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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ASSOCIATION OF AMERICAN,
PHYSICIANS AND SURGEONS, INC.,
1601 N. Tucson Boulevard, Suite 9,
Tucson, AZ 85716-3450,

and

COMPETITIVE ENTERPRISE INSTITUTE,
1001 Connecticut Avenue, N.W.,
Suite 1250,
Washington, D.C. 20036,

and

CONSUMER ALERT,
1001 Connecticut Avenue, N.W.,
Suite 1128,
Washington, D.C. 20036,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG
ADMINISTRATION, 5600 Fishers Lane,
Rockville, MD 20857,

and

UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES,
200 Independence Avenue, S.W.
Washington, D.C. 20201,

Defendants.

Civil Action No.
CASE NUMBER 1:00CV02898

JUDGE: Henry H. Kennedy

DECK TYPE: Civil General

DATE STAMP: 12/[redacted]4/2000

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs Association of American Physicians and Surgeons, Inc. ("AAPS"), the Competitive Enterprise Institute ("CEI"), and Consumer Alert, by their undersigned attorneys, complaining against Defendants the United States Food and Drug Administration ("FDA") and the Department of Health and Human Services ("HHS"), allege the following:

Introduction

1. This action seeks a declaratory judgment holding unlawful and setting aside pursuant to the Administrative Procedure Act, 5 U.S.C.§ 551 et seq. ("APA"), the regulations entitled "Regulations Requiring Manufacturers To Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients" and codified in 21 C.F.R. Parts 201, 312, 314, and 601, 63 Fed. Reg. 66,632 (1998) (hereinafter referred to collectively as "Pediatric Rule" or "Rule"), as contrary to law, in excess of Defendants' statutory jurisdiction and authority, arbitrary, capricious, and an abuse of discretion. This is also an action for permanent injunctive relief.

The Parties

2. Plaintiff AAPS is a not-for-profit membership organization organized under the laws of Arizona with its principal place of business in Arizona. AAPS represents approximately 4,000 physicians nationwide in all practices and specialties, including physicians who practice and specialize in pediatric medicine. AAPS was established to preserve the practice of private medicine and has remained dedicated to the sanctity of the patient-physician relationship, which AAPS believes must be protected from all forms of third-party intervention. AAPS's physician members oppose FDA's Pediatric Rule because the Rule restricts available pediatric and non-pediatric treatment options. Specifically, the Rule has the effect of limiting the availability of the

most effective pharmaceuticals for the treatment of disease, illness, and other afflictions to AAPS's doctor members.

3. Plaintiff CEI is a not-for-profit public policy organization organized under the laws of Washington, D.C. with its principal place of business in Washington, D.C. CEI is dedicated to the principles of free enterprise and limited government. It believes that consumers are best helped by being allowed to make their own choices in a free marketplace rather than by being forced into decisions because of government regulation. CEI reaches out to the public and the media to ensure that its ideas are heard, works with policymakers to ensure that they are implemented, and takes its arguments to court to ensure that the law is upheld. CEI has been involved in analyzing, and advocating reform of, the FDA drug and device approval process for over a decade. CEI opposes FDA's Pediatric Rule because it is an invasive governmental regulation that interferes with private choices made by pharmaceutical companies concerning how best to allocate their finite research and development funds. Because the Rule will force pharmaceutical companies to divert research and development funds away from valuable new drug treatments and toward testing of products for uses that companies do not wish to promote, the Rule will harm CEI's interests by limiting access to the most effective pharmaceuticals for the treatment of disease, illness, and other afflictions.

