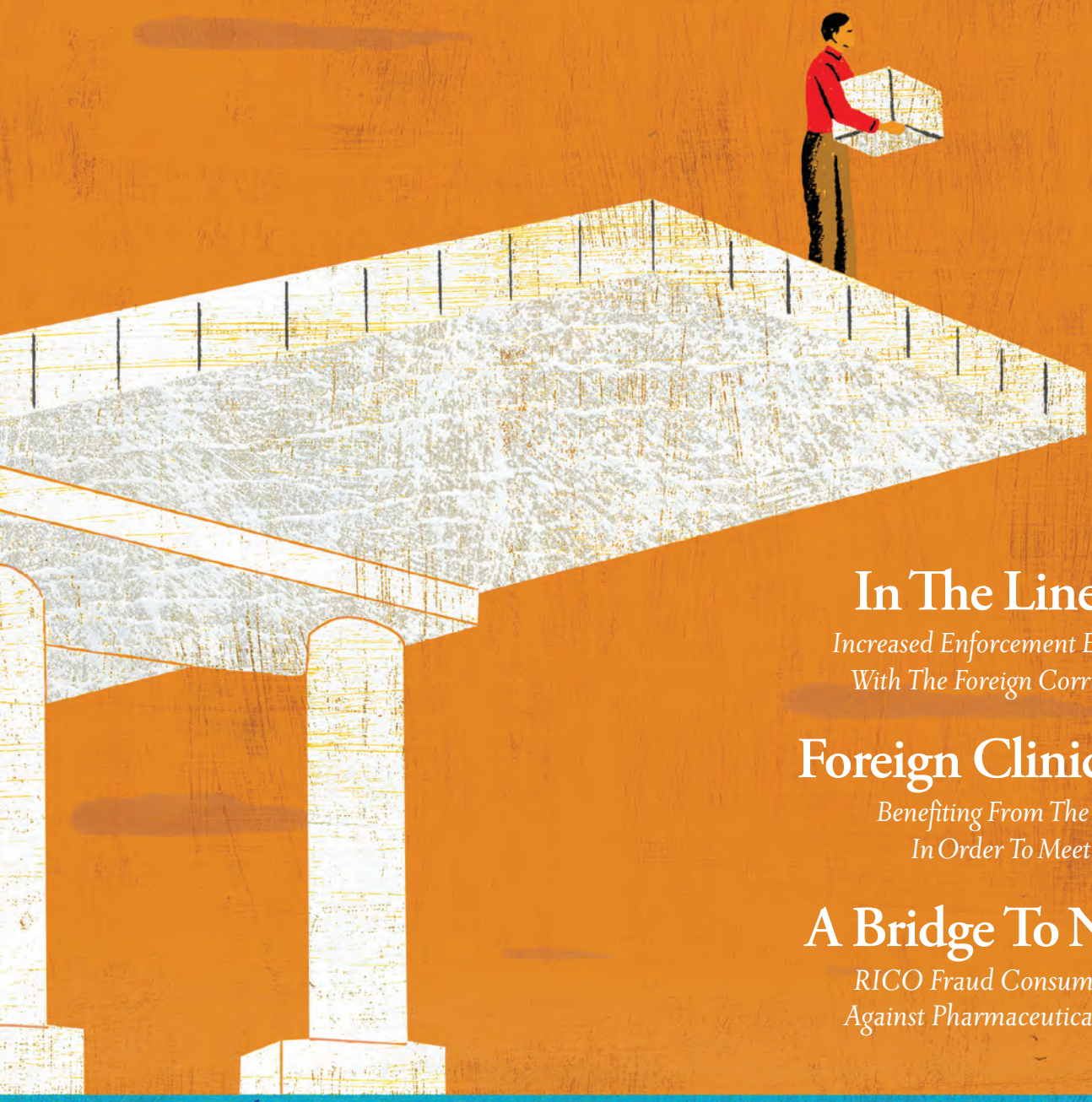
Vol. 5 No. 2 May 2012

# Pro Te: *Solutio*

SOLUTIONS FOR YOU



## In The Line Of Fire

*Increased Enforcement Efforts Associated With The Foreign Corrupt Practices Act*

## Foreign Clinical Trials

*Benefiting From The FDA's Guidance In Order To Meet Study Standards*

## A Bridge To Nowhere

*RICO Fraud Consumer Class Actions Against Pharmaceutical Manufacturers*

Dear Client:

It is no longer a surprise to read about a pharmaceutical or medical device company being investigated by the United States Department of Justice for violation of the Foreign Corrupt Practices Act. The Department of Justice has set up special teams to investigate the healthcare industry and potential violations of the Act. *In the Line of Fire* discusses this focus and also gives some timely advice on how to structure a compliance program which will serve you well if your company is investigated.

Plaintiff's attorneys are always looking for new avenues to bring lawsuits. Racketeering Influenced and Corrupt Organizations Act (RICO) claims against pharmaceutical companies are part of this effort. RICO Class Actions are the focus of *A Bridge to Nowhere: RICO Fraud Consumer Class Actions Against Pharmaceutical Manufacturers Post Bridge v. Phoenix Bond*.

Clinical studies in foreign countries in support of new pharmaceuticals are now more the norm than the exception. *The New Federal Guidance on Foreign Clinical Studies* gives some background on the growth of foreign clinical studies, as well as the FDA's most recent advice as to how best to conduct them.

And don't miss the second installment of our comprehensive fifty state survey on the local federal court rules on protecting confidential information. This issue contains the remaining twenty-four states and Puerto Rico and, with part one in the February 2012 issue of *Pro Te: Solutio*, should be a handy reference source.

Our goal in *Pro Te: Solutio* is not only to keep you abreast of some of the topics important to you, as part of the healthcare industry, but to also offer you some tips and practical suggestions on how to better meet your demanding jobs. We hope this issue attains that goal.

Christy D. Jones
*Co-Chair — Litigation*

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*Co-Chair —*
*Business and Corporate Healthcare*

# Pro Te: *Solutio*

Vol. 5 No. 2 May 2012

## 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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# IN THE LINE OF FIRE

## 2012 RECENT FCPA ENFORCEMENT EFFORTS IN THE PHARMACEUTICAL/MEDICAL DEVICE INDUSTRY AND THE IMPORTANCE OF AN EFFECTIVE COMPLIANCE PROGRAM

**"I MEANT WHAT I SAID AND I SAID WHAT I MEANT."**

— DR. SEUSS, *Horton Hears a Who!*

**"OUR FOCUS AND RESOLVE IN THE FCPA AREA WILL NOT ABATE, AND WE WILL BE INTENSELY FOCUSED ON ROOTING OUT FOREIGN BRIBERY IN YOUR INDUSTRY."**

— LANNY A. BREUER, Assistant Attorney General, Dept. of Justice,
Address to the Tenth Annual Pharmaceutical Regulatory and Compliance Congress, November 2009

Two and half years ago, the U.S. Department of Justice (DOJ) warned the healthcare industry that federal law enforcement would be increasing efforts to monitor pharmaceutical and medical device entities for compliance with the Foreign Corrupt Practices Act (FCPA). Several high-risk factors make the industry an attractive target for FCPA investigations, including the significant amount of sales generated outside the United States where healthcare systems are routinely operated by the government.[1] Additionally, the industry has seen an increasing number of clinical trials and product development activity conducted overseas where interactions with government-employed physicians and healthcare providers are routine and, arguably, significantly less regulated.

The DOJ is as good as its word. The industry has been hit hard by the FCPA in the last two years. In the last twelve months alone, the DOJ announced two significant settlements with major medical device companies reaching combined payments over $90 million. There are at least 78 known ongoing corporate investigations, including at least eighteen healthcare industry players.[2] Many perceive the active enforcement of the FCPA as a natural expansion of the Anti-Kickback laws to the international arena. In fact, the DOJ has noted that "the types of corrupt payments that violate the FCPA because they are given to obtain or retain business in other countries are not any different than the items of value that would violate the Anti-Kickback Statute if given within the United States — cash, gifts, charitable donations, travel, meals, entertainment, grants, speaking fees, honoraria, and consultant arrangements, to name a few."[3] As explained more fully below, failure by any pharmaceutical or medical device entity that has any relation to the United States to heed the express and explicit warnings provided by the DOJ regarding FCPA enforcement would be reckless and the consequences likely to be dire.

### FCPA BASICS: PRIVATELY HELD ENTITIES BEWARE

Enforcement of the FCPA against publicly held corporations attracts significant attention which may lull smaller, privately held entities into a false sense of safety. Yet, both public and private entities are subject to the reach of the FCPA. There are two principal parts to the FCPA: the Anti-bribery Provisions[4] and the Books and Records Provisions.[5] The Anti-bribery Provisions prohibit payments of any "thing of value" to an individual knowing that it will be paid to a foreign official in order to corruptly influence the official or secure an

AS APPLIED WITHIN THE HEALTHCARE INDUSTRY, THE DOJ HAS EMPHASIZED THAT THE "DEPTH OF GOVERNMENT INVOLVEMENT IN FOREIGN HEALTH SYSTEMS, COMBINED WITH FIERCE INDUSTRY COMPETITION AND THE CLOSED NATURE OF MANY PUBLIC FORMULARIES, CREATES A SIGNIFICANT RISK THAT CORRUPT PAYMENTS WILL INFECT THE PROCESS."

improper advantage in an attempt to obtain or retain business. The Books and Records Provision requires that "issuers" "make and keep books, records, and accounts, which, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the issuer."[6] While the Books and Records Provisions apply only to companies that are SEC-registered or reporting "issuers," the Anti-bribery Provisions have a more extensive reach. The Anti-bribery Provisions apply to "domestic concerns" (United States companies, citizens, or residents); any officer, director, employee, or agent of a domestic concern; issuers who have a class of securities registered with the SEC; and, any person who does not fit within the categories listed but violated the FCPA within the territory of the United States. Clearly, the last, catch-all provision is expansive and could apply not only to a publicly held U.S. company, but also to any privately held company that finances a foreign activity with any component occurring in the U.S. Similarly, if a foreign affiliate is acting as an "agent" of a U.S. (domestic) concern in facilitating illegal conduct, then it too will be covered.

The DOJ has consistently taken the position that minimum jurisdictional contacts include *de minimus* activities such as emails, telephone calls, and transfers through correspondent bank accounts that occur in the U.S. Due to the expansive interpretation given the jurisdictional provisions by the DOJ, any company with a nexus to the United States is potentially subject to FCPA enforcement, even if the company and the illegal activity are located outside of the U.S.

As applied within the healthcare industry, the DOJ has emphasized that the "depth of government involvement in foreign health systems, combined with fierce industry competition and the closed nature of many public formularies, creates a significant risk that corrupt payments will infect the process."[7] For instance, the FCPA criminalizes making payments to "foreign officials" for the purpose of obtaining or retaining business or securing any improper business advantage. In his remarks to the pharmaceutical industry, Assistant Attorney General Breuer commented on the potential complexities involved in interpreting the term, which could encompass health ministry and customs officials, doctors, pharmacists, lab technicians, and health professionals at state-owned facilities. As he further explained, "nearly every aspect of the approval, manufacture, import, export, pricing, sale, and marketing of a drug product in a foreign country will involve a 'foreign official' within the meaning of the FCPA."[8]

Because of this expansive approach, industry personnel face a substantially higher likelihood than professionals in other industries that they may interact with "foreign officials" as defined by the FCPA. Accordingly, pharmaceutical and medical device companies must be aware that the seemingly routine engagement of healthcare providers, reimbursements for program participation, travel, gifts, entertainment, charitable contributions, sponsorships, political contributions, clinical trials arrangements, and regulatory approvals abroad all pose significant FCPA risks.

