THE COST OF GETTING NOWHERE AT THE FTC

Bruce Yandle

IN A THIRTY-MINUTE public meeting on February 11, 1981, the five members of the Federal Trade Commission (FTC) unanimously rejected a proposed trade regulation rule governing the advertising of over-the-counter drugs. Thus ended a proceeding that had run for five years and three months, at immense cost to all involved. The FTC had devoted 19,058 staff hours to it (through 1979), and paid an additional $61,000 for the expenses of "public interest" participants. One trade association representing a combination of interests had spent over $2 million in administrative and legal costs, and other associations had spent lesser, but still significant, amounts. The record generated by this effort included 4,230 pages of hearing transcript, 2,300 pages of documents submitted by FTC staff, and 6,000 pages of statements, exhibits, and rebuttal comments by outsiders. The informal hearings alone lasted more than a month and included the testimony of some fifty expert witnesses of various kinds.

On first reading about the decision, one may have an impulse to feel grateful that the commission declined an opportunity to issue a bad rule. The expenditure of so much time and money could easily have created a strong bias to do something—anything—to justify it. But the impulse should be suppressed, for it only shows how completely mistrust has come to dominate one's expectations about regulatory procedures. There are many ideas for regulation in the world and so many of them are wrong that weeding out bad proposals should be routine business for agency regulators—not deserving of much acclaim.

The most important issues here concern not the final result, but how the FTC got there. More precisely, there are two main questions: (1) What did the FTC know at the end that it did not know at the beginning? In other words, was the long proceeding necessary to the final decision? (2) Did the proceeding settle anything? That is, can one be confident that the agency has incorporated the principles that led to rejection into any general policy or even into its institutional memory?

The answers seem to be, respectively, "nothing" and "no." This is especially troubling because the rulemaking was conducted under the procedures of the Magnuson-Moss Act of 1975, which require the FTC to conduct oral hearings, to allow cross-examination and rebuttal with respect to crucial facts, and to engage in various kinds of economic analysis. The theory of the Magnuson-Moss procedures—similar to that of many current proposals for general regulatory reform—is to allow interested persons to test the commission's facts and concepts, thus improving its factual base and its decisions as well. If, in practice, such procedural requirements produce nothing but expensive records unrelated to any final decision, that fact is worth thinking about.

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The Proposed Rule

The FTC's rulemaking was announced on November 11, 1975. It was an outgrowth of a program at the Food and Drug Administration (FDA) to review all over-the-counter (OTC) drugs, with an eye to banning the ineffective ones and, for the others, prohibiting the use on product labels of claims found not to be scientifically supportable.* The FTC reasoned, in accord with its long-standing insistence that advertising claims be substantiated, that if the FDA decides not to allow drug makers to make a certain claim on their labels, the FTC should not allow them to make it in their general advertising to the public. Thus the FTC proposed a rule forbidding any claim in the advertising of an OTC drug that the FDA commissioner "has determined . . . may not appear in the labeling of such drug."

Only a month after the FTC launched the proceeding, the Bureau of Consumer Protection (which had instigated the rulemaking) moved toward a strict interpretation of the language quoted above. Instead of simply requiring that advertisers use language whose substance reflects label claims with sufficient accuracy, the staff concluded that nothing but the exact label language emerging from the FDA's OTC reviews should be acceptable under the rule. As the FTC's assistant director for national advertising described the idea at a conference in December of that year, the commission's proposed rule

> would have the same effects as [the FDA's]. With respect to antacids, it would prohibit advertisers from stating indications for use other than those enumerated by FDA, and from using language other than the language set forth by [the FDA].

This interpretation made the proceeding an exercise in semantics, an inquiry into the nature of synonymy. If many alternative wordings convey to the consumer the same impression as those chosen by the FDA, it would be hard for the commission to argue that those alternatives were deceptive or their use unfair. At the limit, the FTC staff needed to establish the unique nature of every word that drug advertisers are likely to use, while its opponents needed to establish the almost infinite number of ways in which one can make truthful claims.

