COMMONWEALTH OF MASSACHUSETTS

SUPREME JUDICIAL COURT

No. SJC – 11677

LISA RECKIS and RICHARD RECKIS,
Individually, and as Parents and Natural Guardians of
their minor child, SAMANTHA T. RECKIS,
Plaintiffs/Appellees

v.

JOHNSON & JOHNSON and McNEIL-PPC, INC.
d/b/a McNEIL CONSUMER & SPECIALTY PHARMACEUTICALS,
Defendants/ Appellants

ON DIRECT APPELLATE REVIEW OF A
FINAL JUDGMENT OF THE SUPERIOR COURT

JOINT AMICUS CURIAE BRIEF MASSACHUSETTS BAR ASSOCIATION MASSACHUSETTS MEDICAL SOCIETY IN SUPPORT OF THE PLAINTIFFS-APPELLEES

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MASSACHUSETS BAR ASSOCIATION

The Massachusetts Bar Association ("MBA"), founded in 1910, is a non-profit organization that serves the legal profession and the public by promoting the administration of justice, legal education, professional excellence, and respect for the law. As part of its mission, the MBA provides professional support and education to its members, and advocates on behalf of lawyers, legal institutions, and the public. The MBA does not have any financial interest that will be affected by the resolution of this matter.

The MBA is the largest bar association in Massachusetts, with approximately 14,000 members state-wide. The MBA is governed by a set of bylaws, which were most recently approved by the members in March of 2014, which provide for a House of Delegates that consists of a president, president-elect, two vice-presidents, treasurer, secretary, the two most immediate, living past presidents, 18 regional delegates, seven at-large delegates, chairs of its 20 section councils, and others.

The MBA monitors pending litigation and requests from the Supreme Judicial Court for Amicus Briefs to identify cases affecting the public interest, the legal profession, or the administration of justice that warrant participation by the MBA as a friend of the Court. An Amicus Curiae Committee evaluates the cases and assists in preparation of Amicus Briefs advancing the position of the MBA. The MBA's participation and position is determined by vote of the House of Delegates. The ACC and the HOD have determined that the issue of preemption raised in this case warrants the filing of this brief in support of the Plaintiffs-Appellees.

MASSACHUSETTS MEDICAL SOCIETY

The Massachusetts Medical Society ("MMS") is a professional association of physicians in the Commonwealth of Massachusetts. The purpose of the MMS is to work to advance medical knowledge, to develop and maintain the highest professional and ethical standards of medical practice and health care, and to promote medical institutions formed on liberal principles for the health, benefit and welfare of the citizens of the Commonwealth. The MMS does not have

any financial interest that will be affected by the resolution of this matter.

The MMS has an interest in pursuing legal issues that affect the shared interests of physicians and patients in the Commonwealth of Massachusetts. The MMS also has an interest in enhancing and protecting the physician-patient relationship and in preserving the physician's ability to make clinical decisions for the benefit of patients. In the case at bar, a finding of preemption would significantly and detrimentally affect physicians' abilities to properly treat and advise their patients, would improperly shift the risk of manufacturers' failures to warn consumers to physicians, and would ultimately reduce patient safety. The MMS therefore files this brief in support of Plaintiffs-Appellees in an effort to ensure the health and safety of the citizens of Massachusetts.

ISSUE PRESENTED

The Massachusetts Bar Association and the Massachusetts Medical Society jointly submit this Amicus Brief in response to the following question posed by the Court: “Whether the plaintiffs’ failure to warn claim – i.e., that the label on the defendants’ drug should have instructed the consumer to discontinue usage if certain symptoms manifested – was preempted by Federal law on the theory that the proposed warning would have directly conflicted with Federal requirements, making it impossible for the defendants to comply with both Federal law and a State common law duty to warn ...?”

The Amici submit that the answer to the question is no, and that the Court should hold that the law of Massachusetts governs the rights of the parties.

