



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Office of Policy, Planning, and  
Legislation HF-11  
5600 Fishers Lane  
Rockville, MD 20857

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January 8, 2002

Daniel J. Popeo  
Paul D. Kamenar  
Washington Legal Foundation  
2009 Massachusetts Avenue, NW  
Washington, DC 20036

Docket No. 01P-0334

Dear Mr. Popeo and Mr. Kamenar:

This responds to your July 5, 2001, letter to Dr. Schwetz in which you requested that FDA:

- “immediately review all litigation that has resulted in a ruling striking down in whole or in part any regulation, guidance, or other agency directive, and then to revoke all invalid rules by all appropriate methods as soon as possible” (Letter from Daniel J. Popeo and Paul D. Kamenar to the Honorable Bernard A. Schwetz (July 5, 2001), at page 2);
- “promptly post a prominent notice on [FDA’s] home page with an appropriate link to rules, regulations, or guidances that have been struck down by the courts, and to continue to do so on a regular basis as other regulations are struck down” (*id.*) and
- “notify the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget within seven days of a court ruling striking down in whole or in part any agency regulation, and the agency’s plan on how it intends to revoke the rule” (*id.*, at page 3).

Although you initially submitted your requests in a letter, you subsequently converted the letter into a citizen petition filed under 21 CFR 10.30.

For the reasons stated below, your petition is granted in part, and denied in part.

01P-0334

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*The Request to Review Litigation Striking Down Regulations  
and to Revoke Such Regulations*

Your petition asserted that many agencies “fail” to revoke invalid regulations, thereby causing businesses and individuals to “unwittingly expend significant resources to comply with rules that have been judicially determined to be invalid” (*id.*, at pages 2-3). Your petition further stated that, “There is no excuse for any agency to delay revoking an invalid rule except if the court stayed its decision striking down the rule while the agency decides whether to appeal the adverse ruling” (*id.*, at page 2). Your petition also explained how agencies could remove invalid regulations.

We agree that, if a court has determined an agency regulation to be invalid and FDA has decided not to appeal, has otherwise exhausted all options available to the agency to have that decision reconsidered, amended, or otherwise reversed or modified, and acquiesced to the adverse court decision, then FDA should take prompt action to remove the regulation. In the past, FDA has removed invalid regulations or taken other steps to address court decisions as promptly as possible. For example:

- The Supreme Court decided on March 21, 2000, that FDA lacked jurisdiction to regulate cigarettes and smokeless tobacco as customarily marketed (*FDA v. Brown & Williamson Tobacco Corp.*, 120 S. Ct. 1291). FDA revoked its tobacco regulations on March 31, 2000 (see 65 Fed. Reg. 17135).
- From 1997 to 2000, several courts issued decisions concerning FDA’s regulations on 180-day exclusivity for generic drug applications.<sup>1</sup> Throughout this period, FDA issued guidance documents, interim rules, and a proposed rule responding to those decisions. FDA issued or published guidance documents in 1998 and 2000, an interim rule on November 5, 1998 (63 Fed. Reg. 59710), a proposed rule in the *Federal Register* on August 6, 1999 (64 Fed. Reg. 42873), and an interim rule on July 13, 2000 (65 Fed. Reg. 43233). Collectively, the guidance documents, interim rules, and proposed rule are intended to address the issues raised by these court decisions.
- After several years of litigation, FDA revoked a regulation concerning four health claims (see 65 Fed. Reg. 58917 (Oct. 3, 2000)). The Court of Appeals for the District of Columbia Circuit had held that the regulation was invalid in 1999 (see *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999)).

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<sup>1</sup> The principal court decisions were *Mova Pharmaceutical Corp. v. Shalala*, 955 F.Supp. 128 (D.D.C. 1997), *aff’d* 140 F.3d 1060 (D.C. Cir. 1998); *Granutec, Inc. v. Shalala*, 46 U.S.P.Q.2d 1398 (4<sup>th</sup> Cir. 1998), *TorPharm Inc. v. Shalala*, No. 97-1925 (D.D.C. Sept. 15, 1997), *vacated* No. 97-1925 (D.D.C. Apr. 9, 1998); *Mylan Pharmaceuticals, Inc. v. Shalala*, 81 F. Supp. 2d 30 (D.D.C. 2000).

- Although a federal district court strongly criticized an FDA regulation (21 CFR 20.44) in *Teich v. Food and Drug Administration*, 751 F.Supp. 243 (D.D.C. 1990), the court did not hold that the rule was invalid. Nevertheless, FDA has proposed to revoke the rule (64 Fed. Reg. 60143 (Nov. 4, 1999)) and does not currently rely on it.

