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PRACTICE TIP

Did the Affordable Care Act End the Collateral Source Rule?

By Spencer A. Bomar

The Affordable Care Act has the potential to change dramatically many aspects of America's healthcare system, including access to medical care, insurance coverage for medical expenses, and the actual costs of care. As a side effect, there is a growing belief that the passage of the Affordable Care Act could signal the end of the collateral source rule.

With the enactment of the individual mandate, it may be time to question the premise underlying the collateral source rule: namely, that people need incentives to acquire health insurance and that admitting evidence of collateral source benefits creates a windfall for the alleged tortfeasor. Similarly, there is evidence that the Affordable Care Act may result in the "incurred costs" for healthcare services reflecting the actual costs, and not negotiated rates.

This article explores the possibility that as cases are litigated under the Affordable Care Act, there is an opportunity for a change in the collateral source rule and the corresponding impact on the presentation of damages in personal injury cases.

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To Correct or Not Correct Misinformation in Social Media

The Life Science Company's Dilemma

By Alan G. Minsk

In June 2014, the Food and Drug Administration (FDA) issued a draft guidance document, "Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation about Prescription Drugs and Medical Devices." (*See* Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices, available at http://1.usa.gov/1xzU8zo.) While the draft guidance is not legally binding, it offers insight into the FDA's expectations and issues for industry to consider as it continues to develop social media campaigns. The draft guidance indicates that the FDA will not hold responsible companies that choose to correct (or not correct) third-party misinformation. However, companies should consider the product liability implications of whether or not to correct misinformation.

This article briefly summarizes the draft guidance and offers issues to consider. The article is not intended to make recommendations in a vacuum, as each case is fact-specific. However, it is hoped that describing the issues will allow companies to make educated decisions.

Defining Control

Control of the message is central to the FDA's determination of whether the product owner has regulatory obligations to comply with labeling and advertising requirements.

- The agency makes clear that any correction is voluntary and not required by the agency. The FDA's intent is to provide guidance for firms "if they [firms such as manufacturers, distributors, or packers] choose to respond … to misinformation created or disseminated by *independent third parties*" (emphasis added).

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- The new draft guidance *does not apply when the firm is responsible for the product-specific communication* (*i.e.*, "owned, controlled, created, or influenced, or affirmatively adopted or endorsed, by, or on behalf of, the firm").
- The FDA defines "misinformation" as:

  … positive or negative incorrect representations or implications about a firm's product created or disseminated by independent third parties who are not under the firm's control or influence and that is not produced by, or on behalf of, or prompted by the firm in any particular. FDA has determined it may benefit the public health for firms to correct misinformation about their products (including, for example, situations in which a firm is aware of misinformation that may be dangerous or harmful to the public health).
- The draft guidance explains that the agency does not intend to take enforcement action against a firm that corrects misinformation in a truthful and non-misleading manner (within the parameters outlined in the guidance), even without meeting any other applicable labeling and advertising requirements. Again, this relates to misinformation *distributed by independent third parties, where the company is not responsible for the product-related communications*. The company must comply with applicable requirements relating to product information where it controls the message.
- The agency recognizes that it is possible that a company might host a discussion forum about its product, but not participate in the discussion. The FDA recommends that the company "include an overarching clear and conspicuous statement that the firm did not create or control the UGC [user-generated content]." In other words, the company can make clear it is not endorsing or supporting the statement.

How to Correct Misinformation

- Rather than providing the corrective information on the third-party forum, a company may choose instead to provide a "reputable source" as the contact person at the company where correct information can be obtained (*e.g.*, providing the contact information for the firm's Medical Affairs Department).
- The FDA states that "appropriate corrective information" should be: 1) Relevant and responsive to the misinformation; 2) Limited and tailored to the misinformation; 3) Non-promotional in nature, tone, and presentation; 4) Accurate; 5) Consistent with the FDA-required labeling for the product; 6) Supported by sufficient evidence, including substantial evidence, when appropriate, for prescription drugs; 7) Either posted by the company in conjunction with the misinformation in the same area, or, if provided to the author of the misinformation, reference the misinformation with the intent that the correction be posted in conjunction with the misinformation; and 8) A disclosure that the person providing the corrective information is affiliated with the firm that manufactures, packs, or distributes the product.
- The company should provide the FDA-required labeling, such as in a link that goes directly to the labeling or a link that opens a PDF file of the labeling in a new window. The FDA advises against links to a promotional website or a promotional address.