INTRODUCTION AND SUMMARY

At the core of the question posed by this Court is whether federal law insulates Defendant brand-name drug manufacturers from liability when they fail to adequately warn consumers about potential adverse effects of their Over-The-Counter (“OTC”) drugs. Under the explicit terms of the applicable federal statutes

and basic principles of federalism, state law authorizing failue-to-warn claims and compensatory remedies are not preempted. State law does not stand "as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Wyeth v. Levine*, 555 U.S. 555, 589 (2009). On the contrary, "state law offers an additional, and important, layer of consumer protection that complements FDA regulation." *Id*. at 579. (pp. 1-7)

On the record in this case, the Defendants' claim of a direct conflict between the jury's verdict and federal requirements has no merit. "Impossibility pre-emption is a demanding defense." *Wyeth* at 572. The defendants have failed to produce the sort of "clear evidence" needed to establish that it was impossible for defendants to comply with both federal and state requirements. *Wyeth* at 570-73. (pp. 10-19)

Important public policy concerns counsel against preemption in this case. As the Supreme Court has explicitly acknowledged, the FDA admittedly lacks the resources to fulfill its duties. A conclusion that state law has been preempted in this case would put the health and safety of Massachusetts citizens at risk. A preemption conclusion insulating drug

manufacturers from liability would also improperly shift risk and costs to physicians, consumers, and the Commonwealth's taxpayers. (pp. 19-29)

STATEMENT OF THE CASE

The Amici accept and adopt the statement of the case and the statement of facts in the brief of the Plaintiffs-Appellees.

ARGUMENT

I. PLAINTIFFS' STATE LAW CLAIMS FOR FAILURE TO WARN ARE NOT PREEMPTED BY FEDERAL LAW.

A. Basic Preemption Principles

Fundamental presuppositions inherent in our federal system establish the primacy of state law in most fields, and the generally interstitial nature of federal law. It is well-established that "the purpose of Congress is the ultimate touchstone in every pre-emption case." *Wyeth v. Levine*, 555 U.S. at 565 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). In ascertaining legislative intent for purposes of preemption, particularly where "Congress has 'legislated . . . in a field the States have traditionally occupied,'" *Wyeth*, 555 U.S. at 565, a court must "start with the assumption that the historic police powers of the States were not to be

superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Id.; see Sawash, v. Suburban Welders Supply Co.*, 407 Mass. 311, 315 (1990); *Arthur D. Little, Inc. v. Comm'r of Health & Hospitals of Cambridge*, 395 Mass. 535, 546 (1985). "The States traditionally have had great latitude under their police powers to legislate as 'to the protection of the lives, limbs, health, comfort, and quiet of all persons.'" *Arthur D. Little, Inc.*, 395 Mass. at 546 (quoting *Met. Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985).

Moreover, "the presumption against preemption is even stronger against preemption of state remedies, like tort recoveries, when no federal remedy exists." *Abbot by Abbot v. Am. Cyanamid Co.*, 844 F.2d 1108, 1112 (4th Cir. 1988) (citing *Silkwood v. Kerr–McGee Corp.,* 464 U.S. 238, 251 (1984)). In the case at bar, no federal remedy exists and preemption would leave injured consumers without a remedy.

The Supremacy Clause establishes, of course, that in the event of a direct conflict between state and federal law, federal law will control. But such a direct conflict is difficult to establish, and never lightly to be assumed. *See generally, Sawash*, 407

Mass. 311, 314-15 (1990). Accordingly, "[p]reemption ... is not favored, and State laws should be upheld unless a conflict with Federal law is clear." *Id.*, at 315 (quoting *Attorney Gen. v. Travelers Ins. Co.*, 385 Mass. 598, 602 (1982)).

The party "seeking to displace the State action to show preemption" has the burden of doing so "with hard evidence of conflict based on the record." *Comm. Elec. Co. v. Department of Pub. Utils.*, 397 Mass. 361, 376 (1986). State law will be preempted only when "compliance with both state and federal law is impossible,...or when the state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Sawash*, 407 Mass. at 314-15 (internal citations omitted); *Wyeth,* 555 U.S. at 565.

B. Congress Has Expressly Provided That The Federal Food, Drug, And Cosmetic Act Does Not Displace State Tort Law Imposing Product Liability Upon Manufacturers Of Over The Counter Drugs For Failure To Provide Adequate Warnings To Consumers.

In this type of pre-emption case, it is essential to engage in a detailed analysis of Congressional intent and the regulatory system Congress created to carry out its goals. It is a given that "different

federal statutes and regulations may lead[]to different pre-emption results." *PLIVA, Inc. v. Mensing*, 131 S. Ct 2567, 2582 (2011).

