A LEGAL VIRUS ATTACKS FARMERS AND RANCHERS - AND THERE IS NO VACCINE: APHIS HAS LEFT NO TORT REMEDIES AT COMMON LAW

Paul LeRoy Crist[1]

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1. Adjunct Professor, University of Houston Law Center, Houston, TX; LL.M., May 1996, from the University of Houston Law Center, Houston, TX; Certificate in Economic Community and Civil Law, September 1987, from the Goethe University Economic Law Institute, Frankfurt-am-Main, BRD; Recognition of Achievement with Honors, June 1986 from the Parker School of International and Foreign Law of Columbia University, New York, NY; J.D., June 1986 from Columbia University School of Law, New York, NY; B.A., May 1983 from George Washington University, Washington, D.C.; former law clerk to the Hon. Jerry E. Smith, Circuit Judge, United States Court of Appeals for the Fifth Circuit, Houston, TX; business insurance consultant and lawyer in private practice, specializing in coverage litigation and federal appeals.

I. INTRODUCTION TO LYNNBROOK FARMS V. SMITHKLINE BEECHAM

In the tort system, manufacturers of products that are defective or unreasonably dangerous are required to pay compensation for damage or injury caused by the products. Under emerging interpretations of a federal statute for livestock vaccines, the Virus-Serum-Toxin Act (VSTA),[2] compensation under the tort system may no longer be the same, even if a herd is decimated or entirely destroyed by a vaccine or serum that itself proved fatal, or that failed to prevent the disease against which it was intended to immunize.

The Federal Court of Appeals for the Seventh Circuit, which includes Illinois, Michigan, and Wisconsin, has given a startlingly broad application to rules promulgated under VSTA by the Agriculture Department's Animal and Plant Health Inspection Service (APHIS). In *Lynnbrook Farms v. SmithKline Beecham*,[3] the Seventh Circuit has immunized vaccine manufacturers almost completely from *any* liability arising from injury caused by their products, or from disease the inoculations failed to prevent.[4] However, as one skeptical district court observed, "[i]f VSTA is interpreted completely to insulate manufacturers from liability, it cannot achieve its purpose because manufacturers would have no incentive to maintain quality control after [APHIS] approval."[5]

VSTA and APHIS created broad federal regulations that govern the production, manufacture, and distribution of livestock vaccines. These regulations expressly preempt conflicting state regulation,[6] and now, by judicial extension, also bar tort, breach of warranty, and other legal claims for inadvertent injury to livestock. Farmers and ranchers have no recourse against a vaccine manufacturer in compliance with APHIS regulations if vaccine use results in death to cattle, sheep, horses, or other animals. Under the Seventh Circuit's statutory interpretation, almost all tort claims are preempted for harm done by veterinary biologics in deference to APHIS'

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2. 21 U.S.C. §§ 151-159 (1994).

3. Lynnbrook Farms v. SmithKline Beecham Corp., 79 F.3d 620 (7th Cir.), *cert. denied,* ___ U.S. ___, 117 S. Ct. 178, 64 U.S.L.W. 3086 (U.S. Oct. 7, 1996).

4. *Id.* at 622. The family-farm operation claimed its cattle herd was decimated, and many of the rest left injured, after inoculation by two SmithKline Beecham bovine vaccines "specifically licensed by APHIS." *Id.* at 622-23. The court of appeals was even willing to "assume that the vaccines used were either not effective in preventing the maladies they were designed to guard against, or that the vaccines caused other harm to Lynnbrook's cattle." *Id*. at 623.

5. Gresham v. Boehringer Ingelheim Animal Health, Inc., No. 95-CV-3376-ODE, slip op. at 6 (N.D. Ga. Aug. 7, 1996).

6. Except in cases of local disease conditions compelling emergency action by state or county animal-husbandry officials. Final Rule Pertaining to Restrictions' Which May Be Imposed by States on the Distribution and Use of Veterinary Biological Products, 57 Fed. Reg. 38,758, 38,759 (1992) (to be codified at 9 C.F.R. § 101.2 (1996)) [hereinafter Declaration of Preemption].

Declaration of Preemption.

Numerous problems, jurisprudential and practical, exist if there is nearly total preemption, as seems to be the trend. This article's concluding section advances suggestions for congressional action to ameliorate some problems under current law. The bulk of this article (Sections IV-X) examines in turn each category of tort claims that falls under APHIS' Declaration of Preemption. But first, the current preemption doctrine (Section II) and then the relevant background to the APHIS regime (Section III) are discussed.

II. MEDTRONIC, INC. V. LOHR AND ANALOGOUS FIFRA PREEMPTION CASES

The preemption doctrine is neither a new concept nor one necessarily violative of state prerogative. The authority is the United States Constitution,[7] which declares invalid any state laws that "interfere with, or are contrary, to the laws of Congress, made in pursuance of the constitution . . ."[8] Preemption analyzes whether express federal commands bar competing state action, or whether there is an implicit conflict between federal and state action that similarly cuts off the police power of the states to regulate activities within their borders.

Whether a federal statute or regulation preempts state law, and to what extent, is based chiefly on congressional intent.[9] A federal statute may occupy a particular regulatory field so pervasively as to impliedly preclude state action, including tort suits, or it can by its express language declare its preemptive scope, as does the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).[10] While FIFRA has an express preemption provision and APHIS has declared its expansive interpretation of VSTA preemption, the scope of each regime's preemptive reach is as much determined by what the agency must regulate under each statute as by the explicit congressional purpose for the preemption provision.

A. *Supreme Court Preemption Authority*

Such preemption issues came to dominate products-liability defenses--especially under FIFRA--with the new interpretive approach of the United States Supreme Court in *Cipollone v. Liggett Group, Inc.*[11] Employing its traditional presumption against preemption if congressional intent to preempt is not clear, the

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7. U.S. CONST. art. VI, cl. 2.

8. Gibbons v. Ogden, 22 U.S. (9 Wheat.) 1, 211 (1824) *quoted in* Wisconsin Public Intervenor v. Mortier, 501 U.S. 597, 604 (1991).

9. *See* Ingersoll-Rand Co. v. McClendon, 498 U.S. 133, 137-38 (1990).

10. 7 U.S.C. § 136v (1994) (despite savings clause in section 24(a) that would permit any exempted state action other than to allow use or sale of a pesticide banned by the Environmental Protection Agency (EPA), FIFRA section 24(b) prohibits the states from imposing any requirement for labeling or packaging "in addition to or different from those required by" the EPA); *see* Papas v. Upjohn Co., 985 F.2d 516, 519 (11th Cir.) (general FIFRA preemption of tort causes of action), *cert. denied,* 510 U.S. 913 (1993).

11. Cipollone v. Liggett Group, Inc., 505 U.S. 504, 517 (1992).

Supreme Court in *Cipollone* reaffirmed a narrow application of federal preemption over state exercises of police powers through the common law to hold: (i) the federal smoking statutes preempted state-law claims for failure to warn of cigarettes' health effects, but (ii) did not bar some related tort causes of action.[12] Because the statutes at issue explicitly restricted their preemptive effect to state action connected to "smoking and health,"[13] the presumption against preemption significantly limited which contract and tort causes of action were barred.[14] Even though the preemption found was narrowly circumscribed, *Cipollone* established an approach that has weighed even more heavily in the analysis of subsequent decisions, and indeed signaled "a radical readjustment of federal-state relations" on tort liability for federally regulated products.[15]

The Supreme Court's last term may slow the recent trend of federal licensing statutes and regulations foreclosing common-law claims against a manufacturer in compliance with those federal rules. Beginning with a denial of certiorari on an automotive-safety decision from New Hampshire,[16] the Supreme Court this spring

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[12]. *Id.* at 524-25.

[13]. Federal Cigarette Labeling and Advertising Act of 1965, Pub. L. No. 89-92, 79 Stat. 282 ("the 1965 Act") (not preemptive), *as amended by* Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87 ("the 1969 Act") (partially preemptive) (codified as amended at 15 U.S.C. §§ 1331-1341 (1994)).

[14]. *Cipollone*, 505 U.S. at 523-25.

[15]. *Id*. at 540 (Blackmun, J., concurring in part and dissenting in part). While subsequent tort-preemption decisions such as *Freightliner Corp. v. Myrick*, ___ U.S. ___, 115 S. Ct. 1483 (1995) (no preemption), *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658 (1993) (partial preemption), and a few others from the recent past, including *Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133, 137-38 (1990) (total preemption), *English v. General Electric Co.*, 496 U.S. 72, 77-79 (1990) (no preemption), are instructive--especially for divining individual Justice's preemption attitudes--none deals with a safety and licensing statute like VSTA for vaccines or FIFRA for pesticides.

[16]. *Compare* Tebbetts v. Ford Motor Co., 665 A.2d 345, 347 (N.H. 1995) (finding no preemption exists for state common-law design-defect claims premised on the failure to provide airbags as a safer design alternative under the National Traffic and Motor Vehicle Safety Act, 15 U.S.C. §§ 1381-1431 (1994) ("Although the language of the preemption clause alone might suggest that common law actions are preempted, we do not interpret the preemption clause in isolation."), *cert. denied,* 517 U.S. ___, 116 S. Ct. 773 (1996), *reh'g denied* 517 U.S. ___, 116 S. Ct. 1036, 64 U.S.L.W. 3575 (1996), *with* Marrs v. Ford Motor Co., 852 S.W.2d 570, 578 (Tex. Ct. App. 1993) (finding that mandatory automatic-passenger-restraint devices are preemptive of airbag-design-alternative issue, because it "presents an 'actual conflict' with the act"); Boyle v. Chrysler Corp., 501 N.W.2d 865, 871 (Wis. Ct. App. 1993) (finding that design claim for failure to incorporate safer airbag alternative preempted); Wood v. General Motors Corp., 865 F.2d 395 (1st Cir. 1988) (finding preemption for "a state safety standard (vehicles must have air bags) that differs from the federal safety standard covering the same aspect of performance"), *cert. denied,* 494 U.S. 1065 (1990). In addition to the safer-design-alternative theory at issue in *Tebbetts* and most of the federal cases, the previous term of the Supreme Court similarly denied certiorari on a Florida case and returned for further preemption evaluation. Hernandez-Gomez v. Leonardo, 884 P.2d 183, 185 (1994) (preemption of defective seatbelt claims), *vacated and remanded* 516 U.S. ___, 115 S. Ct. 1819 (1995). *Cf.* Hyundai Motor Co. v. Phillip, 639 So. 2d 1064, 1066 (Fla. Dist. Ct. App. 1994) (finding there is neither express nor implied "conflict" preemption of seatbelt-design claims, because Congress included a savings clause that allows for a tort claim even if the minimal federal standards are met), *cert. denied,* 516 U.S. ___, 115 S. Ct. 901 (1995). These cases are still pending, but much federal authority and a number of state cases were in accord with the initial

expressed great reluctance to extend preemptive effect to federal policy decisions.[17] In the last week of the term, the Court issued a highly restrictive preemption decision in *Medtronic, Inc. v. Lohr*,[18] and then made certiorari determinations that indicate further limitations on preemption.[19] Of particular note was denial of certiorari in a Ninth Circuit case, *Kennedy v. Collagen Corp.*,[20] which held the Food and Drug

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Arizona ruling that the Supreme Court vacated and remanded. *See, e.g.,* Dykema v. Volkswagenwerk AG, 525 N.W.2d 754 (Wis. Ct. App. 1994) (seatbelt claims under state negligence, negligence per se and strict-liability theories are "within the purview of the explicit preemption provision prohibiting states from requiring different restraints"); Miranda v. Fridman, 647 A.2d 167 (N.J. Super. Ct. App. Div. 1994) (deciding that claims for design defect and strict liability because of the lack of a lap belt are expressly preempted), *cert. denied,* ___ U.S. ____, 116 S. Ct. 66 (1995).

[17]. *But see* Smiley v. Citibank South Dakota, 517 U.S. ___, ___, ___, 116 S. Ct. 1730, 1733, 1735 (1996) (upholding Comptroller of the Currency regulation pursuant to 12 U.S.C. § 85 (1994), promulgated during the course of ongoing litigation that credit-card late-payment fees are encompassed by "interest" as permitted by bank's home state, rather than borrower's jurisdiction which would deem them an unlawful business practice, unreasonable liquidated damages, usurious, or otherwise limit them) ("Nor does it matter that the regulation was prompted by litigation, including this very suit . . . . [Because it was] adopted pursuant to notice-and-comment procedures of the Administrative Procedure Act designed to assure due deliberation . . . [and because] there is no doubt that § 85 pre-empts state law.").

[18]. Medtronic, Inc. v. Lohr, 518 U.S. ___, 116 S. Ct. 2240 (1996), *rev'g in part ,aff'g in part ,and remanding* Lohr v. Medtronic, Inc., 56 F.3d 1335 (11th Cir. 1995). The Medical Device Amendments (MDA) to the Food, Drug and Cosmetic Act contain an express preemption provision at 21 U.S.C. § 360k (1994), which has been interpreted by a Food and Drug Administration (FDA) regulation. *See* 21 C.F.R. § 808.1(d) (1995).

[19]. A variety of FDA clearance procedures had been brought up for Supreme Court review last term. Besides the substantial-equivalence mechanism (§ 510(k)) at issue in *Lohr*, preemption had generally been extended by the lower courts for claims against medical devices cleared for investigational use and clinical trials, as well as those which had received full premarket approval. Premarket-approved (PMA) devices are often in the FDA's publications referred to as "§ 515 devices"--in contrast to the § 510(k) "substantially equivalent" devices involved in *Lohr*--after the section numbers governing the respective clearance processes. *See* Bingham v. Mentor Corp., 77 F.3d 478 (5th Cir.) (finding preemption of all but design claims against a § 510(k) penile implant), *vacated and remanded,* 116 S. Ct. 2576 (1996); Martin v. Teletronics Pacing Sys., Inc., 70 F.3d 39 (6th Cir. 1995) (finding preemption against investigational pacemaker), *vacated and remanded,* ___ U.S ___, 116 S. Ct. 2576 (1996); Mitchell v. Collagen Corp., 67 F.3d 1268 (7th Cir. 1995) (holding general preemption on PMA lip implant), *vacated and remanded*, ___ U.S. ___, 116 S. Ct. 2576 (1996); English v. Mentor Corp., 67 F.3d 477 (3d Cir. 1995) (§ 510(k) penile implant's malfunction presents no viable claims, including those for design deficiency), *vacated and remanded,* ___ U.S. ___, 116 S. Ct. 2575 (1996); Duvall v. Bristol-Myers-Squibb Co., 65 F.3d 392 (4th Cir. 1995) (finding preemption of claims against a § 510(k) penile implant, including those for breach of express warranty and design deficiency), *vacated and remanded,* ___ U.S. ___, 116 S. Ct. 2575 (1996); Feldt v. Mentor Corp., 61 F.3d 431 (5th Cir. 1995) (holding preemption of all claims except that design inadequacies led to the failure of § 510(k) inflatable penile prosthesis), *vacated and remanded,* ___ U.S.___, 116 S. Ct. 2575 (1996), *remanded to* Feldt v. Mentor Corp., 95 F.3d 4 (5th Cir. 1996).

