

US EPA ARCHIVE DOCUMENT

## SETTLEMENT AGREEMENT

This Settlement Agreement is entered into by and among Petitioners Natural Resources Defense Council, Inc., Pesticide Action Network North America, Pineros y Campesinos Unidos Del Noroeste, Physicians for Social Responsibility - San Francisco, Farm Labor Organizing Committee, AFL-CIO, and Migrant Clinicians Network (collectively "Petitioners") and the U.S. Environmental Protection Agency ("EPA").

WHEREAS, on February 6, 2006, EPA published in the Federal Register a final rule entitled "Protections for Subjects in Human Research." *See* 71 Fed. Reg. 6138 (Feb. 6, 2006) (the "2006 final rule");

WHEREAS, the Petitioners filed four petitions for review of the 2006 final rule, which were consolidated in the United States Court of Appeals for the Second Circuit, Case Nos. 06-0820-ag, 06-1895-ag, 06-2149-ag, 06-2360-ag (2<sup>nd</sup> Cir.);

WHEREAS, the Petitioners and EPA (collectively, "the Parties") briefed the case and presented oral argument before the court on January 17, 2008;

WHEREAS, the Parties wish to settle the Petitioners' petitions for review;

WHEREAS, settlement of the Petitioners' petitions is in the public interest;

NOW, THEREFORE, without admission of any issues of fact or law, or waiver of any claim or defense, either factual or legal, the Parties agree as follows:

### Specific Provisions

1. EPA agrees to conduct notice-and-comment rulemaking in accordance with the Administrative Procedure Act on the issue of whether the 2006 final rule should be amended.

2. No later than seven months after this Settlement Agreement is filed with the court, EPA agrees to sign a notice of proposed rulemaking that proposes, at a

minimum, the amendments to the 2006 final rule as substantially consistent with Exhibit A. After considering any public comments received, EPA agrees to take final action on the proposed rule, which may include signing a notice of final rulemaking. EPA will take such final action no later than eighteen months after this settlement agreement is filed with the court.

### **Procedural Matters**

3. Upon execution of this Settlement Agreement by the Parties, the Petitioners and EPA agree to file a joint motion requesting that the court extend the stay in Case Nos. 06-0820-ag, 06-1895-ag, 06-2149-ag, 06-2360-ag (2<sup>nd</sup> Cir.), pending completion of the activities set forth in paragraphs 1 and 2. This Settlement Agreement shall be appended to that joint motion. This Settlement Agreement will take effect only if the court grants the requested stay.

4. If EPA takes the actions described in paragraph 2, by the schedule contained in paragraph 2, then the Petitioners and EPA agree to file a joint motion in accordance with Rule 42 of the Federal Rules of Appellate Procedure for dismissal with prejudice of Case Nos. 06-0820-ag, 06-1895-ag, 06-2149-ag, 06-2360-ag (2<sup>nd</sup> Cir.).

### **Petitioners' Remedies**

5. If EPA fails to take the actions described in paragraph 2, by the schedule contained in paragraph 2, then the Petitioners' sole remedy shall be the right to reactivate their petitions for review of the 2006 final rule and request that the Court

proceed to issue a decision in the consolidated cases. The Petitioners agree to give EPA thirty days' notice prior to exercising their rights under this paragraph.

6. Any challenge to any amendments to the 2006 final rule must be brought in a new action, and Petitioners reserve whatever rights they may have to bring such a challenge, except as specifically provided below. Notwithstanding the foregoing sentence, if EPA amends the 2006 final rule by adopting the language of Exhibit A without making any material changes to the language of Exhibit A, Petitioners will not exercise whatever rights they may have to seek judicial review of those amendments pursuant to 21 U.S.C. § 346a(h)(1) or otherwise. Nothing in this settlement agreement shall restrict Petitioners' rights to comment on or otherwise participate in the APA rulemaking discussed in paragraph 1.

### **General Provisions**

7. Nothing in the terms of this Settlement Agreement shall be construed to limit or modify the discretion accorded EPA by the Department of the Interior, Environment and Related Agencies Appropriations Act, 2006; the Federal Food, Drug, and Cosmetic Act; the Federal Insecticide, Fungicide and Rodenticide Act; or general principles of administrative law.

8. Nothing in this Settlement Agreement shall be construed to limit or modify EPA's discretion to alter, amend, or revise 40 C.F.R. Parts 26 and 150 through 180, or to promulgate superseding rules or subsequent guidance. Nothing in this Settlement Agreement shall be construed to limit or modify EPA's discretion to propose

additional regulatory changes in the same notice of proposed rulemaking signed pursuant to paragraph 2 and to finalize additional or different regulatory changes in the same notice of final rulemaking signed pursuant to paragraph 2.

9. Until any amendments to the 2006 final rule become effective, the 2006 final rule remains in effect.

10. This is the entire Settlement Agreement between the Parties with respect to the Petitioners' petitions for review of the 2006 final rule. All prior conversations, meetings, discussions, drafts, and writings of any kind are specifically superseded by this Settlement Agreement and may not be used by the Parties to vary or contest the terms of this Settlement Agreement, or as evidence of the Parties' intent in entering into this Settlement Agreement.

11. The Parties may agree in writing to modify any provision of this Settlement Agreement.

12. Nothing in this Settlement Agreement shall be construed to constitute an admission of any issue of fact, law, or liability by any of the Parties. Except as expressly provided in this Settlement Agreement, none of the Parties waives or relinquishes any legal rights, claims, or defenses it may have.

13. EPA agrees to pay Petitioners \$ 135,000 in full satisfaction of Petitioners' claims for attorney fees and costs in this litigation.

14. The undersigned representatives of each Party certify that they are fully authorized by the Party or Parties they represent to bind the respective Parties to the

terms of this Settlement Agreement. This Settlement Agreement may be signed in counterparts, which, taken together, shall constitute the whole. This Settlement Agreement will be deemed to be executed and shall become effective when it has been signed by all of the representatives of the Parties set forth below.

15. No provision of this Settlement Agreement shall be interpreted as or constitute a commitment or requirement that EPA obligate or pay funds in contravention of the Anti-Deficiency Act, 31 U.S.C. § 1341, or take actions in contravention of the Administrative Procedure Act, 5 U.S.C. §§ 551-559, 701-706, or any other law or regulation, either substantive or procedural.

16. It is hereby expressly understood and agreed that this Settlement Agreement was jointly drafted by the Parties. Accordingly, the Parties hereby agree that any and all rules of construction to the effect that ambiguity is construed against the drafting party shall be inapplicable in any dispute concerning the terms, meaning, or interpretation of this Settlement Agreement.

17. Circumstances that are not reasonably foreseeable and that are outside the reasonable control of EPA could possibly delay compliance with the schedule established in paragraphs 2. Such situations include, but are not limited to, a government shut-down such as occurred in 1995 and 1996, or catastrophic environmental events requiring immediate and/or time-consuming response by EPA. Should a delay occur due to such circumstances, any resulting failure to meet the timetables set forth herein shall not constitute a failure to comply with the terms of this

Settlement Agreement, and any deadlines shall be extended one day for each day of the delay. EPA will provide the Petitioners with notice as soon as is reasonably possible under the circumstances in the event that EPA invokes this term of the Settlement Agreement and will provide Petitioners with an explanation of EPA's basis for invoking the provisions of this Paragraph. The provisions of this Paragraph shall not limit Petitioners' right to petition the Court to lift the stay issued pursuant to Paragraph 5, except that the court may take any delays described by this Paragraph into account in determining whether to lift the stay.

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