No. 09-152

IN THE
Supreme Court of the United States

RUSSELL BRUESEWITZ AND ROBALEE BRUESEWITZ,
PARENTS AND NATURAL GUARDIANS OF
HANNAH BRUESEWITZ, A MINOR CHILD,
AND IN THEIR OWN RIGHT,
Petitioners,
v.

WYETH, INC. F/K/A WYETH LABORATORIES,
WYETH-AYERST LABORATORIES, WYETH LEDERLE,
WYETH LEDERLE VACCINES, AND LEDERLE LABORATORIES,
Respondent.

On Writ of Certiorari
to the United States Court of Appeals
for the Third Circuit

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Section 22(b)(1)'s language, structure, and purposes evidence Congress's intent to incorporate the well-recognized standards of comment k to Restatement (Second) of Torts § 402A (1965). Under that rule, a manufacturer is not liable for injuries caused by its vaccine if it can demonstrate that any safety risks were "unavoidable," the vaccine was manufactured properly, and the warning label was adequate. That rule advances the critical policy of incentivizing manufacturers to deploy the latest scientific advances to improve patient safety.

Wyeth's contention that § 22(b)(1) confers blanket immunity from liability for defective design disregards the established meaning of the term "unavoidable" and renders a large portion of § 22(b)(1) surplusage. It also implausibly assumes that Congress displaced longstanding tort remedies recognized in every state and granted immunity for all design defects—even those that are willful or reckless—without saying so in plain language. Congress did not sweep so broadly. Instead, Congress enacted a compromise that conferred major benefits on manufacturers without precluding all design-defect claims. Congress expanded comment k's exemption for unavoidably unsafe designs to include fault-based claims, in addition to strict-liability. But Congress retained comment k's methodology that such exemption applies only if the vaccine is shown on a case-by-case basis to be unavoidably unsafe.

Wyeth's interpretation also reaches an untenable policy result. Under Wyeth's reading, all FDA-approved vaccines are forever deemed "unavoidably unsafe," even though federal regulations do not require manufacturers to upgrade vaccines based on scientific advances. Wyeth claims it had no obli-

gation to improve a DTP vaccine designed using 1940s-era scientific knowledge, even though it knew in the 1960s the design was outmoded; sold the vaccine for another three decades based on a cost-benefit analysis that put corporate profits ahead of patient safety; and eventually withdrew the vaccine from the market in the 1990s. This Court should reject Wyeth's contention as inconsistent with normal modes of statutory interpretation, antithetical to the traditional role of courts to administer justice in individual cases, and anathema to sound public policy.

ARGUMENT

I. SECTION 22(b)(1) PRESERVES LIABILITY FOR INJURIES CAUSED BY AVOIDABLE SIDE EFFECTS

Section 22(b)(1) provides that vaccine manufacturers are exempt from liability "if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. § 300aa-22(b)(1). Under that provision's plain language, Wyeth must meet three requirements for the liability exemption in § 22(b)(1) to apply. The injury must have resulted from side effects that were "unavoidable" as that term was understood when Congress enacted the NCVIA—i.e., not preventable through use of a safer alternative design. In addition, the injury must have "resulted . . . even though the vaccine was properly prepared and was accompanied by proper directions and warnings." The Act's structure reinforces that conclusion, and the presumption against preemption resolves any remaining doubt in favor of preserving design-defect claims. *See* Pet. Br. 28-41.

The contrary arguments of Wyeth and its *amici* are unpersuasive.

A. Wyeth's Textual Arguments Lack Merit

1. Wyeth contends (at 30) that the clause "even though the vaccine was properly prepared and was accompanied by proper directions and warnings" "immediately modifie[s]" the term "unavoidable," such that proper preparation and proper directions and warnings are the only conditions that must be met to establish that a side effect is "unavoidable." *See also* U.S. Br. 10. That textual construction is unpersuasive.

First, Wyeth's interpretation contradicts the established meaning of "unavoidable." *See* Pet. Br. 28-31. Comment k and the cases applying it use "unavoidable" to refer to inherent safety risks in a product that is "*incapable* of being made safe for [its] intended and ordinary use." Restatement § 402A cmt. k (emphasis added); *see* Pet. Br. 30-31 (citing cases). Manufacturing and labeling defects, by contrast, are always *avoidable*. Proper manufacturing and proper warnings are additional requirements to avoid strict liability under comment k, but they are not elements of "unavoidability," which relates to the product's *design*. Wyeth's construction turns comment k upside-down, by reading "unavoidable" to depend solely on two conditions that manufacturers are always capable of controlling and by eliminating comment k's traditional "unavoidability" inquiry into whether the product was "*incapable* of being made safe." Wyeth's interpretation thus violates the canon that Congress intends terms of art to have their established legal meaning. *See* Pet. Br. 31.

Second, Wyeth's interpretation ignores the similarity between the language and structure of § 22(b)(1)

and comment k, which Congress expressly used as a guide. Comment k provides:

> *k. Unavoidably unsafe products.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. . . . The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for the unfortunate consequences attending their use . . . .

Restatement § 402A cmt. k.

As Dean Prosser wrote it, comment k is focused on products that, "in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use." *Id.* "[S]uch products"—i.e., products that are "incapable of being made safe"—are "[u]navoidably unsafe." *Id.* Sellers of unavoidably unsafe products are exempt from strict liability, "*with the qualification that* they are properly prepared and marketed, and proper warning is given." *Id.* (emphasis added). Section 22(b)(1) follows the same structure: Vaccine manufacturers are exempt from liability if the injuries resulted (1) "from side effects that were unavoidable"—i.e., "incapable of being made safe" "in the present state of human knowledge"—and (2) "even though" the vaccine "was properly prepared and was accompanied by proper

directions are warnings." 42 U.S.C. § 300aa-22(b)(1).[1] Interpreting proper manufacturing and proper warning as supplemental requirements also comports with the use of "even though" as a subordinate conjunction. *See* Bryan A. Garner, *The Elements of Legal Style* 64-65 (1991) (explaining that, for clarity, subordinate conjunctions place "lesser ideas"—here, proper warning and manufacture—in subordinate clauses with "greater" ideas—unavoidability—in "main clauses").

Third, had Congress wanted to eliminate design-defect liability, it could have exempted manufacturers from liability "if . . . the vaccine was properly prepared and was accompanied by proper directions and warnings." Wyeth functionally excises the 13 omitted words—"the injury or death resulted from side effects that were unavoidable even though."[2] The point is not simply that Congress could have been more linguistically efficient (*see* U.S. Br. 12): Wyeth's interpretation violates settled canons of construction by rendering void the key statutory term—"unavoidable." *See Duncan v. Walker*, 533 U.S. 167, 174 (2001) (Court is "especially unwilling" to treat statutory terms as surplusage "when the term occupies so pivotal a place in the statutory scheme"). Petitioners' correct interpretation gives effect to all of § 22(b)(1), by retaining comment k's requirement of

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[1] Wyeth (at 32) and the government (at 12) incorrectly assert that petitioners' interpretation disregards the clause following "unavoidable." That clause embodies comment k's "qualification" that, to be exempt from strict liability, the seller of an unavoidably unsafe product must ensure proper preparation and proper warning.

[2] Petitioners' opening brief (at 40) contained a printing error in not italicizing the final two omitted words, "even though."

unavoidability and its additional requirements of proper preparation and warnings.

Fourth, Wyeth's reading of § 22(b)(1) renders largely superfluous § 23(d)(2), which establishes a regulatory-compliance defense to liability for punitive damages. *See TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001) (rejecting interpretation that would render statutory language "insignificant, if not wholly superfluous") (internal quotations omitted); Pet. Br. 36. Under Wyeth's view (at 31), § 22(b)(1) already bars *all* liability except where a manufacturer could not show regulatory compliance because it failed to "adhere to the vaccine's FDA-approved specifications, or . . . did not comply with regulatory requirements or withheld information from FDA."

2. Wyeth (at 41-42) quibbles with petitioners' statement that Congress's use of "unavoidable" reflected its intent to "codify" comment k in § 22(b)(1). Instead, it asserts that Congress merely "looked to 'the principle of Comment k'" in determining that *all* vaccine side effects from design defects are unavoidable as a matter of law. But that categorical approach is directly contrary to comment k's "principle," as shown by the comment's language and the decisions applying it.

First, comment k's text, which Wyeth largely ignores, makes clear that unavoidability is an issue for judges and juries to resolve in each case. Comment k refers to the unavoidable risks of "*some*"—not all—"products" and "*many*"—not all—"vaccines." Restatement § 402A cmt. k (emphases added). That language cannot be reconciled with the categorical approach Wyeth espouses.

