scientific evidence on how cold viruses are spread. This evidence represents a change in the facts underlying the original order and forms the justification for the current modification. In 1974, when the Commission issued the original order, the prevailing view in the scientific community was that airborne germs and viruses were the primary cause of colds. Accordingly, the Commission prohibited any claims that environmental surfaces play a significant role in transmitting colds, and that using household disinfectants such as Lysol can help prevent colds.

Sterling's detailed petition indicates that, contrary to the Commission's premise in bringing this case, there is a substantial body of reputable scientific evidence indicating that environmental surfaces play a significant role in spreading colds. Indeed, at least two of the three experts on whom the Commission relied in bringing the case now support Sterling's position. Moreover, no one disputes that Lysol effectively cleans environmental surfaces. Although Sterling's evidence does not show, nor have they claimed, that spraying Lysol absolutely prevents colds, this should not preclude Sterling from making properly qualified, substantiated efficacy claims.

In moving from a total prohibition of certain claims to allowing those for which there is a reasonable basis, I believe the Commission is recognizing that Sterling currently has a reasonable basis for making some advertising claims concerning the product's effectiveness. If a majority of the Commission did not agree with this, it would have been more appropriate to deny the order modification. Of course, the Commission has not seen any specific advertising claims, and we will scrutinize any Sterling claim to be certain it is substantiated.

As with most medical and many other types of claims, absolute certainty is not feasible. The proper role of the Federal Trade Commission is not to ban all claims unless they can be shown to be true beyond a shadow of a doubt,¹ but to weigh the costs and benefits of

¹ As the Commission indicated in *Pfizer*, 81 F.T.C. 23, 64 (1972), the amount of testing necessary to support a claim depends on the circumstances, including the type of claims, the cost of obtaining the supporting evidence, and the possible consequences of a false claim. Particularly given Commissioner Pertschuk's description of the testing procedure here, obtaining empirical evidence of absolute proof of efficacy would be far more costly than the attendant risks and benefits warrant.

allowing or banning the dissemination of information about which some uncertainty may exist. Here, if the Commission allows claims for which there is a reasonable basis and they are later determined to be false, consumers are injured only to the extent of the cost of their Lysol purchases.² If the Commission bans the claims and they turn out to be *true*, consumers will be prevented from learning of an effective method to reduce the incidence and spread of colds, America's most prevalent disease.

Sterling has made a strong showing that its theory of how colds are spread is valid, and that the Commission's theory in bringing this case is not. Sterling has also provided evidence that Lysol kills cold viruses. Therefore, Sterling should be permitted to make adequately substantiated claims at least on these two points. Prohibiting such claims, as Commissioner Pertschuk apparently prefers (although he supported the change) would not strengthen the advertising substantiation doctrine. It would instead deprive consumers of valuable, truthful information.

SEPARATE STATEMENT OF COMMISSIONER MICHAEL PERTSCHUK

Sterling wants out of a 1974 consent order which prohibits it from claiming that spray Lysol can prevent colds. It says that it now has proof that, contrary to prior scientific understanding, cold viruses can be picked up from environmental surfaces and that Lysol can help prevent colds by killing surface viruses. It now seeks to modify the order to permit it to claim that Lysol can help prevent colds.

I have reluctantly voted in favor of the order modification, simply because the only alternative under consideration by a majority of the Commission would have eroded the advertising substantiation doctrine even further. At the very least, Sterling is cautioned by the Commission letter accompanying the modified order that the modification in no way indicates that Sterling in fact presently has a "reasonable basis" for any claim, express or implied, that Lysol actually prevents colds.

The Commission's concern (however mildly expressed in the letter) is well-founded. The primary piece of evidence which Sterling cites is a study, partly funded by Sterling, conducted by two eminent scientists at the University of Virginia. They directed volunteers with colds to blow their noses on their hands and wipe them on some plastic tiles. Ten minutes later, some tiles were given a three second shot of Lysol; others were not. After fifteen minutes, healthy volunteers were directed to rub their fingers on the tiles, and then pick their noses and rub their eyes. Lo and behold, about half of the healthy volunteers

² Because the product has other values, the expenditures will not be totally wasted for many consumers.

touching the untreated tiles got colds; fewer got colds from touching the tiles that had been sprayed with Lysol, although the results were not statistically significant.

Largely on the basis of this laboratory evidence, demonstrating simply that Lysol killed cold viruses on surfaces that otherwise might be transmitted to people, at least some scientists are now of the opinion that Lysol "may" be of value in reducing colds in the home environment, on the logical assumption that a reduction in the number of viruses will lead to a reduction in colds. Most scientists, however, remain skeptical. They note that, while Lysol might work in *theory*, there's just no *proof* that in fact it does—and reason to think it doesn't. Laboratory results might well be meaningless in the home environment, which is, of course, the only environment consumers care about. (After all, any family that duplicates the bizarre laboratory procedure described above in its own home needs more than a shot of Lysol to solve its problems.) Practical constraints that exist in home environments limit the applicability of the findings. For example, household surfaces are continually being re-infected. Many surfaces which harbor viruses—like skin and clothing—can't be safely sprayed. And perhaps more fundamentally, scientists just don't know the *significance* of the role of surface contamination. Assigning a family member the chore of spraying doorknobs and telephones every ten minutes just isn't likely to be of much help when other sources of cold viruses—such as direct contact with people with colds—may be even more likely to cause colds.