## RECENT FCPA MEDICAL DEVICE-RELATED DPAS

**"I WARN YOU DEAR CHILD, IF I LOSE MY TEMPER, YOU LOSE YOUR HEAD. UNDERSTAND?"**

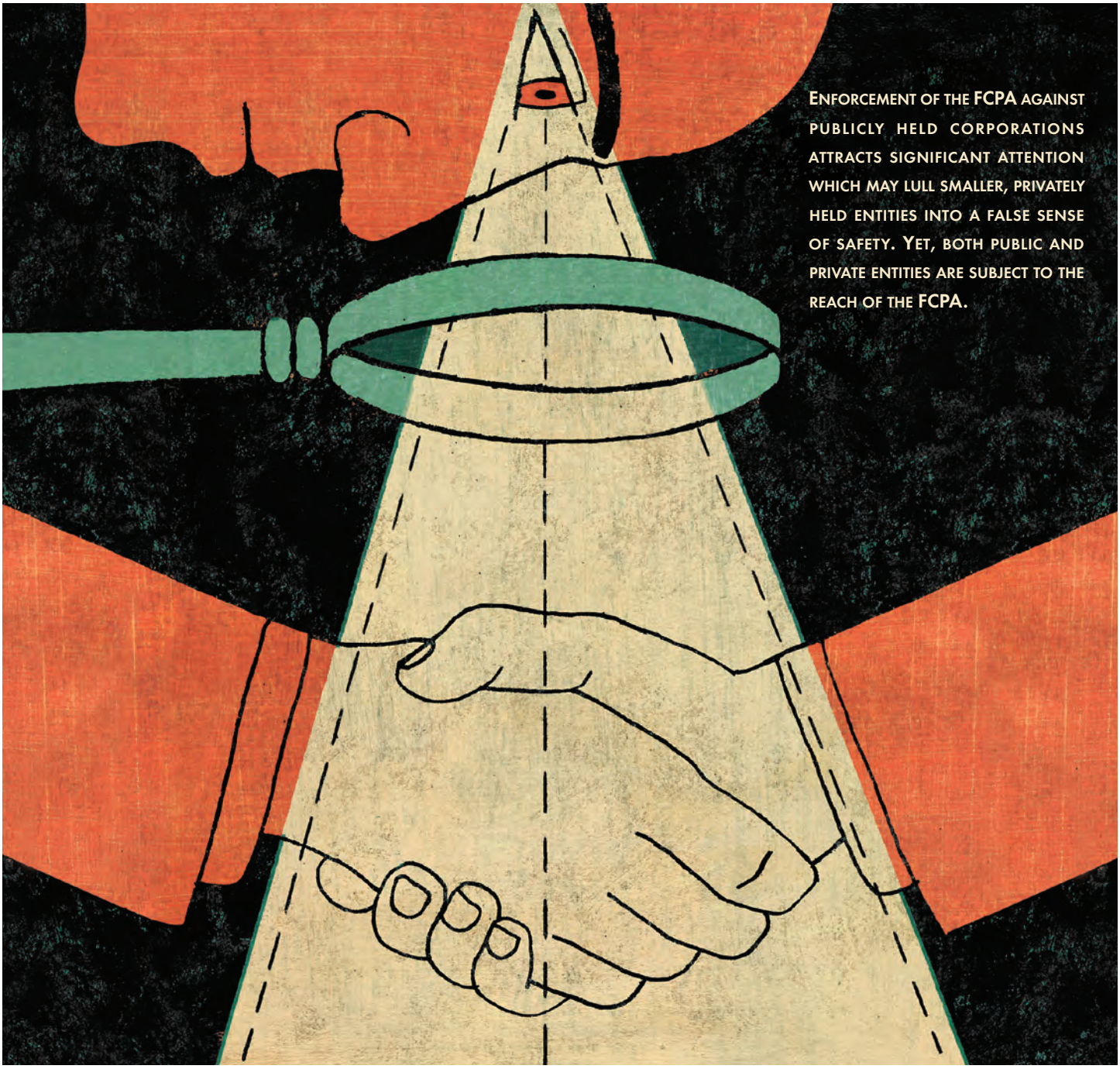
— THE QUEEN OF HEARTS, *Alice in Wonderland*

In late 2009, the DOJ began assembling teams to support its FCPA focus on the healthcare industry by combining the expertise of the healthcare fraud unit with the international bribery expertise of the FCPA unit.[9] Consequently, FCPA enforcement has gained significant momentum and now trails only terrorism as a DOJ enforcement priority.[10] The industry has felt the impact.

Currently known investigations in the pharmaceutical and medical device industry are extensive: AstraZeneca, Baxter International Inc., Biomet, Bio-Rad Laboratories, Bristol-Meyers Squibb, Covidien, Eli Lilly, GlaxoSmithKline, Grifols SA (Talecris Biotherapeutics Holdings Corp.), Ingersoll-Rand, Medtronic Inc., Merck & Co. Inc., Orthofix International NV, Pfizer Inc., Sciclone Pharmaceuticals Inc., Smith & Nephew, Stryker Corporation, Zimmer Holdings Inc. Because this list is based on SEC filings, it likely represents only a fraction of ongoing FCPA enforcement actions. A review of two of the most recent settlements provides valuable insight into the breadth of the investigations and generous elasticity with which the government applies the FCPA provisions.

*United States v. Johnson & Johnson (DePuy Inc.):* In April 2011, the DOJ announced that it had entered into a three-year Deferred Prosecution Agreement (DPA) with Johnson & Johnson, a U.S.-based healthcare company that manufactures and sells pharmaceuticals, medical devices, and consumer healthcare products, to resolve allegations that Johnson & Johnson and its subsidiaries had committed violations of the FCPA. According to the government's allegations, foreign subsidiaries of Johnson & Johnson paid kickbacks to healthcare providers employed at government-owned hospitals in Greece to use its surgical implants, Poland to award contracts to the company, and Romania to prescribe pharmaceuticals. The DOJ also alleged foreign subsidiaries of Johnson & Johnson paid kickbacks to officials of the former government of Iraq in order to receive contracts to provide humanitarian supplies under the United Nations Oil for Food Program. To resolve these charges, Johnson & Johnson agreed to pay more than $48.6 million in disgorgement and prejudgment interest, as well as a $21.4 million criminal fine.

As mitigating factors supporting the DPA settlement, the DOJ noted that Johnson & Johnson had accepted responsibility for

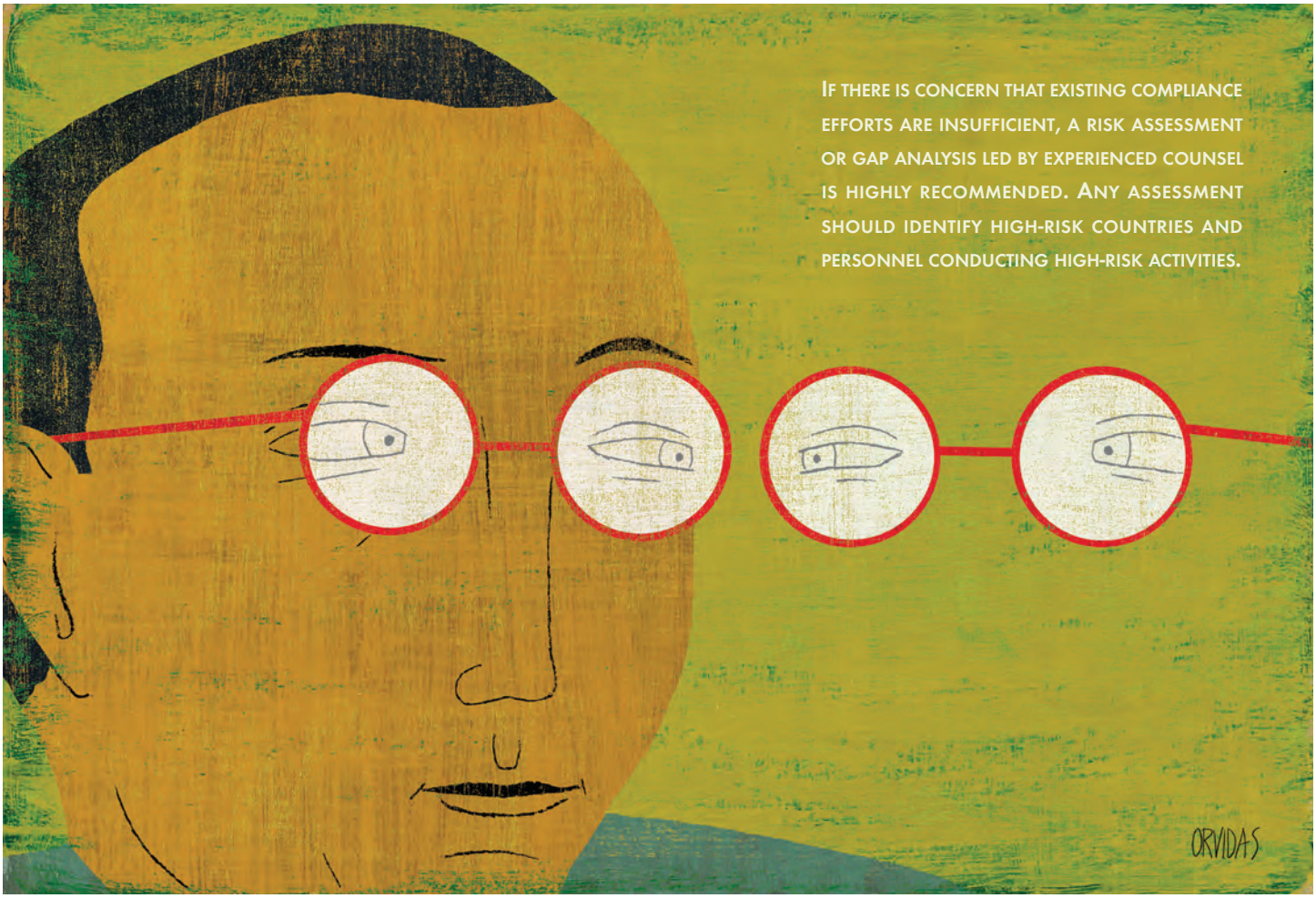


**Enforcement of the FCPA against publicly held corporations attracts significant attention which may lull smaller, privately held entities into a false sense of safety. Yet, both public and private entities are subject to the reach of the FCPA.**

the offending conduct of its subsidiaries. The DOJ recognized Johnson & Johnson's prompt voluntary disclosure and extensive self-investigation of the underlying conduct, the cooperation provided by the company to the government investigators, and the extensive remedial efforts and compliance improvements undertaken by Johnson & Johnson. The DOJ also reported that Johnson & Johnson received a reduction in its criminal fine as a result of its cooperation in the ongoing investigation of other companies.

Significantly, in consideration of Johnson & Johnson's pre-existing compliance programs, remediation efforts, and enhanced compliance commitments included in the DPA, the DOJ did not require the retention of a corporate compliance monitor. Yet, the DPA does require that in addition to adhering to the corporate compliance program commitments common to most DPAs, Johnson & Johnson must comply with some notable "enhanced compliance obligations" for the duration of the DPA. Among the more interesting "enhanced" obligations is the requirement that Johnson & Johnson establish an extensive compliance team network including separate heads of compliance within each business sector and corporate function. The global compliance leadership must include regional compliance leaders and business segment compliance leaders. Every jurisdiction in which the company operates must institute individualized gifts, hospitality, and travel policies and procedures that contain restrictions regarding interactions with government officials — which must explicitly include public healthcare providers.

On a periodic basis, Johnson & Johnson




is obligated to conduct FCPA audits and risk assessments of markets where Johnson & Johnson has government customers. Among other elements, these audits must include on-site visits to high-risk locations, review of a statistically representative sample of contracts with and payments to individual healthcare providers, and a creation of action plans resulting from issues identified during audits. Comprehensive due diligence reviews of sales intermediaries must be conducted regularly. Moreover, Johnson & Johnson is directed to include in contracts (where permitted by law) standard provisions designed to prevent violations of the FCPA. Such provisions must include anticorruption representations, rights to conduct audits of the books and records, and rights to terminate as a result of any breach of anticorruption laws.[11]

*Smith & Nephew, Inc.:* On February 6, 2012, the DOJ disclosed that it had entered into a three-year DPA with Smith & Nephew Inc., a U.S. subsidiary of Smith & Nephew plc, a United Kingdom-based medical device manufacturer, to resolve allegations that certain affiliates had committed violations of the FCPA. According to the allegations, Smith & Nephew, through certain executives, employees, and affiliates, agreed to sell products at full list price to a Greek distributor and then pay the amount of the distributor discount to an off-shore shell company controlled by the distributor. These off-the-books funds were then used by the distributor to pay cash incentives and other things of value to government-employed Greek healthcare providers to induce the purchase of products. In total, from 1998 to 2008, Smith & Nephew, its affiliates, and employees authorized the payment of approximately $9.4 million to the distributor's shell companies; some or all of this payment was passed on to physicians employed by government-owned institutions overseas to corruptly induce them to purchase Smith & Nephew medical devices.

Smith & Nephew agreed to pay a $16.8 million criminal penalty to settle the criminal charges. Additionally, Smith & Nephew was required to retain a corporate compliance monitor for 18 months. In discussing the settlement with Smith & Nephew, the DOJ noted Smith & Nephew's cooperation with the DOJ's investigation, thorough self-

**Substantively, there are a number of essential elements that must be present for any FCPA compliance program to achieve its goals. Regular monitoring and auditing are critical to prevent complacency and enforcement gaps. Robust due diligence processes must be applied to distributors, agents, joint venture partners, and vendor contracts.**

investigation of the underlying conduct, and the remedial efforts and compliance improvements undertaken by Smith & Nephew.

The parent company, Smith & Nephew plc, also entered into a settlement with the SEC to resolve a civil complaint alleging violations of the FCPA. The SEC alleged that Smith & Nephew plc and its subsidiaries made illicit payments to foreign government officials in order to obtain or retain business, failed to have an adequate internal control system in place to detect and prevent the illicit payments, and improperly recorded each of those payments in its accounting books and records. Smith & Nephew plc agreed to settle the SEC's charges by paying more than $5.4 million in disgorgement and prejudgment interest.

