

Pro Te: **SOLUTIO**

SOLUTIONS FOR YOU

DECENNIUM

*A REFLECTION ON THE
FIRST TEN YEARS*



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DEAR CLIENT



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It's hard to believe a decade has passed since we delivered our first edition of *Pro Te: Solutio* to your door. Those years have brought enormous changes in the world and in our industry. Innovation has driven everything we see and touch and has served as a catalyst for much of our content. At the time of his retirement, George Butler, one of the founding members of Butler Snow, remarked that the Xerox machine had been the innovation with the most impact upon the practice of law in his time. Imagine how he might react today as we maneuver our way through social media, autonomous vehicles, 3-D printing, gene therapies, and even digital drugs. The prospect of litigation financing would have truly boggled his mind.

Reflection on the first ten years of *Pro Te* necessarily involves looking through the prism of our own experiences, both personally and professionally. As in the rest of the world, much has also changed at Butler Snow. Only a decade ago, our firm was less than 100 lawyers with three offices. Today, we stand at 350 lawyers in 24 offices in the United States and internationally. Our pharmaceutical, medical device, and healthcare practice has grown into a truly national practice with trials in more than 30 states, regulatory and compliance counseling, and business advice to pharmaceutical and medical device companies as well as to hospitals. We have been privileged to be involved in some of the most exciting and innovative developments affecting our clients this decade.

All of us working with *Pro Te* recall articles discussing new developments, which have become our "go-to's" on the topics. We find those oft-referenced issues dog-eared, tabbed, and stacked on a corner of our desk, under excerpts from the CFR and alongside the Rules of Civil Procedure. We hope you have collected some of those. Other articles addressed more general topics that, once considered, have given us new tools to apply to the challenges we deal with every day. Our hope from the very first issue of *Pro Te* has been to give you, our clients, friends, and colleagues, articles and topics you find valuable and that provide

solutions rather than simply discussions. We try with each issue to identify and explore a spectrum of topics relevant to your work in pharmaceuticals, medical devices, biologics, and health system and healthcare practices. It has been our pleasure to keep our ear to the proverbial ground, and we thank you for the opportunity to serve you in this way.

When the journal's ten-year anniversary came into focus, we pondered what to include in this special issue that you would find valuable. Should we do a retrospective? Should our ten-year issue be forward-looking? Should we wax eloquent on the practice of law and the unique opportunities and responsibilities that we, as lawyers in this field, encounter in the United States and abroad? At the end of the day, we decided it best to cover what birthed this journal and still drives it – content that offers solutions for you. Hence, *Pro Te: Solutio*. We settled on the importance of looking at FDA and regulatory topics that have been relevant for the past ten years and that remain relevant (in some cases even more so) today. See *A Look Back at Ten Key FDA Initiatives over the Past Decade*. We decided it only fitting to take a look back with a more nuanced approach by focusing on what we know now that we wish we had known then. See *What We Wish We Knew Ten Years Ago*. Finally, we also thought it important to include a topic we believe will shape the future of our practice in pharma, device, and biologics. See *Next Decade To-Do: Enforce Preemption for Class II Devices with Special Controls*.

While we recognize our approach has not always been statute-, regulation-, or rule-specific – all of which are central to our practice – we also recognize that the value of a bigger picture view – in law, in life, and in relationships – cannot be overstated. We hope you do, too. As we transition into a new decade of *Pro Te*, Charles and I believe it is time for our editorial board to take on the leadership role and overall management of *Pro Te*. We will still be here encouraging new topics and solutions for our clients, but we know our editorial board is more than prepared for the challenge ahead. We hope you enjoy this special edition and continue to enjoy *Pro Te* for years to come.





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DECENNIUM

A Decade of Contributors



TIME FLIES!

A Look Back at Ten Key FDA Initiatives Over the Past Decade

Richelle W. Kidder and Susanna M. Moldoveanu



Over the past ten years, Butler Snow has stood alongside so many of you – our clients – as key FDA initiatives have been proposed and implemented. These efforts bring to mind the familiar phrase, “time flies when you’re having fun.” We’re not sure it would be fair (or accurate!) to characterize our collaborative work on FDA programs as “fun,” but we are honored to have been your legal counsel navigating the ins and outs of many FDA programs that impact the pharmaceutical industry. We hope you enjoy this “retrospective” piece, knowing that Pro Te: Solutio has been covering many of these topics along the way.

It’s been almost 80 years since passage of the Federal Food, Drug, and Cosmetic Act of 1938, which authorized the FDA to demand evidence of safety and effectiveness for new drugs, issue standards for food safety, and conduct factory inspections.¹ Since that time, the FDA has grown into a comprehensive federal agency, regulating \$1 trillion worth of products annually, from animal drugs and feed to human drugs and medical devices.²

There can be no question that the FDA’s actions impact the consuming public – and necessarily the pharmaceutical industry – in myriad ways. What follows is a snapshot of ten initiatives over the past ten years that have had (or are having) a major impact in the world of drugs and devices. We start with laws signed in 2007 and move forward in time to fairly recent Congressional and FDA activity with a brief look at FDA’s priorities in the year to come.

1 2007: Food and Drug Administration Amendments Act of 2007

President George W. Bush signed the Food and Drug Administration Amendments Act of 2007 (FDAAA) on September 27, 2007.³ The many aspects of this law included reauthorization and expansion of the Prescription Drug User Fee Act and the Medical Device User Fee and Modernization Act, which significantly raised the annual user fees paid by the industry to

the FDA for new drug reviews. The amendments also reauthorized the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act, both directed at research and development of treatments for children. The law further contained amendments to the citizen petition process intended to prevent delay in the approval of pending ANDAs and 505(b)(2) applications.

One of the (many) parts of the 2007 amendments that impacted the pharmaceutical industry was the significant increase in the FDA’s responsibilities, requirements, authority, and resources regarding pre- and post-market drug safety. Together with a doubling of resources allocated to the FDA’s Office of Drug Safety, the amendments added to the FDA’s authority to require post-market studies and clinical trials, safety labeling changes, and Risk Evaluation and Mitigation Strategies (REMS). This included the addition of the FDA’s authority to require application holders to conduct post-marketing studies and clinical trials “to assess a known serious risk, assess signals of serious risk, or identify an unexpected serious risk related to the use of a drug product”⁴ According to the FDA, as of fiscal year 2015, a total of 88 percent of post-marketing requirements overall and 89 percent of FDAAA post-marketing requirements were progressing according to their original schedules.⁵

Not to be overlooked, the amendments in 2007 require the FDA to establish a database of post-marketing adverse drug reactions; more on that, below.

2 2008: FDA's Sentinel Initiative

In May 2008, the FDA launched its Sentinel Initiative in response to requirements of the FDAAA that the FDA work with public and private entities to coordinate a system for providing access to existing electronic healthcare information from across multiple sources.⁶ The FDA would then use this information to help monitor safety of regulated products and take actions such as issuing safety communications or warnings. After a pilot program ("Mini-Sentinel"), the Sentinel System officially launched in 2016.

For a look back at the impact of this program – including a discussion about how, in litigation, plaintiffs' firms try to argue that pharmaceutical companies failed to timely report a key safety signal – we invite you to view the coverage of the Sentinel Initiative in the June 2014 issue of *Pro Te: Solutio*.⁷

3 2010: Patient Protection and Affordable Care Act/Healthcare and Education Reconciliation Act

The Patient Protection Affordable Care Act was a landmark piece of legislation affecting all levels of the healthcare industry. Passed in March 2010 along with the Healthcare and Education Reconciliation Act, the legislation changed the face of healthcare in the United States by, inter alia, imposing a regulatory overhaul and greatly expanding healthcare coverage to Americans.

With respect to the FDA in particular, the Affordable Care Act provided that manufactures and distributors must provide the FDA with specific information concerning drug samples that they distribute, including: (1) the identity and quantity of drug samples requested; (2) the identity and quantity of drug samples distributed; (3) the name, address, professional designation, and signature of any person who makes or signs such a request; and (4) any other category of information determined appropriate

by the Secretary.⁸ The FDA has also issued a Draft Guidance explaining how these provisions work in conjunction with the existing provisions of the Prescription Drug Marketing Act.⁹

Pro Te: Solutio devoted its February 2011 issue to this legislation, and tackled topics including how healthcare reform would affect tax and employee benefits; how governmental enforcement actions of fraud in the healthcare industry were ramping up; and how legal challenges to the Acts were shaping up.¹⁰ To fast-forward to today, the political landscape has changed in Washington, D.C., and, as with any change in administration, the priorities and laws themselves will change. Stay tuned to Butler Snow communications for coverage on developing aspects of this part of the healthcare and pharmaceutical industry.