The recent cases of *PLIVA, Inc. v. Mensing*, 131 S. Ct 2567 (2011) and *Mutual Pharmaceutical, Inc. v. Bartlett*, 133 S. Ct. 2466 (2013), held that state law failure-to-warn suits against generic prescription drug manufacturers were pre-empted because federal law prohibited those manufacturers from changing their label; but the defendants here are brand-name manufacturers of the over-the-counter drug Children's Motrin. "It is beyond dispute that the federal statutes and regulations that apply to brand-name drug manufacturers are meaningfully different than those that apply to generic drug manufacturers." *PLIVA*, 131 S. Ct. at 2582.

For this reason, the Court in *PLIVA* took pains to point out that the *Wyeth* case, which had held that state law was not pre-empted, remains good law because a brand-name drug manufacturer is permitted "to unilaterally strengthen its warning." *PLIVA*, 131 S. Ct at 2581. The federal regulations allowed the company, of its own volition, to strengthen its label in

compliance with its state tort duty. The same is true of the defendants here.

The Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. § 321 et seq., expressly preserves injured consumers' ability to bring state law product liability claims against manufacturers of over-the-counter drugs. Section 379r(e) of the FDCA states:

> Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

21 U.S.C. § 379r(e).

This clause is a clear expression of the intent of Congress not to preempt product liability suits under state law, and the clause expressly preserves the historic role of state tort law claims in protecting the rights of consumers and compensating injured parties.

C. State Failure-To-Warn Suit Are No Obstacle To The Accomplishment And Execution Of The Full Purposes And Objectives Of Congressional Regulation Of Over-The-Counter Drugs.

In creating the FDCA, Congress intended to "protect the public health" and to "assure the safety, effectiveness, and reliability of drugs." 76 Stat. 780. The primary intent of the FDCA is therefore to

protect consumers. *See Kordel v. United States*, 335 U.S. 345, 349 (1948). Congress retained for brand-name manufacturers the obligation to maintain updated warnings labels for their products. Indeed, as the United States Supreme Court stated succinctly in *Wyeth*,

> it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market.

Wyeth, 555 U.S. at 570-71. Congress had no intent to foreclose manufacturers from adding adequate warnings to their OTC drugs and no intent to protect them from suits under state law based on their failure to adequately warn consumers. Thus, requiring the defendant manufacturers of OTC drugs to adequately warn consumers does not stand as an obstacle to the accomplishment of the full purpose and objective of congress.

The FDCA explicitly allows brand-name drug manufacturers to assess their own warning labels and modify them if necessary, even without prior FDA approval. Under the Changes Being Effected regulation, (“CBE”), 21 C.F.R. § 314.70(c)(iii)(A), Congress

provided manufacturers with a mechanism through which they could unilaterally amend a drug label to "add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling under [21 C.F.R. § 201.57(c)]." 21 C.F.R. § 314.70(c)(6)(iii)(A). A manufacturer is entitled to add warnings based on newly acquired information, such as new data and new analyses of data. *See Wyeth*, 555 U.S. at 569.

The Supreme Court has recognized that even where new data does not exist, if prior drug-related injuries could have prompted a manufacturer to conduct new analyses, this is sufficient to support a finding that the manufacturer could have analyzed its data and strengthened its warning label. *See id.*, at 569-70. Moreover, the Supreme Court has held that the CBE regulation reflects Congressional intent to "adopt[] a rule of construction to make it clear that manufacturers remain responsible for updating their labels." *See id.*, at 568.

The CBE regulation also makes it clear that the fact that the FDA has already approved a warning label does not render that label sufficient if new

information a manufacturer has (or should have) should result in additional warnings. It also acknowledges that a manufacturer, and not the FDA, is in the best position to properly assess the risks of its drugs. This results in an increase in safety, by permitting the distribution of important safety information to the public as quickly as possible, and it also gives the FDA additional information from the manufacturers themselves to use in assessing the adequacy of warnings already improved by the manufacturers.

Because of the CBE regulation, a manufacturer is free to amend its warnings as soon as it learns of new risks that its product poses, without running any risk of violating federal law. Compliance with the duty imposed under state law liability suits to adequately warn of the risks of its drugs cannot possibly be an obstacle to the accomplishment and execution of the full purposes and objectives of Congress because the purposes and goals of both state and federal law are mutually compatible.