1) The FDA seems to be comfortable with correcting

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'Unreliable' Articles, 'Trial by Literature' Revisited

By Michael Hoenig

The reliance upon, and use of, unreliable hearsay literature by expert testifiers is a challenging topic that cuts across the spectrum of complex litigation. Often, the literature is comprised of technical or scientific articles published in some journal with a claim that the published work product has been "peer reviewed." Earlier articles have discussed the reliability of such out-of-court articles not authored by the testifier. Due to the increasing trend to "trial by literature," it would be helpful to revisit the subject. Rather than diminish, the problems seem to have exacerbated.

In particular, there has been a global proliferation of journals whose quality review practices function differently from the classic model we used to know. Many so-called "open-access" journals that accept articles charge the author a fee. That dynamic seems to create potential conflicts of interest. Many of these journals publish articles without peer review. Others do a bogus peer review "sting" operation, like when a Harvard science journalist sent a science article to hundreds of journals. The shocking results are discussed below — after presentation of some background information and findings.

Background

There is a place and need for hearsay literature. Much of what we say or do is based on what we learn. Much of what we learn is based on what we read. Much of what we read is based on what others have read. Much of what those others have read is based on what others have written. And so it becomes inevitable that, sooner or later, much of expert testimony boils down to what experts have read or learned or confirmed from writings. There is nothing inherently wrong with that.

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If the expert enhances his or her expertise by reading scientific, technical or professional writings or benefits others by researching and writing as an expert, society is normally better off for the effort. Since the objective in the courtroom is to search for the truth and do justice, the writings the experts rely upon can enhance the expert's — and therefore the jury's … role in the truth-finding process if the expert's writings are trustworthy, accurate and professionally reliable. If, however, the writings are "junk," and the expert relies on them or professes them to be the truth, then the expert's testimony is no better than the junk on which s/he is relying.

Sometimes, the quality and trustworthiness of professional writings fall between the extremes of "reliability" and "junk," into a vast gray area of "quasi-reliability" or "not-quite-junk." The articles may be published by journals with professional-sounding names or by institutions or entities recognized in the technical world, thereby creating an aura of trustworthiness that masks the diminished quality of the substantive content. What happens when the expert relies on such less-than-reliable professional literature? What should be the consequences of such reliance?

In general, the justice system wants the expert to give juries the benefit of his or her expertise, not merely to read out-of-court, hearsay materials to jurors. If the expert becomes merely a reader of someone else's thoughts or opinions, then the "someone else" is really doing the testifying, not the expert. That might not be so bad if we could guarantee that the out-of-court writing is genuine, accurate, trustworthy, reliable, relevant and "fits" the facts and issues in the case. But how can we do that? Ordinarily, we cannot cross-examine the writing, and the author of the technical or scientific or specialized hearsay is not in court to answer questions. Only a surrogate — the so-called trial "expert" — is subject to cross-examination. But he or she often knows only what was stated in the article. Beyond the confines of the actual text, the published findings and explicit writing, the trial expert usually does not know (if s/he is truthful) or is speculating (if s/he indulges in belief or guesswork).

False Findings

Earlier articles have reported on serious problems with reliability of many scientific articles, even those published in vaunted science or technical journals. (M. Hoenig, "Testifying Experts and Scientific Articles: Reliability Concerns," *New York Law Journal*, Sept. 16, 2011, p. 3.) Moreover, the entire June 5, 2002, issue of the prestigious *Journal of the American Medical Association* (*JAMA*) was devoted to a soul-searching, critical analysis of major shortcomings in the articles' research, methodologies, and even the peer-review process. Important weaknesses often were not reported in the published articles. The published reports often masked "the true diversity of opinion among contributors about the meaning of their research findings," resulting in a de facto "hidden research paper" behind the published article. Results sometimes were selectively reported and the authors "drew unjustified conclusions." *JAMA's* details were arresting.