[20]. Kennedy v. Collagen Corp., 67 F.3d 1453, 1455 (9th Cir. 1995), *cert. denied,* ___ U.S. ____, 116 S. Ct. 2579 (1996). While a denial of certiorari is without precedential effect, there may be even more to vitiate the impact of *Kennedy*, which represents the law only in the federal courts on the West Coast. It is certainly counterbalanced by numerous other holdings that the Supreme Court has allowed to stand, all of which found some preemptive effect on tort remedies. *See, e.g.*, Stamps v. Collagen Corp., 984 F.2d 1416, 1420 (5th Cir.), *cert. denied,* 510 U.S. 824 (1993). It seems nearly

Administration's premarket approval for even the most aggressively reviewed and regulated products[21] does not constitute a federal requirement that would trigger preemption of tort claims.

Whether "preemption would be 'rare indeed'" is the question after *Lohr*, which the dissent criticized as "bewildering and seemingly without guiding principles."[22] The plurality upheld the Eleventh Circuit in declining to preempt negligent and strict-liability design claims, but reversed the preemption of manufacturing and warning claims.[23] All nine Justices would allow tort enforcement of FDA regulations or licensing conditions, including noncompliance allegations,[24] and all found no basis in this clearance procedure for preemption of design claims.[25]

Commentators, furthermore, have read much into the Justices allowing (i) the New Hampshire airbag-preemption decision and (ii) the Ninth Circuit's *Kennedy* opinion to stand, while vacating for reconsideration all other decisions that had found preemptive either (i) the federal airbag phase-in, or (ii) the FDA's generally applicable regulations and premarket or investigational clearance. It is not surprising the plaintiffs' bar has heralded this term as having sounded the death knell for preemption based upon federal licensing or regulation.

Such a conclusive statement may not be justified by *Lohr*, however. *Lohr* does

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impossible to see the Supreme Court endorsing the Ninth Circuit's *Kennedy* decision that tort remedies are unaffected by the FDA's regulatory structure, as Justice Breyer's concurrence pointedly differed from the plurality on this threshold issue. Indeed, the *Lohr* plurality expressed only its understanding that the preemption provision "simply was not intended to pre-empt most, let alone all, general common-law duties enforced by damages actions." *Lohr*, 518 U.S. at ___, 116 S. Ct. at 2253 (plurality opinion of Stevens, J.). The negative implication has to be that a specific federal requirement will preempt *some* tort claims.

[21]. In contrast to simple, non-mechanical items such as bedpans and tongue depressors in Class I and a variety of intermediately regulated products from tampons to some osteopathic devices in Class II, so-called "Class III devices" (i) sustain human life, (ii) are of substantial importance in preventing impairment of human health, or (iii) pose potentially unreasonable threats to the health and safety of the consuming public. The category includes almost all life-supporting or life-sustaining medical devices, such as fetal heart monitors, kidney dialysis systems, pacemakers and artificial heart valves, bovine collagen, certain breast implants and other implantable products that present a potentially unreasonable risk of illness or injury. *Lohr*, 518 U.S. at ___, 116 S. Ct. at 2246.

[22]. *Lohr*, 518 U.S. at ___, 116 S. Ct. at 2262 (O'Connor, J., concurring in part and dissenting in part) (referencing 518 U.S. at ___, 116 S. Ct. at 2258-59 (plurality opinion of Stevens, J.)).

[23]. Four dissenters, including the Chief Justice and Justices O'Connor, Scalia, and Thomas would have found preemption for warning and manufacturing claims. *Lohr,* 518 U.S. at ___, 116 S. Ct. at 2264 (O'Connor, J., concurring in part and dissenting in part).

[24]. *Id.* (O'Connor, J., concurring in part); *id*. at ___, 116 S. Ct. at 2255 (majority opinion of Stevens, J., with which Breyer, J., joined). This unanimous ruling implicitly overrules parts of *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1322 (3d Cir. 1994) (stating that even FDA enforcement action concerning violations subject of the tort claims does not avoid preemptive effect on common-law duties), *cert. denied,* ___ U.S.___, 116 S. Ct. 67 (1995); *see* Reeves v. AcroMed Corp., 44 F.3d 300, 305 (5th Cir.), *cert. denied,* ___ U.S. ___, 115 S. Ct. 2251 (1995); National Bank of Commerce v. Kimberly-Clark Corp., 38 F.3d 988, 992 (8th Cir. 1994); King v. Collagen Corp., 983 F.2d 1130, 1140 (1st Cir.) (opinion of Aldrich and Campbell, JJ.), *cert. denied,* 510 U.S. 824 (1993).

[25]. *Lohr*, 518 U.S. at ___, 116 S. Ct. at 2263-64 (O'Connor, J., concurring in part and dissenting in part).

not even indirectly implicate items that have formally received the FDA's full premarket approval (PMA), let alone other kinds of products regulated by other agencies.

The plurality opinion itself is greatly limited,[26] and Justice Stephen G. Breyer's crucial concurrence is expressly open to preemption defenses based upon specific federal policy decisions at variance with a tort "requirement."[27] Congressional intent and the authoritative interpretation of the FDA were the gravamen for the majority, especially Justice Breyer. The result in *Lohr* was plainly reached based on the Court's conclusion that Congress did not contemplate and did not intend for the Medical Device Amendments (MDA) to preempt all state tort law.

This touchstone of preemption analysis--congressional intent--will depend solely upon (i) ambiguities in the preemption provision incorporated into a particular statute, and (ii) the legislative history, or lack thereof. It took years to pass the MDA, and in all that legislative history there was no indication that tort preemption was intended. The *Lohr* majority opinion is rooted in this lack of any legislative intent for the MDA to preempt existing tort law applicable to grandfathered devices. There was not even a clear congressional expression that liability uniformity or product innovation were legislative goals comparable to the oft-articulated purpose of the act: patient safety.[28] Coupled with this silence, the MDA preemption language did not

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[26]. *Id*. at ___, 116 S. Ct. at 2255 (observing that the majority does "not believe that this statutory language necessarily *precludes 'general' federal requirements* from *ever pre-empting* state requirements, or 'general' state requirements from *ever being pre-empted*") (emphasis added). *See supra* note 20 for a discussion of the negative implications of some of the language chosen by the plurality. Justice Stevens' opinion was the holding of only three other Court members on the operative preemption issues. Justices Kennedy, Souter, and Ginsburg joined his entire opinion, while Justice Breyer joined in the judgment, but expressly refused to join Justice Stevens' plurality views on the precise preemptive effect of FDA action. *Id*. at ___, 116 S. Ct. at 2261-62 (Breyer, J., concurring in part and concurring in the judgment). The ambiguity in Justice Stevens' discussion whether more specific federal requirements would preempt *some* tort remedies led Justice Breyer to speculate that, "[The MDA] would also pre-empt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action. It is possible that the plurality also agrees on this point, although it does not say so explicitly." *Id*. at ___, 116 S. Ct. at 2260 (opinion of Breyer, J.).

[27]. *Id*. at ___, ___, 116 S. Ct. at 2259-60, 2261-62 ("One can reasonably read the word 'requirement' as including the legal requirements that grow out of the application, in particular circumstances, of a State's tort law.") (declining to join the most restrictive portion of Justice Stevens' plurality decision and specifically disputing his assertion "that future incidents of MDA preemption of common-law claims will be 'few' or 'rare.'") (referencing *Lohr*, 518 U.S. at ___, 116 S. Ct. at 2259.)

[28]. "[T]he § 510(k) exemption process was intended to do [nothing] more than maintain the status quo with respect to the marketing of existing medical devices and their substantial equivalents. That status quo included the possibility that the manufacturer of the device would have to defend itself against state-law claims . . . ." *Id.* at ___, 116 S. Ct. at 2255. In seeking Supreme Court review a month after *Lohr,* Lynnbrook Farms stated:

> The underlying issue, of course, is whether VSTA should be used as a preemptive sword for vaccine manufacturers or whether it should be utilized as a protective shield for farmers, veterinarians, and the consuming public . . . . This Court's guidance is clearly necessary in this case to return state products liability law in the animal vaccine regime to the status quo before *Lynnbrook Farms*, 79 F.3d 620, and its progeny and to assure that livestock producers, veterinarians and other

plainly foreclose state-law claims and the FDA, in implementing it, stated there was no need for generalized preemption.[29]

Especially in light of Justice Breyer's opinion, *Lohr* is properly limited to the abbreviated section 510(k) clearance procedure specifically at issue.[30] That procedure, based upon substantial equivalence to an already marketed product, will never be preemptive; neither will generally applicable regulations on label content or good manufacturing practices provide a shield to tort liability. There likely still will be tort preemption, however, where manufacturing decisions are affirmatively required by the agency[31] or a particular cautionary wording has been compelled by agency order or regulation.[32]

B. FIFRA Preemption Authority

The full effect of *Lohr* on FIFRA preemption must be shaken out in pending cases, but little in *Lohr* impugns existing precedent, let alone implicitly overrules

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> consumers are once again protected from dangerous and ineffective vaccines as was the original and paramount intent of Congress.

Lynnbrook Farms' Petition for a Writ of Certiorari to the United States Court of Appeals for the Seventh Circuit at 21, 20, Lynnbrook Farms v. SmithKline Beecham Corp., 79 F.3d 620 (7th Cir.) (No. 96-125), *cert. denied,* ___ U.S. ___, 117 S. Ct. 178, 64 U.S.L.W. 3086 (U.S. Oct. 7, 1996).

[29]. 21 C.F.R. § 801(d) (1995). The weight accorded the FDA's interpretation by the majority was decisive. Because this article examines preemption by agency regulation, the deference to administrative expertise under *Lohr* will be elaborated, *infra* notes 105-09 and accompanying text. A jurisprudential approach to agency-preemption issues at variant with that of the Seventh Circuit in *Lynnbrook Farms* was applied by the Northern District of Iowa in the human-exposure decision against warning preemption discussed *infra* notes 114-115.

[30]. In stark contrast to the arduous premarket-approval process (PMA) or even the investigational-device exemption (IDE), the "substantial equivalence" inquiry for section 510(k) clearance involves only a bare-bones premarket notification (PMN) by the manufacturer and very rapid and almost certain FDA clearance for marketing on the basis of that similarity to existing medical devices. *Lohr*, 518 U.S. at ___, 116 S. Ct. at 2247 (quoting Robert S. Adler, *The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction*, 43 FOOD DRUG COSM. L.J. 511, 516 (May 1988)) ("§ 510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets processed very quickly.").

[31]. *See id.* at ___, 116 S. Ct. at 2259-60 (Breyer, J., concurring in part and concurring in the judgment); Stamps v. Collagen Corp., 984 F.2d at 1416, 1422, 1423-24 (5th Cir.) ("Nor . . . [would allegations] based upon the defective design and manufacture of Collagen's products, survive preemption, as the Class III PMA process includes FDA scrutiny and approval of these particular aspects of a device."), *cert. denied,* 510 U.S. 824 (1993); Slater v. Optical Radiation Corp., 961 F.2d 1330, 1333 (7th Cir.) (finding specific regulations relating to intraocular lenses provide general preemption for Class II product), *cert. denied,* 505 U.S. 917 (1992).

[32]. Martin v. Teletronics Pacing, Inc., 70 F.3d 39, 42 (6th Cir. 1995) (finding preemption of all express-warranty claims against an IDE-cleared pacemaker because of comprehensive FDA regulation and because "the representations that can, cannot, and must be made about an investigational device are all determined by the FDA."), *vacated and remanded,* ___ U.S. ___, 166 S. Ct. 2576 (1996); Moore v. Kimberly-Clark Corp., 867 F.2d 243, 247 (5th Cir.), *reh'g denied,* 873 F.2d 297 (5th Cir. 1989) (finding warning claims preempted by specific FDA labeling requirements for tampons).

FIFRA preemption authority.[33] Preemption under FIFRA became a commonly invoked defense in the wake of *Cipollone,* because the express-preemption inquiry under FIFRA parallels exactly the analysis under the cigarette-smoking statutes.[34] Following *Cipollone,* failure-to-warn claims, including those for breach of implied warranties imposed by operation of law, are uniformly treated as expressly preempted by FIFRA.[35] Implied warranties arise by operation of law and call for further labeling description or at least affirmative disclaimer of implied warranties. Breach of implied warranties would require redress by altering product disclosure which cannot be amended without the EPA's approval, and so there is preemption for implied-warranty claims.[36] If a pesticide manufacturer places EPA-approved

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[33]. *See, e.g.,* Taylor AG Indus. v. Pure-Gro, 54 F.3d 555, 558 (9th Cir. 1995); Lowe v. Sporicidin Int'l, 47 F.3d 124, 128 (4th Cir. 1995); Worm v. American Cynamid Co., 5 F.3d 744, 748 (4th Cir. 1993); Papas v. Upjohn Co., 985 F.2d 516, 519 (11th Cir.), *cert. denied,* 510 U.S. 913 (1993). Denial of certiorari in the early Eleventh Circuit case, and similar decisions following *Papas*, influenced a FIFRA preemption opinion in which Justice Breyer joined while still Chief Judge of the First Circuit. King v. E. I. du Pont de Nemours & Co., 996 F.2d 1346, 1349 (1st Cir.) (deciding *Cipollone*'s analysis extended through the ambit of FIFRA claims concerning alleged failures to warn of risks associated with exposure to herbicides), *cert. dismissed,* 510 U.S. 985 (1993). The *King* panel went through which claims impacted upon packaging and labeling decisions expressly preempted by FIFRA, without limitation based upon the description of the particular cause of action. *King*, 996 F.2d at 1349. As senior panel member and furthermore, chief judge, if Justice Breyer disagreed with wholesale preemption under *Papas* and other circuits' authority, or had any objections to the sweeping opinion written by a visiting judge sitting by designation, he could have retained and written the opinion himself. *King*, 996 F.2d at 1350. "[As] 'the Committee has adopted language which is intended to completely [sic] preempt State authority in regard to labeling and packaging,' [and] our conclusion accords with the decisions of the three courts of appeals that, since *Cipollone*, have decided the question," there can be no tort claims challenging the adequacy of labeling and packaging approved by the EPA. *Id.* (quoting H.R. REP. NO. 92-511, at 116 (1972), *reprinted in* 1972 U.S.C.C.A.N. 3895, 3993) (citing decisions of the Seventh, the Tenth, and the Eleventh Circuits). Besides the nuances of his *Lohr* concurrence, *King* is the best indication that Justice Breyer is generally disposed to preemption of tort claims--where the preemption provision's language and legislative history indicate congressional intent to preclude common-law remedies or to occupy the field.

