UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ASSOCIATION OF AMERICAN, PHYSICIANS AND SURGEONS, INC., et al., **Plaintiffs,** **v.** **UNITED STATES FOOD AND DRUG ADMINISTRATION, et al.,** **Defendants.**	**Civil Action 00-02898 (HHK)**

MEMORANDUM OPINION

Plaintiffs, Association of American Physicians and Surgeons ("AAPS"), Competitive Enterprise Institute ("CEI"), and Consumer Alert, bring this lawsuit to challenge the authority of the United States Food and Drug Administration ("FDA") to promulgate "Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients" ("Pediatric Rule"), 21 C.F.R. §§ 201, 312, 314, 601, 63 Fed. Reg. 66,632 (Dec. 2, 1998). Plaintiffs claim that the Pediatric Rule exceeds the FDA's statutory authority and that the Rule's promulgation was arbitrary and capricious. Plaintiffs thus petition this court for relief pursuant to the Administrative Procedure Act ("APA"), 5 U.S.C. § 701 *et seq.*

Before this court are the parties' cross-motions for summary judgment. Upon consideration of the parties' submissions and the summary-judgment record,[1] the court concludes

[1] The court has also considered the views of the amici curiae, the American Academy of Pediatrics, the Elizabeth Glaser Pediatric AIDS Foundation, and the Pediatric Academic Societies.

that defendants' motion for summary judgment must be denied and plaintiffs' motion for summary judgment must be granted.

I. FACTUAL BACKGROUND

The Federal Food Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 321 *et seq.,* provides a systematic scheme for the approval of new drugs and new drug formulations intended to be marketed for use in interstate commerce. Under the FDCA, a new drug product cannot be marketed unless the FDA approves the product and determines that it is safe and effective for its intended use. *See* 21 U.S.C. § 355(a). When the FDA approves a drug, it approves the drug only for the particular use for which it was tested, but after the drug is approved for a particular use, the FDCA does not regulate how the drug may be prescribed. Thus, a drug that has been tested and approved for adult use only can be prescribed by a physician for her pediatric patients.

Because of the expense and difficulty in finding substantial pediatric populations to undergo tests, along with the ethical complications associated with testing new drugs on children, many drugs are tested for safety and effectiveness in adults only. As a result, even though there are many diseases and ailments that are common to both children and adults, physicians with pediatric patients[2] often find their treatment options limited. Some physicians, forced "to choose between prescribing drugs without well-founded dosing and safety information or utilizing other, potentially less effective, therapy" respond by prescribing adult-approved drugs to children, but in a smaller dose. *See* Regulations Requiring Manufacturers to Assess the

[2] The FDA defines "pediatric patients" as "the pediatric age group, from birth to sixteen years, including age groups often called neonates, infants, children, and adolescents." *See* 21 C.F.R. § 201.507(f)(9). In this memorandum opinion, those in the age group affected by the Pediatric Rule will be referred to both as "pediatric patients" and as "children."

Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients, 62 Fed. Reg. 43,900 (Aug. 15, 1997).

Prescribing adult-approved drugs to children is often referred to as going "off-label." An off-label use is the prescription of a drug by a doctor for a condition not indicated on the label or for a dosing regimen or patient population not specified on the label. Off-label use of pharmaceuticals appears to be "generally accepted" in the medical community. *See Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 56 (D.D.C. 1998) *vacated in part on other grounds*, 202 F.3d 331 (D.C. Cir. 2000) (observing that "off-label use of FDA-approved drugs by physicians is an established aspect of the modern practice of medicine"); *Buckman Co. v. Plaintiffs' Legal Comm.*, No. 98-1768, 2001 WL 167647, at * 5 (U.S. Feb. 21, 2001).

While it is a common practice for physicians to prescribe to children pharmaceuticals only approved for adult use, by doing so, they can expose children to various hazards. Children may be given an ineffective dose or an overdose, and they face an increased risk of side effects. *See* 62 Fed. Reg. 43,900, 43,901. This happens because:

> Correct pediatric dosing cannot necessarily be extrapolated from adult dosing information using an equivalence based either on weight . . . or body surface area. . . . Potentially significant differences in pharmacokinetics may alter a drug's effect in pediatric patients. The effects of growth and maturation of various organs, maturation of the immune system, alterations in metabolism throughout infancy and childhood, changes in body proportions, and other developmental changes may result in significant differences in the doses needed by pediatric patients and adults.

62 Fed. Reg. at 43,901.

In the face of insufficient information about a new medication, pediatricians do not merely prescribe inexact doses, however. Physicians sometimes prescribe for their young

patients older, less effective, but well-tested medication–as opposed to newer, more effective, medication that has not been subjected to rigorous study on pediatric populations. This practice keeps children from benefitting from state-of-the-art medication. *See* 63 Fed. Reg. at 66,632.

In response to these concerns, in 1994, the FDA issued a regulation requiring manufacturers of marketed drugs to survey existing data and determine whether the data was sufficient to support pediatric use information on the drug's labeling. If so, the FDA required manufacturers to submit a supplemental new drug application seeking the FDA's approval of the labeling change. If the drug had not been sufficiently tested on children, the rule required the manufacturer to include in the product's labeling a statement to read: "Safety and effectiveness in pediatric patients have not been established." 21 C.F.R. § 201.57(f)(9)(vi).

Also in an effort to encourage pediatric testing, in 1997, Congress passed the Food and Drug Administration Modernization Act ("FDAMA"), Pub. L. No. 105-115, 111 Stat. 2296 (1997). This Act established a five-year experimental program to encourage pediatric drug-testing. Under this Act, the FDA could request (but never require) manufacturers of new drugs to conduct studies on pediatric patients. Drug manufacturers that agreed to conduct these pediatric tests could receive six months of market exclusivity for their products. *See* 21 U.S.C. § 355a(a). Similarly, for already-marketed drugs, Congress required the FDA to publish a "list of approved drugs for which additional pediatric information may produce health benefits." § 355a(b). The statute also contained a requirement that the FDA report to Congress on the effectiveness and adequacy of this provision by January 1, 2001.[3]

[3] The FDA provided this Status Report to Congress in January 2001. The Report provided that the "pediatric exclusivity provision has been highly effective in generating pediatric studies of many drugs and in providing useful new information in product labeling." Status Report to Congress at i.

Finding that the voluntary incentive provisions of FDAMA did not increase pediatric testing as much as the FDA had hoped, after proper notice-and-comment, the FDA issued the "Pediatric Rule" in 1998.[4] *See* 63 Fed. Reg. at 66,632; *see also id*. at 66,639 (providing it "does not believe . . . that incentives alone will result in pediatric studies of some of the drugs and biologics where the need is greatest."); Letter from Hubbard to Rein, 11/1/2000 at 1 (hereafter "HHS Denial") ("the voluntary nature of the pediatric exclusivity incentive is likely to leave many drugs, age groups, and indications unstudied"); *id*. at 7 ("data indicate that voluntary efforts had not, by 1997, substantially increased the number of products entering the marketplace with adequate pediatric labeling"). This Rule's legitimacy is challenged here.

