Legal Backgrounder

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FDA LACKS AUTHORITY TO FORCE OVER-THE-COUNTER DRUG SWITCH

by

Andrew S. Krulwich

Does the Food and Drug Administration ("FDA") have authority to force manufacturers of prescription ("Rx") drug products to switch those products to over-the-counter ("OTC") distribution against their will? FDA is currently grappling with this issue — a dispute that has generated substantial controversy, including statements by FDA officials and coverage in leading newspapers.

The agency has under active consideration a 1998 Citizens Petition filed by WellPoint Health Networks ("WellPoint"), a health insurer, requesting that FDA force the manufacturers of three leading allergy medications — Allegra/Allegra-D, Claritin/Claritin-D, and Zyrtec — to switch these products from Rx to OTC status. In a 2002 Petition, WellPoint added a fourth drug, Clarinex. Claritin's manufacturer has voluntarily switched that product, but the makers of Allegra, Zyrtec, and Clarinex are contesting FDA's authority and the wisdom of forcing a switch. High-ranking FDA officials have been quoted in the press as stating that FDA has such authority.

This LEGAL BACKGROUNDER contends that FDA lacks authority to force an unwilling manufacturer to switch its distribution channels from prescription to OTC. When one examines the applicable section of the Food, Drug and Cosmetic Act ("FDCA" or "Act"), the authority just is not there. FDA may, through a rulemaking, *remove* the *requirement* that a company limit its product to prescription use only. However, nothing in the Act authorizes FDA to take the next step and *prohibit* Rx or *require* OTC distribution of a safe drug.

This controversy is essentially an economic dispute over drug pricing and the allocation of costs between insurers, consumers and manufacturers. It is well beyond FDA's mandate to determine whether particular drugs should be covered by insurance. It is equally beyond FDA's purview to aim regulation at drug pricing. Marketplace analysis and the effects of distribution restrictions on pricing are complicated economic subjects. By wading into what is essentially an economic battle between two giant industries, FDA could unwittingly increase drug costs for low-income consumers while inappropriately exposing

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Andrew S. Krulwich is a partner in the Washington, D.C. law firm Wiley Rein & Fielding LLP, practicing for over thirty years in the area of food and drug law and regulation. This paper is based largely on comments Mr. Krulwich submitted to FDA with Bert W. Rein and Kristin Davis, also of Wiley Rein & Fielding LLP, on behalf of the Association of American Physicians and Surgeons and the Competitive Enterprise Institute.

manufacturers to unwanted product liability risk and uncertainty in investment decisions on drug development.

Statutory Overview. FDA's authority to exempt a drug from its prescription requirements is established by Section 503(b)(3) of the FDCA, one part of the prescription dispensing provisions added to the statute in 1951 by the Humphrey-Durham Amendments. Pub. L. No. 82-215, 65 Stat. 648-649 (1951) (amending 21 U.S.C. § 353(b)). Prior to these amendments, FDA had no authority to require drugs to be dispensed by prescription; such determinations were left solely to the manufacturer's discretion. This presented several health and safety concerns:

- A troubling number of allegedly unsafe drugs (or even safe drugs that presented safety concerns because consumers did not know how to self-medicate with them) were being sold OTC. On the other hand, in some cases, consumers were prevented from buying drugs where self-medication posed no risk.

- Dozens of drugs containing the same active ingredient and dosage form were on the market bearing different labeling; some brands of the drug were labeled for prescription sale, some for OTC distribution, leading to pharmacist confusion about how particular products should be sold.

In response, Congress granted FDA the following specific authority:

1. In Section 503(b)(1), Congress gave FDA power to prohibit OTC sale of any drug which FDA determined was unsafe unless used under a doctor's supervision. 21 U.S.C. § 353(b)(1).

2. Under Sections 503(b)(2) and (4), a drug limited by FDA to prescription sale was required to have "Rx only" on its label. An "Rx only"-labeled drug could not be dispensed without a prescription. At the same time, a drug not limited by FDA to prescription use could not bear the "Rx only" mark and could be sold OTC if the manufacturer supplied adequate directions for consumer use.