Second, a majority of states in 1986 required manufacturers to make a case-specific showing that

a product was "unavoidably unsafe" to qualify for comment k's exemption from strict liability.[3] Wyeth cites (at 43 n.25) the minority of cases holding that all prescription-drug or vaccine side effects are unavoidable. But Wyeth offers no evidence that Congress adopted the *minority* position in § 22(b)(1). *Cf. Field v. Mans*, 516 U.S. 59, 70 n.9 (1995) (the Court construes statutes "to incorporate the general common law" and "the dominant consensus of common-law jurisdictions, rather than the law of any particular State").

Wyeth asserts (at 41-42) that certain differences between comment k and § 22(b)(1)—most notably, that comment k set forth an exemption only from strict liability, whereas § 22(b)(1) is not so limited—preclude reliance on decisions applying comment k in interpreting § 22(b)(1). But the fact that Congress may have altered the *scope* of manufacturers' exemption does not logically imply that it changed comment k's case-specific standard for determining their *eligibility* for exemption. To the contrary, Congress's codification of the term "unavoidable" reflects

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[3] *See* Pet. Br. 34 n.17 (citing cases showing seven states took case-specific approach). Courts applying the laws of four other states similarly had adopted that approach. *See Johnson v. American Cyanamid Co.*, 718 P.2d 1318, 1322-24 (Kan. 1986); *Singer v. Sterling Drug, Inc.*, 461 F.2d 288, 290-91 (7th Cir. 1972) (Indiana law); *Davis v. Wyeth Labs., Inc.*, 399 F.2d 121, 128 (9th Cir. 1968) (Montana law); *Cassisi v. Maytag Co.*, 396 So. 2d 1140, 1146 (Fla. Dist. Ct. App. 1981) (adopting a "balancing approach" to whether a product is unavoidably unsafe). The Oregon case Wyeth cites (at 43 n.25) predated Oregon's 1979 statute enacting comment k. *See* Or. Rev. Stat. § 30.920(3). By 1986, Oregon had adopted the majority case-by-case approach. *See Coursen v. A.H. Robins Co.*, 764 F.2d 1329, 1337 (9th Cir. 1985).

its intent to codify the term's well-known, case-specific understanding.

3. Wyeth (at 34) and the government (at 15) also criticize petitioners' reading of § 22(b)(1)'s text on the ground that it would weaken manufacturers' liability protections and deprive them of any benefit from the NCVIA. Neither is true.

First, § 22(b)(1) created certainty for manufacturers by establishing a uniform national liability rule against the backdrop of unsettled state law. Before 1986, at least one state had rejected comment k. *See Collins v. Eli Lilly Co.*, 342 N.W.2d 37, 52 (Wis. 1984) ("We conclude that the rule embodied in comment k is too restrictive and, therefore, not commensurate with strict products liability law in Wisconsin. Drug companies, like other sellers or manufacturers, have a duty to produce and market reasonably safe products."). Further, many states had not addressed the applicability of comment k to vaccines and could have followed Wisconsin's refusal to adopt comment k. Section 22(b)(1) thus represented an enormous benefit for manufacturers, removing the risk in those states of being held strictly liable for even unavoidable side effects.

Second, in contrast to comment k, which exempted manufacturers only from claims of strict products liability, § 22(b)(1) created a brand-new defense to fault-based liability. The NCVIA thus changed the law "in most states" under which the plaintiff could "proceed under a negligence cause of action even if comment k provide[d] a defense to strict liability." *Toner v. Lederle Labs.*, 828 F.2d 510, 512 (9th Cir. 1987) (Kennedy, J.).

Section 22(b)(1)'s unprecedented exemption from *all* civil liability also answers Wyeth's (at 44) and

the government's (at 17-18) erroneous contentions that petitioners' reading of § 22(b)(1) would make manufacturers worse off in the minority states that followed the categorical approach to comment k. Even assuming § 22(e) would displace a categorical state rule,[4] § 22(b)(1) still provides important additional protections from fault-based liability that did not exist even in states adopting a categorical approach to comment k for strict-liability claims. *See Toner*, 828 F.2d at 512 (holding under Idaho law that a finding of unavoidability provides no defense to negligent design-defect liability).

Third, the NCVIA imposed substantial limitations on failure-to-warn and punitive-damages claims that did not exist under state law. It adopted a presumption of proper directions and warnings for purposes of § 22(b)(1) when the manufacturer obeys federal requirements and codified the learned intermediary doctrine. *See* 42 U.S.C. § 300aa-22(b)(2), (c). It also established a regulatory-compliance defense to punitive damages. *See id.* § 300aa-23(d)(2).

Fourth, the NCVIA barred civil actions by any claimant who has not sought compensation (and rejected any award received) in the Vaccine Court. *See id.* §§ 300aa-11(a)(2)(A), 300aa-21(a). It thus "discourages" litigation "by providing fairly generous,

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[4] Contrary to Wyeth's and the government's assumptions, it is not clear that § 22(e) preempts any state statute establishing categorical comment-k protection for all FDA-approved vaccines. Section 22(e) only prevents states from "barr[ing]" "civil action[s]" permitted by the NCVIA—for example, by creating their own mandatory compensation regimes. *See* H.R. Rep. No. 99-908, pt. 1, at 27 (1986) ("1986 Report"); Pet. Br. 42-43. A liability rule does not "bar" any action. *Cf. Evans v. Lederle Labs.*, 167 F.3d 1106, 1110-11 (7th Cir. 1999) (holding that § 22(e) does not preempt state statutes of limitations).

more easily obtainable, Vaccine Court awards." *Schafer v. American Cyanamid Co.*, 20 F.3d 1, 4-5 (1st Cir. 1994) (Breyer, C.J.). Moreover, Vaccine Court awards are paid with the proceeds of an excise tax levied on vaccines—not out of vaccine manufacturers' corporate coffers—thus functionally creating a valuable insurance policy for vaccine-related injuries. *See* 42 U.S.C. § 300aa-15(i)(2); 26 U.S.C. §§ 4131-4132, 9510.

4. Wyeth (at 31), but not the government, asserts that, by referring to "*the* vaccine" in § 22(b)(1), Congress barred courts from imposing liability if the manufacturer could have avoided the harmful side effect by using a safer alternative design. But Wyeth concedes that § 22(b)(1) permits claims for manufacturing defects and failure to warn. Those claims, too, require courts to consider whether the manufacturer should have sold a different vaccine—namely, one manufactured better or bearing better warnings. Thus, Congress's choice of the definite article does not bar courts from considering whether the manufacturer should have sold a vaccine different from the one actually administered.

Further, Wyeth's argument depends on an erroneous premise. Wyeth asserts (at 31, 37-39) that a vaccine's "labeling" is within the manufacturer's "exclusive control," whereas "manufacturers are absolutely barred from changing the design of an approved vaccine" prior to FDA approval. That mischaracterizes FDA's regulations. Under those regulations, "[b]efore distributing a product made using a change [in the product]," the manufacturer bears responsibility for "assess[ing] the effects of the change and demonstrat[ing]" through appropriate means "the lack of adverse effect of the change" on

the vaccine's safety and effectiveness. 21 C.F.R. § 601.12(a)(2). The manufacturer also must inform FDA about "each change in the product." *Id.* § 601.12(a)(1). "[M]ajor changes" with "a substantial potential to have an adverse effect" on safety or efficacy require FDA approval before the manufacturer may implement them, *id.* § 601.12(b), whereas the manufacturer can implement changes "in the product" with only a "moderate" or "minimal" "potential to have an adverse effect" without preapproval, *id.* § 601.12(c)(1), (d)(1). Design changes that *improve* vaccine safety do not require preapproval. The government offers no authority for its contrary assertion (at 20-21). Indeed, § 601.12(b)(2)(i) specifically contemplates that "changes in the qualitative or quantitative formulation" of a vaccine having only a "moderate" or "minimal" "potential to have an adverse effect" on safety or efficacy may be implemented without prior approval.[5]

Wyeth's related suggestion that, as to vaccine design, it is merely a passive participant in "the federal regulatory process" (Br. 31-32) betrays the same "fundamental misunderstanding" about the federal regulatory scheme this Court corrected in *Wyeth v. Levine*, 129 S. Ct. 1187, 1197 (2009). As the Court there explained, a "central premise" of FDA regulation is that the manufacturer "bears responsibility" for its product. *Id.* at 1197-98. As with labeling,

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[5] Wyeth asserts (at 31), without citation, that vaccine design changes always entail "extensive clinical trials." Under FDA regulations, however, even "major changes" in a vaccine's "formulation" do not necessarily require clinical trials. *See* 21 C.F.R. § 601.12(a)(2) (permitting manufacturers to "assess the effects of [a] change . . . through *appropriate validation* and/*or* other clinical and/*or nonclinical* laboratory studies") (emphases added).

see 21 C.F.R. § 601.12(f), a vaccine manufacturer remains obligated to identify and evaluate proposed design changes, and FDA's role is reactive—to confirm the changes do not adversely affect the vaccine's safety or effectiveness. That regulatory regime reflects the common-sense reality that the manufacturer, not FDA, is best-positioned to know how to design, manufacture, and describe its product. Critically, Wyeth identifies nothing authorizing FDA to require a manufacturer to adopt a safer alternative design for an approved vaccine. *See* Wyeth Br. 11-14; *see also* Pet. Br. 9 (noting absence of such a provision).

