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THE THREE C'S

OPEN SOURCE AND CROWDSOURCED MODELS IN PHARMACEUTICAL DEVELOPMENT

PHYSICIAN DEPOSITIONS: WHO GOES FIRST?

DEAR CLIENT,

Every summer vacation (or, at least, the ability to take the weekend off!) should include a good read. Whether your preference runs toward a memoir with words of wisdom, a review of new technical advancements, issues of strategy, or good-ol' law school basics, we hope that this issue of *Pro Te* offers a little something for everyone.

In *The Three C's*, we gain perspective from a seasoned trial lawyer who has lived in the trenches (and lived to tell about it). His thoughts about three keys to success in the practice of law—Clarity, Credibility, and Conviction—are good touchstones for all lawyers.

For those who tend toward tech topics, you may know that crowdfunding is all the rage on social media. Applied to our "day jobs," this issue is finding a place in the pharmaceutical arena. In *Open Source and Crowdsourced Models in Pharmaceutical Development*, we look at how such models are being used to positively impact drug and medical treatment advances.

If you like strategy, or would just appreciate some insight on a frequently challenging issue in litigation, check out *Physician Depositions: Who Goes First?* This article explores general rules regarding priority in depositions, court orders regarding the same, and why it matters in your litigation.

Finally, for those who are not afraid to admit that Civ Pro was a favorite class, our final article may harken you back to the days of late nights pouring over *International Shoe*. Even if civil procedure is not your "thing," you'd have to have spent your summer vacation on a deserted island to not know that the United States Supreme Court issued a trio of decisions on personal jurisdiction this past term. In New and Noteworthy, we give you the overview of these important decisions that will impact where and how pharmaceutical litigation proceeds in the future.

Happy reading!

CHRISTY D. JONES

Co-Chair
Litigation

CHARLES F. JOHNSON

Co-Chair
Business and Corporate Healthcare

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THE THREE C's

I spoke recently to young lawyers about the keys to a successful law career. I wish I could say that I developed original content for the speech, but I confess that I didn't. I simply repeated portions of a speech delivered by David Boies in 2007 at a convention I was fortunate to attend. Boies, as you probably know, is one of America's greatest trial lawyers. What Boies said that day has never left me.

Success in the practice of law, Boies said, has three components—Clarity, Credibility, and Conviction. Each is a necessity, and the lack of any one is crippling. The path to each is a journey, and none are ever fully mastered. All of us are still learning.

With apologies to Mr. Boies, I shall try to elaborate on each in my own words, as the passage of time has dimmed my recollection of much of what he said.

CLARITY

Clarity – the quality of being clear; the quality of coherence and intelligibility; the quality of being easy to see or hear; sharpness of image or sound.[1] Another puts it as thus: "Freedom from indistinctness or ambiguity."[2]

Most of the people you meet in your professional life (lawyers and judges) are busy and have short attention spans. If psychologists are correct, people form opinions about you in seconds based only on your appearance or your first few utterances. If your writings are confused or weak, your points are lost. You have a short amount of time to grab attention, articulate your client's position, and make a difference. Don't screw it up with unintelligible words and phrases. Speak and write simply, sharply, and cleanly. Be free from indistinctness or ambiguity.

NO LAWYER CAN DECLARE THEIR OWN CREDIBILITY. IT IS EITHER EARNED IN THE MINDS OF THE COURT OR YOUR ADVERSARIES, OR IT PRECEDES YOU IN THE FORM OF REPUTATION.

The single best advice I was ever given about legal writing was this: Write your first draft with reckless abandon and pour your heart into what you want to say. Then, walk away from the document, and when you return, *go through each sentence and remove as many words as you can without destroying the meaning of the sentence.* Remove. Lessen. Reduce. Shrink.

How does one achieve, or rather, *earn* Clarity? Hopefully, you have a trusted someone in your professional life who is your strongest critic. The person that bleeds on your drafts. The person who tells you that you have a lot to learn. The person who tells you less is more and more is waste. Listen and learn from your critics.

A final point on Clarity. I think it is the easiest of the three qualities to improve upon. Credibility and Conviction are more so traits than talents like Clarity. Clarity is subject to trial and error and can be made better over time. If Clarity eludes you, seek and you shall find.

CREDIBILITY

Credibility – the quality of being trusted and believed in; the quality of being convincing or believable; another term for "street cred."[3]

No lawyer can declare their own credibility. It is either earned in the minds of the court or your adversaries (perhaps during a trial or in repeated dealings), or it precedes you in the form of reputation. A dozen truthful statements don't earn you Credibility, but one half-truth destroys it. Clarity is a moment-by-moment thing—you can be unclear and lost in the morning, but return in the afternoon and deliver the most cogent argument of your life. But Credibility is nothing like her sister. When your Credibility is destroyed in the morning, she does not reappear in the afternoon.

Credibility is telling the Court and counsel opposite something they don't know that hurts your case but you are ethically obligated to share. Credibility is showing the jury your most powerful evidence in a truthful manner, even if it means you must also inform them the evidence has caveats that might imperil your case. (Never put your credibility at risk by thinking your opponent might not bring the caveats to light.) Credibility is confessing the countervailing law. Credibility is answering the judge's questions truthfully and accurately.

That sounds easy, but the things that test one's Credibility hide in shadows of gray and in the corners of the mind. What yesterday seemed like an obscure and uncertain issue with little chance of becoming important has today grown into a major Credibility issue. Experience will help you spot the issues sooner and predict the consequences of your response.

When I was younger, I thought Credibility was just the right thing to do because we are officers of the court sworn to conduct ourselves uprightly and according to law. But now, I realize that's Honesty. Credibility is different. Credibility is Honesty plus Zeal. It is the exclamation point behind Clarity. It is the moment of believability. You cannot stand before a jury in closing argument unless your Credibility is intact. If the jury can't believe in you, they will not believe in what you are saying.

CONVICTION IS A PERSONAL MOMENT. IT IS THE MOMENT WHEN YOU BRING YOUR INNER SOUL TO THE SURFACE AND MOLD IT FOR YOUR CLIENT'S PURPOSES.

CONVICTION

Conviction – "a firmly held belief or opinion; *the quality of showing that one is firmly convinced of what one believes or says.*"[4] Synonyms include words like "certitude," "assurance," and "confidence."

Ah, Conviction. The most often misunderstood and abused of the triumvirate. She is elusive and cannot be faked. She is grounded in truth but has an element of theatre. As with other things in life, timing is everything. She is like a high note, to be played in perfect tune but sparingly.

