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PROTECTING REASONABLE PHYSICIAN CHOICE IN MEDICAL PRODUCT CASES

RECENT FDA REGULATORY GUIDANCE INVOLVING MEDICAL DEVICES

WHAT DOES YOUR DISMISSAL WITHOUT PREJUDICE MEAN?

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DEAR CLIENT,

Spring is here! We hope that this issue of *Pro Te* will bring your spring fever to a fevered pitch as we examine together three important topics with practical implications.

In many jurisdictions, the medical judgment of physicians is almost sacrosanct – at least insofar as it is "reasonable." In *Protecting Reasonable Physician Choice in Medical Product Cases,* we ponder five concrete ways in which courts can and should consider a reasonable physician's choice of which medical device is used to treat a patient in the pharmaceutical litigation arena.

From time to time, FDA offers guidance for industry in various and sundry areas. In *Recent FDA Regulatory Guidance Involving Medical Devices,* we examine the newest guidance from FDA concerning medical devices.

Finally, (because who doesn't love a cheat sheet?) we canvassed the country to provide a 50-state survey of savings statutes in *What Does your Dismissal Without Prejudice Mean?* We hope that this article will be useful to you in evaluating the timeliness of re-filed cases, as well as the degree to which dismissed cases may pose a risk for re-filing.

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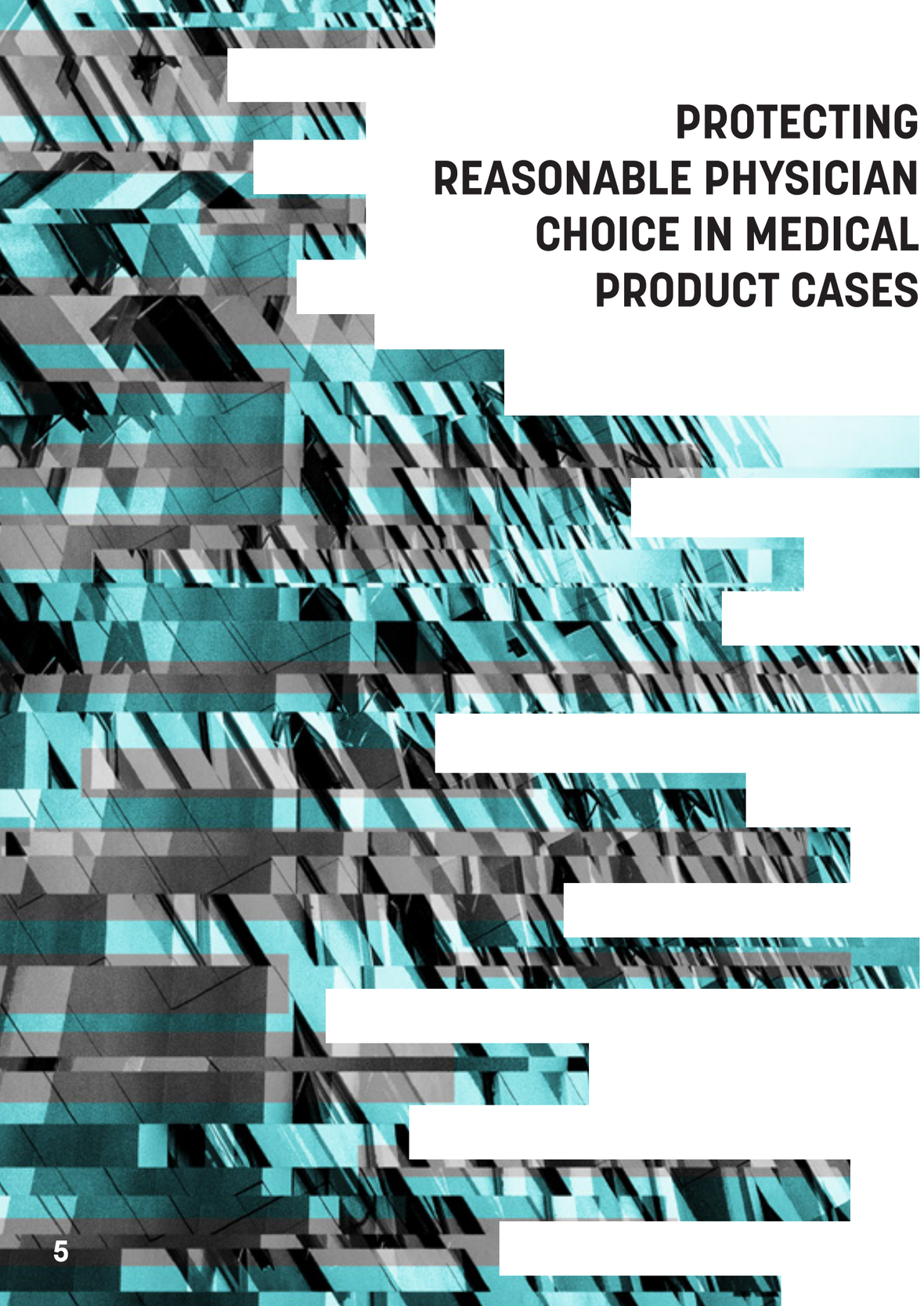


PROTECTING REASONABLE PHYSICIAN CHOICE IN MEDICAL PRODUCT CASES

When the law addresses medical judgment directly, it allows room for reasonable physician choice. It is ironic then, that a product liability suit over design defect may not allow any such room. In order to protect physician choice, courts need to resist the temptation to turn product liability disputes into a contest in which reasonable physician choice has no place.

In medical malpractice litigation, where the standard of care is directly in issue, there is room for diversity of opinion. The jury focuses on the doctor's choices. And if, in the light of a diversity of medical opinion, the doctor's conduct was reasonable, there is no liability.[1] As it is phrased in Pennsylvania, if there are "two schools of thought," the doctor is free to pick one over the other.[2,3]

But in a product liability case over defective design, there may be no room for reasonable choice. Design defect law may ask a jury whether there is any "safer alternative" to a defendant's device, and, if the jury believes there is, the defendant's device may be found defective and presumably unsuitable for sale to anyone. In fact, this question can arise whether or not there is a specific "safer alternative design" requirement in state law because the plaintiff may simply offer such a design as evidence of unreasonable risk. In answering the question, the jury will be asked to choose which expert witness is "most credible" without any allowance for reasonable differences of opinion.

If the law is going to protect a doctor's ability to exercise reasonable medical judgment in choosing among available devices and surgeries, the question is what needs to be done to keep the unsuitable instrument of design defect litigation – where the doctor may not even be a witness and there is no pre-suit screening panel from taking away those choices. Only if the doctor has a choice can the doctor have the ability to determine the best method of treating the patient.

There are at least five ways design defect law can be shaped to protect doctor choice.

First, there is the question of actual doctor choice. Where the surgeon has chosen not to employ an alternative, perhaps because of the surgeon's education, training, and experience, the jury should not be allowed to find the manufacturer liable because a choice the surgeon rejected might be deemed by the jury to be "safer."[4,5]

Second, a court should apply established product liability law principles and exclude from any list of "safer alternatives" those alternatives that present different advantages and disadvantages that require doctor choice, such as a different treatment or different surgery.

