

WASHINGTON LEGAL FOUNDATION

2009 MASSACHUSETTS AVENUE, N.W.  
WASHINGTON, D. C. 20036  
202 588-0302

July 5, 2001

The Honorable Bernard A. Schwetz, Deputy Commissioner  
Food and Drug Administration  
Parklawn Building, Suite 14-71  
5600 Fishers Lane  
Rockville, MD 20857

Re: Petition To Revoke Invalid FDA Regulations

Dear Commissioner Schwetz:

Agency rules, regulations, guidances, and the like are frequently challenged in court by the regulated community for failing to meet procedural and substantive requirements of the Administrative Procedure Act and other laws. In many such cases, the courts have struck down the regulations for failing to comply with these requirements. Unfortunately, however, some agencies often keep the invalid regulations on the books either in the Code of Federal Regulations or in other formats, such as the agency's website where invalid "guidances" or "policy statements" are posted.

The Washington Legal Foundation (WLF) believes that the failure of the agency to revoke the invalid rules is not in the public interest. Accordingly, WLF hereby petitions FDA to review all litigation against the agency to determine which rules have been struck down but not have been revoked, and then to revoke those invalid regulations as expeditiously as possible.

**Interest of WLF.** WLF is a nonprofit public interest law and policy center based in Washington, D.C., with supporters nationwide. WLF devotes substantial resources to defending and promoting free enterprise principles and opposing excessive, unwarranted, and unlawful regulation. In addition to defending individual and economic freedom in the courts, WLF produces timely publications on these topics through its Legal Studies Division. *See, e.g.,* David B. Weinberg, "Informal" Actions Allow Agencies To Duck Rulemaking Requirements (WLF Legal Background, June 19, 1998); Gerald H. Yamada, *Environmental Justice "Guidelines" Avoid Due Process Safeguards* (WLF Legal Opinion Letter, May 28, 1999).

**Agencies' Failure To Revoke Invalid Rules.** Among the many agencies that fail to revoke invalid regulations, the Environmental Protection Agency (EPA) appears to be the worst offender. EPA's failure to revoke invalid rules is succinctly described in the attached WLF publication, Richard G. Stoll, *EPA Ignores Court Mandates To Revoke Unlawfully Issued Rules* (WLF Legal Opinion Letter, June 15, 2001), a copy of which is enclosed. For example,

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The Honorable Bernard A. Schwetz  
July 5, 2001  
Page 2

in *Association of Battery Recyclers v. EPA*, 208 F.3d 1047 (D.C. Cir. 2000), the court struck down certain language from EPA's rules defining "solid waste" under the Resource Conservation and Recovery Act (RCRA). Yet over 14 months later, the EPA has taken no action to delete the invalid provisions from its rules.

As a result, the public and regulated community outside the beltway are left with the false impression that these rules are still valid because they remain on the books. Businesses and individuals unwittingly expend significant resources to comply with rules that have been judicially determined to be invalid. The problem is magnified when state and local agencies often incorporate current agency rules into their regulatory schemes. 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.

Fortunately, this blatant intransigence or bureaucratic lethargy by the agency in removing invalid rules from the books can be easily remedied. Agency rules can be quickly revoked by publication in the *Federal Register* by taking advantage of the "good cause" exemption to notice and comment provided under the APA, 5 U.S.C. § 553(b)(B). The agency can specify that the expedited revocation of the rule is due to the fact that a court has struck it down.

Accordingly, WLF hereby petitions FDA to 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. WLF also petitions the FDA to promptly post a prominent notice on its website'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. With the increased utilization of the Internet by both government and businesses, the regulated community has come to rely on an agency's website as a convenient source for the latest regulatory developments

For example, the FDA's homepage, <http://www.fda.gov>, has a link to "Laws FDA Enforces." When a user clicks on that file, there are several other related links that may be accessed. However, there is no link on this page to current or recent litigation that may have affected the validity of the agency's regulations. Accordingly, WLF requests that FDA add a link to its website to court cases and rulings that have struck down agency regulations in whole or in part. After all, if an agency believes that it is in the public interest to provide information on its website about *proposed* legislation and *proposed* rules, it is certainly in the public interest to inform the public about *invalid* rules and the current state of the agency's rules as affected by recent court decisions.

The Honorable Bernard A. Schwetz

July 5, 2001

Page 3

Finally, WLF requests that FDA 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. WLF recently petitioned OIRA to issue an agency-wide OMB Directive to that effect.

We would be glad to provide you and your office with additional information and materials on this issue, and to meet with you and your staff at your convenience to discuss these matters further.

We appreciate this opportunity to bring this important issue to your attention, and we look forward to working with you on these and other critical issues.