What is Conviction? It is the passionate expression of a belief, but never before your jury is ready to receive it. It can sometimes be a shout of anger, but it is often more effectively expressed as a rhetorical question spoken hardly louder than a whisper. Often, Conviction is the question not asked but which is obvious. Sometimes, it is simply the monotone recitation of the chronological facts of a horrible tragedy expressed through a witness or during an opening statement, punctuated by a pause, and then this question: "And how old was Amy that day?" "She was 14 years old."

Most importantly, Conviction is *a personal moment*. It is the moment when you bring your inner soul to the surface and mold it for your client's purposes. It's where your favorite song or poem meets the evidence. It's where all of your hard work reaches a fulcrum. And it's the maturity of knowing when the food has been fully cooked without the need to glance at the thermometer.

CONCLUSION

After twenty-seven years, I have come to realize that the practice of law is like a steam engine gaining momentum and power downhill, to the point that it surpasses the control of its conductor. Musician Anna Nalik unknowingly captured the sentiment when she wrote:

> 'Cause you can't jump the track, we're like cars on a cable,
> And life's like an hourglass, glued to the table.
> No one can find the rewind button, girl,
> So cradle your head in your hands,
> And breathe... just breathe.'[5]

Years from now, I hope one of you takes what Mr. Boies handed me in 2007 and passes it along to a younger lawyer. Describe the "Three C's" differently and in your own way—but remember to just breathe and enjoy along the way, knowing the hourglass is glued to the table.

1. Google dictionary: https://www.google.com/?gws_rd=ssl#q=clarity&spf=1497487051174.
2. Dictionary.com: http://www.dictionary.com/browse/clarity?s=t.
3. Google Dictionary: https://www.google.com/?gws_rd=ssl#q=credibility&spf=1497487051176.
4. Google Dictionary: https://www.google.com/?gws_rd=ssl#q=conviction&spf=1497487051178.
5. Anna Nalick, *Breathe* (2 AM), (Columbia 2004).

WILLIAM M. GAGE

OPEN SOURCE AND CROWDSOURCED MODELS IN PHARMACEUTICAL DEVELOPMENT

The development of new pharmaceutical products is expensive and increasingly more so. Recently published studies estimate the cost for each new prescription drug approval to average $2.5-$5 billion, including the development costs of the successful compound along with the associated failures along the way.[1] In recent years, pharmaceutical companies have been looking to creative models to curb the drastic increase in development costs. Among other creative solutions, they are experimenting with introducing open source and crowdsourced aspects to various parts of the drug development cycle.

The term “open source” comes from the software industry where a piece of software is considered “open source” if the source code for the software is freely available to the public to use and modify. For example, the Linux® operating system platform is free to download for public use, and users create modifications to improve the platform that are then made available to the broader Linux® community. While the definition of “open source” outside of the software industry is less defined, typically an “open source” research project in the medical field is one where the protocols for the research and/or the data resulting from the research are made freely available to the public for use in further research and development instead of being kept confidential.

A project is considered “crowdsourced” if the research is performed by individuals or teams, typically unrelated to the requestor, who are not hired in a typical fashion to perform the work. Crowdsourced research may occur in a competition setting or in a setting of open collaboration among otherwise unconnected individuals. One of the most widely known examples of crowdsourcing is Wikipedia (http://www.wikipedia.com), a website where members of the general public contribute their knowledge about every topic under the sun by writing pages for and editing an online encyclopedia. Not surprisingly, among its plethora of information, Wikipedia has a page dedicated to a constantly evolving list of crowdsourcing projects available at https://en.wikipedia.org/wiki/List_of_crowdsourcing_projects.

Many parts of the drug development process can benefit from an open source and/or crowdsourced model. Pharmaceutical and other medical research companies are trying many of them, including obtaining samples of biological materials, evaluating how biological structures are likely to be oriented, developing algorithms for identification of likely successful compounds, creating clinical trial protocols, and developing treatments for challenging medical conditions. This article explains a little about each of those ongoing activities and explores the likely intellectual property implications of them.

OBTAINING SAMPLES OF BIOLOGICAL MATERIALS

At least one organization has developed a unique way to obtain free genetic material for its research—The American Gut Project (http://americangut.org and http://humanfoodproject.com/americangut/). The American Gut Project, along with similar projects analyzing samples from individuals around the world, is researching a hot button topic in the medical arena: the microbiome of the human gut and its relationship to disease. It bills itself on its website as “one of the largest crowdsourced, citizen science projects in the country.” People pay $99.00 for a kit to collect samples of microbes from their skin, mouth, and fecal matter and then send them to the American Gut Project’s lab. The lab analyzes the microbial content of the samples as well as information from the donors about key variables that could influence the makeup of their microbiomes, like diet, exercise habits, and geographical location. It then adds the information to their collected research, which is de-identified and made publicly available, and returns a personal sequencing and analysis to

the donor with individualized information about their own microbiome and how it may be affected by their personal experiences. In this way, the project receives for free the biological material that it needs while having the public pay for the donation and the analysis under the premise that a service is actually being performed for the donors. The project uses aspects of crowdsourcing by obtaining the samples from the general public and is also an open source project. The intellectual property rights in the combined de-identified results are granted freely to the public for general interest and to researchers for analysis and use in further research.

EVALUATING HOW BIOLOGICAL STRUCTURES ARE LIKELY TO BE ORIENTED

For its crowdsourced research, the University of Washington has created a gaming platform where users compete to fold proteins in new and creative ways (https://fold.it/portal). The Allen Institute of Brain Science and the Center for Game Science at the University of Washington has created a similar platform where users play games to build models of brain cells (http://mozak.science/landing). All viruses, bacteria, and cancers have proteins involved in their occurrence. The way that a protein is folded predicts what compounds are likely to interact with it, so knowing how those proteins are folded can help researchers create potential treatments for various conditions.

In the FoldIt game, users are trained through a series of easy games to learn the rules of how proteins tend to fold. Next, users advance to trying their hand at folding more complex ones. Points are awarded based on how well a user's protein fold conforms to the rules of folding, and winners are declared. One might ask though, if there are set rules to how proteins are folded, why have humans fold them rather than running the proteins through computer algorithms? The answer to that question sits in the level of complexity of proteins and their degrees of movement. Having a computer attempt all possible folds for a single protein would take a very long time due to the number of potential permutations of the fold. That being the case, though, some folds are more obvious than others, and humans have an innate analytical ability to rule out all the folds that would be clearly incorrect much better than a computer can. The FoldIt game capitalizes on this human intuition. The game includes basic programs to assist in working out minor kinks, while the human makes the major decisions about folding.

