

January 9, 2014

Margaret A. Hamburg, M.D. Commissioner
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Dear Commissioner Hamburg:

Re: FDA Docket No. FDA-2013-N-0500 and RIN 0910-AG94: Comments on Labeling Changes for Approved Drugs and Biological Products

We are members of a law school clinic, Civil Justice Through the Courts, at New York Law School. This is a public policy clinic, the mission of which is to raise awareness about attacks on access to the civil justice system. After studying the issue of generic drug company immunity, we are writing in support of the Food and Drug Administration (FDA)'s proposed rule regarding "Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products,"¹ and hereby submit the following comments in support of the proposed rule.

Currently, 80 percent of prescriptions filled in the US are filled with generic versions of drugs. Generic drugs have gained popularity and managed to dominate the drug market because they are inexpensive "bioequivalents" of the name brand drugs.² In spite of the prevalence of generic drug use, recent Supreme Court cases have essentially eliminated state tort liability against generic drug manufacturers by finding that state tort law against generic drugs for inadequate labeling is preempted by the FDA regulations that require generic warning labels to mimic those of the brand name.³

On November 13, 2013, the FDA published a proposed rule in the Federal Register that is explicitly designed to place generic drug manufacturers and their brand-name counterparts in "parity" with regards to labeling duties.⁴ In its discussion of the recent United States Supreme Court decisions preempting state tort lawsuits against generic drug manufacturers, the FDA stated that this proposed rule may "eliminate the preemption of certain failure-to-warn claims with respect to generic drugs."⁵

Based on a thorough analysis of the proposed rule and the Supreme Court's recent failure-to-warn preemption jurisprudence, this rule seems poised to be successful, not only in placing these

¹ Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, *Pages* 67985 – 67999 [FR DOC # 2013-26799] <https://www.federalregister.gov/articles/2013/11/13/2013-26799/supplemental-applications-proposing-labeling-changes-for-approved-drugs-and-biological-products>

² Depression and Bipolar Support Alliance, *Generic and Brand Name Drugs: Understanding the Basics*, available at <http://www.dbsalliance.org/pdfs/GenericRx.pdf>.

³ *PLIVA, Inc. v. Mensing*, 131 U.S. 2567, 2575 (2011).

⁴ Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, *Pages* 67985 – 67999 [FR DOC # 2013-26799] <https://www.federalregister.gov/articles/2013/11/13/2013-26799/supplemental-applications-proposing-labeling-changes-for-approved-drugs-and-biological-products>

⁵ *Id.* at 67989.

companies in “parity” with regards to labeling duties, but also in removing the unjustifiable bars to civil justice currently faced by those harmed by unsafe generic drugs.⁶

What are Generic Drugs

The FDA defines a generic drug as being “the same as a brand name drug in dosage, safety, strength, how it is taken, quality, performance, and intended use. Before approving a generic drug product, the FDA requires tests and procedures to assure that the generic drug can be substituted for the brand name drug. The FDA bases evaluations of substitutability, or “therapeutic equivalence,” of generic drugs on scientific evaluations. By law, a generic drug product must contain the identical amounts of the same active ingredient(s) as the brand name product. Drug products evaluated as “therapeutically equivalent” can be expected to have equal effect and no difference when substituted for the brand name product.”⁷ This definition can be examined within the discussion of the approval process for generic and brand name drugs.

Approval Process

The brand name drug to which a generic version must be bioequivalent is referred to as “reference listed drug” (RLD).⁸ In order for a brand name drug to obtain approval the company must submit a New Drug Application (NDA).⁹ In anticipation of seeking approval for a drug a drug manufacturer obtains a patent, and goes through an extensive and costly process in order to ensure the safety and effectiveness of a drug.¹⁰ The process of testing a new drug begins with animal testing, after which a manufacturer will submit an Investigational New Drug (IND) application.¹¹ The application will include information regarding animal studies, a proposal for clinical studies, an indication of what the drug does, as well as other information.¹² After a 30 day period without the FDA objecting to the IND application, the drug manufacturer can begin clinical testing.¹³ There are still three phases of clinical testing that a brand name drug must go through before submitting an NDA. Phase I of clinical trials is the beginning of testing in humans in order “to determine dosing, document how a drug is metabolized and excreted, and identify acute side effects.”¹⁴ The next phases of clinical trials involve a larger number of people

⁶ *Id.* at 67985.

⁷ *Drugs@FDA Glossary of Terms*, FDA (Feb. 2, 2012), <http://www.fda.gov/drugs/informationondrugs/ucm079436.htm>.

⁸ *Id.* “A Reference Listed Drug (RLD) is an approved drug product to which new generic versions are compared to show that they are bioequivalent.”

⁹ *New Drug Application NDA*, FDA (Feb. 21, 2013), <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/>.

¹⁰ *How Drugs are Developed and Approved*, “FDA U.S. Food and Drug Administration” (Jan. 03, 2013), <http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/>; *What is the approval process for a new prescription drug?*, FDA U.S. FOOD AND DRUG ADMINISTRATION (Jan. 05, 2013), <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194949.htm>.

¹¹ Susan Thaul, *How FDA Approves Drugs and Regulates their Safety and Effectiveness*, “Federation of American Scientist” (June 25, 2012), <http://www.fas.org/sgp/crs/misc/R41983.pdf>.

¹² *Id.*

¹³ *Id.*

¹⁴ *Id.*

and are meant to test the safety and effectiveness of the drugs.¹⁵ It is after the completion of those three phases that an NDA can be submitted.