[34]. Welchert v. American Cyanamid, Inc., 59 F.3d 69, 71 (8th Cir. 1995) ("[An] extensive analysis of the preemption provision in the Public Health Cigarette Smoking Act of 1969 [reveals that it] is substantially similar to the preemption provision in FIFRA."); Shaw v. Dow Brands, Inc., 994 F.2d 364, 371 (7th Cir. 1993) ("Not even the most dedicated hair-splitter could distinguish these statements" from FIFRA and the cigarette-smoking statutes); *King*, 996 F.2d at 1351 ("FIFRA's prohibition on 'any requirements for labeling or packaging in addition to or different from those imposed by' [the EPA can not be differentiated from the bar under the Public Health Cigarette Smoking Act of 1969] on any 'requirement or prohibition . . . related to smoking and health . . . imposed under State law.'").

[35]. *King*, 996 F.2d at 1349; *Papas*, 985 F.2d at 518. *See Taylor AG Indus.*, 54 F.3d at 562 ("Claims that the Manufacturers failed to accurately [sic] mark their labels will require a showing that the labels should have included additional *warnings*"); *id.* at 564 ("Imposition of state tort liability for failure to warn on pesticide labels constitutes indirect state regulation of labeling and is prohibited by 7 U.S.C. § 136v(b).").

[36]. Because implied warranties concerning merchantability or fitness for a particular purpose arise by operation of law, and are requirements imposed under state law, these implied-warranty claims fall directly under the *Cipollone* analysis. *Taylor AG Indus.*, 54 F.3d at 564 ("FIFRA preempts implied warranty claims because implied warranties arise by virtue of state law to impose labeling requirements

warnings and instructions on the label and packaging of its product, its duties are deemed satisfied. That usually ends a state court's examination of the sufficiency of warnings, adequacy of instructions, breach of any express or implied warranties, misrepresentation, or the like.[37]

Because FIFRA controls the information provided by the manufacturer in connection with the sale of such pesticide, and does not permit any regulation beyond that prescribed by FIFRA, express-warranty claims are held to be preempted, like all other warning claims.[38] Alleged breaches of express warranties stem from representations allegedly made by the manufacturer in connection with the sale of a pesticide regulated by FIFRA. Express-warranty claims also may be preempted if the specific label or disclosure is federally approved by regulation or administrative action;[39] if not, those claims may be viable to the extent they do not relate to a matter of federal policy.

Similarly, preemption of misrepresentation and consumer-protection claims will vary depending upon the context of the manufacturer's representation as it relates to labeling approval. If based upon what was on, or what was omitted from, the product package or in its literature, these claims will be deemed preempted.[40] If wholly unrelated to matters addressed by FIFRA and characterizable as voluntary and contractual--like a trade show hawker's come-ons--no preemption would exist for allegations of deceptive advertising, misrepresentation, or fraud.[41]

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indirectly."); *Papas*, 985 F.2d at 520 ("[T]o the extent the implied warranty claim depends upon inadequacies in labeling or packaging, FIFRA section 136v pre-empts the claim.").

37. *King*, 996 F.2d at 1349; *Papas*, 985 F.2d at 518.

38. *Welchert*, 59 F.3d at 73 ("[T]o allow state courts to sit, in effect, as super-EPA review boards that could question the adequacy of the EPA's determination of whether a pesticide registrant successfully complied with *the specific labeling* requirements of its own regulations would be an 'additional' requirement.") (emphasis added); *Worm*, 5 F.3d at 748-49 (While some statutes would not preempt a contractual commitment and the manufacturer did "make additional disclosures and representations when it modified its label to state that in drought conditions greater carry-over effects" might occur, the label was affirmatively approved and the "statements concerning rotational crop use are expressly required by the EPA"); Higgins v. Monsanto Co., 862 F. Supp. 751, 761 (N.D.N.Y. 1994) ("The rationale that warrantors should be held to contracts that they voluntarily enter into does not apply when their actions are forced.").

39. Lowe v. Sporicidin Int'l, Inc., 47 F.3d 124, 129 (4th Cir. 1995) ("[A]n express warranty claim based upon EPA-approved labeling materials is preempted.").

40. *Papas*, 985 at F.2d 519 ("If a pesticide manufacturer places EPA-approved warnings on the label and packaging of its product, its duty to warn is satisfied, and the adequate warning issue ends. Plaintiffs may not interfere with the FIFRA scheme by bringing a common law action alleging the inadequacy of, for example, point-of-sale signs."); Arkansas-Platte & Gulf Partnership v. Van Waters & Rogers, Inc., 981 F.2d 1177, 1179 (10th Cir.) (finding with regard to labeling and packaging, FIFRA "simply deprives the state of power to adopt *any* regulation," including duty-to-warn tort requirements or statutory requirements concerning packaging and labeling), *cert. denied sub nom.* Arkansas-Platte & Gulf Partnership v. Dow Chemical Corp., 510 U.S. 813 (1993).

41. *Compare* Jenkins v. Amchem Prods., 886 P.2d 869, 882 (Kan. 1994) (finding alleged misrepresentations really are simply failure-to-warn claims rephrased, and so are expressly preempted), *with* Gorton v. American Cyanamid Co., 533 N.W.2d 746, 755 (1995) stating:

> Quite simply, claims based on misrepresentations of fact do not challenge the labeling of a manufacturer's product. . . . These representations were made through

At least some pre-*Lohr* courts allowed tort enforcement of FIFRA violations.[42] While their interpretation was not entirely consistent with some circuits' approach, at least the Fourth and the Fifth Circuits allowed tort challenges to FIFRA product advertising at variance with, or contradictory of, the statement of claims filed at the time of the pesticide's registration.[43] While it is still state court supervision of FIFRA labeling and packaging decisions, the standards being enforced are not imposed by the state, if they are identical to federal requirements.[44] Undoubtedly, *Lohr*'s allowance of noncompliance claims supports the viability of similar FIFRA claims.[45]

There is little doubt after *Lohr* about manufacturing, testing, and design claims being viable under FIFRA, even if a manufacturer attempts to demonstrate the impact of tort liability on labeling decisions. Some circuits had accepted this rationale to support preemption.[46] Even if the allegations pertain to manufacturing defects or

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> written product such as promotional materials, advertisements, technical reports, as well through oral statements made by American Cyanamid's technical service representatives. All of the statements assuring that SCEPTER was "safe" and "extremely safe" had no relation to the labeling or packaging of the herbicide.

Id.

[42]. *Lowe*, 47 F.3d at 128 ("A requirement that is the same as the federal statute, even if the state law provides compensation or other remedies for a violation, 'so long as Congress chooses not to explicitly [sic] preempt the consistent law, it will not be said to be in conflict with federal law.'") (quoting Worm v. American Cyanamid Co., 970 F.2d 1301, 1305-06 (4th Cir. 1992), *aff'd,* 5 F.3d 744 (4th Cir. 1993)).

[43]. MacDonald v. Monsanto Co., 27 F.3d 1021, 1024 (5th Cir. 1994), *aff'd after remand* , 68 F.3d 470 (5th Cir. 1995); *Worm*, 5 F.3d at 749.

[44]. *Cf. Papas*, 985 F.2d at 519 ("FIFRA leaves states with no authority to police manufacturers' compliance with the federal procedures."); *Arkansas-Platte & Gulf Partnership*, 981 F.2d at 1179 (with regard to labeling and packaging, FIFRA "simply deprives the state of power to adopt *any* regulation," even a tort requirement not to violate federal standards); Kemp v. Pfizer, 835 F. Supp. 1015, 1021-22 (E.D. Mich. 1993), *opinion vacated* ,91 F.3d 143 (1996).

[45]. The Justices probably do not view tort enforcement of federal standards to be a state requirement "different from, or in addition to" those federally imposed pursuant to FIFRA, the Federal Hazardous Substances Act, or other statutory programs. While *Lohr* does overrule those medical-device decisions that said fraud on the FDA or violation of licensing conditions would not escape preemption, similar disallowance of FIFRA noncompliance claims in *Papas*, *Arkansas-Platte & Gulf Partnership*, and later cases are not directly implicated. The better interpretation, however, is that state-law noncompliance claims are viable under all the regulatory regimes after *Lohr*. *See* Medtronic, Inc. v. Lohr, 518 U.S. ___, ___,116 S. Ct. 2240, 2264 (1996) (O'Connor, J., concurring in part) ("[A] damages remedy will give manufacturers an additional cause to comply, but the requirements imposed upon them under state and federal law do not differ."); *Lohr*, 518 U.S. at ___, 116 S. Ct. at 2260-61 (Breyer, J., concurring in part and concurring in the judgment); *Lohr*, 518 U.S. at ___, 116 S. Ct. at 2255-56 (plurality opinion of Stevens, J., joined by Breyer, J.).

[46]. Welchert v. American Cyanamid, Inc., 59 F.3d 69, 71 (8th Cir. 1995) (preemption of variety of claims concerning vegetable crop ruined by herbicide); Taylor AG Indus. v. Pure-Gro, 54 F.3d 555, 560 (9th Cir. 1995) (mixture of chemicals that destroyed crop subject to labeling preemption with respect to both manufacturers and the retailer who advised improper application); *Lowe*, 47 F.3d at 129-30 (preemption of all claims against disinfectant manufacturer, except that its advertising was contradictory of and not in compliance with its EPA-approved labeling); *MacDonald*, 27 F.3d at 1025 (preemption of all claims concerning herbicide allegedly linked to cancer); *Worm*, 5 F.3d at 748-49 (no

some other problem with the product, rather than its label, most often other kinds of claims still seek label supplementation or alteration. If a court views the cause of action as analogous to failure-to-warn liability under EPA-required disclosure or as having a direct and substantial effect on those decisions, then there existed before *Lohr* a basis for design and manufacturing preemption without resorting to implied-preemption analysis.

Lohr's palpable restrictions on broadening express preemption provisions beyond their actual scope will restrict FIFRA's effects on design, manufacturing, and testing claims. All such claims are arguably outside the scope of FIFRA's regulatory coverage, because FIFRA expressly preempts only state action with respect to "labeling or packaging in addition to or different from" what the EPA requires.[47] While either actual-conflict or occupation-of-the-field approaches to implied preemption are permissible under *Cipollone* and *Lohr*, there is little statutory basis under FIFRA for preemption of manufacturing and design claims under generally applicable federal requirements.

Common-law negligence claims under FIFRA, nonetheless are, and should continue to be, treated by most courts as impliedly preempted by the extensive review given chemical products by federal agencies prior to entry into the stream of commerce. Separate from product contamination or other outright manufacturing error, any over-exposure, improper-use, or negligent-manufacture claims are based on the manufacturer's alleged failure to make a product that kills plants or pests but does not harm humans. The same summary applies for negligent or strict-liability design claims. Prior to permitting the sale of pesticides, FIFRA requires extensive review of health and safety studies.[48] If the environmental or human hazards outweigh the product's usefulness, the product may not be sold.

Because a federal statutory scheme so thoroughly controls which chemical products are placed into the stream of commerce,[49] and because a federal agency engages in a public-policy analysis prior to permitting them to go on the market, FIFRA regulation has been held to preempt any state-law remedy that would require a safety standard other than that promulgated by the EPA. Negligent or strict-liability design and manufacturing claims are deservedly preempted if all they allege is that the pesticide was not "safe enough" without alleging constituent contamination or another defect in the product as registered.[50] Defects in a product or departures from approved manufacturing practices will, however, undoubtedly state a viable claim after *Lohr*.

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viable claims for crop-rotation damage from carry-over effects of herbicide); King v. E. I . du Pont de Nemours & Co., 996 F.2d 1346, 1349-50 (1st Cir. 1993) (herbicide sprayer presented no viable claims against FIFRA-regulated manufacturer); *Arkansas-Platte & Gulf Partnership*, 981 F.2d at 1179 (preemption of claims against herbicide manufacturer).

47. 7 U.S.C. § 136v(b) (1994). FIFRA also explicitly permits states to "regulate the sale and use of any federally registered pesticide." *Id.* § 136v(a).

48. *Id.* §§ 136a(c)(2)(A), 136e(a); 40 C.F.R. §§ 158.34, 158.202(d), 158.202(e), 158.290, 158.340 (1995).

49. 7 U.S.C. §§ 136a(c)(5)(A)- 136a(c)(5)(D) (1994).

50. Jenkins v. Amchem Prods., 886 P.2d 869, 885-86 (Kan. 1994).

III. BACKGROUND TO FEDERAL LIVESTOCK VACCINE REGULATION

This FIFRA preemption authority has largely guided the analysis under the Virus-Serum-Toxin Act (VSTA).[51] And while there are statutory similarities, wholesale adoption of preemption principles from the FIFRA jurisprudence seems unwarranted by explicit congressional command or articulated legislative purpose in VSTA. Especially as *Lohr* (and even *Cipollone*) cautioned great restraint in finding state-law causes of action preempted, there should be serious limits to tort preemption under the ambiguous authority of VSTA.

A. Statutory Authority

In 1985, Congress found that the domestic livestock market had "changed drastically" since passage of the original livestock-vaccine statute in 1913.[52] The resulting "truly national markets" required (i) expansion of federal jurisdiction to include interstate and intrastate vaccine sale and use,[53] and (ii) increasing the ambit of federal control as "necessary to prevent and eliminate burdens on commerce and to effectively regulate such commerce."[54] The Agriculture Department's Animal and Plant Health Inspection Service ("APHIS") has been delegated the responsibilities under VSTA[55] to promulgate "an extensive regulatory scheme governing the design,

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51. 21 U.S.C. §§ 151-159 (1994); 9 C.F.R. § 101.2 (1996).