FoldIt is open source in the sense that the results of all folds that are competition winners are made publicly available and free for viewing. Any researcher can use the results of the protein folds in their own research to attempt to find compounds that will interact with the proteins that are folded as discovered in the game.

Mozak has a similar concept to FoldIt, but deals with neuron mapping of brain cells rather than mapping of proteins. It capitalizes on the human eye's ability to trace a neuron's structures in three dimensions—a task which is exceedingly difficult for a computer. In future versions of the game, Mozak intends to have humans assist with classifying various neurons based on their structure to help predict the likely function of various neurons. Mozak is still in the early stages of development, but it appears that it will be similar to FoldIt in its implementation. It is currently unclear whether results of Mozak's research will be made available to the public or whether they will be privately used by the Allen Institute for Brain Science in its own neuroscience research.

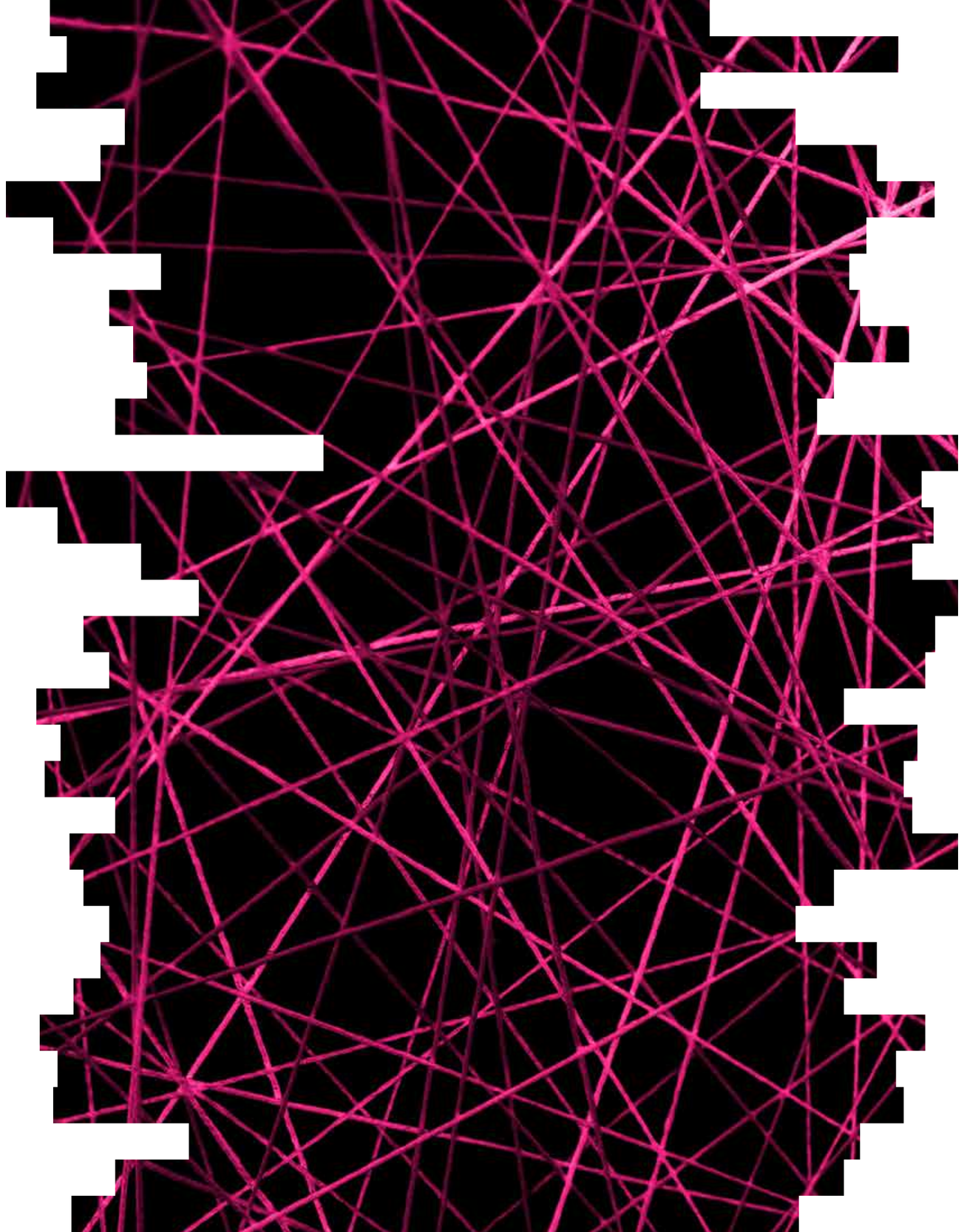
DEVELOPING ALGORITHMS FOR IDENTIFICATION OF LIKELY SUCCESSFUL COMPOUNDS

Open source platforms and research are great for the general advancement of science, yet they are not always the most practical way for commercial entities to make money from their

results. In that arena, platforms like Topcoder (https://www.topcoder.com/), Kaggle (https://www.kaggle.com/), and InnoCentive (https://www.innocentive.com/) allow commercial entities to launch competitions to specific communities, such as the coding community, where monetary prizes motivate the competitors and the sponsors retain intellectual property rights in the submissions. These platforms are not limited to use by pharmaceutical companies, but competitions on Kaggle have shown to be popular in that context, including:

- *a Genentech competition to advance Cervical Cancer Screening that attracted 40 teams and granted $100,000;*
- *a Genentech competition to predict when, where, and how strong the flu will be that attracted 50 teams and granted $125,000;*
- *a Pfizer private, invitation-only competition for prescription volume prediction that attracted 12 teams for an undisclosed prize amount;*
- *a Merck competition to predict molecular activity that attracted 236 teams and granted $40,000;*
- *a Boehringer Ingelheim competition to predict biological responses to molecules from their chemical properties that attracted 699 teams and granted $20,000.*

If one thinks about it, in a standard paid research arrangement, paying $20,000 to have 699 teams of individuals attempt to come up with an algorithm that will decrease a pharmaceutical company's time and expense in molecule selection is an incredible deal. InnoCentive is similar to Kaggle and has 150 past and present competitions across the array of global health as well as a separate section solely with challenges run by AstraZeneca. Some of the InnoCentive challenges result in exclusive licenses or other rights being granted to the sponsoring companies, while others look for more general ideas than the Kaggle competitions and have the potential for the future negotiation of licenses, engagement for future research, or even employment for the winners.