In a less-than-sparkling beginning for an inquiry into linguistic clarity, the FTC's proposed advertising regulation dated September 16, 1976, set forth the issues as follows:

> (1) In general, what is the likelihood that there is terminology, or that terminology can be devised, that will mean the same to consumers as the terminology approved by the Food and Drug Administration?
>
> (2) If there is or can be devised such terminology, will advertisements utilizing that terminology be likely to convey the same meanings to consumers as (a) the Food and Drug Administration approved terminology or (b) the same advertisements using only the Food and Drug Administration approved terminology?
>
> (3) Are measures available to establish that advertisements utilizing those terms will convey to consumers the same meaning as (a) the Food and Drug Administration approved terminology or (b) the same advertisements using only the Food and Drug Administration approved terminology?

Let Me Call You Hyperosmotic

Under the strict interpretation, in other words, the vocabulary choice available to advertisers would be frustratingly narrow. For example, after its review of antacids the FDA approved just four terms—"antacid," "heartburn," "acid indigestion," and "sour stomach"—for antacid labeling. Thus the FTC would police ad copy for nuances of meaning not present in those terms; and it would be a civil offense carrying a $10,000 penalty for a manufacturer to tell consumers through advertising that its antacid "relieves stomach misery due to excess stomach acid" or "relieves excess gastric acidity."

Consumers, for their part, might find some of the "deceptive" phrases more informative and useful than the approved phrases. Among the terms approved by the FDA for label claims are "antiflatulent," "antiemetic," "antitussive," and "hyperosmotic." According to a psychologist testifying for the OTC drug industry, survey data indicate that only 14 percent of the adult population understand "antiemetic," and even fewer understand "antitussive." Former

*The FDA began this program in 1972 and has now completed its review of about a dozen of the seventy-odd categories involved.

FDA Commissioner Sherwin Gardner, testifying in the proceeding, suggested that the use of such words in advertising might itself be deceptive, an example of the very abuse the FTC was intended to eliminate.

The FTC staff ultimately dismissed such concerns, arguing that the FDA always allowed a more colloquial version of technical terms in its label claims—"antitussive" could be rendered as "temporarily helps you cough less," for example—and that in any case manufacturers could petition the FDA for approval of new terms. The first of these contentions, while still offering a restriction on language, has some weight, even though it depended completely on the assumption that the FDA would act judiciously in the future (since the FTC rule was to cover products not yet reviewed by the FDA). The second contention, while accurate, offered little relief. The FDA program was (and is) an extraordinarily slow and expensive effort; alternative language could be proposed, but how long the FDA would take to decide would be anybody's guess.

Opponents of the rule also emphasized the informative purpose of advertising and tried to educate the FTC about contemporary thinking on the economics of consumer information. Testimony by economists portrayed advertising messages as primarily invitations to consumers to investigate further if they were interested in the product. Heavy technical language is not appropriate in such a context. Labeling language, on the other hand, was described as having a different purpose in this scheme: to allow the consumer whose interest has been aroused to gain precise technical information about a product and to compare one product with another. The permanence of labels also allows a consumer to review information at the time of possible use, when exact information is most important. The unrestricted use of truthful information is necessary, these witnesses asserted, if advertising is to be effective in reducing consumer search costs and increasing consumer benefits in the OTC drug market.

Economists arguing for the FTC view conceded that advertising is beneficial in some cases, but noted that it can also confuse and mislead consumers. They went on to suggest, without any particular empirical support, that OTC drug advertising was especially weak on this score. Industry witnesses countered that such deception is inimical to the self-interest of advertisers. Success in the OTC drug market depends on inducing repeat purchases of low-priced products, with advertising serving to inform the consumer of the product's existence and to get him or her to try it out. A customer who tries it and then feels cheated does not buy it again, does not buy the company's other products, and tells others about it to boot. Intelligent advertisers understand the importance of investment in reputation, even if the FTC does not.