In application, the Pediatric Rule distinguishes new drugs from already-marketed drugs. Manufacturers of new drugs "may be required to submit an application containing data adequate to assess whether the drug is safe and effective in pediatric populations. The application may be required to contain adequate evidence to support dosage and administration in some or all pediatric subpopulations, including neonates, infants, children, and adolescents . . . " 21 C.F.R. § 201.23(a). This means, in effect, drug manufacturers may now be obligated to study their product on pediatric populations, even if the product is not explicitly marketed for children's use. In addition, the "applicant may also be required to develop a pediatric formulation for a drug

[4] The Pediatric Rule was actually proposed in 1997, finalized in 1998, and became effective on April 1, 1999. Manufacturers have been required to submit pediatric testing mandated by the Rule since December 2, 2000.

product that represents a meaningful therapeutic benefit [5] to such patients over existing therapies." *Id*.

The FDA presumes that sponsors will study all new drugs in pediatric patients unless the applicant can show that waiver is appropriate. Waivers are granted if: (1) necessary studies are impossible or highly impractical because, e.g., the number of such patients is so small or geographically dispersed; or (2) there is evidence strongly suggesting that the product would be ineffective or unsafe in all pediatric age groups.[6] 21 C.F.R. §§ 314.55(c)(2), 601.27(c)(2). In addition, an applicant may request a partial waiver of the above testing and development requirements if the applicant certifies that the product: (1) does not represent a meaningful therapeutic benefit for pediatric patients over existing treatments; and (2) is not likely to be used in a substantial number of pediatric patients. §§ 314.55(c)(2), 601.27(c)(2); 63 Fed. Reg. at 66,634. Partial waiver may also be available if a manufacturer can demonstrate that reasonable attempts to produce a pediatric formulation necessary for a particular age group have failed. *See* 21 C.F.R. §§ 314.55(c)(3), 601.27(c)(3).

For already-marketed drugs, the Pediatric Rule still applies, but it has a more narrow sweep. For such drugs, the FDA may still require a manufacturer to submit an application containing adequate evidence to support dosage and administration in some or all pediatric subpopulations, and the FDA may also still require an applicant to develop a pediatric drug

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[5] The term "meaningful therapeutic benefit" is defined as a significant improvement in the treatment, diagnosis, or prevention of a disease, compared to marketed products adequately labeled for that use in the relevant pediatric population. 21 C.F.R. § 314.55(c)(5).

[6] If a waiver is granted because the manufacture shows that the product would be ineffective or unsafe in pediatric populations, this information must be included on the product's labeling. *See* 21 C.F.R. § 201.23(c)(3).

formulation. 21 C.F.R. § 201.23(a). In this context, however, the burden is on the FDA show that such testing and analysis is required. *See id*. The FDA satisfies this burden only if the absence of adequate labeling could pose significant risks to pediatric patients; and either (1) the drug is "used in a substantial number of pediatric patients for the labeled indications;" or (2) there is "reason to believe that the drug product would represent a meaningful therapeutic benefit over existing treatments for pediatric patients for one or more of the claimed indications." 21 C.F.R. § 201.23(b).

This Rule's application, for both new and existing drugs, is limited in three other respects as well. First, the Rule does not require a manufacturer to study its product for unapproved or unclaimed indications, even if the product is widely used in pediatric patients for those indications. *See* 63 Fed Reg. 66,658; FDA Denial at 7. This means that a drug marketed as a cure for one disease in adults does not need to be tested for its ability to cure an entirely different disease in children. Second, the Pediatric Rule allows drug manufacturers to defer pediatric testing until after the FDA has approved the product for adult use. *See* 21 C.F.R. § 314.55(b); 63 Fed. Reg. at 66,634, 66,642-44.[7] Third, the Rule only requires testing of new "innovator" drugs. The Rule does not apply to generic copies of previously-approved drugs or for suitability petitions for a change in dosage strength.[8]

[7] Deferrals may be granted if, among other reasons: (1) the drug is ready for approval in adults before studies in pediatric patients are complete; or (2) pediatric studies should be delayed until additional safety or effectiveness data have been collected. § 314.55(b).

[8] A suitability petition is a petition to file an Abbreviated New Drug Application for a product that differs from an approved pioneer drug in its route of administration, dosage form, or strength. *See* 21 U.S.C. § 355(j)(2)(C); 21 C.F.R. § 314.93.

When the Pediatric Rule does apply, however, it has real teeth to force compliance. If a manufacturer refuses to submit an application containing indications for pediatric use or fails to submit a requested pediatric formulation, the FDA may seek a federal court injunction to declare that the product is "misbranded or an unapproved new drug or unlicenced biologic." § 201.23 (d); 63 Fed. Reg. at 66,636. The FDA may also request that the court impose fines or subject the manufacturer to contempt proceedings. *Id*. In addition, in rare cases, the FDA may withdraw approval of the drug or biological product. *Id*.

In 1999, plaintiffs filed a citizen petition with the FDA, challenging the Pediatric Rule's wisdom and legal authority. The FDA denied the petition in 2000, advancing essentially the same defenses it advances here. This suit, brought under the judicial review provisions of the Administrative Procedure Act ("APA"), 5 U.S.C. § 701 *et seq*., followed.

Since the filing of this lawsuit, Congress has passed, and the President has signed into law, the "Best Pharmaceuticals for Children Act," Public Law No. 107-109, 115 Stat. 1408 (2002) ("BPCA"). This Act reauthorized and expanded the pediatric testing incentives set forth in FDAMA. The BPCA endorses the goal of increasing the number of drugs studied in pediatric populations but does not authorize FDA to require manufacturers to conduct pediatric testing. Instead, the Act establishes a legislative framework to encourage voluntary testing. Under the Act, a manufacturer receives an additional six months of market exclusivity on a new or marketed drug if: (1) FDA determines that pediatric testing of the drug "may produce health benefits in that population;" (2) FDA makes a written request to the manufacturer to conduct such testing; (3) the manufacturer agrees to test the drug within an appropriate time-frame; (4)

the manufacturer conducts the tests and submits reports of these tests to the FDA; and (5) the FDA accepts the testing reports. *See* 21 U.S.C. § 355 a(a), (c).

In addition, when the FDA determines that more information about a particular drug is needed, the BPCA establishes two ways third parties may be paid to generate this information. First, the FDA may "refer the drug to the Foundation for the National Institutes of Health" ("the Foundation"), a non-profit organization, and the FDA may authorize the Foundation to collect funds for pediatric pharmacologic research and drug testing. *See* 42 U.S.C. § 284m(a). The Foundation may then award a research grant to a third party who will conduct the necessary studies and provide the FDA with its final report and supporting data. § 284m(b)(6)(A). Alternatively, if the Foundation has insufficient funds to pay for the pediatric testing, the BPCA establishes a public fund of $200 million for fiscal year 2002 and "such sums as are necessary for each of the five succeeding fiscal years" that FDA may use to pay a third party to conduct the relevant tests. § 284m(d).

If relevant new information is discovered as a result of this third-party pediatric testing, the BPCA establishes a multi-step process by which the FDA may seek product reformulations and labeling changes. If the third-party's results indicate that a *formulation* change is necessary and the FDA agrees, FDA will send a "nonbinding" letter of recommendation regarding that formulation change to the drug's manufacturer.[9] *See* § 284m(c)(12). Alternatively, if the FDA determines that a *labeling* change is necessary, the FDA must first attempt to reach agreement with the manufacturer. *See* 42 U.S.C. § 284m(c)(7). If the FDA and drug manufacturer are unable to agree on the proposed change, the FDA "shall refer the request" to a Pediatric

[9] The more precise term is "holder(s) of an approved application," but for ease of reference, the term "manufacturer" is used.

Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee ("Subcommittee"), which will make a labeling recommendation within ninety days. The FDA will then review the Subcommittee's recommendation and, if appropriate, request that the manufacturer change its label accordingly. § 284m(c)(9). If the manufacturer still refuses, after thirty days, the FDA may deem the drug to be misbranded §284m(c)(11). In addition, the United States may bring any other appropriate enforcement action authorized under the FDCA. §284m(c)(11). By statute, the BPCA is to sunset in 2007.

II. ANALYSIS

A. Legal Background

Plaintiffs claim that the FDA had no authority to promulgate the Pediatric Rule. Specifically, plaintiffs argue that the "FDA has no authority to require manufacturers to (1) conduct studies of drug uses for which they do not intend to seek approval or (2) devise

formulations of the drug tailored to those uses." Pls.' Mot. for Summ. J. at 24.[10] Plaintiffs thus petition this court for injunctive and declaratory relief. Complaint ¶ 45.

It is a basic tenet of administrative law that "an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress." *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988). Indeed, "[t]he extent of [an agency's] powers can be decided only by considering the powers Congress specifically granted it in the light of the statutory language and background." *Am. Fin. Servs. Ass'n v. FTC*, 767 F.2d 957, 965 (D.C. Cir. 1985) (citation and internal quotations omitted). *See United States v. Larionoff*, 431 U.S. 864, 873 (1977) (to be valid, regulations must be "consistent with the statute under which they are promulgated"); *INS v. Chadha*, 462 U.S. 919, 953 n. 16 (1983) (providing that agency action "is always subject to check by the terms of the legislation that authorized it"); *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 213-14 (1976) ("The rulemaking power granted to an administrative agency charged with the administration of a federal statute is not the power to

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[10] Plaintiffs also attack the Pediatric Rule on a number of other bases. First, they claim, the FDA has never shown that the purported absence of pediatric labeling information poses significant risks to children and in the absence of such a showing, "the agency's decision should be rejected." Pls.' Mot. for Summ. J. at 40 (citing *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 167 (1962); *Home Box Office, Inc. v. FCC*, 567 F.2d 9, 36 (D.C. Cir. 1977); *Northwest Airlines Inc. v. Goldschmidt*, 645 F.2d 1309, 1317 (8th Cir. 1981)). Second, plaintiffs claim that the FDA's promulgation of the Pediatric Rule is arbitrary, capricious, and an abuse of discretion because, according to plaintiffs, the Pediatric Rule applies different standards to similarly situated persons. *See* Complaint ¶ 41. Third, plaintiffs argue that the FDA's chosen remedy for enforcing the Pediatric Rule conflicts with FDCA's scheme. Here, plaintiffs allege that under the Pediatric Rule, the remedy for misbranding is use of a mandatory injunction forcing manufacturers to conduct the prescribed testing. In contrast, plaintiffs argue, under the FDCA, if a drug is truly "dangerous to health," contains false or misleading labeling, or fails to contain adequate directives for use, the FDA must declare the drug misbranded or withdraw it from the market entirely. *See* Pls.' Mot. for Summ. J. at 28 (citing 21 U.S.C. §§ 334, 355(j)); Pls.' Mem. in Opp. to Defs.' Mot. for Summ. J. at 34, 35. Because the court concludes the FDA lacked jurisdiction to promulgate the Rule, the court need not consider these claims.

make law. Rather, it is the power to adopt regulations to carry into effect the will of Congress as expressed by the statute.") (citations and internal quotations omitted); *Gibas v. Saginaw Min. Co.*, 748 F.2d 1112, 1117 (6th Cir. 1984) ("administrative agencies are vested only with the authority given to them by Congress"). The first issue for the court to consider, therefore, is whether the FDA had statutory authority to enact the Pediatric Rule.

To begin, it is well settled that, when interpreting its own statute, the FDA is to be given deference. *See generally Udall v. Tallman*, 380 U.S. 1, 16 (1965); *Forester v. Consumer Product Safety Comm.*, 559 F.2d 774, 783 (D.C. Cir. 1977). In addition, the FDCA "is to be given a liberal construction consistent with [its] overriding purpose to protect the public health." *United States v. Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 798 (1969). Moreover, the court should not analyze the FDCA's provisions in isolation, divorced from their broader context. The question for this court is "'whether the statutory scheme as a whole justified promulgation of the regulation.'" *Nat'l Confectioners Ass'n v. Califano*, 569 F.2d 690, 693 (D.C. Cir. 1978) (quoting *Toilet Goods Ass'n v. Gardner*, 387 U.S. 158, 163 (1967)). It is that question to which we now turn.

B. The FDA's Authority to Promulgate the Pediatric Rule

Chevron, U.S.A., Inc. v. Natural Resources Def. Council, Inc., 467 U.S. 837 (1984), provides the framework that governs judicial review of agency decisions. In *Chevron*, the Supreme Court set out the now-familiar two-step test for reviewing an agency's interpretation of a statute. First, the reviewing court must ask "whether Congress has directly spoken to the precise question at issue." *Chevron,* 467 U.S. at 842. If so, "that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of

Congress." *Id*. at 842-43. If, however, the statute is silent or ambiguous with respect to the specific issue, "the reviewing court must defer to the agency's construction of the statute, so long as it is reasonable." *Id*. at 843.[11]

This court must determine whether Congress intended to vest the FDA with authority to promulgate the Pediatric Rule. In doing so, we are guided, in part, by the D.C. Circuit's admonishment in *ACLU v. FCC*, 823 F.2d 1554 (D.C. Cir. 1987):

> Where the issue is one of whether a delegation of authority by Congress has indeed taken place (and the boundaries of any such delegation), rather than whether an agency has properly implemented authority indisputably delegated to it, Congress can reasonably be expected both to have and to express a clear intent. The reason is that it seems highly unlikely that a responsible Congress would implicitly delegate to an agency the power to define the scope of its own power. When an agency's assertion of power into new arenas is under attack, therefore, courts should perform a close and searching analysis of congressional intent, remaining skeptical of the proposition that Congress did not speak to such a fundamental issue.

