UNEQUAL PROTECTION UNDER THE LAW: WHY FDA SHOULD USE NEGOTIATED RULEMAKING TO REFORM THE REGULATION OF GENERIC DRUGS

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The duty to ensure the safety of drug products, through adequate warnings or other means, should ultimately rest with the drug's manufacturer regardless of whether the drug is a generic drug or a brand-name drug. Recent U.S. Supreme Court holdings, however, suggest that while the manufacturer of a brand-name drug is always responsible for its label's content, this is not the case for generic drugs. In addition, by holding that failure-to-warn claims against generic drug manufacturers based on state law are preempted, the Court has removed the protections and compensation that state tort law can provide consumers of generic drugs and exposed a gap in the regulation of generic drugs in which no manufacturer is responsible for updating the labeling.

This Article argues that to remedy these issues, the Food and Drug Administration (FDA) should use negotiated rulemaking to work with drug manufacturers, consumer representatives, healthcare providers, and other interests to create new drug regulations. Although FDA has not used the negotiated rulemaking process set forth by the Negotiated Rulemaking Act of 1990 to date, the current regulatory environment has several features that suggest it may be well-suited for negotiated rulemaking. In addition, employing negotiated rulemaking to create new drug regulations may yield benefits over conventional notice-and-comment rulemaking and may ultimately produce a more effective and legitimate rule.

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INTRODUCTION

Suppose that two patients each go to a doctor and receive a prescription for the same brand-name drug. Each patient then takes her prescription to a pharmacist to be filled. One patient receives the brand-name drug. The other—consistent with a state law permitting or requiring that the pharmacist substitute a therapeutically equivalent generic drug for the brand-name drug—receives a generic drug.[1] Each patient suffers a similar drug-caused injury, files a lawsuit against the manufacturer of the drug that she took, and alleges that under state law the manufacturer failed to adequately warn of the risk of the injury she suffered. The patient who took the brand-name drug may recover monetarily from the drug's manufacturer for her injuries, but the patient who took the generic drug cannot.[2] The result for the patient who took the generic drug would not change even if the brand-name drug was no longer on the market.

The duty to ensure the safety of a drug product, through adequate warnings or other means, should ultimately rest with the drug's manufacturer regardless of whether the drug is a generic or brand-name product.[3] Recent U.S. Supreme Court decisions, however, suggest that while the manufacturer of a brand-name drug "bears responsibility for the content of its label at all times,"[4] this is not the case for generic drug manufacturers.[5] In *Wyeth v. Levine*, the Court held that the plaintiff's state failure-to-warn claims against the brand-name manufacturer were not preempted because it was possible for the manufacturer to comply

1 *See* NAT'L ASS'N OF BDS. OF PHARMACY, SURVEY OF PHARMACY LAW 67–70 (2013) (identifying thirty-seven states and the District of Columbia that permit a pharmacist to substitute a generic drug, and thirteen states that require generic substitution if certain requirements are met).

2 This may be the reality confronting patients who allege that they were injured by generic drugs because the drugs' manufacturers failed to adequately warn of the risks. *Compare* Schork v. Baxter Healthcare Corp., No. 4:10-cv-00005-RLY-WGH, 2011 WL 4402602 (S.D. Ind. Sept. 22, 2011) (granting summary judgment pursuant to *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), against a plaintiff who required an amputation after receiving a generic version of the drug Phenergan), *with* Wyeth v. Levine, 555 U.S. 555 (2009) (holding that the state failure-to-warn claims of a plaintiff who required an amputation after receiving Phenergan were not preempted).

3 *See infra* Part I.C.2.

4 *Wyeth*, 555 U.S. at 570–71.

5 *See* PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2592 (2011) (Sotomayor, J., dissenting) (citing *Wyeth*, 555 U.S. at 555); *see also* Mut. Pharm. Co. v. Bartlett, 133 S. Ct. 2466, 2479 (2013).

with both state and federal law.[6] In contrast, in *PLIVA, Inc. v. Mensing*, the Court held that the plaintiffs' failure-to-warn claims against the generic drug manufacturers based on state law were preempted because it was impossible for those manufacturers, who cannot independently change their drugs' labels under the current federal law, "to comply with both their state-law duty to change the label and their federal law duty to keep the label the same."[7] Both the majority and the dissent in *Mensing* recognized that, from the perspective of the plaintiffs, finding preemption in *Mensing* but not in *Wyeth* "makes little sense."[8] This seemingly inconsistent result is due to differences in how brand-name and generic drugs are regulated under federal law.

The preemption of state failure-to-warn claims against generic drug manufacturers—and the Supreme Court's subsequent extension of this holding to at least some design-defect claims[9]—could potentially have a widespread effect due to the scope of the generic drug market and the incidence of adverse drug effects. Generic drugs account for approximately eighty percent of the prescriptions dispensed in the United States,[10] and approximately twenty-three to thirty-two percent of drugs are available solely as generics.[11] In addition, in the United States there are approximately 106,000 deaths per year from "nonerror, adverse effects of medications," and the actual magnitude of adverse drug effects is likely greater because that estimate does "not include adverse effects that are associated with disability or discomfort."[12] By holding that state failure-to-warn claims against generic drug manufacturers are preempted, the Supreme Court eliminated the protections that state tort law can provide to consumers of generic drugs through the law's compensation and information disclosure functions. The Court's opinion also exposed a gap in the federal regulation of

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6 *Wyeth*, 555 U.S. at 581.

7 *Mensing*, 131 S. Ct. at 2578; *see also id.* at 2581. The Supreme Court later relied on this holding to conclude that "state-law design-defect claims that turn on the adequacy of a drug's warnings are pre-empted by federal law . . . ." *Bartlett*, 133 S. Ct. at 2470.

8 *Mensing*, 131 S. Ct. at 2581; *id.* at 2583 (Sotomayor, J., dissenting) (internal quotation marks omitted).

9 *Bartlett*, 133 S. Ct. at 2470.

10 Letter from John E. Dicken, Dir. of Health Care, U.S. Gov't Accountability Office (GAO), to Senator Orrin G. Hatch 2, 9 (Jan. 31, 2012), *available at* http://www.gao.gov/assets/590/588064.pdf; IMS INST. FOR HEALTHCARE INFORMATICS, THE USE OF MEDICINES IN THE UNITED STATES: REVIEW OF 2011, at 26 (Apr. 2012), http://www.imshealth.com/ims/Global/Content/Insights/IMS%20Institute%20for%20Healthcare%20Informatics/IHII_Medicines_in_U.S_Report_2011.pdf. The portion of drugs dispensed as generics is even higher (about ninety-three percent) when only drugs for which a generic is available are considered. Letter from John E. Dicken to Orrin G. Hatch, *supra*, at 9; *see also* IMS INST. FOR HEALTHCARE INFORMATICS, *supra* (ninety-four percent).

11 Brief for Marc T. Law et al. as Amici Curiae in Support of Respondents at 18, *Mensing*, 131 S. Ct. 2567 (Nos. 09-993, 09-1039, 09-1501).

12 Barbara Starfield, *Is US Health Really the Best in the World?*, 284 JAMA 483, 484 (2000).

generic drug labeling in which no manufacturer is responsible for updating the labeling.[13]

In apparent recognition of the gravity of these issues, the U.S. Food and Drug Administration (FDA) is "considering a regulatory change that would allow generic manufacturers, like brand-name manufacturers, to change their labeling in appropriate circumstances."[14] FDA has published a notice of proposed rulemaking (NPRM) proposing to amend its regulations for both brand-name and generic drugs "to revise and clarify procedures for application holders of an approved drug . . . to change the product labeling to reflect certain types of newly acquired information in advance of FDA's review of the change" using a modified "changes-being-effected" (CBE) process (FDA's proposed rule).[15] The publication of an NPRM is the first step in notice-and-comment or informal rulemaking set forth by the Administrative Procedure Act (APA).[16]

This Article argues that, rather than proceed with the conventional notice-and-comment rulemaking procedure, FDA should instead use negotiated rulemaking to work with drug manufacturers, healthcare providers, consumers, and other stakeholders to address the issues raised and exposed by *Mensing* and build consensus. Employing negotiated rulemaking to amend FDA's regulations may offer benefits over notice-and-comment rulemaking by fostering the development of a more effective and enforceable rule and increasing the legitimacy of the final rule.

This Article proceeds in several parts: Part I provides an overview of the relevant drug labeling law and the implications of *Mensing*. Part II describes and analyzes several proposals to address these issues and highlights additional issues that should be considered in formulating and evaluating any proposed remedy. Part III provides a discussion of the negotiated rulemaking literature and an overview of the framework for negotiated rulemaking provided by the Negotiated Rulemaking Act of 1990 (NRA). It also discusses FDA's lack of experience with this process. Part IV argues that FDA should use negotiated rulemaking to

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13 *Mensing*, 131 S. Ct. at 2592 (Sotomayor, J., dissenting); Stacey B. Lee, PLIVA v. Mensing*: Generic Consumers' Unfortunate Hand*, 12 YALE J. HEALTH POL'Y L. & ETHICS 209, 239–40 (2012). For both brand-name and generic drugs, a "label" is the "display of written, printed, or graphic matter upon the immediate container of any article," and "labeling" is "all labels and other written, printed, or graphic matter . . . upon any article or any of its containers or wrappers, or . . . accompanying such article." 21 U.S.C. § 321(k), (m) (2012).

14 Brief for the United States as Amicus Curiae Supporting Petitioner at 15 n.2, *Bartlett*, 133 S. Ct. 2466 (No. 12-142); Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67,985, 67,988–89 (proposed Nov. 13, 2013) (to be codified at 21 C.F.R. pts. 314, 610).

15 Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. at 67,985.

16 *See* 5 U.S.C. § 553.

address the issues highlighted in this Article. It also responds to potential critiques of this proposal.

I. PREEMPTION AND THE REGULATION OF DRUGS

A. *Federal Preemption and State Failure-to-Warn and Design-Defect Claims*

As a result of *Wyeth* and *Mensing*, state failure-to-warn claims may be available to a patient injured by the brand-name version of a drug, but not to a patient injured by a generic version of the drug.[17] Both cases involved patient injuries following the administration of a prescription drug and allegations that the manufacturers of the drug failed to warn the patient plaintiff of the risk of the injuries suffered. In one case, however, a brand-name drug was administered; whereas in the other a generic drug was administered, and the preemption results were different. This Section provides a brief overview of both cases as well as the Supreme Court's decision in *Mutual Pharmaceutical Co. v. Bartlett*,[18] which applied *Mensing* in the context of a state design-defect claim.

1. Brand-Name Drugs: *Wyeth v. Levine*

In *Wyeth*, the Supreme Court examined whether federal law preempted a plaintiff's state-law claim that brand-name drug labeling did not contain an adequate warning; the Court ultimately held that it did not.[19] The plaintiff received Wyeth's brand-name anti-nausea drug, Phenergan, when she sought treatment for a migraine headache and accompanying nausea. As a result of the injection of Phenergan, which "causes irreversible gangrene if it enters a patient's artery," the plaintiff developed gangrene and doctors amputated her hand and forearm.[20] The plaintiff alleged that the Phenergan "labeling was defective because it failed to instruct clinicians to use the IV-drip method of intravenous administration instead of the higher risk IV-push method" that the plaintiff received.[21] Wyeth argued that the plaintiff's claims were preempted because it could not comply with both its federal and state labeling duties; it argued that the Federal Food, Drug, and Cosmetic Act

17 *See* Wyeth v. Levine, 555 U.S. 555 (2009); *Mensing*, 131 S. Ct. at 2567.
18 133 S. Ct. 2466 (2013).
19 *Wyeth*, 555 U.S. at 564–65, 581.
20 *Id.* at 559.
21 *Id.* at 560.

(FDCA) and FDA's regulations required it to keep the drug labeling the same as that in its approved New Drug Application (NDA) and that state law required it to change the drug's labeling.[22] Wyeth also argued that enforcing the state-law duty and holding it liable for not removing IV-push injection from the approved methods of administering the drug would obstruct the "purposes and objectives" of the federal regulatory scheme.[23]

The Court rejected both arguments and held that the plaintiff's claims were not preempted on either ground.[24] According to the Court, Wyeth could have unilaterally strengthened its warning under FDA's CBE regulation; thus, it was not impossible for it to comply with both the federal and state requirements.[25] The Court stated that "it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times."[26] Although *Wyeth* dealt with a brand-name drug, some courts—including the Fifth and Eighth Circuit Courts of Appeals[27]—extended its principles to generic drugs.[28]

2. Generic Drugs: *PLIVA, Inc. v. Mensing*

Approximately two years after the Supreme Court held in *Wyeth* that the plaintiff's state failure-to-warn claims against the manufacturer of a brand-name drug were not preempted by federal law, the Court considered whether similar claims against the manufacturers of generic drugs were preempted in *Mensing*, which consolidated cases from the Fifth and Eight Circuits.[29] In each case, the plaintiff was prescribed

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22 Reply Brief for Petitioner at 1–4, *Wyeth*, 555 U.S. 555 (No. 06-1249); Brief for Petitioner at 33–34, *Wyeth*, 555 U.S. 555 (No. 06-1249).

23 Brief for Petitioner at 27, 40–41, *Wyeth*, 555 U.S. 555 (No. 06-1249) (quoting Hines v. Davidowitz, 312 U.S. 52, 67 (1941)).

24 *Wyeth*, 555 U.S. at 581.

25 *Id.* at 571, 573. The Court acknowledged that FDA could have rejected the manufacturer's labeling changes, but concluded that, "absent clear evidence that the FDA would not have approved a change to Phenergan's label," it was not impossible for Wyeth to comply with both the federal and state requirements. *Id.* at 571.

26 *Id.* at 570–71. The Court also concluded that Levine's tort suit did not obstruct Congress's purpose in enacting the regulatory scheme. *Id.* at 581.

27 Demahy v. Actavis, Inc., 593 F.3d 428 (5th Cir. 2010), *rev'd*, PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011); Mensing v. Wyeth, Inc., 588 F.3d 603 (8th Cir. 2009), *rev'd*, *Mensing*, 131 S. Ct. 2567.

28 *See, e.g.*, Weilbrenner v. Teva Pharm. USA, Inc., 696 F. Supp. 2d 1329, 1337–38 (M.D. Ga. 2010) (collecting cases that rejected generic drug manufacturers' preemption defense). *But see* Morris v. Wyeth, Inc., 642 F. Supp. 2d 677, 680, 689 (W.D. Ky. 2009) (denying motion to reconsider dismissal of plaintiff's failure-to-warn claims against generic drug manufacturers based on federal preemption), *adhered to by* No. 1:07-CV-176-R, 2009 WL 736200 (W.D. Ky. Mar. 4, 2009).

29 *See Mensing*, 131 S. Ct. at 2572–73.

Reglan—the brand-name version of the drug metoclopramide—which is used to treat digestive tract problems.[30] Consistent with state law, each plaintiff received a generic version of metoclopramide from her pharmacist and, after taking the drug for several years, developed a severe neurological disorder—tardive dyskinesia.[31] Each plaintiff sued the manufacturer of the generic metoclopramide that she had taken, alleging that the manufacturer was liable under state law for failing to provide adequate warnings in light of "mounting evidence that long term metoclopramide use carries a risk of tardive dyskinesia far greater than that indicated on the label."[32] The plaintiffs argued that the generic manufacturers could have complied with their state-law duties to adequately warn of the drugs' risks by changing the labeling of their products.

In *Mensing*, the Supreme Court held that state failure-to-warn claims against generic drug manufacturers were preempted because it was "impossible" for the manufacturers to comply with both state and federal law.[33] The generic manufacturers could not independently comply with (1) their federal duty that the labeling of their generic drug products be the same as the corresponding brand-name drug labeling, and (2) their state-law duty to change the labeling to strengthen their warnings.[34] The fact that the manufacturers may have been able to propose changes to FDA, which may have eventually led to revised labeling, was not sufficient to prevent preemption because the Court framed the preemption question as whether a party can, under federal law, independently do what is required under state law.[35]

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30 *Id.*

31 *Id.* at 2572–73.

32 *Id.* (internal quotation marks omitted). One plaintiff sued two generic manufacturers. Mensing v. Wyeth, Inc., 562 F. Supp. 2d 1056, 1057–58 (D. Minn. 2008), *rev'd*, 588 F.3d 603 (8th Cir. 2009), *rev'd*, PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011).

33 *Mensing*, 131 S. Ct. at 2578.

34 *Id.*

35 *Id.* at 2578–79. The Court did not decide whether FDA's regulations require generic drug manufacturers to propose a label change to the agency. *Id.* at 2577; *see also id.* at 2586. The Court referred exclusively to the statutes and regulations predating the Food and Drug Administration Amendments Act of 2007 (FDAAA). *Id.* at 2574 n.1. Although FDAAA increased FDA's safety labeling authority, it does not appear to have changed the preemption analysis for generics. *See* FDAAA, Pub. L. No. 110-85, tit. IX, 121 Stat. 823 (2007); FDA, GUIDANCE FOR INDUSTRY, SAFETY LABELING CHANGES—IMPLEMENTATION OF SECTION 505(O)(4) OF THE FD&C ACT 5–6 (July 2013), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/-Guidances/UCM250783.pdf; *see also* Whitener v. PLIVA, Inc., No. 10-1552, 2011 WL 6056546, at *3 (E.D. La. Dec. 6, 2011); *In re* Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II), MDL No. 2243, Civ. No. 08-008 (GEB-LHG), 2011 WL 5903623, at *7 (D.N.J. Nov. 21, 2011).

Several courts have read *Mensing* as not preempting state failure-to-warn claims against generic manufacturers when it is alleged that the generic labeling differed from that of the brand-name drug. *See, e.g.*, Teva Pharm. USA, Inc. v. Super. Ct., 158 Cal. Rptr. 3d 150, 158–59 (Ct. App. 2013) (collecting cases). *But see* Huck v. Trimark Physicians Grp., No. 12-0596, 2013

FDA's interpretation of its regulations was set forth in the United States' amicus briefs.[36] The Court deferred to FDA's interpretation of its regulations as requiring that the generic manufacturer's labeling "always be the same" as that of the brand-name drug and precluding a generic manufacturer from unilaterally strengthening its drug's warnings using the CBE process.[37] FDA interpreted its regulations as permitting a generic manufacturer to use the CBE process to change the labeling of a generic drug only when the change was to match the labeling of the corresponding brand-name drug or to follow FDA's instructions.[38] The Court also deferred to FDA's interpretation that its regulations prevent a generic drug company from sending a "Dear Doctor letter that contain[s] substantial new warning information."[39] The Court distinguished *Wyeth* on the basis that the regulations for generic drugs are "meaningfully different" from the regulations for brand-name drugs.[40]

3. Generic Drugs: *Mutual Pharmaceutical Co. v. Bartlett*

More recently, in *Bartlett,* the Supreme Court held that "state-law design-defect claims that turn on the adequacy of a drug's warnings are

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WL 1749774, at *3 (Iowa Ct. App. Apr. 24, 2013) (finding plaintiff's argument that the generic drug manufacturer was liable "because it failed to update its label to conform with" that of the brand-name drug was "without merit" as a private attempt to enforce the FDCA).

36 *See* Brief for the United States as Amicus Curiae Supporting Respondents at 14–19, *Mensing*, 131 S. Ct. 2567 (Nos. 09-993, 09-1039, 09-1501) [hereinafter U.S. Brief Supporting Respondents]; *see also* Brief for the United States as Amicus Curiae at 12–18, 22 n.10, *Mensing*, 131 S. Ct. 2567 (Nos. 09-993, 09-1039, 09-1501) [hereinafter U.S. Brief]; Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17,950, 17,961 (Apr. 28, 1992) (rejecting comments that stated that FDA's "labeling provisions should be revised to permit ANDA applicants to deviate from the labeling for the reference listed drug to add contraindications, warnings, precautions, adverse reactions, and other safety-related information"); FDA, GUIDANCE FOR INDUSTRY: CHANGES TO AN APPROVED NDA OR ANDA 24 (Apr. 2004) [hereinafter FDA CHANGES GUIDANCE] ("All labeling changes for ANDA drug products must be consistent with section 505(j) of the Act [(codified at 21 U.S.C. § 355(j))].").

37 *Mensing*, 131 S. Ct. at 2575; *see also* Brief Supporting Respondents, *supra* note 36, at 16.

38 *Mensing*, 131 S. Ct. at 2575; U.S. Brief Supporting Respondents, *supra* note 36, at 14–17 & 16 nn.7–8.

39 *Mensing*, 131 S. Ct. at 2576; U.S. Brief Supporting Respondents, *supra* note 36, at 18–19.

40 *Mensing*, 131 S. Ct. at 2582. The manufacturers did not argue "purposes-and-objectives" preemption before the Court. *Id.* at 2581 n.8, 2587. A plurality of the Court read the clause "any Thing in the Constitution or Laws of any State to the Contrary notwithstanding" as "plainly contemplat[ing] conflict pre-emption by describing federal law as effectively repealing contrary state law." *Id.* at 2579 (internal quotation marks omitted). Justice Kennedy, however, did not join that portion of the opinion. *See id.* at 2572.

Four Justices dissented in *Mensing*, arguing that the state failure-to-warn claims were not preempted because the generic drug manufacturers could have proposed a labeling change to the FDA, and if the FDA agreed with the proposed change, it could "initiate a change to the brand-name label, triggering a corresponding change to the generic labels." *Id.* at 2582 (Sotomayor, J., dissenting).

pre-empted by federal law under [*Mensing*]."[41] The Court stated that the state design-defect law "imposes a duty on manufacturers to ensure that the drugs they market are not unreasonably unsafe," which "is evaluated by reference to both [a drug's] chemical properties and the adequacy of its warnings."[42] The Court found that, since the generic manufacturer could not change the drug's design, the state law "ultimately required it to change [the drug's] labeling"[43]—a course of action that had been foreclosed under the Court's decision in *Mensing*. The Court's finding of preemption in *Bartlett* relied heavily on *Mensing* and the regulatory scheme for drug labeling updates,[44] which are the focus of the remainder of this Article.

B. *The Regulatory Framework for Drugs*

The different results in *Wyeth* and *Mensing*—that failure-to-warn claims are not preempted for brand-name drugs, but are for generic drugs—stem from differences in the federal regulation of brand-name and generic drugs.[45] This Article now turns to those differences.

