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Overview of Testimony, February 2007

The attached testimony supports adopting HB 4044, which would restore proper balance between the rights of Michigan citizens, protection of the public health, deference to the FDA, and respect for the needs of the pharmaceutical industry.

The following arguments are documented in the testimony that follows:

1. **The "fraud and bribery exceptions" in Michigan's 1995 drug industry immunity statute are, de facto, meaningless. First, as our law has been interpreted in federal courts, only the FDA, not individual citizens, can bring action for fraud against the agency. Second, over the past twenty years, there have been essentially *no* instances in which the FDA has brought such action in contexts relevant to Michigan's law (successful prosecution coupled with loss of drug approval). Third, even if the FDA *were* to bring such action, higher court decisions indicate that industry immunity would remain absolute in Michigan.**

   The purported "exceptions" are, therefore, triply illusory.

2. **Beyond fraud or bribery against the FDA, there is a very wide range of other serious delinquencies for which pharmaceutical companies may be held accountable in every other state except Michigan. Such actions, described as "unconscionable" in some state laws, may include: knowingly providing misinformation about a drug to consumers, physicians, and major medical journals; reporting but obscuring, and certainly not red-flagging, important safety data; using threat and intimidation against researchers who question a company's claims; dragging out label change negotiations—in particular, about significant warnings—for market considerations; and so on.**

   For the most part, the FDA has very limited authority to regulate such actions. Some are fully outside its purview. This would be as true of an ideal FDA as the actual agency we have now.

3. **That is why court after court has agreed that the FDA sets only "minimum standards" and that "FDA approval does not shield a manufacturer from liability." That is also why former FDA chief counsel Margaret Porter asserted, "FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection."**

   What is most egregious about Michigan's 1995 law is that an entire layer of consumer protection that functions in every other state has been simply lopped off. And we are left with a regulatory scheme that does not have the means, the mandate, the incentives, the precedents, or the authority to carry the ball.

Henry Greenspan, Ph.D.
February, 2007

Testimony submitted in support of HB 4044

I address the Judiciary Committee of the Michigan House as a private citizen. At the same time, I am a founding member of Justice in Michigan, an organization of physicians and academics all of whom teach at colleges and universities across Michigan (http:/www.justiceinmichigan.org). Our organization is dedicated to rational, fact-based public policy. We support rescinding Michigan's 1995 drug industry immunity statute.

I write here specifically in support of HB 4044, a bill which, in my judgement, would restore proper balance between the rights of Michigan citizens, protection of the public health, deference to the FDA, and respect for the needs of the pharmaceutical companies.

The core of my argument resides in the fact that Michigan's 1995 drug industry immunity law sets very specific, very high, and very narrow criteria for potential civil liability (what have become known as the "fraud and bribery exceptions"). Looking simply at fraud, for example, according to the statute a company must "intentionally withhold from or misrepresent information concerning the drug that is required to be submitted" by FDA regulation *and* "the drug would not have been approved" or approval would have been withdrawn had the information been accurately submitted.

Intentionally withholding or misrepresenting information required by the FDA is, by definition, a criminal felony (and, in Michigan, requires a finding by the FDA—specifically by its Office of Criminal Investigation—that criminal fraud has occurred in the drug approval or post-approval process). It is thus a far more specific criterion than "not acting in good faith," "not playing fair," or other such language that is sometimes used—inaccurately—to describe what the Michigan fraud exception actually requires. Indeed, these vacuous summaries of our law are themselves fraudulent.

In some other states—New Jersey, for example—deliberate fraud against the FDA is specifically reserved as a criterion to assess punitive damages (as occurred in the most recent Vioxx case). Meanwhile, in states like New Jersey, a company remains potentially liable for pursuing actions that are deemed "unconscionable" for a vast range of other behaviors: for example, deliberately misleading physicians, consumers, and medical journals through inaccurate information about a drug, submitting data but "neglecting" to include company interpretations that red-flag safety concerns, deliberately dragging out negotiations over significant warning change, and so on. In Michigan, these sorts of actions—which may well rise to the level of "unconscionable"—are *not* grounds for liability at all.

And it is even more narrow than that in our state. Not only do the "exceptions" require that the FDA successfully prosecutes criminal fraud, but the defrauding in question must have been such that the drug would otherwise not have been approved or approval

withdrawn. The former is hypothetical and, in essence, impossible to prove. The latter can be shown if the drug in question is, in fact, withdrawn in conjunction with the felony fraud prosecution. Withdrawal of approval is a specific *additional* criterion and *need not* follow from felony prosecution. For example, the FDA might decide that the defrauding warrants a fine but not a change in the drug's availability; or they might require a label or warning change as a result of the suppressed information, but not withdrawal of approval; or certain dosing regimens may no longer meet approval but the drug itself is not withdrawn. All of these are regulatory decisions (which happen all the time) and, within the FDA, are carried out separately from the actions of the Office of Criminal Investigation.

