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06-1895-ag (CON), 06-2149-ag (CON), 06-2360-ag (CON)

In the U.S. Court of Appeals for the Second Circuit

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,
Petitioners,
v.

United States Environmental Protection Agency,
Respondent.

On Petition for Review of an Order of the
United States Environmental Protection Agency

PETITIONERS' REPLY BRIEF

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INTRODUCTION

The challenged Human Testing Rule has harmed and will continue to harm Petitioners and their members. The substantial and entirely uncontroverted evidence before this Court belies EPA's factual assertions to the contrary, and this Circuit and the Supreme Court have both rejected EPA's core Article III legal theory. The Court has jurisdiction and should proceed to the merits.

EPA's Human Testing Rule violates Section 201 because it allows intentional pesticide toxicity experiments on pregnant women and children in some circumstances, contravenes the principles proposed by the National Academy's 2004 Report, and is inconsistent with the Nuremberg Code. EPA ignores the statute's clear text in favor of an allegedly narrow legislative "policy," but disregards the stated policy of Section 201's enactors. EPA argues that most of the Nuremberg Code is precatory, although text and history show otherwise. EPA treats the National Academy's proposals as distractions, and disregards the evidence and canons of construction that disprove that treatment.

In short, EPA asks this Court to rewrite the law. The invitation should be rejected.

ARGUMENT

I. Petitioners Have Standing

The Human Testing Rule has caused EPA to raise exposure limits for pesticides to which Petitioners' members are exposed. A judicial order vacating the Rule would remove the cause of this injury. Petitioners' uncontroverted evidence establishes these facts and each element of Article III standing.

A. The Human Testing Rule Injures Petitioners and Their Members

Exposure to a toxic chemical is a well-recognized Article III injury. *See, e.g.*, *Friends of the Earth, Inc. v. Laidlaw*, 528 U.S. 167, 184-85 (2000); *LaFleur v. Whitman*, 300 F.3d 256, 270 (2d Cir. 2002). Indeed, this Court has held that even "health-related uncertainty," *see New York Public Interest Research Group v. Whitman*, 321 F.3d 316, 325, 326 (2d Cir. 2003) ("*NYPIRG*"), or an "increased risk" of exposure to a dangerous substance, *Baur v. Veneman*, 352 F.3d 625, 633 (2d Cir. 2003); *see also id.* at 627-28, 633-35, 641-42, are constitutionally cognizable.[1]

[1] This Court's recognition that increased risk of harm is a cognizable injury comports both with common experience (e.g., people pay for insurance against risks of future injury) and with the law of other Circuits. *See Central Delta Water Agency v. United States*, 306 F.3d 938, 947-948 (9th Cir. 2002); *Hall v. Norton*, 266 F.3d 969, 976 (9th Cir. 2001); *Johnson v. Allsteel, Inc.*, 259 F.3d 885, 888 (7th Cir. 2001); *Friends of the Earth, Inc. v. Gaston Copper Recycling Corp.*, 204 F.3d 149, 160 (4th Cir. 2000); *Louisiana Envtl. Action Network v. EPA*, 172 F.3d 65, 67-68 (D.C. Cir. 1999); *Walters v. Edgar*, 163 F.3d 430, 434 (7th Cir. 1998), *cert.*

The uncontroverted evidence proves precisely such injuries here. Petitioners' members include farmworkers who apply and are exposed to pesticides in the fields where they work; families who live downwind of agricultural spray; and consumers who eat and drink pesticide-contaminated food and water in their normal diet. *See* D8-9, D84-88, D89-90, D91, D92, D93, D94, D96-97, D98, D106-08, D112-14, D117, D122-24, D350.[2] These individuals have "no choice but to breathe the air where [they] live[] and work[]" or to eat the food on their table. *LaFleur*, 300 F.3d at 270; D8-D9, D11-12; D101-102.

The pesticides at issue can cause severe neurological, developmental, and other disorders. *See* D6, D9, D12, D15-16, D28, D101-04. When EPA raises allowable exposure limits for these chemicals, people who live, work, and eat downwind or downstream will thus "undoubtedly" experience "increased levels" of exposure, practically "whenever the wind blows . . . in [their] direction." *LaFleur*, 300 F.3d at 270. Such increased exposure exacerbates health risks and

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denied, 526 U.S. 1146 (1999); *Mountain States Legal Found. v. Glickman*, 92 F.3d 1228, 1234-35 (D.C. Cir. 1996).

[2] Petitioners have concurrently filed a volume of Declarations in Support of Standing, citations to which in this brief follow the form "D[page number]." This volume includes evidence submitted with Petitioners' August 3, 2006 Response to EPA's Motion to Dismiss, including the expert declarations of Gina Solomon, M.D., Adam M. Finkel, Sc.D., Margaret Reeves, Ph.D., and Karen Mountain, M.B.A., M.S.N., R.N., as well as additional percipient witness declarations of Petitioners' members and officers. The declarations volume also includes additional expert and percipient witness declarations that relate to subsequent EPA actions, as well as to a standing issue that EPA did not raise until its merits brief and which is addressed *infra*, at Section I.C.

uncertainty.[3] *See* D5-6, D9, D11-12, D15-16, D28-29, D30, D41, D57, D63-64, D84-88, D90, D91, D92, D107-08.