52. 21 U.S.C. §§ 159, 151 (1994).

53. S. REP. NO. 99-145, at 338-39 (1985), *reprinted in* 1985 U.S.C.C.A.N. 1676, 2004-05. Congressional reappraisal of VSTA authority came in the wake of two court decisions holding that VSTA did not apply to the production and sale of veterinary biologics made and sold within a single state. *See* Animal Health Institute v. USDA., 487 F. Supp. 376 (D. Colo. 1980); Grand Labs Inc. v. Harris, 644 F.2d 729 (8th Cir. 1981), *cert. denied,* 456 U.S. 927 (1982). Because thirty-three states did not actively regulate animal biological products, those intrastate sales were "almost entirely free of any official scrutiny." S. REP. NO. 99-145, at 339 (1985), *reprinted in* 1985 U.S.C.C.A.N. at 2005.

Extension of federal control over intrastate sales of livestock vaccines was a prime motivating concern for the amendments, but Congress' emphasis on the burdens upon interstate and foreign commerce reached beyond merely justifying federal controls of sales entirely within one state. 21 U.S.C. § 159 (1994). Indeed, Congress made plain its desire for "uniform national standards" for animal vaccines manufactured and sold in the United States. S. REP. NO. 99-145 at 339, *reprinted in* 1985 U.S.C.C.A.N. at 2005. "The purpose of the Act is to assure that biologics used in the treatment of animals are pure, safe, potent, and efficacious." Animal and Plant Health Inspection Service, Final Rule Pertaining to Restrictions Which May Be Imposed by States on the Distribution and Use of Veterinary Biological Products, 57 Fed. Reg. 38,758 (1992) (to be codified at 9 C.F.R. § 101.2 (1996)).

54. 21 U.S.C. §§ 159, 151 (1994).

55. *Id.* §§ 151-159; 9 C.F.R. § 101.2 (1996). The primary statutory function was to require all animal vaccines that are produced in the United States, and all establishments manufacturing them, to be licensed by the Department of Agriculture. 21 U.S.C.§§ 151, 154 (1994). APHIS has established comprehensive regulation pursuant to that command, and the Department's express authority to "make and promulgate from time to time such rules and regulations as may be necessary to prevent the preparation [and] sale . . . of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals . . . ." *Id.* § 154.

manufacture, distribution, testing, and labeling of animal vaccines."[56]

1. Registration of Products and Manufacturing Establishments

Following this legislative mandate, APHIS' task is to ensure all animal vaccines prepared and marketed in the United States are pure, safe, potent, and effective.[57] APHIS has comprehensively regulated the manufacture and marketing of vaccines to ensure their efficacy, potency, safety, and purity. In the first instance, the statute requires: (i) all establishments where veterinary biologics are manufactured to be registered and licensed,[58] and (ii) every animal vaccine manufactured or distributed in the United States to be licensed individually by APHIS before any new product can be sold.[59]

Unlike FIFRA registration where potential harm to human health and the environment is evaluated against a new pesticide's utility,[60] vaccine licensure under VSTA is not based upon a balancing of potential risk against vaccination's benefits to animal husbandry. It is dependent upon an affirmative safety-and-efficacy finding by APHIS. Therefore, the approval of a vaccine is not just the agency's decision that the potential disease prevention through vaccination outweighs the particular harms to some animals inevitably caused by biological products. Instead, a registrant must demonstrate to APHIS' satisfaction that (i) the vaccine or serum is within acceptable parameters of safety, and (ii) when properly administered has an effectiveness rate that justifies licensure.[61]

2. Testing Protocols and Manufacturing Requirements

APHIS has decreed as a precondition for licensure that elaborate testing protocols be conducted by the manufacturer or by APHIS itself.[62] All test and research reports must be submitted to APHIS for exhaustive review prior to licensure.[63] There are two APHIS-specified testing protocols: (i) the so-called "Standard Procedures," designed chiefly to assure the safety and purity of biologics generally;[64]

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56. Lynnbrook Farms v. SmithKline Beecham Corp., 79 F.3d 620, 624 (7th Cir. 1996) (citing 9 C.F.R. §§ 101-124 (1996)), *cert. denied,* __ U.S. __, 117 S. Ct. 178, 64 U.S.L.W. 3086 (U.S. Oct. 7, 1996).

57. 9 C.F.R. § 113.5(a) (1996).

58. 21 U.S.C. §§ 151, 154 (1994); 9 C.F.R. § 102.2 (1996).

59. 21 U.S.C. § 151 (1994); 9 C.F.R. § 102.1 (1996).

60. 7 U.S.C. § 136a(c)(5)(A)-(D) (1994); 40 C.F.R. § 158.146 (1995).

61. 9 C.F.R. § 102.3(b)(2)(ii) (1996).

62. *Id.* §§ 113.25-113.55 ("Standard Procedures"). Additionally, there are companion FDA requirements for livestock (or their products like milk) used for human consumption, or to feed food animals (such as dairy cows whose calves are slaughtered for veal). The FDA controls will not be separately analyzed in this article, but the reader should note that it and the Center for Veterinary Medicine, of the Department of Health and Human Services, have counterpart regulations.

63. 9 C.F.R. § 102.3(b)(2)(ii) (1996).

64. *Id.* §§ 113.25-113.55.

and (ii) very specific tests required to assure potency and efficacy of bacterial and viral animal vaccines.[65] As many animal vaccines contain more than one specific viral or bacterial antigen, each component or "fraction" contributes separately to the efficacy of the overall biological product. Where a proposed vaccine contains several fractions, not only must the overall product be tested as required by APHIS, but individual fractions also must be tested as if each were to be manufactured and distributed separately.[66]

After APHIS-specified testing has proven the development of a safe and efficacious product, manufacturers are required to prepare an "Outline of Production" as the first step in the licensing process.[67] The outline must contain highly technical data detailing every step in the design, production, packaging, and testing of a vaccine.[68] APHIS must approve the Outline of Production as a condition to product licensure.[69] No changes in the approved outline can be made without APHIS' prior approval.[70]

3. Labeling Requirements

Similarly, prior to licensure, a draft label and packaging inserts must be submitted and approved.[71] APHIS has promulgated extensive standards for disclosure and labeling.[72] APHIS' regulations prescribe certain information that must appear on all VSTA vials or container labels, carton labels, product inserts, circulars, or leaflets.[73] Depending upon the vaccine, APHIS also will specify additional elements that all labels and warning statements must contain.[74] Indeed, it appears that APHIS (and its FDA counterparts) actively negotiate warning and other product information.[75]

Only approved labels and literature may accompany veterinary biologics sold in the United States.[76] APHIS approval must be in writing, so there is no mere

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65. *Id.* § 113.64-.332.

66. *Id.* § 113.7(a).

67. *Id.* § 114.8-.9.

68. *Id.* § 114.9(d).

69. *Id.* §§ 102.5(d)(1), 114.8(a).

70. *Id.* § 102.5(d)(1).

71. A manufacturer must submit all label text and design features, in final format, to APHIS prior to licensure. 9 C.F.R. § 112.5 (1996).

72. *Id.* § 112.

73. *Id.* § 112.2. Not only must such labeling be reviewed for compliance with the regulations, but the text, layout and design of all labeling on these vaccines, including outer packaging and product inserts, must be specifically approved in writing by APHIS.

74. *Id.* § 112.

75. *Cf.* Lowe v. Sporicidin Int'l, 47 F.3d 124, 126 (4th Cir. 1995) (finding EPA deleted proposed claims from disinfectant label, and required pursuant to FIFRA other cautionary statements and dilution representations).

76. 9 C.F.R. § 112.5(c) (1996).

acquiescence in a manufacturer's submission.[77] APHIS must review and specifically approve any label modifications or new representations or disclosures before a manufacturer can alter its approved literature.[78] This applies not only to new text, but to changes in type or even alteration of logo and trademark after products or companies have been acquired by another manufacturer.[79]

4. Sampling and Batch Testing

When all VSTA requirements have been satisfied, APHIS *may* then issue a license for the vaccine.[80] However, licensure alone still does not automatically permit the product to be sold or distributed. Before any serial or lot of a vaccine or serum can be released to the market, each serial or batch must be tested by the manufacturer for the required levels of purity, safety, potency, and efficacy represented in the Outline of Production.[81] Some of these serial or lot samples must be maintained as controls for random APHIS testing or for APHIS evaluation in the event of later complaints from veterinarians or users.[82] If unsatisfactory results are obtained by the manufacturer or APHIS, the serial *may not* be released on the market.[83]

A product in violation of the statute or an applicable regulation can subject the manufacturer or other violator to significant civil penalties, as well as criminal prosecution.[84] Indeed, any substandard, defective or otherwise unwholesome or dangerous product is considered "misbranded," even if the manufacturer's or APHIS' testing did not find unsatisfactory results in the required sampling.[85]

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77. *Id.* This is in contrast to the lack of a legal requirement under FIFRA for formal, written label approval, though the EPA's practice is to approve labeling affirmatively with such suggested revisions as necessary to assure safe and efficacious use of the products. *Cf.* 7 U.S.C. § 136q (1994); 40 C.F.R. § 156 (1995) (EPA label requirements under FIFRA).

78. 9 C.F.R. § 112.5 (1996).

79. For instance, the vaccines at issue in *Lynnbrook Farms* were registered to the original manufacturer, Norden Laboratories, which SmithKline Beecham acquired prior to the sales in question. The merger of Norden into its successor in interest was completed at the beginning of 1992, but the new literature accompanying the vaccines was not re-approved until almost a year later. Telephone interview with Matthew C. Potts (309-742-2591), Elmwood, IL counsel for Lynnbrook Farms, concerning delays with the United States Department of Agriculture National Agriculture Research Service Animal Welfare Information Center ("AWIC") (July 19, 1996); October 28, 1994 Affidavit of Dr. Cyril G. Gay, D.V.M., Ph.D., Biological Regulatory Affairs Associate Director, SmithKline Beecham Corporation, Appendix B to Respondent SmithKline Beecham Corporation's Brief in Opposition to Petition for a Writ of Certiorari at 17-21, Lynnbrook Farms v. SmithKline Beecham Corp., 79 F.3d 620 (7th Cir.) (No. 96-125), *cert. denied,* ___ U.S. ___, 117 S. Ct. 178, 64 U.S.L.W. 3086 (U.S. Oct. 7, 1996).

80. 9 C.F.R. § 102.3(b) (1996).

81. *Id.* §§ 113.3(b), 113.5(a).

82. *Id.* § 113.6.

83. *Id.* § 113.6(b).

84. 21 U.S.C. §§ 158, 159 (1994).

85. *Id.* § 151.

Through mandatory product testing, evaluation, and monitoring,[86] and its inspection authority,[87] APHIS ensures the compliance of each serial or lot with the individual licensing conditions, the generally applicable standards it promulgates, and with VSTA provisions. "A bad batch" should be an impossibility, though error is inevitable and no set of safeguards is foolproof. Nonetheless, APHIS' imprimatur on each batch, lot, or serial has effectively been considered by the agency and the courts an affirmative determination that the particular vaccine or serum (i) has been designed, manufactured, tested, packaged, and sold pursuant to APHIS standards, and (ii) satisfies all requirements for purity, safety, potency, and efficacy.[88]

B. APHIS' Declaration of Preemption

Obviously, APHIS is working toward the uniformity and comprehensiveness in animal-vaccine regulation Congress mandated. For instance, in reaction to its broadened statutory mission after 1985, APHIS issued a declaration of preemption:

> Where safety, efficacy, purity, and potency of biological products are concerned, it is the agency's intent to occupy the field [because] Congress clearly intended that there be national uniformity in the regulation of these products . . . . Therefore, States are not free to impose requirements which are different from, or in addition to, those imposed by [the Agency] regarding the safety, efficacy, potency or purity of a product. Similarly, labeling requirements which are different from or in addition to those in the regulations under the Act may not be imposed by the States. Such additional or different requirements would thwart the Congressional intent regarding uniform national standards, and would usurp [the Agency's] authority to determine which biologics are pure, safe, potent and efficacious.[89]

It is telling that torts or any common law causes of action are never mentioned in the regulation, even if it is "clear and comprehensive" in its preemption of state law.[90] Neither VSTA nor its legislative history make any reference to concerns over

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86. 9 C.F.R. § 102 (1996).

87. 21 U.S.C. §§ 152, 153, 156, 157 (1994).

88. *See infra* notes 133-46 and accompanying text.

89. Animal and Plant Health Inspection Service, Final Rule Pertaining to Restrictions Which May Be Imposed by States on the Distribution and Use of Veterinary Biological Products, 57 Fed. Reg. 38,758 (1992) (to be codified at 9 C.F.R. § 101.2 (1996)).

90. Lynnbrook Farms v. SmithKline Beecham Corp., 79 F.3d 620, 627 (7th Cir. 1996). This interpretation of the Declaration of Preemption is not wholly irreconcilable with the plurality decision in *Lohr*, but it is at odds with the thrust of the plurality opinions. Nearly identical statutory wording in the Medical Device Amendments to that chosen by APHIS for its preemption regulation, was found to be "highly ambiguous." Medtronic, Inc v. Lohr, 518 U.S. __, __, 116 S. Ct. 2240, 2260 (1996) (Breyer, J., concurring in part and concurring in the judgment). Unlike the MDA, and other health-care statutes, the legislative history of VSTA reflects absolutely no fear of state products-liability claims hampering the innovation of animal vaccine manufacturers or burdening interstate commerce by increasing vaccine prices or forcing certain manufacturers out of business. *Cf. National Childhood Vaccine Injury Compensation Act of 1985: Hearing on S. 287 Before the Senate Comm. on Labor and Human*

common-law products liability or whether Congress considered such actions to be a burden on the animal vaccine industry or on interstate and foreign commerce.[91] In fact, it was three years after the regulation was issued that APHIS "clarified"--and then only by negative implication--its position that tort and other claims would be preempted, except to the extent that they enforce any federal standard or APHIS requirement.[92] Even in the clarification so strongly relied upon by the courts that later interpreted the Declaration of Preemption, APHIS continued to avoid an explicit statement that it found tort enforcement of non-federal standards to be a burden on commerce or that damages liability was incompatible for a manufacturer that was not in actual violation of VSTA or APHIS regulations.