Then a respected epidemiologist, John P.A. Ioannidis, issued an article in the *Public Library of Science Medicine* (*PLOS*), dated Aug. 30, 2005, titled, "Why Most Published Research Findings Are False." An editorial in the same journal conceded that Dr. Ioannidis had argued "convincingly" and that his claim that most conclusions are false "is probably correct."

Courts and litigants should be concerned about unreliable, junky literature masquerading as the testimony of a qualified expert because reliability of expert testimony is a bedrock principle behind admissibility of the testimony in the first place. Even a qualified expert must give testimony that is both relevant and reliable. If, however, the literature the expert relies upon is itself unreliable or partially junk, then his or her testimony can be no better … no matter how articulately stated. It is no better than the expert's guess,

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speculation or conjecture and the justice system demands more.

Concerns about the reliability of scientific literature have increased over the last few years, due, in large part, to the proliferation of so-called "open-access" (OA) journals, which are published by industry giants such as Sage, Elsevier and Wolters Kluwer. After a number of experiences involving prospective authors and article reviewers raised suspicions about OA journals' practices, the *Science Magazine* editorial staff contacted Bohannon. Intrigued, Bohannon looked into and contacted some of the journals' websites, editors and reviewers. What he found was disturbing. He decided to submit a science paper of his own under a fictitious name to a Scientific & Academic Publishing Co. (SAP) journal. He devised a sting operation. To compare the one target to other publications, Bohannon would "replicate the experiment across the entire open-access world."

'Sting' Operation

Bohannon created a "credible but mundane" paper with such "grave errors that a competent peer reviewer should easily identify it as flawed and unpublishable." The hoax article described a sample test to see whether cancer cells grow more slowly in a test tube when treated with increasing concentrations of a certain molecule. In a second "experiment," Bohannon wrote that the cells were treated with increasing doses of radiation to simulate cancer radiotherapy. The data were the same across both papers and so were the bogus conclusions: "The molecule is a powerful inhibitor of cancer growth, and it increases the sensitivity of cancer cells to radiotherapy."

There were numerous "red flags" in the papers. The graph was inconsistent with — indeed the opposite of — accepted data. Any reviewer with more than a high-school knowledge of chemistry and the ability to understand a basic data plot should have spotted the paper's shortcomings immediately. The hoax paper was sent to 304 OA journals at a rate of about 10 a week. The sting article was accepted by 157 of the journals and rejected by 98. Of the 255 versions that went through the entire editing process to either acceptance or rejection, 60% did not undergo peer review. Of the 106 journals that did conduct peer review, some 70% accepted the paper. The *Public Library of Science* was the only journal that called attention to the paper's potential ethical problems and, accordingly, rejected it within two weeks.

Only 36 of the 304 submissions generated peer-review comments recognizing any of the paper's scientific problems. And 16 of those papers were accepted by the editors "despite the damning reviews." One-third of the journals targeted in the sting operation were based in India, but the publishing powerhouses that profited from those activities were in Europe and the United States. The U.S., however, was the next largest base, with 29 acceptances and 26 rejections. As Bohannon reports, one major publication, without asking for any changes to the scientific content, sent an acceptance letter and an invoice for $3,100.

How to Review Articles

Apart from the startling Bohannon experiment, many other problems persist. (*See, e.g.*, Sarah Fecht, "What Can We Do About Junk Science?" *Popular Mechanics*, April 8, 2014, http://bit.ly/1BvX5lK; Henry I. Miller and Bruce Chassy, "Scientists Smell a Rat in Fraudulent Genetic Engineering Study," *Forbes*, Sept. 25, 2012 (Op/Ed), http://onforb.es/1w0qcqK; Beate Wieseler and Others, "Completeness of Reporting of Patient-Relevant Clinical Trial Outcomes: Comparison of Unpublished Clinical Study Reports with Publicly Available Data," *PLOS Medicine*, Oct. 8, 2013, http://bit.ly/1xB4K0Z; David F. Freedman, "Lies, Damned Lies, and Medical Science," *The Atlantic,* Oct. 4, 2010, http://theatln.tc/1s2suud.)