After 1976, when the Supreme Court decided *Virginia State Board of Pharmacy* v. *Citizens Consumer Council*, opponents of the rule could invoke not only economic analysis but also constitutional doctrine. Before that decision commercial speech had generally been regarded as outside the protection of the First Amendment. In *Virginia Pharmacy* the Court made clear that commercial speech—advertising, to be exact—does have at least some constitutional protection. In the advertisers' view, this meant that the FTC could not suppress truthful claims whether or not they accorded with the FDA language.

Staff Recommendations

On May 22, 1979, the Bureau of Consumer Protection's staff made its final recommendation in the form of two versions of the rule—a first and a second choice. The staff was unpersuaded by all the arguments against the rule and continued to favor, as its first choice, the strict interpretation first presented in December 1975. The proposed rule said:

> In an ad for an OTC drug, you can make express or implied indication-for-use claims . . . only if the FDA . . . would allow you to make the same claims on the label of that drug. This means you cannot make claims the FDA has specifically disapproved. It also means that if the FDA only allows indication-for-use claims that use the specific terms it has approved, these are [the] only terms you can use to make indication-for-use claims in your ads.

Virginia Pharmacy did not affect the staff's opinion. The staff report emphasized that the Court's ruling had sought to protect only "truthful and legitimate commercial information," and had specifically endorsed the "elimi-

nation of false and deceptive claims." This was thought to be enough to make *Virginia Pharmacy* irrelevant. In FTC practice, an ad need not actually deceive consumers to be deceptive; it is sufficient if, in the commission's expert opinion, the ad has a "tendency or capacity" to deceive. Since it would be difficult for anyone to show that an OTC drug advertising claim phrased in words other than those approved by the FDA conveyed exactly the same impression to consumers, any use of alternative words would have this tendency or capacity. In FDA logic, this made their use deceptive and thus outside the protection of the First Amendment, even if a particular claim was in fact true. Citing other case law, the staff went on to say that the proposed rule supported an "important or substantial governmental interest . . . unrelated to the suppression of free expression," which was that OTC drugs be safe and effective.

As its second choice rule, the staff recommended that if the commission were inclined to let the industry use words not approved for labels, it should at least require prior substantiation of claim terminology. The staff report set forth details of a statistical procedure for drug makers to use for this purpose.

Dissent from Within

Although a staff recommendation might be thought to reflect a consensus within the FTC, this turned out not to be the case. On December 15, 1980, a memorandum from the Bureau of Economics recommended against adopting a rule on the grounds that the benefits were speculative and the costs appreciable. The bureau's analysis discussed the differences in the economic function of labels and advertisements and then addressed the central controversy of the proceeding—restrictions on truthful advertising. "The cost of adopting staff's preferred rule," it said, "is that it will inevitably prohibit some truthful and useful information." For example, the FDA's proposed language for analgesics prohibited references to specific aches and pains, so that under the recommended FTC rule advertisers could not say that aspirin is good for muscle aches, a clearly truthful statement. The memorandum also noted the anticompetitive effects of forbidding firms to differentiate products by describing truthfully the benefits to be received by the user.

On the same day, the director of the Bureau of Consumer Protection (who supervises the rulemaking staff) weighed in with even stronger criticism, stressing several interesting points: (1) The record showed little, if any, evidence that OTC drug advertising had led to misuse or injury. (2) The FTC had intended that its proceeding would parallel the FDA's OTC drug review process. In fact, the FDA had completed a final monograph for only one class of drugs (antacids), so the FTC was in the position of developing rules for words that had not yet been defined by the FDA. This made it impossible to show that noncompliance with FDA language was widespread. (3) The staff's alternative recommendation that advertisers be allowed to convey claims to consumers in any manner so long as the words chosen communicated the same message to consumers as the FDA language gave inadequate guidance to both the advertisers and the commission. The bureau's director recommended that the proceeding be either suspended until the FDA finished its work or terminated without action.