CREATING CLINICAL TRIAL PROTOCOLS

Transparency Life Sciences (http://transparencyls.com) (or "TLS") is an all-digital clinical development services company seeking to increase efficiency and patient relevance in clinical trials. TLS uses crowdsourcing and mobile health technology (i) to create clinical trial protocols for client compounds using a proprietary, web-based software module called "Protocol Builder," and (ii) to conduct cost-reduced clinical trials using telemonitoring technologies that minimize the need for patient site visits and deliver more informative and relevant data than traditional trials. TLS uses crowdsourcing and open source models for protocol development and patient recruitment, and digitizing, within reason, every part of a clinical trial to reduce drug development costs while bolstering clinical trial quality and data. The company seeks crowd input from patients, doctors, and researchers to review, modify, and affirm the draft study parameters that the TLS team and its partners have formulated. Contributors are rewarded for participation and for selection of their ideas via elevation to leadership roles within the community, along with the potential opportunity to co-author scientific papers based

OPEN SOURCE PLATFORMS AND RESEARCH ARE GREAT FOR THE GENERAL ADVANCEMENT OF SCIENCE, YET THEY ARE NOT ALWAYS THE MOST PRACTICAL WAY FOR COMMERCIAL ENTITIES TO MAKE MONEY FROM THEIR RESULTS.

THE MEDICAL COMMUNITY AT LARGE HAS CREATED A NUMBER OF OPEN SOURCE PROGRAMS FOR THE RESEARCH AND DEVELOPMENT OF TREATMENTS FOR KEY CRITICAL DISEASES HAVING URGENT NEED FOR BETTER TREATMENTS.

on findings of the studies. Patients are motivated to contribute by the desire to make a difference for others dealing with their ailments, while researchers and prescribers with relevant ideas and opinions are given the opportunity to be heard in their fields, even if they are not the key opinion leaders biopharma sponsors typically consult. TLS is focused on transparency and open source access to its data and clinical results consistent with the needs and preferences of its clients. Ideally, the results of many of its trials will be available to the wider community to analyze, interpret, and use in research. Among other projects, TLS has worked in collaboration with Genentech to conduct a pilot study of inflammatory bowel disease patients and with Auven Therapeutics to develop the compound Kiacta for the rare medical condition, pulmonary sarcoidosis.

DEVELOPING TREATMENTS FOR CHALLENGING MEDICAL CONDITIONS

The medical community at large, sponsored generally by public health entities and organizations like Doctors Without Borders, has created a number of open source programs for the research and development of treatments for key critical diseases having urgent need for better treatments. A group formed in 2014, Open Source Pharma Foundation (http://www.opensourcepharma.net), has been pushing to create the "Linux for Drugs" model for development of affordable pharmaceuticals for poorly served conditions. Their website is a wealth of information, and their collaborative foundation represents input from across the life sciences spectrum from Doctors Without Borders to governmental institutions to commercial pharmaceutical companies.

There are also specific programs aimed at finding cures for specifically identified poorly served conditions. One good example of such a program is Open Source Malaria (http://www.opensourcemalaria.org). The Open Source Malaria program uses a distributed collaborative research model with an open "to do list" with details of all aspects of research the program needs. Tasks range from the very simple to the much more complex, and contributors have ranged from researchers to primary school classes. All research results are made public in the spirit of open source innovation, and researchers are unpaid, instead participating in research for the greater good. It will be interesting to see in the future what results come of such open source development without the traditional commercial drivers motivating development.

INTELLECTUAL PROPERTY IMPLICATIONS

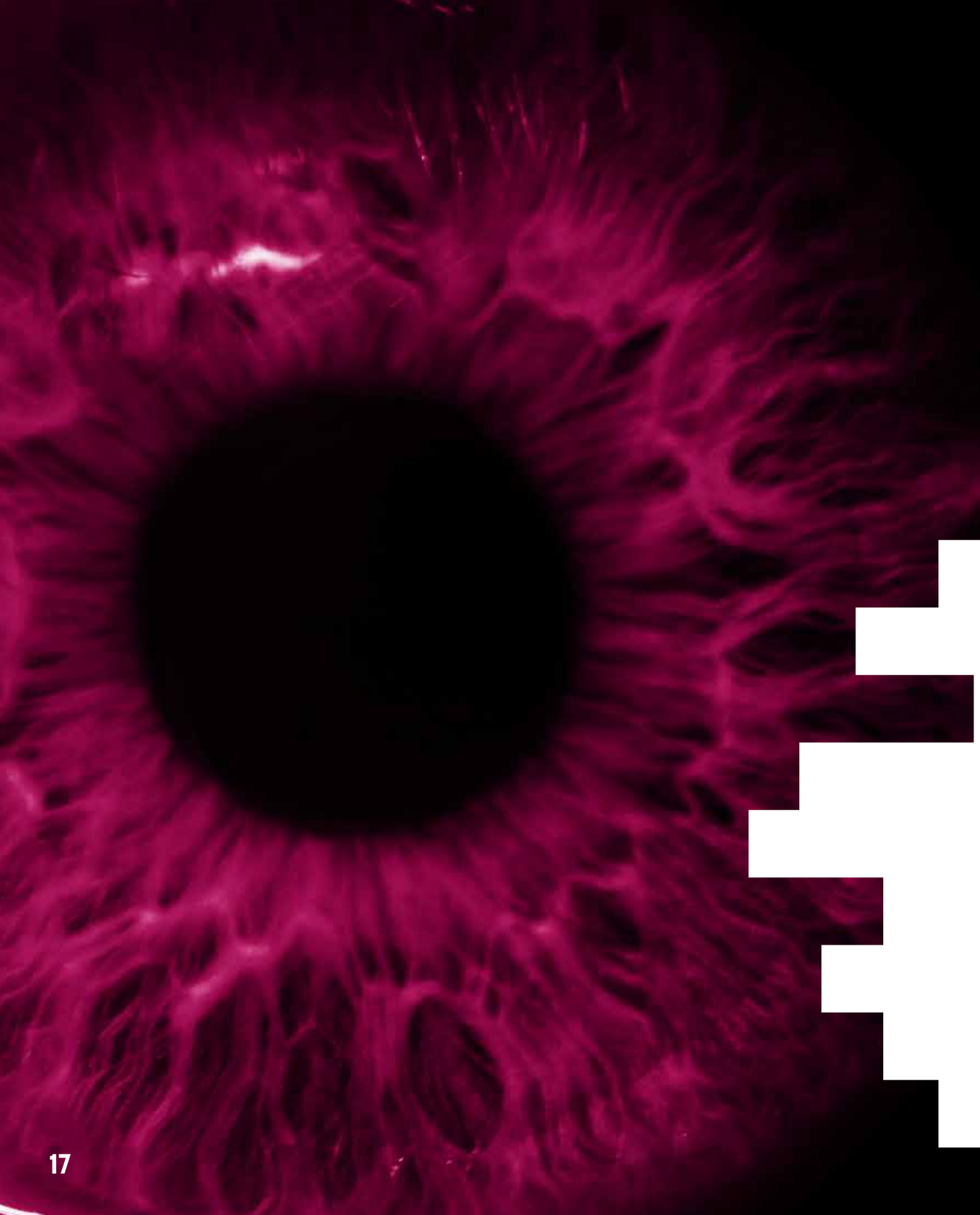
Crowdsourced and open source models of research come in so many variations that there is no simple explanation for what they mean in a legal context. Open source models can have all research results made public with the requirement that any derivative works also be made public. Even so, there are possibilities for commercial entities to pick up some of the open source data to create proprietary products from which they will profit. Crowdsourced models similarly can be either competitions, where results are owned by the sponsors and research is paid for via prize money, or other models, where the sponsors only gain non-exclusive licenses or rights to negotiate licenses to the results and all potential solutions are publicly shared.