1. Brand-Name Drugs

FDA must approve a drug before it can be marketed in the United States.[46] The drug development and approval process for new chemical

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41 Mut. Pharm. Co. v. Bartlett, 133 S. Ct. 2466, 2470 (2013). The plaintiff was prescribed the brand-name non-steroidal anti-inflammatory drug (NSAID) Clinoril for shoulder pain, but instead received a generic form of the drug from her pharmacist. *Id.* at 2472. After the plaintiff took the drug, "[s]ixty to sixty-five percent of the surface of [her] body deteriorated, was burned off, or turned into an open wound," leaving her "severely disfigured," physically disabled, and "nearly blind." *Id.* She sued the generic drug manufacturer, asserting a design-defect claim under state law. The plaintiff also asserted a failure-to-warn claim, which was dismissed by the district court. Bartlett v. Mut. Pharm. Co., 760 F. Supp. 2d 220, 228–29 (D.N.H. 2011).

42 *Bartlett*, 133 S. Ct. at 2470.

43 *Id.* at 2474. The Court rejected the First Circuit Court of Appeals' reasoning that the generic manufacturer could simply stop selling the drug to comply with both state and federal law. *Id.* at 2477.

Justice Breyer, joined by Justice Kagan, dissented; Justice Breyer argued that it was not impossible for the generic manufacturer to comply with both state and federal law, as the manufacturer could comply by not doing business in the state or paying damages. *Id.* at 2480–82 (Breyer, J., dissenting). Justice Sotomayor, joined by Justice Ginsberg, also dissented; Justice Sotomayor argued that *Bartlett* extended *Mensing* "to pre-empt New Hampshire's law governing design-defects with respect to generic drugs" and, in doing so, "left a seriously injured consumer without any remedy." *Id.* at 2482, 2496 (Sotomayor, J., dissenting).

44 *Bartlett*, 133 S. Ct. at 2476 (majority opinion).

45 *Mensing*, 131 S. Ct. at 2582 (stating that the Court "will not distort the Supremacy Clause in order to create similar pre-emption across a dissimilar statutory scheme").

46 *See* 21 U.S.C. § 355(a) (2012).

entity drugs is time intensive and costly; on average, it takes ten to fifteen years of research and development, and costs over $2 billion dollars.[47] To get a drug approved, the manufacturer must file an NDA, which includes "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use."[48] FDA then evaluates the safety and effectiveness of the drug.[49] FDA must deny the application if it finds that there is not "substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its proposed labeling."[50] FDA also evaluates and approves the drug's labeling, which must include warnings that "describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur."[51]

Consistent with the Supreme Court's statement in *Wyeth* "that the manufacturer bears responsibility for the content of its label at all times,"[52] FDA's regulations provide that a manufacturer must revise the labeling "to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug."[53] Failure to do so may render the drug misbranded in violation of the FDCA.[54] This responsibility is important because the risks of a drug may not emerge until after the drug is approved.[55]

FDA's regulations provide several processes by which a manufacturer can change approved drug labeling. Which processes are available to the manufacturer depends on the change and whether it is minor, moderate, or major under FDA's regulations and guidance.[56] Of

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47 *See* PETER BARTON HUTT, RICHARD A. MERRILL & LEWIS A. GROSSMAN, FOOD AND DRUG LAW 643 (4th ed. 2014).

48 21 U.S.C. § 355(b)(1); *see also id.* § 355(d).

49 21 U.S.C. § 355(b) (listing required contents of a new drug application); *id.* § 355(d) (setting forth grounds for refusing an application); *see also id.* § 321(p) (defining the term "new drug"); Drug Amendments of 1962, Pub. L. 87-781, 76 Stat. 780, 784 (codified as amended in scattered sections of 21 U.S.C.).

50 21 U.S.C. § 355(d). Substantial evidence includes clinical trials. *Id.*

51 21 C.F.R. § 201.80(e) (2013); *see also id.* § 201.57(c)(6).

52 Wyeth v. Levine, 555 U.S. 555, 570–71 (2009).

53 21 C.F.R. § 201.57(c)(6)(i); *see also id.* § 201.80(e). Manufacturers are also subject to post-approval reporting requirements; these requirements include the submission of adverse event reports to FDA. *Id.* §§ 314.80, 314.81.

54 21 U.S.C. §§ 331, 352.

55 *See* David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, 96 GEO. L.J. 461, 472, 477 (2008).

56 21 C.F.R. § 314.70; FDA CHANGES GUIDANCE, *supra* note 36, at 24–26. Minor changes—e.g., an editorial labeling change such as adding a distributor's name—may be described by the manufacturer in an annual report. 21 C.F.R. § 314.70(d); FDA CHANGES GUIDANCE, *supra* note 36, at 26. Major changes—e.g., labeling changes associated with new indications and usage—must be submitted to FDA in a supplement and receive FDA approval before use. 21 C.F.R. § 314.70(b); FDA CHANGES GUIDANCE, *supra* note 36, at 24.

particular relevance to the current discussion are the processes for moderate changes, which were central to both *Wyeth* and *Mensing*.[57]

For moderate changes, the manufacturer must submit a CBE supplement to FDA that explains the basis for the change.[58] For certain labeling changes—e.g., "[c]hanges in the labeling to reflect newly acquired information . . . [t]o add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling under" the agency's prescription drug labeling regulations[59]—FDA permits the manufacturer to make the change when the CBE supplement is received by FDA.[60]

A manufacturer can also use "Dear Health Care Provider Letters" or "Dear Doctor Letters"—letters mailed to physicians and other healthcare providers—to describe updated warnings.[61] FDA considers such letters labeling; therefore, such letters must be consistent with the drug's approved labeling.[62] Thus, the relevant regulations for brand-name drugs provide processes by which a manufacturer can update a drug's labeling.

2. Generic Drugs

The approval process for generic drugs differs from that for brand-name drugs. The Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act) created an abbreviated pathway to market for generic drugs—the Abbreviated New Drug Application (ANDA) process.[63]

There is little legislative history for the Hatch-Waxman Act;[64] however, it is often viewed as reflecting a compromise between generic

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57 *See Wyeth*, 555 U.S. at 568–73; PLIVA, Inc. v. Mensing, 131 S. Ct. 2575–76 (2011).

58 21 C.F.R. § 314.70(c); FDA CHANGES GUIDANCE, *supra* note 36, at 25–26.

59 21 C.F.R. § 314.70(c)(6)(iii); *see also id.* § 201.57; *Wyeth*, 555 U.S. at 569 ("'[N]ewly acquired information' is not limited to new data, but also encompasses 'new analyses of previously submitted data.'") (internal quotation marks omitted); Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 49,603, 49,604, 49,609 (Aug. 22, 2008).

60 21 C.F.R. § 314.70(c)(6); FDA CHANGES GUIDANCE, *supra* note 36, at 25–26. FDA considers the "[a]ddition of an adverse event due to information reported to the applicant or Agency" to fall within this category of moderate changes. *Id.* at 26.

61 *See* 21 C.F.R. § 200.5; FDA, GUIDANCE FOR INDUSTRY AND FDA STAFF: DEAR HEALTH CARE PROVIDER LETTERS: IMPROVING COMMUNICATION OF IMPORTANT SAFETY INFORMATION (Jan. 2014), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatory Information/Guidances/UCM233769.pdf.

62 *See* PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2576 (2011).

63 Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 21 U.S.C., 28 U.S.C. and 35 U.S.C.).

64 *See* Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 187 (1999).

drug manufacturers who were granted an abbreviated approval pathway and brand-name drug manufacturers who gained additional patent protections.[65] A generic drug is approved on the basis of information showing that it is bioequivalent to a reference listed drug (RLD), which is generally a brand-name drug.[66] The manufacturer of a generic drug must also show, among other things, that the proposed labeling for the generic drug "is the *same as*" the RLD's approved labeling.[67]

FDA's regulations, like the statute, provide that an ANDA must include a statement that the proposed labeling "is the same as" the RLD's labeling.[68] The regulations also add that one of the grounds for withdrawal of an approved ANDA is if the product's labeling "is no longer consistent with that" of the RLD.[69] The United States' briefs in *Mensing* set forth FDA's interpretation that these regulations create a continuing requirement of sameness and prevent generic manufacturers

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65 *See, e.g.*, Kristin E. Behrendt, *The Hatch-Waxman Act: Balancing Competing Interests or Survival of the Fittest?*, 57 FOOD & DRUG L.J. 247, 250 (2002); Elizabeth Stotland Weiswasser & Scott D. Danzis, *The Hatch-Waxman Act: History, Structure, and Legacy*, 71 ANTITRUST L.J. 585, 590 (2003); *see also* Abbott Labs. v. Young, 920 F.2d 984, 991 (D.C. Cir. 1990).

66 21 U.S.C. § 355(j)(2)(A)(iv), (j)(4)(F), (j)(7) (2012); FDA, *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, http://www.accessdata.fda.gov/scripts/cder/ob/docs/queryai.cfm (last visited Mar. 16, 2014). An RLD is "the listed drug identified by FDA as the drug product upon which an applicant relies in seeking approval of its abbreviated application." 21 C.F.R. § 314.3; *see also* Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17,950, 17,958 (Apr. 28, 1992) (noting, in the preamble to FDA's ANDA Regulations, that, "[g]enerally, the [RLD] will be the NDA drug product for a single source drug product").

67 21 U.S.C. § 355(j)(2)(A), (j)(4) (emphasis added). The FDCA permits some differences between the labeling of the RLD and generic drugs, namely "changes required because of differences approved under" a prior approval petition or because the drugs "are produced or distributed by different manufacturers." 21 U.S.C. § 355(j)(2)(A)(v), (j)(4)(G); *see also Mensing*, 131 S. Ct. at 2574; Abbreviated New Drug Application Regulations, 57 Fed. Reg. at 17,950, 17,953, 17960-61, 17,984-87 (preamble and final regulations); Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 101, 98 Stat. at 1586 (codified as amended at 21 U.S.C. § 355). FDA's regulations provide a nonexclusive list of permissible differences, which "may include differences in expiration date, formulation, bioavailability, or pharmacokinetics, labeling revisions made to comply with current FDA labeling guidelines or other guidance, or omission of an indication or other aspect of labeling protected by patent or accorded exclusivity under section 505(j)(5)(F) of the [FDCA]." 21 C.F.R. § 314.94(a)(8)(iv).

There was little discussion of the term "the same as" in the legislative history of the Hatch-Waxman Act, but the history that exists suggests that the term was intended to permit at least some differences between a generic drug and the corresponding RLD. A 1984 House Report adopts FDA's policy—set forth in the agency's regulations regarding ANDAs for pre-1962 pioneer drugs—of making no distinction between the terms "identical" and "same," but with respect to the requirement that an ANDA "show that the proposed labeling for the generic drug is the same as that of the listed drug," the Report "recognizes that the proposed labeling for the generic drug may not be exactly the same." H.R. REP. NO. 98-857, pt. 1, at 21–22 (capitalization in original removed). For example, "the name and address of the manufacturers would vary as might the expiration dates for the two products," and if the generic drug uses a color different than the brand-name drug, the "generic manufacturer . . . would have to specify a different color in its label." *Id.* (capitalization in original removed).

68 21 C.F.R. §§ 314.94(a)(8)(iii), 314.127(a)(7); *see also id.* § 314.105(c).

69 *Id.* § 314.150(b)(10). There appears to be no parallel withdrawal requirement explicitly provided in the FDCA.

from using the CBE process or Dear Doctor Letters to make the changes to generic drug labeling required by state law.[70] The Court deferred to this interpretation.[71]

C. *Tort Law and the Regulation of Generic Drugs*

1. The Functions of State Failure-to-Warn Claims: Compensation and Information

Both the majority and the dissent in *Mensing* recognized that the different preemption results make little sense from the perspective of the plaintiffs,[72] who are without a remedy against generic manufacturers for failure-to-warn claims.[73] One important function of tort law is that it provides compensation to injured persons.[74] This is not, however, the only way in which tort law complements the regulatory system; tort law can also bring to light and incentivize the disclosure of drug risk information. For example, David Kessler, former FDA Commissioner, and David Vladeck, former Director of the Federal Trade Commission's Bureau of Consumer Protection, have argued that "FDA's ability to assure the safety of the drugs being marketed in the United States. . . . has long been hamstrung by resource limitations and gaps in the agency's statutory authority," and the drug approval system is based on "clinical testing that cannot, and is not designed to, uncover risks that are relatively rare or have long latency periods."[75] Accordingly,

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70 U.S. Brief Supporting Respondents, *supra* note 36, at 14–19; *see also* U.S. Brief, *supra* note 36, at 12–18, 22 n.10; Abbreviated New Drug Application Regulations, 57 Fed. Reg. at 17,961 (preamble).

71 *Mensing*, 131 S. Ct. at 2575–76.

72 *Id.* at 2581; *id.* at 2583 (Sotomayor, J., dissenting).

73 *See* James M. Beck, *Generic Drug Preemption Scorecard*, DRUG & DEVICE L. BLOG (Sept. 20, 2011, 9:35 AM), http://druganddevicelaw.blogspot.com/2011/09/generic-drug-preemption-scorecard.html.

74 *See, e.g.*, Robert L. Rabin, *Poking Holes in the Fabric of Tort: A Comment*, 56 DEPAUL L. REV. 293, 301 (2007) (noting that "[t]ort, whatever its shortcomings, does double-duty: it is an engine of compensation as well as deterrence").

75 Kessler & Vladeck, *supra* note 55, at 483; *David C. Vladeck*, GEORGETOWN L., http://www.law.georgetown.edu/faculty/vladeck-david-c.cfm (last visited Mar. 16, 2014); *see also* Wyeth v. Levine, 555 U.S. 555, 579 (2009) (stating that state tort suits "serve a distinct compensatory function that may motivate injured persons to come forward with information"); Brief for Marc T. Law et al., *supra* note 11, at 6 (discussing the functions of state tort law suits); Mary J. Davis, *The Battle over Implied Preemption: Products Liability and the FDA*, 48 B.C. L. REV. 1089 (2007) (examining the "preemption doctrine as it relates to the food and drug laws"); Lee, *supra* note 13, at 242–44 (discussing the contributions of state tort law to product safety); Richard A. Nagareda, *FDA Preemption: When Tort Law Meets the Administrative State*, 1 J. TORT L. 4 (2006) (examining the relationship between tort law and the administrative state); Rabin, *supra* note 74, at 301–02 (discussing industry capture, underfunded regulators, and use of industry data); Eric S. Almon, Comment, *Preemption of State Failure-to-Warn Claims After*

litigation can serve an important role in bringing to light information not otherwise available to the agency,[76] and providing "incentives for drug manufacturers to disclose safety risks promptly."[77]

By holding that state failure-to-warn claims against generic manufacturers are preempted, the Court in *Mensing* removed an "important[] layer of consumer protection that complements FDA regulation."[78] As the dissent argued, the majority's opinion "strips generic-drug consumers of compensation when they are injured by inadequate warnings," and "eliminates the traditional state-law incentives for generic manufacturers to monitor and disclose safety risks."[79] As a result, the protections for consumers of generic drugs and brand-name drugs are unequal and, as the Court remarked, the plaintiffs were dealt an "unfortunate hand."[80] Any proposal designed to address the holding in *Mensing* should address this inequality and fulfill both the compensatory and informative functions of tort law.

2. Manufacturer Responsibility for Labeling

Mensing also exposed a gap in the federal regulation of generic drugs and their labeling. The manufacturer of a brand-name drug must ensure that the drug's labeling is appropriately updated as long as the drug is marketed.[81] When the brand-name drug labeling is updated, manufacturers are required to update the labeling of their

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Wyeth v. Levine*: The Regulatory Function of State Tort Law*, 45 U.S.F. L. REV. 215 (2010) (arguing that generic manufacturers should not be immune from state tort liability for defective labeling practices).

76 Kessler & Vladeck, *supra* note 55, at 491–95.

77 *Wyeth*, 555 U.S. at 579.

78 PLIVA v. Mensing, 131 S. Ct. 2567, 2592 (2011) (Sotomayor, J., dissenting); *Wyeth*, 555 U.S. at 579. This holding has also been applied by the Supreme Court to foreclose at least some design-defect claims. Mut. Pharm. Co. v. Bartlett, 133 S. Ct. 2466 (2013).

79 *Mensing*, 131 S. Ct. at 2592; *see also* Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67,985, 67,988–89 (proposed Nov. 13, 2013) (to be codified at 21 C.F.R. pts. 314, 610) ("The *Mensing* decision alters the incentives for generic drug manufacturers to comply with current requirements to conduct robust postmarketing surveillance, evaluation, and reporting, and to ensure that the labeling for their drugs is accurate and up-to-date."); FDA's Response to Pub. Citizen Citizen Petition, Docket No. FDA-2011-P-0675, at 3 (Nov. 8, 2013) [hereinafter FDA Response to Public Citizen], *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2011-P-0675-0009 ("The U.S. Supreme Court's decision in *Pliva v. Mensing* prompted FDA to evaluate its current regulations because this decision, as well as the recent decision in *Mutual v. Bartlett*, may alter the incentives for generic drug manufacturers to comply with current statutory and regulatory requirements to conduct robust postmarketing surveillance, evaluation, and reporting, and to ensure that their product labeling is accurate and up to date." (footnote omitted)).

80 *Mensing*, 131 S. Ct. at 2581.

81 *See supra* Part I.B.1.

corresponding generic drugs accordingly.[82] But if the brand-name drug goes off the market, leaving only the generic versions,[83] there is a gap in the regulatory system.[84] Since manufacturers cannot independently change their generic drug labeling under the current regulatory framework, once the brand-name drug leaves the market, there is no manufacturer responsible for updating the warnings on the labeling in light of newly acquired information.[85] This is particularly concerning given that serious drug risks may not be identified until after generic market entry, and many generic drugs no longer have a marketed corresponding brand-name drug.[86] Any proposal to address the holding in *Mensing* should eliminate this regulatory gap.

II. ANALYSIS OF PROPOSALS TO REFORM THE REGULATION OF GENERIC DRUGS

Commentators have engaged in substantial discussion of *Mensing*. This Part reviews and analyzes the literature on *Mensing* and the issues raised by that case with particular attention to those works that have

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82 *See supra* Part I.B.2.

83 Brief for Marc T. Law et al., *supra* note 11, at 18; *see also* Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. at 67,988 ("[A]s we have learned, brand name drug manufacturers may discontinue marketing after generic drug entry, FDA believes it is time to provide ANDA holders with the means to update product labeling to reflect data obtained through postmarketing surveillance . . . .").

84 Lee, *supra* note 13, at 240–41.

85 *See Mensing*, 131 S. Ct. at 2592–93 (Sotomayor, J., dissenting) (quoting Wyeth v. Levine, 555 U.S. 555, 579 (2009)); *see also* Mut. Pharm. Co. v. Bartlett, 133 S. Ct. 2466, 2480 (2013); Brief for Marc T. Law et al., *supra* note 11, at 28–29; Lee, *supra* note 13, at 241; W. Thomas Smith & Eli G. Phillips, Jr., *Generic Liability, or Lack Thereof, Under Duty-to-Warn: It's All About the Labeling*, 25 HEALTH LAW. 12, 17 (2012) (stating that failure-to-warn claims against the manufacturer of a generic drug that has been designated the RLD "have been largely unsuccessful and repeatedly dismissed"); *see also* Cooper v. Wyeth, No. 09-929-JJB, 2012 WL 733846, at *7–9 (M.D. La. Mar. 6, 2012); Kurt R. Karst, *"RLD Theory of Liability" Continues to Fall Flat; Multiple Court Decisions Build Momentum in Generic Drug Failure-to-Warn Preemption Litigation*, FDA L. BLOG (Mar. 19, 2012, 1:31 AM), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2012/03/rld-theory-of-liability-continues-to-fall-flat-multiple-court-decisions-build-momentum-in-generic-dr.html.

86 PUB. CITIZEN, GENERIC DRUG LABELING 11 (June 2013), *available at* http://www.citizen.org/documents/2138.pdf (identifying 434 approved drugs where only a generic version of the drug is on the market). For the period from January 2008 to March 2013, the study also "identified 53 drugs for which a black-box warning calling attention to serious or life-threatening risks was added after generic market entry." *Id.* at 1, 10; *see supra* note 11 and accompanying text; *see also* 21 C.F.R. § 201.57(c)(1) (2013) (describing "black box" or "boxed" warnings); Judith E. Beach et al., *Black Box Warnings in Prescription Drug Labeling: Results of a Survey of 206 Drugs*, 53 FOOD & DRUG L.J. 403, 410 (1998) ("FDA reserves black box warnings generally for those situations in which 1) there is a strong clinical database to define the risk or hazard, and 2) the medical practitioner's attentiveness to the highlighted risk has important clinical significance that requires the judgment of that practitioner.").

made specific proposals for legislative or regulatory change.[87] This Part also examines the bills introduced in Congress to legislatively overturn *Mensing*, FDA's proposed rule, and the changes that the consumer advocacy group Public Citizen petitioned FDA to make.

The purpose of this analysis is to identify additional issues that should be considered in formulating and evaluating any proposed remedy—not to provide a definitive assessment of the relative strengths and weaknesses of the existing proposals. It does, however, find elements of several of the proposals persuasive when viewed against the twin aims of restoring the protections provided by state failure-to-warn claims for consumers of generic drugs and remedying the gap in the regulation of generic drug labeling that exists when the brand-name version of a drug is no longer marketed.

A. *Changes to the Regulation of Generic Drug Labeling*

1. Proposals

Much of the literature argues that there is a need to reform the federal drug-labeling scheme. FDA's proposed rule, the companion legislation introduced in the U.S. Senate and House of Representatives during the 112th Congress, several academic proposals, and Public Citizen's petition would permit manufacturers to make changes to their generic drug labeling unilaterally using the Prior Approval Supplement (PAS) process, the CBE process, or Dear Doctor Letters.[88] In contrast,

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87 This Article does not consider proposals focused on other potential remedies such as innovator liability, Court reversal or limitation of the *PLIVA* holding, waiver of the preemption defense, or changes to state generic substitution laws. *See, e.g.*, Daniel Kazhdan, Wyeth *and* PLIVA*: The Law of Inadequate Drug Labeling*, 27 BERKELEY TECH. L.J. 893, 917–24 (2012); Allen Rostron, *Prescription for Fairness: A New Approach to Tort Liability of Brand-Name and Generic Drug Manufacturers*, 60 DUKE L.J. 1123, 1183–90 (2011).