In the biomedical area, for example, "published research findings are often modified or refuted by subsequent evidence." There is an increasing concern of a publication "bias toward positive results," a competition to "rush findings into print," and an overemphasis on publishing "conceptual breakthroughs" in high-impact journals. Misleading papers result in considerable expenditure of time, money and effort by researchers "following false trails." (Editorial, "Further Confirmation Needed," *Nature Biotechnology*, Sept. 10, 2012, http://bit.ly/1s2sF8F.) Leaders at the U.S. National Institutes of Health are planning "interventions" to ensure the reproducibility of biomedical research. There is, for example, the problem of what is not published. "There are few venues for researchers to publish negative data or papers that point out scientific flaws in previously published work." In addition, there is a difficulty in accessing unpublished data. Francis S. Collins and Lawrence A. Tabak, "Policy: NIH Plans to Enhance Reproducibility," *Nature*, Jan. 27, 2014, http://bit.ly/1BERpne (article by leaders of the U.S. National Institutes of Health; "checks and balances that once ensured scientific fidelity have been hobbled"; article outlines "interventions" planned by the NIH to ensure reproducibility of biomedical research).

As a practical matter, this means that testifying experts relying on published science papers often do not have complete information on the subject because the flaws and negative critiques come later and are largely unpublished. This reality hampers the ability to challenge and cross-examine to expose the flaws and unreliability of the hearsay literature.

Published works need to be exposed to comment, critiques, refutations, and identification of errors and weaknesses. Although, nominally, scientists are welcome to publish contradictory findings, typically by contacting the authors directly or by writing a letter to the journal's editor, these are lengthy processes that "likely will never be heard or seen by the majority of scientists." Thus, "most scientists do not participate in formal reviews."

Although a small number of scholarly journals have launched online fora for scientists to comment on published materials, there is

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inconvenience to scientists in commenting journal by journal. If one wants to comment on a paper in the journal *Nature*, one has to go to the *Nature* site, find the paper and comment. If it is a *PLOS* paper, one has to go to the *PLOS* site. These attempts are major investments in time, "particularly when people may never see the comments."

Several concerned scientists developed a new post-publication peer-review system called "PubMed Commons," housed on the often-accessed National Center for Biotechnology Information (NCBI) biomedical research database. PubMed Commons was announced on Oct. 22, 2013. It allows users to comment directly on any of PubMed's 23 million indexed research articles. For a description of this new PubMed venture, the reader can consult Aimee Swartz's October 2013 article in *The Scientist Magazine*, called "Post-Publication Peer Review Mainstreamed," available at http://bit.ly/1DgIs7V.

Such an organized post-publication peer review system could help "clarify experiments, suggest avenues for follow-up work and even catch errors," said Stanford University's Rob Tibshirani, one of the Commons developers and a professor of health research and policy and statistics. The post-peer review "could strengthen the scientific process." Approximately 2.5 to 3 million people access the online resource each day. Researchers thus may have a resource to check out whether published papers have stimulated objections or controversy or, perhaps, have been retracted.

The Value of Peer Review

The Bohannon sting operation illustrates that peer review may be poorly done or entirely absent. Further, as Dr. Ioannidis has observed, peer review is not a guarantee of accuracy. Even if there are two qualified reviewers, Ioannidis notes that "journal reviewers don't typically scrutinize raw data, re-run the statistical analyses, or look for evidence of fraud." What they are reviewing, says Ioannidis, "are mostly advertisements of research rather than the research itself."

Thus, the peer review process does not guarantee the trustworthiness of the article. University of Miami Law Professor Susan Haack wrote an excellent law review article on this issue in 2007 titled "Peer Review and Publication: Lessons for Lawyers," available at http://bit.ly/1AqBJ7J.