4 2012: Food and Drug Administration Safety and Innovation Act

The Food and Drug Administrative Safety and Innovation Act (FDASIA) was signed into law by President Obama in July of 2012.¹¹ FDASIA consisted of 11 titles. The first five affected pediatric therapy

With respect to the FDA in particular, the Affordable Care Act provided that manufacturers and distributors must provide the FDA with specific information concerning drug samples that they distribute.

development and drug and medical device user fees, establishing new fee statutes for generics and biosimilars. The next two titles concerned changes to medical device regulation and the FDA's inspection authority and global drug supply chain safety. Title VIII created incentives for the development of products to treat antibiotic-resistant infections. Title IX created a "breakthrough therapy" designation intended to expedite development and review of such drugs and expanded the number of products subject to accelerated approval. Title X created new authority for the FDA to address drug shortages, and Title XI reauthorized provisions of the FDA Amendments

Act of 2007, regulated medical gases, and included myriad other provisions such as a 180-day generic drug marketing exclusivity, additional regulations on citizen petitions, and nanotechnology provisions.¹²

FDASIA's user fee provisions are incredibly important to the FDA, as user fees have played an increasingly vital part of the agency's budget. In 2017, user fees accounted for more than 40 percent of the FDA's overall budget.¹³

5 2012: Medical Device User Fee and Modernization Act

The Medical Device User Fee and Modernization Act (MDUFMA III) was enacted in 2012 as part of FDASIA. User fees have been established and implemented in four parts. The Medical Device User Fee and Modernization Act (MDUFMA) first created device user fees in 2002. They were renewed in 2007 with

MDUFMA II, again in 2012 with MDUFMA III, and finally in 2017 with MDUFMA IV. MDUFMA IV will be in effect from October 1, 2017, through September 30, 2022. These provisions authorize the FDA to collect fees from medical device companies at various stages in the regulatory process – for example, when they register their establishments, when they list their devices, when they submit applications or notifications to market new medical devices in the United States, and for other types of submissions.

The FDA issues annual performance reports to Congress under MDUFMA on its progress in the timely completion of application reviews and other items.¹⁴

6 2013: Pandemic and All-Hazards Preparedness Reauthorization Act

Enacted in 2013, the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA) establishes programs permitting the FDA to prepare for and respond to emergency situations, including chemical, biological, radiological, or nuclear crises, but also infectious diseases. PAHPRA reflects an amendment to the existing Emergency Use Authorization already granted the FDA.

Examples of acts permitted by PAHPRA are the authorization of emergency dispensation of products, extended expiration dating of products, and waiver of Current Good Manufacturing Practice and Risk Evaluation and Mitigation Strategies requirements.¹⁵

7 2013: Drug Quality and Security Act

Prompted by a fungal meningitis outbreak and covered in the November 2012 issue of *Pro Te: Solutio*,¹⁶ Congress enacted the Drug Quality and Security Act (DQSA) in 2013 to enhance the FDA's ability to help protect consumers from exposure to counterfeit, stolen, contaminated, or otherwise harmful drugs.

The Act implemented greater regulatory oversight of drug compounding facilities. It also outlined steps for an electronic system to identify and trace certain prescription drugs throughout the United States



to improve detection and removal of potentially dangerous drugs from the drug supply chain. Further, DQSA directed FDA to establish national licensure standards and reporting obligations for wholesale distributors and third-party logistics providers.¹⁷

8 2016: 21st Century Cures Act

One of the more recent initiatives – the 21st Century Cures Act (Cures Act), enacted on December 13, 2016 – seeks to accelerate medical product development, thereby bringing new innovations to patients faster and more efficiently. Among the Act’s objectives are to incorporate patient perspectives into the development and approval of pharmaceutical products; modernize clinical trial designs and clinical outcome assessments to speed development and review of novel medical products; coordinate activities in major disease areas between the drug, biologics, and device centers; improve the regulation of combination products; and provide FDA with authority to recruit and retain scientific, technical, and professional experts. Among others, new product development programs include:

- *The Regenerative Medicine Advanced Therapy, which offers a new expedited option for certain eligible biologics products*
- *The Breakthrough Devices program, designed to speed review of certain innovative medical devices*

One of the more recent initiatives—the 21st Century Cures Act (Cures Act)—seeks to accelerate medical product development, thereby bringing new innovations to patients faster and more efficiently.

In addition, the 21st Century Cures Act clarified FDA’s regulation of medical software; it also amended the definition of a “device” to exclude certain software functions.¹⁸

To date, items completed on the Act’s “deliverables” list include issuance of Guidances and Draft Guidances, submission of Federal Register notices, submission of a work plan and funding allocation to Congress, and presentation of a meeting by NIH in August 2017 of the Task Force on research specific to pregnant and lactating women.¹⁹

Pro Te: Solutio has worked diligently to cover this Act, with articles in Fall 2016 and Spring 2017 addressing everything from an overview of the Act to new clinical research tools.²⁰

9 2017: Medical Device Reporting

This item is not about something the FDA has done, but about what it hasn’t done. In 2007, Congress amended 21 U.S.C. § 360i(a) to ease the burden of medical device reporting for manufacturers and other reporters for Class I and Class II medical devices. Specifically, rather than providing individual medical device reports within 30 days of each qualifying event, reporters would be permitted to file summary quarterly reports of medical device reports to the

FDA. (Congress also gave the FDA authority to create exceptions for certain devices that would have to continue the usual 30-day reports.) But for unexplained reasons, more than a decade later, the FDA still has not implemented the statute.

In December 2017, the FDA announced a “proposed program for manufacturer reporting of certain device malfunction medical device reports (MDRs) in summary form.”²¹ This followed the FDA’s “Pilot Program for Medical Device Reporting on Malfunctions,” announced in 2015, which studied summary medical device reporting. Under the proposed program, reporters for certain products would be permitted to voluntarily opt-in to summary reporting. Though this may ease the reporting burden for some products, it does not reach the scope contemplated by Congress in 21 U.S.C. § 360i(a).

10 Ongoing: Significant Enforcement Actions

A look back at FDA initiatives over the past decade would not be complete without mention of the FDA’s efforts — conducted in conjunction with the Department of Health and Human Services and the Office of Inspector General — to investigate and prosecute fraud in the healthcare industry, including the pharmaceutical industry. *Pro Te: Solutio* has reported throughout the years on many different efforts by federal agencies under their respective jurisdictional domains, ranging from articles on Warning Letters,²² Whistleblower Actions,²³ Healthcare Fraud,²⁴ and the “Park Doctrine” involving prosecution of corporate executives,²⁵ just to name a few. You can be sure we’ll cover developing trends in this important area of healthcare, moving forward.

WHAT LIES AHEAD?

We don’t have a crystal ball, and we cannot predict what lies ahead for the pharmaceutical industry or the FDA. But as a sneak peek, consider recent statements of FDA Commissioner, Scott Gottlieb, M.D., identifying these priorities for the FDA for 2018²⁶:

- *Addressing the Nicotine Addiction Crisis (e.g., proposed rulemaking regarding regulation of tobacco flavors and “premium cigars”)*
- *Advancing drug safety (e.g., issuance of regulations on drug compounding facilities, national standards for licensing of prescription drug wholesale distributors and third-party logistic providers: “track-and-trace” requirements)*
- *Promoting food safety*
- *Empowering consumers (e.g., new proposed patient medication document for drugs or biologics each time a patient receives a medication from the pharmacy and broadening access to non-prescription drugs)*
- *Modernizing standards (e.g., harmonizing global standards, modernizing mammography standards, and embracing electronic submissions)*
- *“Looking to the future” (e.g., reducing drug cost by encouraging competition, spurring innovation, creating regulatory efficiencies in bringing products to market, and addressing the opioid addiction crisis)*

Butler Snow cherishes the work we’ve done with clients on initiatives over the past ten years, and we hope that this trip down memory lane together — with the articles we’ve shared via *Pro Te: Solutio* reminds you of all that has flown by over the last decade. We welcome the challenges yet to come, and we will be right there with you as new issues arise. We look forward to the next decade and beyond.