D. No Conflict Exists Between Federal Law And The Jury Verdict.

Conflict preemption does not exist unless it would be *impermissible* under federal law to comply

with state law. *See Roberts v. Sw. Bell Mobile Sys.*, Inc., 429 Mass. 478, 491 (1999) (quoting *Kargman v. Sullivan*, 552 F.2d 2, 6 (1st Cir. 1977)). There is no actual conflict between federal law and the claim that the warning on Defendants' Children's Motrin label in 2003 was inadequate.

Sammie Reckis suffered her devastating injuries as a result of taking Children's Motrin around Thanksgiving in 2003. The defendants had never tried to modify the warnings on their label before her injuries, despite ample evidence that persuaded the judge and jury below to conclude that their existing label was inadequate, and that the defendants knew or should have known of its inadequacy, but did nothing. The defendant manufacturers do not argue that they attempted to give an adequate warning of any sort about the devastating side-effects suffered by Sammie prior to her injuries but were prohibited from doing so by the FDA. That would be the kind of "clear evidence that the FDA would not have approved a change" to a label's warning referred to by the Supreme Court in *Wyeth,* 555 U.S. 571-73. In fact, defendants made no changes to their label until after the FDA acted in 2006. Absent "clear evidence that the

FDA would not have approved a change" to a drug's warning label, a court "will not conclude that it was impossible for [a manufacturer] to comply with both federal and state requirements." *Wyeth*, 555 U.S. at 571.

The Defendant manufacturers attempt to meet this demanding standard by focusing not on their own efforts prior to the devastating injuries suffered by Plaintiffs, but on a subsequent 2005 Citizens Petition by a consumer protection group requesting that the FDA either (1) require manufacturers of OTC ibuprofen to add a warning to the label stating, among other things, that the drug's use could result in Erythema Multiforme, Stevens Johnson Syndrome and Toxic Epidermal Necrolysis, or (2) withdraw FDA approval for the medication.

By the time it addressed the citizens petition, the FDA itself had completed its own review of ibuprofen, and explicitly found that it was necessary to add a warning to the allergy portion of the drug label stating that skin reddening, rash, and blisters were signs of an allergic reaction. The FDA addressed the petition shortly thereafter, and found that the Children's Motrin warnings did in fact still need to

be strengthened. Specifically, in addition to the new warnings that the FDA had already requested, it stated that:

> We agree that the labeling for OTC NSAIDs, including all ibuprofen products, should be improved to warn consumers about the risks of severe skin reactions associated with OTC ibuprofen products[.] As a result; we have requested that manufacturers include under the ***Allergy alert*** subheading the symptoms associated specifically with SJS and TEN: We do not believe that it is useful to include the specific terms SJS, TEN, or erythema multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis in the OTC label because most consumers are unfamiliar with these terms. In addition, effective OTC labeling communicates warning information in a manner that consumers can quickly and easily identify and understand. Consequently, we believe a description of symptoms is more appropriate. Therefore, prominently displayed under the ***Allergy alert*** subheading in the Drug Facts Label, the labeling will include:
>
> - skin reddening
> - rash
> - blisters
>
> In addition, under the ***Allergy alert*** subheading, the labeling will state: "If an allergic reaction occurs, stop use and seek medical help right away." We believe that adding these symptoms to the ***Allergy alert***, with advice to stop use and seek medical attention immediately, will alert and educate consumers to the nature of the allergic reactions associated with SJS and TEN. Further, we intend to continue our consumer education efforts regarding the

safe and effective use of OTC pain relievers.[1]

The FDA's response to the petition is significant for several reasons. First, the FDA agreed that the warning label for OTC ibuprofen products needed to be improved. Far from rejecting the proposed language, the FDA, on its own initiative in 2005 and before addressing the citizen petition, actually requested that Defendants add a warning to their product stating that use of Motrin can cause an allergic reaction resulting in skin reddening, rash, and blisters.[2]

There was testimony from Lisa Reckis that if the FDA's subsequently approved warning language had been on the label in 2003, she would have stopped giving the Children's Motrin to her daughter (A. 9457), and the jury was warranted in concluding that any parent would have the same reaction to the warning.

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[1] *See* Department of Health & Human Services Response to Citizen Petition, Docket No. 2005P-0072/CPI, at 8-9 (June 22, 2006).