The Human Testing Rule[4] caused EPA to set higher pesticide exposure limits for the pesticides at issue. Promulgation of the Rule lifted Section 201's moratorium on EPA use of human toxicity experiments to set pesticide standards and, shortly after the Rule took effect, EPA began relying on such experiments to increase allowable exposure limits for these pesticides. For example, EPA increased allowable exposure levels for aldicarb, amitraz, dichlorvos, and methomyl – neurotoxins all – by as much as three, five, and even ten times the levels EPA would have set but for its use of these human studies. *See* D9-11, D12, D15, D18-19, D28-29, D31, D54-55, D162-166, D219, D225, D230-231, D381; *cf. Baur*, 352 F.3d at 637 n.11 (holding that evidence of post-filing events can "confirm that a plaintiff's fear of future harm is reasonable").

EPA's reliance on the Human Testing Rule to increase allowable pesticide exposure levels was not only a possible, but the predictable result of the Rule. When the Rule issued, EPA faced an imminent August 2006 deadline for

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[3] The precise level of risk posed by increased exposure is not itself a question of Article III significance. *See Baur*, 352 F.3d at 642-43; *cf. Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982) (holding that even a "perceptibl[e]" injury satisfied Article III).

[4] EPA used to refer to the subject of its rule as "Human Testing," *e.g.*, 70 Fed. Reg. 6661 (Feb. 8, 2005), and to call it the "Human Studies Rule," A1274. That name is more precise than EPA's new term, "Research Rule."

reregistering numerous pesticides and reassessing thousands of pesticide tolerances (i.e., deciding which pesticides and which food uses were sufficiently safe to continue). *See* 21 U.S.C. § 346a(q); 7 U.S.C. § 136a-1(g)(2)(A)(i). To meet that August deadline, EPA relied on human experiments that had already been conducted, and the results of which (purporting to justify a relaxation in pesticide protections) were thus known. *See, e.g.*, A156, A666, A704-06; D130; Wall Decl. in Supp. of Mot. to Complete Admin. R. (Sept. 28, 2006), Ex. B at 2 (EPA memo from July 2005 reciting how EPA could use dichlorvos human study to justify tenfold increase in exposure levels).

Moreover, EPA's promulgation of the Rule resulted in two critical changes to the way EPA set these pesticides standards. First, as noted above, the Rule lifted Section 201's moratorium on EPA use of human toxicity experiments. SPA1. Second, EPA's use of the experiments changed EPA's calculation of allowable exposure levels for a number of pesticides. Under EPA's standard risk assessment methodology, whenever EPA relies on only animal experiments to assess risk, it applies a tenfold safety factor to account for the prospect that humans are more susceptible than animals. A153; D3-5, D44-46, D49-51. Where EPA uses human experiments, it reduces or eliminates this safety factor. Thus, EPA's use of human studies predictably caused EPA to reduce or waive the tenfold safety factor and calculate significantly higher allowable exposure levels for these

pesticides. D3, D5, D28-29, D49-55. This expected result was, of course, precisely why the pesticide manufacturers began aggressively submitting human toxicity tests to EPA in the first place. *See* Pet'rs. Br. 13-14; A666.[5]

In light of this evidence, EPA's description of Petitioners' injury as "speculative" – or, with some rhetorical gusto, as "a hypothetical injury associated with the possibility of higher exposure levels that might be established in future EPA proceedings" – is perplexing. EPA Br. 1-2. The events that EPA calls "speculative" have in fact already occurred. EPA itself admits this, noting that "[t]he declarations and documents submitted by Petitioners related to recent EPA actions regarding tolerance levels demonstrate that this multi-step path was followed in the post-Research Rule actions cited by Petitioners." EPA Br. 25.

The harm to Petitioners' members here is thus far more certain than other, future harms this Court has found to satisfy Article III in previous cases, including a risk that EPA's approval of a flawed state permitting program might cause later increases in air pollution, *see NYPIRG*, 321 F.3d at 324, 325-26, and the risk from a regulation that increased the prospect of exposure to mad cow disease, a pathogen that had not yet been discovered in this country, *see Baur*, 352 F.3d at

[5] Because EPA's Human Testing Rule fails to adopt basic scientific safeguards recommended by the National Academy of Sciences, many of the human toxicity experiments considered by EPA lack the statistical power to detect adverse health effects that would be experienced across a wider population. A60-62; D6-7, D48, D59-61. When EPA relies on such studies, the result is an increase in risk to those exposed. *See id.*; *see also* D11, D15, D19, D29, D41, D63-64.

633-355, 642. EPA ignores this evidence and precedent, instead arguing that an injury is *always* too speculative – as a matter of law – if the challenged agency action is not the very last step in the causal chain. EPA Br. 21, 23, 27 & n.5. As we discuss in the next section, that theory has been rejected both by the Supreme Court and by this Circuit.[6]

B. Petitioners' Injuries Are Fairly Traceable to EPA's Rule

Uncontroverted evidence establishes that the Human Testing Rule changed EPA's pesticide standard setting process, causing EPA to waive a tenfold uncertainty factor and thus, predictably, to increase allowable exposure levels for pesticide to which Petitioners members are exposed. *See supra*, at Section I.A. EPA contends that despite this evidence, Petitioners cannot satisfy Article III's

