PRO TE: SOLUTIO™

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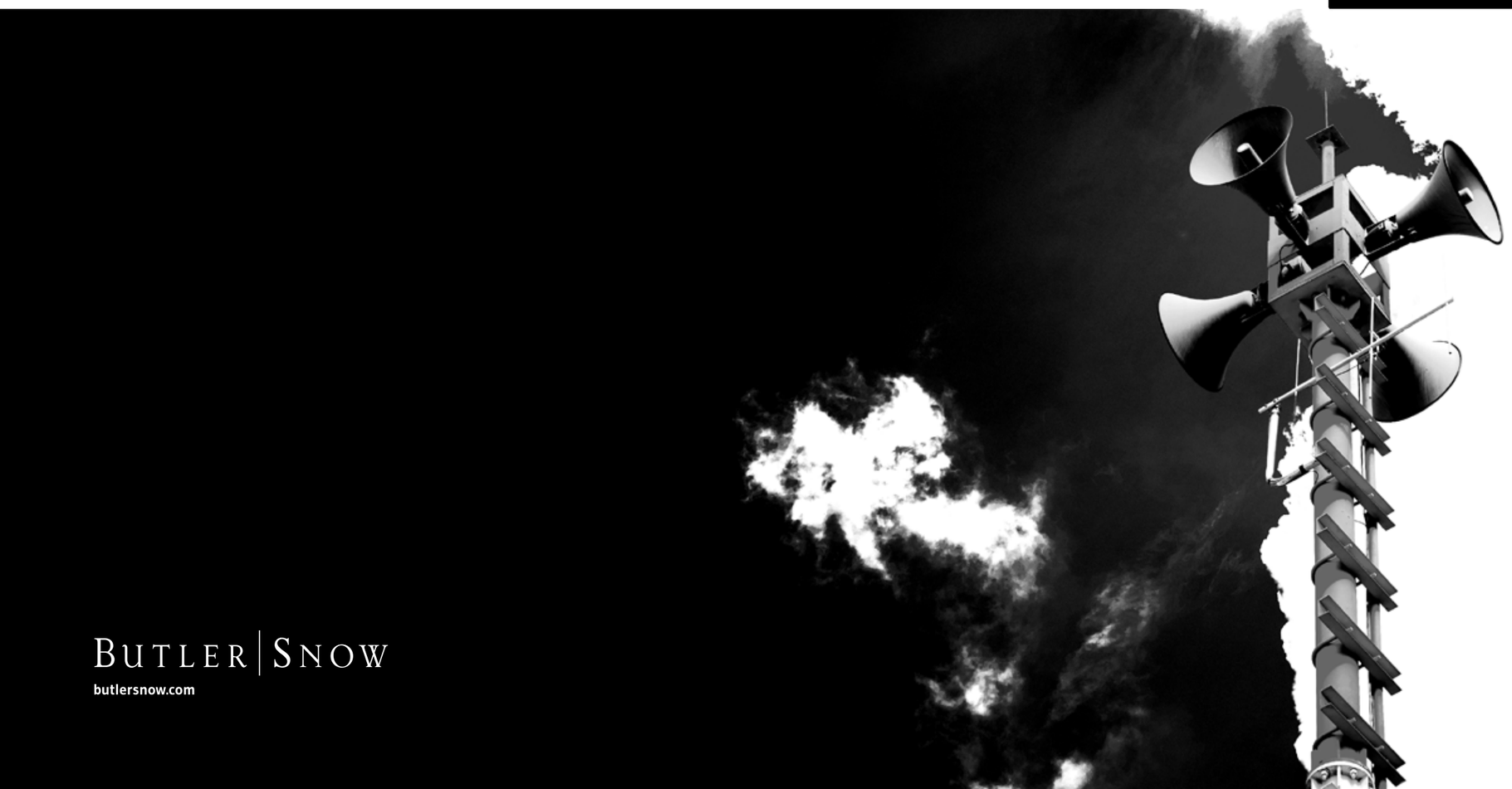
VOL. 10 | NO. 2
SPRING 2017



WARNINGS PROXIMATE CAUSATION

CURES ACT

WEARABLE TECHNOLOGY

NEW AND NOTEWORTHY

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LAW ELEVATED

DEAR CLIENT,

It's Spring! In this issue of Pro Te, we do a little a "spring cleaning" to brush the dust off some familiar topics that we consider in day-to-day pharmaceutical litigation. In *The Forgotten Element? Warnings Proximate Causation in Trial Practice*, we take a fresh look at proximate cause, including how best to maximize testimony from prescribing physicians to reveal why a plaintiff has failed to satisfy this critical element of a products liability claim.

We also raise the shades to illuminate the new Cures Act with a two-part look at how the new law intends to enhance medical care and pave the way for new pathways to develop drugs and medical devices.

Consistent with the notion of spring cleaning, we all know how great it feels to find something you didn't know you had. In *Wearable Technology Discovery in Personal Injury Cases: How Data From a Plaintiff's Wrist Can Make a Difference in the Courtroom*, we discuss how electronics and technology (think FitBit®) can uncover data about plaintiffs—and how that evidence may be admissible in court.

Finally, we do some deep cleaning on an old topic: personal jurisdiction! This is one of the hot topics in law right now, with important decisions looming in several courts, including the U.S. Supreme Court. We highlight some of these important cases in *Norfolk Southern Ry. Co. v. Dolan: The end to litigation tourism in the City of St. Louis?*

So: let's brush off some of those legal cobwebs and embrace Spring!

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THE FORGOTTEN ELEMENT?

WARNINGS PROXIMATE CAUSATION IN TRIAL PRACTICE

THE BEGINNING.

Everything should be made as simple as possible, but not simpler.
— Einstein

Stereotypes begin with a kernel of truth. Admit it, you've seen them within your virtual firm. Maybe it's the science wonk, convinced that no jury could award damages if they could only be made to *truly* understand the esoteric biological principle—the one that can only be described via acronym. Perhaps it's the detail-oriented associate or nurse analyst, uncovering the pivotal blip in the plaintiff's timeline that calls the entire injury claim into question. Then, of course, there's the

weary "handler," charged with preparing your company witness or regulatory expert. A handler's job is to anticipate any possible critique of the client's conduct from the time of its founding, and to defend a product warning against a myriad of attacks, like a careless internal email, an unfavorable—but isolated—scientific finding, or even so-called "common sense."

These stereotypes may ring familiar because the driver of so many drug and device products cases is the warnings claim. Plaintiffs routinely allege that drug and device manufacturers withheld critical risk information—information that, if properly shared, would have made all the difference to an unsuspecting and vulnerable plaintiff. And, while the substantive law on failure-to-warn across jurisdictions can vary—in some instances, widely—there is a prevailing pattern to the elements of proof in a warnings claim.

Using a matrix to illustrate a concept in a section touting simplicity is, admittedly, cringe-worthy. It is also valid. Virtually all failure-to-warn or inadequate warnings claims begin with four elements to be proven:

1. ***general medical causation*** *— can the offending product cause (or, in some jurisdictions, merely contribute to) the alleged injury;*
2. ***specific medical causation*** *— did the product cause this plaintiff's injury;*
3. ***warnings adequacy*** *— are the product warnings in effect at the time of the plaintiff's use consistent with reasonable practice; and*
4. ***proximate cause*** *— if the warnings are deemed inadequate or unreasonable, are those failings responsible for the outcome.*

	CAUSATION	WARNING
GENERAL	General Medical Causation	Warnings Adequacy
SPECIFIC	Specific Medical Causation	**"PROXIMATE CAUSE"**

PLAINTIFFS ROUTINELY ALLEGE THAT DRUG AND DEVICE MANUFACTURERS WITHHELD CRITICAL RISK INFORMATION THAT WOULD HAVE MADE ALL THE DIFFERENCE TO AN UNSUSPECTING AND VULNERABLE PLAINTIFF.

Plotted this way, the elements fall into two pairs of concepts: (1) causation and warnings along one axis; and (2) general and specific along the other. Now, look again at our stereotypes on the previous page. Three of these elements are described, but the fourth—proximate causation—is not. Why?

One possible explanation for this discrepancy is the nearly unconscious deference to an insurmountable piece of evidence. In every failure-to-warn claim, inevitably the plaintiff will be asked by her attorney: *if you had known that using **this** product would result in **this** injury, would you have ever used it?* It's a hindsight question, of course, and one loaded with assumptions, but the answer is typically automatic and emphatic. *Of course not.* If this ultimate question is so firmly within the direct control of the plaintiff, then it makes sense to marshal the defense elsewhere.

Advantage, plaintiff?

THE MIDDLE.