Authors



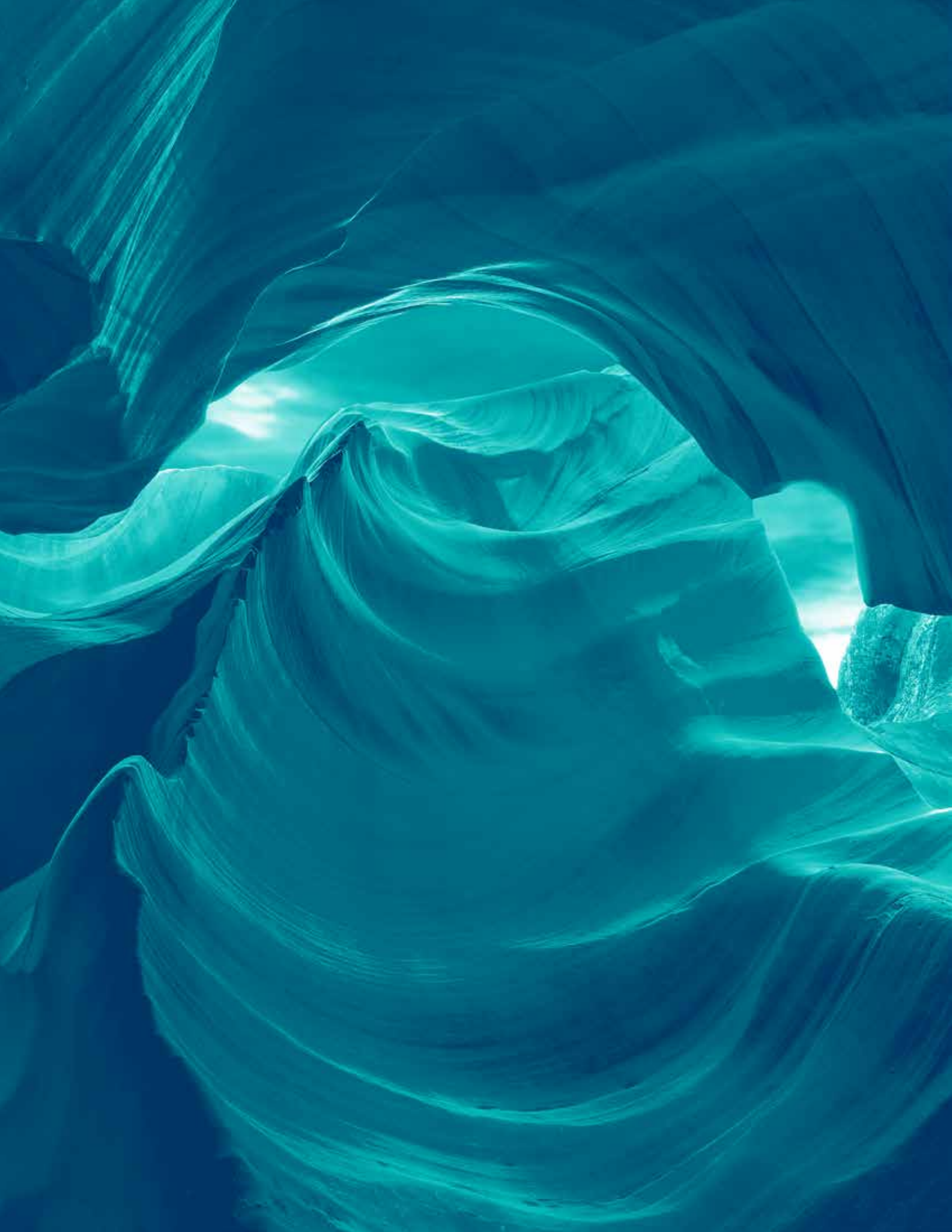
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WHAT WE WISH WE KNEW TEN YEARS AGO

Michael B. Hewes and Kari L. Sutherland



“It is fun to be in the same decade with you.”

-Franklin D. Roosevelt

As we reminisce over the last ten years, a lot has changed in our chosen profession. We look back at the way we practiced law a decade ago with both wistfulness and incredulity. But time inevitably marches on without ceasing. If we are lucky, we pick up a few things along the way, and this article encapsulates what we have learned (and are still learning) about our practice this past decade. All ideas do not work in all situations, but all probably are worthy of some consideration.

From Kari's Perspective:

THE EXPERIENCE OF BEING A JUROR

While I have tried pharmaceutical cases, I also had the unusual gift of being selected to serve as a juror in a significant criminal trial relatively recently. The things learned from this experience are invaluable. While trial lawyers learn a lot by doing, this peek behind the curtain put things in a whole different light.

A A View of Voir Dire from the Box

The morning began a bit more leisurely than normal. Our courthouse is located right in the middle of the town square and there is a very convenient coffee shop nearby. I indulged in a white chocolate mocha and looked forward to visiting with the other members of the community who had not been able to avoid showing up for jury duty.

- *Most venire members do not want to be there*

I was sure neither side would want me for the trial, and I intended to help the decision-makers reach this correct conclusion however I could. Unfortunately, 90 percent of the panel was thinking the same thing, and I was a novice compared to some of the more practiced duty-dodgers. The process actually went very smoothly and those statutorily-excused lucky ones soon were culled and the real work began. The judge gave a concise statement of the case and then we were ready for the lawyers.

- *The statement of the case really can be concise*

We were not swayed yet by any spoken words; everything uttered up to this point had been boringly neutral. But the non-verbal language was at times cacophonous. What do I mean by that? I mean the confidence that can be portrayed just by the way you walk. I mean the gravitas displayed in the stillness with which you sit. But it also can mean the awkwardness displayed by your client because she is sitting by herself at the counsel table facing the courtroom, and we are all looking at her (and she is looking at us) like a bug on a petri dish, because we have nowhere else to look.

The case for which we had been called was a very serious criminal case. I gradually began to understand why the judge had been reluctant to excuse potential jurors, but I was even more optimistic of my chances for not serving. In addition to being a defense lawyer, I am a former law enforcement officer. Neither side would ever want to seat me! But sitting through voir dire was fascinating. I found myself drawn in and wanting to participate, making friends with my neighbors, and placing bets on who would get picked.

I learned how quickly a bond can be formed between potential jurors just because they sit next to each other in voir dire. My new-found friends and I also found ourselves unduly put out by Mr. Know-It-All venire member. You know him. He's the one who raises his hand to answer every question because he knows everything about everything. NOTE: Don't pick

Mr. Know-It-All to be on your jury. The other jurors will hold a grudge. Trust me.

- *Tips for voir dire from the other side*

If you google how to conduct an effective voir dire, the interweb provides a ton of options. There's "Ten Tips For an Effective Voir Dire," "Eight Tips for Better Voir Dire," and "Five Voir Dire Tips." You get the picture. I read the one for five tips because ... well, it was only five. But they lost me when they suggested using a PowerPoint for jury selection. Having sat through this process, I can tell you that you do not want to do this. You will be dealing primarily with folks who do not want to be there and are desperately searching for ways to get out. Subjecting this type of crowd to "Death by PowerPoint" – even if allowed by your judge – is a recipe for danger and disaster. I will, however, make these suggestions for voir dire:

1. Questionnaires

If you are lucky enough to get to use a questionnaire, read it! Please do not ask your venire the same questions that we already answered in the questionnaire. It will frustrate us. We took the time to fill out your doggone questionnaire; you should take the time to review it. Caveat: If you do want to confirm an answer from the questionnaire, tell us that is what you're doing and refer to the questionnaire so we know you read it. Also, don't do this too often.

2. Pressure

We can tell if there is a particular juror that you want to retain, but who has claimed a legitimate hardship. Putting too much pressure on that potential juror as to whether it really will be an undue economic hardship if he has to close his sole proprietorship for the week will not make us like you. In fact, it will evoke strong protective feelings for that guy. And if he is selected, grudges will be held. Again. Similarly, if there is a particular juror you want to strike for cause, we can tell that, too. Once you have established cause, let it lie.

3. The Senses

- *Eyes.* Persuasion works best with eye contact. Please look at us. All of us.
- *Ears.* Persuasion works best when we can hear you. While shouting probably won't engender endearment, whispering won't, either. And if someone on the front row asks a question, please repeat it when you are answering so those of us on the back row can catch the gist.
- *Touch.* Please be cognizant of the fact that we may be sitting on hard wooden benches while we see you lounging in comfortable padded chairs. You also are getting to stand up and walk around, stretching out your legs ... while we remain sitting for long periods of dull time on hard wooden benches. After long intervals, it may be appropriate to ask the judge for a break on our behalf or even ask the court if we might want to stand for 5 minutes.

4. We are Always Watching

Keep in mind that we are always watching you. And your client(s). We have nothing better to do at the moment. You are the entertainment, and we are your captive audience. We are studying your facial expressions, your mannerisms, how you treat the other side, how the other side treats you and your reaction to that, how you treat the judge, whether your client is sitting there paying attention or whether she is busily working on her computer (but we were not allowed to bring ours!), whether you are asking your co-counsel or your client for advice or whether you are the solo star.

Persuasion works best when we can hear you. While shouting probably won't engender endearment, whispering won't, either.



We also are watching you and your client outside the courtroom during breaks. It sounds like another verse of Sting’s “Every Breath You Take,” but it’s true:

Every question you ask
Every uncompleted task
Every sip from that flask
Every rip to your mask
We’ll be watching you

This advice gem should be considered throughout the trial.

B A Juror’s Perspective on the Trial

While I thought it unfortunate at the time, I was picked for the trial. Unbelievable. But it turned out to be a fabulous learning experience and a sobering community experience. The facts were graphic. What was interesting, however, was what was not said in opening statements – by either side. Imagination will fill in a lot of blanks. While the story needs to be sketched out, it does not need to be fully fleshed out.

- *The gory details are not needed in opening*

Listening to a story is easy to do. And a roadmap of what evidence is going to come in is very helpful. Weaving the two together is a skill worth developing, and doing so in 30 minutes or less is even more valuable. We heard two different stories in our trial,

told by two very different narrators. One was stoic and calm; the other more dramatic. Both seemed to work because they both were genuine. I will offer one word of caution for those doing opening statements: don’t stray too close to us. While we have developed somewhat of a relationship through the voir dire process, we aren’t that close yet.

- *Eye contact and earnestness are needed*

I cannot stop with just one, so I’ll offer another word of caution. We actually do listen to opening statements. And if we are allowed to take notes, we will note specifically what you say is important. If your story does not play out like you said it would, grudges will be held. Where you have some holes in your narrative or some bad facts, go ahead and let us know that. We’re going to find out anyway, so why not take the sting out early? Hearing something the second time is never as shocking.