88 *See* Patient Safety and Generic Labeling Improvement Act, S. 2295, 112th Cong. § 2 (2d Sess. 2012); Patient Safety and Generic Labeling Improvement Act, H.R. 4384, 112th Cong. § 2 (2d Sess. 2012); Supplemental Applications Proposed Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. at 67,989 (CBE and Dear Health Care Provider Letters); Citizen Petition, Pub. Citizen, Docket No. FDA-2011-P-0675, at 9–10 (Aug. 29, 2011) [hereinafter Citizen Petition], *available at* http://www.regulations.gov/#!document Detail;D=FDA-2011-P-0675-0001 (CBE and PAS); Lee, *supra* 13, at 252-58 (CBE process and Dear Doctor Letters); Allison Stoddart, Note, *Missing After* Mensing*: A Remedy for Consumers of Generic Drugs*, 53 B.C. L. REV. 1967, 1993–96 (2012) (CBE process); Wesley E. Weeks, Comment, *Picking up the Tab for Your Competitors: Innovator Liability After* PLIVA, Inc. v. Mensing, 19 GEO. MASON L. REV. 1257, 1259 (2012) (CBE process and Dear Doctor Letters).

In its response to Public Citizen's Citizen Petition, FDA noted that "many of the issues raised by [the] Petition and the comments submitted to the Petition docket would be more appropriate to address in the context of the proposed rule." FDA Response to Public Citizen, *supra* note 79, at 2; *see also* Supplemental Applications Proposed Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67,985. Accordingly, "[t]o the extent

another proposal (the mandatory-labeling proposal) would make FDA responsible for writing "all mandatory labels for generic drugs" using information from a variety of sources including brand-name and generic drug manufacturers.[89]

These labeling proposals vary with respect to whether they attempt to reconcile different warnings between brand-name drugs and generic drugs, attempt to reconcile different warnings among generic drugs, or permit continuing differences among the labeling of equivalent products. A couple of the proposals that generic drug manufacturers be given control over their labeling also suggest that all manufacturers—whether brand-name or generic—should be required to match label changes regardless of the identity of the manufacturer initiating the change.[90] While such proposals could lead to temporary differences between the labeling of the same drug product, these proposals suggest that any such differences would be short-lived.[91] FDA's proposed rule would also temporarily permit differences between the labeling of the brand-name and generic drugs.[92] In addition, it appears that it would temporarily permit differences between the labeling of generic versions of the same drug.[93] The proposed legislation would permit—but not require—the Secretary of the Department of Health and Human Services (HHS) to "order conforming changes" to the labeling of corresponding versions of the drug—whether brand-name or generic—once a labeling change was made.[94] The mandatory-labeling proposal would require a uniform label for all generic versions of a drug, but is silent as to whether it would require uniformity between the labeling of the brand-name and generic versions of a drug.[95]

In contrast, another proposal states that giving generic drug manufacturers control over their labeling would lead to chemically identical drugs having different labels.[96] Similarly, the Citizen Petition does not include a procedure to reconcile differences between the labels

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that [the] proposed rule, if finalized, would address some (but not all) of [Public Citizen's] requested revisions to the regulations," FDA granted the petition in part and denied it in part. FDA Response to Public Citizen, *supra* note 79, at 2.

See *infra* note 267 for a description of FDA's proposed rule.

89 Sarah C. Duncan, Note, *Allocating Liability for Deficient Warnings on Generic Drugs: A Prescription for Change*, 13 VAND. J. ENT. & TECH. L. 185, 209–10 (2010).

90 *See, e.g.*, Kazhdan, *supra* note 87, at 919; Stoddart, *supra* note 88, at 1996.

91 *See* Kazhdan, *supra* note 87, at 919. See *infra* note 267 for a discussion of FDA's proposed rule and its proposed application to generic drugs.

92 *See* Supplemental Applications Proposed Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. at 67,988.

93 *See id.* at 67,999.

94 Patient Safety and Generic Labeling Improvement Act, S. 2295, 112th Cong. § 2 (2d Sess. 2012); Patient Safety and Generic Labeling Improvement Act, H.R. 4384, 112th Cong. § 2 (2d Sess. 2012).

95 Duncan, *supra* note 89, at 209–10.

96 Weeks, *supra* note 88, at 1289.

of equivalent drug products. Instead, it requests that FDA amend its regulation that permits withdrawal of an approved ANDA if the labeling is no longer consistent with that of the RLD so that the regulation does not apply to a generic manufacturer "permitted to supplement [its] labeling through CBE or PAS procedures."[97]

2. Analysis

a. Labeling Responsibility

i. Generic Drug Manufacturers

The proposals that would make generic drug manufacturers responsible for the labeling of generic drugs and allow them to make labeling changes would restore the consumer protections provided by state failure-to-warn claims and eliminate the gap in the regulation of generic drug labeling that exists when the brand-name version of a drug is no longer marketed.[98] In *Mensing*, the Supreme Court's preemption holding was based on its conclusion that the generic drug manufacturers could not independently change their labels to satisfy their state-law duty.[99] If the generic drug manufacturers could independently change their generic drug labels under federal law to satisfy their state-law duty, it would no longer be impossible for these manufacturers to comply with both state and federal law and the situation would be similar to that in *Wyeth*.[100]

Allowing generic drug manufacturers to unilaterally update their generic drug labeling would also eliminate the gap in the current regulatory scheme because there would always be at least one manufacturer responsible for a drug's labeling. This would be consistent with the "central premise of federal drug regulation" described in *Wyeth* "that the manufacturer bears responsibility for the content of its label at all times."[101]

One critique of permitting generic drug manufacturers to unilaterally update their labeling is that they may over-warn to try to avoid liability.[102] But if the experience with brand-name manufacturers post-*Wyeth* can be used as a guide, this may not be an issue; "in FDA's

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97 Citizen Petition, *supra* note 88, at 1–2.

98 *See, e.g.*, S. 2295; H.R. 4384; Citizen Petition, *supra* note 88, at 1; Kazhdan, *supra* note 87, at 919–20; Lee, *supra* note 13, at 254–56; Stoddart, *supra* note 88, at 1993–94; Weeks, *supra* note 88, at 1289.

99 PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2578 (2011).

100 *See* Wyeth v. Levine, 555 U.S. 555, 572 (2009).

101 *Id.* at 570–71.

102 *See, e.g.*, Duncan, *supra* note 89, at 209.

experience thus far [*Wyeth*] has not unleashed a surge of defensive CBE supplements."[103]

ii. FDA

The mandatory-labeling proposal[104] is less persuasive than the proposals that would make generic manufacturers responsible for the labeling. First, while the mandatory-labeling proposal suggests that the labeling scheme be coupled with a no-fault trust fund to compensate those injured by generic drugs,[105] standing alone, it would not change the preemption result in *Mensing*. If only FDA could draft generic drug labeling, it would still be impossible for manufacturers to independently change their generic drug labeling.[106] Accordingly, the mandatory-labeling proposal would not restore the layer of consumer protection that state failure-to-warn claims can provide through its compensatory, deterrent, and informative functions.

The mandatory-labeling proposal also would not address the regulatory gap exposed by *Mensing*. If a brand-name drug leaves the market after generic entry, the gap where no manufacturer is responsible for the labeling would remain. While the proposal would make FDA responsible for the content of the generic labeling in this situation[107]—as well as when the brand-name is on the market—FDA may not have the resources to effectively update the labeling for all of the generic drugs on the market. The Court recognized a similar concern in *Wyeth*, stating that "[t]he FDA has limited resources to monitor the 11,000 drugs on the market."[108] The resource limitation concern carries over to the generic drug context, as many brand-name drugs have generic versions.[109] The studies the Court cited in *Wyeth* in support of this concern identify issues that are not confined to brand-name drug regulation—specifically, scientific deficiencies resulting from increased demands on FDA and resource limitations, and post-market safety process and data issues[110]—and are sufficient to raise serious

103 U.S. Brief Supporting Respondents, *supra* note 36, at 34.

104 *See* Duncan, *supra* note 89, at 209–10.

105 *Id.*

106 *See* PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2577 (2011).

107 Duncan, *supra* note 89, at 209–10.

108 Wyeth v. Levine, 555 U.S. 555, 578 (2009); *see also id.* at 578 n.11.

109 *See supra* note 11 and accompanying text; *see also* Transcript of Oral Argument at 37, *Mensing*, 131 S. Ct. 2567 (Nos. 09-993, 09-1039, 09-1501) (arguing on behalf of respondents that FDA "doesn't have the resources necessary to pay attention to every adverse event report it gets and every report that is published in the scientific literature").

110 FDA SCI. BD., SUBCOMM. ON SCI. & TECH., FDA SCIENCE AND MISSION AT RISK 2 (2007), *available at* http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_01_fda%20report%20on%20science%20and%20technology.pdf; INST. OF MED. OF THE NAT'L ACADS., THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC 193–94 (Alina Baciu et al. eds., 2007); U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-06-402, DRUG

questions about FDA's ability to effectively handle the responsibility of drafting labels for all generic drugs.[111]

b. Uniformity

The proposals differ with respect to whether they contemplate uniform labeling for different versions of the same drug or permit continuing labeling differences.[112] There are three primary results that could flow from the proposals. First, the law could require uniform labeling for all versions of a drug (whether brand-name or generic).[113] Second, it could permit the labeling for generic versions of a drug to differ from the brand-name drug and from each other.[114] Third, it could require uniform generic drug labeling but permit differences between the labeling of brand-name and generic versions of a drug.[115] Regardless of the degree of uniformity required, the labeling of different versions of the same drug may differ for a period of time due to a delay between when one manufacturer changes its labeling and the other manufacturers make conforming changes.[116]

Differences in the labeling of different versions of the same drug—whether continuing or short-lived—have the potential to create confusion.[117] While this may weigh against creating a drug labeling system in which labeling differences are permitted to persist, this should not be a basis for keeping the status quo with respect to generic drug labeling. The current regulatory system for drug labeling also results in differences between the labeling of brand-name drugs and their generic

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SAFETY: IMPROVEMENT NEEDED IN FDA'S POSTMARKET DECISION-MAKING AND OVERSIGHT PROCESS 5 (Mar. 2006).

111 *See* Kessler & Vladeck, *supra* note 55, at 483–86; *see also* Mut. Pharm. Co. v. Bartlett, 133 S. Ct. 2466, 2484 (Sotomayor, J., dissenting) (discussing the "important 'complementary' role" state common law plays to federal drug regulation and the limitations of federal regulatory review and FDA's resources).

112 *See supra* Part II.A.

113 *See, e.g.*, Stoddart, *supra* note 88, at 1994–96.

114 *See, e.g.*, Weeks, *supra* note 88, at 1289.

115 *See, e.g.*, Duncan, *supra* note 89, at 209–10.

116 *See, e.g.*, Supplemental Applications Proposed Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67,998–99 (proposed Nov. 13, 2013) (to be codified at 21 C.F.R. § 314.70(c)(8)(iii), (iv)); Comments of Am. Ass'n for Justice in Response to Citizen Petition, Docket No. FDA-2011-P-0675 (Mar. 2, 2012), *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2011-P-0675-0007; Kazhdan, *supra* note 87, at 919.

117 *See, e.g.*, U.S. Brief Supporting Respondents, *supra* note 36, at 4 (stating that "FDA places 'a very high priority [on] assuring consistency in labeling,' so as 'to minimize any cause for confusion among health care professionals and consumers as well as to preclude a basis for lack of confidence in the equivalency of generic versus brand name products.'" (alteration in original)); Duncan, *supra* note 89, at 209 (arguing against giving generic manufacturers more control over the labeling of their drugs because it "would lead to confusing differences in warning labels, not only between generics and brand-name drugs, but also among generics"). *But see* Weeks, *supra* note 88, at 1289–90 (arguing that doctors could evaluate labeling differences).

counterparts. A recent study looking at safety labeling consistency found that "bioequivalent medications frequently differ in their safety labeling."[118] The study suggests that many of these differences may result from generic drug manufacturers' delays in implementing labeling changes following a brand-name manufacturer's labeling update.[119] The study noted that "[f]rom a practical perspective, achieving true harmonization across all versions of a drug is a tremendous challenge," and some delay between the time when a brand-name manufacturer changes its labeling and when the generic drug manufacturers update their labeling is inevitable.[120] Indeed, FDA guidance recognizes that generic labeling updates will not be instantaneous.[121] This suggests that reform should seek to decrease the amount of time between one manufacturer's label change and others' conforming updates. For example, the proposed legislation would permit the Secretary to order conforming changes to corresponding versions of the drug,[122] and an academic proposal suggests a regulation requiring "sameness among all manufacturers' labels."[123] Procedural mechanisms could be used to minimize the period in which labeling differences persist. For example, a manufacturer that initiates a label change for a drug could be subject to reporting and notification requirements, and other manufacturers making versions of that drug—whether brand-name or generic—could be required to update their labels within a specific time period following the initial change.[124]

Permitting generic drug manufacturers to independently change their labeling may lead to differences among the labeling of different versions of the same drug and contradict FDA's policy of promoting the sameness of brand-name and generic drugs.[125] But under the current

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118 Jon Duke et al., *Consistency in the Safety Labeling of Bioequivalent Medications*, 22 PHARMACOEPIDEMIOLOGY & DRUG SAFETY 294, 299 (2013).

119 *Id.* at 300.

120 *Id.*

121 *See id.*; FDA, GUIDANCE FOR INDUSTRY: REVISING ANDA LABELING FOLLOWING REVISION OF THE RLD LABELING 5 (May 2000), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072891.pdf (stating that generic drug labeling revisions to match the labeling of the RLD "should be made at the very earliest time possible").

122 Patient Safety and Generic Labeling Improvement Act, S. 2295, 112th Cong. § 2 (2d Sess. 2012); Patient Safety and Generic Labeling Improvement Act, H.R. 4384, 112th Cong. § 2 (2d Sess. 2012).

123 Stoddart, *supra* note 88, at 1996.

124 *See* Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67,985, 67,998–99 (proposed Nov. 13, 2013) (to be codified at 21 C.F.R. § 314.70(c)(8)(ii)–(iv)).

125 *See, e.g.*, Comments of Pharm. Assocs., Inc., in Response to Citizen Petition, Docket No. FDA-2011-P-0675 (Oct. 14, 2011), *available at* http://www.regulations.gov/#!document Detail;D=FDA-2011-P-0675-0005; *see also* U.S. Brief Supporting Respondents, *supra* note 36, at 4; David M. Dudzinski, *Reflections on Historical, Scientific, and Legal Issues Relevant to Designing Approval Pathways for Generic Versions of Recombinant Protein-Based Therapeutics*

regulatory system, generic and brand-name versions of a drug are not the same with respect to an injured person's potential remedies,[126] which is not consistent with the principle of sameness.[127] Changing the preemption result in *Mensing* by permitting generic manufacturers to independently change their labeling removes this inconsistency in potential remedies and is consistent with the principle of sameness.

c. Information

Another critique of making generic manufacturers responsible for updating the labeling of their generic drugs is that—although it would give those injured by generic drugs a potential remedy in the form of state failure-to-warn claims—it would not advance the other purposes of tort law because "brand-name manufacturers are better positioned to revise warning labels than generic drug companies."[128] Underlying this objection is the idea that generic manufacturers do not have the information needed to meaningfully fulfill new labeling obligations.[129] If generic manufacturers do not have access to such information, then it does not make sense to make them responsible for labeling and to use tort liability to incentivize them to update their labels and to expose information.[130] While it has been argued that generic drug manufacturers do not have the information needed to meaningfully fulfill an obligation to update their labels,[131] the focus should be on tools that would enable generic drug manufacturers to fulfill this obligation going forward.

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and Monoclonal Antibodies, 60 FOOD & DRUG L.J. 143 (2005) (quoting an FDA advertisement for generic drugs as stating, "To make sure your *generic drug* meets your approval, it first has to get ours. . . . We make it tough to become a generic drug in America so it is easy for you to feel confident. . . . *Generic Drugs: Safe. Effective. FDA Approved.*").

126 *See generally* PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011); Wyeth v. Levine, 555 U.S. 555 (2009).

127 *Mensing*, 131 S. Ct. at 2593 (Sotomayor, J., dissenting).

128 Duncan, *supra* note 89, at 209; *see also* Comments of Actavis, Inc., in response to Citizen Petition, Docket No. FDA-2011-P-0675, at 3–5 (Nov. 8, 2011) [hereinafter Actavis Comment], *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2011-P-0675-0008.

129 *See* Actavis Comment, *supra* note 128, at 3–5.

130 *See supra* Part I.C.1.

131 *See* Transcript of Oral Argument at 24, *Mensing*, 131 S. Ct. 2567 (Nos. 09-993, 09-1039, 09-1501) ("Generics don't have a practice—they're not even set up—to go and figure out what label changes would be appropriate."); Actavis Comment, *supra* note 128, at 3–5 (arguing that "ANDA Sponsors Receive Only a Small Fraction of Adverse Reaction Reports Sent and Do Not Have the Resources to Contextualize Those They Receive"); Lee, *supra* note 13, at 245 (arguing that generic drug manufacturers do not have the knowledge base to suggest labeling changes).

B. *Increased Information Sharing and Reporting*

1. Proposals

Two of the proposals would couple generic manufacturer labeling responsibility with additional tools to fulfill that responsibility. One proposal argues that, in order for generic drug manufacturers to be able to "make meaningful labeling suggestions, they need complete access to the clinical, animal, and bioequivalence data submitted in the brand-name manufacturer's NDA."[132] It proposes that generic manufacturers be given access to—and be required to analyze—"(1) post-approval safety activities, (2) reports to worldwide regulators, (3) safety-focused epidemiologic activities, (4) activities required for safety-related labeling changes, (5) literature review for adverse-event information, and (6) safety information provided to healthcare professionals."[133] Furthermore, the proposal suggests that generic manufacturers be included in discussions with FDA and the brand-name manufacturer to discuss labeling revisions once the brand-name manufacturer's patent expires.[134] Another proposal argues that generic drug manufacturers should be given access to an adverse event reporting database, which brand-name and generic drug manufacturers would contribute to and monitor.[135]

Although it does not request that generic manufacturers be given access to additional information to help them fulfill their proposed labeling obligations, the proposal in Public Citizen's petition would require generic drug manufacturers to report all clinically significant hazards to FDA.[136]

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132 Lee, *supra* note 13, at 252.

133 *Id.* at 253.

134 *Id.* at 254.

135 *See* Stoddart, *supra* note 88, at 1994–95.

136 Citizen Petition, *supra* note 88, at 2, 10–11. FDA denied Public Citizen's request "that FDA amend its regulations to clarify that all ANDA holders are required to report safety concerns to FDA as soon as they become aware of a clinically significant hazard . . . . because the current regulations at 21 CFR 314.80 [(Postmarketing Reporting of Adverse Drug Experiences)], 314.81 [(Other Postmarketing Reports)], and 201.57(c)(6) [(Specific Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products Described in § 201.56(b)(1); Full Prescribing Information; Warnings and Precautions)] clearly apply to ANDA holders." Response to Public Citizen Petition, *supra* note 79, at 5.

2. Analysis

One possible objection to placing increased monitoring or analytic responsibilities on generic drug manufacturers is that doing so will increase the price of generic drugs.[137] The intent of the Hatch-Waxman Act, however, was to produce safe and effective drugs—not just cheaper drugs.[138] Furthermore, much of the cost savings for generic drugs is because the manufacturers must show that their generic drug is bioequivalent to the RLD and do not have to conduct costly clinical trials.[139] Even if generic drugs had increased regulatory responsibilities under a revised generic labeling system, these development cost savings would persist.[140]

Brand-name manufacturers and commentators may object to generic manufacturers accessing data from brand-name manufacturers because of intellectual property concerns.[141] The disclosure of additional data, however, may be justified as a means of protecting the public health.[142] Addressing any concerns will likely require the participation of both brand-name and generic drug manufacturers.

C. *Creation of a No-Fault Generic Trust Fund*

1. Proposal

One proposal suggests that, in addition to making FDA responsible for generic drug labeling, Congress should create a no-fault, government-administered generic drug trust fund to provide compensation for unforeseen adverse generic drug reactions.[143] The trust fund would be similar to the National Childhood Vaccine Injury

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137 *See, e.g.*, Duncan, *supra* note 89, at 209.

138 Abbreviated New Drug Application Regulations, 54 Fed. Reg. 28,872, 28,884 (proposed July 10, 1989) (stating that the purpose of section 505(j) of the FDCA "is to assure the marketing of generic drugs that are as safe and effective as their brand-name counterparts").

139 *See* 21 U.S.C. § 355(j) (2012). For example, according to FDA, "[t]he main reason generic drug companies can market their drugs at lower prices is that they don't face the same development costs as brand-name companies." *Greater Access to Generic Drugs*, U.S. FDA (Jan. 2006), http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143545.htm; *see also* Lee, *supra* note 13, at 252.

140 Lee, *supra* note 13, at 252.

141 *See id.*

142 *See* Aaron S. Kesselheim & Michelle M. Mello, *Confidentiality Laws and Secrecy in Medical Research: Improving Public Access to Data on Drug Safety*, 26 HEALTH AFF. 483, 490 (2007) (suggesting that "[d]isclosing safety data from clinical trials would allow protection of most commercially valuable information and better balance our interests in drug innovation and patient safety"); *see also* Lee, *supra* note 13, at 259 (arguing that "Congress did not aim to bar the public from safety and effectiveness data").

