

WASHINGTON LEGAL FOUNDATION

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May 11, 2001

Food and Drug Administration
Center for Drug Evaluation and Research (HFD-21)
Attn: Sandra Titus
5630 Fishers Lane, Room 1093
Rockville, MD 20857

Re: Response to Citizen Petition Requesting That Certain Prescription Allergy
Medication Be Switched to OTC Status
Docket No. 98P-0610/CP

Dear Ms. Titus:

The Washington Legal Foundation (WLF) is submitting these comments in opposition to the above-referenced Citizen Petition filed by Blue Cross of California Pharmacy on July 22, 1998. WLF believes that the requested switch not only would undermine the intellectual property rights of the manufacturers of the drugs in question, but also would have significant long-term adverse effects on health care in this country.

WLF understands that a joint meeting today of the Nonprescription Drugs Advisory Committee and the Pulmonary-Allergy Drugs Advisory Committee is considering certain aspects of the Citizen Petition. WLF understands that the Advisory Committees are looking into the question of whether allowing consumers to purchase the drugs in question on a non-prescription basis would raise significant safety concerns. WLF's opposition to the switch to over-the-counter (OTC) status for the drugs in question is not based on a belief that consumers would use the drugs inappropriately if permitted to purchase them without consulting a physician. WLF lacks the medical expertise to offer a reasoned opinion on that issue. Accordingly, WLF has not submitted comments to the Advisory Committees nor has it sought to testify at today's hearing.

Rather, WLF is filing these comments separately because it believes that the Citizen Petition ought to be denied without regard to whether the proposed switch to OTC status would raise safety concerns among users of the drugs. The switch to OTC status is being proposed precisely because the drugs in question have proven to be a hit among doctors and consumers; because so much money is being spent to purchase the drugs, the insurance industry is searching for a way to reduce costs it incurs in reimbursing consumers for those purchases. Any reduction in those costs will, of course, reduce the income of the pharmaceutical manufacturers who spent countless millions of dollars on research and development for the drugs. Thus, if the Citizen Petition is granted, the lessons to be learned

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by manufacturers is that the financial rewards they heretofore have hoped to gain from the successful development and marketing of pioneer drugs can no longer be counted on. The inevitable result will be a reduction in research and development expenditures by major pharmaceutical companies. Such a reduction inevitably will have long-term adverse effects on health care.

Interests of Washington Legal Foundation. WLF is a nonprofit public interest law and policy center with supporters in all 50 states. While WLF engages in litigation and administrative proceedings in a variety of areas, WLF devotes a substantial portion of its resources to promoting the interests of a free-market economy and to defending the rights of individuals and businesses to go about their affairs without undue interference from government regulators. For example, WLF recently successfully challenged the constitutionality of FDA restrictions on commercial speech regarding off-label uses of FDA-approved products. *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dismissed*, 202 F.3d 331 (D.C. Cir. 2000). WLF also litigates actively in support of private property rights. The U.S. Supreme Court recently sided with WLF in a major property-rights case involving the scope of the Fifth Amendment's Takings Clause. *Phillips v. Washington Legal Found.*, 524 U.S. 156 (1998). WLF has worked hard to protect private property -- intellectual property as well as other forms of personal and real property -- from unwarranted government intrusion. WLF has litigated in support of pharmaceutical companies whose patent rights have been subjected to unwarranted judicial challenge. *See, e.g., Mylan Pharmaceuticals, Inc. v. Thompson*, 2001 U.S. LEXIS 2662 (D.D.C. Mar. 13, 2001), *on appeal*, No. 01-1257 (Fed. Cir., dec. pending). WLF has also litigated in opposition to efforts by states to impose price controls on prescription drugs. *See, e.g. Pharmaceutical Research and Manufacturers of America v. Concannon*, No. 00-2446 (1st Cir., dec. pending).

WLF believes that if advances in health care are to continue, it is vital that substantial economic incentives be provided for new product development. Pharmaceutical companies will not gamble the substantial sums necessary for the development of new therapies unless they can be assured that they will reap substantial rewards in those few instances in which their research and development expenditures bear fruit. WLF is concerned that the involuntary switch from prescription to OTC status proposed by the Citizen Petition would substantially undermine manufacturer confidence that they will be rewarded for developing new products.