Respectfully submitted,



Daniel J. Popeo

Chairman and General Counsel



Paul D. Kamenar

Senior Executive Counsel

encl



Vol. 11 No. 8

June 15, 2001

## EPA IGNORES COURT MANDATES TO REVOKE UNLAWFULLY ISSUED RULES

by  
Richard G. Stoll

In the past year, the U.S. Court of Appeals for the D.C. Circuit has issued a number of opinions that disapproved of the Environmental Protection Agency's (EPA) failure to use the Administrative Procedure Act (APA) rulemaking process. See Richard G. Stoll, *Court Forces EPA to Comply With Due Process Standards*, 15 LEGAL BACKGROUNDER 46 (Wash. Lgl. Fndt.), Sept. 8, 2000. The D.C. Circuit — which has exclusive jurisdiction to review most significant EPA actions — had vacated documents the EPA had released as informal “guidance” because the guidance should have been issued as a rule. *Appalachian Power Company v. EPA*, 208 F.3d 1015 (D.C. Cir. 2000); *Barrick Goldstrike Mines v. Browner*, 215 F.3d 45 (D.C. Cir. 2000).

This LEGAL OPINION LETTER presents the inverse situation. Just as the EPA may fail to issue a rule that should as a matter of law be issued, it may also fail to revoke a rule that should as a matter of law be revoked. The D.C. Circuit may decide a rule is invalid for substantive and/or procedural reasons and may accordingly vacate the rule. If the court vacates the rule, as a matter of law it should no longer be in force or effect. But the EPA can be slow to recognize such a court ruling. Sometimes for many months, the EPA leaves the rule on the books as if it were valid and enforceable.

For instance, in April, 2000, the D.C. Circuit decided *Association of Battery Recyclers v. EPA*, 208 F.3d 1047 (D.C. Cir. 2000). At issue were EPA rules defining “solid waste” under the Resource Conservation and Recovery Act (RCRA). The industry petitioners argued certain types of covered materials and activities could not be subject to RCRA jurisdiction and urged the Court to vacate those portions of the rules. The court agreed and vacated certain language in the rules. 208 F.3d at 1060. And in June, 2000, the D.C. Circuit decided *American Petroleum Institute (API) v. EPA*, 216 F.3d 50 (D.C. Cir. 2000). The industry petitioners argued other types of covered materials and activities could not be subject to RCRA jurisdiction. The court agreed and vacated additional portions of the EPA's rules. 216 F.3d at 58.

It is now 14 months after *Battery Recyclers* and 12 months after *API*. The EPA, however, has taken no action to delete the illegal provisions from its rules. To anyone who turns to EPA rules in the Code of Federal Regulations, the Web, or commercial compilations of the EPA's rules, the offending provisions still appear fully effective. Even in its semi-annual “regulatory agenda” of May 14, 2001, in which the EPA lists plans for scores of amendments to RCRA rules, there is no mention of plans to comply with these decisions.

It should be emphasized the vacated portions of the rules hardly constitute esoteric *minutiae* with little

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Richard G. Stoll practices environmental and administrative law with the D.C. office of Foley & Lardner. He has written and spoken extensively on federal rulemaking and judicial review topics.

real-world impact. Especially in the case of the rules vacated in *Battery Recyclers*, some of the most fundamental premises of EPA claims to RCRA jurisdiction have been declared invalid.

One might argue that the EPA's non-responsiveness to judicial decisions is not that significant. If a rule has been vacated by a court of competent jurisdiction, so the argument would go, the EPA cannot enforce it in any event. So what is the harm in letting a judicially-vacated rule languish on the books?

The answer has both legal and practical dimensions. Under the APA, the Code of Federal Regulations (C.F.R.) is supposed to stand as the official compilation of current, legally effective federal agency rules. Under 5 U.S.C. § 552(a)(1), each federal agency is to "currently" publish in the Federal Register, "for the guidance of the public," all substantive rules of general applicability that are "authorized by law." See especially § 552(a)(1)(D). Once codified in the C.F.R., the rules as published in the codification stand as "prima facie evidence" of the fact they "are in effect." 44 U.S.C. § 1510(e). For the EPA to let judicially-vacated rules remain on the books for months or years is certainly not consistent with these statutory provisions, as the EPA is not keeping the public informed "currently" as to which rules "are in effect."

As a practical matter, it is easy to see how regulated parties and the interested public could be confused and misled by this inaction. Many EPA rules affect tens of thousands of individuals or entities throughout the nation. These parties cannot be presumed to read D.C. Circuit opinions, and/or to maintain their own personal catalogues of which rules are vacated by various opinions.

This may be an especially acute problem in many state environmental programs for which state agencies routinely copy or incorporate by reference federal regulations. For instance, a state agency might (as many do) decide to update its state hazardous waste regulations in 2001 by copying or incorporating by reference the EPA's definition of solid waste. If a state agency did this right now, it would copy or incorporate provisions that have been held illegal as a matter of federal law. As many states have statutes prohibiting state agencies from adopting regulations more stringent than federal rules, this can cause all sorts of practical and legal complications at the state level.