143 Duncan, *supra* note 89, at 209–15.

Compensation Program (VICP);[144] it would provide a remedy outside of the tort law system for certain individuals injured by a generic drug which would be paid for with "minor taxes on generic drugs."[145] Under the VICP, a plaintiff alleging that a vaccine covered by the program caused harm must file a petition pursuant to the National Childhood Vaccine Injury Compensation Act of 1986 (the Vaccine Act), and may not bring a civil action against a vaccine manufacturer unless certain conditions are met.[146] The generic drug trust fund would "only compensate individuals for unforeseen adverse reactions" and "cap compensation, bar punitive damages, and offer the right to accept or appeal judgments."[147]

2. Analysis

The proposal that FDA-controlled generic drug labeling be coupled with a no-fault trust fund for generic drugs may restore one of the important functions of tort law—the compensation of consumers injured by generic drugs.[148] Despite its statement to the contrary, the proposal would neither change the preemption result in *Mensing* nor incentivize manufacturers to bring to light information that is not otherwise available to FDA.[149] The proposal advances FDA labeling and a trust fund for generic drugs as an alternative to the tort law system on the basis that "in certain critical respects, generic drugs resemble vaccines."[150] Although the proposal acknowledges that differences between vaccines and generic drugs may make proving causation difficult in the context of generic drugs, it does not examine or account for the differences between generic drugs and vaccines that may render the proposed trust fund for generic drugs unworkable.

First, the public health benefits of vaccines in reducing the prevalence of preventable diseases have been widely recognized.[151]

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144 While not entirely clear, the proposal appears to differ from the VICP (which permits a petitioner to file a civil suit against the vaccine manufacturer after complying with certain requirements of the Vaccine Act), at least when coupled with the mandatory-labeling proposal, because it states that use of the FDA labeling would preempt failure-to-warn claims against the manufacturer. *Compare* 42 U.S.C. § 300aa-21(a) (2012), *with* Duncan, *supra* note 89, at 210.

145 Duncan, *supra* note 89, at 213.

146 *Id.* at 210–15; 42 U.S.C. § 300aa-11.

147 Duncan, *supra* note 89, at 213–14.

148 *See id.* at 214. The proposal may not provide all consumers a remedy because the proposal suggests that "[t]he fund should only compensate individuals for unforeseen adverse reactions." *Id.* Thus, a person injured by an inadequate warning on a generic drug where the adverse reaction was foreseeable would not be eligible for compensation.

149 *See id.*

150 *Id.* at 213.

151 *See, e.g.*, Gordon Ada, *Vaccines and Vaccination*, 345 NEW ENG. J. MED. 1042, 1051 (2001) ("The remarkable success of many vaccines, especially those administered in childhood,

Vaccines not only offer potential benefits to individuals who are vaccinated, but (when vaccination rates are high) also provide community immunity.[152] In contrast, generic drugs have a variety of indications, which are not limited to disease prevention,[153] and discussions of the public health benefits of generic drugs focus on cost savings and adherence rates.[154]

Second, the generic drug market differs from the vaccine market. Prior to the enactment of the Vaccine Act, one vaccine manufacturer had temporarily withdrawn from the market, citing the lack of affordable liability insurance, and there was concern that other vaccine manufacturers would follow.[155] In 1983, "there were only five major commercial manufacturers of vaccines that are widely used in the United States."[156] Accordingly, there was concern that if any of the manufacturers left the market it "could create a genuine public health hazard"—"vaccine shortages, . . . increasing numbers of unimmunized children, and, perhaps, a resurgence of preventable diseases."[157] Even today the number of vaccines licensed in the United States is limited, and there is only a single sponsor for many of the vaccines.[158] In

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and their impressive safety record, together with the eradication of smallpox, are regarded among the greatest public health achievements of the 20th century."); Saad B. Omer et al., *Vaccine Refusal, Mandatory Immunization, and the Risks of Vaccine-Preventable Diseases*, 360 NEW ENG. J. MED. 1981, 1981 (2009) (stating that "[v]accines are among the most effective tools available for preventing infectious diseases" and that "[h]igh immunization coverage has resulted in drastic declines in vaccine-preventable diseases").

152 *Community Immunity ("Herd" Immunity)*, NAT'L INST. OF ALLERGY & INFECTIOUS DISEASES (Oct. 21, 2010), http://www.niaid.nih.gov/topics/pages/communityimmunity.aspx ("When a critical portion of a community is immunized against a contagious disease, most members of the community are protected against that disease because there is little opportunity for an outbreak" and "[e]ven those who are not eligible for certain vaccines . . . get some protection because the spread of contagious disease is contained.").

153 The FDA maintains a searchable database of drugs which contains information about brand-name and generic drugs approved by FDA. *See Drugs@FDA*, U.S. FDA, http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm (last visited Feb. 9, 2014).

154 *See, e.g.*, GENERIC PHARM. ASS'N (GPHA), GENERIC DRUG SAVINGS IN THE U.S. (4th ed. 2012), *available at* http://www.gphaonline.org/media//cms/IMSStudyAug2012WEB.pdf; William H. Shrank et al., *The Implications of Choice: Prescribing Generic or Preferred Pharmaceuticals Improves Medication Adherence for Chronic Conditions*, 166 ARCHIVES OF INTERNAL MED. 332, 332–37 (2006) (finding that prescribing generic drugs is associated with improvements in medication adherence).

155 H.R. REP. NO. 99-908, at 6–7 (Sept. 26, 1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6347–48; *see also* Peter H. Meyers, *Fixing the Flaws in the Federal Vaccine Injury Compensation Program*, 63 ADMIN. L. REV. 785, 788 n.11 (2011) ("Prior to the passage of the Vaccine Act, the persistent threat of tort liability claims caused pharmaceutical companies to consider and threaten to abandon the vaccine market, and some had already done so. There was real concern that there might be no manufacturers for certain vaccines in the United States.").

156 Walter A. Orenstein et al., *Immunizations in the United States: Success, Structure, and Stress*, 24 HEALTH AFF. 599, 603 (2005).

157 H.R. REP. NO. 99-908, at 7.

158 *See id.*; *Complete List of Vaccines Licensed for Immunization and Distribution in the US*, U.S. FDA (Nov. 25, 2013), http://www.fda.gov/BiologicsBloodVaccines/Vaccines/Approved

contrast, the current generic drug market appears to be growing,[159] the number of approved generic drugs is much greater,[160] and multiple manufacturers often make generic versions of a single drug.[161] In addition, the indications for generic drugs are diverse and include both potentially lifesaving drugs and drugs for less serious conditions.[162]

The differences between vaccines and generic drugs are significant for the no-fault trust fund proposal. The VICP distinguishes between "Table" and "off-Table" injuries.[163] The vaccine injury table (the Table) lists illnesses, disabilities, injuries, and conditions that are presumed to have been caused by the listed vaccine if the claimant can show that the injury or condition occurred within the specified time frame.[164] Currently, there are seventeen categories of vaccines listed on the Table.[165] If the injury or condition is not on the Table or did not occur within the specified time period, the claimant must prove that the

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Products/ucm093833.htm; *see also* Aaron Kesselheim, *Safety, Supply, and Suits—Litigation and the Vaccine Industry*, 364 NEW ENG. J. MED. 1485, 1486 (2011).

159 *See generally* SOPHIA SNYDER, IBISWORLD INDUSTRY REPORT 32541b: GENERIC PHARMACEUTICAL MANUFACTURING IN THE US 14 (June 2012) [hereinafter GENERIC INDUSTRY REPORT] (discussing growth in the generic drug industry).

160 *See, e.g.*, *ANDA (Generic) Drug Approvals*, U.S. FDA, http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/drugandbiologicapproval reports/andagenericdrugapprovals/default.htm (last visited Mar. 17, 2014); *Drugs@FDA*, *supra* note 153 (search original abbreviated new drug approvals (ANDAs) by month).

161 *See* FDA, FACTS ABOUT GENERIC DRUGS 3 (2012), *available at* http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/Understanding GenericDrugs/UCM305908.pdf.

162 Two examples serve to illustrate the diversity of generic drug indications. Lamivudine, an antiretroviral agent for the treatment of human immunodeficiency virus (HIV-1), and Finasteride, a drug for the treatment of male pattern hair loss, have both been approved by the FDA in generic form. *Drugs@FDA*, *supra* note 153 (search "lamivudine" and "finasteride"); *see, e.g.*, APOTEX CORP., *Lamivudine*, FDA ONLINE LABEL REPOSITORY (Aug. 2013), http://www.accessdata.fda.gov/spl/data/c4fb4148-5693-f27c-ff69-adc021f93091/c4fb4148-5693-f27c-ff69-adc021f93091.xml (ANDA No. 091606); DR. REDDY'S LABS. LTD., *Finasteride*, FDA ONLINE LABEL REPOSITORY (Aug. 2012), http://www.accessdata.fda.gov/spl/data/0917aaac-8122-3208-97f8-33205bc7dbb2/0917aaac-8122-3208-97f8-33205bc7dbb2.xml (ANDA No. 076436); Press Release, Dr. Reddy's, Dr. Reddy's Announces the Launch of Finasteride Tablets (Jan. 3, 2013), *available at* http://www.drreddys.com/media/popups/02-jan-2013.html. The diversity of generic drug indications raises the question of whether all drug injuries should be treated the same. For example, should the program cover equally a generic drug that is indicated to treat male patterned baldness and a potentially lifesaving antiretroviral generic drug for the treatment of HIV? And, if not, is there a principled and workable way to distinguish between different generic drugs? Furthermore, if generics are covered by a non-fault trust, should this protection be expanded to brand-name drugs—the manufacturers of which invest substantial resources in developing the new drug products in the first place—or other products, whether FDA-regulated or not?

163 42 U.S.C. § 300aa-11 (2012) (describing the process of filing petitions for compensation for vaccine-related injuries); Meyers, *supra* note 155, at 796–98 (discussing the vaccine injury table and its significance in the VICP).

164 *See* 42 C.F.R. § 100.3 (2013) (Vaccine Injury Table).

165 *Id.*

vaccine caused the injury or condition.[166] In effect, the Table makes it easier for some claimants to prove that vaccine caused the injury and, accordingly, to get compensation.[167]

Creating a similar table for generic drugs is likely to be challenging due to the number of generic drugs and, as the proposal recognizes, the "many confounding factors [that] could contribute to an adverse reaction."[168] Thus, many of the claims in a generic drug no-fault trust fund likely would be off-Table.[169] If the trust fund were restricted to cover only "unforeseen adverse reactions" (as proposed),[170] all of the claims would be off-Table claims. This is significant because it has been argued that the shift to off-Table claims in the VICP has contributed to "serious problems" and that the VICP does not meet the needs of potential claimants who may have been injured by vaccines.[171] The no-fault generic drug trust fund proposal does not address these critiques and challenges. Significant differences in the public health benefits of vaccines and generic drugs, the markets for such products, and the array of indications approved for such products, as well as critiques of the VICP, weigh against creating a no-fault trust fund for generic drugs.

D. *Summary: Issues for Consideration*

The analysis of the proposals suggests that, in addition to restoring the protections that state failure-to-warn claims provide for consumers of generic drugs and eliminating the gap in the regulation of generic drug labeling that exists when the brand-name version of a drug is no longer marketed, there are several other issues that should be considered and addressed in any proposal. These issues include: (1) who should be able to make labeling changes and under what circumstances; (2) how to encourage appropriate and timely warnings; (3) whether and how to reconcile differences between the labeling of different versions of a drug

166 42 U.S.C. §§ 300aa-11, -13; *see* Meyers, *supra* note 155, at 798.

167 *See* Meyers, *supra* note 155, at 798.

168 Duncan, *supra* note 89, at 214.

169 Indeed, in recent years, "almost 90% of the petitions filed [under the VICP] assert only non-Table injuries." Meyers, *supra* note 155, at 798.

170 Duncan, *supra* note 89, at 214.

171 Meyers, *supra* note 155, at 788, 791, 799–806 (arguing that, while the interests of vaccine manufacturers, healthcare providers, and federal health care agencies have largely been met by the Vaccine Act, which created the VICP, "[f]or persons who may have been injured by vaccinations, the need for expeditious, generous, and predictable compensation remains unmet. . . . [T]he process of adjudicating vaccine cases today is seriously flawed and in need of repair."); *see also* U.S. GOV'T ACCOUNTABILITY OFFICE, GAO/HEHS-00-8, VACCINE INJURY COMPENSATION: PROGRAM CHALLENGED TO SETTLE CLAIMS QUICKLY AND EASILY 12–14 (Dec. 1999); Lainie Rutkow et al., *Balancing Consumer and Industry Interests in Public Health: The National Vaccine Injury Compensation Program and Its Influence During the Last Two Decades*, 111 PENN ST. L. REV. 681, 717–21 (2007) (examining criticisms of the VICP).

after a labeling change; and (4) whether there is a need for increased information sharing, reporting, or producing in order for manufacturers to fulfill any new regulatory responsibilities.

III. NEGOTIATED RULEMAKING

This Article began by identifying issues in generic drug regulation that flow from and are highlighted by the *Mensing* decision. It then critiqued several proposals to address those issues. In so doing, it identified additional issues for consideration in any reform. This Part provides an overview of negotiated rulemaking and the academic literature on negotiated rulemaking. It also examines FDA's lack of experience with negotiated rulemaking. Part IV then builds on this Part to argue that FDA should employ negotiated rulemaking to address the identified issues.

A. *History and Background*

Negotiated rulemaking—also called regulatory negotiation or "reg-neg"[172]—developed in response to the increasingly formal and adversarial notice-and-comment rulemaking process.[173] In 1982, the Administrative Conference of the United States (the Conference) recommended procedures for negotiating proposed regulations "with a view to minimizing protracted adversary proceedings and litigation" and creating "an improved process and better rules."[174] The Conference

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172 *See, e.g.*, DAVID M. PRITZKER & DEBORAH S. DALTON, ADMIN. CONFERENCE OF THE UNITED STATES, NEGOTIATED RULEMAKING SOURCEBOOK 1 (1995) [hereinafter SOURCEBOOK] (discussing the terminology for negotiated rulemaking); Philip J. Harter, *Assessing the Assessors: The Actual Performance of Negotiated Rulemaking*, 9 N.Y.U ENVTL. L.J. 32, 33 n.1 (same); Jeffrey S. Lubbers, *Achieving Policymaking Consensus: The (Unfortunate) Waning of Negotiated Rulemaking*, 49 S. TEX. L. REV. 987 (2008) (noting that "'regulatory negotiation' or simply 'reg-neg'" are alternative terms for negotiated rulemaking).

173 *See, e.g.*, 5 U.S.C. § 553 (2012) (describing informal or "notice and comment" rulemaking procedures); Recommendations of the Administrative Conference, 47 Fed. Reg. 30,701, 30,708 (July 15, 1982) (discussing the formalization of the rulemaking process and the adverse consequences arising as a result); Philip J. Harter, *Negotiating Regulations: A Cure for Malaise*, 71 GEO. L.J. 1, 28 (1982) (discussing the evolution of the regulatory process and arguing that negotiated rulemaking is preferable to the adversarial process); *see also* Siobhan Mee, Comment, *Negotiated Rulemaking and Combined Sewer Overflows (CSOS): Consensus Saves Ossification?*, 25 B.C. ENVTL. AFF. L. REV. 213, 245 (1997) (discussing the Combined Sewer Overflows negotiated rulemaking and concluding that the negotiations created a consensus that "prevented ossification").

174 Recommendations of the Administrative Conference, 47 Fed. Reg. at 30,701, 30,709; *see also* 1 C.F.R. § 305.82-4 (1983). The Conference is an independent federal agency intended to improve the regulatory process. *See* 5 U.S.C. § 591. Congress defunded the agency in 1995. Treasury, Postal Service, and General Government Appropriations Act of 1996, Pub. L. No.

also urged Congress to pass legislation authorizing agencies to conduct regulatory negotiation.[175]

The Conference's 1982 recommendation was based on a report prepared by Philip Harter.[176] That same year, Harter published a seminal law review article proposing negotiated rulemaking—the development of "rules through negotiation among interested parties"—as an alternative to traditional informal notice-and-comment rulemaking procedures set forth by the Administrative Procedure Act (APA).[177] The informal rulemaking process, Harter argued, had become mired in a "malaise."[178] Harter described aspects of the rulemaking process as having become "bitterly adversarial," and argued that while the adversarial process has benefits in the form of information generation, "quality control," and participation, it also has many drawbacks.[179] Harter argued that it forces participants to take and defend "extreme positions," affects both the selection and presentation of issues, is not suited to "resolving polycentric disputes," encourages defensive factual research, relies heavily on intermediaries, and may create a "perceived lack of legitimacy" in the final rule and decrease

104-52, 109 Stat. 468, 480 (1995); *see also* Gary J. Edles, *The Continuing Need for an Administrative Conference*, 50 ADMIN. L. REV. 101 (1998) (discussing the functions of the Conference and its demise); Toni M. Fine, *A Legislative Analysis of the Demise of the Administrative Conference of the United States*, 30 ARIZ. ST. L.J. 19 (1998) (exploring the demise of the Conference). The agency was subsequently refunded in 2009. *See* Omnibus Appropriations Act of 2009, Pub. L. No. 111-8, 123 Stat. 524, 656; Regulatory Improvement Act of 2007, Pub. L. No. 110-290, 122 Stat. 2914 (2008) (codified at 5 U.S.C. § 596); *see also* Gary J. Edles, *The Revival of the Administrative Conference of the United States*, 12 TEX. TECH ADMIN. L.J. 281 (2011) (discussing the revival of the Conference).

175 Recommendations of the Administrative Conference, 47 Fed. Reg. at 30,709. In 1985, the Conference provided additional recommendations on the procedures for negotiated proposed regulations. Procedures for Negotiating Proposed Regulations, 50 Fed. Reg. 52,893, 52,895 (Dec. 27, 1985); *see also* 1 C.F.R. § 305.85-5 (1986).

176 Harter, *supra* note 173; *see also* SOURCEBOOK, *supra* note 172, at 414 (listing Harter article and background report).

177 Harter, *supra* note 173, at 28; *see also* Danielle Holley-Walker, *The Importance of Negotiated Rulemaking to the No Child Left Behind Act*, 85 NEB. L. REV. 1015, 1036–41 (2007).

In notice-and-comment rulemaking, which is governed by § 553 of the APA, an agency must publish an NPRM in the *Federal* Register, which must be followed by a period of time for comment. 5 U.S.C. § 553; *see also "Informal Rulemaking" Under Administrative Procedure Act*, Drug & Cosm. L. Rptr. (CCH), ¶ 2077 (2013), *available at* 2013 WL 6021251. If, after considering all of the submitted comments, the agency decides to promulgate a final regulation, it must include a "concise general" statement of the "basis and purpose" of the rule. 5 U.S.C. § 553(c). As a result of judicially imposed obligations on notice-and-comment rulemaking, which have "provided parties who are interested in the outcome of a rulemaking a powerful incentive to submit voluminous comments that include multiple objections, criticisms, and proposed alternatives," agencies have "had to issue 'concise, general' statements of basis and purpose hundreds of pages long addressing at length the scores of issues raised in comments." Richard J. Pierce, Jr., *Rulemaking and the Administrative Procedure Act*, 32 TULSA L.J. 185, 192–93 (1996).

178 Harter, *supra* note 173, at 6.

179 *Id.* at 18–19.

"voluntary compliance."[180] This process, Harter noted, leaves businesses, beneficiaries of regulations, and federal agencies dissatisfied.[181]

Harter argued that negotiated rulemaking has significant "advantages over the adversarial process."[182] Negotiation, Harter asserted, permits participants to focus on maximizing their interests rather than staking out extreme positions.[183] He also argued that negotiation can be less costly and time-intensive than the conventional rulemaking process, permit participants to create "workable solutions," and increase the legitimacy of the final rule.[184] However, Harter recognized that negotiation is not appropriate for all rulemaking.[185]

Harter identified several factors that, while not determinative, may help guide the determination of whether negotiations are appropriate:[186] The parties must believe that participation is in their best interests and no party should have the power to impose its will on the others.[187] In addition, the number of parties should be limited; the issues to be resolved concrete and ready for resolution; a decision inevitable or even imminent; the dispute capable of being "transformed into a 'win/win' situation" for the parties; the parties able to agree on fundamental principles; the number of issues sufficient to permit trade-offs; the "[r]esearch [n]ot [d]eterminative of [the o]utcome"; and the implementation of the negotiated agreement likely.[188] Harter emphasized the importance of identifying the interests that should be represented in the negotiations, identifying appropriate representatives of such interests, and obtaining their participation.[189] He argued that the federal agency participation in negotiated rulemaking is appropriate and may be beneficial to the agency.[190] He also suggested processes for assembling negotiators, conducting negotiations, and reporting an agreement.[191]

B. *The Negotiated Rulemaking Act*

In 1990, the NRA was enacted to create a framework for the negotiated rulemaking process and "to encourage agencies to use the

180 *Id.* at 19–22.
181 *Id.* at 24.
182 *Id.* at 28.
183 *Id.* at 29.
184 *Id.* at 28, 30–31.
185 *Id.* at 42.
186 *Id.* at 42–52.
187 *Id.* at 45–46.
188 *Id.* at 46–52.
189 *Id.* at 52–57.
190 *Id.* at 57–67.
191 *Id.* at 67–102. He also discussed judicial review of negotiated rules. *Id.* at 102–07.

process when it enhances the informal rulemaking process."[192] The NRA defines "negotiated rulemaking" as rulemaking using a "negotiated rulemaking committee,"[193] which is an advisory committee established in accordance with the NRA and the Federal Advisory Committee Act (FACA) "to consider and discuss issues for the purpose of reaching a consensus in the development of a proposed rule."[194] The NRA was intended "to provide some basic ground rules and safeguards" for negotiated rulemaking and "was not intended to create new authority."[195] An agency's use of a negotiated rulemaking committee must comply with the FACA—which establishes standards and procedures for the "establishment, operation, administration, and duration of advisory committees"—except as otherwise provided by the NRA.[196] For example, the NRA provides that, notwithstanding the FACA, an agency may nominate a person to serve as a facilitator for the committee negotiations.[197] If the committee does not approve any agency nominee for facilitator, the committee must select a facilitator by consensus.[198] The NRA's provisions are specifically directed to negotiation and consensus as part of the rulemaking process.[199]

Pursuant to the NRA, negotiated rulemaking proceeds in several steps.[200] Before an agency can establish a negotiated rulemaking committee, its head must determine "that the use of the negotiated rulemaking procedure is in the public interest."[201] In making this determination, the agency must consider whether: (1) the rule is needed; (2) "there are a limited number of identifiable interests that will be significantly affected by the rule"; (3) it is reasonably likely "that a committee can be convened with a balanced representation of persons

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192 Negotiated Rulemaking Act of 1990, Pub. L. No. 101-648 § 3, 104 Stat. 4969, 4970 (codified as amended at 5 U.S.C. §§ 561–70a (2012)).