It is critical, then, to understand the specificity and narrowness of the Michigan criteria—criminal fraud prosecution *and* drug withdrawal—which must both be met as the law is written. For reasons summarized below and documented in the attached, fuller testimony, the specificity of Michigan's criteria are part of their undoing—for a number of interrelated reasons, they are narrow enough to make them, in practice, meaningless. Meanwhile, in Michigan, there is no accountability at all for the vast range of "unconscionable" behavior more generally, a good deal of which remains largely or fully outside the purview of the FDA (even an ideal FDA) but common as the focus of civil liability. That is why I believe Michigan needs to rejoin the other forty-nine states in which *both* FDA regulation *and* civil liability protect citizen's rights and serve public health. The FDA alone does not have the means or the mandate to do that alone.

The above argument is supported and, most importantly, documented by the following more specific points:

I. The so-called "fraud and bribery exceptions" of the 1995 drug immunity law are, de facto, meaningless.

a) In a recent paper which focuses on the 1995 Michigan law, Daniel Troy himself—former FDA chief counsel and architect of the contemporary "FDA preemption" argument upon which our law is premised—acknowledges that, as the 1995 Michigan law has been interpreted in federal courts, only the FDA can take action for being defrauded. On their own, individual citizens can do nothing. Troy writes:

> "To avoid constitutional difficulties, the United States Court of Appeals for the Sixth Circuit has held that the fraud and bribery exceptions require an FDA finding that fraud or bribery has occurred."[1]

[1] Daniel Troy, "State Level Protection for Good-faith Pharmaceutical Manufacturers." 2006. An earlier version of this paper was presented as the keynote address for a panel on the FDA Compliance Defense, sponsored by the Federalist Society at Ave Maria Law School, on March 21, 2006. Mr. Troy was FDA chief counsel from 2001-04, and is generally considered the primary national spokesperson for the "FDA compliance defense" and its correlate that an FDA ruling ought to "preempt" the findings of state juries, thus the notion of "FDA preemption" which is the philosophic basis of the 1995 Michigan law. In the

This point is now beyond dispute.

b) The question, therefore, arises: How often is it that the FDA ever does find that felony fraud or bribery has occurred in the initial and continuing drug approval process, coupled with withdrawal of the drug, which are the relevant conditions for the "exceptions" to full immunity in the 1995 Michigan law?

The answer is surprisingly simple. In my own search over several months, which includes a FOIA request and direct consultation with FDA officials, I have not found a single case that meets these criteria since the FDA's Office of Criminal Investigation was established in 1992. While there have been a handful of FDA prosecutions for fraud in the context of prescription drug manufacture, none of these have been associated with actual or imaginable withdrawal. Rather, they have involved the cover-up of problems in a particular batch of a medication or some similar manufacturing irregularity.[2] In most such cases, the company is fined while the problem is resolved through fixing the irregularity, not withdrawing the drug.[3]

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immediate context of the quotation above, he is referring to the decision in Garcia v. Wyeth-Ayerst Labs, 385 F.3d 961, 966-67 (6th Cir. 2004).

[2] An example is a 1995 action against Warner-Lambert for covering up dosing problems caused by manufacturing defects in its anti-seizure drug, Dilantin. There was never any question of removing Dilantin itself from the market.

[3] This interpretation is supported by my own FOIA request in which I asked the following question: "Since the founding of he FDA's OCI in 1992, how many times has an OCI action led to the successful prosecution (on either felony or misdemeanor charges) of a pharmaceutical company, specifically for fraud in the new drug approval process (suppression, misrepresentation, delay in reporting data) or in the post-marketing reporting of such data as required by the FDA?" Note that this is actually a wider question that the criteria of the Michigan law. "Misedemanor" prosecutions are included (failure to report which may not have been deliberate, but negligent), and there is no reference to the additional criterion of the drug having been withdrawn.

FDA's OCI office was very forthcoming, both in responding to my request with diligence and speed, and in being willing to discuss the findings with me. The answer to the main question: 3 such cases were identified. As far as fraud, there was no question—documents were shredded, etc.. Every one of these cases concerned a generic version of very common drugs (one an OTC antihistamine) , and thus the drugs in question *all remain on the market.* The OCI had no information suggesting that even these generic companies could not continue to manufacture their versions of these drugs, or that any patients were harmed by them. Rather, fines were paid, and—in the most likely scenario according to an OCI official (the final regulatory outcome is determined not by OCI but by another office in the FDA)—the problems were remedied or additional information was requested—and selling the drug went on. Assuming so, none of these cases meet the Michigan criteria.