This is consistent with the way product liability generally protects consumer choice. It is generally accepted that, to be a "safer alternative design," the design must be for the same product, not a different one. A different product may be safer in one respect, but if it serves different distinct purposes, it cannot provide a basis for finding the less safe product defective. Informed consumers remain free to choose, and manufacturers are allowed to innovate. The issue comes up in a variety of product liability contexts.

For example, the Fourth Circuit held in an early negligence case that, given the "peculiar purposes of [the] design" of a Volkswagen bus to provide room for passengers and cargo by placing the

ONLY IF THE DOCTOR HAS A CHOICE CAN THE DOCTOR HAVE THE ABILITY TO DETERMINE THE BEST METHOD OF TREATING THE PATIENT.

driver in front of the engine, a plaintiff could not argue that the design was unsafe because it was not as crashworthy as that of a passenger sedan. The court granted judgment as a matter of law for the defendant.[6] Similarly, a safer bullet proof vest does not make a bullet proof vest with less coverage unreasonably dangerous when the vest allows a greater range of motion.[7,8]

This principle is particularly apt in the field of medical devices where different products offer different sets of benefits and complications and whose "safety" depends on professional judgment and, in the case of devices, surgical skill. Like the learned intermediary doctrine, device defect law should recognize that the doctor relies not only on what the manufacturer has supplied, but also "other medical literature, and any other source available to him, and ... the personal medical history of his patient."[9] The Texas Court of Appeals so held in a hormone therapy case:

> [A] plaintiff cannot prove that a safer alternative design exists by pointing to a substantially different product, even when the other product has the same general purpose as the allegedly defective product . . . Thus, a safer alternative design must be one for the product at issue . . . [Plaintiff] does not explain how [the drug] could have been modified or improved . . . In essence, [plaintiff] argues that the [drug] should have been a different product . . . But, as the supreme court has explained, Texas law does not recognize this sort of categorical attack on a product.[10,11]

In medical device cases, courts have held that different devices that perform in different ways cannot be treated as safer alternatives. The principal authorities come from the pedicle screw cases where the courts refused to accept other fixation devices, such as those involving hooks and wires, as presenting safer alternative designs.

The Fifth Circuit explicitly gave doctor choice as a primary reason for its holding. It said:

> [Plaintiff] therefore argues that other products that do not use pedicle screws should be considered as alternative designs . . . Underlying this argument is the assumption that all pedicle screws are defective and there can be no system using pedicle screws that would be an acceptable product. The problem with this argument is that it really takes issue with the choice of treatment made by [plaintiff's] physician, not with a specific fault of the pedicle screw sold by [defendant].[12]

Similarly, in other device cases it has been held that a treatment that uses no device at all cannot be considered as a safer alternative. As the United States District Court for the District of Nevada explained:

> Neither is the Court swayed by Plaintiff's argument that the testimony of [the expert] to the effect that Plaintiff's [surgery] could have been accomplished without use of [the product]. The fact that an alternative method of [surgery] was potentially available does not support Plaintiff's design defect claim. As argued by Defendants, non-mesh repair is not an alternative design and does not meet Plaintiff's burden to support this particular claim.[13]

IN MEDICAL DEVICE CASES, COURTS HAVE HELD THAT DIFFERENT DEVICES THAT PERFORM IN DIFFERENT WAYS CANNOT BE TREATED AS SAFER ALTERNATIVES.

While this rule would have its most direct application in states with a safer alternative design requirement, it would not be limited to those states. It should apply wherever alternative design is used as a basis for declaring a device unreasonably dangerous. In *Driesenstock,* the Fourth Circuit's Volkswagen bus case, the issue was whether the alternative could be used to prove the defendant's negligence. And in *Linegar,* the Eighth Circuit's bullet-proof vest case, the question was whether the vest was unreasonably dangerous. In neither case was there a specific safer alternative design requirement.[14]

Third, even where the products might be very similar, the jury should not be asked to choose between two products where either one is supported by a "school of thought" or "substantial medical opinion." From the "doctor's choice" perspective, it is error for a court to intervene in the diagnosis and treatment of a patient in order to dictate the treatment of a patient when reasonable medical professionals could disagree. For example, one court recognized the "same product" requirement but nevertheless said a jury could find that an alternative was safer if it did not alter "a fundamental and necessary characteristic of the product."[15] In that case the court said it was for the jury to decide whether natural progestin and synthetic progestin were different products. Id. at *9. But if either choice would be within the doctor's standard of care, that difference should not matter.

Fourth, the principle of reasonable doctor choice could also be used to interpret comment k to the RESTATEMENT (SECOND) OF TORTS § 402A. That comment rules out design defect liability for medical products if a proper warning is given and the device is "unavoidably unsafe." This has sometimes been incorrectly said to simply import a risk-utility test.[16] But a better reading would be to say that a medical product is "unavoidably unsafe" and so qualifies for comment k protection if its use,

within the professional standard of care, presents a risk of injury to the patient. That would, for example, be true of nearly all implantable medical devices.[17]

Finally, the principle of doctor choice might be a basis for excluding from evidence actions of the federal Food and Drug Administration based on a comparison of one treatment to another if both treatments were considered to be within the doctors' standard of care. Congress has told the FDA that it is not to "limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient...." 21 U.S.C. § 396 (2009). Nevertheless, the FDA does take regulatory actions based not on independent judgments about safety and effectiveness but rather upon comparisons among methods of treatment. A negative comparison that failed to recognize reasonable doctor choice should be just as inadmissible as expert testimony that failed to apply the correct liability standard.[18]

If the principle of doctor choice were applied in design defect law, it would be necessary to decide what theories of design defect liability would survive. Certainly, a device not considered to be within the standard of care would face liability if it were so egregiously dangerous as not to have any justifiable therapeutic use. Or if scientific testing proved a way to design the same product so that it was both safer and equally effective, that might be considered in some jurisdictions.

And none of this would affect liability for failure to warn, because any rule that rests on doctor's choice has to assume that doctors are aware of the complications that may arise out of use of the device.

This article previously appeared in the Drug and Device Law Blog and Law360 Product Liability.