The Citizen Petition. In its July 22, 1998 Citizen Petition, Blue Cross of California Pharmacy requested that the following drugs, currently limited to prescription sales only, be exempted from that limitation:

Allegra (60 mg fexofenadine);

Allegra-D (60 mg fexofenadine, 120 mg pseudoephedrine);

Claritin (5 mg loratadine);

Claritin-D (5 mg loratadine, 120 mg pseudoephedrine);

Claritin-D 24 Hour (10 mg loratadine, 240 mg pseudoephedrine); and

Zyrtec (5 mg cetirizine and 10 mg cetirizine strengths).

Allegra/Allegra-D, Claritin/Claritin-D, and Zyrtec are antihistamine and antihistamine/decongestant combination medications used for the relief of nasal and non-nasal symptoms of seasonal allergic rhinitis (referred to herein as "allergies"). They are so-called "second-generation" antihistamines and have been approved for marketing (on a prescription basis only) for less than eight years. All "first-generation" antihistamines that are available to consumers on an OTC basis have a much more significant sedative effect than do Allegra/Claritin/Zyrtec. Although all such OTC antihistamines are considered safe and effective by the Food and Drug Administration (FDA), many consumers prefer Allegra/Claritin/Zyrtec because the latter drugs allow them to experience relief from allergy symptoms without the drowsiness that can interfere with day-to-day functions. On the other hand, because the second-generation products have been on the market for a far-shorter period of time, less is known about the ability of the consuming public to self-medicate in a safe and effective manner.

The Citizen Petition refers to the OTC antihistamines as "more dangerous" alternatives to Allegra/Claritin/Zyrtec, and alleges that continuation of the prescription-only status for the latter drugs adds "considerable unnecessary medical costs to the health care system." The Petition predicts, "based on recent historical precedent," that a switch from prescription to OTC status would result in a 50% reduction in the price of the drugs. The Petition alleges that many consumers cannot afford the cost of the medical appointment necessary to obtain a prescription for Allegra/Claritin/Zyrtec and thus are priced out of the market.

Blue Cross of California Pharmacy later supplemented its Petition with a cost-effectiveness study purporting to show that a conversion from prescription to OTC status would not only be cost-effective to society but also would result in cost savings. See "Cost-Effectiveness of Converting Non-Sedating Antihistamines from Prescription to Over-the-Counter Status." The study based its conclusion of cost savings on a prediction that

increased use of non-sedating antihistamines would lead to a reduction in motor vehicle accidents.

Cost-Savings to the Insurance Industry. The Citizen Petition is undoubtedly correct that a conversion to OTC would result in a reduction in the price of Allegra/Claritin/Zyrtec. But in evaluating the propriety of such a conversion, it is important to bear in mind just who would benefit from the conversion. There can be little doubt that the primary beneficiary of a price reduction would be the insurance industry, not the consuming public.

Most existing health insurance policies in this country provide coverage for prescription drugs but not for OTC drugs. Thus, for the majority of Americans who are covered under a health insurance plan, obtaining Allegra/Claritin/Zyrtec on a prescription basis costs nothing more than the small co-payment required under most plans. If those drugs are switched to OTC status, those consumers will lose their insurance coverage for the drug purchases; thus, even if the retail price of the drugs decreases sharply, the costs to insured consumers will rise. Only the minority of consumers who currently lack insurance coverage (and any other funding source, such as Medicaid) would derive any benefit from the switch to OTC status.

The primary beneficiary of any switch would, of course, be the insurance industry. Because the industry generally is not required under the terms of their insurance plans to provide coverage for OTC drugs, the switch to OTC status would eliminate the substantial reimbursement costs currently being borne by the industry. In contrast, the manufacturers of Allegra/Claritin/Zyrtec would be the big losers in a switch to OTC status; any resultant increase in unit sales volume would be more than offset by the expected reduction in retail price. So the principal policy issue to be addressed by FDA ought to be: would this significant shift in resources from the pharmaceutical industry to the health insurance industry serve the nation's long-term public health interests, and would it provide proper protection for the pharmaceutical industry's property rights?