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[6] Petitioners have standing to sue to protect their own organizational interests, as well as those of their members. Petitioners Pineros y Campesinos Unidos del Noroeste and Farm Labor Organizing Committee, AFL-CIO, for example, expend resources to investigate and respond to pesticide incidents affecting any of their numerous members. *See* D111, D113-16; D124-26. Petitioner Migrant Clinicians Network expends resources training the thousands of doctors, nurses, and other clinicians it represents to respond to such incidents. *See* D117-20. The resulting costs to Petitioners are established Article III injuries, *see Havens*, 455 U.S. at 379; *cf. Sierra Club v. Morton*, 405 U.S. 727, 737-38 (1972), that are "germane," *Hunt v. Washington State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977), to Petitioners' purposes. *See* D93, D99-100, D109, D117, D12. Indeed, the chance that one of Petitioners will expend resources to respond to such an incident is the aggregate of the risk to all of their thousands of members. *See* D109, D116, D117-19, D122; *cf. Utility Air Regulation Group v. EPA*, __ F.3d __, No. 05-1353, 2006 WL 3590194, *6 (D.C. Cir. Dec. 12, 2006) ("[G]iven the organization's large membership . . . we find it reasonable to infer that at least one member will suffer injury-in-fact.").

causation requirement because EPA's Rule was not the very last, or "operative," cause of their injury. EPA Br. 26-27 & n.5. Precedent says otherwise.

The Supreme Court expressly rejected EPA's argument a decade ago, in *Bennett v. Spear*, 520 U.S. 154 (1997). The *Bennett* plaintiffs sued the Fish and Wildlife Service ("FWS") over a biological opinion FWS provided to the Bureau of Reclamation ("Bureau"). *Id.* at 159. FWS challenged plaintiffs' standing, claiming that its biological opinion was not the "proximate cause" of the plaintiffs' anticipated injuries, which would occur (if at all) only after an "as yet unidentified" later decision by the Bureau. *Id.* at 168. The Court, per Justice Scalia, rejected that theory as "wrongly equat[ing] injury 'fairly traceable' to the defendant with injury as to which the defendant's actions are the very last step in the chain of causation."[7] *Id.* at 168-69; *see also Metropolitan Washington Airports Auth. v. Citizens for Abatement of Aircraft Noise*, 501 U.S. 252, 261-62, 264-65 (1991) (holding plaintiffs had standing to challenge a law that gave a review board power

[7] *Bennett* found the plaintiffs' injury "fairly traceable" to the FWS biological opinion because the facts supported that finding. The Court concluded that the FWS biological opinion would be "virtually determinative" of the Bureau's later decision because, if the Bureau disagreed with FWS, it would have to articulate the basis for its disagreement on the record and run the risk of being sued if it were wrong. 520 U.S. at 169, 170. Far from distinguishing the present case, this aspect of *Bennett* supports Petitioners' standing here. Petitioners' uncontroverted causation evidence – including the extensive testimony of one of the leading risk assessment experts in the country, *see* D37-41 – is both stronger and more direct than the circumstantial evidence *Bennett* found sufficient. Moreover, *Bennett* approached causation with particular care because the ultimate agency actor in that case, the Bureau, was not even a party. *Id* at 169. The same is not true here.

to veto a development plan because the power, although unexercised, had "influenced" plan adoption).

This Circuit, too, has rejected EPA's "operative cause" theory of standing. In *NYPIRG*, for example, the petitioners challenged EPA's authorization of New York's air pollution permit program.[8] 321 F.3d at 320-22, 324. EPA's approval of that program did not itself require or permit any increase in air pollution. Such a pollution increase would arise, if at all, only when New York later issued permits under its flawed program. This Court nevertheless found standing because EPA's authorization of the state program would increase the petitioners' members' "uncertainty" about pollution from nearby factories. *Id.* at 325-26. EPA's decision to permit the New York program was not the final step in the causal chain; EPA was not even the final actor. Yet standing existed because the members' injuries were "fairly traceable" to EPA's decision. Under *NYPIRG*, Petitioners here plainly have standing.

The two out-of-Circuit decisions on which EPA relies do not support a departure from this Court's precedent. In *Louisiana Environmental Action Network v. Browner*, 87 F.3d 1379 (D.C. Cir. 1996) ("*LEAN*"), the plaintiffs challenged an EPA rule that they feared would create an "enforcement gap," but

[8] EPA mischaracterizes *NYPIRG* as a challenge to an EPA decision that "regulated emissions of air pollutants from several facilities." EPA Br. 22. *NYPIRG* involved, and found standing for, three consolidated lawsuits, at least two of which EPA's characterization ignores. 321 F.3d at 324.

apparently presented no evidence that such an enforcement gap was likely, let alone likely where their members lived. *Id.* at 1383. At most, *LEAN* shows that an injury based on future agency action *can* be too speculative where the plaintiff introduces no evidence to prove causation; it does not show that such an injury is *always* too speculative, regardless of the evidence. As for *Shoreham-Wading River Central School District v. Nuclear Regulatory Commission*, 931 F.2d 102, 105 (D.C. Cir. 1991), its holding – that a plaintiff lacks standing to challenge an agency action if that action is a "but for" cause of the plaintiff's injury but not the "operative" cause – did not survive *Bennett*, 520 U.S. at 168-69, and has never been cited by any published decision of any court.