The record showed little, if any, evidence that OTC drug advertising had led to misuse or injury.

The Last Hearing

Under the FTC's rules of practice for rulemaking, interested parties have one last opportunity to state their case in oral presentations to the assembled commissioners. The hearing on this proposal, held January 28, 1981, focused on the some questions that had been debated since the beginning, almost as if the entire long proceeding had never occurred.

The attorney for the industry spoke of the benefits to health care provided by OTC drugs, the lack of any evidence of deceptive practices in the industry's advertising, and the differing functions of label and advertising language. Commissioner Paul Rand Dixon seemed to agree: "It is kind of crazy for us right now to write any kind of rule, guessing what is going to be in FDA monograph No. 47." Commissioner Robert Pitofsky entered the discussion. "They say you should not describe a product as

a cold remedy." But why not, he asked. "Products have been described as cold remedies as long as I can remember. Who is harmed when a product is described as a cold remedy when in fact it treats the symptoms but not the cold?" Pitofsky turned to an example to make his point:

> As I understand it, if we promulgated the preferred rule in the advertising campaign, "Give your cold to Contac" would be illegal, a violation of federal law. . . . I don't know the record on this, but I agree Contac is pretty good for colds. Why do we want to declare "Give your cold to Contac" to be fraudulent?

An attorney for a "public interest" group answered the question: The statement "is far too broad and led consumers to believe that Contac did something to cure colds. And it does not." The exchange ended with Pitofsky reminding him that labels, not thirty-second TV commercials, are the appropriate place for detailed discussion of cold remedies.

Fourteen days later, in announcing the final decision, Commissioner Pitofsky reiterated his basic point:

> I am not convinced that FDA determinations with regard to labeling claims are always or even usually appropriate for drug advertising. There is a danger that a rigid approach which ties advertising to government-approved words could restrict the dissemination of truthful and useful information.

The commission vote rejecting the rule was unanimous.

Some Final Thoughts

It is difficult to see the point of this long war. What did the five-year proceeding do that might not have been done (or that was not done) by the two dissenting memoranda and the brief hearing in the final days of the rulemaking? Surely the danger that the rule might suppress truthful information was as clear in 1975 as in 1981, especially after the staff had adopted its rigid interpretation. If the commission thought that interpretation pushed the rule too far, why did it not say so then? Similarly, if there was no evidence of consumer injury from OTC drug ads at the end of the proceeding, obviously there was none at the beginning. Why did the commission start and continue such a large enterprise if there was no particular reason to think there was a problem? Was it really necessary to build a record of over 13,000 pages, to bring in fifty expert witnesses, and to make everyone endure the cost of the struggle just to learn that truthful advertising should be allowed—especially when the rule's proponents could not even show that curbing it would produce any compensating benefit?

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It may well be that the very elaborateness of the Magnuson-Moss process as adapted by the FTC makes it more difficult for the commission to recall a defective proceeding once it is under way. If regulatory reformers make Magnuson-Moss the general principle of all federal regulatory proceedings, their victory could be a Pyrrhic one indeed.

Even worse, it is by no means certain that the drug advertisers won anything more than a truce. A law suit that is terminated "with prejudice" cannot be brought again, but the termination of this proceeding carries no such guarantee. Here the FTC issued no comprehensive statement spelling out the lessons it drew from the proceeding and setting forth how it would apply them in the next one. One is left with the disturbing feeling that in 1975 the commission thought, based on staff recommendations, that the rule was a good idea, and that in 1981 the commission thought, based on policy problems apparent from the outset, that it was not. Interestingly, as a footnote that may reveal more about trends in opinion on regulation than about this decision, it is the second group of commissioners that seems the more liberal of the two. In any event, if the political climate or the composition of the commission changes yet again, FTC staffers could gain approval for another proposed rulemaking based on exactly the same theories and start down the long Magnuson-Moss track once more—in the hope that the second time around they would have their way. ■