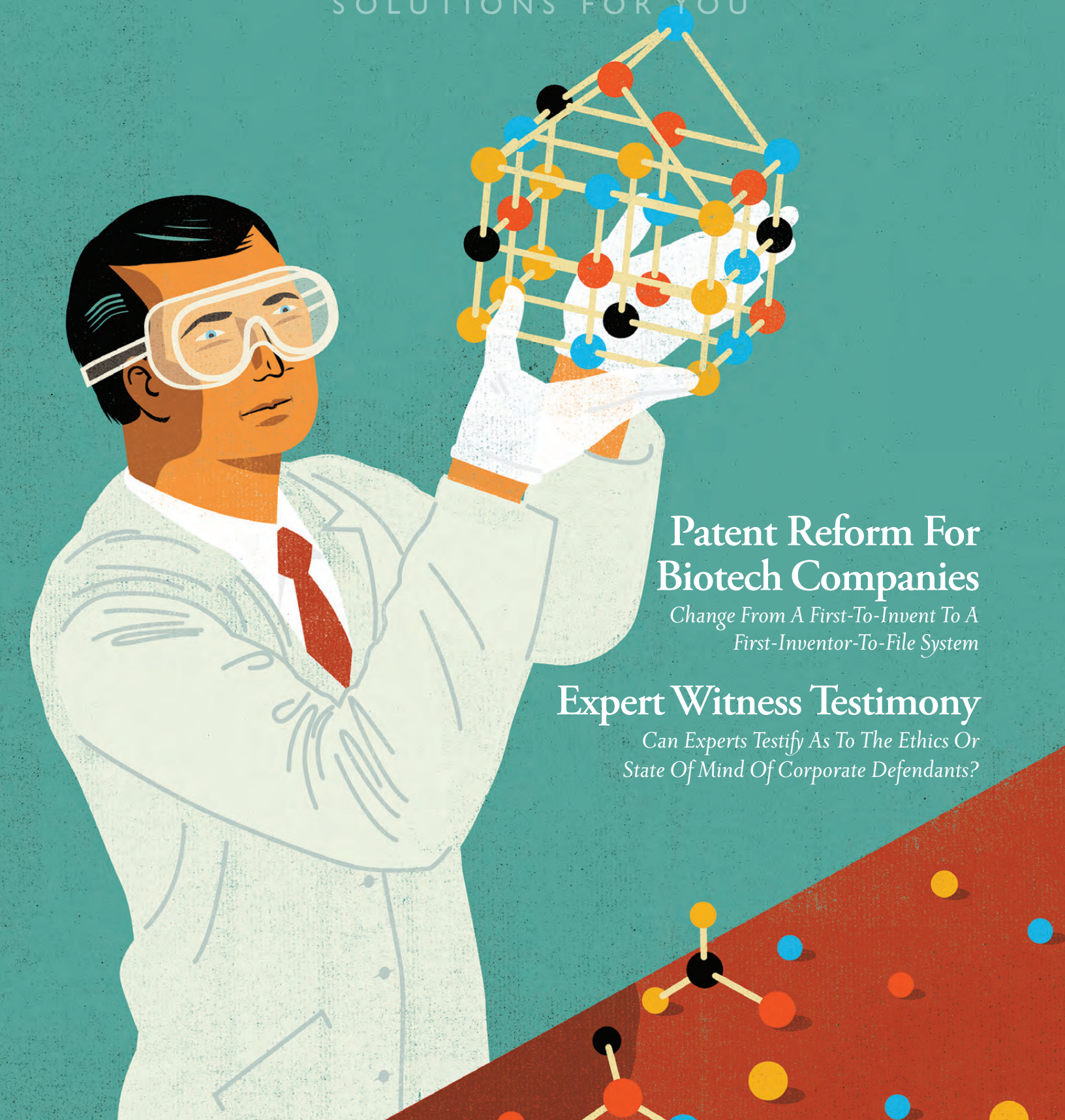
Vol. 6 No. 1 February 2013

Pro Te: *Solutio*

SOLUTIONS FOR YOU



Patent Reform For Biotech Companies

Change From A First-To-Invent To A First-Inventor-To-File System

Expert Witness Testimony

Can Experts Testify As To The Ethics Or State Of Mind Of Corporate Defendants?

Dear Client:

Complaints about the U.S. patent system have been growing over the last decade, and Congress responded with the first significant changes to the patent system in sixty years in passing the Leahy-Smith America Invents Act. *Patent Reform for Biotech Companies* addresses how the new law may affect your business.

Off-label prescription of pharmaceuticals by doctors is prevalent and acknowledged as appropriate by the FDA. However, off-label promotion of a pharmaceutical by the company that manufactures it has led to criminal and civil actions against the company. Huge fines have been paid by pharmaceutical companies to settle such claims. *United States v. Caronia and its Implications for Off-label Marketing of Pharmaceuticals* discusses whether, in the future, pharmaceutical manufacturers might be able to promote scientifically supported off-label benefits of their products.

Your company is in court and the person testifying about your company's ethics and state of mind is the plaintiff's expert! Can you prevent those experts from presenting themselves as mind readers? *Can Experts Testify as to the Ethics or State of Mind of Corporate Defendants?* provides some tips and case law to deal with this tactic.

We hope this issue gives you some information relevant to the challenges you face every day.

Christy D. Jones
Co-Chair — Litigation

Charles F. Johnson
Co-Chair —
Business and Corporate Healthcare

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Sharing Solutions

It's human nature to share problems. But how often is someone willing to share solutions? Butler Snow wants to do just that — provide scenarios and the solutions that turned a client's anxiety into relief and even triumph. That's why we created this magazine, *Pro Te: Solutio*, which explores how real-life legal problems have been successfully solved.

That's also why we at Butler Snow redesigned and expanded our unique health-oriented industry group, now comprised of two major sections that handle business and litigation. The Pharmaceutical, Medical Device, and Healthcare Industry Group has more than 50 multi-disciplinary attorneys who provide creative solutions for the complex issues of the healthcare industry. This group includes product liability and commercial litigators; corporate, commercial, and transaction attorneys; labor and employment attorneys; intellectual property attorneys; and those experienced in government investigations.

Pro Te: Solutio is a quarterly magazine available only to the clients of Butler Snow. If you have questions or comments about its articles, you're invited to contact Christy Jones and Charles Johnson, as well as any of the attorneys listed on the last page of this publication.