In a case before the United States District Court for the District of Kansas, the court had to answer the plaintiff's insistence that the preemption declaration was intended to supersede "only 'positive enactments,' *i.e.*, state statutes and regulations, not common law actions. The plaintiff also argues that APHIS intended that its regulations set only minimum standards, and that the agency meant to leave tort remedies intact."[93] Citing the Tenth Circuit FIFRA case *Arkansas-Platte & Gulf Partnership* for the proposition that "the common law duty is no less a 'requirement' in the preemption scheme than a state statute imposing the same burden,"[94] the court

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Resources, 99th Cong. pt. 2 (1985); *Vaccine Injury Compensation: Hearings on H.R. 5810 Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 98th Cong. (1984). As the MDA's legislative history on nurturing product innovation was insufficient indication of congressional intent to preempt pacemaker liability in *Lohr*, even less affirmative showing of congressional interest in vaccine manufacturers' common-law liability should be yet weaker support for the Declaration of Preemption. Rather, again as with the MDA, Congress' articulated purposes in the 1985 amendments that rewrote VSTA were (i) to bring intrastate vaccines under APHIS control even if manufactured and sold entirely within a single state, and (ii) to promote safe end effective vaccines for the benefit of animal husbandry. S. REP. NO. 99-145, at 1 (1985), *reprinted in* 1985 U.S.C.C.A.N. 1676. While APHIS permissibly could have expressed a need to preempt tort claims, it chose ambiguously to remain silent, employing instead a prohibition on any state "requirements which are different from, or in addition to, those imposed by [the Agency]." Animal and Plant Health Inspection Service, 57 Fed. Reg. at 38,759.

[91]. S. REP. NO. 99-145, at 338-39 (1985), *reprinted in* 1985 U.S.C.C.A.N. 1676, 2004-05.

[92]. Dec. 22, 1995, Letter from Animal and Plant Health Inspection Service Acting Administrator Terry L. Medley, to Senator Paul David Wellstone *re*: Brandt v. Marshall Animal Clinic, 540 N.W.2d 870 (Minn. Ct. App. 1995) stating:

> Our intent in promulgating the rule was, and continues to be, to preempt states from imposing requirements either through statutes, regulations, *or other means* that are different from, or in addition to, those imposed by [APHIS . . . .] We did not intend to preempt *common law actions for damages arising from noncompliance with . . . regulatory standards*.

Id. (emphasis added). Did APHIS then intend to preempt tort actions where compliance is affirmatively established by a manufacturer? Where a plaintiff fails to allege a regulatory violation? The courts have answered affirmatively to both. *See infra* notes 144-49 and accompanying text.

[93]. Murphy v. SmithKline Beecham Animal Health Group, 898 F. Supp. 811, 816 (D. Kan. 1995).

[94]. Arkansas-Platte & Gulf Partnership v. Van Waters & Rogers, Inc., 981 F.2d 1177, 1179 (10th Cir.), *cert. denied sub nom.* Arkansas-Platte & Gulf Partnership v. Dow Chemical Corp., 510 U.S. 813 (1993).

prefaced its claim-by-claim preemption evaluation by noting:

> [T]he language used by APHIS is quite broad: the agency preempts state requirements "regarding the safety, efficacy, potency or purity" as well as the labeling of animal vaccines. Therefore the fact that the *Cipollone* Court found that the Federal Cigarette Labeling and Advertising Act did not pre-empt all of the petitioner's claims is not dispositive . . . . The key inquiry is "whether the legal duty that is the predicate of the common law damages action constitutes" a "requirement which (is) different from, or in addition to, those imposed by [APHIS]."[95]

The Declaration of Preemption was premised on APHIS' conclusion that permitting each of the fifty states through regulations or other means to impose requirements upon animal vaccine manufacturers different from or in addition to those imposed under VSTA would undermine Congress' call for uniform national standards and the elimination of undue burdens upon commerce.[96] Key to finding that APHIS had not acted arbitrarily, capriciously, or manifestly contrary to congressional intent behind VSTA in its decision "to occupy the field," are three indicia that Congress' delegation included the authority apparently exercised to preempt state tort law. First, APHIS enjoyed the authority to promulgate such "rules and regulations as necessary" to prevent and eliminate burdens upon and to regulate effectively interstate and foreign commerce in vaccines and analogous products. Second, it had the concomitant power to impose regulations to prevent the manufacture, sale, and distribution of any worthless, contaminated, dangerous, or harmful vaccine.[97] Third, and perhaps most importantly in adjudging the scope of its congressionally delegated power to usurp state common law and regulations on pure, safe, potent and efficacious vaccines, Congress expressed its desire in the legislative history for "uniform national standards."[98]

While a court may regret wholesale preemption that leaves a plaintiff without a remedy at law, the APHIS declaration leaves it no alternative in light of "Congress' broad grant of authority . . . and the agency's permissible exercise of that

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95. *Murphy*, 898 F. Supp. at 817 (alterations in the original indicated parenthetically) (citing Cipollone v. Liggett Group, Inc., 505 U.S. 504, 521 (1992); Animal and Plant Health Inspection Service, 57 Fed. Reg. at 38,759). Like the federal court in *Murphy*, which it in part followed, a Minnesota state appeals court recognized APHIS' use of certain magic words, such as stating its intent to "occupy the field," and its intent to preempt state requirements different from or in addition to those imposed by APHIS. Brandt v. Marshall Animal Clinic, 540 N.W.2d 870, 876-78 (Minn. Ct. App. 1995), *review denied* (Feb. 9, 1996).

96. Animal and Plant Health Inspection Service, 57 Fed. Reg at 38,758 ("Seven commenters indicated that States should have the authority to add to Federal restrictions, as appropriate . . . . APHIS, however, does not agree that States should be allowed to add various restrictions as appropriate . . . .").

97. 21 U.S.C. § 151 (1994).

98. S. REP. NO. 99-145, at 338-39 (1985), *reprinted in* 1985 U.S.C.C.A.N. 1676, 2004-05.

authority."[99] Expressing a similar attitude in *Lynnbrook Farms v. SmithKline Beecham*, the Seventh Circuit is the only federal appellate court to have yet adjudicated VSTA preemption:[100] "[W]e are not at liberty to reverse the judgments of an agency acting within its congressionally delegated authority. It is evident not only that APHIS intended claims such as those brought by Lynnbrook to be preempted,

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[99]. *Murphy*, 898 F. Supp. at 818. The Minnesota Court of Appeals was even more expansive in its rejections of policy objections to preemption and the lower courts' reluctance to deprive a claimant of all remedies, because the judiciary has no authority for the proposition that these concerns can be employed to limit the breadth of preemption that is rooted in broad regulatory powers granted by Congress. *Brandt*, 540 N.W.2d at 876, 878. The court in *Brandt* stated:

> It is worthy of note that both the [federal district] courts in *Lynnbrook Farms* and *Murphy* and the trial court below expressed concern and regret for the remedies lost by preemption in these cases. We are mindful of theses concerns. But the Inspection Service's broad determination of preemption, which represents a permissible course of action under a broad grant of Congressional authority, do not give us liberty to withhold the conclusion that respondents' common law claims are federally preempted.

Id. at 878.

[100]. According to plaintiff's counsel in *Lynnbrook Farms*, the Eighth Circuit has been asked to review an unpublished summary judgment order, but to date there is no action on the appellate level, other than the Seventh Circuit's decision. *See* Garrelts v. SmithKline Beecham Corp., No. C-95-3081 (N.D. Iowa Oct. 29, 1996) (order denying summary judgment, but certifying interlocutory appeal). In addition to the district court opinions referenced herein, the same source indicates that federal courts in South Dakota and Indiana have followed APHIS' preemption declaration. Telephone interviews with James A. Davis, Counsel for the Brandts and for Lynnbrook Farms (May 6, 1996 & Sept. 3, 1996). The only courts to have rejected the preemption defense based upon the APHIS regulation, so far as is known to Lynnbrook Farms' counsel or to the various defense attorneys involved in these suits are: *Garrelts*, slip op. at 93-95; Vasgaard v. SmithKline Beecham Animal Health, CIV 93-4029 (S.D.S.D. Sept. 5, 1995) (unpublished decision of District Judge John B. Jones denying in all respects a motion for summary judgment based upon APHIS preemption); Stange v. Norden Labs., Inc., CIV 91-4125 (S.D.S.D. tried Nov. 1992) (case involving the same vaccine in *Lynnbrook Farms*, where a jury instruction was given stating that, "Compliance with Regulations is not, in and of itself, sufficient to exempt a manufacturer from liability . . . ."), *settled pending appeal* (8th Cir.). The later South Dakota decision (*Vasgaard*) was influenced by the earlier vaccine case from before the preemption regulation was issued, which was tried in the same court.

No doubt courts entertained and awarded damages on claims that livestock vaccines caused injuries or economic losses, before the Declaration of Preemption in August 1992. *See, e.g.,* Overstreet v. Norden Labs., Inc., 669 F.2d 1286 (6th Cir. 1982); Alman Brothers Farms & Feed Mill, Inc. v. Diamond Labs., Inc., 437 F.2d 1295 (5th Cir. 1971); Krupp v. Norden Labs., Inc., 393 N.W.2d 548 (Wis. 1986); Van Wyk v. Norden Labs., Inc., 345 N.W.2d 81 (Iowa 1984); Lovington Cattle Feeders, Inc. v. Abbott Labs., 642 P.2d 167 (N.M. 1982); Pearson v. Franklin Labs., Inc., 254 N.W.2d 133 (S.D. 1977); Colorado Serum Co. v. Arp, 504 P.2d 801 (Wyo. 1972); Carter Farms Co. v. Hoffman-Laroche, Inc., 492 P.2d 1000 (N.M. 1971); O.M. Franklin Serum Co. v. C.A. Hoover & Son, 418 S.W.2d 482 (Tex. 1967); Chandler v. Anchor Serum Co., 426 P.2d 82 (Kan. 1967); Brown v. Globe Labs., 84 N.W.2d 151 (Neb. 1957).

The liability cases before *Cipollone* and APHIS' Declaration are easily distinguishable, but it is harder to dismiss the Northern District of Iowa and the two Southern District of South Dakota cases, *Vasgaard* and *Stange*, as cases in which the court failed to write an opinion or where the preemption defense was not originally asserted. Respondent SmithKline Beecham Corporation's Brief in Opposition to Petition for a Writ of Certiorari at 15 &n.2, Lynnbrook Farms v. SmithKline Beecham Corp., 79 F.3d 620 (7th Cir.) (No. 96-125), *cert. denied,* ___ U.S. ___, 117 S. Ct. 178, 64 U.S.L.W. 3086 (U.S. Oct. 7, 1996).

but also that Congress granted APHIS the power to act on those intentions."[101]

Finding the agency interpretation reasonable,[102] the Seventh Circuit had only to determine whether particular claims would impose duties in addition to or different

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[101]. *Lynnbrook Farms*, 79 F.3d at 630; *see also* Gresham v. Boehringer Ingelheim Animal Health, Inc., No. 95-CV-3376-ODE, slip op. at 4 (N.D. Ga. Aug. 7, 1996) ("Courts uniformly have found that APHIS acted within the authority granted to it by Congress in issuing this statement of preemption."). *But see Gerralts*, slip op. at 23-38.

[102]. To reach blanket preemption, the Seventh Circuit's analysis addressed many arguments. First, VSTA was silent on any type of preemption, let alone preemption of tort claims traditionally within the police powers of the states. "The Supreme Court has warned that a 'narrow focus on Congress' intent to supersede state law (is) misdirected.'" *Lynnbrook Farms* 79 F.3d at 624 (alteration in the original indicated parenthetically) (quoting Fiedelity Federal Savings & Loan Ass'n v. de la Cuesta, 458 U.S. 141, 154 (1988) ("A pre-emptive regulation's force does not depend on express congressional authorization to displace state law.")). Because a federal agency acting within its delegated authority may effectively preempt state law, "it is significant to note that an express congressional authorization to displace state law in the delegating statute is unnecessary." *Id*. (citing City of New York v. FCC, 486 U.S. 57, 64 (1988)).

Second, the plaintiff drew a distinction between permissible preemption by APHIS of state or local vaccine regulation, and agency authority to foreclose tort liability without providing a federal right of action. The Seventh Circuit held that APHIS' delegation was not as broad as the power the Supreme Court construed in *de la Cuesta*, where "Congress' delegation placed no limits on the [Federal Home Loan Bank] Board's authority to regulate the lending practices of federal savings and loans and included the power to create and regulate a 'uniform system of (savings and loan) institutions where there are not any now.'" *Lynnbrook Farms*, 79 F.3d at 626 (citing *de la Cuesta*, 458 U.S. at 161, 166) (alterations in the original indicated parenthetically).

A Minnesota appellate court also exhaustively addressed these arguments, and utilized almost exactly the same approach. *Brandt*, 540 N.W.2d at 874-75, 878. The *Brandt* court held that state laws can be preempted by federal regulations as well as by federal statutes and stated:

> That the preemptory language at issue is not contained in the Virus-Serum-Toxin Act itself but rather in [an agency statement, at best] changes the field of the dispute from the topic of express preemption to one of an implication of preemption by the breadth of the federal regulations and the accompanying declarations of the Inspection Service. The Supreme Court has stated that agencies may speak to the question of preemption through a variety of means, "including regulations, preambles, interpretive statements, and responses to comments."

Id. at 878 (citing Hillsborough v. Automated Medical Labs., Inc., 471 U.S. 707, 718 (1985)).

> [T]he Supreme Court has never intimated a distinction between agency authority to preempt state law generally and the authority to preempt state common law. [And on] the contrary the *de la Cuesta* Court, without hesitation, upheld agency preemption of a state common law rule-- a state regulation or statute was not involved.

Lynnbrook Farms, 79 F.3d at 627. The Seventh Circuit concluded APHIS was perfectly within its discretion to deem common-law damages actions as much of a threat to national uniformity as affirmative state regulation. The court stated:

> [w]ithout any congressional indication to the contrary, it follows that Congress included within its grant of preemption power, the power to preempt state common law [notwithstanding] "the presumption against preemption and the heightened presumption in areas that have traditionally been the province of the states, such as health and safety."