Haack's article elaborates many of the limitations inherent in peer review identified in my columns in the *New York Law Journal*. Her article sketches the origins of and many roles peer review now plays; the rationale for pre-publication review and its shortcomings as a quality control mechanism; the changes in science and scientific publication that have put the peer-review system "under severe strain"; recent examples of flawed or even fraudulent work that passed peer review; and the role peer review ought to play in courts' assessments of "reliability."

Imperfect System

Some persons are "tempted to exaggerate" regarding the virtues of pre-publication peer review. Instead of viewing it as a "rough-and-ready preliminary filter," some consider it a "strong indication of quality." But, in reality, "the system now works very imperfectly." Peer review cannot be expected to "guarantee truth, sound methodology, rigorous statistics, etc." Scientific editors have stressed that they and their reviewers "have no choice but to rely on the integrity of authors." In addition, when the author is not present to testify and be cross-examined, the testifier's parroting of the hearsay can create a testimonial integrity gap that should signal gatekeeping courts to be cautious.

Citing a noted editor, Haack describes the review process roughly like this: An editor classifies articles into self-evident masterpieces, obvious rubbish, and the remainder as needing careful consideration. The latter is the large majority. The editor then chooses one or two reviewers to look at each paper selected with a checklist against which to check for aspects of style, presentation and certain kinds of obvious error. The reviewers are given a time limit — often no more than two weeks — to respond with their assessments and recommendations. Reviewers "spend an average of around 2.4 hours evaluating a manuscript." Many journals do not check the statistical calculations in accepted papers, and reviewers are in no position to repeat authors' experiments or studies, which ordinarily have taken a good deal of time and/or money. Acceptance rates vary. Where the acceptance rate is low, most of the rejected papers submitted to the "most desirable" journals eventually appear in some lower-ranked publication. A paper "may have been rejected by 10 or 20 journals before it is finally accepted."

With more and more papers submitted to more and more journals, the quality of reviewers and the time and attention they can give to their task "is likely to decline." Prestigious journal editors have expressed major concerns. Richard Smith, editor of "*The Lancet*," wrote that peer review is "expensive, slow, prone to bias, open to abuse, possibly anti-innovatory and unable to detect fraud." Drummond Rennie of *JAMA* wrote: "[T]here seems to be no study too fragmented, no hypothesis too trivial, no literature citation too biased or too egotistical, no design too warped, no methodology too bungled, … no argument too circular, no conclusion too trifling or too unjustified, and no grammar or syntax too offensive for a paper to end up in print."

Haack advises: The fact that a work has passed pre-publication peer review is "no guarantee that it is not flawed or even fraudulent; and the fact that it has been rejected by reviewers is no guarantee that it is not an important advance." Publication does, in the long run, make the article available for the scrutiny of other scientists. This increases the likelihood that eventually any serious methodological flaws will be spotted. Haack's discussion of how this all affects the quest for "reliability" in the courtroom is too lengthy to review here. But she posits a "whole raft of questions" lawyers should ask that might throw light

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on the significance of publication in a peer-reviewed journal. These can be of value to litigators preparing to challenge the hearsay article.

Conclusion

The courts' task is to gatekeep expert testimony to ensure that scientific evidence is relevant and reliable before it is ruled admissible. Anything less obscures the search for the truth and distorts the justice system. Somehow, the professionally-reliable-hearsay exception — permitted only because it is supposed to be trustworthy — has morphed into a "trial by literature" stampede in which expert testifiers use all manner of hearsay articles to quote or to bolster their testimony. Often, the magic words "peer review" are flashed as a talismanic admissibility-gate-opener.

Sometimes, the tactic works. The search for the truth deserves better, however. Litigators have been furnished with abundant information about peer review's shortcomings. Armed with such knowledge, they can fashion compelling advocacy. A battle over reliability can dictate the lawsuit's outcome.