C. Petitioners Have Standing to Challenge the EPA's Failure to Regulate All Toxicity Experiments Covered by Section 201

Petitioners' uncontroverted evidence also establishes standing to challenge the Rule's failure to regulate human dosing pesticide toxicity experiments (including experiments on pregnant women and children) unless "intended" for EPA's consideration under FIFRA or FFDCA. EPA uses human toxicity experiments to set pesticide standards under other statutory programs, *see* Pet'rs. Br. 9-10, D29-33, as do other governmental agencies, *see, e.g.*, Pet'rs. Br. 28 & n.9; D33-34. Regulatory decisions under these other statutes increase Petitioners' members' risks of exposure in precisely the same way as do EPA's decisions under FIFRA and FFDCA.

For example, EPA regulates human exposure to pesticides under the Safe Drinking Water Act ("SDWA"), 42 U.S.C. § 300g-1(b). *See, e.g.*, 40 C.F.R. § 141.61(c) (setting SDWA maximum contaminant levels for numerous pesticides). Tens of thousands of Petitioners' members live in cities for which the source of drinking water has been contaminated with pesticides, including aldicarb, methomyl, and oxamyl – all chemicals for which EPA has received and is considering human dosing toxicity experiments. *See* D30-31, D91, D92, D95, D96-97, D98, D233 (¶ 4), D350. EPA is required by SDWA to reevaluate all existing drinking water standards every six years,[9] *see* 42 U.S.C. § 300g-1(b)(9), and to set new standards periodically, *see id.* at § 330g-1(b)(1)(B)(ii). It is predictable that when EPA does so, reliance on human experiments will lead to increases in allowable exposures levels, as has been true in EPA's FIFRA and FFDCA risk assessment process. 40 C.F.R. § 141.61(c); D28-29, D32-33.

Indeed, pesticide-industry human toxicity studies have already caused EPA to reduce drinking water protections for at least one pesticide. EPA set a drinking water standard for aldicarb, but later suspended that standard when the pesticide's manufacturer claimed that EPA had improperly relied on an animal study and should instead have relied on a particular human study. 57 Fed. Reg. 22178, 22179 (May 27, 1992). EPA reconsideration of that aldicarb drinking water

[9] EPA last reevaluated its oxamyl drinking water standard, for example, in 2003. *See* 68 Fed. Reg. 42908 (July 18, 2003).

standard is still pending, and EPA is considering human studies in that ongoing proceeding. *See id*. Had EPA's Human Testing Rule complied with Section 201, however, a different and more protective standard would govern EPA's use of human studies in that and other drinking water standard setting proceedings.[10]

Petitioners cannot wait to challenge EPA's failure to regulate the conduct and use of such experiments – which are covered by Section 201 but ignored by EPA's Rule, *see* Section II, *infra* – in assurance that a challenge could be launched when EPA uses such an experiment in a later proceeding. Were Petitioners to delay in challenging the unlawfully narrow scope of the Rule, EPA would no doubt argue that the FFDCA's sixty-day statute of limitations barred their litigation. *See* 21 U.S.C. § 346a(h)(1); *cf. NRDC v. Johnson*, 461 F.3d 164, 173-176 (2d Cir. 2006) (reading this FFDCA provision's judicial review exclusivity clause broadly).

Petitioners have challenged EPA's Rule in part to protect their members from predictable future risks resulting from the Rule's unlawfully narrow scope. As was the case in *NYPIRG*, 321 F.3d at 325-26, and *Baur*, 352 F.3d at 633-35, Article III poses no obstacle to this suit.

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[10] EPA's own aldicarb risk assessment shows that, when drinking water exposures are included, risks to every subgroup considered – the general population, infants, children age 1-2, and females age 13-49 – exceed the risk thresholds EPA would have used had it relied on an animal study rather than a human experiment. D29, D277 (defining level of concern), D279 (comparing exposure to human-based and animal-based levels of concern).

II. The Rule Violates Section 201's Blanket Ban on the Use of Pregnant Women and Children as Subjects in Pesticide Toxicity Experiments

Section 201 directed EPA to issue a rule, applicable to "intentional dosing human toxicity studies for pesticides," that "shall not permit the use of pregnant women, infants, or children as subjects." SPA1. There is no dispute that EPA did not adopt such a categorical rule. Instead, the Human Testing Rule regulates only those toxicity experiments that are "intended" to be submitted to EPA for consideration under FIFRA or FFDCA. SPA40 (§ 26.1201). The Rule's narrow scope violates Section 201 by, among other things, permitting many pesticide toxicity experiments on pregnant women and children and allowing EPA to consider such tests under statutes other than FIFRA and the FFDCA. These other statutes include the Safe Drinking Water Act and Clean Water Act, pursuant to which EPA also regulates human exposure to pesticides. *See* Pet'rs. Br. 9-10.[11]

EPA's contention that its narrowing construction conforms to Section 201's "object and policy," EPA Br. 30, fails for two reasons. First, the task of interpreting statutory language properly begins, not with an inquiry into "purpose," but with the statutory language itself. *See, e.g. Raila v. United States*, 355 F.3d 118, 120 (2d Cir. 2004) ("Statutory construction begins with the plain text, and, 'where the statutory language provides a clear answer, it ends there as well.'"

[11] Pesticides contaminate drinking water and surface waters regulated by the Safe Drinking Water Act and Clean Water Act when the pesticides run off agricultural fields or facilities where they have been applied.