Id. at 1567 n. 32. *See also Continental Air Lines, Inc. v. Dept. of Transp.*, 843 F.2d 1444, 1449 n. 4 (D.C. Cir. 1988) ("Congress can reasonably be expected to be quite precise in defining critical jurisdictional terms going to the very power of the agency to regulate."). "The more intense scrutiny that is appropriate when the agency interprets its own authority may be

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[11] The FDA relies heavily on the Supreme Court's recent decision in *United States v. Mead Corp*., 533 U.S. 218 (2001). *See* Defs.' Mem. in Supp. of Mot. for Summ. J. at 14-15. In that decision, the Supreme Court upheld a United States Custom Service tariff classification, finding that the rule was entitled to *Chevron* deference. The Supreme Court stressed that "considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer." *Mead,* 533 U.S. at 227 (citing *Chevron*, 467 U.S. at 844). While this case highlights the deference that is due administrative agencies, given their "body of experience and informed judgment," the case is inapposite to the instant action. *Id. Mead* clearly provides that deference is due "*[a]ssuming in each case, of course, that the agency's exercise of authority . . . does not exceed its jurisdiction*." *Id.* at 228 n. 6 (emphasis added). The precise issue in this case, however, is whether the FDA has exceeded its jurisdiction in promulgating the Pediatric Rule.

grounded in the unspoken premise that government agencies have a tendency to swell, not shrink, and are likely to have an expansive view of their mission." *Hi-Craft Clothing Co. v. NLRB*, 660 F.2d 910, 916 (3d Cir. 1981). For that reason, although some deference is still due, "an agency ruling that broadens its own jurisdiction is examined carefully." *Id.*

To determine whether Congress has delegated to the FDA the authority to promulgate the Pediatric Rule, the court must examine the FDCA, which the FDA claims provides the basis for its authority,[12] and the ever-evolving statutory scheme, recognizing that the FDCA's meaning "may be affected by other Acts, particularly where Congress has spoken subsequently and more specifically to the topic at hand." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (citing *United States v. Estate of Romani*, 523 U.S. 517, 530-31 (1998); *United States v. Fausto*, 484 U.S. 439, 453 (1988)); *see Dunn v. CFTC*, 519 U.S. 465, 475 (1997). After examining: (1) specific provisions of the FDCA, as well as the Act's broader context; (2) the legislative history of the BPCA; and (3) the conflict between the BPCA and Pediatric Rule, this court concludes that Congress has directly spoken to the issue here and has precluded the FDA's jurisdiction to promulgate the Pediatric Rule.

1. The FDCA

We first turn to the FDCA, which the FDA claims serves as the basis for its authority. The FDA claims that its authority to promulgate the Pediatric Rule comes, generally, from 21 U.S.C. § 371(a). This Section provides: "The authority to promulgate regulations for the

[12] If statutory language is unambiguous and "the statutory scheme is coherent and consistent," the inquiry begins and ends with statutory text. *See Robinson v. Shell Oil Co*., 519 U.S. 337, 340 (1997). But, where, as here, the language is ambiguous, the court must examine the entire context of the statutory scheme. *See United States v. Storer Broad. Co.,* 351 U.S. 192, 203 (1956).

efficient enforcement of this chapter . . . is vested with the Secretary." As the Second Circuit has provided "'the validity of a regulation promulgated'" under § 371 "will be sustained so long as it is 'reasonably related to the purposes of the enabling legislation.'" *United States v. Nova Scotia Food Products Corp*., 568 F.2d 240, 246 (2d Cir. 1977) (quoting *Mourning v. Family Publ'ns Serv., Inc*., 411 U.S. 356, 369 (1973)).

Although deference is due, it is equally true that regulations issued under 21 U.S.C. § 371(a) "must effectuate a congressional objective expressed elsewhere in the Act." *Pharm. Manuf. Assoc. v. FDA*, 484 F. Supp. 1179, 1183 (D. Del. 1980). *See Mourning*, 411 U.S. at 371. Section 371 does not constitute an independent grant of authority that permits FDA to issue *any* regulation the agency determines would advance the public health. Rather, § 371 permits the FDA to use rules as a means of administering authorities otherwise delegated to it by the Congress. *See generally Nat'l Confectioners Ass'n v. Califano*, 569 F.2d 690, 695 (D.C. Cir. 1978); *Pharm. Mfrs. Ass'n,* 484 F. Supp. at 1183. Review of other specific FDCA provisions is therefore required.

a. Labeling Provisions

FDA bases the Pediatric Rule, in part, on its authority under 21 U.S.C. §§ 352(a), 352(f), 355(d)(7), and 321(n), which pertain to labeling. *See* 62 Fed. Reg. at 43,907. Section 352(a) provides that drugs or devices are misbranded if they contain false or misleading labels, and Section 352(f) requires labels to contain adequate directions for use. Section 321(n) defines labeling as misleading if it "fails to reveal facts . . . material with respect to consequences which may result" from the use of the product as labeled or "from use of the article . . . under such conditions of use as are customary or usual." 21 U.S.C. § 321(n).

Plaintiffs claim that § 352(n) and the other labeling provisions cannot support the Pediatric Rule because, according to plaintiffs, the FDA's ability to require manufacturers to include "adequate directions for use," simply permits the FDA to ensure that a product bears adequate directions for its *claimed* uses. In addition, plaintiffs contend that these provisions give the FDA limited power–power that truly extends to only "labeling and reporting" matters. According to plaintiffs, these provisions only authorize the FDA to require manufacturers to "(a) include in their labeling certain *known* material facts about products and (b) report to FDA on the use of the drugs in certain circumstances." Pls.' Mem. in Opp. to Defs.' Mot. for Summ. J. at 25. Plaintiffs argue that "in no event" do these statutory provisions give the FDA the authority to "require manufacturers to generate new data and formulations." *Id*.

The question is a close one, however. Section 321(n) plainly provides that, in determining whether a label is misleading, the agency should look to whether the "labeling fails to reveal [material] facts . . . under such conditions of use as are *customary or usual*" (emphasis added). In adopting the Pediatric Rule, the FDA relied on extensive evidence demonstrating that at least some drugs are "commonly" or "usually" used by children, despite the absence of pediatric labeling. 62 Fed. Reg. at 43,900-01, 43,908; 63 Fed. Reg. at 66,636-38, 66,658. In addition, there is authority for the proposition that a label can be misleading based on what it

fails to say, in addition to what is actually said.[13] *See Pharm. Manuf. Assoc.*, 484 F. Supp. at 1184-85.

Although § 201(n) and the other sections regarding labeling speak to some of the matters at issue here, FDA's power to promulgate the Pediatric Rule cannot rest solely on these provisions. Most problematic are those Pediatric Rule provisions that require manufacturers to (1) conduct studies of drugs for unclaimed uses or (2) devise formulations of the drug tailored to those uses. It is simply difficult to see how such power can be wholly derived from the FDA's power over drug labeling. Moreover, if Congress had intended for these sections to authorize the FDA to require manufacturers to test their drugs for unclaimed uses, Congress would likely have spoken more clearly, especially since "Congress can reasonably be expected to be quite precise in defining critical jurisdictional terms going to the very power of the agency to regulate." *Continental Air Lines, Inc. v. Dept. of Transp.*, 843 F.2d 1444, 1449 n. 4 (D.C. Cir. 1988). Finally, the Pediatric Rule primarily impacts new drugs, which do not yet have any "customary or usual" use. The FDCA's labeling provisions, therefore, do not provide a clear basis for the Pediatric Rule.[14]

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[13] FDA also points to 21 U.S.C. §§ 355(i) and (k) as well as 42 U.S.C. § 262. *See* 62 Fed. Reg. at 43,908. Section 355 (i) authorizes the FDA to regulate the use of drugs for investigational purposes. Section § 355(k) requires that regulations issued under § 355(i) be promulgated with "due regard for the . . . interests of patients" and authorizes the FDA to order the holders of approved drug applications to submit reports necessary to determine whether there are grounds to withdraw approval of the applications. Title 42 U.S.C. § 262, a provision of the Public Health Service Act, requires a showing of drug "potency" or effectiveness. The court finds that these provisions do not, even arguably, provide a statutory basis for the Pediatric Rule.