Following announcement of the settlement, the SEC cryptically stated that its investigation of the medical device industry is continuing.[12]

## COMPLIANCE PROGRAMS: PREVENTION & REDEMPTION

### "Be Prepared"

— Motto, Boy Scouts of America

With the looming specter of continuing government FCPA investigations into the medical device industry, prevention and early detection of potential issues should be a priority for all healthcare entities with ties to the United States. While implementation and enforcement of corporate compliance programs focused on the anti-kickback statute and Stark laws are now the norm, active compliance efforts concentrated on the FCPA are notably less prevalent — particularly in privately held corporations that may not be subject to the Books and Records Provisions of the FCPA. Not only does this failure expose the company to liability from rogue actors whose activities go undetected, but it also represents a missed opportunity to gain leniency should the company become an FCPA target. As stated by DOJ, "[t]here are many steps that you can be taking that would put your organization in a better position for the day we do come knocking, or that could prevent us from coming at all."[13] In order to be an effective preventative tool, however, a compliance program must be active and comprehensive.

If there is concern that existing compliance efforts are insufficient, a risk assessment or gap analysis led by experienced counsel is highly recommended. Any assessment should identify high-risk countries and personnel conducting high-risk activities. Similar reviews and updates should be conducted on an annual basis — a practice reflected in the recent Johnson & Johnson DPA enhanced compliance obligations. Identified deficiencies should be promptly addressed through a detailed remedial plan.

From a practical standpoint, there are certain key elements that are routinely overlooked when FCPA compliance programs are designed and implemented. At a fundamental level, any compliance initiative must be supported by the tone at the top level of the company. Similarly, no program will be broadly followed if it is not easily understood. The policies and procedures must be written in plain English: short, crisp, concise, avoiding legalese. Canned policies found on basic internet searches should be avoided in favor of tailored policies that reflect the culture of the corporation, as well as the particular realities and concerns of the business. Moreover, the procedures must provide specific directions regarding where to obtain guidance on complex issues. Once written policies are in place, proper training must be provided across all levels of the business.

Substantively, there are a number of essential elements that must be present for any FCPA compliance program to achieve its goals. Regular monitoring and auditing are critical to prevent complacency and enforcement gaps. Robust due diligence processes must be applied to distributors, agents, joint venture partners, and vendor contracts. Along those lines, and as required in the recent Johnson & Johnson DPA, contracts should incorporate audit rights, representations regarding FCPA compliance, and clear grounds for termination related to FCPA violations. Payments should be subject to an approval process involving knowledgeable personnel trained to detect at-risk payments, coupled with clear reporting procedures for suspected violations. Finally, detection will be meaningless unless there is a prompt and proper response to detected offenses.

While no compliance program can prevent all illegal conduct, the failure to proactively deploy an effective program can have dire consequences. Early detection is key to avoiding larger scale offenses. Similarly, the existence of robust programs will likely mitigate any enforcement actions that do occur.

[1] *See, generally*, Lanny A. Breuer, Assistant Attorney General, Criminal Division, "Prepared Address to the 22nd National Forum on the Foreign Corrupt Practices Act," (Nov. 17, 2009). *Available at* <http://www.justice.gov>.

[2] See FCPA Blog at <http://www.fcpablog.com/blog/2012/1/4/the-corporate-investigations-list-january-2012.html>, identifying investigations based on SEC filing disclosures. The number of FCPA investigations focused on non-public entities is unknown.

[3] As quoted in Sampson & Wesoloski, "Increased Targeting of the Pharmaceutical and Medical Device Industries Under the Foreign Corrupt Practices Act," 6 MELR 140, 02/22/2012.

[4] 15 U.S.C. §§ 78dd-1, et seq.

[5] 15 U.S.C. § 78m.

[6] 15 U.S.C. § 78m(b)(2)(A).

[7] Lanny A. Breuer, Assistant Attorney General, Criminal Division. "Prepared Address to the 22nd National Forum on the Foreign Corrupt Practices Act." (Nov. 17, 2009). PDF available at <http://www.justice.gov/criminal/pr/speeches-testimony/documents/11-17-09aagbreuer-remarks-fcpa.pdf>. Last accessed Apr. 27, 2012.

[8] *Id.*

[9] *Id.*

[10] Michael Li-Ming Wong and Emily Proskine, "The Foreign Corrupt Practices Act and Pharma: Is DOJ Following Through on Its Tough Talk Towards the Industry?" Bloomberg Law Reports: Risk & Compliance (2010), citing Charles McKenna, Chief, Criminal Division, U.S. Attorney's Office for the District of New Jersey, as a panelist in the American Bar Association's Program, "Current Issues in Medical Device and Pharmaceutical Litigation," held at the Schering-Plough Corporation in Kenilworth, New Jersey.

[11] For a complete discussion of the allegations and settlement terms, see Robert Tarun, *The Foreign Corrupt Practices Handbook*, p. 401 (2nd Ed., 2012).

[12] *See* "SEC Charges Smith & Nephew PLC with Foreign Bribery," (Feb. 6, 2012). *Available at* <http://www.sec.gov/news/press/2012/2012-25.htm>. Last accessed Apr. 27, 2012.

[13] Lanny A. Breuer, Assistant Attorney General, Speech to the 24th National Conference on the Foreign Corrupt Practices Act, (Nov. 16, 2010). *Available at* <http://www.justice.gov/criminal/pr/speeches/2010/crm-speech-101116.html>. Last accessed Apr. 27, 2012.

Written by Amy Pepke

# THE NEW FDA GUIDANCE *on* FOREIGN CLINICAL TRIALS

## WILL YOUR STUDIES MEET THE STANDARDS?

Clinical trials are the lifeblood of new pharmaceuticals in the United States. Investigational new drugs require such studies as proof of the safety and efficiency of the drug. Over the past fifteen years, however, it has become increasingly clear that it is not possible or practicable to have all of the clinical trials take place in the United States. Increasingly, more trials are being done in Eastern Europe, South America, and Asia.[1] These studies take place outside the United States for a variety of reasons:

- There are not enough competent clinical investigators in the United States to conduct all the new studies for the increasing number of new drugs and devices being tested.
- Cost of the trials is often less overseas — especially in Eastern Europe, Asia, and South America.
- There is increasing concern in the United States over doctors who conduct studies and who are also paid consultants by pharmaceutical companies, which may mean even fewer available clinical investigators.
- In Eastern Europe, South America, or Asia, the study subjects are less likely to already be on drug therapy.
- Tests can be done out of season. For example, tests of an allergy drug can be done in South America in January.

Over the last decade, however, this trend has also caused some concern and some criticism. As early as 2001, the Office of Inspector General (OIG) of the Department of Health and Human Services authored *The Globalization of Clinical Trials: A Growing Challenge in Protecting Human Subjects*.[2] This report found that foreign clinical investigators conducting drug research under an Investigational New Drug Application (IND) had increased sixteen-fold over the past decade.[3] The Office of Inspector General recommended that the Food and Drug Administration obtain more information about the performance of foreign institutional review boards and encourage sponsors to obtain attestations from investigators that they would adhere to ethically sound principles of research. The OIG also urged the FDA to take a leadership role in ensuring that there were adequate human safety protections in all non-U.S. clinical trials.

Since the release of this report, the use of foreign clinical trials in support of FDA-

approved pharmaceuticals has increased dramatically. A study in the *New England Journal of Medicine* looked at the *Clinical Trials.gov* registry to find the countries in which studies were taking place. It found that, as of November 2007, for the twenty largest U.S.-based pharmaceutical companies, approximately one-third of the Phase 3 trials were being conducted solely in foreign countries and that a majority of study sites were outside of the United States.[4] In recognition of this trend, in April 2008, the FDA amended its regulations on the acceptance of foreign studies not conducted under an Investigational New Drug as support for the approval of the drug being studied.[5] These amendments were made to ensure that all such studies were conducted in accordance with good clinical practices. This final rule is codified at 21 CFR § 312.120.[6]

In March 2012, the FDA issued the *Guidance for Industry and FDA Staff: FDA Acceptance of Foreign Clinical Studies Not Conducted under an IND Frequently Asked Questions* ("Guidance").[7] The Guidance notes that a sponsor may choose, but is not required, to conduct a foreign clinical study under an IND, and in such a case, all the requirements of an IND must be met unless waived. But if the foreign clinical study is not conducted under an IND, it must comply with the requirements of 21 CFR Section 312.20. This Guidance seeks to answer questions as to how sponsors of a new drug can demonstrate compliance with these regulations regarding foreign clinical studies, in particular that such studies be conducted with good clinical practice (GCP). Good clinical practice is defined by regulation as a "standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials in a way that provides assurance that the data are credible and accurate and the rights, safety, and well-being of trial subjects are protected."[8] Additionally, the Guidance notes there are certain international ethical and policy standards for clinical trials, such as the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) "Good clinical Practice: Consolidated Guideline" ("ICH E6"), which the FDA has adopted for use as further guidance.

The Guidance states that GCP requires review and approval of a foreign study by an independent ethics committee ("IEC") before the study is started to ensure that the rights and safety of the participants in the study are being protected. It indicates, however, that the FDA is flexible about the requirements of an adequate IEC because the membership and organization of the committee may vary from country to country based on local needs and customs.[9] The FDA considers an independent ethics committee to be adequate if it has "a reasonable number of members who collectively have the qualifications and experience to review and evaluate the science, medical aspects, and ethics of the proposed trial."[10] The Guidance also refers the sponsor to ICH E6, section 3.2, which requires there be at least five members of an IEC and at least one member to be someone who is not affiliated with the institution where the research will be conducted. The Guidance notes that the sponsor only has to provide to the FDA the name and address of the IEC that reviewed the study along with a statement that the IEC meets the applicable requirements for an IEC, but the sponsor must maintain records supporting this submission, including qualifications of members of the committee.[11] The IEC has to approve the study and any modifications to it, and must continually review the study. Documentation of such actions, however, need not be submitted to the FDA. Such documentation should be kept and provided to the FDA upon request.[12]

The IEC must also approve the informed consent. ICH E6 defines informed consent as "a process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate."[13] The Guidance notes that under 21 CFR section 312.120 (b) (8), a description of how the informed consent was obtained must be provided. It also states that the FDA believes that the informed consent documents should notify the subjects that international regulatory authorities may need to have direct access to their medical records for verification of study procedures and data.[14] Additionally, the informed consent would normally contain a brief statement of any type of incentives that were given study participants. If it does not contain such a statement, the FDA should be given a brief narrative description of such incentives.[15]

The Guidance also addresses what must

A STUDY IN THE *NEW ENGLAND JOURNAL OF MEDICINE* LOOKED AT THE *CLINICALTRIALS.GOV* REGISTRY TO FIND THE COUNTRIES IN WHICH STUDIES WERE TAKING PLACE. IT FOUND THAT, AS OF NOVEMBER 2007, FOR THE TWENTY LARGEST U.S.-BASED PHARMACEUTICAL COMPANIES, APPROXIMATELY ONE-THIRD OF THE PHASE 3 TRIALS WERE BEING CONDUCTED SOLELY IN FOREIGN COUNTRIES AND THAT A MAJORITY OF STUDY SITES WERE OUTSIDE OF THE UNITED STATES.

be submitted to the FDA about the investigators for the study. Documentation must be submitted to the FDA to show that each investigator has the experience and training "specifically related" to the proposed clinical study.[16] Usually, the Guidance states such information would include the investigator's CV and, if the study is novel or has increased risks of mortality and morbidity, additional information regarding the investigator's experience. Such experience might include, for example, recent presentations or publications. A statement should also be submitted describing how the investigators were trained to comply with GCP and to conduct the study in accordance with the study protocol. Sponsors are also encouraged to obtain written commitments that the investigators will comply with GCP and the protocol.[17] The FDA recognizes, however, that such commitments may be prohibited in some countries and does not want to "preclude submission of well-designed and ethically conducted foreign clinical studies solely because a written commitment was not obtained."[18]

The Guidance also addresses requirements for information about the foreign institutions in which the study will take place. It specifically states that the name and address of the research facility is not enough information to meet the requirements of the regulations, pointing out that the FDA is generally less likely to be familiar with foreign facilities. According to the Guidance, a description of the research facility would

GOOD CLINICAL PRACTICE IS DEFINED BY REGULATION AS A "STANDARD FOR THE DESIGN, CONDUCT, PERFORMANCE, MONITORING, AUDITING, RECORDING, ANALYSIS, AND REPORTING OF CLINICAL TRIALS IN A WAY THAT PROVIDES ASSURANCE THAT THE DATA ARE CREDIBLE AND ACCURATE AND THE RIGHTS, SAFETY, AND WELL-BEING OF TRIAL SUBJECTS ARE PROTECTED."