Id. (citing Abbott v. American Cyanamid Co., 844 F.2d 1108, 1112 (4th Cir.), *cert. denied,* 488 U.S. 908, (1988)); *City of New York*, 486 U.S. at 63-69; *de la Cuesta*, 458 U.S. at 152-67.

from those APHIS had implemented for vaccine manufacturers and marketers.[103] In the first decision on APHIS preemption in the aftermath of *Lohr*, the Northern District of Georgia federal court denied generalized preemption, but differentiated APHIS' express intent to preempt from the FDA's reluctance to deem federal medical-device regulations preemptive of tort causes of action.[104] The Seventh Circuit in advance of *Lohr* drew just such a distinction: "[T]he FDA has never expressed any intent to pre-empt state tort law. On the contrary, the FDA has expressly preserved state tort labeling claims."[105]

This deference to agency interpretation is particularly alarming, because APHIS' tort preemption (i) is so broad, (ii) is simply implied by the Declaration of Preemption's occupation of the field of vaccine regulation, and (iii) has no direct support whatsoever in the legislative history of VSTA. Nonetheless, the courts do not challenge (i) APHIS' 1992 field-preemption intent, (ii) the 1995 clarification, or (iii) the implied delegation of preemptive power within VSTA's generalized authority for APHIS to implement and enforce the program as necessary. As Justice Breyer's concurrence in *Lohr* states, an agency "fully responsible for administering" a statutory program that might conflict with state law "means informed agency involvement, and, therefore, special understanding of the likely impact of both state and federal requirements, as well as an understanding of whether (or the extent to which) state requirements may interfere with federal objectives."[106] Even more

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[103]. *Lynnbrook Farms*, 79 F.3d at 630.

[104]. Gresham v. Boehringer Ingelheim Animal Health, Inc., No. 95-CV-3376-ODE, slip op. at 6 & n.2 (N.D. Ga. Aug. 7, 1996) ("APHIS has interpreted VSTA to allow it to 'occupy the field' of veterinary biological products, while the FDA has interpreted the [Medical Device Amendments] to preempt state regulation of medical devices only where the FDA has established 'specific requirements applicable to a particular device.'") (quoting 21 C.F.R. § 808.1(d) (1995)).

[105]. *Lynnbrook Farms*, 79 F.3d at 627. SmithKline Beecham seems to have successfully exploited this difference with the FDA's stance in *Lohr*:

> VSTA warrants and APHIS intends a broader preemptive effect than that provided by the FDA for the MDA [because of] the different missions of the two agencies, the different statutes they must implement, and fundamental differences in the products and industries they regulate. . . . The fact that the FDA intended a *different* preemptive effect for claims arising under the MDA's preemption clause, as illustrated by 21 C.F.R. § 808.1(d), is of no moment.

Respondent SmithKline Beecham Corporation's Brief in Opposition to Petition for a Writ of Certiorari at 25, 24, Lynnbrook Farms v. SmithKline Beecham Corp., 79 F.3d 620 (7th Cir.) (No. 96-125), *cert. denied,* ___ U.S. ___, 117 S. Ct. 178, 64 U.S.L.W. 3086 (U.S. Oct. 7, 1996).

[106]. Medtronic, Inc. v. Lohr, 518 U.S. ___, 116 S. Ct. 2240, 2260 (1996) (Breyer, J., concurring in part and concurring in the judgment) (citing*, inter alia, Hillsborough* , 471 U.S. at 721); *accord id*. at ___, 116 S. Ct. at 2255 (opinion of Stevens, J.) ("[T]he agency is uniquely qualified to determine whether a particular form of state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'") (quoting Hines v. Davidowitz, 312 U.S. 52, 67 (1941)). *But see id*. at ___, 116 S. Ct. at 2263 (O'Connor, J. concurring in part and dissenting in part) ("It is not certain that an agency regulation determining the preemptive effect of *any* federal statute is entitled to deference.") (citing Smiley v. Citibank South Dakota, 517 U.S. ___, ___, 116 S. Ct. 1730, 1734 (1996), discussed *supra* note 17).

sweepingly than the plurality's deference,[107] Justice Breyer ruled "that in the absence of a clear congressional command as to preemption, courts may infer that the relevant administrative agency possesses a degree of leeway to determine which rules, regulations, or other administrative actions will have pre-emptive effect."[108] Much as the Seventh Circuit panel did in deference to APHIS' preemption declaration in *Lynnbrook Farms,* Justice Breyer saw in *Lohr* "a reasonable exercise of the leeway that the statutory language and practical administrative circumstance suggest Congress intended to grant to the agency."[109]

As the *Lynnbrook Farms* appeals panel did for Illinois common law and consumer-protection statutory claims, it is time to examine VSTA preemption of each category of torts and other claims. The identity of issues and outcomes with FIFRA cases should be readily apparent, even where existing VSTA authority did not expressly rely on FIFRA precedents.

IV. VACCINE LABELING CLAIMS ARE EXPRESSLY PREEMPTED

APHIS singled out "labeling requirements which are different from or in addition to those in the regulations" it promulgates pursuant to VSTA.[110] No more express preemptive intent could be manifested, so all such claims concerning adequate warnings on, or associated with, vaccines are barred.[111] This preemption applies to claims denominated as failure-to-warn, inadequate-disclosure, failure-to-instruct, and in all likelihood all similar claims about product literature, except a manufacturer's failure to comply with APHIS' labeling and packaging requirements.[112] "The same is true [for] strict liability failure to warn claims."[113]

The only exception is where a particular warning issue is not considered in the vaccine licensure or dealt with in any way in the regulations. A federal case in Sioux

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107. *Lohr*, 518 U.S. at ___, 116 S. Ct. at 2256 (opinion of Stevens, J.) (delegated authority to "assess the preemptive effect that the Act and its own regulations will have on state laws . . . provide a 'sound basis,' . . . for giving substantial weight to the agency's view of the statute"); *Hillsborough* , 471 U.S. at 714 (considering FDA understanding of preemptive effect of its regulations "dispositive").

108. *Lohr*, 518 U.S. at ___, 116 S. Ct. at 2260 (Breyer, J., concurring in part and concurring in the judgment).

109. *Id.* at ___, 116 S. Ct. at 2261 (Breyer, J., concurring in part and concurring in the judgment). Despite denial of certiorari in *Lynnbrook Farms v. SmithKline Beecham Corp.*, 79 F.3d 620 (7th Cir.), *cert. denied,* 518 U.S. ___, 117 S. Ct. 178, 64 U.S.L.W. 3086 (U.S. Oct. 7, 1996), Justice Breyer and the *Lohr* dissenters likely would have comprised a majority willing to affirm the Seventh Circuit's broad interpretation of the APHIS regulation. *See* King v. E.I. du Pont de Nemours & Co., 996 F.2d 1346 (1st Cir.) (nearly total preemption under FIFRA, *see supra* note 33), *cert. dismissed* 510 U.S. 985 (1993).

110. Animal and Plant Health Inspection Service, 57 Fed. Reg. 38,758, 38,759 (1992).

111. Murphy v. SmithKline Beecham Animal Health Group, 898 F. Supp. 811, 818 (D. Kan. 1995) (Counts VI & VII).

112. *See supra* note 92 and *infra* note 137 discussing the interpretive letter from the Acting Administrator of APHIS on the scope of the preemption declaration. *Cf.* Lowe v. Sporicidin Int'l, 47 F.3d 124 (4th Cir. 1995); Worm v. American Cyanamid Co., 5 F.3d 744 (4th Cir. 1993).

113. *Lynnbrook Farms*, 79 F.3d at 630.

City, Iowa involves the inadvertent injection of a farmer with a viral agent when the calf he was holding darted.[114] Though the manufacturer argued general preemption under *Lynnbrook* Farms, the case appears headed for trial because the court distinguished prior precedent where regulations addressed the label content; this vaccine's label bore no mention of effects on humans, and there was no other cautionary language to avoid human injection, so prior APHIS label approval alone did not assure that the agency determined that no such warnings were appropriate.[115] While reconcilable with other VSTA cases, this denial of summary judgment where APHIS did not even consider a labeling question, let alone made a preemptive determination, is probably the extent of the warning claims that will survive preemption. If it is upheld on appeal, this exception will survive only so long as APHIS continues to ignore the potential for human injection.

V. IMPLIED-WARRANTY CLAIMS ARISE BY OPERATION OF STATE LAW AND ARE ALSO PREEMPTED BY THE AGENCY DECLARATION

Because a vaccine's "safety, efficacy, potency or purity" is directly challenged by allegations that the product was not fit for its intended purpose or was not of merchantable quality, there is again direct preemption under *Cipollone*'s rationale that such claims implicitly challenge the adequacy of disclosure and labeling.[116] As these implied warranties arise by operation of law, and so are imposed by the state, they are directly preempted under *Cipollone*. Additionally, because APHIS pre-approves in writing any disclosure or warning information, it is not within the province of a state court jury to deem a disclaimer of implied warranties necessary to obviate additional duties imposed by operation of law.[117]

This is currently the unquestioned law of APHIS preemption, but the unsuccessful plaintiffs in these actions make what should have been a compelling positivist argument. APHIS' own regulations specify: "Labels may also include any other statement which is not false or misleading and may include factual statements regarding variable response of different animals when vaccinated as directed but may not include disclaimers of merchantability, fitness for the purposes offered, or responsibility for the product."[118] This regulation (i) clearly acknowledges implied-warranty claims, if not actual liability therefor, and (ii) affirmatively prohibits the

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114. Garrelts v. SmithKline Beecham Corp., No. C-95-3081 (N.D. Iowa Oct. 29, 1996) (summary judgment denied on preemption of claims for failure to warn of animal vaccine's permanent and nearly fatal effects on humans), *appeal pending* (8th Cir.).

115. Telephone interview with John G. Martens, Estherville, Iowa (Sept. 11, 1996).

116. *Lynnbrook Farms*, 79 F.3d at 630 ("Counts II & III state claims for breach of implied warranties of fitness for a particular purpose and of merchantability. These actions clearly implicate the efficacy and safety of the vaccines and would likewise impose higher or different standards on SBC."); *Murphy*, 898 F. Supp. at 818 (Counts II & III); Brandt v. Marshall Animal Clinic, 540 N.W.2d 870, 878 (Minn. Ct. App. 1995) ("[B]reach of implied warranties of merchantability and fitness, all impose requirements different from or in addition to the Inspection Service's standards.")

117. 9 C.F.R. § 112 (1996).

118. *Id.* § 113.2(b) (emphasis added).

disclaimer required under the Uniform Commercial Code to avoid such liability.[119] It is hard to dispute that "the regulations themselves defy a finding of preemption on the issue of an implied warranty."[120]

VI. CLAIMS FOR BREACH OF EXPRESS WARRANTIES WILL UNDOUBTEDLY BE PREEMPTED AS WELL

There is no case precedent yet,[121] but clearly the same agency approval of labeling, package inserts, and additional product information,[122] carries with it the imprimatur of agency validation of all representations that go with the vaccine. While it is conceivable, as in the context of direct product representations verbally or in point-of-sale signs not pre-cleared under FIFRA, to hypothesize advertising or other non-labeling representations that could be construed as affirmative warranties or contractual undertakings voluntarily made a vaccine manufacturer, each would necessarily touch upon the product's purity, potency, safety, or effectiveness. In the FIFRA context it is possible to conceive of trade-show promotions or other direct sales come-ons that would not relate to either EPA's approved warning language, or to representations or information contained in EPA-mandated disclosure. Under APHIS' much broader regulatory sphere of labeling standards, product effectiveness and purity, animal safety, and biological and immunological control, it is hard to fashion any potential warranty that would not impinge on a pre-empted aspect of vaccine regulation. All express-warranty claims are probably pre-empted.[123]

VII. NON-LABELING FAILURE-TO-WARN AND MISREPRESENTATION CLAIMS IN MOST INSTANCES ARE TREATED AS PREEMPTED

Allegations that a manufacturer falsely advertised or represented that its vaccine was effective and safe, or suitable for a particular treatment, and all similar

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119. *See, e.g.,* ARIZ. REV. STAT. ANN. §§ 47-2314 to 47-2316 (West Supp. 1994); TEX. BUS. & COMM. CODE ANN. §§ 2.314 to 2.316 (West Supp. 1995).

120. Plaintiff James V. Gresham's Brief in Opposition to Defendant's Motion for Summary Judgment at 8, Gresham v. Boehringer Ingelheim Animal Health, Inc., No. 95-CV-3376-ODE (N.D. Ga. order denying summary judgment Aug. 7, 1996); *see also* Lynnbrook Farms' Petition for a Writ of Certiorari to the United States Court of Appeals for the Seventh Circuit at 11, Lynnbrook Farms v. SmithKline Beecham Corp., 79 F.3d 620 (7th Cir.) (No. 96-125), *cert. denied,* ___ U.S. ___, 117 S. Ct. 178, 64 U.S.L.W. 3086 (U.S. Oct. 7, 1996).

121. Count III in *Gresham* "involves at least one cause of action which has, to date, never been expressly preempted by any court of record." Plaintiff James V. Gresham's Brief in Opposition, at 7, *Gresham* (No. 95-CV-3376-ODE). The closest "ruling" on preemption of express-warranty claims now in fact is the Northern District of Georgia's alternative holding in an unpublished memorandum opinion rejecting APHIS preemption across the board, because there were allegations that the vaccine that injured the livestock came from a "bad batch." *Gresham*, slip op. at. 7 & n.3 (citing American Airlines, Inc. v. Wolens, ___ U.S. ___, ___, 115 S. Ct. 817, 824 (1995); Cipollone v. Liggett Group, Inc., 505 U.S. 504, 525-26 & n.24 (1992)).

122. 9 C.F.R. § 112 (1996).

123. *See also* the medical-device cases *supra* note 32.

allegations go again, directly to the product's purity, potency, safety, and effectiveness and must be deemed expressly preempted. According to the Seventh Circuit: "In order to succeed on these claims, a jury would have to find that the vaccines were not safe and effective. However, APHIS has already declared the products safe and efficacious by its standards. Thus, if tort liability were allowed a different standard would be enforced."[124]

Alternatively, as the written representations involved APHIS-approved language, the misrepresentation, fraud, and similar claims can be viewed as tantamount to expressly preempted failure-to-warn claims that seek to impose "labeling requirements distinct from those dictated by APHIS."[125] In either instance, non-labeling claims will in all likelihood be preempted whether presented as a straightforward failure to warn through advertising, point-of-sale, or other displays, or on theories of fraud, misrepresentation, or material non-disclosure under the common law or under consumer-protection or false-advertising statutes.

