WASHINGTON LEGAL FOUNDATION
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May 13, 2003

Mark B. McClellan, M.D., Commissioner
Food and Drug Administration
14-71 Parklawn Bldg.
5600 Fishers Lane
Rockville, MD 20857

Re: FDA Authority to Mandate, Over Manufacturer's Objections, that Drugs Be Sold as Over-the-Counter Products; Potential FDA Actions in Response to July 22, 1998 Citizen Petition, Docket No. 98P-0610/CP

Dear Commissioner McClellan:

The Washington Legal Foundation (WLF) submitted comments (attached) on May 11, 2001, in opposition to the above-referenced Citizen Petition (the "Citizen Petition"), which requested that FDA mandatorily switch three allergy medications from prescription to over-the-counter (OTC) status. WLF's principal argument in opposition was that the proposed switch constituted poor health care policy.

Recent press accounts suggest that: (1) FDA attorneys have advised you that the agency possesses legal authority to require involuntary switches; and (2) you are "actively considering" forcing a switch to OTC status for the allergy medications that are the subject of the July 1998 Citizen Petition. We are writing to explain why FDA does not, in fact, possess statutory authority to require switches over the objection of the drugs' manufacturers. Accordingly, quite apart from the policy reasons (outlined in our May 2001 comments) for avoiding any involuntary switches, FDA should take no such action because doing so would be contrary to the Administrative Procedure Act. WLF's members and supporters include numerous individuals who are regular users of the prescription allergy medications that are the subject of the Citizen Petition; they would be injured if FDA, in violation of its statutory authority, were to require that the medications be marketed only as OTC products -- because such a requirement almost certainly would increase their costs in obtaining a regular supply of the medications. On behalf of those members and supporters, WLF respectfully requests that FDA not carry through on its threat to require involuntary switches.

Interests of Washington Legal Foundation. WLF is a nonprofit public interest law and policy center with supporters in all 50 states. WLF devotes a substantial portion of its resources to promoting the interests of a free-market economy and to defending the rights of individuals to go about their affairs without undue interference from government regulators. For example, WLF 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 dis'd,* 202 F.3d 331 (D.C. Cir. 2000).

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. The July 1998 Citizen Petition requested that several antihistamines used for relief of allergy symptoms, limited at that time to prescription sales only, be exempted from that limitation. One of the drugs in question, Claritin, has since been switched to OTC status with the assent of its manufacturer. The other two drugs, Allegra and Zyrtec, remain prescription-only products. The Citizen Petition was later supplemented to include a request that another antihistamine, Clarinex, be switched to OTC status. The principal justification for the involuntary switch advanced by the Citizen Petition is economic: a switch to OTC status generally results in substantial price reductions. Of course, those benefits inure primarily to insurers rather than consumers, because most health insurance plans cover virtually all the costs of prescription drugs but none of the costs of OTC medications.

Recent press accounts indicate that FDA attorneys have concluded that the agency possesses statutory aithority to mandate involuntary switches from prescription-only to OTC status. Those same press accounts indicate that FDA is strongly considering granting the Citizen Petition and ordering that Allegra, Zyrtec, and Clarinex be marketed as OTC drugs. WLF respectfully urges FDA to reconsider both issues -- both for the policy reasons outlined in WLF's 2001 comments and because (as detailed below) FDA lacks statutory authority to require such a switch.

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." FDA is under no obligation, of course, to remove the prescription-only requirement simply because that requirement is not necessary to protect public health; § 503(b)(3) merely states that FDA "may" remove the requirement under those circumstances. In the case of Allegra and Zyrtec, an FDA Advisory Panel has determined that

lifting the prescription-only requirement for those drugs would not cause significant public health concerns. If one assumes that that determination is sound, FDA undoubtedly would be acting within its authority were it to lift the prescription-only requirement.

But there is a vast difference between, on the one hand, lifting the prescription-only requirement for a drug and, on the other hand, *requiring* a manufacturer to market its products on an OTC basis only. Nothing in the FDCA so much as suggests that FDA possesses statutory authority to impose an OTC-only requirement.[1] FDA's mandate is to ensure that drugs being marketed in this country are safe and effective for their intended uses. There is no plausible claim that by marketing a product on a prescription-only basis, a manufacturer is in any way impairing the product's safety or effectiveness. In the absence of such a claim, FDA has no legitimate basis upon which to insist that a manufacturer not adopt a marketing policy -- continuing to sell its products on a prescription-only basis -- whose only possible safety-related effect is to *increase* safety.

Forced Switches Are Inconsistent with the FDCA. Section 503(b) was added to the FDCA in 1951 by the Humphrey Durham Drug Prescription Act (the "Humphrey-Durham Amendments"), Pub. L. No. 82-215, 65 Stat. 648-649. The Humphrey-Durham Amendments were adopted primarily to address safety concerns: health care officials feared that many of the drugs then being sold on an OTC basis could not safely be self-administered. Congress wanted to establish uniform standards for determining whether potential safety concerns dictated that a drug should be dispensed on a prescription-only basis. *See* H.R. Rep. No. 82-700 (1951). The Congressional Record is devoid of any evidence that Congress was concerned that consumers were being harmed because some of the drugs being sold on a prescription-only basis should have been more readily available on an OTC basis.