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The History

The modern collateral source rule prevents the jury from receiving evidence that a third party paid for expenses incurred by an injured party. The collateral source rule originated in England during the 1820s and was first accepted in the United States in 1854. Robert Hernquist, *Arthur v. Catour:* "An Examination of the Collateral Source Rule in Illinois," 38 *Loyola U. Chicago L.J.* 169, 176 (2006). The United States Supreme Court adopted the rule in the case of *Monticello v. Mollison*, 58 U.S. 152, 155 (1854). In that case, the Court held that a defendant's liability "could not be offset by [an] insurance policy," since it was "a wager between third parties." *Id*. The Court reasoned that a liable defendant was "bound to make satisfaction of the injury" even if a plaintiff recovered insurance benefits. *Id*. Since then, many states have adopted a similar form of the rule, excluding evidence of benefits from presentation to the jury.

The main criticisms of the collateral source rule are that excluding such evidence leads to inflated damages awards and a windfall to the claimant. Over the years, a number of justifications for the collateral source rule were given by courts. Historically, most people did not have health insurance or other collateral sources from which to obtain payments for medical care. Joshua Congdon-Hohman and Victor A. Matheson, "Potential Effects of the Affordable Care Act on the Award of Life Care Expenses," College of the Holy Cross, Department of Economics Faculty Research Series, Paper No. 12-01 (September 2012). *See also* William A. Olson, "The Collateral Source Rule: Double Recovery and Indifference to Societal Interest in the Law of Tort Damages," 2 *U. Puget Sound L. Rev*. 197 (1978). As a matter of public policy, the courts did not want to discourage people from obtaining insurance because "it is beneficial to encourage the public to acquire insurance coverage," if possible, and "the defendant should not be allowed to benefit from the plaintiff's foresight in acquiring insurance." *Hernquis*, at 178.

The courts also reasoned that tort law was a deterrent to negligence. Failing to require defendants to pay the full amount of damages caused by their negligence would diminish the deterrent effect. *Id*. *See also Amalgamated Transit Union Local 1324 v. Roberts*, 434 S.E.2d 450 (Ga. 1993).

Over time, however, it became commonly known that a healthcare provider's billed "price" was not the same as the actual cost of the service, or even what the provider expected to receive in full payment. With the ever increasing role played by health insurance (public and private), medical costs were negotiated down and, frequently, the actual payment by the payor to the provider did not reflect the price on the bill or statement of account. Joseph Goldstein, "Exerting Their Patients," *ABA Journal* (May 1, 2009). As one commenter remarked, "The evolution of the nation's health care payment systems" has made the "list price" in a medical bill "meaningless" and "almost entirely a fictitious number." James McGrath, "Overcharging the Uninsured in Hospitals: Shifting a Greater Share of Uncompensated Medical Care Costs to the Federal Government," 26 *Quinnipiac L. Rev.* 173, 185 (2007); Mark A. Hall & Carl E. Schneider, "Patients As Consumers: Courts, Contracts, and the New Medical Marketplace," 106 *Mich. L. Rev.* 643, 664-665 (Feb. 2008).

Enter the Act

The Affordable Care Act (the Act) (Pub. L. No. 111-148, 124 Stat. 119 (2010)) was passed and signed into law on March 23, 2010. The Act included an individual mandate that went into effect on Jan. 1, 2014, which requires all citizens to have health insurance. With this requirement, and assuming full implementation of the Act, it is now time to question the continued viability of the collateral source rule. Specifically, if the main premise supporting the collateral source rule is a public policy in favor of encouraging people to obtain health insurance, that policy should now be less of a concern.

With the passage of the Act, it is less likely that juries will see injured parties who do not have health insurance. Moreover, juries "will rarely, if ever, encounter uninsured plaintiffs whose medical bills are paid in full at the billed rate rather than at the lower negotiated rate paid by insurance companies" and/or government insurers, such as Medicaid. Ann S. Levin, "The Fate of the Collateral Source Rule After Healthcare Reform,"

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60 *UCLA L. Rev.* 736, 742 (2013). This is because everyone is now required by law to be insured, or they must pay a substantial penalty. Therefore, plaintiffs will benefit from and actually pay the lower negotiated costs of health care rather than the artificially inflated prices charged.