[14] FDA spends considerable energy arguing that "[a]gencies are permitted to promulgate requirements that are not stated explicitly in the authorizing statute." Defs.' Reply Mem. in Supp. of Mot. for Summ. J. at 10. FDA argues, for instance, that 21 C.F.R. § 201.57 spells out exactly what headings drug labels should include (e.g., Description, Clinical Pharmacology, Indications and Use, etc.), even though the "statute says very little about the content of drug

b. "Prescribed, Recommended, or Suggested"

The FDA also relies upon 21 U.S.C. §§ 321(p), 331(a) and (d), and 355(a), (j), and (d). *See* 62 Fed. Reg. at 43,908. Section 321(p) defines "new drugs" as those not recognized to be safe and effective under conditions "prescribed, recommended, or suggested" in product labeling. Section 355(a) forbids new drugs' distribution. Section 352(j), provides that a drug shall be deemed misbranded if it is "dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." § 352(j). Sections 331(a) and (d) proscribe misbranded drugs' sale or introduction into interstate commerce. Finally, § 355(d) provides that manufacturers seeking to market a new drug must demonstrate that the product is safe "for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof." 21 U.S.C. § 355(d)(1).

The applicability of the above provisions all turns on what is "*prescribed, recommended, or suggested*" in a product's labeling. Thus, the import of those three words must be scrutinized, and the analysis may apply to all.[15] To begin, the Act defines "labeling" to include "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m). The FDA argues, in essence,

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labeling, let alone section headings or the order for such headings." *Id*. at 10. This misses the point, however. No one challenges the FDA's authority to promulgate rules in the "exercise [of] its judgment as to how best to implement a general statutory mandate." *Am. Mining Congress v. MSHA*, 995 F.2d 1106, 1110 (D.C. Cir. 1993) (quoting *United Technologies Corp. v. EPA*, 821 F.2d 714, 719-20 (D.C. Cir. 1987). The question here is whether the FDA can promulgate a rule largely untethered from any federal statute.

[15] The following analysis highlights § 355(d), since the FDA emphasizes that section and, according to Judge McGowan, § 355(d) is the "pivotal provision of the Federal Food, Drug, and Cosmetic Act." *Am. Pharm. Assoc. v. Mathews*, 530 F.2d 1054, 1055 (D.C. Cir. 1976) (McGowan, J., concurring).

that notwithstanding the plain meaning of the statutory language, these provisions give the agency the authority to regulate drugs for pediatric uses even when such uses are not explicitly claimed by a drug manufacturer in a product's labeling.

Plaintiffs argue that, traditionally, the FDA has required manufacturers to test products only for the product's labeled use. The Pediatric Rule, in contrast, requires manufacturers to test products for use on children, even if such a use is not "prescribed, recommended, or suggested" by the product's label. Plaintiffs maintain that the Rule is all the more remarkable because it requires manufacturers to test products for use on children even if, in compliance with another FDA regulation, 21 C.F.R. § 201.57(f)(9)(vi), the label specifically disclaims the product's effectiveness for pediatric populations. Plaintiffs contend that the Pediatric Rule, therefore, conflicts with the FDCA's plain statutory language. Pls.' Mem. in Opp. to Defs.' Mot. for Summ. J. at 8.

FDA counters by claiming that the Pediatric Rule does not so expand its reach. FDA argues that the Rule "simply requires, in some instances, data on a reasonable sample of patients likely to be given a drug or biological product." Defs.' Mem. in Supp. of Mot. for Summ. J. at 12 (citing 62 Fed. Reg. at 43,907). FDA provides that, since there is uncontroverted evidence that many drugs officially indicated for adult use are *routinely* used by pediatric patients, "such pediatric use is 'suggested.'" *Id*. at 19; Defs.' Reply Mem. in Opp. to Pls.' Mot. for Summ. J. at 13. This is true, according to the FDA, even if pediatric use is specifically disclaimed on the product's labeling. *See* 63 Fed. Reg. at 66,658 ("FDA may also consider pediatric use to be 'suggested' in a drug's labeling even where such use is not expressly recommended or is even

disclaimed.").[16] FDA argues, then, since "pediatric use is a 'suggested' use," the FDA has authority to regulate it, under its authority to ensure that products are safe and effective for all of their suggested conditions.

The FDA reaches its conclusion by conflating what is "suggested" with what is "likely" or "foreseeable."[17] It is this court's task to determine whether this conflation may be supported, even giving the FDA the deference that is due.

Defendants and plaintiffs each cite a number of cases that concern whether a given article is a "drug" within the meaning of the FDCA. Under the Act, that question turns on manufacturer intent. *See* 21 U.S.C. § 321(g)(1)(B) (defining as a drug "articles *intended for use* in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals. . . ") (emphasis added). Thus, plaintiffs and defendants spend enormous energy feuding over how manufacturer intent may be discerned.

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[16] In FDA Denial at 8, FDA reiterated this exact (and unfortunate) position.

[17] The FDA also relies on its own regulation defining the term "intended uses." This definition provides, in part, that a manufacturers' intent "may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised." 21 C.F.R. § 201.128. While this definition is surely broad enough to encompass the circumstance here, that fact is of no legal consequence because "no order or regulation issued by an administrative agency can confer on it any greater authority than it has under statute." *Office of Consumers' Counsel v. FERC*, 655 F.2d 1132, 1149 n. 32 (D.C. Cir. 1980). *See Nat'l Assoc. of Regulatory Util. Comm'rs v. FCC*, 533 F.2d 601, 617-18 (D.C. Cir. 1976); *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 213-14 (1976). Moreover, because FDA's regulation is interpretive in nature, it lacks the force of law. *See Chamber of Commerce v. OSHA*, 636 F.2d 464, 468 (D.C. Cir. 1980) (describing an "interpretive" rule as one that does not "hav[e] the force of law" and "no more than an expression of [the agency]'s construction of a statute"). Nor is the regulation independently reviewable absent unusual circumstances in which a plaintiff can demonstrate actual harm. *See Baltimore Gas & Elec. Co. v. ICC*, 672 F.2d 146, 148 (D.C. Cir. 1982) (holding that "the Commission's interpretive order, which currently threatens no hardship to BG&E, is not reviewable"); *Consolidation Coal Co. v. Fed. Mine Safety and Health Review Comm'n*, 824 F.2d 1071, 1082-83 (D.C. Cir. 1987).

Plaintiffs point to a number of cases which provide that to determine "manufacturer intent," the court need only look to the manufacturer's specific and explicit representations. *See, e.g., Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155, 163 (4th Cir. 1998) *aff'd on other grounds*, 529 U.S. 120 (2000) ("no court has ever found that a product is 'intended for use' or 'intended to affect' within the meaning of the [FDCA] absent manufacturer claims as to that product's use."); *Action on Smoking & Health v. Harris,* 655 F.2d 236, 243 (D.C. Cir. 1980).[18]

Defendants, on the other hand, cite cases that support a broader view. Cases cited by defendants indicate that a product's "intended use" can be determined not only from its label but also from "promotional claims, advertising, and any other relevant source." *Harris*, 655 F.2d at 239 (quoting *Hanson v. United States*, 417 F. Supp. 30, 35 (D. Minn.) *aff'd* 540 F.2d 947 (8th Cir. 1976)).[19] Under this line of cases, to discern "manufacturer intent" courts can look to "evidence that the vendor is aware that his product is being offered or used by others for a purpose for which it is neither labeled nor advertised." *United States v. Kasz Enters., Inc*., 855 F. Supp. 534, 539 (D.R.I. 1994). Even consumer intent can be relevant to the inquiry. *United States v. Travia*, 180 F. Supp.2d 115, 119 (D.D.C. 2001).