193 5 U.S.C. § 562(6) (2012).

194 *Id.* § 562(7); *see also* Federal Advisory Committee Act, 5 U.S.C. app. 2 §§ 1–15.

195 SOURCEBOOK, *supra* note 172, at 67; Negotiated Rulemaking Act, § 2, 104 Stat. at 4969 ("Agencies have the authority to establish negotiated rulemaking committees under the laws establishing such agencies and their activities and under the Federal Advisory Committee Act.").

196 5 U.S.C. app. 2 § 2(b)(4); 5 U.S.C. §§ 564(a), 565(a), 566(d); *see also* Procedures for Negotiating Proposed Regulations, 50 Fed. Reg. 52,893, 52895 (Dec. 27, 1985) ("[I]t appears that caucuses and other working group meetings [in a negotiated rulemaking] may be held in private, where this is necessary to promote an effective exchange of views."); Steven P. Croley, *Practical Guidance on the Applicability of the Federal Advisory Committee Act*, 10 ADMIN. L.J. AM. U. 111, 121 (1996) (indicating that regulatory negotiation under the NRA triggers FACA).

197 5 U.S.C. § 566(c); *see also id.* app. 2 § 10(e).

198 *Id.* § 566(c).

199 *See id.* §§ 561–570a.

200 The NRA establishes a framework for the process and is not intended "to limit innovation and experimentation with the negotiated rulemaking process." *Id.* § 561.

201 *Id.* § 563. The agency may use a "convener," a person who assists it in "identifying persons who will be significantly affected by a proposed rule" and determining whether negotiated rulemaking is feasible and appropriate. *Id.* §§ 562(3), 563.

who . . . can adequately represent the [identified] interests . . . and . . . are willing to negotiate in good faith to reach a consensus on the proposed rule"; (4) it is reasonably likely that a committee will reach such a consensus "within a fixed period of time"; (5) the "procedure will not unreasonably delay the notice of proposed rulemaking and the issuance of the final rule"; (6) "the agency has adequate resources . . . [that it] is willing to commit . . . to the committee"; and (7) "the agency, to the maximum extent possible consistent with [its] legal obligations . . . will use the consensus of the committee with respect to the proposed rule as the basis for the rule proposed by the agency for notice and comment."[202]

If the agency decides to establish a negotiated rulemaking committee, it must publish a notice in the Federal Register announcing its intention to do so and provide a period for the submission of comments and applications for membership on the committee.[203] The agency may establish a negotiated rulemaking committee if it determines that such a committee "can adequately represent the interests that will be significantly affected by a proposed rule and that it is feasible and appropriate in the particular rulemaking."[204] The committee, including the agency representatives, must negotiate to attempt to reach a consensus on a proposed rule.[205] If the committee reaches a consensus on a proposed rule, it must provide the agency with a report and the proposed rule.[206] If it is unable to reach such a consensus, the committee may provide a report on any areas of consensus.[207] Negotiated rulemaking supplements informal rulemaking under the APA: A rule based on the committee's consensus that is proposed by an agency is still subject to the rulemaking requirements in § 553 of the APA.[208] The committee terminates when the final rule is promulgated unless an earlier date is set forth according to the provisions of the NRA.[209] While agency actions "relating to establishing, assisting, or terminating a negotiated rulemaking committee" are not subject to judicial review, rules created by negotiated rulemaking are subject to judicial review and are not given "any greater deference by a

202 *Id.* § 563.

203 *Id.* § 564.

204 *Id.* § 565(a)(1).

205 *Id.* § 566(a). "Consensus" is defined as "unanimous concurrence" unless the committee "agrees to define [it as] . . . a general but not unanimous concurrence; or . . . agrees upon another specified definition." *Id.* § 562(2).

206 *Id.* § 566(f).

207 *Id.*

208 *See id.* § 561; SOURCEBOOK, *supra* note 172, at 2 ("Negotiated rulemaking should be viewed as supplement to the rulemaking provisions of the [APA]."). See *supra* note 177 for a discussion of the notice-and-comment rulemaking process.

209 5 U.S.C. § 567.

court than a rule which is the product of other rulemaking procedures."[210]

C. *The Debate Concerning Negotiated Rulemaking*

Although negotiated rulemaking has been used infrequently,[211] it has been the subject of ongoing debate. Following Harter's first article on negotiated rulemaking, there has been substantial academic literature in support of negotiated rulemaking;[212] however, there also has been literature critiquing negotiated rulemaking.[213] Commentators are divided over questions of the legitimacy, benefits, and effectiveness of negotiated rulemaking: Supporters of negotiated rulemaking have argued that negotiated rulemaking may further legitimacy and accountability.[214] Critics have countered that it lacks legitimacy and undermines the public interest with private bargaining.[215]

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210 *Id.* § 570.

211 *See* Cary Coglianese, *Assessing Consensus: The Promise and Performance of Negotiated Rulemaking*, 46 DUKE L.J. 1255, 1276, 1277 tbl.2 (1997) (finding that from 1983 to 1996, negotiated rulemaking overall has accounted for less than one-tenth of one percent of final rules); *see also* Lubbers, *supra* note 172, at 1007–17 (listing negotiated rulemaking committees formed or announced from January 1, 1990 to December 1, 2007).

212 *See* William Funk, *Bargaining Toward the New Millennium: Regulatory Negotiation and the Subversion of the Public Interest*, 46 DUKE L.J. 1351, 1353 (1997) (describing the literature on negotiated rulemaking up until the time of his article as "[v]irtually all . . . supportive").

213 *See, e.g.*, Coglianese, *supra* note 211, at 1316–17 (arguing that negotiated rulemaking has not decreased rulemaking time or litigation); Funk, *supra* note 212, at 1356 (arguing that negotiated rulemaking subverts the agency's pursuit of the public interest and replaces it with "privately bargained interests as the source of putative public law"); William Funk, *When Smoke Gets in Your Eyes: Regulatory Negotiation and the Public Interest—EPA's Woodstove Standards*, 18 ENVTL. L. 55, 66–78, 92–96 (1987) (arguing that EPA's regulatory negotiation of woodstove standards had "grave legal infirmities" and substantive problems and turned the agency's role as the representative of the public interest "on its head"); Susan Rose-Ackerman, *Consensus Versus Incentives: A Skeptical Look at Regulatory Negotiation*, 43 DUKE L.J. 1206, 1211 (1994) ("[R]egulatory negotiation is not democratically legitimate unless all interested parties are adequately represented. Agreement among only the subset of interests that have organized advocates is not sufficient.").

214 *See, e.g.*, Jody Freeman, *The Private Role in Public Governance*, 75 N.Y.U. L. REV. 543, 548–49, 666 (2000) [hereinafter Freeman, *The Private Role*] (proposing a conception of administration that views administrative power as a set of negotiated relationships between public and private actors and arguing that "formal legal procedures and agency oversight may provide the appearance of adequate accountability, but a variety of other mechanisms and an array of private parties play an important and undervalued role in legitimizing public/private arrangements"); Jody Freeman, *Collaborative Governance in the Administrative State*, 45 UCLA L. REV. 1, 30–33 (1997) [hereinafter Freeman, *Collaborative Governance*] (discussing accountability in a collaborative system and arguing that there is a need to go beyond traditional notions of accountability and experiment); Jody Freeman & Laura I. Langbein, *Regulatory Negotiation and the Legitimacy Benefit*, 9 N.Y.U. ENVTL. L.J. 60 (2000) (summarizing and analyzing empirical evidence on negotiated rulemaking); Harter, *supra* note 173, at 22, 31, 69, 84, 94 (arguing that the perceived lack of legitimacy resulting from an adversarial rulemaking process may decrease voluntary compliance and that consensus may

There has also been debate over the potential benefits of negotiated rulemaking (such as decreased rulemaking time and fewer judicial challenges to rules) and whether negotiated rulemaking has been successful in producing those benefits. One scholar, Cary Coglianese, challenged the "promise" of negotiated rulemaking as initially described by Harter, concluding that it has not sped up rulemaking or reduced litigation.[216] Harter countered that Coglianese's conclusion was based on research that was "significantly flawed, and hence misleading."[217]

Harter argued that negotiated rulemaking has decreased both rulemaking time and litigation relative to traditional rulemaking.[218] Furthermore, he argued that the central aim of negotiated rulemaking is to create better and more widely accepted rules:[219] In negotiated rulemaking, benefits "flow[] from the participation of those affected, who bring with them a practical insight and expertise that can result in rules that are better informed, more tailored to achieving the actual regulatory goal, and hence, more effective and more enforceable."[220] When viewed through this lens, Harter argued, negotiated rulemaking has been "remarkably successful in fulfilling its promise" as participants have identified a range of positive values.[221] In support of the benefits of negotiated rulemaking, Harter referred to a study of negotiated rulemaking versus conventional rulemaking by Laura I. Langbein and Cornelius M. Kerwin.[222] The study authors stated that there was "strong but qualified support for the continued use of negotiated rule making."[223] In an article summarizing and analyzing that study, Jody Freeman and Langbein noted that, according to study participants, negotiated rulemaking produces "more learning, better quality rules, and higher satisfaction compared to conventional rulemaking."[224] In

confer added legitimacy on a rule); Lawrence Susskind & Gerard McMahon, *The Theory and Practice of Negotiated Rulemaking*, 3 YALE J. ON REG. 133, 133 (1985) (examining the Environmental Protection Agency's first two negotiated rulemakings and concluding that the process, with some refinements, "appears to hold great promise for remedying the crisis of regulatory legitimacy").

215 *See, e.g.*, Funk, *supra* note 213, at 57; Rose-Ackerman, *supra* note 213, at 1208–12.

216 Coglianese, *supra* note 211, at 1335–36.

217 Harter, *supra* note 172, at 40.

218 *Id.* at 45–52.

219 *Id.* at 52–54.

220 *Id.* at 53–54.

221 *Id.* at 33.

222 *Id.* at 55.

223 Laura I. Langbein & Cornelius M. Kerwin, *Regulatory Negotiation Versus Conventional Rule Making: Claims, Counterclaims, and Empirical Evidence*, 10 J. PUB. ADMIN. RES. & THEORY 599, 625 (2000). The authors found that the overall assessments of participants in negotiated rulemaking were "significantly more positive than those of participants in conventional rule making." *Id.* at 626. With respect to the question of whether negotiated rulemaking reduces litigation, the authors found that "negotiated rules appear no more (or less) subject to litigation than conventional rules." *Id.* at 625.

224 Freeman & Langbein, *supra* note 214, at 62.

addition, negotiated rulemaking "reduced conflict between the regulator and regulated entities," "was no less fair to regulated entities than conventional rulemaking," and "increase[d] legitimacy."[225] Freeman has further argued that negotiated rulemaking may "facilitate policy implementation or improve relationships among repeat players, producing payoffs down the line."[226]

D. *FDA and Negotiated Rulemaking*

To date, FDA has not used or been required by Congress to use the negotiated rulemaking process set forth in the NRA.[227] The other major health and safety agencies,[228] however, have used negotiated rulemaking,[229] as have other entities within HHS.[230] Despite having not

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225 *Id.* at 63. There were, however, some weaknesses of negotiated rulemaking, including "the disproportionate costs it imposes on smaller groups with comparatively fewer resources." *Id.*

226 Freeman, *The Private Role*, *supra* note 214, at 656–57.

227 Because the NRA requires that an agency must announce its intention to establish a negotiated rulemaking committee in the Federal Register, *see* 5 U.S.C. § 564(a) (2012), if FDA had formed a negotiated rulemaking committee, there would have been a notice in the Federal Register to that effect. A search of the Federal Register, however, revealed no such notices. *See also* Julia Kobick, *Negotiated Rulemaking: The Next Step in Regulatory Innovation at the Food and Drug Administration?*, 65 FOOD & DRUG L.J. 425, 425 (2010). In addition, searches of the FDCA and the U.S. Public Laws and Statutes at Large revealed no instances in which Congress had required FDA to conduct negotiated rulemaking. *See id.*

The Senate clinical trial reporting bill would have required FDA to use negotiated rulemaking to determine the information and trials to be reported to the clinical trial register, but the final act, the FDAAA, did not. *See id.*; *see also* Food and Drug Administration Revitalization Act, S. 1082, 110th Cong. (1st Sess. 2007). That Congress did not include negotiated rulemaking in the final act, however, should not weigh against using negotiation in the current situation. As Freeman has argued, legislation specifically authorizing an agency to use negotiated rulemaking "may actually be an obstacle to collaboration," and "might undermine local efforts at problem-solving and institutional design." Freeman, *Collaborative Governance*, *supra* note 214, at 92.

228 *See About OSHA*, U.S. DEP'T OF LAB. OCCUPATIONAL SAFETY & HEALTH ADMIN., http://www.osha.gov/about.html (last visited Mar. 18, 2014) (stating that OSHA's mission is "to assure safe and healthful working conditions for working men and women by setting and enforcing standards and by providing training, outreach, education and assistance"); *NHTSA's Core Values*, NAT'L HIGHWAY TRAFFIC SAFETY ADMIN., http://www.nhtsa.gov/About+NHTSA/NHTSA%27s+Core+Values (last visited Mar. 18, 2014) (stating that NHTSA's mission is to "[s]ave lives, prevent injuries and reduce economic costs due to road traffic crashes, through education, research, safety standards and enforcement activity"); *Our Mission and What We Do*, U.S. ENVTL. PROT. AGENCY, http://www2.epa.gov/aboutepa/our-mission-and-what-we-do (last updated Mar. 16, 2014) ("The mission of EPA is to protect human health and the environment.").

229 *See* Coglianese, *supra* note 211, at 1274 tbl.1, 1277 tbl.2 (listing pending and final negotiated rulemakings, including rulemakings of EPA and OSHA, and tallying agencies' use of negotiated rulemaking from 1983 to 1996); Lubbers, *supra* note 172, at 1007–17 (listing negotiated rulemaking committees formed or announced from January 1, 1990 to December 1, 2007, including committees formed for EPA, OSHA, and NHTSA).

used negotiated rulemaking, FDA has shown a willingness to experiment with other possible alternatives to notice-and-comment rulemaking, including informal guidance,[231] which (like negotiated

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230 *See* Lubbers, *supra* note 172, at 1007–17; *see also* Medicare Program; Establishment of Special Payment Provisions and Standards for Suppliers of Prosthetics and Certain Custom-Fabricated Orthotics; Intent to Form Negotiated Rulemaking Committee, 67 Fed. Reg. 13,297, 13,297 (Mar. 22, 2002) (announcing the intent of the Centers for Medicare and Medicaid Services (CMS) to form statutorily mandated negotiated rulemaking committee); Medicare Program: Ambulance Fee Schedule; Intent to Form Negotiated Rulemaking Committee, 64 Fed. Reg. 3474 (Jan. 22, 1999) (announcing the intent of the Health Care Financing Administration (HCFA) to form a statutorily mandated negotiated rulemaking committee); Medicare Program; Coverage and Administrative Policies for Clinical Diagnostic Laboratory Tests; Intent to Form Negotiated Rulemaking Committee, 63 Fed. Reg. 30,166 (June 3, 1998) (announcing the intent of the HCFA to form a statutorily mandated negotiated rulemaking committee); Health Care Programs, Fraud and Abuse; Intent to Form the Negotiated Rulemaking Committee for the Shared Risk Exception, 62 Fed. Reg. 28,410 (May 23, 1997) (announcing the intent of the Office of Inspector General of Department of Health and Human Services (HHS) to form a statutorily mandated negotiated rulemaking committee); Indian Self-Determination and Education Assistance Act Amendments, 61 Fed. Reg. 32,482 (June 24, 1996) (codified at 25 C.F.R. pt. 900) (promulgating final rules for joint Department of Interior (DOI) and HHS statutorily required negotiated rulemaking); Hospice Services Under Medicare Program; Intent to Form Negotiated Rulemaking Committee, 59 Fed. Reg. 52,129 (Oct. 14, 1994) (announcing proposal of the HCFA to use negotiated rulemaking).

231 Informal guidance—"informal agency advice that influences regulated entities but does not carry the force and effect of law"—has been described as FDA's "policymaking weapon of choice." K.M. Lewis, *Informal Guidance and the FDA*, 66 FOOD & DRUG L.J. 507, 507–08 (2011); *see also* Connor N. Raso, Note, *Strategic or Sincere? Analyzing Agency Use of Guidance Documents*, 119 YALE L.J. 782, 783 n.1, 788–89 (2010) (discussing the meaning of "guidance document"). FDA has undertaken reforms of its informal guidance in part aimed at "allowing for greater public participation and clarity in the policymaking process." Lewis, *supra*, at 523; *see also* Todd D. Rakoff, *The Choice Between Formal and Informal Modes of Administrative Regulation*, 52 ADMIN. L. REV. 159, 166–70 (2000). Questions remain, however, as to whether FDA has fully achieved that goal. Lewis, *supra*, at 523. As K.M. Lewis notes, "even though [FDA's Good Guidance Practices] allow for greater public participation, industry representatives still have less ability to provide input on the policies that will ultimately control their operations than [they] would obtain if FDA used notice-and-comment rulemaking," and "regulatory beneficiaries are less likely to involve themselves in guidance development than regulated businesses because the marginal benefit to any one individual from any given change in regulatory policy is unlikely to outweigh the costs of organizing." Lewis, *supra* at 541–42. In addition, there are still unsettled questions about the effect of guidance documents on the agency and the level of deference that courts should give to such documents. *Id.*; *see also* 21 C.F.R. § 10.115 (2013) (describing good guidance practices).

FDA has also experimented with the streamlined processes of direct final rulemaking and interim-final rulemaking. *See* Ronald M. Levin, *Direct Final Rulemaking*, 64 GEO. WASH. L. REV. 1 (1995) [hereinafter Levin, *Direct Final Rulemaking*]; Ronald M. Levin, *More on Direct Final Rulemaking: Streamlining, Not Corner-Cutting*, 51 ADMIN. L. REV. 757, 767 (1999) [hereinafter Levin, *More on Direct Final Rulemaking*]. Direct final rulemaking is "a variation on the normal notice-and-comment model of informal rulemaking," in which "an agency publishes a rule in the Federal Register with a statement that the rule will become effective unless the agency receives an adverse comment or a written notice that someone intends to submit an adverse comment." Levin, *Direct Final Rulemaking*, *supra*, at 1; *see also* Adoption of Recommendations, 60 Fed. Reg. 43,108, 43,110–11 (Aug. 18, 1995) (promulgating the Conference's recommendation that agencies may want to use direct final rulemaking for rules developed through negotiated rulemaking). One analysis of direct final rulemaking at FDA noted that between 1997 and 2008, FDA had proposed direct final rulemaking for thirty-eight

rulemaking) can be viewed as a return to setting policy in less formal ways.[232]

FDA has expressed openness to at least considering the use of negotiated rulemaking.[233] FDA's regulations contain one reference to negotiated rulemaking: the regulations setting forth the required content of a petition to establish or amend a reference amount customarily consumed per eating occasion—which is used to determine serving sizes of foods.[234] These require that a petitioner include a statement in its petition "concerning the feasibility of convening associations, corporations, consumers, and other interested parties to engage in negotiated rulemaking to develop a proposed rule consistent

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rules. Michael Kolber, *Rulemaking Without Rules: An Empirical Study of Direct Final Rulemaking*, 72 ALB. L. REV. 79, 93 (2009). That analysis also found that, rather than using direct final rulemaking for noncontroversial rules (as intended), FDA has instead "often used direct final rulemaking for the opposite: regulations that may be expected to be controversial." *Id.* at 79; *see also* Guidance for FDA and Industry: Direct Final Rule Procedures, 62 Fed. Reg. 62,466 (Nov. 21, 1997) (announcing availability of guidance); FDA, GUIDANCE FOR FDA AND INDUSTRY, DIRECT FINAL RULE PROCEDURES (Nov. 21, 1997), *available at* http://www.fda.gov/RegulatoryInformation/Guidances/ucm125166.htm (describing FDA's direct final rulemaking procedures); *see generally* Lars Noah, *Doubts About Direct Final Rulemaking*, 51 ADMIN. L. REV. 401, 423–28 (1999).

Interim-final rulemaking occurs when an agency adopts a rule that becomes effective without prior notice and public comment and invites public comment after the rule becomes effective. Adoption of Recommendations, 60 Fed. Reg. at 43,111–12; Michael Asimow, *Interim-Final Rules: Making Haste Slowly*, 51 ADMIN. L. REV. 703 (1999) (considering the legal issues arising out of the use of interim-final rules and making recommendations for improvements to the process). A search of the Federal Register identified a number of instances in which FDA has promulgated interim final rules. *See, e.g.*, Establishment, Maintenance, and Availability of Records: Amendment to Record Availability Requirements, 77 Fed. Reg. 10,658 (Feb. 23, 2012) (codified at 21 C.F.R. pt. 1); Exceptions or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile, 72 Fed. Reg. 73,589 (Dec. 28, 2007) (codified at 21 C.F.R. pts. 201, 312, 314, 601, 610, 801, 807, 809, 812, 814); Food Labeling: Health Claims; Plant Sterol/Stanol Esters and Coronary Heart Disease, 65 Fed. Reg. 54,686 (Sept. 8, 2000) (codified at 21 C.F.R. pt. 101); Fees for Certification of Drugs Composed Wholly or Partly of Insulin, 60 Fed. Reg. 56,515 (Nov. 9, 1995); *see also* 21 C.F.R. § 10.40(e) (providing that FDA's regulations regarding notice and public procedure in 21 C.F.R. § 10.40(b) do not apply when FDA "determines for good cause that they are impracticable, unnecessary, or contrary to the public interest"); Administrative Functions, Practices, and Procedures, 42 Fed. Reg. 4680 (Jan. 25, 1977) (notice of final rule); Administrative Practices and Procedures, 40 Fed. Reg. 40,682, 40,689 (proposed Sept. 3, 1975) (notice of proposed rulemaking for 21 C.F.R. § 2.10, which subsequently became 21 C.F.R. § 10.40(e)).