4. Plaintiff Consumer Alert is a national, non-partisan, not-for-profit organization organized under the laws of Washington, D.C. with its principal place of business in Washington, D.C. Consumer Alert's mission is to enhance understanding and appreciation of the consumer benefits of a free market and to promote sound economic, scientific, and risk data in public policy decisions. Consumer Alert's members are harmed by the more restrictive and slower access to valuable pediatric and nonpediatric treatments that FDA's Rule causes. Because

the Rule forces pharmaceutical companies to divert research and development funds away from valuable new drug treatments and toward testing of products for uses that companies do not wish to promote, the Rule has the effect of hindering Consumer Alert's members from receiving the most effective pharmaceuticals for the treatment of disease, illness, or other afflictions.

5. Defendant FDA is an agency within HHS and is an "agency" within the meaning of the APA. FDA is presently located at 5600 Fishers Lane, Rockville, MD 20857.

6. Defendant HHS is an executive agency of the United States government and is an "agency" within the meaning of the APA. HHS is presently located at 200 Independence Avenue, S.W., Washington, D.C. 20201.

Jurisdiction and Venue

7. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331, 5 U.S.C. § 551 et seq., 28 U.S.C. §§ 2201-2202, and 28 U.S.C. § 1361. There exists between the parties an actual and justiciable controversy in which Plaintiffs seek declaratory and injunctive relief to protect their rights.

8. Venue in this Court is proper pursuant to 28 U.S.C. § 1391(e).

9. The Pediatric Rule constitutes final agency action by FDA. See 21 C.F.R. § 10.45(d). FDA's Pediatric Rule was published in the Federal Register on December 2, 1998 and became effective on April 1, 1999. Since that date, FDA has enforced the Rule as published.

10. Moreover, Plaintiffs have fulfilled the procedural requirements necessary to file a lawsuit by requesting Defendant FDA to revoke the Rule. On December 2, 1999, Plaintiffs filed a Citizen Petition (Docket No. 99P-5215CP) challenging FDA's Pediatric Rule, in accordance with the requirement of 21 C.F.R. § 10.25(a) and pursuant to 21 C.F.R. § 10.30. The Citizen

Petition, attached as Exhibit 1 hereto, requested that Defendant FDA revoke its Pediatric Rule and refrain from taking any administrative action pursuant to the Rule.

11. On November 1, 2000 – after nearly double the six months accorded to FDA by its own regulations to decide Citizen Petitions – FDA denied Plaintiffs' Citizen Petition. See 21 C.F.R. § 10.30(e)(2); see also Ex. 2 hereto. Accordingly, Plaintiffs have exhausted their administrative remedies, and their challenge to the Pediatric Rule is ripe for judicial action.

Congress's Drug Approval Scheme Prior to 1997

12. Pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321 et seq. ("FDCA"), a new drug cannot be marketed in the United States until FDA first determines that it is safe and effective for use "under the conditions prescribed, recommended, or suggested in the proposed labeling." See 21 U.S.C. § 355(a). Once FDA makes this determination, the FDCA requires FDA to approve the drug, provided that the drug also meets certain other requirements not at issue in this lawsuit. 21 U.S.C. § 355(c)(1)(A), (d); see id. § 355(j)(2), (j)(4). The FDCA does not grant FDA discretion to refuse to approve NDAs or ANDAs if the specified conditions are met.

13. Even where a manufacturer has established that a drug is safe and effective for use in adults, it does not necessarily follow that the drug will be safe and effective in children: drugs often operate differently in children than in adults. Moreover, differences between children and adults in the way that drugs are physically absorbed, metabolized, and excreted means that it is not always possible to determine the proper strength of a pediatric dosage merely by extrapolating from adult dosing information. Because of these differences, Defendants have long required manufacturers seeking to market a drug to both adult and pediatric populations to submit separate testing and labeling for these groups. FDA has further subdivided the pediatric

population into four groups and requires separate testing and labeling for each group: neonates, infants, children, and adolescents. See 21 C.F.R. § 201.57(f)(9)(i).