[2] *See* FDA Supplemental Labeling Request (6/15/2005), http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm106252.pdf. In 2005, when the FDA issued this request, it lacked the authority to mandate that a manufacturer revise a product warning. Congress first granted the FDA the authority to do so in 2007. *See Wyeth*, 555 U.S. at 567; 121 Stat. 924-26.

Although the FDA chose not to require manufacturers to add the scientific names of medical reactions to their labels, the FDA itself began distributing a Medication Guide directly to consumers along with the prescription version of ibuprofen.[3] That Guide warns consumers of potential life-threatening skin reactions that could result from ibuprofen use. Given that the FDA presumably believed that such a warning was sufficiently important to relay to consumers of prescription ibuprofen, there is no reason to believe that the FDA would prohibit a similar warning in the case of OTC ibuprofen.

In denying the citizens petition, the FDA commented that it did not believe that references to the "specific terms SJS, TEN, or erythema multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis in the OTC label" would be helpful to include on a warning label, since "most consumers are unfamiliar with these terms."[4] Defendants pounce on

[3] *See* Brief for the Plaintiffs-Appellees, Lisa Reckis and Richard Reckis, Individually, and as Parents and Natural Guardians of Their Minor Child, Samantha T. Reckis, 18 (citing to A. 11399).

[4] *See* Department of Health & Human Services Response to Citizen Petition at 8-9, *supra* note 1.

that one comment, *dicta* at best, as the basis for "impossibility" and the reason why reversal is required. But the case that went to the jury below did not include a claim that these terms, or any other scientific term, should have been included as a warning.[5] The phrase life-threatening was certainly consistent with the FDA's description of the risks posed by Children's Motrin.

The jury ruled only on the inadequacy of the 2003 label. It was never asked to identify the specific inadequacy. The defendants never asked that the jury in its verdict be requested to distinguish between hypothetical labels with SJS/TEN, or life-threatening, or merely the label in use since 2006, or something else. In fact, fairly read as a whole, the record of this case and the closing argument of defense counsel demonstrate that detailed analysis of the warning label options was not a theory submitted to the jury

[5] In their Reply Brief, Defendants claim that the jury may have based its award on some misconception that Defendants were responsible for providing a technical warning to their consumers. *See* Reply Brief, at 2. This argument, however, is belied by the trial judge's instruction to the jury, explicitly stating that a warning had to be "understandable to the average user" (10328) – which a technical warning by definition would not be. There is no reason to believe that the jury did not follow this instruction.

at all, let alone a matter of multiple theories they were asked to choose from. Instead, the defendants cast their lot on causation. They should not be permitted to argue for reversal on appeal on a theory of the case different from that pursued at trial.

The FDA was never in a position to simply approve or reject a requested amendment to the Children's Motrin label because a citizens' group filed the petition, as opposed to the manufacturers themselves. There is no way to evaluate what the FDA's response would have been had it had full access to all of the manufacturers' information concerning OTC Children's Motrin.

Wyeth's clear evidence standard is not met by speculation about whether the FDA's adoption, subsequent to the injury in this case, of stronger warning label requirements, in a proceeding the manufacturers declined to participate in, can be taken to prohibit the manufacturers from adopting even stronger warnings. That the FDA was unwilling to *require* manufacturers to provide specific additional warnings to their labels does not mean that the FDA would not have *allowed* the manufacturers to include those warnings had the manufacturers themselves

requested permission to do so. *See, e.g., Wyeth*, 555 U.S. at 573 ("...the mere fact that the FDA approved Phenergan's label does not establish that it would have prohibited . . . a change.").

In essence, therefore, the purported actual conflict argument proffered on appeal by the defendants amounts to no more than a repackaging of the discredited idea that the FDA's labeling determinations are both a floor and a ceiling. *Wyeth,* 555 U.S. at 573-74. No ceiling can be implied under these statutory provisions; the fact that acting on its own the FDA requested stronger labels does not justify a conclusion that it had prohibited a manufacturer from doing even better.

In sum, the relevant inquiry is not whether the FDA required the warning that the citizens' group requested. Instead, the relevant inquiry is whether it would have been impossible for the manufacturers to comply with a state-law duty to modify their warnings without violating federal law. *See Wyeth*, 555 U.S. at 563; *Fidelity Fed. Sav. & Loan Assn. v. de la Cuesta*, 458 U.S. 141, 153 (1982).