5. Finally, Wyeth (at 45) and the government (at 18) argue that the presumption against preemption should not apply in this case because § 22(e) would preempt state laws eliminating design-defect claims if petitioners' reading of § 22(b)(1) were adopted. It is far from clear that § 22(e) has that effect. *See supra* note 4. In all events, this Court has recognized that the presumption has particular force when preemption would abolish "state-law causes of action." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). The presumption thus supports petitioners' reading of § 22(b)(1), which preserves traditional defective-products liability claims.

B. The NCVIA's Structure Supports Preserving Design-Defect Claims

Wyeth's arguments regarding the NCVIA's structure (at 36-40) are principally unpersuasive policy arguments masquerading as statutory construction. Wyeth suggests that the Act fulfills tort law's two primary functions—encouraging manufacturers to exercise due care and compensating injured victims—and thus renders design-defect liability unneces-

sary and counterproductive. The Act, however, was not intended to, and does not, supplant tort law's traditional roles.

1. Wyeth first contends (at 37) that "administrative regulation" ensures "the best vaccine design." But Wyeth can identify no statutory or regulatory requirement that manufacturers continue to improve vaccine designs to eliminate avoidable side effects. Wyeth highlights (at 36) Congress's general instruction to *the Secretary of Health and Human Services* ("HHS") to promote the development of safer vaccines. *See* 42 U.S.C. § 300aa-27(a). But that direction imposes no enforceable mandate on, and creates no incentives for, *manufacturers*. Wyeth also invokes (at 37) precatory language announcing Congress's intention that the National Vaccine Program "achieve optimal prevention against adverse reactions to vaccines," 42 U.S.C. § 300aa-1, but that likewise does nothing to alter manufacturer behavior.

Because nothing in the federal regulatory regime obligates manufacturers to adopt safer vaccine designs, Wyeth's hackneyed claim (at 36-37) that this case presents a choice between "expert federal agencies" and "lay juries" is misplaced. In fact, for design claims, the choice is between state law and no regulation. If Wyeth prevails, vaccine manufacturers will have no legal duty to improve the design of their vaccines to account for scientific advances and instead will be free to continue marketing more dangerous vaccines that earn greater profits.[6]

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[6] Wyeth asserts (at 38) that liability for defective design risks "produc[ing] varying decisions in different States about whether any given vaccine design is defective." But § 22(b)(1) avoids that result by creating a *federal* standard exempting manufacturers from liability for "unavoidable" side effects.

Wyeth also contends (at 37-39) that § 22(b) provides incentives for manufacturers to produce safer vaccines by permitting liability for improper manufacturing and failure to warn subject to a regulatory-compliance defense. But encouraging vaccine makers to manufacture their products properly and to comply with applicable statutory and regulatory labeling provisions provides no incentive to improve vaccine designs. Further, the folly of Wyeth's description of the regulatory requirements for disclosure of information and reporting of adverse events (at 37-39) lies in the inherent limitations of those duties: neither Wyeth nor the government disputes that FDA receives *no* reports about safer alternative designs. *See* Pet. Br. 9.

Wyeth also suggests (at 39) that this case is different from *Levine* because the manufacturer there could have changed the labeling pending FDA approval. As the *Levine* Court recognized, however, "FDA retains authority to reject labeling changes made pursuant to the [changes-being-effected] regulation." 129 S. Ct. at 1198. Thus, in both cases, FDA ultimately must approve any change in labeling or design, and in both situations the proposed change originates with the *manufacturer*, not FDA. Moreover, as with prescription drugs, FDA permits changes to vaccines before agency approval if they do not have a "substantial potential to have an adverse effect" on safety or efficacy. 21 C.F.R. § 601.12(c)(1), (d)(1). Thus, as in *Levine*, vaccine manufacturers can *improve* the safety and efficacy of their designs without prior FDA approval.

2. Wyeth also contends (at 39-40) that the NCVIA's administrative compensation scheme performs the compensatory function of civil actions. But

it ignores the Compensation Program's real and substantial limitations—including the severe restrictions on discovery, the omissions in the Vaccine Injury Table, and the difficulties of proving causation for non-Table injuries. *See* Willner *Amicus* Br. 20-31 (describing Program's operation).

More fundamentally, Wyeth's contention conflicts with the NCVIA's structure. Congress created an administrative compensation process (§§ 10-19), authorized injured patients to file civil actions after pursuing claims through that process (§ 21), and provided a limited exemption from liability for injuries resulting from unavoidable side effects (§ 22(b)(1)). Considering that Congress plainly intended for civil actions to continue notwithstanding the creation of the Compensation Program, the Program's existence alone cannot justify transforming § 22(b)(1)'s liability exemption into an immunity for all design-defect claims.

II. THE NCVIA'S LEGISLATIVE HISTORY DEMONSTRATES CONGRESS'S INTENT TO PRESERVE DESIGN-DEFECT LIABILITY

Contrary to Wyeth's unpersuasive reading of a few snippets from the 1986 House Report, the legislative record contains clear indicia that Congress intended to preserve, rather than eliminate, design-defect liability (*see* Pet. Br. 44-51).

A. The 1986 Report Supports Petitioners' Interpretation Of § 22(b)(1)

Wyeth misreads both passages from the 1986 Report on which it relies. First, the 1986 Report's statement that the Committee "intends that the principle in Comment K regarding 'unavoidably unsafe' products, i.e., those products which in the

present state of human skill and knowledge cannot be made safe, apply to the vaccines covered in the bill and that *such products* not be the subject of liability in the tort system" supports petitioners' position. 1986 Report at 26 (emphasis added). The phrase "such products" comes directly from comment k and refers to "those products which in the present state of human skill and knowledge cannot be made safe." *See id.*; *accord* Restatement § 402A cmt. k. That language confirms that Congress intended "unavoidable" in § 22(b)(1) to incorporate comment k's core principle that a particular product is exempt from liability only if it cannot be *designed* more safely. Contrary to Wyeth's suggestion, "such products" does not refer categorically to all "vaccines covered in the bill," because, even under Wyeth's interpretation of § 22, covered vaccines *are* "the subject of liability in the tort system" if they are improperly manufactured or labeled.

Wyeth's misunderstanding of "such products" also leads it to misinterpret the Committee's ensuing statement: "Vaccine-injured persons will now have an appealing alternative to the tort system. Accordingly, if they cannot demonstrate under applicable law either that a vaccine was improperly prepared or that it was accompanied by improper directions or inadequate warnings should [sic] pursue recompense in the compensation system, not the tort system." 1986 Report at 26. The omission of defective design from that passage does not indicate an intent to eliminate liability for unsafe vaccines, because the 1986 Report already had made clear in the preceding paragraphs that it was adopting comment k and exempting from design-defect liability only "those products" that are unavoidably unsafe. Congress's

reference to the NCVIA's Compensation Program as an "*appealing alternative* to the tort system" also confirms that it was meant to be a carrot, not a stick. *Id.* (emphasis added); *see also id.* at 12-13 (stating that the "speed of the compensation program, the low transaction costs of the system, the no-fault nature of the required findings, and the relative certainty and generosity of the system's awards will divert a significant number of potential plaintiffs from litigation").

The full legislative record presaging passage of the NCVIA confirms petitioners' reading. *See*, *e.g.*, *Board of Governors v. First Lincolnwood Corp.*, 439 U.S. 234, 245 n.11 (1978) (consulting floor statements to resolve ambiguity in House report). First, the Committee rejected an amendment that would have expressly eliminated design-defect liability for failure to develop a safer vaccine. *See* Pet. Br. 45. Wyeth asserts that the mark-up session is not authoritative, but the Committee's rejection of a proposal embodying the very liability rule Wyeth now advocates evidences the "collective understanding of those Congressmen involved in drafting" the NCVIA that liability for avoidable injuries should be preserved. *Garcia v. United States*, 469 U.S. 70, 76 (1984) (internal quotations omitted). The floor speeches by the Act's proponents and statements by industry leaders further corroborate Congress's intent to preserve design-defect liability. *See Atherton v. FDIC*, 519 U.S. 213, 228-30 (1997) (relying on floor statements and Senate report).[7] Tellingly, Wyeth

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[7] Wyeth's efforts to explain away those statements are unpersuasive. The bill on which Lederle's President, Robert Johnson, commented, H.R. 5184, 99th Cong. (1986), was more manufacturer-friendly than the final legislation because it contained, in addition to § 22(b)(1), a separate provision precluding

cannot cite a single statement in the 1986 debates supporting its interpretation of § 22(b)(1).