POSSIBILITIES FOR THE FUTURE

The use of open source and crowdsourced models in the development of pharmaceutical and other life sciences products is very new. What drug development may look like in the not-too-distant future will likely largely depend on the success of these early projects. Still-open questions include how motivated researchers will stay when they are working for uncertain prize money or the greater good of humanity rather than a set wage, and how companies will make it financially worthwhile to pick up products that may have incredible promise but open data and no mechanism for launching in a brand form, the way pharmaceutical companies traditionally recoup their development expenses. There are many ways that the future could unfold in this space, and it will be very interesting to see the course that pharmaceutical research takes through these new waters.

1. *See, e.g.*, Matthew Herper, *The Cost of Creating a New Drug Now $5 Billion, Pushing Big Pharma to Change*, Forbes (Aug. 11, 2013, 11:10 AM), https://www.forbes.com/sites/matthewherper/2013/08/11/how-the-staggering-cost-of-inventing-new-drugs-is-shaping-the-future-of-medicine/#38c780a13c33; Joseph A. DiMasi, Ph.D., Director of Economic Analysis at Tufts Center for the Study of Drug Development, *Innovation in the Pharmaceutical Industry: New Estimate of R&D Costs*, Address Before Tufts Center for the Study of Drug Development (Nov. 18, 2015), *available at* http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf.

CARA R. BAER



PHYSICIAN DEPOSITIONS:
WHO GOES FIRST?

It is generally agreed that damaging testimony from a treating physician can make or break a pharmaceutical or medical device case at trial. The treating physician typically represents the first factual link between plaintiff and any causation opinion regarding injury. Additionally, treating physician testimony that supports plaintiffs' causation theories could potentially allow plaintiffs to get over the *Daubert* hurdle.

Courts vary as to whether plaintiffs' lawyers are allowed to prepare and meet with these witnesses. Typically, contact by plaintiffs' lawyers with physicians is allowed, although defendants may be successful in limiting the contact or the use of documents during the contact. Even better, defendants may be permitted their own ex parte meeting with the physician. But if you are in a jurisdiction where the plaintiff is allowed unfettered contact with the treating physician, thereby increasing the likelihood of tainted testimony from the physician, the order of questioning in the treating physician's deposition becomes even more important.

Against this backdrop, pharmaceutical and medical device defense attorneys should consider whether the order of who deposes certain physicians can be maneuvered and used to our advantage. Here, we review the governing rules, sample orders, and analysis as a guide.

THE USE OF THE DEPOSITION AT TRIAL MAKES IT CRITICAL.

In federal court proceedings, the deposition may be your only shot to obtain favorable testimony from the treating physician. The use of depositions at trial, particularly videotaped ones, has become increasingly common. Rule 32 of the Federal Rules of Civil Procedure governs the use of a deposition at trial. Rule 32(a)(1) states:

> At a hearing or trial, all or part of a deposition may be used [when]... (A) the party was present or represented at the taking of the deposition or

IN MOST INSTANCES, THE PARTY WHO QUESTIONS FIRST AND NOTICES THE DEPOSITION, ALSO PAYS FOR THE DEPOSITION.

had reasonable notice of it; (B) it is used to the extent it would be admissible under the Federal Rules of Evidence if the deponent were present and testifying; and (C) the use is allowed by Rule 32(a)(2) through (8).[1]

Rule 32(a)(2) through (8) outlines various circumstances including: using a deposition to impeach a deponent or witness; an adverse party using, for any purpose, the deposition of a party, agent, or designee; and using a deposition of a witness who is later "unavailable," which includes a witness who resides more than 100 miles from the location of the hearing or trial. Rule 32 is significant in that it provides plaintiffs with the ability to present to jurors the deposition testimony of company agents and designees. Furthermore, in today's transient society, witnesses often reside more than 100 miles away from the location of trial. As such, parties can take advantage of Rule 32 and present significant portions of a case through videotaped deposition testimony.

The question remains: who goes first?

THE FEDERAL RULES DO NOT SPECIFY THE ORDER OF QUESTIONING.

In most instances, a party can depose almost anyone without leave of the court.[2] However, the Federal Rules do not provide specific guidance on the issue of which party questions the deponent first during the deposition. "Under the federal rules, a discovery priority is not [explicitly] established based upon which party noticed a deposition first, but rather, Rule 26(d) authorizes the court to order the sequence of discovery upon motion."[3] In other words, Rule 26 provides the court with great discretion in establishing the timing and sequence of discovery.[4] In exercising such discretion, "courts…faced with the question of priority have, in the main, concluded that the first party to serve a notice of deposition is entitled to priority of questioning at that deposition."[5]

In *Dargis v. Wyeth, Inc.*, the court faced the same issue, but with a twist.[6] In *Dargis*, both parties claimed priority to question the treating physicians during depositions. At the outset, the court recognized the custom and practice within the jurisdiction to allow the party who first noticed the deposition to assume priority in questioning. The court also recognized that other jurisdictions follow the same custom. But in *Dargis*, the parties noticed multiple treating physician depositions on the very same day. The court ultimately instituted a "draft-selection process" for the deponents that the parties simultaneously noticed (i.e., those noticed on the same day). The draft-selection process involved the parties alternating in selecting deponents for whom they would have priority in questioning. The selection process continued until all deponents whom the parties simultaneously noticed were selected.[7] Thus, while "first to notice" seems to be the general rule, courts have the authority to use creative devices to determine priority of questioning during a deposition.