In addressing those issues, FDA should not lose sight of the insurance industry's obvious self-interest in bringing the Citizen Petition. In light of that self-interest, it is essential at all times in the evaluation process to bear in mind the distinction between steps that serve the public interest and steps that serve the interest of one industry.

FDA's Authority to Order a Switch to OTC Status. Section 503(b)(3) of the Federal Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. § 353(b)(3), authorizes FDA under certain circumstances to remove the requirements that a drug be sold only pursuant to a doctor's prescription "when such requirements are not necessary for the protection of the public health." By regulation, FDA has defined the "protection of the public health"

requirement to mean that drugs "shall" be exempted from "prescription-dispensing requirements when the Commissioner finds such requirements are not necessary for the protection of the public health by reason of the drug's toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, and he finds that the drug is safe and effective for use in self-medication as directed in proposed labeling." 21 C.F.R. § 310.200(b).¹ The regulation states further that a proposal to exempt a drug from prescription requirements may be initiated by FDA or "any interested person." *Id.*

WLF understands that the Advisory Committees have been addressing the safety-related issues described in 21 C.F.R. § 310.200(b). As noted above, WLF does not possess any specialized medical expertise and thus expresses no view regarding whether self-medication with Claritin/Allegra/Zyrtec would raise serious health-related concerns.

Nor does WLF take a position on the issue of whether FDA possesses statutory authority to switch a drug from prescription to OTC status over the objection of the exclusive manufacturer of that drug. WLF notes, however, that the switch requested in this case is unprecedented: FDA has never switched a drug from prescription to OTC status without the consent of the exclusive manufacturer. The issue of FDA's statutory authority is sufficiently in doubt that, at the very least, the issue ought to cause FDA to reject such a switch in any "close" case. But as WLF demonstrates below, this is not a close case; the reasons for denying the Citizen Petition far outweigh reasons put forth by its supporters.

Incentives to Engage in Research and Development. The Citizen Petition alleges that the price of Allegra/Claritin/Zyrtec is too high and that the drugs would be more readily available to allergy sufferers if the drugs were switched to OTC status, thereby likely triggering price reductions. As noted above, a switch to OTC status would actually increase out-of-pocket costs for most consumers, even as it greatly reduces the insurance industry's costs. But even if that were not true, a switch would be ill-advised because it would significantly reduce current incentives for pharmaceutical companies to engage in research and development.

¹ The regulation's use of the word "shall" is clearly contrary to FDA's statutory mandate set forth in FDCA § 503(b)(3). The statute states that, if the prerequisites are met, FDA "may" remove the prescription requirement. Accordingly, notwithstanding the wording of the regulation, FDA is under no obligation to remove the prescription requirement from Allegra/Claritin/Zyrtec, regardless what findings it may make with respect to health and safety issues.

Any claim that drug prices are too high must take into account the tremendous cost of new product development. On average, it costs anywhere from \$500 million to \$1 billion in research and development (R&D) costs to get a drug approved for use in the United States. "Drug Price Controls: A 'Cure' Worse Than the Disease," The Independent Institute (2000). Once the drug is approved, the costs of manufacturing and distributing the drug are relatively low. However, basic economics dictate that pharmaceutical companies must recover all their costs, plus a reasonable profit, in order to spur them to continue to develop new medicines.

In recognition of the need for financial incentives for R&D, federal patent law provides pioneer companies that develop new drugs and medical devices with a substantial period of exclusivity, during which potential competitors are not permitted to market the same product. When it adopted the Hatch-Waxman Act in 1984, Congress recognized that that exclusivity period was being unduly shortened because of the many years usually required to obtain FDA marketing approval after a patent is initially issued. Accordingly, Hatch-Waxman grants pioneer manufacturers patent-term extensions to make up for the period during which manufacturers cannot exploit their patents while they await marketing approval. 35 U.S.C. § 156. Because involuntary switches to OTC were unheard of in 1984 (and still are), Congress clearly legislated with the understanding that pioneer manufacturers seeking to recover research and development costs for approved drugs would be entitled to charge monopolistic, prescription-range prices until (at the very least) the expiration date of the patent. Accordingly, any involuntary switch of Allegra/Claritin/Zyrtec to OTC status would undercut Congress's considered judgment regarding the amount of financial reward to provide to pioneer manufacturers that successfully gamble that their massive R&D expenditures will produce marketable products.