An NDA is the FDA's means of gaining and understanding all of the information related to the drug.¹⁶ The NDA needs to include all of the information regarding the clinical tests, drug ingredients, the drug's behavior in the body, and manufacturing, processing and packaging methods.¹⁷ Manufacturers have gone through years of testing in order to provide this information to the FDA. The FDA utilizes this information to determine the safety and effectiveness of a drug and if the benefits outweigh the risks.¹⁸ The NDA will include a proposed labeling, and the FDA will determine the appropriateness of the information.¹⁹ The FDA will also make a determination as to the adequacy of the methods that are used when manufacturing drugs.²⁰ There is then a 6 month period in which the FDA reviews the drug for approval.²¹ There are a variety of reasons why the FDA may reject a proposed drug, and a rejection may result in the manufacturer engaging in even further clinical studies to potentially gain approval in the future.²²

The entirety of the process that a brand name manufacturer must go through prior to obtaining approval is possible only at an exceptional cost to the manufacturer. This process, which could take up to 15 years, costs companies an average of \$500 million.²³ The astronomical cost to develop a drug and gain approval is often the reason for the brand name version of a drug being more expensive.²⁴ The availability of generic drugs is important in order to alleviate some of the costs to consumers. The concern with affordability led to the enactment of the Hatch-Waxman Act, which allowed generic drugs to become available even sooner.²⁵

The Hatch-Waxman Act allows manufacturers of generic drugs to obtain approval through the Abbreviated New Drug Application (ANDA) process.²⁶ The "abbreviated" application process allows generic drugs to benefit from the research and clinical trials performed by the brand name manufacturer. Instead of performing clinical trials in order to gain approval, a generic manufacturer need only show the scientific bioequivalence of the drug to the RLD.²⁷ Bioequivalence is defined as "the absence of a significant difference in the rate and extent to

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *New Drug Application (NDA)*, FDA (Feb. 21, 2013),

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/>.

¹⁹ *Id.*

²⁰ *Id.*

²¹ Susan Thaul, *How FDA Approves Drugs and Regulates their Safety and Effectiveness*, "Federation of American Scientist" (June 25, 2012), <http://www.fas.org/sgp/crs/misc/R41983.pdf>.

²² *Id.*

²³ Milton Zall, *The Pricing Puzzle*, ACS PUBLICATIONS,

<http://pubs.acs.org/subscribe/archive/mdd/v04/i03/html/03zall.html> (last visited Nov. 22, 2013).

²⁴ Depression and Bipolar Support Alliance, *Generic and Brand Name Drugs: Understanding the Basics*, available at <http://www.dbsalliance.org/pdfs/GenericRx.pdf>.

²⁵ Sarah E. Eurek, *Hatch-Waxman Reform and Accelerated Market Entry of Generic Drugs: Is Faster Necessarily Better*, available at <http://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=1087&context=dltr>.

²⁶ *Id.*

²⁷ *Abbreviated New Drug Application (ANDA): Generics*, FDA (July 17, 2013),

<http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/abbreviatednewdrugapplicationandgenerics/default.htm>.

which the active ingredient or active moiety in pharmaceutical alternatives becomes available at the site of a drug action when administered at the same molar dose under similar conditions in an appropriately designed study.”²⁸ Essentially the concern is on the release and absorption rate of the drug and the “standards for strength, quality, purity, and identity as the branded product.”²⁹ If generic drug contains the same active ingredients as the RLD and is bioequivalent, the drug will likely be approved, but this approval requires that the labeling be identical to the RLD.³⁰ It is important to note that though there is a requirement for certain similarities between the generic and the RLD, there are some differences between the drugs. The rate at which the generic drug enters the blood stream does not have to be identical to the RLD.³¹ The color shape and the flavor of a drug, along with the inactive ingredients, which may cause allergies or drug sensitivity, can all be different.³²

Generic drugs are significantly less expensive for consumers than the brand name drug. The difference in the costs to consumers is contributed to the difference in costs associated with gaining approval to market a drug. Generic drugs are much less expensive to produce and therefore to purchase, because they are able to utilize the extensive research done by brand name manufacturers.³³

Post Approval Responsibilities

After a brand name drug is approved and available to consumers, there is still a continued responsibility to monitor the drugs for safety. Since there may be negative effects of a drug that did not appear during the development of the drug, the continued monitoring is essential. Offices within the FDA’s Center for Drug Evaluation and Research (CDER) are responsible for the surveillance of drugs after they have been approved.³⁴ The different offices within the CDER continue to regulate the FDA approved drugs. The way in which the offices attempt to continue to monitor the safety is through consumer, clinicians, and manufacturers reports that identify adverse effects.³⁵ One office with the CDER is the Office of Surveillance and Epidemiology (OSE). OSE utilizes a post-marketing system that continues to assess potential risks of a drug.³⁶ OSE provides recommendations to improve the safety, update labels, provide the public with

²⁸ 21 C.F.R. § 320.1.

²⁹ Sarah E. Eurek, *Hatch-Waxman Reform and Accelerated Market Entry of Generic Drugs: Is Faster Necessarily Better*, available at <http://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=1087&context=dltr>.

³⁰ Depression and Bipolar Support Alliance, *Generic and Brand Name Drugs: Understanding the Basics*, available at <http://www.dbsalliance.org/pdfs/GenericRx.pdf>.

³¹ Tod Cooperman, *What You Need to Know About Generic Drugs*, “The Dr. Oz Show” (April 08, 2013), <http://www.doctoroz.com/videos/what-you-need-know-about-generic-drugs>.

³² Melissa Stoppler, *Generic Drugs, Are They as Good as Brand Names?*, “Medicine Net” (Sep. 28, 2009), <http://www.medicinenet.com/script/main/art.asp?articlekey=46204>., Tod Cooperman, *What You Need to Know About Generic Drugs*, “The Dr. Oz Show” (April 08, 2013), <http://www.doctoroz.com/videos/what-you-need-know-about-generic-drugs>.

³³ Depression and Bipolar Support Alliance, *Generic and Brand Name Drugs: Understanding the Basics*, available at <http://www.dbsalliance.org/pdfs/GenericRx.pdf>.

³⁴ Susan Thaul, *How FDA Approves Drugs and Regulates their Safety and Effectiveness*, “Federation of American Scientist” (June 25, 2012), <http://www.fas.org/sgp/crs/misc/R41983.pdf>.

