Henry Hank Greenspan, Ph.D., Ann Arbor, Michigan
To: Michigan House Judiciary Committee
Re: In favor of SB 410

October 24, 2023

I write as a private citizen. I have provided testimony on this issue to Michigan legislative committees in 2006, 2007, 2009, and 2023. I am not a lawyer and have never been a plaintiff. Before I retired from teaching and became emeritus at the University of Michigan, I taught courses on pharma, FDA, and policy. I bring that background to my comments.

1. Beyond Partisanship

Opposition to the Michigan statute has been surprisingly bipartisan. People of principle across the political spectrum have sought its repeal. Republican State Senator Alan Cropsey, for example, said about this law: "It's devastating to consumers. It's so un-Republican for Republicans to be saying it's up to a government agency to determine what's right or wrong. We have to get more people in the Legislature who understand how people have been hurt by this." The bill to repeal Michigan's law in 2006 was introduced by State Representative Leon Drolet, a libertarian Republican who was then Chair of the Michigan Taxpayer Alliance. Drolet's bill to rescind passed 70-39 in the Michigan House. Unfortunately, in the view of those legislators, the Michigan Senate narrowly blocked votes on repeal in 2006 and 2008. The Senate's recent 30-8 vote in favor of rescinding has returned us to rational, bipartisan policy.

2. Absolute Immunity

Michigan is the only state in which FDA approval provides absolute immunity for drug companies. Thus the *Drug and Device Law Blog* (DDL), one of the most referenced voices of lawyers who defend the drug industry, wrote about Michigan: "For all intents and purposes, if a drug complies with the terms of the FDA's approval…the defense wins." During the past dozen years, states like Georgia, Wisconsin, and North Carolina considered a law like ours. It was soundly rejected by bipartisan majorities every time.

3. Illusory Exceptions

The same DDL post cited above noted that what appears to be a "fraud exception" in Michigan's law is illusory, since case law has determined that only the FDA-- really DOJ and HHS—can prove fraud on FDA, not outside litigants. And, most critically "***intentional***" withholding or misrepresenting to FDA information required by law constitutes a criminal felony. A felony finding would exclude a company from selling to programs like Medicare or Medicaid. Such exclusion would not only bankrupt a company but also leave millions of patients without access to *any* of the drugs that company sells—with devastating consequences.

For that reason, the FDA/HHS/DOJ ***never do pursue felony fraud convictions against such companies, and no petition from an outside party would change that*** (despite what some of our law's defenders have claimed). Rather, when FDA/DOJ has "the goods" on a company, the result is typically a combination of fines, misdemeanor charges, and a "corporate integrity agreement." None of this meets the exceptions to absolute immunity in the Michigan statute. The "fraud exceptions" are thus themselves, de facto, meaningless. They are premised on a scenario that never happens.

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4. Delinquency Beyond Defrauding FDA

Beyond their dealing with FDA there are a range of delinquencies for which pharma companies are found liable in other states: sub rosa post-approval marketing of a drug for uses and at doses never approved by FDA; misrepresenting data to prescribers and the medical journals on which prescribers rely; direct financial kickbacks to corruptible prescribers; coordinating smear campaigns against critics; ; going out of their way to *not* go out of their way to pursue safety "red flags" about which a company is aware. **Because it is their product, companies will always know more and sooner about their drug than FDA. Whether or not a company appropriately assesses anticipated risks is grounds for accountability in other states. In Michigan, our law provides no such accountability.**

4. Public Health

In Michigan, supporters of drug industry immunity sometimes refer to our statute as an "FDA defense law." This is ironic because, for seventy years, the FDA has viewed state tort liability as complementary to its public health mission. Thus FDA Chief Counsel Margaret Porter wrote in 1997: "FDA's view is that product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection." Conservative economist Milton Friedman justified radical deregulation of FDA on the grounds that lawsuits would keep companies accountable. In Michigan, we have *nothing* to keep companies accountable.

During a brief period during the G.W. Bush administration, FDA's Office of Chief Counsel did advocate an FDA-only policy. The doctrine was rejected 6-3 by the Supreme Court in *Wyeth v. Levine*. In an amicus brief filed in that case, eleven current and former editors of the *New England Journal of Medicine* (NEJM) noted: "Without the tort system, the FDA would be stripped of an essential source of information that the agency has consistently relied on when making its regulatory decisions, and the American public would be deprived of a vital deterrent against pharmaceutical company misconduct. Thus, rather than promote public health, the preemption of failure-to-warn claims would substantially *threaten* it." [emphasis in original]

5. Conclusion

I am not anti-pharma. Some of my best students have gone on to work in the industry, and I applaud them. My own life has depended on receiving the right drug several times. Rather than being anti-pharma, I am anti-corruption and anti-fraud--not only on FDA, but in relationships with prescribers, agencies like Medicare, in direct marketing to patients, and with other stakeholders.

Rhetoric notwithstanding, the forty-nine other states in which liability is possible have not created a catastrophe either for the industry or for those who rely on it. The opposite is true. **As the NEJM editors agree, accountability is correlated with more responsible companies, safer drugs, and—as a result--better healthcare.**

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