1. Steven E. Pegalis, 1 Am. Law Med. Malp. § 3:3 (2017) ("reasonably applicable alternative methods of diagnosis or treatment" allowed).
2. *Jones v. Chidester,* 610 A.2d 964, 969 (Pa. 1992) ("school of thought" means "a considerable number of recognized and respected professionals").
3. *Velazquez ex rel. Velazquez v. Portadin,* 751 A.2d 102, 107-108 (N.J. 2000) (allowing practice with "substantial support as proper practice by the medical profession") (quoting *Schueler v. Strelinger,* 204 A.2d 577, 585 (N.J. 1964).
4. *See Anderson v. PA Radocy & Sons, Inc.,* 865 F. Supp. 522, 531 (N.D. Ind. 1994) (manufacturer not liable for employer's decision to purchase uninsulated fiberglass bucket rather than insulated one).
5. James A. Henderson & Aaron D. Twerski, *Optional Safety Devices: Delegating Product Design Responsibility to the Market,* 45 Ariz. St. L.J. 1399, 1417 (2013) (delegation to learned intermediary defeats design liability).
6. *Dreisonstok v. Volkswagenwerk,* A.G., 489 F.2d 1066, 1074 (4th Cir. 1974), *followed in* RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY § 2, cmt. f, illus. 9 (1998).
7. *Linegar v. Armour of Am., Inc.,* 909 F.2d 1150, 1154 (8th Cir. 1990).
8. *Hosford v. BRK Brands, Inc.,* 223 So.3d 199, 208 (Ala. 2016) (smoke alarm not defective just because a more expensive dual-sensor alarm was sold).
9. *Lebowitz v. Ortho Pharmaceutical Corp.,* 307 A.2d 449, 457 (Pa. Sup. 1973).
10. *Brockert v. Wyeth Pharm., Inc.,* 287 S.W.3d 760, 770-71 (Tex. App. 2009).
11. *See also* In re Propulsid Prod. Liab. Litig., No. MDL 1355, 2003 WL 367739, at *3-4 (E.D. La. Feb. 18, 2003) (alternative or different methods of treatment insufficient to prove alternative design).
12. *Theriot v. Danek Med., Inc.,* 168 F.3d 253, 255 (5th Cir. 1999).
13. *Schmidt v. C.R. Bard, Inc.,* No. 2:11-CV-00978-PMP, 2013 WL 3802804, at *2 (D. Nev. July 22, 2013).
14. James Beck ("Bexis"), *On Alternative Design, Take Two – Negligence,* Drug and Device Law Blog (Feb. 27, 2017) (use of alternative design in negligence cases).
15. *Hines v. Wyeth,* No. CIV. A. 2:04-0690, 2011 WL 1990496, at *8 (S.D.W. Va. May 23, 2011) (citing Torkie-Tork v. Wyeth, 739 F. Supp. 2d 895, 900 (E.D. Va. 2010)).
16. *Mullins v. Ethicon, Inc.,* 117 F. Supp. 3d 810, 818-819 (S.D.W. Va. 2015).
17. James Beck (Bexis), *Unavoidably Unsafe PMA Medical Devices,* Drug and Device Law Blog (Nov. 30, 2017).
18. *United States v. Wintermute,* 443 F.3d 993, 1001 (8th Cir. 2006).

LUTHER T. MUNFORD

RECENT FDA REGULATORY GUIDANCE INVOLVING MEDICAL DEVICES

While FDA has developed and overhauled the regulatory landscape as applied to food and drugs since 1906, the emphasis on regulating devices has essentially been evolving only over the last 40 years or so. The concept of providing reasonable assurances of safety and efficacy of devices is well-founded, but the need to adapt the regulatory framework developed for drugs and apply it to medical devices continues to evolve, particularly regarding the differences in the benefits and risks associated with devices versus drugs. Following is a summary overview of FDA and its laws, regulations, and oversight of drugs and devices, including recent guidance documents that provide insight into FDA's current thinking on determinations of safety and efficacy with respect to devices.

OVERVIEW OF FDA

The Food & Drug Administration (FDA) was originally created through the Food & Drugs Act of 1906 in an effort to provide public health and consumer protections related to drug products. The federal Food, Drug & Cosmetic Act (FDCA) authorized FDA to take a more active role in public health, including additional requirements that any companies selling new drugs provide evidence to FDA that the drugs be safe for consumers and that drugs and devices not be adulterated or misbranded. In 1962, the FDCA added more stringent drug safety requirements, including that companies prove drugs are effective through controlled clinical studies, post-market surveillance, and adverse event reporting. The Medical Device Amendments of 1976 and the Safe Medical Devices Act of 1990 required that devices also be safe and effective and required post-market surveillance and adverse event reporting for devices.

More recently, the 21st Century Cures Act (Cures Act) funds grants to spur innovation, accelerate product development, and put drugs and devices in the hands of patients who need them in a more expedient and effective manner.[1] The Cures Act addresses devices specifically and grants authority to FDA to prioritize product development for particular devices that address life-threatening and irreversibly debilitating diseases or conditions ("Breakthrough Devices").[2] In implementing these latest programs, FDA reiterated that while speeding up the approval process is the intent, it will not reduce or eliminate any requirements of safety and effectiveness.

FDA APPROVAL PROCESS

In reviewing a drug or a device for approval/clearance, FDA's objective is to weigh the benefits and corresponding risks associated with each and to confirm its safety and effectiveness. The process for this determination may differ between drugs and devices. The oversight responsibility for drugs is regulated and managed by FDA through its Center for Drug Evaluation and Research (CDER) while the responsibility for devices is regulated and managed through its Center for Devices and Radiological Health (CDRH). A product is regulated as a drug if the primary intended use is achieved through a chemical action or by being metabolized by the body. A product is regulated as a device if it is an "instrument, apparatus, machine, implant, or other similar product which is (1) a device recognized in an established formulary or supplement, (2) intended for use in the diagnosis,

THE [21ST CENTURY] CURES ACT ADDRESSES DEVICES SPECIFICALLY AND GRANTS AUTHORITY TO FDA TO PRIORITIZE PRODUCT DEVELOPMENT FOR PARTICULAR DEVICES THAT ADDRESS LIFE-THREATENING AND IRREVERSIBLY DEBILITATING DISEASES OR CONDITIONS.

cure, mitigation, treatment, or prevention of disease or other conditions, or (3) intended to affect a structure or function of the body, and does not achieve its primary intended purpose through chemical action and is not dependent upon being metabolized to achieve its intended purpose."

DRUG APPROVAL PROCESS

Prior to seeking approval to market and sell its drug product, the sponsor conducts preclinical animal testing to assess the potential product's safety and the biological activity triggered by such product. If satisfactory, the sponsor will submit an Investigational New Drug (IND) application to FDA. FDA reviews the IND and determines whether a Phase I study is appropriate in order to obtain information about the pharmacologic actions caused by the drug (typically testing 20-80 healthy participants). If successful, the sponsor seeks FDA confirmation to conduct a Phase II study within the targeted disease state to confirm appropriate dosage and preliminary efficacy along with the associated risks and side effects (30-300 patients). If the Phase II study confirms the expected results, FDA may authorize a Phase III clinical study with larger samples of patients to verify prior results and provide additional significant data on safety and efficacy (200-3,000 patients). Upon completion of the Phase III study, the sponsor submits a New Drug Application (NDA) with relevant preclinical and clinical data, including data on manufacturing and quality systems, to FDA for review and approval determination. All new drugs must go through this process to be marketed and sold.

The FDA review process for the NDA generally takes 10-15 months, although expedited reviews are potentially available to reduce that time-line for certain drugs that meet the expedited review requirements. This does not consider the time between initiating product development through submission of the NDA, which on average extends this time-line to 8-10 years.[3] According to a 2012 Tufts study, the estimated cost of a new prescription drug approval was $2,558,000,000 (inclusive of all clinical, research and preclinical development costs, success and phase attrition rates, development times, and cost of capital).