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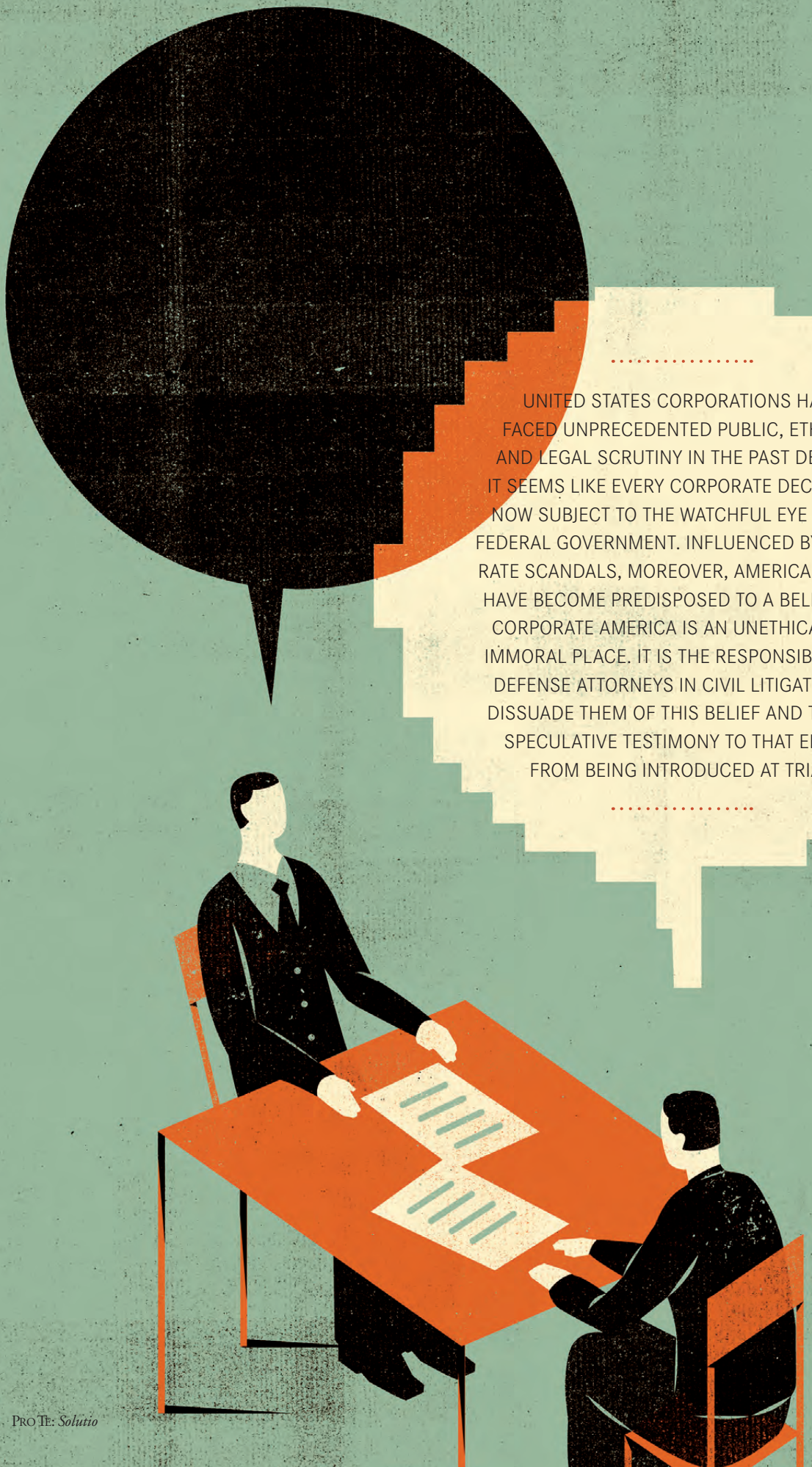
UNITED STATES CORPORATIONS HAVE FACED UNPRECEDENTED PUBLIC, ETHICAL, AND LEGAL SCRUTINY IN THE PAST DECADE. IT SEEMS LIKE EVERY CORPORATE DECISION IS NOW SUBJECT TO THE WATCHFUL EYE OF THE FEDERAL GOVERNMENT. INFLUENCED BY CORPORATE SCANDALS, MOREOVER, AMERICAN JURIES HAVE BECOME PREDISPOSED TO A BELIEF THAT CORPORATE AMERICA IS AN UNETHICAL AND IMMORAL PLACE. IT IS THE RESPONSIBILITY OF DEFENSE ATTORNEYS IN CIVIL LITIGATION TO DISSUADE THEM OF THIS BELIEF AND TO KEEP SPECULATIVE TESTIMONY TO THAT EFFECT FROM BEING INTRODUCED AT TRIAL.



CAN EXPERTS TESTIFY AS TO THE ETHICS OR STATE OF MIND OF CORPORATE DEFENDANTS?

In pharmaceutical litigation, plaintiffs routinely seek the admission of expert testimony as to what constitutes ethical or moral conduct for a pharmaceutical company as well as the motive, intent, and state of mind of company employees. These experts seek to opine that the pharmaceutical company endangered public safety by misrepresenting or not disclosing information. Or to allege that the pharmaceutical company did not perform scientific studies, or if it did conduct studies, that the company concealed or mischaracterized the studies' results. These experts also purport to "know" that prescribing physicians and/or the public would have acted differently if the pharmaceutical company had been truthful. This type of corporate ethical conduct testimony is offered only to elicit an emotionally charged response and thereby prejudice the jury against the pharmaceutical company.

Courts trying drug and medical device cases have generally held corporate ethical conduct testimony inadmissible under *Daubert v. Merrell Dow Pharms. Inc.*, 509 U.S. 579 (1993), its state counterpart, and other evidentiary rules, which require that experts be qualified and that their opinions be reliable, relevant, and the product of specialized knowledge based on sufficient facts and data. Such opinions, moreover, should be helpful to the trier of fact, proper subjects of expert opinions, and not unfairly prejudicial.

BASIS FOR CHALLENGING PLAINTIFFS' EXPERT WITNESS ETHICAL CONDUCT TESTIMONY

Because of the speculative, irrelevant, and potentially prejudicial and confusing nature of these types of opinions, they are

ripe for a preemptive *Daubert* challenge. Typically, the starting point for this analysis is Federal Rule of Evidence (FRE) 702 (or its state counterpart) and the standards set forth in *Daubert*. FRE §702 provides that "if scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue," a witness who has been properly qualified as an expert may offer opinion testimony only if: "1) the testimony is based upon sufficient facts or data; 2) the testimony is the product of reliable principles and methods; and 3) the witness has applied the principles and methods reliably to the facts of the case."[1]

Daubert states that trial court judges are responsible for ensuring expert testimony is based on reliable methodology and is applicable to the facts at issue. *Daubert* instructs federal judges to act as "gatekeepers" to avoid the presentation of subjective speculation.[2] Indeed, various jurisdictions have excluded corporate conduct, motive, and intent evidence under FRE 702 and *Daubert*.[3] This article will examine a number of the cases in which corporate conduct testimony was excluded.

EXPERT TESTIMONY AS TO THE ETHICS OF CORPORATE CONDUCT

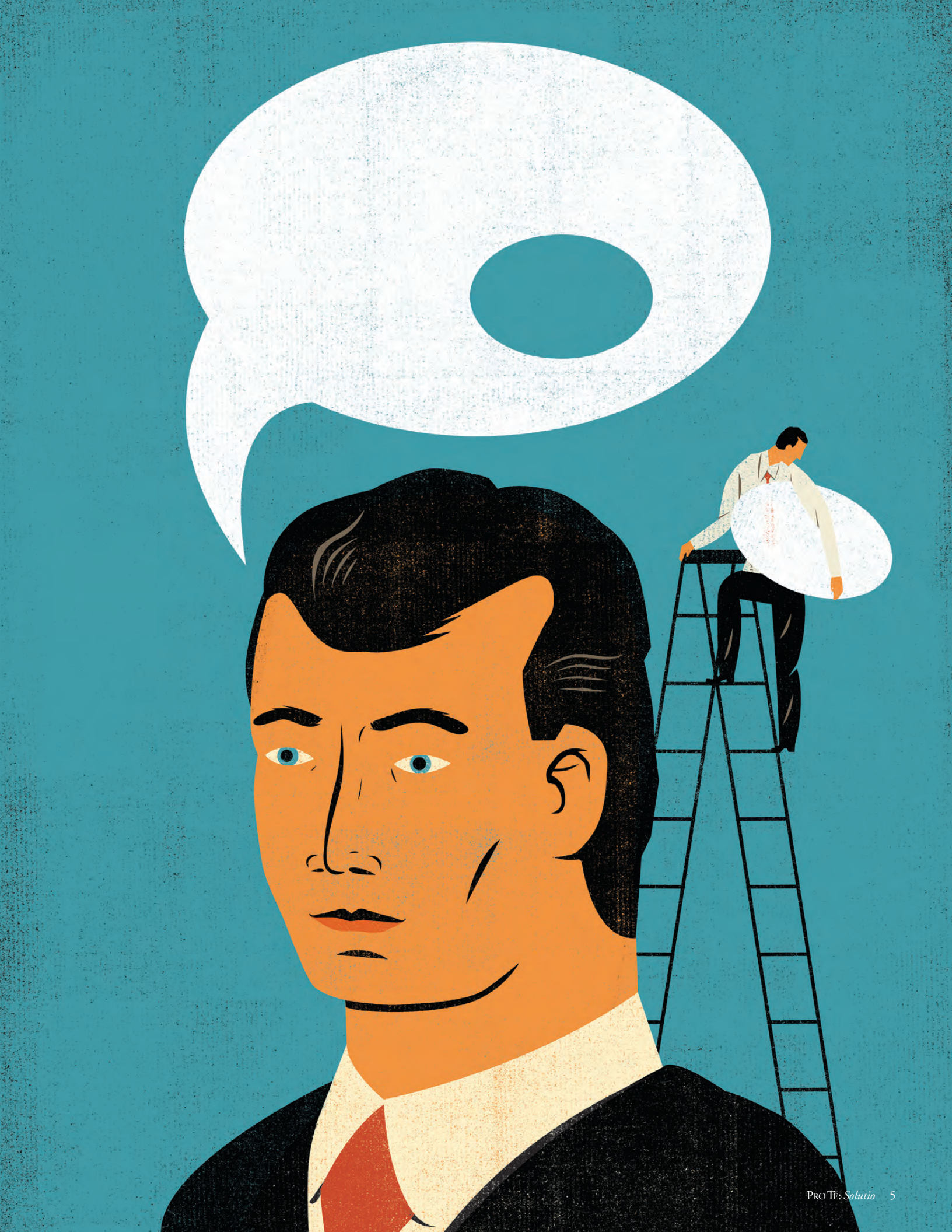
In *In re Rezulin Products Liability Litigation*, the court concluded that plaintiffs' experts' opinions concerning the ethical obligations and conduct of pharmaceutical companies were inadmissible, finding that the opinions were: 1) unreliable under Rule 702 and *Daubert* because they were not based on knowledge but instead on personal views; 2) irrelevant under Rule 702 and *Daubert*; and 3) likely to unfairly prejudice the jury by introducing the "experts' opinions and rhetoric concerning ethics as an alternative and improper grounds for decisions."[4]