The trial progressed as trials do ... with multiple delays and bench conferences. Now the bench conferences were not too bad because we had some entertainment in that we could watch the lawyers, look at the client, and glance at the audience. Before folks figured out that there was a separate microphone picking up the conversation, we could even hear the bench conferences. That was quickly rectified, unfortunately, when one of our number reported it. But we also were frequently ushered out so important things could really be discussed outside our hearing. This was very

frustrating! First of all, there is literally nothing to do in the jury waiting room (except eat; we had great snacks!). And if one of your jurors is the school hall monitor (i.e., the same guy who tattled about the open microphone), you can't even talk about the trial. This seemed like a lot of wasted time, and it interrupted the flow of the trial.

- *Limit as best you can the number of bench conferences and other interruptions.*
- *Consider jointly providing the jury waiting room with cards and/or dominoes.*
- *Ensure your "private" arguments are actually kept private.*

The witnesses were especially interesting. In this particular case, most of the witnesses were law enforcement personnel, but a family member also testified. While no Perry Mason moments occurred, their stories were riveting. I found myself wanting to hear what they had to say and getting put out when a lawyer – even the lawyer directing them – interrupted their testimony. While control must be kept of witnesses, how that control is exercised (especially over your own witnesses!) is absolutely crucial. And until a witness has shown us, the jury, that he's earned it, attacking or berating him will cause a grudge to be held.

I wish I could provide insight on juror deliberations; but, alas, our case did not proceed to closing arguments. I tried to drink in as much of it as I could. A few last thoughts:

1. *Say what you mean and mean what you say. We really can tell the difference.*
2. *Saying things once ... maybe twice ... is sufficient. We really are listening.*
3. *How you treat others matters to us (whether it's venire members, co-counsel, clients, adversaries, or the judge, deputy clerk, court security officer, or others).*
4. *Number 3 is especially important with witnesses.*
5. *Pay attention to us (but not too closely or we'll get uncomfortable).*
6. *Please be prepared.*

I expect this experience to be foremost in my mind the next time I try a case. And I also will never seek to get out of jury service again.

But, I reserve the right to hold a grudge.

From Michael's Perspective:

THE NECESSITY OF TEAMWORK

Not every case leads to a trial. In fact, as I have learned over the last decade, they rarely do. But, with few exceptions, I also have learned that every case must be worked up as if it will go to trial. How do you accomplish that to the best benefit of the client (substantively and economically) when everyone has a different gift? Not all want to be a trial lawyer; some people write better than others; and then there are the gifted ones who can see the forest and not just each individual tree. The intrinsic value of esprit de corps has become obvious now that I am older, more experienced, and hopefully a better arborist.



A Supporting Synergy

In 2008, having just made partner, I was grappling with the mantle of responsibility that came with such a designation. Thus far, my work had been interesting, rewarding, and very hands-on – especially for a junior lawyer. As a JAG Officer in the Army, I had defended Colonels in trials and had served as a Judicial Advisor in hearings. On the civilian side, I did a little bit of everything at Butler Snow, from taking a plaintiff’s deposition over a back table in a laundromat in the middle of the summer to cross-examining a well-heeled surgeon from one of the most prolific teaching hospitals in the United States. Some worked out better than others, and each experience was a fantastic learning opportunity that made me a better lawyer. I attended and spoke at drug and device conferences, staffed complex trials that stretched for weeks and months, and found myself making contacts and lifelong friends both with in-house counsel and with lawyers from other defense firms. It was a great time. I actually thought I knew what I was doing. I had not yet grasped the concept that none of us is as smart as all of us.

It was not until a few short years later, when I was given management responsibilities for a newly filed, soon-to-be mass tort, that I realized I didn’t know what I didn’t know. Now, having worked on the litigation from the first filing through trial, and ultimately through the conclusion of the MDL, my eyes have been opened. I now have a new perspective and appreciation for the one intangible that serves the client more than any other, and it does so by fostering an environment of efficiency, productivity, and success. That intangible is teamwork.

B Scouting Talent

It is important to recognize that every person on the team brings to the table a different background, a different perspective, and a different skillset. All opinions are valuable – and many are invaluable. For a lawyer to ignore the deep bench of expertise around him or her would be a disservice to all involved. Put

the ego away. Step out of the spotlight. Sharing, collaborating, and using the talent available are the most effective and efficient means to get a positive result. Harry Truman said it best: “It is amazing what you can accomplish if you do not care who gets the credit.”

That said, litigation is no panacea. There are days, nights, and weeks that are extremely stressful. A deposition goes off the rails; a judge repeatedly rules against you; counsel opposite’s behavior is a continuous thorn in your side; nerves get frazzled and tempers grow short after multiple 18-hour days away from home. All of those stressors will be present in any litigation; to think otherwise would be imprudent. However, when you have a team that shares the same focus and philosophy – own your work, accept blame, share praise, step up – the noise of the process can be collectively reduced to a hum, allowing the opportunity for clarity and judgment to shine through.

Not to mention the fact that maximizing the team model saves money. Skillsets should be identified and jobs assigned accordingly. An effective brief writer can do in a matter of days what it may take the corporate witness handlers weeks to do – and, without a doubt, the work product of those taking and defending the depositions would not be nearly as on point, measured, or persuasive as those people who draft briefs and motions day in and day out. The same can be said for almost any of the tasks necessary for an effective outcome – electronic discovery, document production, expert research, etc. Let the right people do the right job, and everyone wins.

**Put the ego away.
Step out of the spotlight.
Sharing, collaborating, and
using the talent available
are the most effective and
efficient means to get a
positive result.**

C And the Inevitable Football Analogy (After all, most of us are football fans)

It is good to be the quarterback. But a quarterback without a strong front line cannot execute the plays. A quarterback without receivers, running backs, and blockers cannot advance the ball. If a quarterback does not have a great defense, a quarterback will spend little time, if any, on the field. If your team is not on the field, you can't win. And when the quarterback, who happens to be blessed with top shelf talent all around, doesn't care who spikes the ball when the team crosses the end zone, the players, the coaches, the team – and the owners – share in the victory.

Butler Snow has the privilege of working with clients who understand our philosophy and who partner with us in embracing the team dynamic. Our team could not – and would not – function without the input and guidance we receive from our clients. We do not take this responsibility lightly. Every case – no matter how big or how small – is important. We will never forget this.

So, looking back ten years, I have personally experienced how the team model plays out in our firm philosophy of client first, firm second, and individual third. Both in theory and in practice.

Having now seen it, I cannot imagine doing it any other way.

THE VALUE OF CIVILITY

**“Never give way,
and never give
offense.”**

-Barbara Tuchman

It has been said that the internet is the best invention ever and the worst invention ever, and in the past ten years, we have seen a sea change in the way social

media has shaped the collective personality of our citizens. The anonymity that comes with posts, blogs, and online comments has been at the expense of courtesy, respect, and reverence. Respect for others' opinions, measured debate, and consideration in general has been tossed out the window. Attacks, counterattacks, and caustic behavior have become commonplace. Civility, as a word, as a pretext, and as an integral element of relationships, now seems antiquated; the word itself echoes as some remnant of a bygone era where people, at one time, treated each other with respect and engaged in substantive debate as opposed to creative name-calling. Ah, the good old days.

Unfortunately, as a litigator, I have seen the lack of civility carried over into our practice. It surfaces in emails, in correspondence, at depositions, and on the phone. Many lawyers pride themselves on their inability to play well with others, and they advance their cases with a pen in one hand and a torch in another, burning bridges as they cross them. Litigating a case is not easy in the best of environments. It can become downright fatiguing when dealing with a table-flipper at every turn. While it may be intuitive to respond with an equally spiteful demeanor, to do so clouds judgment, takes away from the focus of our defense, and it could lead a judge or another lawyer to question our motives and, even more importantly, our integrity. It should never happen on our side. We should be better than that.

As defense lawyers, we do not have to get in the ditch to be effective. Instead, we must be ambassadors – for our profession, for our clients, and for our firm. The word “lawyer” is sullied enough in the public's collective conscience. We should do everything in our power to right the ship. The impact of taking the high road can be felt on all levels – in the way we work with others, in the way we make our decisions, and, as a practical point, in how effective we ultimately are in the courtroom. How do I know? I learned from the best.

For reasons that I cannot explain, the stars have lined up for me in this, the most noble of professions. I am

The word “lawyer” is sullied enough in the public’s collective conscience. We should do everything in our power to right the ship.

working for a firm I love with people I am proud to call friends. On top of that, I have had the privilege of being mentored by one of the best pharmaceutical and device trial lawyers ever to grace a courtroom. While she has left many impressions (and a couple of scars) on me as I have grown in my practice, the one thread that has run through almost every lesson is the importance of civility and the importance of your word. Whether dealing with an irate plaintiffs’ lawyer, a court clerk, a young associate, a seasoned partner, or a learned judge, I have come to appreciate that it is always best to keep out of the fray to the extent possible, to be honest, to remain calm, and not to take things personally, no matter how personal the attack may seem.

Over the past decade, I had the opportunity to observe the effect of civility in trial practice by watching, listening, and observing as our consolidated cases worked their way through discovery, motion practice, and trial. Opposing counsel was not afraid to take the scorched earth approach, and they were not selective as to who observed their behavior – co-counsel, opposing counsel, witnesses, judge, and jury all got a taste. We took the high road. We said what we were going to say and what we were going to prove, and we did just that. When we did lose our cool at a deposition or during a telephone conference early on, we learned from our mistakes and did our best to stay within the lines going forward. And as the days stretched into months and the months, years, it paid off. We stood on the goodwill inherent in the integrity and good name we built time and time again. We had no trouble sleeping at night because of a prior misplaced action

or word. We never had to second guess the claims and arguments we made in our pleadings. We had the confidence to tell the story truthfully and without the need for half-statements or innuendo. We were persuasive on the merits.