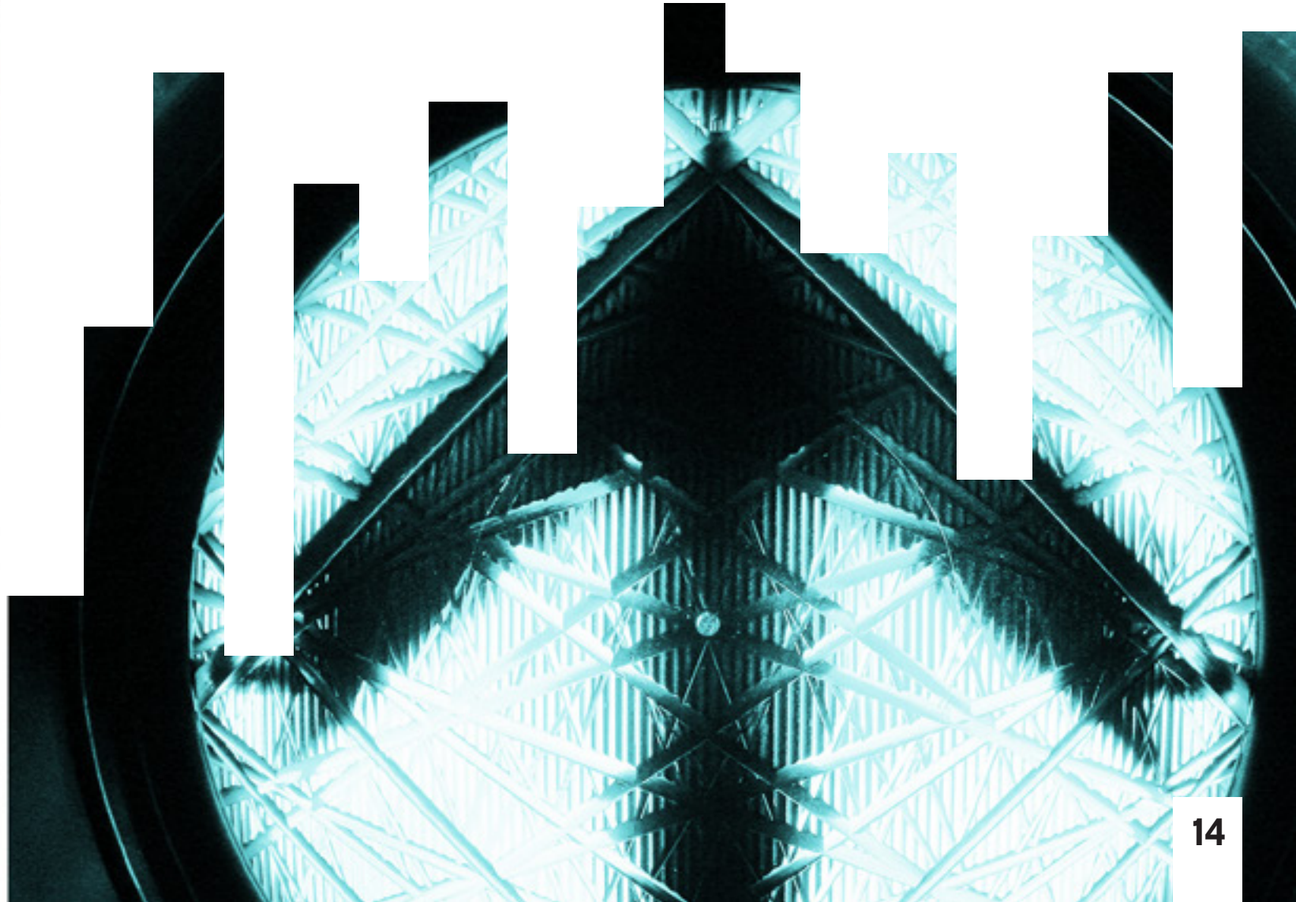
DEVICE APPROVAL PROCESS

For devices, FDA's review process depends on the applicable classification for the device. Devices are separated into Class I, II, and III based on the perceived risk level from those products, subject to conditions and controls increasing as the risk level increases. Class I devices are generally subject to establishment registration, labeling requirements, and compliance with manufacturing requirements. Class II devices are either subject to premarket notification (i.e., 510(k) devices) or exempted from such premarket notification requirements. To qualify as a 510(k) device, the sponsor must demonstrate that the device is "substantially equivalent" to a predicate device marketed prior to May 28, 1976. Class II devices are subject to conditions and controls, such as performance standards, post-market surveillance, patient registries, special labeling, premarket data requirements, and other guidelines. Class III devices, which present potential unreasonable risk of illness or injury where existing information or regulatory controls are insufficient, typically require the sponsor to demonstrate safety and effectiveness by providing nonclinical data on toxicology, biocompatibility, stress, wear, shelf life, and laboratory or animal test results along with clinical trial data as set out in the trial protocol. Initially, the sponsor selects and prepares the necessary information (such as design controls, nonclinical testing, clinical evidence, and labeling) for the premarket submission required for the proposed classification and submits the packet for administrative review and interaction with the company.[4] A large majority of devices fall within Class I and II categories.

DEVICES ARE SEPARATED INTO CLASS I, II, AND III BASED ON THE PERCEIVED RISK LEVEL FROM THOSE PRODUCTS, SUBJECT TO CONDITIONS AND CONTROLS INCREASING AS THE RISK LEVEL INCREASES.

As for the time-lines applicable to devices, they also increase in accordance with the applicable classification. Given that devices can differ from each other in almost every respect, including how they work, how they are applied to the patient, and how their effectiveness is measured, this forces FDA to adopt ad hoc rules for testing of new devices in order to properly gauge safety and effectiveness, resulting in a fair amount of differentiation in the approval processes and timelines. However, approvals for Class I and exempt Class II devices, as applicable, are likely to take less than one month. Non-exempt Class II devices took an average of just under six months, but the average time-frame went from a low of 112 days for radiology devices to 250 days for immunology devices.[5]

From a cost standpoint, the average cost-to-market for high-risk devices under Class III was $94,000,000. Class III devices can take 18-30 months for the approval process, unless under an expedited program, and a total of 3-7 years for the typical product development cycle.[6]



RECENT FDA GUIDANCE DOCUMENTS

FDA has issued various draft and final guidance documents since December 1, 2017 related to medical devices. These cover FDA's current position on medical device accessories and classification, additive manufacturing of medical devices, review of premarket approval applications, the Breakthrough Devices program, and making the approval/clearance decisions based on means less burdensome to the sponsors.

FINAL GUIDANCE DOCUMENTS

Medical Device Accessories – Describing Accessories and Classification Pathways

This guidance issued December 20, 2017 modifies the historical rationale for classification of accessories that require FDA to classify accessories based on the risks of that accessory when used as intended and the level of regulatory controls necessary to provide reasonable assurance that such use is safe and effective.[7] This determination is made independently of the parent device and may result in a classification that is different from the parent device. FDA first determines whether the article meets the definition of an accessory, and then it determines the risk of the accessory and necessary regulatory controls to provide reasonable assurance of safety and effectiveness when used with the intended parent device.