B. The 1987 Report Is Authoritative And Confirms Petitioners' Interpretation Of § 22(b)(1)

The 1987 Report unequivocally answers the question presented: "[T]here should be *no misunderstanding* that the Act undertook to decide as a matter of law whether vaccines were unavoidably unsafe or not. The question is left to the courts to determine in accordance with applicable law." H.R. Rep. No. 100-391, pt. 1, at 691 (1987) ("1987 Report"). Wyeth dismisses that as unreliable "post-enactment legislative history" (at 49). But the 100th Congress's intent is, if anything, *more* relevant to the proper interpretation of § 22(b)(1) than that of the 99th Congress, because the later Congress enacted the funding legislation necessary to give the 1986 law, including § 22(b)(1), any legal effect. Without the 1987 bill, § 22(b)(1) was a nullity. Consequently, the 1987 Report should control because the 100th Congress, in substance, "enacted" § 22(b)(1) into law. *See Oscar Mayer & Co. v. Evans*, 441 U.S. 750, 758 (1979) ("It is the intent of the Congress that enacted [the section] . . . that controls.") (internal quotations omitted, alterations in original).

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a plaintiff from bringing a civil action for damages "on a theory of strict liability, absolute liability, or any other theory in which the wrongful conduct of the defendant is not the basis of liability." *Id.* § 2122(c)(1). Mr. Johnson's observation that H.R. 5184 left "open to litigation" claims asserting defective design applies *a fortiori* to the NCVIA. *See* Pet. Br. 44-45. Wyeth does not dispute that other vaccine company officials' statements support petitioners' position.

It is inconsequential that the 100th Congress "did not modify" § 22(b)(1). Wyeth Br. 50. Members of Congress voted for the 1987 law, and the President signed it, after extensive further debate about the provisions of the 1986 bill, including specifically § 22(b)(1). *See* Pet. Br. 48-50. Statements by all participants in that debate—including members of Congress, the Reagan Administration, and industry officials—confirm that vaccine manufacturers were not exempt from design-defect liability for injuries due to avoidable side effects.[8] The understanding of the 100th Congress, as the lawmakers who put § 22(b)(1) into effect, is authoritative. *See District of Columbia v. Heller*, 128 S. Ct. 2783, 2805 (2008).

III. IMMUNIZING VACCINE MANUFACTURERS FROM LIABILITY FOR FAILING TO MAKE THEIR PRODUCTS AS SAFE AS REASONABLY POSSIBLE DOES NOT PROMOTE THE NCVIA'S PURPOSES

No sound policy rationale supports exempting vaccine manufacturers from civil liability when they design vaccines that are more dangerous than necessary. Holding manufacturers accountable in these circumstances will not cause them to stop supplying vaccines, because they reap enormous profits and face little competition in that lucrative market.

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[8] Wyeth baselessly disparages the 1987 Report as representing a "strategic manipulation[] of legislative history" "to amend a statute through a committee report." Wyeth Br. 50 (internal quotations omitted). The Energy and Commerce Committee's composition barely changed between the 99th and 100th Congress. The same chairman, Rep. Waxman, oversaw both the 1986 and 1987 Reports, and his floor statements in both Congresses confirm that § 22(b)(1) was not intended to eliminate design-defect claims.

A. Immunizing Vaccine Manufacturers From Civil Liability For Avoidable Side Effects Will Jeopardize Public Health

This Court has long recognized that an "important purpose of defective-product tort law is to encourage the manufacture of safer products." *Saratoga Fishing Co. v. J.M. Martinac & Co.*, 520 U.S. 875, 881 (1997); *see Levine*, 129 S. Ct. at 1202-03; *Bates v. Dow AgroSciences LLC*, 544 U.S. 431, 450-51 (2005); *Schafer*, 20 F.3d at 3; *Toner*, 828 F.2d at 513. Civil liability for avoidable design flaws promotes public health by incentivizing manufacturers to "forestall [civil] actions through product improvement." *Bates*, 544 U.S. at 451 (internal quotations omitted). It also encourages childhood vaccination by promoting public confidence that children will not be harmed by outmoded designs such as the 1940s-era whole-cell pertussis vaccine at issue here.

Wyeth nonetheless argues (at 54) that design-defect claims should be eliminated because the NCVIA provides "comprehensive" "incentives to develop safe and efficacious vaccines without such tort liability." As discussed above (*supra* p. 13), the Act generally charges HHS with promoting safer vaccines, but it creates no obligation or incentives for manufacturers to design, seek approval for, or market safer vaccines. Nor does the fact that pharmaceutical companies have brought vaccines to market since 1986 show that tort liability is unnecessary to promote product safety: Manufacturers have tremendous profit motive to bring *new* vaccines to market,[9] and new vaccines (*e.g.*, cancer, HIV/AIDS)

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[9] *See* Gloria Lau, *Wyeth Looks Toward Future While Past Still Haunts*, Investor's Bus. Daily, Nov. 28, 2005, at A8 (quoting Wyeth's CFO, Ken Martin, as reporting "an 85% to 90%

also are the focus of the government research funding the government touts (at 22). But the admitted lack of robust competition, with only one or two manufacturers for most vaccines (*see* Wyeth Br. 55), creates little market incentive for manufacturers to replace established but outmoded designs with safer alternatives. *See* 2 Earl W. Kintner, *Federal Antitrust Law* § 11.3, at 306 (1980); Michael Mussa & Sherwin Rosen, *Monopoly and Product Quality*, 18 J. Econ. Theory 301, 301 (1978) ("[T]he monopolist almost always reduces the quality sold to any customer compared with what would be purchased under competition.").

This case demonstrates the important incentives civil liability creates. Government studies show that the DTaP vaccine is "much safer than" DTP. CDC, Diphtheria, Tetanus, and Acellular Pertussis (DTaP) Vaccine, *available at* http://www.cdc.gov/vaccinesafety/Vaccines/dtap/dtapindex.html. Lederle was aware of that as early as the 1960s, but, according to its own internal documents, deliberately stopped research on an acellular alternative because the economic gains did not justify the costs. *See* Pet. Br. 18. Neither federal regulation nor market incentives sufficiently motivated Lederle to invest in product improvement, and the whole-cell DTP vaccine continued to be administered to children for decades longer. Under Wyeth's untenable interpretation of § 22(b)(1), the whole-cell vaccine that Wyeth withdrew from the market would be considered unavoidably unsafe today if properly manufactured and labeled.

It is no answer that design changes require significant research and FDA approval. *See* Wyeth Br. 20-

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gross profit margin" on the vaccine Prevnar, with substantially lower marketing costs compared to other drugs).

21; U.S. Br. 32. Lederle's knowing abandonment of promising research delayed the very testing and study that could have led to the acellular alternative being approved and marketed long before 1996. Wyeth's extreme position would immunize manufacturers even where they *knowingly* or *intentionally* sacrifice children's safety in the name of profit. No sound public policy supports that result.[10]

B. Wyeth's Assertion That Civil Liability For Injuries Caused By Outmoded Designs Will Cause Vaccine Shortages Is Unfounded

Obligating manufacturers to make safer vaccines will not lead to a rash of meritless lawsuits, force them to exit the market, or destabilize the vaccine supply. Nearly 25 years of experience disproves Wyeth's prediction (at 55) that claimants denied recovery in the Vaccine Court will "forg[e] ahead" with meritless court claims. "Virtually all . . . petitioners, *even those who were not awarded compensation under the [Compensation Program]*," have chosen to accept that court's determination. Stanley A. Plotkin et al., *Vaccines* 1673 (5th ed. 2008) (emphasis added); *see also Schafer*, 20 F.3d at 5 ("[A] petitioner to whom the Vaccine Court gives nothing may see no point in trying to overcome tort law's yet more serious

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[10] The government contends (at 21, 25) that liability is unwarranted because vaccines have "such a low rate of unavoidable serious side effects . . . that they may not be discovered even in massive clinical trials." But side effects unknowable to the manufacturer are considered "unavoidable" under comment k. *See* Restatement § 402A cmt. k (product is unavoidably unsafe if it has "*known* but apparently reasonable risk") (emphasis added); *Ortho Pharm. Corp. v. Heath*, 722 P.2d 410, 415 (Colo. 1986) ("the risk must be a *known* one") (emphasis added), *overruled on other grounds*, *Armentrout v. FMC Corp.*, 842 P.2d 175 (Colo. 1992).

obstacles to recovery."); U.S. Br. 26-28. Moreover, decades of adjudicating claims against prescription-drug manufacturers for avoidable injuries in states that apply comment k on a case-specific basis have not discouraged the marketing of prescription drugs.

Wyeth also offers no reason why judges cannot dispose of meritless claims that do find their way into court. Judges routinely grant summary judgment if, as Wyeth asserts is true of the autism cases, there is no evidence of product defect or causation.[11] The presumption against preemption, which reflects respect for federalism, means little if this Court accepts Wyeth's invitation to *assume* that courts are incapable of adjudicating state-law claims responsibly and in accordance with law.