You keep using that word. I do not think it means what you think it means.

— Inigo Montoya, The Princess Bride

At the same time, attend any drug and device seminar, approach an attendee at random, and pose the question: What does the "learned intermediary" doctrine mean? The answer is rote: *Why, the manufacturer's duty to warn runs to the doctor, not the patient.* That is the undeniably correct answer. It is also, as a practical matter, incomplete. It doesn't mean what you think it means, at least, not entirely. From a trial defense perspective, the learned intermediary doctrine should mean that the proximate cause element of a failure-to-warn claim is properly satisfied not by the plaintiff, but by the prescriber. Because drug and device manufacturers warn these specialized-knowledge-wielding proxies, rather than the ultimate consumers of their products, then any

EVEN IN "PATIENT DISCUSSION" JURISDICTIONS WHERE CASE-ENDING TESTIMONY IS DIFFICULT TO OBTAIN, COUNSEL SHOULD BE AWARE OF AND SEEK TO FRAME FAVORABLE PROXIMATE CAUSE TESTIMONY.

failings in the product warnings are assessed against the prescriber's knowledge and decision to use, not the plaintiff's. Taken to its logical end, the application of the learned intermediary doctrine should render the plaintiff's ultimate question above ineffectual, even irrelevant.

This tension—between competing interpretations of proximate causation in the learned intermediary context—has played out in multiple jurisdictions. One effect is a distinction between the "prescribing decision" and the "patient discussion" as the determinative facts for a proximate causation analysis. That is, there are competing positions for what satisfies the elemental burden of proximate cause: whether the doctor (or other healthcare provider) would have continued to prescribe the product, or whether the interaction and discussion with the patient regarding the product would have changed. Plaintiffs prefer the latter, because any admission by a prescriber that different information would alter the interaction with the patient funnels the decision point toward the ultimate, plaintiff-controlled question. By contrast, defendants prefer the former, and not merely as an "anti-plaintiff" position. Prescribers are being asked to confirm and reinforce their own judgment regarding the decision they previously made with respect to this individual patient, i.e., the decision to use the product.

In *Gaghan v. Hoffmann-LaRoche, Inc., et al.*,[1] the New Jersey Appellate Division reversed a verdict awarded to an Accutane user on the basis of California's interpretation of the proper scope of the proximate cause inquiry:

> The question of law is whether the conduct of the doctor that would be altered by a stronger warning is limited to the doctor's prescribing decision or, as the trial court concluded here, also includes the doctor's decision to provide a stronger warning to the patient. In the absence of a decision by a California appellate court contradicting the holdings of the federal courts, we conclude that California law focuses on the **prescribing decision** of the doctor as the learned intermediary.
>
> A number of other jurisdictions have held similarly that the relevant conduct that would be altered by a stronger warning is the **doctor's decision to prescribe** the drug. See *Ackermann v. Wyeth Pharms.,* 526 F.3d 203, 213-14 (5th Cir. 2008) (Texas law); *Ralston v. Smith & Nephew Richards, Inc.*, 275 F.3d 965, 976-77 (10th Cir. 2001) (Kansas law); *Wheat v. Pfizer, Inc.*, 31 F.3d 340, 343 (5th Cir. 1994) (Louisiana law); *Hoffmann-La Roche, Inc. v. Mason*, 27 So.3d 75, 77 (Fla. Dist. Ct. App. 2009) (Florida law), *review denied*, 37 So.3d 848 (Fla. 2010).
>
> Our own Supreme Court in New Jersey has reached the same conclusion. See *Strumph v. Schering Corp.*, 133 N.J. 33, 626 A.2d 1090 (1993), *rev'ing on dissent*, 256 N.J. 309, 323, 606 A.2d 1140 (App. Div. 1992) (Skillman, J.A.D., dissenting) (under New Jersey law, plaintiff must show adequate warnings would have altered physician's prescribing decision). *But cf. Niemiera v. Schneider*, 114 N.J. 550, 565-66, 555 A.2d 1112 (1989) (under New Jersey's learned intermediary doctrine, doctor's responsibility is to inform patient about information that enables patient to use product safely); *In re: Diet Drug Litig.*, 384 N.J. Super. 525, 541, 895 A.2d 480 (Law Div. 2005) (leaving prescribing decision solely in hands of learned intermediary runs afoul of New Jersey's public policy).
>
> (emphasis added)

Other states, like Mississippi, Alabama, and Georgia, have also adopted the "prescribing decision" interpretation of warnings proximate causation.[2] However, the issue is not fully settled. "Patient discussion" advocates do find legal support, as some courts are reluctant to cede all decision-making authority to the prescribers, when the plaintiff ultimately decides to use a product now claimed to have caused harm.[3]

THE END.

Do, or do not. There is no try.
— Yoda, The Empire Strikes Back

The takeaway from all of this is the importance of the prescriber's testimony on this issue, which makes the available prescriber's deposition critical in any drug or device products case. Defense counsel should never approach a prescriber deposition seeking only to regurgitate a treatment

timeline. Nor should they settle for favorable, but ultimately derivative or cumulative proof on elements of medical causation. Even in "patient discussion" jurisdictions where case-ending testimony is difficult to obtain, counsel should be aware of and seek to frame favorable proximate cause testimony. A dispositive element of plaintiff's claim hinges on the results.

As this is a lawyerly piece, disclaimers apply. Rules beget exceptions, and individual judgment should always trump checklists in defending products cases. Perhaps the prescriber consults regularly for plaintiffs' lawyers, or has a known bias against manufacturers, or has suspect credentials or a vast litigation history. There are a variety of reasons to modify an approach to a prescriber deposition. However, the very fact that the product was prescribed is a powerful indicator in many cases that favorable testimony on proximate cause can be had.

As a result, consider the following as potential lines of inquiry for prescribers.

- **Establish "learned-ness."** As noted, in some cases, perhaps qualifying the prescriber as a pseudo-expert is not the preferred course. But where favorable testimony is anticipated, tracking the highlights of the prescriber's education, training, and experience reinforces the specialized knowledge the learned intermediary doctrine represents. As a corollary, determine whether the prescriber has contributed to key opinions for industry, participated in sponsored clinical trials, or developed new products in the field as an indicator of alignment.
- **Sources of information.** Plaintiffs' warnings claims hinge on poking holes in specific labeling materials, such as package inserts or instructions for use. Expect that opposing counsel will put before the prescriber some piece of information that is not set out in the labeling. As such, it is important to establish other sources of information, often ranging from experience to professional associations/discussions with colleagues to literature as a means of shoring up the prescriber's knowledge of either the potential for injury or its alleged relationship with the product.
- **Give the indication its due.** Plaintiffs tend to focus on one medical condition—the alleged injury. In fact, drug and device products cases always involve (at least) two. The underlying condition for which the product was prescribed should be explored, in part to establish the ramifications of non-treatment. Put another way: establish the benefits of the use of the product where available.
- **Product usage.** Similarly, look for opportunities to establish safe, effective use of the product with other patients both before the plaintiff's use and after, including present and ongoing use where possible. This is one of the signals of potential favorable testimony with the ultimate question.
- **Reinforce the prescriber's judgment.** A by-product of plaintiff's warnings claim is an inference that the prescriber's judgment was impaired by insufficient knowledge. Many prescribers inherently reject challenges to their medical judgment. Mine that tendency.
- **Establish "standard" and "case-by-case" warnings practice.** It may be the case that the prescriber did not warn the plaintiff of the specific alleged injury. And it is typical for prescribers to acknowledge that, as between less information and more information, they prefer the latter: they would "want to know." Plaintiffs' lawyers tend to pivot from these questions to low-risk, general questions like, *And if you had additional information, you would pass that on to your patients?* Prescribers often agree, leaving plaintiff's counsel one step away from setting up their ultimate question. One hedge against that is to test the notion that prescribers deliver certain "standard" warnings for products (most common side effects, e.g.) as well as warning on a case-by-case basis (certain patients tolerate certain amounts of risk information).
- **Test the alternate warning.** To the extent plaintiffs have developed a proposed alternate warning addressing the alleged deficiencies in the product warnings, consider directly confronting the prescriber with loaded questions: *E.g., plaintiff's expert has opined that if this warning had been available when you prescribed to the plaintiff, then your understanding of the risks and benefits of the product would have been so altered that you would not have prescribed. Is that true?* Recognize that these are high-risk, high-reward questions; judgment is critical.
- **Ultimate question.** Similarly, information obtained over the course of a deposition can signal whether to attempt a "prescribing decision" ultimate proximate cause question. If successful, consider a series of questions designed to satisfy the "patient discussion" prong as well, e.g., *if plaintiff presented to you in [original date of use], would your approach and course of treatment have been the same, with or without this additional information?"*

Warnings proximate causation is an essential element of a plaintiff's warnings claim. Under the learned intermediary doctrine, that proof comes from the prescriber's understanding of the warning and any alleged flaws, in conjunction with the prescriber's general knowledge as a physician. Defense counsel should recognize the parameters of the doctrine where an action is pending and should be deliberate in their approach to prescriber depositions.