In *In re Rezulin*, plaintiffs' clinical trial experts sought to opine that the companies failed to adequately disclose material facts about the drug to the FDA.[5] One of the experts admitted at deposition that he was not an expert on ethics, but that he nevertheless held an opinion about the behavior of pharmaceutical companies.[6] Another expert admitted that his opinion on ethics was a personal belief.[7] The court excluded the clinical trial experts' testimony, finding that the experts were "unqualified to testify about the facts of the disclosures to the FDA because they lack firsthand knowledge of the fact underlying their opinion.[8] The court also found that experts' ethics opinion testimony "based on their personal, subjective views" was also irrelevant because "[w]hile the [pharmaceutical company] may be liable in the court of public opinion, or before a divine authority for their ethical lapses, expert opinion as to the ethical character of their action simply is not relevant to these lawsuits."[9] In analyzing Rule 403,[10] the court concluded that allowing expert witnesses to offer what amounted to personal opinions of corporate behavior would be confusing and unfairly prejudicial because the jury might base its decision on those ethical standards rather than the pertinent legal standard.[11]

As to plaintiffs' regulatory expert, the court excluded his narrative testimony on the "history of Rezulin" and actions taken by the pharmaceutical company with respect to Rezulin.[12] In looking at the substance of the expert's testimony, the court observed:

> [The] history of Rezulin is merely a 'narrative of the case which a juror is equally capable of constructing' […] Such material, to the extent it is admissible, is properly presented through percipient witnesses and documentary evidence [.... T]he glosses that [the witness] interpolates into his narrative are simple inferences drawn from uncomplicated facts that serve only to buttress plaintiffs' theory of the case. As plaintiffs' Rezulin 'historian,' therefore, [the witness] does no more than counsel for plaintiff will do in argument, i.e., propound a particular interpretation of [the company's] conduct.[13]

PLAINTIFFS IN PHARMACEUTICAL LITIGATION WILL OFTEN SEEK TO PRESENT EXPERT TESTIMONY AS TO HOW DEFENDANT'S CONDUCT WAS UNETHICAL AND/OR SPECULATE AS TO DEFENDANT'S STATE OF MIND OR INTENT. DEFENSE COUNSEL SHOULD CLOSELY READ AN EXPERT'S REPORTS FOR ANY OPINIONS REGARDING CORPORATE INTENT AND ADDRESS SUCH ISSUES WITH THE EXPERT AT DEPOSITION. A MOTION TO EXCLUDE SUCH TESTIMONY SHOULD BE CONSIDERED SO THAT THE JURY HEARS ONLY RELIABLE AND RELEVANT EXPERT TESTIMONY OFFERED BY QUALIFIED WITNESSES.



Thus, the court held the expert's testimony regarding the "history of Rezulin" was inadmissible.[14]

In re Rezulin demonstrates that there are two types of conduct evidence that plaintiffs routinely seek to have admitted in pharmaceutical litigation: opinions about whether the pharmaceutical company acted ethically and opinions that provide some sort of narrative of facts, with expert commentary on selected regulatory and corporate documents.

Similarly, in *In re Trasylol Products Liability Litigation*, the Southern District of Florida excluded plaintiffs' expert testimony regarding ethical conduct finding that the opinion was a reflection of the expert's "own subjective beliefs and personal views and [did] not rest on knowledge as required by Rule 702."[15] Plaintiffs' corporate conduct expert opined that the pharmaceutical company breached "ethical standards" for failing to respond to "safety signals" regarding the drug Trasylol.[16] The expert's deposition made clear that his opinion was not based on "scientific, technical, or other specialized knowledge."[17] The court looked at the substance of the expert's testimony and found that he was offering an opinion about what the pharmaceutical company should have done to comply with drug safety principles.[18] The expert conceded that he was not an expert in corporate ethics and testified, "The average lay person could have some opinions about corporate ethics."[19] He also acknowledged that his opinion was not based on FDA regulations or guidelines:

> Just because I can't name these guidelines doesn't mean they don't exist. I think that they probably do exist, but whether they exist or not, any reasonable person who saw a safety signal with a drug would want to pursue that to ensure the patient's safety is ensured. It's, you know, common sense. If you ask a man on the street about this they would say: Yes, I want to know whether this drug is harmful to me. And it's the responsibility of the drug company to do that.[20]

Largely following the ruling of/in *In re Rezulin*, the court found the expert's opinions on corporate ethics inadmissible because they were based only on his subjective beliefs rather than expert knowledge.[21]

The court also addressed the expert's narrative of the regulatory documents.[22] Most of the expert's testimony, the court determined, "did not involve any regulatory analysis and instead consisted of conclusions made from a review of the regulatory history and [the pharmaceutical company's] internal documents […] An instance [the court] found particularly egregious was [the expert's] apparent effort to construct a factual scenario, entirely divorced from any regulatory expertise, to support the plaintiffs' theory as to the [pharmaceutical company's] knowledge."[23]

The court concluded that plaintiffs' expert was an advocate "presented with the trappings of an expert but with no expectation or intention of abiding by the opinion constraints of Rule 702. She comes armed with a Report designed to be broad enough to allow her to gather and stack inference upon inference in order to offer her 'takeaway' or 'take home message' with respect to intent, knowledge, or causation in a manner unrelated to regulatory expertise. Her testimony is unreliable and would not be of assistance to the jury."[24]

The Eastern District of Arkansas was confronted with a similar situation in *In re Prempro Products Liability Litigation*.[25] There, plaintiff put forth three corporate conduct experts to testify that the pharmaceutical companies violated various standards of care, including an alleged FDA "standard of reasonable care."[26] At a *Daubert* hearing, plaintiff's counsel could not provide a defined standard of reasonable care in industry custom and practice once a drug has been approved by the FDA and placed on the market.[27]

MANY PLAINTIFFS' EXPERTS WANT TO TESTIFY ABOUT WHAT THE PHARMACEUTICAL COMPANY KNEW, WHAT ITS INTENTIONS WERE, AND OTHER MATTERS THAT REFLECT CORPORATE STATE OF MIND. COURTS HAVE HELD THAT "STATE OF MIND TESTIMONY" IS IMPROPER BECAUSE IT DESCRIBES LAY MATTERS WHICH A JURY IS CAPABLE OF UNDERSTANDING AND DECIDING WITHOUT AN EXPERT'S HELP.

In excluding the experts, the court stated, "Plaintiff's counsel admitted the standard could be different in every circumstance — therein lies the rub — there is no set standard."[28] The court also added that the "witnesses' proposed expert testimony is not expert in nature because plaintiff is unable to point to the existence of a reasonable standard of care or a custom and practice established by either industry or governmental standards […plaintiff's experts] cannot be qualified as experts simply to testify what they believe [the companies] could have done versus what they should have done."[29] The court held that because plaintiff could not show some objective validation, plaintiff's corporate conduct

witnesses could not be permitted to testify as experts.[30]

EXPERTS AS "MIND READERS"

Many plaintiffs' experts want to testify about what the pharmaceutical company knew, what its intentions were, and other matters that reflect corporate state of mind. Courts have held that "state of mind testimony" is improper because it describes lay matters which a jury is capable of understanding and deciding without an expert's help.[31] Courts, like the Southern District of New York in *In re Fosamax Prods. Liability Litigation*, have excluded testimony about a company's knowledge, motives, or state of mind as speculative; beyond the scope of proper expert testimony; and inadmissible under FRE 702.[32] In particular, the court in *In re Fosamax* held that plaintiff's expert testimony as to corporate motives and state of mind was "conjecture […and] not a proper subject for expert or even lay testimony.[33]

In *Jenkins v. Novartis*, the most recent decision handling the subject of corporate state of mind testimony, plaintiffs proffered an expert to testify as to corporate conduct, about FDA standards, and whether the company failed to adequately disclose material facts to the FDA.[34] Although the court acknowledged that plaintiffs' regulatory expert was qualified in her field, it nevertheless found her unqualified to discuss corporate state of mind.[35] The court observed that the expert's discipline does not "provide her with a superior ability to judge [the pharmaceutical company's] knowledge, and there is no basis for finding that the jury needs her assistance in evaluating [the company's] knowledge."[36]

SOLUTIONS

The case law above regarding corporate conduct demonstrates that issues of corporate ethics and other matters that reflect corporate state of mind are non-scientific and non-technical matters that are within the common understanding of jurors. Various jurisdictions have properly held that expert testimony on these issues is improper because few, if any, experts called in pharmaceutical litigation can qualify as experts on corporate intent and decision-making. Plaintiffs in pharmaceutical litigation will often seek to present expert testimony as to how defendant's conduct was unethical and/or to speculate as to defendant's state of mind or intent. Defense counsel should closely read an expert's reports for any opinions regarding corporate intent and address such issues with the expert at deposition. A motion to exclude such testimony should be considered so that the jury hears only reliable and relevant expert testimony offered by qualified witnesses.