The individual mandate eradicates the notion that society should encourage people to purchase health insurance, or that buying insurance was the result of a plaintiff's prudence. Rather, with the individual mandate, the opposite presumption about health insurance should be made: Plaintiffs have at least the minimum level of coverage required by law. Rebecca Levenson, "Allocating the Costs of Harm to Whom They Are Due: Modifying the Collateral Source Rule After Health Care Reform," *U. Penn. L. Rev.* 922, 935 (2012).

As for deterrence of torts, the defendant will still pay the actual cost of the harm caused rather than a fictitious figure, which has nothing to do with the harm caused to the plaintiff. Put simply, the previous justifications for the collateral source rule no longer exist. All Americans must now be insured and all Americans will benefit from the negotiated rates the healthcare providers will accept as full payment. If the collateral source rule remains in place, the potential for the presentation of misleading evidence exists.

Actual Payments

Even before passage of the Affordable Care Act, courts began considering the evolution of healthcare payment systems concerning medical bills versus actual medical costs or actual damages. Concerns regarding the presentation of evidence to a jury of medical bills that did not represent the actual costs incurred have long been considered, but inconsistently addressed. This is due to traditional presumptions in favor of the injured party over concerns for the tortfeasor. *See, e.g., Amalgamate*, 434 S.E.2d at 452.

In recent years, state appellate courts have started to address the issue and are not permitting evidence of a medical bill that does not reflect the actual amounts paid. For instance, the California Supreme Court held that the plaintiff could only recover what was actually paid through her health insurance and accepted by the provider as full payment because the difference between what was billed and what was accepted was not a collateral source. *Howell v. Hamilton Meats & Provisions*, 257 P.3d 1130 (Ca. 2001). In another example, the Florida Supreme Court held that the "[R]ecovery for medical expenses [is limited] to the amount of medical expenses that he actually was obligated to pay." *Goble v. Frohman,* 901 So.2d 830 (Fla. 2005). The Kansas Supreme Court held that the amount accepted as full payment for medical services is the amount relevant to prove the reasonable value of the medical treatment, but held that the source of payment (health insurance) is inadmissible. *Martinez v. Milburn Enterp., Inc.*, 233 P.3d 205, 207 (Kan. 2010). The Pennsylvania Supreme Court held that "the injured party should be limited to recovering the amount paid for the medical services." *Moorhead v. Crozer Chester Med. Ctr.,* 765 A.2d 786, 789-90 (Pa. 2001), abrogated on other grounds by *Northbrok life Ins. Co. v. Commonwealth*, 949 A.2d 333 (Pa. 2008). The Texas Supreme Court held that "the common-law collateral source rule does not allow recovery as damages of medical expenses a health care provider is not allowed to charge." *Haygood v. De Esabedo*, 356 S.W.2d 390, 396 (Tex. 2011).

Now, with the implementation of the Affordable Care Act, the assumption will be that all persons have insurance coverage; therefore, all courts should consistently allow only presentation of damages that were actually paid, *i.e.*, the negotiated rate insurance companies pay for the health care provided.

The same holds true for any projected future medical costs related to the injury. This, however, will be somewhat more complex, as insurance plans may change, along with the negotiated rates in the future. Some will likely even argue that future medical costs should be limited to the maximum out-of-pocket expenses allowable under the Affordable Care Act, but this would likely be an overreach. Such limitations might: 1) unjustly shift liability onto a health care insurer who may have a valid lien; and/or 2) shift a burden onto Medicare/Medicaid, which is not allowed under Federal law. Of course, separating out future medical expenses related to the injury litigated versus routine or unrelated expenses is an entirely different issue for consideration.

With the Affordable Care Act in place, if juries assume that every plaintiff is insured, but is ultimately responsible for costs paid by their insurer, the only costs that should be presented as evidence of damages are the costs actually paid to and accepted by the health care provider as full payment. To do anything else seems to allow the potential for perjury or testimony regarding damages not really incurred. Over the next few years, this issue will likely receive a lot of attention from lawyers and judges, alike, as the Affordable Care Act, which is still in

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misinformation to properly educate, but it does not want such corrections to become promotional opportunities.