And who knows? Perhaps with consistent and heightened attention to this element of proof, a new defense lawyer stereotype will emerge.

1. 2014 WL 3798338, *15 (N.J. App. Div. 2014).
2. *See, e.g., Janssen Pharmaceutia, Inc. v. Bailey*, 878 So.2d 31, 58 (Miss. 2004) ("The Plaintiffs bear the burden of establishing that Propulsid was the cause of their injuries and that 'an adequate warning would have convinced the treating physician **not to prescribe** the product for the [P]laintiff[s].'") (Miss. law); *Wyeth v. Weeks*, 159 So.3d 649, 673-74 (Ala. 2014) ("In short, the patient must show that, but for the false representation made in the warning, the prescribing physician **would not have prescribed** the medication to his patient.") (Ala. law); *Porter v. Eli Lilly & Co.*, 291 Fed. Appx. 963 (11th Cir. 2008) ("Under Georgia law, Porter was required to prove that, but for the alleged inadequate warning, Dr. Wolfberg, decedent's physician, **would not have prescribed** Prozac to decedent.") (Ga. law) (emphasis added).
3. *See, e.g., Giles v. Wyeth, Inc.*, 500 F. Supp. 2d 1063 (S.D. Ill. 2007) (Ill. law); *Gilliland v. Novartis Pharmaceuticals Corp.*, 34 F. Supp.3d 960 (S.D. Iowa 2014) (Iowa law); *Rossitto v. Hoffmann-LaRoche, Inc., et al.*, 2016 WL 3943335, *24 (N.J. App. Div. 2016) ("'The 'prescribing decision'—insofar as it logically entails both a physician's recommendation and a patient's assent to follow that recommendation after being apprised of the pertinent risks—could have been affected by the absence of a stronger warning. Although a physician can function as a 'learned intermediary,' *Niemiera v. Schneider*, 114 N.J. 550, 559 (1989), it should not be assumed that a doctor will issue a prescription to an informed patient who is unwilling to risk a drug's side effects.") (N.J. law).

MARK A. DREHER

INTRODUCTION TO THE CURES ACT

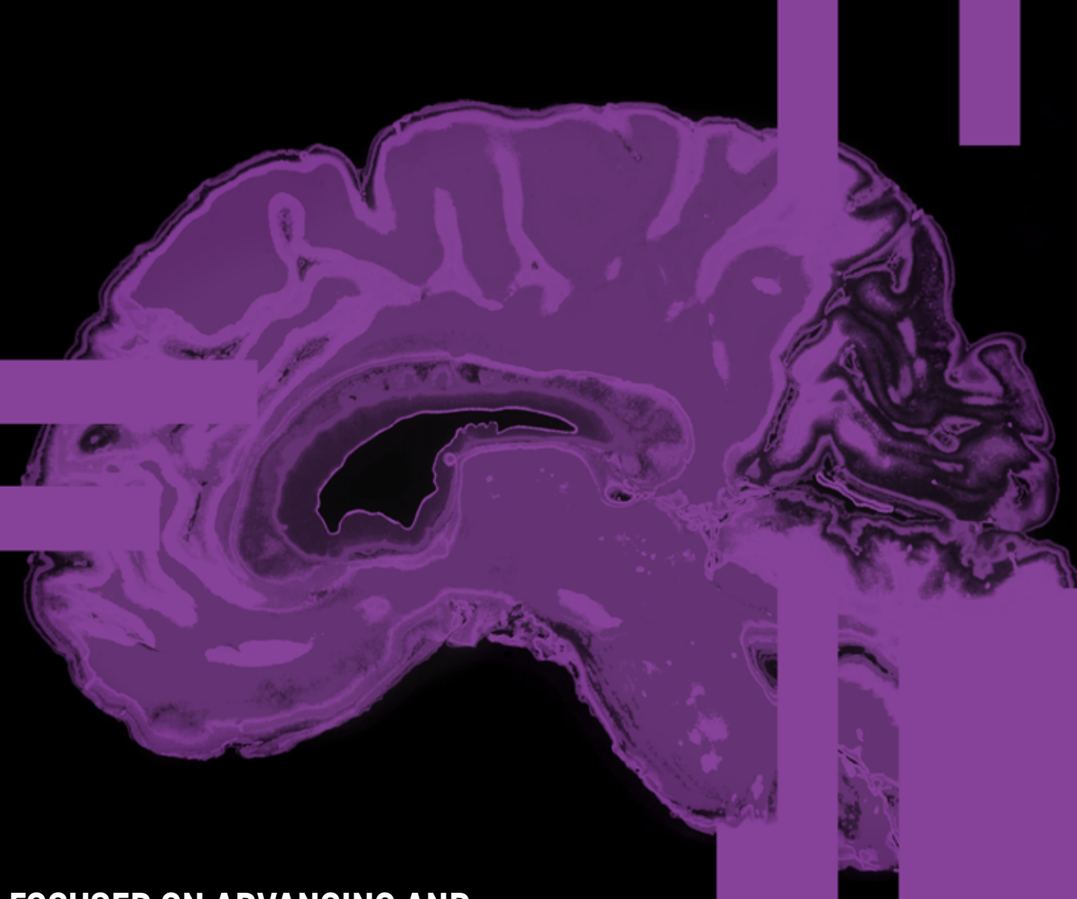
The 21st Century Cures Act (the "Act"), a sweeping piece of legislation with overwhelming bipartisan support, was signed into law on December 13, 2016. Focused on advancing and accelerating medical research, combating America's opioid abuse epidemic, and improving mental health care, the 21st Century Cures Act will unquestionably affect patients, healthcare providers, medical researchers, and pharmaceutical and device manufacturers.

This feature explores two sections of the Act that will specifically impact healthcare providers and manufacturers. Healthcare providers will want to take note of the first article, which examines mandates to improve medical care through better access to and interoperability among electronic health records. The second article, which details plans for opening new drug and device development pathways, will be of particular interest to pharmaceutical and device manufacturers.

While these articles discuss only a fraction of the Act's scope, they clearly convey the message that the Act is "[a]n innovation game-changer, a once-in-a-generation, transformational opportunity to change the way we treat disease."[1]

1. https://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/documents/114/analysis/20161128%20Cures%20Fact%20Sheet.pdf

KIMBERLY S. COGGIN



FOCUSED ON ADVANCING AND ACCELERATING MEDICAL RESEARCH, COMBATING AMERICA'S OPIOID ABUSE EPIDEMIC, AND IMPROVING MENTAL HEALTH CARE, THE 21ST CENTURY CURES ACT WILL UNQUESTIONABLY AFFECT PATIENTS, HEALTHCARE PROVIDERS, MEDICAL RESEARCHERS, AND PHARMACEUTICAL AND DEVICE MANUFACTURERS.

HEALTH INFORMATION TECHNOLOGY (HIT) INOPERABILITY

UNDER THE 21ST CENTURY CURES ACT

THE STAGE IS SET

The 21st Century Cures Act[1] (the "Act") is a multifaceted piece of healthcare and life sciences legislation designed to accelerate discovery, development, and delivery of innovative cures and treatments.

Title IV of the Act focuses on the delivery of medical care and includes some notable mandates to improve access and interoperability[2] of healthcare information technology (HIT). Sec. 4003(b) establishes new requirements and supports interoperability among disparate electronic health records (EHRs). The Office of the National Coordinator for Health Information Technology (ONC) is the principal federal entity designated to implement and advance HIT and the electronic exchange of health information under the Act.[3] Rapidly driving network-to-network interoperability forward, the ONC is directed to convene, **within six months of enactment**,[4] a public-private stakeholder convention to develop a trusted exchange framework for trust policies and practices and a common agreement for use among existing health information networks nationally (i.e., a "network of networks"). The Act ambitiously provides that the trusted exchange framework and common agreement will be established and published **within one year** after the convention of the stakeholders.