14. In light of these testing and labeling requirements, manufacturers who bring drugs on the market for adult use only often decide not to seek approval for pediatric uses. Apart from the obvious safety and ethical concerns with administering an untested drug on a child, it is often difficult to obtain parental consent to test such drugs on children. In addition, it can be quite difficult to obtain blood samples from children. Moreover, children often become anxious when they are separated from their parents during testing, and they often experience more discomfort and fear than do adults during the testing process. As a result, many drugs on the market have been approved and labeled for use on adult populations but carry no approval or labeling for use on children.

15. In 1994, FDA recognized this situation by requiring such drugs to carry an express disclaimer that "Safety and effectiveness in pediatric patients have not been established." See Specific Requirements on Content and Format of Labeling for Human Prescription Drugs; Revision of "Pediatric Use" Subsection in the Labeling, 59 Fed. Reg. 64,240, 64,241 (1994); 21 C.F.R. § 201.57(f)(9)(vi). If manufacturers have tested their drugs for some, but not all, pediatric age groups, the labeling must state that "Safety and effectiveness in pediatric patients below the age of (--) have not been established." Id. § 201.57(f)(9)(v).

16. Physicians remain free to prescribe to pediatric patients drugs that are approved for adult use, but which carry pediatric disclaimers. Physicians make prescribing decisions based on their knowledge of the product and its demonstrated safety and effectiveness in adult populations, their professional judgment, and their experience – without interference from FDA. See H.R. Rep. No. 105-310, at 60 (1997) ("[I]t has been the long held view of Congress that the

FDA should not regulate the practice of medicine. In general, the 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."); see also 21 U.S.C. § 396. Like other "off-label" uses – i.e., the treatment of a condition not indicated on the label and the treatment of an indicated condition for a dosing regimen or patient population not specified on the label – pediatric "off label" uses are widespread. In Plaintiffs' view, such uses make a substantial contribution to pediatric care by ensuring that adults gain access to products expeditiously, without waiting for pediatric testing, and that children may still benefit from these new treatments in accordance with the professional judgment of their pediatrician.

17. Despite the recognized and substantial benefits of off-label pediatric uses, Defendants and certain interest groups remained concerned about the number of drugs not labeled for pediatric use, and they explored ways to increase pediatric labeling. To address this perceived problem, Congress established an incentive scheme to encourage manufacturers to seek pediatric approvals. Later, FDA issued a mandatory set of regulations to force manufacturers to test their drugs on pediatric populations.

Congress's Voluntary Incentive Scheme To Enhance Pediatric Labeling

18. As part of the 1997 FDA Modernization Act ("FDAMA"), Congress established a voluntary incentive scheme that encourages manufacturers to submit pediatric tests and labeling for drugs that "may produce health benefits in the pediatric population." 21 U.S.C. § 355a(a). In return for conducting pediatric tests that are accepted by FDA, a manufacturer is entitled to six months of market exclusivity in certain circumstances. Id. Similarly, for marketed drugs, FDA is required to publish a "list of approved drugs for which additional pediatric information may

produce health benefits." Id. § 355a(b). The manufacturer of a listed drug is also entitled to exclusivity benefits similar to those available for new drugs if: (1) FDA requests a manufacturer to conduct studies for the listed drug; (2) the manufacturer conducts such studies; and (3) FDA accepts the studies. See id. § 355a(c).

19. The pediatric testing provisions of FDAMA are voluntary. FDAMA allows FDA and manufacturers to agree that manufacturers will conduct pediatric studies, but it does not permit FDA to require pediatric studies. Id. § 355a(d). Rather, FDA may only "suggest" modifications to the FDAMA pediatric exclusivity provisions. Id. § 355a(k)(4). While 21 U.S.C. § 355a(i) alludes to pediatric studies "required pursuant to regulations promulgated by the Secretary," it does not independently grant FDA the authority to require such testing. Thus, FDAMA is consistent with the FDCA, which allows manufacturers to determine the uses of their drug products to be approved and included on the label.