This disposition in *Lynnbrook Farms* and the lower court cases is arguably in conflict with *Cipollone*'s holding that the general common-law duties "not to deceive" and "not to make fraudulent statements" were beyond the scope of preempted "requirements."[126] In placing claims for fraud outside the labeling claims expressly preempted by the Public Health Cigarette Smoking Act of 1969, the *Cipollone* plurality analyzed the roots of the common-law claims in a way the Seventh Circuit did not in ruling that "requirements" encompass misrepresentation, fraud, and false-advertising claims. True reconciliation on this issue is not possible, but to date APHIS' rule appears to foreclose all representation claims associated with approved labeling.

VIII. COMMON-LAW NEGLIGENCE CLAIMS ARE EXPRESSLY PREEMPTED

The agency maintains, and the courts also have accepted that, of necessity, APHIS approved the content and sufficiency of all design, manufacturing, and testing data submitted prior to licensure of each vaccine, and adequately monitors ongoing compliance through its sampling protocols. While a negligence cause of action seldom does more than denominate whether it addresses failures to warn, manufacturing errors, or design and testing problems, the Kansas case did deal with specific complaints that cattle had been damaged by "defects, irregularities and lack of vigor, potence [*sic*], safety or effectiveness" in the vaccine.[127] That plaintiff

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[124]. *Lynnbrook Farms*, 79 F.3d at 630 (Count IV (fraudulent misrepresentation and false advertising under the common law) & V (Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILL. COMP. STAT. 505/2 (West 1992))); Murphy v. SmithKline Beecham Animal Health Group, 898 F. Supp. 811, 818 (D. Kan. 1995) (Counts IV & V); Brandt v. Marshall Animal Clinic, 540 N.W.2d 870, 878 (Minn. Ct. App. 1995) (misrepresentation and false-advertising claims).

[125]. *Lynnbrook Farms*, 79 F.3d at 630 (citing King v. Collagen Corp., 983 F.2d 1130, 1136 (1st Cir.), *cert. denied,* 510 U.S. 824 (1993)).

[126]. *Cipollone*, 505 U.S. at 528-29 & n.27; *see also* American Airlines, Inc. v. Wolens, ___ U.S. ___, ___, 115 S. Ct. 817, 824 (1995).

[127]. *Murphy*, 898 F. Supp. at 818.

tracked the preemption declaration's terms and naturally fell directly within its scope.[128] The cattle involved in the Georgia case suffered $180,000 allegedly lost sales value from non-life-threatening side effects directly caused by the antigen's inevitable swelling around the inoculation site. These hard knots were "neither temporary nor transient in nature and did not dissipate . . . contrary to the warnings set forth on the Serum bottle."[129] The federal courts in Kansas and Georgia dismissed any argument concerning the adequacy of APHIS regulation and monitoring, of product formulation, design, or testing.[130]

On more vague negligence allegations, the Seventh Circuit was just as succinct and definite:

> APHIS has licensed . . . and thus declared the vaccines are safe, efficacious, potent and pure by its measures. By bringing claims that clearly implicate and call into question these qualities, Lynnbrook seeks to "impose requirements which are different from, or in addition to, those imposed by [APHIS] regarding safety, efficacy, potency or purity of a product." The claims are thus preempted in their entirety.[131]

The Seventh Circuit held that preemption of tort claims upon compliance is entirely justified, "as it is precisely when APHIS regulations have been satisfied that a common-law action imposes requirements in addition to, or different from, those mandated by APHIS."[132] The court continued *obiter dictum*: "Where noncompliance is involved, a common-law action could simply serve to impose the standards of APHIS."[133]

IX. "NONCOMPLIANCE" CLAIMS AND MANUFACTURING CLAIMS UNRELATED TO APHIS OVERSIGHT SHOULD NOT BE PREEMPTED UNLESS SHOWN TO HAVE "SOME DIRECT AND SUBSTANTIAL EFFECT" ON REGULATED DECISIONS

The Seventh Circuit's Lynnbrook Farms decision did not involve allegations that the manufacturer had failed to meet any of APHIS' standards for labeling, manufacture, testing, or design.[134] In pure *dictum*, however, the court offered that

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128. *Id*.

129. Plaintiff James Gresham's Brief in Opposition to Defendant's Motion for Summary Judgment at 1, 6-7, Gresham v. Boehringer Ingelheim Animal Health, Inc., No. 95-CV-3376-ODE (N.D. Ga. order denying summary judgment Aug. 7, 1996) ("If this Court were to adopt Defendant's preemption proposition, negligent dissemination of a 'bad batch' of Serum, as in the instant case, will permit Defendant to be insulated from liability.")

130. *Gresham*, slip op. at 8; *Murphy*, 898 F. Supp. at 818.

131. Lynnbrook Farms v. SmithKline Beecham Corp., 79 F.3d 620, 630 (7th Cir. 1996) (citing King v. Collagen Corp, 983 F.2d 1130, 1136 (1st Cir. 1993)).

132. *Id*. at 629.

133. *Id*. at 629-30.

134. *Id*. at 630.

"state tort claims are available when APHIS regulatory standards are violated or disregarded."[135] This statement was premised upon acceptance of a letter from the Acting Administrator giving a *post facto* interpretation of the Declaration for purposes of ongoing litigation.[136] Responding at the end of 1995 to a Senator's inquiry on behalf of a constituent involved in a state court suit over vaccine damages, the Acting Administrator opined that in promulgating the final rule in 1992, APHIS "did not intend to preempt common law actions for damages arising from noncompliance with [agency] regulatory standards."[137]

As the only circuit-level pronouncement on the scope of VSTA preemption, these comments likely would carry some weight of their own. Additionally, *Lohr*'s unanimous disposition of noncompliance claims and direct parallels to pre-existing FIFRA jurisprudence supported the Seventh Circuit's reliance on the APHIS clarification of VSTA preemption. Under the prevailing law in the Fourth and the Fifth Circuits, allegations that a pesticide manufacturer failed to meet EPA standards or otherwise comply with FIFRA present a viable claim.[138] Accordingly, *Lynnbrook*

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135. *Id*. at 629.

136. *Id.*

137. *Id*. at 629 & n.7 (relying on a Letter dated Dec. 22, 1995 from Animal and Plant Health Inspection Service Acting Administrator Terry L. Medley, to Senator Paul David Wellstone *re*: Brandt v. Marshall Animal Clinic, 540 N.W.2d 870 (Minn. Ct. App. 1995), *review denied* (Feb. 9, 1996)). Following the Minnesota Court of Appeals decision in *Brandt*, the plaintiffs in that case enlisted the aid of Senator Wellstone in an effort to cause APHIS to clarify its intentions with regard to tort preemption. At the beginning of December 1995, the Senator requested APHIS to "clarify" its preemption declaration before December 26, 1995, so that the Brandts could wield APHIS' "clarification" to their benefit when seeking discretionary review before the Minnesota Supreme Court. In response to this congressional inquiry, and within the time frame required for the Brandts, APHIS confirmed its intent to preempt all non-identical state law. The confirmation of the scope of intended preemption obliquely included state tort law other than to enforce federal standards, but did not expressly so state. *See supra* notes 90-92 and accompanying text. The clarification came in the wake of the Minnesota Appeals Court's and two federal district courts' holdings that APHIS preempted state-law claims in actions alleging harm to cattle by vaccines where it was undisputed that the vaccines fully complied with APHIS' requirements. *Brandt*, 540 N.W.2d at 875 n.3 ("[Plaintiffs] contemplate common law actions involving standards independent of federal standards and do not demonstrate any evidence that the serums used here were in violation of federal standards.") SmithKline Beecham advises that, "Counsel for Lynnbrook [Farms...] also represented the plaintiffs in *Brandt*. Unlike this case, the preemption motion in *Brandt* was not brought until essentially all discovery was completed. . . . Thus it is hardly surprising that Lynnbrook has never claimed, until this Court's decision in *Lohr*, that [the] vaccines failed to meet APHIS standards." Respondent SmithKline Beecham Corporation's Brief in Opposition to Petition for a Writ of Certiorari at 28 &n.8, Lynnbrook Farms v. SmithKline Beecham Corp., 79 F.3d 620 (7th Cir.) (No. 96-125), *cert. denied,* ___ U.S. ___, 117 S. Ct. 178, 64 U.S.L.W. 3086 (U.S. Oct. 7, 1996).

138. *Compare* MacDonald v. Monsanto Co., 27 F.3d 1021, 1024 (5th Cir. 1994) (FIFRA "does not preempt . . . those state laws concerned with herbicide labeling that do not impose any requirement 'in addition to or different from' the FIFRA requirements."), *and* Worm v. American Cyanamid Co., 5 F.3d 744, 748-49 (4th Cir. 1993) (*dictum* to the effect that FIFRA noncompliance might be a basis for a tort action), *and* Moss v. Parks Corp., 985 F.2d 736, 738 (4th Cir.) (consumer could bring private tort action for violation of Federal Hazardous Substances Act's labeling requirements), *cert. denied,* 509 U.S. 906 (1993), *with* Papas v. Upjohn Co., 985 F.2d 516, 519 (11th Cir. 1993), *and* Arkansas-Platte &

Farms' *dicta* should be some limit on wholesale preemption of tort claims that a vaccine did not even meet APHIS' own standards. The only district court decision after *Lohr* to find preemption under VSTA similarly limited its reach: To the extent the plaintiff "intends to prove that the particular batch of [serum] which he received was not in compliance with federal regulations, these actions do not impose requirements different from or in addition to those established by APHIS."[139] Claims should be viable for livestock damage when caused by or attributable in part to demonstrable violation of APHIS standards,[140] or fraud or material non-disclosure in the licensing application, accompanying testing data, or the Outline of Production.[141]

Lynnbrook Farms' counsel developed a valid statutory basis for this preemption "exception" for noncompliance claims, which arguably expands the types of allegations that will survive preemption. Any substandard, defective or otherwise unwholesome or dangerous product is considered "misbranded," even if the manufacturer's or APHIS' testing did not find unsatisfactory results in the required sampling.[142] The argument is that a manufacturer may be in violation of the statute *both* (i) for preparing or selling any worthless, contaminated, dangerous, or harmful vaccine, *and* (ii) for preparing or selling a vaccine that is not registered under or in compliance with APHIS regulations.[143] Greatly abstracted, the provision reads:

Gulf Partnership v. Van Waters & Rogers, Inc., 981 F.2d 1177, 1179 (10th Cir. 1993) both discussed in *supra* notes 44-45.

139. Gresham v. Boehringer Ingelheim Animal Health, Inc., No. 95-CV-3376-ODE, slip op. at 7-8 (N.D. Ga. Aug. 7, 1996) (relying independently upon *Lynnbrook Farms* and its own interpretation of APHIS' December 22, 1995 "clarification" letter to sustain a "bad batch" theory for both negligence and strict-liability claims that the vaccine was "defective"; "Plaintiff's claims may go forward to the extent that they are premised on a 'bad batch' theory. It is important to note, however, that in prosecuting these claims Plaintiff may not challenge the adequacy to the federal regulations or the formula of Alpha-7 approved by [APHIS].").

140. *Cf.* Talbott v. C. R. Bard, Inc., 63 F.3d 25, 29-30 (1st Cir. 1995) (guilty plea to administrative violations does not remove preemption defense in subsequent tort suit), *overruled by* Medtronic, Inc. v. Lohr, 518 U.S. ___, ___, 116 S. Ct. 2240, 2255-61 (1996).

141. *Cf.* ICI Americas, Inc. v. Banks, 440 S.E.2d 38, 42 (Ga. Ct. App. 1993), *aff'd in relevant part* , 450 S.E.2d 671 (Ga. 1994) (finding, lest such allegations become routine and impossible to resolve, that there is preemption for noncompliance claims and even for allegations of fraud in procuring agency approval).

142. 21 U.S.C. §§ 151-153, 156-157 (1994); 9 C.F.R. §§ 102, 102.3, 102.4 (1996).

143. In its attempt to gain Supreme Court review, Lynnbrook Farms advanced its interpretation of section 151 both as a prop for truly viable noncompliance claims (not just for a proven violation which will seldom be known at the time preemption is being adjudged), but also as a statutory indication that compliance alone does not provide a preemptive shield from potential liability. Lynnbrook Farms' Petition for a Writ of Certiorari to the United States Court of Appeals for the Seventh Circuit, at 17-18. ("[The] statute plainly does *not* exempt a corporation from liability for preparing or selling a worthless, contaminated, dangerous or harmful vaccine *even though* the vaccine may have been licensed by APHIS and prepared and sold under and in compliance with [APHIS] regulations.") (original underscoring). In short, a very valid statutory construction was expanded to argue (i) implausibly that tort preemption was beyond delegated authority, or (ii) at least--and much more validly--that Lynnbrook Farms' state-law claims should have been allowed, regardless whether SmithKline Beecham's vaccines were in compliance with APHIS regulations, so long as Lynnbrook

> It shall be unlawful for any person, firm, or corporation to prepare, sell, barter, or exchange . . . any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product intended for use in the treatment of domestic animals, *and* no person, firm, or corporation shall prepare, sell, barter, exchange or ship [such product] as aforesaid...unless and until the said virus, serum, toxin, or analogous product shall have been prepared, under and in compliance with regulations prescribed by the Secretary of Agriculture at an establishment holding an unsuspended and unrevoked license issued by the Secretary of Agriculture [APHIS] as hereinafter authorized.[144]

Bifurcating Section 151 at the conjunctive prohibitions, a manufacturer can be in violation of the statute for selling a worthless, contaminated, dangerous, or harmful vaccine, even if it had been prepared in a duly licensed facility and in full compliance with applicable regulations and production conditions. A violation of the first half of the section is completely separate from a showing that the product was not prepared under and in compliance with APHIS requirements or that the manufacturing facility was unlicensed, or had its registration suspended or revoked.