The ONC is instructed to work with the National Institute of Standards and Technology and other relevant agencies within HHS to pilot test and provide technical assistance on how to implement the trusted exchange network and common agreement. The Secretary of the Department of Health and Human Services (HHS) shall, through notice and comment rulemaking, establish a process for health information networks that voluntarily elect to adopt the trusted exchange framework and common agreement to attest to such adoption of the framework and agreement.[5]

The ONC will publish a list of health information networks that have adopted the voluntary model exchange framework and are capable of trusted exchange pursuant to the common agreement, and the HHS Secretary will set up a comprehensive digital index for health professionals and health facilities that have adopted the agreement and exchange standards.[6]

A new federal HIT Advisory Committee is established in Section 4003(e)[7] to address issues related to achieving an interoperable health technology infrastructure (nationally and locally). The new HIT Advisory Committee is directed to work with private and public stakeholders and make recommendations to the ONC in targeted areas regarding:

- Technology that provides accurate patient information for the correct patient, including exchanging such information, and avoids the duplication of patient records.
- Privacy and security of health information in HIT, including technologies that allow for an accounting of disclosures and protections against disclosures of individually identifiable health information made by a covered entity for purposes of treatment, payment, and healthcare operations pursuant to HIPAA, as well as segmentation and protection from disclosure of specific and sensitive individually identifiable health information.
- The facilitation of secure access by an individual to his/her protected health information, and access to such health information by a family member, caregiver, or guardian acting on behalf of a patient (including due to age-related and other disability, cognitive impairment, or dementia).

SETTING PRIORITIES FOR ADOPTION OF STANDARDS[8]

The ONC is required to convene the HIT Advisory Committee, **not later than six months** after the date on which the HIT Advisory Committee first meets, to identify priority uses of HIT and standards and implementation specifications that support such

uses of HIT,[9] and publish a report of findings and recommendations regarding priorities, focusing on uses of HIT arising from/related to:

- The implementation of incentive programs to promote the adoption and meaningful use of certified EHR technology (CEHRT), the Merit-based Incentive Payment System (MIPS), Alternative Payment Models (APMs), the Hospital Value-Based Purchasing Program (HVBP), and any other value-based payment program determined appropriate by the HHS Secretary;
- Quality of patient care
- Public health
- Clinical research
- Privacy and security of electronic health information
- Innovation in the field of HIT
- Patient safety
- Usability of HIT
- Individuals' access to electronic health information
- Other priorities determined appropriate by the HHS Secretary

Beginning five years after the enactment of the Act, and every three years after that, the ONC must convene stakeholders to review and make recommendations with respect to maintaining or phasing out adopted standards and implementation specifications.

BAN ON INFORMATION BLOCKING

Notably, Sec. 4004 of the Act[10] explicitly prohibits "information blocking," which is defined as a practice that, except as required by law or specified by HHS Secretary rulemaking, is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information; and

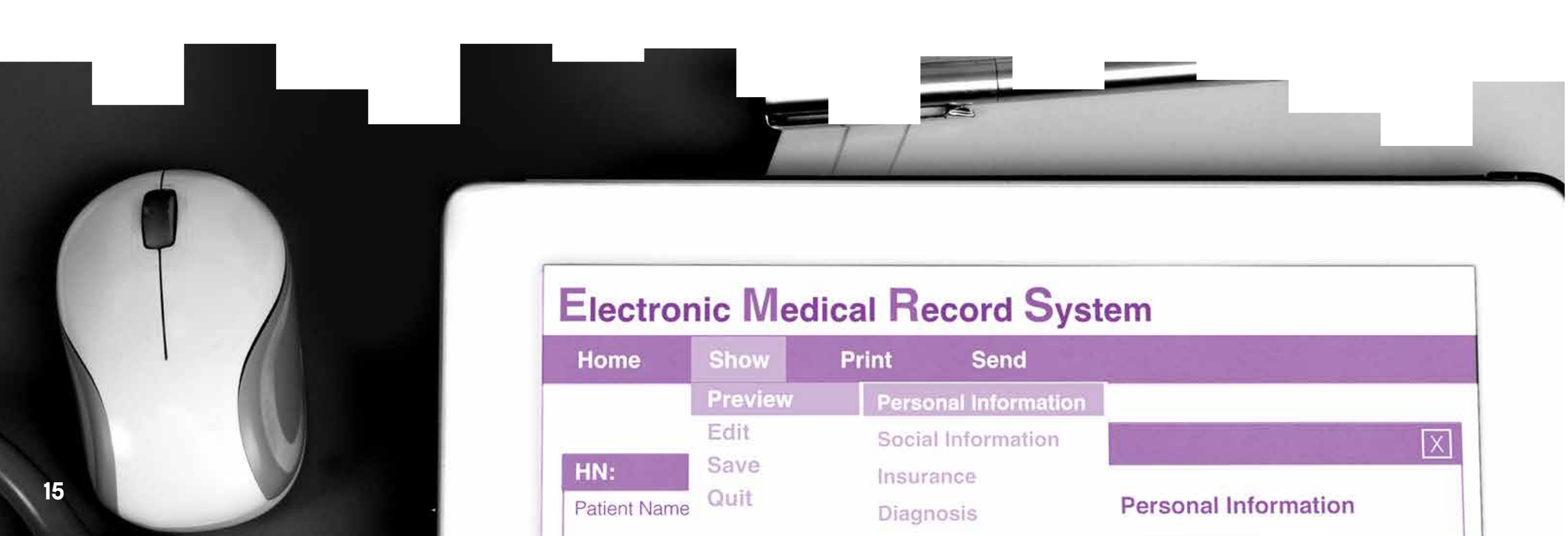
- if conducted by a *health information technology developer, exchange, or network*, such developer, exchange, or network **knows, or should know**, that such practice is likely to interfere with, prevent, or materially discourage the access, exchange, or use of electronic health information; or
- if conducted by a *healthcare provider*, such provider **knows** that such practice is unreasonable and likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.

Specific descriptions of "information blocking" practices include:

- Practices that restrict the authorized access, exchange, or use of electronic health information for treatment or other permitted purposes under applicable state/federal law, including transitions between certified HIT systems.
- Implementing HIT in nonstandard ways likely to substantially increase the complexity or burden of accessing, exchanging, or using electronic health information.
- Implementing HIT in ways likely to:
  - restrict access, exchange, or use of electronic health information with respect to exporting complete information sets or in transitioning between HIT systems, or
  - lead to fraud, waste, or abuse, or impede innovations and advancements in health information access, exchange, and use, including care delivery enabled by HIT.

The Inspector General of the Department of Health and Human Services (OIG) is authorized to investigate information blocking claims. Health-information vendors found to have committed information blocking (including false attestations) will be subject to civil monetary penalties **up to $1 million per violation**. Health providers determined

THE 21ST CENTURY CURES ACT HAS SET THE STAGE FOR INDUSTRY-WIDE INTEROPERABILITY THAT WILL MODERNIZE AND PERSONALIZE HEALTHCARE.



to have committed information blocking will be subject to other "appropriate disincentives," as the HHS Secretary sets forth through notice and comment rulemaking.

The Cures Act legislation also promotes patient access to secure and up-to-date electronic health information through interoperable health information exchanges. Pursuant to Section 4006, the HHS Secretary is tasked to encourage partnerships among health information exchanges, healthcare providers, and health plans to offer patients access to their electronic information in "a single longitudinal format that is easy to understand, secure, and may be updated automatically." Further, Section 4006 amends the Health Information Technology for Economic and Clinical Health Act (HITECH) providing that business associates may directly transmit or grant designee(s) access to an individual's Protected Health Information (PHI) in response to a request from the individual.[11]

WHAT NOW?

The 21st Century Cures Act has set the stage for industry-wide interoperability that will modernize and personalize healthcare. The exchange of accurate and complete electronic health information and advanced technology may be leveraged in ways that improve patient care and outcomes, enable patients to access and use their health data to collaborate in their care, advance precision medicine tailored to individual patients, reduce errors, increase efficiency, lower costs, and optimize reimbursements for healthcare providers. The health information technology provisions in the Cures Act should stimulate the rapid advancement of such interoperability and exchange. Once new HHS leadership and essential rulemaking take shape this year, compliance will be the name of the game!

1. Pub. L. No 114-255, 130 Stat. 1033 (2016).
2. The Act defines **interoperability** with respect to HIT, as technology that:
   - enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user;
   - allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable state or federal law; and
   - does not constitute information blocking (as defined in the Act).