³⁵ *Id.*

³⁶ *Office of Surveillance and Epidemiology*, FDA (Aug. 21, 2013), <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm106491.htm>.

information regarding a drug, “implementing or revising a risk management program, [and] on rare occasions, reevaluating approval or marketing decisions.”³⁷ Though this method does allow for the FDA to continue to review the safety of a drug, most of this review is dependent on the reports the manufacturers, clinicians, and consumers have submitted. It is then important to understand what responsibility is on the manufacturers to submit these reports.

The reporting requirements for brand name drugs does not refer to continued clinical tests. In fact, clinical trials that occur after the approval of a drug are referred to as Phase IV trials and are only required some of the time.³⁸ Phase IV trials occur in order to assess “long-term risks, benefits, and optimal use...”³⁹ Since these trials are only required in a limited number of circumstances, the reports required of the manufacturers actually refers to adverse information the manufacturer obtains.⁴⁰ Brand name drug manufacturers are required to “...review all adverse drug experience information obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from commercial marketing experience, postmarketing clinical investigations, postmarketing epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific papers.”⁴¹ This does not require the manufacturers to report every single adverse drug experience as it occurs. Those that are not reported using the first method are reported at quarterly intervals for three years after the date of approval and then the reports become annual.⁴² The manufacturer is also responsible for submitting scientific literature regarding adverse drug experiences.⁴³ All of the information regarding the adverse experiences is required to be kept for a minimum of ten years.⁴⁴ Failure to adhere to any of these requirements can result in the FDA withdrawing their approval of the brand name drug.⁴⁵ All of these requirements are set out in reference to the post-approval of brand name drugs.

Overall, the FDA must be aware and approve any changes made to an approved drug. However, there are designated categories in which a brand name manufacturer may make certain changes prior to the approval of the FDA.⁴⁶ These changes are known as Changes Being Effectuated (CBE).⁴⁷ CBE’s allows brand name manufacturers to make changes prior to FDA approval.⁴⁸ The changes to “methods or controls” to ensure that the “characteristics of identity, strength, quality, purity, or potency that it purports or is represented to possess”⁴⁹ An important change that brand name manufacturers can make are labeling changes. If a brand name manufacturer receives new information regarding the drug, they are able to make a variety of changes associated with the

³⁷ *Id.*

³⁸ *Inside Clinical Trials: Testing Medical Products in People*, FDA (April 12, 2013), <http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143531.htm>.

³⁹ *Id.*

⁴⁰ 21 C.F.R. § 314.80 (LexisNexis 2013).

⁴¹ 21 C.F.R. § 314.80(b) (LexisNexis 2013).

⁴² 21 C.F.R. § 314.80(b)(2) (LexisNexis 2013).

⁴³ 21 C.F.R. § 314.80(d) (LexisNexis 2013).

⁴⁴ 21 C.F.R. § 314.80(i) (LexisNexis 2013).

⁴⁵ 21 C.F.R. § 314.80(j) (LexisNexis 2013).

⁴⁶ *See* 21 C.F.R. § 314.70(c) (LexisNexis 2013).

⁴⁷ 21 C.F.R. § 314.70(c)(3) (LexisNexis 2013).

⁴⁸ 21 C.F.R. § 314.70(c)(6) (LexisNexis 2013).

⁴⁹ *Id.*

label if they are meant to make the label stronger by adding important information or removing inaccurate information.⁵⁰

Though generic drugs have a significantly different process for approval the post marketing requirements are identical. “Except as provided in paragraph (b) of this section, each applicant having an approved abbreviated new drug application under § 314.94 that is effective shall comply with the requirements of § 314.80 regarding the reporting and recording keep of adverse drug experience.”⁵¹ Once a generic drug has been approved through an ANDA, they are responsible, in the same way that a brand name manufacturer is, to report any adverse effects.

The biggest difference between a generic drug and brand name, after the approval of the drug, is the CBE. Since the labeling for the drug is required to be the same as the RLD in order to receive approval, the FDA has interpreted the CBE regulations to not apply to ANDA drugs.⁵² If an ANDA manufacturer has reason to believe the labeling is no longer consistent the FDA has identified the responsibility of the generic drug manufactures to “ask the agency to work toward strengthening the label that applies to both the generic and brand-name drug.”⁵³ In fact, if an ANDA’s label no longer matches the RLD, the FDA may withdraw the approval.⁵⁴ The inability to make any changes has recently allowed generic manufacturers to escape state tort liability with any problems associated with the labeling of an ANDA. The ANDA’s have essentially been given immunity. It does not matter whether the ANDA is aware of new adverse side effects, they are still not required to make any changes without FDA approval. Without being allowed to make the changes, they cannot be held responsibility for any harm caused by the drug, even when they knew the drug had the potential to cause that harm. However, the proposed FDA rule will eliminate ANDA’s immunity to liability.

The Impact of Recent Supreme Court Cases

As the result of three United States Supreme Court decisions since 2009, the current status of the state tort system provides generic drug manufacturers immunity from failure-to-warn and design defect liability, while their brand name counterparts remain open to suit.⁵⁵ Considering the large majority of drug consumers are prescribed the generic versions of drugs, most drug consumers are left without legal remedy if harmed by an inadequately labeled drug.⁵⁶ Such a result is completely divorced from the intent of Congress and, as expressed vehemently by the dissent in *PLIVA*, is “absurd.”⁵⁷

⁵⁰ 21 C.F.R. § 314.70(c)(6)(iii) (LexisNexis 2013).

⁵¹ 21. C.F.R. § 314.98(a) (LexisNexis 2013).

⁵² *PLIVA, Inc. v. Mensing*, 131 U.S. 2567, 2575 (2011) (citing the interpretation of the FDA that appeared in the brief they submitted to the Supreme Court).

⁵³ *PLIVA, Inc. v. Mensing* 131 U.S. 2567, 2577 (2011) (citing the FDA’s brief).

⁵⁴ 21 C.F.R. § 314.150(b)(10) (LexisNexis 2013).