The FDA's decision in 2006 that the label on Children's Motrin was inadequate is not "clear

evidence" that the FDA would not have approved a change in the defendants' 2003 label to adequately warn consumers in a manner that would have alerted Sammie Reckis's parents to the serious risks posed by her reaction to Children's Motrin. There is no conflict between federal law and the jury's verdict that the 2003 label's warnings were inadequate.

II. IMPORTANT PUBLIC POLICY CONSIDERATIONS COUNSEL AGAINST ANY CONCLUSION THAT PREMPTION IS WARRANTED IN THE CIRCUMSTANCES OF THIS CASE.

A. Since The FDA Is Not Capable Of Acting As The Sole Source For OTC Drug Warnings, A Conclusion That State Law Has Been Prempted Would Put The Health And Safety Of Massachusetts Citizens At Risk.

As of 2006, the FDA regulated approximately 11,000 drugs.[6] The prospect that FDA would have up-to-date and complete information at all times concerning each drug is simply not realistic. The FDA is also tasked with attempting to monitor adverse reactions from OTC drugs through its receipt and analysis of medication error reports. Through this program, healthcare professionals "review medication error

[6] *See* Michelle Meadows, *Promoting Safe and Effective Drugs for 100 Years, Food and Drug Administration,* Feb. 2006, http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/PromotingSafeandEffectiveDrugsfor100Years/.

reports sent to MedWatch, evaluate causality, and analyze the data to provide solutions to reduce the risk of medication errors to industry and others at FDA."[7] In attempting to monitor adverse reactions, however, the FDA must rely on third party reporting –- a time consuming and unreliable source of data.

As the Supreme Court explicitly acknowledged in Wyeth, *see* 555 U.S. at 578 n. 11, the FDA admittedly already lacks the resources that it needs to fulfill its duties. Specifically, in 2006 and 2007, the Science and Technology Committee of the FDA Science Board (the "Subcommittee") was charged with "assess[ing] whether science and technology at the FDA can support current and future regulatory needs."[8] Following its study, the Subcommittee found that "the FDA is in a precarious position: the Agency suffers from serious scientific deficiencies and is not positioned to meet current or emerging regulatory

[7] U.S. Department of Health & Human Services, *Postmarketing Surveillance Programs*, Food and Drug Administration, last visited Oct. 30, 2014, http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194879.htm.

[8] Subcommittee on Science and Technology, *FDA Science and Mission at Risk*, 2007, http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_01_FDA%20Report%20on%20Science%20and%20Technology.pdf.

responsibilities." The Subcommittee found that this occurred for two reasons:

- The demands on the FDA have soared due to the extraordinary advance of scientific discoveries, the complexity of the new products and claims submitted to FDA for pre-market review and approval, the emergence of challenging safety problems, and the globalization of the industries that FDA regulates.

- The resources have not increased in proportion to the demands. The result is that the scientific demands on the Agency far exceed its capacity to respond. This imbalance is imposing a significant risk to the integrity of the food, drug, cosmetic and device regulatory system, and hence the safety of the public.

The FDA therefore lacks the resources that are necessary to fulfill its current daunting obligations and its mounting responsibilities. Were the FDA put in a position where it became the sole gatekeeper in analyzing and monitoring drug risks, with the manufacturers sitting quietly by without any incentive to improve and adapt product warnings, it would be hard-pressed to take on that responsibility and the inevitable result would be higher overall health and safety risks to consumers.

The United States Government Accountability Office (the "GAO") has also raised concerns about the effectiveness of FDA review. In particular, the GAO found that the FDA lacks the ability to properly

regulate post-approval drugs, in part due to lack of sufficient information and in part due to ineffective processes:

> FDA lacks a clear and effective process for making decisions about, and providing management oversight of, postmarket drug safety issues. The process has been limited by a lack of clarity about how decisions are made and about organizational roles, insufficient oversight by management, and data constraints. We observed that there is a lack of criteria for determining what safety actions to take and when to take them.[9]

The GAO also found that there is insufficient communication between various subdivisions of the FDA, and that

> FDA faces data constraints that contribute to the difficulty in making postmarket safety decisions. For example, FDA relies on clinical trials, reports of adverse drug reactions, and studies following the use of drugs in ongoing medical care in order to evaluate safety concerns and support its decisions, but each type of data has weaknesses. FDA also lacks authority to require certain studies and has resource limitations for obtaining data.[10]

The FDA agreed with the U.S. GAO's findings.[11]

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[9] U.S. Government Accountability Office, Report to Congressional Requesters, *Drug Safety: Improvement Needed in FDA's Postmarket Decision-making and Oversight Process*, GAO-06-402 (March 2006), http://www.gao.gov/new.items/d06402.pdf.