   Sec. 4003(a) (to be codified at 42 U.S.C. § 300jj).
3. Sec. 4003(b) (to be codified at 42 U.S.C. § 300jj-11(c)).
4. The 21st Century Cures Act was signed into law on December 13, 2016.
5. While no health information network will be required to adopt the trusted exchange framework, federal agencies may require adoption within their networks.
6. *See* Sec. 4003(c) (to be codified at 42 U.S.C. 300jj-11).
7. The HIT Advisory Committee combines and replaces the previous HIT Policy Committee and the HIT Standards Committee. The new HIT Advisory Committee will consist of at least 25 members who represent a balance among various sectors of the healthcare system so that no single sector unduly influences the recommendations of the Committee. Members must include providers, ancillary healthcare workers, consumers, purchasers, health plans, health information technology developers, researchers, patients, relevant federal agencies, and individuals with technical expertise on healthcare quality, system functions, privacy, security, and on the electronic exchange and use of health information), eight of whom shall be appointed by Congress, three appointed by the HHS Secretary, and the remainder will be appointed by the Comptroller General of the US Government Accountability Office (GAO). See Sec. 4003(e) (to be codified at 42 U.S.C. §300jj).
8. *See* Sec. 4003(f) (to be codified at 42 U.S.C. § 300jj-13).
9. In identifying such standards and implementation specifications, the HIT Advisory Committee must give deference to standards and implementation specifications developed by consensus-based standards development organizations in the private sector.
10. Sec. 4004 (to be codified at 42 U.S.C. § 300jj-51 et seq.).
11. Sec. 4006 (b) (to be codified at 21 U.S.C. § 17935(e)(2)).

HOLLIE A. SMITH

21ST CENTURY CURES ACT: NEW CLINICAL RESEARCH TOOLS

"Title III — Development" of the 21st Century Cures Act (the "Act") contains several significant provisions devoted to facilitating new pathways for both drug and medical device development. Patient-focused drug development, new drug development tools, new approaches to clinical trial design, and the use of real-world evidence for certain clinical purposes all represent a theme in the Act to allow for new and flexible approaches to research, testing, and approval of drugs in appropriate circumstances.

PATIENT-FOCUSED DRUG DEVELOPMENT

Section 3002 of the Act establishes a framework to collect and use "patient experience data" and related information in support of applications submitted under Section 569C of the Federal Food, Drug, and Cosmetic Act (the "FDCA") or Section 351(a) of the Public Health Service Act (the "PHSA"). Patient experience data is intended to provide information about patient experiences with a health condition, including the impact of the health condition or related therapy on patients' lives, and patient preferences with respect to treatment of a health condition. Patient experience data may be collected from patients, family members and caregivers of patients, patient advocacy organizations, disease research foundations, researchers, and drug manufacturers.

The Secretary of Health and Human Services (the "Secretary") is required, pursuant to Section 3002 of the Act, to develop a plan to issue draft and final guidance documents, over a period of five years, regarding collection of patient experience data and the use of such data in drug development. A draft version of at least one such guidance document must be issued within 18 months after the enactment of the Act, and no later than 18 months following the end of the public comment period, either revised draft guidance or final guidance must be issued.

The guidance is intended to be used by any person seeking to collect patient experience data for submission to and proposed use by the Secretary in regulatory decision-making. The guidance documents must, among other requirements, address specific methodological approaches that are relevant and objective and ensure that data is accurate and representative of the intended population. The guidance documents must include methods to collect meaningful patient input throughout the drug development process and methodological considerations for data collection reporting, management, and analysis. Finally, at least 180 days following enactment of the Act, the Secretary is required to provide a brief public statement regarding the patient experience data and related information, if any, submitted and reviewed as part of an application.

ADVANCING NEW DRUG THERAPIES

Section 3011 of the Act amends Chapter V of the FDCA to include a new Section 507 addressing a process of qualification for "drug development tools." A drug development tool is intended to be used for supporting or obtaining approval or licensure (as applicable) of a drug or biological product, or supporting the investigational use of a drug or biological product under section 505(i) of the FDCA or section 351(a)(3) of PHSA. The term "drug development tool" is defined to include a biomarker, a clinical outcome assessment, and any other method, material, or measure that the Secretary determines aids drug development and regulatory review. The term "biomarker" means "a characteristic that is objectively measured as an indicator of normal biologic processes, pathologic processes, or biological responses to a therapeutic intervention, and includes a surrogate endpoint." A surrogate endpoint is a marker such as a laboratory measurement, radiographic image, physical sign, or other measure that is known to predict or reasonably likely to predict clinical benefit and could be used to support traditional approval

or accelerated approval of a drug or biological product. A "clinical outcome assessment" means "a measurement of a patient's symptoms, overall mental state, or the effects of a disease or condition on how the patient functions and includes a patient-reported outcome." A patient-reported outcome is reported by the patient regarding a health condition without interpretation by a clinician or other person.

The Act directs that drug development tools be approved by the Secretary through a defined process of qualification whereby the drug development tool is deemed a "qualified" drug development tool. A drug development tool is "qualified" if in its proposed context of use the tool can be relied upon to have a specific interpretation and application in drug development and review under the Act. The qualification process will consist of several steps, beginning with submission of a letter of intent by a requestor to the Secretary for review. Upon acceptance of a letter of intent by the Secretary, the requestor would then submit a qualification plan to the Secretary for review, and upon acceptance, a full qualification package would be submitted. The Secretary is required to develop draft guidance on the implementation of this section not later than three years following enactment of the Act, and final guidance must be developed not later than six months following closing of the comment period for the draft guidance.

NOVEL CLINICAL TRIAL DESIGNS

Section 3021 of the Act requires the Secretary to conduct a public meeting and issue guidance that addresses the use of complex adaptive and other novel trial designs in the development and regulatory review and approval or licensure for drugs and biological products. The guidance must specifically include how such proposed clinical trials help satisfy the substantial evidence standard under section 505(d) of the FDCA. Additionally, the guidance must address

how sponsors can obtain feedback from the Secretary on technical issues related to modeling and simulations prior to (i) completion of the modeling or simulations, or (ii) the submission of resulting information to the Secretary. Finally the guidance must include the provisions for the types of quantitative and qualitative information that should be submitted for review and recommended analysis methodologies. Before issuing the described guidance, the Secretary must hold a public meeting no later than 18 months after the date of enactment of the Act, for consultation and discussion with representatives of regulated industry, academia, patient advocacy organizations, consumer groups, and disease research foundations. Draft guidance must be issued no later than 18 months following the date of the public meeting and final guidance no later than one year after the close of the public comment period for the draft guidance.

EVEN THOUGH GUIDANCE AND IMPLEMENTATION WILL NOT BE FULLY IN PLACE FOR SOME TIME, THE NEXT TWO TO THREE YEARS PROVIDE AN OPPORTUNITY FOR STAKEHOLDERS IN RESEARCH AND DEVELOPMENT OF DRUGS OR BIOLOGICAL PRODUCTS TO ACTIVELY FIND HOW THEY MIGHT POTENTIALLY PROPOSE AND USE DRUG DEVELOPMENT TOOLS...