2) Firms are cautioned not to provide information that goes beyond correcting the misinformation and crosses into proactive promotion. For example, if a company fixes information specific to one indication, it should not discuss other approved indications.

- Companies are not expected to correct all misinformation in a forum; however, if a company chooses to correct misinformation in one portion, it should correct *all* of the misinformation in that clearly defined portion of a forum on the Internet or social media. The company cannot choose to respond only to

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negative misinformation in the forum (whether in one defined area or over several postings) or correct overstatement of risks while ignoring other information that overstates a product's benefit (*i.e.*, be careful about selective correction).

- If a company provides corrective information to the independent third party, the FDA will not hold the company responsible for the third party's subsequent actions (or lack thereof).
- Companies are not required to submit corrections to the FDA. However, the agency suggests that firms maintain records in case the agency has questions, such as the nature or content of the misinformation, where it appeared, the date it appeared, and the content and date of the corrective information.
- While the FDA does not specifically identify Wikipedia by name, it refers to an "Internet-based, interactive, collaboratively edited encyclopedia." The agency recommends that, if there is misinformation, the company might contact the webpage author and provide corrective information to the author.

Liability Considerations

The FDA's guidance makes clear that, if the company does not control the venue or the message, the agency will not require correction of misinformation. Despite that comforting thought, a company may still believe that a correction is needed to, for example, preserve the product's good name, to minimize liability exposure so that social media users don't rely to their detriment on wrong information, or because they think "it's the right thing to do" to protect public health. All of these reasons are valid, but may not be a complete or satisfactory response. Does correction in one place but not another imply acceptance or confirmation of the latter? If the company corrects and the initial post responds with more misinformation, will the corrections continue? And, if the firm thinks a fix is needed, who will be responsible at the company for making the changes? And, is the response to answer the misinformation on the site itself where the misinformation was posted or to the author directly but privately, if known?

There might be tens, hundreds, or thousands of blogs, websites, chatrooms, and other venues not run or controlled by the product owner, where wrong information about a product is presented. The FDA states that the company is not responsible nor must it make corrections. But senior management may want to defend the shield. Nevertheless, it must ask itself whether it is prepared to fight a battle that may never be won, and who will lead the charge.

Such is the balancing act and the life science's dilemma — to correct or not correct misinformation.

Observations

Control, control, control. The FDA continues to emphasize that a company's control of the message is an important factor when evaluating whether the company has regulatory obligations. Companies that control the message must comply with applicable labeling and promotional regulatory requirements. A company that wants the commercial benefits of social media must also recognize it assumes the potential regulatory and liability risks.

In all social media guidances, one of the FDA's goals is to *educate* the consumer. The FDA seeks to ensure that truthful, complete, and prominent information is provided (*e.g.*, link or reputable source). The agency discourages using educational opportunities as excuses for promotional messaging.

The FDA recognizes the challenges with social media. The agency is attempting to find a balance between the company's regulatory obligations concerning product promotion versus the inevitable inability for the company to monitor and control other independent parties' messages. The fact that, for example, the agency *will not require* correction of misinformation on an independent third-party site or a company can correct some, but not all, misinformation that might exist in cyberspace indicate an agency acceptance of certain limitations.

While the FDA appreciates the potential benefits of social media in product promotion and information dissemination, it will not suspend its regulatory expectations for compliance. There is no requirement that companies use social media; if they do, they must consider the regulatory and liability consequences.

The draft guidance focuses on the FDA's interpretation and expectations. Companies must also consider potential liability and commercial exposure. Therefore, any social media planning requires the input of different groups of a company, including commercial, medical, regulatory, legal and potentially quality assurance and compliance, depending on the specific postings. Furthermore, companies might want to revisit existing standard operating procedures and evaluate whether revisions and subsequent training are needed.

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Practice Tip

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its infancy, is implemented and/or revised.

Conclusion

The law of the land has dramatically changed after a slow, but evolving process related to health care payment systems over time. The collateral source rule, long established as it has been, will likely end or be substantially altered along with the other dramatic changes ushered in with the Affordable Care Act.

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