3. At the crux of the issue here, Congress added Section 503(b)(3), requiring FDA to reverse a prescription-only determination, through rulemaking, "when such requirements are not necessary for the protection of the public health."

The plain language of Section 503(b)(3) addresses only the removal of drugs "from the requirements of [Section 503(b)(1)]." Nothing in the new provisions *prohibited* a manufacturer, at its own discretion, from continuing to limit distribution to prescription sales as long as the drug continued to have the prescription labeling FDA had already approved. Rather, to address the concerns about potential confusion, the Humphry-Durham Amendments, taken as a whole, created powerful *marketplace pressures* for uniform dispensation. Where consumer safety was at issue, FDA could mandate uniform prescription status. Where safety issues did not preclude OTC sale, the prohibition against using "Rx only" not only facilitated OTC sale but also permitted competitors, distributors and consumers — and, it turns out, insurers — to exert market leverage against an unwilling manufacturer to force OTC distribution. Consequently, multisource drugs not requiring prescription limitations by FDA almost certainly would be available OTC. In single source situations, a manufacturer's decision to continue prescription distribution with the FDA-approved prescription labeling would be without the government imprimatur conveyed by the "Rx only" symbol, but would cause neither safety concerns nor confusion.

FDA's regulations implementing 503(b)(3) indicate that FDA will not remove an Rx requirement unless it is prepared to approve proposed OTC labeling so that the drug can be dispensed safely and

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effectively OTC:

> "Any drug limited to prescription use under section 503(b)(1)(C) of the act shall be exempted from prescription-dispensing requirements when the Commissioner finds such requirements are not necessary … 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). (Emphasis added).

Prescription drugs are approved by FDA pursuant to a New Drug Application ("NDA") filed by the manufacturer. NDAs include proposed labeling from the manufacturer. *FDA has never ordered a switch over the objection of a manufacturer*. Virtually all Rx-to-OTC switches have been initiated by a manufacturer coming to FDA with new OTC labeling and the scientific evidence to support the labeling. This has permitted FDA to consider together whether safety concerns no longer require Rx distribution only and whether OTC distribution can be authorized in accordance with proposed labeling. Under the FDCA, and the agency's implementing regulations and past practice, the responsibility for proposing OTC labeling for an NDA'd drug lies with its manufacturer. *See id.* (requiring submission of proposed labeling for a switch in status); *Id.* at 314.70(b)(3) (requiring submission of a supplement by the NDA applicant before this labeling change can be made); *Id.* at 314.71(a) (specifying that only the NDA applicant can submit a supplement to its application).

Even if FDA attempted as part of a 503(b)(3) rulemaking both to remove a prescription restriction and adopt FDA-proposed OTC labeling, the agency would still have to withdraw approval of the prescription labeling in the approved NDA. To do that, FDA would need to find that the labeling no longer permitted the drug to be sold Rx safely and effectively or was now false or misleading. 21 U.S.C. § 355(e). How could FDA make such a determination where the claim is, essentially, that current methods of distribution are, if anything, *too safe*?

It is true that if FDA removed the prescription limitation, the manufacturer would have to drop the "Rx only" legend. However, nothing in the statute forecloses a manufacturer from using an alternative legend stating, for example, "Manufacturer, but not FDA, requires this drug be dispensed only in accordance with a prescription from a licensed practitioner." Indeed, during its consideration of the Humphrey-Durham Amendments, Congress *rejected* a version of Section 503(b)(4) which would have barred any "statement which represents or implies that the dispensing of the drug without the prescription of a licensed practitioner is prohibited." *See* H.R. REP. NO. 82-700, at 2 (1951).