While these cases are all tangentially relevant, none really speaks to the issue at hand. Here, we are not determining whether something is a drug; we are looking to a different section

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[18] *See also, e.g.*, *Nat'l Nutritional Foods Ass'n v. Mathews*, 557 F.2d 325, 335 (2d Cir. 1977); *Am. Health Prods. Co. v. Hayes*, 574 F. Supp. 1498, 1505 (S.D.N.Y. 1983), *aff'd on other grounds*, 744 F.2d 912 (2d Cir. 1984).

[19] *See, e.g., United States v. Storage Spaces Designated Nos. "8" and "49"*, 777 F.2d 1363, 1366 (9th Cir. 1985); *United States v. An Article of Drug . . . "Sudden Change*", 409 F.2d 734, 739 (2d Cir. 1969); *United States v. 789 Cases . . . Latex Surgeons' Gloves,* 799 F. Supp. 1275, 1285, 1294-95 (D.P.R. 1992); *United States v. 22 . . . Devices . . . "The Stero-o-lizer MD-200*, 714 F. Supp. 1159, 1165 (D. Utah 1989); *United States v. 250 Jars, Etc. of U.S. Fancy Honey,* 218 F. Supp. 208, 211 (E.D. Mich. 1963).

of the FDCA entirely. And this section requires that a drug be safe and effective for those uses "prescribed, recommended, or suggested *in the proposed labeling*." § 355(d) (emphasis added).[20] The only case cited by either party relevant to this specific inquiry is *Am. Pharm. Ass'n v. Weinberger*, 377 F. Supp. 824 (D.D.C. 1974) *aff'd per curiam sub nom. Am. Pharm. Ass'n v. Mathews*, 530 F.2d 1054 (D.C. Cir. 1976). This case, therefore, deserves careful consideration.

In *Weinberger*, the plaintiffs challenged an FDA regulation restricting the distribution of methadone. The FDA promulgated the regulation because the agency feared that methadone was being diverted from its intended use–that of a "safe, useful, and effective agent in the treatment of severe pain." *See Weinberger*, 377 F. Supp. at 825. The question for the court was whether, under the FDCA, the FDA had the authority to enact the regulation.

The FDA argued for a broad reading of § 355, which would divorce the word "safe" from the rest of the statutory provision, providing the FDA with the authority to regulate methadone, not just for labeled uses, but also for possible misuses. *Id*. at 828. As explained by Judge McGowan, "The FDA contends that where there exists a documented pattern of drug misuse contrary to the intended uses specified in the labeling, the drug is unsafe for approval unless

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[20] At times, the FDA appears to argue that pediatric use is not "off-label" use but rather use for labeled indications in a distinct patient population. It has long been recognized that pediatric use is off-label use. *See Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 55 (D.D.C. 1998) ("Off-label uses include treating a condition not indicated on the label, or treating the indicated condition but varying the dosing regimen or the patient population."), *vacated in part on other grounds*, 202 F.3d 331 (D.C. Cir. 2000); S. Rep. No. 107-79, at 2 (2001) (referring to pediatric use as "off label" use); Janet Woodcock, Director of FDA's Center for Drug Evaluation and Research (1997) (Pls.' Mem. in Opp. to Defs.' Mot. for Summ. J., Ex. 2 at 3) (defining off-label use as "[u]se for [an] indication, dosage form, dose regimen, *population* or other use parameter not mentioned in the approved labeling) (emphasis added); James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 Food & Drug L.J. 71, 80 (1998) (providing that pediatric use is the most common "off label" use); Veronica R. Henry, *Off-Label Prescribing Legal Implications*, 20 J. of Legal Medicine 355 (1999).

controls . . . are imposed." *Mathews*, 530 F.2d at 1055 (McGowan, J., concurring). Both the district court and circuit court rejected this interpretation, however. The *Weinberger* court found that "the term 'safe' was intended to refer to a determination of the inherent safety or lack thereof of the drug under consideration [only] when used for its intended[21] purposes." *Weinberger,* 377 F. Supp. at 829. After this determination, the court went on to conclude "that FDA has overstepped the bounds of its authority in purporting to limit the distribution of methadone in the manner contemplated by its regulations." *Id*. at 831. In a *per curiam* opinion, the D.C. Circuit affirmed this decision "on the basis of the opinion of the District Court." *Mathews*, 530 F.2d at 1054.

This court concludes that use of a drug nowhere indicated by the label and, in fact, specifically disclaimed by the label is, quite simply, not "suggested" by that label. For that reason, the court finds that the FDA's expansive interpretation of the FDCA lacks firm support in law.

The FDA's reading also lacks support in tradition. As plaintiffs point out, in recent years, even the FDA has repeatedly stated that it may only regulate claimed uses of drugs, not all foreseeable or actual uses. Especially persuasive is a statement made in 1992 by then-FDA

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[21] *Weinberger's* use of the word "intended" has potentially led the FDA to conclude that the instant inquiry melts into an inquiry of "intended" under 21 U.S.C. § 321(g)(1)(B), the statute governing the definition a drug under FDCA. Such an interpretation would be inappropriate. The court must, as always, base its decisions in the plain meaning of a statute, if that statute is clear, and the court must "give effect to all words of a statute when construing it." *State of N.J., Dept. of Envtl. Prot. and Energy v. Long*, 30 F.3d 403, 417 (3d Cir. 1994). *See Hartford Fire Ins. Co. v. Lawrence, Dykes, Goodenberger, Bower & Clancy*, 740 F.2d 1362, 1365 (6th Cir. 1984) ("Courts are directed to give effect to the words of a statute, and not to modify an unambiguous statute by deleting words used or inserting words not used.") (citation omitted). Here, the statute provides that a drug must be safe and effective for those uses "prescribed, recommended, or suggested" on the "product's labeling." 21 U.S.C. § 355(d).

Commissioner David Kessler regarding the problem of drug testing on pediatric populations. Here, Mr. Kessler publicly stated:

> I need to acknowledge the limits of FDA's authority. It is our job to review drug applications for the indications suggested by the manufacturer. We do not have the authority to require manufacturers to seek approval for indications which they have not studied. Thus, as a matter of law, if an application contains indications only for adults, we're stuck.