The American consuming public has been well served by a system of drug pricing that rewards innovation. Although drug prices are, on average, higher here than elsewhere in the world, the result has been tremendous breakthroughs over the past several decades by American companies in developing new life-saving therapies for patients. Now is not the time for FDA to begin tinkering with that record of success by drastically reducing the financial rewards available to manufacturers that develop those new therapies. Switching Allegra/Claritin/Zyrtec to OTC status may produce short-term benefits for a minority of allergy sufferers, but doing so would mortgage our future by ensuring cutbacks in pharmaceutical industry R&D.

Moreover, an involuntary switch would be of doubtful constitutionality. The Takings Clause of the Fifth Amendment to the U.S. Constitution prohibits the government from taking private property without providing just compensation. Intellectual property such as patents is as fully protected under the Takings Clause as is real property. *See, e.g., Ruckelshaus v. Monsanto*, 467 U.S. 986 (1984). Were FDA to switch Allegra/Claritin/

Zyrtec to OTC status, its actions would substantially reduce the value of the manufacturers' patents for those products. The Supreme Court has repeatedly held that government regulation that substantially reduces the value of private property implicates the Takings Clause and may well require the government compensate the owner for his loss. *See, e.g., Lucas v. South Carolina Coastal Council*, 505 U.S. 1003 (1992).

WLF notes finally that the study submitted on April 11, 2001 by Blue Cross of California Pharmacy ("Cost Effectiveness of Converting Non-Sedating Antihistamines from Prescription to Over-the-Counter Status") makes no effort to quantify the costs of its proposed switch in terms of decreased R&D by pharmaceutical companies. In the absence of any effort to quantify those substantial costs, the study is without value and should be ignored.

The Efficacy of Involuntary Switches. Even if FDA concludes that it possesses statutory authority to order an OTC switch over a manufacturer's objection and that it is willing to tolerate R&D cutbacks as the cost of short-term price reductions, FDA should still deny the Petition because there is no practical method of ensuring a smooth transition to OTC status without the full cooperation of the manufacturers involved. For one thing, although FDA is entitled to lift the prescription-only requirement from a drug, it has no authority to mandate that the drug actually be sold on an over-the-counter basis. A drug manufacturer has the same right as any other manufacturer to dictate to drug stores how it wants its products to be sold. If the manufacturers of Allegra/Claritin/Zyrtec enter into distribution contracts that prohibit retailers from selling the drugs without a doctor's prescription, FDA would have no basis for objecting.²

Moreover, developing labeling that would ensure the safety of consumers who buy a drug without the benefit of a doctor's prescription is no easy task even when the manufacturer is cooperating voluntarily with the conversion process. Without that full cooperation, the task is virtually impossible. When a manufacturer argues (as here) that the switch should not take place because the switch raises several as-yet-unexamined safety concerns, it is not difficult to imagine that the manufacturer will never be satisfied with

² FDCA § 503(b)(4)(B) prohibits the labeling of OTC products as "Rx only." That prohibition would not prevent a manufacturer from including in its labeling a statement that *it* does not permit its product to be sold OTC, particularly if a disclaimer is included (stating expressly that it is the manufacturer, not FDA, that is preventing OTC sales). To the extent that FDA interprets § 503(4)(B) as preventing such labeling, the statute would be of doubtful constitutionality; FDA almost surely would be unable to meet its heavy First Amendment burden of demonstrating why it would be justified in suppressing such truthful speech.