232 *See, e.g.*, Rakoff, *supra* note 231, at 166 (describing negotiated rulemaking, interpretative rules, and guidance as part of the trend toward informality following the ossification of notice-and-comment rulemaking); *see also* Levin, *Direct Final Rulemaking*, *supra* note 231, at 1–2.

233 *See* 21 C.F.R. § 101.12(h). Recent presidential administrations have expressed support for negotiated rulemaking. *See* Exec. Order No. 13563, Improving Regulation and Regulatory Review, 76 Fed. Reg. 3821 (Jan. 18, 2011); Exec. Order No. 12866, Regulatory Planning and Review, 58 Fed. Reg. 51,735, 51,740 (Oct. 4, 1993) ("Each agency . . . is directed to explore and, where appropriate, use consensual mechanisms for developing regulations, including negotiated rulemaking.").

234 21 C.F.R. § 101.12(h).

with the [NRA]."[235] While several companies have submitted petitions,[236] FDA does not appear to have formed a negotiated rulemaking committee to develop a proposed rule in response to such a petition.[237]

The reference to negotiated rulemaking in FDA's food labeling regulations came about as a result of FDA's efforts to reform the food labeling system.[238] In late 1989, FDA issued an advance notice of proposed rulemaking seeking public comment on various aspects of food labeling,[239] which it followed the next year with a proposed rule.[240] Following FDA's proposal, however, there were two developments that shaped the course of its rulemaking: the publication of a report by the National Academy of Sciences' Institute of Medicine on nutrition labeling and the enactment of the Nutrition Labeling and Education Act of 1990 (NLEA).[241] In light of the NLEA, FDA re-proposed its proposed regulation, noting that there were some differences between the NLEA and FDA's earlier proposal as well as some questions.[242] In the preamble to the second proposed regulation, FDA noted that members of the food industry had commented that FDA had developed the 1990 proposal without input from industry and that "[o]ne company [had] suggested negotiated rulemaking on serving sizes to reach a consensus."[243] FDA responded that "negotiated rulemaking was not a practical option," in part due to time constraints imposed by the NLEA, and noted that it

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235 *Id.* § 101.12(h)(14).

236 *See* Food Labeling; Serving Sizes; Reference Amount for Baking Powder, Baking Soda, and Pectin, 64 Fed. Reg. 12,887 (Mar. 16, 1999) (referencing petition from Church Dwight Co. (Docket No. 94P-0240)); Food Labeling; Serving Sizes; Reference Amounts for Candies, 63 Fed. Reg. 1078 (proposed Jan. 8, 1998) (referencing petitions from Nutrition Research Group and Andes Candies, Inc. (Docket No. 96P-0023) and the Chocolate Manufacturers Association (Docket No. 96P-0179)), *withdrawn,* Withdrawal of Certain Proposed Rules and Other Proposed Actions, 69 Fed. Reg. 68,831 (Nov. 26, 2004); Food Labeling; Serving Sizes; Reference Amount and Serving Size Declaration for Hard Candies, Breath Mints, 62 Fed. Reg. 67,775 (proposed Dec. 30, 1997) (referencing petition from Ferrero USA (Docket No. 94P-0168)); Food Labeling; Serving Sizes; Reference Amount for Salt, Salt Substitutes, Seasoning Salts (e.g., Garlic Salt), 62 Fed. Reg. 63,647 (Dec. 2, 1997) (referencing petition to modify the reference amount for salt products (Docket No. 93P-0448)); W. Dale Parker et al., Citizen Petition, Docket No. FDA-2005-P-0269 (June 24, 2005), *available at* http://www.fda.gov/ohrms/dockets/dockets/05p0269/05p-0269-cp00001-toc.htm; *cf.* Kobick, *supra* note 227, at 436.

237 *See supra* note 227.

238 *See also* Kobick, *supra* note 227, at 435–36 (discussing history of 21 C.F.R. § 101.12(h)).

239 Advanced Notice of Proposed Rulemaking, Request for Public Comment, Food Labeling, 54 Fed. Reg. 32,610 (proposed Aug. 8, 1989).

240 Food Labeling; Mandatory Status of Nutrition Labeling and Nutrient Content Revision, 55 Fed. Reg. 29,487 (proposed July 19, 1990).

241 *See* Food Labeling; Serving Sizes, 56 Fed. Reg. 60,394 (proposed Nov. 27, 1991); *see also* Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (codified as amended in scattered sections of 21 U.S.C.); National Academy of Sciences, Institute of Medicine Report on Nutrition Labeling; Availability, 55 Fed. Reg. 40,944 (Oct. 5, 1990).

242 Food Labeling; Serving Sizes, 56 Fed. Reg. at 60,394.

243 *Id.* at 60,397.

had held a public meeting and met with individual companies.[244] Nevertheless, FDA noted that, "in certain circumstances, negotiated rulemaking may be a useful tool in developing new or amended reference amounts" and, as a result, proposed making information about the feasibility of negotiated rulemaking part of a petition to establish or amend a reference amount.[245] This requirement became part of the final rule.[246] In the preamble to the final regulation, FDA responded to a comment from a consumer organization that opposed using negotiated rulemaking to establish reference amounts through petition[247] and retained the requirement that a petition contain a statement regarding the feasibility of negotiated rulemaking.[248] FDA stated that it has discretion with respect to whether to convene a negotiation and that it "is convinced that it is frequently useful to provide a forum for open discussion of particularly contentious issues."[249]

There have also been several reports that FDA has considered using negotiated rulemaking to develop other regulations.[250] Despite expressing an openness to at least consider the use of the negotiated rulemaking process set forth in the NRA, FDA has not acted on suggestions that it use negotiated rulemaking.[251]

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244 *Id.*

245 *Id.*

246 Food Labeling; Serving Size; Technical Amendments, 58 Fed. Reg. 44,039 (Aug. 18, 1993) (codified at 21 C.F.R. pt. 101); s*ee also* 21 C.F.R. § 101.12(h)(14) (2013).

247 Food Labeling; Serving Sizes, 58 Fed. Reg. 2229, 2288 (Jan. 6, 1993) (codified at 21 C.F.R. pt. 101).

248 *Id.*; *see also* 21 C.F.R. § 101.12(h); Kobick, *supra* note 227, at 435–38 (discussing the history of 21 C.F.R. § 101.12(h)(14)).

249 Food Labeling; Serving Sizes, 58 Fed. Reg. at 2288. FDA has indicated that it is considering whether regulations including the regulations in 21 C.F.R. § 101.12 should be retained, amended, or rescinded. *See* Food Labeling; Serving Sizes and Nutrition Labeling (Section 610 Review), 73 Fed. Reg. 71,361 (Nov. 24, 2008).

250 For example, in 1994, it was reported that Office of Chief Mediator and Ombudsman Regulatory Counsel Suzanne O'Shea said that the FDA was considering negotiated rulemaking for a rulemaking on the waiver provisions of the Prescription Drug User Fee Act of 1992 (PDUFA); O'Shea was quoted as saying that it is "the first time FDA has actively considered using [negotiated rulemaking] for issuing a rule." *FDA Waiver of User Fees,* THE PINK SHEET (Nov. 7, 1994) (alteration in original) (internal quotation marks omitted). In 1995, it was reported that FDA was "in the 'early stages' of using the negotiated rulemaking process to develop a proposal on certain waiver provisions authorized by [PDUFA]" and had compiled a list of candidate rules for negotiated rulemaking. *OTC Label Reform, Supplement GMPs Seen as Candidates for Negotiated Rulemaking—HHS,* THE TAN SHEET (Sept. 11, 1995). And in 1996, it was reported that Harvey Rudolph, acting Deputy Director of the Office of Science and Technology in FDA's Center for Devices and Radiological Health indicated that negotiated rulemaking was one option FDA was considering for device software policy development. *Device Software Policy Revisions via Negotiated Rulemaking Under Consideration by FDA*, THE GRAY SHEET (Dec. 23, 1996). He identified "some problems" with negotiated rulemaking, including resource limitations, but said "it is possible." *Id.*

251 For example, in letters in 1995, the American Feed Industry Association (AFIA) requested that in considering amendments to FDA's regulations for liquid medicated animal

Although FDA has not used the negotiated rulemaking process set forth in the NRA, some have argued that FDA has engaged in similar processes in other contexts.[252] For example, FDA's participation in the Second International Conference on Harmonisation (ICH)—a conference that "brings together the regulatory and industry authorities of Europe, Japan and the United States" with the goal of "harmoniz[ing] the interpretation and application of technical guidelines"[253]—has been described as "an international manifestation of negotiated rulemaking."[254] The member regulatory authorities, including FDA, and industry representatives worked to create consensus guidelines to be implemented according to each member country's requirements.[255] The

feed, FDA should use negotiated rulemaking. Requirements for Liquid Medicated Animal Feed and Free-Choice Medicated Animal Feed, 68 Fed. Reg. 31,645, 31,645 (proposed May 28, 2003). AFIA later retreated from this suggestion, indicating that it "anticipated that its concerns would be addressed in the proposed rule and that '[i]f further rulemaking is necessary, then [it] believe[d] negotiated rulemaking would be in order.'" *Id.* The preamble to the final rule did not address this proposal. *See* Requirements for Liquid Medicated Animal Feed and Free-Choice Medicated Animal Feed, 69 Fed. Reg. 30,194 (May 27, 2004) (codified at 21 C.F.R. pts. 510, 558). The AFIA also suggested that FDA consider negotiated rulemaking for reform of claims on pet foods and animal fees in 2002 in response to FDA's request for comments on First Amendment issues. Comments from Feed Control and Nutrition, Am. Feed Indus. Ass'n, in Response to Request for Comment on First Amendment Issues, Docket No. FDA–02N-0209 (Oct. 28, 2002), *available at* http://www.fda.gov/ohrms/dockets/dockets/02n0209/02n-0209-c000091-vol19.pdf. FDA has not responded to this comment to date.

252 In addition, FDA has used consensus standards to address aspects of the safety and effectiveness of medical devices. *See* 21 U.S.C. § 360d(c) (2012); *Guidance for Industry and FDA Staff—Recognition and Use of Consensus Standards*, U.S. FDA (Sept. 17, 2007), http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077274.htm (providing guidance on the use of and voluntary conformance with consensus standards—"[m]any of [which] have been developed with the participation of [FDA's] Center for Devices and Radiological Health . . . staff"); s*ee also Recognized Consensus Standards*, U.S. FDA, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm (last updated Aug. 5, 2013) (listing standards organizations).

253 *International Programs, International Conference on Harmonization (ICH)*, U.S. FDA, http://www.fda.gov/InternationalPrograms/HarmonizationInitiatives/ucm114571.htm (last updated Oct. 11, 2011); *see also Vision*, INT'L CONF. ON HARMONISATION, http://www.ich.org/about/vision.html (last visited Mar. 18, 2014).

254 Joseph G. Contrera, Comment, *The Food and Drug Administration and the International Conference on Harmonization: How Harmonious Will International Pharmaceutical Regulations Become?*, 8 ADMIN. L.J. AM. U. 927, 939 (1995); *see also id.* at 931, 937–40, 940.

255 *See About ICH, Process of Harmonisation, Formal ICH Procedure*, INT'L CONF. ON HARMONISATION, http://www.ich.org/about/process-of-harmonisation/formalproc.html (last visited Mar. 18, 2014) [hereinafter *Formal ICH Procedure*]; *see also* Contrera, *supra* note 254, at 940 n.57 (summarizing the ICH procedure). The harmonization process is overseen by a Steering Committee (SC); the SC includes two voting members from a regulatory authority and two members from an industry trade association from each of the following: the United States, the European Union, and Japan. *About ICH, Organisation of ICH, Steering Committee*, INT'L CONF. ON HARMONISATION, http://www.ich.org/about/organisation-of-ich/steering.html (last visited Mar. 18, 2014). For the United States, FDA and the Pharmaceutical Research and Manufacturers of America (PhRMA) participated. *Id.* The SC appoints and oversees expert working groups (EWG), and EWG committees work to create consensus draft guidelines. *Formal ICH Procedure*, *supra*. When the SC agrees with the EWG "that there is sufficient scientific consensus on the technical issues for the Technical Document to proceed to the next

process was similar to negotiated rulemaking in that it involved negotiation and consensus building;[256] however, it did not follow the formal process set forth in the NRA. It was an international exercise, and the end result in the United States was guidance—not rules.[257] Another example is the process used to amend FDA's regulations as part of its implementation of the Food and Drug Administration Modernization Act of 1997 (FDAMA).[258] Before promulgating a rule through direct final rulemaking, FDA "convened a public meeting . . . to provide interested parties with an opportunity to comment on FDA's current thinking on administration of the . . . process," "received comments," and "considered those comments in developing th[e] direct final rule and the companion proposed rule."[259] While the agency did not use the formal negotiated process set forth by the NRA, the process used has been described as "an analogous process";[260] the agency solicited comment before publishing the direct final rule and only received one comment on the direct final rule.[261]

Furthermore, while FDA has not used a negotiated rulemaking committee, it uses other advisory committees to provide "independent expert advice . . . on a range of complex scientific, technical, and policy

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stage," the SC signs off on the consensus text. *Id.* The regulatory parties develop a draft guideline, which then proceeds to regulatory consultation and discussion. *Id.* In the United States, the draft guideline "is published as draft guidance in the Federal Register." *Id.* Following the consultation process, the EWG group works to address the comments and reach consensus. *Id.* If consensus is reached, the EWG signs-off on the guideline and submits it to the SC for sign-off by the signatories for the regulatory parties. *Id.* The final guideline—an ICH Harmonised Tripartite Guideline—is then implemented "according to the same national/regional procedures that apply to other regional regulatory guidelines and requirements" in the countries. *Id.*

256 *Compare* 5 U.S.C. §§ 561–70a, *with Formal ICH Procedure*, *supra* note 255.

257 *See* 5 U.S.C. §§ 561–70a; *see also Regulatory Information, ICH Guidance Documents*, U.S. FDA, http://www.fda.gov/RegulatoryInformation/Guidances/ucm122049.htm (last updated June 4, 2010).

258 Food and Drug Administration Modernization Act of 1997 (FDAMA), Pub. L. No. 105-115, 111 Stat. 2296 (codified as amended in scattered sections of 21 U.S.C.); Kolber, *supra* note 231, at 101.

259 National Environmental Policy Act; Food Contact Substance Notification System, 65 Fed. Reg. 30,352, 30,353 (May 11, 2000) (codified at 21 C.F.R. pt. 25); *see also* National Environmental Policy Act; Food Contact Substance Notification System; Confirmation of Effective Date, 65 Fed. Reg. 60,359 (Oct. 11, 2000) (confirming effective date of direct final rule and noting FDA only received one comment on the rule, which "reiterated the association's views presented in response to an agency public meeting held prior to the initiation of this rulemaking"); Premarket Notification for Food Contact Substances; Public Meeting, 64 Fed. Reg. 8577, 8578 (Feb. 22, 1999) (stating that the public meeting "will provide manufacturers and suppliers of food contact substances, consumer groups, and other interested members of the public with an overview of FDA's current plans for the implementation of the notification process," and that "FDA is seeking the views of interested parties on all aspects of the notification process for food contact substances").

260 Kolber, *supra* note 231, at 101.

261 *See* sources cited *supra* note 259.

issues" and "a forum for a public hearing on important matters."[262] FDA's regulations set forth extensive procedures to govern the use and conduct of advisory committees.[263] The regulations permit policy advisory committees, which advise on "broad and general matters," as well as technical advisory committees, which advise on "specific technical or scientific issues, which may relate to regulatory decisions before FDA."[264] The members of a policy advisory committee are not required to have "specific technical expertise" and "because members representing particular interests, e.g., a representative of labor, industry, consumers, or agriculture, are included on advisory committees specifically for the purpose of representing th[o]se interests," they are subject to modified conflict of interest requirements.[265] FDA's experience with advisory committees may inform its use of a negotiated rulemaking committee.

IV. THE CASE FOR NEGOTIATED RULEMAKING

In July 2013, FDA announced its intent to issue an NPRM proposing to amend its regulations regarding supplements and changes to and withdrawal of an approved NDA or approved ANDA to "create parity between NDA holders and ANDA holders with respect to submission of CBE labeling supplements."[266] Shortly thereafter, in November 2013, FDA issued an NPRM which would permit ANDA holders to update their product labeling through the CBE process.[267]

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262 FDA, DRAFT GUIDANCE: GUIDANCE FOR THE PUBLIC AND FDA STAFF ON CONVENING ADVISORY COMMITTEE MEETINGS 3 (Aug. 2008), *available at* http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125651.pdf; *see also* 21 C.F.R. § 14.100 (2013); *Advisory Committees, Committees & Meeting Materials*, U.S. FDA, http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/default.htm (last updated Dec. 16, 2011); Linda Ann Sherman, *Looking Through a Window of the Food and Drug Administration: FDA's Advisory Committee System*, 2 PRECLINICA 99, 99–102 (2004).

263 *See* 21 C.F.R. §§ 14.1–14.174.

264 *Id.* § 14.1(b)(2).

265 *Id.* § 14.80(a).

266 *Unified Agenda, Historical Unified Agenda and Regulatory Plan, Spring 2013, Department of Health and Human Services*, *Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products*, OFFICE OF INFO. & REG. AFFS., OFFICE OF MGMT. & BUDGET, http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201304&RIN=0910-AG94 (last visited Mar. 18, 2014).

267 FDA had not finalized this rule as of the date this Article was written. Although the proposed rule describes processes for NDA, ANDA, and BLA holders, the focus herein will be on its proposed application to ANDA holders.

The proposed rule would amend 21 C.F.R. § 314.70(c) to permit FDA to designate a category of changes that an application holder may make to its drug product labeling upon submission of a supplemental application for the change to FDA (a CBE-0 supplement). Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67,985, 67,989, 67,998 (proposed Nov. 13, 2013) (to be codified at 21 C.F.R. § 314.70(c)(6)). These labeling changes include changes "to reflect newly acquired

Although such a proposal is a step toward addressing the issues raised and highlighted by *Mensing*, this Part proposes that, rather than proceed with the conventional notice-and-comment rulemaking process,[268] FDA should instead utilize negotiated rulemaking as a supplement to the

information . . . [t]o add or strengthen a . . . warning." *Id.*; 21 C.F.R. § 314.70(c)(6)(iii)(A). The proposed rule would apply equally to application holders and abbreviated application holders, meaning that generic drug manufacturers who hold ANDAs would be permitted to use the modified CBE process. *See* Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. at 67,998 (to be codified at 21 C.F.R. § 314.70(c)(8)).

Under the proposed rule, when an ANDA holder submits a CBE supplement to FDA, it "must send notice of the labeling change proposed in the . . . [CBE] supplement . . . to the application holder for the [RLD]." *Id.* at 67,998 (to be codified at 21 C.F.R. § 314.70(c)(8)(ii)). The proposed rule provides that "FDA will promptly post on its Web site information regarding the labeling changes proposed in the . . . [CBE] supplement." *Id.* at 67,998 (to be codified at 21 C.F.R. § 314.70(c)(8)); *see also id.* at 67,990. The applicant must verify that the posted information is correct and, if it is not, notify FDA within five business days. *Id.* at 67,998.

The ANDA holder may distribute the drug with the revised labeling pending review of the CBE supplement by FDA. *Id.* (to be codified at 21 C.F.R. § 314.70(c)(8)(iii)). If FDA determines that the supplement does not meet the criteria for submission as a supplement under proposed § 314.70(c)(6) then "the manufacturer must cease distribution of the drug product(s) accompanied by the revised labeling." *Id.* (to be codified at 21 C.F.R. § 314.70(c)(7).

In the preamble to its proposed rule, FDA notes that "[i]t is expected that a valid safety concern regarding a generic drug product also would generally warrant a change to the labeling through a CBE-0 supplement by the NDA holder for the RLD and, as a consequence, other generic drug products that reference the RLD." *Id.* at 67,992. The proposed rule provides that a supplement for a safety-related labeling change to an abbreviated application "will be approved upon approval of the same labeling change for the [RLD]." *Id.* at 67,999 (to be codified at 21 C.F.R. § 314.97). If the RLD has been withdrawn, "FDA may approve . . . a supplement to an approved abbreviated application." *Id.*

If an ANDA holder submits a labeling supplement and "the NDA holder for the RLD does not submit a supplement seeking approval for a related or conforming labeling change, FDA may send a supplement request letter to the NDA holder or, if appropriate, notify the responsible person of new safety information under section 505(o)(4) of the [FDCA]." *Id.* at 67,992. FDA "expect[s] that NDA holders will implement safety-related labeling changes requested by FDA even if not required under [FDCA § 505(o)(4)]." *Id.*

The proposed rule also would require that when FDA approves changes to the RLD labeling—or if the application for the RLD has been withdrawn, when FDA approves changes to the labeling of an ANDA that relied on the RLD—"any other abbreviated application holder that relied upon the [RLD] must submit a supplement . . . with conforming labeling revisions." *Id.* at 67,999 (to be codified at 21 C.F.R. § 314.70(c)(8)(iv)). The supplement generally must be submitted within thirty days of FDA posting the approval of the labeling changes on its website. *Id.*

The proposed rule would also "add a new exception" to the regulations that provide grounds for withdrawal of an ANDA. *Id.* at 67,986, 67,999 (to be codified at 21 C.F.R. § 314.150). Currently, the regulations "provide that FDA may take steps to withdraw approval of an ANDA if the generic drug labeling is no longer consistent with the labeling for the RLD." *Id.* at 67,986; 21 C.F.R. § 314.150(b)(10); *see also supra* note 69 and accompanying text. The new exception would permit "generic drug labeling that is temporarily inconsistent with the labeling for the RLD due to safety-related labeling changes submitted by the ANDA holder in a CBE-0 supplement." *Id.* at 67,986, 67,999 (to be codified at 21 C.F.R. § 314.150).

268 Kazhdan, *supra* note 87, at 920.

conventional rulemaking process.[269] This Part uses the factors set forth in the NRA, as well as Harter's criteria, to argue that the issues raised and highlighted by the *Mensing* decision appear to be well-suited to negotiation and that the use of negotiated rulemaking may further the public interest.[270] It also responds to several anticipated critiques of this proposal.