⁵⁵ *See Mutual Pharm. Co., Inc. v. Bartlett*, 133 S.Ct. 2466 (2013); *PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567 (2011); *Wyeth v. Levine*, 555 U.S. 555 (2009).

⁵⁶ *See Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products*, 78 Fed. Reg. at 67988; Katie Thomas, *Why the Bad Rap on Generic Drugs?*, “New York Times”, Oct. 5, 2013, <http://www.nytimes.com/2013/10/06/sunday-review/why-the-bad-rap-on-generic-drugs.html?pagewanted=all>.

⁵⁷ *PLIVA, Inc. v. Mensing* 131 S.Ct. at 2592 (Sotomayor, J. dissenting).

In *Wyeth v. Levine*, the Court held that state failure-to-warn claims against brand-name drug manufacturers were not preempted, rejecting both the “impossibility” and “purposes and objectives” preemption arguments by the manufacturers.⁵⁸ As relevant here, the manufacturers argued that it was impossible for them to change their labels to comply with their state tort-law duties because they were required to have FDA approval before they could do so.⁵⁹ However, the Court rejected this argument of impossibility, hinging its reasoning on the brand-name manufacturer’s unilateral ability to strengthen its labels under the CBE regulations.⁶⁰ The Court expressed the importance of the recent Congressional amendment, which had made it “clear that manufacturers remain responsible for updating their labels” and, in fact, required them “to change [their] drug label based on safety information that becomes available after a drug’s initial approval.”⁶¹ As the Court stated, while usually “a manufacturer may only change a drug label after the FDA approves a supplemental application,” the CBE regulations enabled them to change their labels while filing a supplemental application and they “need not wait for FDA approval.”⁶² It is the absence of this option under the CBE regulations that provided the Court in *PLIVA, Inc. v. Mensing* and *Mutual Pharmaceutical Co., Inc. v. Bartlett* an opportunity to distinguish generic drug companies from their brand-name counterparts and, thus, immunize them from liability.⁶³

In holding that state failure-to-warn claims are preempted under the “impossibility” doctrine because they directly conflict with FDA regulations, the Court in *PLIVA* stressed the differences in labeling requirements for generic drug companies and their brand-name counterparts.⁶⁴ The Court pointed out that, while a brand-name manufacturer is “responsible for the accuracy and adequacy of its label,” a generic manufacturer is “responsible for ensuring that its warning label is the same as the brand names.”⁶⁵ The Court then rejected the plaintiff-respondents’ arguments that the same CBE process, which permitted the plaintiff’s in *Wyeth* to proceed forward with their claims, would allow these generic manufacturers to change their labels.⁶⁶ In addition, the court rejected the argument that the manufacturers could send *Dear Doctor* letters with additional warnings to the prescribing healthcare professionals in order to comply with their state-law duties.⁶⁷

In rejecting these arguments, the Court deferred to the FDA’s interpretation of its regulations, which is that the generic companies would be in violation of their federal duty to have the same label as the brand-name manufacturers by attempting to unilaterally change their labels through the CBE process or through *Dear Doctor* letters.⁶⁸ Thus, because it was “impossible” for generic manufacturers to unilaterally comply with their state-law duties to strengthen the labels on their

⁵⁸ *Wyeth*, 555 U.S. at 568–81.

⁵⁹ *Id.* at 568.

⁶⁰ *Id.* at 573.

⁶¹ *Id.* at 567–68.

⁶² *Id.* at 568.

⁶³ *Mutual Pharm. Co., Inc. v. Bartlett*, 133 S.Ct. 2466, 2476 (2013); *PLIVA, Inc.*, 131 S.Ct. at 2575–76.

⁶⁴ *PLIVA, Inc.*, 131 S.Ct. at 2572, 2574–76.

⁶⁵ *Id.* at 2574 (internal citations omitted).

⁶⁶ *Id.* at 2575.

⁶⁷ *Id.* at 2576.

⁶⁸ *Id.* at 2575–76 (citing U.S. Brief 15–16, 18); *see also* Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. at 67988.

drugs without violating federal law, it was held that such failure-to-warn claims are preempted.⁶⁹ However, the Court called out for legislative and administrative action: “Congress and the FDA retain the authority to change the law and regulations if they so desire.”⁷⁰

In her dissent in *Pliva*, Justice Sonia Sotomayor notes that, “Today’s decision leads to so many absurd consequences that I cannot fathom that Congress would have intended to pre-empt state law in these cases.”⁷¹ Justice Sotomayor further writes that, “[a] drug consumer’s right to compensation for inadequate warnings now turns on the happenstance of whether her pharmacist filled her prescription with a brand-name drug or a generic. If a consumer takes a brand-name drug, she can sue the manufacturer for inadequate warnings under our opinion in *Wyeth*. If, however, she takes a generic drug, as occurs 75 percent of the time, she now has no right to sue.”⁷²

The dissent further explains that the majority’s holding would adversely affect American citizens by removing access to civil courts for wrongdoing caused generic drug companies.⁷³ Justice Sotomayor writes, “[t]oday’s decision eliminates the traditional state-law incentives for generic manufacturers to monitor and disclose safety risks. When a generic drug has a brand-name equivalent on the market, the brand-name manufacturer will remain incentivized to uncover safety risks. But brand-name manufacturers often leave the market once generic versions are available, meaning that there will be no manufacturer subject to failure-to-warn liability. As to those generic drugs, there will be no ‘additional...layer of consumer protection.’ *Wyeth*, 555 U.S., at 579, 129 S. Ct. 1187”⁷⁴

Nevertheless, this was not the end of the Court’s preemption undertaking. Two years later, in *Bartlett*, the Court extended its reasoning from *PLIVA* to design defect claims, holding that state design defect claims that hinge on the adequacy of a drugs label are preempted pursuant to *PLIVA*.⁷⁵ There, the majority reasoned that because New Hampshire’s design defect cause of action included the adequacy of the drugs label as a factor, and because it was scientifically impossible to change the chemical design of the drug without creating a “new drug,” the design defect claim required a label change in order to comply with state law.⁷⁶ As per *PLIVA*, such a label change was not permitted, as it would violate federal law.⁷⁷ Thus, the Court held that such design defect claims are preempted.⁷⁸ Again, while recognizing the unfairness of the decision, the Court targeted the FDA and Congress as the source of such results and called out for legislative action, “[T]he Court would welcome Congress’ ‘explicit’ resolution of the difficult pre-emption questions that arise in the prescription drug context.” The Court’s callings have now been answered.⁷⁹

⁶⁹ *Id.* at 2577.