We got a defense verdict.

Civility in our profession should carry over to civility in our life, in our families and in our relationships. At the end of the day, we need each other. While a short-term gain – via a contentious argument or one-upsmanship – may feel good at the moment, in the long term, it affects our judgment, potentially nudges our case in the wrong direction, and makes what should be an exercise in strategy, tactics, and reasoned arguments, turn into a quagmire that serves no one.

So yes, I consider myself extremely fortunate to have worked under someone who not only preaches – but practices – the need for civility and integrity in our lives. Her word is golden; and when she speaks, she speaks the truth without insult, without hyperbole, and without hesitation. I know it. My partners know it. Plaintiff lawyers know it. Judges know it.

I believe our jury knew it too.

THE IMPORTANCE OF DEPOSITIONS

This lofty idea of civility has every day applications, and this lesson cannot be learned too soon. Below are a few more tips learned over the years when taking and defending depositions.

From Kari’s Perspective:

A Taking Plaintiffs

1. Setting the Tone

The plaintiff is not your enemy. Not really. In my experience, the vast majority of the time she is uncomfortable if not downright frightened. This is particularly true in MDL or class litigation where she

actually never expected to have to testify. Part of the job entails allaying at least some of that concern so that rapport can be built and facts eventually uncovered (or admitted). Once some trust exists, truth can as well. On the other hand, she may not be frightened; she may just be mad. If that is the case, I have found that allowing a bit of venting goes a long way. Once it is out and she has had her say, a plaintiff generally will be more amenable to answering the question before her.

2. Using Some Sense

Actually, use all your senses. When you shook the plaintiff's hand, did he have a strong grip with callouses? Did she have an interesting piece of jewelry? Did you see any scars? If you notice something like that, and assuming his lifestyle is germane to the case in some way (as it always will be in a personal injury case), it will hurt nothing to ask a couple of questions in follow up. I have done this a number of ways, including the direct approach: what caused those callouses? Does he lift weights (or did he before he ostensibly hurt his back on your client's premises)? Does he garden or farm? Where did she get that necklace? Was it a memorable piece purchased on a dream vacation (that occurred after your client's supposedly egregious and life-changing negligence)? Be curious about this person and follow up on your instincts. Not to mention that talking about things the plaintiff perceives as conversation and not litigation can help them relax and, potentially, let their guard down. A relaxed plaintiff is a sharing plaintiff.

Use your eyes to look at more than your outline – actually observe things. Did the plaintiff walk in with a limp? What caused that? Who came with the plaintiff to the deposition? What does the plaintiff do during the deposition breaks? (i.e., did he take any medication during the break? Did he forget to walk with a limp?) I am not suggesting stalking, but the point is: look up from your outline and your phone! At one deposition, the plaintiff came in with beautifully manicured fingernails. In following up on that observation, I

learned that she drove herself every other week to the salon and not only had her fingernails done, but also her toenails and her hair, all while sitting in the salon chair. While this discovery might not sound very dramatic, it could make a difference in a case where one of the allegations is that the plaintiff cannot sit comfortably for any longer than 30 minutes at a time. Also, never forget to look for (or ask about) what the plaintiff brought with her to the deposition, including any relevant documents contained in her very large purse.

Use your ears to actually hear the answers. This means that you should not be reading your next question from the outline while the plaintiff is answering your last question. Listen. This will come with experience, but straying from the outline to follow a relevant rabbit trail more times than not yields rewards. Just be familiar enough with the topics you need to cover – and the admissions you need to get – to do this comfortably and get back on track when the trail ends. After all, as noted below, the purpose of a deposition is not to make it through the outline.

Lastly, smell the roses. Or the cigarette smoke. Smoking is a risk factor for just about every malady known to man. Obtaining a vague admission that the plaintiff smokes “sometimes” is vastly different than getting an admission that the plaintiff smoked two cigarettes during every break ... and you took five breaks before 3:00 p.m. ... not counting lunch.

3. Seal the Deal

Depositions are two-pronged tools: (1) find out facts and (2) get clean admissions. By “clean,” I do not mean a rambling back-and-forth session that eventually winds its way down to this:

Q: So, the answer to my question is “yes”?

A: I suppose so.

By that time, we all have already forgotten what the question even was, and its great impact is certainly diluted. Strive to have the admission consist of either

“yes” or “no.” Even more difficult for some, have your question be no more than two lines at most out of your 25-line deposition page. This is the “Three Line Rule for Impeachment”. If the road to get to that admission has been long and hard fought, try something akin to this:

Q: I understand what you’ve told me, and I appreciate it; but in fairness, you did take opioids for back pain before you had this surgery, right?

A: Yes.

This hopefully conveys that you listened to all the caveats and justifications. Having acknowledged all the excuses, you now just want (and are entitled to) a straight answer to a very straightforward question. The onus is on us, however, to craft those straightforward questions.

Finally, once you have sealed the deal and your clean admissions are memorialized in black and white, do not revisit the subject. Resist the temptation to get the same admission again – even if it’s a really good one. Let it lie. Change subjects so that the plaintiff cannot undo what you just got done, and move on.

4. Remember All of the Potential Uses for the Deposition

Always keep in mind how the deposition will be used for pre-trial practice and at trial. A good snippet about when the plaintiff knew of her injuries can be all that’s needed for a summary judgment motion on the statute of limitations. And information from the plaintiff may even tie into motions related to her experts and the reliability of their opinions. Assuming the motions are unfairly denied, trial counsel, whether you or someone else, will be standing up in front of jurors attempting to conduct a smooth and as-short-as-it-can-be cross examination. Sometimes impeachment is needed right at the beginning to lay out the ground rules: Yes, I have your deposition. Yes, I read it. Yes, I know how to use it quickly and efficiently, so going forward, you should just answer me truthfully. And



sometimes impeachment is needed right at the height of the cross examination to get that one piece of crucial evidence to support a motion for JNOV or a critical aspect of closing argument. Either way, this needs to be a seamless and fast process.

From Michael's Perspective:

B Defending Clients in the MDL and Reptile Era

Defending clients in this age of the ever-present MDL has become quite the stressful and very important endeavor. Multidistrict litigation is a creature of the 1960s. Like many ideas born in that decade, some were better than others (i.e., landing on the moon versus, say, bell-bottoms). The ostensible goals of this particular bright idea include avoiding duplicative discovery, lowering costs, and reducing the burdens on witnesses and parties.

One way that these goals were to be accomplished was with the advent of the videotaped deposition of the corporate witness. At first blush, it sounds fantastic. Instead of putting up your company witness in multiple actions across the nation, preserve her testimony for all upcoming cases in a single deposition. The downside is that her testimony – the good, bad, and ugly – is indeed preserved for all upcoming cases. That one unfortunate sound bite, accompanied by that one ugly facial expression, will get played in every subsequent trial.

Now, add a reptile.

In 2009, jury consultant David Ball and trial attorney Don Keenan published a book on trial strategy entitled *Reptile: The 2009 Manual of the Plaintiff's Revolution*. It was a watershed event in terms of how plaintiff lawyers prepared for their cases during discovery and how they presented their cases at trial. In a nutshell, plaintiff lawyers shifted the jury's focus away from the damage done to their individual client and toward

the jurors themselves, making the jurors feel like they, personally, could be impacted by the asserted dangerous behavior of defendant. Plaintiffs' lawyers started to use this "Reptile" approach to sell danger – make the jurors believe that the dangers identified in the lawsuit go well beyond the courtroom and into their cities, neighborhoods, and homes.

It has been quite effective. Ten years ago, verdicts in excess of fifty million dollars for a pharmaceutical or device case were almost unheard of. Now, it is not uncommon for juries to return verdicts in that range or higher, due in part to effective use of the Reptile theory – especially in jurisdictions that have been known to be plaintiff-friendly.

Since 2009, the Reptile theory has been discussed and debated in every context possible – journal articles, presentations, workshops, and even in some motion practice, and will not be repeated here.¹ What is worth discussing is what we have learned during these years as to how to address and minimize the impact of Reptilian behavior on our witnesses and on our cases. A brief summary of counter-Reptilian strategies is itemized below.

1. Prepare Your Witnesses

There are not many worse feelings than defending a deposition and watching your witness go slack-jawed when faced with what seems like an unanswerable Reptile question. "What do you consider safe?" "If your company could have made this product safer, shouldn't they have acted?" "Don't you think the public would have wanted to know what we are reading in this [bad document]?" "Shouldn't your client warn of known and reported risks?" The list of potentially problematic questions goes on and on. When these are presented to an unprepared witness, you can almost see the gears spin out of control and panic set in as the witness struggles to find an answer that he/she believes to be reasonable (or that he/she believes will be best to get them out of the room quickest – which is never good).

There is no substitute for adequate witness preparation.