(internal citation omitted)). "[A]lthough a court appropriately may refer to a statute's legislative history to resolve statutory ambiguity, there is no need to do so here," because the statutory text itself is clear. *Toibb v. Radloff*, 501 U.S. 157, 162 (1991). "Studies for pesticides" means just that – *i.e.*, "studies with respect to pesticides," *see* Random House Unabridged Dictionary 747 (2d ed. 1993) (defining "for") – not "studies for pesticides intended for EPA's consideration under FIFRA or FFDCA." Where, as here, "the statutory language is unambiguous and 'the statutory scheme is coherent and consistent,'" judicial inquiry "must cease." *Robinson v. Shell Oil Co.*, 519 U.S. 337, 340 (1997) (internal citation omitted).

EPA originally acknowledged Section 201's obvious meaning. Shortly after Section 201's enactment, EPA issued a formal interpretative Guidance that concluded that the phase "studies for pesticides" encompassed studies *of* pesticides, even if not "submitted or otherwise available for consideration under [FIFRA or FFDCA § 408]." Wall Decl. in Supp. of Mot. to Complete Admin. R. (Sept. 28, 2006), Ex. A-1 at 14-15 (EPA Guidance setting out "[w]hat is meant by a study 'for pesticides'"). EPA's original administrative usage "confirms our understanding of the everyday sense of the term." *S.D. Warren Co. v. Maine Bd. Envt'l Prot.*, 126 S. Ct. 1843, 1849 (2006).[12]

[12] EPA's brief attempts to minimize the force of the Agency's original interpretation by labeling the Guidance "interim" and asserting it was drafted "broadly" to "avoid inadvertent noncompliance" with Section 201. EPA Br. 36.

Second, even if the statutory text were not clear, the legislative history belies EPA's claim that Congress intended to prohibit only those studies conducted and submitted for FIFRA and FFDCA purposes. EPA identifies no statement, from any Member of Congress, that Section 201 would allow dosing pregnant women and children with pesticides if the experiment was intended for EPA's use under other laws. When Senator Burns proposed an amendment that would have applied Section 201 to existing studies only if "submitted to the Agency under FIFRA," 151 Cong. Rec. S7552 (June 29, 2005), the Conferees rejected that approach, SPA1. *See* Pet'rs. Br. 21, 30.[13]

Instead, the legislative history shows that Section 201's proponents were appalled that researchers were dosing pregnant women and children with pesticides *at all*. Representative Solis, the lead House sponsor, summarized this sentiment, saying: "[i]t should never have taken place, the testing of pesticides on humans, particularly children." A647. Senator Boxer, the lead Senate sponsor, asked "what more of a moral issue can we be facing than allowing these students to have

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This explanation, which rests entirely on litigation counsel's say so rather than citation to the record, does not advance EPA's cause; the Agency obviously remains obliged to "avoid . . . noncompliance" with Section 201, inadvertent or otherwise.

[13] Nothing in the record remotely supports EPA's new assertion that Section 201 will deter development of mosquito repelling products. EPA Br. 34 n.10. Pesticides need not be applied to *children* to test their effectiveness against *mosquitoes*, and EPA has repeatedly made clear it does not need human studies to regulate pesticides in a manner that is protective of human health. *See* 151 Cong. Rec. H3671; A650.

chloropicrin pumped through their nostrils at a level 12 times higher than the safety level that OSHA, our Federal Government, says is safe?" 151 Cong. Rec. S7553 (June 29, 2005). Criticizing another study, involving infants, Section 201's co-sponsor, Senator Nelson, wondered: "Can anyone believe this is going on in the United States of America in the year 2005? . . . I certainly was not going to let that sort of thing go on in my State and it should not be going on in any State." 151 Cong. Rec. S7553-S7554 (June 29, 2005).

These floor statements reflect congressional recognition that the dangers of human dosing experiments have nothing to do with whether the study is intended for EPA's consideration under a particular statute. The dangers inhere in the experiments. This is why Section 201 expressly applies not only to EPA's "consider[ation]" of such experiments, but also to the studies' "conduct," regardless of the study sponsors' intentions.[14] SPA1.

[14] Some of the studies that horrified Section 201's proponents were no doubt intended for EPA consideration under the FQPA. This hardly proves EPA's claim, EPA Br. 31-33, that despite the clear language of Section 201, Congress meant *not* to regulate identical experiments conducted with a different intention. Indeed, a number of the studies that Section 201's sponsors condemned were conducted long before the FQPA was enacted. A705-06. EPA cites no evidence that these studies were "intended" for use under FIFRA or FFDCA.

III. The Rule Contravenes the National Academy's Proposed Principles

Section 201 required EPA to promulgate a rule that "shall be consistent with the principles proposed in the 2004 report of the National Academy of Sciences on intentional human dosing." SPA1. The Academy's Report makes only one set of proposals; they are set forth in seventeen, enumerated Recommendations. Petitioners' opening brief demonstrated that EPA's Rule is inconsistent with these Recommendations, and EPA does not disagree.

Instead, EPA claims that when Congress referred to the "principles proposed by the 2004 report of the National Academy of Sciences," Congress was referring to three principles ("beneficence," "justice," and "respect for persons") identified in a 1979 document called the "Belmont Report." A1286. EPA contends that these three "principles" are also "contained in the NAS Report," EPA Br. 37, and "form the basis for *many* of" the Report's recommendations, EPA Br. 39 (emphasis added). From these premises, EPA urges the Court to conclude that the Belmont Report's principles are "the principles proposed" by the Academy, and adopted by Congress, even though neither the text of Section 201 nor its legislative history ever mention these principles.