[1] Fed. R. Evid. § 702.

[2] *See generally Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993).

[3] *See In re Trasylol Prods. Liab. Litig.* 2010 U.S. LEXIS 14222, * at 169 (S.D. Fla. Feb. 24, 2010); *In re Fosamax Prods. Liab. Litig.*, 645 F.Supp.2d 164, 192 (S.D.N.Y. 2009); *In re Rezulin Prods. Liab. Litig.*, 309 F.Supp.531, 543-47 (S.D.N.Y. 2004).

[4] *In re Rezulin Prods. Liab. Litig.*, 309 F.Supp.2d 531, 543-47 (S.D.N.Y. 2004) (citations omitted).

[5] *Id.* at 547.

[6] *Id.* at 543, fn. 27.

[7] *Id.*

[8] *Id.* at 549.

[9] *Id.* at 544.

[10] Rule 403 of the Federal Rules of Evidence states, "Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." Fed. R. Evid. § 403.

[11] *In re Rezulin*, 309 F.Supp.2d at 545 (acknowledging risk that legal standard of care and purported ethical standard will be "blurred").

[12] *Id.* at 553.

[13] *Id.* at 551-52.

[14] *Id.*

[15] *In re Trasylol Prods. Liab. Litig.*, 2010 U.S. LEXIS 142228, at *169 (S.D. Fla. Feb. 24, 2010)(citing *In re Rezulin*, 309 F.Supp.2d at 544).

[16] *Id.* at *160-*61.

[17] *Id.* at *170.

[18] *Id.* at *168.

[19] *Id.* at *170 (citation omitted).

[20] *Id.* at *171-*172.

[21] *Id.* at *173. "Despite Plaintiffs' argument that the opinion at issue is not an ethical opinion because [the witness] does not use the word 'ethical' or 'unethical' in his Report […] this Court will consider [its] substance. […]. Much of the testimony in dispute relates to [defendant's] responsibilities, the studies that [it] should have done to comply with drug safety principles, and the issues that [defendant] should have addressed earlier than it did. The Court finds that this proffered testimony is akin to the ethics testimony found to be inadmissible in Rezulin. […]. The Court finds this testimony inadmissible because it is a reflection of [the witness'] own subjective beliefs and personal views and does not rest on knowledge as required by Rule 702." *Id.* at *168-*69. See also *In re Baycol Prods. Liab. Litig.*, 532 F.Supp.2d 1029, 1053 (D. Minn. 2007) ("Personal views on corporate ethics and morality are not expert opinions").

[22] *In re Trasylol Prods. Liab. Litig.*, 709 F.Supp.2d 1323, 1329 (S.D. Fla. 2010).

[23] *Id.* at 1342.

[24] *Id.* at 1351.

[25] *In re Prempro Prods. Liab. Litig.*, 2010 U.S. Dist. LEXIS 142558, at *5-*7 (E.D. Ark. Sept. 16, 2010).

[26] *Id.*

[27] *Id.*

[28] *Id.* at *8.

[29] *Id.* *5-*9.

[30] *Id.* at *9. Proposed expert testimony must be supported by appropriate validation — *i.e.*, good grounds, based on what is known. When a plaintiff cannot show some independent objective validation, courts generally exclude such unsupported speculation. See *In re Baycol Prods. Liab. Litig.*, 532 F.Supp.2d 1029, 1053 (D. Minn. 2007) ("Personal views on corporate ethics and morality are not expert opinions"); *In re Diet Drug Prods. Liab. Litig.*, 2001 U.S. Dist. LEXIS 1174, *31 (E.D. Pa. Feb. 1, 2001) (holding purported expert testimony about ethics is inadmissible because it is "inherently susceptible to subjective personal influence and lacking indicia of reliability").

[31] *In re Baycol*, 532 F.Supp.2d at 1053-54 (excluding expert testimony that "speculates as to Bayer's motives, intent, or state of mind, or speculates as to the motives of the FDA or what other drug companies would do" because "[p]ersonal views on corporate ethics and morality are not expert opinions").

[32] *In re Fosamax Prods. Liab. Litig.*, 645 F.Supp.2d 164, 192 (S.D.N.Y. 2009).

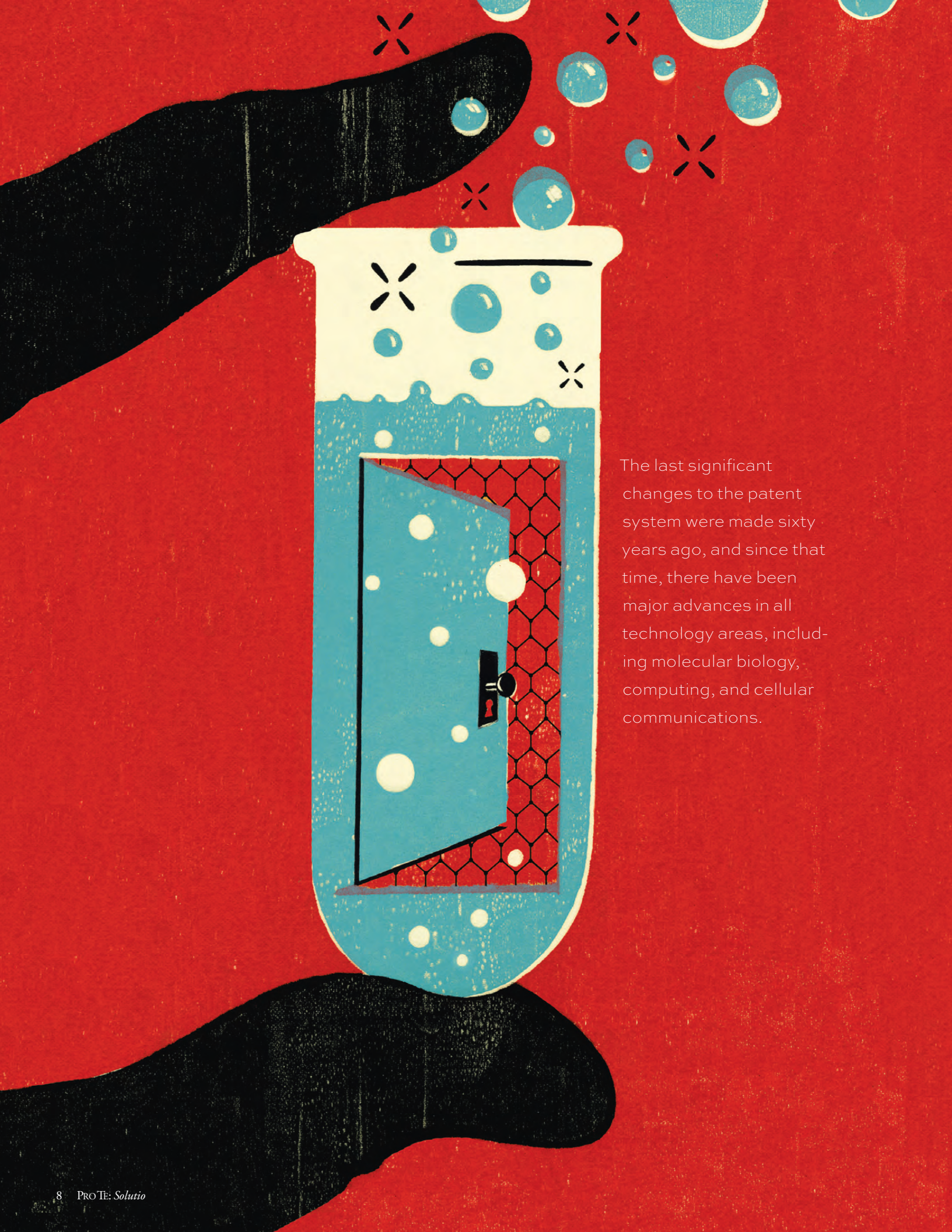
[33] *Id.*; *See also Deutsch v. Novartis Pharms. Corp.* 768 F.Supp.2d 420, 467 (E.D.N.Y. 2011) (noting that the witness "scatters improper personal opinions, speculation, and state of mind inferences throughout the narratives in her report. Such opinions are inadmissible insofar as 'the opinions of [expert] witnesses on the intent, motives, or states of mind of corporations, regulatory agencies, and others have no basis in any relevant body of knowledge or expertise'"); *In re Diet Drug*, 2001 U.S. Dist. LEXIS at 31 (testimony that pharmaceutical company was driven by its desires to increase profits is inadmissible holding purported expert testimony about ethics is inadmissible).