There is no substitute for adequate witness preparation. Of course, preparing a witness involves covering substantive issues: case history, case facts, timelines, relevant documents, etc. Prior to getting into those issues, however, the persons responsible for preparing the witness should consider addressing the Reptile questions first. Using a Reptilian exercise at the outset lets the witness know that the questions are serious and dangerous. Reptilian questions also provide the witness with a good mental workout up front, and they provide a proper context for discussing the substantive deposition materials later in the prep session.

2. Ensure the Witness Understands the Process

We get it. We do it every day. It makes us a bit anxious at times, but taking and defending depositions is part of our job. Most of us like it; after all, we do not get to try as many cases as we used to and this is as close as it gets. Not so for the person who is being deposed. They need to understand that while the litigation will not likely rise or fall on their testimony, their time under oath is nevertheless extremely important. Whether they are a file clerk or a CEO, they need to understand that plaintiff lawyers are not necessarily looking for good, substantive testimony, but rather an effective sound bite. It does not matter whether they work in a cubicle or manage out of a penthouse corner office, to the jury, the witness is the face of the company – no matter their title.

The witness should also understand that whether the deposition takes one hour, seven hours, or three days, in all likelihood only a fraction of the deposition will be played, so the witness has to be on at all times because that ten-minute excerpt where he is frowning at the camera or snaps out an ill-tempered or improper

response without thinking could be played over and over again during the next 15 trials. Also, the witness should have an understanding as to how and where their testimony may be played at trial. We don't know when it is going to be played, or if it is going to be played at all. Regardless, we must treat every question – and every answer – as if it will be front and center. It could be played at the end of three days of video testimony when the jury is sleepy, hungry, and ready to go home for the weekend. It could also be played on the heels of the live testimony of a very emotional, grievously injured party, when many in the courtroom – including members of the jury – are crying, sad, upset, and/or angry. Treat every question like it is the most important question and answer accordingly.

3. Identify Reptile Questions

Depending on time considerations, the preparation session should cover as many Reptile questions and answers as time permits. The more questions are covered, the better equipped the witness will be not only to answer Reptile-type inquiries, but to recognize Reptile questions when they are shuffled into the case-specific substantive areas of inquiry.

4. Develop and Cover Themes

By the time the corporate depositions begin, you, as counsel, should have a decent understanding of the general themes of the case. These themes should be addressed during prep, and the witness should understand how to use these themes to advance the truth during a Reptile deposition. These themes are generally product-specific, and include: 1) the witness having an understanding of his/her role and responsibilities – and to not stray from that no matter the questioning; 2) the witness understanding the risks and benefits inherent in the product at issue; 3) a review and understanding of hot documents – and whether they may or may not apply to that witness; and 4) a general understanding of the regulatory and marketing history of the product.

5. Conduct a Mock Examination

After the witness has been prepped, conduct an effective mock cross-examination. This is no longer just a suggestion, but a must. To be effective, it must stretch the witness. Bring in a colleague that the witness has not met before to conduct the examination. Have the questioning attorney blend Reptile questions with key documents of the case. Be fairly aggressive to see how far the witness can be pushed. Know when to call time out and know when to keep going, no matter how uncomfortable everyone may feel. Perhaps most importantly, at the end of the day, conduct a thorough afteraction review. Walk the witness through the highs and lows so that he or she understands where to pivot and/or deflect and where to stand firm. Then assess the witness. If he or she needs more work on a particular point, or issue(s), make it happen.

6. Prepare and Conduct a Thorough and Targeted Redirect

The corporate witness should be reminded that when the plaintiffs' counsel completes his questioning, the deposition is not over. In today's drug and device litigation, plaintiffs' lawyers are trending towards marathon depositions, trying every possible angle and tactic to exhaust the witness, and in so doing, get the sound bites and admissions they seek for purposes of settlement or jury consideration. There is rarely a situation in the current environment where defense counsel should forego the opportunity to conduct a thorough redirect.

A redirect serves a number of purposes: 1) it can rehabilitate any questionable or unclear testimony from the corporate witness; 2) it provides an opportunity to place the themes developed by the plaintiff's lawyer into context and to show the jury the flip side of the proverbial coin; 3) it gives the witness a venue to discuss those topics where he or she has expertise and by so doing provides an opportunity to build the witnesses' credibility with the jury. Finally,

and perhaps most importantly, if the testimony of the witness is played via video at trial, it creates a bookend to counter the points made by plaintiffs and doesn't leave unfinished or unrealized issues dangling in front of the jury during the critical days or weeks before plaintiff rests and you are able to put on your case.

As with all things, this redirect too will require prep. First, prepare your schedule. Do not plan to catch a flight home the night of the deposition. You will have either gone late in order to get your part done, or you will be starting the next morning fresh with your part, the latter being preferable.

Second, prepare your witness. Walk through a planned outline of topics to get the client's story out. This is not just the time to bring some perspective to the less than fortunate documents displayed during the plaintiff's part, but it's a great time to tell "the rest of the story." Also, assuming the deposition consumes more than one day, consider having your witness wear the same clothes so that the video itself appears more fluid.

Third, prepare your documents. This is the chance to get the client's good documents into evidence during



the plaintiff's case. Keep in mind that video testimony can be more engaging and more persuasive when a document is put up that corroborates the testimony.

Fourth, prepare with your team. There may be aspects of the litigation with which you just are not familiar, but that your witness may be perfectly capable of addressing. Discuss with your team where the holes are and what you and your witness can do to fill them.

Lastly, be prepared for the plaintiff lawyer (assuming time permits) to want the last word. The demeanor of your witness should not change from when he or she was answering your questions to the now most-likely-more-aggressive tone of the plaintiff lawyer. That the plaintiff gets the last word is of no moment if that last word is not memorable.

We know that we've learned much over the last ten years, and we look forward to the opportunities that lie ahead.

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¹ See M. Hewes, *Cutting the Head off the Snake: Blunting the Effect of the Reptile Approach During Corporate Depositions*, *Pro Te: Solutio*, Spring 2015, available at <https://www.butlersnow.com/2015/05/pro-te-solutio-march-2015>.









NEXT DECADE TO-DO:

Enforce Preemption for Class II Devices with Special Controls

Luther T. Munford and Erin P. Lane

The common assumption is that FDA premarket approval of a Class III device is a necessary prerequisite for express federal preemption of state law design defect claims.

But that assumption is wrong. FDA adoption of special controls for Class II devices can also expressly preempt design defect claims even though those devices are not subject to premarket approval and are cleared using the §510(k) notice process.

The operative word is “can.” Some special controls are more likely to preempt than others. In the broadest terms, the more specific the control, the more likely it is to preempt state tort law. Controls expressed in regulations are more likely to preempt than controls in the form of a FDA guidance adopted by a regulation. And courts should be more likely to recognize the preemptive effect of a control when the FDA itself has done so. At this point, though, these are mere likelihoods, not certainties.

But even if the path to express preemption is muddled, it is not impassable. The time has come to consider express federal preemption anytime a state tort suit is brought challenging a Class II device whose classifying regulation adopts a special control. Success in a strong case would clear the way for others to follow.

THE GAP THAT OPENS THE DOOR FOR THE CHALLENGE

There remains a gap in the kind of device regulations whose preemptive effect the U.S. Supreme Court has considered. While the Court has soundly precluded preemption for Class I devices as a whole and soundly upheld design preemption for Class III devices, in the middle fall Class II devices, some subject to special controls and others not. Assuming there is no preemption for any Class II device overlooks the law that governs devices which are subject to “special controls.”

The FDA regulates medical devices in three different ways, each roughly corresponding to the degree of risk the FDA believes the device poses. It places the least

Some special controls are more likely to preempt than others. In the broadest terms, the more specific the control, the more likely it is to preempt state tort law.

risky devices in Class I and allows them to be marketed without any premarket FDA review. More risky devices go in Class II and may be subject to special controls. In any event, they generally may be marketed only after clearance using the §510(k) notice process. That process requires a showing of safety and equivalence to a device already on the market. Finally, the most risky devices are placed in Class III and may only be sold after being approved based on independent evidence of their safety and effectiveness.

The Food, Drug, and Cosmetic Act provides that a state may not “establish or continue in effect” any “requirement” which is “different from, or in addition to, any requirement applicable under this chapter to the device....”¹ This broad language would appear to foreclose a state tort suit against any regulated device now that it has been made clear that the word “requirement” includes state tort law rules.²

The FDA, however, has attempted to narrow the statute by construing “requirement applicable ... to the device” to apply only where the FDA “has established specific counterpart regulations, or there are other specific requirements applicable to a particular device under the act....”³ Construing this language, the U.S. Supreme Court has said that *general* FDA regulations – regulations applicable to all devices – do not count as “requirements.”⁴ Thus there is no express preemption for Class I devices or Class II devices not subject to special controls. And, at the other end, the Court has said that FDA approval

of Class III devices does give rise to requirements “applicable to a particular device” that preempts state design defect law.⁵

The category that the Court has not addressed – and which bears consideration by defendants in device litigation – falls in the middle: Class II devices, which are subject to special controls. The 1976 Act establishes the framework for classification and the imposition of special controls. It instructs the FDA to convene panels of medical experts, whose qualifications are dictated by statute, to classify medical devices. The panels consider available medical literature, review injury reports sent to the FDA, hold hearings, and then decide how devices are to be classified in order to provide “reasonable assurance of safety and effectiveness.” 21 U.S.C. §360c(a)(1). A device or category of devices can only be placed in Class II if the panel concludes it does not present “a potential unreasonable risk of illness or injury” that would require it to be placed in Class III. 21 U.S.C. §360c(a)(1)(C)(ii)(II).