David Kessler, Speech of FDA Commissioner to the American Academy of Pediatrics (Oct. 14, 1992) (Pls.' Mot. for Summ. J., Ex. 6).[22]

In addition, the FDA's argument proves too much. If 21 U.S.C. § 355(d) truly gave the FDA the authority that it claims, the door would be open to FDA's regulation of all off-label uses, based solely on the manufacturer's knowledge that those uses are common-place. This authority would surely conflict with Congress' will[23] and would eviscerate the long-established foundation of federal food and drug law, which allows, not the FDA, but the "manufacturer of the article, through his representations in connection with its sale, [to] determine the use to which the article is to be put." S. Rep. No. 73-493, at 3 (1934). *See Harris*, 655 F.2d at 238-39 (quoting the Senate Report and providing: "These comments reveal the understanding even in 1934 that the crux of FDA jurisdiction over drugs lay in manufacturers' representations as

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[22] The court recognizes that these comments are not binding on the FDA and do not represent the FDA's "formal position." *See* 21 C.F.R. § 10.85(k). Nevertheless, like the Fourth Circuit in *Brown & Williamson*, the court finds these statements to be illuminating. *See Brown & Williamson*, 153 F.3d at 168-70 (analyzing FDA officials' assertions that the FDA did not have the authority to regulate tobacco products).

[23] *See* H.R. Conf. Rep. No. 105-399, at 97 (1997), *reprinted in* 1997 U.S.C.C.A.N. 2880-2887 ("The off-label use of a medical device by a physician using his or her best medical judgment in determining how and when to use the medical product for the care of a particular patient is not the province of the FDA.").

revelatory of their intent"). In sum, to quote Judge McGowan in *Mathews*: "There would be almost no limit to the FDA's authority were its view adopted." *Mathews* 530 F.2d at 1056.

c. Other Statutory Provisions

Lastly, given that the court is to examine the statute in context, the court must consider the effects of 21 U.S.C. § 355(c) and (d), if any. These sections provide that once the FDA has determined that the new drug is safe and effective "for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof," and once the manufacturer meets certain other requirements not at issue here, the FDA "*shall* issue an order approving the application." *See* 21 U.S.C. § 355(c), (d) (emphasis added). While approval appears non-discretionary once certain congressionally-prescribed conditions are satisfied, under the Pediatric Rule, the FDA can withhold approval merely because a manufacturer has failed to test the drug on children. This tension between § 355(c) and (d) and the Pediatric Rule suggests at least some inconsistency between the Pediatric Rule and the broader context of the FDCA.

For the foregoing reasons, this court concludes that the Pediatric Rule does not have a sound statutory basis in the FDCA. Next, the court must look to the evolving congressional regulation of the area to determine whether Congress intended for the FDA to promulgate the Pediatric Rule and whether the Pediatric Rule "fit[s] into the overall regulatory scheme created by Congress." *Brown & Williamson*, 153 F.3d at 163.

2. Evolving Regulation of the Area: BPCA

As previously noted, Congress enacted the FDAMA after the FDA had drafted, but before it had issued, the Pediatric Rule. When the FDAMA sunsetted in 2002, Congress reenacted a similar statutory provision, the BPCA. These two statutes address the same issue as

that addressed by the Pediatric Rule: the need for drugs to be tested on children. This situation is therefore analogous to the one faced by the Supreme Court in *Brown & Williamson*; the FDA and Congress have both spoken and have taken two different approaches to respond to the same public health issue. *Brown & Williamson* suggests that by enacting a "distinct regulatory scheme" to address a given issue, as Congress did when it enacted the BPCA, Congress demonstrates its intention to occupy the field, and any attempt by the FDA to intervene with an inconsistent regime shall be deemed in excess of its authority. 529 U.S. at 154-55. This militates strongly in favor of concluding that the FDA exceeded its authority when it enacted the Pediatric Rule. *See also, e.g., Transamerica Mortgage Advisors, Inc. v. Lewis*, 444 U.S. 11, 19-20 (1979) ("[w]hen a statute limits a thing to be done in a particular mode, it includes the negative of any other mode") (internal quotations omitted) (emphasis removed); *Weinberger*, 377 F. Supp. at 830-31 (ruling that FDA exceeded its authority by issuing a regulation restricting the distribution of methadone in a manner inconsistent with Congress' distribution scheme).

a. The Legislative History is Inconclusive

On the other hand, militating in the Pediatric Rule's favor is the fact that, when enacting the BPCA, Congress failed to expressly reject the Pediatric Rule, even though Congress was well aware of its existence. Generally, Congress' "failure to revise or repeal the agency's interpretation is persuasive evidence that the interpretation is the one intended by Congress." *Young v. Cmty. Nutrition Inst.*, 476 U.S. 974, 983 (1986) (quoting *NLRB v. Bell Aerospace, Co.*, 416 U.S. 267, 275 (1974)). *See FDIC v. Philadelphia Gear Corp.*, 476 U.S. 426, 437 (1986); *Zenith Radio Corp. v. United States*, 437 U.S. 443, 457 (1978); *United States v. Rutherford*, 442 U.S. 544, 554 n. 10 (1979) ("once an agency's statutory construction has been 'fully brought to

the attention of the public and the Congress,' and the latter has not sought to alter that interpretation although it has amended the statute in other respects, then presumably the legislative intent has been correctly discerned") (quoting *Apex Hosiery Co. v. Leader*, 310 U.S. 469, 487-489 (1940)); *Maryland Dep't of Human Resources v. U.S. Dep't of Agric.*, 976 F.2d 1462, 1473 (4th Cir. 1992).[24]

Congress' inaction does not provide overwhelming support to the FDA, however, given the "general reluctance of courts to rely on congressional inaction as a basis for statutory interpretation." *Brown & Williamson*, 153 F.3d at 170 (citing *Brecht v. Abrahamson*, 507 U.S. 619, 632 (1993) ("As a general matter, 'we are reluctant to draw inferences from Congress's failure to act'") (quoting *Schneidewind v. ANR Pipeline Co.*, 485 U.S. 293, 306 (1988)). In addition, Congress' silence cuts both ways. In enacting the BPCA, Congress was well aware of the Pediatric Rule. Nevertheless, Congress failed to expressly endorse the Pediatric Rule, even though the FDA requested that it do so. *See* FDA, *The Pediatric Exclusivity Provision: January 2001 Status Report to Congress* 21 (2001). *C.f., Brown & Williamson*, 529 U.S. at 144 (refusing to give FDA jurisdiction over tobacco where, *inter alia* "Congress considered and rejected bills that would have granted the FDA such jurisdiction").[25]

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[24] FDA cites extensively to *Pfizer v. Shalala*, 1 F. Supp.2d 38, 47 (D.D.C. 1998) *aff'd in part and rev'd in part*, 182 F.3d 975 (D.C. Cir. 1999). *See* Defs.' Mem. in Supp. of Mot. for Summ. J. at 36. In *Pfizer*, the court provided: "When Congress passed the Hatch-Waxman Amendments the FDA already had an abbreviated drug application procedure in place . . . Congress' choice not to address or revisit the ongoing FDA system of classifying dosage forms strongly suggests both that it was aware of the system and that it did not intend to change it." *Id.* at 46 (citations omitted). This case is distinguishable, however, because in *Pfizer*: "The FDA's current and long-standing dosage form classification system appears to be fully in tune with the objectives of the Hatch-Waxman Amendments." *Id.* at 48. That is not the case here.

[25] In fact, two Senators did contemplate giving the FDA such authority. "Senator Kennedy offered and then withdrew an amendment to require pediatric testing of new drugs for

Some affirmative legislative history does support the Pediatric Rule, however. This history may be found in the Senate Report accompanying the BPCA. The Report provides:

> [The Pediatric Rule] requires the manufacturers of certain new and marketed drugs and biological products to provide adequate labeling for the use of the products in children. The rule is both broader and narrower than the pediatric exclusivity provision enacted by congress in 1997. When their scopes overlap, Congress provided that pediatric studies required under the rule could also satisfy the requirements for market exclusivity.