20. In addition to being voluntary, FDAMA's pediatric exclusivity provisions are experimental, as underscored by Congress's imposition of a sunset provision and Congress's requirement that FDA conduct a study and report to Congress, by January 1, 2001, on the effectiveness of the pediatric testing provisions and the adequacy of the incentives contained therein. Id. § 355a(j), (k).

21. The voluntary pediatric exclusivity provisions in FDAMA represent Congress's policy judgment of how best to balance the desire to encourage manufacturers to seek approval for pediatric uses of drugs – thereby increasing pediatric labeling information – against the concern that the costs and other problems related to mandatory pediatric testing could inhibit the production and marketing of valuable pharmaceuticals.

22. Incentive schemes, such as the scheme established in FDAMA, are a well-recognized congressional method of increasing the availability of new drug entities in certain contexts when preexisting market conditions are inadequate to do so. See, e.g, Orphan Drug Act, Pub. L. 97-414, 96 Stat. 2049 (1983) (providing incentives for increasing availability of treatments for rare diseases and conditions).

Effectiveness of Pediatric Exclusivity Provisions

23. Congress's voluntary pediatric testing incentives embodied in FDAMA are working well, as demonstrated by the comments that FDA received in response to its May 5, 2000 request for comments on FDAMA's pediatric exclusivity provisions. See Report to Congress on Pediatric Exclusivity, 65 Fed. Reg. 26,217 (2000). Interested parties commenting on the provisions have observed that "FDAMA has had an immediate and profound positive impact on drug development for children to an extent not seen during the preceding 30 years" and that "[t]he pediatric exclusivity program is the most successful program the FDA has developed to generate studies of medications in children." See Letter from National Institutes of Health to FDA at 1 (June 3, 2000) (providing data to substantiate assertions); Letter from American Academy of Pediatrics to FDA at 1 (June 5, 2000). Even FDA acknowledged in its letter denying Plaintiffs' Citizen Petition that FDAMA's "pediatric exclusivity provides a substantial incentive for some sponsors to conduct pediatric studies." Ex. 2, at 1.

FDA's "Command and Control" Approach

24. Rather than adhering to Congress's voluntary incentive scheme embodied in FDAMA and applicable FDCA provisions, Defendants instead have employed a "command and control" approach to pediatric testing – even before FDAMA had been fully implemented. Specifically, Defendants issued a Proposed Rule that requires manufacturers to submit testing in pediatric populations for the vast majority of new drugs and biological products as well as certain

marketed products. See Regulations Requiring Manufacturers To Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients, 62 Fed. Reg. 43,900 (proposed August 15, 1997).

25. After a notice and comment period, Defendants issued the Final Rule, a true and correct copy of which is attached hereto as Exhibit 3. See 63 Fed. Reg. 66,632 (1998). The Rule, which became effective on April 1, 1999, forces manufacturers to test new drugs and biological products on the four different pediatric subpopulations to evaluate the products' safety and effectiveness and to develop formulations of those products that are appropriate for each subpopulation in which the drug is safe and effective for use. The Rule also authorizes FDA to impose similar testing and formulation requirements on products already on the market. Although the Rule permits waiver of these requirements under certain circumstances and deferral with respect to new drugs and biological products, a manufacturer cannot obtain a waiver or deferral merely by certifying that it neither markets nor intends to market (i.e., label or promote) the product for pediatric use. See 21 C.F.R. §§ 201.23(c), 314.55.

26. Without setting forth the logical basis for doing so, the Rule requires manufacturers to perform pediatric testing on drugs for which they will file New Drug Applications ("NDAs"), but exempts manufacturers filing generic Abbreviated New Drug Applications ("ANDAs"). It does, however, require pediatric testing from manufacturers filing a suitability petition – i.e., a request to file an ANDA for a drug that has a "different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug." See 21 U.S.C. § 355(j)(2)(C).

27. If a manufacturer refuses to perform pediatric testing on a drug that is the subject of a NDA or a suitability petition or a new biological product, FDA will (absent discretionary waiver or deferral) refuse to approve the product until the appropriate tests have been performed.