Wyeth also warns that the vaccine market is as precarious today as it was in 1986. On Wall Street, however, manufacturers are touting the "golden age of vaccines." Robert Langreth, *Booster Shot*, Forbes, Nov. 12, 2007, at 78, 80 (noting Lehman Brothers' prediction that "[t]he $13 billion global vaccine business will grow 18% a year to $30 billion in 2011," "well above the 4.4% annual growth expected for the drug industry overall"). The limited number of manufacturers highlights the high profit margins of entrenched manufacturers whose competitors face daunting barriers to entry. *See* FD Wire, *Wyeth at Bear, Stearns & Co. Healthcare Conference—Final* (Sept. 10, 2007) (statement by head of Wyeth's vaccine unit that vaccines have "very strong business characteristics," "[i]ncluding long product life cycles

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[11] *See*, *e.g.*, *Brockert v. Wyeth Pharms., Inc.*, 287 S.W.3d 760 (Tex. App. 2009); *Viramontes v. Pfizer, Inc.*, No. C054574, 2008 WL 2477443 (Cal. Ct. App. June 20, 2008); *Savina v. Sterling Drug, Inc.*, 795 P.2d 915 (Kan. 1990).

and high barriers to entry" and "significant growth potential"). Wyeth itself views the "ongoing strength of [its] . . . vaccine franchises" as a main driver of its overall revenue growth. Wyeth, News Release (July 23, 2009), *at* http://www.wyeth.com/irj/servlet/prt/portal/prtroot/com.sap.km.cm.docs/wyeth_xml/home/news/announcements/1248346908863.pdf.[12] Wyeth's alarmist warnings of imminent market exit are simply implausible given the lucrative profits it earns from vaccines and the significant protections it enjoys under the NCVIA.

CONCLUSION

The judgment of the court of appeals should be reversed.

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[12] On October 15, 2009, Pfizer acquired Wyeth for $68 billion, in significant part because of Wyeth's vaccine business. *See* Press Release, *Pfizer To Acquire Wyeth* (Jan. 26, 2009), *at* http://media.pfizer.com/files/investors/presentations/Acquisition_Press_Release_012609.pdf.

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APPENDIX

STATUTORY AND REGULATORY PROVISIONS

42 U.S.C. § 300aa-11. Petitions for compensation

(a) General rule

(1) A proceeding for compensation under the Program for a vaccine-related injury or death shall be initiated by service upon the Secretary and the filing of a petition containing the matter prescribed by subsection (c) of this section with the United States Court of Federal Claims. The clerk of the United States Court of Federal Claims shall immediately forward the filed petition to the chief special master for assignment to a special master under section 300aa-12(d)(1) of this title.

(2)(A) No person may bring a civil action for damages in an amount greater than $1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, and no such court may award damages in an amount greater than $1,000 in a civil action for damages for such a vaccine-related injury or death, unless a petition has been filed, in accordance with section 300aa-16 of this title, for compensation under the Program for such injury or death and –

(i)(I) the United States Court of Federal Claims has issued a judgment under section 300aa-12 of this title on such petition, and

(II) such person elects under section 300aa-21(a) of this title to file such an action, or

(ii) such person elects to withdraw such petition under section 300aa-21(b) of this title or such petition is considered withdrawn under such section.

(B) If a civil action which is barred under subparagraph (A) is filed in a State or Federal court, the court shall dismiss the action. If a petition is filed under this section with respect to the injury or death for which such civil action was brought, the date such dismissed action was filed shall, for purposes of the limitations of actions prescribed by section 300aa-16 of this title, be considered the date the petition was filed if the petition was filed within one year of the date of the dismissal of the civil action.

(3) No vaccine administrator or manufacturer may be made a party to a civil action (other than a civil action which may be brought under paragraph (2)) for damages for a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988.

(4) If in a civil action brought against a vaccine administrator or manufacturer before October 1, 1988, damages were denied for a vaccine-related injury or death or if such civil action was dismissed with prejudice, the person who brought such action may file a petition under subsection (b) of this section for such injury or death.

(5)(A) A plaintiff who on October 1, 1988, has pending a civil action for damages for a vaccine-related injury or death may, at any time within 2 years after October 1, 1988, or before judgment, whichever occurs first, petition to have such action dismissed without prejudice or costs and file a petition under subsection (b) of this section for such injury or death.

(B) If a plaintiff has pending a civil action for damages for a vaccine-related injury or death, such person may not file a petition under subsection (b) of this section for such injury or death.

(6) If a person brings a civil action after November 15, 1988[1] for damages for a vaccine-related injury or death associated with the administration of a vaccine before November 15, 1988, such person may not file a petition under subsection (b) of this section for such injury or death.

(7) If in a civil action brought against a vaccine administrator or manufacturer for a vaccine-related injury or death damages are awarded under a judgment of a court or a settlement of such action, the person who brought such action may not file a petition under subsection (b) of this section for such injury or death.

(8) If on October 1, 1988, there was pending an appeal or rehearing with respect to a civil action brought against a vaccine administrator or manufacturer and if the outcome of the last appellate review of such action or the last rehearing of such action is the denial of damages for a vaccine-related injury or death, the person who brought such action may file a petition under subsection (b) of this section for such injury or death.

(9) This subsection applies only to a person who has sustained a vaccine-related injury or death and who is qualified to file a petition for compensation under the Program.

(10) The Clerk of the United States Claims Court is authorized to continue to receive, and forward,

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[1] So in original. Probably should be followed by a comma.

petitions for compensation for a vaccine-related injury or death associated with the administration of a vaccine on or after October 1, 1992.

(b) Petitioners

(1)(A) Except as provided in subparagraph (B), any person who has sustained a vaccine-related injury, the legal representative of such person if such person is a minor or is disabled, or the legal representative of any person who died as the result of the administration of a vaccine set forth in the Vaccine Injury Table may, if the person meets the requirements of subsection (c)(1) of this section, file a petition for compensation under the Program.

(B) No person may file a petition for a vaccine-related injury or death associated with a vaccine administered before October 1, 1988, if compensation has been paid under this part for 3500 petitions for such injuries or deaths.

(2) Only one petition may be filed with respect to each administration of a vaccine.

(c) Petition content

A petition for compensation under the Program for a vaccine-related injury or death shall contain –

(1) except as provided in paragraph (3), an affidavit, and supporting documentation, demonstrating that the person who suffered such injury or who died –

(A) received a vaccine set forth in the Vaccine Injury Table or, if such person did not receive such a vaccine, contracted polio, directly or indirectly, from another person who received an oral polio vaccine,

(B)(i) if such person received a vaccine set forth in the Vaccine Injury Table –

(I) received the vaccine in the United States or in its trust territories,

(II) received the vaccine outside the United States or a trust territory and at the time of the vaccination such person was a citizen of the United States serving abroad as a member of the Armed Forces or otherwise as an employee of the United States or a dependent of such a citizen, or

(III) received the vaccine outside the United States or a trust territory and the vaccine was manufactured by a vaccine manufacturer located in the United States and such person returned to the United States not later than 6 months after the date of the vaccination,

(ii) if such person did not receive such a vaccine but contracted polio from another person who received an oral polio vaccine, was a citizen of the United States or a dependent of such a citizen,

(C)(i) sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table in association with the vaccine referred to in subparagraph (A) or died from the administration of such vaccine, and the first symptom or manifestation of the onset or of the significant aggravation of any such illness, disability, injury, or condition or the death occurred within the time period after vaccine administration set forth in the Vaccine Injury Table, or

(ii)(I) sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by a vaccine referred to in subparagraph (A), or

(II) sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine referred to in subparagraph (A),

(D)(i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention, and

(E) has not previously collected an award or settlement of a civil action for damages for such vaccine-related injury or death,

(2) except as provided in paragraph (3), maternal prenatal and delivery records, newborn hospital records (including all physicians' and nurses' notes and test results), vaccination records associated with the vaccine allegedly causing the injury, pre- and post-injury physician or clinic records (including all relevant growth charts and test results), all post-injury inpatient and outpatient records (including all provider notes, test results, and

medication records), if applicable, a death certificate, and if applicable, autopsy results, and

(3) an identification of any records of the type described in paragraph (1) or (2) which are unavailable to the petitioner and the reasons for their unavailability.

(d) Additional information

A petition may also include other available relevant medical records relating to the person who suffered such injury or who died from the administration of the vaccine.

(e) Schedule

The petitioner shall submit in accordance with a schedule set by the special master assigned to the petition assessments, evaluations, and prognoses and such other records and documents as are reasonably necessary for the determination of the amount of compensation to be paid to, or on behalf of, the person who suffered such injury or who died from the administration of the vaccine.