INCREASINGLY, PHARMACEUTICAL COMPANIES ARE MULTINATIONAL. CHANCES ARE THAT YOUR PHARMACEUTICAL COMPANY HAS BEEN GRAPPLING WITH THE ISSUE OF FOREIGN CLINICAL TRIALS FOR YEARS: WHERE THE STUDY SHOULD TAKE PLACE, WHO WILL BE THE INVESTIGATORS, HOW GOOD GCP CAN BE ASSURED AND DOCUMENTED. THE GUIDANCE PROVIDES INFORMATION IN AN EASY-TO-USE QUESTION-AND-ANSWER FORMAT.

include enough information, such as the staffing, equipment, and the ability to provide any emergent or supportive care, to enable the FDA to assess the adequacy of the facility. All of this information is needed to demonstrate that the study is adequate and well managed.

The Guidance makes it clear that the FDA may need to review source documents of the study such as hospital records: "If the necessary records are not available, FDA may not accept the study data in support of an IND or application for marketing approval. If the records exist but a sponsor cannot disclose them to FDA because such disclosure is prohibited by applicable foreign law, the sponsor or applicant may seek a waiver of this requirement."[19] For such data to be relied upon, the sponsor and the FDA would have to agree on another way to validate the data: "[T]he sponsor or applicant should also explain how the foreign data are applicable to the U.S. population and U.S. medical practice."[20]

Under 21 CFR 312.120 (c), requests for waivers from these regulations are allowed, but the Guidance makes it clear that the FDA expects few requests for such waivers. Since the regulations were published, few waivers have been requested.[21] A waiver request must contain at least one of the following criteria: Why compliance with the regulation is "unnecessary or cannot be achieved," a description of an alternative action that satisfies the purpose of the requirement, or other information that justifies a waiver from a specific regulation.[22] The Guidance gives some examples of the types of situations in which the FDA might expect a waiver request to be made. For example, a waiver would be anticipated if privacy laws in a foreign country prohibit the disclosure of the members of the IEC or of hospital records. In such situations, the sponsor or applicant has to document all attempts to get the information and why the laws prohibit such disclosure.

Increasingly, pharmaceutical companies are multinational. Chances are that your pharmaceutical company has been grappling with the issue of foreign clinical trials for years: where the study should take place, who will be the investigators, how good GCP can be assured and documented. The Guidance provides information in an easy-to-use question-and-answer format. It would be prudent to review the Guidance as well as the international agreements regarding clinical studies before sponsoring any foreign clinical studies. Having all the these issues covered before the study even starts will lead to fewer problems and cost savings when the study is later considered as part of the new drug's approval process with the FDA.

[1] This trend means that pharmaceutical companies conducting or sponsoring clinical trials abroad must have knowledge of foreign laws that will apply to the trial, including the European Union Directive on Privacy and the European Clinical Trial Directive. They should also comply with the World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects.

[2] September 2001, OEI-01-00-00190.

[3] *Id.* page i.

[4] Glickman, Seth, M.D., et. al. "Ethical and Scientific Implications of the Globalization of Clinical Research," *New England Journal of Medicine* Volume 360, No. 8, February 19, 2009.

[5] 21 CFR § 312.20 requires that a sponsor submit an INDA to the FDA if it wishes to conduct a clinical investigation of a new drug and cannot begin such a trial until it has done so. Under 21 CFR § 312.21, an INDA may be submitted for one of more phases of an investigation. The FDA has to review the application to assure the safety of all the subjects and, in Phases 2 and 3, to determine that the scientific evaluation of the drug is adequate to determine if the drug is safe and effective. 21 CFR § 312.22.

[6] *See also* 21 CFR § 314.106.

[7] This Guidance was issued by the FDA, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, Office of Good Clinical Practice. This Guidance is the current thinking of the FDA but is not binding, and alternative approaches can be taken if the approach satisfies the requirements of the applicable regulations.

[8] 21. CFR § 312.120(a)(1)(i).

[9] *See p.4 of* U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Center of Biologics Evaluation and Research, Office of Good Clinical Practice, *Guidance for Industry and FDA Staff*, March 2012. PDF available at <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM294729.pdf>. Last accessed April 17, 2012.

[10] *Id. at* 9.

[11] *Id. at* 10.

[12] *Id. at* 10-11.

[13] International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. Guideline for Good Clinical Practice: E6(R1). 10 June 1996. 1.28. PDF available at <http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6_R1/Step4/E6_R1__Guideline.pdf>. Last accessed April 17, 2012.

[14] *Guidance for Industry and FDA Staff* at p. 8.

[15] *Id. at* 11.

[16] *Id. at* 6.

[17] *Id. at* 12.

[18] *Id. at* 12. For more information on this issue, this Guidance refers the reader to the FDA's Guidance, *Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs: Frequently Asked Questions – Statement of Investigator* (form FDA 1572), available at <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf>. Last accessed April 17, 2012.

[19] *Id. at* 8.

[20] *Id. at* 9.

[21] *Id. at* 12.

[22] *Id.*

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## PART 2: A FEDERAL SURVEY ON PROTECTING CONFIDENTIAL INFORMATION

The February 2012 issue of *Pro Te: Solutio* provides information on how federal district courts across the United States (from Alabama through Montana) handle the filing of confidential information. Part Two of this article surveys district courts in Nebraska through Wyoming.

Nebraska: The U.S. District Court for the District of Nebraska has enacted Local General Rule 1.3 regarding restrictions on access to sealed documents and documents containing personal identifying information protected by the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899 (Dec. 17, 2002) (codified at 5 U.S.C. §§ 3701-3707 and scattered sections). Parties and their attorneys are responsible under the rule for preventing the disclosure of certain confidential information in case filings. The clerk does not review case filings for compliance or independently redact or seal non-complying filings. Nebraska District Court's Local Civil Rule 5.0.3 regarding privacy addresses mandatory and discretionary redaction for all filings with the court. Under this rule, the filing party may redact the following information from all documents and exhibits filed electronically or non-electronically, unless the assigned judge orders otherwise:

(1) personal identifying numbers, such as driver's license numbers;
(2) home street addresses;
(3) medical or psychological records;
(4) employment history;
(5) individual financial information;
(6) proprietary or trade secret information;
(7) information that may identify a cooperating individual;
(8) information regarding a crime victim;
(9) national security information;
(10) sensitive security information as described in 49 U.S.C. § 114(s);
(11) education records as defined by 20 U.S.C. § 1232g(a)(4)(A); and
(12) other data as the court orders.

Nebraska Civil Rule 5.0.3 also provides that a party may restrict access to unredacted documents with the court's leave. Nebraska Civil Rule 7.5 provides the procedure for sealing documents and objects.

Nevada: Rule 10-5 of the Local Rules for the U.S. District Court for the District of Nevada provides for notices for *in camera* submissions and motions seeking leave to seal documents. Rule 16.1-4 regarding confidentiality mandates that "[d]iscovery and initial disclosures […] cannot be withheld on the basis of confidentiality absent court order. Not later than fourteen (14) days after the Initial Scheduling Conference, the parties shall file a proposed protective order. Pending entry of a discovery confidentiality protective order, disclosures deemed confidential by a party shall be produced with a confidential designation (e.g., 'Confidential — Attorneys Eyes Only'), and the disclosure of the information will be limited to each party's outside counsel of record, including employees of outside counsel of record, and used only for litigation purposes."

New Hampshire: Rule 37.1 of the Local Rules of the U.S. District Court of New Hampshire Motions provides the process for obtaining a protective order and sealing documents, which includes a requirement of a verbatim recitation of each interrogatory, request, answer, response, and objection, or a copy of the actual discovery document which is the subject of the motion, provided that the party shall file only that portion of the discovery document that is objected to or is the subject of the motion. When the court rules on a discovery motion, the discovery requested or relief sought shall be provided within fourteen (14) days of the court order, unless the order specifies a different time. All filings, orders, and docket entries shall be public unless a filing, order, or docket entry must be sealed pursuant to state law, federal law, the Federal Rules of Criminal or Civil Procedure, or Local Rules; a filing, order, or docket entry has been sealed by order of another court or agency; or the court issues an order sealing a filing, order, or docket entry. Rule 37.1 also provides for two levels of sealed filings. Filings, orders, and docket entries sealed at Level I may be reviewed by any attorney appearing in the action without prior leave of court. Filings, orders, and docket entries sealed at Level II may be reviewed only by the filer or, in the case of an order, the person to whom the order is directed without prior leave of court.

A motion to seal must be filed before the sealed material is submitted or, alternatively, the item to be sealed may be tendered with the motion

and both will be accepted provisionally under seal, subject to the court's subsequent ruling on the motion. The motion must explain the basis for sealing, specify the proposed duration of the sealing order, and designate whether the material is to be sealed at Level I or Level II. Any motion to seal, upon specific request, may also be sealed if it contains a discussion of the confidential material. If the court denies the motion to seal, any materials tendered under provisional seal will be returned to the movant. This rule sets forth filing procedures for submitting materials under seal or requesting sealed status.

Local Rule 83.8 presents provisions for special orders in "widely publicized and sensational cases," including issuance of a special order governing matters such as extrajudicial statements by parties and witnesses likely to interfere with the conduct of a fair trial by an impartial jury, the seating and conduct in the courtroom of spectators and news media representatives, the management and sequestration of jurors and witnesses, and any other matters which the court deems appropriate.

New Jersey: In the U.S. District Court for the District of New Jersey, Rule 5.3 addresses protective orders and public access under CM/ECF. Subject to this rule and to statute or other law, all materials and judicial proceedings are matters of public record and shall not be sealed. Notwithstanding, parties may enter into written agreements to keep materials produced in discovery confidential and to return or destroy such materials as agreed by parties and as allowed by law. Parties may submit to a judge or magistrate judge an agreed-upon form of order which embodies a written agreement. Any such form of order must be accompanied by an affidavit or attorney certification filed electronically under the designation "affidavit/certification in support of discovery confidentiality order." The affidavit or attorney certification shall describe: (a) the nature of the materials to be kept confidential: (b) the legitimate private or public interests which warrant confidentiality: and (c) the clearly defined and serious injury that would result should the order not be entered. The affidavit or attorney certification shall be available for public review. No form of order submitted by parties shall supersede the provisions of this rule with regard to the filing of materials or judicial proceedings. The form of order may, however, provide for the return or destruction of discovery materials as agreed by parties. The form of order shall be subject to modification by a judge or magistrate judge at any time. Any dispute regarding the entry of, or the confidentiality of discovery materials under, any order under this section shall be brought before a magistrate judge pursuant to L. Civ. R. 37.1(a)(1).

Any request by a party or parties to seal, or otherwise restrict public access to, any materials or judicial proceedings shall be made by formal motion per L.R. 5.3(c). However, any motion to seal or otherwise restrict public access shall be available for review by the public. The motion papers shall describe: (a) the nature of the materials or proceedings at issue: (b) the legitimate private or public interests which warrant the relief sought: (c) the clearly defined and serious injury that would result if the relief sought is not granted: and (d) why a less restrictive alternative to the relief sought is not available. Proposed Findings of Fact and Conclusions of Law shall be submitted with the motion papers in the proposed order. If the information required is not within the knowledge of the movant, supplemental motion papers in support of the motion may be filed by a party, individual, or entity having such knowledge not later than fourteen (14) days after the filing of the motion. Any materials deemed confidential by a party or parties and submitted with regard to a motion to seal or otherwise restrict public access shall be filed electronically under the designation "confidential materials" and shall remain sealed until such time as the motion is decided. When a document filed under seal contains both confidential and non-confidential information, an unredacted version shall be filed under seal, and a version with only the confidential portions redacted shall be filed publicly. Any interested person may move to intervene pursuant to Fed. R. Civ. P. 24 (b) before the return date of any motion to seal or otherwise restrict public access.

Notwithstanding the above, on emergent application of a party or parties or *sua sponte*, a judge or magistrate judge may seal or otherwise restrict public access to materials or judicial proceedings on a temporary basis. The judge or magistrate judge shall do so by order which sets forth the basis for the temporary relief and which shall be filed electronically under the designation "temporary order to seal." Any interested person may move pursuant to L. Civ. R. 7.1 and Fed. R. Civ. P. 24 (b) to intervene, which motion shall be made returnable on the next available return date.

No party or parties shall submit a proposed settlement agreement for approval by a judge or magistrate judge unless required to do so by statute or other law or for the purpose of retaining jurisdiction. Any settlement agreement filed with the court or incorporated into an order shall, absent an appropriate showing under federal law, be deemed a public record and available for public review.

Local Rule 5.3 also contains a comprehensive explanatory note, including the history of the Rule and its amendments, as well as annotations regarding each subsection.

New Mexico: Rule 37.1 of the Local Rules of the New Mexico U.S. District Court sets forth the procedure for submitting a motion for relief sought by protective order in discovery, including requirements that the movant attach a copy of the interrogatory, request for production or inspection,

relevant portion of deposition transcript, or request for admission; and the response or objection thereto, and that the motion must comply with the requirements of the Local Rules. D.N.M.LR-Civ. 7.