28. If a manufacturer of a marketed drug product does not comply with FDA's pediatric testing requirements, FDA asserts the authority to seek a court injunction declaring the offending product to be misbranded and "requir[ing] the company to submit an assessment of pediatric safety and effectiveness for the product." 21 C.F.R. § 201.23(d); 63 Fed. Reg. at 66,636; see 21 U.S.C. §§ 352, 355(d); 42 U.S.C. § 262. If a manufacturer refuses to submit the required assessment, FDA may pursue judicial contempt proceedings. FDA also leaves open the possibility that it might, in some cases, withdraw approval of the drug or biological product. 63 Fed. Reg. at 66,636.

Defendants Lack Statutory Authority To Issue the Rule

29. Although FDA claims in its November 1, 2000 letter denying Plaintiffs' Citizen Petition that it "has the legal authority to require pediatric studies" (Ex. 2, at 4), the FDCA prohibits FDA from taking the actions purportedly authorized under the Rule. Specifically, the FDCA requires FDA to approve all drugs that have been established to be safe and effective for the uses prescribed, recommended, or suggested in the proposed labeling and that meet certain other statutory requirements not at issue in this lawsuit. See supra para. 12. If the labeling on a new or marketed drug does not prescribe, recommend, or suggest use of the product on pediatric populations, the FDCA does not permit FDA to require pediatric testing on that product.

30. The Rule also contravenes the long-standing and universal understanding of Congress, the courts, and FDA that the "intended uses" of a drug product subject to FDA's regulatory authority include only those uses "prescribed, recommended, or suggested" by the

product's labeling. In the Pediatric Rule, FDA asserts the right to require drug and biological product manufacturers to seek approval for use of their products on four separate pediatric subpopulations and to develop new formulations for those populations – even though the manufacturers may only wish to label and promote their products for adult populations. See 21 C.F.R. §§ 201.23, 314.55; 63 Fed. Reg. at 66,657-58. FDA justifies the Rule by arguing that pediatric uses of a product are "foreseeable" – even though those uses are disclaimed, as they must be to market a product approved for adult use only, and even if the product has never been marketed – so long as the disease treated by the product occurs in pediatric populations. 63 Fed. Reg. at 66,645, 66,653, 66,658; 21 C.F.R. § 201.57(f)(9)(v). Carried to its logical conclusion, FDA's novel "foreseeable use" theory would fundamentally disrupt the drug approval and misbranding process by allowing FDA to refuse to approve, or to ban, any product with a purportedly "foreseeable" use – even if the manufacturer has decided not to market the drug for that use – that had not been tested to FDA's satisfaction.

31. The Rule is also inconsistent with the FDCA's prohibition against FDA's regulation of the practice of medicine. See H.R. Rep. No. 105-310, at 60 (1997); 21 U.S.C. § 396. Under the Rule, FDA asserts the authority to predict when physicians will prescribe a particular drug in pediatric populations and to regulate that drug accordingly – even if the manufacturer does not intend to label the drug for children. Moreover, when an off-label use of a drug becomes prevalent in pediatric patients, FDA may consider this popular off-label use as a basis for imposing pediatric testing and labeling requirements. FDA's decision **may** result in the popular drug's removal from the market, which will prevent physicians from prescribing the drug not only for popular off-label uses but for on-label uses as well. Moreover, if FDA is now permitted to require testing on four separate pediatric subpopulations before approving a product,

there is nothing to prevent FDA from creating further patient subgroups based on age, race, or gender and withholding a product's approval until all purportedly foreseeable uses are tested in those groups – regardless of the manufacturer's marketing intent with respect to those groups.