Lest it me presumed that this small number of prosecutions refkects the difficulty of winning such cases, I also asked for the number of cases "for which prosecution was initiated by an OCI action but was not successful (no charges or penalties resulted). OCI's answer to this question: "0". (FDA DFOI [HFI-35])

It is, therefore, noteworthy that, in his discussion of our Michigan law, Mr. Troy insists that "manufacturers who mislead the FDA do so at their peril."[4] Yet—in support of that claim—he gives as his sole example a case of no relevance to pharmaceuticals at all. Instead, he cites the Guidant case of 2003, one which did not concern drugs but rather a malfunctioning medical device, which device was also withdrawn when the facts came out. It seems reasonable to assume that if there had been a relevant case of FDA fraud prosecution of a drug manufacturer, coupled with product withdrawal, a former FDA chief counsel chief counsel would have known about it. And, to make his point, he would use it. He does not.

Guidant's behavior was, indeed, heinous. Yet it was not uncovered by the FDA alone. Rather, as is quite often the case, the actions of whistleblowers inside the company made the difference. As summarized in one report: "The FDA approved the device for sale in the USA in 1999. But regulators ordered the product suspended two years later after seven anonymous employees sent letters to the FDA and Guidant warning about the device."[5]

The FDA's Office of Criminal Investigations (OCI) should not be faulted for relying on whistleblowers in cases like Guidant (and many others), and for the apparent absence of cases relevant to the Michigan law. The simple reality is that they have limited resources and other fish to fry—e.g., Medicare fraud, counterfeit copies of drugs (a very serious and under appreciated problem) , the marketing of illicit and unapproved therapies, issues related to homeland security, and much more. Indeed, they have relied on civil liability to take the lead in cases of the sort relevant to the Michigan law—precisely the kind of liability that the Michigan law forbids.

Interestingly, there are two cases from the mid-80s, before the OCI was established, that do fit the criteria of the Justice Department prosecuting pharmaceutical companies for fraud against the FDA and which also involved the drugs being withdrawn. Just as in the Guidant case, these followed the unearthing of evidence in other contexts—here, civil litigation—which showed behavior so outrageous (deliberate covering up of drug-caused deaths) that there was also a good deal of media insistence on criminal prosecution. Yet, even then, the actual federal fines were less than slaps on the wrist.[6]

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[4] See *supra* note 1.

[5] Edward Iwata, "Class action suit coming after Guidant fined $92M in cover-up." *USA Today*, 6/13/2003.

[6] These cases involved the drugs Oraflex (Lilly) and Selacryn (SmithKline). In both cases, the companies admitted that (a) their drug killed people in pre and post-marketing use and (b) they did not report those deaths to the FDA. What the companies also argued was that they simply "neglected" to report the deaths. The FDA believed the evidence developed mainly in civil litigation showed knowing and willful cover-up and pressed for criminal felony prosecution. The Justice Department, however, decided not to push it. Lilly, for was convicted of 25 *misdemeanor* counts, with a resultant fine of $25,000. Thus, "knowing" deception was not prosecuted so that these cases, too, would not fit the Michigan criteria.

In summary, then: As the Michigan law has been interpreted by higher courts, only the FDA can take action for fraud against itself. And, in the relevant context of that law, the FDA essentially never does.

c) And it gets worse. According to Professor Lars Noah, a conservative legal scholar and no proponent of the civil liability system, citizens in Michigan would have no legal recourse even if the FDA *did* successfully prosecute a drug company for criminal fraud and the drug was withdrawn. Professor Noah made this comment as part the same panel in which Mr. Troy spoke last March. He was responding directly to Mr. Troy's paper cited above:

> I'm going to spend my limited time today trying to flesh out some of the more technical issues, if you will, having to do with the interplay between the Michigan statute and the federal preemption arguments—something that Dan [Troy] touched on in his paper, but less so in his presentation today. Because they are terribly important in terms of how those two avenues, if you will, are going to operate in practice.
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> I should also say that this puts me in an awkward position. My scholarly publications generally align with the views that Dan expresses, but I think it's only fair that I should play devil's advocate today. As a law professor, I'm apt to ask hypothetical questions, so let me start with one:
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> Imagine that the FDA concludes that a drug manufacturer headquartered in the State of Michigan had withheld some material information. To make it even starker, let's assume that the Agency actually succeeds in bringing some kind of enforcement action, criminal charges, if you will, against the company.
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> The question is: Could a person who is injured by that drug—and we'll assume that the FDA would not have approved the drug had it been aware of the information that had been withheld by the company—could an injured victim bring a product liability claim against the company?
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> OK, as a law professor, let me answer my own question! It's a trick question. The first part of the trick, if you will, is that it all depends on where the lawsuit is filed. If it's filed in any state other than Michigan, I daresay that the choice of law analysis would not respect the Michigan compliance statute as a defense. If filed in

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In these cases, at least—as egregious as such cases ever get--it is clear relying on FDA action alone, without concurrent civil liability, provides no accountability whatsoever.