[34] *Jenkins v. Novartis Pharmas. Corp.* 2012 U.S. Dist. LEXIS 176697, at *17 (E.D. Tenn. Dec. 13, 2012).

[35] *Id.*

[36] *Id.* at *17-*18.

WRITTEN *by*
KEISHUNNA RANDALL



The last significant changes to the patent system were made sixty years ago, and since that time, there have been major advances in all technology areas, including molecular biology, computing, and cellular communications.

PATENT REFORM FOR BIOTECH COMPANIES

With the patent office backlogged by hundreds of thousands of applications and corporations being hit with soaring patent damages awards, patent holders and corporations sought help in the form of Congressional action. These stakeholders argued that the United States patent system was not keeping pace with the rapid growth of technology and that it was due for an overhaul. The last significant changes to the patent system were made sixty years ago, and since that time, there have been major advances in all technology areas, including molecular biology, computing, and cellular communications. Many companies felt that the patent system needed to be updated to address the current patent climate. Others argued that the U.S. patent system needed to be changed in order to better compete globally. The U.S. system was the last remaining patent system that granted patents to the earliest inventor, regardless of who first filed. They contended that foreign corporations were more likely to file patents and operate in the United States if the patent systems were similar.

After years of failed attempts at legislation in Congress, significant patent reform was finally passed in the form of the Leahy-Smith America Invents Act (AIA) on September 16, 2011. The changes were intended to harmonize the United States' patent system with those of much of the rest of the world while updating the legislation to ensure that higher quality patents issued. The sweeping changes have been hailed by some as much needed — and strongly disliked by others. Critics assert that the changes benefit large corporations at the expense of small inventors and fledgling companies and that the switch to a first-to-file system makes the U.S. less competitive.

The various provisions of the AIA are phased in so that they become effective at different times. This article addresses the most important changes of which

companies should be aware. Biotechnology companies should pay particular attention to provisions directly aimed at them.

First-Inventor-To-File

The most significant change as a result of the passage of the AIA is that patents filed on or after March 16, 2014, will be granted to the inventor who first *files* a patent application. This change is in stark contrast to the first-to-invent system that had been in place for over 200 years.

Under the first-to-invent system, the inventor who first conceived of the invention and then reduced it to practice is entitled to the patent. The system was intended to reward the inventor who first conceived of the idea, regardless of the time that it took to develop it. Under this system, an applicant could challenge the priority of multiple applications or patents filed by others. A special proceeding before the United States Patent and Trademark Office's (USPTO) Board of Patent Appeals and Interferences, called an interference proceeding, was used to ascertain which applicant was entitled to the patent.

Under the AIA's new system, referred to as a first-inventor-to-file system, an inventor who first files the patent application is entitled to the patent. In essence, it creates a race to the patent office, and the patent can be granted to an applicant who may have conceived of the invention at a later date than an earlier inventor but who files an application first. Because interference proceedings are no longer necessary, the AIA changed the name of the Board of Patent Appeals and Interferences to the Patent Trials and Appeals Board.

The AIA also adds a one-year "grace period" that will exist prior to patent filing during which an inventor's disclosure will not be a bar to patentability. However, a *third-party disclosure* prior to filing will become a novelty bar to patentability, unless it occurs *after* the inventor's disclosure during the grace period. Thus, in some cases, it will make sense for a company to disclose its inventions that it does not intend to patent. This will prevent a competitor from seeking a patent on that same technology.

Proponents of the change from a first-to-invent to a first-inventor-to-file system argue that it puts the United States on equal footing with the patent statutes of the rest of the world. The U.S. was the only remaining country using the first-to-invent system. However, detractors believe that the change only benefits larger corporations that have significant legal budgets to prepare and file applications quickly. Smaller companies and independent inventors are theoretically at a disadvantage because they may not have the capital immediately available to prepare and file applications.

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Derivation Proceedings

The change from a first-to-invent to a first-inventor-to-file system theoretically creates the opportunity for "patent theft" in which someone steals the idea from the inventor and files the application first. The AIA addresses this possibility by establishing a system for inventors to assert that the patentee had used information that was learned from the inventor. These proceedings are referred to as derivation proceedings and become available in March of 2013. According to the AIA, a petition for a derivation proceeding must be filed within a year from the publication date of the claims that are purportedly "the same or substantially the same as the earlier application's claim to the invention."[1]

Expanded Opportunities to Challenge Issued Patents

The AIA attempts to improve the quality of patents and decrease time spent in litigation by expanding the options for challenging the validity of an issued patent. Currently, patent validity can be challenged through reexamination (ex parte and inter partes) and through infringement litigation. Third parties will have a right within nine months of patent issue to request further USPTO review of the patent claims by raising a novel legal issue or submitting evidence of unpatentability of at least one claim. However, this post-grant review process will only be available for patents that issue under the first-inventor-to-file system.

A new inter partes review ("IPR") procedure is also established by the AIA that allows any enforceable patent to be challenged. The IPR will replace the current inter-partes reexamination system and will be handled by a panel of administrative judges on the Patent Trial and Appeals Board. The AIA mandates that the IPR be initiated no earlier than nine months after the issuance of the patent. It also requires that the IPR be completed within eighteen months, which is significantly less than the time it typically takes to challenge the validity of a patent through the federal courts.

Patent Marking Requirements

Prior to enactment of the AIA, there had been a sharp increase in false patent marking lawsuits by plaintiffs that had claimed that goods or services had been marked with expired, invalid, or inapplicable patents. The increase in filings could be attributed to the *qui tam* provision of 35 U.S.C. § 292(b) under which "any person may sue for the penalty, in which event

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one-half shall go to the person suing and the other to the use of the United States." In one case, a plaintiff had alleged that each of the plastic cups sold by the Solo Cup Company was a falsely marked product because it was stamped with an expired patent number.[2] The plaintiff had asked for $500 damages for each of the 21 billion cups that had been sold, thus potentially entitling him to damages in the trillions of dollars. Due to the explosion of such filings, patent holders sought to have the false marking provisions revised in the AIA.

The AIA relaxed the patent marking requirement and changed the *qui tam* provision. Under the new act, patent markings no longer have to be on the product but can now be implemented by reference to a freely accessible webpage, making it significantly easier for a company to update the list of patents. Instead of changing the manufacturing or labeling process, they can make changes to the website. Additionally, under the AIA, only the government or a person who can prove competitive injury can pursue a false marking claim. Furthermore, marking a product with an expired patent number is no longer actionable. These changes became effective immediately upon enacting the AIA and have already greatly reduced the number of false marking lawsuits.

Prior User Defense

Prior to the enactment of the AIA, only accused infringers of business method patents could assert that their use of a patented technology for more than a year prior to the filing date was not infringement. However, in a first-inventor-to-file system, it would be possible for a company that chose not to file an application on an invention to be sued for infringement once a patent is issued to a later filing applicant. The AIA addressed this possibility by expanding the scope of the prior user defense so that it covers all technology areas and applies to almost all patents not owned by universities. The prior user defense benefits those who commercially used the patented technology at least one year prior to the effective patent filing date. Thus, a company that was already using the technology more than a year before the filing date can continue to use it without being liable for patent infringement.

Changes for Biotechnology Companies

Two provisions of the AIA were specifically aimed at biotechnology companies. The first, detailed in Section 33(a) of the AIA, prohibits patent claims directed toward inventions that encompass human organisms. Such claims will be considered unpatentable subject matter by the USPTO and will be rejected. Biotech companies should ensure that their patent claims should either specifically exclude human organisms or ensure that the claim is written in a manner that could not be interpreted to include humans.

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The second provision of the AIA directed toward biotech companies is Section 27 of the AIA. This provision directs the USPTO to conduct studies on how patents on genetic testing will have an effect on healthcare. Specifically, they were tasked with ascertaining whether a patent on a genetic diagnostic test would inhibit the use of second opinion diagnostic testing due to the exclusivity of the patented tests. The USPTO is still in the process of preparing the report that will be delivered to Congress in 2013. Biotech companies that may be developing genetic diagnostic tests should pay close attention to the forthcoming report as it could potentially sway future legislation on this topic.