The modified order would require Sterling to prove that an unqualified medical efficacy claim, such as "Lysol reduces the incidence of colds," is in fact recognized by the scientific community to be an established fact. The effect of this standard is properly to prohibit such claims, since it is evident that there is simply no proof that Lysol works to reduce colds. All that Sterling has is an unproved theory.

Nevertheless, apparently motivated by the belief that *all* information has inherent value, the Commission has modified the Order to permit Lysol to make certain "qualified" claims, as long as those claims are supported by "competent and reliable scientific evidence"—in other words, a reasonable basis. In my opinion, the only claim for which Sterling has a reasonable basis goes something like this: "While many scientists disagree, some scientists are of the opinion that in certain circumstances, Lysol may, with an unknown probability, reduce the incidence of colds to an unknown extent in a home environment."

The mischief with this elegant formulation is that the only claims which Sterling is actually likely to make in a typical 30-second television ad will fall far short of giving consumers the complete context

they need to properly interpret the claim. After all, Sterling isn't interested in making these claims to educate the public to the possible health hazards of cold viruses harboring on doorknobs and countertops. It wants to make them to sell more Lysol.

Simply put, any "qualified" claim Sterling is likely to make by permission of the revised order must invariably make an implied claim that Lysol reduces colds—precisely the claim for which Sterling lacks proof. As a result, such "qualified" claims have a capacity to mislead which far outweighs their capacity to inform. For that reason, I would have preferred to retain the existing prohibitions on making even qualified claims. As an alternative, I would have been willing to support these modifications with a letter that plainly stated that Sterling presently does not have a reasonable basis for any claim, express or implied, that Lysol reduces colds.

I would note, however, that even under the modified order, the burden will be on Sterling to make sure that their "qualified" claims do not make an implied claim that Lysol reduces the incidence of colds. To that end, Sterling would be well-advised, to the extent that it wishes to avoid making any implied efficacy claims when it makes the qualified claims permitted by the order modification, to disclose that Lysol has not been proven to reduce colds in actual home settings.

IN THE MATTER OF

THOMPSON MEDICAL COMPANY, INC.

Docket 9149. Interlocutory Order, March 11, 1983

ORDER ON RESPONDENT'S APPLICATION FOR INTERLOCUTORY REVIEW

It has long been the Commission's policy to provide to the respondents in its administrative proceedings copies of all prior statements of complaint counsel's witnesses, for use in cross-examination. *Inter-State Builders, Inc.*, 69 F.T.C. 1152 (1966); *Ernest Mark High*, 56 F.T.C. 625 (1959). While the Commission is not bound by the Jencks Act, 18 U.S.C. 3500, or compelled to adhere to its principles, it does look to court decisions interpreting it for guidance in enforcing its own policy. *USLife Credit Corp.*, 91 F.T.C. 984, 1036-37 (1978).

On April 30, 1979, the Federal Rules of Criminal Procedure were amended, effective December 1, 1980, to require the production of "Jencks-type" prior statements of *all* witnesses (except the defendant) in criminal trials, on motion of the opposing party. Fed.R.Crim.P. 26.2(a), 18 U.S.C. Rule 26.2 (1982 Supp.). On July 5, 1982, the trial in this proceeding began. On July 30, 1982, complaint counsel moved for an order directing respondent to produce Jencks-type statements of its witnesses, consistent with the amended Rules. The Administrative Law Judge ("ALJ") concluded on August 19, 1982, that the circumstances of this particular case justified an order for the production of such statements by respondent's *expert* witnesses. On September 15, 1982, respondent applied for review of the order, and on October 21 the ALJ certified the review to the Commission under Section 3.23(b) of the Commission's Rules of Practice, 16 U.S.C. 3.23(b), as involving a controlling question of policy as to which there is substantial ground for differences of opinion. The ALJ further concluded that immediate appeal may materially advance the ultimate disposition of the litigation. The trial continued, with respondent tendering all required statements of its expert witnesses, subject to an agreement that this would not be deemed a waiver of respondent's rights to pursue its appeal. On December 17, 1982, respondent completed the presentation of its witnesses.

The Commission has determined to grant review of the order because it presents a controlling question of policy on which the Commission has as yet provided no guidance, and there is substantial ground for differing views. Furthermore, resolution of the question will facilitate the ultimate resolution of this case.

In establishing the defendant's right to examine and use in cross-