Technical Considerations for Additive Manufactured Medical Devices

FDA issued recent guidance on its view of technical considerations applicable to various types of additive manufacturing (i.e., manufacturing that builds devices using newly available technologies, such as stereo-lithography or 3D printing). FDA recognizes the value of using these new technologies to create devices that match a patient's anatomy or create devices with complex internal, geometric, or porous structures more easily. FDA reiterated that regulatory requirements and expectations associated with devices made with additive manufacturing will be the same as those used to assess devices made with traditional manufacturing methods for the same type of device. The sponsor must maintain their manufacturing quality system as required under 21 CFR 820.30 and must still establish, monitor, and validate the manufacturing process requirements, including those related to any necessary software applications, raw materials, and post-processing testing and specifications. Any changes to the above must be analyzed to determine if revalidation is necessary.[8]

KEY DRAFT GUIDANCE DOCUMENTS

Breakthrough Devices Program

FDA published guidance on implementation of the Breakthrough Devices Program (Breakthrough Program) that identifies the criteria FDA proposes to use to accelerate the approval time-line of certain Breakthrough Devices.[9] As draft guidance, it provides FDA's current thinking on a topic, but is not a legally enforceable requirement. The Breakthrough Program guidance outlines principles proposed by FDA to approve Breakthrough Devices, including: (1) a structured communication process with a collaborative, interactive approach to address the regulatory approval pathway; (2) a risk-benefit analysis balancing possible risk of harm to patients with the benefits of earlier patient access; (3) developing steps to provide scientifically appropriate, but efficient and flexible clinical trial design, if applicable; (4) required training for FDA's review team on the requirements of the Breakthrough Program in their respective area of expertise; and (5) expedited review of manufacturing and quality systems, taking into consideration the manufacturing and quality history of the sponsor and its manufacturing sites and possible post-approval inspection. If the Breakthrough Device qualifies, the Breakthrough Program permits different approaches for FDA review, including either a "Sprint Discussion" (which is limited to a single topic with defined schedule and documentation requirements); a

"Data Development Plan" (which outlines data collection expectations for the entire product life-cycle, including premarket and post-market data, clinical and nonclinical data, and reviews following the same general schedule and documentation requirements as the Sprint Discussion); or "Clinical Protocol Agreement" (which defines agreed endpoints to meet for safety and effectiveness of the device). In each case, FDA and the sponsor may agree to have regular status updates on the progress of the review and projected next steps and time-lines.

The Least Burdensome Provisions: Concept and Principles

Although the "least burdensome" concept has been in place, the original concept focused on a device's premarket evaluation only. The Cures Act modified those least burdensome principles to apply them throughout the entire life-cycle of a medical device, both premarket and post-market, to assure the safety and effectiveness of new and existing medical devices at any point that they are available to consumers, which FDA has clarified in this guidance issued on December 15, 2017.[10] The least burdensome concept requires the FDA to require the minimum amount of information necessary to adequately address a current regulatory question or issue. While reasonable assurance of safety and effectiveness is still required, that evidence may be provided from alternative sources of existing data, such as nonclinical data, peer-reviewed literature, non-US data, and real-world evidence, to analyze patient usage data, registries and claims data, and/or well-documented case histories. The guidance suggests that FDA and sponsors should consider the most efficient ways to obtain necessary evidence. Efforts to improve efficiency may potentially include: reducing requirements of traditional clinical studies by using historical or non-comparative control groups or study results; use of alternative study designs; streamlining of processes and administrative burdens to reduce redundancies; use of more efficient tools or methods to collect data; and in some cases, allowing sponsors to utilize post-market data to confirm safety and effectiveness.

SUMMARY

The enactment of the Cures Act and subsequent final and draft guidance may not reduce the requirements that FDA assure drugs and devices are safe and effective, but they do show that FDA is working toward finding different alternatives to bring those products to the consumer where the benefits of the products outweigh the risks. It is encouraging to have FDA consider how to permit sponsors of new products to use existing real world data to support the approval or clearance of their new products and not look at each product in a vacuum, thereby reducing each sponsor's time and costs to bring new and innovative products to the patients that need them. FDA has also shown interest in bringing products to the patients more quickly where no or only extremely limited alternatives exist. While not replacing the existing systems, they can potentially enhance the lives of patients in a more efficient and timely manner.

1. P.L. 114-255.
2. 21 USC 515B(b).
3. *Journal of Managed Care Pharmacy,* Jan/Feb. 2011 (Vol 17, No. 1), at 43.
4. https://www.emergogroup.com/resources/worldwide/global-regulatory-comparison-tool.
5. 5. https://www.forbes.com/sites/hbsworkingknowledge/2015/08/11/new-medical-devices-get-to-patients-too-slowly/2/#6dbb48f73c34.
6. 21 USC 814.82.
7. 7. 21 U.S.C. 360c(f).
8. *Technical Considerations for Additive Manufactured Medical Devices - Guidance for Industry and Food and Drug Administration Staff* (12/5/2017).
9. *Breakthrough Devices Program – Draft Guidance for Industry and Food and Drug Administration Staff* (10/25/2017).
10. *The Least Burdensome Provisions: Concept and Principles - Draft Guidance for Industry and Food and Drug Administration Staff* (12/15/2017).

DAVID W. OHLWEIN

WHAT DOES YOUR DISMISSAL WITHOUT PREJUDICE MEAN?

A 50-STATE SURVEY OF SAVINGS STATUTES

Many jurisdictions have "savings statutes" that are designed to provide a window of opportunity for a plaintiff to re-file a claim that was dismissed for non-merits reasons. The availability of such savings provisions varies widely from no provision at all to including claims where process has never been served or claims that were voluntarily dismissed. The time limits to be "saved" are also disparate and range from 90 days to three years. Following is a survey of all 50 states, providing the statutory basis for such savings statutes along with other helpful information.

ALABAMA

"Alabama does not have a general saving statute or a constitutional savings clause." *Burt v. State,* 149 So.3d 1110, fn. 5 (Ala. Crim. App. 2013).

ALASKA

Alaska Stat. § 09.10.240 provides that a plaintiff "may commence a new action upon the cause of action within one year after the dismissal or reversal on appeal." Mere filing of the initial action without notice or service of process is sufficient. *Am. Marine Corp. v. Sholin,* 295 P.3d 924, 927 (Alaska 2013).

ARIZONA

Ariz. Rev. Stat. Ann. § 12-504(a) allows six months to re-file a dismissed claim. But, if the claim is terminated by abatement, voluntary dismissal by order of the court, or dismissal for lack of prosecution, the savings statute is discretionary, and plaintiff must establish entitlement to the statutory provision. *Jepson v. New,* 792 P.2d 728, 734 (Ariz. 1990).

ARKANSAS

Ark. Code Ann. § 16-56-126(a) includes a one-year period to save a claim. A plaintiff must serve process of the first action in order to use this provision; and it applies only where the limitations period expires between the initial filing and the non-merits dismissal. *Tucker v. Sullivant,* 370 S.W.3d 812, 814-815 (Ark. 2010).

CALIFORNIA

Cal. Code Civ. Proc. § 355 provides a one-year window to re-file if a judgment for plaintiff is "reversed on appeal other than on the merits." It was extended by case law to a claim that is voluntarily dismissed, but only if three factors are met: "(1) the trial court erroneously granted the initial nonsuit; (2) dilatory tactics on the part of the defendant 'prevented disposition of the first action in time to permit a second filing within the [limitations period]'; and (3) the plaintiff had at all times proceeded in a diligent manner." *Dimcheff v. Bay Valley Pizza Inc.,* 84 F. App'x 981, 982-83 (9th Cir. 2004) (quoting *Wood v. Elling Corp.,* 20 Cal. 3d 353, 361 (Cal. 1977)).