Preparing for the Changes

The USPTO is still in the process of adopting rules to implement and clarify some of the changes. However, it is clear that businesses and individual inventors need to prepare now for the changes. First, inventors should consider filing provisional applications on inventions as soon as possible to prevent a possible competitor from filing first. For each invention, companies will be forced to quickly evaluate whether they wish to pursue a patent for themselves on a technology or whether they should publicly disclose the technology to prevent a competitor from getting a patent on it. Second, companies should monitor their competitors' patent applications and consider challenging the patent within the statutory time frame. If the company recognizes that prior art was not considered in allowing claims, the company should challenge the patent during the time frame set for post grant review. Finally, companies should consider moving their listing of patents on their products to a website where it can easily be updated.

[1] 35 USC § 135(a).

[2] *Pequignot v. Solo Cup Co.* (Fed. Cir. 2010).

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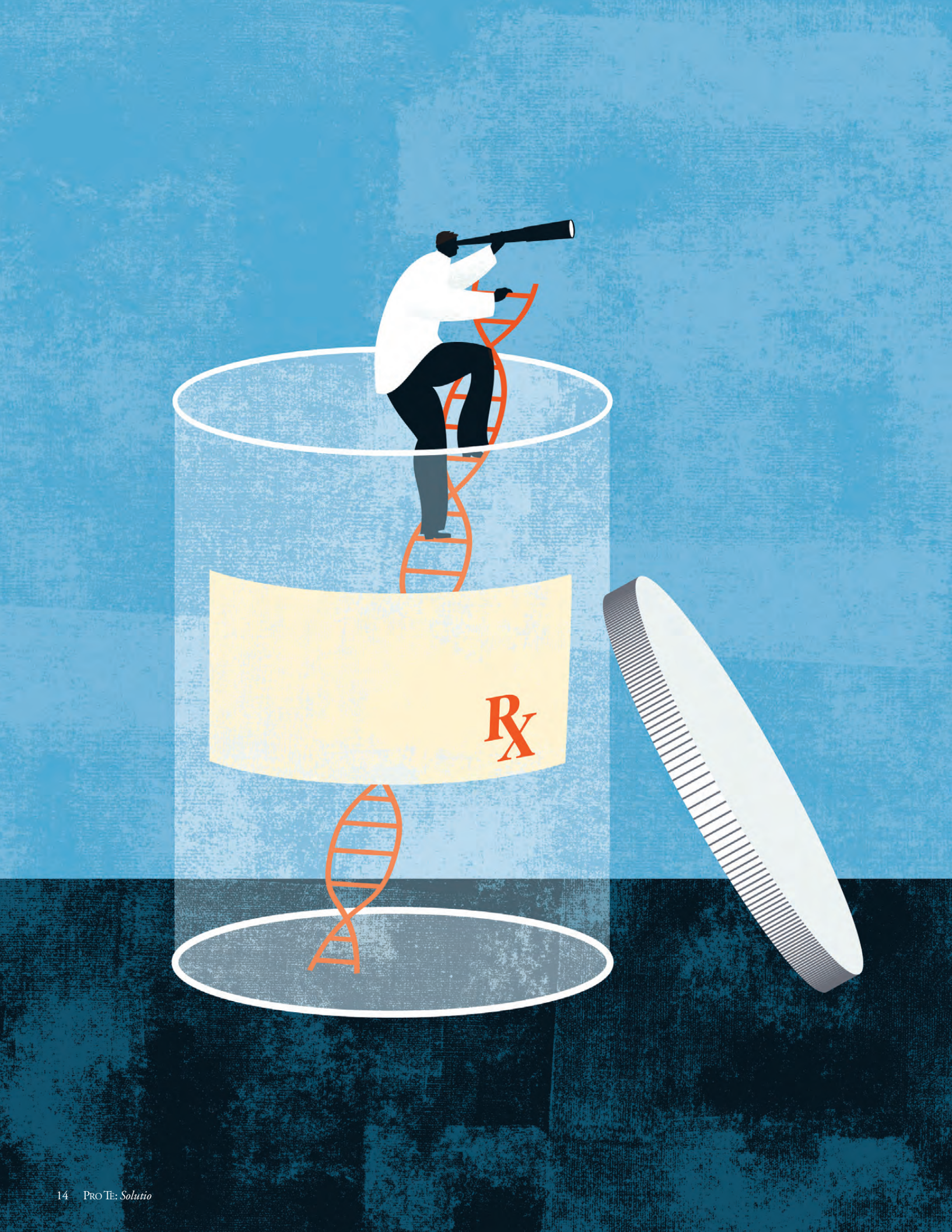
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UNITED STATES V. CARONIA AND ITS IMPLICATIONS FOR OFF-LABEL MARKETING OF PHARMACEUTICALS

Off-label drug use is the physician practice of prescribing drugs to patients for a purpose not included on the Federal Drug Administration-approved label. Recent studies have indicated that nearly a quarter of drug prescriptions are "off-label" in nature.[1] At least 79% of off-label prescriptions are made without support from "strong scientific evidence."[2] Despite the prominent use of off-label prescriptions and the perceived lack of scientific evidence for their use, pharmaceutical manufacturers have long been prohibited from educating physicians regarding the potential benefits of off-label uses for their drugs. In fact, the Department of Justice has appropriated billions of dollars in plea deals and settlement agreements from pharmaceutical manufacturers for impermissibly marketing off-label uses of their drugs. In a recent potentially groundbreaking decision, however, the Second Circuit has opened the door for such efforts to be protected from criminalization on the grounds that off-label commercial marketing is protected under the First Amendment. If the Second Circuit's decision stands and is adopted by other jurisdictions, a framework will be laid to permit pharmaceutical manufacturers to market truthful, scientifically supported off-label benefits of their products.

A. Current Regulatory Framework of Off-Label Marketing

The Federal Food, Drug, and Cosmetic Act (FDCA) governs the introduction of new pharmaceuticals into the marketplace.[3] Prior to the distribution and sale of any new drug, a manufacturer must demonstrate through clinical trials the safety and effectiveness of the proposed drug.[4] The Food and Drug Administration (FDA) will then approve the pharmaceutical for specific uses and/or demographics.[5]

The FDCA explicitly authorizes physicians to prescribe drugs for off-label uses, either through varying dosages, treatment modalities, or for diseases and conditions not originally contemplated in the FDA trials.[6] The FDA has recognized the potential public value of unapproved drug use, and often these off-label uses are subjects of medical literature and publications and supported by a significant portion of the medical community. In other instances, however, off-label prescriptions and uses are given with little documented support or scientific justification. Some commonly prescribed off-label medications are in need of additional study to determine whether their off-label uses are appropriate and beneficial.[7] Despite this cloud of potential misinformation, pharmaceutical manufacturers are generally not permitted to educate physicians regarding any potential benefits of off-label use.[8]

While the FDCA authorizes the prescription of pharmaceuticals by physicians for unapproved treatments, the FDCA and FDA regulations have criminalized the promotion and marketing of those same off-label uses by pharmaceutical companies. Specifically, the FDCA prohibits "misbranding," or "[t]he introduction or delivery for introduction into interstate commerce of any […] drug […] that is […] misbranded."[9] Such misbranding occurs when a product

fails to bear adequate directions for use for the purposes for which it is intended.[10] Such misbranding includes "oral or written statements" by "persons legally responsible for the labeling of drugs."[11] Some proponents of off-label drug marketing have argued that the FDA, in effect, "increasingly criminaliz[es] 'what reasonable people might argue is a reasonable exchange of important clinical information between drug companies and doctors.'"[12]

B. Regulatory Framework Has Resulted in Significant Prosecutions for Off-Label Marketing

In recent years, the FDA and the Department of Justice has repeatedly prosecuted, levied significant fines, and reached multi-million-dollar plea deals with pharmaceutical manufacturers for impermissible off-label marketing.[13]

In 2012, drug manufacturer GlaxoSmithKline agreed to pay a $3 billion fine in the largest healthcare settlement in United States history.[14] Included within an array of charges levied against GlaxoSmithKline was the alleged promotion of the antidepressant Paxil for children and adolescents even though it only had FDA approval for adult use. Compounding GSK's potential exposure were medical studies that had found Paxil ineffective and potentially dangerous for children. GSK was also charged with marketing Wellbutrin, FDA-approved as an anti-depressant, for weight loss, the treatment of sexual dysfunction, and substance addictions.

