

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

NATIONAL ASSOCIATION OF CHAIN)	
DRUG STORES and NATIONAL)	
COMMUNITY PHARMACISTS)	
ASSOCIATION,)	
)	Civil Action No. 1:07-cv-02017 (RCL)
Plaintiffs,)	
v.)	
)	
UNITED STATES DEPARTMENT OF)	
HEALTH AND HUMAN SERVICES, <i>et al.</i>,)	
)	
Defendants.)	

**MOTION OF THE NATIONAL ASSOCIATION OF CHAIN
DRUG STORES AND NATIONAL COMMUNITY PHARMACISTS
ASSOCIATION TO SUPPLEMENT ADMINISTRATIVE RECORD**

The National Association of Chain Drug Stores (“NACDS”) and the National Community Pharmacists Association (“NCPA”) move this Court to supplement the Administrative Record with the expert report of Stephen W. Schondelmeyer, Pharm.D, Ph.D, FAPHA (a copy of which is attached as Exhibit A). In support of their motion, NACDS and NCPA state as follows:

1. On July 17, 2007, the Secretary of the United States Department of Health and Human Services (“HHS”), through the Centers for Medicare and Medicaid Services, promulgated a final rule related to the calculation of Average Manufacturer Price (“AMP”) and Federal Upper Limits (the “AMP Rule”). 72 Fed. Reg. 39142 (July 17, 2007). NACDS and NCPA filed a complaint for declaratory and injunctive relief, arguing that the AMP Rule disregards the plain language of the Social Security Act, Congress’ clear intent when it enacted that statutory language, Defendants’ prior application of the statutory language, dozens of federal and state statutes and regulations, long-standing industry practice, and common sense.

Concurrently with the filing of this motion, NACDS and NCPA have filed their motion seeking a preliminary injunction and requesting an expedited hearing.

2. In the memorandum in support of the preliminary injunction, NACDS and NCPA demonstrate that the statutory definition of AMP is clear and simple: AMP is the average price paid to drug manufacturers by wholesalers for drugs distributed to the retail pharmacy class of trade. 42 U.S.C. §1396r-8(k)(1). In their memorandum in support, NACDS and NCPA also demonstrate that the AMP rule cannot survive an analysis under Step One of *Chevron USA, Inc. v. NRDC*, 467 U.S. 837 (1984) because the AMP Rule clearly exceeds the plain language of the Social Security Act. In addition, NACDS and NCPA also demonstrate that the AMP Rule cannot withstand analysis under Step Two of *Chevron* because the definition of AMP promulgated by HHS in the AMP Rule arbitrarily and capriciously disregards the plain language of the Social Security Act, Congress' clear intent when it enacted that statutory language, the Defendants' prior application of the statutory language, dozens of federal and state statutes and regulations, long-standing industry practice, and common sense.

3. In conducting the *Chevron* analysis under Step One and Step Two, reliance on expert definitions of terms and terms of art is a sound "general rule of construction." *Massachusetts v. Blackstone Valley Electric Co.*, 67 F.3d 981, 986 (1st Cir. 1995); *see also*, *Corning Glass Works v. Brennan*, 417 U.S. 188, 201 (1974) ("[W]here Congress has used technical words or terms of art, 'it [is] proper to explain them by reference to the art or science to which they [are] appropriate.'") The statutory language defining AMP uses certain terms of art and this Court may benefit from expert analysis in its *Chevron* Step One analysis. In addition, the Schondelmeyer report amply demonstrates the arbitrary and capricious nature under *Chevron* Step Two of the AMP Rule.

4. Finally, the Schondelmeyer report provides this Court with an economic analysis of the impact of the faulty AMP Rule on pharmacies.

5. Moreover, in cases involving rule making by an agency, “where relief is at issue, especially at the preliminary injunction stage,” supplementing the record with an expert report is appropriate. *Amfac Resorts, LLC v. U.S. Department of Interior*, 143 F. Supp. 2d 7, 11 (D.D.C. 2001).

6. The undersigned certifies that consent to this Motion could not be obtained from opposing counsel pursuant to LCvR 7(m) because opposing counsel has not yet been identified by Defendants.

WHEREFORE, the National Association of Chain Drug Stores and the National Community Pharmacists Association respectfully request that this Court enter an Order supplementing the Administrative Record with the expert report of Stephen Schondelmeyer.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on the 15th day of November, 2007, true copies of the foregoing Motion of The National Association of Chain Drug Stores and National Community Pharmacists Association To Supplement Administrative Record and Order were served via certified mail, return receipt requested, postage pre-paid on the following:

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