MDLS AND THE POWER TO NEGOTIATE THE ORDER

In the ever-so-popular MDL proceedings, the parties typically negotiate, or the Court enters unilaterally, a Case Management Order (bellwether cases, depositions, or case work up protocol) that dictates which party proceeds first in depositions.

The provisions contained in these orders vary greatly. To demonstrate the great variety, below are different examples of these types of provisions:

IN RE ZOLOFT[8]: THE SEQUENCE DEPENDS ON WHO SELECTED THE CASE FOR WORK UP:

- Sequence of Examination of Non-Party Healthcare Provider Witnesses. **At depositions of healthcare providers in Discovery Group or Trial Pool cases selected by Plaintiffs**, plaintiffs will be the first questioner in depositions of prescribers and OBGYNs, and Pfizer will be the first questioner in depositions of all other healthcare providers. **At depositions of healthcare providers in Discovery Group or Trial Pool cases selected by Defendants**, defendants will be the first questioner in depositions of prescribers and OBGYNs, and plaintiffs will be the first questioner in depositions of all other healthcare providers.

IN RE XARELTO[9]: A MIX OF WHO SELECTED AND RANDOM SELECTION.

- Order of depositions. The order of deposition shall be plaintiff, prescriber, and treater, with the detail representative going before or after the treater as scheduling permits.
- Order of questioning. For detail representatives, plaintiffs first. For prescribers and treaters, as set forth on table below:
  - *Random selections – alternate defense first; plaintiff first*
  - *Defense selections – defense first*
  - *Plaintiff selections – plaintiff first*

IN RE BENICAR[10]: ALTERNATING ORDER

- Order of questioning. For detail representatives, plaintiff's counsel shall proceed first. For prescriber and treater depositions, the party shall alternate who leads off first as follows:
  - *Random selection – alternating defense first; plaintiff first*

IN RE FLUOROQUINOLONE[11]: ALTERNATING ORDER

- Depositions of Plaintiffs – Defendants shall have priority of examination in the deposition of any plaintiff in this MDL.
- Depositions of Plaintiffs' Healthcare Providers – Priority of examination at the depositions of the plaintiffs' healthcare providers, including prescribing and primary treating physicians, shall alternate between the parties.

WHO GOES FIRST MAY IMPACT THE OBLIGATION TO PAY THE PHYSICIAN'S DEPOSITION FEE

One thing to remember is payment to the treating physicians for the depositions. In most instances, the party who questions first and notices the deposition, also pays for the deposition. Provisions governing these types of logistics should also be included in the Case Management Order. In particular, defense counsel should protect the client by trying to negotiate for a provision by which all payments for physician depositions will be split evenly by the parties to avoid paying large costs for depositions that ultimately yield slanted testimony beneficial to the plaintiff.

In conclusion, defense counsel in pharmaceutical and medical device litigation are seeing more variation governing the order of questioning in treating physician depositions in the MDL and mass tort settings with bellwether procedures. There is certainly not a one-size-fits-all strategy, and reviewing various proposals to be creative as to what works best for the litigation is a worthwhile strategic exercise before entering into these types of orders.

1. Fed. R. Civ. P. 32(a)(1).
2. Fed. R. Civ. P. 30(a).
3. *Lumpkin v. Kononov*, 2013 WL 1343666, at *1 (N.D. Ind. Apr. 3, 2013) (holding that, although not prescribed by rule, "Generally, it is understood that the party who notices a deposition will have priority in asking questions, and that opposing counsel will have priority to question the other side's witnesses.").
4. Fed. R. Civ. P. 26(d).
5. *Schlein v. Wyeth Pharm,, Inc.*, 2012 WL 10359554, at *1, *2 (S.D. Ga. Dec. 13, 2012) (citing *Occidental Chem. Corp. v. OHM Remediation Servs.*, 168 F.R.D. 13, 14–15 (W.D.N.Y. 1996); *Smith v. Logansport Cmty. Sch. Corp.*, 139 F.R.D. 637, 642 (N.D. Ind. 1991)).
6. Dargis v. Wyeth, Inc., 2012 U.S. Dist. LEXIS 189881 (D. Minn. 2012).
7. *Id.*
8. Pretrial Order No. 30 at 4-5, *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, MDL No. 2342, 26 F. Supp. 3d 449 (E.D. Pa. June 27, 2013).
9. Pretrial Order No. 26 at 1-3, *In re Xarelto (Rivaroxaban) Prods. Liab. Litig.*, MDL No. 2592, 2016 WL 2855221 at *1 (E.D. La. April 20, 2016), http://www.laed.uscourts.gov/sites/default/files/xarelto/Pretrial%20Order_26.pdf SAME.
10. Case Management Order No. 7 at 2, *In re Benicar (Olmesartan Medoxomil)*, Case No: 299, (N.J. Super. Ct. Law Div.: Atlantic County Oct. 11, 2016), http://www.njcourts.gov/attorneys/assets/mcl/benicar/orders/cmo7.pdf.
11. Pretrial Order No. 9 on Fact Deposition Discovery at 16, *In re Fluoroquinolone Prods. Liab. Litig.*, MDL No. 2642 (JRT), Case No. 0:15-md-02642, (D. Minn. July 5, 2016), http://www.mnd.uscourts.gov/MDL-Fluoroquinolone/Orders_Minutes/2016/2016-0705-PTO-09-DepositionProtocol.pdf.

ALYSON B. JONES

ANDREW D. THARP

NEW AND NOTEWORTHY:

A JURISDICTIONAL TRIFECTA: THE SUPREME COURT RESTORES ORDER ON VENUE AND JURISDICTION

The Supreme Court has issued a trio of decisions this term signaling a tightening of limitations on courts' authority over out-of-state corporations. These opinions solidify that the once little-used doctrines of venue and personal jurisdiction are now important tools for defendants seeking to stave off forum-shoppers.

TC HEARTLAND LLC V. KRAFT FOOD GROUP BRANDS LLC.

137 S. Ct. 1514 (May 22, 2017). In this 8-0 opinion authored by Justice Thomas (Justice Gorsuch was not yet on the Court when the case was argued), the Court reversed the Federal Circuit's decision that a corporation may be sued for patent infringement wherever it is subject to personal jurisdiction. This had been the Federal Circuit's position on the issue for nearly 30 years.