42 U.S.C. § 300aa-12. Court jurisdiction

(a) General rule

The United States Court of Federal Claims and the United States Court of Federal Claims special masters shall, in accordance with this section, have jurisdiction over proceedings to determine if a petitioner under section 300aa-11 of this title is entitled to compensation under the Program and the amount of such compensation. The United States Court of Federal Claims may issue and enforce such orders as the court deems necessary to assure the prompt payment of any compensation awarded.

(b) Parties

(1) In all proceedings brought by the filing of a petition under section 300aa-11(b) of this title, the Secretary shall be named as the respondent, shall participate, and shall be represented in accordance with section 518(a) of Title 28.

(2) Within 30 days after the Secretary receives service of any petition filed under section 300aa-11 of this title the Secretary shall publish notice of such petition in the Federal Register. The special master designated with respect to such petition under subsection (c) of this section shall afford all interested persons an opportunity to submit relevant, written information –

(A) relating to the existence of the evidence described in section 300aa-13(a)(1)(B) of this title, or

(B) relating to any allegation in a petition with respect to the matters described in section 300aa-11(c)(1)(C)(ii) of this title.

(c) United States Court of Federal Claims special masters

(1) There is established within the United States Court of Federal Claims an office of special masters which shall consist of not more than 8 special masters. The judges of the United States Court of Federal Claims shall appoint the special masters, 1 of whom, by designation of the judges of the United States Court of Federal Claims, shall serve as chief special master. The appointment and reappointment of the special masters shall be by the concurrence of a majority of the judges of the court.

(2) The chief special master and other special masters shall be subject to removal by the judges of the United States Court of Federal Claims for incompetency, misconduct, or neglect of duty or for physical or mental disability or for other good cause shown.

(3) A special master's office shall be terminated if the judges of the United States Court of Federal Claims determine, upon advice of the chief special master, that the services performed by that office are no longer needed.

(4) The appointment of any individual as a special master shall be for a term of 4 years, subject to termination under paragraphs (2) and (3). Individuals serving as special masters on December 19, 1989, shall serve for 4 years from the date of their original appointment, subject to termination under paragraphs (2) and (3). The chief special master in office on December 19, 1989, shall continue to serve as chief special master for the balance of the master's term, subject to termination under paragraphs (2) and (3).

(5) The compensation of the special masters shall be determined by the judges of the United States

Court of Federal Claims, upon advice of the chief special master. The salary of the chief special master shall be the annual rate of basic pay for level IV of the Executive Schedule, as prescribed by section 5315, Title 5. The salaries of the other special masters shall not exceed the annual rate of basic pay of level V of the Executive Schedule, as prescribed by section 5316, Title 5.

(6) The chief special master shall be responsible for the following:

(A) Administering the office of special masters and their staff, providing for the efficient, expeditious, and effective handling of petitions, and performing such other duties related to the Program as may be assigned to the chief special master by a concurrence of a majority of the United States Claims Courts[1] judges.

(B) Appointing and fixing the salary and duties of such administrative staff as are necessary. Such staff shall be subject to removal for good cause by the chief special master.

(C) Managing and executing all aspects of budgetary and administrative affairs affecting the special masters and their staff, subject to the rules and regulations of the Judicial Conference of the United States. The Conference rules and regulations pertaining to United States magistrate judges shall be applied to the special masters.

(D) Coordinating with the United States Court of Federal Claims the use of services, equipment, personnel, information, and facilities of the United

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[1] So in original. Probably should be a reference to the United States Court of Federal Claims.

States Court of Federal Claims without reimbursement.

(E) Reporting annually to the Congress and the judges of the United States Court of Federal Claims on the number of petitions filed under section 300aa-11 of this title and their disposition, the dates on which the vaccine-related injuries and deaths for which the petitions were filed occurred, the types and amounts of awards, the length of time for the disposition of petitions, the cost of administering the Program, and recommendations for changes in the Program.

(d) Special masters

(1) Following the receipt and filing of a petition under section 300aa-11 of this title, the clerk of the United States Court of Federal Claims shall forward the petition to the chief special master who shall designate a special master to carry out the functions authorized by paragraph (3).

(2) The special masters shall recommend rules to the Court of Federal Claims and, taking into account such recommended rules, the Court of Federal Claims shall promulgate rules pursuant to section 2071 of Title 28. Such rules shall –

(A) provide for a less-adversarial, expeditious, and informal proceeding for the resolution of petitions,

(B) include flexible and informal standards of admissibility of evidence,

(C) include the opportunity for summary judgment,

(D) include the opportunity for parties to submit arguments and evidence on the record without

requiring routine use of oral presentations, cross examinations, or hearings, and

(E) provide for limitations on discovery and allow the special masters to replace the usual rules of discovery in civil actions in the United States Court of Federal Claims.

(3)(A) A special master to whom a petition has been assigned shall issue a decision on such petition with respect to whether compensation is to be provided under the Program and the amount of such compensation. The decision of the special master shall –

(i) include findings of fact and conclusions of law, and

(ii) be issued as expeditiously as practicable but not later than 240 days, exclusive of suspended time under subparagraph (C), after the date the petition was filed.

The decision of the special master may be reviewed by the United States Court of Federal Claims in accordance with subsection (e) of this section.

(B) In conducting a proceeding on a petition a special master –

(i) may require such evidence as may be reasonable and necessary,

(ii) may require the submission of such information as may be reasonable and necessary,

(iii) may require the testimony of any person and the production of any documents as may be reasonable and necessary,

(iv) shall afford all interested persons an opportunity to submit relevant written information –

(I) relating to the existence of the evidence described in section 300aa-13(a)(1)(B) of this title, or

(II) relating to any allegation in a petition with respect to the matters described in section 300aa-11(c)(1)(C)(ii) of this title, and

(v) may conduct such hearings as may be reasonable and necessary.

There may be no discovery in a proceeding on a petition other than the discovery required by the special master.

(C) In conducting a proceeding on a petition a special master shall suspend the proceedings one time for 30 days on the motion of either party. After a motion for suspension is granted, further motions for suspension by either party may be granted by the special master, if the special master determines the suspension is reasonable and necessary, for an aggregate period not to exceed 150 days.

(D) If, in reviewing proceedings on petitions for vaccine-related injuries or deaths associated with the administration of vaccines before October 1, 1988, the chief special master determines that the number of filings and resultant workload place an undue burden on the parties or the special master involved in such proceedings, the chief special master may, in the interest of justice, suspend proceedings on any petition for up to 30 months (but for not more than 6 months at a time) in addition to the suspension time under subparagraph (C).

(4)(A) Except as provided in subparagraph (B), information submitted to a special master or the court in a proceeding on a petition may not be disclosed to a person who is not a party to the proceed-

ing without the express written consent of the person who submitted the information.

(B) A decision of a special master or the court in a proceeding shall be disclosed, except that if the decision is to include information –

(i) which is trade secret or commercial or financial information which is privileged and confidential, or

(ii) which are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy,

and if the person who submitted such information objects to the inclusion of such information in the decision, the decision shall be disclosed without such information.

(e) Action by United States Court of Federal Claims

(1) Upon issuance of the special master's decision, the parties shall have 30 days to file with the clerk of the United States Court of Federal Claims a motion to have the court review the decision. If such a motion is filed, the other party shall file a response with the clerk of the United States Court of Federal Claims no later than 30 days after the filing of such motion.

(2) Upon the filing of a motion under paragraph (1) with respect to a petition, the United States Court of Federal Claims shall have jurisdiction to undertake a review of the record of the proceedings and may thereafter –

(A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,

(B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or

(C) remand the petition to the special master for further action in accordance with the court's direction.

The court shall complete its action on a petition within 120 days of the filing of a response under paragraph (1) excluding any days the petition is before a special master as a result of a remand under subparagraph (C). The court may allow not more than 90 days for remands under subparagraph (C).

(3) In the absence of a motion under paragraph (1) respecting the special master's decision or if the United States Court of Federal Claims takes the action described in paragraph (2)(A) with respect to the special master's decision, the clerk of the United States Court of Federal Claims shall immediately enter judgment in accordance with the special master's decision.

(f) Appeals

The findings of fact and conclusions of law of the United States Court of Federal Claims on a petition shall be final determinations of the matters involved, except that the Secretary or any petitioner aggrieved by the findings or conclusions of the court may obtain review of the judgment of the court in the United States court of appeals for the Federal Circuit upon petition filed within 60 days of the date of the judgment with such court of appeals within 60 days of the

date of entry of the United States Claims Court's[1] judgment with such court of appeals.

(g) Notice

If –

(1) a special master fails to make a decision on a petition within the 240 days prescribed by subsection (d)(3)(A)(ii) of this section (excluding (A) any period of suspension under subsection (d)(3)(C) or (d)(3)(D) of this section, and (B) any days the petition is before a special master as a result of a remand under subsection (e)(2)(C) of this section), or

(2) the United States Court of Federal Claims fails to enter a judgment under this section on a petition within 420 days (excluding (A) any period of suspension under subsection (d)(3)(C) or (d)(3)(D) of this section, and (B) any days the petition is before a special master as a result of a remand under subsection (e)(2)(C) of this section) after the date on which the petition was filed,

the special master or court shall notify the petitioner under such petition that the petitioner may withdraw the petition under section 300aa-21(b) of this title or the petitioner may choose under section 300aa-21(b) of this title to have the petition remain before the special master or court, as the case may be.