> Michigan, and there is some case law for this proposition, the choice of law defaults to forum, and the state has an interest by virtue of its legislative enactment in this case, so the statute would, in fact, apply.
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> But there's another trick to this question. There is a clear exception—in fact, there're two exceptions—in the Michigan compliance statute as there are exceptions in comparable state statutes that prevent punitive damage actions against drug companies in a few other states—for either fraud or bribery.
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> But in a case called *Garcia v. Wyeth-Ayerst* involving the withdrawn drug Duract a couple of years ago, the U.S. Court of Appeals for the Sixth Circuit concluded that the fraud exception was impliedly preempted by virtue of a 2001 decision by the U.S. Supreme Court in *Buckman*. Not only that, it was severable, and, therefore, removed from operation, if you will, from the Michigan statute.
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> So the punch line is that this person, this plaintiff, would not successfully be able to sue because the Michigan compliance statute remains in place, but the fraud exception goes away.[7]

I don't often agree with Dan Pero. But I absolutely agreed with him when he wrote last year that, if a company withholds significant safety information from the FDA, we should "throw the book at 'em."[8]

The only problem is that, in actuality, the 1995 drug industry immunity law has left us without a book to throw.

II. Fraud and bribery against the FDA are egregious. But there is a very wide range of additional behavior that is normally relevant to a company's accountability and potential liability—deliberately misleading consumers, physicians, major medical journals, and more. Indeed, it is often these other delinquencies, uncovered in civil litigation, that lead to the concurrent conclusion of outright FDA fraud as well, as happened in the most recent New Jersey verdict against Merck.

As amplified below, in other states, judges or juries may find that a company did not technically defraud the FDA (a finding

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[7] Comments made at panel on FDA Compliance, see *supra* note 1.

[8] Dan Pero, "Michigan's Drug Liability Law: Safe Harbor or Corporate boon?" Last accessed on May 15, 2006, at http://www.legalreforminthenews.com/Op-Ed_Pero-Vioxx.html.

reserved for punitive damages, as Professor Noah noted), but still acted in ways that were "unconscionable" (the term from New Jersey's recent Vioxx case) and for which they ought to be held accountable. In Michigan, there is no accountability for such unconscionable behavior at all.

As just a few examples:

a) A company may submit raw data to the FDA, but the company's own interpretation of that data, and its potentially ominous significance, is left out. Or the company later acknowledges that an interpretation of data was faulty or incomplete. Or the most relevant safety data are present but camouflaged behind other data in a variety of ways, and certainly not red-flagged.[9]

   The truckload of boxes that a New Drug Approval entails can be used to bury information or to reveal it. Which it does often has less to do with a company's decision *whether* to "play by the rules" than with *how* to play by them (or *with* them).

b) Deliberately misleading information about a drug is submitted, not to the FDA, but to physicians and the public, as Merck was severely chastised for doing in a September, 2001, FDA warning letter. In that letter, a number of Merck's communications to the public and to physicians were described as "false, lacking in fair balance, or otherwise misleading." Merck was directly told: "Your minimizing these potential risks and misrepresenting the safety profile for Vioxx raise significant public health and safety concerns."[10]

c) Negotiations over adding or refining warnings on a drug's label are dragged out for months—not because of honest scientific disagreement, but because of pure market considerations. Vioxx is only the best known such example. As suggested in note 9 below, other label and warning sagas have been more chilling.

d) Going after academic researchers who question company claims, including the use of bald threat and intimidation. Dr. Gurkipal Singh of Stanford described his own experience of this at the November, 2004, Senate Finance Committee hearings following the Vioxx

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[9] These are, sadly, not uncommon practices. Readers familiar with the Vioxx case will recognize some of them there. But some or all are also present in a series of other cases—Redux (fen-phen), Rezulin, Baycol, and others—often in more chilling form. I use examples relevant to Vioxx only because they have become particularly well known. My personal belief, however, is that Merck's general practices remain at the high end of ethical spectrum, at least as measured against behavior in several of the non-Vioxx cases. That adds one further tragic dimension to Vioxx.