[10] *Id.*, at 5.
[11] *Id.*, at 6.

Moreover, the FDA simply does not have the information that manufacturer have (or should have) concerning OTC drugs. Although the FDA has significant information concerning a drug when it first approves that drug, its knowledge decreases as time passes, as more and more consumers use the OTC drug, and as more adverse reactions occur.[12] Indeed, "[o]nce the drug enters the marketplace, risks that are relatively rare, that manifest themselves only after an extended period of time, or that affect vulnerable subpopulations, begin to emerge." At this point, although the manufacturer presumably continues to study and assess its OTC drugs, the FDA lacks complete information concerning the drug that a manufacturer would have, or effective processes for reviewing the information that it does have.

The FDA generally cannot acquire complete information concerning drugs from manufacturers. It has no ability to subpoena materials from manufacturers in order to gain the same level of information that the manufacturers already has within its own files, nor does it have access to, or any

[12] David A. Kessler and David C. Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, 96 Geo. L.J. 461, 466 (2008).

ability to participate in, internal manufacturer communications concerning OTC drugs. The FDA therefore must rely on information that manufacturers choose to provide to it and on incomplete third party reports.

Yet the trial Court found that for years the defendant manufacturers failed to apprise the FDA of studies linking their product to SJS and TEN.[13] Without full information to evaluate OTC drugs, the FDA is simply not in a position to properly evaluate the risks that the many drugs that it regulates pose to consumers.

Furthermore, a finding of preemption would further decrease the information available to the FDA. Manufacturers would be less likely to root out and report risks. As the Vice President of Marketing for McNeil acknowledged at trial, Defendant McNeil's marketing budget amounts to approximately $450 million, annually. Those funds were used to positively communicate the benefits of the Defendant's OTC drugs to the public, not to warn consumers of potential

[13] *Findings of Fact, Rulings of Law, and Order for Judgment on Plaintiffs' Cause of Action for Violation of General Laws Chapter 93A*, at 10-11 (June 26, 2013), A. 2608-09.

dangers. The Vice President acknowledged that increased warnings of adverse side effects "affect a brand's reputation and . . . cause sales to go down."[14] Manufacturers have an incentive to limit their warnings in order to maximize their profits but that incentive is offset by the risk of tort liability for failure to warn. Were the risk of tort liability shifted away from manufacturers, however, they would have little incentive to add warnings to their drug labels that admittedly drive down their profits. With no cost to balance out the benefit of failing to warn of adverse side effects, manufacturers would have little incentive to monitor for potential risks, conduct ongoing studies of their OTC products, identify risks and provide information concerning those risks to the FDA, or ultimately to add warnings to their products.

Indeed, a published Perspective in the New England Journal of Medicine acknowledged this concern in a 2008 editorial, writing that "[i]n stripping patients of their right to seek redress through due process of law, preemption of common-law tort actions is not only unjust, but will also result in the

[14] A. 2608-17.

reduced safety of drugs and medical devices for the American people."[15] Ultimately, preemption would harm consumers, in direct contravention of the very purpose of the FDCA and the fundamental premises underlying common law tort liability. Permitting preemption in the case at bar would result in higher health and safety risks, with a concomitant increase in costs, and shift both existing and increased costs away from drug manufacturers.

B. Preemption Would Insulate The Defendant Drug Manufacturers From Liability And Would Improperly Shift Risk And Costs To Physicians

Physicians would ultimately bear much of the cost of any such shift. Even though they do not directly prescribe OTC drugs to patients, physicians remain highly involved in the selection of OTC drugs by recommending OTC drugs to patients, advising patients concerning OTC drugs that they may or may not take, and advising patients concerning how OTC drugs might interact with a patient's other medications. Indeed, certain OTC medications explicitly warn patients to

[15] Gregory D. Curfman, Stephen Morrissey & Jeffrey M. Drazen, *Why Doctors Should Worry About Preemption*, 359 New. Eng. J. Med. 1, 1 (2008).

consult physicians prior to their use.[16] In addition, physicians often become involved with OTC drug use when patients who experience adverse reactions to the drugs turn to physicians for treatment of those reactions.