New York: The Southern and Eastern Districts of New York do not have specific local rules addressing the filing of confidential documents. Rule 2.2 of the Local Rules for the Northern District of New York provides that not later than fourteen days (14) prior to the initial Rule 16 Conference and after conferring regarding the matter, the parties may, if desired, submit either a stipulated protective order pursuant to Fed. R. Civ. P. 26(c) or, if agreement cannot be reached, may each submit a counter-proposed protective order for the court's consideration, highlighting for the court any areas of disagreement. In the event that the parties do not request the entry of a different Rule 26(c) confidentiality order at or prior to the Rule 16 scheduling conference, or if otherwise deemed appropriate, the court will enter a protective order pursuant to Fed. R. Civ. P. 26(c) in the form of that provided on the court's webpage at www.nynd.uscourts.gov.

In the Western District of New York, Rule 5.3 addresses the sealing of complaints and documents in civil cases. This rule sets forth that, except where restrictions are imposed by statute or rule, there is a presumption that court documents are accessible to the public and that a substantial showing is necessary to restrict access. Upon a proper showing, the court may, *sua sponte*, enter an order directing that a case be sealed in its entirety, or as to certain parties or documents. The court may do so when the case is initiated, or at any stage of the proceeding. A party seeking to have a document, party, or case sealed shall comply with the procedures set forth in the court's CM/ECF Administrative Procedures Guide (*available at* http://www.nywd.uscourts.gov/mambo/index.php?option=com_content&task=view&id=21&Itemid=26). A complaint presented for filing with a motion to seal and proposed order shall be treated as a sealed case pending approval of the proposed order, and the filing party shall comply with the sealing procedures set forth in the Guide. Unless otherwise directed by the court, a sealed document or case shall remain sealed even after final disposition of the case. A party seeking to have a sealed document unsealed must seek relief by motion on notice.

North Carolina: In the Eastern District of North Carolina, Rule 79.2 addresses the submission and filing of sealed documents. No cases or documents may be sealed without an order from the court. A party desiring to file a document under seal must first file a motion seeking leave in accordance with the court's CM/ECF Policy Manual (*available at* http://www.nced.uscourts.gov/cmecf/default.aspx). All sealed and proposed documents shall be maintained electronically in CM/ECF unless otherwise ordered by the court. Unless otherwise permitted by the Policy Manual or order of the court, all proposed sealed documents must be accompanied by a motion to seal. The motion to seal shall be a public document and noted with a docket entry that gives the public notice of the request to seal. The docket entry for the proposed sealed document shall identify it as a "proposed" sealed document and describe the type of document it is (*e.g.*, affidavit, record) and the substantive motion or other specific proceedings in the case to which it relates (*e.g.*, "in support of defendant's motion to compel at D.E.____"). The proposed sealed document is deemed to be provisionally sealed until the court rules on the motion to seal. If the motion to seal is granted, the clerk will remove the word "proposed" from the docket entry. If the motion to seal is denied, the document will remain sealed and the word "proposed" will remain in the docket entry for the document in order to preserve the record. The document will not be considered by the court, except as provided by the Rule or as otherwise ordered by the court. A party desiring to remove a proposed sealed document or docket entry from the docket sheet must file a motion to strike in accordance with Local Civil Rule 7.1. A party whose motion to seal is denied but that desires the court to consider a proposed sealed document as a publicly filed document shall file the document as a public document within three (3) days after entry of the order denying the motion to seal or within such other period as the court directs. This Rule also provides the process for the return of sealed documents.

In the Western District of North Carolina, Rule 6.1 addresses sealed filings and public access. Under this rule, no materials may be filed under seal except by order of the court, pursuant to a statute, or in accordance with a previously entered Rule 26(e) Protective Order. A request by a party to file materials under seal shall be made by formal motion, separate and apart from the motion or other pleading sought to be sealed, pursuant to the Local Rules. Such motion shall be filed electronically under the designation "Motion to Seal." The motion or supporting brief shall set forth:

(1) a non-confidential description of the material sought to be sealed;
(2) a statement as to why sealing is necessary and why there are no alternatives to filing under seal;
(3) unless permanent sealing is sought, a statement as to the period of time the party seeks to have the material maintained under seal and as to how the matter is to be handled upon unsealing; and
(4) supporting statutes, case law, or other authority.

If necessary, information deemed confidential by a party may be redacted from the filed motion or brief and an unredacted version submitted under seal for in camera review. Materials deemed confidential may be submitted under seal for in camera review via cyberclerk. No motion to seal or otherwise restrict public access shall be determined

without reasonable public notice. Notice shall be deemed reasonable where a motion is filed in accordance with the provisions of Rule 6.1. Other parties, interveners, and non-parties may file objections and briefs in opposition or support of the motion within the time provided by L.R. 7.1 and may move to intervene under Fed. R. Civ. P. 24. Orders sealing or otherwise restricting access shall reflect consideration of the factors set forth in Rule 6.1. In the discretion of the court, such orders may be filed electronically or conventionally and may be redacted. After an order permitting the filing under seal has been entered, any materials filed pursuant to that order shall be filed electronically with a non-confidential description of the materials filed. However, this Local Rule shall not limit the right of a party, intervenor, or non-party to file a motion to unseal material at any time. Such a motion to unseal shall include a statement of reasons why the material should be unsealed and any change in circumstances that would warrant unsealing. Unless otherwise ordered by a court, any case file or documents under court seal that have not previously been unsealed by the court shall be unsealed at the time of final disposition of the case. Unless otherwise ordered by the court, access to documents and cases under court seal shall be provided by the clerk of court only pursuant to court order. Unless otherwise ordered by the court, the clerk of court shall make no copies of sealed cases files or documents. However, nothing in this Local Rule limits the ability of parties, by agreement, to restrict access to discovery or other materials not filed with the court or to submit motions pursuant to Fed. R. Civ. P. for a Protective Order governing such materials.

North Dakota: Local Civil Rule 37.1 mandates an obligation to confer prior to a party submitting a motion for protective order, for the purpose of making a reasonable, good faith effort to resolve the dispute without involving the court. The filing of sealed documents and sealed files is governed by the court's "Administrative Policy Governing Electronic Filing and Service," *available at* http://www.ndd.uscourts.gov/cm_ecf.html.

Ohio: There is no local rule in the Northern District of Ohio governing confidentiality or sealing of information in civil cases. However, the Southern District's Local Rule 26.2 governs the protection of personal privacy in civil actions.

Oklahoma: In the Western district of Oklahoma, the court's form for the parties' Joint Status Report and Discovery Plan provides for the identification of necessary protective orders in the initial case management order. (Local Rules, Appendix II).

In the Eastern District of Oklahoma, Local Rule 79.1 provides that it is the court's policy that sealed documents, confidentiality agreements, and protective orders are disfavored. Sealed documents and confidentiality agreements may be approved by the court only upon a showing that a legally protected interest of a party, non-party, or witness outweighs the compelling public interest in the disclosure of records. A party seeking to file a document under seal shall file a motion which meets the specific requirements of Rule 79.1. Titles of sealed pleadings will be docketed publicly, so caution should be taken to remove confidential information from such titles.

Similarly, in the Northern District of Oklahoma, Local Rule 79.1 provides that sealed documents, confidentiality agreements, and protective orders — which are disfavored — may be approved by the court only upon a showing that a legally protected interest of a party, non-party, or witness outweighs the compelling public interest in disclosure of records. All protective orders dealing with confidentiality must be approved by a magistrate judge and filed of record. In civil cases in which confidential information covered by a protective order must be attached to a pleading, attorneys should file an unsealed pleading with non-confidential exhibits and redacted confidential exhibits. At the same time, attorneys should file a supplemental sealed pleading which contains the unredacted exhibits covered by the protective order. The court strongly urges attorneys to present all arguments and all documents in unsealed pleadings. In an effort to do this, the Rule states that attorneys should use good judgment in generically referring to matters covered by a protective order without revealing confidential information. In those rare instances where specific confidential documents must be attached to a pleading, attorneys should file the supplemental sealed pleading referenced above. A person seeking to file a document under seal in a public case shall electronically file both a motion to seal and the sealed document separately. The motion seeking such an order must contain sufficient facts to overcome the presumption in favor of disclosure and may itself be filed under seal. The relief sought shall be narrowly tailored to serve the specific interest sought to be protected. A proposed order shall be submitted. If the motion to seal is denied, the court will direct that the document either be stricken or be unsealed.

Oregon: In Oregon U.S. District Court, Local Rule 5.2 governs the redaction of filings, stating that the responsibility to redact filings pursuant to Fed. R. Civ. P. 5.2 rests with counsel and the party or non-party making the filing. The clerk's office is not required to review documents filed with the court for compliance with Fed. R. Civ. P. 5.2. Local Rule 26-4 sets forth the provision for motions for protective orders: "A party or person asserting there is good cause for the court to make an order that would limit access to discovery materials not filed with the court, or would authorize a party or person to file any materials with the court under seal, must show with

respect to each particular material or category of materials that specific prejudice or harm will result if no order is granted. The showing must be sufficiently detailed to permit the court in its good cause examination to identify specific factors supporting entry of the order sought. Where the order sought would authorize a party to file materials under seal, the showing also must articulate why, as an alternative to filing under seal, the information sought to be protected could not be redacted. Broad allegations of harm, unsubstantiated by specific examples or articulated reasoning, do not satisfy the requirements of this rule. The showing must be made even if the other party stipulates to the entry of the order."

Pennsylvania: In the Eastern District of Pennsylvania, Local Rule 5.1.2 directs that documents ordered to be placed under seal must be filed in paper copy filed in the traditional manner and not electronically. A motion to file documents under seal may be filed electronically unless prohibited by law. The order of the court authorizing the filing of documents under seal may be filed electronically unless prohibited by law. A paper copy of the order must be attached to the documents under seal and be delivered to the clerk of court.

In Pennsylvania Federal Court's Middle District, Local Rule 7.5 requires that if a party submits a motion seeking a protective order, a supporting brief shall be filed with the motion. However, a brief shall not be required in support of any motion which has concurrence of all parties, and the reasons for the motion and the relief sought are fully stated therein. Rule 5 of the Middle District's Local Rules provides that if entry of a protective order is sought, the movant must attach to such statement a copy of the proposed order, and include a statement justifying the propriety of such a protective order under existing Third Circuit precedent. Under Rule 5.2, if there is a dispute about whether a protective order should be entered, or about certain terms of the proposed order, each party's position should be summarized.

District of Puerto Rico: The U.S. District Court for the District of Puerto Rico does not have a specific local rule regarding confidentiality or protective orders.

Rhode Island: General Local Rule 102 addresses documents containing confidential information. It states that, in compliance with Fed. R. Civ. P. 5.2, Fed. R. Crim. P. 49.1, and the policy of the Judicial Conference of the United States, and in order to address the privacy concerns created by internet access to court documents, parties or non-parties shall refrain from including, or shall partially redact where inclusion is necessary, the enumerated personal data identifiers from all documents filed with the court. It is the responsibility of any party or non-party filing a document, not the clerk's office, to review each document to determine if pleadings must be modified and are in the proper form. In cases where the personal information does appear on documents filed with the court, the party or non-party responsible for the filing shall file a Motion to Redact, along with a redacted version of the document containing personal information in compliance with Fed. R. Civ. P. 5.2, Fed. R. Crim. P. 49.1, and Judicial Conference policy. Upon receipt of the Motion to Redact, the clerk shall grant the motion by text order, restrict the document containing the above personal information from the docket, and replace it with the redacted version. Documents filed with the court may not be sealed unless ordered by the court. If a party or non-party filing a document has a good faith basis for believing that a document should be sealed, the document shall be accompanied by a motion to seal, which explains why the document should be sealed. Unless the court otherwise permits, if a party or non-party has good reason to believe that a document that such party or non-party proposes to file contains material that another party or non-party would maintain is confidential, the document shall not be filed until such other party or non-party has been notified and afforded an opportunity to file a motion to seal. If only a portion of a document contains confidential information, the party or non-party requesting sealing shall file both an unredacted version of the document and a redacted version that excises the confidential information. The motion to seal shall not be filed electronically, but shall be filed by hand or by mail, together with the documents or materials which are the subject of the motion. Upon receipt of a motion to seal in a civil case, the clerk shall docket the motion but not the documents which are the subject of the motion and shall immediately transmit the motion and documents to the chambers of the judge to whom the case has been assigned. If the court grants the motion to seal and unless otherwise ordered by the court, the sealed envelope shall be retained by the clerk in a secure location until further order of the court. If the court denies the motion to seal, the motion shall be docketed and filed in accordance with these Local Rules, and the memorandum and the documents accompanying the motion shall be returned to the filer, unless otherwise ordered by the court.

South Carolina: Under South Carolina District Court's Local Rule 5.03, absent a requirement to seal in the governing rule, statute, or order, any party seeking to file documents under seal shall follow the mandatory procedure described in the Rule. Failure to obtain prior approval shall result in summary denial of any request or attempt to seal filed documents. Nothing in the Rule limits the ability of the parties, by agreement, to restrict access to documents which are not filed with the court.

