FDA presents several recommendations to sponsors concerning steps that should be taken to make an adequate premarketing risk assessment and how to present that assessment in the NDA. Abiding by FDA’s recommendations or creating an approval letter but also in obtaining a defense verdict.

**V. Presenting the Information**

Most Phase 3 studies are directed towards efficacy. FDA’s point with this Guidance, however, is that safety should not be relegated to a back seat. In one sense, sponsors should place a big net under their Phase 3 trials to catch all of the safety data available. One way to ensure accurate identification of safety signals is to ensure that investigators describe and code adverse events consistent- ly. Throughout Phase 3, sponsors should use one dictionary and one coding convention. Additionally, sponsors should perform audits prior to analysis of the safety database to determine the extent of any variability with respect to coding. Acknowledging that product development may be years in duration, subsequent versions of dictionaries and coding conventions should be avoided as much as possible. However, the same version should be used for analysis and for proposed labeling. FDA recommends that sponsors prospectively develop definitions and groupings expected adverse event terms. All such definitions and groupings, of course, must be adequate- ly explained in the NDA so that the review- ers clearly understand the information. Sponsors also should avoid characterizing syndromes and withdrawals from trials with single terms. Further explanation is re- quired. Was the withdrawal due to a safety concern or simply because the patient moved from the area? Sponsors should take adequate follow-up measures to ascertain specific information. Temporal associations must be critically considered as well and accurately reported. This includes the time between exposure and the adverse event but also involves the total duration of the adverse event itself. Analyzing changes in both over time (i.e., long-term intermittent use leads to shorter duration of AE) is crucial to a full understand- ing of the total safety profile. Study of concomitant drug use also should be consid- ered temporally. Does a concomitant drug decrease the length of time between exposure and AE? Or does a concomi- tant therapy increase the actual length of the AE?

The use of pooled data can be problem- atic as well when sponsors consider how to report the information gleaned from pooled trials. For instance, if a single trial detected a serious adverse event but the total pooled analysis lessened the risk below statistical significance, is it proper to ignore the single trial? It depends. Sometimes, pooled analy- sis protects against too much weight being given to chance happenings. At the same time, if the single trial is superior in design or if it considered a distinct population, it may be worthwhile for the sponsor to separately report the findings. Factors to consider when deciding whether to pool data include any differences in duration or dose and distinct differences in popula- tion groups. FDA specifically recommends “[w]hen there is clinical heterogeneity among trials with regard to the safety out- come of interest […] sponsors should present risk information that details the range of results observed in the individual studies, rather than producing a summary value from a pooled analysis.”

**VI. Conclusion**

FDA presents several recommendations to sponsors concerning steps that should be taken to make an adequate premarketing risk assessment and how to present that as- sessment in the NDA. Abiding by FDA’s recommendations or creating a thorough audit trail otherwise generally will be help- ful in not only obtaining an approval letter but also in obtaining a defense verdict.

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1 Guidance, at 4. (Emphasis in original.)
2 Guidance, at 9.
3 Guidance, at 16.
4 Guidance, at 22.

**Written by Keri Sutherland**

The following states have placed limits on either non-economic damages, the total amount recoverable against a healthcare provider or institution, or punitive damages in personal injury or wrongful death actions:

- **Alabama:** Ala. Code, §55-5-160 (2007) limits total non-economic damages based on wrongful death or personal injury to $500,000. If the damages include loss of consortium, the total recoverable damages are $400,000.
- **Arkansas:** Ark. Code Ann., §16-55-208 (2007). In calculating the punitive dam- ages, plaintiff may receive no more than the greater of $250,000 or three times the amount of compensatory damages, not to exceed $1 million (adjusted for inflation).
- **California:** Cal. Civ. Code §3352.5 (2007) limits non-economic damages to $250,000. This cap has been interpreted to extend to past and future non- economic damages reduced to a lump sum. Solvay v. County of Los Angeles, 967 F.2d 585 (9th Cir. 1992).
- **Colorado:** Colo. Rev. Stat. §13-64-302 (2007) limits all damages against healthcare providers to $1 million and non-economic damages to $250,000.
- **Florida:** Fla. Stat. §766.207 (2007) limits non-economic damages to $250,000.
- **Georgia:** Ga. Code Ann., §51-12-5.1 (2007) limits punitive damages to $250,000 except in cases where the defendant acted intentionally or under the influence of drugs or alcohol, and here no limitations on punitive damages exist. Under §51-13-1, non-economic damages are limited to $350,000 per medical provider or a single medical facility; if there is more than one medical facility, the total damages against multiple facilities may not exceed $700,000.
- **Hawaii:** Haw. Rev. Stat. §663-8.7 (2007) caps pain and suffering damages at $375,000.
- **Idaho:** Idaho Code Ann., §6-1605 (2007) places a maximum $250,000 limitation on non-economic damages (adjusted for inflation). Under §6-1604, punitive damages are limited to the greater of $250,000 or three times the amount of compensatory damages awarded.
- **Indiana:** Ind. Code §34-18-14-3 (2007) limits the total recovery of damages in wrongful death actions to $1.25 million and the total portion of damages recoverable from a healthcare provider to $250,000 if the act of malpractice occurs after June 30, 1999. Under Ind. Code §34-51-3-4 (2007), the plaintiff may receive maximum punitive damages of the greater of three times the amount of compensatory damages or $50,000.
- **Kansas:** Kan. Stat. Ann. §60-5701 (2007) limits exemplary and punitive damages to the lesser of $5 million or defendant’s highest gross annual income as calculated in the previous five years.
- **Maine:** Me. Rev. Stat. Ann. tit. 18-A, §2-804 (1997) caps non-economic damages for wrongful death at $150,000, and punitive damages are limited to $75,000.
- **Maryland:** Md. Code Ann., Tit. 11-108 (1997) limits non-economic damages for any personal injury cause of action for medical malpractice to $710,000 (increasing to $1,050,000 every October 1). The statute applies to wrong- ful death cases as well as personal injury, with the total damages recovered by all beneficiaries limited to 75% of the cap.
- **Massachusetts:** Mass. Gen. Laws Ch. 231, §60H (2007) limits punitive damages to $500,000 (and $50,000 for certain strokes including permanent bodily loss or impairment or substantial disfigurement).
- **Michigan:** Mich. Comp. Laws §600.1485 (2007) caps non-economic damages recoverable in a medical malpractice action at $280,000 for all the plaintiffs unless a specific situation is present (brain or spinal injury, permanent cognitive impairment).
- **Mississippi:** Miss. Code Ann., §11-1-60 (2007) limits any non-economic damages received in a suit filed after September 1, 2006, to $1 million; any suit filed before September 1, 2006, will have non-economic damages limited to $300,000. Miss. Code Ann. §11-1-45 (2007) caps punitive damages on a sliding-scale method, with the cap decreasing as defendant’s net worth decreases.
- **Missouri:** Mo. Rev. Stat. §538.210 (1988) provides a statutory limit, adjusted every January 1, on a claimant’s recovery of non-economic damages in any medical malpractice action.
- **Montana:** Mont. Code Ann., §25-9-411 (2007) caps non-economic damages per plaintiff at $250,000 based on a single incident of malpractice against one or more healthcare providers. Mont. Code Ann. §27-1-220 (2007) limits punitive damages to $10 million or 3% of the defendant’s net worth, whichever is less; however, this limitation does not apply in class action lawsuits.
- **Nevada:** Nev. Rev. Stat. §41A.035 (2007) caps non-economic damages at $350,000 or injury or wrongful death actions against a healthcare provider. Nev. Rev. Stat. §42.005 (2007) limits exemplary and punitive damages in those three times the amount of recovered compensatory damages if those damages are greater than $100,000, or if the compensatory damages are less than $100,000, the exemplary and puni- tive damages awarded is capped at $300,000.
- **New Jersey:** N.J. Stat. Ann. §2A:15-14.1 (2007) limits the amount of punitive damages recoverable to other five times the amount of awarded compensatory damages or $50,000, whichever is greater.
- **New Mexico:** N.M. Stat. Ann. §41-5-6 (2007) limits the aggregate recoverable amount for all persons incident to injury or death as a result of malpractice to $600,000. This amount, however, does not include punitive damages and medical care and related benefits. An individual healthcare provider’s liability is limited to $200,000.
- **North Carolina:** N.C. Gen. Stat. §51D-25 (2007) caps punitive damages at the greater of $250,000 or three times the amount of compensatory damages.
North Dakota: N.D. Cent. Code §26.1-14-11 (2007) places total limitations of $500,000 on punitive damages awarded in physical injury or wrongful death actions against healthcare providers, regardless of the number of defendants or causes of action. N.D. Cent. Code §26.1-14-11(1) (2007) places additional limitations concerning insured parties. If the insured has coverage with a limit of at least $500,000, then the insured is not liable for damages in excess of those limits.