When the FDA adopts a regulation that puts a device or category of devices in Class II, it may or may not impose “special controls” that, under the statute, can include “performance standards ... development and dissemination of guidelines (including guidelines for the submission of clinical data in [510(k) notifications]), recommendations, and other such actions as the Secretary deems necessary” to provide reasonable assurance of safety and effectiveness.⁶

When the FDA adopts a regulation that puts a device or category of devices in Class II, it may or may not impose “special controls” [...]

The question then arises as to whether “special controls” included in the FDA regulation, which classifies the device or category of devices, are “requirements” that trigger express federal preemption. If they are, then the fact that individual Class II devices are cleared using §510(k) notice rather than premarket approval is irrelevant. The 510(k) process ensures compliance with special controls for that category of devices, and that is all that is needed for preemption.

“SPECIAL CONTROLS” CAN BE REQUIREMENTS THAT SUPPORT PREEMPTION

In the wake of claims that tampons caused “toxic shock” in women, the FDA’s Obstetrics-Gynecology and Radiologic Devices Panel recommended, and the FDA adopted in 1982, 21 C.F.R. § 801.430, “User labeling for menstrual tampons.” The FDA kept tampons in Class II but required this language:

ATTENTION: Tampons are associated with Toxic Shock Syndrome (TSS). TSS is a rare but serious



disease that may cause death. Read and save the enclosed information.

The FDA also said manufacturers had to address certain subjects, such as the warning signs of toxic shock syndrome and how to treat it.⁷ In 1989, the FDA amended the regulation to require testing and to standardize absorbency labeling.⁸ The same regulation also required a description of toxic shock risk and a warning to use tampons with minimum absorbency.⁹

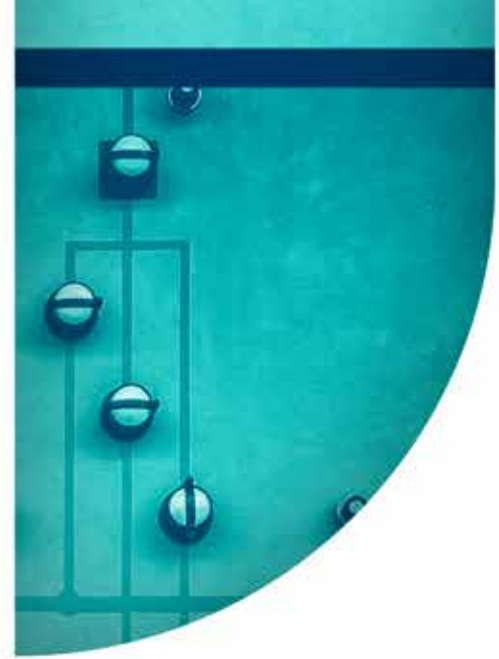
In *Papike v. Tambrands Inc.*,¹⁰ the Ninth Circuit held that the tampon regulation preempted not only failure to warn claims, but also design defect claims based on a consumer expectations theory and express warranty claims. According to the court, the FDA “regulation mandating the specific substantive content of the TSS warnings on tampon boxes and/or tampon package inserts” in 21 C.F.R. § 801.430 was “not only device-specific (tampons), but also disease-specific (TSS).”¹¹ The Ninth Circuit also said that the FDA’s statement that regulatory standards could be met in other ways, i.e. that manufacturers could draft their own warning language, did not defeat preemption.¹²

The FDA recognizes that its special controls can have preemptive effect. A 1999 Presidential Executive Order requires that federal agencies issue a “federalism summary impact” statement when a regulation preempts state law.¹³ After the Supreme

Court squarely held in *Riegel v. Medtronic*¹⁴ that state tort law rules can be preempted, the FDA began issuing federalism statements when it designated special control guidance. There are at least 26 final rules beginning in 2008 that contain these statements.

The earliest example came with the final adoption of a condom regulation in 2008. That regulation, 21 C.F.R. §884.5300, does not expressly impose standards but instead provides: “The guidance document entitled ‘Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms Classified Under 21 CFR 884.5300’ will serve as the special control.”

The FDA recognizes that its special controls can have preemptive effect. A 1999 Presidential Executive Order requires that federal agencies issue a “federalism summary impact” statement when a regulation preempts state law.



The guidance, in turn, requires that labeling specify an expiration date, give the natural rubber latex warning, and include adequate directions for use. It also recommends that labeling specify that condoms reduce but do not eliminate the risk of pregnancy and sexually transmitted diseases. The labels must list the failure rate and the condom’s relative lack of effectiveness in preventing certain diseases. Examples of acceptable statements are given, e.g., “Latex condoms do not completely eliminate the risks of pregnancy and sexually transmitted infections (STIs).” And six specific directions for use are given. See <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm107076.htm>.

In describing the preemptive effect of the regulation, the FDA acknowledged that normally a “guidance” need not be followed and so cannot be considered a “requirement.” But it distinguished a “guidance” that constitutes a special control:

Unlike a regular guidance, which imposes no requirements, where a guidance document has been designated as a special control by a rule, *manufacturers must address the issues identified in the guidance*, either by following the recommendations in the guidance or by some

other means that provides equivalent assurances of safety and effectiveness. At the same time, establishing a guidance document as a special control affords greater flexibility than a rule mandating specific labeling language and can facilitate updating labeling as new scientific information becomes available because *the special control permits manufacturers to use any labeling that affords equivalent assurances of safety and effectiveness for latex condoms*.¹⁵

It identified the issues requiring the special control as unintended pregnancy, sexually-transmitted infections, and incorrect use.

In describing the preemptive effect of the regulation, the FDA acknowledged that normally a “guidance” need not be followed and so cannot be considered a “requirement.”

In *Rasheed v. Church & Dwight Co.*,¹⁶ the plaintiff sued the manufacturer of Trojan condoms after condom use was followed by a severe reaction. Because the guidance addressed the potential for allergic reactions to natural rubber latex or the condom lubricant, the Court, in an alternate ruling, held that plaintiff's failure to warn claim was preempted. In so holding, it relied on the applicable federal regulation and the tampon precedents.¹⁷

THE CHARACTERISTICS OF A PREEMPTIVE SPECIAL CONTROL

Either case law or FDA federalism statements have now recognized that a special control for a Class II device can preempt state law claims with respect to a wide variety of devices. These include not only tampons and condoms but also latex gloves,¹⁸ contact lenses,¹⁹ angioplasty catheters,²⁰ wound dressing,²¹ tissue adhesive with wound closure device,²² a hemorrhoid prevention pressure wedge,²³ and electrical stimulation devices.²⁴ But courts have rejected preemption claims with respect to bone cement²⁵ and IVC filters.²⁶

Some of these regulations have prescribed labeling,²⁷ but most have not. Some have identified special control features in the regulation itself,²⁸ but others have simply adopted a guidance as a special control.²⁹

A few things can be said, however, about the cases in which courts have refused to give preemptive effect to a special control. Both of them concerned regulations adopted before 2008; meaning they did not consider FDA federalism statements, either with respect to the device in issue or in general.³⁰ One simply dismissed the idea that a special control guidance could impose any "requirements" and, confusing the issues, thought that it mattered that the device was cleared using §510(k).³¹ Another questioned whether a guidance, even one required by a classifying regulation, was sufficiently device-specific, and similarly opined that §510(k) review was not the same as a premarket approval.³²

In addition, some courts have distinguished among state tort claims and refused, for example, to give a labeling requirement preemptive effect with respect to a design defect claim based on a risk-benefit analysis.³³

Some of these criticisms, however, appear to be misplaced.

First of all, the continued validity of the FDA's narrowing regulation, 21 C.F.R. § 808.1(d), is subject to question. As far back as 1996, four justices – Sandra Day O'Connor, Antonin Scalia, Clarence Thomas, and Chief Justice William H. Rehnquist – doubted that the FDA had the authority to narrow the statute.³⁴ And, in an opinion as a Court of Appeals judge, Justice Neil Gorsuch noted that the regulation conflicts with "the statute's literal language," something he called "no small mystery."³⁵

Second, the language of the regulation when read carefully does not require that the "specific counterpart regulations" be specific to an individual manufacturer's device. In fact the Supreme Court case that first limited express preemption, *Medtronic v. Lohr*,³⁶ referred to the kind of federal regulations to be protected from state interference as regulations "regarding a specific device or field of device."³⁷

Third, there is no reason for courts to be dismissive of §510(k) clearance when that clearance rests on medical panel classification of a device or "field of device" in Class II, for that constitutes a finding that the device does not present an "unreasonable risk of illness or injury." There was no such panel action or classification at issue in *Lohr*, the case mistakenly relied upon as being typical of §510(k) review and used to defeat preemption for §510(k) cleared devices.

