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March 18, 2009

To: Members of the Michigan House Judiciary Committee
From: Michigan Lawsuit Abuse Watch, M-LAW
Re: Michigan's "FDA Defense" law

M-LAW would like to thank the distinguished members of this committee for the opportunity to express our opinion on House Bills 4316, 4317 and 4318.

Our consumer advocacy group urges this committee to oppose these bills and preserve the state's "FDA defense law" for two primary reasons: 1) to protect the availability of medicine for patients, and 2) to make Michigan more attractive to companies considering creating jobs in the life sciences industry.

The leadership team of M-LAW is comprised of small business owners, doctors, and community leaders who are well-known for providing valuable services for the poor and disadvantaged. We care deeply about the safety and well being of Michigan's families, and from the day we launched our organization, we have advocated on behalf of families who have been negatively affected by the impact baseless lawsuits have had on health care.

At M-LAW's first news conference, a Farmington Hills father talked about his fear that lawsuits against the manufacturers of brain shunts his daughter needed were forcing an end to the production of these life-saving devices. At that time, the number of companies making brain shunts had decreased from 14 to 2 because of the threat of litigation, and the health risk to thousands of patients like his daughter was very real. Congress later passed a law to provide legal protection to biomaterial manufacturers, and we believe Michigan's groundbreaking law providing pharmaceutical makers with reasonable protections from lawsuits when their medicine receives FDA approval was a forward thinking attempt to make sure such a crisis would not happen with medicine.

Today, Michigan has the highest unemployment rate in the nation, and we believe the last thing the legislature should do is make it easier to sue job providers who are already complying with strict federal regulations. House Bills 4316-4318 would open the floodgates to lawsuits against the very type of life sciences companies we need to attract to Michigan. In addition, these bills will expose Michigan's family physicians to more frivolous lawsuits.

In the two years since this committee last considered legislation to repeal the FDA defense law, the U.S. Supreme Court has provided guidance to lawmakers who must wrestle with the difficult issues we are considering here today. In a



near unanimous 8-1 decision in the Riegel v. Medtronic case, the Court recognized that it is sometimes necessary to place limits on lawsuits in order to protect the common good.

Although that lawsuit involved medical devices rather than medicine, the questions posed to the attorneys by the members of the Supreme Court were just as important as their ultimate ruling to limit lawsuits. During questioning, the Court recognized that since juries look only at the unique facts of a particular injured patient, they are prone to weighing only the dangers of a medical device. To quote the Court, a jury "is not concerned with its benefits," or the fact that "the patients who reaped those benefits are not represented in court."

Michigan's FDA defense law -- by protecting the interests of the millions of people who are not represented in court -- addresses the Court's concerns about letting personal injury lawyers set public health policy through lawsuits. It recognizes that the methodical research and testing performed by the FDA, while not perfect, still provides the best assurance that those of us who need medicine will have access to the safest and most effective medicine that can be made available.

Opponents of Michigan's FDA defense law are now arguing that another recent Supreme Court ruling upholding a verdict in favor of a plaintiff in a lawsuit involving FDA-regulated medicine means Michigan should repeal its FDA defense law. However, we believe that the Court's ruling in the Wyeth v. Levine case actually underscores the need for Michigan's law. The circumstances of the Riegel and the Wyeth cases were very different, with one case involving express pre-emption and one involving implied pre-emption. Those differences account for the much different outcomes in each case.

In the wake of these two landmark Supreme Court decisions, the underlying reasons supporting pre-emption remain the same. Since lawsuits can have such an enormous effect on public health policy, it is the responsibility of the government to protect the interests of patients who are not parties to the lawsuits. That's exactly what Michigan's FDA defense law does. M-LAW believes that the safeguards provided by this law provide a much-needed balance between the right of victims to sue and the right of individuals with health problems to receive the medicine they need.

While Michigan is just one state, states are supposed to be incubators for legal reform. Michigan happened to lead on this important issue because of the vision of leaders in the legislature at that time. It would be wrong to wait for Congress and other states to act to protect the medicine our families need. That is why we urge the Michigan House to vote 'No' on House Bills 4316-4318. Thank you for your consideration.

M-LAW statement to
Michigan House
Judiciary Committee

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