COLORADO

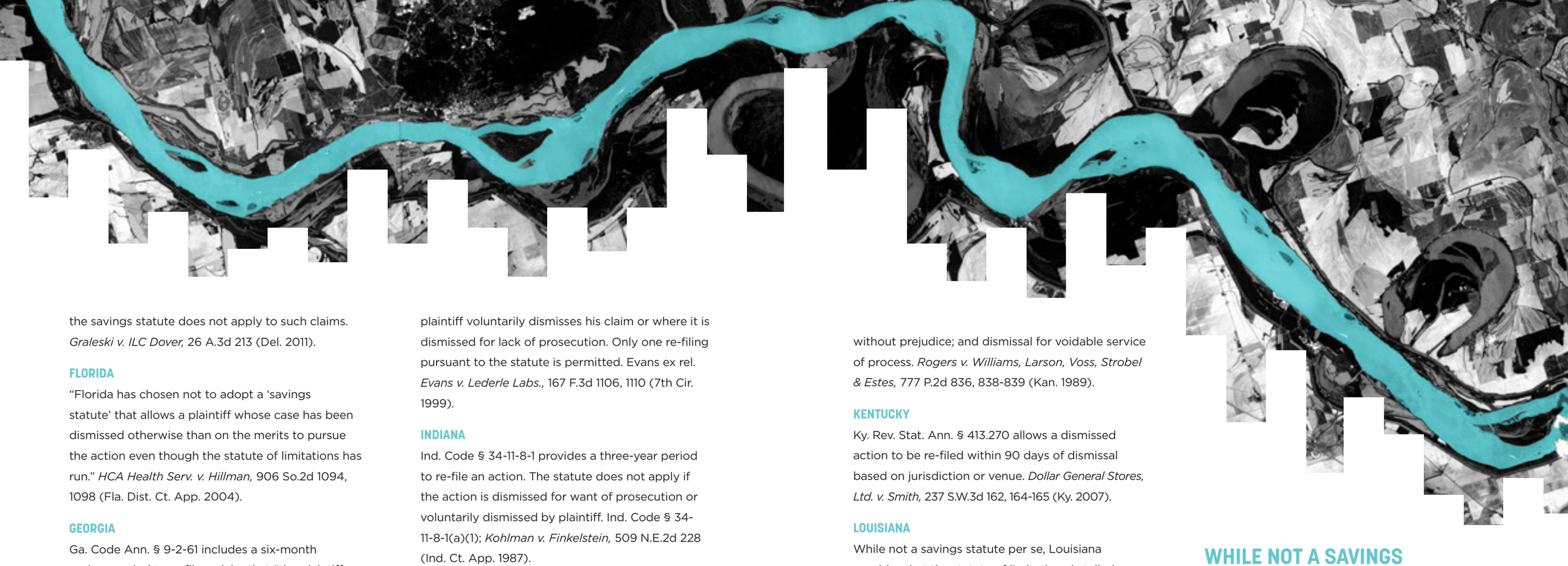
Colo. Rev. Stat. § 13-80-111 affords 90 days to re-file an action that was dismissed for lack of jurisdiction or venue, including actions first filed in federal court and recommenced in state court. Multiple filings within the 90-day window are permitted. *Sharp Bros. Contracting Co. v. Westvaco Corp.,* 817 P.2d 547, 551 (Colo. Ct. App. 1991).

CONNECTICUT

There are two separate savings statutes. One allows the re-filing of claims dismissed for a non-merits failure of the suit within one year, Conn. Gen. Stat. § 52-592 (six months if claim is against executor); the second allows a one-year period to re-file if the original suit named the wrong defendant. Conn. Gen. Stat. § 52-593. An original action is deemed "commenced" for purposes of the savings statute when the defendant has effective notice of the action within the one-year savings time. *Rocco v. Garrison,* 848 A.2d 352, 359 (Conn. 2004).

DELAWARE

Del. Code Ann. tit. 10 § 8118 creates six circumstances where claims are saved and can be re-filed within one year of a non-merits dismissal. Voluntary withdrawal of a complaint does not constitute a dismissal for any matter of form, and



the savings statute does not apply to such claims. *Graleski v. ILC Dover,* 26 A.3d 213 (Del. 2011).

FLORIDA

"Florida has chosen not to adopt a 'savings statute' that allows a plaintiff whose case has been dismissed otherwise than on the merits to pursue the action even though the statute of limitations has run." *HCA Health Serv. v. Hillman,* 906 So.2d 1094, 1098 (Fla. Dist. Ct. App. 2004).

GEORGIA

Ga. Code Ann. § 9-2-61 includes a six-month savings period to re-file a claim that "the plaintiff discontinues or dismisses." This statute forbids successive re-filings. Ga. Code Ann. § 9-2-61(a).

HAWAII

"There is no savings statute in Hawaii." *Eto v. Muranaka*, 57 P.3d 413, 427 (Haw. 2002).

IDAHO

Idaho permits the re-filing of an action within one year only when a judgment for plaintiff is reversed on appeal. Idaho Code § 5-233. This provision applies only when the original action is timely filed. Steinour v. Oakley State Bank, 287 P. 949 (Idaho 1930).

ILLINOIS

The savings statute contains a one-year provision allowing a claim to be re-filed if it was dismissed for procedural reasons. 735 Ill. Comp. Stat. 5/13-217. The statute expressly does not apply where a plaintiff voluntarily dismisses his claim or where it is dismissed for lack of prosecution. Only one re-filing pursuant to the statute is permitted. Evans ex rel. *Evans v. Lederle Labs.,* 167 F.3d 1106, 1110 (7th Cir. 1999).

INDIANA

Ind. Code § 34-11-8-1 provides a three-year period to re-file an action. The statute does not apply if the action is dismissed for want of prosecution or voluntarily dismissed by plaintiff. Ind. Code § 34-11-8-1(a)(1); *Kohlman v. Finkelstein,* 509 N.E.2d 228 (Ind. Ct. App. 1987).

IOWA

Iowa allows six months to re-file a non-merits dismissal, provided the case is not voluntarily dismissed by plaintiff or dismissed for lack of prosecution. Iowa Code § 614.10; Furnald v. Hughes, 804 N.W.2d 273 (Iowa 2011). Successive re-filings are not permitted. *Veatch v. Bartels Lutheran Home,* 804 N.W.2d 530, 537 (Iowa Ct. App. 2011).

KANSAS

An action may be re-filed within six months if there is a non-merits dismissal of the claim after the statute of limitations has otherwise expired. Kan. Stat. Ann. § 60-518. Examples of non-merits dismissals include denial of class certification for lack of numerosity; dismissal for failure to file an amended petition following a partially successful motion for a more definite statement; dismissal without prejudice; and dismissal for voidable service of process. *Rogers v. Williams, Larson, Voss, Strobel & Estes,* 777 P.2d 836, 838-839 (Kan. 1989).