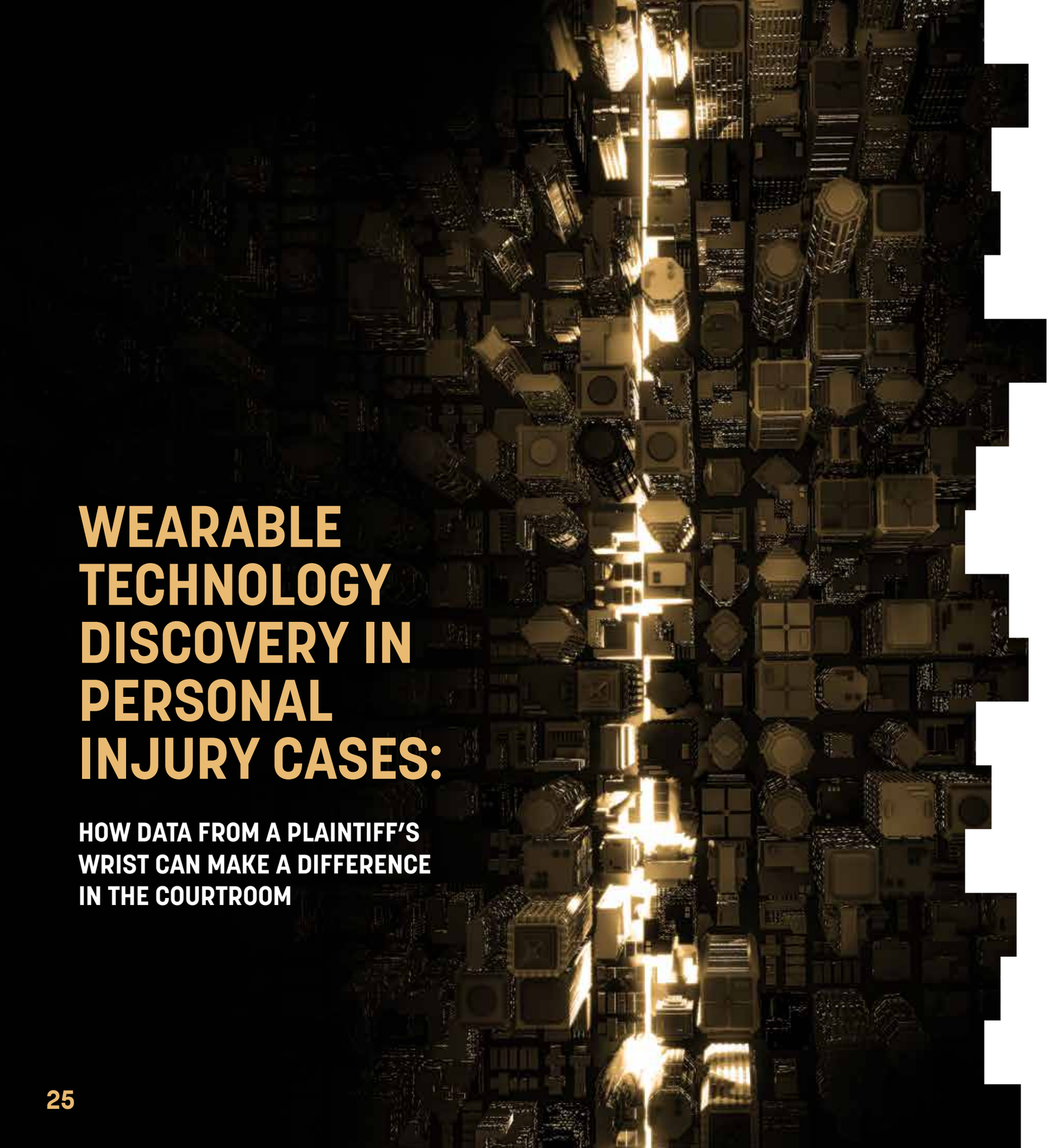
REAL-WORLD EVIDENCE

Section 3022 of the Act amends Chapter V of the FDCA to include a new section 505F, dealing with "real-world evidence," defined as "data regarding the usage, or the potential benefits or risks, of a drug derived from sources other than randomized clinical trials." The potential use of real-world evidence would be in the context of helping support the approval of a new indication for an approved drug and supporting or satisfying post-approval study requirements. The Secretary is charged with developing a draft framework to implement the program concerning real-world evidence within two years after the date of enactment of the Act. The framework must be developed in consultation with stakeholders in the field including the regulated industry, academia, medical professional organizations, representatives of patient advocacy organizations, consumer organizations, disease research foundations, and other interested parties. The framework must include information describing sources of real-world evidence, including ongoing safety surveillance, observational studies, registries, claims, and patient-centered outcomes research activities. It must also address gaps in data collection activities and the standards and methodologies for collection and analysis of real-world evidence. This framework is designed to provide a foundation for industry guidance on the proper circumstances under which drug sponsors and the Secretary may rely on real-world evidence to help support approval of a new indication for an approved drug and to help support or satisfy post-approval study requirements. Guidance must also provide appropriate standards and methodologies for collection and analysis of real-world evidence. The Secretary is required to issue draft guidance no later than five years following enactment of the Act. Within 18 months of the close of the comment period for draft guidance, either revised draft guidance or final guidance must be published.

CONCLUSION

The provisions of the Act that are discussed above will not take on concrete form immediately, but are designed to evolve over the next three to five years. Even though guidance and implementation will not be fully in place for some time, the next two to three years provide an opportunity for stakeholders in research and development of drugs or biological products to actively find how they might potentially propose and use drug development tools, novel clinical trial designs, real-world evidence, and/or patient experience data to expand the potential of research and development, and ultimately approval, of new treatments. While these innovations will not replace the need for traditional clinical trial structure, they potentially can enhance clinical trials and expand the general methodologies available for research.

VIRGINIA B. WILSON



WEARABLE TECHNOLOGY DISCOVERY IN PERSONAL INJURY CASES:

HOW DATA FROM A PLAINTIFF'S WRIST CAN MAKE A DIFFERENCE IN THE COURTROOM

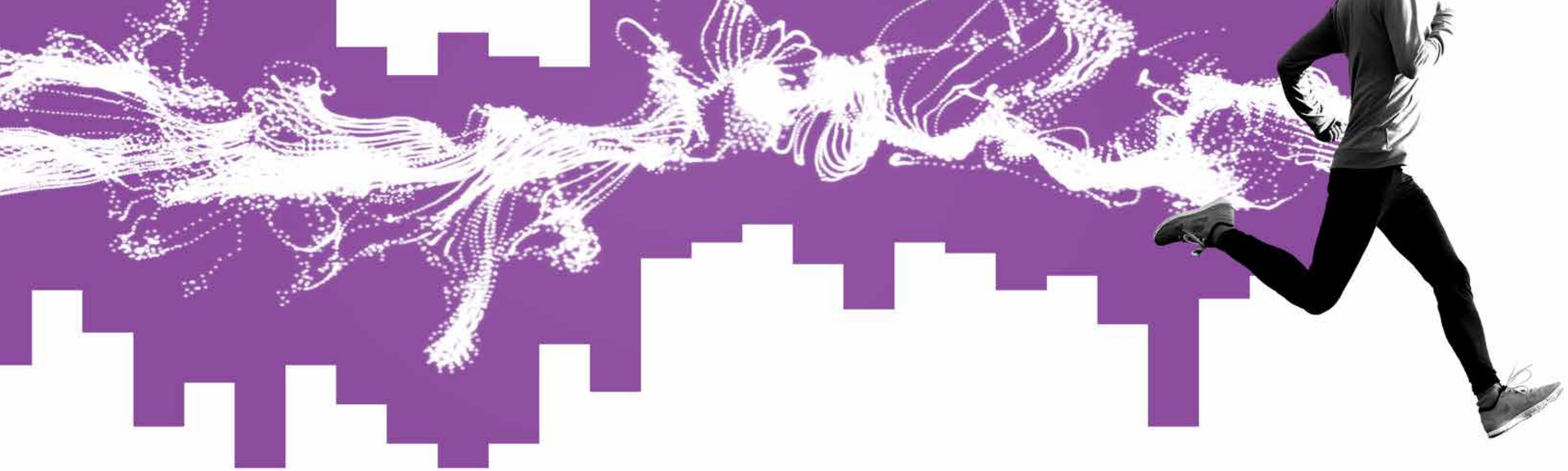
Defense counsel should consider calling a new, wearable witness to the stand in personal injury cases.

One in six American consumers currently owns and uses wearable technology[1]—smart devices such as watches and fitness monitors that allow compilation and exchange of data without the user's involvement. Activity monitors such as Fitbit® are capable of tracking nearly every facet of the human body. The devices compile extensive information on bodily systems—including activity levels, exercise attainment, food consumption, weight, sleep, heart rate, skin temperature, and respiratory rate. They can compile data on location using GPS functionality. And they can even measure vital signs, stress levels, and hydration levels, as well as be used to monitor diseases and chronic conditions. As the proliferation of these devices—and their capabilities—increases, so also does the potential for their use in litigation.

Production of this information will constitute the next wave of discovery challenges in personal injury lawsuits. The use of fitness tracker data in personal injury litigation is obvious: A plaintiff claiming injury could have his claim undermined by Fitbit® data showing that he ran his customary four-mile jog, even *after* his alleged back injury. The wearable device compiles an extensive track record of objective data entries that can be used to undermine a claimant's case.

On the plaintiff's side, one Canadian law firm has already called on Fitbit® data to buttress a plaintiff's claim that her activity levels drastically declined due to a car accident. The plaintiff used this evidence to show that her activity levels had decreased lower than is typical of someone of her age and profession, and thus entitling her to compensation.[2] And in the criminal investigation context, at least one Pennsylvania court has upheld use of Fitbit® data to contradict a 911 caller's assault claim.[3] In that case, Fitbit® data showed that the alleged victim was actually walking around the house at the time of the alleged attack, and not sleeping, as she had claimed.

Currently, no federal statute regulates Fitbit® or other wearable devices. HIPAA does not safeguard the information stored on these devices because they do not qualify as "covered entities" under the statute.[4] Moreover, it is unlikely that the FDA will ever regulate wearables, as they are advertised as promoting health instead of serving purely medical purposes.[5] Additionally, while the Electronic Communications Privacy Act of 1986 (ECPA) might enable federal regulation in this space, the statute has a carve-out that allows companies to produce customer records, as long as they are not



deemed communications. Data from wearables would not constitute a communication because there is no intent to convey information. Therefore, the information would more properly be classified as customer records, leaving them unregulated.[6]

Although personal injury litigants have no federal statutory concerns, there are still issues presented by federal and state rules of civil procedure and evidence.