⁷⁰ *PLIVA, Inc. v. Mensing*, 131 S.Ct. at 2582 (2011).

⁷¹ *Id.* at 2592.

⁷² *Id.*

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 133 S.Ct. 2466, 2470 (2013).

⁷⁶ *Id.*

⁷⁷ *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2577 (2011).

⁷⁸ *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 133 S.Ct. at 2470 (2013).

⁷⁹ *Id.* at 2480.

As Justice Stevens wrote in *Wyeth*, and as the dissents pointed out in both *PLIVA* and *Bartlett*, “the purpose of Congress is the ultimate touchstone in every preemption case.”⁸⁰ Moreover, the areas historically governed by the police powers of the states should be afforded a presumption against preemption unless it is “the clear and manifest purpose of Congress” to preempt state law.⁸¹ The majority did not mention Congress’ purpose nor address the importance of these federalism concerns in either the *PLIVA* or *Bartlett* cases. It is, therefore, not surprising that these decisions have produced “absurd” consequences over the last few years.⁸² Countless cases dealing with harms caused by inadequately labeled pharmaceutical drugs have been dismissed with respect to the generic companies, while allowing those who took the brand-name drugs to proceed. Lower court judges have pointed out the absurdity of this precedent.⁸³ Generic pharmaceutical companies are left disincentivized to conduct the thorough oversight of the adequacy of their labels required by the FDA⁸⁴ and, furthermore, which the state tort law system has historically and complementarily pressured them to conduct.⁸⁵

Cases Pre-Empted As a Result of Supreme Court Decisions

As foretold by Justice Sotomayor, federal courts have followed the Supreme Court’s precedent, resulting in disastrous outcomes for injured parties. Plaintiffs seeking compensation for injuries have regularly been denied access to civil courts due to federal pre-emption.

For example in *Smith v. Wyeth, Inc.*, 657 F.3d 420 (6th Cir. 2011), three plaintiffs were prescribed Reglan to treat gastro esophageal reflux.⁸⁶ In Kentucky, where the plaintiffs reside, the state has a “generic-substitution law requiring pharmacies to fill prescriptions with a lower-priced, therapeutically-equivalent generic drug unless the doctor or purchaser explicitly instructs otherwise. See KY.REV.STAT. §217.822(1) (2010).”⁸⁷ As a result of the Kentucky state law, Plaintiffs were supplied with the generic form of their prescribed drug.⁸⁸ As a result of their “long-term” use of the generic drug, each plaintiff developed tardive dyskinesia, a severe neurological disorder similar to Parkinson’s disease.⁸⁹ Each action was heard in federal court, where the plaintiffs brought state-law-failure-to-warn claims against the generic manufacturers.⁹⁰ Defendants moved for summary judgment on all claims, which the district court subsequently granted.⁹¹ Plaintiffs then appealed to the Sixth Circuit Court of Appeals. The Sixth Circuit held that “The Supreme Court held unequivocally that federal law preempts state laws that impose on

⁸⁰ *Bartlett*, 133 S.Ct. at 2483 (Sotomayor, J. dissenting); *PLIVA, Inc.*, 131 S.Ct. at 2586 (Sotomayor, J. dissenting); *Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)).

⁸¹ *Wyeth v. Levine* 555 U.S. at 565 (2009).

⁸² *PLIVA, Inc.*, 131 S.Ct. at 2592 (Sotomayor, J. dissenting) (“Today’s decision leads to so many absurd consequences that I cannot fathom that Congress would have intended to pre-empt state law in these cases.”).

⁸³ See, e.g., *In re Budeprion XL Mktg. & Sales Litig.*, No. 09-md-2107, 2012 WL 2527021, at *16 (E.D. Pa. July 2, 2012).

⁸⁴ Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. at 67988–89.

⁸⁵ *Wyeth v. Levine*, 555 U.S. at 578 (2009).

⁸⁶ *Smith v. Wyeth, Inc.*, 657 F.3d 420, 422 (6th Cir. 2011)

⁸⁷ *Id.*

⁸⁸ *Id.*

⁸⁹ *Id.*

⁹⁰ *Id.*

⁹¹ *Id.*

generic-drug manufacturers the duty to change a drug’s label, thus barring the plaintiffs’ state-law tort claims. The plain language of the *PLIVA* decision compels the same result here.”⁹²

In *Coney v Mylan Pharm., Inc.*, 2012 WL 170143 [SD Ga Jan. 19, 2012], plaintiff brought claims on behalf of himself and his deceased wife, of alleged wrongdoing against Pfizer, Inc., Warner-Lambert Company LLC, and Pfizer Pharmaceuticals⁹³. Plaintiff’s deceased wife was “hospitalized for treatment of seizures associated with her breast cancer after it metastasized to her brain.”⁹⁴ Her doctor “prescribed and administered Dilantin... the brand name under which Pfizer markets the drug Phenytoin Sodium.” Plaintiff’s wife’s prescription was filled with the generic version of Dilantin, known as Phenytoin. As a result of this treatment, Bertha developed a severe skin rash, and was later diagnosed with Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis Syndrome.⁹⁵ These diseases are “known to develop in African-American patients on Dilantin.”⁹⁶ Among other claims, plaintiff alleged that defendants had failed to warn with an inadequate label on the drug. In his argument to the court, Plaintiff attempted to circumvent *PLIVA v. Mensing*, arguing that “his failure to warn claims target Mylan’s failure to include warnings that were included on the FDA-approved label.” As per the Supreme Court’s decision in *PLIVA v. Mensing*, the court here dismissed the claims saying they were preempted.⁹⁷