KENTUCKY

Ky. Rev. Stat. Ann. § 413.270 allows a dismissed action to be re-filed within 90 days of dismissal based on jurisdiction or venue. *Dollar General Stores, Ltd. v. Smith,* 237 S.W.3d 162, 164-165 (Ky. 2007).

LOUISIANA

While not a savings statute per se, Louisiana provides that the statute of limitations is tolled ("interruption of prescription") when a suit is filed, and that tolling continues during the pendency of the case. La. Civ. Code Ann. art. 3463. However, such "interruption" is deemed not to have occurred if the plaintiff abandons, voluntarily dismisses, or fails to prosecute her claim. "The effect of interruption of prescription, as contrasted with suspension of prescription, is that the time that has run prior to the interruption is not counted; prescription commences to run anew from the last day of the interruption." *Cichirillo v. Avondale Indus.,* 917 So. 2d 424, 430 (La. 2005).

MAINE

The savings statute is applicable to cases "defeated for any matter of form" or the death of a party, which can be re-filed within six months. 14 Me. Rev. Stat. § 855. Excusable failure to serve as well as jurisdiction and venue issues fall within the savings statute. *Brown v. Thaler,* 2006 WL 2959682 (Me. Super. Ct. July 21, 2006).

WHILE NOT A SAVINGS STATUTE PER SE, LOUISIANA PROVIDES THAT THE STATUTE OF LIMITATIONS IS TOLLED ("INTERRUPTION OF PRESCRIPTION") WHEN A SUIT IS FILED, AND THAT TOLLING CONTINUES DURING THE PENDENCY OF THE CASE.

MARYLAND

Maryland does not have a general savings statute. *Levasseur v. Ekuno,* 2016 WL 392419 (Md. Ct. Spec. App. Feb. 2, 2016). There are two separate savings provisions. Maryland Code Ann. Cts. & Jud. Proc. § 5-119 provides 60 days to re-file a medical malpractice claim when it was dismissed for "failure to file a report in accordance with § 3-2A-04(b)(3) of this article" (i.e., a certificate of a qualified expert) and does not apply to voluntary dismissals by the plaintiff. Maryland Rule 2-101 allows plaintiff 30 days to re-file in state court an action that was dismissed in federal court for want of jurisdiction or under a limitations period under federal law.

MASSACHUSETTS

Mass. Gen. Laws ch. 260, § 32 provides a one-year time period to re-file an action dismissed for "a matter of form." The statute applies to pendent claims dismissed in a federal court. *Liberace v. Conway,* 574 N.E. 2d 1010 (Mass. App. Ct. 1991).

MICHIGAN

Michigan does not have a general savings statute. It does have a limited savings statute of two years for wrongful death claims where the person dies before the limitations period expired or within 30 days of the expiration. Mich. Comp. Laws § 600.5852.

MINNESOTA

Minnesota Stat. § 541.18 allows one year to re-file a claim that is dismissed for non-merits reasons, including jurisdictional issues. A plaintiff must establish that the defendant received timely notice of the claim. *Kulinski v. Medtronic Bio-Medicus,* 577 N.W.2d 499, 504 (Minn. 1998).

MISSISSIPPI

If a case is dismissed for a "matter of form," it may be re-filed within one year of dismissal. Miss. Code Ann. § 15-1-69. A voluntary dismissal without prejudice in federal court was considered a matter of form where it was based on subject matter jurisdiction. *Marshall v. Kan. City S. Rys.*, 7 So. 3d 210 (Miss. 2009).

MISSOURI

Missouri Rev. Stat. § 516.230 permits an action dismissed without prejudice to be re-filed within one year. The statute provides that the action may be commenced "from time to time," which allows multiple re-filings within the one-year savings period. *Foster v. Pettijohn*, 213 S.W.2d 487, 490 (Mo. 1948).

MONTANA

Montana's savings statute includes a one-year window to re-file a claim dismissed for non-merits reasons and other than a plaintiff's voluntary dismissal or failure to prosecute. Mont. Code Ann. § 27-2-407.

NEBRASKA

Nebraska's only savings statute concerns the viability of claims that are pending at the time the statutory basis for the claims is repealed. Neb. Rev. Stat. § 49-301.

NEVADA

A dismissed claim is covered by the savings statute only if it is dismissed for lack of subject matter jurisdiction. Nev. Rev. Stat. Ann. § 11.500. The re-filing must occur within the original limitations period or within 90 days of the dismissal, whichever is later.

NEW HAMPSHIRE

An action may be re-filed within one year of any dismissal that does not bar the right of action. N.H. Rev. Stat. Ann. § 508:10. A voluntary non-suit does not bar a right of action. *Milford Quarry & Constr. Co. v. Boston & M. R.R.*, 97 A. 982 (1916).

NEBRASKA'S ONLY SAVINGS STATUTE CONCERNS THE VIABILITY OF CLAIMS THAT ARE PENDING AT THE TIME THE STATUTORY BASIS FOR THE CLAIMS IS REPEALED.

NEW JERSEY

New Jersey Stat. Ann. § 2A:14-28 includes one year to re-file a claim where a judgment that was rendered for plaintiff is reversed on appeal or dismissed on post-judgment motion by the court. The statute is not applicable where the plaintiff has not recovered a judgment. *Zaccardi v. Becker,* 88 N.J. 245, 263 n.3 (N.J. 1982).

NEW MEXICO

If a claim is dismissed for any non-merits reason other than failure to prosecute, it may be re-filed within six months of the dismissal. N.M. Stat. Ann. § 37-1-14. To be afforded the protection of Section 37-1-14 when commencing an action, "the plaintiff must choose a forum that arguably has the power to decide the matter involved." *Foster v. Sun Healthcare Group, Inc.,* 284 P.3d 389, 394 (N.M. Ct. App. 2012).

NEW YORK

The savings statute allows a claim to be re-filed within six months. N.Y.C.P.L.R. § 205. This provision does not apply to claims that are voluntarily dismissed by the plaintiff, for failure to prosecute, for lack of personal jurisdiction over the defendant, or for claims that are dismissed on the merits. Where first action was in court of another state, the statute applies only where that action was brought within the time limited for such action by the law of New York. *De Luca v Atlantic Refining Co.,* 176 F.2d 421 (2d Cir. 1949).

NORTH CAROLINA

A voluntarily dismissed claim may be re-filed within one year of dismissal. N.C. Gen. Stat. § 1A-1, Rule 41. This does not apply to merits-based dismissals, failure to prosecute, or failure to comply with orders of the court. Id. In addition, in any order of dismissal, the court may specify a shorter period for re-filing. Id. A voluntary dismissal under federal rule 41 in a non-diversity case does not toll the statute of limitations or implicate the savings provision of N.C. Rule 41(a). *Harter v. Vernon,* 532 S.E.2d 836, 841 (N.C. Ct. App. 2000).

NORTH DAKOTA

North Dakota has not enacted a savings statute and has not judicially adopted the doctrine. *Reid v. Cuprum* SA, de C.U., 611 N.W.2d 187, 190 (N.D. 2000).

OHIO

Ohio Rev. Code Ann. § 2305.1 contains a one-year time period to re-file a claim that "fails otherwise than upon the merits." In order to invoke this provision, the limitations period must expire during the pendency of the first suit. Id. The statute does not apply to protect actions originally filed in other states. *Monroe v. Stop-N-Go Food Stores,* 631 N.E.2d 1138 (Ohio Ct. App. 1993).