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[1] So in original. Probably should be a reference to the United States Court of Federal Claims.

42 U.S.C. § 300aa-21. Authority to bring actions

(a) Election

After judgment has been entered by the United States Court of Federal Claims or, if an appeal is taken under section 300aa-12(f) of this title, after the appellate court's mandate is issued, the petitioner who filed the petition under section 300aa-11 of this title shall file with the clerk of the United States Court of Federal Claims –

> **(1)** if the judgment awarded compensation, an election in writing to receive the compensation or to file a civil action for damages for such injury or death, or
>
> **(2)** if the judgment did not award compensation, an election in writing to accept the judgment or to file a civil action for damages for such injury or death.

An election shall be filed under this subsection not later than 90 days after the date of the court's final judgment with respect to which the election is to be made. If a person required to file an election with the court under this subsection does not file the election within the time prescribed for filing the election, such person shall be deemed to have filed an election to accept the judgment of the court. If a person elects to receive compensation under a judgment of the court in an action for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, or is deemed to have accepted the judgment of the court in such an action, such person may not bring or maintain a civil action for damages against a vaccine administrator or manufacturer for the vaccine-related injury or death for which the judgment was entered. For limitations

on the bringing of civil actions for vaccine-related injuries or deaths associated with the administration of a vaccine after October 1, 1988, see section 300aa-11(a)(2) of this title.

(b) Continuance or withdrawal of petition

A petitioner under a petition filed under section 300aa-11 of this title may submit to the United States Court of Federal Claims a notice in writing choosing to continue or to withdraw the petition if –

(1) a special master fails to make a decision on such petition within the 240 days prescribed by section 300aa-12(d)(3)(A)(ii) of this title (excluding (i) any period of suspension under section 300aa-12(d)(3)(C) or 300aa-12(d)(3)(D) of this title, and (ii) any days the petition is before a special master as a result of a remand under section 300aa-12(e)(2)(C) of this title), or

(2) the court fails to enter a judgment under section 300aa-12 of this title on the petition within 420 days (excluding (i) any period of suspension under section 300aa-12(d)(3)(C) or 300aa-12(d)(3)(D) of this title, and (ii) any days the petition is before a special master as a result of a remand under section 300aa-12(e)(2)(C) of this title) after the date on which the petition was filed.

Such a notice shall be filed within 30 days of the provision of the notice required by section 300aa-12(g) of this title.

(c) Limitations of actions

A civil action for damages arising from a vaccine-related injury or death for which a petition was filed under section 300aa-11 of this title shall, except as provided in section 300aa-16(c) of this title, be

brought within the period prescribed by limitations of actions under State law applicable to such civil action.

42 U.S.C. § 300aa-22. Standards of responsibility

(a) General rule

Except as provided in subsections (b), (c), and (e) of this section State law shall apply to a civil action brought for damages for a vaccine-related injury or death.

(b) Unavoidable adverse side effects; warnings

(1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

(2) For purposes of paragraph (1), a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 et seq.] and section 262 of this title (including regulations issued under such provisions) applicable to the vaccine and related to vaccine-related injury or death for which the civil action was brought unless the plaintiff shows –

(A) that the manufacturer engaged in the conduct set forth in subparagraph (A) or (B) of section 300aa-23(d)(2) of this title, or

(B) by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with such Act and section (and regulations issued under such provisions).

(c) Direct warnings

No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, solely due to the manufacturer's failure to provide direct warnings to the injured party (or the injured party's legal representative) of the potential dangers resulting from the administration of the vaccine manufactured by the manufacturer.

(d) Construction

The standards of responsibility prescribed by this section are not to be construed as authorizing a person who brought a civil action for damages against a vaccine manufacturer for a vaccine-related injury or death in which damages were denied or which was dismissed with prejudice to bring a new civil action against such manufacturer for such injury or death.

(e) Preemption

No State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this part.

42 U.S.C. § 300aa-23. Trial

(a) General rule

A civil action against a vaccine manufacturer for damages for a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, which is not barred by section 300aa-11(a)(2) of this title shall be tried in three stages.

(b) Liability

The first stage of such a civil action shall be held to determine if a vaccine manufacturer is liable under section 300aa-22 of this title.

(c) General damages

The second stage of such a civil action shall be held to determine the amount of damages (other than punitive damages) a vaccine manufacturer found to be liable under section 300aa-22 of this title shall be required to pay.

(d) Punitive damages

(1) If sought by the plaintiff, the third stage of such an action shall be held to determine the amount of punitive damages a vaccine manufacturer found to be liable under section 300aa-22 of this title shall be required to pay.

(2) If in such an action the manufacturer shows that it complied, in all material respects, with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 et seq.] and this chapter applicable to the vaccine and related to the vaccine injury or death with respect to which the action was brought, the manufacturer shall not be

held liable for punitive damages unless the manufacturer engaged in –

(A) fraud or intentional and wrongful withholding of information from the Secretary during any phase of a proceeding for approval of the vaccine under section 262 of this title,

(B) intentional and wrongful withholding of information relating to the safety or efficacy of the vaccine after its approval, or

(C) other criminal or illegal activity relating to the safety and effectiveness of vaccines,

which activity related to the vaccine-related injury or death for which the civil action was brought.

(e) Evidence

In any stage of a civil action, the Vaccine Injury Table, any finding of fact or conclusion of law of the United States Court of Federal Claims or a special master in a proceeding on a petition filed under section 300aa-11 of this title and the final judgment of the United States Court of Federal Claims and subsequent appellate review on such a petition shall not be admissible.

21 C.F.R. § 601.12. Changes to an approved application.

(a) *General.* (1) As provided by this section, an applicant must inform the Food and Drug Administration (FDA) (see mailing addresses in § 600.2 of this chapter) about each change in the product, production process, quality controls, equipment, facilities, responsible personnel, or labeling established in the approved license application(s).

(2) Before distributing a product made using a change, an applicant must assess the effects of the change and demonstrate through appropriate validation and/or other clinical and/or nonclinical laboratory studies the lack of adverse effect of the change on the identity, strength, quality, purity, or potency of the product as they may relate to the safety or effectiveness of the product.

(3) Notwithstanding the requirements of paragraphs (b), (c), and (f) of this section, an applicant must make a change provided for in those paragraphs in accordance with a regulation or guidance that provides for a less burdensome notification of the change (for example, by submission of a supplement that does not require approval prior to distribution of the product or in an annual report).

(4) The applicant must promptly revise all promotional labeling and advertising to make it consistent with any labeling change implemented in accordance with paragraphs (f)(1) and (f)(2) of this section.

(5) A supplement or annual report must include a list of all changes contained in the supplement or annual report. For supplements, this list must be provided in the cover letter.

(b) *Changes requiring supplement submission and approval prior to distribution of the product made using the change (major changes).* (1) A supplement shall be submitted for any change in the product, production process, quality controls, equipment, facilities, or responsible personnel that has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as they may relate to the safety or effectiveness of the product.

(2) These changes include, but are not limited to:

(i) Except as provided in paragraphs (c) and (d) of this section, changes in the qualitative or quantitative formulation, including inactive ingredients, or in the specifications provided in the approved application;

(ii) Changes requiring completion of an appropriate human study to demonstrate the equivalence of the identity, strength, quality, purity, or potency of the product as they may relate to the safety or effectiveness of the product;

(iii) Changes in the virus or adventitious agent removal or inactivation method(s);

(iv) Changes in the source material or cell line;

(v) Establishment of a new master cell bank or seed; and

(vi) Changes which may affect product sterility assurance, such as changes in product or component sterilization method(s), or an addition, deletion, or substitution of steps in an aseptic processing operation.

(3) The applicant must obtain approval of the supplement from FDA prior to distribution of the product made using the change. Except for submissions under paragraph (e) of this section, the following shall be contained in the supplement:

(i) A detailed description of the proposed change;

(ii) The product(s) involved;

(iii) The manufacturing site(s) or area(s) affected;

(iv) A description of the methods used and studies performed to evaluate the effect of the change on the identity, strength, quality, purity, or potency of the product as they may relate to the safety or effectiveness of the product;

(v) The data derived from such studies;

(vi) Relevant validation protocols and data; and

(vii) A reference list of relevant standard operating procedures (SOP's).

(4) An applicant may ask FDA to expedite its review of a supplement for public health reasons or if a delay in making the change described in it would impose an extraordinary hardship on the applicant. Such a supplement and its mailing cover should be plainly marked: "Prior Approval Supplement-Expedited Review Requested."