REQUEST A LITIGATION HOLD IMMEDIATELY

Fitbit® data may be a form of "initial required disclosure" under Federal Rule of Civil Procedure 26(a)(1).[7] The information stored there relates directly to the allegations in a personal injury complaint. Such information could easily support a plaintiff's or defendant's claims or defenses by either strengthening or undermining the asserted facts pertaining to injury. Because the Fitbit® user has control over the data, per company policy, discovery requests should be served directly on the user. And because a Fitbit® user can delete his data at any time, defense counsel should request a litigation hold as soon as possible.[8] The deletion of wearable technology data by a personal injury plaintiff could constitute spoliation of evidence. In addition, defense counsel should include in discovery requests information from such wearable devices that may have been submitted to a plaintiff's employer in conjunction with a health insurance wellness program. Any such evidence of physical wellness and activity can undercut claims of permanent or pervasive injury, and GPS data can establish a plaintiff who claims to have been debilitated was traveling or on vacation during the pertinent time period.

WEARABLES DATA IS ESI

Fitbit® data also qualifies as appropriate ESI under Federal Rule of Civil Procedure 34, which allows for production of data stored in any medium that can be obtained directly from the opposing party.[9] Because a Fitbit® user can access the information on her personal computer, direct access would be present here and entitle the opposing party to production. Defense counsel should, however, narrowly tailor the time frame of requested information in order to satisfy Rule 26(b)(1) proportionality requirements. Additionally, a defendant might avoid a Rule 26(b)(1) challenge by paying for collection of the data by a third-party service, thus minimizing the burden on the plaintiff.

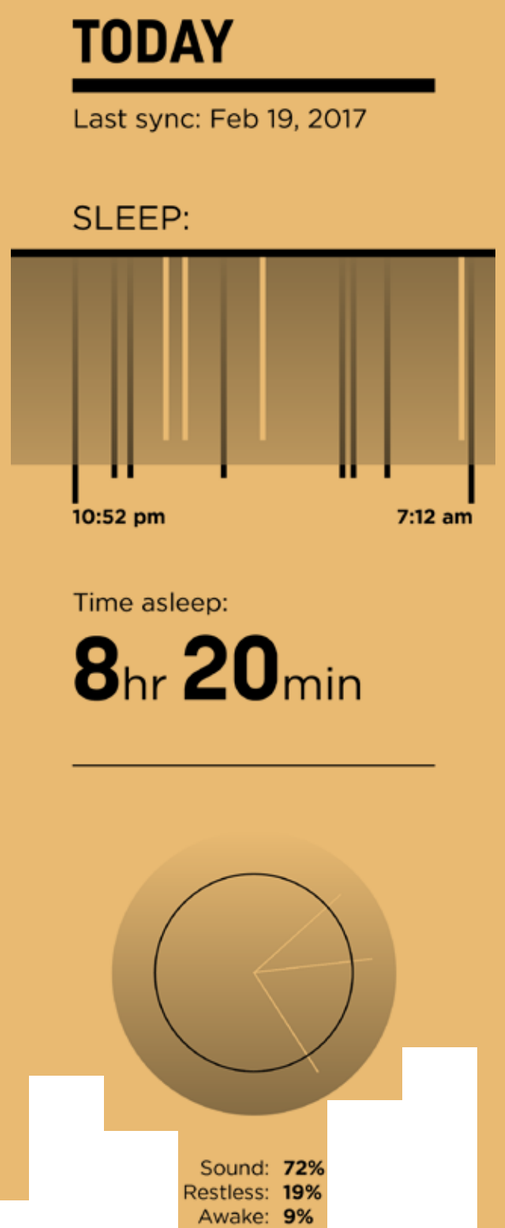
Rule 34 also allows for objection if the party requesting the ESI fails to specify the form or fails to state the intended use of the information.[10] Accordingly, a defendant must give particular reasons for requesting the plaintiff's Fitbit® data and concretely describe the intended use of this information. A blanket request for this data—merely hoping to find something to undermine plaintiff's claim—is insufficient.[11]

Defense counsel must specify the medium by which they want the ESI data produced—whether via email, screenshots, printouts, etc.[12] Rule 34(b)(2)(E)(ii) requires production in the form in which the data is usually maintained, if no other form is specified. As such, the data by default would come from printouts or screenshots from the plaintiff's computer, where the data is typically displayed for the Fitbit® user.[13]

ADMISSION OF WEARABLES DATA AT TRIAL

A defendant asking for admission of Fitbit® information must also demonstrate the touchstone requirements of relevance, authenticity, and reliability.

Relevance should be fairly straightforward. Data on activity levels tends to strengthen or weaken the facts establishing injury. And because some wearables can even measure emotional states or stress levels, there is potential to have this data admitted for claims of emotional and psychological injury, as well.



Authenticity may be established through several channels.[14] Federal Rule of Evidence 901(b)(1) allows the Fitbit® owner to authenticate the data through questioning on the stand. Such a person appropriately qualifies as a witness with knowledge under the rule.[15] Rule 901(b)(4) can provide for authenticity through distinctive features of the data—the Fitbit® information may, for example, refer to a particular exercise location uniquely associated with the plaintiff, thus proving its genuine tie to that individual. Rule 901(b)(9) could potentially allow evidence about the Fitbit® device's data collection method and accuracy rate to be presented in order to establish authenticity. Under this rule, the proponent may need to present evidence that users do not commonly falsify Fitbit® data, for example, by having another individual wear the device in their stead. Finally, Rule 901(b)(3) allows for authentication through a computer forensics expert, who could verify the data's origin.[16]

Within the authenticity concern lies the issue of reliability. Fitbit® and other similar devices sometimes erroneously track steps while a user travels by car. Other devices do not easily track cycling as an activity or will sometimes falsely count arm-waving as walking.[17] The proponent of this evidence must show that its data collection methods are sound by presenting evidence from the manufacturer on error rates or possibly collecting information on subsequent remedial measures taken to correct earlier malfunctions in the devices.

Even if the raw data itself cannot be admitted, the proponent may still get its broad strokes admitted through the testimony of an expert witness, who herself need not rely on admissible evidence in preparing a report or testifying at trial.[18] The surest way of getting wearable device data before the jury may indeed be to have the expert review it and rely upon it as the basis for an expert opinion.[19]

Depending on the case, an expert witness could also rely upon such data to establish that a plaintiff did not suffer from an alleged condition and discredit causation, based on the physical metrics shown from the data (i.e., a plaintiff claiming a particular injury would not exhibit the physical data demonstrated from such metrics). It is also worth mention that wearable technology data should be sought in discovery from spouses with consortium claims. Plaintiff spouses claiming they were forced to work more or "fill in" for their injured spouses for income or at home, or that they suffered debilitating depression rendering them unable to work or go about their usual activities, can be impeached with data from such devices showing facts to the contrary.

Defense counsel may also consider employing a third-party data analytics service to handle the Fitbit® ESI. In the Canadian case mentioned above, the plaintiff proponent of the Fitbit® information employed an analytics company to compare her activity levels to those of her demographic using industry and public research.[20] This comparison aided her claim that her activity levels had dropped to abnormal levels as a result of the defendant's negligence. On the defense side, an analytics company could compare a personal injury plaintiff's activity levels to the general population to establish the opposite point—that no meaningful decrease in energy or capacity had occurred as a result of the accident, thus undermining any claim for damages.

As wearables continue to grow in popularity, defense counsel must realize their evidentiary value and strategically request production of this type of ESI. Fitbit® may be the surprise witness to seal a defense victory.

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5. Langley, *supra* note 1, at 1649-50.
6. *Id.* at 1642-43.
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8. Carol Michel & Rick Sager, *Wearable Fitness Devices: A New Frontier in Discovery*, LAW 360 (Mar. 28, 2016, 10:10 AM), https://www.law360.com/articles/775527/wearable-fitness-devices-a-new-frontier-in-discovery.
9. FED. R. CIV. P. 34(a)(a)(A).
10. *Id.* (b)(2)(D).
11. Chauriye, *supra* note 4, at 519.
12. *Id.* at 520.
13. *Id.* at 519-20.
14. John G. Browning, *Fitbit Data Brings Another Dimension to Evidence*, IADC COMMITTEE NEWSLETTER: TECHNOLOGY, July 2015.
15. FED. R. EVID. 901(b)(1).
16. Browning, *supra* note 10.
17. Kate Crawford, *When Fitbit is the Expert Witness*, THE ATLANTIC (Nov. 19, 2014), https://www.theatlantic.com/technology/archive/2014/11/when-fitbit-is-the-expert-witness/382936/.
18. *See* FED. R. EVID. 703.
19. Laura P. Paton, Sarah E. Wetmore & Clinton T. Magill, *How Wearable Fitness Devices Could Impact Personal Injury Litigation in South Carolina*, 27 S.C. LAW. 44, 48 (2016); Michel & Sager, *supra note 8*.
20. *Id.*

CLINT COWAN, JR.