S. Rep. No. 107-79, at 4 (2001). This language demonstrates some desire for the Pediatric Rule to exist along-side Congress' scheme, and it is somewhat persuasive. However, given that the relevant legislative history is contradictory,[26] this statement shall not be accorded undue weight.

Given this conflicting authority, the court turns to the BPCA and Pediatric Rule themselves to determine whether the two regimes are indeed "perfectly harmonious," as the FDA claims. Defs.' Reply Mem. in Supp. of Mot. for Summ. J. at 18. After careful analysis, the court finds that they are not; the two methods of solving the same problem differ in key respects and are, in fact, incompatible.

b. BPCA and the Pediatric Rule are Incompatible

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their approved uses in adults." S. Rep. No. 107-79, at 7 (2001). In addition, Senator Clinton offered and then withdrew an amendment to "require manufacturers to include in an application for study of a new drug their intent for pediatric studies of the drug." *Id*.

[26] For instance, the House Report that accompanied the FDA Modernization Act ("FDAMA") stated that "FDA has no authority to regulate how physicians prescribe approved drugs in the context of their medical practice. Physicians prescribing off-label uses of approved drugs is not within the jurisdiction of the FDA." H.R. Rep. No. 105-310, at 60 (1997). This Report provides some evidence of Congress' intent for such off-label use not to be regulated. This conflicting authority further underlines the fact that looking to legislative history can sometimes be akin to "looking over a crowd and picking out your friends." *United States v. Bohai Trading Co., Inc*., 45 F.3d 577, 581 n. 11 (1st Cir. 1995) (citation and internal quotations omitted).

Congress adopted an incentive scheme while the FDA adopted a command and control approach. The two schemes differ in almost every possible regard. First, as far as drug approval, the Pediatric Rule gives the FDA the authority to refuse to approve new drug applications if manufacturers refuse to conduct pediatric studies. The BPCA does not. Second, in terms of drug testing on pediatric populations, the Pediatric Rule provides that the FDA may "require" manufacturers to tests new drugs on pediatric populations. In contrast, the BPCA provides these tests may be merely "requested," and the BPCA establishes a public fund to pay for third parties to conduct pediatric tests if the FDA determines that such tests are necessary but the manufacturer elects not to conduct them. *See* 42 U.S.C. § 284m(c)(1) and (d). For already-marketed drugs, the BPCA, unlike the Pediatric Rule, allows manufacturers to decline to conduct pediatric testing without any risk that their products will be deemed misbranded and pulled off the market. As for labeling changes, the BPCA sets up an elaborate scheme to force labeling changes if, as a result of what was unearthed during pediatric testing, the FDA determines that such changes are necessary. See § 284m (c)(8), (9). In contrast, the Pediatric Rules gives the FDA the authority to simply declare a drug misbranded. In regard to pediatric formulations, the Pediatric Rule requires their development, but the BPCA provides that the FDA "shall send a nonbinding letter" recommending a change in formulation "if a pediatric study completed under public contract indicates that a formulation change is necessary and the Secretary agrees." § 284m(c)(12). Finally, the very thrust of the BPCA–providing marketing incentives to encourage voluntary testing–is entirely anomalous with the very thrust of the Pediatric Rule–requiring such tests in the absence of a deferral or waiver.

Far from complementing Congress's voluntary incentive scheme, the Pediatric Rule usurps it by superimposing an often-incompatible regime. This case, therefore, is like *Ragsdale v. Wolverine World Wide, Inc.,* 122 S.Ct. 1155, 1163 (2002). In *Ragsdale*, the Supreme Court reviewed a regulation promulgated by the Department of Labor which provided that if an employer did not notify an employee that his leave was counting against his 12-week allotment under the Family and Medical Leave Act ("FMLA"), the clock did not run. The Court ultimately invalidated this regulation because the Court found that it contradicted and undermined the FMLA's remedial scheme, as established by Congress. In words that may be applied to the case at hand, the Court provided: "Congress resolved the conflict by choosing a middle ground . . . . Courts and agencies must respect and give effect to these sorts of compromises." *Id*. at 1164 (citing *Mohasco Corp. v. Silver*, 447 U.S. 807, 818-819 (1980)).

Here, Congress clearly considered a command and control approach. During passage of FDAMA (BPCA's predecessor), Senator Christopher Dodd, one of the co-sponsors of FDAMA's pediatric exclusivity provisions stated that in drafting these provisions:

> [I]n 1997 . . . there was a debate on whether we should mandate [pediatric drug testing provisions] and say you have to do it whether you like it or not, which is one approach, or should we say we will give you a chance to prove to us you can do it by providing 6 months of exclusivity in the marketplace. . . .

147 Cong. Rec. S10826 (daily ed. October 18, 2001). Congress opted for the latter tack. The FDA, as well as this court, must respect this judgment. "Regardless of how serious the problem an administrative agency seeks to address . . . it may not exercise its authority 'in a manner that is inconsistent with the administrative structure that Congress enacted into law.'" *Brown &*

Williamson, 529 U.S. at 125 (quoting *ETSI Pipeline Project v. Missouri*, 484 U.S. 495, 517 (1988)).

III. CONCLUSION

In its submissions to this court, the FDA provides, time and time again, that "[i]t is significant that drug manufacturers, who are those most affected by the Pediatric Rule, are not complaining about the requirements." Defs.' Reply Mem. in Supp. of Mot. for Summ. J. at 1. In so arguing, the FDA misses the point. This court does not pass judgment on the merits of the FDA's regulatory scheme. The Pediatric Rule may well be a better policy tool than the one enacted by Congress; it might reflect the most thoughtful, reasoned, balanced solution to a vexing public health problem. The issue here is not the Rule's wisdom. Indeed, if that were the issue, this court would be a poor arbiter indeed. The issue is the Rule's statutory authority, and it is this that the court finds lacking.

For the foregoing reasons, this court finds that the Pediatric Rule exceeds the FDA's statutory authority and is therefore invalid. Accordingly, plaintiffs' motion for summary judgment is granted, and defendants' motion for summary judgment is denied. An appropriate order accompanies this memorandum.

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Henry H. Kennedy, Jr.
United States District Judge

Dated: October17, 2002

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ASSOCIATION OF AMERICAN, PHYSICIANS AND SURGEONS, INC., et al., **Plaintiffs,** **v.** **UNITED STATES FOOD AND DRUG ADMINISTRATION, et al.,** **Defendants.**	**Civil Action 00-02898 (HHK)**

ORDER

Pursuant to Fed. R. Civ. P. 58 and for the reasons stated by the court in its memorandum opinion docketed this same day, it is this 17th day of October, 2002, hereby

ORDERED that judgment is entered in favor of plaintiffs; it is further

ORDERED that the Food and Drug Administration and the Department of Health and Human Services, and all persons acting under their direction or authority, or in active concert or participation with them, are hereby enjoined from enforcing the Pediatric Rule.

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Henry H. Kennedy, Jr.
United States District Judge