Johnson & Johnson

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Memo To: Michigan House Judiciary Committee

From: Greg Aronin, Director, State Government Affairs

Re: HB 4044 & HB 4045 – Repeal of FDA Defense Law

On behalf of Johnson & Johnson, I would like to request that you vote against reporting HB 4044 & HB 4045 from Committee. As you know, HB 4044 seeks to repeal the government standard provision for drugs approved by the U.S. Food and Drug Administration (FDA). HB 4045 seeks to make the repeal retroactive to 1996.

At Johnson & Johnson, our pharmaceutical companies take great care to comply with the specific provisions and requirements of the FDA when seeking approval of a new medication and meet, and oftentimes exceed, FDA requirements in conducting post-marketing surveillance of drugs to ensure drug safety. We remain in constant contact with the FDA on our marketed products and work hand-in-hand with the FDA when any questions or concerns arise. The 12 to 15 year approval process is rigorous and is supplemented by constant post-marketing vigilance. Drug safety is always our primary concern.

While other states have similar laws to that in Michigan, and still others have years of case law that support an FDA government standard, Michigan has taken the lead to clarify the important role of the FDA as the final arbiter of what responsible drug manufacturers should reasonably inform prescribers about the risks and benefits of drugs. Michigan has rightly concluded that the FDA, with its expert scientists who are committed to drug safety, is best suited to make such decisions as opposed to a lay jury with no experience in such matters.

Michigan has developed into a leader in innovation in the life sciences, which has been recognized worldwide. For example, in 2005, Johnson and Johnson companies invested nearly $12 million in expenditures for clinical trials for pharmaceuticals and devices in the State of Michigan.

There are many reasons for this progress, and among them are policies that encourage investment in this important area. While there are innate risks in drug development, there are also potentially high rewards for the patients that will benefit and for a regional or state economy. Johnson & Johnson encourages you to continue to support policies that will further Michigan's advance as a World leader in life sciences.

Please oppose reporting HB 4044 and HB 4045 from the House Judiciary Committee.

Thank you for considering our position regarding this important matter.

MICHBIO Statement on the Proposed Repeal of Michigan's Tort Reform Laws.

Stephen Rapundalo, Ph.D., Executive Director.

February 14, 2007

In his definitive 1990 study of international trade, *The Competitive Advantage of Nations*, Harvard Business School professor Michael E. Porter cited that...*"In the United States... product liability is so extreme and uncertain as to retard innovation. The legal and regulatory climate places firms in constant jeopardy of costly and...lengthy product suits. The existing approach goes beyond any reasonable need to protect consumers, as other nations have demonstrated through more pragmatic approaches."*

The fact is that Michigan, through its current tort reform laws, has not followed the above tenet. Instead, it has been progressive in its balanced understanding of how best to protect consumers while demonstrating a positive business climate for life sciences companies. A repeal of the laws enacted in 1996 would be to the detriment of the life sciences industry, would reverse 10 years of steady growth, neuter the economic development impact of the 21st Century Jobs Fund, and without a doubt diminish future investments in this market sector.

How can we preach the need for greater innovation in R&D on the one hand, then turn around and stifle it by repealing the product liability laws? How can we look upon the life sciences to assist in the badly needed diversification of our economy, only to dim the embers of the industry's sustainability? Michigan is bleeding life sciences talent following the Pfizer announcement to close its Ann Arbor and Kalamazoo human health operations. How can we ask Pfizer scientists to stay and initiate new biotech ventures, but at the same time place impediments to their chances of commercialization success because the laws were changed to give them less security, or at the very least liability insurance rates would be dramatically increased and impose on their bottom line? We must stem the talent outflow, rather than hasten it with repeal of tort reform that would create open season for our life science companies to look to more business-friendly states, and take their highly skilled workforce with them. The proposed repeal is simply at odds with our state's economic development strategy at a time when we can least afford further losses in the life sciences industry.

The 230 members of MichBio, along with another 310 companies, that collectively make up the life sciences-related industry in Michigan look to the Legislature for leadership in our mutual bid to create a vibrant life sciences community. However, the possibility of a dramatic rise in the level of risk that companies may have to incur in conducting their R&D activities, would be alarming. Worse yet, would be to expose the industry to a backlog of product claims with a potential devastating impact that goes far beyond the pharmaceutical industry.

The fact is that drugs and medical devices are simply the most regulated products around. Less than 1/100 of a percent of potential medications investigated survive the FDA regulatory review gauntlet and become product launches. An even then, they continue to face "cradle to grave" surveillance and reporting requirements. The contention that lay juries with no medical or science training, or understanding of the new drug application process, are better judges of relatively brief testimony, as opposed to the 12-18 month exhaustive review by experts in the field, is irresponsible. The tort system is simply ill-suited to reach a better conclusion than the FDA on drug or medical device safety.

So let's leave product liability to the experts, and leave the tort system as is. Current law and process present an appropriate balance whereby the FDA is allowed to perform its regulatory duties, but allowing for punishment of companies that willfully withhold information or interfere with the drug approval process. Let's not unduly raise the risks for the many due to failures of the few, where current law and tort reform already provides for meaningful recourse to the injured.

Be reminded that tort reform repeal would not only target the large pharmaceutical manufacturers like Pfizer, but would be more far-reaching. Included would be medical device manufacturers like Stryker, Terumo, Atek, and Medtronic and other smaller ventures, generic manufacturers like Perrigo, biologics manufacturers such BioPort, and even animal health companies like NeoGen. At even greater risk would be the small biotech start-ups like Pipex Therapeutics, ProNAi, NanoBio, Cerenis Therapeutics and Meditrina Pharmaceuticals, among many, many others – all are potential casualties with repeal. Instead let's insure that they are the future of Michigan's renaissance into a leading biotech economy.