In *Beck v. Teva Pharm. Indus. Ltd.*⁹⁸, Plaintiff sustained “debilitating neurological damage from taking methotrexate to treat a bad case of psoriasis.”⁹⁹ Plaintiff filled his prescription for methotrexate, and became gravely ill after taking the medication.¹⁰⁰ As a result of taking the medication, plaintiff experienced a lack of oxygen to his brain, which lead to severe brain damage.¹⁰¹ Plaintiff is “now unable to walk or take care of himself without constant supervision.”¹⁰² Plaintiff brought suit against Teva Israel and Teva USA under Nevada state law, claiming that the medication was unreasonably dangerous because “the manufacturers failed to provide an adequate warning for their product.”¹⁰³ In response, Defendants moved to dismiss the claims and argued the claims were preempted by federal law, pursuant to the Supreme Court’s decision in *PLIVA v. Mensing*.¹⁰⁴ The Eastern District of Louisiana found that “The Supreme Court expressly rejected the argument that generic manufacturers could discharge their state-law duties without violating federal law”¹⁰⁵ and also that defendants would not be able to “satisfy their state law duties by asking the FDA to modify the labeling requirement for both brand-name and generic drug manufacturers.”¹⁰⁶ Finally, in granting Defendant’s motion for summary judgment motion based on preemption, the court quoted *PLIVA v. Mensing*, stating that, “the duty for

⁹² *Id.*

⁹³ *Coney v Mylan Pharm., Inc.*, 2012 WL 170143* at 1(SD Ga Jan. 19, 2012).

⁹⁴ *Id.*

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ *Id.*

⁹⁸ *Beck v Teva Pharm. Indus. Ltd.*, 2011 WL 4062219*1 (ED La Sept. 13, 2011)

⁹⁹ *Id.*

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ *Id.*

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

generic producers to comply with federal labeling regulations preempts the state-law duty to provide adequate labels under the [Louisiana Products Liability Act].”¹⁰⁷

Several cases have been preempted as a result of *Bartlett* as well. In *Strayhorn v. Wyeth Pharmaceuticals, Inc.*, the U.S. Court of Appeals, Sixth Circuit, heard an action, which consisted of seven consolidated cases. Here, the plaintiffs alleged that they ingested Reglan’s generic equivalent, metoclopramide, and as a result developed tardive dyskinesia. Plaintiffs brought this action pursuant to state-tort law, alleging that there were design defects that should have been corrected by the generic manufacturers¹⁰⁸. The Sixth Circuit Court of Appeals found that plaintiff’s claims against the generic manufacturer were pre-empted.

The Court stated “[a]lthough we feel compelled to affirm the judgment below in light of the controlling case law, we cannot help but note the basic unfairness of this result. The plaintiffs’ problem is that all of their claims fall within the purview of the TPLA as a “product liability action.” See Tenn.Code Ann. § 29-28-102(6). This is true despite their most artful efforts to dress up a relatively simple failure-to-warn claim in a great variety of tort and contract causes of action. The plaintiffs are therefore caught in a classic “catch 22,” barred from all claims against the generic manufacturers whose drug they ingested (due to federal preemption) and from all claims against the Brand-Name manufacturers (due to federal preemption) and from all claims against the Brand-Name Manufacturers (Due to the TPLA). See *Pliva, Inc. v. Mensing* (Sotomayor, J., dissenting)(‘if a consumer takes a brand-name drug, she can sue the manufacturer for inadequate warnings...If, however, she takes a generic drug, as occurs 75 percent of the time, she now has no right to sue.’).

“This unfairness has been acknowledged by the Supreme Court in both ... and *Bartlett* ..., but the Court has suggested that any resolution of this dilemma rests with Congress. Relief could also come from the Tennessee General Assembly revising the TPLA to allow claims against brand-name manufactures whose labels control the warnings that the generic manufacturers are compelled by federal law to duplicate. But unless or until such change comes, we find no basis to afford the plaintiffs any relief.”¹⁰⁹

In *Tillman v. Woldenberg Village, Inc.*¹¹⁰, the Court considered motions stemming from a wrongful death and survival action. Plaintiffs Jahmal and Jirus Tillman brought these claims as a result of the death of their mother.¹¹¹ Plaintiffs alleged that their mother died as a result of “an adverse reaction to a prescription drug, phenytoin.”¹¹² Numerous companies distribute the drug which is used to treat seizures. Plaintiffs alleged that in March 2012, “Plaintiffs’ mother was taken to the hospital after suffering a stroke. Plaintiffs allege that their mother was given Dilantin or its generic version phenytoin.¹¹³ Plaintiffs further allege that as a result of the medication, their mother developed hives, blisters, bleeding and exfoliation over her entire body,

¹⁰⁷ *Id.*

¹⁰⁸ *Strayhorn v Wyeth Pharm., Inc.*, 2013 WL 6224337* at 14 (6th Cir Dec. 2, 2013)

¹⁰⁹ *Id.* at 26.

¹¹⁰ *Id.* at 1.