A threshold difficulty with EPA's argument is that Congress did not require consistency with some subset of principles "contained in" (EPA Br. 37) the Academy's Report. Congress required consistency with the principles that Report

"proposed." SPA1. A "proposal" is, of course, a "recommendation." *Random House Unabridged Dictionary* 1551 (2d ed. 1993). The Academy explicitly set forth its "proposals" in its Recommendations. A129 ("Because of . . . the need to be specific about the proposals being made, the recommendations follow.").

By contrast, the Academy never "proposed" the Belmont principles, let alone proposed those principles as *the* sole principles of the Academy's Report. The Belmont Report was just one of the several "authoritative statements" that the Academy concluded *collectively* represented the (then-existing) "basic standards that govern human research in the United States." A127, 234; Pet'rs. Br. 46-47. Far from "proposing" these principles, however, the Academy found them too "unclear, indeterminate, inconsistent, and frequently contradictory" to provide appropriate guidance for toxicant research. A235. This was why the Academy offered its "own judgments," *id.*, as set forth in its Recommendations. EPA's selective adoption of the most "unclear" and "indeterminate" of the several pre-existing statements of principle would turn the Academy's work on its head.[15]

EPA's claim (EPA Br. 37) that the Academy's Recommendations do not set forth "principles" is also wrong. In one meaning, a "principle" is "a standard . . .

[15] EPA's unprincipled selectivity is highlighted by its implicit admission that the Belmont principles were not a basis for all of the Academy's proposals. EPA Br. 39. For example, the Belmont principles were never mentioned in the Academy's chapter setting forth scientific principles, which is not surprising, since the Belmont Report addresses ethics, not science. A189-206.

for guiding conduct or practice," *Random House Unabridged Dictionary* 1539 (2d ed. 1993). This meaning aptly describes the Academy's Recommendations. That this was the meaning Congress used in Section 201 is demonstrated by Section 201's other use of this word to refer to the "principles of the Nuremberg Code." EPA concedes that the Nuremberg Code's "principles" are the ten standards enumerated in that Code. A529. Notably, the Nuremberg Code's principles are specific, codified rules of conduct. They are similar in enumeration, structure, and detail to the Academy's Recommendations – and entirely dissimilar to the Belmont Report's vague invocations of "justice," "beneficence," and "respect." Thus, Congress' use of the phrase "principles proposed" to refer to the Academy's Recommendations is not only consistent with common usage, it is the only usage of "principles" that is consistent with Congress' other use of that same word, in the same sentence, to refer to the Nuremberg Code.

Nor does our reading of the statute render Section 201's requirement of an "*independent* Human Subjects Review Board," SPA1 (emphasis added), redundant with the Academy's recommendation of a "Human Studies Review Board," A258. The Academy proposed a Review Board "internal" to EPA and explicitly recommended that this Board *not* be "independent." A259. Congress' requirement of an "independent" board is thus not "redundant," EPA Br. 38, but reflective of Congress' disagreement with this single aspect of the Academy's proposals.

To be sure, Congress *could* have referred to the Academy's seventeen proposals as "Recommendations," rather than as "principles proposed," but there was no need for Congress to do so. The English language is sufficiently resilient to allow Congress to choose among words and phrases that, in context, convey the same meaning. In ordinary English, "principles proposed" means "recommended standards for guiding conduct." That phrase succinctly and accurately describes the Academy's Recommendations.

Congress' meaning is confirmed by the legislative history. The floor debates are replete with statements by Section 201's proponents that the law would require EPA to abide by the Academy's "recommendations." 151 Cong. Rec. H7019; 151 Cong. Rec. H7020-H7021; Pet'rs. Br. 44-45. The Belmont principles are not mentioned. This legislative history thus reinforces the textual analysis.

"Even for an agency able to claim all the authority possible under *Chevron*, deference to its statutory interpretation is called for only when the devices of judicial construction have been tried and found to yield no clear sense of congressional intent." *General Dynamics Land Sys., Inc. v. Cline*, 540 U.S. 581, 600 (2004). Here, the text and history of Section 201 do provide a "clear sense" that Congress intended EPA to conform to the Academy's Recommendations, not the Belmont principles. EPA's unreasonable interpretation should be rejected.

IV. The Rule Violates the Nuremberg Code and FIFRA Section 12

Section 201 requires EPA's Rule to be "consistent" with the Nuremberg Code. SPA1. In normal usage, "consistent" means "agreeing or accordant." *See Random House Unabridged Dictionary* 434 (2d ed. 1993). The Human Testing Rule, however, authorizes human experiments that are not consistent with, and in some cases violate, the Nuremberg Code. The Rule also contravenes FIFRA section 12(a)(2)(P). SPA2.

A. The Rule Authorizes Toxicity Experiments Without the Subject's Fully Informed, Comprehending, and Voluntary Consent

Petitioners' opening brief showed that EPA's Rule allows someone other than the human subject to "consent" to the experiment, in violation of the Nuremberg Code and FIFRA section 12(a)(2)(P); fails to require that the human subject be free of "any element . . . of constraint or coercion," in violation of the Nuremberg Code; and fails to ensure that the human subject "comprehen[ds]" the risks, also in violation of the Nuremberg Code. *See* Pet'rs. Br. 49-55; A529. EPA's defenses are unpersuasive.