We disagree, however, with your blanket statement declaring that there is “no excuse for any agency to delay revoking an invalid rule except if the court stayed its decision striking down the rule while the agency decides whether to appeal the adverse ruling.” Of course, FDA, like other federal agencies, regularly complies with the terms of a court judgment in a particular case. However, under Article III of the Constitution, the “judicial power” vested in the Supreme Court and the lower courts is limited to “Cases” and “Controversies.” A necessary element of the judicial power under Article III is that the judgment of the court is final as between the parties to the particular case and cannot be made subject to revision by the Executive or Legislative Branch. Conversely, the prescription of general rules of conduct that operate directly on persons outside the Judicial Branch is the province of Congress in passing laws and of the Executive Branch in issuing regulations or taking other administrative action in the execution of the laws.

Professor Wechsler put it succinctly: “[U]nder *Marbury [v. Madison]*, the court decides a case; it does not pass a statute calling for obedience by all within the purview of the rule that is declared.” Herbert Wechsler, *The Courts and the Constitution*, 65 Colum. L. Rev.1001, 1008 (1965). See, e.g., *Virginia Society for Human Life v. FEC*, 263 F.3d 379, 392-93 (4th Cir.2001) (district court abused its discretion by issuing a nationwide injunction preventing the FEC from enforcing the regulation against any party anywhere in the United States; such an injunction is broader than necessary to afford full relief to the plaintiff and encroaches on the ability of other circuits to consider the constitutionality of the regulation); *Meinhold v. United States Dep't of Defense*, 34 F.3d 1469, 1480 (9th Cir.1994)(injunction prohibiting Department of Defense from enforcing ban on gays in the military against all persons nationwide was invalid because it was not necessary to provide complete relief to the plaintiff). Thus, the Constitution does not bar a federal agency from declining to apply the legal reasoning of a particular lower court decision in the agency's further administration of a statutory program outside the context of the particular case in which the court rendered its decision (although there are often good reasons to apply such reasoning). Moreover, as commentators have realized, there are a number of legitimate reasons why an agency may under certain circumstances decline to apply the holding of one court decision when enforcing its statutes and regulations against parties not affected by the court's judgment. See generally *Estreicher & Revesz, Nonacquiescence by Federal Administrative Agencies*, 98 Yale L. J. 679 (1989).

In sum, FDA is not granting in full your request because the agency can foresee a court of appeals deciding a case involving agency policy while similar cases are pending elsewhere. FDA might decide not to immediately revoke a rule disapproved by one court while it waits for the remaining cases to be decided. We must emphasize that this does not mean that FDA will not

routinely acquiesce to adverse court decisions. There are a host of practical and statutory restrictions on nonacquiescence (*see* Statement of William B. Schultz, Deputy Assistant Attorney General, Before the Subcommittee on Commercial and Administrative Law, House Committee on the Judiciary (October 27, 1999)). We are simply saying that there may be valid reasons why FDA might not immediately revoke a rule because of a single, adverse court decision if the agency continues to be of the view that the rule is lawful.

Although your petition did not identify any specific FDA regulation as being invalid as a result of a court decision, we have already begun a review of past litigation and agency regulations to determine whether any recent court decisions have called into question an existing or pending regulation or guidance document. We also invite you to bring such regulations to our attention so that we may determine whether they need to be removed or modified.

*The Request to Post Notices of Regulations and Guidance Documents  
Struck Down by Court Decisions*

Your petition noted that FDA's web site contains a link to laws that FDA enforces, but does not contain a link to current or recent litigation that may have declared invalid an agency regulation. Your petition stated that such a link to court cases and rulings with another link to the affected regulation or guidance document would be in the public interest because it would inform the public about invalid rules and the current state of FDA regulations as construed by recent court decisions.

We decline to grant your request. As you know, courts may reach different conclusions about the same provision of law or regulation. For example, one court may disapprove of a rule, but another court, located in the same or another jurisdiction, might find the same rule to be authorized by law. The extent to which such a rule, or policies embodied by that rule, may still be applied or enforced in either jurisdiction, or in the nation as a whole, is a complex question that may involve legal or policy judgments that cannot be decided in the abstract without an in-depth assessment of the specific facts and judgments at issue. Courts may issue varying types of relief to aggrieved parties, including injunctive relief, remand, vacature, or other remedies that can require different reactions from affected agencies. In such a scenario, creating a link to the adverse court decision, but not to the favorable court decision, could mislead the public into thinking that the rule was invalid throughout the nation. If the agency created links to both court decisions, the result might be equally, if not more, confusing or misleading because a person might be unsure whether the rule is valid or erroneously assume that the most recent court decision, regardless of its jurisdictional reach, is controlling.

