

Statement of
Richard F. Kingham
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before the
Food and Drug Administration Hearing
on
Over-the-Counter Cough-Cold Medications
(Docket No. FDA-2008-N-0466)
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My name is Richard F. Kingham. I am a partner in the law firm of Covington & Burling LLP. I appear today to address issues presented by Question 2 in the public notice: “Should cough and cold products for the pediatric population continue to be available OTC, or should they be made available only by prescription?” Although I appear at the request of the Consumer Healthcare Products Association (CHPA), the views expressed are my own and do not necessarily represent those of the association or any of its members.

Since joining Covington & Burling in 1973, my law practice has focused on regulation of drugs and other consumer products by the Food and Drug Administration and other agencies. I have served as outside counsel to the CHPA and other industry associations and have advised many manufacturers of FDA-regulated products. I have also taught food and drug law at the University of Virginia School of Law and the Georgetown University Law Center, as well as universities in the United Kingdom. I have served on committees of the Institute of Medicine of the National Academy of Sciences and the National Institutes of Health.

I do not take a position on the medical issues presented by Question 2, which I expect others will address, but focus instead on legal and practical issues it presents.

First, I do not believe that a switch of the products in question from nonprescription to prescription status is a practical or efficient way to deal with the real issue that confronts FDA, which is whether these products have been shown to be safe and effective for

pediatric use, and if so under what conditions. The answer to that question depends on scientific data. The Agency can best deal with the question in the context of the OTC Drug Review, under which it can review new data submitted by manufacturers and other interested persons. The procedures for the Review are well suited to developing an industry-wide answer, in an open and transparent manner, and would therefore be superior to the review of new drug applications for individual products, which is the primary mechanism ordinarily used for evaluation of prescription drugs. The ultimate resolution might well consist of a combination of revised OTC labeling directed to consumers and labeling for health professionals, as has been done for other OTC drugs.

Second, an attempt to switch these products to prescription status for pediatric use would present difficult legal and regulatory problems, including the need for an amendment to the relevant final OTC drug monograph and the approval of new drug applications for the affected products.

At present, all of the products in question are generally recognized as safe and effective and not misbranded for OTC use, in accordance with the provisions of the final monograph. Among other things, that monograph constitutes an official determination by FDA that these products are not prescription drugs within the meaning of section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act. Including the Rx legend in the labeling for such a product would render it misbranded under section 503(b)(4).

As a result, FDA cannot require products subject to the monograph to bear the Rx legend without first amending the monograph appropriately. Under general provisions of the Administrative Procedure Act and the procedures governing the OTC Drug Review, this will require notice-and-comment rulemaking.

If the monograph is amended to exclude these products, they will lose the safe harbor of monograph status and thus will no longer be exempt from the requirement for an approved new drug application. FDA has made clear in numerous enforcement actions and in its Compliance Policy Guide on Marketed Unapproved Drugs (section 440.100, CPG 7132c.02) that drugs marketed without NDAs, except for those governed by the OTC Drug Review, are unlawful. There is, in effect, no FDA-recognized category of “old” drugs marketed outside the monograph process (with the possible exception of certain radioactive drugs whose status is *sui generis*). Prescription drugs marketed without approved NDAs are therefore subject to FDA enforcement action at any time. As its resources permit, the Agency has traditionally brought compliance actions to remove such products from the market. Any other approach could be deemed inconsistent with the ruling in *Cutler v. Kennedy*, 475 F. Supp. 838 (D.D.C. 1979), which held that the Agency cannot “affirmatively sanction” the marketing of new drugs without approved NDAs.

As a practical matter, this means that, following amendment of the monograph to exclude products for pediatric use, FDA must require manufacturers to submit NDAs. It is possible that these can be submitted under section 505(b)(2), which FDA interprets to permit applications based on a “finding” of safety and effectiveness, including a finding made in the context of the OTC Drug Review. Such applications might not need to contain the full safety and effectiveness data ordinarily required in an NDA submitted under section 505(b)(1). It is also possible that FDA might allow a grace period for submission and approval of NDAs, but this would need to be done in a manner that could withstand judicial review and congressional scrutiny.

In any event, when NDAs were submitted, they would be required to contain full information on chemistry, manufacturing, and controls, in the same detail as required for any new drug. That information would need to be reviewed by officials within the Center for Drug Evaluation and Research, and preapproval inspections would need to be conducted of facilities described in NDAs, including facilities overseas. Estimates vary, but it is likely that hundreds of individual products would require NDAs, imposing a substantial burden on industry and FDA, including FDA headquarters and field personnel. User fees would most likely not be available to defray the cost of the new burden. The result would be a needless diversion of Agency resources from review and approval of genuinely new drug products.

In these circumstances, an attempt to limit these products to prescription use in pediatric populations would entail unnecessary administrative effort and expense, potentially requiring years to complete, and would do nothing to address the actual problem that FDA confronts, which is whether these products are safe and effective for pediatric use. The preferable approach would be to deal with that question in the context of the OTC Drug Review, through the submission and review of new data and a final determination that relies on a combination of consumer labeling and, if necessary, professional labeling.

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