EPA first suggests that all the studies with which Petitioners are concerned – studies that EPA admits contained "misleading statements in the informed consent materials" – are irrelevant because those studies "took place *prior*" to the Rule. EPA Br. 45 (emphasis in original). EPA misses the point. Section 201 does not only restrict EPA's consideration of experiments that may be conducted in the

future. It also restricts EPA's consideration of *existing* studies, including studies conducted before the Rule was promulgated. Section 201's text suggests no exception for EPA consideration of past studies, SPA1, and the legislative history makes clear Congress' specific purpose to stop EPA from using these studies. A647 (Rep. Solis) ("All of the studies currently pending before EPA . . . fall far short of the stringent criteria for EPA consideration outlined by the NAS and the Nuremberg Code, and required by this amendment."); 151 Cong. Rec. S7553 (June 29, 2005) (Sen. Boxer) (similar); 151 Cong. Rec. S7557 (June 29, 2005) (Sen. Burns) (critiquing Boxer amendment for prohibiting use of existing studies).

Nor does the Rule ensure prospective consistency with the Nuremberg Code. The Agency's lead argument is that because the Nuremberg Code's first principle uses the word "should," rather than "shall," most of the principle is optional. EPA Br. 46. Consistency with an optional principle would not be difficult. However, EPA's argument ignores the first sentence of this principle: "The voluntary consent *of the human subject* is absolutely essential." A529 (emphasis added). Consent by someone other than the human subject violates this standard.

EPA's argument would also eviscerate virtually the entire Nuremberg Code, as well as Congress' direction to conform to that Code. "Should" is the operative word in nine of the Nuremberg Code's ten principles – none of which use "shall." A529. That the Nuremberg Code uses the language of ethics ("should"), rather

than the mandatory language of law ("shall"), cannot mean that Congress intended compliance with its principles to be voluntary. If that were the case, the most fundamental requirements of the Code – including the principles that a human subject "should" be protected against death or disability (Principle 7) and "should" be able to withdraw from an experiment while it is underway (Principle 9) – would amount to little more than a nice idea.[16]

Petitioners do not, as EPA claims (EPA Br. 44), demand "exact correspondence" between EPA's Rule and the text of the Nuremberg Code. What Section 201 requires is substantive consistency. EPA's Rule allows experiments to be conducted that violate the Code. The Rule is therefore inconsistent with that Code and Section 201.[17]

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[16] EPA's "should" argument also fails because EPA did not articulate this rationale at any point during the Rulemaking. *See Motor Vehicle Mfrs. Ass'n, Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50 (1983) (agency action "must be upheld, if at all, on the basis articulated by the agency itself"); *Gifford Pinchot Task Force v. U.S. Fish & Wildlife Serv.*, 378 F.3d 1059, 1072 n.9, 1074 (9th Cir.) (a court may "only rely on what the agency said in the record"), *amend. on other grounds*, 387 F.3d 968 (9th Cir. 2004).

[17] EPA's defenses to two of Petitioners' other concerns are equally unavailing. First, the Rule's direction only to "minimize the possibility of coercion or undue influence" plainly does not ensure that a human subject must "be able to exercise free power of choice, *without* . . . *any* element of . . . constraint or coercion," as required by the Nuremberg Code. An *element* of constraint can remain even after coercion has been "minimized" to the extent the circumstances (of, say, imprisonment) allow. Second, EPA's claim that its Rule ensures "comprehension" by human subjects ignores the only evidence on this issue before EPA, which was

Nor is EPA correct that "the issue of legal representatives providing consent on behalf of children . . . is not at issue." EPA Br. 47. EPA has placed such experiments at issue by declining to prohibit pesticide toxicity experiments on children unless the experimenter intends to submit the results for EPA's consideration under FIFRA or FFDCA. *See supra*, at Argument II. In any event, EPA's argument simply highlights the Rule's authorization of pesticide toxicity experiments on persons who are mentally infirm, incapacitated, or imprisoned, if a "representative" provides "consent." EPA defends this chilling proposition by arguing that the Declaration of Helsinki, Common Rule, and Belmont Report do not prohibit consent by a "representative." EPA Br. 47. EPA similarly argued, during the rulemaking, that ethical principles had "evolved," A1277, and that later statements of ethics provided "much more viable guidance" than the Nuremberg Code itself. A1182; *see also* EPA Br. 47. Congress required consistency with the Nuremberg Code, however, and EPA may not discard that Code whenever EPA believes it to be dated. *See* A647 (151 Cong. Rec. H7020 (July 28, 2005)

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the Academy's conclusion that the Common Rule standards that EPA's Rule adopted provide too little guidance to ensure comprehension. A244.

In any event, EPA's rationalizations of how the Rule conforms to the Nuremberg Code's "comprehension" and "without any element of . . . constraint" requirements come too late in the day. Neither explanation was ever articulated by EPA during the Rulemaking. A1277-78. When Petitioner objected that the draft rule failed to ensure full comprehension, for example, EPA ignored the comment. A1180-81. EPA's action "must be upheld, if at all, on the basis articulated by the agency itself" during the Rulemaking, not "counsel's post hoc rationalizations." *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 50.