***CLINT COWAN AND THE PRO TE EDITORIAL BOARD WOULD LIKE TO ACKNOWLEDGE THE CONTRIBUTIONS TO THIS ARTICLE BY LIZ SMITHHART, OUR LATE PARTNER AND FRIEND.**

NEW AND NOTEWORTHY:

NORFOLK SOUTHERN RY. CO. V. DOLAN: THE END TO LITIGATION TOURISM IN THE CITY OF ST. LOUIS?

In recent years, the City of St. Louis has been a plaintiffs' favorite for litigation tourism, particularly in drug and medical device cases. And for good reason: By September of 2016, three of the year's six-largest products liability verdicts in the United States—totaling $173.5 million—were from the St. Louis City circuit court.[1] This earned the City of St. Louis its status as the #1 "judicial hellhole" in the United States in the American Tort Reform Foundation's most recent report.[2]

Plaintiffs' tactic is to join together multiple plaintiffs from across the country with one or more unrelated St. Louis plaintiffs. The only commonality is typically that the plaintiffs were prescribed the same drug or device. This practice developed because Missouri federal courts have disallowed removals based on fraudulent misjoinder or lack of personal jurisdiction under *Ruhrgas v. Marathon Oil Co. and Daimler AG v. Bauman,*[3] and Missouri state courts have denied motions to sever and motions to dismiss based on lack of venue, lack of personal jurisdiction, and forum non conveniens.

But a recent Missouri Supreme Court decision may put an end to this practice.

On February 28, 2017, the Missouri Supreme Court decided *State ex rel. Norfolk Southern Ry. Co. v. Dolan* ("*Norfolk*").[4] In that case, an Indiana resident who worked for Norfolk in Indiana brought suit for injury allegedly sustained during his employment under the Federal Employer's Liability Act (FELA). Norfolk is a Virginia corporation. The plaintiff never worked in Missouri and did not allege any action by Norfolk in Missouri caused him harm. Rather, he claimed there was jurisdiction over his claim in Missouri because Norfolk did business in that state (by maintaining train tracks running through Missouri and having employees in Missouri) and because Norfolk complied with Missouri's business registration statutes (by registering with the state and designating a registered agent for service of process in the state). Granting a writ of prohibition, the Missouri Supreme Court rejected plaintiff's argument.

In its opinion, the Missouri Supreme Court found:

1. **General personal jurisdiction *cannot* be based on the mere fact that a company does business continuously or systematically in the state.** "Prior to *Daimler*, this would have been a valid argument. But it is no longer the law." Under *Daimler*, general jurisdiction would exist in Missouri only (i) if the corporation is incorporated in Missouri, (ii) if the corporation has its principal place of business in Missouri, or (iii) "in the exceptional case when [the corporation's] contacts with Missouri are so extensive and all-encompassing that Missouri, in effect, becomes another home state." As to the last ground, that would only exist if the state became the "surrogate for place of incorporation or home office." That was obviously not the case in *Norfolk,* where only about 2% of the company's train tracks and employees were in the State of Missouri.

2. **There can be specific jurisdiction only if the plaintiff's claims arise out of the defendant's contacts with Missouri.** It is not enough that the Indiana injuries arose from the same "type" of activities as Norfolk's Missouri activities. Nor did FELA itself provide for specific jurisdiction in any place a railroad corporation has tracks.

3. **A company does not consent to personal jurisdiction by complying with a state's foreign corporation registration statute.** Implied consent is a question of statutory interpretation, and nothing in the Missouri registration statutes gives any indication that compliance would constitute consent to personal jurisdiction. In fact, the statutes do not mention consent at all. The court found that to the extent any holdings or dicta in other cases suggested otherwise, "they go beyond the language of the relevant statutes and should no longer be followed."

Thus, *Norfolk* held unequivocally that a plaintiff whose claim arises out of state does not have any business filing suit in Missouri if Missouri is not the defendant corporation's home state or "surrogate" home state.

Although *Norfolk* did not explicitly address the issue of joinder, the Missouri Supreme Court indicated that joinder cannot extend personal jurisdiction when it acknowledged that doing business in Missouri can subject a corporation to specific jurisdiction in Missouri, "[b]ut that jurisdiction would exist only over ***claims that are related to those contacts***" and that jurisdiction could not be extended simply because they are the same "type" of activities. The court provided an example that perfectly illustrates the problem with the plaintiffs' jurisdiction-by-joinder theory:

> Just because a company like Ford, for example, sells cars in Iowa and in California, does not mean there is jurisdiction in California for injuries that occurred in Iowa simply because Ford engages in the same "type" of activity—selling cars—in both states. Such an argument goes even further than the pre-Daimler approach to general jurisdiction that Daimler rejected as providing no authority for general jurisdiction over a company. To say this same conduct confers specific jurisdiction over suits the facts of which have no relationship to the forum state would be to turn specific jurisdiction on its head.

And even if *Norfolk* did not put the last nail in the coffin for multi-plaintiff pharmaceutical litigation tourism in Missouri, there are a number of other developments on the horizon that might:

- Bills pending in the Missouri House and Senate, which would put an end to the practice by requiring that joinder or intervention cannot establish venue or personal jurisdiction if the party could not establish it independently, and conversely, that joinder or intervention is improper if the party cannot independently establish venue or jurisdiction.[5]
- *Bristol-Myers Squibb Co. v. Superior Court of California*, which is scheduled for oral argument in the United States Supreme Court on April 25, 2017, and should be decided before the end of the Court's term in June of this year. That case addresses whether there is personal jurisdiction over the claims of multiple out-of-state plaintiffs who joined with California plaintiffs to file suit in California.[6]
- A products liability appeal in the Missouri Supreme Court, which challenges whether joinder can extend venue.[7] The appeal is set for oral argument on May 11, 2017.
- Appeals from the talc products liability verdicts in the Missouri Court of Appeals, which address whether joinder can extend personal jurisdiction.[8] Oral argument is set for May 10, 2017.
- An appeal in the Eighth Circuit Court of Appeals, which addresses the propriety of the removal of a case involving 64 unrelated plaintiffs from 29 different states—only four from the State of Missouri—under *Ruhrgas* and *Daimler.* Oral argument is scheduled in that case for April 5, 2017.[9]

Defense counsel across the country are closely watching these developments, because to the extent *Norfolk* has not already done it, any one of these events could be the final death knell for litigation tourism in the City of St. Louis.

1. *See* Margaret Cronin Fisk, *Welcome to St. Louis, the New Hot Spot for Litigation Tourists*, BloombergBusinessweek (Sept. 29, 2016), available at http://www.bloomberg.com/news/articles/2016-09-29/plaintiffs-lawyers-st-louis (last accessed Mar. 10, 2017).
2. American Tort Reform Foundation, *2016-2017 Judicial Hellholes*, available at http://www.judicialhellholes.org/wp-content/uploads/2016/12/JudicialHellholes-2016.pdf (last accessed Mar. 10, 2017).
3. *Ruhrgas v. Marathon Oil Co.*, 526 U.S. 574, 588 (1999); *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014).
4. *State ex rel. Norfolk Southern Ry. Co. v. Dolan*, 2017 WL 770977 (Mo. banc Feb. 28, 2017).
5. *See* Mo. HB 460, HB 461, HB 462, HB 463, SB 258, SB 259, SB 260, SB 261, SB 262.
6. *See* Supreme Court Dkt. No. 16-466.
7. *See Barron v. Abbott Labs.*, Case No. SC96151.
8. *See, e.g., Fox v. Johnson & Johnson*, Case No. ED104580.
9. *Robinson v. Pfizer, Inc.*, Case No. 16-2524 (8th Cir.).

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BIOS:

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THE 21ST CENTURY CURES ACT

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WEARABLE TECHNOLOGY DISCOVERY IN PERSONAL INJURY CASES: HOW DATA FROM A PLAINTIFF'S WRIT CAN MAKE A DIFFERENCE IN THE COURTROOM

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NORFOLK SOUTHERN RY. CO. V. DOLAN: THE END TO LITIGATION TOURISM IN THE CITY OF ST. LOUIS?

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