32. None of FDA's asserted bases of statutory authority support issuance of the Rule. For example, FDA cites its authority to "prohibit false or misleading labeling." 21 C.F.R. § 201.57(f)(9)(v); 63 Fed. Reg. at 66,657; 21 U.S.C. §§ 352(a), (f), 355(d)(7). FDA's pre-Pediatric Rule regulations, however, already ensure that the labeling for drugs that the manufacturer seeks, or has obtained approval to market, for adult use only will not be "false" or "misleading" with respect to pediatric uses. Specifically, those regulations require manufacturers either to submit substantial evidence to support a pediatric indication and label their drugs for pediatric indications, or to include a disclaimer that "[s]afety and effectiveness in pediatric patients have not been established." 21 C.F.R. § 201.57(f)(9)(v), (vi). Such labeling cannot credibly be deemed "misleading" because it unambiguously discloses that an adult-use drug has not been established as safe or effective for pediatric populations.

33. FDA further invokes its authority to "require products to bear adequate directions for use." Ex. 2 at 4; 63 Fed. Reg. at 66,657-58; 21 U.S.C. § 352(f). Because drugs marketed for adult use only contain FDA-approved directions for each indicated use, however, and, indeed, carry explicit disclaimers with respect to pediatric uses, they bear adequate directions for each claimed – i.e., labeled – use despite the lack of pediatric labeling.

34. FDA also relies upon its authority to prohibit the marketing of drugs that are "dangerous to health when used in the manner suggested in their labeling" or "not generally recognized as safe and effective or approved for the conditions prescribed, recommended, or suggested in the labeling." Ex. 2 at 4; 63 Fed. Reg. at 66,657; 21 U.S.C. §§ 352(d), 335(j). The

labeling of a drug approved for adult use only, however, does not prescribe, recommend, or suggest use in pediatric populations. To the contrary, it contains an express disclaimer advising that "[s]afety and effectiveness in pediatric patients have not been established." 21 C.F.R. § 201.57(f)(9)(vi). With respect to marketed drugs, moreover, FDA cannot credibly assert that drugs which it previously approved as "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof," are now unsafe as a general matter. 21 U.S.C. § 355(d).

35. FDA also relies upon its authority to require manufacturers to submit reports of the data obtained as a result of the investigational use and/or clinical testing of a drug to support the Rule. See Ex. 2 at 4; 63 Fed. Reg. at 66,657; 21 U.S.C. § 355(i). This provision, however, only contains reporting requirements concerning previously conducted clinical studies and other already available information with respect to the drug at issue. It does not authorize FDA to require the manufacturer to generate new data.

36. FDA further relies upon its authority "to issue regulations for the efficient enforcement of the act" to support the Rule. See 63 Fed. Reg. at 66,657-58; 21 U.S.C. § 371. This provision, however, does not support the Rule because it does not give FDA carte blanche to issue regulations beyond what Congress has authorized. Absent an independent statutory basis for the Pediatric Rule, this provision grants no authority to FDA for the Rule's issuance.

The Rule Is Arbitrary and Capricious and Conflicts with Congressional Purposes

37. FDA's issuance of the Pediatric Rule is arbitrary, capricious, and an abuse of discretion.

38. Congress specifically chose in FDAMA to increase the availability of information concerning pediatric uses through a voluntary incentive scheme rather than a heavy-handed, coercive approach. Congress also indicated its preference for incentives over coercion in the

1983 Orphan Drug Act, Pub. L. 97-414, 96 Stat. 2049 (1983), which gives manufacturers certain incentives to develop drugs to treat rare diseases or conditions. In addition, Congress included other provisions that encourage manufacturers to submit supplemental applications for new uses of approved drugs to bring off-label uses on-label. See id. § 371 note. The Pediatric Rule, by contrast, forces manufacturers to perform pediatric testing, possibly develop pediatric formulations, and seek approval for pediatric uses. Although FDA has asserted a belief that the congressional regime is inadequate, it has neither published its report evaluating public comments on the incentive scheme nor cited empirical evidence in support of its position.