The patent venue statute at issue, 28 U.S.C. § 1400(b), provides that "[a]ny civil action for patent infringement may be brought in the judicial district where the defendant resides, or where the defendant has committed acts of infringement and has a regular and established place of business." Fifty years ago, the Supreme Court determined that for purposes of this statute, a domestic corporation "resides" only in the state where it is incorporated.[1]

Since that time, § 1400(b) has not been amended, but the general venue statute, 28 U.S.C. § 1391(c), has been amended twice to state a broader interpretation of "residence." Section 1391 now states that "[e]xcept as otherwise provided by law" and "[f]or all venue purposes," a corporation "shall be deemed to reside, if a defendant, in any judicial district in which such defendant is subject to the court's personal jurisdiction with respect to the civil action in question."[2]

In *TC Heartland*, the Federal Circuit below concluded that the § 1391(c) amendments effectively amended § 1400(b). The Supreme Court rejected that view, finding no basis in the statute for that conclusion, noting that "[w]hen Congress intends to effect a change of that kind, it ordinarily provides a relatively clear indication of its intent in the text of the amended provision."

The Court reaffirmed its holding in *Fourco* fifty years ago: For domestic corporations "residen[ce]" in § 1400(b) means only state of incorporation.

BNSF RAILWAY CO. V. TYRRELL.

137 S. Ct. 1549 (May 30, 2017). In this 8-1 decision, the Supreme Court reversed the Montana Supreme Court's finding of personal jurisdiction over railroad BNSF Railway Co., reaffirming its test for general jurisdiction stated three years earlier in *Daimler AG v. Bauman*.

In *BNSF*, the plaintiffs—one a North Dakota resident and the other an estate administrator appointed in South Dakota—had filed suit against BNSF under the Federal Employers' Liability Act (FELA) in Montana, even though the plaintiffs did not live in Montana, did not work in Montana, and did not allege any injuries related to Montana. BNSF is incorporated in Delaware with its principal place of business in Texas.

In the opinion authored by Justice Ginsburg, the Court found there was no personal jurisdiction over the claims. First, the Court held that FELA does not address personal jurisdiction of state courts. The Court then addressed the remaining argument: whether general personal jurisdiction comports with due process. On this point, the plaintiffs in *BNSF* contended that BNSF was subject to general jurisdiction in Montana based on its extensive business contacts in Montana. BNSF has over 2,000 miles of railroad track and more than 2,000 employees in the State of Montana. The Supreme Court held the exercise of personal jurisdiction under these circumstances does not comport with due process, reaffirming its decisions in *Goodyear* and *Daimler*.[3]

Under *Goodyear* and *Daimler*, a corporation is only subject to general personal jurisdiction in the state of its incorporation or its principal place of business, or in exceptional cases, where the operations in another forum are so substantial that the corporation is essentially "at home" in that other state. Though BNSF certainly did substantial business in Montana, general jurisdiction is not about quantity, but rather "calls for an appraisal of a corporation's activities in their entirety" to determine where the company is "at home."[4] A corporation that does business in many states cannot be considered "at home" in each of them.

With *BNSF*, the Supreme Court made clear that Daimler's holding is not limited to its facts. Rather, *Daimler* "applies to all state-court assertions of general jurisdiction over nonresident defendants; the constraint does not vary with the type of claim asserted or business enterprise sued."[5] And *Daimler* means exactly what it says: a corporation is only subject to general personal jurisdiction where it is "at home"—typically, only in its principal place of business and state of incorporation.

BRISTOL-MYERS SQUIBB V. SUPERIOR COURT OF CALIF.

No. 16-466, ____ S. Ct. ____, 2017 WL 2621322 (June 19, 2017). In this 8-1 decision authored by Justice Alito, the Supreme Court reversed the California Supreme Court's finding of specific personal jurisdiction over non-California residents' claims in that state.

In *Bristol-Myers Squibb*, more than 600 plaintiffs from around the country joined together to file suit in California, all alleging injuries related to the drug Plavix, sold by defendant Bristol-Myers Squibb. Bristol-Myers Squibb is incorporated under the laws of the State of Delaware and has its principal place of business in New York. Plaintiffs also sued McKesson Corporation, a California distributor of Plavix.

The California Supreme Court ruled that there was no general personal jurisdiction over Bristol-Myers Squibb under *Daimler*, but found that there was specific jurisdiction based on the company's activities in the state.

The Supreme Court reversed, finding that "settled principles regarding specific jurisdiction control this case."[6] The Court rejected California's "sliding scale" test for specific jurisdiction, instead reaffirming the traditional test: "In order for a court to exercise specific jurisdiction over a claim, there must be an 'affiliation between the forum and the underlying controversy, principally, [an] activity or an occurrence that takes place in the forum State.'"[7]

The Court also clearly established that personal jurisdiction must be established by **each** plaintiff as to **each** defendant. Thus, the fact that the non-California plaintiffs had joined with California plaintiffs to file suit did not extend personal jurisdiction: Each plaintiff had to establish jurisdiction independently. Nor did the presence of McKesson Corporation create jurisdiction, as the requirements of personal jurisdiction must be met as to **each** defendant.

In sum, under the facts of *Bristol-Myers Squibb*, the plaintiff had two and only two options for suing the company in state court: (1) his or her home state, (2) the defendant's home state. Anywhere else would be a violation of due process.

1. *Fourco Glass Co. v. Transmirra Products Corp.*, 353 U.S. 222, 226 (1957).
2. 28 §§ 1391(a), (c).
3. *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014); *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 564 U.S. 915, (2011).
4. BNSF Ry. Co., 137 S. Ct. at 1559 (quoting *Daimler*, 134 S. Ct. at 762 n.20).
5. Id. at 1553.
6. *Bristol-Myers Squibb Co. v. Superior Ct. of Calif.*, 2017 WL 2621322, at *7 (U.S. June 19, 2017).
7. *Id.* (quoting *Goodyear*, 564 U.S. at 919).