FDA's proposed labeling. Given that it is the manufacturer that will be the target of any product liability lawsuits, it has every right to insist that its safety concerns be adequately addressed. To the extent that the manufacturer believes that the only way to address those concerns is to retain the prescription requirement, an impasse is highly likely to develop.

Finally, WLF notes that the FDCA grants manufacturers an additional period of exclusivity in return for conducting the studies necessary to support a switch from prescription to OTC status. Congress thereby recognized the importance of manufacturer involvement in any successful conversion process. It would be unprecedented were FDA to determine that it can go ahead with a switch even without such studies. It would also be a guarantee of massive future litigation over whether a manufacturer who did not decide to go ahead with conversion studies until after FDA had ordered the switch would nonetheless be entitled to a patent extension.

DTC Advertising of Prescription Drugs. The manufacturers of Allegra/Claritin/Zyrtec are, in a sense, being punished for their success. Had their products been only mildly successful in meeting the medical needs of the American public, the insurance industry would have had significantly lower reimbursement costs and would never have filed its Citizen Petition. If the Petition is granted, one can expect many more similar petitions to be filed. The result will be to create incentives inimical to public health: the message to manufacturers will be to refrain from promoting their products too hard lest their products become the target of a switch-to-OTC-status campaign.

The FDA should reject out of hand the Petition's suggestion that drug promotion is wasteful. Dr. Robert C. Seidman of Blue Cross testified at the June 28, 2000 FDA hearing that he views the huge amounts spent on DTC advertising of Allegra/Claritin/Zyrtec as wasteful and as having caused patients to inappropriately "force" doctors to write them prescription.³ He apparently wishes to see the manufacturers punished for having engaged in such wasteful conduct. WLF could not disagree more strongly with that sentiment. The large increase in DTC advertising of prescription drugs in the past several years has been a tremendous boon to consumers. It has provided consumers with large amounts of important medical information, particularly information that drugs on the market meet their unique needs. Allegra/Claritin/Zyrtec have been successful precisely because they meet an important need: antihistamines that do not cause drowsiness. It is only through advertising

³ It is difficult to comprehend how these comments can be squared with Dr. Seidman's other comments that Allegra/Claritin/Zyrtec are such wonderful drugs and so superior to current OTC alternatives that they should be switched immediately to OTC status over the manufacturers' opposition.

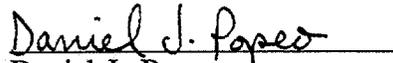
that large numbers of consumers have become aware of these products. If Dr. Seidman had his way, there would have been fewer DTC advertisement, fewer consumers would have been aware of these products, and society's total expenditures for prescription drugs would have been somewhat lower. While WLF can understand the insurance industry's concerns about rising costs of prescription drugs, WLF does not believe that minimizing those costs should be the sole or even the primary focus of the American health delivery system. Far more important is ensuring that consumers receive therapies that improve their health.

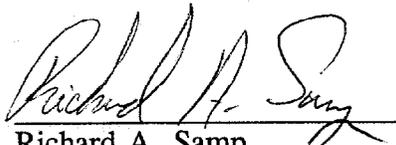
If Allegra/Claritin/Zyrtec are switched to OTC status, reduced prices will significantly reduce the manufacturers' incentives to engage in OTC advertising -- and could lead to decreased public awareness of these drugs. As a result, access to these drugs by allergy sufferers could well decrease, even among the uninsured who to date have had only limited access. Punishing the manufacturers of Allegra/Claritin/Zyrtec for having done such a good job of increasing public awareness of the products they offer will significantly set back health care in this country.

CONCLUSION

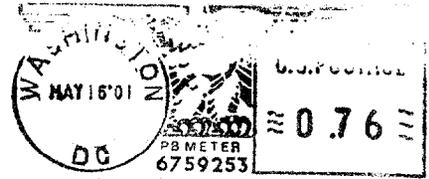
The Washington Legal Foundation respectfully requests that FDA deny the July 22, 1998 Citizen Petition discussed herein.

Respectfully submitted,


Daniel J. Popeo
Chairman & General Counsel


Richard A. Samp
Chief Counsel

cc: Dockets Management Branch



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