In 2009, pharmaceutical giant Pfizer reached a $2.3 billion settlement with the Department of Justice to resolve criminal charges and civil claims related to off-label marketing of a then discontinued pain-reliever, Bextra, as well as several other medications.[15] Pfizer was found, among other marketing activities, to have published a press release touting Bextra as an effective analgesic after knee surgery. Bextra, however, was not approved for post-surgery pain. The size of Pfizer's penalty was based both on Pfizer's marketing efforts as well as its recidivism — Pfizer had been previously fined on several occasions for the marketing of off-label uses for its drugs.

In light of significant continuing prosecutions by the federal government, some medical device and pharmaceutical companies have begun both to challenge and seek exception from the government's authority to bring enforcement actions under the FDCA. In October 2009, Allergan Inc. sued the FDA claiming that its off-label marketing was protected as free speech under the First Amendment.[16] The thrust of Allergan's suit was that the FDA's enforcement prohibited manufacturers from communication with physicians regarding safe and effective off-label uses. Allergan considered itself caught in an unwinnable position — if it knew that one of its medications was being prescribed off-label in a potentially unsafe manner, it would either expose itself to negligence liability by doing nothing, or it would expose itself to criminal liability if it educated physicians and provided appropriate directions for off-label use. Allergan ultimately abandoned its suit as part of a $600 million settlement with the DOJ over Allergan's alleged off-label marketing of Botox.[17]

> THE SECOND CIRCUIT RECOGNIZED ONGOING DISCOURSE BETWEEN PHARMACEUTICAL COMPANIES AND PHYSICIANS WOULD BE IN THE BEST INTEREST OF THE PATIENT: THE GOVERNMENT'S CONSTRUCTION OF THE FDCA ESSENTIALLY LEGALIZES THE OUTCOME – OFF-LABEL USE – BUT PROHIBITS THE FREE FLOW OF INFORMATION THAT WOULD INFORM THAT OUTCOME. IF THE GOVERNMENT'S OBJECTIVE IS TO SHEPHERD PHYSICIANS TO PRESCRIBE DRUGS ONLY ON-LABEL, CRIMINALIZING MANUFACTURER PROMOTION OF OFF-LABEL USE WHILE PERMITTING OTHERS TO PROMOTE SUCH USE TO PHYSICIANS IS AN INDIRECT AND QUESTIONABLY EFFECTIVE MEANS TO ACHIEVE THAT GOAL.

In July 2011, seven drug and device manufacturers, including Allergan, petitioned the FDA for greater clarification on the scope of permissible and impermissible off-label directions of use.[18] The petition stated that the "lack of clarity and vagueness surrounding the contours of permissible manufacturer speech has significant consequences to manufacturers, the government, physicians, and patients," that manufacturers expend "substantial resources" attempting to interpret and comply with FDA regulations, but despite their best efforts, "each individual manufacturer may either over or under communicate clinically relevant information, with significant attendant consequences for the public health."[19]

C. *United States v. Caronia*

In 2005, the Department of Justice began investigating pharmaceutical company Orphan Medical for its alleged off-label promotion of the drug Xyrem.[20] Xyrem was a drug that received FDA approval in 2005 for treatment of narcolepsy patients who suffered from weak or paralyzed muscles related to their condition.[21] As part of its approval process, the FDA required that Xyrem carry a black box warning — the most serious warning placed on prescription medication labels — that it was not approved for use in people under the age of 16 and had limited evidence of efficacy amongst elderly patients.[22] The basis of this warning was Xyrem's active ingredient GHB, a medication affecting the central nervous system that has been federally classified as the "date rape drug."[23]

As part of its investigation, the federal government wire-tapped two conversations between Alfred Caronia, a sales representative with Orphan Medical, and physicians cooperating with the DOJ's investigation.[24] During those conversations, Caronia marketed Xyrem as a drug with possible uses for other muscle disorders such as fibromyalgia, restless leg syndrome, and Parkinson's disease.[25] Moreover, Caronia explicitly stated that Xyrem was an effective treatment option for patients under the age of 16 and over the age of 65.[26] Mr. Caronia was indicted, along with his employer,[27] for allegedly introducing a misbranded drug into interstate commerce in violation of 21 U.S.C. §§ 331(a) and 33(a)(2)

DESPITE THE PROMINENT USE OF OFF-LABEL PRESCRIPTIONS AND THE PERCEIVED LACK OF SCIENTIFIC EVIDENCE FOR THEIR USE, PHARMACEUTICAL MANUFACTURERS HAVE LONG BEEN PROHIBITED FROM EDUCATING PHYSICIANS REGARDING THE POTENTIAL BENEFITS OF OFF-LABEL USES FOR THEIR DRUGS. IN FACT, THE DEPARTMENT OF JUSTICE HAS APPROPRIATED BILLIONS OF DOLLARS IN PLEA DEALS AND SETTLEMENT AGREEMENTS FROM PHARMACEUTICAL MANUFACTURERS FOR IMPERMISSIBLY MARKETING OFF-LABEL USES OF THEIR DRUGS. IN A RECENT POTENTIALLY GROUND-BREAKING DECISION, HOWEVER, THE SECOND CIRCUIT HAS OPENED THE DOOR FOR SUCH EFFORTS TO BE PROTECTED FROM CRIMINALIZATION ON THE GROUNDS THAT OFF-LABEL COMMERCIAL MARKETING IS PROTECTED UNDER THE FIRST AMENDMENT.

by knowingly marketing and "misbranding" Xyrem for medical indications that were not approved by the FDA.[28]

As part of his defense, Caronia adopted the position previously taken by Allergan and moved to dismiss the charges against him on the grounds that his verbal marketing efforts were protected as free speech by the First Amendment.[29] The trial court denied Caronia's motion by concluding that the FDCA's criminalization of Caronia's off-label marketing was permitted under the commercial speech doctrine — speech regarding a commercial transaction that is not entitled to the same protections as other speech — "because the FDCA was not more extensive than necessary to achieve the FDA's objectives."[30] Mr. Caronia took his case to trial where he was found guilty and sentenced to one year of probation, 100 hours of community service, and a twenty-five-dollar fine.[31]

Caronia appealed, arguing that the First Amendment protected off-label marketing 1) of an FDA-approved drug when 2) the off-label marketing was truthful and not misleading and 3) the use itself is not illegal and others, namely the prescribing physicians, are permitted to engage in the same activity.[32] The DOJ took the position that Caronia's speech "was not speech at all but was conduct evidence of intent to misbrand."[33]

In a two-to-one decision, the Second Circuit Court of Appeals overturned Caronia's conviction, not because it found the off-label marketing to be free speech, but because it found the statutory and regulatory framework of the FDCA did not actually criminalize off-label marketing.[34] The court stated:

> To the extent there is any ambiguity as to whether off-label promotion is tantamount to illegal misbranding, we construe the FDCA narrowly to avoid a serious constitutional question. As we now explain, we decline the government's invitation to construe the FDCA's misbranding provisions to criminalize the simple promotion of a drug's off-label use by pharmaceutical manufacturers and their representatives because such a construction — and a conviction obtained under the government's application of the FDCA — would run afoul of the First Amendment.[35]

D. Second Circuit's Free Speech Analysis

The Second Circuit, in reaching its decision, relied heavily on the reasoning of the United States Supreme Court's decision in *IMS v. Sorrell*, in which the Supreme Court first held that "[s]peech in aid of pharmaceutical marketing […] is a form of expression protected by the […] First Amendment."[36] As in *Sorrell*, the Second Circuit conducted a two-step inquiry: 1) whether the government regulation restricting speech was content- and speaker-based; and 2) whether the government had shown the restriction of speech was consistent with the First Amendment.[37] The Second Circuit found that the FDCA's misbranding provisions imposed content- and speaker-based restrictions subjecting the FDCA's restrictions to heightened scrutiny and concluded that "the government cannot justify a criminal prohibition of off-label promotion […]."[38]

IN LIGHT OF SIGNIFICANT CONTINUING PROSECUTIONS BY THE FEDERAL GOVERNMENT, SOME MEDICAL DEVICE AND PHARMACEUTICAL COMPANIES HAVE BEGUN BOTH TO CHALLENGE AND SEEK EXCEPTION FROM THE GOVERNMENT'S AUTHORITY TO BRING ENFORCEMENT ACTIONS UNDER THE FDCA.