FDA will, of course, comply with a court order in the particular case in which the order was issued, but the agency might - in some cases - decide against following that adverse court precedent with respect to parties unaffected directly by the court's judgment. A recent example of this is the *Pharmanex* litigation, where a district court "set aside" an FDA final administrative decision, but was later reversed by the Tenth Circuit Court of Appeals (*Pharmanex, Inc. v.*

*Shalala*, 35 F.Supp.2d 1341 (1999), *rev'd* 221 F.2d 1151 (10<sup>th</sup> Cir. 2000)). FDA respected the district court's opinion, and continued to allow the company to market the product at issue in the litigation, but did not extend the district court's reasoning to permit other companies to market similar products without objection. FDA was convinced that it was correct, and did not believe it was in the public interest to permit unfettered marketing of what it believed to be an illegal product. The agency's position was ultimately vindicated by the higher court. If FDA decides to not apply an adverse court decision to other parties, creating a link to the decision might mislead people into believing that the agency had endorsed that view. If FDA had created a link to the adverse court decision and explained that it had not acquiesced, a person might be confused as to FDA's position on the matter.

Nevertheless, you should note that FDA has either promptly posted or created links to some significant court decisions on its web site, when the agency believed, in its discretion, it was appropriate to do so. For example, on February 6, 2001, the United States Court of Appeals for the Ninth Circuit decided a case on pharmacy compounding (*Western States Medical Center v. Shalala*, 238 F. 3d 1090) and held invalid the statutory provisions regarding such compounding in the Ninth Circuit. On February 12, 2001, FDA posted the decision on its web site (see [www.fda.gov/cder/pharmcomp](http://www.fda.gov/cder/pharmcomp)).<sup>2</sup>

#### *The Request to Notify OIRA Within Seven Days of an Adverse Court Decision*

Your final request was to notify OIRA within seven days of an adverse court decision striking down in whole or in part any FDA regulation and to notify OIRA about FDA's plan for revoking the rule. Your petition did not explain why notifying OIRA would be valuable or beneficial, whether OIRA would want such information, or what OIRA would do with such information.

We decline to grant your request to notify OIRA in the manner your petition had suggested. As a preliminary matter, we note that a seven-day notification period would be premature because a decision whether to seek further review of an adverse court decision might not occur or be completed within your suggested seven-day deadline. For example, if FDA were to seek appellate review of an adverse district court decision, the district court might not transmit a notice of appeal within your suggested seven-day notification period. If FDA were to file a petition for rehearing in the Court of Appeals for the District of Columbia Circuit, it would have 45 days, from the date of a judgment, to submit the petition (*see* D.C. Cir. Rule 35(a)). If the United States were to decide to file a petition for writ of certiorari to the Supreme Court, it would have 90 calendar days from the date of entry of the judgment, order, or opinion (absent an extension) to file the petition (*see* Sup. Ct. Rule 13).

Furthermore, as stated earlier, with the exception of Supreme Court decisions, a single, adverse court decision does not necessarily mean that a regulation is invalid nationally. So, unless and until events require FDA to revoke, withdraw, or amend a regulation on a nation-wide basis, it

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<sup>2</sup> The Supreme Court granted certiorari in this case on October 29, 2001.

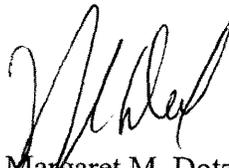
would be premature to have FDA notify OIRA about an adverse court decision and FDA's plan to revoke a rule.

Moreover, as a practical matter, if FDA were to revoke a regulation, it would observe normal rulemaking procedures and publish the revocation in the *Federal Register*. The Office of Management and Budget (OMB) would have notice of the revocation because FDA routinely notifies OMB of pending regulations and significant regulatory developments. Similarly, if FDA were to amend a regulation, it would observe normal notice-and-comment rulemaking requirements, and, again, OMB would have notice of that rulemaking. In either case, OMB would be informed, and, if relevant, FDA would also inform OMB about litigation that affected the rulemaking process.

*Conclusion*

We appreciate your interest in FDA's regulations. We grant your request to review court decisions that have, in whole or in part, held invalid any FDA regulation, guidance, or other directive, and, when appropriate, to revoke all invalid rules promptly. FDA is not aware of any regulation, guidance document, or directive that must be revoked or removed, and we invite you to identify any such documents to us. We decline your requests to post a prominent notice regularly on FDA's home page with an appropriate link to rules, regulations, or guidances that have been struck down by the courts, and also decline to notify OIRA within seven days of a court ruling striking down in whole or in part any agency regulation and to notify OIRA about the agency's plan for revoking that regulation.

Sincerely,



Margaret M. Dotzel  
Associate Commissioner for Policy

Mr. Popeo and Mr. Kamenar

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file name: wlfreply3.wpd

R/D: P.Chao: 8/16/01

concur: S.Falter: 8/17/01

rev: V.Beakes: 8/22/01

rev: L.Brock: 9/6/01

concur: C.Haley: 9/6/01

concur: J.Sheehan: 9/18/01

concur: L.Fraser: 10/1/01

rev: N.Parker: 10/3/01

concur: J.Axelrad: 10/5/01

rev: D.Maloney: 10/10/01

rev: L.Kahan: 10/12/01

rev: N.Parker: 10/18/01

rev: P.Colburn/M.Lederman: 10/01

rev: D.Troy/N.Parker: 10/23/01

rev: A. Wion: 12/30/01

rev: D. Troy 1/2/02