¹¹¹ *Id.*

¹¹² *Id.*

¹¹³ *Tillman v Woldenberg Vil., Inc.*, 2013 WL 6198864* at 1 (E.D La Nov. 27, 2013)

until in May 2012, she passed away.”¹¹⁴ Plaintiffs sought compensatory relief against the generic drug companies based on a design defect claim.¹¹⁵ Here, as in previous cases, the Court dismissed the design-defect claim based on federal preemption. The Court states, “[w]hile the Court sympathizes with the position that the Plaintiffs find themselves in, it is beyond this Court’s authority to do anything but apply the established Supreme Court precedent. For this reason, the Court finds that Plaintiffs’ claims against the generic manufacturers are pre-empted and voided by federal law. Accordingly, the generic manufacturers’ motions to dismiss are granted.”¹¹⁶

How the FDA Rule Would Change Things

The proposed FDA rule would work to change this new immunity and bring generic drug companies and brand-name drug companies in parity. First and perhaps most importantly, the proposed rule allows the generic manufacturers to “submit a CBE-0 supplement for generic drug labeling that differs from the labeling of the RLD. . . .”¹¹⁷ Furthermore, to bring the generic companies in line with their brand-name counterparts, both generic and brand-name manufacturers “*must submit a CBE-0 supplement*” if they “obtain[] or receive[] newly acquired information that should be reflected in product labeling” as required by the FDA’s regulations.¹¹⁸ This would “expressly permit [generic drug manufacturers] to update product labeling promptly to reflect newly acquired information . . . irrespective of whether the revised labeling differs from that of the [brand-name manufacturer].”¹¹⁹ The generic drug manufacturers will also be able to submit “Dear Health Care Provider” (“*Dear Doctor*”) letters in the “same manner” that the brand-name manufacturers may and be subject to the same statutory restrictions regarding marketing and misbranding.¹²⁰

The aforementioned proposed changes to the FDA’s regulations should bring the brand-name and generic manufacturers into “parity” regarding their labeling duties, reaffirm the importance of the principle that “the manufacturer bears responsibility for its label at all times,” and remove the immunity generic manufacturers have gained through “impossibility” preemption.¹²¹ The key reasoning which allowed the *PLIVA* Court to rule in favor of the generic manufacturers was the absence of the CBE process and *Dear Doctor* letters as methods for unilaterally changing their labels.¹²² Under the proposed rule, not only will these options be available to generic drug manufacturers, but they will also be required to use them in many circumstances.¹²³ Therefore, assuming this rule is enacted in its current form and a failure-to-warn claim is brought against a generic drug manufacturer, no longer will the company be able to argue that it was impossible

¹¹⁴ *Id.*

¹¹⁵ *Id.* at 3.

¹¹⁶ *Tillman v Woldenberg Vil., Inc.*, 2013 WL 6198864* at 3 (E.D La Nov. 27, 2013)

¹¹⁷ Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. at 67989.

¹¹⁸ *Id.* (emphasis added).

¹¹⁹ *Id.*

¹²⁰ *Id.*

¹²¹ *Wyeth v. Levine*, 555 U.S. at 567–68, 570–71 (2009).

¹²² *PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567, 2575–76 (2011).

¹²³ Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. at 67989.

for them to unilaterally strengthen the warning on their drug. In fact, not only will it have been possible for them to employ the CBE process to comply with their state tort law duties, just like the brand-name manufacturers could have in *Wyeth*, but it is quite possible that they had a duty under the federal law to file a CBE supplement.¹²⁴ In addition, if the manufacturer had submitted a CBE supplement, they would also be able to send *Dear Doctor* letters.¹²⁵

The proposed rule will bring the generic companies directly in line with brand-name manufacturers. First, a generic manufacturer will now be able to make “certain changes to its label before receiving the agency’s approval” under the CBE regulation.¹²⁶ The changes will be limited to those based on “newly acquired information,” which takes into account “new analyses of previously submitted data.”¹²⁷ Such label changes may or may not render the generic drugs as “new drugs” in violation of “federal law governing unauthorized distribution and misbranding” for the same reasons as discussed in *Wyeth* pertaining to the brand-name drugs.¹²⁸ Furthermore, as *Wyeth* makes clear, such proposed regulations will not interfere with “the purposes and objectives” of Congress because “Congress has repeatedly declined to preempt state law” and “may also have recognized that state-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings.”¹²⁹ It was these key points of reasoning on which the *Wyeth* Court’s denial of preemption stood, and it is these same points which will support the abrogation of the Supreme Court’s recent decisions under this proposed rule.

Considering the importance of the availability of state-law tort remedies in pharmaceutical drug cases and the prevalence of generic drugs in the current market, the rule stands to make a lasting impression on our legal system and benefit many people. However, until these speculations come to light, Justice Sotomayor’s closing statement in *Bartlett* stands true: “[T]he Court has left a seriously injured consumer without any remedy despite Congress’ explicit efforts to preserve state common-law liability.”¹³⁰

The Generic Drug Industry’s Concerns are Misguided

¹²⁴ *Id.*; *Wyeth v Levine*, 555 U.S. at 571 (2009).

¹²⁵ Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. at 67989.

¹²⁶ *Wyeth*, 555 U.S. at 568; Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. at 67989.

¹²⁷ *Id.*

¹²⁸ *Wyeth*, 555 U.S. at 570; Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. at 67989 (“Section 502 of the FD&C Act (21 U.S.C. 352) provides that a drug or biological product will be considered misbranded if, among other things, the labeling for the product is false or misleading in any particular (21 U.S.C. 352(a); see also 42 U.S.C. 262(j)). Under section 502(f) of the FD&C Act, a product is misbranded unless its labeling bears adequate directions for use, including adequate warnings against, among other things, unsafe dosage or methods or duration of administration or application. Moreover, under section 502(j) of the FD&C Act, a product is misbranded if it is dangerous to health when used in the manner prescribed, recommended, or suggested in its labeling.”).

¹²⁹ *Wyeth v Levine*, 555 U.S. at 574, 581 (2009).

¹³⁰ *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 133 S.Ct. at 2496 (Sotomayor, J. dissenting).

The generic manufacturers claim that “by imposing a duty on generic manufacturers to update their labeling – and creating significant financial liability for generic manufacturers – the Rule could very well have the unintended consequence of driving up the cost of generic drug products...”¹³¹ They also allege that “...because there are usually numerous (sometimes dozens) generic versions of a given drug product, it is very likely that there will often be multiple differently worded CBE supplements on the same drug, complicating not only a RLD labeling change, but creating mass confusion among health care providers and patients.”¹³² There is no evidence that the cost of generics would rise, or that there would be significant confusion regarding the changes.