[10] The warning letter last accessed on June 3, 2006 at: http://www.ssem.com/investigations/vioxx/fda_letter_to_merck.html.

withdrawal.[11] It makes for chilling reading. Dr. Singh and his Dean resisted. But we have no idea how many young researchers have been silenced by these kinds of tactics, relevant in civil litigation but entirely outside the purview of the F.D.A.

e) Manipulating endpoints and design of studies after the fact in order to make the results look more favorable for the product than they were. In an article that appeared three weeks *before* the Vioxx withdrawal, a Merck senior vice president and former FDA medical reviewer noted: "When I was at the FDA, I would read peer-reviewed articles in journals and realize that the endpoints weren't the original ones from the study because I had reviewed the original protocols myself."[12]

   Such articles in major medical journals are the information on which physicians rely, and over which the FDA has no editorial control whatsoever. A 2001 article about the Celebrex that appeared in the Journal of the American Medical Association (JAMA)--authored entirely by Pharmacia employees or the company's paid consultants--turned out to have left out the results of last six months of the original study. With that data included, all the apparent gastrointestinal benefits of Celebrex disappeared.

   But the purpose of the deception was accomplished. "When the JAMA article comes out and confirms the hype, that probably has more impact than our labeling does," said Dr. Robert Temple, as seasoned an FDA director of medical policy as there has ever been.[13]

"We should continue to hold accountable any company or manufacturer that knowingly tries to mislead or defraud unsuspecting consumers," a member of the Michigan Senate and former House representative recently wrote.[14] The examples I have given here—just the tip of the tip of a very large iceberg—are precisely knowing attempts "to defraud and mislead unsuspecting consumers," including physicians, even if they do not all rise, or fall, to the level of defrauding the FDA itself. As Dr. Temple noted, deceptive "hype" may, in practice, trump the FDA in any case, and often appears in contexts—like major medical journals—over when the FDA has no control.

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[11] Dr. Singh's testimony, along with the prepared statements of all the presenters at the Finance Committee's 2004 hearings, can be found at http://www.findlaw.org.

[12] Preceding the quotation above, the article summarizes this Merck official, Dr. Peter Honig, as saying "that companies sometimes changed the parameters of their studies after they had been completed to make the results look better." http://onlypunjab.com/fullstory904-insight-Merck+Says+It+Will+Post+the+Results+of+All+Drug+Trials.

[13] Susan Okie, "Missing Data on Celebrex: Full Study Altered Picture of Drug," *Washington Post*, August 5, 2001.

[14] State Rep. Roger Kahn, MD, "Michigan's Drug Defense Law Must be Preserved," Michigan Forward, March/April, 2006.

III. All of this is why FDA compliance alone—even if we had an ideal, even utopian, FDA—could never be enough to protect consumers' rights and the public health. And it is also why court after court has ruled that FDA compliance is a "minimum standard" that does not, and should not, shield companies from wider accountability.

a) As emphasized, FDA compliance covers only one part of a wide range of company behavior some of which may be misleading, fraudulent, and "unconscionable," but entirely outside the purview of FDA regulation.

b) That is why former FDA chief counsel Margaret Porter asserted that "FDA's view is that FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection."[15]

c) That is why court after court has ruled that an FDA determination "may be sufficient for federal regulatory purposes but still not be sufficient for state tort law purposes" and that "FDA approval does not shield a manufacturer from liability."[16]

d) That is why every state except Michigan have preserved both "layers of consumer protection," recognizing that fraud against the FDA might be needed to prove punitive damages but not the sole criterion for liability in totality.

e) That is why even the best FDA imaginable (and, yes, we are far from achieving one) would still have to rely on companies to respond appropriately to red flags, and not delay, not camouflage, not distract, not obscure safety information in some sort of cat-and-mouse game at the expense of public health.

f) What is extremist and irrational about Michigan's 1995 law is that one-half of the system of consumer protection present in every other state has been simply lopped off.

And what are left with is a regulatory scheme that does not have the means, the mission, the incentive, the precedents, or the authority to carry the ball.

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[15] Margaret Jane Porter, "The Lohr Decision: FDA Perspective ad Position," 52 Food and Drug L.J. 7 n a1 (1997).

[16] See especially Witczak v. Pfizer, United States District Court, District of Minnesota, July 20, 2005, which includes citation of several earlier cases to the same effect (04-CV-2819 JMR/FLN). The Chief District Judge in Witczak also reiterated that "State consumer law complements, rather than frustrates, the FDA's protective regime."