Other applicable provisions of the FDCA support this reading. *See FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (citations omitted) (FDA must interpret the FDCA "'as a symmetrical and coherent regulatory scheme' and 'fit, if possible, all parts into an harmonious whole.'") In approving an NDA, FDA determines under Section 505(d) whether the manufacturer's proposed "use under the conditions prescribed, recommended or suggested in [its] proposed labeling" will be safe and effective. If those findings are made, FDA must approve the application even if the agency would prefer different proposed conditions or methods of distribution. *Ass'n of American Physicians & Surgeons, Inc. v. FDA*, 226 F. Supp. 2d 204 (D.D.C. 2002) (finding it would take an Act of Congress to permit FDA to initiate and then mandate an indication for a drug product). FDA may deny applications on safety or effectiveness grounds. It has no power to rewrite applications or to refuse approval for other reasons. If FDA has found that a drug meets the Section 505 criteria when sold Rx and has approved its sale, the fact that the agency later determines that it is also safe under alternative conditions — *i.e.*, OTC use — does not give FDA authority to revoke its prior determination of safety and effectiveness.

In Section 505(e), Congress has specified the exclusive grounds for withdrawal of approval. FDA may withdraw an NDA, after opportunity for hearing, only if evidence now shows the drug is unsafe or ineffective or its labeling is false or misleading. A prescription drug approved as safe and effective based

on the labeling in its NDA hardly becomes unsafe or ineffective for the same Rx use with the same labeling simply because it is also safe and effective OTC. Similarly, an FDA decision that a drug is now safe for OTC use hardly makes the approved prescription labeling "false or misleading," as long as the "Rx only" symbol is deleted and the labeling does not imply that FDA requires Rx sale. If Congress had intended 503(b)(3) to provide another basis for removal of an NDA, it would surely have added that basis to the long list already in 505(e).

Policy Considerations. In essence, a health insurer seeks FDA's assistance in dropping these drugs from its coverage. However, the reality may simply be a "shift" in burden from insurers to consumers. In any event, the marketplace is already showing that insurers do not need FDA's help. To FDA: Beware of the law of unintended consequences!

Since a patient must pay the manufacturer's full price of an OTC drug rather than the lower co-pay of an insurance policy, insured consumers now pay considerably more for OTC Claritin than when the drug was Rx. In fact, a number of patients' groups have submitted comments to FDA opposing the forced switch.

Even without FDA action, the marketplace is beginning to adopt methods for pressuring manufacturers to switch to OTC. A number of insurers have withdrawn or reduced coverage for this entire class of drugs. Some require "prior authorization" by the physician, a burdensome process. A competing allergy drug manufacturer has taken full-page newspaper ads asserting that consumers can still limit out-of-pocket costs to a co-pay amount by buying its product, which it states insurers still cover.

Thus, the marketplace is providing powerful incentives for manufacturers to switch to OTC, in addition to the obvious benefits of broadening consumer promotion and increasing sales. FDA decisions just to remove the Rx requirement can, by themselves, have a powerful market impact. FDA should permit the continuing interplay of these market forces to sort out the dispute and remain neutral.

In addition, it is the manufacturer, not FDA, that pays product liability costs, which can be enormous. Some manufacturers may be more risk averse than FDA in evaluating safety issues. Moreover, in making investment choices of drugs to be developed, manufacturers take into account, among other things, the expected channels of distribution and the type of competition, over a predictable period of time. A mandatory switch policy disrupts the ability to make knowledgeable decisions by introducing uncertainty, thus threatening to raise development costs to the detriment of innovation.

Finally, a mandatory switch policy may limit manufacturers' flexibility to develop pricing and distribution systems that increase access and lower drug costs. Pharmaceutical manufacturers are just beginning to explore, through means such as discount cards, differential pricing regimes which permit drugs to be sold at reduced prices to those whose limited means make their demand for such drugs highly elastic. In order to explore such differential pricing, manufacturers need freedom to choose their distribution systems without government interference. Prescription dispensing requirements are a useful tool for differential pricing, even in cases where the same active ingredient is made available OTC. By correctly interpreting 503(b)(3), FDA can permit the marketplace to develop this tool, just as experiments in the deregulated airline industry established the enormous potential of differential pricing for expanding airline access at advantageous prices for consumers.

In sum, then, sound policy reasons counsel FDA to let manufacturers decide between distribution alternatives when neither choice adversely effects safety and effectiveness.

Conclusion. FDA's mandate in this area is limited to protecting public health by ensuring that drugs are safe and effective for use as labeled. The agency's credibility is built on its scientific judgments. Economic regulation is not FDA's area. The agency has neither cause nor authority to go there.

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