Continuing its *Sorrell*-based analysis, the Second Circuit then analyzed the FDCA's restriction on commercial speech under *Central Hudson Gas & Electric Corp. v. Public Service Commission*.[39] In applying *Central Hudson*, the Second Circuit concluded that the government's criminalization of Caronia's off-label marketing was unconstitutional because it did not directly advance the government's interest in drug safety and public health when narrower and less burdensome regulations would have sufficed.[40]

Specifically, the Second Circuit found that the FDCA's restrictions failed to advance the government's interest in protecting the public safety, holding that:

> [P]rohibiting off-label promotion by a pharmaceutical manufacturer while simultaneously allowing off-label use 'paternalistically' interferes with the ability of physicians and patients to receive potentially relevant treatment information; such barriers to information about off-label use could inhibit, to the public's detriment, informed and intelligent treatment decisions. Moreover, in the fields of medicine and public health, 'where information can save lives,' it only furthers the public interest to ensure that decisions about the use of prescription drugs, including off-label usage, are intelligent and well-informed.[41]

Moreover, the Second Circuit recognized that ongoing discourse between pharmaceutical companies and physicians would be in the best interest of the patient:

> The government's construction of the FDCA essentially legalizes the outcome — off-label use — but prohibits the free flow of information that would inform that outcome. If the government's objective is to shepherd physicians to prescribe drugs only on-label, criminalizing manufacturer promotion of off-label use while permitting others to promote such use to physicians is an indirect and questionably effective means to achieve that goal. Thus, the government's construction of the FDCA's misbranding provisions does not directly advance its interest in reducing patient exposure to off-label drugs or in preserving the

> efficacy of the FDA drug approval process because the off-label use of such drugs continues to be generally lawful. Accordingly, the government's prohibition of off-label promotion by pharmaceutical manufacturers 'provides only ineffective or remote support for the government's purpose.'[42]

The Second Circuit also concluded that the FDA, which the Second Court fully endorsed as having the authority to regulate marketing of pharmaceuticals, had numerous options at its disposal to manage off-label marketing including "guiding physicians and patients in differentiation between misleading […] and truthful […] information," developing "warning or disclaimer systems […] within the off-label market," requiring "pharmaceutical manufacturers to list all applicable or intended indications when they first apply for FDA approval," placing "ceiling or caps on off-label prescriptions," and reminding physicians and manufacturers that they can be held liable on negligence and malpractice theories for off-label drug use.[43]

Judge Debra Ann Livingston wrote a vehement dissent and argued that by vacating the conviction, the Second Circuit had called "into question the very foundations of our century-old system of drug regulation."[44] Judge Livingston performed the same analysis under *Sorrell* and *Central Hudson* and concluded that the FDCA's off-label marketing regulations withstood attack.

E. *Caronia* Aftermath

Dissection of the *Caronia* opinion notwithstanding, the important question remains — how will the Second Circuit's opinion affect government prosecutions of off-label marketing in the future? By the date of this article's publishing, we will know whether the Department of Justice will choose to seek an *en banc* review before the Second Circuit, choose to file an appeal before the United States Supreme Court, or let the *Caronia* decision stand and avoid a potentially more damaging opinion from the Supreme Court.

Two weeks after the *Caronia* decision was published, the DOJ announced a $762 million plea deal with Amgen, Inc. regarding its off-label promotion of its anemia drug Aranesp.[45] Clearly, the government will continue to prosecute misbranding cases until the *Caronia* saga reaches completion. Until then, pharmaceutical companies will have to continue to tread lightly and institute policies and controls that will carefully manage how off-label information is disseminated.

[1] Stafford, Randall S., "Regulating Off-Label Drug Use: Rethinking the Role of the FDA," *N. Engl. J. Med.* 358.14 (2008): 1,427–29. (Discussing 2003 study of 160 common drugs where off-label use accounted for approximately 21% of prescriptions.) *But see* Eguale, Tewodros et al., "Drug, Patient, and Physician Characteristics Associated with Off-Label Prescribing in Primary Care," *Archives of Internal Medicine*, 172 (2012): 781–88. (A more limited Canadian study finding that 11% of prescriptions are off-label.)

[2] Eguale, Tewodros et. al., "Drug, Patient, and Physician Characteristics Associated with Off-Label Prescribing in Primary Care," *Archives of Internal Medicine*, 172 (2012): 781–88.

[3] 21 U.S.C. § 355(a).

[4] 21 U.S.C. § 355(d).

[5] *Id.*

[6] 21 U.S.C. § 353(b) (2012). *See also Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 350 (2001). (Recognizing that off-label use is an "accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine.")

[7] Walton, S.M. et al., "Prioritizing Medications for Policy and Research Initiatives Examining Off-Label Prescribing," *Pharmacotherapy*, 28 (2008): 1,443–452.

[8] 21 U.S.C. §§ 331(a), 333(a) (2).

[9] *Id.*

[10] 21 U.S.C. § 352(f); 21 C.F.R. § 201.5.

[11] 21 C.F.R. § 201.128.

[12] Harris, Gardiner, "Pfizer Pays $2.3 Billion to Settle Marketing Case," *The New York Times*, Sept. 2, 2009. *Available at* <http://www.nytimes.com/2009/09/03/business/03health.html?_r=0>. *Last accessed* Jan. 3, 2013.

[13] *See e.g., United States v. GlaxoSmithKline, LLC*, 12-cr-10206 (D. Mass. July 10, 2012); *United States v. Merck Sharp & Dohme Corp.*, No. 11-cr-10384 (D. Mass. May 18, 2012).

[14] Thomas, Katie, "Glaxo Agrees to Pay $3 Billion in Fraud Settlement," *The New York Times*, July 2, 2012. *Available at* <http://www.nytimes.com/2012/07/03/business/glaxosmithkline-agrees-to-pay-3-billion-in-fraud-settlement.html>. *Last accessed* Jan. 3, 2013.

[15] U.S. Department of Health and Human Services, "Justice Department Announces Largest Health Care Fraud Settlement," Sept. 2, 2009. *Available at* <http://www.hhs.gov/news/press/2009pres/09/20090902a.html>. *Last accessed* Jan. 3, 2013.

[16] *See* Beck, Jim, "Allergan's Free Speech Attack on FDA Regulations," *Drug and Device Law Blog*, Oct. 3, 2009. *Available at* <http://druganddevicelaw.blogspot.com/2009/10/allergans-free-speech-attack-on-fda.html>. *Last accessed* Jan. 3, 2013.

[17] Comer, Ben, and Matthew Arnold, "Allergan Drops FDA Lawsuit as Part of Off-Label Settlement," *Medical Marketing & Media*, Sept. 2, 2010. *Available at* <http://www.mmm-online.com/allergan-drops-fda-lawsuit-as-part-of-off-label-settlement/article/178168>. *Last accessed* Jan. 3, 2013.

[18] *See* Mack, John, "Citizen Petition Filed by Pharma Likely to Delay Indefinitely the Issuance of FDA Social Media Guidance," *Pharma Marketing Blog*, July 6, 2011. *Available at* <http://pharmamkting.blogspot.com/2011/07/citizens-petition-filed-with-fda-likely.html>. *Last accessed* Jan. 3, 2013.

[19] *Id.*

[20] *United States v. Caronia*, No. 09-5006-cr, 2012 WL 5992141, – F.3d – (2d Cir. Dec. 3, 2012), slip op. at 14.

[21] *Id.* at 12.

[22] *Id.*

[23] *Id.*

[24] *Id.* at 14.

[25] *Id.* at 15.

[26] *Id.* at 15–16.

[27] Orphan Medical settled the claims against it for $20 million. *See* Berenson, Alex, "Maker of Narcolepsy Drug Pleads Guilty in U.S. Case," *The New York Times*, July 14, 2007. *Available at* <http://www.nytimes.com/2007/07/14/business/14jazz.html>. *Last accessed* Jan. 3, 2013.

[28] *Caronia*, slip op. at 17–19.

[29] *Id.* at 19.

[30] *Id.* at 20.

[31] *Id.* at 24.

[32] *Id.* at 25.

[33] *Id.* at 27.

[34] *Id.* at 26.

[35] *Id.* at 32.

[36] *Id.* at 35.

[37] *Id.* at 39.

[38] *Id.*

[39] *Id.* at 42.

[40] *Id.* at 43–51.

[41] *Id.* at 44 (citations omitted).

[42] *Id.* at 47 (citations omitted).

[43] *Id.* at 48–50 (citations omitted).

[44] *Id.* at 53.

[45] Terhune, Chad, "Amgen Pleads Guilty to Improper Marketing of Anemia Drug Aranesp," *The Los Angeles Times*, Dec. 18, 2012. *Available at* <http://articles.latimes.com/2012/dec/18/business/la-fi-amgen-plea-20121219>. *Last accessed* Jan. 3, 2013.

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