A. *The Need for a Rule*

There is a need for new drug labeling regulations. As discussed in Part I, by finding that state failure-to-warn claims against the manufacturers of generic drugs are preempted under FDA's current regulatory regime, the Supreme Court in *Mensing* removed the protections that state tort law can provide to consumers of generic drugs. In addition, that decision highlighted a gap in the regulation of generic drug labeling: Because under FDA's current interpretation of its regulations generic drug manufacturers cannot use the CBE process or Dear Doctor Letters to independently change their labeling (e.g., to include a new or updated warning), when the brand-name version of a drug is no longer marketed there is no manufacturer that is responsible for updating the labeling. This is especially concerning given that "[m]any serious [Adverse Drug Reactions (ADRs)] are discovered only after a drug has been on the market for years"[271] and FDA "faces

269 *See* 5 U.S.C. § 561 (2012). It is not too late for FDA to employ negotiated rulemaking. While generally negotiated rulemaking is initiated before an NPRM, nothing in the NRA prohibits an agency from using negotiated rulemaking after an NPRM so long as the requirements of the NRA are met. *See id.* §§ 561–570a. Indeed, the Conference has indicated that negotiated rulemaking can be used at other stages of rulemaking. 1 C.F.R. § 305.85-5(3) (1992); SOURCEBOOK, *supra* note 172, at 2 (stating that "negotiation sessions generally take place prior to issuance of the notice and opportunity for the public to comment on a proposed rule that are required by the Act (5 U.S.C. § 553)," but that "[i]n some instances, negotiations may be appropriate at a later stage of the proceeding"); *see also* Recommendations and Statements of the Administrative Conference Regarding Administrative Practice and Procedure, 50 Fed. Reg. 52,893, 52,895 (Dec. 27, 1985) ("The agency should recognize that negotiations can be useful at several stages of rulemaking proceedings. For example, negotiating the terms of a final rule could be a useful procedure even after publication of a proposed rule."). Indeed, several agencies have created negotiated rulemaking committees after publication of an interim or proposed rule. *See* Notice of Intent to Form a Negotiated Rulemaking Advisory Committee, Vehicles Built in Two or More Stages, 64 Fed. Reg. 27,499 (May 20, 1999); Notice of a Negotiated Rulemaking, Paleontology; Negotiated Rulemaking, 54 Fed. Reg. 48,647 (Nov. 24, 1989); Withdrawal of Proposed Rule, Varroa Mite Regulations, 54 Fed. Reg. 15,217 (proposed Apr. 17. 1989). FDA's publication of an NPRM regarding supplemental applications proposing label changes for approved drugs may provide further support for negotiated rulemaking. *See infra* Part IV.D.

270 *See* 5 U.S.C. §§ 561–570a; Harter, *supra* note 172.

271 K.E. Lasser et al., *Timing of New Black Box Warnings and Withdrawals for Prescription Medications*, 287 JAMA 2215, 2218 (2002) ("Premarketing drug trials are often underpowered to detect ADRs, and have limited follow-up." (footnotes omitted)).

significant resource constraints that limit its ability to protect the public from dangerous drugs."[272] Furthermore, the different potential remedies for injured consumers of generic versus brand-name drugs are inconsistent with the principle of the "sameness" of brand-name and generic drugs.[273]

FDA could change its interpretation of its regulations, which was set out in the United States' amicus brief,[274] by promulgating new regulations through the notice-and-comment rulemaking process,[275] which negotiated rulemaking supplements. The Court in *Mensing* noted that FDA retains the authority to change its regulations if it so desires,[276] and several members of Congress have called upon FDA to consider changes to its regulations.[277] In apparent recognition of the need for regulatory change, FDA has proposed new regulations using the notice–and-comment rulemaking process.[278]

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272 Mut. Pharm. Co. v. Bartlett, 133 S. Ct. 2466, 2485 (2013) (Sotomayor, J., dissenting).

273 *See supra* notes 125–27 and accompanying text.

274 U.S. Brief Supporting Respondents, *supra* note 36, at 15, 17 (stating that "[t]he CBE process was not available to [the generic drug manufacturers] to unilaterally change their drugs' approved labeling," and that "[t]he PAS process also was not available"). The *Mensing* opinion also cites the preamble to FDA's ANDA Regulations. PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2575 (2011). In that preamble, in response to comments that generic drug manufacturers should be able "to deviate from the labeling for the [RLD] to add contraindications, warnings, precautions, adverse reactions, and other safety-related information," FDA stated that "[e]xcept for labeling differences due to exclusivity or a patent and differences under section 505(j)(2)(v) of the [FDCA], [the generic drug's] labeling must be the same as the listed drug product's labeling." Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17,950, 17,961 (Apr. 28, 1992).

The Court relied on *Mensing* in its decision in *Bartlett*, stating that *Mensing* "made clear, federal law prevents generic drug manufacturers from changing their labels." *Bartlett*, 133 S. Ct. at 2476 (citing *Mensing*, 131 S. Ct. at 2577).

275 *See* Kazhdan, *supra* note 87, at 920 (noting that while FDA may not be able to use an interpretative rule to change its interpretation, FDA "could clearly change its regulations (at least through notice-and-comment)"); *see also id.* at 917–24.

276 *Mensing*, 131 S. Ct. at 2582.

277 *See* Letter from Senator Patrick Leahy et al., to Dr. Margaret Hamburg, Commissioner, FDA (June 24, 2013) [hereinafter Letter], *available at* http://www.leahy.senate.gov/download/06-24-13-pjl-et-al-to-fda-re-bartlett. While bills were introduced in the 112th Congress that would have permitted generic drug manufacturers to change the labeling of the drugs in the same manner as brand-name drug manufacturers may do under current law, both bills died in committee. *See* S. 2295, 112th Congress, THE LIBRARY OF CONGRESS: THOMAS, http://thomas.loc.gov/home/LegislativeData.php?n=BSS;c=112 (search "S. 2295" & "H.R. 4384"). No similar bills have been introduced in the 113th Congress. Several of the co-sponsors of the legislation introduced in the 112th Congress (along with others), however, have urged FDA "to expedite its consideration of revisions to the FDA's drug labeling regulations." Letter, *supra*.

278 *See* Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67,985 (proposed Nov. 13, 2013) (to be codified at 21 C.F.R. pts. 314, 610); *see also* FDA Response to Public Citizen, *supra* note 79, at 4.

B. *The Issues Are Concrete, Ready for Decision, and Sufficient to Permit Trade-Offs*

The issues for consideration are concrete and ready for decision.[279] Three recent Supreme Court decisions—*Wyeth*, *Mensing*, and *Bartlett*—have turned on FDA's regulation of drug labeling.[280] Additionally, the regulation of generic drug labeling and the potential implications of the Supreme Court's findings of the preemption of state failure-to-warn claims and at least some design claims have been explored in dissenting opinions,[281] briefing,[282] and a growing body of academic literature,[283] which have helped to define the issues for consideration.

In addition, there are multiple issues, which may permit trade-offs among the parties to maximize their interests.[284] As discussed in Parts I and II, the issues for consideration should include: (1) the preemption of state failure-to-warn claims; (2) the concomitant removal of the protective and compensatory functions that state tort law can provide to generic drug consumers; (3) the gap in the regulation of generic drug labeling in which no manufacturer is responsible for labeling updates; (4) who should be able to make labeling changes and under what circumstances; (5) how to encourage appropriate and timely warnings; (6) whether and how to reconcile differences between the labeling of different versions of a drug after a labeling change; and (7) whether there is a need for increased information sharing, reporting, or producing in order for manufacturers to fulfill any new regulatory responsibilities. While not an exhaustive list of potential issues (and additional issues could arise during negotiated rulemaking), this list serves to illustrate that while FDA's regulation of drug labeling is likely to be at the heart of any rulemaking, there are several other issues and sub-issues.

The various interests are likely to prioritize these issues differently and have different values, which may further negotiation by permitting trade-offs; however, the interests might all share the value of consumer access to safe and effective drugs.[285] This shared value may serve as the

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279 *See* Harter, *supra* note 173, at 47 (identifying "Mature Issues" as one of the criteria for determining when negotiation is likely to be fruitful).

280 *See* Mut. Pharm. Co. v. Bartlett, 133 S. Ct. 2466, 2476–77 (2013); *Mensing*, 131 S. Ct. at 2574–77; Wyeth v. Levine, 555 U.S. 555, 568–73 (2009).

281 *See Bartlett*, 133 S. Ct. at 2480 (Breyer, J., dissenting); *id.* at 2483 (Sotomayor, J., dissenting); *Mensing*, 131 S. Ct. at 2582 (Sotomayor, J., dissenting).

282 *See, e.g.*, Brief for Marc T. Law et al., *supra* note 11; U.S. Brief Supporting Respondents, *supra* note 36; U.S. Brief, *supra* note 36.

283 *See supra* Part II.

284 *See* Harter, *supra* note 173, at 50; Susskind & McMahon, *supra* note 214, at 152.

285 While this Article does not seek to identify particular representatives for the proposed negotiated rulemaking, the mission statements of FDA and associations of the brand-name and generic pharmaceutical industries, healthcare providers, and consumers suggest that this may

foundation for regulatory negotiation. According to Harter, "the more the parties agree on fundamental principles that shape the decision, the more likely it is that negotiations will be successful."[286]

C. Interests Likely to Be Impacted and Representation

There appears to be a limited number of identifiable interests that would be significantly affected by a rule to address the issues implicated by the *Mensing* decision. Pursuant to the NRA, an "interest" is "multiple parties which have a similar point of view or which are likely to be affected in a similar manner" with respect to an issue.[287] So, for example, although a change in the regulation of generic drug labeling may affect all generic drug companies,[288] the companies may be affected in a similar manner and therefore represent one interest.

The negotiated rulemaking committee membership must include at least one person representing FDA.[289] Given the issues identified in the prior section, there are several other interests that may be significantly impacted by a new rule and should be represented on the committee.[290] For example, any rule that changes the regulation of

be a shared value. *See, e.g.*, *About AMA, Our Mission*, AM. MED. ASS'N, http://www.ama-assn.org/ama/pub/about-ama/our-mission.page (last visited Mar. 18, 2014); *About FDA, What We Do*, FDA, http://www.fda.gov/AboutFDA/WhatWeDo/default.htm (last updated Sept. 19, 2013); *About PhRMA*, PHRMA, http://www.phrma.org/about (last visited Mar. 18, 2013); *About, The Association*, GPHA, http://www.gphaonline.org/about/the-gpha-association (last visited Mar. 18, 2014); *Health and Safety*, PUB. CITIZEN, http://www.citizen.org/Page.aspx?pid=524 (last visited Mar. 18, 2014); *see also* 21 U.S.C. § 393(b) (2012) (FDA's Mission).

286 Harter, *supra* note 173, at 49.

287 5 U.S.C. § 562(5).

288 GENERIC INDUSTRY REPORT, *supra* note 159, at 4, 50 (stating that the number of enterprises is "[t]he most relevant measure of the number of firms" in the generic drug industry and that there were 1103 enterprises in 2012).

289 5 U.S.C. § 565(b).

290 As of the date this Article was written, FDA's proposed rule was still pending. FDA, following several requests for an extension, extended the comment period to March 13, 2014. *See* Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products; Correction and Extension of Comment Period, 78 Fed. Reg. 78,796, 78,796 (Dec. 27, 2013). As a result, the scope of the comments that the FDA will receive in response to its proposed rule and the identities of the eventual commenters are not known. The requests for an extension of the comment period and the comments that were publically available when this Article was written, however, suggest several interests that may be significantly impacted by a new rule—including brand-name and generic pharmaceutical companies, consumers, health care providers, pharmacists, pharmacies, and pharmacy benefit management organizations. *See, e.g.*, Acad. Managed Care Pharmacy (AMCP) et al., Request for Extension of Comment Period on Proposed Rule Regarding Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, Docket No. FDA-2013-N-0500 (Dec. 17, 2013); Biotechnology Indus. Org. (BIO) & PhRMA, Request for an Extension of Comment Period: Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, Docket No. FDA-2013-N-0500 (Dec. 17, 2013); Cornerstone Regulatory on FDA Proposed Rule: Supplemental Applications Proposing Labeling Changes for Approved Drugs

generic drugs—by changing the labeling requirements or information sharing, reporting, or producing requirements—will likely significantly impact generic drug manufacturers. Regulatory change may also similarly impact brand-name manufacturers.[291] Consumers may be significantly impacted by changes in the regulation of drugs and in the preemption of state failure-to-warn claims because such changes may impact the safety and efficacy of generic drugs and potential remedies available to consumers injured by such drugs. A regulatory change may also significantly impact healthcare providers because prescription drug labeling is written for healthcare providers licensed to administer prescription drugs,[292] who use the labeling to make prescription decisions.[293] A regulatory change may significantly impact doctors. The American Medical Association (AMA) has argued that differences in liability rules for generic and brand-name drugs "pose an ethical dilemma for physicians" because there is "no guarantee that the product safety information accompanying a generic drug is current or reliable."[294]

Other potential interests that may be significantly impacted by a new rule include states, biologic manufacturers, and pharmacists. The aim of this discussion is not to identify an exclusive list of interests for

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and Biological Products, Docket No. FDA-2013-N-0500 (Nov. 20, 2013); GPhA, Request for Extension of Comment Period on Proposed Rule Regarding Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, Docket No. FDA-2013-N-0500 (Nov. 27, 2013); Mylan, Request for Extension of Comment Period on Proposed Rule "Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products," Docket No. FDA-2013-N-0500 (Dec. 17, 2013); Patient, Consumer, & Pub. Health Coalition on the FDA's Proposed Rule: Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, Docket No. FDA-2013-N-0500 (Feb. 5, 2014); Perrigo, Request for Extension, Proposed Rule: Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, Docket No. FDA-2013-N-500 (Dec. 9, 2013).

291 For example, a change might require the manufacturers of brand-name drugs to update their drug labeling following generic drug labeling updates. It might also require brand-name drug manufacturers—which hold the NDAs and clinical trial data, and may receive adverse event reports for both the brand-name and generic versions of a drug—to provide information to facilitate generic labeling updates. *See* Transcript of Oral Argument at 23, PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011) (Nos. 09-993, 09-1039, 09-1501) (arguing that generics "rarely" get adverse event reports because doctors typically report the adverse event to the brand-name manufacturer); FDA, MANUAL OF POLICIES AND PROCEDURES: HANDLING OF ADVERSE EXPERIENCE REPORTS AND OTHER GENERIC DRUG POSTMARKETING REPORTS 1 (Nov. 1, 2005), *available at* http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ManualofPoliciesProcedures/ucm079791.pdf (stating that "[g]enerally, [FDA's Office of Generic Drugs] receives few [Adverse Experience Reports] or similar reports since the reports may not specify a generic manufacturer for the drug product").

292 A prescription drug is a drug for which adequate directions for use for a layperson cannot be written. *See* 21 U.S.C. §§ 352(f)(1), 353(b)(1)–(2); 21 C.F.R. § 201.5 (2013).

293 21 U.S.C. §§ 352(f)(1), 353(b)(1)–(2); 21 C.F.R. § 201.5; Brief of the Am. Med. Ass'n et al. as Amici Curiae in Support of Respondents at 5–6, 13–14, *Mensing*, 131 S. Ct. 2567 (Nos. 09-993, 09-1039, 09-1501) [hereinafter AMA Brief].

294 AMA Brief, *supra* note 293, at 29–30.

participation in a negotiated rulemaking, but rather to suggest that the "number of identifiable interests that will be significantly affected by the rule" (and thus, the number of committee members needed to represent such interests) is limited, and appears likely to be less than the twenty-five-member limit generally provided by the NRA.[295] FDA could use a convener to assist it in "identifying persons who will be significantly affected by a proposed rule" and conducting discussions with them to identify their issues of concern.[296]

The NRA requires that before convening a negotiated rulemaking committee, FDA must consider whether it is reasonably likely that it could convene a negotiated rulemaking committee with a balanced representation of persons who (1) can "adequately represent" the interests identified as "significantly affected by the rule;" and (2) "are willing to negotiate in good faith to reach a consensus" on a proposed rule.[297] It seems reasonably likely that FDA could convene such a committee.[298] For example, trade associations, such as the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Generic Pharmaceutical Association (GPhA), may be able to represent the interests of brand-name and generic drug manufacturers, respectively.[299] Similarly, consumer and professional organizations, such as Public Citizen and the AMA, may be able to represent the consumer and healthcare provider's interests. [300] FDA may be able to draw on its

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295 5 U.S.C. §§ 563(a)(2), 565(b); *see also* Recommendations of the Administrative Conference, 47 Fed. Reg. 30,701, 30,709 (July 15, 1982) (suggesting that there should be a limited number of interests significantly affected by the rule and represented in negotiations); Harter, *supra* note 173, at 46.

296 *See* 5 U.S.C. § 563(b); *see also id.* § 562(3).

297 *Id.* § 563; *see also id.* § 565.

298 The requests for an extension of the comment period and the comments that were publically available when this Article was written suggest that FDA may be able to identify trade associations, professional associations, and coalitions to represent the different interests. *See, e.g.*, AMCP et al., *supra* note 290; BIO & PhRMA, *supra* note 290; GPhA, *supra* note 290; Patient, Consumer, Public Health Coalition, *supra* note 290.

299 *About, The Association*, GPHA, *supra* note 285 (describing the GPhA as "the nation's leading trade association for manufacturers and distributors of generic prescription drugs, manufacturers of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic industry"); *About PhRMA*, PHRMA, *supra* note 285 (describing PhRMA as "represent[ing] the country's leading biopharmaceutical researchers and biotechnology companies"); *see also supra* note 255 (noting PhRMA's participation in the analogous ICH negotiations).

300 *Health and Safety*, PUB. CITIZEN, *supra* note 285 ("Public Citizen's health and safety work protects consumers by advocating for safer, more effective drugs . . . ."); AMA Brief, *supra* note 293, at 1 (stating that the AMA "is the largest professional association of physicians, residents and medical students in the United States" and that "through state and specialty medical societies and other physician groups seated in its House of Delegates, substantially all United States physicians, residents and medical students are represented in the AMA's policy making process").

experience in convening advisory committees to facilitate this process.[301]

D. *Potential Gains*

There are several reasons why the significantly affected interests may be "willing to negotiate in good faith to reach a consensus on the proposed rule"[302] to reform the regulation of drug labeling and believe that negotiated rulemaking would be for their benefit.[303]

First, the inevitability and imminence of FDA's promulgation of a proposed rule may encourage the interests to negotiate in good faith. FDA has proposed a rule that would revise the procedures for changes to the labeling of an approved drug, which suggests that a new rule is inevitable, if not imminent.[304] This may create a sense of urgency on the part of the participants in the proposed negotiated rulemaking and may speed up negotiations.[305] The participants may view the proposed negotiated rulemaking as an opportunity for meaningful participation in and some control over the creation of a new regulatory system for drugs, which the participants may view as a gain.[306] If the negotiated rulemaking committee failed to reach a consensus, FDA could continue with the notice-and-comment rulemaking process. This possibility may further encourage negotiation because the participants would know that if negotiation failed they would be deprived of the opportunity for meaningful participation in the rulemaking.[307] For example, while generic drug manufacturers may prefer the status quo—in which their labeling responsibilities are limited and they are shielded from state tort claims—they may be willing to participate in negotiations to create new regulations if they know that change is inevitable.

Second, the fact that the drug industry is a "highly regulated industry, in which all the players—including the agency, the drug companies, and even the representatives of consumers—are repeat

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301 *See supra* notes 262–65 and accompanying text.

302 5 U.S.C. § 563(a)(3)(B).

303 *See* Recommendations and Statements of the Administrative Conference Regarding Administrative Practice and Procedure, 50 Fed. Reg. 52,893, 52,895 (Dec. 27, 1985); Harter, *supra* note 173, at 42–43.

304 *See* Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67,985 (proposed Nov. 13, 2013) (to be codified at 21 C.F.R. pts. 314, 610).

305 *See* Harter, *supra* note 173, at 47–48.

306 *See* Freeman & Langbein, *supra* note 214, at 62 (finding that all participants in a study by Langbein & Kerwin "reacted more favorably to their experience with negotiated rules than do participants in conventional rulemaking").

307 *See* Freeman & Langbein, *supra* note 214, at 63–69.

players"[308] may encourage the participants to negotiate in good faith, as they are likely to have to have future interactions.[309]

Third, although the current regulatory system's impact on the various interests is highly complex (and empirical evidence would be needed to make any definitive statements about its impact), certain aspects of the current system may harm each of the interests likely to be impacted by a rulemaking. The preemption of state tort claims against the manufacturers of generic drugs based on the current regulatory regime could potentially harm generic drug manufacturers by decreasing the market for generic drugs: Doctors concerned about the "ethical dilemma" of prescribing generics over brand-name drugs may prescribe generic drugs less and may prevent generic substitutions.[310] Consumers concerned about the different potential legal remedies for brand-name and generic drugs may request brand-name drugs.[311] And states concerned about preemption of state tort law claims against generic manufacturers may change their laws to discourage generic substitution.[312] The current regime also could potentially harm brand-name manufacturers if injured generic drug consumers foreclosed from bringing claims against a generic manufacturer looked to the manufacturer of the corresponding brand-name drug for recovery on the basis that the brand-name manufacturer was responsible for the content of the labeling.[313] While many courts have declined to permit such "innovator liability" suits, these decisions were based in part upon

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308 Rakoff, *supra* note 231, at 169–70; *see also* Sindell v. Abbott Labs., 607 P.2d 924, 935 (Cal. 1980) ("[T]he drug industry is closely regulated by [FDA], which actively controls the testing and manufacture of drugs and the method by which they are marketed, including the contents of warning labels.").

309 Additional reasons why the representatives may be willing to negotiate in good faith are discussed *infra* Part V.F.

310 AMA Brief, *supra* note 293, at 29–30; *see also* Kazhdan, *supra* note 87, at 914–15; Katherine A. Helm, Note, *Protecting Public Health from Outside the Physician's Office: A Century of FDA Regulation from Drug Safety Labeling to Off-Label Drug Promotion*, 18 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 117, 162 (2007).

311 Eric G. Campbell et al., *Physician Acquiescence to Patient Demands for Brand-Name Drugs: Results of a National Survey of Physicians*, 173 JAMA 237, 238 (2013) ("Approximately 4 of 10 physicians report that they sometimes or often prescribe a brand-name drug to a patient when a generic is available because the patient wanted it."); Kazhdan, *supra* note 87, at 915.