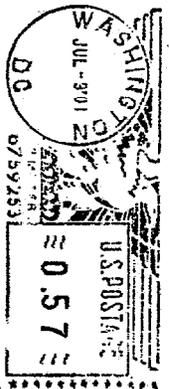
Granted, EPA personnel are busy and overworked, but that does not justify the current situation. The EPA need invest little time or resources in taking the necessary legal action. Where words of a rule must be deleted to comply with a court mandate, "good cause" exists to revoke the offending language in an immediately final rule without first having to propose it for public comment. 5 U.S.C. § 553(b)(B). Moreover, the EPA need spend little time or effort explaining the basis for the revocation — as long as the EPA makes clear it is taking the action to comply with a court decision and cites the court decision, little more need be said. The EPA recently revoked certain rules that had been vacated by the D.C. Circuit eleven months earlier. The Federal Register notice shows the revocation process can be short, simple, and direct. 66 Fed. Reg. 24270 (May 14, 2001).

Also granted, the appropriate response to a judicial vacatur may not always be so simple as deleting a few words. It could be, for instance, that as a result of a court's opinion, the EPA should not only delete certain provisions but also propose new language to replace the offending language. Even in this situation, however, the EPA could easily and quickly place the public on notice as to the correct state of the law by publishing a C.F.R. "NOTE" or "COMMENT" immediately after the offending regulatory language. (EPA regulations often use such "NOTES" and "COMMENTS" for other purposes. See 40 C.F.R. § 261.33 for examples of "COMMENTS"; 40 C.F.R. § 262.82 for examples of "NOTES".)

The "NOTE" could simply state that the above-cited regulatory language was vacated by a court — citing the name and date of the opinion — and furthermore state that the EPA is working on a response to the court's opinion. At least in this mode the public would not be misled, as they are now, into thinking that words appearing in the C.F.R. are legally valid and enforceable when they are not.

**WLF** Washington Legal Foundation  
effective advocate of free enterprise®  
2009 Massachusetts Ave., NW  
Washington, DC 20036

To:  
Mr. Bernard A. Schwetz,  
Deputy Commissioner, FDA  
Parklawn Building, Suite 14-71  
5600 Fishers Lane  
Rockville, MD 20857



**ROUTING SLIP**  
**GENERATED BY: HF-40**  
**DATE: JUL 12, 2001**

**FDA CONTROL NUMBER:** 01 3505

**TRACER #:**           **OS #:**

**DATE OF CORRESPONDENCE:** 07/05/01

**DATE INTO FDA:** 07/12/01

**TO:** BERNARD A SCHWETZ HF-1

**FROM:** DANIEL J POPEO, WASHINGTON LEGAL FOUNDATION  
PAUL D KAMENAR, WASHINGTON LEGAL FOUNDATION

**SYNOPSIS:** WRITES REGARDING INVALID FDA REGULATIONS

**LEAD OFFICE:** HF-22

**HOME OFFICE:** HF-40

**CONTACT/PHONE#:** VALERIE A JACKSON WATSON 301-827-4434

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GCF-1

**COORDINATION:**

**SIGNATURE REQUIRED:**

**REFERRALS FROM HF-40**

<b>ASSIGNED TO</b>	<b>ACTION</b>	<b>DUE DATE</b>
----- HF-22            HUBBARDW	----- PREPARE DIRECT REPLY	----- 07/23/01
REMARKS: PLEASE SEND COPY OF RESPONSE TO VJACKSON-WATSON, HF-40		

WASHINGTON LEGAL FOUNDATION

2009 MASSACHUSETTS AVENUE, N.W.  
WASHINGTON, D. C. 20036  
202 588-0302

July 27, 2001

Rec'd 7/31/01  
JK

Jenny Butler  
Dockets Management Branch  
Food and Drug Administration  
5630 Fishers Lane  
HFA 305  
Room 1061  
Rockville, MD 20852

Re: WLF Petition of July 12, 2001 Regarding Revoking Invalid Regulations

Dear Ms. Butler:

Per our telephone conversation today, the following is the certification and environmental statement for our petition:

**Environmental Assessment**

Petitioner claims a categorical exclusion for the preparation of an environmental assessment or environmental impact statement under 21 C.F.R. § 25.30(a).

**Economic Impact Statement**

Petitioner will submit this information upon request of the Commissioner if required. In short, petitioner believes that FDA's failure to revoke any invalid regulation has a detrimental economic impact because companies are required to expend resources to comply with the invalid rules.

**Certification**

The undersigned certify that, to the best of their knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes all representative data and information known to the petitioner which are unfavorable to the petition. WLF reserves the right to submit supplement information and argument in support of its petition.

Sincerely yours,



Paul D. Kamenar  
Senior Executive Counsel