To the contrary, courts should be particularly deferential to Class II designations and special controls found in regulations adopted only after prior notice and opportunity for comment in the Federal Register. That is a level of public scrutiny that "approved" devices do not get. And the deference would be

justified: The likelihood that a Class II device cleared using §510(k) will result in a serious recall is lower than the likelihood that a Class III premarket approved device will result in a serious recall.³⁸

Fourth, affording express preemptive effect to a special control would be consistent with the law of conflict preemption. Conflict preemption arises where the FDA's "special permission or assistance" is required to market a device.³⁹ A manufacturer cannot make a "significant change" to a device without first obtaining FDA clearance.⁴⁰ If a question should arise as to whether a change is "significant," there could be no better evidence of significance than the existence of a special control guidance that has identified the design characteristic being changed, e.g., the material used, as something that must be disclosed in a §510(k) application.

For all these reasons, express preemption should be considered in any defense of a Class II medical device for which the FDA has adopted a regulation imposing special controls.

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1. 21 U.S.C. §360(k).
2. See *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324-25 (2008); *id.* at 327-28.
3. 21 C.F.R. §808.1(d).
4. *Medtronic v. Lohr*, 518 U.S. 470, 498-501 (1996).
5. *Riegel*, 522 U.S. at 322-23.
6. 21 U.S.C. §360c(a)(1)(B).
7. 47 Fed. Reg. 26982-01 (June 22, 1982).
8. 54 Fed. Reg. 43766 (Oct. 26, 1989).
9. *Id.*
10. 107 F.3d 737, 742-44 (9th Cir. 1997).
11. *Id.* at 740.
12. *Id.* at 741. See also *Murphy v. Playtex Family Prods. Corp.*, 69 F. App'x. 140, 143-44 (4th Cir. 2003) (preemption of failure to warn and consumer expectations design defect claim).
13. 64 Fed. Reg. 43255 (Aug. 4, 1999).
14. 552 U.S. 312 (2008).
15. 73 Fed. Reg. 66522-01, 66524 (Nov. 10, 2008) (emphasis added).
16. 2012 WL 262619, *1-2 (E.D. Tex. 2012).
17. *Id.* at 7-8.
18. 21 C.F.R. § 801.437; *Busch v. Ansell Perry, Inc.*, 2005 WL 877805, at *2-3 (W.D. Ky. Mar. 8, 2005); *Morgan v. Abco Dealers, Inc.*, 2007 WL 4358392, at *6-7 (S.D. N.Y. Dec. 11, 2007).
19. 21 C.F.R. § 886.5918; *Tuttle v. CIBA Vision Corp.*, 2007 WL 677134, at *2 (D. Utah Mar. 1, 2007); *Degelman v. Advanced Medical Optics, Inc.*, 659 F.3d 835, 841-42 (9th Cir. 2011), *vacated due to settlement*, 699 F.3d 1103 (9th Cir. 2012).
20. 21 C.F.R. § 870.5100; 75 Fed. Reg. 54637-01 (Sept. 8, 2010).
21. 21 C.F.R. § 878.4015; 74 Fed. Reg. 53269-01 (Oct. 16, 2009).
22. 21 C.F.R. § 878.4011; 75 Fed. Reg. 68972-02 (Nov. 10, 2010) (guidance-imposed requirements "to address each health risk identified with these devices").
23. 21 C.F.R. § 884.5200; 76 Fed. Reg. 21237-01 (April 15, 2011).
24. 81 Fed. Reg. 24386-01 (April 25, 2016) (proposed 21 C.F.R. § 882.5235 and 21 C.F.R. § 895.105).
25. 21 C.F.R. §888.3027; *Thompson v. DePuy Orthopaedics, Inc.*, 2015 WL 7888387, *8-10 (S.D. Ohio Dec. 4, 2015).
26. 21 C.F.R. § 870.3375; *In re: Bard IVC Filters Products Liability Litigation*, 2017 WL 5625547 (D. Ariz. Nov. 22, 2017).
27. See 21 C.F.R. § 801.430 (tampons); n. 4 (latex gloves), *supra*.
28. See n. 9 (hemorrhoid prevention pressure wedge) and n.10 (electrical stimulation devices), *supra*.
29. See n.5 (contact lens); n.6 (angioplasty catheters); n.7 (wound dressing); n.8 (tissue adhesive with wound closure device); n. 11 (bone cement); n.12 (IVC filters), *supra*.
30. *Thompson*, 2015 WL 7888387 at *8-10; *In re: Bard IVC Filters*, 2017 WL 5625547 at *5-9.
31. *Thompson*, *supra*, n. 11, at *8-9.
32. *Bard IVC Filters*, *supra*, n. 12, at *8-11.
33. See *Busch*, *supra* n. 4 at *1-4.
34. *Lohr*, 518 U.S. at 513-14.
35. *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1339-40 (10th Cir. 2015) (Gorsuch, J.).
36. 518 U.S. 470, 498-501 (1996).
37. *Id.* at 501 (emphasis added).
38. Jeffrey K. Shapiro, *Substantial Equivalence Premarket Review: The Right Approach for Most Medical Devices*, 69 Food & Drug L.J. 365, 389-90 (2014).
39. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2580-81 (2011).
40. See 21 U.S.C. § 360c(i)(1)(B); 21 C.F.R. § 807.81(a)(3); 21 C.F.R. § 807.100(a)(5). See also *Mensing*, 131 S. Ct. at 2576-77; *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013); *Yates v. Ortho-McNeil Pharm., Inc.*, 808 F.3d 281, 298 (6th Cir. 2015).



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Next Decade To-Do: Enforce Preemption for Class II Devices with Special Controls

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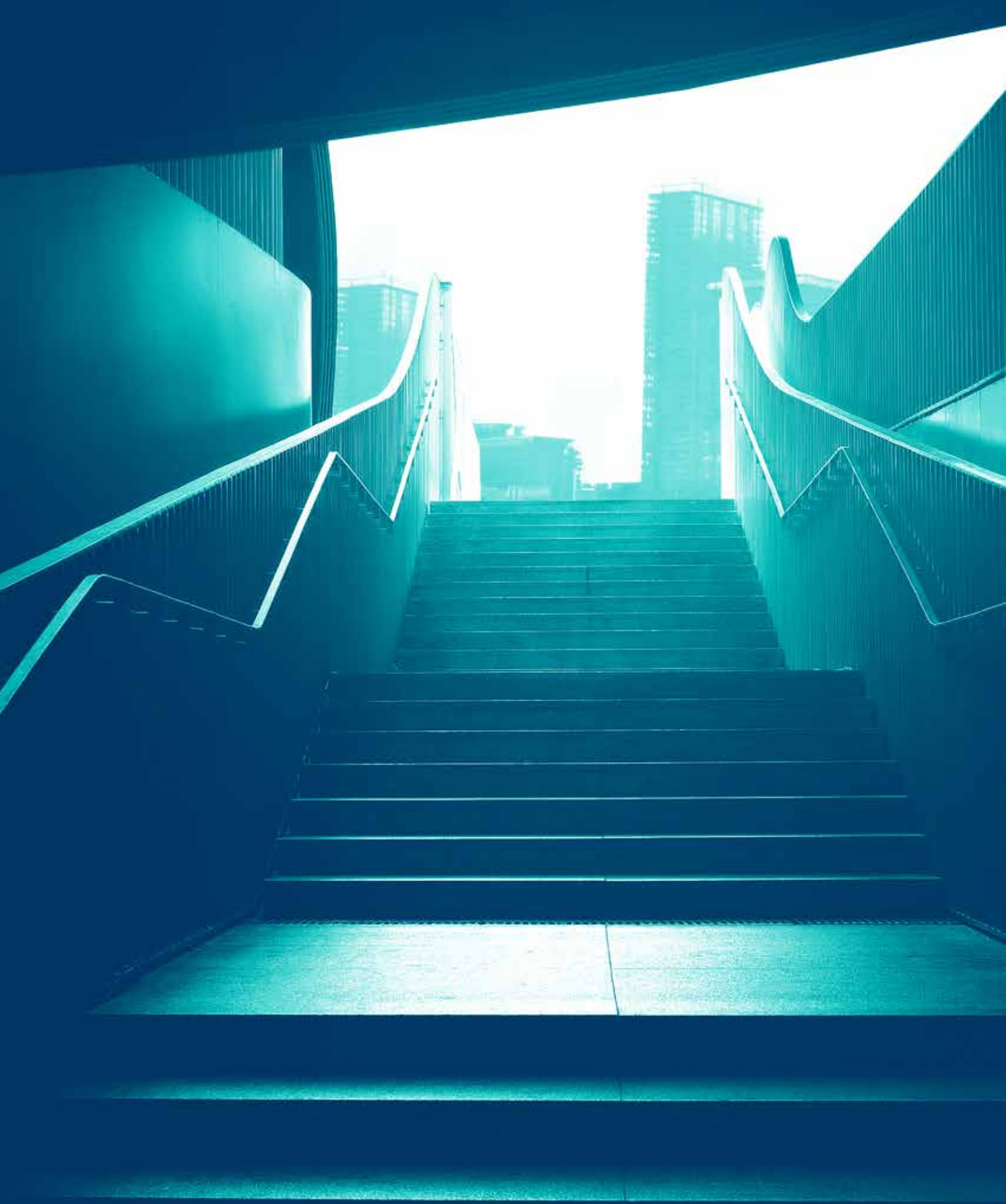
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