Local Civil Rule 26.08 sets forth that there is no requirement for prior judicial approval of protective agreements intended to limit access to and

use of materials gained in discovery. Protective agreements or orders which address the filing of documents with the court shall, however, require compliance with Local Civil Rule 5.03, or such other procedures as the court directs, before any document is filed under seal. Discovery materials protected by a court order issued pursuant to Fed. R. Civ. P. 26(c) shall not be filed without compliance with Local Civil Rule 5.03 unless the order provides other procedures to satisfy the requirements of governing case law.

South Dakota: In U.S. District Court in South Dakota, Civil Local Rule 5.2 requires parties to refrain from including or to partially redact certain personal information where inclusion is necessary. The Rule also provides that, when the court has entered a Protective Order, there is no need to file a redacted document. Rather, the party is to deliver the protected document to be filed under seal to the clerk's office with a cover sheet stating: "This document to be filed under seal pursuant to the Protection Order issued on [insert date]." When received, the clerk's office will file the document using the "Sealed Document" event.

Tennessee: In the Eastern District of Tennessee, Local Rule 26.2 sets forth the process of sealing of court records. Except as otherwise provided by statute, rule, or order, all pleadings and other papers of any nature filed with the court shall become a part of the public record. Court records or portions thereof shall not be placed under seal unless and except to the extent that the person seeking the sealing thereof shall have first obtained, for good cause shown, an order of the court specifying those court records, categories of court records, or portions thereof which shall be placed under seal; provided, however, documents that are the subject of a motion to seal may be temporarily placed in the court record under seal pending a ruling on the motion. Unless the court orders otherwise, the parties shall file with the court redacted versions of any court record where only a portion thereof is to be placed under seal.

Local Rule 8.1 of the Rules of the Western District of Tennessee provides the policy of the court that whenever an e-filer desires to electronically file a document under seal, the e-filer may do so, and ECF has been designed to allow the filer to make that option available whenever desired. The court will subsequently decide precisely how long a sealed filing will remain under seal, but initially any document can be filed under seal. Further, a document subject to an existing sealing order or sealing statute shall be filed electronically under seal pursuant to those procedures set forth in the court's ECF User Manual. Under Local Rule 13.3, any case or document under seal shall not be available to the public through electronic or any other means; however, attorneys may be permitted access to sealed documents in cases in which they appear with permission of the court. Rule 13.4 mandates that attorneys are responsible for ensuring that their clients have sufficient information so that informed decisions are made regarding the inclusion, redaction, and exclusion of personal information in filings with the court. This Rule goes on to set forth the mandatory and discretionary redaction requirements of certain personal identifiers. Rule 13.4.3 requires attorneys and parties to exercise caution and consider redaction or consider filing a sealed document if specific other sensitive information is referenced, including medical records, proprietary or trade secret information, or employment history. Responsibility for redacting this information rests solely with attorneys and the parties. The clerk of court will not review filings for compliance. Attorneys and the parties are cautioned that their failure to protect the above-listed information may subject them to the disciplinary power of the court and may be the basis for claims against them.

In the Middle District, Local Rule 37.01 requires counsel for a party moving for a protective order to file with the court, at the time of the filing of the motion, a statement certifying that he has conferred with counsel for the opposing party in a good faith effort to resolve by agreement the issues raised and that counsel have not been able to do so. No such motion shall be considered by the court absent compliance with this Rule. If certain of the issues have been resolved by agreement, the statement shall specify the issues remaining unresolved.

Texas: In the Northern District of Texas, Local Rule 79.3 provides the process for a party wishing to file a motion to seal a document. A party may file under seal any document that a statute or rule requires or permits to be so filed. If no statute or rule requires or permits a document to be filed under seal, a party may file a document under seal only on motion and by permission of the presiding judge. When a party files on paper a motion for leave to file a document under seal, the clerk must file the motion under seal. The party must attach as an exhibit to the motion a copy of the document to be filed under seal. The party must also submit with the motion the original and a judge's copy of the document to be filed under seal. The original of the document must neither be physically attached to the motion nor made an exhibit to the motion. If leave to file the document under seal is granted, the clerk must file the original of the document under seal. When a party files by electronic means a motion for leave to file a document under seal, the party may file the motion under seal and must attach the proposed sealed document as an exhibit. If leave is granted, the party must file the document under seal by electronic means. Unless the presiding judge otherwise directs, all sealed documents maintained on paper will be deemed unsealed 60 days after final disposition of a case. L.R. 79.4. A party that desires that such a document remain sealed must move for this relief before the expiration of the 60-day period.

Local Rule 5 of the Eastern District of Texas provides that, unless authorized by statute or rule, a document in a civil case shall not be filed under seal unless it contains a statement by counsel following the certificate of service that certifies that: (1) a motion to seal the document has been filed or; (2) the court already has granted authorization to seal the document. A motion to file document(s) under seal must be filed separately from the document(s) sought to be sealed. A motion to seal that is filed as a sealed document does not need to include the certification. Documents requested or authorized to be filed under seal or *ex parte* shall be filed in electronic form. Counsel is responsible for serving documents under seal to opposing counsel and may do so in electronic form. When a sealed order is entered by the court, the clerk will send a sealed copy of the order only to the lead attorney for each party who is responsible for distributing the order to all other counsel of record for that party.

Local Rule 5-2 of the Eastern District of Texas addresses the privacy of court filings, namely the redaction of personal identifying information from transcripts.

In the Western District of Texas, Rule 26(c) sets forth that, upon a motion by any party, the court shall enter a protective order in the form set out in Appendix "H" to the Local Rules, absent a showing of good cause by any party opposing entry of the order. In cases where the parties agree to a protective order, the form set out in Appendix "H" is approved.

In Texas District Court's Southern District, Local Rule 83.6 addresses preserving confidentiality. On the filing of a civil action that the party desires be sealed, the party shall present an application to the clerk attaching the complaint and accompanying materials in a sealed envelope marked "sealed exhibit." A miscellaneous case number will be assigned and the case file presented to the miscellaneous judge. Once that judge has ruled on the application, the case file and order will be returned immediately to the clerk for the drawing of a civil action number and random assignment to a judge.

Utah: Local Rule 5-2 provides for the procedure for filing cases and documents under seal. On motion of one or more parties and a showing of good cause, the court or, upon referral, a magistrate judge, may order all or a portion of the documents filed in a civil case to be sealed. A case may be sealed at the time it is filed upon *ex parte* motion of the plaintiff or petitioner and execution by the court of a written order. The case will be listed on the clerk's case index as *Sealed Plaintiff vs. Sealed Defendant*. A pending case may be sealed at any time upon motion of either party and execution by the court of a written order. Unless the court otherwise orders, neither the clerk's automated case index nor the existing case docket will be modified. No document may be designated by any party as "Filed under Seal" or "Confidential" unless: (1) it is accompanied by a court order sealing the document; (2) it is being filed in a case that the court has ordered sealed; or (3) it contains material that is the subject of a protective order entered by the court. Unless otherwise ordered by the court, the clerk will provide access to cases and documents under court seal only on court order. Unless otherwise ordered by the court, the clerk will make no copies of sealed case files or documents.

Rule 5.2 also addresses redacting personal identifiers in pleadings. The filer shall redact personal information in filings with the court, as required by Fed. R. Civ. P. 5.2. The court may order redaction of additional personal identifiers by motion and order in a specific case or as to a specific document or documents. Any protective order under Fed. R. Civ. P. 26(c) may include redaction requirements for public filings. This Local Rule also provides the requirements and responsibilities of attorneys to review transcripts for personal information which is required to be redacted under Fed. R. Civ. P 5.2 and provide notice to the court reporter of the redactions.

Vermont: Rule 5.2 of the Local Rules of the U.S. District Court for the District of Vermont provides the procedure for sealing documents. Cases or court documents cannot be sealed without a court order. Otherwise, all official files in the court's possession are public documents. In order to seal a document, a party must: (1) file a separate motion for each document; (2) place the document in a sealed envelope; (3) affix a copy of the document's cover page (with confidential information redacted) to the outside of the envelope; and (4) conspicuously mark the envelope with "SEALED DOCUMENT" or the equivalent.

Virginia: Rule 5 of the Eastern District of Virginia's local civil rules provides that unless otherwise provided by law or court rule, no document may be filed under seal without an order entered by the court. A party submitting a document or portion of a document for filing under seal pursuant to a governing statute, rule, or order shall note on the face of the document that it or a portion of it is filed under seal pursuant to that statute, rule, or order. Any motion for a protective order providing prospectively for filing of documents under seal shall be accompanied by a non-confidential supporting memorandum, a notice that identifies the motion as a sealing motion, and a proposed order. A confidential memorandum for *in camera* review may also be submitted. The non-confidential memorandum and the proposed order shall include: (1) A non-confidential description of what is to be sealed; (2) A statement as to why sealing is necessary, and why another procedure will not suffice; (3) References to governing case law; and (4) Unless permanent sealing is sought, a statement as to the period of time the party seeks to have the matter maintained under seal and as to

how the matter is to be handled upon unsealing. The proposed order shall recite the findings required by governing case law to support the proposed sealing. Other parties and non-parties may submit memoranda in support of or opposition to the motion, and may designate all or part of such memoranda as confidential. Any confidential memoranda will be treated as sealed pending the outcome of the ruling on the motion. Nothing in this Local Civil Rule limits the ability of the parties, by agreement, to restrict access to documents which are not filed with the court. Trial exhibits, including documents previously filed under seal, and trial transcripts will not be filed under seal except upon a showing of necessity demonstrated to the trial judge.

Similarly, in the Western District of Virginia, Rule 9 governs sealed documents and states that a document (including a motion or other pleading) may be filed or placed under seal only if permitted by order of the court. Portions of a document cannot be filed or placed under seal — only the entire document may be sealed. A sealed document is a document to which access other than by the court or authorized court personnel is prohibited or restricted. The clerk may not otherwise disclose any sealed document except upon order of the court. To obtain an order allowing a document to be filed or placed under seal, a party must file an unsealed written motion containing: (1) a non-confidential description of the document to be sealed; (2) the non-confidential reasons why sealing is necessary, including the reasons why alternatives to sealing are inadequate; and (3) the duration for which sealing is requested. The party must also submit to the court at the same time a proposed unsealed order granting the motion, which order must contain findings setting forth the matters contained in (1), (2), and (3) above. The motion to seal must be accompanied by the document that is to be placed under seal, if it has not already been submitted. The document will be kept under seal by the clerk temporarily pending a decision by the court on the motion to seal. If the motion to seal is denied, the document will be returned by the clerk to the party submitting it, unless the court orders otherwise. Any motion requesting an order allowing a document to be filed under seal must be docketed in such a way to give public notice of its nature as a motion to seal. Any party or nonparty may file an objection to any motion to seal or to the sealing of any document or may file a motion to unseal a document previously sealed. These provisions do not limit the ability of the parties by a confidentiality agreement or otherwise to restrict access to documents that are not filed with the court. No confidentiality agreement or other agreement of the parties, however, will allow the filing of sealed documents without adherence to these provisions. A separate motion must be filed in each instance that a document is to be filed under seal. Whenever a document is unsealed, any related order or motion under seal will be unsealed, unless the court orders otherwise. In order to extend the period of time for which a document is to be sealed, an order of the court must be obtained using the procedures set forth in Rule 9. No motion or order, however, is required for the filing under seal of an unredacted version of a document or a reference list containing personal data identifiers, in compliance with these rules, the federal rules of procedure, or the E-Government Act, or an *ex parte* motion, under circumstances where such *ex parte* application is permitted.

Washington: In U.S. District Court for the Western District of Washington, Local Civil Rule 26(c) addresses protective orders, setting forth that any motion for a protective order must include a certification that the movant has in good faith conferred, or attempted to confer, with other affected parties in an effort to resolve the dispute without court action. A good faith effort to confer under the Rule requires a face-to-face meeting or a telephone conference. If the court finds that counsel for any party, or a party proceeding *pro se*, willfully refuses to confer, fails to confer in good faith, or fails to respond on a timely basis to a request to confer, the court may take actions including a determination of an abandonment or failure to prosecute or defend diligently, and judgment may be entered against the defaulting party either with respect to a specific issue or the entire case, or it may issue other sanctions as the court may deem appropriate. The court will not sign stipulated protective orders to allow the sealing of unidentified documents that the parties have marked or expect to mark as confidential during discovery. Instead, parties seeking to file documents under seal must comply with the requirements of Local Civil Rule 5(g).

In the Eastern District of Washington, Local Rule 37.1 governs discovery motions and provides that motions for protective orders must set forth, without reference to other pleadings or documents, the objects sought to be produced. This rules also mandates an obligation to confer prior to submitting such motion. If they are unable to do so, at least fourteen (14) days before the date of the hearing, the parties shall file a statement setting forth the matters on which they have been unable to agree.

West Virginia: Rule 5.2.1 of the Local Rules of West Virginia's Southern District recognizes privacy protection for filings made with the court and transcripts of hearings, and provides for specific information to be partially redacted or omitted. The responsibility for redacting these personal identifiers rests solely with counsel and the parties. The clerk will not review each pleading for compliance with this rule.