It is true that nothing in § 503(b) explicitly prohibits FDA from forcing a manufacturer to sell its products on an OTC-only basis. But such an FDA policy would be inconsistent with numerous other provisions of the FDCA. The Supreme Court has cautioned that discerning congressional intent requires that the FDCA be interpreted "as a symmetrical and coherent regulatory scheme and fit, if possible, all parts into an harmonious whole." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (citations

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[1] Indeed, manufacturers of OTC drugs have been the targets of tort suits filed by plaintiffs who allege that the manufacturers failed to impose adequate restrictions on the distribution of their products. An assertion that FDA can *mandate* that a drug be sold on an OTC basis logically suggests that such tort claims are preempted by federal law once FDA, acting pursuant to § 503(b)(3), has lifted a prescription-only requirement. Yet, WLF is unaware of a single court decision so holding.

omitted). Section 503(b) cannot plausibly be interpreted as permitting forced switches to OTC status when such an interpretation would be inconsistent with basic assumptions of other portions of the FDCA.

First, interpreting § 503(b) as providing FDA with authority to force manufacturers to market their products on an OTC-only basis would be inconsistent with FDCA § 505, 21 U.S.C. § 355. Section 505 establishes the regulatory process by which new drugs can be brought onto the market. In general, § 505(d) provides that a new drug application (NDA) *must* be approved by FDA if it finds that the NDA meets all the conditions set forth therein; those conditions focus on the safety and effectiveness of the product as it is proposed to be marketed, not on whether FDA approves of proposed distribution methods that do not adversely affect safety and effectiveness. Similarly, § 505(e), which spells out the circumstances under which FDA may withdraw its prior approval of an NDA, does not permit FDA to withdraw approval for reasons unrelated to safety or effectiveness -- such as a manufacturer's insistence that it wishes to market its products on a prescription-only basis. Because FDA is barred under § 505 from preventing the marketing of Allegra, Zyrtec, and Clarinex if the manufacturers of those products insist on selling those products on a prescription-only basis, it makes no sense to interpret § 503(b) as granting FDA that power *sub silentio*.

Second, interpreting § 503(b) as providing FDA with authority to force manufacturers to market their products on an OTC-only basis would be inconsistent with the Hatch-Waxman Act -- at least to the extent that FDA is acting for the purpose of reducing the price of the drugs at issue. In recognition of the need for financial incentives for R&D, federal patent law provides pioneer companies that develop new drugs with a substantial period of exclusivity, during which potential competitors are not permitted to market the same product. When it amended the FDCA by adopting 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 status 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/Zyrtec/ Clarinex to OTC status -- if done for the purpose of driving down the price of those drugs -- would undercut Congress's considered judgment regarding the level of financial reward to provide to pioneer manufacturers that successfully gamble that their massive R&D expenditures will produce marketable products.

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/Zyrtec/ Clarinex 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 that the government compensate the owner for his loss. *See, e.g., Lucas v. South Carolina Coastal Council,* 505 U.S. 1003 (1992).

Section 503(b)(4)(B) Does Not Authorize Involuntary Switches. Supporters of involuntary switches have relied on FDCA § 503(b)(4), 21 U.S.C. § 353(b)(4), in support of their argument that FDA possesses the requisite statutory authority. Such reliance is misplaced.

Section 503(b)(4) provides:

> (A) A drug that is subject to paragraph (1) [which imposes a prescription-only requirement on the sale of certain FDA-approved drugs] shall be deemed to be misbranded if at any time prior to dispensing the label of the drug fails to bear, at a minimum, the symbol "Rx only."
>
> (B) A drug to which paragraph (1) does not apply shall be deemed to be misbranded if at any time prior to dispensing the label of the drug bears the symbol described in subparagraph (A).

Section 503(b)(4)(B) clearly prohibits a manufacturer from labeling one of its drugs "Rx only" once FDA has lifted the drug's prescription-only restriction. But nothing in the language of that provision suggests that the manufacturer of such a drug may not nevertheless insist that any retailer wishing to handle the drug sell it only to those possessing a doctor's prescription.

The legislative history of § 503(b)(4)(B) supports that common-sense reading of the statute. Among the concerns that led Congress to adopt the Humphrey-Durham Amendments was a concern that pharmacists were often confused regarding when ***FDA*** required that a drug be sold by prescription only and when it did not. Section 503(b)(4) was designed to eliminate that confusion; thereafter, a pharmacist could rest assured that drugs labeled "Rx only" were required by FDA to be sold by prescription only and those drug lacking such labeling were not required by FDA to be sold by prescription. Nothing in the history of

§ 503(b)(4)(B) suggests that Congress intended thereby to prohibit drugs lacking the "Rx only" labeling from being sold on a prescription-only basis. As a result of § 503(b)(4)(B), pharmacists can rest assured that they will not be sanctioned by government regulators for selling drugs lacking "Rx only" labels on an OTC basis; but nothing in the statute prohibits manufacturers and pharmacists from agreeing among themselves that sales of a product will be by prescription only.

CONCLUSION

The Washington Legal Foundation respectfully requests that FDA deny the July 22, 1998 Citizen Petition discussed herein. As outlined in our May 2001 comments, we believe that adoption of a policy permitting involuntary switches of drugs to OTC status constitutes poor health care policy. But quite apart from those policy concerns, adoption of such a policy would be illegal because FDA lacks statutory authority to do so.

Respectfully submitted,

Daniel J. Popeo
Chairman and General Counsel

Richard A. Samp
Chief Counsel

cc: Daniel Troy, Esq.
The Honorable Tommy Thompson
The Honorable Robert F. Bennett
The Honorable Herb Kohl
The Honorable Judd Gregg
The Honorable Edward Kennedy
The Honorable Henry Bonilla
The Honorable Marcy Kaptur
The Honorable Billy Tauzin
The Honorable John Dingle

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 lessen to be learned

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.

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[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, basis 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

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[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,

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Chairman & General Counsel

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cc: Dockets Management Branch