It is well-recognized that physicians have many obligations to their patients, including obligations to:

- "be dedicated to providing competent medical care, with compassion and respect for human dignity and rights[;]"
- "continue to study, apply, and advance scientific knowledge, maintain a commitment to medical education, make relevant information available to patients, colleagues, and the public, obtain consultation, and use the talents of other health professionals when indicated[;]," and
- "regard responsibility to the patient as paramount."[17]

In order to fulfill these duties to their patients, physicians must have full information concerning the OTC medications that they recommend,

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[16] *See, e.g.*, 21 C.F.R. 201.66(c)(5)(iv),(v), concerning warnings that instruct patients to consult a medical doctor prior to use of an OTC drug.

[17] American Medical Association, *Principles of Medical Ethics* (last visited Oct. 31, 2014), http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/principles-medical-ethics.page?.

advise, and treat their patients with, including potential adverse effects of those medications. Drug manufacturers are best situated to identify, investigate, and warn of potential risks from their products. If drug manufacturers lost their incentive to provide robust information to the FDA, and in turn, to physicians and consumers, the ensuing knowledge deficit would seriously jeopardize patient safety. As the experiences of Samantha Reckis demonstrate, when both consumers and physicians lack information known to the manufacturer regarding life-threatening risks of medications, the consequences can be devastating.

Due to their necessary involvement with OTC drugs, physicians will be in the precarious position of facing liability for the failure of drug manufacturers to adequately warn consumers who are thereafter injured by manufacturers' OTC drugs. Essentially, then, despite their lack of information, physicians will be called upon to complete the task of identifying and educating themselves concerning adverse effects that manufacturers fail to warn of, both to protect their patients and to protect themselves from liability. When they are not able to do so, those physicians will bear the costs of the

choice of drug manufacturers not to provide adequate warnings. This inappropriate result should not be permitted to occur.

C. Insulating Drug Manufacturers From Liability For Failure To Warn Would Shift Risk And Costs To Consumers And To The Commonwealth.

To the extent that injured consumers are not permitted to seek relief from drug manufacturers and are unable to obtain compensation from physicians, consumers will necessarily be called upon to absorb the costs of drug manufacturers' failure to warn. Moreover, at the same time that injured patients are called upon to pay the costs of medical treatment and care, they may also be facing a lower income base, as a result of lost wages or diminished earning capacity. If consumers themselves are unable to bear these costs, the Commonwealth and its citizens, will have to shoulder this burden.

In 2006, Massachusetts spent approximately $1 billion on its Medicaid program, on individuals with medium to low income, and on other health care programs.[18] Between 2006 and 2010, the Commonwealth's

[18] *See* Shawn Tully, *5 painful health-care lessons from Massachusetts*, Fortune (June 16, 2010), http://archive.fortune.com/2010/06/15/news/economy/massachusetts_healthcare_reform.fortune/index.htm.

healthcare spending rose to $1.75 billion.[19] As of 2012, Massachusetts already had the highest per capita healthcare costs in the country.[20] If the Commonwealth were put in the position of paying higher healthcare costs as a result of adverse outcomes attributable to the failure of drug manufacturers to provide adequate warnings about their OTC products, in addition to supporting residents that are no longer able to support themselves because of their injuries due to inadequate warnings, costs to the Commonwealth and its taxpayers would be driven up even further. Since drug manufacturers are in the best position to properly assess the risk their products pose, they should be responsible for costs generated by their failure to adequately warn consumers of those risks.

CONCLUSION

The Court should hold that federal law does not pre-empt the Plaintiffs' state law claims, and proceed

[19] *See id.*
[20] *See* Dan Gorenstein*, Massachusetts and the high price of health care*, Marketplace audio (last visited Oct. 31, 2014), http://www.marketplace.org/topics/business/health-care/massachusetts-and-high-price-health-care.

to resolve the remaining issues in the case under

Massachusetts law.

Respectfully submitted,

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MASS. R. A. P. 16(k)CERTIFICATION

The undersigned counsel certifies that this brief complies with the Massachusetts Rules of Appellate Procedure pertaining to filing of briefs including, but not limited to, the Rules noted in Mass. R. A. P. 16(k).

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