In the Northern District of West Virginia, Local Rule 6.0.1 states the requisites for filing a document under seal, including the requirement that a party must first electronically file a Motion for Leave to File Under Seal. If the Motion for Leave to File Under Seal itself contains sensitive

information, the party shall: (1) Electronically file it under seal in CM/ECF and, because this is a sealed event that is inaccessible to recipients of the notice of electronic filing, parties shall effect service of process traditionally, or (2) File the motion with the clerk's office in paper. The clerk's office will then file the motion under seal. The parties remain responsible for effecting service of process traditionally. Along with the motion to file under seal, the party shall file a memorandum of law that explains why sealing is required. If necessary, the filer may present exhibits that contain the sensitive information in an envelope marked "sealed" to the clerk's office. If filing the Motion for Leave to File Under Seal is itself filed under seal, the filer may attach the exhibits to the Motion for Leave to File Under Seal. If the court grants the Motion for Leave to File Under Seal, the judge will electronically enter the order authorizing the filing of the documents in the appropriate manner. The party then may file the document under seal in CM/ECF or may bring the document to the clerk's office to be filed as appropriate. Sealed filings produce a notice of electronic filing, but the recipient cannot open the attached document. Consequently, filers must effect service through traditional means, as appropriate.

The Northern District's Local Rule 26.05 governs protective orders and sealed documents. It provides that if a party, or parties jointly, seek entry of a protective order to shield information from dissemination, the movant or movants must demonstrate with specificity that: (1) the information qualifies for protection under F. R. Civ. P. 26(c); and (2) good cause exists for restricting dissemination on the grounds that harm would result from its disclosure. The rule notes that requiring public inspection of court documents is necessary to allow interested parties to judge the court's work product in the cases assigned to it, and that this rule may be abrogated only in exceptional circumstances. Unless otherwise authorized by law, a motion to seal shall be accompanied by a memorandum of law which contains the reasons why sealing is necessary, including the reasons why alternatives to sealing, such as redaction, are inadequate; the requested duration of the proposed seal; and a discussion of the propriety of sealing, giving due regard to the parameters of the common law and First Amendment rights of access as interpreted by the Supreme Court and the Court of Appeals.

Wisconsin: In the Eastern District of Wisconsin, General Local Rule 79(d) addresses confidential matters and sealed records. Subject to its Local Rules, the court will consider all documents to have been filed publicly unless they are accompanied by a separate motion requesting that the documents, or portions thereof, be sealed by the court. Any motion to seal must be accompanied by proof of good cause for withholding the material from the public record. All material that a party seeks to have treated as confidential, but as to which no sealing order has been entered, must be filed in a sealed envelope conspicuously marked "Request for Confidentiality Pending," together with a motion requesting an order to seal. The separate motion for sealing must be publicly filed and must generally identify the documents contained in the sealed envelope. The documents must be transmitted by the clerk of court in a sealed envelope to the judge, together with the moving papers. If the motion is denied, the documents must be filed by the clerk of court in an open file, unless otherwise ordered by the judge assigned to the case. To the extent that any answers to interrogatories, transcripts of depositions, responses to requests for admissions, or any other papers filed or to be filed with the court contain material designated as confidential, these papers, or any portion thereof, must be filed under seal by the filing party with the clerk of court in an envelope marked "SEALED." Any party filing material claimed to be confidential must include with that filing either: (1) a motion to seal the material pursuant to this rule; or (2) an objection to the designation of the material as confidential and a statement that the objection to the designation has been provided to the person claiming confidentiality. If such an objection is made, the person having designated the material as confidential may file a motion to seal within twenty-one (21) days of the objection. The comment to this rule notes that a motion to seal should be limited to that portion of the material necessary to protect the movant from the harm that may result from disclosure, *e.g.*, the fact that a single page or paragraph of a document contains confidential material generally will not support a motion to seal the entire document. Counsel may, and in most circumstances should, submit a redacted version of the document, with a separate request to seal the portions containing confidential material.

In Wisconsin's Western District, Administrative Order 296 provides that, in civil cases, documents may be sealed only if they are subject to a prior protective order or are accompanied by contemporaneous motion to seal (the motion to seal may also be filed under seal).

Wyoming: Rule 37.2 of the Local Rules for the U.S. District Court provides that the filing of a motion for a protective order shall stay the discovery to which the motion is directed pending further order of the court.

Written *by*
Elizabeth Moccaldi

# A Bridge To Nowhere

## RICO FRAUD CONSUMER CLASS ACTIONS AGAINST PHARMACEUTICAL MANUFACTURERS POST *BRIDGE V. PHOENIX BOND*

In 2008, the United States Supreme Court made an otherwise simple pronouncement on the requisite elements of fraud claims made pursuant to the Racketeering Influenced and Corrupt Organizations Act[1] (RICO): "first-party reliance" (i.e., reliance by the plaintiff) was not an essential element. The plaintiffs' bar heralded this innocuous holding as an end to the general prohibition on RICO fraud class actions, concluding that because individualized reliance had been the bar to establishing predominance and superiority under Fed. R. Civ. P. 23(b)(3), the elimination of first-party reliance would open the flood gates for new consumer RICO fraud class actions. A slew of putative class actions were filed against pharmaceutical manufacturers alleging that consumers and third-party payors had been induced to purchase new name-brand pharmaceuticals under allegedly fraudulent promises of increased efficacy or safety.

Despite these suits and the enthusiasm of the plaintiffs' bar, in the more than four years since the United States Supreme Court decided *Bridge v. Phoenix Bond*,[2] the practical fallout from the decision has been underwhelming at best. Pre-*Bridge*, certification of a RICO fraud-based class action was a near impossibility because the courts held that questions of individualized first-party reliance predominated over whatever common questions of law or fact existed. Post-*Bridge*, the plaintiffs' bar has attempted to usher in a new era of RICO consumer fraud class actions, arguing that the removal of "first-party" reliance as an element of RICO allows the common issues to predominate. However, individual issues of reliance — be it by the patient or the prescribing physician — remain a bar to such aggregate litigation.

### A Review of Fed. R. Civ. P. 23

The prerequisites for certification of a class are enumerated in Fed. R. Civ. P. 23(a) and are usually referred to as the prerequisites of "numerosity, commonality, typicality, and adequate representation."[3] If a plaintiff's claim for certification of a class survives the required "rigorous analysis"[4] of the Rule 23(a) prerequisites, the district court then must proceed to examine Rule 23(b). In addition to satisfying the prerequisites, the proposed class must also satisfy one of the three class definitions: the limited fund Rule 23(b)(1) class; the injunctive relief Rule 23(b)(2) class; or the opt-out, monetary damages Rule 23(b)(3) class. Typically, a proposed class action seeking to recover for alleged consumer fraud will proceed under Rule 23(b)(3).

A class for monetary damages will only be certified if "the court finds that the questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy."[5] "Predominance" and "superiority" are the keystones of a Rule 23(b)(3) class.

"Determining whether the plaintiffs can clear the predominance hurdle set […] requires district courts to consider 'how a trial on the merits would be conducted if a class were certified.'"[6] Accordingly, on the predominance inquiry, the district court must identify the substantive issues that will control the outcome of the litigation.[7] That is, the district court must turn to the

elements of the claims and defenses and look to see how the plaintiffs will prove the elements of their claims on a class-wide basis. When questions requiring individualized proof predominate over the common questions, certification is not warranted.

## A Primer on RICO

At its heart, RICO is a criminal statute originally designed to combat the American mafia. Without delving too deeply into the inner working of the statute, RICO essentially provides four bases for finding a violation of its provision:

> (a) when a person earns an income from a pattern of racketeering and uses that income to acquire an interest in an enterprise;[8]
>
> (b) when a person acquires or maintains an interest in or control of an enterprise through a pattern of racketeering;[9]
>
> (c) when a person participates through a pattern of racketeering in an enterprise;[10] and
>
> (d) when a person conspires to violate any of the other three provisions.[11]

The statute defines "racketeering activity" as including (among numerous other specific conduct) "any act which is indictable under any of the following provisions of title 18, United States Code: […] section 1341 (relating to mail fraud), section 1343 (relating to wire fraud)."[12] RICO consumer fraud claims will typically arise under the mail fraud/wire fraud sections, alleging that the defendant sent fraudulent information through the mail or via the internet.

From a criminal justice perspective, violating RICO subjects the violators to enhanced sentences. In addition to the heightened penal remedies of RICO, Congress created an avenue whereby private litigants also were given avenue for individual redress within the civil justice context. If a plaintiff is successful in proving a violation of RICO, he is entitled to recover treble damages plus attorneys' fees.[13] It is the allure of treble damages and attorneys' fees on a class-wide basis that fuels the heightened desire for the plaintiffs' bar to bring consumer fraud claims under RICO, as opposed to other common law and statutory schemes.

## A Brief History of RICO's Proximate Cause Requirement

To bring suit, the plaintiff must satisfy RICO's statutorily imposed standing requirements: The plaintiff must be (1) a person (2) who suffered injury (3) to his business or property (4) "by reason of" the defendant's violation of § 1962.[14] The statute's "by reason of" phrase injects the concept of proximate cause into the standing requirement.

Historically, the courts have required RICO plaintiffs to demonstrate that the defendants' violative conduct was both a "but-for" and a proximate cause of the plaintiff's injury.[15] Within the context of a RICO fraud claim, this showing required a "direct relation between the injury asserted and the injurious conduct alleged. Thus, a plaintiff who complained of harm flowing merely from the misfortunes visited upon a third person by the defendant's acts was generally said to stand at too remote a distance to recover."[16]

The Supreme Court's *Anza v. Ideal Steel Supply Corp.*[17] provides a concrete example of the types of attenuated injuries that are not cognizable under RICO. There, the plaintiff alleged that the defendant (a competitor of the plaintiff) was not collecting and remitting sales tax to the state on products that the defendant sold, that the defendant was using this scheme to undercut the plaintiff's price for similar goods, and that this scheme allowed the defendant to increase its market share.[18] The *Anza* Court held that the plaintiff could not satisfy the proximate cause requirement of RICO because the plaintiff could not establish the "directness" requirement — the alleged fraud was directed at the state (failing to pay sales tax), but the purported injury was allegedly sustained by the plaintiff-competitor (loss of market share). This argument was too attenuated.[19]

In discussing the failure to establish proximate cause, the *Anza* Court noted that "[o]ne motivating principle [behind the directness requirement] is the difficulty that can arise when a court attempts to ascertain the damages caused by some remote action."[20] The Court recognized the reality that there are numerous reasons that the defendant may have lowered its prices; the alleged fraud was not the only basis for the price decrease.[21] Additionally, the plaintiff's alleged injuries — lost sales — may have been the result of any number of factors other than the alleged fraud.[22] For example, "A RICO plaintiff cannot circumvent the proximate cause requirement simply by claiming that the defendant's aim was to increase market share at a competitor's expense. […] When a court evaluates a RICO claim for proximate causation, the central question it must ask is whether the alleged violation led directly to the plaintiff's injuries."[23]

## The Pre-*Bridge* Prohibition on RICO Fraud Claims

Based on the "directness" requirement announced by the Supreme Court, several circuit courts required that a plaintiff alleging a violation of RICO based on mail fraud or wire fraud must show first-party reliance (i.e., reliance by the plaintiff) to have standing.[24]

The interrelationship of RICO and Rule 23(b)(3) created a broad prohibition against RICO fraud class actions. It was generally held that because first-party reliance was required and individualized proof would be required to establish each absent class member's claim, the common issues of fact did not predominate over the individualized issues.[25] As noted in *Sandwich Chef of Texas, Inc.*, "'A fraud class action cannot be certified when individualized reliance will be an issue' […] because cases that involve individual reliance fail the predominance test."[26] Then came *Bridge*.[27]

## *Bridge*: First-party Reliance Not Required, But Probably Necessary

The peculiar facts of *Bridge* were a perfect storm that required the Court to confront directly the issue of whether first-party reliance was a required element of a fraud claim under RICO. Cook County, Illinois, annually holds an auction at which it sells the tax liens it holds on real property within its boundaries. Bidders do not bid in dollar amounts but instead bid in terms of a percentage penalty that would attach to the property. A property owner wanting to

THE POST-*BRIDGE* WORLD IS NOT SO DIFFERENT FROM PRE-*BRIDGE*. PLAINTIFFS MUST STILL PROVE PROXIMATE CAUSE TO ESTABLISH A FRAUD CLAIM UNDER RICO. ATTEMPTING TO ESTABLISH PROXIMATE CAUSE THROUGH INDIVIDUALIZED PROOF STILL DEFEATS CLASS CERTIFICATION UNDER RULE 23. WHILE *BRIDGE* ELIMINATED A BRIGHT-LINE TEST, IT DID NOTHING MORE.

redeem the property must pay the winning bidder the percentage penalty. The bidder willing to accept the lowest percentage penalty wins the auction. If the property owner chooses not to redeem the property within the applicable time period, the winning bidder can obtain the deed to the property and is then free to sell the property. Such sale is often at a price significantly greater than what was paid to obtain the deed.[28]