Ohio: Ohio Rev. Code Ann. §2323.43 (2008) limits non-economic damages to the greater of $250,000 or three times the amount of economic loss. The statute also places a total cap of $350,000 for each plaintiff at $500,000 for each occurrence.

Oklahoma: Okla. Stat. §51-1708.1F (2007) caps non-economic damages in medical malpractice actions, except wrongful death actions, to $300,000, regardless of the number of defendants or number of actions brought.


South Carolina: S.C. Code Ann. §15-32-220 (2007) limits non-economic damages to $350,000 per claimant for claims against a single healthcare provider. If the claim is against multiple healthcare providers, non-economic damages are limited to a total of $1,050,000.

South Dakota: S.D. Codified Laws §21-3-11 (2007) limits non-economic damages in medical malpractice actions to $500,000.

Texas: Tex. Civ. Prac. & Rem. Code Ann. §74.301 (2007) limits non-economic damages in medical malpractice claims against healthcare providers and institutions to a total of $250,000 per claimant, regardless of the number of actions asserted or the number of healthcare providers/physicians named. Tex. Civ. Prac. & Rem. §74.303 (2007) limits both economic and non-economic damages, including exemplary damages, to a total $500,000, adjusted for inflation, with the addition of any necessary medical or custodial care costs in wrongful death actions. Tex. Civ. Prac. & Rem. Code Ann. §41.008 (2007) limits exemplary damages to greater of: (1) two times the amount of economic damages plus an amount equal to non-economic damages; (2) $250,000.


Virginia: Va. Code Ann. §8.01-581.15 (2008) places a cap on all damages in medical malpractice cases. For actions accruing before August 1, 1999, the cap is $1 million; for actions accruing between August 1, 1999, and July 1, 2000, the cap is $1.5 million; and for actions accruing after that date, the cap is increased annually every July 1 by $50,000; for 2007, this increase is $75,000; and the final increase will be $85,000 on July 1, 2008 (brining the cap to $1.95 million).


The following states have attempted to limit damages. In each case, the legislation was struck down when the state supreme court found it to be unconstitutional.

Alabama: Ala. Code §§5-5-547 (2007) provides an absolute limit to wrongful death actions against a healthcare provider to $1 million. In Mutual Assurance, Inc. v. Sobada, 798 So.2d 292, 295 (Ala. 2007), however, the Supreme Court of Alabama held this provision violated the right to a jury trial as provided in the Alabama Constitution.

Illinois: Although 735 Ill. Comp. Stat. §5-115.1 (1997) limited non-economic damages, the Illinois Supreme Court held this provision arbitrary and not rationally related to the legislative interest in reducing state-wide tort litigation costs. The Court also found the damages limitation violated the separation of powers doctrine by undermining the judiciary's responsibility to reduce excessive judgments and by unconstitutionally expanding the remitter doctrine.


Oregon: Or. Rev. Stat. §51.711 (2007) was enacted to place a $500,000 monetary cap on non-economic damages recoverable under tort actions; however, in Lakin v. Mutual Assurance, Inc., 987 P.2d 463 (Or. 1999), the Supreme Court of Oregon found this cap unconstitutional because it infringed on factual issues left to the jury and thus violated the right to a trial by jury as guaranteed by the Oregon Constitution.

Washington: Wash. Rev. Code Ann. §§4.82.220 (1998) placed a limitation on non-economic damages; however, in Sofie v. Fireboard Corp., 771 P.2d 711 (Wash. 1980), the Supreme Court of Washington held that the statute was an unconstitutional violation of the right to trial by jury.

The following states have placed no limitations on damages:

Arizona, Connecticut, Delaware, Iowa, Kentucky, Minnesota, Nebraska, New York, Tennessee, Vermont, Wyoming

You've just contracted with a prominent surgeon to develop and market a device that he created to provide better care to his patients. Of course, your agreement provides that your company will provide compensation to that surgeon for the years of toil he spent refining his invention, whether through a lump sum payment or continuing royalty payments. As a result of this transaction, does your company have any requirement to publicize your arrangement with the surgeon? Not yet, but it may soon.

2. Id. at 1075-80.

Bulder Snow summer associate Shannon Hafferts contributed to this piece.