312 Kazhdan *supra* note 87, at 915–17.

313 *See* Wyeth, Inc. v. Weeks, No. 1:10-cv-602, 2013 WL 135753, at *15 (Ala. Jan. 11, 2013), *reh'g granted* (June 13, 2013) (noting that *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165 (4th Cir. 1994), was issued before the *Mensing* decision and that "[t]he *Foster* court's finding that manufacturers of generic drugs are responsible for the representations they make in their labeling regarding their products is flawed based on the 'sameness' requirement discussed in [*Mensing*]"); Rostron, *supra* note 87, at 1135 (stating pre-*Mensing* that "if the Supreme Court should find that federal law preempts claims against generic drug manufacturers, the question of whether brand-name drug makers can be liable to those who took generic drugs will take on greater significance than ever before"); Weeks, *supra* note 88, at 1258 ("While . . . so-called innovator liability suits have generally been unsuccessful in the past, the *Mensing* decision undermines a large part of the rationale for not allowing these suits." (footnotes omitted)).

the conclusion that generic drug manufacturers could supplement their drug warnings.[314] A few courts have extended liability to brand-name manufacturers on the basis that such manufacturers owe a duty of care to generic drug consumers.[315] Furthermore, as discussed in Part IV.C, the current regulatory system may pose an "ethical dilemma" for healthcare providers and may have negative implications for consumers. The potential for these harms may further encourage negotiation.

E. *Countervailing Power*

Power appears to be divided among the interests in the proposed negotiation such that no interest would hold all of the power. The existence of a balance of power is one of the criteria that Harter identified as predictive of successful negotiations because if a party "has the power to achieve its goal" without having to negotiate with others, it will do so.[316] Both brand-name and generic drug manufacturers are likely to have significant power in a negotiated rulemaking regarding the regulation of drug labeling due to the extent of their markets and importance of the drugs that they produce to the public health.[317] Brand-name drug manufacturers may also have significant power because they control a lot of the information about the drugs that they

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314 *See* Foster v. Am. Home Prods. Corp., 29 F.3d 165 (4th Cir. 1994); Conte v. Wyeth, Inc., 85 Cal. Rptr. 3d 299, 317 (Ct. App. 2008) (noting that in declining to follow *Foster* the court was "depart[ing] from the majority of courts to have wrestled with th[e] particular issue"); Weeks, *supra* note 88, at 1267–69, 1290; *see also* Jim Beck & Mark Herrmann, *Scorecard: Innovator Liability in Generic Drug Cases*, DRUG & DEVICE L. BLOG (Nov. 12, 2009, 12:17 PM), http://druganddevicelaw.blogspot.com/2009/11/scorecard-non-manufacturer-name-brand.html (listing cases).

315 *See, e.g.*, Kellogg v. Wyeth, 762 F. Supp. 2d 694, 708–09 (D. Vt. 2010) (denying brand-name manufacturer's motion for summary judgment on the basis that brand-name manufacturer had a duty of care in disseminating information about a drug and it was "reasonably foreseeable that a physician will rely upon a brand name manufacturer's representations—or the absence of representations—about the risk of side effects of its drug, when deciding to prescribe the drug for a patient, regardless of whether the pharmacist fills the prescription with a generic form of the drug"); *Weeks*, 2013 WL 135753, at *19 (holding that "[u]nder Alabama law, a brand-name drug company may be held liable for fraud or misrepresentation (by misstatement or omission), based on statements it made in connection with the manufacture of a brand-name prescription drug, by a plaintiff claiming physical injury caused by a generic drug manufactured by a different company"); *Conte*, 85 Cal. Rptr. 3d at 320–21 (holding that the brand-name manufacturer's "common-law duty to use due care in formulating its product warnings extends to patients whose doctors foreseeably rely on its product information when prescribing [the drug], whether the prescription is written for and/or filled with [the brand-name drug] or its generic equivalent").

316 Harter, *supra* note 173, at 45.

317 *See, e.g.*, SOPHIA SNYDER, IBISWORLD INDUSTRY REPORT 32541A, BRAND NAME PHARMACEUTICAL MANUFACTURING IN THE US 4–5 (June 2012) (stating that brand name pharmaceutical manufacturing industry had revenue of $156.3 billion in 2011); GENERIC INDUSTRY REPORT, *supra* note 159, at 4–5 (stating that the generic manufacturing industry had revenue of $52.8 billion in 2011).

produce, having sponsored the NDA and undertaken clinical trials to provide substantial evidence of the drug's safety and efficacy.[318] Generic drug manufacturers may also have significant power as a result of the cost savings,[319] as well as structures such as state laws and insurance plans, that encourage generic drug use.[320] FDA also may have significant power by virtue of its broad "authority to promulgate regulations for the efficient enforcement" of the FDCA and the fact that if a negotiated rulemaking committee could not reach a consensus, it could proceed with notice-and-comment rulemaking.[321] Healthcare providers may have significant power in their role as prescribers and learned intermediaries.[322] Consumers may have power based on their ability to request drugs and make purchasing choices,[323] although this power may be somewhat constrained by state substitution laws and insurance. Even if the parties to negotiated rulemaking were to have unequal power, however, the use of negotiated rulemaking may still be appropriate because the process may empower and constrain each of the parties.[324] For example, although FDA could abandon the negotiated rulemaking process at any point, it may refrain from doing so because it may not want to appear responsible for a failure to reach consensus.[325]

F. *Potential Benefits*

There are several reasons why using negotiated rulemaking to create new drug regulations may be in the public interest.[326] First, using negotiated rulemaking to create new drug regulations may be faster than conventional rulemaking. To date, FDA has not used negotiated rulemaking, and the discussions of the use of this process have been based on the experiences of other agencies such as the Environmental

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318 *See, e.g.*, 21 C.F.R. § 314.430 (2013).

319 *See, e.g.*, GPHA, *supra* note 154, at 1 ("[G]eneric drug use has saved the U.S. health care system approximately *$1.07 trillion* over the past decade (2002 through 2011) with $192.8 billion in savings achieved in 2011 alone.").

320 *See, e.g.*, NAT'L ASS'N OF BDS. OF PHARMACY, *supra* note 1, at 67–70; *Save with Generic Drugs*, AETNA, http://www.aetna.com/individuals-families-health-insurance/pharmacy-prescription-drugs/generic-drugs/index.html (last visited Mar. 18, 2014) (indicating that Aetna promotes the use of generic drugs and that some of its health plans provide a lower co-pay for generic drugs).

321 21 U.S.C. § 371(a) (2012).

322 *See id.* § 353; Lars Noah, *This Is Your Products Liability Restatement on Drugs*, 74 BROOK. L. REV. 839, 890 (2009) (describing the learned intermediary doctrine).

323 *See* Campbell, *supra* note 311, at 238.

324 *See* Susskind & McMahon, *supra* note 214, at 154–55 ("Unequal power entering a negotiated rulemaking turned out to be much less of a problem than Harter and others imagined because the process empowers all the parties in various ways and constrains the most powerful.").

325 *Id.*

326 *See* 5 U.S.C. § 563.

Protection Agency (EPA).[327] There are empirical data which suggest that, when measured by the average time for the EPA to fulfill its goal, negotiated rulemaking was "thirty-two percent faster than traditional rulemaking," even though the rules selected for negotiation are "highly complex and controversial" and "dynamics surrounding these rules are by no means 'average.'"[328] Negotiated rulemaking may save time by reducing the time the agency "ordinarily would have spent to collect and analyze data and to respond to public comments" in conventional notice-and-comment rulemaking.[329] If using negotiated rulemaking to address the issues raised by and flowing from the *Mensing* decision reduces the rulemaking time (as compared to notice-and-comment rulemaking), this may promote the public health because drug labeling is an important component of drug safety.[330] But even if negotiated rulemaking is not faster than conventional rulemaking,[331] it may hold other benefits.[332]

By engaging persons who can adequately represent the interests that will be significantly affected by a new drug labeling rule, negotiated rulemaking may produce "better rules."[333] The literature on negotiated rulemaking suggests that negotiated rulemaking may produce regulations that reflect the insight and expertise of stakeholders, are innovative, and "take account of issues that would likely escape the attention of an agency in a traditional rulemaking."[334] These potential benefits may be important in the context of drug labeling regulation, which is a central means by which FDA seeks to ensure that marketed drugs are safe and effective.[335] The current regulations governing drug labeling changes establish processes for when and how manufacturers may update their drug labeling and communicate these changes to FDA. As discussed in Part I.C, there are issues that stem from FDA's current approach to drug labeling regulation, including a gap in which there is

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327 *See, e.g.*, Coglianese, *supra* note 211, at 1273 (stating that "much of the current empirical analysis of negotiated rulemaking focuses on the EPA[, which]. . . . has attempted and completed the most negotiated rulemakings").

328 Harter, *supra* note 172, at 49.

329 Freeman & Langbein, *supra* note 214, at 75.

330 *See* Helm, *supra* note 310, at 186 ("FDA has long endeavored to protect the public health through its restrictions on drug labels"); *see also id.* at 120–21; Alison G. Vredenburgh & Ilene B. Zackowitz, *Drug Labeling and Its Impact on Patient Safety*, 33 WORK 169, 169 (2009) ("The drug safety system relies on the pharmaceutical companies to provide accurate and complete warnings and contraindications to physicians and patients.").

331 *See supra* Part III.C.

332 *See* Harter, *supra* note 173, at 28–31.

333 *Id.* at 115.

334 Philip J. Harter, *Fear of Commitment: An Affliction of Adolescents*, 46 DUKE L.J. 1389, 1403 (1997); *see also* Freeman & Langbein, *supra* note 214, at 66–67; Langbein & Kerwin, *supra* note 223, at 605–08.

335 *See* 21 U.S.C. § 355(b)(1)(A) (2012); 21 C.F.R. pts. 201, 314 (2013); *see also* Helm, *supra* note 310, at 120–22.

no manufacturer responsible for the labeling of some drugs and the removal of the protections that state tort law can provide generic drug consumers. In addition, the current regulatory procedure for labeling updates (in which a manufacturer must update its generic drug labeling to match that of the corresponding brand-name drug following an update to the brand-name labeling) may not be functioning optimally; this may result in differences between the labeling of the brand-name and generic versions of a drug product.[336] While the impact of these differences on patient safety is not known, there may need to be "changes in the labeling cascade . . . to ensure ongoing synchronization of drug safety warnings."[337] The existing labeling regime was created by FDA regulations promulgated through notice-and-comment rulemaking and supplemented by the agency's interpretations in preambles, briefs, and guidance.[338] Negotiated rulemaking may result in a process that functions better than the existing process.

Using negotiated rulemaking to create new drug labeling and post-market safety rules may also increase the legitimacy of FDA's final rule.[339] An empirical study of negotiated rulemaking found that "[t]here is no evidence that negotiated rules comprise an abrogation of agency authority."[340] In fact, "there is some indication that rules that emerge from reg negs are more stringent than those the agency would have been able to issue on its own."[341] The determination of which interests "are substantially affected, and hence entitled to participate," in the drug rulemaking is crucial to the legitimacy of the process and the legitimacy of the final rule, which "must reflect the consensus among the affected interests."[342] The FACA may further enhance the legitimacy of the negotiations.[343] Because negotiated rulemaking is a supplement to notice-and-comment rulemaking, it also incorporates the procedural protections that the later process affords: The agency must still publish

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336 *See* Duke, *supra* note 118, at 299–300.

337 *Id.* at 300; *see also supra* note 35 (discussing court cases in which it was alleged that the generic drug label differed from that of the brand-name drug).

338 *See* discussion *supra* Part I.B; *see also* Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17,950 (Apr. 28, 1992) (preamble and final rule); New Drug and Antibiotic Regulations, 50 Fed. Reg. 7452, 7466–70, 7498–99 (Feb. 22, 1985) (preamble and final rule).

339 *See* Freeman & Langbein, *supra* note 214, at 63, 124–127. Legitimacy in the context of notice-and-comment rulemaking has been defined as the "acceptability of the regulation to those involved in its development." *Id.* at 63.

340 Langbein & Kerwin, *supra* note 223, at 625.

341 Harter, *supra* note 334, at 1403–04.

342 Philip J. Harter, *The Political Legitimacy and Judicial Review of Consensual Rules*, 32 AM. U. L. REV. 471, 480 (1983); *see also id.* at 489 ("[A] consensual rule derives its validity from the fact of consensus—within the contours of authorizing legislation defined by the body politic—whereas rules outside that consensus derive their validity through the traditional means of testing the rationality of the process."); *see also* Harter, *supra* note 334, at 1407.

343 *See* Daniel J. Fiorino & Chris Kirtz, *Breaking Down Walls: Negotiated Rulemaking at EPA*, *in* SOURCEBOOK, *supra* note 172, at 839, 841.

the NPRM in the Federal Register, give interested persons the opportunity for comment and, after consideration of those comments, include a concise general statement of the rule's basis and purpose when it publishes the final rule.[344] Using negotiated rulemaking and consensus building to create new drug regulations may also lead to better relationships among the participants, which are likely to be repeat players in the world of drug regulation.[345] The perceived legitimacy of the final rule and the interactions among participants in the rulemaking may be significant because, while promulgation of a new final rule is an important first step in reform, once a new rule goes into effect the success of any new regulatory regime will depend on the participation of FDA and the stakeholders.

In sum, using negotiated rulemaking to create new drug regulations may be faster, produce better and more widely accepted rules, and create better relationships among participants than conventional notice-and-comment rulemaking. While other agencies' experiences with negotiated rulemaking inform the current analysis, the potential benefits of FDA's use of negotiated rulemaking to create new regulations are largely theoretical. To date, FDA has not used negotiated rulemaking and, thus, there are and can be no studies of how negotiated rulemaking has served FDA. Unless FDA is willing to employ negotiated rulemaking, the potential benefits will remain theoretical. In light of this, the characteristics of the current regulatory issues, and the potential benefits of regulatory negotiation, this Article concludes that FDA should use negotiated rulemaking to create new drug regulations.

G. *Response to Anticipated Criticisms*

Despite the potential benefits of negotiated rulemaking, there may be critiques of the proposal that FDA use negotiated rulemaking to address the issues flowing from the *Mensing* decision. First, critics may argue that FDA does not need to use negotiated rulemaking because FDA already provides for public participation in the rulemaking process through its use of advisory committees and public meetings.[346] This

344 *See* 5 U.S.C. § 553 (2012); *see also* Freeman, *Collaborative Governance*, *supra* note 214, at 89 (stating that in negotiated rulemaking "[t]he public is certainly no less represented . . . than it is in traditional notice and comment"); Harter, *supra* note 334, at 1405 ("[C]onvening is a form of outreach in which the agency actively seeks diverse representatives to take part in the development of the rule from its infancy. As a result, a far greater range of interests actually participates in the rule than in customary notice-and-comment rulemaking where the agency passively receives comments."); Harter, *supra* note 342, at 472–76.

345 *See* Freeman, *The Private Role*, *supra* note 214, at 656–57; Rakoff, *supra* note 231, at 169–70.

346 *See* 21 C.F.R. §§ 10.65; 14.1–14.174 (2013); HHS & FDA, JUSTIFICATION FOR ESTIMATES FOR APPROPRIATIONS COMMITTEES 364 (2013), *available at* http://www.fda.gov/downloads/

critique, however, neglects to account for the unique features of the NRA framework. Although a negotiated rulemaking committee established by FDA pursuant to the NRA would be an advisory committee, it would differ in important ways from FDA's other advisory committees due to its focus on negotiation. The NRA's provisions are tailored to the purpose of utilizing negotiation to generate consensus among stakeholders for use as the basis for a proposed rule. For example, the NRA provides for the use of a convener to assist the agency in assessing whether to undertake negotiated rulemaking and the use of facilitators to assist the negotiation process.[347] A negotiated rulemaking committee's purpose would be to use negotiation to produce a consensus among stakeholders to be used as the basis for a proposed rule and not simply to "provide advice and recommendations to the [FDA] Commissioner."[348] Furthermore, the agency's commitment to use the consensus of the committee as a basis for a proposed rule "to the maximum extent possible consistent with the legal obligations of the agency"[349] is an "essential ingredient of the success" of the process.[350] As discussed in Parts III.C and IV.F, many of the potential benefits of negotiated rulemaking may flow from the negotiations and consensus building that characterize the process—benefits that the standard advisory committee process may not produce.[351]

Second, critics may argue that negotiated rulemaking could cost both FDA and participants more than conventional notice-and-comment rulemaking.[352] FDA's resources are limited,[353] and FDA has expressed concerns about resource limitations and negotiated rulemaking.[354] There are several reasons, however, why negotiated

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AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM347422.pdf ("FDA currently has 51 advisory committees and panels with 634 authorized positions. The agency holds approximately 85 meetings per year with the participation of over 1,300 outside experts."); Kobick, *supra* note 227, at 439–40.

347 5 U.S.C. §§ 562(2)–(3), 563(b), 566; *see also* 1 C.F.R. § 305.82-4 (1983); Harter, *supra* note 173, at 77–79.

348 21 C.F.R. § 14.5(a) (2013). *Compare* 21 C.F.R. § 14.5 (discussing FDA advisory committees), *with* 5 U.S.C. §§ 561–570a (describing negotiated rulemaking under the NRA). *See generally* Harter, *supra* note 173.

349 *See* 5 U.S.C. § 563(a)(7) (stating that "the head of the agency shall consider whether . . . the agency, to the maximum extent possible consistent with the legal obligations of the agency, will use the consensus of the committee with respect to the proposed rule as the basis for the rule proposed by the agency for notice and comment"); *see also* Recommendations of the Administrative Conference, 47 Fed. Reg. 30,701, 30,710 (July 15, 1982) (recommending that "[t]he agency should publish the negotiated text of the proposed rule in its [NPRM]" and, if it does not, "it should explain its reasons").

350 Harter, *supra* note 173, at 100.

351 *See supra* Part IV.F.

352 *See* Lubbers, *supra* note 172, at 997–98; Kobick, *supra* note 227, at 438–39.

353 *See, e.g.*, Mut. Pharm. Co. v. Bartlett, 133 S. Ct. 2466, 2485 (2013) (Sotomayor, J., dissenting).

354 *See* Contrera, *supra* note 254, at 952–53; Kobick, *supra* note 227, at 437–39.

rulemaking may still be beneficial and may lead to some cost savings. The members of the negotiated rulemaking committee may bring to the table important information about how changes in the regulation may impact the prescription drug industry, individual businesses, healthcare providers, and consumers that the agency would otherwise have to speculate about or invest resources in locating or developing.[355] In addition, negotiated rulemaking may save the agency and stakeholders costs at the end of the rulemaking (i.e., through fewer comments and court challenges) as well as in the implementation of, compliance with, and enforcement of a new rule by creating a more effective rule.[356] In addition, FDA likely does not have the resources to effectively monitor and update generic drug labeling.[357] Accordingly, investing in the creation of a better regulatory system in which drug manufacturers are responsible for labeling updates and state failure-to-warn claims are not preempted may be especially important in promoting drug safety.[358] Furthermore, FDA is not unique in its resource limitations.[359] Other agencies have employed negotiated rulemaking even after considering their resources as required by the NRA.[360] Also, the NRA permits the agency to provide assistance to negotiated rulemaking committee members whose participation is necessary to assure adequate representation and who "certif[y] a lack of adequate financial resources to participate in the committee."[361]

A third anticipated criticism is that negotiated rulemaking may create rules that are no less subject to litigation than conventional rules.[362] But even if rules produced using negotiated rulemaking have a similar rate of judicial review as those produced by conventional rulemaking, using negotiated rulemaking to create new drug rules may still be valuable in light of the potential benefits that negotiated

355 *See* Freeman, *The Private Role*, *supra* note 214, at 641.

356 *See* Harter, *supra* note 172, at 56 (stating that negotiated rules were viewed more favorably by participants with respect to "the economic efficiency of the rule and its cost effectiveness"); Harter, *supra* note 334, at 1403–04 (stating that there is some indication that rules produced through negotiated rulemaking "are cheaper to implement precisely because the committee can focus on ways to get the greatest return"); Lubbers, *supra* note 172, at 997; Thomas W. Merrill, *The Constitution and the Cathedral: Prohibiting, Purchasing, and Possibly Condemning Tobacco Advertising*, 93 NW. U. L. REV. 1143, 1180 n.137 (1999) (suggesting that regulated parties may "place a higher value on comprehensibility and ease of administration").

357 *See* Wyeth v. Levine, 555 U.S. 555, 578 & n.11 (2009).

358 *See supra* Part I.C.

359 *See* Kobick, *supra* note 227, at 442.

360 *See* 5 U.S.C. § 563(a)(6) (2012); Kobick, *supra* note 227, at 442–43.

361 *See* 5 U.S.C. § 568(c); Lubbers, *supra* note 172, at 998 (noting that the NRA anticipated participant resource concerns, but that funds for assistance "have been scarce").

362 *See* Coglianese, *supra* note 211, at 1286–1309; Harter, *supra* note 172, at 55 (quoting Langbein & Kerwin, *supra* note 223, at 625–26); Kobick, *supra* note 227, at 441–42.

rulemaking may offer as compared to notice-and-comment rulemaking, as discussed in Part IV.F.[363]

CONCLUSION

Using negotiated rulemaking to bring together generic drug manufacturers, brand-name drug manufacturers, consumers, healthcare providers, FDA, and other interests to work towards consensus on new drug labeling regulations may be particularly appropriate in light of the fact that the Hatch-Waxman Act (which laid the foundation for the modern generic market) is commonly viewed as compromise legislation.[364] While negotiated rulemaking is not appropriate for all rulemaking, there are reasons to think that it may be appropriate and offer benefits in the current situation. To date, FDA has not used the negotiated rulemaking process set forth in the NRA but, to quote Harter, "[a]t the very least, regulatory negotiation is worth a try."[365]

363 *See* Harter, *supra* note 172, at 52–56.

364 *See supra* note 65 and accompanying text.

365 Harter, *supra* note 173, at 113; *see also* Jody Freeman, *Remarks by Professor Jody Freeman to Japanese American Law Society*, 83 WASH. U. L.Q. 1859, 1868 (2005) ("To assess whether the theory works in practice, however, more experimentation is needed along with monitoring and empirical evaluation.").