The viability of a vaccine claim absent a material question of fact on the manufacturer's actual violation of a regulatory protocol or licensing condition is quite distinct from the Seventh Circuit's formulation. There is no doubt that the actual number of claims that will fit into the *Lynnbrook Farms* exception is narrower than the noncompliance universe entertained by the *Lohr* plurality,[145] or by the only post-*Lohr* preemption ruling yet to issue under VSTA. The Northern District of Georgia could conform its order more to *Lohr*, naturally, then could the Seventh Circuit in its *Lynnbrook Farms* opinion issued before the Supreme Court's decision. Under the formulation seemingly adopted for the Northern District of Georgia, allegations of defect or ineffectiveness might survive preemption even without a

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Farms alleged that they were worthless, contaminated, dangerous or defective when sold. *See* Stange v. Norden Labs**.,** Inc., CIV 91-4125 (S.D.S.D. tried Nov. 1992) (trial involving the identical vaccine involved in Lynnbrook Farms on a jury instruction that "Compliance with Regulations is not, in and of itself, sufficient to exempt a manufacturer from liability.") (suit was filed before the Preemption Declaration was issued, and the court refused retroactive application of APHIS' regulation), *settled pending appeal* (8th Cir.).

144. 21 U.S.C. § 151 (1994) (emphasis added).

145. The *Lohr* Court stated the following:

> Although the precise contours of their theory of recovery have not yet been defined (the pre-emption issue was decided on the basis of the pleadings), it is clear that [their] allegations may include claims that [the manufacturer] has, to the extent that they exist, violated [federal] regulations. At this early stage in the litigation, there was no reason for the Court of Appeals to preclude altogether the Lohrs' manufacturing and labeling claims to the extent that they rest on claims that [the manufacturer] negligently failed to comply with duties "equal to, or substantially identical to, requirements imposed" under federal law.

Lohr, 518 U.S. at ___, 116 S. Ct. at 2255-56.

specific allegation of an affirmative violation of a regulatory standard.

Under this somewhat more generous interpretation offered by the Northern District of Georgia in the wake of *Lohr*, few, if any, plaintiffs could survive summary judgment once proof of licensure and required testing is presented by the manufacturer. Still more plaintiffs will be defeated after discovery fails to produce facts establishing an outright violation, even where there is no material question that the harm suffered by the inoculated livestock was caused by the vaccine. Even the Northern District of Georgia formulation does not permit challenge to the approved formula or manufacturing practices, though there might be liability only in instances where the defective or dangerous product can be shown to have originated with a batch or lot not made in compliance with the Outline of Production or other applicable regulations.[146]

In refusing to stay the mandate or reconsider its opinion in light of *Lohr*, the Seventh Circuit made evident the panel's (and a majority of the active judges') belief that no changes were necessitated by the intervening damper on medical-device preemption.[147] By limiting its holding on noncompliance claims to allegations of actual regulatory violations by the manufacturer, the Seventh Circuit narrowed the claims not preempted to a very limited group. So restricted, the noncompliance "exception" to preemption is essentially nullified except in those rare instances where known violations exist.

It must be noted, however, that the case went to summary judgment on

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[146]. Gresham v. Boehringer Ingelheim Animal Health, Inc., No. 95-CV-3376-ODE, slip op. at 8 (N.D. Ga. Aug. 7, 1996). In stipulating that there was no violation of SmithKline Beecham's Outline of Production or the applicable regulations, Lynnbrook Farms also was led at oral argument before the Seventh Circuit to concede that all counts of its amended complaint would be preempted if the Court were to find that APHIS' declaration covered state tort claims where the product was either ineffective at stopping disease or was itself harmful or unsafe. Respondent SmithKline Beecham Corporation's Brief in Opposition to Petition for a Writ of Certiorari at 11, Lynnbrook Farms v. SmithKline Beecham Corp., 79 F.3d 620 (7th Cir.) (No. 96-125), *cert. denied*, ___ U.S. ___, 117 S. Ct. 178, 64 U.S.L.W. 3086 (U.S. Oct. 7, 1996).

[147]. The interplay of developments in *Lynnbrook Farms* and the litigation of *Lohr* is an interesting aside. Not only had *Lynnbrook Farms* enlisted the advice and counsel of Public Citizen Litigation Group that represented the Lohrs, but the Seventh Circuit's denial of the original April 3, 1996 petition for rehearing and suggestion for rehearing *en banc* came on April 22, 1996, the day before the Supreme Court heard argument in *Lohr*. Following *Lohr*, Lynnbrook Farms filed a motion with the Seventh Circuit again to reconsider either its judgment of March 21, 1996, or the April 22, 1996 order denying rehearing. In recognition that the mandate had issued, Lynnbrook Farms next moved the Seventh Circuit to recall the mandate on July 8, 1996. Even though the appeals court had ordered SmithKline Beecham to brief a response, the Supreme Court's deadline required Lynnbrook Farms to file its petition for a writ of certiorari on July 22, 1996. Thereafter, and upon consideration of the parties' substantive arguments concerning the effect of the various *Lohr* opinions, the Seventh Circuit on Aug. 5, 1996, denied the motion to recall the mandate. This action allowed SmithKline Beecham to argue that application of *Lohr* to the facts of the case had already been evaluated by the Seventh Circuit. Respondent SmithKline Beecham Corporation's Brief in Opposition at 11-12. As no other circuit had ruled on the scope of APHIS preemption and there was no way to predict whether a split in authority would develop, SmithKline Beecham argued that the Supreme Court did not need to address the questions raised by Lynnbrook Farms and that there was no need to remand the case to the Seventh Circuit because it had already reviewed its judgment in light of *Lohr*. *Id*. at 13-14.

Lynnbrook Farms' stipulation of no contested facts and no need for discovery on preemption issues, because it did allege in its complaint that the vaccines were defective and ineffective in that they failed to protect against the diseases they were designed to counteract, or alternatively were unreasonably dangerous, unsafe, and harmful in that the vaccines caused other injuries to the cattle.[148] While these contentions were accepted as true for purposes of the preemption upheld in *Lynnbrook Farms*,[149] no more specific noncompliance allegations could be offered by Lynnbrook Farms.[150] In later cases it may be possible to distinguish the extremely narrow exception accepted by the Seventh Circuit, based upon the procedural posture on which the plaintiff rested. However, there is nothing in the opinion itself on which definitely to restrict insistence on a manufacturer's failure to meet some APHIS standard for distribution, packaging, labeling, manufacture, testing, or design.

Summary judgment on the pleading alone can be justified only by rejecting a distinction between a proven violation and a vaccine that did not work or caused harm, as suggested by Lynnbrook Farms' bifurcating interpretation of Section 151: VSTA can be violated by the manufacture or sale of a worthless, contaminated, dangerous, or harmful vaccine, even if the vaccine has been prepared in a duly licensed facility and in full compliance with applicable regulations. Even without showing a violation of the latter licensing conditions, a unwholesome, dangerous, or ineffective vaccine violates VSTA in a way that permits a damages action at common law.

A possible legislative revision to the existing jurisprudence should clarify whether the sale of a product that is worthless, contaminated, dangerous, or harmful is still in violation of VSTA when all APHIS regulations and requirements have been met. Such a clarification of section 151 will broaden the number of noncompliance claims that are provable, but also will breathe life into an exception that seems stillborn in the Seventh Circuit.

X. STRICT-LIABILITY CLAIMS ARE PREEMPTED

Lynnbrook Farms involved two counts sounding in strict products liability, "apparently based on the theory that the vaccines were defective and unreasonably dangerous."[151] As with the generic negligence allegation that the vaccines caused or failed to prevent infections or diseases that struck treated livestock, any strict-

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148. *Id*. at 6-7.

149. Lynnbrook Farms v. SmithKline Beecham Corp., 79 F.3d 620, 623 (7th Cir. 1996).

150. Lynnbrook Farms argued:

> [S]ince the preemption issue in this case was decided at the pleading stage and since no discovery regarding compliance had yet been taken, Lynnbrook Farms had no ability on personal knowledge, other than by alleging in its complaint that the vaccines were unsafe and inefficacious, to develop a factual dispute regarding the compliance issue.

Lynnbrook Farms' Petition at 17.

151. *Lynnbrook Farms*, 79 F.3d at 630.

liability theory would impose a requirement "regarding at least the safety (if not also the efficacy, purity and potency) of the cattle vaccines different from the requirements enforced by APHIS."[152] All such claims for strict product liability, whether premised in design, testing, manufacture, or otherwise, would be preempted,[153] as were strict-liability failure-to-warn claims mentioned above.[154]

XI. CONCLUSIONS IN THE AFTERMATH OF LYNNBROOK FARMS

There is little doubt of APHIS' authority to pre-empt tort claims, and that the Seventh Circuit's *Lynnbrook Farms* approach was generally consistent with existing preemption analysis. *Lohr* not only fails to impugn the preemption found, but reinforces most of the tenets of the Seventh Circuit decision. All three *Lohr* opinions emphasize the implementing agency's interpretation, and the plurality and Justice Breyer's concurrence accord the FDA's preemption interpretation almost dispositive credence. In the context of APHIS' declaration, similar deference to agency authority will undoubtedly validate the near total preemption the Seventh Circuit and lower courts have deemed APHIS to have established. This article will not comment on the merits of barring recovery to those who suffer injury or other damages from livestock vaccines, but unequivocally supports four proposed legislative actions.

A. Make Tort Preemption Express

At the outset, Congress should have done its job and clarified exactly how much of state tort law the APHIS regulatory program is intended to preempt in the interest of national uniformity under the Virus-Serum-Toxin Act. Leaving that decision to APHIS bureaucrats or the politically appointed head of the Department of Agriculture may be a permissible delegation of power, but such delegation is most objectionable when wholesale usurpation of state judicial power is accomplished merely by notice-and-comment rulemaking within the agency. If tort preemption is consistent with Congress' view of the required uniformity of vaccine administration, it should explicitly delineate the scope of federal preemption as it has with regard to human vaccines for the inoculation of children and others.[155]

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152. *Id.*

153. *Id.*; Gresham v. Boehringer Ingelheim Animal Health, Inc., No. 95-CV-3376-ODE, slip op. at 8 (N.D. Ga. Aug. 7, 1996) (challenges to a vaccine's APHIS-approved formula or to "the adequacy of federal regulations . . . are clearly preempted"); Murphy v. SmithKline Beecham Animal Health Group, 898 F. Supp. 811, 818 (D. Kan. 1995) (Count I for strict liability for defective products is preempted); Brandt v. Marshall Animal Clinic, 540 N.W.2d 870, 878 (Minn. Ct. App. 1995) (total preemption because "claims of strict liability, defective design, negligence, misrepresentation, false advertising, and breach of implied warranties of merchantability and fitness, all impose requirements different from or in addition to the Inspection Service's standards.").

154. *Lynnbrook Farms*, 79 F.3d at 630.

155. Congress can act directly, as it did in the National Childhood Vaccine Injury Act (NCVIA), 42 U.S.C. §§ 300aa-1 to 300aa-34 (1994), and companion Vaccine Compensation Amendments, 26 U.S.C. §§ 9510-9510(a) (1994), in which Congress established an administrative compensation scheme that (i) is no-fault, (ii) is without required proof of causation if the injuries are consistent with vaccine

B. Consumer Disclosure of Preemption and Lack of Compensation

Additionally, those using vaccines on their livestock should receive full disclosure that no compensation mechanisms, including those traditionally available at common law, exist for livestock losses if a VSTA product is ineffective in preventing disease or itself injures the animals. Legislation concerning human vaccines include notification of the administrative compensation scheme and the requirements it imposes. Only with similar advance knowledge can cattle breeders and other livestock producers make an informed decision to utilize available products. While APHIS might have sufficient confidence in a vaccine's purity, potency, safety, and effectiveness to deem damages actions preempted in almost every instance, those whose livelihoods depend upon their animals might risk disease rather than the gamble of a vaccine causing injury or death.

C. Clarify Noncompliance Liability in Line with Lohr *by Redrafting Section 151*

Even where a vaccine manufacturer could demonstrate its compliance with all regulatory requirements, some tort liability may be justified—as it is justified for human-vaccine injuries if administrative compensation is waived. While the agency believes manufacturers who have violated VSTA standards would be subject to common-law liability, there is no guarantee that courts will so limit the preemptive effect of APHIS' comprehensive regulatory framework. Consequently, there is potentially no recovery for livestock losses even where a manufacturer is alleged to have violated or entirely disregarded APHIS requirements. Additionally, given the realities of litigation, such an exception to preemption likely will benefit few injured vaccine users, even if alleging a "bad batch." Escaping preemption at the discovery stage is far from accumulating the factual proof of a manufacturer's noncompliance sufficient to support a verdict. Congress should clarify that Section 151 can be violated by the manufacture or sale of a worthless, contaminated, dangerous, or harmful vaccine, even if it had been prepared in a duly licensed facility and in full compliance with applicable regulations.

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reactions, and (iii) is relatively quick and uncomplicated in comparison to a common-law liability suit. If an injured person opts out of the compensation fund, for example because the special magistrates award too little economic damages, or because non-economic recovery is limited to $250,000, the effect of the NCVIA on tort remedies is explicitly stated. First, the NCVIA requires that the trial of any tort liability under state law take place in three phases--liability, compensatory damages, and punitive damages--and limits the amount of punitive damages potentially recoverable. 42 U.S.C. §§ 300aa-23(a), 300aa-23(d) (1994). It also extinguishes any common-law claim that direct warnings were owed to the injured person and forbids a state-law award intended to compensate for the unavoidable side effects of biologic inoculation, or injuries that flow therefrom. 42 U.S.C. §§ 300aa-22(b)(1), 300aa-22(c) (1994). Finally, the NCVIA makes presumptive for injuries arising after the effective date of the compensation program, that a vaccine's warning was valid if it complied with FDA requirements. 42 U.S.C. §§ 300aa-22(b)(1), (2) (1994). The legislative purposes and history behind this vaccine scheme are cited *supra* note 90.

D. Administrative Compensation?

Indeed, the current state of the law has no administrative compensation for livestock damages, has almost entirely eliminated common-law or statutory remedies, and will possibly prevent recovery even for violations of APHIS standards if the courts do not expand the minor limitation *Lynnbrook Farms* and APHIS' clarification place on its preemptive reach. Congressional action is certainly required to establish exactly what virulence APHIS regulation should have over state common-law duties, and to require warnings to livestock interests that vaccine preemption may be worse than risking the diseases and maladies treatment is intended to prevent.

In the best of all possible worlds, perhaps a marginal tax on animal vaccines should be imposed by Congress to create a fund for the compensation of livestock losses unavoidably caused by vaccines and serums. If such a no-fault scheme is adequate for childhood-vaccine injuries, surely it should be for animal husbandry. If the burden of a tax was justified for the human compensation scheme, obviously it would satisfy the purely monetary, and probably more restricted, damages suffered when animal vaccines cause losses.