OKLAHOMA

A plaintiff may re-file a claim dismissed for non-merits reasons within one year of the dismissal. 12 Okla. Stat. § 100. The right to re-file is limited to actions commenced within the State of Oklahoma. *Morris v. Wise,* 293 P.2d 547 (Okla. 1955). The statute permits only one re-filing. *Hull v. Rich,* 854 P.2d 903, 904 (Okla. 1993).

OREGON

Oregon Rev. Stat. § 12.220 contains a 60-day period for re-filing an action that "is involuntarily dismissed without prejudice on any ground not adjudicating the merits of the action." A claim may also be re-filed if it is dismissed for failure to properly effect service and the limitations period has expired. Id. This applies to claims originally filed in federal court and dismissed for lack of jurisdiction that are re-filed in state court. *Hatley v. Truck Ins. Exchange,* 494 P.2d 426, 429 (Or. 1972).

PENNSYLVANIA

Under 42 Pa. Cons. Stat. § 5535, a terminated action may be re-filed within a year. The statute expressly does not apply to personal injury or wrongful death claims or claims that are voluntarily dismissed by plaintiff, dismissed for failure to prosecute, or

dismissed on the merits. Id. The savings statute does not preserve time-barred claims in a Pennsylvania state court if they were first filed in federal court and then re-filed in state court. Jewelcor Inc. v. Karfunkel, 517 F. 3d 672 (3d Cir. 2008).

RHODE ISLAND

An action may be re-filed within one year of a non-merits dismissal, provided the dismissal is not voluntary by the plaintiff or for failure to prosecute. R.I. Gen. Laws § 9-1-22. A claim dismissed for failure to effectuate service of process can be re-filed under the savings statute. *Furtado v. Laferriere,* 839 A.2d 533, 538 (R.I. 2004). The savings statute does not protect a new action when it was first filed in another state. *Goyette v. Suprenant*, 622 A.2d 1001 (R.I. 1993).

SOUTH CAROLINA

"It is well settled in South Carolina that when an action is dismissed without prejudice, the statute of limitations will bar a subsequent suit if the statute runs in the interim." *Rink v. Richland Mem. Hosp.*, 422 S.E.2d 747, 749 (S.C. 1992).

SOUTH DAKOTA

The South Dakota legislature has not adopted a savings statute, and the courts have expressly declined to judicially create one. *Peterson v. Hohm,* 607 N.W, 2d 8, 13 (S.D. 2000).

TENNESSEE

Any action that is dismissed for reasons "not concluding the plaintiff's right of action" may be re-filed within one year of the dismissal. Tenn. Code Ann. § 28-1-105. It is wholly immaterial whether a nonsuit was voluntary or involuntary, so long as the dismissal was not on a ground concluding plaintiff's right of action. *Privett v. West Tennessee Power & Light Co.,* 19 F. Supp. 812 (W.D. Tenn. 1937). The savings statute does not apply to actions commenced in another state, *Elias v. A&C Distrib.,* Co., Inc., 588 S.W.2d 768, 772 (Tenn. Ct. App. 1979), but it does apply to actions originally commenced in federal court. Privett, 19 F. Supp. 812. Multiple re-filings are permitted, but all must occur within one year of the original dismissal. *Rector v. DACCO, Inc.*, 2006 WL 1749525, *3 (Tenn. Ct. App. June 26, 2006).

TEXAS

A plaintiff may re-file a dismissed action within 60 days of dismissal if the action is dismissed for lack of jurisdiction. Tex. Civ. Prac. & Rem. Code § 16.064. A federal court's decision not to exercise pendent jurisdiction was construed as a dismissal for lack of jurisdiction. *Vale v. Ryan,* 809 S.W.2d 324, 327 (Tex. App.—Austin 1991), no writ. Where filing of an action in federal court was made in intentional disregard of the jurisdiction of the federal court, the tolling of the statute of limitations did not occur for purposes of Tex. Civ. Prac. & Rem. Code Ann. § 16.064 and the suit was barred. *French v. Gill,* 252 S.W.3d 748 (Tex. App.—Texarkana 2008), pet. denied.

UTAH

A plaintiff may re-file a claim once within one year of dismissal other than on the merits. Utah Code Ann. § 78B-2-111. A new action may be commenced within one year after granting the nonsuit, if causes of action in both complaints are the same. *Williams v. Nelson,* 145 P. 39 (Utah 1914).

VERMONT

Vermont's only savings statute applies to claims or criminal prosecutions based on repealed statutory provisions. See 1 Vt. Stat. Ann. § 214(b).

VIRGINIA

Virginia Code Ann. § 8.01-229(e) states a plaintiff may re-file an action within one year of a reversal of a judgment for plaintiff that does not preclude a new cause of action. If a plaintiff voluntarily dismisses her claim, a new action may be brought within six months of the dismissal or within the original statute of limitation, whichever is longer. Id. The savings statute applies whether the original action was filed first in federal court and then in state court or vice versa. *Blakely v. Austin-Weston,* 348 F. Supp. 2d 673, fn 4 (E.D. Va. 2004).

WASHINGTON

Washington has a savings statute that applies to preserve claims arising under a statutory framework even if the statute is subsequently amended or repealed. Wash. Rev. Code § 10.02.040; *State v. Gradt,* 366 P.3d 462 (Wash. Ct. App. 2016).

WEST VIRGINIA

A plaintiff may re-file a dismissed action within one year of dismissal if the action was involuntarily dismissed for a non-merits reason. W. Va. Code R. § 55-2-18. The statute does not apply to voluntary dismissals by the plaintiff or to dismissals based on plaintiff's negligence. *Ryan v. Piney Coal & Coke* Co., 73 S.E. 330 (W. Va. 1911). The extension granted by this section applies whether the first action was in another state court or in a federal court. *Stare v. Pearcy,* 617 F.2d 43 (4th Cir. 1980).

WISCONSIN

Wisconsin's only savings statute concerns the viability of pending actions after repeal of a statute. Wis. Stat. § 990.04.

WYOMING

Under Wyoming Stat. Ann. § 1-3-118, a plaintiff has one year to re-file an action that is dismissed for non-merits reasons if the limitations period expired by the time of dismissal. This section affords a plaintiff a year from a federal court dismissal to commence a new action in the state court. Ball v. Renner, 54 F.3d 664 (10th Cir. 1995). This section does not apply to actions brought in a state other than Wyoming. Riley v. Union P. R. Co., 182 F.2d 765 (10th Cir. 1950).

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Luther Munford works primarily on medical device product liability defense and on appeals. Luther clerked for U.S. Supreme Court Justice Harry A. Blackmun and has served on the Appellate Rules Advisory Committee to the Judicial Conference of the United States as well as the lawyer advisory committee to the U.S. Court of Appeals for the Fifth Circuit. He is the author of Mississippi Appellate Practice (2010). A past president of the American Academy of Appellate Lawyers, he has been recognized by *Chambers USA, The Best Lawyers in America®,* and *Mid-South Super Lawyers®* for his expertise in appellate law.

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