Because the sale of the property is a highly lucrative business, bidders would often bid for a 0% penalty. If a bidder agreed to accept a 0% penalty, there could be no lower bidder. Confronted with the situation where there would often be multiple 0% bidders, the county developed a rotational system. All bidders would register with the county. When a parcel was up for auction, the county would work through the rotation until it found a 0% bidder. If no 0% bidder was identified, then the property continued to a traditional auction. However, there was a distinct opportunity to game the system. If a bidder registered multiple strawmen with the county, then its opportunity to make a 0% bid would arise more often in the rotation than bidders with only one name. To avoid this problem, the county required all bidders to submit an affidavit stating that they were not acting as a strawman and were bidding in their individual capacity.[29]

The plaintiff in *Bridge* was an aggrieved bidder who alleged a competitor had violated RICO by registering multiple strawmen and mailing fraudulent affidavits to the county clerk.[30] The *Bridge* Court recognized that a scheme to concentrate bids favoring one party disproportionately would injure competitor bidders even though the fraud was perpetrated not directly against the other bidders but against the county. That is, the *injury* was attached to one party (the legitimate competitor) while the *fraud* was committed on a third-party (the county). The *Bridge* Court determined that such a claim was viable and that first-party reliance (*i.e.*, that the *injured* party relied on the *fraudulent* misrepresentation) was not a required element of the RICO claim.[31] Furthermore, the defendant could not bar the RICO claim by recasting first-party reliance as a dispositive element of a proximate causation analysis.[32]

The plaintiffs' bar latched on to the specific holding of *Bridge* — that reliance is not an element of a RICO fraud claim — to argue that plaintiffs never need to show reliance (first-party or third-party) to establish their fraud claim. *Bridge*, however, was not so expansive. It did not overturn the long-standing proximate cause requirement from *Holmes*. Instead, *Bridge* simply clarified that first-party reliance was not a bright-line test for satisfying the directness requirement. In fact, the Court expressly stated in *Bridge* itself that, in many cases, first-party reliance will be required to prove proximate cause and that in almost all cases at least third-party reliance would be required:

> [N]one of this is to say that a RICO plaintiff who alleges injury 'by reason of' a pattern of mail fraud can prevail without showing that *someone* relied on the defendant's misrepresentations. […] In most cases, the plaintiff will not be able to establish even but-for causation if no one relied on the misrepresentation. […] In addition, the complete absence of reliance may prevent the plaintiff from establishing proximate cause. […] Accordingly, it may well be that a RICO plaintiff alleging injury by reason of a pattern of mail fraud must establish at least third-party reliance in order to prove causation.[33]

To the extent that any confusion existed in the wake of *Bridge* regarding RICO's proximate cause requirement, it was alleviated by the subsequent *Hemi Group, LLC v. City of New York, NY*.[34] There, the Court reinforced its long-held positions regarding proximate cause on RICO fraud claims: proximate cause is a necessary element of RICO and "[a] link that is 'too remote,' 'purely contingent,' or 'indirec[t]' is insufficient."[35]

## Post-*Bridge* Consumer Class Actions

Following *Bridge*, the plaintiffs' bar jumped in head first, attempting to have certified consumer fraud class actions under RICO (and, thus, taking advantage of the treble damages and attorneys' fees remedies on a class-wide basis). Their exuberance, however, has gone largely unrewarded.

As an initial matter, where a plaintiff attempts to establish RICO's proximate cause requirement through the use of first-party reliance, the pre-*Bridge* prohibition on such class actions appears to remain in full effect. In a non-pharmaceutical putative Rule 23 class action, the United States District Court for the Northern District of Texas held that where a plaintiff pleads first-party reliance as the basis for proximate cause, the case cannot be certified.[36] "While first-person reliance may not be an essential element of the RICO claims, it remains a central focus of the allegations and claims in this case (including the common-law and RICO claims). Accordingly, reliance continues to be a predominant issue in this case and the holding in *Bridge* does not constitute a change in controlling law […]."[37]

The bigger question after *Bridge* is what happens when a plaintiff alleges a RICO violation but argues proximate cause is satisfied through the third-party reliance of multiple individuals. The first major pharmaceutical manufacturer defense victory following Bridge answered this question. In *UFCW Local 1776 v. Eli Lilly & Co.*,[38] a group of third-party payors filed a putative class action complaint against Eli Lilly & Co., arguing that the Eli Lilly had violated RICO by making fraudulent statements regarding its schizophrenia medication, Zyprexa. Zyprexa was a second-generation antipsychotic medication. The plaintiffs allege that Eli Lilly had made fraudulent statements regarding the drug's efficacy. Specifically, they alleged that Zyprexa had been touted as being more effective than the older, cheaper first-generation antipsychotic medications. The plaintiffs also alleged that Eli Lilly promoted off-label uses for the drug, thus causing more prescriptions of Zyprexa to be dispensed than otherwise would have been. The plaintiffs proceeded under two theories of injury: (1) that they had paid for too many prescriptions due to the off-label promotions; and (2) that they overpaid for all prescriptions because Zyprexa was not more effective than the first-generation antipsychotic medications. The plaintiffs alleged that damages under these theories ranged between $4 billion and $7.7

billion. At the district court level, the class was certified. The Second Circuit Court of Appeals reversed.

The Second Circuit quickly disposed of the argument that *Bridge* opened the door for the underlying class to be certified: "[W]hile reliance may not be an element of the cause of action, there is no question that in this case the plaintiffs allege, and must prove, third-party reliance as part of their chain of causation. Plaintiffs allege an injury that is caused by physicians relying on Lilly's misrepresentations and prescribing Zyprexa accordingly. Because reliance is a necessary part of the causation theory advanced by the plaintiffs, we must ask whether reliance can be shown by generalized proof."[39]

The Second Circuit then turned to the plaintiffs' specific claims: "[U]nder the 'loss-of-value' or 'excess price' theory, the claimed harm was the monetary difference between what the plaintiff class was allegedly led to believe Zyprexa was worth and the actual economic value of Zyprexa, taking into account the lesser efficacy and greater harmful side effects allegedly hidden or misrepresented by [defendant]."[40] The court rejected the payors' argument that proximate cause could be established by common proof.[41] The Second Circuit held that it could not be presumed that the defendant's marketing campaign led to the plaintiffs' alleged injuries and, thus, that the claim was not subject to general proof.[42] While *Bridge* permits plaintiffs to prove proximate cause through third-party reliance, it did nothing to cure the predominance issues that exist where multiple third parties are the alleged target of the fraud.[43]

## Conclusion

The post-*Bridge* world is not so different from pre-*Bridge*. Plaintiffs must still prove proximate cause to establish a fraud claim under RICO. Attempting to establish proximate cause through individualized proof still defeats class certification under Rule 23. While *Bridge* eliminated a bright-line test, it did nothing more.

When a RICO fraud case class action is filed, a well-crafted motion to dismiss and/or motion for a more definite statement may force the putative class representatives to articulate at an early stage how they intend to prove proximate cause on a class-wide basis. If plaintiffs disclose that their plan involves proving proximate causation based on the reliance of either consumers or their physicians, then individualized proof will be required to establish proximate cause. Plaintiffs will have then defeated their own action because class certification should be denied due to the failure to meet the basic Rule 23(b)(3) requirements of predominance and superiority.

[1] 18 U.S.C. §§ 1961 – 1968.

[2] 553 U.S. 639 (2008).

[3] *Wal-Mart Stores, Inc. v. Dukes*, 131 S. Ct. 2541, 2550 (2011).

[4] *Id.* at 2551.

[5] Fed. R. Civ. P. 23(b)(3).

[6] *Madison v. Chalmette Refining, L.L.C.*, 637 F.3d 551, 555 (5th Cir. 2011). *Quoting Sandwich Chef of Texas, Inc. v. Reliance Nat'l Indem. Ins. Co.*, 319 F.3d 205, 218 (5th Cir. 2003).

[7] *Id.* Quoting *O'Sullivan v. Countrywide Home Loans, Inc.*, 319 F.3d 732, 738 (5th Cir. 2003).

[8] *See* 18 U.S.C. § 1962(a).

[9] *See id.* § 1962(b).

[10] *See id.* § 1962(c).

[11] *See id.* § 1962(d).

[12] 18 U.S.C. § 1961(a).

[13] *See id.*

[14] *See id.* § 1964(c).

[15] *Holmes v. Secs. Investor Protection Corp.*, 503 U.S. 258, 265-68 (1992). The Supreme Court has held that the "by reason of" language is not so expansive as to allow claims where only factual — or "but for" — causation is shown. *Id.* at 266-68. Rather, "[p]roximate cause is required." *Id.* at 268.

[16] *Id.* at 268-69.

[17] 547 U.S. 451 (2006).

[18] *See id.* at 457-58.

[19] *See id.* at 459.

[20] *Id.* at 458.

[21] *See id.* at 458-59.

[22] *See id.* at 459. "Businesses lose and gain customers for many reasons, and it would require a complex assessment to establish what portion of [plaintiff's] lost sales were the product of [defendant's] decreased prices."

[23] *Id.* at 460-61.

[24] *VanDenBroeck v. CommonPoint Mortg. Co.*, 210 F.3d 696, 701 (6th Cir. 2000); *Sikes v. Teleline, Inc.*, 281 F.3d 1350, 1360-61 (11th Cir. 2002).

[25] *Sandwich Chef of Texas, Inc.*, 319 F.3d at 224. "[P]laintiffs must demonstrate causation on an individual basis, which defeats predominance and certification of a Rule 23(b)(3) class."

[26] *Id.* at 219.Quoting *Castano v. Am. Tobacco Co.*, 84 F.3d 734, 745 (5th Cir. 1996).

[27] 553 U.S. 639.

[28] *Id.* at 642.

[29] *Id.* at 642-43.

[30] *Id.* at 644.

[31] *Id.* at 649-50.

[32] *Id.* at 655.

[33] *Id.* at 657-59 (italics in original; internal citations omitted).

[34] 130 S. Ct. 983, 989 (2010). See *Hope For Families & Cmty. Serv., Inc. v. Warren*, 721 F. Supp. 2d 1079, 1130 (M.D. Ala. 2010) — "*Bridge*, however, did not disturb Anza's and Holmes's holdings that the alleged violation must be both the 'but for' and the proximate cause of the injury to demonstrate that the injury was 'by reason of' a RICO violation. […] Hence, *Anza's* and *Holmes's* principles still must be satisfied in that a plaintiff must demonstrate that the alleged violation led directly to the plaintiff's injuries" (internal quotation marks omitted); *see also UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 132 (2d Cir. 2010); *District 1199P Health & Welfare Plan v. Janssen, L.P.*, 784 F. Supp. 2d 508, 524-25 (D.N.J. 2011); *Bridgewater v. Double Diamond-Delaware, Inc.*, Civ. A. No. 3:09–CV–1758–B, 2011 WL 1671021, at *10-11 (N.D. Tex. Apr. 29, 2011); *Warnock v. State Farm Mut. Auto. Ins. Co.*, Civ. A. No. 5:08-cv-001-DCB-JMR, 2011 WL 1113475, at *5 (S.D. Miss. Mar. 24, 2011); *In re Actimmune Marketing Litig.*, 614 F. Supp. 2d 1037, 1050 (N.D. Cal. 2009); *Southeast Laborers Health & Welfare Fund v. Bayer Corp.*, 655 F. Supp. 2d 1270, 1280 (S.D. Fla. 2009).

[35] *Id.* at 989. "[T]o state a claim under civil RICO, the plaintiff is required to show that a RICO predicate offense 'not only was a "but for" cause of his injury, but was the proximate cause as well.' Proximate cause for RICO purposes […] should be evaluated in light of its common-law foundations; proximate cause thus requires 'some direct relation between the injury asserted and the injurious conduct alleged.'" (Citing *Holmes*, 503 U.S. at 268, 271, 274).

[36] *See Bridgewater*, 2011 WL 1671021, at *10 (holding post-*Bridge* that plaintiffs needed to prove individual reliance because "Plaintiffs do not claim third-party reliance and it is not clear how they may show causation without first-party reliance."); *Dungan v. Academy At Ivy Ridge*, Civ. A. No. 06-CV-0908, 2008 WL 2827713, at *3 (N.D.N.Y. July 21, 2008).

[37] *Dungan*, 2008 WL 2827713, at *3.

[38] 620 F.3d 121 (2d Cir. 2010).

[39] 620 F.3d at 133.

[40] *Id.*

[41] *See id.* at 133.

[42] *UFCW Local 1776*, 620 F.3d at 133.

[43] *See also District 1199P Health & Welfare Plan, L.P.*, 784 F. Supp. 2d at 524 — "Plaintiffs may not aver 'causation by way of generalized allegations and aggregate proof,' […] because there are numerous factors that could influence a physician when deciding to prescribe a certain drug" (quoting *In re Schering–Plough I*, No. 2:06-cv-5774 (SRC), 2009 WL 2043604, at *25 (D.N.J. July 10, 2009).

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