Costs

Section III explains the requirements for NDA’s and ANDA’s: ANDA’s are responsible for the same level of post-approval surveillance as NDA’s. The requirements to submit reporting has been the same for both brand name and generic drug manufacturers. Any concerns with potential costs associated with post-approval surveillance insinuates that ANDA’s would have to make drastic changes in their surveillance measures. However, the proposed rule states:

“Application holders must promptly review all adverse drug experience information obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from commercial marketing experience, postmarketing clinical investigations, postmarketing epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific papers, and comply with applicable reporting and recordkeeping requirements (see §§ 314.80(b), 314.98(a), and 600.80(b)). Application holders also must comply with requirements for other postmarketing reports under § 314.81 (21 CFR 314.81) and 21 CFR 600.81 and section 505(k) of the FD&C Act (21 U.S.C. 355(k)).”¹³³

The proposed rule does not seek to make changes to the current reporting requirements that are already in place. The costs associated with post-approval surveillance of ANDA’s will not change to match the costs associated with post-approval surveillance of NDA’s considering the requirements are already the same.

As to the potential costs of litigation, it should be noted that before the Hatch-Waxman Amendments were even enacted, drug manufacturers were subject to tort liability. Until the recent Supreme Court decisions creating immunity for generic manufacturers, they too have faced liability claims. There is no question that tort litigation costs manufacturers.¹³⁴ But despite these costs, generic manufacturers have continued to thrive. The prices of generic drugs have

¹³¹ Jose P. Sierra, *FDA proposed rule would “preempt” Supreme Court rulings in Pliva and Bartlett* (Nov. 14, 2013), <http://www.lexology.com/library/detail.aspx?g=3d890d6f-8fee-4f9f-aa08-b7cb2321cf5c>.

¹³² *Id.*

¹³³ Supplemental Applications Proposing Labeling Change for Approved Drugs and Biological Products, 78 FR 67985 (proposed Nov. 13, 2013).

¹³⁴ Jason C. Miller, *When and How to Defer to the FDA: Learning from Michigan’s Regulatory Defense*, 15 Mich. Telecomm. Tech. L. Rev. 565, 569 (2009).

steadily fallen while their control over the market has grown.¹³⁵ It is impossible to say that generic companies would not have costs associated with tort claims. However, these costs have been incurred by generic manufacturers for years, and there is no indication that the costs are forcing up the cost of drugs. It is a fear and concern that is unwarranted because there is no basis or proof to believe that tort litigation will suddenly drive up the costs of generic drugs.

Confusion

The FDA proposed rule would permit generic manufacturers to change the labeling of their drugs without permission from the FDA. The concern is that “this could create a state of chaos in the marketplace as no one would actually know which warnings were approved and which were not.”¹³⁶ This concern is important. Consistency in labeling helps ensure the safety of the consumers of a drug. It is unknown the potential confusion that may be caused if for some reason multiple ANDA’s with the same RLD change their labels. However, the FDA has attempted to limit any potential confusion.

The FDA acknowledged that there would be concerns with generic drugs having different labels.¹³⁷ In an attempt to develop a solution to these concerns the FDA proposed making changes to their existing website, or creating a new one dedicated to this specific issue.¹³⁸ “The FDA web page would provide information about pending CBE-0 supplements for safety-related labeling changes, including but not limited to: The active ingredient, the trade name (if any), the application holder, the date on which the supplement was submitted, a description of the proposed labeling change and source of the information supporting the proposed labeling change (e.g., spontaneous adverse even reports, published literature, clinical trial, epidemiologic study), a link to the current labeling for the drug product containing the changes being effect, and the status of the pending CBE-0 supplement (e.g., whether FDA is reviewing the proposed labeling change, has taken an action on the CBE-0 supplement, or has determined that the supplement does not meet the criteria for a CBE-0 supplement).”¹³⁹ Furthermore, the FDA is open to comments regarding the effectiveness of a new page, updates to the existing page, or overall methods to make sure that the amount of confusion is limited.¹⁴⁰

A separate website is also the most efficient way to relay the information. The FDA is providing a way to limit any possible confusion through the use of a daily updated website that has complete information. This is a method that can continued to be improved upon. The website decreases the chance of confusion. The minimal chance of confusion is a small risk that is

¹³⁵ Brief for respondent at 14, *Mutual Pharmaceutical Company, Inc. v. Karen L. Bartlett*, 570 U.S. ___ (2013) No. 12-142, available at http://www.americanbar.org/content/dam/aba/publications/supreme_court_preview/briefs-v2/12-1142_resp_amcu_th_hw.authcheckdam.pdf.

¹³⁶ Ed Silverman, *The Op-Ed: The FDA Should Not Change Generic Labeling Rules*, PHARMALOT (Nov. 12, 2013), <http://www.pharmalive.com/the-op-ed-the-fda-should-not-change-generic-labeling-rules>.

¹³⁷ Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, *Pages 67985 – 67999* [FR DOC # 2013-26799] <https://www.federalregister.gov/articles/2013/11/13/2013-26799/supplemental-applications-proposing-labeling-changes-for-approved-drugs-and-biological-products>

¹³⁸ *Id.*

¹³⁹ *Id.*

¹⁴⁰ *Id.*

outweighed by the importance of the rule. There needs to be a way to hold generic manufacturers liable when they have put consumers at risk.

The FDA proposed rule is necessary and important for the safety of consumers. Currently there is no way for those harmed by generic drugs to be compensated for their injuries. It was never intended for ANDA's to receive immunity from state tort liability. The Supreme Court wrongfully preempted state tort liability. The best and most immediate way to rectify the problem is to make changes to FDA's requirement that an ANDA's label must, at all times, match the RLD. The proposed FDA rule fixes the problem by allowing ANDA's to make temporary changes. The FDA considered the potential problems that could occur and were correct in determining that the benefits of the rule outweigh the potential issues that may arise.

Thank you for taking the time to consider our views. If you have any questions, please contact Hayley Pine, hayley.pine@law.nyls.edu; Zachary Perceman, zachary.perceman@law.nyls.edu; or Bryan Assael, bryan.assael@law.nyls.edu.

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