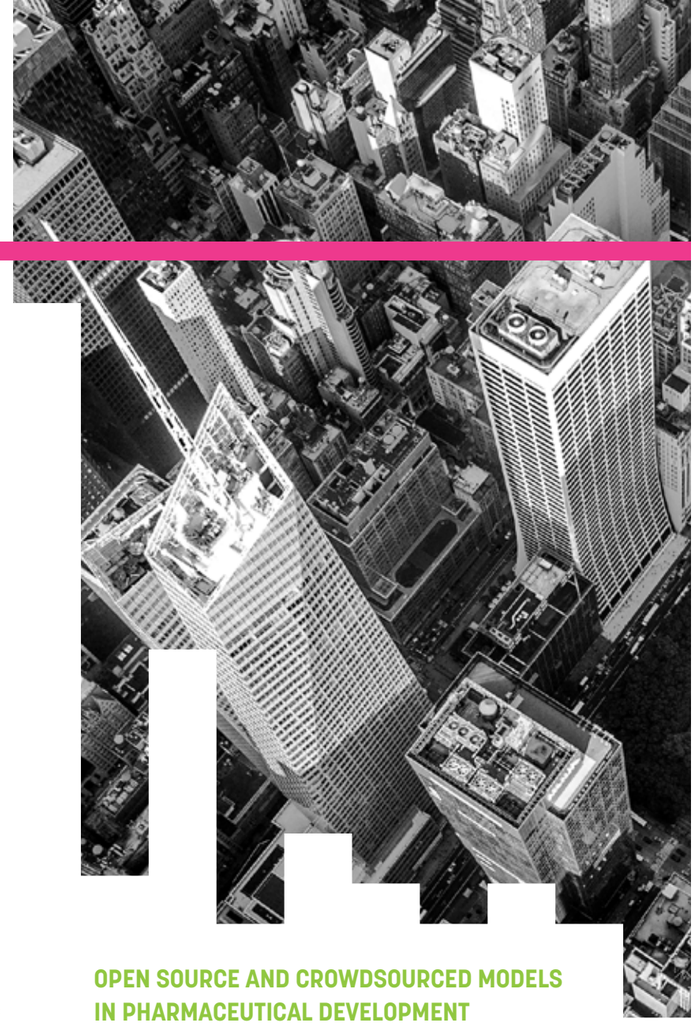
SUSANNA M. MOLDOVEANU

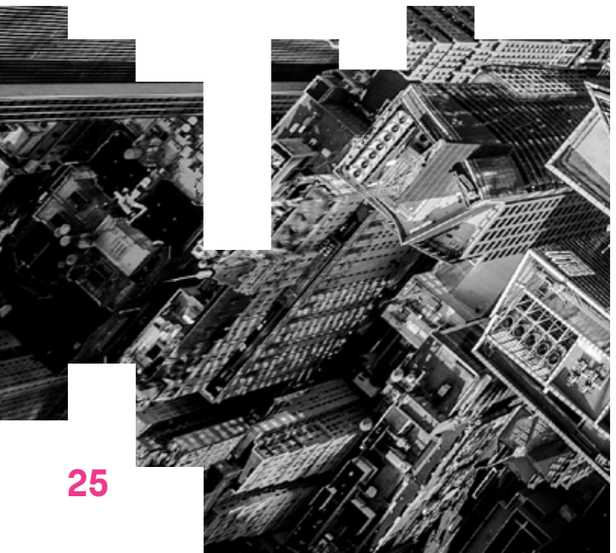
BIOS:

THE THREE C'S

WILLIAM M. GAGE

William Gage is a trial attorney with twenty-seven years' experience in drug and medical device, product liability, and personal injury litigation. He has served as statewide coordinating counsel for the Wyeth diet drug litigation, and more recently, as trial counsel in the New Jersey Accutane litigation. William currently serves as lead trial counsel on behalf of several defendants in the pelvic mesh litigation. William has tried six mesh cases to verdict over the past four years, which include defense verdicts in the Philadelphia Court of Common Pleas (June 2017) and in state court in Dallas, Texas (October 2015). The Texas trial was one of *Law360*'s 2015 Product Liability Trials to Watch and the subsequent verdict was named as one of CVN's "Top 10 Defense Verdicts of 2015." William is the past Litigation Department Chair and former Practice Group Leader for Butler Snow's Pharmaceutical and Medical Device Practice group. He is a member of the Defense Research Institute (DRI), the Mississippi Defense Lawyers Association, and the International Association of Trial Lawyers. William is recognized by *The Best Lawyers in America®, Mid-South Super Lawyers®, Who's Who Legal – Product Liability Defence, Benchmark Litigation* as a "Litigation Star," and is a graduate of the International Association of Defense Counsel's Trial Academy.





OPEN SOURCE AND CROWDSOURCED MODELS IN PHARMACEUTICAL DEVELOPMENT

CARA R. BAER

Cara Baer focuses her practice on transactions for life sciences companies and intellectual property counseling, and she works with some of the world's largest pharmaceutical, medical device, and biopharmaceutical corporations, facilitating business and commercial transactions and joint ventures and strategic collaborations. In addition to her transactional practice, she is experienced in the negotiation and drafting of drug and device development, manufacturing, and products supply agreements. She also assists clients in formulating their international intellectual property strategies including trademark clearance, filing, and protection as well as IP licensing. She has been published in *Intellectual Property Litigation*, *Law360*, and *Pointe Innovation*, and has published a chapter in Aspatore's book, *Inside the Minds: Navigating Legal Issues in the Biotechnology Industry*.

PHYSICIAN DEPOSITIONS: WHO GOES FIRST?

ALYSON B. JONES

Alyson Jones, Practice Group Leader of Butler Snow's Pharmaceutical, Medical Device, and Healthcare Group, focuses her practice on defending pharmaceutical and medical device manufacturers in product liability litigation, and she has particular expertise in the management and coordination of complex multi-district litigation. Alyson's recent experience includes serving as national coordinating counsel for several international pharmaceutical manufacturers managing nationwide litigation involving thousands of lawsuits. She is a member of the 2017-2018 Next Generation Board for The Institute for Complex Litigation and Mass Claims at Emory University School of Law, a contributing editor to the Duke Law Institutes Updated Standards and Best Practices for Large and Mass-Tort MDLs, recognized as a *Mid-South Rising Star®*, and a graduate of the International Association of Defense Counsel's Trial Academy.

ANDREW D. THARP

Andrew Tharp has extensive litigation experience with more than 35 federal trials, and he was consistently ranked one of the top litigators in the United States Air Force. He has represented more than 800 clients in federal criminal investigations and disciplinary actions.

NEW AND NOTEWORTHY

SUSANNA M. MOLDOVEANU

Susanna Moldoveanu focuses her practice on drug and medical device litigation and appellate litigation. She has appeared before the Fourth, Fifth, Sixth, and Seventh Circuit Courts of Appeals.