39. The Rule also conflicts with Congress's judgment that the appropriate tradeoff for increased pediatric labeling is to defer entry of competitive generic drug products into the market for a specified time period. FDA's Pediatric Rule, by contrast, will keep new chemical entities off the market altogether unless they first have secured "proper" pediatric labeling.

40. The Pediatric Rule also conflicts with FDAMA's goal of reducing the inordinate amount of time and money necessary to obtain approval of new drug applications. For example, FDAMA contains a fast-track approval process to expedite the approval of drugs that demonstrate the potential to address unmet medical needs for serious and life-threatening conditions. Likewise, FDAMA contains provisions designed to streamline clinical research on drugs. Additionally, FDAMA permits FDA to approve a NDA based on only one adequate and well-controlled clinical investigation and confirmatory evidence, rather than the two investigations that FDA often had required. By contrast, the Pediatric Rule requires additional clinical studies as well as the potential development of pediatric formulations of certain drugs, rendering the approval process more cumbersome, protracted, and costly. FDA acknowledged as much in its letter denying Plaintiffs' Citizen Petition when it stated that, although the agency

"recognizes that there will be certain costs associated with complying with the pediatric rule, the Agency believes these costs are necessary[.]" Ex. 2, at 3.

41. Without explanation, the Rule also applies different legal standards to similarly situated persons. To apply the FDCA's statutory requirements consistently, FDA must either exempt all drug applicants from pediatric testing or require all drug applicants to perform such testing. FDA, however, exempts ANDA applicants from pediatric testing but requires pediatric testing of all other new drug products even though it is equally foreseeable that ANDA, NDA, and suitability petition drugs will be used in pediatric populations. FDA's uneven application of the Rule is particularly troubling given that many ANDAs will be based on marketed pioneer drugs for which pediatric testing was not, and never will be, required. Under FDA's application, the Rule would require testing of most drugs but would irrationally exempt similarly situated ANDA drugs, even if the drug treats a disease that occurs in pediatric populations and the pioneer had never been established to be safe and effective for pediatric use.

Count I

42. Plaintiffs incorporate the allegations in Paragraphs 1 - 41 above.

43. Defendants' issuance and continued enforcement of the Pediatric Rule should be set aside as in excess of its statutory jurisdiction, authority, or limitations, and short of statutory right, in violation of 5 U.S.C. § 706(2)(C).

Count II

44. Plaintiffs incorporate the allegations in Paragraphs 1 - 41 above.

45. Defendants' issuance and continued enforcement of the Pediatric Rule should be set aside as arbitrary, capricious, an abuse of discretion, and not otherwise in accordance with law, in violation of 5 U.S.C. § 706(2)(A). The Rule conflicts with FDAMA and applies the

FDCA's statutory requirements differently to similarly situated persons, all without adequate explanation of the basis for doing so.

WHEREFORE, Plaintiffs pray that this Court:

1. Declare that FDA's issuance of the Pediatric Rule lacks statutory authority and, in fact, is contrary to FDA's clear statutory mandate, in violation of 5 U.S.C. § 706(2)(C) in that it is in excess of FDA's statutory jurisdiction, authority, or limitations and short of statutory right;

2. Declare that Defendants' issuance and continued enforcement of the provisions of the Pediatric Rule that conflict with FDAMA and the FDCA is unlawful, arbitrary, capricious, an abuse of discretion, not otherwise in accordance with law, and in violation of the FDCA, FDA's own regulations, and 5 U.S.C. § 706(2)(A);

3. Permanently enjoin and restrain Defendants and all persons acting under their direction or authority, or in active concert or participation with them, from enforcing or causing to be enforced or from attempting to enforce or cause to be enforced, by any administrative action, civil or criminal proceeding, or otherwise, the Pediatric Rule alleged herein as being null and void;

4. Award Plaintiffs their costs in this action, including their reasonable attorneys' fees incurred; and

5. Award such other relief as the Court deems just and proper.

Respectfully submitted,

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Consumer Alert

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