(c) *Changes requiring supplement submission at least 30 days prior to distribution of the product made using the change.* (1) A supplement shall be submitted for any change in the product, production process, quality controls, equipment, facilities, or responsible personnel that has a moderate potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as they may

relate to the safety or effectiveness of the product. The supplement shall be labeled "Supplement–Changes Being Effected in 30 Days" or, if applicable under paragraph (c)(5) of this section, "Supplement–Changes Being Effected."

(2) These changes include, but are not limited to:

(i) [Reserved]

(ii) An increase or decrease in production scale during finishing steps that involves different equipment; and

(iii) Replacement of equipment with that of similar, but not identical, design and operating principle that does not affect the process methodology or process operating parameters.

(iv) Relaxation of an acceptance criterion or deletion of a test to comply with an official compendium that is consistent with FDA statutory and regulatory requirements.

(3) Pending approval of the supplement by FDA, and except as provided in paragraph (c)(5) of this section, distribution of the product made using the change may begin not less than 30 days after receipt of the supplement by FDA. The information listed in paragraph (b)(3)(i) through (b)(3)(vii) of this section shall be contained in the supplement.

(4) If within 30 days following FDA's receipt of the supplement, FDA informs the applicant that either:

(i) The change requires approval prior to distribution of the product in accordance with paragraph (b) of this section; or

(ii) Any of the information required under paragraph (c)(3) of this section is missing; the applicant

shall not distribute the product made using the change until FDA determines that compliance with this section is achieved.

(5) In certain circumstances, FDA may determine that, based on experience with a particular type of change, the supplement for such change is usually complete and provides the proper information, and on particular assurances that the proposed change has been appropriately submitted, the product made using the change may be distributed immediately upon receipt of the supplement by FDA. These circumstances may include substantial similarity with a type of change regularly involving a "Supplement–Changes Being Effected" supplement or a situation in which the applicant presents evidence that the proposed change has been validated in accordance with an approved protocol for such change under paragraph (e) of this section.

(6) If the agency disapproves the supplemental application, it may order the manufacturer to cease distribution of the products made with the manufacturing change.

(d) *Changes to be described in an annual report (minor changes).* (1) Changes in the product, production process, quality controls, equipment, facilities, or responsible personnel that have a minimal potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as they may relate to the safety or effectiveness of the product shall be documented by the applicant in an annual report submitted each year within 60 days of the anniversary date of approval of the application. The Director, Center for Biologics Evaluation and Research or the Director, Center for Drug Evaluation

and Research, may approve a written request for an alternative date to combine annual reports for multiple approved applications into a single annual report submission.

(2) These changes include, but are not limited to:

(i) Any change made to comply with a change to an official compendium, except a change described in paragraph (c)(2)(iv) of this section, that is consistent with FDA statutory and regulatory requirements.

(ii) The deletion or reduction of an ingredient intended only to affect the color of the product, except that a change intended only to affect Blood Grouping Reagents requires supplement submission and approval prior to distribution of the product made using the change in accordance with the requirements set forth in paragraph (b) of this section;

(iii) An extension of an expiration dating period based upon full shelf life data on production batches obtained from a protocol approved in the application;

(iv) A change within the container closure system for a nonsterile product, based upon a showing of equivalency to the approved system under a protocol approved in the application or published in an official compendium;

(v) A change in the size and/or shape of a container containing the same number of dosage units for a nonsterile solid dosage form product, without a change from one container closure system to another;

(vi) The addition by embossing, debossing, or engraving of a code imprint to a solid dosage form biological product other than a modified release dosage form, or a minor change in an existing code imprint; and

(vii) The addition or revision of an alternative analytical procedure that provides the same or increased assurance of the identity, strength, quality, purity, or potency of the material being tested as the analytical procedure described in the approved application, or deletion of an alternative analytical procedure.

(3) The following information for each change shall be contained in the annual report:

(i) A list of all products involved; and

(ii) A full description of the manufacturing and controls changes including: the manufacturing site(s) or area(s) involved; the date the change was made; a cross-reference to relevant validation protocols and/or SOP's; and relevant data from studies and tests performed to evaluate the effect of the change on the identity, strength, quality, purity, or potency of the product as they may relate to the safety or effectiveness of the product.

(iii) A statement by the holder of the approved application or license that the effects of the change have been assessed.

(4) The applicant shall submit the report to the FDA office responsible for reviewing the application. The report shall include all the information required under this paragraph for each change made during the annual reporting interval which ends on the anniversary date in the order in which they were implemented.

(e) An applicant may submit one or more protocols describing the specific tests and validation studies and acceptable limits to be achieved to demonstrate the lack of adverse effect for specified types of manufacturing changes on the identity, strength, quality,

purity, or potency of the product as they may relate to the safety or effectiveness of the product. Any such protocols, or change to a protocol, shall be submitted as a supplement requiring approval from FDA prior to distribution of the product which, if approved, may justify a reduced reporting category for the particular change because the use of the protocol for that type of change reduces the potential risk of an adverse effect.

(f) *Labeling changes*. (1) Labeling changes requiring supplement submission–FDA approval must be obtained before distribution of the product with the labeling change. Except as described in paragraphs (f)(2) and (f)(3) of this section, an applicant shall submit a supplement describing a proposed change in the package insert, package label, container label, or, if applicable, a Medication Guide required under part 208 of this chapter, and include the information necessary to support the proposed change. An applicant cannot use paragraph (f)(2) of this section to make any change to the information required in § 201.57(a) of this chapter. An applicant may report the minor changes to the information specified in paragraph (f)(3)(i)(D) of this section in an annual report. The supplement shall clearly highlight the proposed change in the labeling. The applicant shall obtain approval from FDA prior to distribution of the product with the labeling change.

(2) *Labeling changes requiring supplement submission–product with a labeling change that may be distributed before FDA approval*. (i) An applicant shall submit, at the time such change is made, a supplement for any change in the package insert, package label, or container label to reflect newly acquired information, except for changes to the package insert

required in § 201.57(a) of this chapter (which must be made under paragraph (f)(1) of this section), to accomplish any of the following:

(A) To add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling under § 201.57(c) of this chapter;

(B) To add or strengthen a statement about abuse, dependence, psychological effect, or overdosage;

(C) To add or strengthen an instruction about dosage and administration that is intended to increase the safety of the use of the product; and

(D) To delete false, misleading, or unsupported indications for use or claims for effectiveness.

(E) Any labeling change normally requiring a supplement submission and approval prior to distribution of the product that FDA specifically requests be submitted under this provision.

(ii) Pending approval of the supplement by FDA, the applicant may distribute a product with a package insert, package label, or container label bearing such change at the time the supplement is submitted. The supplement shall clearly identify the change being made and include necessary supporting data. The supplement and its mailing cover shall be plainly marked: "Special Labeling Supplement–Changes Being Effected."

(3) *Labeling changes requiring submission in an annual report.* (i) An applicant shall submit any final printed package insert, package label, container label, or Medication Guide required under part 208 of this chapter incorporating the following changes in

an annual report submitted to FDA each year as provided in paragraph (d)(1) of this section:

(A) Editorial or similar minor changes;

(B) A change in the information on how the product is supplied that does not involve a change in the dosage strength or dosage form;

(C) A change in the information specified in § 208.20(b)(8)(iii) and (b)(8)(iv) of this chapter for a Medication Guide; and

(D) A change to the information required in § 201.57(a) of this chapter as follows:

(*1*) Removal of a listed section(s) specified in § 201.57(a)(5) of this chapter; and

(*2*) Changes to the most recent revision date of the labeling as specified in § 201.57(a)(15) of this chapter.

(E) A change made pursuant to an exception or alternative granted under § 201.26 or § 610.68 of this chapter.

(ii) The applicant may distribute a product with a package insert, package label, or container label bearing such change at the time the change is made.

(4) *Advertisements and promotional labeling.* Advertisements and promotional labeling shall be submitted to the Center for Biologics Evaluation and Research or Center for Drug Evaluation and Research in accordance with the requirements set forth in § 314.81(b)(3)(i) of this chapter, except that Form FDA-2567 (Transmittal of Labels and Circulars) or an equivalent form shall be used.

(5) The submission and grant of a written request for an exception or alternative under § 201.26 or

§ 610.68 of this chapter satisfies the requirements in paragraphs (f)(1) through (f)(2) of this section.

(6) For purposes of paragraph (f)(2) of this section, information will be considered newly acquired if it consists of data, analyses, or other information not previously submitted to the agency, which may include (but are not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses) if the studies, events or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA.

(g) *Failure to comply*. In addition to other remedies available in law and regulations, in the event of repeated failure of the applicant to comply with this section, FDA may require that the applicant submit a supplement for any proposed change and obtain approval of the supplement by FDA prior to distribution of the product made using the change.

(h) *Administrative review*. Under § 10.75 of this chapter, an applicant may request internal FDA review of FDA employee decisions under this section.