(statement of Rep. Solis) ("This amendment forbids the EPA from considering any intentional human dosing study unless it meets the minimum ethical and scientific safeguards outlined in . . . the 1947 Nuremberg Code adopted after World War II.")).

The Rule also is contrary to FIFRA section 12(a)(2)(P), 7 U.S.C. § 136j(a)(2)(P), which bars human pesticide experiments without the "fully informed" consent of "such human beings" on whom pesticides are tested. SPA2; Pet'rs. Br. 51-52, 53. Notwithstanding EPA's summary conclusion to the contrary, EPA Br. 48, the Rule obviously allows tests to proceed without the consent of "such human beings" when "consent" is given by a representative. The Rule is contrary to FIFRA section 12(a)(2)(P) and should therefore be set aside. *See* 5 U.S.C. § 706(2)(A).

B. The Rule Contravenes the Nuremberg Code's Requirement that Human Experiments Be Based on Prior Animal Studies

The Nuremberg Code allows human experimentation only if the experiment is "so designed and based on the results of animal experimentation . . . that the anticipated results justify the performance of the experiment." A 529. EPA's Rule, by contrast, authorizes human toxicity experiments without regard to whether they are (or are not) based on prior animal studies.

EPA's response, that it "has access to all *available* laboratory animal studies," simply begs the question. EPA Br. 51 (emphasis added). Neither the

Human Testing Rule nor any other authority cited by EPA actually requires that animal studies be "available" before a human experiment is conducted; EPA's implication that "the animal studies" are "required to be submitted under" the Rule, EPA Br. 51, is thus at best misleading and at worst untrue. Nor does the Rule require, as it should, that human experiments be based on prior animal studies. While EPA *may* review any animal studies that happen to be available, nothing in the Rule directs EPA to do so. A1278 (EPA acknowledgement that its rule does not address Nuremberg Code principle three "directly").

The Nuremberg Code sets forth a clear requirement that EPA's Rule ignores. In lieu of the Code's substantive standard, EPA offers process. Process is not substance, however. Nothing in the Rule directs EPA to ensure consistency with the Code, and EPA could as easily decline to do so. EPA's claim that the Rule's procedures *allow* EPA later to correct the Rule's substantive deficiency falls short.

C. The Rule Ignores the Nuremberg Code's Requirement that Human Experimentation Be Conducted Only When Necessary

The Nuremberg Code's second principle prohibits human experimentation unless the experiment is "such as to yield fruitful results . . . unprocurable by other . . . means of study, and not . . . unnecessary . . . ." A529. EPA's Rule contains no substantively consistent condition. Instead, EPA asserts that it will review experiments to ensure that "[r]isks to subjects are reasonable in relation to anticipated benefits." EPA Br. 52 (alteration in original). The Nuremberg Code's

second principle does not articulate a balancing test, however, but a bright line: Human experiments may not be conducted unless other types of studies cannot procure the information. Because the Rule allows experiments that would violate this principle, the Rule contravenes Section 201.

V. The Court Should Vacate and Remand the Human Testing Rule

This Court should vacate the Human Testing Rule rather than accepting EPA's invitation to leave the Rule in place while EPA revisits its flaws. EPA Br. at 54 n.16. The difference is important. Section 201 imposed a moratorium on EPA's conduct and use of intentional human dosing pesticide toxicity experiments until EPA promulgated a Rule that met certain standards. SPA1. This moratorium is not a "regulatory gap," as EPA suggests, EPA Br. 54 n.16; it is a ban. Petitioners do not "favor" EPA's issuance of a substantively inadequate regulation that lifts that ban on EPA conduct and use of human toxicity experiments.

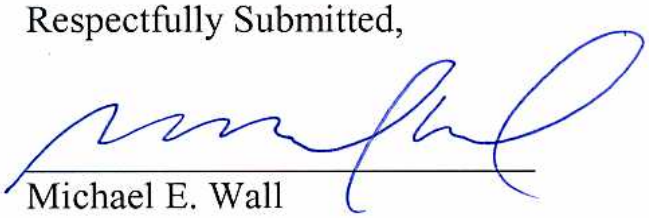
EPA's promulgation of the Human Testing Rule has had real, harmful consequences for Petitioners and their members. In the months after EPA promulgated the Rule, EPA relied on human dosing toxicity experiments to increase allowable pesticide exposure limits and to weaken public health protections. Had EPA *not* promulgated this Rule, the Agency could not have used the human studies to justify these weakened standards. If this Court vacates the

Rule, EPA will be obligated to revisit those standards. Petitioners therefore urge the Court to vacate the Rule at this time.

CONCLUSION

This Court should vacate the Human Testing Rule and direct EPA to issue a new rule in accordance with law.

December 14, 2006 Respectfully Submitted,

By: 

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This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B)(ii) because it contains 6995 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii). This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Office Word 2003 in a 14 point, Times New Roman font.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that she is an employee in the San Francisco Office of the Natural Resources Defense Council, 111 Sutter Street, 20th Floor, San Francisco, CA, 94104; is a person of such age and discretion to be competent to serve papers; and that on December 14, 2006 she served copies of the attached:

- Petitioners' Reply Brief
- Declarations in Support of Petitioners' Standing

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I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Dated: December 14, 2006

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